Background: There is a great concern nowadays in medicine about "new drugs" or "monoclonal antibodies" or "generics" or "biosimilars" and their clinical and economic burden. But slowly we have forgotten another great problem of the true costs of "cheap" medications to the medical system.
Aim: the aim of this study is to show that normally thought as "cheap" medications could be as expensive to the medical system an "new drugs".
Methods. We evaluated a pharmacovigilance database of a tertiary care hospital. We separated two great NSAIDs—induced ADR (gastrointestinal bleeding and renal failure) and we performed the economic (direct and indirect) burden of this ADR.
Results: For a population of approximately 200,000 inhabitants, the direct and indirect economic burden of NSAIDs—induced ADR is 347,749.73 US dollars per year. This is near one fourth of the economic burden of hemophilic treatment according to prevalence in this population or one third of the economic burden of Gaucher disease according to prevalence in this population.
Discussion: Despite NSAIDs could be cheap medications for the patient, they generate extremely high economic burden for the health system. We urgent need to encourage professional community and general population to use cautiously this medication.

29 Characteristics of adverse events following influenza vaccination: comparison between spontaneous reports and reports from an intensive monitoring programme

L. van Balveren-Slingerland[1], S. Vorstenbosch[1], E. van Puijenbroek[1]

[1]*Lareb, 's-Hertogenbosch, the Netherlands*

Introduction: Most reported adverse events (AEs) following influenza vaccination are well-known. One commonly used method to retrieve information on AEs is spontaneous reporting. Information concerning the course of reported AEs is highly dependent on the time of reporting. If reported in an early stage, this information cannot yet be provided. Data can also be obtained through intensive monitoring of patients, thereby facilitating to report (the course) of AEs. Both methods provide information concerning the frequencies of reported AEs, latency time, outcome and recovery time. However, whether or not both approaches yield comparable information in respect to the aforementioned aspects, is unknown.
Aim: To determine differences between spontaneous reporting and an intensive monitoring programme in frequencies of reported AEs, latency time and recovery status and -time of the reported AEs.
Methods: Comparison between the characteristics of most reported AEs reported in spontaneous reports and in an intensive monitoring programme following influenza vaccination. All spontaneous reported AEs of patients received within 40 days after influenza vaccination in 2013, 2014 and 2015 were included. In the same years an intensive monitoring programme was performed. Patients received three questionnaires on day 5, 15 and 30 (valid thru day 40) after vaccination. Of the ten most reported AEs the recovery status, latency- and recovery time were calculated. The latency- and recovery time were categorized into four groups for different intervals (0–24 ; 24–48; 48–72; >72 h). To compare the early (<72 h) and late (>72 h) latency- and recovery times between both methods, Fisher Exact Tests were performed.

Reported AE	% of total reported AE: spontaneous (1488 AE) vs monitor (2588 AE)	% recovered AE: spontaneous vs monitor
Injection site inflammation	21.3 - 22.4	25.0 - 76.7
Myalgia	9.7 - 14.9	36.6 - 77.7
Headache	11.1 - 14.3	43.2 - 79.5
Pyrexia	8.2 - 5.6	46.7 - 80.0
Injection site pain	2.1 - 5.6	45.2 - 84.0
Extensive swelling of vaccinated limb	4.0 - 1.8	29.3 - 72.3
Fatigue	2.1 - 2.4	32.3 - 54.7
Malaise	2.8 - 3.0	29.3 - 72.7
Influenza like illness	2.7 - 2.8	48.7 - 68.1

Results: The most reported AEs in both methods were comparable. The table below shows the frequencies of occurrence of these reported AEs. In both methods most reported AEs started within 72 h after vaccination. Significant differences were seen for the latency time of pyrexia, headache and malaise. These AEs were more frequently reported after 72 h in the monitoring programme. Data on recovery was more frequently available in the intensive monitoring (see Table). Yet, no differences were seen between the recovery time of reported events for both methods.
Conclusion: This study shows that the pattern of reported AEs is comparable between both methods. Possibly more events in the monitoring programme were reported because patients were monitored over time and asked to report the (course of) AEs. Consequently, more data on recovery was available, which illustrates the strength of monitoring in providing in-depth information about the course of the AEs.

30 Deaths from medicines: a systematic analysis of UK Coroners' reports to prevent future deaths

A. R. Cox[1,2], C. Easton[1], R.E. Ferner[1,2]

[1]*Institute of Clinical Sciences, University of Birmingham, Birmingham, UK,* [2]*West Midlands Centre for Adverse Drug Reactions, Birmingham, UK*

Introduction: Coroners in England and Wales investigate unexplained deaths. Since legislation in 2009, they must make reports following deaths where they believe it is possible to prevent future deaths (PFDs). [1] PFDs are sent to relevant people or organizations, asking for recommendations on how to prevent future deaths. They could provide information relevant to pharmacovigilance.
Aim: We wished to establish how often PFDs implicated medicines and other drugs, the extent to which they revealed preventable medication errors or novel adverse drug reactions, and the concerns raised by coroners.
Methods: We examined coroners' reports by pre-defined criteria to identify those in which medicines played a part, and to collect information on coroners' concerns. We included a PFD if it mentioned part of the medication process (for example, administration), or if a specific medicine (or both) that caused or contributed to death. We included drugs of abuse such as diamorphine (heroin) and cocaine. We excluded cases where the medicine or part of the medication process mentioned did not cause or