

## STELLINGEN

behorende bij het proefschrift:

### **Drug Safety in Children: Focus on hepatic concerns**

1. Due to underreporting we cannot calculate the absolute risk of an event using data from spontaneous reporting systems, however due to the low proportion of case reports it is generally perceived that hepatic injury is an infrequent adverse drug reaction in children and adolescents. (*this thesis*)
2. Active drug surveillance in the paediatric population should use age-appropriate events and definitions. (*this thesis*)
3. Use of electronic medical record databases allows research on less severe cases and captures them in the beginning of disease process as compared to disease registries. This may impact on the ability to study risk factors. (*this thesis*)
4. Children currently exposed to ceftriaxone, co-trimoxazole and some macrolides (i.e. clarithromycin and rokitamycin) have an increased risk to develop hepatotoxicity. Paediatricians prescribing these antibiotics should carefully monitor liver function in children. (*this thesis*)
5. Combining and sharing data from different databases and across countries is essential for active drug surveillance studies in children. (*this thesis*)
6. A signal is more than just a statistical association. It consists of a hypothesis together with data and arguments, arguments in favour and against the hypothesis. These relate to numbers of cases, statistics, clinical medicine, pharmacology and epidemiology, and may also refer to findings with an experimental character. (*Meyboon et al. Drug Saf 1997; 16 (6): 355-65*)
7. The language of truth is unadorned and always simple. (*Ammianus Marcellinus*)
8. All grown-ups were once children... but only few of them remember it. (*Antoine de Saint-Exupéry, Le Petit Prince - 1943*)
9. There are no safe drugs, only safe ways of using them. (*Voltaire*)
10. The wing structure of the Bumblebee, in relation to its weight, it is not airworthy, but he does not know and flies the same (*A. Einstein*).
11. You do not always know what you are looking for, but it is important to recognize it when you find it.