



**ACADEMIC UNIT OF GENERAL PRACTICE AND COMMUNITY
HEALTH**

THE BENZODIAZEPINE VOLUNTARY UNDERTAKING

**A DATA AUDIT
AND
RETROSPECTIVE EVALUATION
IN THE ACT**

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EXECUTIVE SUMMARY

A Benzodiazepine Voluntary Undertaking (BVU) is a tool used by general practitioners (GPs) in the Australian Capital Territory (ACT) to improve the medical management of patients with known or suspected excessive benzodiazepine use.

A BVU consists of an agreement between a patient and their doctor, whereby the patient agrees to attend only one identified medical practitioner to receive their prescriptions for benzodiazepines, and to attend only one identified pharmacy to have their prescriptions for benzodiazepines dispensed.

The BVU Program, established in 1996, is coordinated by the ACT Health Protections Service (HPS) and requires the participation of GPs and private pharmacies in the ACT.

This study explored the effectiveness of the BVU program in the ACT between 2004 and 2008. This study audited data held by ACT HPS and explored GP's, pharmacist's and patient's satisfaction with the program. In addition, this study established the parameters for a full evaluation of the BVU Program; one which considers both its clinical effectiveness and the efficiency of its processes.

This study was funded by ACT Health, the Australian Capital Territory's department of health, and conducted by the Academic Unit of General Practice and Community Health (AUGPCH). A report of the study has been provided to ACT Health.

METHOD

This study employed both quantitative and qualitative methods to collect and analyse data. We:

1. Conducted an audit of data held by ACT HPS for the years 2004-2008. Data regarding patients on BVUs, patient contacts with the BVU program, GPs involved in the BVU program and pharmacies involved in the program are reported.
2. Conducted semi-structured interviews with GPs, pharmacists and patients to establish their understanding of the program and its procedures, and their opinions of what worked and how things could be improved.

RESULTS

Results are reported for both the data audit and qualitative interviews.

DATA AUDIT

Between 2004 and 2008, 129 doctors, 68 pharmacies and 606 patients participated in the BVU program in the ACT.

Definition of a "Contact"

In this audit, we define *a contact* as any of the following: i) establishing a new BVU, ii) renewing a BVU, iii) changing a BVU (e.g. nominated doctor or pharmacy) or iv) cancelling a BVU. There were 1,815 contacts with the BVU program between 2004 and 2008. Therefore, one patient might account for more than one contact in this total.

PATIENTS

The age range of patients who signed a BVU between 2004 and 2008 was 15-77 years. The average age for patients on a BVU was 37.3 years.

The number of patients signing BVU each year ranged between 205 and 265. Fifteen patients had 100% continuity between 2004-2008, that is, they renewed a BVU within two months of its expiry. Two-hundred and twelve patients only had one contact with the BVU program. The remaining patients had varying contact.

GENERAL PRACTITIONERS AND GENERAL PRACTICES

The number of GPs participating in the BVU program remained relatively constant between 2004 and 2008 (range 57-67 in each year).

Twenty-one doctors were consistently involved with the BVU program and were responsible for 50.5% of BVUs (n=916 contacts). The doctor most involved in the BVU program had 203 contacts, more than double the second most active doctor. Thirty-one doctors only participated once in the BVU program. There was a lessening of contacts by doctors in December each year.

Sixty-six general practices participated in the BVU program between 2004 and 2008. The top five practices were responsible for three-quarters of BVUs. The most active practice recorded 739 contacts, four times more than the next most active practice. Thirteen practices only participated once in the BVU program.

PHARMACIES

The number of participating pharmacies remained relatively constant between 2004 and 2008 (range 44-49 in each year).

The 10 most active pharmacies in the BVU program accounted for three-quarters of BVUs. The most popular pharmacy recorded 233 contacts. Twenty-one pharmacies had only one contact in the entire five-year period.

QUALITATIVE ANALYSIS

Reasons for involvement in the BVU program were fairly consistent among GPs and pharmacists – they wanted to minimise the abuse of benzodiazepines by patients and ensure that the patients received continuity of care. The BVU allowed monitoring of benzodiazepine use and provided an element of control. Some pharmacists also noted that an element of “community service” was integral to their involvement in the BVU program.

The procedure for commencing a BVU was fairly consistent, with most GPs explaining to the patient how the program works. The amount of contact between GPs and pharmacists about BVUs was variable and pharmacists indicated a preference for more contact with GPs. The patient interviewed for this project also described the process as simple and straight forward and that the GP explained the program.

Pharmacies used a variety of means to verify the legitimacy of the script, including consulting ACT HPS lists or pharmacy records, and contacting the GP. When dispensing the script the pharmacists took the opportunity to re-enforce terms and conditions of the patient's BVU.

The data revealed variable use of daily and monthly lists faxed by ACT HPS to GPs and pharmacies. Some GPs did not refer to them at all and some noted that ACT HPS reminders prompted them to renew a patient's BVU. GPs saw renewal of a BVU as an opportunity to review the patient's dose of benzodiazepines.

BVUs were used overwhelmingly for patients with existing drug problems or who were also on methadone or buprenorphine programs. They were not generally used for elderly patients.

All pharmacists had experienced problems with aggressive or abusive behaviour of patients.

The benefits of the program, expressed by GPs and pharmacists, were consistent with their stated reasons for participation – to minimise drug abuse and ensure continuity of care.

The overwhelming suggestion was that computerisation of the administrative elements of the system would ease the burden on GPs and pharmacists, alike.

The patient interviewed for this project also described the process as simple and straight forward, well explained by the doctor and a beneficial program.

RECOMMENDATIONS

The results of the audit and interviews have contributed to our understanding of the BVU program and have led to the following recommendations:

Goals of the Program

- Review objectives of the BVU program and identify suitable measures.
- Define the target population for the BVU program. For example, patients with high use of benzodiazepine, poly drug users or those on methadone or buprenorphine programs.
- Use a Delphi process (1) to establish desirable benchmarks for GP, pharmacist and patient participation in the program.
- Incorporate the benefits to patients of participating in a BVU program into all documentation and promotional material.

Administration

- Develop an information sheet for patients outlining how the BVU program works and what benefits they can expect from participation.
- Introduce to ACT HPS a computerised system for receiving, storing and distributing information among participating GPs and pharmacies.
- Provide all GPs and pharmacies with software to facilitate involvement in the program.

Promotion

- Promote the BVU program to all ACT based GPs and pharmacies. Such as through the ACT Health website, sessions for GPs and pharmacies or through professional newsletters or posters about the BVU program to all general practices in the ACT.

Future evaluation

- Convene an evaluation committee that includes representatives from ACT HPS, general practice, pharmacy profession (independent of ACT Health) and the AUGPCH.
- Consider the detail of this report and develop a plan to conduct a *prospective, goal-oriented evaluation* six months after BVU program goals have been reviewed, and any changes that emerged from it have been widely promoted.

CONCLUSION

The goals of the BVU program appear to be well understood and supported by ACT GPs and pharmacists. However, the goals as they currently stand do not enable measurement and therefore they cannot be adequately evaluated.

A meaningful goal-oriented evaluation can only take place once the goals of the program have been clarified and measures specified. Improvements in the administrative aspects of the program would best take place before a further process evaluation.

Computerisation of administrative elements of the program would most likely facilitate use, decrease workload (after an initial settling period) and facilitate evaluation.

The continuation of the BVU program would benefit from the input of a small advisory group. Finally, the program may become more widely known and used if it were promoted periodically.

1.0 INTRODUCTION

A Benzodiazepine Voluntary Undertaking (BVU) is a tool used by general practitioners (GPs) in the Australian Capital Territory (ACT) to improve the medical management of patients with known or suspected excessive benzodiazepine use. The BVU Program, established in 1996, is coordinated by the ACT Health Protections Service (HPS) and requires the participation of GPs and private pharmacies in the ACT. It has never been evaluated.

Early conversations with those intimately involved in the BVU program revealed differing knowledge of its operation and purpose, written goals for the program were difficult to locate, and the available data comprised filed hardcopies of BVUs and electronic versions of monthly participant lists. This study establishes the parameters for a full evaluation of the BVU Program; one which considers both its clinical *effectiveness* and the *efficiency* of its processes.

This study was funded by ACT Health, the Australian Capital Territory health department, and conducted by the Academic Unit of General Practice and Community Health (AUGPCH).

2.0 BACKGROUND

A BVU is a non-binding, written contract (see Appendix 1) between a GP and his/her patient that is valid for six months. The BVU states that:

1. The patient will attend only one identified doctor or practice to receive their prescriptions for benzodiazepines; and
2. The patient will attend only one identified pharmacy to have their prescriptions for benzodiazepines dispensed.

A copy of the BVU is sent to ACT HPS. A list of new, renewed and cancelled or changed BVUs is faxed to all ACT pharmacies (approximately 70) daily by ACT HPS. A monthly summary is faxed to all ACT pharmacies and GPs, and ACT HPS also fields calls from pharmacies, doctors and patients regarding BVUs.

The stated aims of the BVU Program are to:

- *Encourage continuity of care.*
- *Promote the safe and controlled prescription and use of benzodiazepines.*
- *Minimise the harm associated with benzodiazepine use and concomitant alcohol and/or other drug use.*
- *Assist doctors to achieve the best possible health outcomes for patients using alcohol and other drugs.*
- *Reduce the incidence of 'doctor shopping' by patients.*
- *Enlist the patient onto a gradual, supervised reducing regimen, where possible and realistic. (2 p.1).*

The BVU program is unique to the ACT and relies to a large extent on its geographical isolation. People inclined towards the excessive use of benzodiazepine cannot easily move beyond the territory boundaries to find a GP and/or pharmacy willing to prescribe and/or dispense.

An unpublished clinical audit of a local ACT general practice's patient files reveals that patients who sign BVUs are most likely to be intravenous drug users ($p < 0.005$), on a methadone program ($p < 0.025$) or using large amounts of benzodiazepines ($p < 0.001$). Additionally, the adherence (attendance) of patients on voluntary undertakings to the practice was better than other patients, although the difference was not significant ($p = 0.316$).

3.0 LITERATURE REVIEW

A large volume of research into the treatment of patients addicted to benzodiazepines has previously been reported in the literature. In this section of the report we describe the methodology employed to search the literature, define benzodiazepines, and present a review of key studies regarding benzodiazepine use, for the ten-year period to April 2010.

3.1 LITERATURE REVIEW METHODOLOGY

The MEDLINE/Pubmed and PsychINFO databases available through OVID were searched to identify studies relating to the treatment of patients addicted to benzodiazepines. The search terms used to identify relevant English language articles published between 2000 and 2010 were:

- Benzodiazepine use
- Doctor shopping
- Prescription shopping
- Benzodiazepine Dependence Questionnaire
- Withdrawal from benzodiazepines
- Management of benzodiazepines
- Reducing benzodiazepine prescribing in general practice.

From the citations identified, abstracts were screened to exclude irrelevant studies. The remaining papers were read and were retained if they satisfied the inclusion criteria. Key studies included were those which were written in English, published between 2000 and 2010, and had a primary focus on the treatment of patients addicted to benzodiazepines. In addition, the reference lists of the relevant articles were examined and additional articles were obtained, reviewed and included if appropriate.

3.2 WHAT ARE BENZODIAZEPINES?

Benzodiazepines represent a class of drugs commonly prescribed for insomnia and anxiety disorders. They are also indicated in the treatment of panic disorder, epilepsy, muscle relaxation, manic episodes, movement disorders, alcohol withdrawal, sedation and anaesthesia (3). However, there is strong evidence that benzodiazepines have the potential to be misused or abused, especially by people who use illicit drugs, are on methadone or who have a history of excessive alcohol use (3). Risk of dependence has also been demonstrated in people who take benzodiazepines therapeutically, for three months or longer (3).

3.3 SUMMARY OF THE LITERATURE

Most of the literature addressing treatment of patients addicted to benzodiazepines has explored the effectiveness of current treatment approaches to assist benzodiazepine discontinuation in general practices. A total of 32 studies were included in the review. They are presented in a table in Appendix 2. The study methodology, year the study took place, number of participants, country where study was conducted, type of study, and main findings are described for each study. Each study has been assigned a study number from four to 35.

The table at Appendix 2 describes two systematic reviews, eight cross sectional studies/surveys, eight qualitative analyses, five randomised controlled trials, three questionnaires, and one each of a survey of participants in a randomised controlled trial, case study, experimental intervention, practical information article, expert opinion and a crossover study. The studies reported in this literature review came from 10 countries, including Australia, Austria, Belgium, Canada, France, Israel, Scotland, Thailand, The Netherlands, United Kingdom, United States of America and Spain.

In most of the articles, routine care reduction, which involves reducing benzodiazepine use with an aim of total cessation, was compared with a brief intervention (e.g. GP sending a letter or a booklet providing advice on self-help strategies), gradual dose reduction and psychological interventions (e.g. relaxation training). The articles show that gradual dose reduction and brief intervention provides superior cessation rates at post-treatment compared to routine care (2-10), while psychological interventions provided a small but significant benefit at post-cessation compared to routine care (8-10). The conclusion drawn from the literature review is that providing an intervention is more effective for benzodiazepine discontinuation than routine care.

Only one article (32) looked at a formal maintenance program for the treatment of patients with benzodiazepine dependency but this took place in a clinic for drug dependency disorders and only lasted for a year.

It was not possible to identify any studies that have used the same approach as used in ACT BVU program. The majority of reviewed studies aimed for cessation of benzodiazepine use in patients. Although this is also one of the stated aims of the ACT BVU program - *enlist the patient onto a gradual, supervised reducing regimen, where possible and realistic* (2 p.1) - the ACT BVU program recognises that this is not always possible and that where this is the case, its aim is to *promote the safe and controlled prescription and use of benzodiazepines* (2 p.1). It is therefore of great importance to get a better understanding of the local BVU program and eventually examine if its effect is similar, or different, to the published studies described in Appendix 2.

4.0 METHODOLOGY

This study employed both quantitative and qualitative methods to collect and analyse data. Specifically, we:

1. Conducted an audit of data held by ACT HPS for the years 2004-2008
2. Conducted semi-structured interviews with GPs, pharmacists and patients to establish their understanding of the program and its procedures, and their opinions of what worked and how things could be improved.

These methodologies are now described in detail.

4.1 DATA AUDIT

ACT HPS holds data on all patients who have signed a BVU, all doctors who have entered into BVU agreements with patients, and all pharmacies who have been nominated to dispense benzodiazepines to BVU patients in the ACT. The ACT HPS data available for analysis comprised filed hardcopies of BVUs and electronic versions of monthly participant lists.

The researchers sought access to this information in order to quantify the outcomes of the BVU program, determine the quality of the available data and to identify what qualitative data should be collected in the face-to-face interviews to enhance our knowledge about the BVU program.

When a patient has signed a BVU, a copy of the agreement is sent to ACT HPS who inform all pharmacies and GPs in the ACT about the agreement. In addition, ACT HPS hold data from renewal lists provided to pharmacies on a monthly basis. Some of these data were extracted for use in this project. Data collected between 2004 and 2008 were provided to the researchers and contained information about:

1. The start date, expiry date and changes to BVUs for individual patients
2. Demographic information about patients (ID number, suburb, data of birth)
3. Demographic information about GPs (ID number, suburb)
4. Demographic data about nominated pharmacies (ID number, suburb)

4.1.1 QUANTITATIVE ANALYSIS

The data comprised filed hardcopies of BVUs and electronic versions of daily and monthly participant lists. One of the research team (NB) undertook the process of creating a database from the lists that were faxed to pharmacies and GPs between 2004 and 2008. This timeframe was chosen because ACT HPS could only guarantee the completeness of their paper and electronic records from 2004 onwards. Where information was missing from the daily and monthly lists, the researcher sought it from the filed hardcopy of the BVU and, if available, it was added to the database. The data extraction process took place within the offices of ACT HPS. Once, the researcher was confident that he had the most complete database achievable, the data were de-identified and the only copy of the code was given to the ACT Chief Pharmacist for safe keeping, along with and a copy of the de-identified database. Only then was a copy of the de-identified database removed from ACT HPS for analysis.

Simple descriptive statistics were calculated and graphs were produced in Excel, to provide information about the use of BVUs in the ACT from 2004 to 2008.

4.2 INTERVIEWS

Qualitative data were collected through semi-structured face-to-face interviews with six GPs (n=6), seven pharmacists (n=7) and one (n=1) patient involved in the BVU program. Each interview took approximately 30 minutes. All participants were assigned a unique identifying number and no identifying information is presented in this report.

4.2.1 RECRUITMENT

A selection of GPs, pharmacists and patients who had participated in the BVU program were recruited for interviews.

GENERAL PRACTITIONERS

All GPs who had signed a BVU with a patient were identified from data collected by ACT HPS. Initially, a representative from ACT HPS was going to contact a range of GPs (two each who had a low, moderate and high number of patients on a BVU). However, due to unforeseen circumstances a sample of these GPs were contacted by telephone by a researcher (MZ) from the AUGPCH and invited to participate in a face-to-face semi-structured interview. MZ had difficulty recruiting GPs, so the GP researcher (TMS) contacted GPs, via telephone, to invite them to participate (Appendix 3). Interested GPs were provided with the researcher's (MZ) contact details and were subsequently contacted by her to arrange a suitable interview time.

Access to the ACT HPS data enabled us to use a maximum variation sampling strategy. The doctors were selected according to general practice variation (doctors from different general practices) and variation in numbers of BVUs signed with patients. This sampling strategy was employed because it enabled us to determine whether GPs from different general practices had a different understanding of, or experience with, BVUs. It also enabled us to identify any differences in the experiences of GPs according to whether they had a high use of BVUs compared with those doctors who rarely use BVUs. By including doctors from different general practices and with different use of BVUs, it was possible to detect any variations in the group and to understand variation in experiences, while also investigating core elements and shared outcomes.

PHARMACISTS

ACT HPS hold data about which pharmacies dispense benzodiazepines to patients on a BVU. A list with names of all pharmacies was generated from this data and seven pharmacies were

contacted by ACT HPS and invited to nominate a pharmacist who had some knowledge of the BVU program, and who had dispensed benzodiazepines to patients on a BVU, to participate in a face-to-face semi-structured interview (Appendix 4).

We attempted to include pharmacies from different suburbs and that dispense benzodiazepines to different numbers of patients. This strategy was chosen because it enabled us to determine whether pharmacies with different characteristics reported different experiences with BVUs.

PATIENTS

To protect patient confidentiality, the selected GPs were asked to invite one or two patients with whom they had signed a BVU, to participate in the study. The inclusion criteria for patients were that they were 18 years of age or older, had signed a BVU, and were capable of being interviewed. Contact details for patients that agreed to participate in the study were forwarded to the interviewer, who contacted the patient to arrange a suitable time for the interview. Despite repeated attempts to recruit patients, we were only able to engage one patient in an interview. Patients repeatedly did not return phone calls from the researchers or failed to attend pre-arranged interview appointments.

When using this sampling strategy it was not possible to ensure that the respondents were representative of the variety of subgroups that sign BVUs.

4.2.2 ORDER OF INTERVIEWS

The interviews were completed for one group at a time. This provided us with the opportunity to use the knowledge obtained from interviewing one group to improve the interviews with the next group.

4.2.3 LOCATION AND DURATION OF INTERVIEWS

The interviews with GPs and pharmacists were held in the different medical practices and pharmacies. The patient was interviewed in their GP's surgery. The duration of the interviews was approximately 30 minutes. Respondents were offered compensation for lost working time. GPs and pharmacists received \$120 per interview. The patient received a movie voucher and taxi vouchers to cover any transportation costs to and from the venue where the interview was conducted.

4.2.4 CONSENT

All GPs, pharmacists and patients were provided with an information sheet (Appendix 5) describing the aims and procedures of the study. If, after reading the information sheet, they wished to participate in the study, they were asked to sign an informed consent form (Appendix 6).

4.2.5 DATA COLLECTION PROCEDURE

One researcher (MZ) conducted all interviews. All interviews followed a semi-structured interview guide with open-ended questions exploring experiences, opinions, attitudes, and feelings about their day-to-day experience of the BVU program. Interview questions are displayed in Table 1 according to the five characteristics being measured; involvement, procedure, patient behaviour, benefits and improvement.

All interviews were audio taped and additional notes were taken concurrently throughout the interview. The audiotapes were transcribed verbatim by a transcription service. Potentially identifying information was removed from the transcripts, and the transcripts were assigned a code number. Due to equipment failure, one GP interview could not be used in the analysis.

Table 1: Interview questions for GPs, pharmacists and patients

Characteristic	GP	Pharmacist	Patient
Involvement	Why do you use the BVU program?	Why has the pharmacy chosen to participate in the voluntary undertakings?	Why do you think your doctor asked you to sign a BVU? Why did you choose to sign?
Procedure	What is the usual procedure when you use a BVU program with a patient for the first time? What information do you give the patient about the BVU? How do you handle the undertaking? When you receive a list of the BVU patients from the pharmacy what action do you take?	How does a doctor usually contact the pharmacy to inform the pharmacist about the BVU patient? What is the procedure when you are asked to participate in a voluntary undertaking? How do you file the information? How do the staff get informed?	Do you remember the first time you signed a BVU? Can you tell me about it? Who brought it up? What information were you given about the BVU program? What is your perception of the information given?
	What is the usual procedure when you renew a BVU?		What is the normal procedure when you have your BVU renewed?
	Have you ever experienced a patient cancelling a BVU? Reasons? Procedure? Consequences? Have you ever cancelled a BVU? Can you tell about the situation?	What is the procedure when a patient attends your pharmacy with a prescription for benzodiazepines? Can you tell me about a situation where you have identified a patient using a doctor or pharmacy other than those nominated in the undertaking?	Have you ever cancelled a BVU? Can you tell me about the situation? Why did you cancel the BVU? What was the reaction of your doctor?
Patient Behaviour	What kind of patients do you normally ask to sign a BVU? Why? (Long-term users/short-term users, young/old, male/female)	Have you ever had a problem with a patient on a BVU? Can you tell me about the situation?	Can you remember how many times you have renewed your BVU? Why did you choose to renew your BVU?
Benefits	What do you see as the advantages of the BVU program? For GPs? For patients?	What do you see as the greatest advantages of the BVUs? For the pharmacy? For the patients?	How do you think you benefit from signing a BVU?
Improvement	Do you see any disadvantages of the BVU program? Have you any suggestions about how the program could be improved?	Do you see any disadvantages of the BVU program? Have you any suggestions about how the program could be improved?	Do you see any disadvantages of signing a BVU? Have you any suggestions to how the program could be improved?

4.2.6 QUALITATIVE DATA ANALYSIS

Qualitative data were analysed using the principles of thematic analysis, which is a method for identifying, analysing and reporting patterns within data. The thematic analysis was carried out for one group at a time. The process started when the researchers read and reread all transcripts and began to look for issues of potential interest in the data. One researcher (LB) assigned each segment of interest a code, which helped organise the data into meaningful groups. The next phase of analysis involved sorting the different codes into potential themes and collating all the relevant coded data segments within the identified themes. Data were then examined collectively, thus permitting relationships between, and among, central themes to emerge. The content and meaning of patterns in the data were then interpreted and are presented in the results section of this report.

4.3 HUMAN ETHICS APPROVAL

The study design conformed to the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct of Research Involving Humans*. Approval for the study was granted by the ACT Health Human Research Ethics Committee and the Australian National University Human Research Ethics Committee in 2009.

5.0 RESULTS

The results from the data audit of ACT HPS data and the semi-structured face-to-face interviews with GPs, pharmacists and patients are presented in this section of the report.

5.1 DATA AUDIT

Data collected by ACT HPS between 2004 and 2008 were analysed for this project. Specifically, data regarding patients on BVUs, patient contacts with the BVU program, GPs involved in the BVU program and pharmacies involved in the program are reported.

5.1.1 DEMOGRAPHICS

The age range of patients who signed a BVU between 2004 and 2008 was 15-77 years. The average age for patients on a BVU was 37.3 years. The median age of patients on a BVU was 36.6 years. Between 2004 and 2008, 129 doctors, 68 pharmacies and 606 patients participated in the BVU program in the ACT.

The Primary Health Care Research and Information Service (PHC RIS) provides a data base of division of general practice characteristics. For the ACTDGP, PHC RIS estimated that the number of practicing GPs was 380 in 2004-2005, 330 in 2005-2006 and 2006-2007 and 336 in 2007-2008. Thus, the average number of practicing GPs in the ACT each year, between 2004-2008, was estimated at 344 for this project. Based on estimates of the number of GPs working in Canberra between 2004 and 2008, this means that over one third of Canberra GPs participated in the BVU program over the study period.

5.1.2 OVERVIEW OF BVU DATA 2004-2008

DEFINITION OF A “CONTACT”

A contact was defined as any of the following:

1. Establishing a new BVU
2. Renewing a BVU
3. Changing a BVU (e.g. nominated doctor or pharmacy)
4. Cancelling a BVU

Between 2004 and 2008 there were 1,815 contacts with the BVU program. Therefore, one patient might account for more than one contact in this total.

Table 2 presents a summary of BVU data collected between 2004 and 2008. The table shows, for each year, the number of patients signing a BVU, the total number of contacts with BVU program, number of doctors signing a BVU and number of pharmacies nominated on BVUs. The number of patients signing BVUs ranged from a low of 205 in 2004 to a high of 265 in 2006. The number of patient contacts with the program varied between a low of 313 in 2004 and a high of 422 in 2006, remembering that one patient could have multiple contacts in a year. The number of GPs participating in the BVU program (range 57-67) has remained relatively constant over the past five years, as has the number of participating pharmacies (range 44-49).

Table 2: Summary of BVU data 2004-2008

	2004	2005	2006	2007	2008
Number of patients signing BVUs	205	214	265	228	260
Number of contacts with BVU program	313	337	422	357	386
Number of doctors signing BVUs	63	61	67	57	57
Number of pharmacies nominated on BVUs	48	46	44	45	49

Table 3 describes the characteristics of how we defined a contact, namely; a new BVU, a renewed BVU, a changed BVU, or a cancelled BVU. The number of renewals remained relatively constant between 2004 and 2007, but dropped significantly in 2008. There was a large increase in the number of new BVUs established in 2008, compared to previous years. An average of 53.5 changes per year to BVUs were made between 2004 and 2007. Considerably fewer changes (n=15) were made in 2008. Cancellations were low between 2004 and 2005 relative to cancellations between 2006 and 2008.

Table 3: New, renewed, changed or cancelled BVUs, 2004-2008

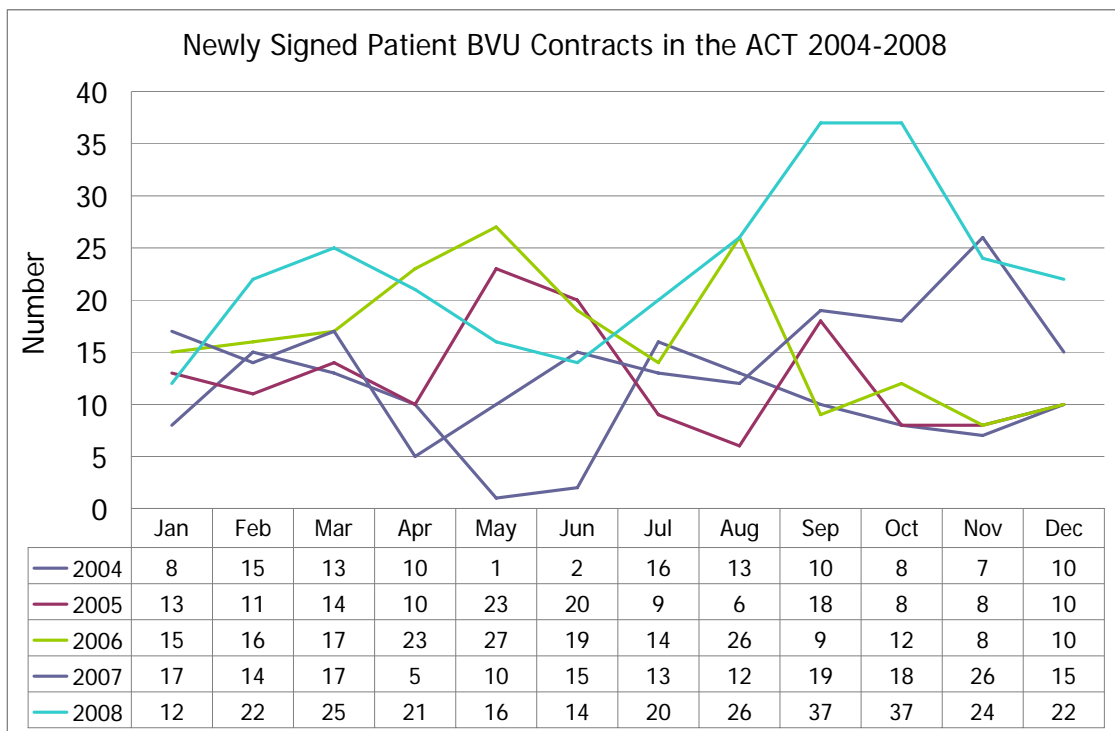
	2004-08	2004	2005	2006	2007	2008
New	916	113	150	196	181	276
Renewals	766	175	158	191	147	95
Changes	229	60	48	62	44	15
Cancellations	105	13	14	25	30	23

5.1.3 PATIENTS

Six hundred and six patients signed a BVU at some stage between 2004 and 2008. On average there were 29.4 (SD=8.1) BVU contacts each month (new, renewed, changed or cancelled BVUs), with an average of 30.3 (SD=7.8) GP visits. September of 2008 was the most active month with 52 patients participating that month. The least active month was May 2004 with 15 patients participating in the program. The monthly data is relevant as it enables us to determine the trend of “ups and downs” in the program.

September and October of 2008 saw the highest number of additions of new patients to the program, with 37 new patients. May 2004 had the lowest number of additions, with just one. The most number of GP visits by a single patient was 15 over the five-year period. Fifteen patients had 100% continuity over the five-year period and the remaining patients had varying contact. Continuity was defined as renewing a BVU within two months of its expiry. Two-hundred and twelve patients only participated once in the program between 2004-2008.

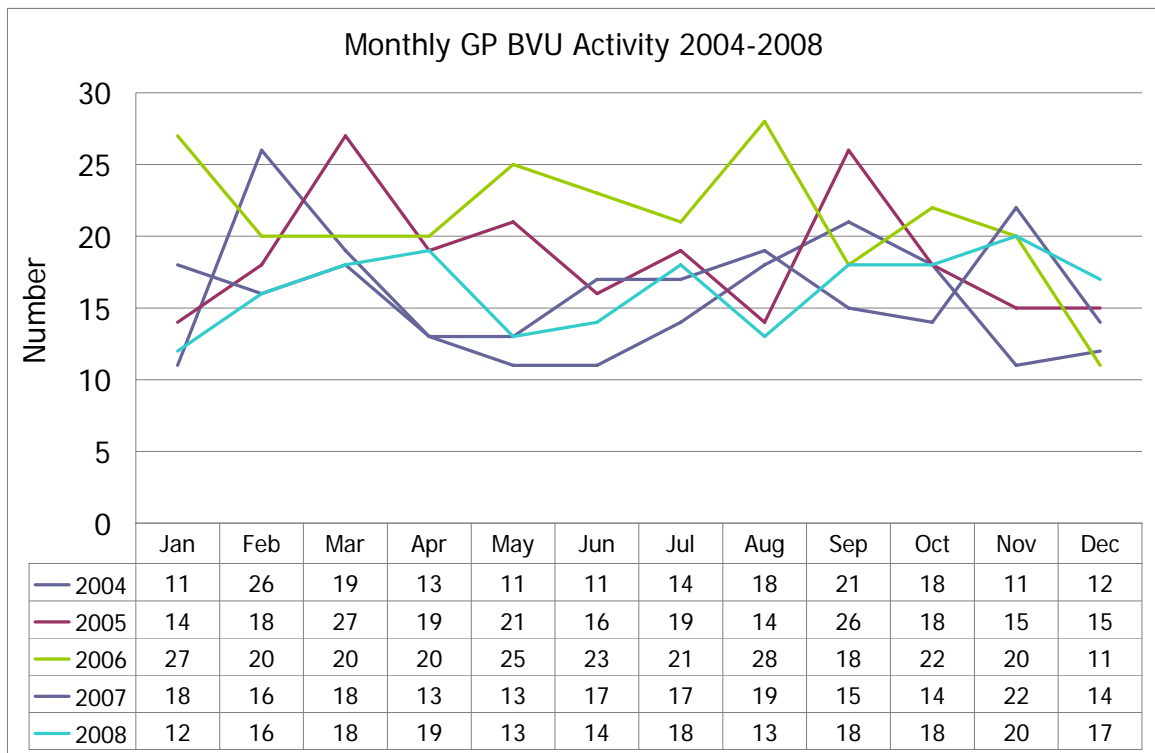
Figure 1: Newly signed patient BVU contracts in the ACT, 2004-2008



5.1.4 GPs

One hundred and twenty nine GPs participated in the BVU program between 2004 and 2008. Twenty-one doctors were consistently involved with the program over the five-year study period, with at least one contact in a year (Figure 2). These 21 GPs were responsible for 50.5% of BVUs (n=916 contacts) during the five-year study period.

Figure 2: Monthly GP ACT BVU Activity, 2004-2008



The highs and lows per year varied greatly. August of 2006 was the busiest month, with 28 contacts, while January 2008 and December 2006 were the least busy months with 11. The data demonstrate that there is a lessening in activity by doctors in December each year. The doctor most involved in the program had 203 contacts between 2004 and 2008 (Table 4), more than double the second most active doctor. Thirty-one doctors only participated once in the program.

Table 4: Number of BVU contacts by the top 10 most active GPs, 2004-2008

Doctor	Number of BVU Contacts
Doctor 1	203
Doctor 2	94
Doctor 3	87
Doctor 4	81
Doctor 5	79
Doctor 6	73
Doctor 7	58
Doctor 8	57
Doctor 9	53
Doctor 10	46

5.1.5 GENERAL PRACTICES

Sixty-six general practices participated in the program. The top five practices accounted for three-quarters of BVUs (Table 5). The most active practice recorded 714 contacts over the period, four times more than the next most active practice. Thirteen practices only participated once in the program over the 5 year period. Twelve practices had active BVUs throughout the study period.

Table 5: Number of BVU contacts by the top 10 most active GP practices, 2004-2008

Practice	Number of BVU Contacts
Practice 1	714
Practice 2	162
Practice 3	112
Practice 4	85
Practice 5	80
Practice 6	79
Practice 7	51
Practice 8	38
Practice 9	29
Practice 10	24

5.1.6 PHARMACIES

Sixty-eight pharmacies participated in the program. The 10 most active pharmacies in the BVU program accounted for three-quarters of BVU activity (table 6). The most popular pharmacy recorded 233 contacts between 2004 and 2008. Twenty-one pharmacies had only one entry in the entire five-year period. In most cases, the doctor and/or patient determine the pharmacy to be nominated on a BVU. In some cases, the pharmacy may be contacted to confirm that it is willing to participate.

Table 6: Number of BVU contacts by the top 10 most active pharmacies, 2004-2008

Pharmacy	Number of BVU Contacts
Pharmacy A	233
Pharmacy B	148
Pharmacy C	131
Pharmacy D	125
Pharmacy E	92
Pharmacy F	89
Pharmacy G	74
Pharmacy H	68
Pharmacy I	67
Pharmacy J	56

5.1.7 CANCELLATIONS

A BVU may be cancelled by a patient, GP or pharmacist for any reason at any time. During our five-year study BVUs were cancelled 105 times. These cancellations involved 85 patients. Lapsing BVUs were not tracked throughout the study period.

Two patients had 5 BVU cancellations in the five-year period, and one of these patients had three cancellations in one month alone.

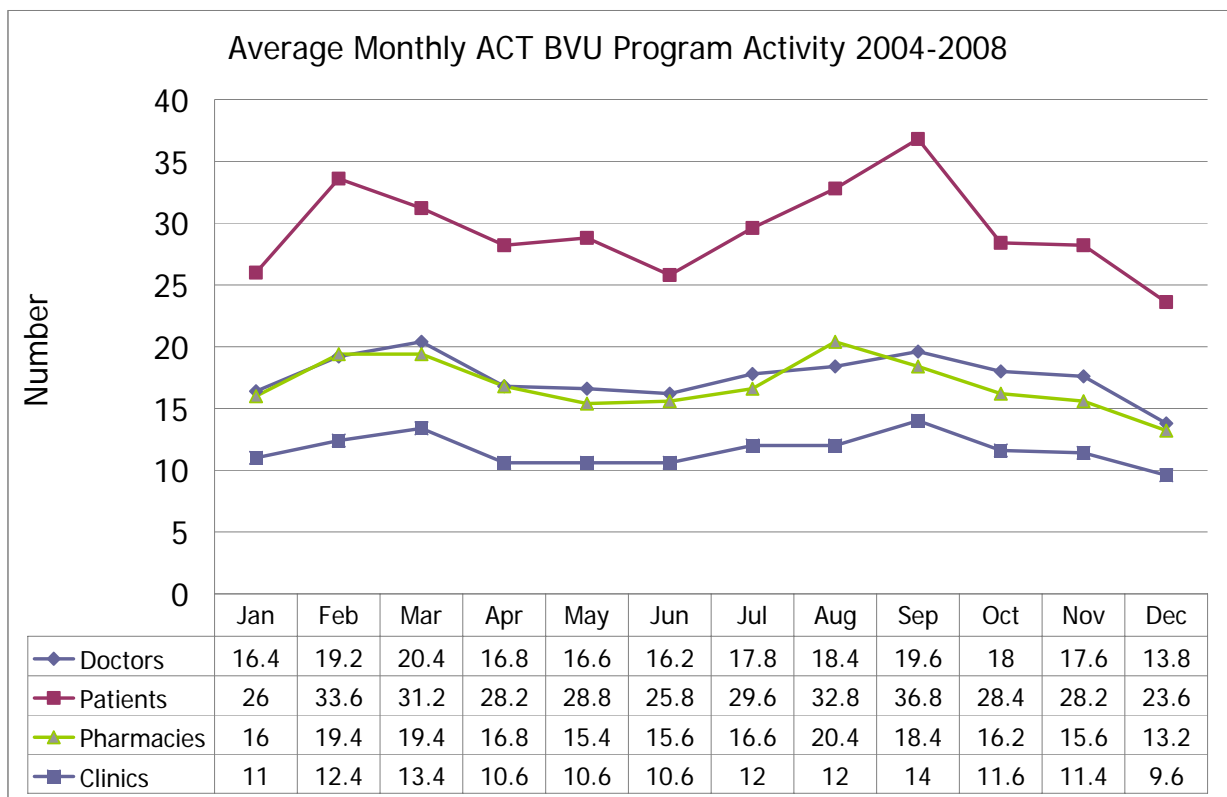
Fifty percent of cancellations occurred with 9 doctors. The highest number of cancellations by an individual doctor over the five-year period was eight. For patients with two or more doctors (at the same clinic) the highest number of cancellations was 17. These patients did not have a single identifiable doctor who was solely responsible for their care. The top 3 practices composed the majority of cancellations. The top clinic had 26 cancellations.

The two most active pharmacies for cancellations recorded 13 cancellations each.

5.1.8 AVERAGE MONTHLY DATA

The average monthly activity over the period of the study (Figure 6) suggests that changes in the number of patient contacts with BVU program is reflected in the activity of GPs, practices and pharmacies. That is, the more BVUs that are initiated, renewed, changed or cancelled, the more likely it is a greater number of GPs, practices and pharmacies are involved.

Figure 3: Average Monthly ACT BVU program Activity, 2004-2008



5.2 INTERVIEWS

Interviews were conducted with six GPs, seven pharmacists and one patient between January and April 2010.

5.2.1 PARTICIPANT CHARACTERISTICS

The only demographic characteristic collected for this component of the research was gender. Given the small workforce in Canberra and the potential for identification of GPs and pharmacists, no other demographic data were collected. The gender of participants of each of the three interview groups is presented in Table 5.

Table 7: Gender of BVU study participants

Interview Group	Male (N)	Female (N)
GPs	5	1
Pharmacists	4	3
Patients	1	-

As Table 5 shows, males comprised the majority of participants in the GPs group. Females and males were represented in approximately equal proportions in the pharmacist group. As described earlier, there were repeated attempts to recruit patients. Patients repeatedly did not return phone calls from the researchers or failed to attend pre-arranged interview appointments. Consequently, we were only able to engage one male patient in an interview.

5.2.2 FINDINGS

Results of the interviews are presented according to the five nominated characteristics this project was attempting to measure, as described in Table 2 – involvement, procedure, patient behaviour, benefits and improvement. The major themes arising from the interviews are presented, discussed and illustrated with selected quotations from participants. Where quotations come from different GPs, pharmacists and patients, they are identified by GP1, GP2 etc. (for GPs), PH1, PH2 etc. (for pharmacists) and PA1, PA2 etc. (for patients).

INVOLVEMENT

GPs responded that they were most likely use the BVU program in their practice to monitor and control the use of benzodiazepines by their patients. Specifically, GPs were concerned with ensuring that patients did not abuse benzodiazepines and that they used them safely. In addition, GPs were keen that patients receive continuity of care by both their GP and pharmacist. GPs thought that one advantage of patients signing a BVU was a potential reduction in patients seeking prescriptions from multiple doctors (this is commonly known as 'doctor shopping').

GP4: I use it [the BVU] to help control the use of benzodiazepines by these patients that I get to sign contracts and to make sure that I am in some sort of control and the pharmacist is in some sort of control, that they aren't doctor shopping and that I've got a limit on the amount of benzodiazepines that they're using.

GP6: In the past, I've been caught once or twice with people using benzodiazepines inappropriately and I think it's a good way of monitoring the... as you know the... you should be the only practitioner who prescribes the benzo and you nominate a pharmacist who is the only pharmacist that dispenses the drug so the patient gets a clear feeling that they are

being properly monitored, the use of the benzodiazepine and it prevents doctor shopping to some extent.

Pharmacists chose to participate in the program for a number of reasons. Similar to GPs, pharmacists thought that they had a role to play in monitoring and controlling the use of benzodiazepines in patients presenting to their pharmacy. More importantly, pharmacists thought they provided an important service to the community, with two of the pharmacists participating in the BVU program for several years. Other reasons they participate in the program were to prevent doctor shopping and to assist GPs with the program.

PH5: *We feel that there is a need in the community to help people manage their addictions so we want to be part of that and offer that service.*

PH1: *...as I said, it's a service to the community and it helps prevent issues associated with benzodiazepine addiction and doctor shopping.*

The patient interviewed in this study decided to sign the BVU agreement because they thought it was the simplest and easiest thing to do. The patient also commented that the doctor asked them to sign the agreement for the "doctor's security and my security."

PROCEDURE

Recruitment into BVU program

GPs described the procedure by which patients are recruited into the BVU program for the first time. GPs were consistent in their description of recruitment. All six GPs reported that the first step would involve a discussion with a patient about signing a BVU contract. In addition, five GPs indicated that they would also explain how the program works, such as why the program should be put in place, where to pick up prescriptions, who supervises the agreement, the process of seeing only one GP and getting prescriptions from only one pharmacy. Three of the GPs indicated that they would not prescribe benzodiazepines unless their patient had signed a BVU contract.

GP5: *What I usually do is I explain to the patient that one of the preconditions for me supplying benzodiazepines to them is that they will enter a voluntary agreement with me and I explain what that means, who supervises that and the fact that their agreement is that they will see just one medical practice and one pharmacy and if they're not happy to go along with that then I'm probably not happy to prescribe Benzodiazepines to them.*

The patient interviewed for this project had been on Valium for about 10 years for anxiety and decided to sign a BVU contract after the death of a parent seven years ago. The patient became involved after a suggestion from the GP and thought it would be good to sign a BVU.

PA1: *The doctor brought it [the BVU] up and I was given the information to go to only one chemist and one doctor to get the Valium. The information is simple and straight forward. If I have a script and the contract runs out I just will renew it.*

Contact between general practitioners and pharmacists

Pharmacists were asked about whether they were informed by the GP about a patient on a BVU agreement and the procedure they followed when they were asked to participate in a BVU.

Three pharmacists indicated that they had either never, or rarely, been contacted by a GP about a BVU. Three pharmacists said that the GP either telephoned or faxed information to them about a BVU. Those pharmacists who were not regularly contacted by GPs tended to learn about an agreement through the ACT Health document which lists new BVU contracts, or when a patient presented with a script. One pharmacist who had not been contacted by a GP

wished to impress upon GPs that they would like to be contacted regarding their involvement in a BVU as a common courtesy. This same pharmacist would like all GPs to include the tablet names, directions and participating BVU pharmacy on all prescriptions so that pharmacists could avoid problems where a patient comes in and has a BVU contract elsewhere, and the pharmacist has to advise the patient that they can't fill the script because they have a BVU contract with another pharmacy.

***PH2:** Usually the doctor will ring in the first instance to see if we are happy to take a particular client in an undertaking, if we have any knowledge of that client or any experience of that client and that's usually followed up by a prescription or a fax just to confirm in writing the intention.*

***PH3:** This is one of the problems that I have. In the majority of cases the doctor does not [contact the pharmacy]. In the majority of cases the first we hear about it is when we get the document from ACT Health each day saying who is on the program and with which pharmacy and which doctor.*

***PH5:** I'll be honest; I haven't had a doctor contact me yet about that [a BVU].*

Pharmacy procedures

Pharmacists were asked to comment on the procedures they follow when they are asked to participate in a BVU. Not all pharmacists were asked by the GP if they would be happy to participate in a BVU. Nevertheless, they all appeared to demonstrate similar procedures when they were asked to participate or when they encountered a patient presenting with a script. Three pharmacists indicated that they would contact the GP to verify the information and to check whether there were any further stipulations on the prescriptions. Two would check the notification from ACT health and two would ensure their records were up to date. Four pharmacists mentioned that they would check the prescription and check client details to ensure that these corresponded.

***PH4:** Procedure would be we would contact the doctor and say "That's OK," that we agree to it and normally we would actually check then to whether there is any further stipulations on the prescriptions because some of our patients they get... as well as getting their scripts filled here they pick their tablets up maybe weekly or daily or a couple of times a week so we just clarify whether there is any restrictions on how they pick their medication up as well.*

***PH2:** ... yes, the physical procedure is of course to get the prescription, that is the most important thing to get the instructions because often clients will call and prescribers may call but until you get that prescription with written instructions you really can't proceed. So that's our principal focus, to get the paperwork, to meet the client and then instigate whatever other procedures we need for the fulfilling of the doctor's intention.*

Pharmacists were also asked to describe the procedure they employ when a patient attends the pharmacy with a script. Six pharmacists agreed that they would check the script to ensure that it was legitimate and not forged. Five pharmacists would also check to ensure that the prescription accorded with the patient's BVU contract. If the prescription was legitimate, medication would be dispensed in a timely manner. Three pharmacists would re-enforce the terms and conditions of the BVU with the patient. If a patient is found to have a BVU with another pharmacist, the script will not be dispensed and some pharmacists will write on the prescription 'contract with such-and-such a pharmacy.'. Similarly, if the prescription is forged, the pharmacist may confiscate it.

***PH2:** We certainly dispense the prescription in a timely manner, ensure that it's not in breach of the particular voluntary undertaking that the patient has entered into and then of course there's perhaps a more engaging encounter with the patient just to make sure they*

understand they are obliged to attend this pharmacy and not others, to reinforce the fact that we will be sticking to the time dose consideration that is on the prescription and just variously to make them sure about the fact that they are in a contract, as it were, not just random prescribing.

PH1: *If it's a known BVU with us basically it's generally just a case of checking that the prescription appears to be legitimate, from the correct doctor, generally it's the same medication they've been on previously, obviously checking for increased quantities and things like that that would make prescription suspicious.*

All seven pharmacists indicated that they would not dispense a prescription, and would inform the patient, if they suspected that a patient was using a doctor or pharmacy other than the one mentioned on their BVU undertaking. In addition, all pharmacists responded that they would contact the patient's GP and any other pharmacies (if appropriate) to inform them of a breach of a BVU contract. Two pharmacists would also mark the patient's prescriptions with details about the current BVU contract.

PH1: *Somewhere in the order of six months ago I had a young male, probably mid-twenties, come in and present a prescription to me. I can't remember the exact benzo. He came in, I started to dispense it, entered his name, noticed there was a benzodiazepine contract current, it was with a separate pharmacy to us and a separate doctor to the prescription. At that stage I informed the customer that I was unable to dispense that prescription because of the BVU in place. I also told him that I wouldn't be able to... that he wouldn't be able to get that prescription dispensed because it was from a doctor other than his prescribing doctor. He took the prescription away and left the pharmacy in a fair hurry. I then contacted his BVU doctor and informed him of the situation and also the doctor that had prescribed the second prescription or the prescription that had been presented. I'm not sure of the follow-up that occurred between the doctors at that stage.*

Pharmacists were also asked about how they file BVU information within their pharmacy and how they inform their staff about patients on a BVU. All seven pharmacists kept a hard copy of all the paperwork relevant to the BVU program. Three pharmacists kept this information in the dispensary and the remaining pharmacists did not specify where they kept this confidential information. Four pharmacists also responded that they entered the information into a computer database. However, when we asked the pharmacists how staff are informed about patients on BVUs, all seven pharmacists responded that this information is available on their computer system, suggesting that all pharmacies do indeed enter their data into a database.

In terms of informing staff about the BVUs, all pharmacists responded that staff have access to the information on the computer system. Two pharmacists also said that senior staff were notified if a person was on a BVU. One pharmacy also kept a diary which listed new patients. This diary was read by all pharmacists each day.

Renewal of BVU contract

In terms of renewing a BVU contract, most GPs required their patient to attend for an appointment to review their dose and to resign a BVU agreement. Two of the GPs aimed to wean their patients off benzodiazepines. Two GPs flagged that they are reminded to renew a patient's BVU agreement through faxes that are sent out from ACT HPS.

GP4: *I just go through the use of their benzodiazepines that they're taking and just make sure that they're happy to sign a contract and that we've got control of the use of their benzodiazepines.*

GP2: *If they need some more prescriptions well they have to re-sign. But I think most of them I aim to get off before 6 months is up.*

GP5: *Well we're generally reminded by ACT Health when the contract is nearly running out and we place a contract in their file. My secretary places another contract in their file and when that patient next comes in I remind that patient it's run out, I ask them if they're still happy to continue the contract and they usually are and we just renew the contract.*

Changes to BVU contract

When GPs receive the list of BVU patients from ACT Health, three checked to see whether any of their own patients were on the list, whilst the remaining three took no immediate action. Of those who took no immediate action, two GPs previously used to check the list but no longer did so. One GP did not use the list because they were unsure of the usefulness of the list and would prefer information to be displayed on the internet. Two of the GPs who checked the list also used it to determine a patient's history of contact with GPs in the ACT and to determine whether a patient was under the care of another GP prior to considering whether they would write a script. One of the GPs who claimed not to take any action when the list arrived also used it for this purpose.

GP1: *I used to check and to make sure my patients were on it but I don't do that any more.*

GP3: *I notice well this is the patient, if they are coming here for the medication if they see other doctor I'll notice that, and then I will let them know they shouldn't.*

GP6: *That long list of names, I don't take... I used to check to make sure my patients were on it but I must admit I don't do that any more. I usually have a cursory look at the list and to be frank I'm not sure how useful that list is. I think... I've never put it to any practical use. I would be quite happy not to receive the list. I don't know whether it would be useful or whether it would be possible to have it on the net.*

Four GPs had experienced a patient that had cancelled a BVU whilst two had not experienced a patient cancelling a BVU. Three GPs suggested that the main reason for cancelling a BVU was that a patient transferred to another GP or clinic. One GP thought it co-incident with a reduction in bulk billing within the practice and one GP thought that the rigidity of a BVU was too difficult for some patients.

GP1: *Yes I have and that's usually been a patient that is transferring to another doctor or something like that or a patient that no longer wants me as their prescriber basically.*

GP3: *Often I find the reason is that it's [the BVU] too rigid for them.*

Only one of the six GPs interviewed had ever cancelled a BVU with a patient. The reason that this was cancelled was that the patient was transferring to another doctor. The procedure the doctor followed was to notify ACT HPS and the pharmacy by fax that the BVU was no longer active.

The patient interviewed for this project had never cancelled a BVU themselves or had their GP cancel their BVU. When renewing the BVU, the patient normally saw the doctor and had the BVU resigned by the GP.

PA1: *I see the doctor, then the form is signed by one or two doctors.*

PATIENT BEHAVIOUR

GPs were asked to nominate the kinds of patients they get to sign a BVU agreement. The majority of GPs agreed that patients using other drugs (either legal or illegal) and long term benzodiazepine users should sign a BVU. GPs also thought that patients on another program, such as the methadone or buprenorphine program, should sign a BVU agreement. Two of the GPs thought that all patients should sign a BVU. There was no specific consensus on the age or gender of patients that GPs get to sign BVUs, although two GPs suggested that younger people

were the most likely demographic. Only one GP nominated males as more likely to be on a BVU. Three GPs agreed that even though they have elderly patients taking benzodiazepines, they do not ask this demographic to sign a BVU contract.

***GP1:** Mainly the patients that I've got on the benzo contracts would be the people that are using other drugs or people that are also on either methadone or buprenorphine program and have been on sort of long term benzodiazepines, they would be the ones.*

***GP3:** Usually it's younger, yeah. I haven't had anyone older to do the contract.*

***GP4:** These are usually long term benzodiazepine users, they are nearly all male, my particular patients that I'm asking to sign these contracts, they are usually patients who have other substance abuse problems, and frequently they're patients on the methadone program. I do have elderly patients who use benzodiazepines but I find I'm not asking them to sign contracts.*

Pharmacists were invited to comment on any problems they had experienced with a patient on a BVU. All seven pharmacists had experienced a problem with a patient at some point. The main issue they identified was related to the behaviour of a patient on a BVU, which was described as aggressive or abusive, and often included yelling or swearing at the pharmacist. Problems most often arose when patients wanted their prescription filled earlier than they were allowed. Pharmacists report that patients often presented a number of excuses to explain why they should receive their medication earlier than they were allowed, such as 'the dog ate them' or 'I've lost my tablets'. In response, pharmacists would normally use their own judgement or contact the patient's GP to determine whether to dispense the prescription. Whilst some pharmacists may ask the patient to leave, one pharmacist suggested that other pharmacists may fill the script, especially if they felt threatened.

***PH6:** We occasionally have problems with the people on the three times a week pick up [or] twice a week pick up [or] whatever that is where they come in early and we hear all the excuses in the world on why they've... they've lost the tablets, the dog ate the tablets, my girlfriend threw the tablets out, my mother's sick and I've got to go down to Sydney to see her. We get all the stories in the world about why people need things early or more than they should get and we just have to take an appropriate action based on how we assess the person – whether they're telling the truth or not, whether they've conformed and behaved previously. Occasionally you ring a doctor and say "this person is doing something that we're suspicious about."*

The patient who participated in the BVU program was unable to remember how many times their BVU had been renewed. The patient chose to renew the BVU on the advice of their GP.

BENEFITS

GPs were asked to describe the advantages of the BVU program for both GPs and patients. All of the GPs thought that a BVU enabled the GP to exercise a level of control with their patients. Specifically, the BVU enabled the GPs to manage the medical side of things and ensure that the patient's drug habit didn't escalate. Three GPs thought that an advantage of the BVU program was that it enabled them to monitor their patients. Four GPs also thought that BVUs enabled the patient to have a sense of control and of responsibility. Two GPs thought that it reduced the risk of benzodiazepine abuse and two GPs thought that the BVU was a good way of helping patients to come off benzodiazepines.

***GP4:** For GPs and patients alike it gives us both control, control of use I believe.*

GP3: *The advantage would be the mechanism of showing the patient there is the control there where people monitor this and they should not over abuse it and then we have all this record and we try to help them to get off this problem.*

Pharmacists were also asked to describe the advantages of the BVU program for their pharmacy and their patients. There were a wide range of answers to this question. Pharmacists thought that the BVU program had a positive effect on reducing doctor shopping and pharmacy shopping, it enabled them to develop relationships with patients and enabled them to monitor potentially problematic benzodiazepine users. In addition, pharmacists believe that it helps them fulfil their obligation to the client and the community and presents the pharmacy and medical profession as a united team working together to help manage a person's addiction.

PH5: *For the pharmacy. It just gives us, as I said, that interaction directly with the patient, it gives us another reference point if the person... we can keep track of them if they're starting to go off the rails a little bit or they don't seem to be... they're coming in appearing intoxicated or there are issues we've got a contact point with the doctor, we've often got a history and its easy to contact and find out what's going on, perhaps help them a little bit better so that helps us and helps the patient.*

Pharmacists also identified a number of benefits for patients on BVUs. They identified that a BVU provides stability for a patient's dependence, it protects the patient, gives the patient a sense of control and commitment and enables them to build up a relationship with the pharmacist.

PH6: *Well I think it makes the patient realise that they make a commitment and it's the first step in a very long and ongoing process. They make a commitment to themselves number one, they make a commitment to their doctor and they make a commitment to their pharmacist. So they realise these people are working with them to help them with their addiction. So I think that's important.*

The patient we interviewed also thought the program was beneficial ...*"I think it is beneficial because the doctor can trust the patient."*

IMPROVEMENT

GPs and pharmacists were asked whether they believed there were any disadvantages of the BVU program and to suggest any ways in which it could be improved.

Four GPs did not think there were many disadvantages to the BVU program. Two GPs thought that one disadvantage of the BVU program was that it required extra paperwork and that they needed to remember to complete this paperwork. One GP thought the only disadvantage *"is if every doctor in Canberra doesn't use it (GP2)."* Another GP identified a problem when a BVU lapses and then patients may abuse the system. When quizzed about the disadvantages of the BVU program, three doctors actually nominated an advantage of the program – that patients don't really mind it, it is a mechanism for showing the patient that the doctor and pharmacist are monitoring them and that there is a level of control being exercised.

GP1: *The main disadvantages I think probably is its another system that needs to... the pharmacist have to look after and its another system that we have to look after as well and I suppose that's the main disadvantages, more paperwork and that sort of thing. Generally I think most of my patients actually don't resent it or don't mind it basically. I don't think there are really big disadvantages. I think that probably it works in a smaller jurisdiction like we are than it probably might work in bigger places.*

GP6: *Initially I felt simply doing the form, remembering to do it, remembering to fill out the form and faxing it off was just a little tedious but it's really quite a simple system so I quickly reframed that. So is there... so that wasn't really a disadvantage, just a perceived*

disadvantage perhaps initially. Are there any disadvantages now that I see? No, I don't think so. Disadvantages. No.

In terms of improvements to the program, one GP thought it was an excellent program, one thought it should be compulsory, one thought that we should look at ways of improving the uptake of the program and two other GPs had no suggestions about how the program could be improved. In terms of specific improvements, two GPs thought that the list supplied by ACT HPS was useful and one of these GPs thought this list could be improved by just sending each doctor a list of his/her patients on a BVU, rather than the whole list. This GP would also like ACT HPS to notify them if any of their patients on a BVU attend another pharmacy or GP other than those specified in their BVU agreement. One GP would like to set up some sort recall system so that when a patient's BVU has elapsed, they are reminded to renew or review the BVU. One GP would also like to see an education program for doctors who overprescribe benzodiazepines.

GP5: *I think it works pretty well. I don't have any other suggestions.*

GP2: *I think there's a case for making it compulsory. Certainly, yeah, I think there is a case for that but I think the ultimate is the sort of education of the doctors who are over prescribing. I think it's an excellent program and I think we're so much luckier in A.C.T than places like Sydney. One of the great strengths of this is that if I have a patient comes in to see me who I don't know I can ring up State Pharmacy and find out details from them.*

GP6: *I think it would be useful if pharmaceutical divisions let us know, instead of sending that list of everybody's... all the patients on a contract in the ACT, which is what they do currently I believe, they could just send each doctor a list of his or her patients on a contract just as a memory aid rather than the whole list. I don't know whether the whole list is useful. I'm not quite sure for the reason for that. And also to indicate when any of our patients are attending a different doctor and has taken up a new contract.*

Four pharmacists thought that the BVU program is "a really good program (**PH4**)" and that there were no great disadvantages. There was no consensus amongst pharmacists regarding the disadvantages of the BVU program.

One pharmacist identified that "a certain amount of administration is required (**PH1**)" and that the system could become unwieldy if the client base expanded and it could become difficult to maintain accurate records. Two pharmacists would like to see some sort of dispensing software that could be automatically updated. One pharmacist would like to be able to identify a patient by something in addition to their name and address, such as through the use of a Medicare number. One pharmacist identified time, storage constraints and the effort required to fulfil frequent small dose pickups with no monetary compensation. Another disadvantage was that patients on additional contracts, such as a methadone contract, often fill their prescriptions at different pharmacies. This pharmacist would like to see clients filling all of their contracts at the same pharmacy. In addition, this pharmacist would like all doctors to support the program and not prescribe to habitual users who don't have a BVU contract. One pharmacist would also like to be informed, in a timely manner, when a person goes off a BVU.

PH3: *The only disadvantage... look I don't see any disadvantages because I think it is good health policy to try and help people manage their medication and not abuse and not misuse. The only disadvantage from a pharmacist point of view is the time and the storage space and the effort in the frequent small dose pick ups and that's something that I know we all want to rationalise and be... it's time where we're not compensated for what we're doing.*

PH7: *I do think instead of us getting faxes every day or via email or whatever it should be part of a monthly update where our updates get updated in the computer on a monthly basis. It should become part of that where it just automatically gets loaded into the computer and we do not have to manually enter in the patients on a daily or second daily basis.*

In terms of improvements to the program, four of the seven pharmacists indicated that a non paper-based centrally available database, such as a secure website or a program within dispensing software, which automatically updated BVU data, would be useful. Two pharmacists thought that the program was working well and two pharmacists thought that better communication with GPs would be useful. Similar to the disadvantages listed above, one pharmacist would like to see a reduction in the time taken to administer the program, one pharmacist thought that all scripts for patients on multiple contracts (eg BVU and methadone) should be dispensed from the one pharmacy, one pharmacist would like to see patients on contracts for any medication they abuse, not just benzodiazepines and one pharmacist would like to see all doctors making use of the BVU program.

PH1: Again if the administration time could be reduced I think that would be of benefit. Also, again, in some ways I think if there was a centrally available database that wasn't paper managed so it was possible to access either a secure website or within your dispensing software to check for up to date additions to the BVU program.

PH 4: Well I guess I said it just in the last question, just greater... more doctors that actually use the program or they're stricter with their clients that they have to be on a contract or they won't just prescribe for them. And again, if they're on methadone and they're dosing at a pharmacy that their contract would be at the same pharmacy.

PH5: It seems fairly good. I mean its daily updates on changes as its going. Perhaps, we flagged earlier in the interview, as you said we don't actually tend to talk very often with the doctors, we're just getting faxes daily which leaves us out of the loop a tiny bit in that there's not a lot of actual interaction with the doctors.

The patient in this study did not see any disadvantages to signing a BVU and had no suggestions for how the program could be improved.

6.0 DISCUSSION

6.1 DATA AUDIT

The purpose of this study was to establish the parameters for a full evaluation of the BVU program; one which considers both its clinical *effectiveness* (a goal-oriented evaluation) and the *efficiency* of its processes (a process evaluation). Notably, this was the first time the information collected by the BVU program has been audited since its inception in 1996. The audit indicated that involvement in the BVU program by general practices (n=66) and pharmacies (n=68) remained stable over the five-year study period. The number of patients in the program in any one year also remained relatively stable (range 205-265). However, more than two thirds of these had one-off or inconsistent contact with the program. In comparison, slightly less than 20 percent of patients, in the final two years of the program, maintained continuity, defined as renewal of an existing BVU within two months of its end date. The relatively low numbers maintaining continuity may reflect some combination of the mobility of the ACT population and the quality of the data. The measurement of continuity was also probably affected by the efficacy of GPs processes for the renewal of BVUs. Furthermore, some GPs and patients may have continued to adhere to the spirit of the BVU even though the BVU contract had expired.

Interestingly, all the cancellations to BVUs over the five-year study period were made by 14 percent of patients. However, we are unable to determine whether BVU contracts are predominantly cancelled by doctors or patients, or whether there is consensus doctor/patient consensus in cancelling a BVU. Contacts were more likely to lapse than be cancelled.

Over a third of the GPs practicing in Canberra participated in the BVU program during the study period; of these, almost a fifth participated only once. It is unclear whether this is because those GPs not returning to the program do not have many patients who would benefit from signing a BVU or because the GPs see no value in the BVU program. Furthermore, we do not have any benchmarks for levels of desirable involvement.

Participation in this program is unevenly spread across GPs and pharmacies. The top five practices (<8% of involved practices) accounted for three quarters of all the BVU activity, while a fifth of practices had only one entry in the entire five-year period. The most active practice, which also contained the most active GP, had four times more contacts than the next most active practice. Likewise, the burden was spread unevenly among pharmacies. While the majority of ACT pharmacies participated in the BVU program (2004-08), the top ten pharmacies (15% of involved pharmacies) accounted for three quarters of the BVU activity, and a third of pharmacies had only one entry in the entire five-year period. In addition, GPs choose whether or not to enter in to BVU agreement and get paid for the consultation. Conversely, pharmacists may or may not get a chance to accept their role in the BVU. Pharmacists do not get paid for their time and/or efforts.

The monthly data suggest that activity – the number of new, renewed, changed or cancelled BVU contracts – peaks in February and September and tends to ease off May-June and in December. We note that the peaks and troughs are roughly six months apart, but proffer no explanation.

The process of the audit has taught us the following:

- We lack any benchmarks about desirable levels of continuing participation in the Program.
- The data is not kept in a manner suitable for any type of audit or analysis. In particular, the data requires semi-manual extraction and de-identification.
- Each BVU is filed in triplicate: individual patient record, renewal folder (filed under the month preceding cessation of the BVU contract), and folder of all current notices.
- Inconsistencies exist between the hardcopies of the BVUs and the electronic versions of the daily and monthly lists. We were not made aware of any quality assurance to ensure the accuracy of the data.
- Initially it was difficult to locate a written version of the goals of the BVU program. However, one is available on the ACT Health website now (2).

6.2 INTERVEIWS

When interpreting the data one must bear in mind the likely predisposition of the interviewees' to support the BVU program. Reasons for involvement in the BVU program were fairly consistent among GPs and pharmacists. Ultimately, all wanted to minimise the abuse of benzodiazepines by patients and ensure that the patients received continuity of care. The BVU allowed monitoring of benzodiazepine use and provided an element of control. Some pharmacists also noted that an element of "community service" was integral to their involvement in the BVU program.

The procedure for commencing a BVU was fairly consistent, with most GPs explaining to the patient how the program works. It was not clear from the data if GPs routinely explained what benefits the patient would receive. The amount of contact between GPs and pharmacists about BVUs appeared to be variable. Pharmacists indicated a preference for more contact with prescribing GPs.

Pharmacies used a variety of means to verify the legitimacy of the script, including consulting ACT HPS lists or pharmacy records, and contacting the GP. When dispensing the script the pharmacists took the opportunity to re-enforce terms and conditions of BVU, and would not dispense if they were not met.

The data revealed variable use of daily and monthly lists faxed by ACT HPS to GPs and pharmacies. Some GPs did not refer to them at all, some noted that ACT HPS reminders prompted them to renew a patient's BVU. GPs saw renewal of a BVU as an opportunity to review the patient's dose of drug.

BVUs were used overwhelmingly for patients with existing drug problems or who were also on methadone or buprenorphine programs. They were not generally used for elderly patients. The reasons for this were not explored in interview.

All pharmacists had experienced problems with aggressive or abusive behaviour of patients, but this was not mentioned by any of the GPs.

The benefits of the program, expressed by GPs and pharmacists, were consistent with their stated reasons for participation – to minimise drug abuse and ensure continuity of care. In the eyes of one GP it also helped involve patients in their own care. Some pharmacists felt it helped them meet their obligations to clients and the broader community. They also felt it was valuable for the two health professions to present a consistent message to patients.

The overwhelming suggestion was that computerisation of the administrative elements of the system would ease the burden of GPs and pharmacists, alike. The inclusion of a Medicare numbers on BVUs was also raised. It was felt that the BVU program would be more effective if all GPs in the ACT used it. The desire to be monetarily compensated for involvement in the program was noted by several participants. GPs wanted to see an education programs for GPs who overprescribe benzodiazepines, and pharmacists would like more regular contact with prescribing GPs.

The interviews have taught us the following:

- The goals of the program are supported by the GPs and pharmacists interviewed.
- The target group for the BVUs appeared to be polydrug users, not simply patients with high use of benzodiazepines.
- The administrative elements of the program would be improved by computerisation.
- Pharmacists are very committed to the BVU program and any future discussion or evaluation of the BVU program should include a non-ACT Health representative from the profession.

7.0 RECOMMENDATIONS

The results of the audit and interviews have contributed to our understanding of the BVU program and have led to the following recommendations.

Goals of the Program

- Review the objectives of the BVU program, to clarify definitions and identify suitable measures. For instance,
 - Goal* Assist doctors to achieve the best possible health outcomes for patients using alcohol and other drugs
 - Measure* Validated quality of life scale
 - Timeframe* Conducted every 12 months
 - Analysis* Conducted by the Academic Unit of General Practice & Community Health, ANU Medical School

NB We recommend that a committee is convened for this purpose and that it includes representatives from

- ACT HPS
- General practice profession (possibly nominated by ACT Division of GP)
- Pharmacy profession (NB independent of ACT Health)
- Academic Unit of General Practice and Community Health, ANU Medical School

- Define the target population for the BVU program. For example, criteria may include one or some combination of
 - Patients with high use of benzodiazepine
 - Poly drug users
 - Patients also on methadone or buprenorphine programs.
- Use a Delphi process (1) to establish desirable benchmarks for GP, pharmacist and patient participation in the program.
- Incorporate the *benefits to patients* of participating in a BVU program into all documentation and promotional material.

Administration

- Develop an information sheet for patients outlining how the BVU program works and what benefits they can expect from participation.
- Introduce to ACT HPS a computerised system for receiving, storing and distributing information among participating GPs and pharmacies. For example,
 - An online central database, with appropriate security provisions, to allow viewing access by GPs and pharmacists, and to provide automatic renewal notices tailored to the GP and pharmacy that receives them.
- Provide all GPs and pharmacies with software that will facilitate their involvement in the BVU program. For example,
 - Software which provides a computerised form for GPs to complete and email to ACT HPS, where it is then automatically loaded into central database
 - Viewing access to online central database, for all GPs and pharmacists, with appropriate security provisions.

Promotion

- Promote the BVU program to all ACT based GPs and pharmacies. Options include,
 - Easier searching of ACT Health website for information on BVU program (include all the following search terms "BVU" "BVU program", "voluntary undertaking" "benzo contract")
 - Running sessions for GPs and pharmacies explaining BVU, in collaboration with appropriate professional bodies
 - Promoting the BVU program regularly in the professional newsletters
 - Provide posters about the BVU program to all general practices in the ACT.

Future evaluation

- Convene an evaluation committee that includes representatives from
 - ACT HPS
 - General practice profession (possibly nominated by ACTDGP)
 - Pharmacy profession (NB independent of ACT Health)
 - Academic Unit of General Practice and Community Health, ANU Medical School
- Consider the detail of this report and develop a plan to conduct a *prospective, goal-oriented evaluation* six months after Program goals have been reviewed, and any changes that emerged from it have been widely promoted.

8.0 CONCLUSION

Although around half the people who die from poly-drug overdose in the ACT have benzodiazepines in their system (3), ACT PSS does not have any record of any patients who died from a poly-drug overdose involving benzodiazepines while on the BVU program. While the reporting mechanisms for this are not well-established, information is often shared informally in

a small geographic area like the ACT. This suggests that the ACT BVU program is safe to use in cases of benzodiazepine dependence.

The goals of the BVU program appear to be well understood and supported by ACT GPs and pharmacists. However, the goals as they currently stand do not enable measurement and therefore they cannot be adequately evaluated.

A meaningful goal-oriented evaluation can only take place once the goals of the program have been clarified and measures specified. Improvements in the administrative aspects of the program would best take place before a further process evaluation.

Computerisation of administrative elements of the program would most likely facilitate use, decrease workload (after an initial settling period) and facilitate evaluation.

The program may become more widely known and used if it were promoted periodically.

The continuation of the BVU program would benefit from the input of a small advisory group that includes a GP and a non-ACT Health representative from the pharmacy profession.

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APPENDICIES

Appendix 1 – BVU Contract



VOLUNTARY UNDERTAKING

I

Of

(dob) / / Medicare Number

voluntarily agree to the conditions, as set out below for a period of six months.

I understand that the purpose of the undertaking is to prevent me obtaining prescriptions for the following medicines from more than one doctor:

- Benzodiazepines
- Opioids (e.g. morphine, oxycodone)
- Other (e.g. 'codeine-containing preparations')

Please tick and/or insert name of medicine as necessary.

I agree I will only obtain prescriptions for these medicines from:

Dr of

Ph: Fax: as discussed and agreed.

And that I will pick up these prescriptions only from Pharmacy
at

Ph: Fax:

I agree that a copy of this signed undertaking will be sent to the Health Protection Services who may advise doctors and pharmacies about the Undertaking.

I understand that should circumstances change this Undertaking can be cancelled by my doctor, pharmacist or me and written advice will be sent to the Health Protection Service.

Signed: Signed: Dr

Print Name: Print Name:

Date: / / Date: / /

Witnessed by Date: / /

Please verify that the nominated pharmacy is willing to participate in this voluntary undertaking before it is signed and sent to the Health Protection Service.

The information above is confidential and is intended for use by, the Health Protection Service.
Locked Bag 5, Weston Creek 2611. Telephone: (02) 6207 3974 Fax: (02) 6205 0997

Voluntary Undertaking Form – Version 2 Last update 17 August 2009 Page 1 of 1

Appendix 2: Key studies of benzodiazepine reduction in adult populations, 2000-2010

Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
(4)	2009	Analysis of different interventions and outcomes for benzodiazepines	United Kingdom	Systematic Review	3234	Benzodiazepines remain controversial in both the general public and amongst doctors. Long-term use does not seem to be justified, especially in the elderly. The method of discontinuation should always include tapering; however, the rate of tapering remains controversial. The best strategy is to remain flexible but to try to avoid prolonging the process beyond 6 months. Adjunctive medication is not firmly established, except that the depressed individual should be treated appropriately, usually with an antidepressant. Only weak evidence supports the use of other medications such as carbamazepine. Counselling may be effective but this has not been studied in great enough detail
(5)	2009	Buprenorphine patients treated for over three months were recruited via physicians. Patients answered a self-administered questionnaire, and the goal of the study was to understand how use, abuse and dependence of benzodiazepines correlates.	France	Cross-sectional Study	170	Characteristics of simple benzodiazepine users were distinct from problematic users but not from non-users in this sample of buprenorphine patients. This should be taken into account in the clinical management of benzodiazepine use among buprenorphine patients. Problematic users of benzodiazepines had higher depression and anxiety levels, correlated with quality of life impairment and precariousness. They used higher dosages of benzodiazepines than simple users
(6)	2009	Review of treatment approaches to benzodiazepine discontinuation in general practice and out-patient settings.	Australia	Systematic Review	N/A	Providing an intervention is more effective than routine care. Psychological interventions may improve discontinuation above gradual dose reduction alone. Although some pharmacotherapies may have promise, there is insufficient evidence to support their use.
(7)	2009	4499 patients who received psychotropic drugs were	Thailand	Qualitative Analysis	4499	The rate of psychotic drug prescribing increased with age and female patients. Benzodiazepines were 10 times more likely to be

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Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
		analysed, to evaluate the prevalence, pattern, and rational of psychotropic drugs prescribing by primary care physicians				prescribed than any other drug.13.4% of patients were found to fill their prescription at multiple pharmacies. Psychological conditions were the most likely disorder for the reason for prescription. Insomnia, tension headache and anxiety were the most common psychological diagnosis. A quarter of all patients were long-term users (greater than 2 months). Benzodiazepines were prescribed not only for mental but often for chronic pain and musculoskeletal disorders. A quarter of the patients received psychotropic drugs as well as long-term medications without diagnosis. Some patients were put on psychotropic drugs combination
(8)	2008	A controlled stepped-care intervention program was compared against a control to decrease long-term benzodiazepine use.	Netherlands	Randomised Controlled Trial	1879	No clinically important differences in practice contacts were observed when the course of the number of contacts and non-benzodiazepine prescriptions were compared between the experimental and control groups. Family practitioners do not have to anticipate an increased workload associated with participation in such a benzodiazepine discontinuation programme. Benzodiazepine quitters also are shown to decrease their prescriptions for other medications. These observations support the view that quitting benzodiazepines will not result in other patient demands.
(9)	2008	Postal survey conducted with 56 GPs exploring the opinions of a stepwise benzodiazepine reduction programme (above).	Netherlands	Cross-sectional Survey	56	A stepwise benzodiazepine reduction programme was well received by GPs. Most GPs (82%) experienced no increase in medical consumption. Possibilities for individual tailoring may enhance satisfaction of GPs participating in benzodiazepine reduction programmes. The support and backup given by the researchers, e.g., identifying long-term users, preparing discontinuation letters, and defining the taper schemes, may have increased the enthusiasm of GPs. It may be worthwhile to offer this support to GPs when our programme is implemented in clinical practice.
(10)	2008	Compared prescriptions for opioid maintenance and	Austria	Qualitative Analysis	21,145	Opioid prescription more than doubled between 2003 and 2005, while the ratio of benzodiazepines to opioids declined

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Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
		concomitant benzodiazepine prescriptions.				significantly. Many patients were prescribed concomitant benzodiazepines by a secondary physician. Safe guards are necessary to ensure that GPs have sufficient training and support to safely provide treatment, including reduction in concomitant benzodiazepine use.
(11)	2008	PBS used to obtain dispensing data and benzodiazepine usage was compared with Nova Scotia prescribing.	Australia, Canada	Qualitative Analysis	N/A	Large differences exist between the type and rate of benzodiazepine prescribing in Nova Scotia and Australia, with Nova Scotia reporting more than twice as much use. Benzodiazepine use in both jurisdictions is increasing. The Canadian findings are especially concerning as benzodiazepine use in the Atlantic provinces has been reported to be less than other provinces. The variations between the 2 jurisdictions may be due to factors such as fewer benzodiazepines available in Australia, differences in prescriber, patient attitudes and behaviours, or different initiatives to influence benzodiazepine use.
(12)	2008	Questionnaire of GPs and pharmacists about their intent to educate patients about benzodiazepines	Netherlands	Cross-sectional Survey	1604	General practitioners and pharmacists intend to educate in cases where they think that benzodiazepines have well-defined disadvantages, when the education they undertake leads to success, when they feel pressure to educate from their surroundings and when they are capable of educating. Beliefs, outcome expectation, social norm and self-efficacy all play a significant role in intent to educate. GPs considered more factors while pharmacists considered just the social norm and positive factors when intending to educate patients about benzodiazepines
(13)	2007	Phenomenological qualitative approach. GPs were asked to join focus groups, and then their opinions recorded on their prescribing of benzodiazepines in	Belgium	Qualitative Analysis with systematic content analysis	35	GPs often report that they are cautious in initiating benzodiazepine scripts. They feel overwhelmed by the psychosocial problems of patients and often believe benzodiazepines are the lesser evil. Many doctors resort to benzodiazepines due to time constraint and lack of alternatives, and don't often think of the addictive nature of the drug when first prescribing. Patients demanding the drug is not a common

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Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
		practice.				reason for starting.
(14)	2007	Focus group discussion involving drug workers, high-dose benzodiazepine users and GPs, and their opinions on benzodiazepine withdrawal and how to better service.	United Kingdom	Questionnaire	231	GPs were more likely to have interactions with benzodiazepine users over drug workers. Benzodiazepine were considered an important cause of physical and social problems by all, but only a very small number of GPs thought users wanted to withdraw, and less than half felt confident in carrying out withdrawal. Key service priorities identified by the consultation include specialist benzodiazepine drug workers based in general practice, educational support and guidelines for GPs and clinical psychological output.
(15)	2007	Semi-structured interviews were carried out on a sample GPs drawn from a variety of localities across a major north-western English city, regarding opinions of benzodiazepine prescribing. The group included new GPs as well as long-practising GPs. The interviews were transcribed and grouped into four major themes.	United Kingdom	Qualitative Analysis	22	The accounts of the respondents highlight a number of points about: blame allocation, past and present; clinical challenges about risk management; and deserving and undeserving patients. There appears to have been a cultural shift in the way in which GPs have viewed the risks associated with benzodiazepine use. Comparison with other drugs indicate that benzodiazepines are similar to other drugs in that they are very addictive and can be compared to previous alternatives that have now been discredited. It is concluded that, while there has been a recent consensus that the benzodiazepines have been problematic, when they are placed in a longer historical context, a different picture is apparent because other psychotropic drugs, like anti-psychotics and anti-depressants have raised similar problems as well.
(16)	2007	Benzodiazepine users were randomly picked to receive a letter with the advice to stop or reduce use of benzodiazepines after GPs attended a course on benzodiazepine users. The results were then compared.	Netherlands	Randomised Controlled Trial with multilevel analysis	8,170	Reduction in benzodiazepine prescribing was significantly larger in the intervention group over the control group. Educating GPs on benzodiazepine use can help reduce benzodiazepine prescriptions. Elderly patients were more likely to reduce their dosage when recommended to by their GP. Older men were likely to obey their doctor's recommendation letter.

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Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
(17)	2006	All benzodiazepines prescribed for one month at a time and could be renewed only by the doctor after a personal consultation. The goal was to reduce the use of addictive drugs	Netherlands	Experimental Intervention	18,513	After 15 months, the patients' use of benzodiazepine was reduced by 50%. The process of changing prescription habits was far easier than expected. An entire group of patients, previously invisible to the doctors, was exposed. During the first three months, only four to five additional consultations for every 1,000 assigned patients were required each week. There was practically no need of any assistance from our usual partners, such as psychiatrists, hospitals, special wards for addictive treatment or primary health care. The authors strongly recommend that this simple procedure be made a daily routine when prescribing a benzodiazepine.
(18)	2006	benzodiazepine users were given a questionnaire four times over 21 months to evaluate their benzodiazepine craving after reduction or cessation of use.	Netherlands	Questionnaire	317	Results indicated that (1) benzodiazepine craving severity decreased over time, (2) patients still using benzodiazepines experienced significantly more severe craving than patients who had quit their use after one of the two interventions, and (3) the way in which patients had attempted to quit did not influence the experienced craving severity over time, however, (4) patients who had received additional tapering off, on average, reported significantly more severe craving than patients who had only received a letter as an incentive to quit. Although benzodiazepine craving is prevalent among (former) long-term benzodiazepine users during and after discontinuation, craving severity decreases over time to negligible proportions.
(19)	2006	Semi-structured interviews were undertaken with both GPs and benzodiazepine users to see their views on benzodiazepine prescribing.	Australia	Qualitative Analysis	51	Users felt there was greater need for GPs to routinely advise patients about non-pharmacological management of their problems and potential adverse consequences of long-term use before commencing benzodiazepines. Lifestyle change should receive a greater focus at all stages of treatment. Cessation should be discussed with patients who use longer than 3 months and strategies offered to assist with management of withdrawal and anxiety.
(20)	2006	Benzodiazepine users	United	Randomised	139	Patients in the intervention group were five times more likely to

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Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
		randomised into routine clinical practice group and standardised advice, dose reduction group, and followed for a year. The intervention program was then evaluated.	Kingdom	Controlled Trial. Non-blinded.		have discontinued benzodiazepine use over those in the control group. Almost half of the intervention group achieved withdrawal, and another quarter reduced their dose. Standardised advice together with a tapering off schedule seems to be effective for withdrawing long-term benzodiazepine use and is feasible in primary care.
(21)	2005	The Benzodiazepine Craving Questionnaire (BCQ) and other self-report questionnaires were administered once to long-term and former long-term GP benzodiazepine users participating in a large benzodiazepine reduction trial in. The goal was to describe characteristics of patients reporting benzodiazepine craving.	Netherlands	Cross-Sectional Survey	193	Patients reporting craving differed significantly from patients not reporting craving on aspects of benzodiazepine dependence severity, psychopathology, negative mood state, and personality. Negative mood and somatisation were positively associated with benzodiazepine craving, although only the contribution of negative mood to craving was statistically significant. It is becoming obvious that personality factors play a large role in benzodiazepine craving and dependence.
(22)	2004	Semi-structured interviews were conducted with patients recruited to the trial, and non-standardised (conversational) interviews with practice staff. The focus was to explore beliefs and attitudes about continuing or stopping benzodiazepines amongst older patients, and amongst their GPs.	United Kingdom	Survey of Randomised Controlled Trial Participants	192	Beliefs in the efficacy of hypnotics, and self-report of insomnia despite their use, varied according to the willingness to attempt withdrawal. The majority of patients reported no warnings from professionals about adverse effects of using benzodiazepine hypnotics. Half had tried to stop at some time but most attempts had been short-lived. Patients and doctors had distinctly different views of the advantages, disadvantages and risks of stopping benzodiazepine hypnotic use. Both increased patient awareness of the problems of long-term benzodiazepine use and an evidence-based approach to withdrawal efforts in primary care are necessary to reduce the consumption of medication that has little real benefit.

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Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
(23)	2004	Guide for GPs for benzodiazepine cessation in benzodiazepine dependent patients.	Australia	Practical Information Article	N/A	Some patients may have common medical presentations and coexisting drug dependence. It is often difficult to separate these two issues. In the case of benzodiazepine dependence, gradual withdrawal over time and nonpharmacological treatment of the symptoms of withdrawal such as anxiety or insomnia is effective. Better outcomes are achieved where the GP discusses and plans strategies well in advance with the patient. Treatment often involves multiple interventions from various health professionals. General practitioners are ideally placed to coordinate such treatment.
(24)	2004	Study undertaken in family practices among benzodiazepine users with regard to DSM-IV diagnosis, coping and psychosocial characteristics of long-term and short-term users.	Netherlands	Cross-sectional Study	322	Having a DSM-IV disorder and psychiatric co-morbidity, being older, less educated, lonely and using more avoidance coping behaviour were all associated with long-term use of benzodiazepines compared with short-term use. These associations point to possibilities in reducing long-term benzodiazepine use, like using alternatives to benzodiazepines or closer monitoring for a short period after commencement of benzodiazepine prescription.
(25)	2003	At baseline and yearly follow-up for six years, 203 patients with co-occurring severe mental illness and substance use disorder were prospectively assessed for medication use, substance use, psychiatric symptoms, use of hospitalisation, and quality of life.	United States	Cross-Sectional Survey	203	Patients taking prescribed benzodiazepines were more likely to have high scores on measures of overall symptoms and affective symptoms (anxiety and depression) and low ratings for general quality of life throughout the study. Benzodiazepine use was unrelated to remission of substance use disorder or hospitalisation. Prescription benzodiazepine use was common among patients with co-occurring severe mental illness and a substance use disorder and was not associated with any of the measured outcomes other than increasing the likelihood of benzodiazepine abuse. Physicians should consider other treatments for anxiety in this population.
(26)	2003	Representative sample of patients currently receiving benzodiazepine treatment for 1 month or longer. The	Spain	Cross-Sectional Survey	1,048	Of patients using benzodiazepines for more than 1 month, 47% developed dependence to these compounds. Benzodiazepine dependence was more prevalent among women who were middle aged, separated, of low educational background,

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Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
		focus was to estimate the prevalence, characteristics and risk factors associated with the development of benzodiazepine dependence users.				unemployed or housewives. Patients using short half-life benzodiazepines registered higher rates of dependence as well as those using higher doses or the patients with longer use. However, multivariate logistic regression analysis shows that benzodiazepine dependence was closely related only to three of the variables considered: the benzodiazepine dose used, the duration of this use and to the concomitant use of antidepressants.
(27)	2003	Survey was sent out by post to general practitioners regarding their opinions on illicit drug management and how experience, training, and guidelines affect their practice.	Scotland	Cross-Sectional Survey	926	The majority of physicians who responded treated drug users and provided methadone maintenance, and slightly less provided benzodiazepine maintenance. The vast majority had read the guidelines for treating drug users, but many did not believe these guidelines affected their practice. Maintenance prescribing of dihydrocodeine and benzodiazepines were common despite a lack of clinical evidence supporting the effectiveness of these treatments. This may reflect the nature of the presenting drug problems and highlights the difficulties some GPs may face in managing multiple drug dependencies within current guidelines. More training is recommended for implementing guidelines.
(28)	2003	Examination of dose and frequency of dose escalation among new and continuing users of benzodiazepines, and to determine whether long-term benzodiazepine use is associated with dose escalation.	United States	Qualitative Analysis	2,440	No clinically or statistically significant changes in dosage were observed over time. The incidence of escalation to a high dose was 1.6%. Subgroups with a higher risk of dose escalation included antidepressant recipients and patients who filled duplicate prescriptions for benzodiazepines at different pharmacies within seven day. Elderly and disabled persons were less likely to escalate their dose compared to younger patients. The study concludes that long-term use of benzodiazepines does not frequently result in notable dose escalation.
(29)	2003	A questionnaire was applied to users of benzodiazepines users. Age, depressive behaviour, addiction, satisfaction and	Netherlands	Questionnaire	506	The majority of benzodiazepine users are long-term users women are more likely to be long-term users. Health problems more than social problems led to the use of benzodiazepines in the first place. Long-term use was associated with older age, depression, higher score on the medical addiction index,

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Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
		problems and the computerised medical records were analysed.				problems with children or housing, and satisfaction with the effects of the drugs. Gender is not a risk factor however, although the other mentioned variables are all significant factors.
(30)	2003	3-month randomised, controlled trial was conducted in which 180 people attempting to discontinue long-term benzodiazepine use were assigned to tapering off plus group CBT, tapering off alone or usual care. The focus was to to evaluate the efficacy and feasibility of tapering off long-term benzodiazepine use in general practice, and to evaluate the value of additional group cognitive-behavioural therapy.	Netherlands	Randomised Controlled Trial	180	Tapering off led to a significantly higher proportion of successful discontinuations than usual care (62% v. 21%). Adding group CBT did not increase the success rate (58% v.62%). Neither successful discontinuation nor intervention type affected psychological functioning. Tapering off is a feasible and effective way of discontinuing long-term benzodiazepine use in general practice. The addition of group CBT is of limited value. Tapering off was tolerated well in general practice: the general practitioners did not report any major adverse event during or after the tapering-off process. The good compliance and high level of satisfaction with the programme among both doctors and participants further strengthen the feasibility of tapering off as a strategy to discontinue long-term benzodiazepine use in general practice.
(31)	2003	Baseline assessment and prospective monitoring for relapse of patients who quit long-term benzodiazepine use after a minimal intervention strategy in general practice.	Netherlands	Qualitative Analysis	109	Two independent predictors of relapse were identified by Cox regression analysis: use of more than 10 mg diazepam equivalent and poor general health perception. Short-term success rates after a minimal intervention were maintained well during long-term follow-up. High-dose users have the highest risk of relapse. Long-term follow-up data is not available.
(32)	2003	Benzodiazepine dependent patients substituted their benzodiazepine of abuse for clonazepam and were	Israel	Randomised Controlled Trial	66	Survival analysis showed maintenance therapy to be more successful than the detoxification therapy. Axis I psychiatric comorbidity (clinical disorders like depression, anxiety, bipolar disorders etc.) was found to be positively related to treatment

ACADEMIC UNIT OF GENERAL PRACTICE AND COMMUNITY HEALTH

Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
		then either detoxified or a maintenance dose was reached and maintained. Treatment outcome was evaluated based upon self and staff reports over 1 year after beginning treatment. DSM Axis I and II psychiatric diagnosis was assessed and methadone dosage and history of abuse was recorded.				success in the maintenance group while axis II antisocial personality disorder was found to be negatively related to treatment success in that group. Maintenance strategy with clonazepam is a useful benzodiazepine treatment modality for benzodiazepine-dependent methadone maintenance treatment patients with a long-term history of abuse and previous attempts at detoxification. Psychiatric comorbidity may have an important role in choosing the adequate treatment modality and influencing treatment outcome.
(33)	2002	Fixed and symptom-triggered taper methods during in-patient benzodiazepine withdrawal treatment were compared.	Australia	Randomised Controlled Trial	44	No significant treatment between treatment groups in terms of withdrawal severity. Duration of in-patient treatment, amount of diazepam administered, treatment attrition and benzodiazepine use at follow-up. Both groups showed a reduction in benzodiazepine dosage over the first 8 days up to 1 month post-discharge. This study shows that benzodiazepine users entering treatment have relatively poor health and that and symptom-triggered taper methods are as effective as fixed dose taper methods.
(34)	2002	A questionnaire mailed to the NHS alcohol and drug treatment services asked respondents to rate the acceptability and availability of 11 pharmacological interventions for substance misuse employed to relieve withdrawal, reduce the likelihood of relapse and opiate overdose and substitute pharmaceuticals	United Kingdom	Questionnaire	265	Substitute methadone for opiate addiction, substitute benzodiazepines for benzodiazepine-dependent patients, lofexidine for opiate detoxification, naltrexone for opiate relapse prevention and acamprosate for alcohol relapse prevention were widely acceptable and available interventions. Another subset of medications-buprenorphine for opiate detoxification, take-home naloxone for overdose prevention and substitute prescribing of levo-alpha-acetyl-methadol (LAAM), heroin and dexamphetamine-garnered less support, but the majority of participants rated even these therapies as acceptable. Differences among specific medications notwithstanding, a wide range of harm-reduction and abstinence-orientated interventions were acceptable to and

ACADEMIC UNIT OF GENERAL PRACTICE AND COMMUNITY HEALTH

Reference Number	Year	Methodology	Country of Study	Type of Study	Number of subjects	Main Findings
		for illicit drugs.				available from NHS services. Acceptance and availability are probably limited by a combination of practical, economic, safety, efficacy and theoretical considerations.
(35)	2000	Discussion on drug-seeking patients and strategies for identifying those patients.	United States	Expert opinion	N/A	The desire to treat versus the desire to avoid embarrassment and avoid sanctions must be balanced so as to provide the best patient care possible. Patient characteristics vary greatly but there are several behaviours that tend to occur when patients who abuse drugs interact with medical care systems: escalating-use patterns, drug-seeking behaviour, doctor shopping and the use of scams.

Appendix 3 – Letter of Invitation for GPs to Participate in the BVU Study



Dear _____

Date_____

Evaluation of the Benzodiazepine Voluntary Undertaking program

As you know the Pharmaceutical Services Section manages Benzodiazepine Voluntary Undertaking (BVU) program.

The Academic Unit of General Practice and Community Health in the ANU Medical school, is currently undertaking a preliminary study to evaluate the BVU program.

The BVU program is unique in its approach to improve the medical management of patients with known benzodiazepine use. However, the program has not previously been evaluated and consequently, there is limited knowledge about the program.

This study aims to collect a detailed description of the BVU program in order understand the day-to-day reality of the program. We will examine how the program is functioning and how patients, GPs and pharmacists experience the program.

The participation in the project is **purely voluntary** and if you choose to participate in the study you will be asked to take part in an interview focusing on attitudes and experiences with the BVU program. The interview will be completed at your office and the length of the interview will be 45-60 minutes. You will be offered an honorarium of \$120 for participating in the study

If you are interested in participating in the study please complete the attached form and fax it to Maya Zwikael, Research assistant, Academic Unit of General Practice and Community Health.

Yours sincerely,

Dr Tuck Meng Soo
General Practitioner
Interchange General Practice

ACADEMIC UNIT OF GENERAL PRACTICE AND COMMUNITY HEALTH

To: Maya Zwikael
Research Assistant
Academic Unit of General Practice.
Fax number: (02) 62444105

- I am interested in participating in the evaluation of the BVU program.
- I am **not** interested in participating in the evaluation of the BVU program.

Date: _____ Name: _____(please print)

Signature: _____

Practice/ Pharmacy

address: _____

Appendix 4 – Letter of Invitation for Pharmacists to Participate in the BVU Study

Dear _____

Date_____

Evaluation of the Benzodiazepine Voluntary Undertaking program

As you know the Pharmaceutical Services Section manages Benzodiazepine Voluntary Undertaking (BVU) program.

The Academic Unit of General Practice and Community Health in the ANU Medical school, is currently undertaking a preliminary study to evaluate the BVU program.

The BVU program is unique in its approach to improve the medical management of patients with known excessive benzodiazepine use. However, the program has not previously been evaluated and consequently, there is limited knowledge about the program.

This study aims to collect a detailed description of the BVU program in order understand the day-to-day reality of the program. We will examine how the program is functioning and how patients, GPs and pharmacists experience the program.

The participation in the project is **purely voluntary** and if you choose to participate in the study you will be asked to take part in an interview focusing on attitudes and experiences with the BVU program. The interview will be completed at your office and the length of the interview will be 45-60 minutes. You will be offered an honorarium of \$120 for participating in the study

If you are interested in participating in the study please complete the attached form and fax it to Maya Zwikael, Research assistant, Academic Unit of General Practice and Community Health.

Yours sincerely,

Jane Strang
Chief Pharmacist
Health Protection Service

Appendix 5 – Information Sheets for Pharmacists and GPs, Patients



Medical School
Academic Unit of General Practice and Community Health

Information sheet for GP and pharmacist Evaluation of the Benzodiazepine Voluntary Undertaking program

The Academic Unit of General Practice and Community Health in the ANU Medical school, is currently undertaking a preliminary study to evaluate the Benzodiazepine Voluntary Undertaking (BVU) program in ACT. The focus of this study is to get a detailed description of the BVU program and it is anticipated that the results will be used to improve the quality and efficiency of a bigger evaluation study, which is planned for late 2010.

Why are we carrying out this research?

A BVU is a signed agreement entered into by a patient with their doctor, whereby the patient agrees to:

- Attend only one doctor or practice to receive their prescriptions for benzodiazepines.
- Attend only one identified pharmacy to have their prescriptions for benzodiazepines dispensed.

The BVU program is unique in its approach to improve the medical management of patients with known excessive benzodiazepine use. However, the program has not previously been evaluated and consequently, there is limited knowledge about the program.

This study aims to collect a detailed description of the BVU program in order understand the day-to-day reality of the program. We will examine how the program is functioning and how patients, GPs and pharmacists experience the program.

What does the research involve?

If you have been involved in the BVU program and wish to participate in this study we will ask you to sign a consent form and take part in an interview focusing on attitudes and experiences with the BVU program. The interview can be completed at your office or at another mutually agreed location and the length of the interview will be 45-60 minutes. If you accept, we will record the interview on audio tape.

You may be asked to invite 1-2 of your patients, who have signed a BVU to participate in the study. You should discuss the project to the potential patient and asked them to sign a consent form.

You will be provided a short (1 page) summary of the results.

The full report will be provided to ACT Health and may be published in academic journals or books. However, your name or work place will not be mentioned in the document. You will not receive any information about patient.



Medical School
Academic Unit of General Practice and Community Health

Information sheet for patient Evaluation of the Benzodiazepine Voluntary Undertaking program

The Academic Unit of General Practice and Community Health in the ANU Medical school, is currently undertaking a preliminary study to evaluate the Benzodiazepine Voluntary Undertaking (BVU) Program.

What is the BVU program?

A BVU is a signed agreement entered into by a patient with their doctor, whereby the patient agrees to:

- Attend only one doctor or practice to receive their prescriptions for benzodiazepines.
- Attend only one identified pharmacy to have their prescriptions for benzodiazepines dispensed.

Who are involved in the study?

- The research team at the Academic Unit of General Practice and Community.
- The general practitioners (GP) that are involved in the BVU program.
- The pharmacists that are involved in the BVU program.

What is known so far?

The BVU program has not previously been evaluated. Consequently, there is limited knowledge about the program.

This study aims to collect a detailed description of the BVU program in order understand the day-to-day reality of the program. We will examine how the program is functioning and how patients, GPs and pharmacists experience the program.

What will the study involve me doing?

It is completely **voluntary** to participate in this study. If you have signed a BVU with your GP and pharmacist, he/she may invite you to participate in the study. If you agree to participate and sign the consent form you will be contact by a researcher, who will arrange an interview with you. During the interview you will be asked questions about your experiences, opinions, attitudes and feelings about the BVU program. The interview will be completed at the general practice you belong to. The interview will take 45-60 minutes.

Appendix 6 – Informed Consent Forms for Pharmacists and GPs, Patients



Medical School, Academic Unit of General Practice and Community Health

Consent Form (GP and Pharmacist)

Evaluation of the Benzodiazepine Voluntary Undertaking (BVU) program

1. I _____ (please, print) consent to take part in a preliminary study to evaluate the BVU program. I have been provided with a written plain language statement to keep. I have read the information sheet for this program and understand its contents. My consent is freely given.
2. I understand that if I agree to participate in the evaluation program I will be asked to attend an interview and my interview will be audio taped. The interview will take up to one hour and will involve question about the evaluation of the BVU program.

I agree to be interviewed by the researcher Yes No

I agree to be audio taped during the interview Yes No

3. I acknowledge that:
 - (a) the possible risks of participating in the interview have been explained to my satisfaction;
 - (b) my participation is voluntary and I am free to withdraw from the program at any time without explanation or prejudice and to withdraw any unprocessed data I have provided;
 - (c) the project is for the purpose of research and evaluation only;
 - (d) the participation in this program will not result in any extra costs to me;
 - (e) I will be offered an honorarium of \$ 120 for participating in the study;
4. I understand that my personal information will be kept confidential as far as the law allows. My personal information and any other identifying materials will be stored separately in a locked office at the Australian National University.

After considering all these points, I accept the invitation to participate in the Evaluation of the BVU program.

Signed _____ Date _____



Medical School, Academic Unit of General Practice and Community Health

Consent Form (Patient) **Evaluation of the Benzodiazepine Voluntary Undertaking (BVU) program**

1. I _____ (please, print) consent to take part in a preliminary study to evaluate the BVU program. I have been provided with a written plain language statement to keep. I have read the information sheet for this program and understand its contents. My consent is freely given.

2. I understand that if I agree to participate in the evaluation program I will be asked to attend an interview and my interview will be audio taped. The interview will take up to one hour and will involve question about the evaluation of the BVU program.

I agree to be interviewed by the researcher Yes No

I agree to be audio taped during the interview Yes No

3. I acknowledge that:

(a) the possible risks of participating in the interview have been explained to my satisfaction;

(b) my participation is voluntary and I am free to withdraw from the program at any time without explanation or prejudice and to withdraw any unprocessed data I have provided;

(c) the project is for the purpose of research only;

(d) the participation in this program will not result in any extra medical and hospital costs to me;

(e) I will be offered a double pass movie voucher for participating in the study;

4. I understand that my personal information will be kept confidential as far as the law allows. My personal information and any other identifying materials will be stored separately in a locked office at the Australian National University.

After considering all these points, I accept the invitation to participate in the Evaluation of the BVU program.

Signed _____ **Date** _____