POTENTIALLY INAPPROPRIATE PRESCRIBING AMONG CRITICALLY ILL CHILDREN: POPI-CRITERIA IN RUSSIA

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The POPI criteria (Pediatrics: Omission of Prescriptions and Inappropriate prescriptions) for assessment of treatment of comorbidities, complications and underlying conditions in children that are accepted as the only existing instrument for detection of potentially inappropriate prescriptions, make it possible to evaluate prescriptions in children at the inpatient and outpatients stages of care provision, similar to the Beers criteria for adults. The study was aimed to assess the structure and rate of potentially inappropriate prescribing in the pediatric anesthesiology and resuscitation department of the multidisciplinary children's hospital based on the adapted version of POPI criteria for non-antibiotic concomitant therapy of nosocomial infections. We analyzed 305 cases of non-antibiotic medication prescription per 100 patients included. The rate of potentially inappropriate prescribing was 31 cases (10.5%), among which potentially inappropriate medication was prescribed in 29 cases (9.5%), and potentially missed medication took place in three cases (1%). The highest rate of potentially inappropriate prescribing was reported for respiratory diseases. Assessment of concomitant therapy in the critically ill children with infections revealed no significant effects on the rate of adverse reactions to antibiotics in children. In the context of implementing medical information systems (MIS) and prescription sheets, integration of the adapted POPI criteria is topical in terms of maintaining the quality and safety of drug therapy for treatment of concomitant diseases, conditions, and complications in children.

Keywords: children, potentially inappropriate prescriptions, potentially missed medication, medication errors

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ПОТЕНЦИАЛЬНО НЕПРИЕМЛЕМЫЕ НАЗНАЧЕНИЯ ЛЕКАРСТВЕННЫХ ПРЕПАРАТОВ У ДЕТЕЙ В КРИТИЧЕСКИХ СОСТОЯНИЯХ: POPI-КРИТЕРИИ В РОССИИ

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POPI-критерии (Pediatrics: Omission of Prescriptions and Inappropriate prescriptions) для оценки терапии сопутствующих заболеваний, осложнений и фоновых состояний у детей, по аналогии с критериями Бирса у взрослых, признаны единственным существующим инструментом выявления потенциально неприемлемых назначений, позволяют оценить назначения лекарственных препаратов у детей на стационарном и амбулаторном этапе оказания медицинской помощи. Целью исследования было изучить структуру и частоту потенциально неподходящих назначений лекарственных препаратов в детском отделении АиР детского многопрофильного стационара на основе адаптированной версии POPI-критериев для сопутствующей неантимикробной терапии при нозокомиальных инфекциях. Проводили анализ 305 случаев назначения неантимикробных лекарственных препаратов на 100 включенных пациентов. Частота потенциально неприемлемых назначений составила 31 (10,5%) случай, из них потенциально ненадлежащее лекарство назначено в 29 (9,5%) случаях и потенциально пропущено лекарство — в трех (1%) случаях. Самый высокий уровень потенциально неприемлемых назначений выявлен при респираторных заболеваниях. Оценка сопутствующей терапии у детей с инфекцией в критических состояниях не выявила статистически значимых влияний на частоту нежелательных реакций на антибиотики у детей. В условиях внедрения медицинских информационных систем (МИС) и листа назначений интеграция адаптированных POPI-критериев актуальна для поддержания качества и безопасности лекарственной терапии сопутствующих заболеваний, состояний и осложнений у детей.

Ключевые слова: дети, потенциально неприемлемые назначения, потенциально пропущенное лекарство, потенциально ненадежащее лекарство

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The incidence of adverse drug reactions (ADRs) in pediatric population reported for hospitalized patients is 9.53%, while that reported for ambulatory patients is 1.46%; the rate of ADRs resulting in hospitalization of children is 2.09% [1].

The incidence of ADRs among children is twice higher than among adults (it is four times higher among newborns); about 7000 children die annually due to medication errors, and the rate of irrational drug use reaches 12–32% [2, 3].

The limited data on the impact of drug therapy in pediatric patients with comorbidities on the ADR incidence make assessing safety of prescriptions at the anesthesiology and resuscitation departments a pressing issue. Studies of the procedure of using the Pediatrics: Omission of Prescriptions and Inappropriate Prescriptions (POPI) criteria for assessment of therapy for concomitant disorders, complications, and underlying conditions on children [2, 4–6], similar to the Beers criteria for adults [6], in the context of implementing medical information systems and prescription sheets require assessment of medication prescription practice existing in each medical institution aimed at reducing errors.

Many researchers believe that development of the criteria for prescription appropriateness evaluation in children is in its infancy; only three criteria sets were available for children [6–8]. The criteria for prescription evaluation in children were first developed by pediatric medical experts from France in 2011 [6], then POPI criteria were issued in the UK [7]. In 2022, the Chinese researchers, who were puzzled by the lack of instrument for prescription appropriateness evaluation in children after assessment of their own clinical practice, published a comprehensive systematic review of the existing instruments for determination of prescription appropriateness in children and fesibility of these prescriptions in clinical practice [2]. Prescription is considered to be appropriate when it is complicant with the indications, well-tolerated by the majority of patients, and economically justified. According to one of the proposed concepts [9], potentially inappropriate prescribing (PIP) is characterized by the presence of one component out of two: potentially inappropriate medication (PIM) and potentially omitted medication (POM). The judgment of PIM is based on the cases, when potential risks of ADRs outweight potential clinical benefits, especially when there is a more safe or effective alternative. PIM usually includes prescription errors: wrong choice, dose, duration, risk of potential interaction with other drugs or foods, etc., or overprescribing (polypharmacy). The judgment of POM is based on the identified cases of withholding showing significant benefits potentially imporoving the patients' life expectancy or quality of life provided that there are no contraindications, including cases of prescribing the drug approved by the national authorities or clinical guidelines [9].

The study was aimed to assess the structure and rate of potentially inappropriate mediation in the pediatric anesthesiology and resuscitation department based on the adapted version of POPI criteria.

METHODS

A prospective observational study conducted at the Morozov Children's City Clinical Hospital between 01 February 2020 and 01 September 2021 was focused on assessing concomitant therapy with the regularly used drugs in 100 critically ill children with nosocomial infections (44 boys, 56 girls) aged 0–17 years [10]. The average age of children was 5.36 ± 5.5 years, no significant differences in gender and age were reported. Inclusion of patients in the study was interrupted from 20 February 2020 to 30 November 2020 for the period, when the hospital accepted patients with novel coronavirus infection (COVID-19).

Inclusion criteria: infections with the risk factors of multidrug-resistant pathogens — types II–IV if stratified by AMS1; presence of symptom complex based on the criteria for compliance with the definite, probable or possible nosocomial infection based on the microbiological data [11] according to the definition of the US Centers for Disease Control and Prevention (CDC) [12] and the European Centre for Disease Prevention and Control (ECDC) [13]; positive results of the biomaterial microbiological testing involving isolation of the etiologically significant multidrug-resistant microorganism.

All the patients had indications for the use of antimicrobials in accordance with the established criteria for complicance with the standard case of determining the nosocomial infection caused by resistant microorganisms based on the CDC and ECDC criteria [11–13].

Exclusion criteria: novel coronavirus infection (COVID-19); cancer; community-acquired infections with no risk factors of multidrug-resistant pathogens — type I if stratified by AMS; end-stage organ and system failure as competing with the infection for primary diagnosis or condition. Other exclusion criteria: children under guardianship.Previous/concomitant therapy was of no importance for inclusion in the study.

Evaluation of concomitant therapy (non-antimicrobial) in critically ill children was performed using POPI criteria (2019 version, amended and supplemented) [5]. The method is similar to the Beers criteria for adults. The plan of evaluation procedures and personalized assessment of the use of POPI criteria are provided in Table 1.

In critically ill patients, systemic unflammation associated with infection was assessed based on the levels and dynamics of inflammatory markers: C-reactive protein and procalcitonin. The antimicrobial therapy efficacy was estimated based on the 2-fold decrease in the levels of procalcitonin and/or C-reactive protein. When estimating the dynamics, the imaging results for to the infection site were taken into account. When there were multiple infection sites, during assessment priority was given to the zone of interest showing the most prominent signs of involvement.

Statistical processing of the results was performed using the IBM SPSS Statistics v26 software package (IBM; USA). The odds ratio was used to compare the chances of obtaining the desired results in two groups of dichotomous variables.

Inclusion in the study took place at the time of infection: in 81 children, infection developed during their stay at the anesthesiology and resuscitation department agaist the background of underlying disorder or postoperative condition; in 19 patients, the infection caused by resistant pathogens resulted in admission to the anesthesiology and resuscitation department.

The characteristics of patients based on their underlying disorders are provided in Table 2. A total of 49 pediatric patients predominated in the structure of patients based on the primary diagnosis. Among them 19 children were initially admitted to the anesthesiology and resuscitation department due to devere pneumonia: 12 children with community-acquired pneumonia and 7 with aspiration pneumonia. Children with pneumonia had a comorbidity, epilepsy (regular use of low-to-medium doses of valproates at the prehospital stage of the use of these in combination with lamotrigine). Among them 30 children had multiple developmental defects: malformations of the kidney, GIT, CNS (regular use of proton pump inhibitors prescribed at the prehospital stage and resumed at the time of inclusion in the study). Postoperative surgical conditions ranked second

Table 1. Personalized assessment of non-antibiotic therapy based on POPI criteria for 100 patients of the anesthesiology and resuscitation department [5]

Assessment criterion	Present, 1 point (yes/no), number of patients assigned 1 point		
NSAIDs as antipyretics:			
Oral drug other than paracetamol as first-line treatment	1	yes	3
Rectal paracetamol as first-line treatment	1	no	0
Two antipyretics (paracetamol + ibuprofen) as first-line treatment	1	no	0
Oral ibuprofen 10 mg/kg 3 times/day	1	no	0
Combination of 2 NSAIDs is prescribed (except rectal paracetamol)	1	yes	14
Score ≥ 1 — therapy adjustment is required		total	17
Treatment of pain syndrome:			
The use of oral sugar or glucose solution 2 min before venipuncture in is not prescribed to newborns and infants under the age of 4 months	1	yes	9
Osmotic laxative is NOT prescribed for more than 48 h after prescription of morphine	1	yes	0
Score ≥ 1 — prescription adjustment is required		total	9
Vitamins [5]:			
Breastfeeding: vitamin D in a dose of 1000–1200 IU/day	1	yes	9
Bottle-feeding, age under 18 months, infant formula is enriched with vitamin D: 600–800 IU/day	1	no	0
Children aged between 18 months and 5 years and adolescents aged 10–18 years in witer: taking two doses of vitamin D per quarter (80 000–100 000 IU/day) [5]	1	no	0
Score ≥ 1 — no prescription adjustment is required		total	9
Nausea, vomiting, gastroesophageal reflux:			
Metoclopramide is prescribed	1	no	0
Domperidone is prescribed	1	yes	2
Oral administration of intravenous proton pump inhibitor or administration by nasogastric tube	1	no	0
Proton pump inhibitors or type H2 antihistamines are prescribed to individuals with the following disorders: gastroesophageal reflux, indigestion (nausea, vomiting)	1	no	0
Proton pump inhibitors are prescribed to patients with no risk factors, who are through the short course of NSAID, as a preventive measure	1	no	0
Type H2 antihistamines are used for long periods	1	no	0
Score ≥ 1 — prescription adjustment is required		total	2

in the structure of patients based on the primary diagnosis: 22 patients with multiple developmental defects who were through postoperative period: nine patients after gastrostomy feeding tube insertion and 13 patients after reconstructive surgery of the GIT; among them six children still needed pain relief (NSAIDs) during the postoperative period, and proton pump inhibitors were regularly used in 12 children. Congenital heart defects in the postoperative period without artificial circulation were reported in 20 children, among them three children needed pain relief (NSAIDs) for more than three days; regular use of spironolactone was reported in one child, and regular use of PPIs in three children. Neonatal diseases were reported in nine children (accompanying treatment with drugs for regular use is provided in Table 2); two vasopressors due to infectious disease were used in six children, and diuretics were used in eight children.

Patients were included in the observational study at the time of infection. Furthermore, in 81 children, manifestation of the infection occurred during their stay at the anesthesiology and resuscitation department against the background of the

Table 2. Characteristics of patients based on the underlying disease

Concomitant diseases (conditions)	Number of patients (n = 100)	Therapy for concomitant disease, number of children	Non-antimicrobial therapy at the time of enrollment in the anesthesiology and resuscitation department
Neonatal diseases	9 (9%)	No	Two vasopressors due to infectious disease — six children, diuretics — eight children
Congenital heart defects in the postoperative period without artificial circulation	20 (20%)	Of those: NSAIDs — 3, diuretics — 1, PPI — 3	Two vasopressors due to infectious disease — 12 children, diuretics — 20 children
Postoperative surgical conditions	22 (22%)	Of those: NSAIDs — 6, PPI — 12	Two vasopressors due to infectious disease — 8 children, diuretics — 8 children
Somatic perdiatric diseases (epilepsy, multiple developmental defects)	49 (49%)	Of those: anticonvulsants — 20, NSAIDs — 8, PPI — 29	Two vasopressors due to infectious disease — 18 children, diuretics — 20 children

underlying disorder or postoperative condition; in 19 cases, infections caused by resistant pathogens resulted in admission to the anesthesiology and resuscitation department. Children with ventilator-associated pneumonia (VAP) predominated among individuals included in the observational study — 41 (41%), along with children with catheter-associated bloodstream infections (CRBSI) — 30 (30%) and surgical site infections (SSI) — 19 (19%); nosocomial urinary tract infections (nosocomial UTI) reported in seven children (7%) and skin and soft tissue infections (SSTI) reported in three children (3%) were less frequent. *Predominance* of *Enterobacterales* associated with VAP in the anesthesiology and resuscitation department should be noted in 16 cases (40%), among which high levels of resistance took place in four cases (10%). *Acinetobacter complex* was often isolated from the trachea (11 patients (27%)), mostly having preserved susceptibility to the major classes of antimicrobials. However, a pan-drug resistant strain of *Acinetobacter complex* was isolated in two patients. Isolation of *P. aeruginosae* was reported in 9 patients (23%). Gram-negative bacteria with high levels of antibiotic resistance were most often plated in 30 children with c CRBSI. Thus, carbapenemase-producing bacteria were isolated in seven patients (34%): *Pseudomonas aeruginosa* in two cases and entherobacteria in five cases. The *Candida* pathogenic fungi were isolated from the blood cultures of 10 patients (33%); predominance of *C. parapsilosis* resistant to the azole antifungal agents was reported. Gram-positive bacteria were isolated from the blood cultures of nine patients (30%): coagulase-negative staphylococci in six patients and *Staphylococcus aureus* in three patients. *C. parapsilosis* was isolated from the intraoperaive material of 19 patients admitted to the anesthesiology and resuscitation department with SSI, members of the genus *Enterobacterales* and coagulase-negative staphylococci were reported in five patients (26.5%), respectively.

The length of children's stay at the anesthesiology and resuscitation department associated with various infections was on average 18–26 day. The longest patients' stay at the anesthesiology and resuscitation department was reported for VAP — about 26.46 days, CRBSI — 23.83 days, and complicated UTI — on average 23.43 days; the length of stay for SSI was 18.26 days and that for SSTI was 18.33 days. Thus, patients usually stayed in the ICU until their third week at the anesthesiology and resuscitation department.

RESULTS

Among all children enrolled, the initially prescribed antimicrobial therapy was effective in 85 children (85%). Timing of the antimicrobial de-escalation (ADE) was estimated. In 64 children (75.3%), treatment was changed on day 8.28 (14.51) as part of de-escalation, which was assessed as one course of antimicrobial therapy. In patients with severe systemic inflammation (high levels of CRP and procalcitonin), ADE was delayed or not performed throughout the patient's stay at the department. When de-escalation was performed in the line unit after transfer from the anesthesiology and resuscitation department, the fact of de-escalation was not considered in accordance with the protocol of our observational study. Among all the patients enrolled, de-escalation was not performed in 15 children (15%) due to inefficient antimicrobial therapy. Among them 12 children (12% of patients included in the study) needed prescribing the second course of antimicrobial therapy due to alternation of the clinically significant microorganism without alternation of the site of infection, the so-called "leading" causative agent of infection amidst "slipping away" of the applied therapy effect. Three children (3% of patients included in the study) needed prescribing the third course of antimicrobials due to "slipping away" of the effect against the background of antimicrobial drug therapy and alternation of the site of infection. In such cases there was CRBSI with subsequent VAP.

In our observational study, during three weeks of stay at the anesthesiology and resuscitation department each pediatric patient with infection experienced 1–2 changes in the course of antimicrobial therapy; combinations of antibacterial and antifungal drugs were used. According to Table 2, 40 children (40% of all patients included in the study) received concomitant treatment. The use of NSAIDs required adjustment in 17 patients (17%), treatment of pain syndrome had to be adjusted in 9 patients (9%), and adjustment of antireflux medication was required in 2 patients (2%).

In accordance with the aim of the study, we assessed the rate of potentially inappropriate prescribing in the anesthesiology and resuscitation department based on the adapted version of POPI for concomitant treatment. The number of concomitant prescriptions was 305 per 100 patients enrolled, which corresponded to 3.05 prescriptions per patient. Furthermore there were 31 cases (10.5%) of potentially inappropriate prescribing, among them potentially inappropriate medication was prescribed in 29 cases (9.5%) and potentially omitted medication took place in 3 cases (1%).

DISCUSSION

We have found several studies focused on assessing the rate of potentially inappropriate prescribing in pediatric hospitals; only one study was matched by the patient sample size for comparative analysis. In this study the rate of potentially inappropriate prescribing in the pediatric anesthesiology and resuscitation department reached 5.2% of cases, among which potentially inappropriate medication took place in 2.9% of cases and potentially omitted medication in 2.3% of cases; in contrast, the rate of potentially inappropriate prescribing in the pediatric emergency department was 18.4%, among which potentially inappropriate medication took place in 12.3% of cases and potentially omitted medication in 6.1% of cases. The highest rates of potentially inappropriate prescribing were reported for respiratory diseases and gastrointestinal tract disorders. The authors have shown that POPI criteria are currently the only available instrument for identification of potentially inappropriate prescriptions of concomitant therapy to children, which in practice has shown its effectiveness in an inpatient pediatric emergency department and turned out to be not entirely suitable for assessing concomitant therapy in children admitted to the anesthesiology and resuscitation department [2, 3].

The findings of our observational study focused on assessing concomitant therapy in children staying at the anesthesiology and resuscitation department show that the rate of potentially inappropriate prescribing is 10.5%, of that the rate of potentially inappropriate medication is 9.5% and the rate of potentially omitted medication is 1%. The highest rate of potentially inappropriate prescribing has been reported for treatment of respiratory diseases.

The identified differences between two studies of similar cohorts can, on one hand, be explained by different models of building a prescription sheet in the medical information system, but on the other hand these may point to the national specifics of the clinical decision-making support systems in China and Russia based on the clinical recommendations and guidelines supported in each country. Currently, POPI criteria are considered to be the only available instrument for identification of potentially inappropriate prescriptions that can be used for comparative assessment and improvement of pediatric clinical practice.

CONCLUSIONS

In this observational study, we analyzed potentially inappropriate prescribing of concomitant therapy to children with infections in the anesthesiology and resuscitation department: the number of concomitant therapy prescriptions was 305 cases per 100 patients included in the study, which corresponded to 3.05 prescriptions per patient; the rate of potentially inappropriate prescribing was 10.5% of cases, of that the rate of potentially inappropriate medication was 9.5% and the rate of potentially omitted medication was 1% of cases. The highest rate of potentially inappropriate prescribing was reported in patients with the primary diagnosis of "respiratory infection". The difficulties of selecting tools enabling assessment in real clinical practice has been shown. The findings can help develop the system for assessment of potentially inappropriate prescribing in the context of the electronic prescription sheet implementation and integration of the clinical decision-making support system based on the clinical guidelines.

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