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# **Beginner's guide to using pharmaceutical benefits scheme data**

## **Tips and pitfalls**

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## Overview

### What is the PBS?

**The Pharmaceutical Benefits Scheme (PBS)** is an administrative dataset initiated to monitor publically-subsidised prescription medicines. It does not list all medicines available in Australia, only those paid for by PBS.

It was established in 1948 amid concerns about access to essential medicines. It initially listed about 100 essential medicines which were available for free to all people. This has changed over time to include many more medicines including non-essentials however, these are no longer free to access.

The PBS covers anyone with Medicare card and those visiting from countries with a reciprocal health care agreement. All Australian citizens and permanent residents have Medicare cards (or are entitled to have one).

The main advantage of the PBS for researchers is that it provides whole-population coverage and is one of few schemes in the world to offer this. Many other international health care schemes are available only to specific groups of people (for example, low income earners) and the datasets therefore cover non-representative sections of the population.

The main disadvantage of the PBS from a research perspective is that it was not designed for research use. The PBS dataset captures PBS-subsidised medicines dispensed in Australia. It does not include:

- all medicines dispensed in Australia
- how much of the medicine was used
- what the medicine was prescribed for

This has many implications for using PBS data in research and these will be discussed below.

### What medicines are listed on the PBS?

**The Pharmaceutical Benefits Advisory Committee (PBAC)** considers which medicines are to be listed on the PBS and makes recommendations to the Minister for Health. The Minister then makes the ultimate decision about which medicines will be listed on the PBS.

All drugs considered for listing on the PBS must be approved by the Therapeutic Goods Administration for use in Australia. In addition, PBAC considers both the effectiveness and the cost-effectiveness of the medicine when making recommendations. If a new medicine covers the same indication/condition as another medicine on the list, and it is not more effective or cost-effective then it will not be included on the PBS.

The [PBS schedule](#) lists all medicines covered by the PBS and is updated monthly. Updates to the PBS schedule may include:

- additions of new medicines
- removal of medicines
- changes to conditions for which the medicines is subsidised (authority restrictions and restricted benefits)

With exceptions, medicines are usually removed from the PBS because the item ceases to be manufactured or new evidence accumulates that the medicine is not safe.

## Beneficiary categories and co-payments

There are two main beneficiary categories: concessional beneficiaries and general beneficiaries.

**Concessional beneficiaries** constitute a small proportion of the population but account for most of the medicine use. Concessional status is dependent on income and beneficiaries typically include the aged, people with disabilities, single parent pensioners, Health Care Card holders, and Commonwealth Seniors Health Card holders. As a group, concessional beneficiaries tend to be older, sicker and poorer than the rest of the population.

**General beneficiaries** include everyone else who does not qualify for concessional status.

Before the 1960s medicines listed on the PBS were available for free. Co-payments were introduced during the 1960s whereby patients contribute toward the cost of their medicines at the point of dispensing. A prescription in Australia is for one medicine and a co-payment is required for each prescription. Concessional beneficiaries pay less than general beneficiaries; in 2012 these rates were \$5.80 and \$35.60, respectively. Co-payments typically increase every year and the patient will pay either the co-payment or the full cost of the medicine, whichever is cheaper. Therefore, dispensing of a medicine is only recorded in the PBS database if the price of the medicine is above the co-payment threshold (until April 2012. See 'Below co-payment medicines' below).

**The PBS safety net** is intended to protect patients against high cumulative costs. When an individual or family reaches the safety net threshold they are entitled to discounted co-payments for the remainder of the calendar year. If concessional beneficiaries reach the safety net threshold, medications listed on the PBS become free for the rest of the year. General beneficiaries reaching the safety net are entitled to pay the concessional co-payment rate for medications for the rest of the year. It is important to note that the PBS safety net and Medical Benefits Scheme (MBS) safety net are completely independent.

There is also one further beneficiary scheme: the **Repatriate Pharmaceutical Benefits Scheme (RPBS)**. This is a small cohort of approximately 250,000 people who are veterans, war widows/widowers, or their dependents. The RPBS is funded by the Department of Veteran Affairs. Patients covered by this scheme will have RPBS listed as their beneficiary status on the PBS dataset. The medicines funded by the RPBS are decided by the Department of Veteran Affairs and may include medicines not listed on the PBS. RPBS beneficiaries pay the same co-payment and safety net thresholds as concessional beneficiaries.

**Section 100 medicines** allow for drugs to be supplied free to individuals in Indigenous remote communities. There is no way of knowing the identity of individuals provided with Section 100 drugs. Indigenous people in remote or very remote communities (according to the Accessibility/Remoteness Index of Australia) are likely to be getting medicines supplied through Section 100 and therefore may be under-represented in PBS data. This is an important consideration to take into account if researching medicine use in indigenous communities

## Prescription types

**Private prescriptions** are medicines which are either not listed on the PBS, or where the medicine is listed but the patient does not meet conditions (authority restrictions) to access the medicine under the PBS. Private prescriptions are not captured in PBS data and do not count toward the PBS safety net.

Prescriptions can be either one-off or repeats. Repeat prescriptions allow a number of repeats to be filled (typically 1-5) (current limit is 9 repeats) before the person needs to go back to the doctor for a new prescription. Under the PBS there are rules about the number of

repeats that can be given for a certain items and the current maximum limit for repeats of any item is 9. On the PBS dataset a repeat can be identified by an 'R' (the repeat number is not provided) while a designation of 'OR' means it is the original.

### **Authority restrictions/restricted benefits**

Authority restrictions/restricted benefits are used where the subsidy of medicines is only allowed under certain conditions. Some medicines may only be PBS-subsidised for specific populations or indications, or only after other therapies have failed. Drugs which are more expensive tend to have authority restrictions. As an example, there is a PBS authority restriction for clopidogrel (a blood-thinner). Aspirin can be prescribed for this indication but is much cheaper. The authority restriction outlines a series of conditions that must be met before clopidogrel can be accessed under the PBS (e.g. where disease has progressed despite aspirin therapy or the risk of gastric bleeds is high if aspirin is used). This ensures that the Government does not subsidise expensive medicines where a cheaper medicine will be just as effective, and does not subsidise unnecessary medicines.

## Key points

- The PBS is an administrative dataset; it is not designed for research use.
- The PBS dataset reflects subsidised medicine dispensed in Australia. It does not include all medicines and does not provide information about how much of the medicine was used, or what it was prescribed for.
- Concessional beneficiaries account for a small proportion of the population but most of the medicine use. These patients pay a lower co-payment than general beneficiaries.
- Once the PBS safety net is reached concessional beneficiaries are entitled to medicines (listed on the PBS) for free for the remainder of the year, and general beneficiaries pay a greatly reduced co-payment.
- Some medicines listed on the PBS may have authority restrictions which outline the conditions which must be met before the medicine can be accessed under the PBS.

## Quick links

PBS current schedule:

<http://www.pbs.gov.au/pbs/home>

PBS past schedules:

<http://www.pbs.gov.au/info/publication/schedule/archive>

Historical co-payment amounts and safety net thresholds:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pbs-copayment.htm>

## Dealing with common pitfalls

There are some major pitfalls to using PBS data. You can save time, stress and embarrassment by understanding the pitfalls and how to navigate them. Some of the more common pitfalls and methods for dealing with them are listed below.

### Below co-payment medicines

At the moment there are no medicines listed on the PBS priced below the concessional co-payment amount. As such, 'below co-payment' medicines are defined as those that are below the *general* co-payment amount.

Prior to April 2012 below co-payment medicines were not captured in PBS data. Essentially, this means below co-payment dispensings to general beneficiaries are missing from PBS data. This can be particularly problematic when a medicine of interest falls below co-payment during the study period.

Co-payments increase over time and this means that medicines fall below the co-payment every year. Generally these increase with inflation but there are also occasional steep increases (refer to **Figure 1** for an example). As a result, the medicines you are studying may be captured at the beginning of the study period but fall off during.

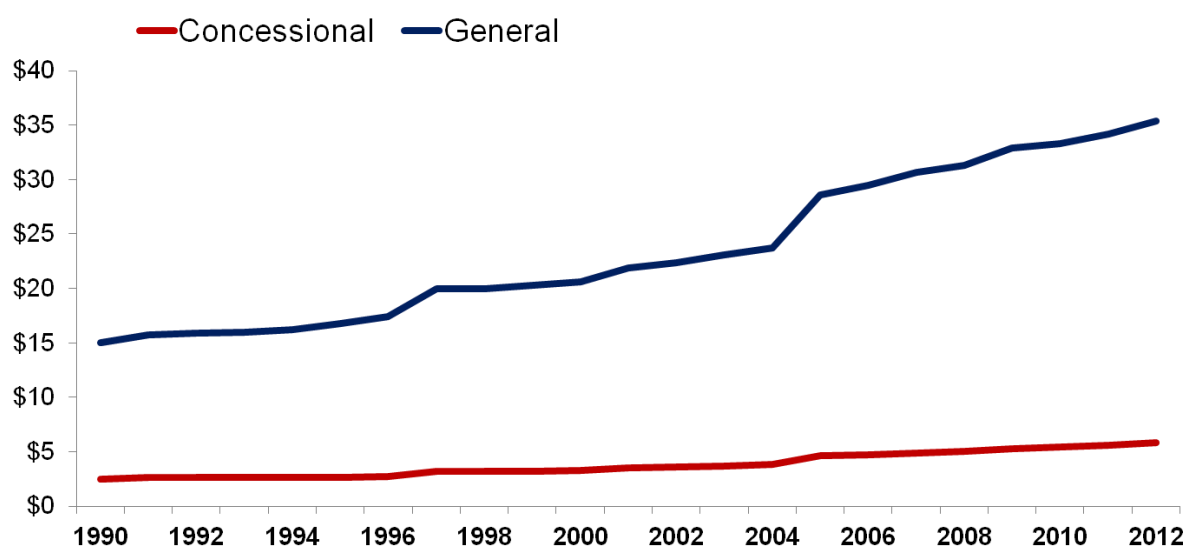


Figure 1: Change in patient co-payment amounts for general and concessional beneficiaries over time.

This issue was addressed in April 2012, with all PBS dispensings now captured. However, it is important to remember that below co-payment medicines will be missing from PBS data prior to this time point.

Below co-payment medicines tend to be older classes of medicines (for examples medicines that are off-patent) and common examples include:

- Analgesics
- Antibiotics
- Antidepressants
- Anti-epileptics
- Anti-gout treatments
- Anti-hypertensives

- Benzodiazapines
- Contraceptives
- Laxatives
- Typical antipsychotics.

### Dealing with it:

It is best to begin by considering which medicines you are interested in. how much do they cost on the current PBS schedule, and on previous schedules? Are they consistently above or below the co-payment? Do they fall below the co-payment during the study period? Consider analysing data for general and concessional beneficiaries separately. If the medicine of interest is below co-payment or fell below co-payment during the study period, then an option is to look only at data of concessional beneficiaries.

### Seasonality in PBS data

Some drugs appear to have a seasonal pattern of usage. **Figure 2**, below, shows the number of prescriptions of statins over time. There is an increase in the number of prescriptions during November/December each year followed by a steep decline during January. This seasonality is due to the safety net being reached. As the safety net is reached people stock up on cheaper medicines before the end of the year.

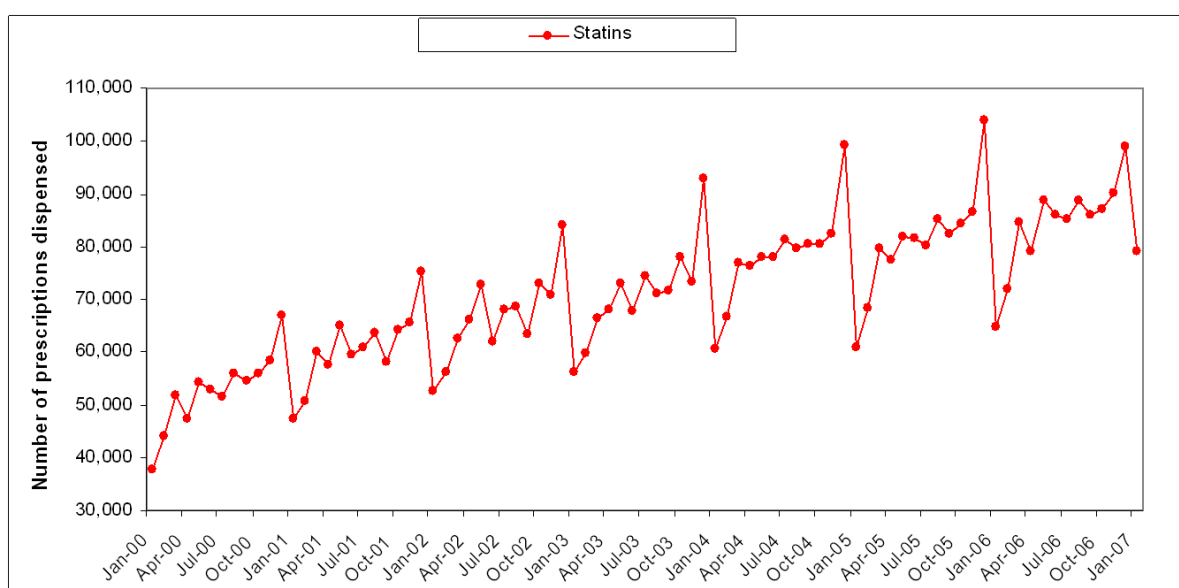


Figure 2: Number of prescriptions of statins dispensed to concessional beneficiaries over time from 2000 to 2007.

### Dealing with it:

The best way to deal with seasonality is to be aware that it is there and take this into account when interpreting data. Seasonality may be particularly difficult to see when analysing data from short time periods. Using a time-series modelling approach can adjust for seasonality.

## Authority changes, listing of new medicines and off-label prescribing

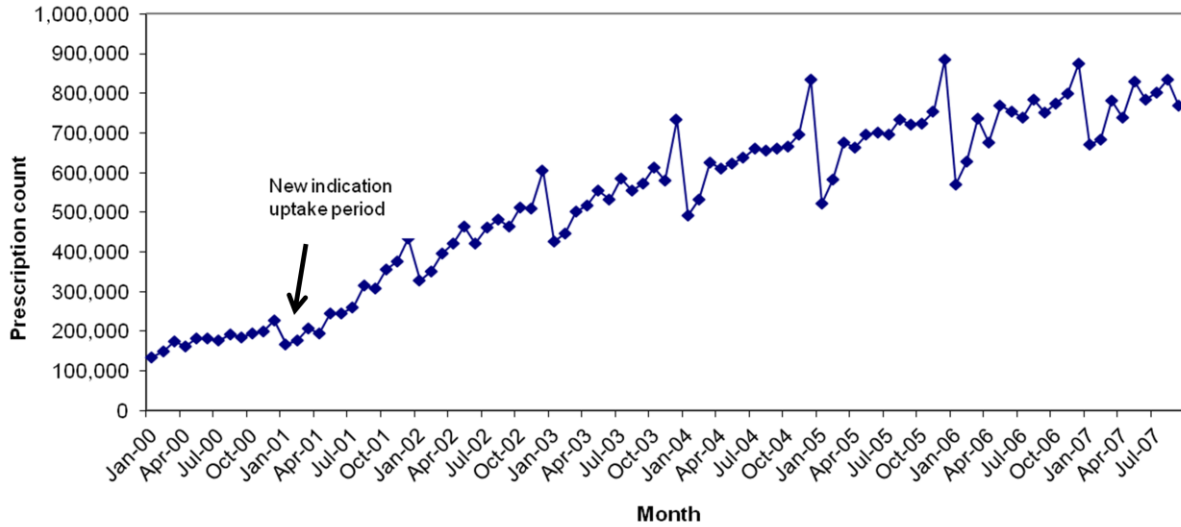
### Authority changes

Large changes in the utilisation of a medicine may reflect a change in the rules for access to the drug (change in authority restrictions). This can be observed by examining aggregate



data (available through the [Medicare](#) website) for a particular medicine over time and can be confirmed by looking at the PBS schedules for the time at which the change occurs. The aggregate data from Medicare is an efficient first pass at these data; a way to quickly identify trends that may be explained by authority changes.

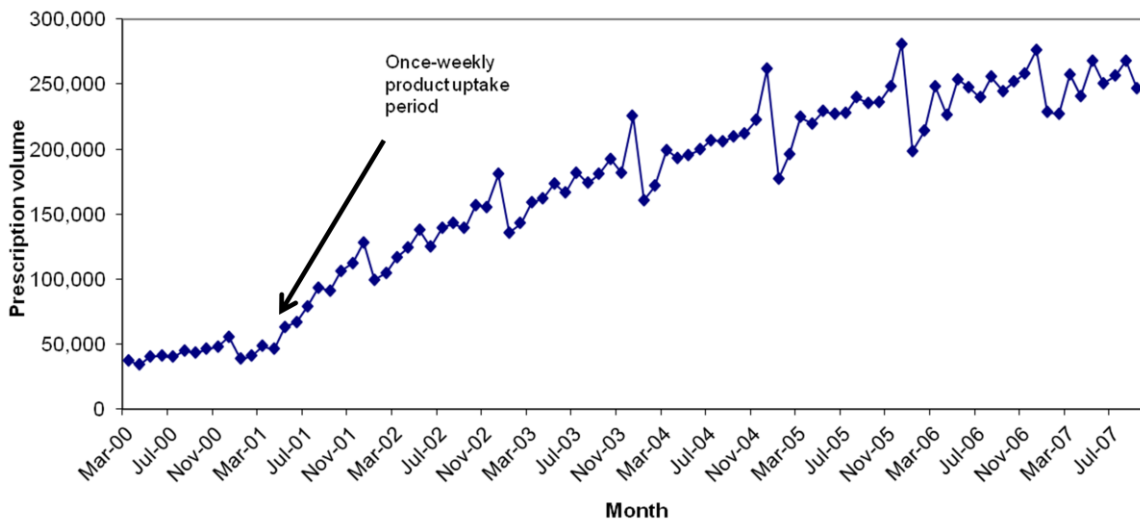
An example of changes to authority restrictions is depicted below. **Figure 3** shows that a relaxation of subsidy conditions for proton pump inhibitors resulted in a large increase in dispensings after April 2001.



**Figure 3: Number of prescriptions of proton pump inhibitors dispensed to general beneficiaries over time from 2000 to 2007**

**Listing of new medicines**

Similarly listing of new medicines in a class can also result in a change to utilisation figures. For example, the new listing of a once-weekly osteoporosis treatment resulted in a sustained increase to prescription numbers (**Figure 4**). Prior to this listing, only a daily treatment was available.



**Figure 4: Number of prescriptions of osteoporosis treatments dispensed to general beneficiaries over time from 2000 to 2007**

### Off-label prescribing

Medicines are often used for purposes not included in product information. This is referred to as off-label prescribing. An example is antidepressant medications which may be prescribed for:

- Depression
- Anxiety
- Post-traumatic stress
- Neuropathic pain
- Side effects of some breast cancer medicines
- Premature ejaculation
- Migraine headache.

### Dealing with it:

It is important to remember that many medicines can be prescribed and used for more than one condition. As such, be cautious about defining conditions through use of medicines.

There are four main ways to address changes in authority restrictions, listing of new medicines, and off-label prescribing:

1. Speak to clinicians (and/or pharmacists) who prescribe the medicines of interest to find out:
  - a. What changes have occurred during the study period
  - b. What else the medicines may be prescribed for?
2. Search literature for common off-label uses
3. Look at historical PBS schedules for changes or additions
4. Look at time trends to identify suspicious change-points in your data.

### Delisting of medicines

At times medicines may be removed from the PBS list. This may be due to the manufacturer discontinuing production, or due to safety concerns. Data requests which only include medicines on the current PBS schedule will miss medicines which were delisted during the study period.

### Dealing with it:

Don't request data by PBS code but request by Anatomic Therapeutic Chemical (ATC) code; this ensures you pick up all codes that are added or removed during study period.

Appropriate ATC codes can be obtained through the [International Coding System for Medicines](#) by searching for the generic drug name in the ATC/DDD index.

### Identity confusion

Identity confusion is a problem for data on the PBS and MBS before May 2002. Medicare cards may be held by individuals or families. Identity confusion arose because prescriptions were automatically assigned to those listed as '1' on a Medicare card, regardless of who the medicine was actually prescribed to. Men are often listed as 1 on a Medicare card which can particularly cause confusion if analysing individual records for women's medicines use.

**Dealing with it:**

There are two possible approaches for dealing with identity confusion. First, you could restrict analyses to aggregate level data. Or second, if individual-level data is required, then do not use data from before May 2002.

**Changing beneficiary status**

While many people may have a stable beneficiary status for several years, this status can change. Concessional beneficiary status changes with income. For example, students and low income earners may change beneficiary status more often (eligibility is re-assessed every eight weeks) than aged pensioners. Another issue is that some individuals reach the safety net in the later part of the year and before April 2012, below co-payment dispensing were missing for general beneficiaries until they reached the safety net.

**Dealing with it:**

There are three ways to deal with changing beneficiary status:

1. Use beneficiary status as a time-varying covariate
2. Exclude those with a change in status over the study period
3. Carefully define who you are including in your study and state this in the methods. For example, you may choose to define concessional beneficiaries as those who have not had a change from concessional status during the previous year.

Be aware that accurate population-denominators for concessional beneficiaries are difficult to determine.

**Key points**

- The main pitfalls of using PBS data include:
  - Below co-payment medicines
  - Seasonality in PBS data
  - Changes to authority restrictions
  - Listing of new medicines on the PBS
  - Off-label prescribing
  - Delisting of medicines
  - Identity confusion
  - Changes to beneficiary status.
- There are several ways to address these pitfalls but primarily it is important to be aware of them and their implications for interpretation of results.

**Quick links**

International Coding System for Medicines:

[http://www.whooc.no/atc/structure\\_and\\_principles/](http://www.whooc.no/atc/structure_and_principles/)

Pharmaceutical Benefits Scheme on Medicare website:

<http://www.medicareaustralia.gov.au/provider/pbs/>

## Tips for using PBS data

There are multiple ways of undertaking analyses using PBS data. The most appropriate approach will depend on your specific research question, which condition you are researching, and the medicine of interest. Below are some tips and basic guidelines for using PBS data.

## Available documentation

Limited documentation is available on:

- Current and previous PBS schedules
- Historical co-payments and safety net thresholds
- [Department of Health and Ageing PBS](#) information on eligibility for concessional status, the safety net, Section 100, and Regulation 24
- [Recommendations made by PBAC](#)
- Upcoming: the Drug Utilisation Sub-Committee (DUSC) is working on compiling a PBS data dictionary.

## Variables in the PBS dataset

Available PBS variables are listed below. It is better to request all variables unless there is a good reason not to, however you may need to justify your need for each variable.

- Date of supply (date the drug was dispensed (differs for repeats))
- Date of prescription (date the prescription was given by doctor (the same for repeats))
- PBS item code (items codes differ for same drug for different strength or preparation)
- ATC code
- Generic name
- Brand name
- Quantity supplied
- Dose/mass amount
- DDD amount
- Benefit category
- Authority prescription
- Regulation 24 status
- Original or repeat script
- CTG annotations (changes to lower or no co-payments for eligible Aboriginal and Torres Strait Islanders living with, or at risk, of chronic disease as part of the closing the gap scheme)

## How many prescriptions can be filled at Once

Unlimited prescriptions for different medicines can be filled at one time but usually only one prescription for the same medicine is filled at one time. Usually repeats cannot be refilled within 20 days unless the pharmacist considers immediate supply is necessary.

The exception to this is '**Regulation 24**'; this allows for genuine difficulty in accessing a pharmacy for filling prescriptions (for example, in the case of people living in a remote area, or those going overseas for an extended period of time).

Repeats filled within 20 days do not contribute towards the safety net, and once the safety net is reached they cannot be refilled at the safety net price.

## Defining medication use and users

Defining medication use is particularly challenging as PBS data only captures what is dispensed. It is not possible to know what the prescriber intended or how the medicine was used. It is important to reflect this in the language you use when writing about your research.

While there are no hard and fast rules, several factors are important to consider. Start by defining the medicine class and deciding if the medicine of interest will be treated as an exposure, outcome, or used for risk adjustment. For example, if a medicine is an exposure for a safety study then a one off prescription may be enough to define a user. However, if you are looking at effectiveness then you may define a user with more repeat dispensations. It is also important to consider:

- Is the medicine for an acute, intermittent, or chronic condition?
- How will ever users, current users, long-term users, and intermittent users be defined and distinguished? Defining users will depend on the class of medicines and the condition being studied.

## Defining the supply period

The pack size and consumer information for the medicine (for example the consumer information indicates daily administration schedule) can help define the supply period. Half-life of the medicines is also important. For example if the medicine has a short half-life than the medication needs to be taken more often.

For chronic conditions, you can make assumptions about dosage based on the number of pills in package and time between dispensing to define a supply period. For example, for a chronic condition, if a pack size is 30 and the consumer information indicates once-daily administration, it may be safe to assume the supply period is 30 days.

A reliable sign of a medicine for chronic condition is that repeat prescriptions are allowed under the PBS and the pack size is often 30 for medicines taken daily and 60 for medicines taken twice-daily.

If an individual needs a larger-than-standard dose (for example, they would take two daily tablets to get a clinical effect), the PBS allows for an 'authority script' whereby the individual is given a larger supply of the medicine for the one co-payment. The 'quantity supplied' field in the PBS dataset will identify dispensing of doses higher than usual.

## Calculating dose and defined daily dose

To calculate dose you can request variables to indicate the strength of the medicine (dose amount) and quantity supplied. This can allow for assumptions about the dosage to be made but due to pill splitting, poor adherence, and sharing drugs these assumptions may be incorrect. As such, it can be more useful to focus on the average dose over a period of time.

The **defined daily dose (DDD)** is an international metric defined by World Health Organization (WHO) and is like an exchange rate for doses of drugs. The DDD is the amount of maintenance dose given to a 70kg adult. WHO sets a [DDD](#) for each ATC code where the DDD is for the main indication. The DDD is not the actual dose used but provides a convenient way of comparing medicines.

For example the DDD for simvastatin is 30mg. Under the PBS, simvastatin can be supplied in 10mg, 20mg, 40mg, or 80mg. These can be converted to a DDD for easier comparison between groups. A common use of the DDD is to compare the number of standard doses of a particular medicine being dispensed to different populations. DDD is typically expressed per 1000 population per day for comparing doses dispensed between groups or over time. For example, at a population level the DDD/1000/day for a medicine may be 200 for WA and 282 NSW. DDD tends to be used as an aggregate statistic.

## Defining discontinuation and intermittent use

Defining discontinuation and intermittent users depends heavily on the study. You need to consider what makes sense given the medicines' pharmacology, indication, and characteristics of the condition. When determining how much time between dispensings (treatment gap) is considered 'discontinuation' of therapy, you should consider allowing:

- a 'grace' period of five days for refill of prescriptions, particularly for asymptomatic conditions. For some symptomatic conditions it may make more sense for the grace period to be less.
- for end-of-year stockpiling (due to safety net being reached).

## Example case-studies: ways to approach analyses using PBS data

When planning an analysis using PBS data it is important to define:

- the supply period (may equal pack size depending on the administration schedule) plus a refill period
- treatment duration
- treatment gap
- discontinuation period
- A medication user.

The case studies below highlight different analysis approaches. Case study one presents a fairly straight forward study where the medicine is prescribed for only one condition and the daily administration schedule is consistent. Case study two is a more complex example where the medicine of interest can be used for a number of conditions, is available in several forms, and the administrative schedule is varied.

### Case study one: Hormone therapy for breast cancer

Selective-oestrogen receptor blockers such as tamoxifen are used to treat breast cancer. Tamoxifen is given after the initial tumour is removed to prevent recurrence. Tamoxifen (20mg) is taken as a daily tablet and dispensed in packs of 30. Therapy is recommended for  $\geq 5$  years and it is not PBS-subsidised for any indication other than breast cancer.

- The **Supply period** can be defined as 35 days (pack size plus 5 days for prescription refill)
- **Treatment duration** is the number of days between the first dispensing, and date of the last dispensing plus 35 days (or the end of the study period, or death)
- **Treatment gap** is the sum of the days with no dispensing record, minus the 35 days since the last dispensing
- **Discontinuation** is defined as a gap of  $>105$  days between dispensations (three-times the usual supply period).

### Case study two: Opioid analgesics for non-cancer pain

Opioid analgesics were originally intended for acute pain (i.e. post-surgery) but have also demonstrated to be effective for some forms of cancer pain. This class of medicines are

increasingly used off-label to treat chronic non-cancer pain. The class spans codeine through to morphine and medicines come in the form of tablets, oral liquid, injectable liquids, suppositories, patches, and lozenges. Pack/bottle sizes range from single injections to boxes of 60 but many tablets come in packs of 5-10. There is no such thing as a 'standard' dose for long-term users of opioid analgesics because tolerance and pain severity vary widely.

This study was approached by excluding participants with a history of cancer, and excluding PBS items restricted to use for palliative care. Users were categorised as:

- **Acute users:** gap between first and last dispensing of an opioid was  $\leq 90$  days
- **Long-term users:** gap between first and last dispensing of an opioid was  $>90$  days *and* the individual had  $\geq 3$  authority dispensings for opioids (indicates that the standard pack is not sufficient for 30 days supply)
- **Episodic users:** gap between first and last dispensing of an opioid was  $>90$  days *and* the individual had  $<3$  authority dispensings for opioids.

#### Other approaches to defining medication use

- The 'standard' supply period can be derived from the dataset
  - For example, the supply period is the number of days in which 75% of the participants had refilled a script
  - This is particularly suitable for intermittent therapies
- Long term versus short term use can be defined by the total number of dispensations over a specified period
- Look at published pharmacoepidemiological papers that have looked at the medicine class of interest and adapt their definitions for the PBS context. Be careful if these are international papers and consider how they translate to the PBS.
- Consider the clinical significance of the definitions.

#### General advice

- Make friends with prescribers and pharmacists
- Talk to anyone and everyone who will give you an opinion on the drug class you're looking at
- Talk to consumers (these are often the best people to help you understand quirks in your data)
- Treat every situation/medicine/disease as unique (the rules from one class of medicines may not translate to others)
- Look at aggregate trends to identify major changes in use of medicines or errors in data extraction

## Key points

- When requesting PBS data, ask for all available variables (unless there is a good reason not to).
- Defining medication use is challenging as PBS data only capture what is dispensed, not what is used. When defining use it is important to consider the medicine class, the condition of interest, and the specific study question.
- The supply period depends on the pack size, administration schedule, half-life of the medicine, and the condition it is prescribed for.
- The defined daily dose is an international metric which provides a way of comparing dispensation between groups.
- The discontinuation period depends on the medicines' pharmacology, indication, and characteristics of the condition. It is important to allow for a grace period for refilling of prescriptions, and allow for stockpiling.

## Quick links

Department of Health and Ageing PBS information:

<http://www.health.gov.au/pbs>

Recommendations made by PBAC:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-listing-pbacrec-prevpbacrec.htm>

ATC DDD Index:

[http://www.whocc.no/atc\\_ddd\\_index/](http://www.whocc.no/atc_ddd_index/)

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