Chapter 1 describes how the levels of maturation of enzymes is affected by growth. The new findings about pharmacodynamics (PD) of paracetamol in fact refer to pharmacokinetics (PK) of paracetamol after repeated administration (a typographical error). Nevertheless, this point is interesting and its clinical relevance in neonates could have been discussed in more detail. Briefly, this refers to induction of metabolizing enzymes with repeated use of paracetamol with change in pathways for elimination. The next chapter discusses the translation of PK data to dosing regimens in neonates. Admittedly, the available information is scarce, and only for a few drugs. The authors correctly acknowledge that individualization of dosing regimens particularly for neonates, more so for preterm babies, will remain challenging in spite of some of the novel approaches being tested.

The chapter on pharmacovigilance discusses the difficulties of adverse drug reaction monitoring in the setting of a neonatal ICU. The tools for pharmacovigilance and the differences between existing tools of causality assessment and the ones validated for neonates could have been discussed in more detail. The next chapter discusses neonatal formulations and additives. The authors make an interesting point with respect to excipients – which can cause adverse reactions, a point that may often be overlooked during practice.

The chapter on PBPK models puts forth a fairly obvious point– there are less number of models for paediatric populations, only a few for neonates, and fewer for premature infants. There is a definite need for developing more PBPK models and the difficulties in the development of new models have been discussed in this chapter.

The systematic review of paracetamol versus ibuprofen for closure of patent ductus arteriosus answers an important clinical question, although this could have been conducted in a more systematic manner. For example, the search strategy is not clearly defined, the inclusion/exclusion criteria for studies are not mentioned and so on. Nevertheless, the conclusion appears to be reasonable in that paracetamol can be an alternative to indomethacin and ibuprofen, with a different adverse effect profile.

The chapter on preterm infant formulas is probably less relevant to our populations – not all the formulas discussed will be available in India, and if available, their cost probably limits affordability for a majority.
In addition, food safety standards that the companies follow in India are likely to be different when compared to developed countries.

The chapter on regulatory affairs is well written. It is well known that there are insufficient trials to support paediatric use, much so for neonates and premature infants – all of whom are independent populations. It also seems difficult to envisage a change in scenario particularly with respect to the near future. Initiatives like justification of exclusion of neonates by the US FDA is a welcome step. The point about opportunistic studies is appropriate and should be extended to all drugs, even approved ones. The French system appears to be worth emulating – in this system a drug is allowed to be used in a non-approved indication for three years during which data from the drug usage are collected for making a risk versus benefit assessment. Final decision is taken by the drug regulatory authority after this period.

Being an update it assumes significant background knowledge of readers. Also more figures and tables would have added value. At some places the language becomes a little dry and it is difficult to sustain interest. Nevertheless, most of the topics are covered well, particularly the one on regulatory affairs. The authors’ description of the procedures followed in different countries is useful. Overall, this book provides useful information and is suitable for paediatricians, neonatologists and residents pursuing their degrees. It will be useful for the teaching faculty as well.

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