Hollingworth, S. A., Symons, M., Khatun, M., Loveday, B., Ballantyne, S., Hall, W., & Najman, J. M. (2013). Prescribing databases can be used to monitor trends in opioid analgesic prescribing in Australia. *Australian and New Zealand Journal of Public Health, 37,* 132-138.. Prescribing databases can be used to monitor trends in opioid analgesic prescribing in Australia. *Australian and New Zealand Journal of Public Health* 2013; **37**: 132-38

There are increasing concerns about the prescription, and possible diversion to non-medical uses, of opioid analgesic pharmaceuticals.1 There are more deaths in the US attributed to the use of prescribed opioids than to heroin and cocaine use combined.2–5 Opioid-related harms have increased as the prescription volume of opioid drugs has increased.2,6–8 This includes growing numbers of pharmaceutical opioid overdose deaths, persons treated for pharmaceutical opioid dependence and opioid overdose in hospital emergency departments.7,9–11

A Cochrane review examined opioid use in chronic non-malignant pain (CNMP)12 and suggested that, “proper management of a type strong painkiller (opioids) in well-selected patients with no history of substance addiction or abuse, can lead to long-term pain relief for some patients with a very small risk of developing addiction, abuse, or other serious side effects…”.12 It is suggested that more than one-third of the Australian population would experience such a condition at some point in their life.13,14

Opioid drugs present as a potentially effective and accessible treatment for individuals whose chronic pain conditions will not be otherwise medically resolved.

In Australia, the prescribing rates of opioid analgesics have steadily increased over the past two decades.9,10 There is some limited evidence based on large-scale community surveys and key informant research that some prescribed opioids are being used for non-medical purposes and being used by illicit drug users as substitutes for illicit heroin.10,15–17 There is minimal information about the extent of the inappropriate use of these drugs, and of the harms they might be causing in the Australian population and in Australian jurisdictions.

There is no complete national register of prescribed medications in Australia. Medicare Australia collects data on dispensed drugs that are subsidised by the Australian Government under the Pharmaceutical Benefits Schedule (PBS). It has not, however, routinely collected data on two types of non-subsidised drugs: those dispensed to general patients and priced under the general patient co-payment ($35.40 in 2012); and private prescriptions where a patient meets the full costs of the medication. PBS data may therefore underestimate the use of prescribed opioid analgesics in the general population. Data obtained from the Drug Utilisation Sub Committee (DUSC) of the Pharmeceutical Benefits Advisory Committee (PBAC) includes some information on both subsidised and non-subidised pharmaceuticals.18

Each Australian state or territory individually regulates access to opioid medications and monitors their use. State jurisdictions are not able to access nationally collected PBS information and therefore rely on their own information systems to monitor prescribing activity. All Australian states and territories, with the exception of New South Wales (NSW) and Victoria, have some form of central database that collates prescription records of opioid medications. Queensland is one of the few jurisdictions that monitors all Schedule 8 prescriptions, including both PBS subsidised, under co-payment and private prescriptions in the community. The Drugs of Dependence Unit (DDU) in Queensland Health maintains a prescription database of this information. Opioid medications dispensed from public and private hospital pharmacies for out-patients and for hospital in-patients are not recorded by the DDU.

It is unclear whether there is a significant volume of non-subsidised opioid medications that are not recorded by the PBS. The DDU information captures all dispensed opioid use whether subsided or

not, so if there is a substantial difference between PBS and DDU data then this would indicate that DUSC fails to capture current opioid prescribing.

This paper compares concordance between the trends in opioid prescriptions in Australia both subsidised by the PBS and non-subsidised (from DUSC) and Queensland DDU data for Schedule 8 drug prescriptions. Our aim was to see whether PBS and DUSC data could be used to monitor all opioid use in Australia, including non-subsidised prescribing.

Methods

The data were obtained from the national Drug Utilisation Sub Committee of the Pharmeceutical Benefits Advisory Committee and the Drugs of Dependence Unit in Queensland Health for opioid analgesics. Four classifications of prescribed drugs were used and respectively titled:

1. Australia (Aus) Total: The national and most complete data were drawn from two different databases. The first was the Medicare Australia records of prescriptions submitted for payment of a subsidy under the (PBS) or Repatriation PBS (RPBS). The second was an ongoing survey of a representative sample of community pharmacies, which provides an estimate of the non-subsidised use (below the general co-payment and private scripts) of prescription medicines extrapolated for the entire Australian community, administered by the Drug Utilisation Sub-Committee.18 There are two levels of PBS patient co-payments, one for general and the other for concession patients. Concession beneficiaries hold a Pensioner card, a Health Care card or Commonwealth Seniors Health card. De-identified data includes details of the drug product dispensed (i.e. generic drug name, dose formulation, PBS item number, etc) The use of prescription medicines dispensed to inpatients in public hospitals is not available from these sources. In Australia, patients discharged from hospital are typically provided with only a short supply of medications, typically less than one month's supply. Further prescriptions are provided by general practitioners in the community.

2. Australia (Aus) PBS: These data are for all Australian PBS prescriptions only (i.e. government-subsidised medications).

3. Queensland (Qld) PBS: These data are for Queensland PBS prescriptions only (i.e. government-subsidised medications).

4. Queensland (Qld) DDU: The DDU introduced a computer system – Monitoring of Drugs of Dependence System (MODDS) database – in 1983. The MODDS collects all dispensing information for controlled (Schedule 8) drugs19 dispensed by community pharmacies in Queensland. This information is collected from prescriptions, which community pharmacies are required to submit to Queensland Health monthly under Queensland legislation. The current version of MODDS has operated since 1996 to collate and store this information. Information collected includes: patient identification and demographics, the drug type, formulation and amount prescribed, the date of prescription and dispensing and details about the prescribing doctor and dispensing pharmacy. More than 95% of prescriptions are entered into MODDS via the electronic data interchange (EDI) system that allows pharmacies to submit information via USB or internet. Doctors are required by law to include date of birth information on prescriptions for S8 drugs but this information is not always present on prescriptions (estimated 30% missing data). Age and gender of persons receiving drugs is checked internally against existing records and against the electoral roll where possible. Only medications dispensed by hospital pharmacies are not included in the DDU (Queensland) database. We have treated QLD DDU data as the most complete source of data on opioid use in Queensland.

The amount of drug supplied was standardised using the defined daily dose (DDD) per 1,000 population per day for all drugs with an anatomical therapeutic chemical (ATC) code starting with N02A (opioid analgesics). The defined daily dose (established by the WHO Collaborating Centre for Drug Statistics Methodology) corresponds to an estimated mean daily dose of the drug when used for its main indication in adults.20 The DDDs for each drug were: morphine (100 mg oral); hydromorphone (20 mg oral); oxycoone (75 mg oral); pethidine (400 mg oral); fentanyl (1.2 mg

transdermal); and tramadol (300 mg oral). It should be noted that, for some drug formulations, WHO does not state a DDD. The following values were used based on consultation with Queensland Health: oxycodone rectal 30 mg; and fentanyl parenteral 0.05 mg. The number of Australians and Queenslanders in each year (mid-year estimate) was used to standardise the defined daily dose by population.21

The average use of the selected opioid analgesic medications (DDD/1,000 population/day) was calculated using Microsoft Office Excel 2007. The Pearson correlation coefficients were used to measure concordance between Queensland DDU with the three other data sources. Linear regression trend lines for different opioid analgesics were calculated using the regression intercept and slope to monitor average drug use over time. In the regression, use of a selected drug from a particular data source was defined as an outcome variable and time was the explanatory variable. We have tested whether the estimate of the slope of each trend line was significantly different from zero. We have used Stata Version 11 (Texas, USA) for this test.

Morphine and hydromorphone use were measured from July 2003 onward. Fentanyl was analysed separately for two phases: June 2002 to July 2006 (Phase I); and August 2006 to June 2009 (Phase II); after the subsidised indications were expanded from treating only cancer pain to include CNMP not responding to nonnarcotic analgesics. Pethidine was analysed from January 2003 to March 2007 because of the anomalous increase between July and December 2002. All data have been used (i.e. July 2002 to June 2009) for oxycodone.

Results

The dispensed use of opioid analgesic medications (subsidised and non-subsidised) for Australia, 2002 to 2009, is shown in Table 1. There was a decrease in dispensed use of pethidine (82%) and morphine (13%) and an increase in oxycodone, fentanyl and tramadol. The dispensed use of hydromorphone was low and only increased slightly. Dispensed use of opioid-type analgesics increased 53% from 5.102 DDD/1,000 population/day in 2002 to 7.826 DDD/1,000 population/day in 2009 – an annual average increase of 6.7%. If we exclude tramadol, which is not an opioid but has a similar action via a metabolite, there was a 60% increase in opioid dispensing over the 2002–2009 period.

Table 1. Total Australian (Aus Total) dispensed use (DDD/1,000 population/day) of selected opioid analgesic medications (averaged over each year or part thereof as indicated).

Opioid analgesics (ATC N02A) 2002

There is a higher level of utilisation towards the end of each calendar year. This peak is due to the safety net provisions introduced to the PBS in November 1986 to ensure patients with multiple medical conditions, who genuinely need a number of medicines, are not financially prevented from obtaining them. Once the cash-based safety net level is reached prescriptions on the scheme are either free (concessional patients), or available at the concessional co-payment amount (general patients). The safety net period is the calendar year, and the highs and lows are due to stockpiling of medication once the safety net level is reached, which usually occurs towards the end of the year.18

Oxycodone was the most commonly dispensed opioid analgesic. Its use increased 180% over the period, from 0.769 to 2.157 DDD/1,000 population/day. This corresponds to about 0.22% of the Australian population taking a standard dose of oxycodone each day. Fentanyl use increased 293% after an expansion in its indications (hence the split into two phases). Tramadol, however, was the most commonly used opioid-like medication; its use increased 44%.

The correlations between the three data sources (Australian total, Australian PBS and Queensland PBS; Table 2) were strong for all opioid analgesics except hydromorphone. All sources except QLD DDU showed an increase over time in hydromorphone ($p= 0.512$). Generally, there was substantial concordance in the absolute amounts of use between each of the four sources, suggesting that they all

reflect national and state trends in dispensed prescribing. There were differences among sources for pethidine and hydromorphone (as indicated by the intercept) whose absolute amounts of use were quite low compared to the other opioid analgesics. The proportion of non-subsidised prescribing (i.e. private and below the general co-payment) in 2008 was: 8.2% for oxycodone, 1.0% for fentanyl, 6.1% for morphine and 17.1% for tramadol (data not shown).

Table 2.
Dispensed use of selected opioid analgesics (ATC N02A): comparison of time trends (slope and intercept) for the four data sources (Australian total, Australian PBS, Queensland PBS and Queensland DDU) and correlation coefficients compared to the reference category of Queensland DDU. Thumbnail image of
The trend (regression) line for the Australian total data is given in each figure for each drug together with the absolute use for each source. There was a consistent decline in the rate of morphine dispensed (Figure 1). The prescribing of morphine in Queensland hospital pharmacies is not recorded by DDU but accounted for an additional 6.9% of prescribed morphine. Dispensed use of hydromorphone increased slightly (Figure 2) from absolute levels approximately one-tenth that of morphine. While all four sources of data show similar trends over time, the dispensed use from the Queensland PBS source was higher than from the Queensland DDU source. Hospital prescribing of hydromorphone represented an additional 27% of prescribing not recorded by DDU. This may explain why the hydromorphone estimates derived from the PBS (Queensland) appear to be substantially higher than DDU (Queensland). Based upon these figures the level of prescribing and dispensing of hydromorphone in Queensland may be higher than in other Australian states and territories.

Figure 1.

Morphine dispensed use (trend line for data from July 2003 onward) for four different data sources (Australian total, AUS PBS, QLD PBS, and QLD DDU). The regression line is shown for the Aus total source.

Figure 2.

Hydromorphone dispensed use from July 2003 onward for four different data sources (Australian total, AUS PBS, QLD PBS, and QLD DDU). The regression line is shown for the Aus total source.

Oxycodone use was a matter of particular concern (Figure 3) given the high levels and steep increase over time across all data sources. While the dispensed use of pethidine (Figure 4) is about one-tenth of oxycodone, there has nevertheless been a decrease in use across the four sources. There is a higher level of dispensed use based on the Queensland DDU data but the absolute differences compared to the other three sources are quite small.

Figure 3.

Oxycodone dispensed use from July 2002 onward for four different data sources (Australian Total, AUS PBS, QLD PBS, and QLD DDU). The regression line is shown for the Aus total source.

Figure 4.

Pethidine dispensed use from January 2003 to March 2007 for four different data sources (Australian Total, AUS PBS, QLD PBS, and QLD DDU). The regression line is shown for the Aus total source.

The dispensed use of fentanyl was divided into two time periods because of its expanded indications (Figure 5). It showed a steady increase over both phases. There was considerably more fentanyl use in the Queensland DDU data compared to the other sources. Only DUSC-derived data were available for the dispensed use of tramadol because as a non-opioid its use is not recorded by DDU. There was a

high level of prescribing compared to other opioid medications and an increased level of prescribing over time. All three data sources suggest a similar trend over time.

Figure 5.

Fentanyl dispensed use for four different data sources (Australian Total, AUS PBS, QLD PBS and QLD DDU) for July 2007 to March 2006 (Phase I, upper panel) and August 2006 to June 2009 (Phase II, lower panel). The regression line is shown for the Aus total source.

Discussion

We confirm a large increase in opioid analgesic prescribing between 2002 and 2009. There were marked increases in the use of oxycodone, fentanyl and tramadol, and decreased use of pethidine and morphine. Reduction in pethidine prescribing is likely to be related to the removal of pethidine from the PBS in 2007 and the PBS Emergency (Doctor's Bag) supply in 2006, following concerns about potentially serious side effects and the potential for abuse. Oxycodone and morphine were the most commonly dispensed opioid analgesics.

Our results are consistent with previous reports of increasing use of opioids in Australia.3,22,23 The reasons for the increasing use of pharmaceutical opioid analgesic drugs could include: an increasing prevalence of chronic pain conditions;24–26 improved quality of care by use of these drugs in palliative care and pain management;25,27 safer and improved controlled-release and transdermal preparations resulting in more consistent plasma levels and therefore more effective ongoing pain relief;28 more confidence or less reticence by medical practitioners in the use of these drugs;29,30 increased use in the hospital setting translating to increased use in the community as patients move through the health system; and successful marketing and promotion of particular drugs by pharmaceutical companies.29,31 There is a need, however, for more research in this area to determine particular issues related to increases in the Australian context.

image(6)
[Tramadol dispensed use for four different data sources (Australian Total, AUS PBS, QLD PBS, and QLD DDU). The regression line is shown for the Aus total source.]

Concomitant with this increase in prescribing has been an increase in the harms of these medications leading to concerns about the non-medical use of these medications.3 Development of appropriate policies to reduce the diversion and non-medical use of these medications is required. There is a need to develop appropriate training for medical practitioners in the use of opioids for CNMP, national guidelines for the management of CNMP in the general practice setting, and increased access to both specialist multidisciplinary pain management clinics and drug dependence services.32 Although a complex health matter, a number of simple strategies can reduce the harms from the misuse of opioid analgesics.32 Australia is currently developing a National Pharmaceutical Drugs Misuse Strategy to carefully balance the need for appropriate access to opioid analgesic drugs and to mitigate the problems arising from inappropriate use of these drugs in the community.33 There are deficiencies in current Australian prescribing monitoring systems and, in particular, a paucity of information on private prescriptions.33 Our data would suggest that such private use is minimal.

Generally, our findings confirm the consistency between DDU, PBS and DUSC data sources on trends. With only a few exceptions, the conclusions drawn about trends in use from any of these data sources would be the same. There appeared to be some under-enumeration in the PBS data reflecting non-capture of private scripts and some hospital prescribing (for example comparing QLD PBS with QLD DDU data). Over time, some of these problems will be reduced. The DDU is examining means of recording hospital outpatient dispensed prescriptions, as well as those prescriptions dispensed at community pharmacies. From 1 April 2012, Medicare Australia will collect data on PBS prescriptions that are priced below the general co-payment level.34

The dispensed use of fentanyl and hydromorphone in Queensland (PBS and DDU sources) was higher than that in the rest of Australia. This could reflect a different profile or proportion of patients using these medications in Queensland. Another possible explanation is that some hospitals operate community pharmacies that dispense PBS medications for community patients. The DDU might not capture this dispensing because it does not receive records from these pharmacies. It could be that hospital PBS pharmacies are mainly responsible for this difference.

The strength of this study is that it represents the complete capture of all subsidised dispensing of opioid analgesics in the Australian community and the complete capture of all dispensing of S8 medications in Queensland (with the exception of hospital prescribing) in the study period. All dispensed medications were standardised to the defined daily dose. There was complete utilisation information by source (subsidised, under co-payment and private) for 2002–2009.

There are several limitations in this study. We are unable to describe other characteristics of opioid analgesic users. In particular, we are unable to link this prescribing information to the diagnoses of individuals to assess the appropriateness of prescribing. Dispensed prescriptions may not reflect actual medication use. Consumer compliance with prescription instructions across all medications is known to be poor.35,36 Furthermore, with prescription opioids, this compliance could be inflated if these medications are sold to others for monetary gain or diverted to the illicit drug market.12,37

The Royal Australasian College of Physicians examined the management of CNMP and prevention of problems associated with prescription opioid use.26 One of their recommendations was to monitor the prescription of drugs of dependence for the treatment of CNMP. It noted governments needed to monitor the overall use of these medications and evaluate the effectiveness of policy and other interventions.38 The Australian Government recently announced the development of an electronic recording and reporting of controlled drugs (ERRCD) initiative.16 The system will monitor the use of pharmaceutical opioid prescriptions using a database separate from that of the PBS and administered by the respective states and territories. This means there will be two discrete repositories of prescription drug information extant in Australia.

Since 2002, different data sources reveal similar trends, namely a substantial increase in the prescribing of opioid medications. With only a few exceptions, the conclusions derived from using any of these data sources were the same. PBS data for those mediations priced above the general co-payment are freely available from Medicare Australia. However, improved access to more detailed PBS (including private and below general co-payment) data for all relevant stakeholders could provide an efficient and cost-effective way to monitor the use of prescription opioids as advocated.
Acknowledgements

The data in the paper were produced from two main sources: 1) the Drug Utilisation Sub-Committee (DUSC), Pharmaceutical Benefits Branch, Pharmaceutical Benefits Division, Commonwealth Department of Health and Ageing; and 2) the Drugs of Dependence Unit, Queensland Health, Queensland Government. This study was funded from existing salaries.

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