Stellingen

The role of signal detection in Pharmacovigilance

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1. The contribution of various datasources to signal detection appears to be correlated with the background incidence of the investigated events, being directly proportional to the incidence in electronic healthcare records and inversely proportional in spontaneous reports databases. *(This thesis)*

2. Contrary to the commonly held perception, drugs with lower pre-approval exposure (e.g., small clinical trials populations) do not necessarily have more safety issues discovered in the initial period on the market, while the opposite is true for drugs with increased post-approval exposure. *(This thesis)*

3. Age stratification in paediatric signal detection can increase sensitivity and lead to discovery of signals and should be used complementary to standard methods. *(This thesis)*

4. Multi-national reporting and report quality should be considered when prioritising signals. In contrast, reporter qualification should not be considered as a prioritisation criteria since it was not proven to be associated with true signals. *(This thesis)*

5. Triptans' treatment might be associated with ischaemic colitis, especially when used in the year previous the diagnosis. *(This thesis)*

6. The ultimate test for pharmacovigilance systems is the demonstration of public health benefit. (*Practical Aspects of Signal Detection in Pharmacovigilance: Report of CIOMS Working Group VIII, WHO, 2010, p. 6*)

7. The essence is to collect facts that individually tell little but collectively form a clue of drug dangers. (*Finney DJ. The detection of adverse reactions to therapeutic drugs. Stat Med. 1982;1:153-161*)

8. The use of off label and unlicensed medicines implies that there are no proper labelling and dosing recommendations, which can potentially be harmful to children. (*Sturkenboom Miriam C J M, Verhamme Katia M C, Nicolosi Alfredo, Murray Macey L, Neubert Antje, Caudri Daan et al. Drug use in children: cohort study in three European countries BMJ 2008; 337 :a2245*)

9. Translating medical research into clinical practice guidelines is not trivial. *(Naidus, Elliot, and Leo Anthony Celi. "Big Data in Healthcare: Are We close to It?" Revista Brasileira de Terapia Intensiva 28.1 (2016): 8–10. PMC. Web. 11 Apr. 2018.)*

10. The safest drug that no one can afford or that arrives too late is of no benefit to a patient. *(Eichler HG, Baird LG, Bloechl-Daum B, et al. From adaptive licensing to adaptive pathways: delivering a flexible life-span approach. Clin Pharmacol Ther 2015;97:234-46.)*

11. The surveillance of drugs post-licensure has become both a science and a crusade. *(Coloma P, mining electronic healthcare record databases to augment drug safety surveillance, PhD thesis, May 2012, ISBN: 978-94-6191-258-9)*

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