

183. Evaluation of Pharmacoepidemiology Trials: Rigour Methodologica Versus Rigor Mortis

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Background: Most interventions to improve the quality and cost-effectiveness of drug therapy implementation are complex interventions (multi-faceted, multidisciplinary, often multi-system). Methods to evaluate these interventions have been slow to develop thus hindering high quality evaluations.

Objectives: To determine how 9 key methodologic issues are best handled through focused critical literature reviews; to develop guidance for researchers and users of the literature.

Methods: A focused, critical review of the literature on methods quality and reporting for each topic was completed, interpreted through expert workshops, and guidance formulated. The topics were: intervention components that determine success or failure, cluster vs individual randomization, blinding, composite outcomes and scores, measurement of harm, minimal clinically important difference (MCID), generalizability, surrogate outcomes, transferability and scalability of cost-effectiveness.

Results: Complex interventions are usually too poorly described to dissect factors that predict success or failure. Benefits of cluster randomization may be offset by biases and complexities of analysis. Outcome assessment appears to be most important blinding target. Composite outcomes and scores may reduce sample size but are often not validated. Measurement of harm has been weak in complex interventions. MCID decisions require grounding. Generalizability of complex interventions may be more environment-dependant than for simple drug trials. The use of surrogate outcomes is common however their validity has repeatedly been shown to be flawed. Transferability and scalability of cost-effectiveness are complicated by the difficulties generalizing both effectiveness and costs.

Conclusions: Many of these methodologic issues bedevil complex pharmacoepidemiology studies and require further guidance development.

184. Choosing an Intervention To Reduce the Use of Benzodiazepine and Related Compounds in Australia

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Background: The prescription of benzodiazepines (bzd) can be a problem if used for long periods, or in at-risk populations, such as the elderly. Epidemiological data indicate that between 4 and 6% of the general population take bzd.

Objectives: To evaluate previous interventions to determine a strategy to increase the appropriate prescribing of bzd and related compounds in Australia.

Methods: Online databases were searched for interventions designed to improve use of bzd, conducted in the last 20 years. The retrieved articles were screened by title, and any which clearly did not include an intervention about bzd were excluded. Then abstracts were scanned to select potentially eligible studies. Studies which aimed to change bzd prescribing in a population either through education or by raising awareness with consumers and/or health professionals or in long term care (LTC) facilities were included for full text analysis.

Results: Thirty-one articles met the inclusion criteria. Interventions which used a multi-factorial approach had the largest and most sustained reductions in bzd use. Support groups for patients, non-voluntary recruitment of General Practitioners (GPs), and oral delivery of alerts or feedback may all improve the outcomes of interventions.

Conclusions: The evidence can now be built upon to develop an intervention, using the factors predicting success in influencing use of bzd. To date, no electronic media intervention strategy has been reported for bzd prescribing, but this is known to work as part of a multi-factorial strategy to influence prescribing of other medications. This review supports the trial of a strategy including educating GPs, pharmacists and LTC staff on the appropriate use of bzd through email bulletins, with a website, and providing bzd consumers with access to electronic resources, to try to improve use of bzd. LTC drug utilisation evaluations and other bzd utilization data from study and control areas before and after the intervention period can be used to evaluate such a strategy.

185. Real Time Post Marketing Evaluation of Therapeutic Risk Management Plans (RMPs) – A Novel Pharmacoepidemiological Tool?

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Background: Evaluation of risk minimisation programs remain an important challenge in pharmacoepidemiology. Whilst Phase IV post marketing studies and registries are options to evaluate RMPs and REMS, the review of individual tools are often limited to surveys, with their attendant

problems of bias. A new tool has been developed that provides feedback enabling evaluation of the use and impact of risk minimisation tools. The results of the pilot have been previously presented.

Objectives: Experience with a decision support analytical tool adapted for full EU live rollout as a web based prescribing checklist for a drug to treat ADHD for physicians with real time evaluation is described.

Methods: Following a pilot in 2007, the web based tool was rolled-out as a live alternative to a paper based checklist to all prescribing specialist physicians using the drug in 7 EU countries. Statistics were descriptive.

Results: Physician uptake of the tool was in line with expectations with a significant number converting from the paper checklist to the web based tool. This meant that real time evaluation was *de facto* performed in a significant and representative physician sample, providing a statistically robust pharmacoepidemiological tool. The real-time, anonymised and confidential recording of decision-making data showed physicians followed guidelines, indicated the most common prescribing decisions and resulted in more appropriate prescribing decision making and compliance with risk minimisation measures. This information in turn informed improvements to the design of the educational program and wording of tools.

Conclusions: Results indicated that the tool offers rapid and efficient evaluation of physician use and compliance with educational risk minimisation programs. Other advantages included cost, efficiency and data integrity and robustness. This tool offers an original approach for evaluating post marketing pharmacoepidemiological commitments.

186. What Is the Effectiveness of Computerised Alerts and Prompts on Clinicians' Prescribing Behaviour?

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Background: Inadequacies in medication prescribing result in considerable levels of morbidity, mortality and missed opportunities for effective and appropriate treatment. Many of these inadequacies could be addressed by the use of computerised alerts and prompts.

Objectives: To evaluate the effectiveness of computerised drug alerts and prompts on clinicians' prescribing behaviour.

Methods: A systematic review was conducted searching CINHAL, EMBASE, Inspec, MEDLINE and PsychINFO

in May 2007 using a predefined search strategy. Comparative studies evaluating electronic alerts aiming at changing clinicians' prescribing behaviour were selected and assessed. Outcomes were any changes in prescribing towards more appropriate prescribing (primary) and improvements in clinical care or health service management (secondary). Studies were grouped according to alert types to allow independent comparison of results.

Results: The search contained 14,137 articles of which 20 were included in the review. Of these, 16 showed significant benefits in terms of change in **prescribing behaviour** and/or **reduction in medication errors**. 4 studies reported impact on **clinical outcomes** such as reduction of prescribing related renal impairment (risk reduction of 0.45, CI 0.22–0.94), shorter hospital stays (decreasing from 4.5 to 4.3 days, $p < 0.009$), less falls in the elderly (decreasing from 64 to 28 per 1000 patient days, $p < 0.001$) and a trend towards reduction in serious adverse drug events. Cost savings were reported by 2 studies.

Conclusions: The majority of studies evaluating computerised prompts and alerts show positive and substantial effects on prescribing behaviour. Current literature provides little evidence about factors to consider when designing alerts for prescribing. There is a need for further studies to determine the most effective approaches when presenting information to clinicians.

187. Concurrent Use of SSRIs and NSAIDs: Estimating the Number of Potential Gastrointestinal Events in Belgium Using an Ambulatory Prescription Database (Farmanet)

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Background: There's a wide body of scientific evidence that the concurrent use of SSRIs and NSAIDs can lead to gastrointestinal events, some quite severe. Furthermore, treating these GI-events puts an extra (financial) burden on the health-care system of a country.

Objectives: Estimating the number of potential upper gastrointestinal bleedings in Belgium by using prescription data and estimating the resulting health-care costs. Using this data to translate epidemiological data in to real-life figures.

Methods: The Farmanet-database of ambulatory prescriptions was used to identify those patients with chronic (>364 DDD/year) SSRI use. From this group, those patients who received at least one package of an NSAID were then selected. Other data collected were the patients age and gender.

Results: In 2006 43,060 chronic SSRI-users received at least one package of an NSAID. Of these patients 75.14%