

EVALUATION OF HARMFUL AND POTENTIALLY HARMFUL EXCIPIENTS FOR NEWBORNS FOUND IN MEDICATIONS USED IN CHILDREN'S CLINICAL UNIVERSITY HOSPITAL (DEPARTMENT OF NEONATOLOGY) IN 2019

Aiva Birne¹, Inese Sviestīņa²

¹ First-year student of the master's study program "Pharmacy" of the Faculty of Medicine of the University of Latvia

² Supervisor, clinical pharmacist and assistant professor at the University of Latvia

BACKGROUND AND IMPORTANCE

Not all excipients are biologically inert and therefore may cause adverse effects which makes **neonate** population especially vulnerable. Although excipients are essential components of a medicinal product that are needed in the manufacturing process, there are **growing concerns about their safety**.

STUDY AIM

To study the safety of industrially produced medicines used for neonates in the Neonatology Clinic of the Latvian Children's Clinical University Hospital from the point of view of excipients.

METHODS

Data on medications used in the Neonatology Clinic was obtained from the hospital's drug accounting software *Horizon*. Using the summaries of product characteristics, the excipients of each medicine were determined, grouping them into 3 parts:

harmful excipients, potentially harmful excipients, and other excipients.

Data collection was performed using *Microsoft Office Excel 2019* and descriptive statistical methods (natural numbers and percentage distribution), which were presented in the form of graphs.

In addition, alternatives to the potentially harmful medicines were evaluated.

Table 1.

Excerpt from the generated report

Name of the medicinal product	Harmful excipients						
	E218	E420	E433	C ₂ H ₅ OH	C ₇ H ₈ O	E211	E210
Luminal 200 mg/ml solution for injection				1			
Morphin SANITAS 10 mg/ml solution for injection							
Diazepeks 5 mg/ml solution for injection				1	1	1	1
Diazepam Desitin 5 mg rectal solution				1	1	1	1

RESULTS

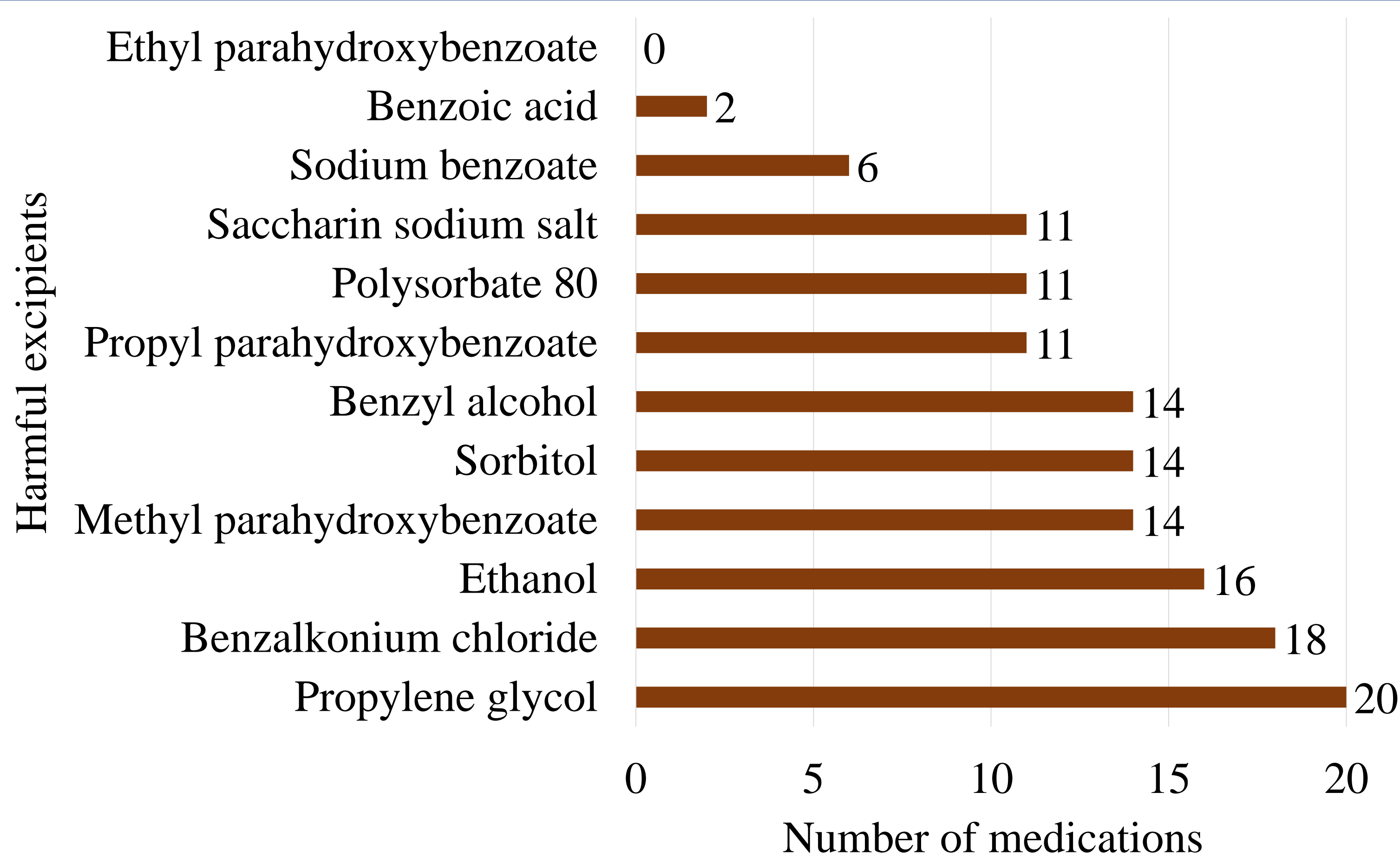


Figure 1. Distribution of harmful excipients

Of the purchased medicines, 133 (57%) contained at least one undesirable excipient, and in 99 (43%) medicines they were not present.

Propylene glycol was the most common harmful excipient, used in 20 medicines. Similarly, benzalkonium chloride was used in 18 and ethanol in 16 of the medicines.

■ Potentially harmful medicines
■ Potentially safe medicines

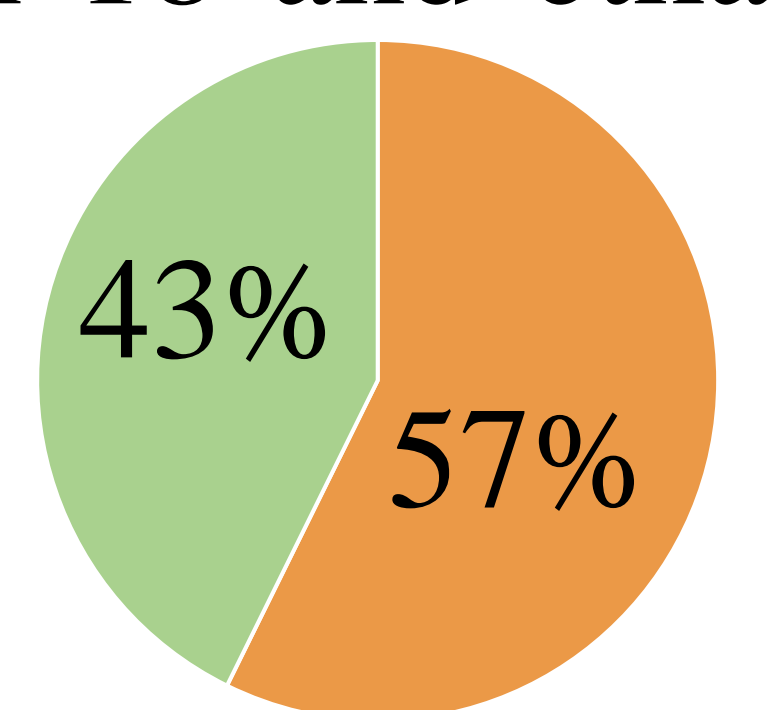


Figure 2. 2019 Neonatology Clinic drug evaluation based on the safety of excipients

Among the potentially harmful excipients, the most common were **titanium dioxide** and disodium edetate, which were used in 21 and 20 of the drugs, respectively.

22 medicines contained at least 4 undesirable excipients, of which only 3 can be replaced by other medicines available in Latvia which have a lower number of undesirable excipients.

CONCLUSIONS

Most of the industrially manufactured medicines used by the Neonatology Clinic in 2019 are not appropriate for newborns. The next step would be to analyze the doses of the excipients taken by newborns and other possible solutions.