

SAND abstract No. 160 from the BEACH program 2009–10

Subject: Prevalence, cause, manifestation and severity of adverse pharmacological events

Organisations supporting this study: Australian GP Statistics and Classification Centre

Issues: The proportion of general practice patients who have experienced an adverse event resulting from the use of a medication during the preceding 6 months. For the most recent event, the cause, clinical manifestation, severity, duration and any resulting hospitalisation.

Sample: 5,497 respondents from 189 GPs; data collection period: 19/01/2010–29/03/2010.

Method: Detailed in the paper entitled *SAND method 2009–10* at:
<www.fmrc.org.au/publications/SAND_abstracts.htm>.

Summary of results

Sex of patient was recorded at 5,463 encounters, and 63.5% (95% CI: 61.4–65.7) of these were with female patients, a significantly higher proportion than in total 2009–10 BEACH encounters (60.4%, 95% CI: 59.5–61.3). The age distribution did not differ from patients at all 2009–10 BEACH encounters.

Of the 5,497 respondents, 466 (8.5%; CI: 7.4–9.6) had experienced an adverse drug event in the previous 6 months. There was no difference in occurrence of adverse events between the sexes. The proportion of patients who reported an adverse drug event increased with age, from 1.8% of infants aged less than 1 year to 11.6% of patients aged 75 years or more.

Of 484 drugs suspected of causing adverse events, 'natural opium alkaloids' and 'other antidepressants' were the medication groups most often cited. However, they accounted for only 4.8% and 4.6% respectively of the medications, due to the wide variety of medications implicated. The most common individual medications were atorvastatin, which accounted for 2.5%, tramadol (2.3%), amlodipine (1.9%), and metformin (1.9%).

Among 442 respondents, the most commonly listed manifestations/symptoms of the adverse event were digestive in nature (28.1% of all manifestations), followed by skin problems (16.4%), and problems which were general and unspecified (14.2%). At individual condition level, the most common were nausea (9.1% of all listed manifestations), followed by localised rash (8.3%), vomiting (6.0%), vertigo/dizziness (3.6%) and diarrhoea (3.5%). Within individual drug groups, opioids most commonly caused vomiting (drug specific rate 15.3%), nausea (13.9%) and/or constipation (12.5%); antidepressants caused sleep disturbance (13.4%), anti-arthritis caused epigastric pain (19.4%), lipids caused muscle pain (30.8%) and penicillins caused rashes (28.6%) and diarrhoea (19.1%).

Among 446 respondents, the adverse drug event was classed as mild for 41.7%, moderate for 46.2%, and severe for 11.7%.

Of 445 patients with an adverse drug event for whom this information was known, 5.4% were hospitalised due to the event. Of 52 patients with a severe event, 28.9% were hospitalised. Information on the duration of the event was available for 441 patients. For 42.2% the adverse event lasted for less than 1 week, for 19.1% it lasted 1–2 weeks, for 14.3% it lasted 3–4 weeks, for 15.2% it lasted 1–2 months, and for 9.3% it lasted more than 3 months.

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PLEASE READ CAREFULLY

The shaded section of the following forms asks questions about **ADVERSE PHARMACOLOGICAL EVENTS**.
You may tear out this page as a guide to completing the following section of forms.

INSTRUCTIONS

These questions are about measuring the level of impact of medication events in the community. You will need to ask the patient for information when answering the following questions as you may not know if an adverse event occurred e.g. if the patient did not inform you of side effects they experienced or if the medication in question was prescribed / advised / supplied by another doctor / health professional in any setting (e.g. hospital inpatient, outpatient, primary care etc).

If you are interested in our previous work on this topic, please see Miller GC, Britt HC, Valenti L. Adverse drug events in general practice patients in Australia. Med J Aust 2006 Apr; 184(7):321-4.

ASK THE PATIENT

Please ask the patient if they have **experienced an adverse event from the use of any medication** in the **past six months**.

An adverse event is an unintended event which could have harmed or did harm the patient. 'Harm' includes physical, psychological or emotional suffering.

If **no** adverse events were experienced, **end the questions here**.

Manifestation of the event

From the patient's description or your knowledge of the **most recent adverse event**, what was/were the **manifestation/s or symptom/s** (e.g. rash, vomiting, dementia)?

Severity of the event

Please indicate the **severity of the event** in terms of harm to the patient (in your clinical opinion).

Mild - a reaction of limited duration not requiring further treatment; minimum impact on daily activities.

Moderate - a reaction of longer duration or which requires further treatment; limits daily activities.

Severe - a reaction of any duration which results in hospitalisation and/or long term limitation of daily activities.

Medication involved in the event

Please **list the drug (or drugs** in the case of interactions) **that you suspect were the cause of the most recent adverse event**.

The drug(s) may be listed using the **generic or brand name**.

Hospitalisation

As a result of this adverse event, was the patient **hospitalised**?

Duration of the event

Please ask the patient how long the most recent adverse event lasted.

In the past six months has this patient experienced an adverse event in response to use of a medication:

- Yes
 No → End questions

Please list the drug(s) you suspect caused the most recent event:

Please specify the manifestation(s) (e.g. rash, vomiting) of the most recent adverse event:

Was the event -

- Mild
 Moderate
 Severe
 Don't know

Was the patient hospitalised due to this event?

- Yes
 No

What was the duration of the most recent adverse event?

- <1 week
 1-2 weeks
 3-4 weeks
 1 to 3 months
 > 3 months