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To what extent do data from pharmaceutical claims under-estimate opioid analgesic utilisation in Australia?

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To what extent do data from pharmaceutical claims under-estimate opioid analgesic utilisation in Australia?

Abstract

Purpose: Although pharmaceutical claims are an essential data source for pharmacoepidemiological studies, these data potentially under-estimate opioid utilisation. Therefore, this study aimed to quantify the extent to which pharmaceutical claims from Australia's national medicines subsidy programs (Pharmaceutical Benefits Scheme (PBS) and Repatriation Schedule of Pharmaceutical Benefits (RPBS)), under-estimate prescription-only and total national opioid utilisation across time and for different opioids. A secondary aim was to examine the impact of the 2012 policy change to record all PBS/RPBS dispensed medicines, irrespective of government subsidy, on the degree of under-estimation.

Methods: Aggregated data on Australian opioid utilisation were obtained for the 2010-2014 calendar years, including all single ingredient and combination opioid analgesic preparations available on prescription or over-the-counter (OTC). Total opioid utilisation (oral morphine equivalent kilograms) was quantified using sales data from IMS Health and compared to pharmaceutical claims data from the PBS/RPBS.

Results: PBS/RPBS claims data did not account for 12.4% of prescription-only opioid utilisation in 2014 and 19.1% in 2010 and 18.4%-25.4% of total opioid use when accounting for OTC preparations. Between 2010-2014, 5.6%-5.3% of buprenorphine, 8.1%-6.3% fentanyl, 17.7%-10.7% oxycodone, 18.4%-11.0% tramadol, 38.4%-21.0% hydromorphone and 28.6%-21.0% of prescription-only codeine utilisation were not accounted for in PBS/RPBS claims.

Conclusions: Despite increased capture of less expensive (under co-payment) opioid items since 2012, PBS/RPBS claims still under-estimate opioid use in Australia, with varying degrees across opioids. The estimates generated in this study allow us to better understand the degree of under-estimation and account for these in research using Australia's national pharmaceutical claims data.

Key words: pain, analgesics, opioids, drug utilization, pharmacoepidemiology

Word count: Abstract – 250 words; Main text – 2003 words

Tables: 1

Figures: 1

Online supplementary material: 1

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KEY POINTS

- In many countries, pharmaceutical claims generated through drug subsidy by third party payers are widely used to examine opioid utilisation.
- However, due to various legislative and health system reimbursement policies governing opioid availability and supply, there is the potential for data from pharmaceutical claims to under-estimate opioid utilisation.
- Using pharmaceutical claims from Australia's national medicines subsidy programs (PBS/RPBS), this study quantifies the extent to which these data under-estimate prescription-only and total opioid utilisation in Australia across time, and for different opioids.
- In 2014, pharmaceutical claims data from the PBS/RPBS did not account for 12.4% of prescription-only opioid utilisation in Australia and 18.4% of total use when including OTC codeine preparations.

INTRODUCTION

Following evidence of pronounced increases in opioid use, misuse and associated harms in high-income countries,¹ there has been growing interest in undertaking pharmacoepidemiological studies examining both individual and population-level trends in opioid utilisation, access patterns and prescribing practices, as well as outcomes.² In particular, studies of opioid use in Australia have been increasing following recognition that it has one of the highest rates of national pharmaceutical opioid utilisation worldwide,³ with approximately 13% of the population estimated to use prescription opioids in a given year.

Historically, data on the utilisation of opioids and other medicines in Australia and internationally have been based largely on databases of pharmaceutical claims. These databases are readily accessible in many countries and generally provide comprehensive data on dispensings of reimbursed or subsidised prescriptions in community and outpatient settings.^{4, 5} However, these data are also prone to under-estimating medicines use. Estimates based on pharmaceutical claims alone are especially problematic for studies of opioids in countries such as Australia where formulations and items below a reimbursement (or co-payment) threshold are not recorded,⁶ and where some opioids are available for purchase over-the-counter (OTC).^{7, 8} Unsubsidised medicines dispensed 'privately' in the community (e.g. for increased quantities or other therapeutic indications) are also often excluded.

In Australia, many prescribed medicines are funded through two national medicine subsidy programs, the Pharmaceutical Benefits Scheme (PBS – for all Australian citizens and permanent residents) and the Repatriation Schedule of Pharmaceutical Benefits (RPBS – for Australian defence force veterans and their families). Prior to April 2012, claims data from these programs only included medicines which attracted government subsidy. Hence, many low cost medicines, including some prescribed opioids, dispensed to and paid in full by patients, have not formed part of the collection. Wholesale data, however, captures all medicines sales and can act as a robust proxy for total use. Therefore, using opioid wholesale data as the comparator, this study aimed to quantify the extent to which pharmaceutical claims from the PBS/RBS under-estimate prescription-only and total opioid utilisation in Australia, and for different opioids, between 2010 and 2014; and to examine the impact

of the 2012 policy change to record all PBS/RPBS dispensed medicines, irrespective of government subsidy, on the degree of under-estimation.

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METHODS

Aggregated data on Australian opioid utilisation were obtained from two sources for the 2010-2014 calendar years: (1) IMS Health and (2) the Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee. Specifically, this study involved a secondary analysis of IMS Health⁹ and DUSC¹⁰ data from previously published studies. All single ingredient and combination opioid products available in Australia for pain-related indications were included (see Supporting Information). Preparations of methadone and buprenorphine used for the treatment of opioid dependence were excluded.

Opioid sales data

Sales data from IMS Health were used to represent total opioid utilisation in Australia and included all prescription-only and OTC opioid purchases (products containing low-dose codeine combinations) made through pharmaceutical wholesalers and manufacturers who sold direct to pharmacies and hospitals, representing over 94% of the Australian market.¹¹ Due to the legal requirements for secure storage in pharmacies, and monitoring and recording of some opioids, the number of packs sold to community pharmacies and hospitals over a 12 month period is expected to closely approximate the number used at a macro level.

Opioid pharmaceutical claims

Pharmaceutical claims for all opioids dispensed through the PBS and the RPBS over the study period were obtained from DUSC. These are federally-funded government schemes that subsidise the cost of many prescription medicines dispensed in community pharmacies, private hospitals and on discharge from some public hospitals. Each year two co-payment thresholds are set for (a) patients with a low household income (concessional) and (b) all other (general) patients. Since 1 April 2012, pharmaceutical claims data for opioids listed on the PBS and RPBS that are priced below the under co-payment threshold have been routinely collected. Private prescriptions and low-dose codeine combinations sold OTC are not included in the dataset. However, a limited number of low-dose codeine preparations are subsidised through the RPBS (but not the PBS) when dispensed from a doctor's prescription and are therefore included in the dataset. Medicines dispensed to public hospital inpatients are funded by state governments and are not represented in these data.

However, they do include medicines dispensed to public hospital outpatients and inpatients being discharged in most jurisdictions,⁶ as well as medicines dispensed to both private hospital inpatients and outpatients.

Statistical Analyses

Analyses were conducted using SAS Enterprise Guide 6.1 and Microsoft Excel 2010. To allow for comparisons across the two data sources, opioid utilisation was presented in oral morphine equivalent (OME) kilograms (kg).¹² The advantages of using OME to represent opioid utilisation over defined daily doses (DDD) are increasingly being acknowledged.^{13, 14} In particular, DDDs do not account for the highly individualised nature of opioid dosing in clinical practice, especially in the management of chronic non-cancer pain, the most common indication for which opioids are currently prescribed.¹⁴ OMEs are especially useful for quantifying total opioid utilisation as they account for potency differences between individual opioids.

Amounts of each opioid were converted into OME kg according to existing guidelines (see Supporting Information) using the formula: strength of preparation x quantity (number of individual units sold or dispensed) x OME conversion factor. Opioid sales data were used to determine the percentage of total opioid utilisation accounted for by PBS/RPBS pharmaceutical claims. In order to better represent actual utilisation of patch formulations of fentanyl and buprenorphine, the amount in mg represents the total amount of opioid released if used in accordance with the manufacturer's directions (i.e. every 3 days for fentanyl¹⁵ and every 7 days for buprenorphine¹⁵), rather than the total milligrams of active opioid contained in the patch.

RESULTS

Table 1 compares the total utilisation in Australia of each opioid and overall, across the two data sources for the 2010-2014 calendar years, and Figure 1 presents the results graphically for the year 2014. In 2014, pharmaceutical claims from the PBS/RPBS did not account for 12.4% of prescription-only opioid utilisation in Australia, and 18.4% of total opioid utilisation when OTC codeine preparations are included. Prior to the routine collection of dispensings of under co-payment prescriptions that was implemented in 2012, PBS/RPBS pharmaceutical claims did not account for

19.1% of prescription-only opioid utilisation in 2010 and 20.0% in 2011, or 25.4% in 2010 and 26.0% in 2011 when including OTC codeine sales.

Oxycodone accounted for almost one third of total use (28.2%-31.6%) across all study years. Across opioids, PBS/RPBS claims accounted for most of the national utilisation of buprenorphine (5.6% under-estimation in 2010 and 5.3% in 2014) and fentanyl (8.1% under-estimation in 2010 and 6.3% in 2014) in all study years. At least 21% of hydromorphone (38.4% in 2010, decreasing to 21.0% in 2014) and prescription codeine (28.6% in 2010, decreasing to 21.0% in 2014) utilisation were not accounted for in PBS/RPBS claims.

Similarly, under-estimation of oxycodone utilisation decreased following the inclusion of under co-payment data in the PBS/RPBS data collection in 2012, from 17.7% in 2010 to 10.7% in 2014; under-estimation of tramadol utilisation decreased by a similar amount, from 18.4% in 2010 to 11.0% in 2014. Dextropropoxyphene, pethidine and OTC codeine had limited capture in PBS/RPBS claims as they were either not PBS-listed during the study period, or were only subsidised for patients eligible to receive medicines through the RPBS.¹⁰

DISCUSSION

This study quantifies for the first time, the extent to which pharmaceutical claims data from Australia's national medicine subsidy programs under-estimate national opioid utilisation across time and for different opioids. With increased research focusing on understanding the extent and drivers of opioid use and harms across Australia, from a health policy perspective, these results are particularly useful in guiding interpretation of findings arising from studies based on PBS/RPBS claims data and how they represent the context of opioid use in the general Australian population. In 2014, pharmaceutical claims from the PBS/RPBS did not account for approximately 12.4% of opioid utilisation in Australia, or 18.4% of total opioid utilisation when including OTC codeine preparations. Notably, the degree of under-estimation varied across opioids and over time, and was dependent on the cost of individual items and whether they met reimbursement criteria (i.e. were over the annual set co-payment thresholds). Hence, while PBS/RPBS pharmaceutical claims were shown to be a relatively complete data source for opioids over the general beneficiary co-payment

threshold, such as fentanyl and buprenorphine, for most other opioids, relying on pharmaceutical claims from the PBS/RPBS alone may under-estimate national utilisation.

The issue of under-ascertainment is a known limitation cited by researchers in many countries that use prescription registers and commercial claims databases to undertake pharmacoepidemiological studies.^{4, 5} Given that pharmaceutical claims data primarily record dispensings of subsidised or insured prescription medicines, sales of unsubsidised and OTC opioids represent an important gap in data on opioid utilisation. Yet despite being widely accessible in several countries worldwide,⁷ there is limited data available quantifying the contribution of OTC items to total opioid use. As demonstrated in this and previous studies, while OTC codeine items account for 40-50% of codeine sales in Australia,⁸ they comprise only about 6% of total opioid utilisation in OME. Hence, at a population level, most of the opioid utilisation across Australia can be accounted for by data on utilisation of prescription opioids.

Although the routine recording of under co-payment dispensings in recent years has been beneficial in reducing some of the gaps in data capture (by 6-7 percentage points), a significant gap remains. This gap currently comprises of private community prescriptions (potentially accounting for a further 6% of opioid utilisation in total¹⁰), as well as opioid use by inpatients in public hospitals. There is scope to include community-based private prescriptions in routine data collections of dispensed medicines in the future; however, given that medicines for inpatients in Australian public hospitals are funded separately by individual State/Territory governments, this proportion of opioid utilisation will continue to be unaccounted for in data from PBS/RPBS pharmaceutical claims and is an artefact of the funding structure in place for accessing medicines in Australia. These issues are also apparent in countries where similar national schemes support access to health care and prescription medicines for all residents such as across Europe,⁴ as well as in the United States where medicines are accessed predominately through commercial health insurance plans.⁵

Despite the use of complete and population-level data sources being a key strength of this study, there are some limitations to consider when interpreting the findings. In particular, it is important to acknowledge that dispensed quantities, or the number of packs sold, do not directly equate to the

amount used at the individual level, and there may be some deviations from the totals presented if accounting for differences between potential and actual use. OMEs were considered to be the most appropriate metric to compare utilisation across the two data sources and although unweighted totals may change the rank order of the most frequently used opioids, they are unlikely to change the percentage by which PBS/RPBS pharmaceutical claims account for total use given that the totals will be reduced proportionally across both data sources. Whether these observations remain consistent in the future will be dependent on the introduction and subsidy of new formulations and dosage forms, as well as clinician prescribing preferences for inpatients in public hospitals. Furthermore, the impact of the decision to restrict the availability of OTC codeine preparations in Australia from 2018 is yet to be seen.

CONCLUSIONS

Pharmaceutical claims are an essential data source for pharmacoepidemiological studies of opioids at the population and individual level. This study has quantified for the first time, the extent to which data based on pharmaceutical claims from Australia's national medicine subsidy programs under-estimate opioid utilisation in Australia. Despite increased capture of less expensive opioid items since 2012, PBS/RPBS claims still under-estimate opioid use in Australia, with varying degrees across opioids. Understanding the strengths and limitations of these data will be beneficial for future opioid studies, including adjusting for the potential degree of under-estimation for different opioids over various time periods.

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CONFLICTS OF INTEREST

SP is a member of the Drug Utilisation Sub-Committee of the Australian Pharmaceutical Benefits Advisory Committee (PBAC). The views presented are those of the authors and do not reflect those of the PBAC. BL and LD have received untied educational grants from Reckitt Benckiser/Indivior for post-marketing surveillance of buprenorphine-naloxone tablets and film in the treatment of opioid dependence in Australia, development of an opioid-related behaviour scale, and a study examining opioid substitution therapy among chronic non-cancer pain patients. BL and LD have received untied educational grant funding from Mundipharma for post-marketing surveillance of Reformulated OxyContin® in Australia. LD and SL have received an untied educational grant from Indivior to examine the safety of pharmaceutical opioids, and measures to improve patient safety. None of the companies listed had any knowledge or involvement in this study.

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Table 1. Opioid analgesic utilisation in Australia as represented by data from opioid sales and pharmaceutical claims* between 2010-2014¹

	2010				2011				2012 ³				2013 ³				2014 ³			
	Sales OME kg	Claims OME kg	% PC	% Not PC	Sales OME kg	Claims OME kg	% PC	% Not PC	Sales OME kg	Claims OME kg	% PC	% Not PC	Sales OME kg	Claims OME kg	% PC	% Not PC	Sales OME kg	Claims OME kg	% PC	% Not PC
Buprenorphine ²	437.4	412.8	94.4	5.6	505.0	479.1	94.9	5.1	566.5	540.5	95.4	4.6	606.6	581.5	95.9	4.1	641.4	607.4	94.7	5.3
Codeine	1555.8	573.5	36.9	63.1	1723.9	582.8	33.8	66.2	1779.3	730.9	41.4	58.9	1773.0	788.3	44.5	55.4	1771.3	789.2	44.6	55.4
Prescription-only	801.6	572.4	71.4	28.6	962.0	581.9	60.5	39.5	1009.8	730.4	72.4	27.6	1006.6	787.9	78.3	21.7	998.7	789.0	79.0	21.0
Over-the-counter	754.2	1.1	0.1	99.9	761.9	0.9	0.1	99.9	769.5	0.5	0.1	99.9	766.4	0.4	0.0	100.0	772.6	0.2	0.0	100.0
Dextropropoxyphene	124.9	4.2	3.3	96.7	114.9	3.3	2.9	97.1	52.2	0.5	1.0	99.0	31.7	0.0	0.0	100	10.3	0.0	0.0	100.0
Fentanyl	1135.6	1043.8	91.9	8.1	1271.5	1162.1	91.4	8.6	1301.2	1231.3	94.6	5.4	1326.4	1258.0	94.8	5.2	1341.5	1257.0	93.7	6.3
Hydromorphone	194.2	119.5	61.6	38.4	290.9	207.3	71.3	28.7	378.4	288.9	76.3	23.7	393.1	308.2	78.4	21.6	404.5	319.4	79.0	21.0
Methadone ²	418.5	345.7	82.6	17.4	416.3	359.2	86.3	13.7	421.3	373.5	88.7	11.3	431.1	380.0	88.1	11.9	420.9	373.7	88.8	11.2
Morphine	1393.8	1119.6	80.3	19.7	1327.1	1052.6	79.3	20.7	1246.9	1004.1	80.5	19.5	1109.5	934.9	84.3	15.7	1075.8	884.8	82.2	17.8
Oxycodone	2706.9	2228.9	82.3	17.7	2933.3	2417.0	82.4	17.6	3256.9	2832.0	87.0	13.0	3481.4	3108.6	89.3	10.7	3559.2	3178.4	89.3	10.7
Pethidine	25.4	0.0	0.0	100.0	21.4	0.0	0.0	100.0	18.1	0.0	0.0	100.0	15.8	0.0	0.0	100.0	13.9	0.0	0.0	100.0
Tapentadol	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	6.7	0.0	0.0	100.0	104.9	71.4	68.1	31.9
Tramadol	1602.3	1307.8	81.6	18.4	1672.4	1344.8	80.4	19.6	1735.7	1517.4	87.4	12.6	1804.0	1620.9	89.9	10.1	1893.4	1686.0	89.0	11.0
Total – excluding OTC codeine	8840.6	7154.7	80.9	19.1	9514.8	7607.3	80.0	20.0	9987.0	8518.6	85.3	14.7	10212.9	8980.0	87.9	12.1	10464.5	9167.1	87.6	12.4
Total – including OTC codeine	9594.8	7155.8	74.6	25.4	10276.7	7608.2	74.0	26.0	10756.5	8519.1	79.2	20.8	10979.3	8980.4	81.8	18.2	11237.0	9167.3	81.6	18.4

¹ Refer to Supporting Information for PBS /RPBS listings for each of the opioids over the study period

² Includes analgesic formulations only i.e. those not indicated for the treatment of opioid dependence

³ PBS under-co-payment prescription data was routinely collected from April 2012

N/A: Not Applicable – opioid was not registered in Australia; OME kg: Oral Morphine Equivalent kilograms; OTC: Over-the-counter; PC: Pharmaceutical Claims* (including opioid prescriptions subsidised by the Pharmaceutical Benefits Scheme (PBS) and Repatriation Schedule of Pharmaceutical Benefits (RPBS))

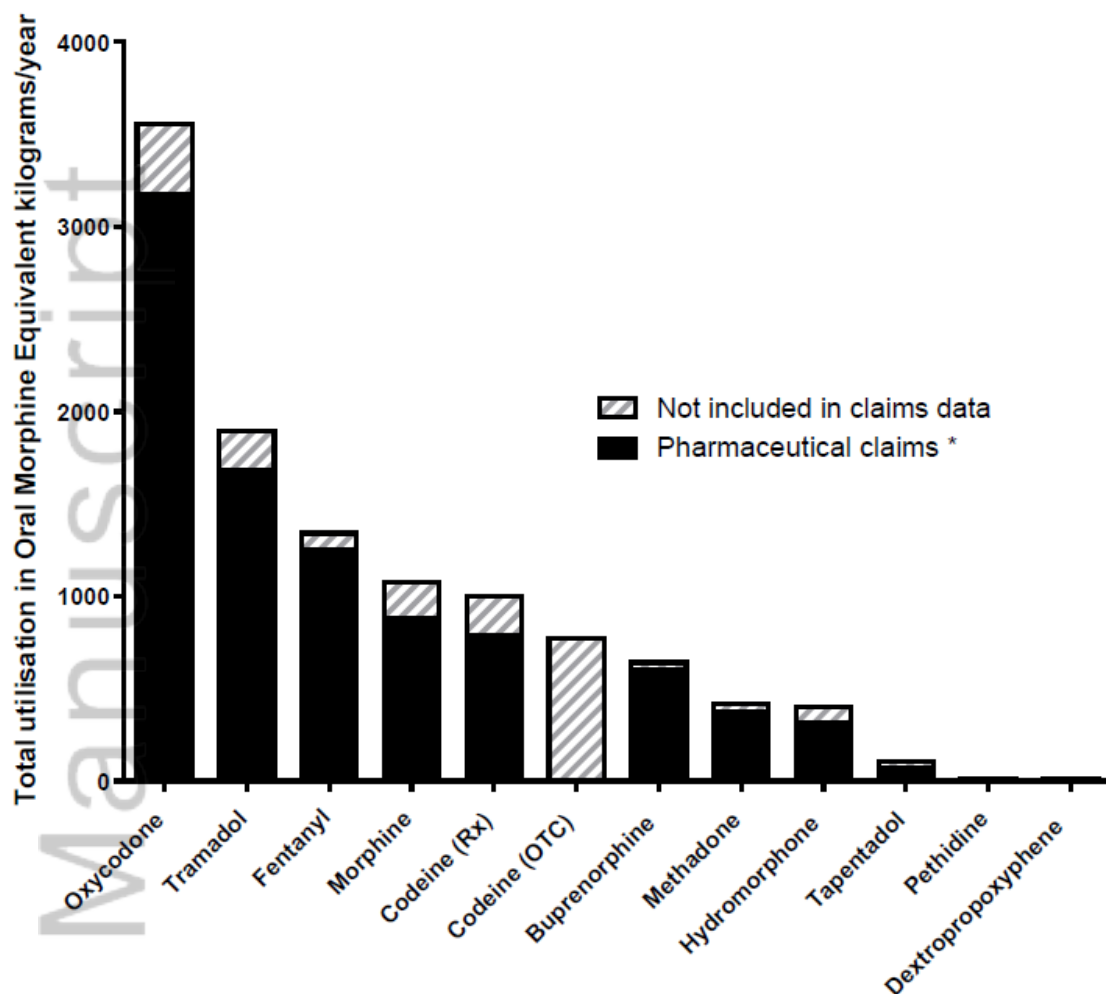


Figure 1. Opioid analgesic utilisation in Australia in 2014 as represented by data from opioid sales and pharmaceutical claims* (Pharmaceutical Benefits Scheme (PBS)/Repatriation Schedule of Pharmaceutical Benefits (RPBS))