Signal detection in electronic medical records

PROTECT Symposium

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Are we fine-tuning an outdated model?
A 14-year-old presented with elevated anxiety.
Are we fine-tuning an outdated model?

Can longitudinal observational data offer an alternative?
Pharmacovigilance
What would real-world signal detection in electronic medical records look like and what value can it bring?
Statistical signal detection is just the first step!

In fact, pharmacovigilance detected the early signals of an increased risk of cardiovascular disorders with rofecoxib. At the annual meeting of the national centres participating in the WHO Programme for International Drug Monitoring in Tunis (October 2000) the Netherlands Monitoring Centre (Lareb) presented new evidence of cardiovascular disorders related to rofecoxib, with reporting of a high odds ratio for adverse cardiovascular effects, with some
Recommendation

“Safety signal detection in longitudinal observational data should include clinical, pharmacological, and epidemiological review of identified temporal associations”
6 assessors  x  7 drugs per assessor  x  20 events per drug
Comparator + self-control
OMOP comparison of methods – Phase I
Preliminary results

820
Preliminary results

820 \rightarrow 509

\downarrow 38\%

311

Not relevant terms
Preliminary results

820 → 509 → 382

311 Not relevant terms
127 Already known
Preliminary results

820 → 509 → 382 → 91

Not relevant terms: 311 (38%)
Already known: 127 (25%)
Dismissed: 291 (76%)

Merit further evaluation
Skin sensation disturbance with salmeterol
Epiphora with amiloride
Preliminary results

820 → 509 → 382 → 91

311 Not relevant terms
127 Already known
291 Dismissed

Merit further evaluation

38% 25% 76%
Confounding by underlying disease
Protopathic bias?
Recommendation

“Longitudinal observational data should be further explored as a complement to individual case reports for safety signal detection, but are not in a position to replace individual case reports for this purpose”
65% of the drugs have less than 100 prescriptions in total in THIN

- Not marketed in the UK at the time
- Used in secondary care
Longitudinal observational data

+ Denominators
+ Longitudinal
+ ’Objective’

− No clinical suspicion
− Data not collected for causality assessment
− Restricted scope
A 14 year old presented with elevated anxiety.
14 year old presented with elevated anxiety 2 days later he developed significantly. A regimen of 2 mg daily for two weeks was withdrawn. Causality assessment by the centre suggested not only had he developed but so to had...
References


