2 Methods

2.1 BEACH

The BEACH program is a continuous national study of general practice activity in Australia. It uses details of about 100,000 encounters between GPs and patients (about a 0.11% sample of all general practice encounters) from an ever changing random sample of 1,000 recognised practising GPs. The methods are described in detail in *General practice activity in Australia 2005–06*.[8]

In summary:

- each year BEACH involves a random sample of approximately 1,000 GPs
- the GP sample is a rolling (ever-changing) sample
- approximately 20 GPs participate each week, for 50 weeks a year
- each GP can be selected only once per RACGP (Royal Australian College of General Practitioners) quality assurance triennium
- each GP records details about 100 doctor–patient encounters of all types
- information is recorded by the GPs on structured paper encounter forms
- each GP participant also completes a questionnaire about themselves and their practice
- the program generates records for about 100,000 encounters per year.

Random samples of GPs who claimed at least 375 general practice Medicare items of service in the previous 3 months are regularly drawn from Medicare Australia data by the Primary Care Division of the Australian Government Department of Health and Ageing (DoHA).

- We approach the randomly selected GPs by letter, posted to the address provided by DoHA.
- Over the following 10 days we use the electronic telephone books to check the telephone numbers generated from the Medicare data. This is necessary because many of the telephone numbers provided from the Medicare data are incorrect.
- We then telephone the GPs in the order in which their letters were posted and, referring to the approach letter, ask whether they will participate.
- On initial telephone contact with the practice we often find that the selected GP has moved elsewhere, but is still in practice. Where forward address and/or telephone number can be obtained, we try to contact the GPs at their new address.
- GPs who agree to participate are set an agreed recording date several weeks ahead.
- We send a research pack to each participant about 10 days before the planned start date.
- A telephone reminder is made to each GP in the first days of the agreed recording period—this also provides the GP with an opportunity to ask any questions they have about the recording process.
- We follow-up non-returns by regular telephone calls for up to 3 months after the set recording time.

- Participating GPs earn up to 60 Clinical Audit points towards their quality assurance (QA) requirements through the RACGP. As part of this QA process, each receives an analysis of his or her results compared with those of nine other de-identified GPs who recorded at approximately the same time. Comparisons with national averages are also provided. In addition, GPs receive some educational material related to the identification and management of patients who smoke or consume alcohol at hazardous levels.

Previous work has demonstrated the reliability of the methods adopted in BEACH.[5,6,9–14]

Detailed methods are described in all BEACH annual reports, the most recent of which is *General practice activity in Australia 2005–06* and can be downloaded from <www.fmrc.org.au/publications/Books3.htm>.[8]

2.2 SAND—Supplementary Analysis of Nominated Data

A section on the bottom of each recording form investigates aspects of patient health or health care delivery in general practice not covered by the consultation-based data. Each component covers a specific topic, and involves a line of questioning that is asked of the patient and/or the GP in addition to the encounter-based information.

- In every GP's pack of 100 forms there are 40 forms that contain questions about patient risk factors: patient height and weight (used to calculate body mass index, BMI), alcohol intake and smoking status (patient self-report), and start time and finish time of the encounter (for calculation of and the length of consultation measured by recorded finish time minus recorded start time for Medicare claimable A1 items of service).
- The remaining 60 forms in each pack are divided into two blocks of 30. Different questions are asked of the patient/GP in each block of 30 forms and these vary throughout the year.
- The annual BEACH data collection period is broken down into 10 five-week periods of recording and new SAND substudies are introduced (unless the topic is to be repeated) at the end of a five-week block.
- With the exception of the standard risk factor SAND substudies that run throughout the year, other topics run for a five-week period collecting information from about 100 GPs (20 recording per week), with a potential sample size of about 3,000 patient encounters in each topic.
- The order of SAND sections in the GP recording pack is rotated, so that the 40 patient risk factor forms may appear first, second or third in the pad. Rotation of ordering of the components ensures there is no order effect on the quality of the information collected.

Each organisation supporting the BEACH program has access to a subsample of 6,000 encounter forms per year (or two subsamples of 3,000 each) in which to insert a series of questions on a subject or subjects of their choice.

The development of the tools for SAND substudies

Organisations supporting the BEACH program financially are given set dates for the two blocks they can use in the coming BEACH year. Consideration is given to any specified seasonal needs (such as studies of patient influenza vaccination status which are of more value in winter than in January before the annual round of vaccinations).

Organisations are actively encouraged to select subjects that will arise with sufficient frequency in the sample to make the study worthwhile. For example, while prostate cancer is an increasingly important risk for men's health, asking questions about its management among males attending general practice would provide a very small sample of respondents since: 60% of the respondents in the 3,000 sample would be female (and therefore not asked the question); of the remaining 1,200 males encountered by the GP in that sample, only about 220 would be aged 45 years or over (on average). Since those at highest risk are patients aged 75 years and over, and GPs are advised against routine screening for prostate cancer, the chances of picking up more than a couple of cases are minimal.

The organisation sends their nominated topic and a series of research questions to the SAND coordinator in the BEACH team. Sometimes the research questions could be seen as a 'wish list' and the challenge is to design a SAND substudy that will answer as many of these questions as possible within the limited space available and without demanding too much of the GP.

The characteristics of tools that can be used within the confines of the GP–patient encounter, by GPs pressed with time issues, are brevity, face validity and simplicity. The tool should be easy to administer verbally and quick to complete.

The SAND coordinator works with the representatives of the organisation to refine the objectives to a workable level, and prepares an initial draft of questions and instructions. It then becomes an iterative process between the researchers and the client organisation. At various stages of development input is gained from other members of the research team. The analysts' comments are useful to ensure that at the end of the process, the data can be analysed in a manner that will satisfactorily answer the research questions. The view of the database manager is important in ensuring that the new SAND database can be built in a manner that assists the coding staff. Coder training staff views are useful in picking up questions which have the potential to generate wide ranging responses and present coders with problems in reliable data entry. Often the input of the Medical Director is required to ensure clinical accuracy and relevance of the questions being asked, but most importantly to ensure that the final set of questions and its accompanying instructions will 'make sense' to the GP in a clinical setting. Throughout this process the research team use their extensive experience to hypothesise the many likely responses to the questions and revise response options as appropriate.

By the time the questions are completed and ready to be sent to the Ethics Committee for approval, an average of five drafts will have been developed over a period of about 4 weeks.

The final tools, (and where appropriate the rationale for this SAND study) are then sent to the AIHW Ethics Committee for approval (on behalf of the Institute and the University of Sydney) prior to printing and distribution to the GPs.

Wherever possible we try to use questions and definitions that have been validated and published elsewhere. For example, the definitions for severity of asthma in adults and in children (Abstract 96) rely on the severity classifications produced by the National Asthma Council. If all the questions utilise internationally or nationally accepted published tools, there is no need to apply for Ethics approval. However this is rarely the case.

The relationship of the SAND substudies to the data elements collected in the total BEACH program is graphically presented in Figure 1. It demonstrates that the SAND data can be cross analysed with data about the GP, the patient, or the content of the encounter.

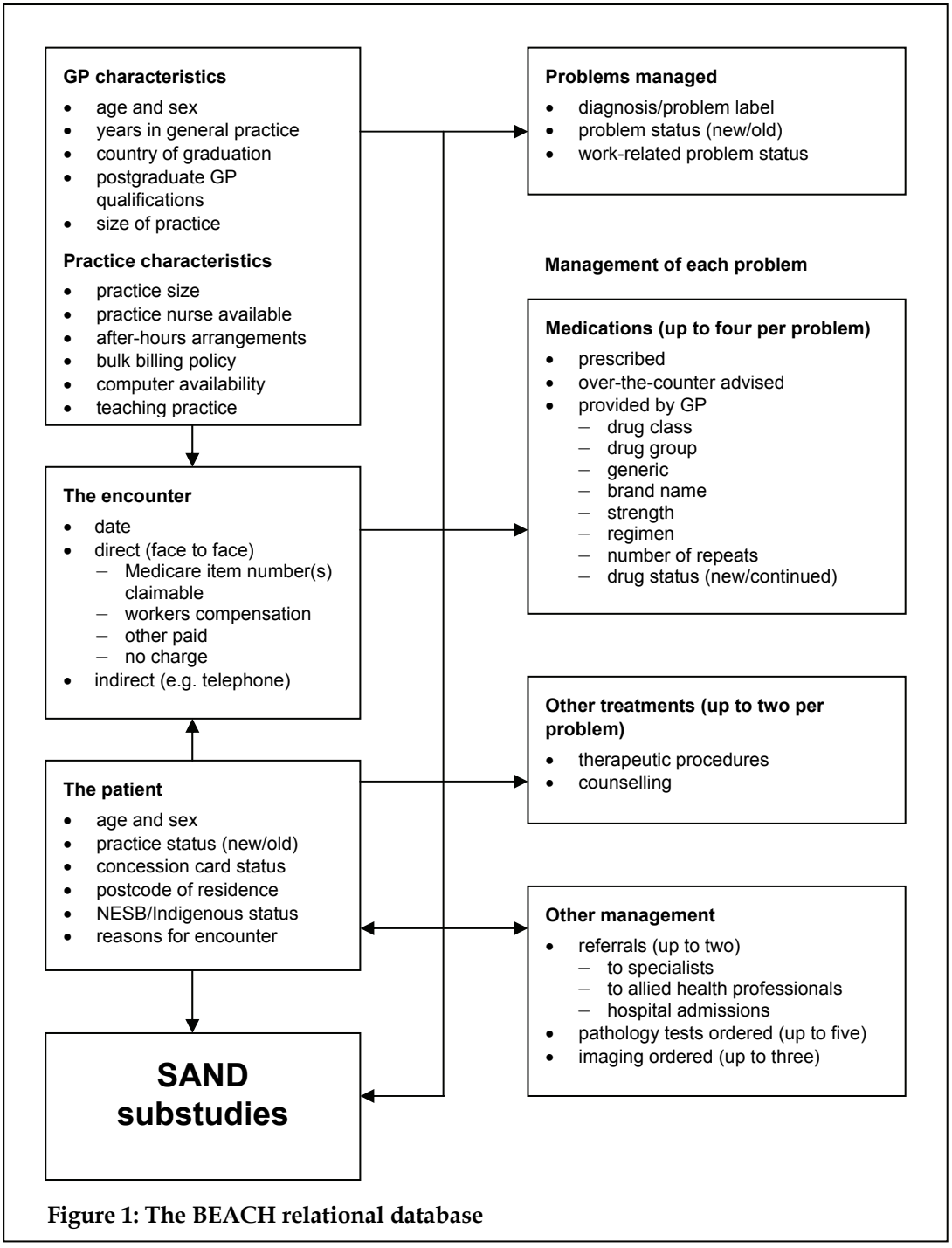

Figure 1: The BEACH relational database

Statistical methods

The analysis of the SAND substudies included in this report were conducted with SAS version 6.12[15] for all studies conducted between 1999–00 and 2004–05. Topics investigated since then were analysed using SAS 9.1.[16]

The BEACH study is a random sample of GPs, each providing data about a cluster of patients on a specific topic. We use the patient as the unit of inference when the data are analysed and interpreted. However, the cluster sampling study design violates the simple random sample (SRS) assumption of equal probability of selection of a patient, because the

probability of a patient being included is a function of the probability of the GP being selected.[17] Cluster samples also violate the assumption of independence of observations, as there is an inherent relationship between patients sampled in the same cluster. Therefore the certainty that the sample estimates reflect the true underlying population values is reduced by cluster sampling, and decreases the precision of prevalence or management estimates. When a study design other than SRS is used, analytical techniques that consider the study design must be employed.

In this report, the standard error calculations used in the 95% confidence intervals accommodate the single-stage clustered study design according to Kish's description of the formulae.[18] SAS version 9.1 includes procedures that calculate the robust standard error to adjust for the intra-cluster correlation of the cluster sample. In contrast, SAS version 6.12 is limited in its capacity to calculate the standard error for the current study design, so additional programming was required to incorporate these formulae, in earlier years.

Classification of data

If recorded in free text in a SAND substudy, the following data elements are classified according to the International Classification of Primary Care—Version 2 (ICPC-2), a product of the World Organization of Family Doctors (Wonca):[19]

- problems managed
- clinical treatments (e.g. counselling, advice) and therapeutic procedures
- referrals to specialists and allied health providers, pathology and imaging tests ordered.

Pharmaceuticals recorded in free text in SAND substudies are coded and classified according to an in-house classification, the Coding Atlas for Pharmaceutical Substances (CAPS).

- This is a hierarchical structure that facilitates analysis of data at a variety of levels, such as medication class, medication group, generic composition, brand name. Strength and regimen are independent fields which, when combined with the CAPS code, allows us to derive prescribed daily dose for any prescribed medication or group of medications.
- CAPS is mapped to the Anatomical Therapeutic Chemical (ATC)[20] classification which is the Australian standard for classifying medications at the generic level. The ATC has a hierarchical structure with five levels. For example:
  - Level 1: C—Cardiovascular system
  - Level 2: C10—Serum lipid reducing agents
  - Level 3: C10A—Cholesterol and triglyceride reducers
  - Level 4: C10AA—HMG CoA reductase inhibitors
  - Level 5: C10AA01—Simvastatin (the generic drug).