Pharmacy Research Review™

Making Education Easy

Issue 45 – 2015

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Abbreviations used in this issue

ADR = adverse drug reaction
MI = myocardial infarction

PHARMACY GUILD OF NEW ZEALAND

Welcome to issue 45 of Pharmacy Research Review.

Three papers in this issue involve different aspects of adverse drug reaction (ADR) reporting: levels of satisfaction among patients reporting non-serious ADRs whose reports are acknowledged by the pharmacovigilance centre; ADR studies in children; and an investigation that used a novel approach to mine clinical pharmacovigilance data demonstrates an association between use of proton pump inhibitors and risk of myocardial infarction in the general population.

The last study reports on the extent, reasons and factors that contribute to the storage of unused prescription medications in US households. National projected costs ranged from $US2.4B for the elderly to a staggering $US117B, based on estimates that 42% of the 3.9B prescriptions remain unused. The study authors call on pharmacists to educate patients about medication disposal to help resolve this problem and to prevent economic loss associated with unused medications.

I hope you find the papers in this issue useful in your practice and I welcome your comments and feedback.

Kind regards,

Chloë Campbell
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Hospital staff views on their role in providing information to patients on medication side effects

Authors: Wilcock M et al.

Summary: Outcomes are reported from an electronic survey completed by 275 clinical staff of a National Health Service hospital Trust in England. They were asked 10 questions about their views on when, how and by whom information on medication side effects should be provided to inpatients. While fewer than half (40.4%) of staff talk about side effects with patients when medicines are prescribed, more (58.8%) indicated that they would prefer to give this information when medicines are prescribed. Amongst the reasons cited for not doing so, the main one was not having time to talk to patients (stated by 91.4% of staff). Having insufficient knowledge of side effects was perceived to be a barrier by 38.8% of nurses and 54.2% of Foundation Year 1/Foundation Year 2 doctors). Pharmacists were seen as having the primary responsibility for providing verbal information about side effects by 59.9% of staff.

Comment: This is an interesting snap shot of one hospital that provides food for thought. It highlights assumptions that can be made about the role of other professions, as well as our own. The authors emphasise the importance of communication and clarity of role, though I suspect that an overlap of role could be beneficial in this context. Different professions have opportunities to provide information and some degree of repetition will help consolidate patient knowledge.

Reference: Eur J Hosp Pharm. 2015;22(2):102-6
Abstract

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Effectiveness of clinical pharmacy services: an overview of systematic reviews (2000–2010)

Authors: Rotta I et al.

Summary: This systematic review included 49 randomised controlled trials published between 2000 and 2010 that assessed the impact of clinical pharmacy services on the medication use process or patient outcomes. Clinical pharmacy services that focused on specific medical conditions, such as hypertension or diabetes mellitus, had a positive impact of pharmacists' interventions on patient outcomes. Results were inconclusive for other medical conditions with a broader target, such as dyslipidaemia or thromboprophylaxis. Similarly, interventions that targeted medication adherence and assessed the impact of clinical pharmacy services in prescription appropriateness also produced inconclusive results because of the variability of methods used to assess both medication adherence and medication appropriateness.

Comment: This overview raises some interesting points about studies evaluating the effectiveness of clinical pharmacy services and provides insight into reasons for variability in outcomes. One aspect that caught my eye was mention of a recently developed tool called 'DEPICT' (Descriptive Elements of Pharmacist Intervention Characterization Tool). I gather it breaks down pharmacist interventions into specific components and the authors suggest it may be used to help identify which components are common to successful clinical pharmacy services.

Reference: Int J Clin Pharm. 2015 May 23. [Epub ahead of print]
Abstract

GPs, community pharmacists and shifting professional boundaries

Authors: Bidwell S. Thompson L

Summary: This qualitative investigation explored how GPs and pharmacists understand the professional role of the pharmacist and its expansion, extension and calls for increased collaboration. Semi-structured interviews were conducted with 16 GPs and 17 pharmacists in the Canterbury region. Analysis of the transcripts by descriptive thematic analysis revealed broad, overall acceptance of the contribution that community pharmacists can offer via role, evolution and increased collaboration and integration between community pharmacy and primary care. There was evidence of attitudinal and practical barriers in both professional groups, hindering more collaborative forms of working, although some GPs expressed greater acceptance of medicines management by pharmacists. The article concludes that it takes time to build trusting interprofessional relationships and it suggest that effective communication, discussion and negotiation must be carried out with this in mind.

Comment: This study provides current insight into views of community pharmacists and GPs from one region in New Zealand about shifting professional boundaries. The authors point out that tensions are not inevitably negative and/or destructive but may be productive and result in new and improved ways of working. Local research such as this helps us to understand local tensions and hopefully in turn helps us to figure out new and improved ways of working together.

Reference: N Z Med J. 2015;128(1414):19-26
Abstract

Anticoagulation management by community pharmacists in New Zealand: an evaluation of a collaborative model in primary care

Authors: Harrison J et al.

Summary: This group of researchers evaluated the quality of anticoagulation control in the Community Pharmacy Anticoagulation Management Service (CPAMS), a programme of care that was piloted in New Zealand between November 2010 and July 2011. Fifteen community pharmacies across New Zealand took part in the project, which recruited 693 patients, predominantly males aged >65 years with atrial fibrillation. To enable a meaningful comparison of international normalised ratio (INR) control during GP-led care and pharmacist-led care, GPs supplied pre-pharmacy INR data, to allow a paired before–after comparison. Follow-up data (at a median 197 days) were available for 671 participants. Outcomes included time in therapeutic range (TTR), time above and below range, number and proportion of results outside efficacy and safety thresholds, and a comparison of care led by pharmacists and care led by a primary-care GP. The mean TTR was 78.6% (95% CI, 49.3% to 100%). The paired comparison between GP- and pharmacist-led care involved historical community laboratory data from 221 patients and revealed an increase in mean TTR from 61.8% under GP-led care to 78.5% under pharmacist-led care ($p<0.001$), reflecting a reduction in the time above and, in particular, below the range. The mean TTR by pharmacy ranged from 71.4% to 84.1%. The median number of tests per month was not statistically different between GP- and pharmacist-led care.

Comment: I must admit, this kind of feels like old news and when you look at the time frame on this paper you can see why – received in 2013, accepted for publication 2014, and now finally published in 2015! This paper is a companion for the previously published work showing the new model of care was highly valued by patients and supported by primary care practitioners. It provides a local example illustrating concepts from the previous two items in this review: shifting professional boundaries and successful clinical pharmacy services. The authors highlight that successful implementation relies on close professional relationships, good communication and the full support of the GPs involved.

Reference: Int J Pharm Pract. 2015;23(3):173-81
Abstract

Older peoples' attitudes regarding polypharmacy, statin use and willingness to have statins deprescribed in Australia

Authors: Qi K et al.

Summary: This study explored older peoples' attitudes and beliefs regarding medication use and their willingness to have regular medications, particularly statins, deprescribed. The authors explain that deprescribing is the process of medication withdrawal with the aims of reducing the harms of potentially inappropriate medication use and improving patient outcomes. The study involved 180 patients aged ≥65 years (median 78 years) receiving statin therapy who were admitted to an Australian acute-care hospital. Patients were questioned about attitudes and beliefs regarding medication use with the validated Patients' Attitudes Towards Deprescribing questionnaire, supplemented with additional statin-specific questions. A high percentage (89%) of participants reported that they would be willing to stop one or more of their regular medications if their doctor said it was possible and 95% agreed that they would be willing to have a statin deprescribed. With respect to statins, 94% of participants expressed concern regarding the potential side effects of these medications.

Comment: Deprescribing is a term I am seeing more frequently lately. The authors explain that there is emerging evidence from observational and limited interventional studies in older people suggesting that deprescribing is associated with improvements in quality of life and survival. It was interesting to observe that a very high proportion (over 90%) of participants expressed concern about potential side effects of statins. The authors suggested this could be due in part to recent media coverage about the adverse effects of statins.

Reference: Int J Clin Pharm. 2015 Jun 6. [Epub ahead of print]
Abstract

Health literacy and 30-day hospital readmission after acute myocardial infarction

Authors: Bailey SC et al.

Summary: These researchers describe a method that can successfully map health literacy to 30-day readmissions on a population level. They explain that health literacy, or one's ability to obtain, process and understand the health information needed to make informed health decisions, is thought to influence hospital admission and readmissions. Current, validated literacy assessments are often time-intensive and logistically challenging, with most requiring in-person administration. This study evaluated the validity of an alternative approach using a predictive model as a measure of health literacy. The researchers first determined the validity of derived health literacy estimates by examining their association with 3 commonly used, test-based literacy assessments (Newest Vital Sign, Test of Functional Health Literacy in Adults, and Rapid Estimate of Adult Literacy in Medicine) among a cohort of 696 adult, English-speaking primary care patients, aged 55–74 years. They then examined the relationship between the derived health literacy estimates and 30-day hospital readmissions among 7733 Medicare beneficiaries discharged from a hospital stay for acute myocardial infarction (AMI) in 2008 in Illinois and North Carolina, USA. There was fair agreement between derived estimates and in-person literacy assessments (Pearson Correlation coefficients: 0.38–0.51; κ scores: 0.38–0.40). Patients with above basic health literacy according to the derived health literacy estimates had an 18% lower risk of a 30-day readmission (RR 0.82; 95% CI, 0.73 to 0.92) and 21% lower incidence rate of 30-day readmission (IRR 0.79; 95% CI, 0.68 to 0.87) than patients with basic or below basic literacy. In multivariable models adjusting for both patient demographic and clinical characteristics, the risk of 30-day readmission was 12% lower (p=0.03) and the incidence rate 16% lower (p<0.01) for patients with above basic literacy.

Comment: It's important to keep in mind that the modelling tool being assessed in this study was only found to have 'fair' agreement with individually assessed measures, which is recognised as less than ideal. However, it was also highlighted that levels of agreement between the three individual-level measures of health literacy were comparable with those between the individual measures and the predictive model. Thus, variation exists even among accepted individual health literacy measures. Certainly an interesting area to watch.

Reference: BMJ Open. 2015;5:e006975
Abstract

Feedback for patients reporting adverse reactions; satisfaction and expectations

Authors: Rolfes L et al.

Summary: These researchers investigated the manner in which feedback is provided to patients reporting non-serious adverse drug reactions (ADRs) and how satisfied they are with this feedback. The study collected information from all ADRs reported by patients to the Dutch Pharmacovigilance Centre for the first time during the period from 1 October 2012 to 1 April 2013. A total of 471 patients were sent a web-based questionnaire asking them about their sociodemographic characteristics; expectations about what the pharmacovigilance centre would do with their report (processing); usefulness, clarity, expectations and level of satisfaction with the feedback; previous experience with reporting. Satisfaction was measured on a 5-point Likert scale, in which responses were rated from 'very good' (1) to 'very poor' (5). The patients had received either personalised feedback (n=217) or a general acknowledgement letter (n=254) in the previous week. The total response was 52.5%: 123 patients (56.7%) who received personalised feedback responded to the invitation email to participate in the study; 122 patients (48.3%) responded to the acknowledgement letter. The overall score for satisfaction towards the received feedback was 2.0 (good) for both groups. However, in linear regression analysis, respondents in the personalised feedback group expressed greater satisfaction (score 2.0 vs 2.5; p<0.001) and considered the feedback to be clearer (1.6 vs 1.7; p=0.01) and more useful (2.1 vs 2.5; p<0.001) compared with respondents in the acknowledgement letter group.

Comment: In New Zealand, anyone may report a suspected adverse event to CARM, although reports from health professionals are preferred. CARM's website mentions that in recent years, increasing numbers of consumers and patients have reported adverse events. They also point out that, where possible, an attempt is made to involve the patient's practitioner who often may be unaware of the reaction.

Reference: Expert Opin Drug Saf. 2015;14(5):625-32
Abstract

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Time spent reading this publication has been approved for CME for Royal New Zealand College of General Practitioners (RNZCGP) General Practice Educational Programme Stage 2 (GPEP2) and the Maintenance of Professional Standards (MOPS) purposes, provided that a Learning Reflection Form is completed. Please **CLICK HERE** to download your CPD MOPS Learning Reflection Form. One form per review read would be required.

Pharmacovigilance in children: detecting adverse drug reactions in routine electronic healthcare records – a systematic review

Authors: Black C et al.

Summary: These researchers systematically reviewed the literature published in English over 10 years (between 1999 and 2010) in order to describe the use of electronic healthcare data in the identification of potential ADRs in paediatric patients (aged 0–18 years). The study used a broad definition of ADR, accepting papers reporting the investigation of any potentially adverse clinical event (e.g. specific clinical signs, symptoms or diagnoses, or a clinical event such as an admission to hospital or a visit to a physician) associated with a medicinal product, including vaccines. Seventy-one titles were included in the review, 50 of which were published in North America, 10 in Scandinavia, and 4 in the UK. Study population sizes ranged from fewer than 1000 children to more than 10 million. Sixty percent of studies used data from one source. A range of pharmacovigilance methods were used, most commonly comparative observational methodology (66%), 21% used passive surveillance and only 4% reported active surveillance using routine healthcare data. Electronic healthcare data set linkage methods were poorly reported, as was the quality of the data source. The study researchers note the growth in use of routine electronic healthcare datasets for pharmacovigilance in children, which they say could be enhanced by consistent reporting of studies to improve the identification, interpretation and generalisability of the evidence base. Moreover, they identify that there is room for improvement around reporting of key quality issues.

Comment: Although this review indicates that literature in this area is increasing (as illustrated by the next paper), the key messages were around areas for improvement. The authors explained that it was difficult to identify relevant studies due to issues with how they are reported – even down to details like identifying the methods that had been used within the title. Well, they did identify 14,804 titles in their initial electronic search! The authors also point out that active surveillance such as this is complementary to passive or spontaneous reporting, rather than looking to replace it.

Reference: Br J Clin Pharmacol. 2015 May 28. [Epub ahead of print]
Abstract

Proton pump inhibitor usage and the risk of myocardial infarction in the general population

Authors: Shah NH et al.

Summary: Most research into the safety of proton pump inhibitors (PPIs) has focused on adverse clinical outcomes associated with clopidogrel treatment in patients with an acute coronary syndrome. These researchers used a novel approach for mining clinical data for pharmacovigilance to query over 16 million clinical documents on 2.9 million individuals, to examine whether PPI usage was associated with cardiovascular risk in the general population. In multiple data sources, patients with gastroesophageal reflux disease (GERD) treated with PPIs had a 1.16-fold increased risk of myocardial infarction (95% CI, 1.09 to 1.24). Survival analysis in a prospective cohort identified a 2-fold increased risk of cardiovascular mortality in PPI users (95% CI, 1.07 to 3.78; p=0.031). This association existed independently of clopidogrel use. H2 blockers (such as famotidine and ranitidine), an alternate treatment for GERD, were not associated with increased cardiovascular risk.

Comment: This paper provides an illustration of the concept from the previous paper of using electronic medical records for pharmacovigilance activities. The authors stipulate that their findings are hypothesis-generating and suggest a prospective randomised study in the general population is required before changing clinical practice. As this research may hit the news, I thought it might be useful to mention the UK NHS Choices website, which has a section called 'Behind the Headlines' designed to explain the science behind news headlines to patients. Although there is not an item on this particular study yet, a recent example is a story about the safety of paracetamol in pregnancy.

Reference: PLoS One. 2015;10(6):e0124653
Abstract

CONGRATULATIONS TO **Jacqui Adair** who won the iPad mini 3 by taking part in our recent Subscriptions Update promotion. Jacqui is a Clinical Nurse Specialist at Middlemore Hospital in Auckland.

Taking stock of medication wastage: Unused medications in US households

Authors: Law AV et al.

Summary: This 2-phase study explored the extent of unused prescription medications in US households and reasons for nonuse, using a convenience sample in Southern California. In Phase I, a web-based survey was completed by 238 individuals at a health sciences institution. In Phase II, a paper-based survey was conducted in 3 community pharmacies participating in a drug take-back campaign and was completed by 68 pharmacy patrons returning their unused medications (except controlled substances) for disposal. Approximately 2 of 3 prescription medications were reported unused; reasons for medication nonuse included improvement in the disease/condition (42.4%), forgetfulness (5.8%) and side effects (6.5%). "Throwing medications in the trash" was the most common method of disposal (50%), followed by "flushing it down the toilet" (26%). In Phase I, pain medications (15%) and antibiotics (6.7%) were most commonly reported as unused, whereas in Phase II, approximately 17% of medications for chronic conditions (hypertension, diabetes, cholesterol, heart disease) and 8.3% of medications for mental health problems were most commonly reported as unused. Phase II participants indicated pharmacy as a preferred location for drug disposal. The total estimated cost for unused medications was approximately $US59,264.20 (average retail Rx price) to $US152,014.89 (AWP) from both phases, borne largely by private health insurance. When extrapolated to a national level, costs ranged from $2.4B for elderly patients on 5 prescription medications, to $5.4B for the 52% of US adults who take 1 prescription medication daily, and to as much as $US117B, based on estimates that 42% of the 3.9B prescriptions remains unused.

Comment: Although set in the US, this paper serves as a reminder that this issue is ongoing and gives pause for reflection on the situation in our own backyard. How would New Zealanders compare with the 63% in this study that disposed of medications in the 'trash'? Although the general advice in New Zealand is to return unused medicines to pharmacies, is there enough public awareness of this, and is it 'easy' for people to do?

Reference: Res Social Adm Pharm. 2015;11(4):571-8
Abstract

Independent commentary by Chloë Campbell

Chloë Campbell has been a Medicines Information pharmacist for 13 years. She has experience in both hospital and community pharmacy in New Zealand and the United Kingdom. Chloë is currently co-convenor of the Medicines Information and Clinical Pharmacy Special Interest Group of the New Zealand Hospital Pharmacists Association. She has been involved in intern pharmacist assessment with the Pharmaceutical Society of New Zealand and is a member of the Editorial Advisory Board of the New Zealand Formulary. Chloë trained at Otago University School of Pharmacy and is interested in the interface between research and practice.