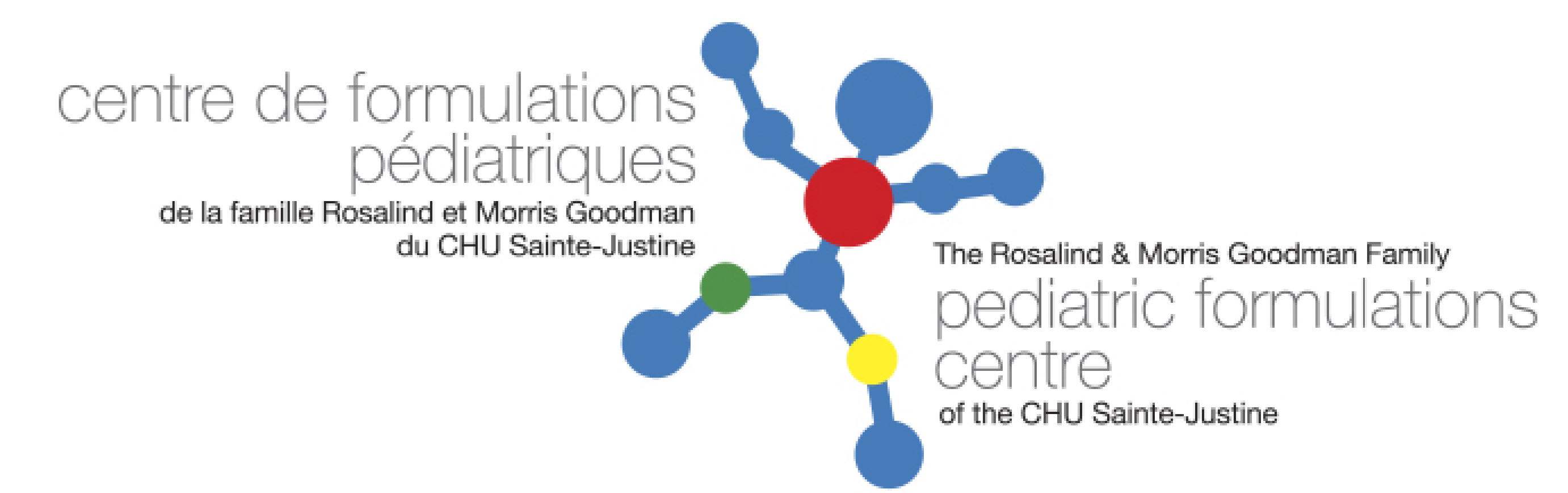


A Pan-Canadian Study On The Compounded Medicines Most In Need Of Commercialized Oral Pediatric Formulations

J. Autmizguine^{1,2,3,5}, Z. Allakhverdi^{1,2}, A. Gilpin¹, J.-E. Tessier¹, D. Giroux¹, D. Lebel^{1,4}, C. Litalien^{1,2,3,5}

¹The Rosalind & Morris Goodman Family Pediatric Formulations Centre, ²Department of Pediatrics, ³Department of Pharmacology and Physiology, ⁴Department of Pharmacy, ⁵Research Center, CHU Sainte-Justine/Université de Montréal, Montréal, Québec, Canada



Introduction

- In 2018, drug compounding is still commonly used to compensate for the lack of oral formulations adapted to children's needs
- Manipulation of dosage forms designed for adults may increase the risk of dosing errors, adverse events, exposure to unsafe excipients, and therapeutic failure in children
- The Rosalind and Morris Goodman Family Pediatric Formulations Centre of the CHU Sainte-Justine (the Goodman Centre), established in 2016, aims to promote and facilitate the development and market authorization of pediatric formulations, for both off- and on-patent drugs, through partnership with multiple stakeholders:
 - Pharmaceutical industry
 - Pediatric hospitals
 - Regulatory agencies
 - Reimbursement bodies
- It also aims at promoting practices that increase safety of pediatric medicines
- Using a patient-focused approach, the Goodman Centre has undertaken a mapping of the needs for pediatric formulations in Canada

Objectives

- To determine the most frequently compounded medicines in Canadian pediatric hospitals and the challenges associated with drug compounding
- To identify compounded medicines most in need of commercialized oral pediatric formulations in Canada

Methods

- The Head of the Pharmacy Department of each of the 16 Canadian university affiliated teaching hospitals was contacted to identify pharmacist(s) best placed, in their institution, to participate in the study
- We designed a questionnaire to determine which drugs are currently compounded and to assess the needs in terms of pediatric formulations
- The questionnaire included 12 open-, close-ended or Likert-scale questions and was sent electronically to each participant 1 week before the telephone survey
- The duration of the telephone survey was up to one hour
- Median, counts and proportions were computed using STATA 13
- This study was approved by a central Research Ethics Board

Results

- Thirteen centers among 16 contacted, completed the telephone survey between April and June 2017 (81.3%)
- Sixteen pharmacists from 13 centers participated in the survey
- When sites were asked to list their 10 most commonly compounded medicines, a total of 43 drugs were identified
- Twelve drugs/class of drugs were reported by 4 or more hospital centers as most in need for a commercialized oral pediatric formulations in Canada (Table 1)

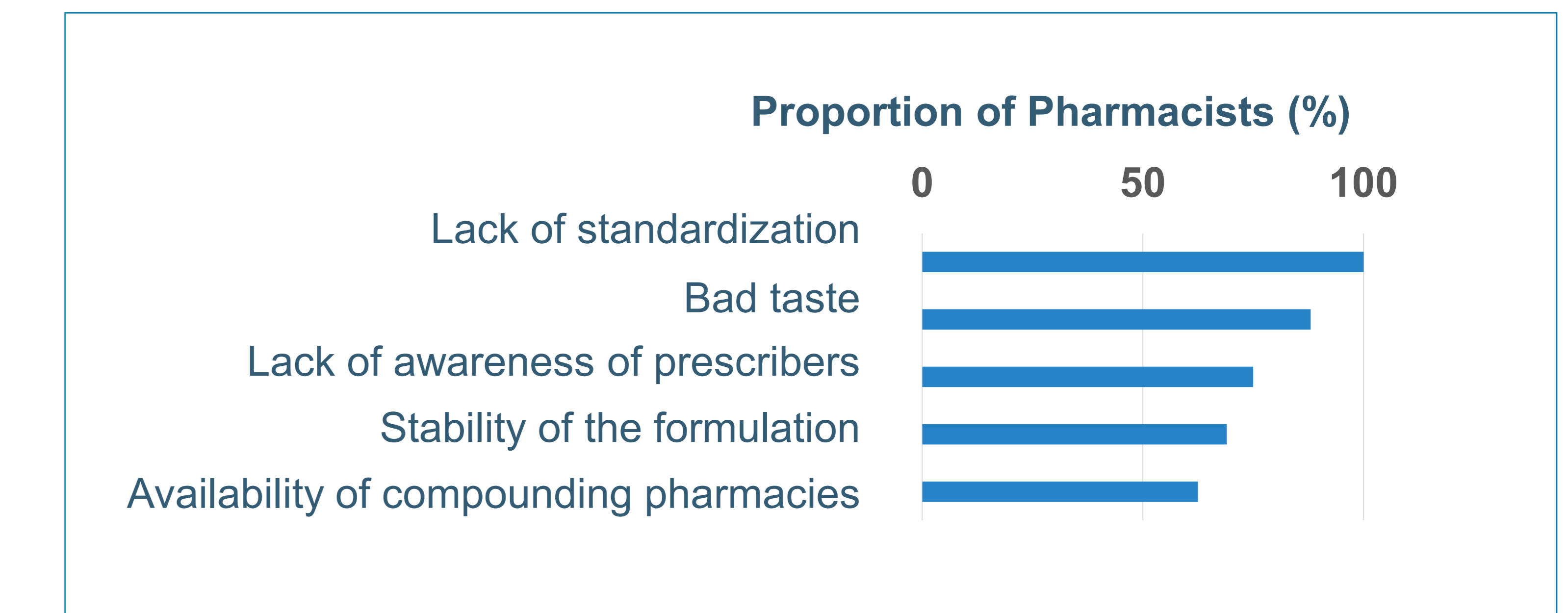
Table 1: Drugs most in need of commercialized oral pediatric formulations and most compounded according to Canadian pediatric hospitals

Drugs	Number of hospitals that ranked drug as :		Availability of pediatric oral formulations outside of Canada	
	Most in need of a pediatric formulation, n (%) N=13	Most frequently compounded, n (%) N=13	United States	Europe
Levetiracetam	8 (62)	10 (77)	Oral solution	
Spiroonolactone	8 (62)	7 (54)	No	
Tacrolimus	8 (62)	7 (54)	No	Sachets for oral suspension
Clonidine	7 (54)	7 (54)	No	
Hydro-chlorothiazide	6 (46)	6 (46)	No	
PPI ¹	6 (46)	7 (54)	Sachets for oral suspension ²	
ACE inhibitors ³	4 (31)	5 (38)	Oral solution	
Amlodipine	4 (31)	2 (15)	No	Oral solution
Dexamethasone	4 (31)	10 (77)	Oral solution ⁴	
Hydroxyurea	4 (31)	2 (15)	No	
Sildenafil	4 (31)	4 (31)	Oral solution ⁵	
Topiramate	4 (31)	4 (31)	Sprinkle hard capsules	

¹Proton pump inhibitors; ²for omeprazole and esomeprazole in the US and for esomeprazole in Europe; ³Angiotensin converting enzyme inhibitors (captopril, enalapril); ⁴contains propylene glycol and sorbitol; ⁵contains sorbitol

Results continued

Figure 1: The most frequently mentioned challenges associated with drug compounding



Conclusions

- This study highlights which drugs are most in need for pediatric oral formulations in Canada
- For compounded medicines with pediatric formulations available outside Canada, the Goodman Centre is currently assessing their adequacy. The Centre is also looking for pharmaceutical partners willing to bring these formulations to the Canadian market. A better understanding of why Canada has fallen behind regarding the access to some pediatric formulations is part of the Centre's mandate
- For those medicines without available commercialized pediatric formulations, the Goodman Centre is looking for pharmaceutical partners interested in developing such formulations. The Centre intends to promote their access to the largest number of children, across boundaries, by working with different stakeholders to facilitate data sharing and regulatory harmonization

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