

# THERAPEUTIC CHALLENGES IN NEONATES

## Elizabetha Zisovska<sup>1</sup> and Renata Raicki<sup>2</sup>

<sup>1</sup> University Clinic for Ibs&Gyn, Skopje, Macedonia

<sup>2</sup> Pharmaceutical faculty, UKIM, Skopje, Macedonia

### Introduction

There is no other age as challenging as neonatal, due to the immaturity of organs and the unpredictable pharmacokinetics, like the mode of application, biotransformation, distribution and elimination. The reasons for this challenge are specific receptor reactions, narrow therapeutic window, and burden of diseases specific only for this age, therefore lack of evidence for drug efficacy. The prescription of medicines in neonate is in direct relation of the gestational age, postnatal age, birth weight, associated morbidity. Many of the drugs are used as off-label, or even unlicensed, thus creating higher risk of medical errors, especially in NICU. These medicines can be used out of age, regimen, indication, or route of administration.

### Objectives

The aim of this paper is to present the extent to which off-label and/or unlicensed medicines are used in neonatal unit within Obstetric&Gynecology Clinic in Skopje.

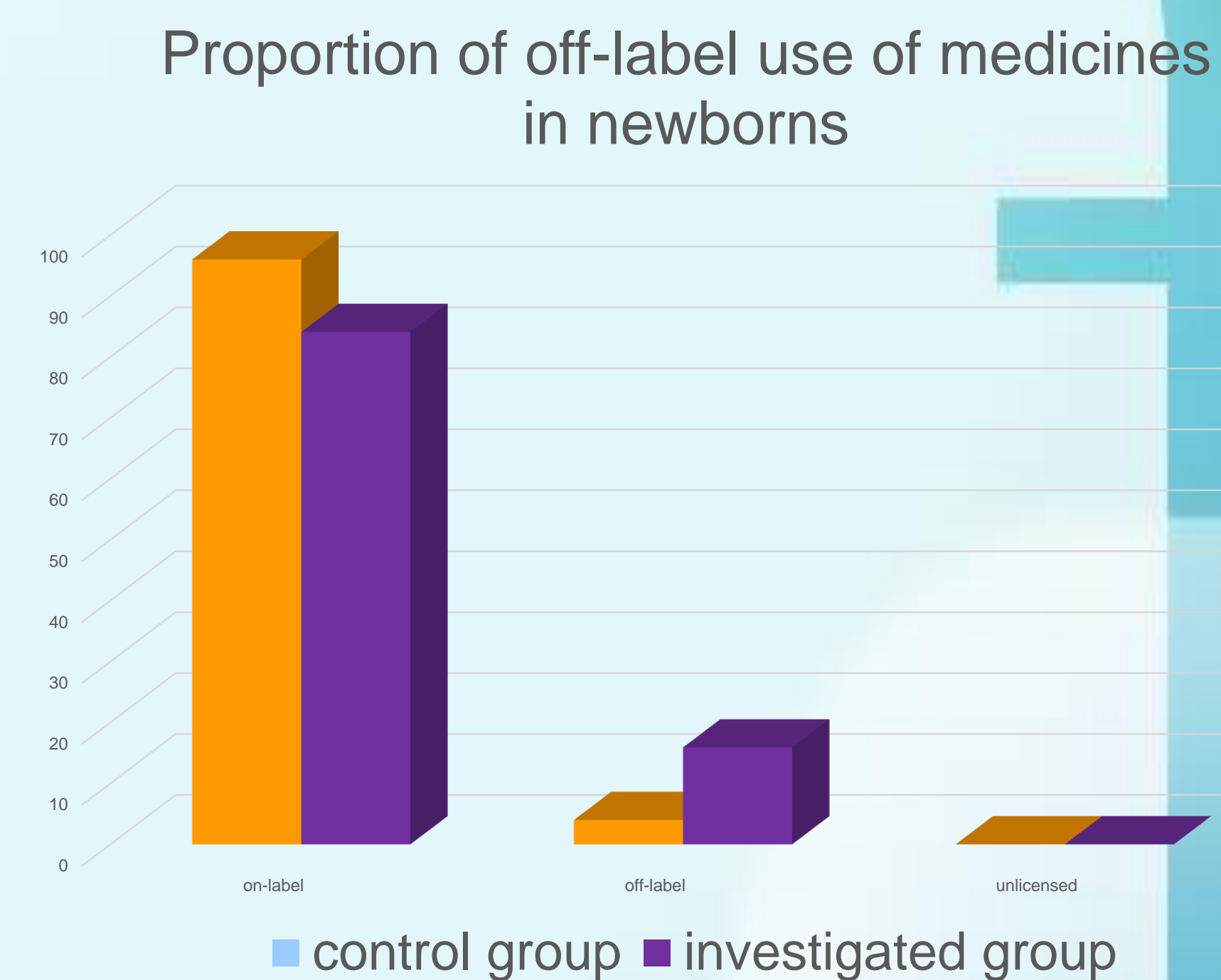
### Methods

This was an observational, cohort study, including 200 healthy newborns, term or near-term, (control group) and 100 newborns, receiving therapy, and non-dependent of intensive care. Intravenous replacement solutions and blood products were not included.

### Results

Results: there were 176 prescriptions in total in the investigated group; 148/176 (or 84,1%) of them were according to the prescribed drug guidelines, and 15,9% were off-label. In the control group, there were 110 prescriptions and only 3,6% were off-label. The difference had high statistical significance.

### Results Cont'd



Majority of the off-label reasons were use out of dose, indication, and age. The mostly prescribed off-label medicines were Gentamicin, Cefotaxime, Amikacin, Furosemide, Dexamethasone.

### Discussion

It is worth mentioning that this is a part of a broader study, including newborns with more severe diseases, where much more prescriptions are given, and the risk of toxicity is manifold increased. These data show only the iceberg of the problem of neonatal pharmacotherapy. More detailed analysis will highlight this issue and give more information in terms of efficient neonatal treatment.

### References

1. De Souza ASJ, Dos Santos DB, Rey LC, Medeiros MG, Vieira M, Coelho HL. Off-label use and harmful potential of drugs in a NCU in Brazil: a descriptive study. *BMC Pediatr.* 2016;16(1):13. The larger your font, the easier it will be for others to read your poster.
2. Jain L. The conundrum of off-label and unlicensed drug usage in neonatology. *J Pediatr.* 2012;88(6):449-51.