



Paediatric Oral Extemporaneous Preparations and Practices: FIP Pediatric Formulation Focus Group (PFFG) Global Survey



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Background

The extemporaneous preparation of oral compounded (unlicensed) medications is a common practice in hospital and community pharmacies worldwide. Paediatric patients have specific needs that require age-appropriate formulations, including personalized strengths, child-friendly dosage forms and adequate palatability. Despite the widespread use of paediatric oral extemporaneous preparations, little is known about this practice on a global scale. National and regional studies have shown that there is considerable variability amongst the most frequently dispensed oral extemporaneous preparations, as well as current practices and regulations.

Purpose

The FIP Pediatric Formulations Focus Group (PFFG) strives to achieve global harmonization of paediatric oral extemporaneous preparation practices and research into affordable age-appropriate formulations. A FIP PFFG global survey was launched to identify current oral extemporaneous preparation practices, challenges and needs in different geographic regions across the globe.

Methods

An anonymous web-based survey (Qualtrics) was developed and translated into 9 languages in collaboration with compounding experts from all WHO regions (Figure 1). The survey includes 16 closed and open-ended questions distributed in three parts: (1) Paediatric oral extemporaneous preparations: dosage forms and active pharmaceutical ingredients (2) Paediatric oral liquids: solutions, suspensions and syrups; and (3) Pharmacy practice. The introduction to the survey included a consent statement and a conditional branching question to identify respondents that currently prepare paediatric oral extemporaneous preparations. A pilot survey was used to test and optimize the official survey, which was launched on November 1st, 2021 and closed on June 1st, 2022. The FIP PFFG global survey was distributed through FIP member organizations, as well as professional networks and contacts by compounding experts worldwide.



Figure 1. FIP PFFG global survey.

Results

A total of 730 valid responses were collected during the 7-months duration of the survey. Most responses came from Europe, Western Pacific, Eastern Mediterranean and South America. Hospital pharmacy and community/compounding pharmacy were equally represented in the survey; outsourcing facilities were a minority. Over 60% of respondents currently prepare paediatric oral extemporaneous preparations; the reasons appointed by the others for not compounding were as follows: ordered from outsourcing facilities; not needed for their patient populations; lack of resources and expertise (Figure 2).



Figure 2. Most prevalent reasons why paediatric oral extemporaneous preparations are not pursued.

- This survey shows that the most frequently dispensed oral dosage forms for children are liquids (solutions, suspensions and syrups), prepared from bulk powders and/or commercial tablets/capsules (opening, cutting and/or crushing).
- The top 20 active substances compounded for children are: atenolol, baclofen, caffeine citrate, captopril, carvedilol, chloral hydrate, clonidine, dexamethasone, enalapril, furosemide, hydrochlorothiazide, hydrocortisone, melatonin, omeprazole, phenobarbital, propranolol, sildenafil, spironolactone, trimethoprim and ursodeoxycholic acid. The most commonly compounded pharmacological or therapeutic groups are displayed in Figure 3.
- Globally, the major needs and/or challenges related to the paediatric oral extemporaneous preparations and practices are as follows: database with comprehensive access to standardized formulations, updated compounding information; validated stability studies with extended beyond-use-dates, training on modern compounding practices to ensure competence and safety; and improved access to resources including active substances, excipients, vehicles and dosing devices (Figure 4).

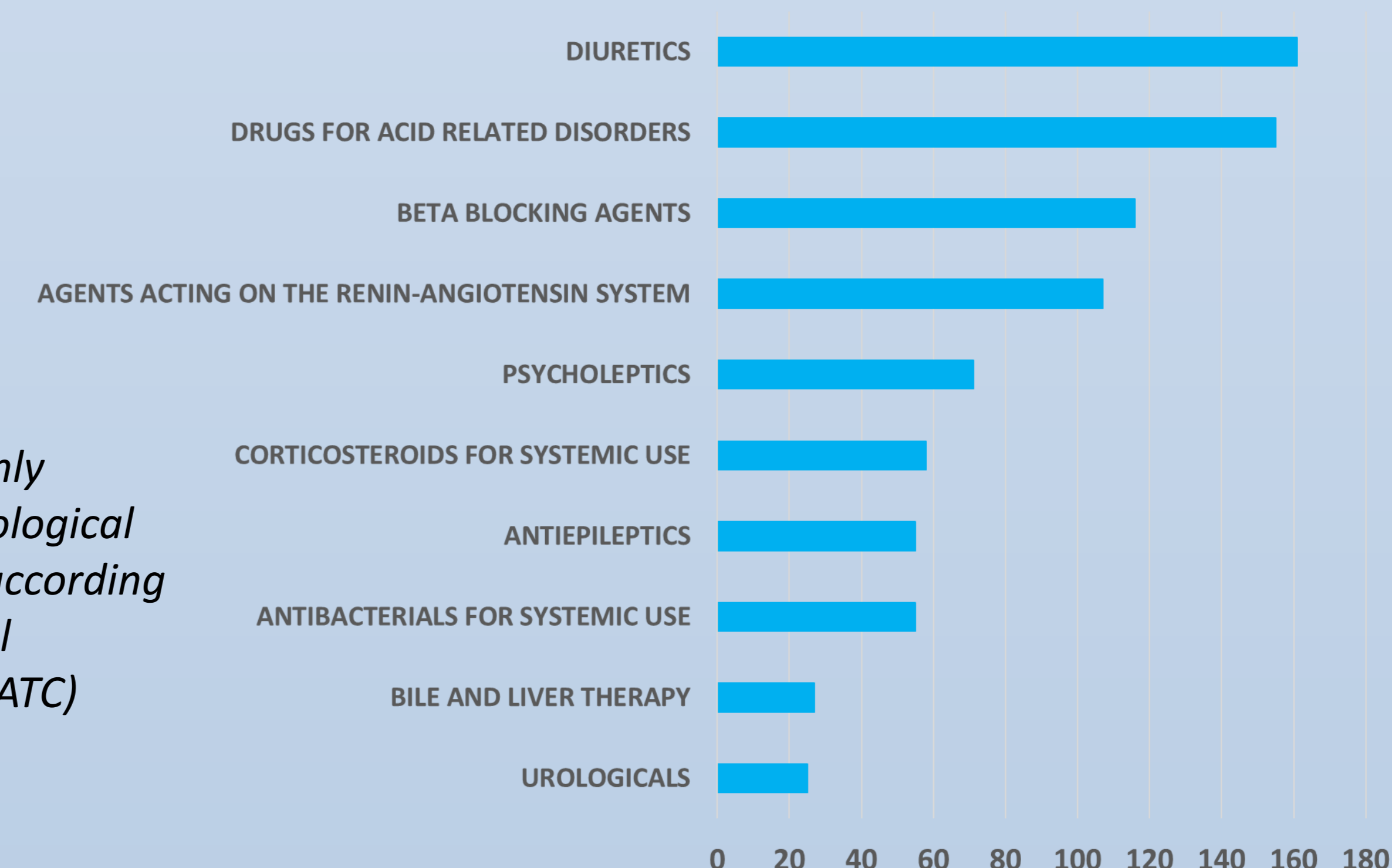


Figure 3. Most commonly compounded pharmacological or therapeutic groups according to the WHO Anatomical Therapeutic Chemical (ATC) classification 2nd level.



Figure 4. Areas of development for paediatric oral extemporaneous compounding.

Conclusion

The FIP PFFG global survey demonstrates that despite the diversity of paediatric extemporaneous preparations and practices worldwide, there is a common global need for freely accessible compounding formulations, stability studies and information resources.

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