EVIDENCE BASED CLINICAL GUIDELINES AS A POTENTIAL FOR IMPROVEMENT OF THE NEWBORN INFANTS PATIENT SAFETY

Elizabeta Zisovska¹ Renata Slaveska Raichki² and Vasilka NIcha³,

¹Faculty of Medicine, University Clinic for Gynecology and Obstetrics, University Ss Cyril and Methodius, Mother Theresa 47, Skopje, zisovska@yahoo.com

²Faculty of Pharmacy, University Ss Cyril and Methodius, Mother Theresa 47, Skopje, rera@ff.ukim.edu.mk

³Public Institution in the Health Sector, for the needs of PHI University Clinics, Institution and Urgent Centre, Mother Theresa 47, Skopje, vasilkanica@yahoo.com

The greatest challenge to the prescribing physician is the newborn infants. There are many reasons for this issuesuch as marked changes in maturation that cause different drug-receptor reaction over the maturation period; differences in pharmacokinetics and pharmacodynamics; narrow therapeutic index; risk from diseases not seen in other subsets of pediatric population and impossibility to scale down information; lack of appropriate information and lack of licensed medicines on the global market. Possible reasons for the knowledge gap in this area lay in ethical concerns, limited populations for certain diseases, difficulties in conducting trials in neonates, lack of infrastructure, errors in dose calculations limited marketing potential compared to adults, etc.

Pharmacotherapy in newborn infants very often is based on low level of evidence; therefore many of the recommendations are weak, and frequently empirical, or based on expert's opinion and consensus. The development of Clinical Guidelines in all fields of the clinical medicine offer an opportunity to increase the safety of this particularly vulnerable population, and in Neonatology are of special interest and value, considering the above mentioned obstacles. In this paper the intention is to describe the possibilities to improve newborn infants pharmacotherapy, to reduce risks for iatrogenic errors, and to increase the patient safety implementing Evidence based Clinical Guidelines.

No other child offers greater challenges to the prescribing physician than the newborn. There are many reasons for this: marked changes in maturation that cause reacting differently at the drug receptor site over the maturation period; differences in pharmacokinetics and pharmacodynamics; narrow therapeutic index; risk from diseases not seen in older groups and impossible to scale down information; lack of appropriate information; lack of licensed medicines. Possible reasons for the knowledge gap are: ethical concerns, limited populations for certain diseases, difficulties in conducting trials in neonates, lack of infrastructure, belief that the dosing could be determined by weight based calculations ("little children"), limited marketing potential compared to adults, etc.