

Collaboration between community pharmacists and mental health care practitioners: a case conferencing model

Project: 2003-028

January 2007



**Faculty Of Pharmacy
The University Of Sydney**



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This project was funded by the Australian Government Department of Health and Ageing through the Third Community Pharmacy Agreement Research and Development Grants Program, administered by the Pharmacy Guild of Australia.

Acknowledgements

We wish to acknowledge the financial support for this project through the Australian Government Department of Health and Ageing via the Third Community Pharmacy Agreement Research and Development Grants Program, administered by the Pharmacy Guild of Australia.

We wish to acknowledge the contributions made by Dr Grenville Rose and Dr Julija Filipovska, who have worked as research assistants, and Ms Natasa Gisev, a vacation scholar, at The University of Sydney. We would also like to acknowledge the contribution made by Dr Rebekah Moles, Associate Lecturer at the University of Sydney.

We are thankful to Associate Professor Alan Rosen, Director Clinical Services, Royal North Shore Hospital and Community Mental Health Services, and Professor Ian Hickie, Executive Director, Brain and Mind Research Institute, The University of Sydney, who have provided valuable input into the study, have helped liaise with community mental health teams and have been supportive of the project since its inception. The authors thank Ms Sue Sacker, General Manager, and Ms Melina Tsembis, Education Coordinator, Schizophrenia Fellowship of New South Wales for their assistance to develop and implement the education programme. The authors also thank Mr Paul Clenaghan, Eastern Sector Manager, Sydney South West Mental Health Services, for his support and advice.

The authors acknowledge the generosity of Thomson Scientific Pty Ltd for donating five applications of MICROMEDEX ® medicines information software for use by the study pharmacists.

Finally, we are grateful to the study pharmacists, case managers, psychiatrists and clients with mental illnesses who have participated in the study.



EXECUTIVE SUMMARY

Executive Summary

Introduction

The World Health Organization has estimated that mental illness accounts for 12% of global disease burden, with one in four people directly affected at some point in their lives.^[1] More than 450 million people are believed to suffer a mental or neurological disorder at any one time.^[1]

Affective disorders such as depression, anxiety disorders and sleep disturbance are commonly managed in primary care through general practice in Australia. Psychotic disorders, such as schizophrenia, are more commonly managed under specialised community mental health services. As this study was conducted within the context of community-based services, the emphasis of this section will be on the conditions managed under such services.

Schizophrenia is a group of psychiatric disorders characterised by disturbance in thought, emotion and behaviour.^[2] A recent systematic review put the point prevalence of schizophrenia at 4.6 per 1000 people, with a lifetime morbid risk of developing the disease at 7.2 per 1000.^[3] Although schizophrenia has a much lower prevalence in the community when compared to depression or anxiety, people with the condition utilise 40% of all mental health care services.^[2]

People living with schizophrenia in Australia who experience frequent relapses and ongoing symptoms are primarily managed by community mental health teams.^[4] These teams comprise psychiatrists, mental health nurses, social workers and case managers who perform the role of care coordinators and operate from community mental health centres. Sixty percent of Australians with psychotic disorders attend a community mental health centre and 56% have a case manager.^[4] Although there are variations in the type of case management services provided by different teams, there is growing consensus that case management achieves important outcomes for clients.^[4] Models of multidisciplinary teamwork among members of community mental health teams are well established.^[5-8]

Medications are the primary treatment modality for people with schizophrenia.^[9] Community-based pharmacy services are well suited to optimising the use of medicines for mental illness.^[10, 11] Despite the potential value of pharmaceutical

services for people with psychotic illnesses, most clinical case conferences at community mental health centres in Australia do not involve a pharmacist. A 1996 review of community mental health centres in New South Wales found that just one in five community mental health teams had a designated pharmacist.^[12]

The aim of this study was to develop, implement and evaluate a model for pharmacists' participation in community mental health teams for the purposes of treatment planning in community mental health centres. The primary clinical evaluation measures used were the Kessler Psychological Distress Scale (K10), Health of the Nation Outcomes Scale (HoNOS) and medication numbers and costs.

Objectives of the Study

The specific objectives of this study were to:

1. Consult with all relevant stakeholders in defining and developing a role for the community pharmacist as a member of the multidisciplinary mental health care team;
2. Develop a training package for community pharmacists' participation in case conferences for the purposes of treatment planning in mental health centres;
3. Undertake a process evaluation of the role of community pharmacists in a community mental health setting;
4. Undertake a content analysis of the contribution of community pharmacists to multidisciplinary treatment planning in case conferences;
5. Undertake an impact evaluation of the role of community pharmacists in a community mental health setting using standardised and validated measures;
6. Undertake an economic evaluation of the role of community pharmacists in a community mental health setting.

Null Hypotheses

1. There are no statistically significant differences in the K10 or HoNOS scores, between the groups, before and after the intervention.
2. There are no statistically significant differences in the number of changes in the use of medications by clients between groups, before and after the intervention.

Study Design

A quasi-experimental cluster comparative design was utilised. It was anticipated at the start of the study that ten community mental health teams would be recruited, with five allocated to receive standard pharmacy services plus additional input from a study pharmacist (intervention arm) and five to receive standard pharmacy services (comparison group). Nine community mental health teams were subsequently recruited, with five allocated to the intervention group, and four allocated to the comparison group. One community mental health team recruited to the comparison arm provided services through several community mental health centres.

Intervention Group

The study intervention predominantly involved the participation of trained pharmacists in clinical case conferences, with psychiatrists, case managers and other mental health care professionals, on a regular basis, over the intervention period, following a three week orientation. The community mental health teams also received standard pharmacy service over the study period, that is, the distribution and supply of medications by community and/or hospital pharmacists.

Pharmacists' participation in the case conference meetings provided them with an opportunity to contribute to the medication treatment planning for recruited clients. Pharmacists were also able to assist the case managers in practical aspects of medication administration and adherence and provide medication information for case managers and psychiatrists. Additionally pharmacists provided medication review services to consenting clients in the centres. Although the training programme for pharmacists focused on mental disorders, their contribution was not restricted to the management of these conditions, and importantly included physical comorbidities such as cardiovascular disease and diabetes.

Comparison Group

Those community mental health teams allocated to the comparison group received standard pharmacy services over the duration of the study, that is, the distribution and supply of medications by community and/or hospital pharmacists.

Baseline and post-test measures were recorded in both groups, in order to make comparisons between the groups and over time.

Results

Key stakeholders were consulted in the development, implementation and evaluation of a model for pharmacists' participation in community mental health teams. A training programme for pharmacists using consumer educators was conducted.

There were 115 clients recruited to participate in the study, 63 clients in the intervention group and 52 clients in the comparison group. Fifty-six percent of clients were female ($n=64$) and the mean age was 47.7 ($SD=15.8$; range 18-83). Of the 63 clients recruited in the intervention group, 55 received a medication review conducted by one of the five study pharmacists.

The mental health of the clients, as measured by the HoNOS, deteriorated more significantly over the course of the study in the comparison group than in the intervention group ($F_{(1,54)}=5.612$, $p=0.021$). There were no statistically significant differences in the mental health of clients between study groups, or before and after the intervention, when measured using the K10.

The number of medications used by clients in the intervention and comparison groups did not change differentially over the course of the study. However, when the baseline and follow-up numbers of medications taken by clients in the intervention group were compared, the mean number of medications increased significantly over the course of the study from 6.5 to 7.1 ($F_{1,58}=4.429$, $p=0.04$). There was no corresponding increase in the number of medication doses or medication costs per day, either between groups, or before and after the study.

In the 55 medication reviews, pharmacists reported 183 findings and made 182 recommendations for clients in the intervention group. The most frequent findings related to suspected side effects (n=21), lack of clear indications for medication use (n=21) and lack of biochemical or pathology tests (n=19). The most common recommendations were to provide further information about medications (n=25), the need to clarify the dose or medication regimen (n=21), to switch medications (n=19) and to conduct haematology pathology testing (n=19). Findings and recommendations related to medications used to treat both mental and physical illnesses.

The estimated cost of including a trained pharmacist as a member of the community mental health team, for one day per week, was approximately \$617 to \$1415 per month.

The intervention was associated with a high level of satisfaction among psychiatrists, case managers, clients and pharmacists. The role of pharmacists included provision of medication information, medication review, participation in case conferences, providing information talks and completing client's medication records. These services were provided either to the clients directly or to the health professionals at the centres. The specific contributions made by pharmacists could be classified as mental health related, non-mental health related or technical (eg Pharmaceutical Benefits Scheme).

Discussion

This study was the first controlled study in Australia, and one of few conducted internationally, to assess a role for pharmacists as members of community mental health teams. People with mental illnesses frequently report their dissatisfaction with the quality and quantity of information provided about their medications. Given the high potential for medication related problems among people with mental illnesses, the services provided by pharmacists in this study fulfilled an important public health need.

There was a differential effect on clinical outcomes for clients in the intervention and comparison groups when measured using the Health of the Nation Outcomes Scale.

This is at odds with previous studies of pharmacists' interventions, primarily conducted for people with depression, that have generally failed to demonstrate an impact on clinical outcomes.^[13-18]

The mean number of medications taken by clients in the intervention group increased over the course of the study. This may reflect, in part, a greater recognition of the need to manage comorbid physical illnesses. Physical comorbidities account for 60% of premature deaths in people with schizophrenia.^[19] In the 1997 Australian National Survey of Mental Health and Wellbeing, 43% of people with mental illnesses reported also suffering one or more physical illnesses.^[2]

The quantitative results in the study, however, should be interpreted cautiously. The collection rate of the K10 and HoNOS at two time points across the study was relatively low, and case managers may have selectively recruited clients in the intervention group who they believed were most likely to benefit from the pharmacists' service.

Nevertheless, the pharmacists involved in this study successfully integrated into mental health care teams in the community setting and were able to make centre and client specific contributions. The study has shown that there are a number of defined services that the pharmacists can provide in this setting, including case conferencing with other team members, provision of information (to team members and clients both individually and collectively) and medication management review.

Conclusion

This study has demonstrated that pharmacists can be successfully integrated into community mental health teams and contribute to the overall management of clients. Pharmacists' contributions to the community mental health teams were well received by psychiatrists, case managers and clients alike. Pharmacists' primary roles were to provide medication information and to review clients' medication regimens. Case managers and psychiatrists found the pharmacists' participation particularly valuable in respect of reviewing the use of medications for physical co-morbidities, and drug-drug interactions of these medications with those prescribed for mental illnesses. The overall number of medications dispensed per client, but not the number of doses or the daily cost of medications to the Pharmaceutical Benefits Scheme,

increased in the intervention group. Mental health, as measured by the Health of the Nation Outcomes Scales, deteriorated in both study groups, but to a greater extent in the comparison group. Further studies of a longer duration, larger sample size and more user friendly evaluation measures are required before more definitive conclusions about the values of these services can be made.

Recommendations

1. It is recommended that further feasibility studies be conducted to explore and further define a role for pharmacists within specific community mental health teams. This may be an important precursor to the dissemination of the model prior to wider adoption by the mental health community and pharmacy profession.
2. Given the complexity of the mental health system, and the multiplicity of mental health care providers, future studies should be of longer duration, larger sample size and utilise more user-friendly evaluation measures.
3. In response to the overwhelmingly positive feedback from clients and consumer organisations, especially those involved in the education programme, additional steps should be taken to develop and consolidate links between the pharmacy profession and mental health consumer groups.
4. It is recommended that the role of consumer educators as providers of mental health pharmacy education be researched further, with a view to possible wider uptake of this model in continuing and undergraduate professional education.
5. It is recommended that community pharmacists make themselves more familiar with the structure and functions of community mental health teams that operate in their locality. Similarly, case managers and psychiatrists should be encouraged to introduce themselves to community pharmacists practicing in their area, perhaps with a view to that pharmacy or pharmacist becoming a source of information about medications for their clients.
6. It is recommended that case managers and psychiatrists encourage their clients to use one general practitioner and one community pharmacy where possible.
7. When making changes to clients' medication regimens, general practitioners, psychiatrists and case managers should be encouraged to inform the community pharmacy, and general practitioner (in cases when changes are made by the psychiatrist or case manager) or community mental health team (in cases when are changes made by general practitioners). This may help avoid the many

discrepancies that were present between community mental health centre records and community pharmacy dispensing histories.

8. When conducting medication management reviews, pharmacists should use both the community mental health centre medication records and the community pharmacy dispensing histories as a basis for their findings and recommendations.
9. To meet the unmet need for information about medications it is recommended that community pharmacists be more proactive in offering Consumer Medicines Information to people with mental illnesses.
10. For the purposes of conducting reliable and routine checks for drug-drug interactions and medication appropriateness, it is recommended that community and hospital pharmacies have complete records of the medications taken by their clients. This particularly applies to the dispensing of clozapine. Community pharmacists were often unaware that clozapine was being taken by their regular clients. Conversely, hospital pharmacists may not be aware what other medications are being taken by the clients for whom they regularly dispense clozapine. In the longer term, community mental health teams should investigate having all medications, including clozapine, dispensed through one source. If through community pharmacies, then clients would be able to have their medications dispensed under the Pharmaceutical Benefits Scheme (PBS).
11. It is recommended that more formal links between hospital and community pharmacies be established. Community pharmacists were generally unaware that community mental health centres were being visited by a hospital pharmacist.



TABLE OF CONTENTS

Table of Contents

Acknowledgements	3
Executive Summary	4
1. Introduction	16
1.1 Aims and objectives	20
2. Literature review: Community Pharmacy Services	21
2.1 Introduction.....	22
2.2 Literature search strategy.....	23
2.3 Inclusion criteria and review procedure	24
2.4 Results	24
2.5 Discussion	30
2.6 Conclusion.....	32
3. Overview of Methods	34
3.1 Ethics Approval	35
3.2 Study Design	35
3.3 Recruitment of Study Pharmacists	37
3.4 Development and Delivery of Training Package for Pharmacists.....	37
3.5 Recruitment of Community Mental Health Teams	38
3.6 Recruitment of Clients	38
3.7 Intervention Sites.....	38
3.8 Comparison sites.....	39
3.9 Evaluation Measures	40
3.9.1 Quantitative Evaluation Measures	40
3.9.2 Qualitative Evaluation Measures	43
3.10 Sample Size and Statistical Power	45
3.11 Data Analyses	45
3.12 Null-hypotheses.....	45
3.13 Study Limitations.....	45
4. Stakeholder consultation.....	48
4.1 Engagement with Key Stakeholders	49
4.2 Steering Committee	49
4.3 Other external consultation.....	50
5. Development of a training package for community pharmacists.....	51
5.1 Improving community care for people with mental illnesses.....	52
5.2 Community pharmacy services for people with mental illnesses.....	52
5.3 Stakeholders in mental health education.....	53
5.4 Consumer educators in mental health care	54
5.5 Design	54
5.6 Assessment and Results	55
5.7 Discussion	57
5.8 Conclusion.....	58
6. RESULTS	60
6.1 Overview of Results	62

6.2 Clinical Evaluation Measures	62
6.2.1 Health of the Nation Outcomes Scales	62
6.2.2 Kessler-10	65
6.3 Medication Numbers and Costs	66
6.4 Pharmacists' Medication Review Findings and Recommendations.....	70
6.5 Economic Evaluation	72
6.6 Qualitative Results	74
6.6.1 Role of Pharmacist in Community Mental health Teams	74
6.6.2 Contribution made by the pharmacist to team	83
6.6.3 Perceived benefits of providing the intervention	86
6.6.4 Shortfalls in the intervention.....	90
6.6.5 Potential modifications to the intervention for future research	92
6.6.6 Personal outcomes for health professionals	98
7. Discussion.....	99
7.1 Quantitative Evaluation.....	100
7.1.1 Clinical Outcome Assessment	100
7.1.2 Medication numbers and costs	101
7.1.3 Types of Pharmacists' Findings and Recommendations	104
7.2 Content and Process Evaluation of Pharmacists' Contributions.....	105
7.3 General discussion	108
7.3.1 Triangulation of data	108
7.3.2 Non-biased information.....	109
7.3.3 Establishing relationships between pharmacists and centres	109
7.3.4 Future of the service	110
7.4 Limitations	111
7.5 Summary	112
Conclusion	113
Recommendations	114
References.....	116
Appendix 1: Human Ethics Committee Approvals.....	128
Appendix 2: Steering Committee	132
Appendix 3: Letters of Support.....	138
Appendix 4: Evaluation Measures (K10 and HONOS).....	141
Appendix 5: Consent Forms and Subject Information Sheets.....	149
Appendix 6: Qualitative Semi-structured Interview Guides	167
Appendix 7: Peer-reviewed Scientific Publications	171
Appendix 8: Pharmacist Diaries	188



1. INTRODUCTION

1. Introduction

The World Health Organization (WHO) has estimated that mental illness accounts for 12% of global disease burden, with one in four people directly affected at some point in their lives.^[1] More than 450 million people are believed to suffer a mental or neurological disorder at any one time.^[1] Comorbid psychoactive substance abuse is common among people with mental illnesses and contributes an additional 8.9% to global disease burden.^[20] In Australia, mental illness is a national disease priority area,^[21] accounting for 27% of all years lived with disability, and 60% of all health-related disability costs in 15 to 34 year olds.^[22]

Mental health is a broad term used to describe the capacity of individuals and groups to interact with one another and the environment in a positive way resulting in subjective wellbeing, optimal development and use of cognitive, affective and relational abilities. This includes an individual's capacity to cope with daily activities and social interactions without excessive emotional or behavioural incapacity. The major types of mental illnesses include schizophrenia, depression, anxiety disorders, dementia and substance use disorders.^[2]

The most prevalent mental disorders in Australia include anxiety disorders (9.7%), affective disorders (eg depression) (5.8%) and substance use disorders (7.7%). Correspondingly these disorders account for a significant proportion of people for whom treatment is provided from all mental health services in Australia.^[2] In contrast, the prevalence of psychotic disorders such as schizophrenia is much lower. A recent systematic review put the point prevalence of schizophrenia at 4.6 per 1000, with a lifetime morbid risk of developing the disease at 7.2 per 1000.^[3] Although schizophrenia has a much lower prevalence in the community when compared to depression or anxiety, people with the disease utilise 40% of all mental health care services.^[2] The annual direct cost of all non-drug psychoses in Australia is estimated at more than \$572 million.^[2]

The shift from long term institutional to community-based rehabilitation has been one of the most significant advances in mental health care.^[23] Rehabilitation in the community is more cost-effective, respectful of human rights, and associated with less stigma and discrimination than hospital based treatment.^[23] From 1991 to 1996 the number of persons employed in psychiatric hospitals in Australia was reduced by 40%.^[2] This reduction was partially offset by a six percent increase in the

number of medical and 21% increase in the number of allied mental health staff employed in community based settings.^[2] Benefits of discharging consumers to the community after closure of a long stay psychiatric hospital in Sydney included improved psychotic symptoms and increased satisfaction with treatment.^[24]

Affective disorders such as depression, anxiety disorders and sleep disturbance are the most commonly managed mental disorders seen in primary care through general practice in Australia. In contrast, psychotic disorders such as schizophrenia are more commonly managed under specialised community mental health services. As this study was conducted within the context of community-based mental health services, the emphasis of this section will be on the conditions managed under such services.

People living with schizophrenia in Australia who experience frequent relapses and ongoing symptoms are primarily managed by community mental health teams (CMHTs).^[4] These teams comprise psychiatrists, mental health nurses, social workers and case managers.^[5-8] Case managers (often with a nursing, social work or occupational therapy background) perform the role of care coordinators. Case managers facilitate clients' access to medical and social care services. These CMHTs operate from community mental health centres. Sixty percent of Australians with psychotic disorders attend a community mental health centre and 56% have a case manager.^[4] Although there are variations in the type of case management services provided by different CMHTs, there is growing consensus that case management achieves outcomes among clients that are important for reintegrating people into the community.^[4]

Providing community-based care, however, is not without challenges. Social isolation and a lack of purpose are commonly reported among those receiving treatment for psychotic illnesses in the community. Eighty-four percent are single, separated, divorced or widowed; 85% are reliant on welfare benefits and 72% are unemployed.^[4, 25] Of those in employment, many have difficulties performing their daily duties. Issues associated with the quality and accessibility of community-based services were addressed in the 2002 report *Mental Health Services in New South Wales*.^[26] Despite general practitioners in Australia conducting more than 10.4 million mental health related consultations in 2003-04,^[27] less than 40% of people with mental disorders received health care specific to their condition, compared with 80% for those suffering common physical illnesses.^[22] Additionally,

up to 30-40% of people with schizophrenia are managed by their general practitioner alone.^[28] Many of these people have dropped out of contact with specialist services, or have been discharged from specialist to primary care.^[28] In some states and territories in Australia, clients who are involuntary admitted to an acute care facility may be discharged on a community treatment order (CTO).^[4] These orders require clients to receive compulsory community based treatment or return to hospital.

Medications are the primary treatment modality for people with schizophrenia.^[9] The WHO has recognised, however, that psychotropic medicines prescribed for mental illnesses are commonly taken inappropriately.^[29] When classified using Beers Criteria, more than 27% of psychotropic prescribing for community dwelling elderly people may be inappropriate.^[30] People taking medicines for mental illnesses may receive no or limited information about their treatments.^[31-33] People have also expressed their dissatisfaction with the quantity and quality of information provided by their health professionals.^[34] Antipsychotic, antidepressant and mood stabilising medicines have a high potential to cause drug related problems,^[35-39] and are associated with adverse effects, including cardiac toxicity, confusion and unwanted sedation.^[40] Medical comorbidity is also common among people with psychotic disorders, and polypharmacy increases the risk of drug-drug interactions.^[19] Poor communication with and between health professionals is a leading cause of harm among people receiving medication treatment.^[41] Promoting greater access to Consumer Medicines Information (CMI) has been described as a key strategy to prevent drug related problems.^[42]

Community-based pharmaceutical services are well suited to optimising the use of medicines for mental illness.^[10, 11] A survey of pharmacists' interventions at 12 mental health trusts in the United Kingdom reported the detection of 579 cases of sub-optimal prescribing, 60% of which were clinical in nature.^[43] A cohort study of a pharmacist's activities at a community mental health centre in the United States found that participation in weekly team meetings was associated with a decline in the number and cost of prescription medications dispensed.^[44] Despite the potential value of pharmaceutical services for people with psychotic illness, most clinical case conferences at community mental health centres in Australia do not include a pharmacist. A 1996 review of community mental health centres in New South Wales found that just one in five CMHTs had a designated pharmacist.^[12]

1.1 Aims and objectives

The aim of this study was to develop, implement and evaluate a model for pharmacists' participation in community-based multidisciplinary case conferences for the purpose of treatment planning in mental health centres.

The specific objectives of this study were to:

1. Consult with all relevant stakeholders in defining and developing a role for the community pharmacist as a member of the multidisciplinary mental health care team;
2. Develop a training package for community pharmacists' participation in case conferences for the purposes of treatment planning in mental health centres;
3. Undertake a process evaluation of the role of community pharmacists in a community mental health setting;
4. Undertake a content analysis of the contribution of community pharmacists to multidisciplinary treatment planning in case conferences;
5. Undertake an impact evaluation of the role of community pharmacists in a community mental health setting using standardised and validated measures;
6. Undertake an economic evaluation of the role of community pharmacists in a community mental health setting.



2. LITERATURE REVIEW

2. Literature review: Community Pharmacy Services to Optimise the Use of Medications for Mental Illnesses

Please note that this chapter has been published in Australia and New Zealand Health Policy 2005;2:e29. Further reproduction and publication is subject to approval by the authors. The full text version of the journal article is available online at www.anzhealthpolicy.com and is included as Appendix 7.

2.1 Introduction

Mental and behavioural disorders are estimated to account for 12% of the global burden of disease.^[1] More than 450 million people worldwide suffer from a diagnosable mental illness, and four of the six leading causes of years lived with disability are due to neuropsychiatric disorders.^[1] Much of the burden of mental illness is managed in the community setting. In 2003-04 mental health related medications accounted for 10.9% (17.8 million) of all medications prescribed by general medical practitioners in Australia.^[27] Although community care offers many advantages over institutional care, community care can place extra demands on family, friends and primary health practitioners.^[28] Health professionals have identified people with mental illness as among their most challenging patients to manage.^[45] Improving the quality and accessibility of community care for people with mental illnesses is an aim outlined in the parliamentary report *Mental Health Services in New South Wales*.^[26]

The appropriate use of medications is central to the effective management of mental illnesses, however, there is evidence that psychotropic medications are often used inappropriately.^[29, 46] Elderly people are especially sensitive to the effects of psychotropic medications, and may be susceptible to adverse reactions including cardiac toxicity, confusion and unwanted sedation.^[47] Psychosocial problems, the emergence of side effects, and the delayed onset of action of anti-depressant medications, may be contributing factors in high rates of medication non-adherence.^[48, 49] Medical co-morbidity is also common, and polypharmacy increases the risk of drug-drug interactions and medication misadventure.^[19]

The World Health Organization (WHO) has recognised including pharmacists as active members of the health care team as one approach to improving psychotropic medication use.^[29] The National Strategy for the Quality Use of Medicines in Australia highlights the importance of a multidisciplinary approach to improving medication use.^[50] The development of new roles for pharmacists has expanded the opportunities for pharmacists to provide community-based services to users of psychotropic medications. The Third Community Pharmacy Agreement, signed between the Australian Government and Pharmacy Guild of Australia in 2000, provided remuneration for pharmacists in Australia to conduct medication management reviews in the community setting (referred to as 'Home Medicines Review') and to provide consumer medicine information (CMI).^[51]

Residential medication management reviews, initially funded through the Second Community Pharmacy Agreement in 1995, are available to all permanent residents of accredited aged care facilities in Australia.^[52] A systematic review of the role of pharmacists in mental health care, published in 2003, concluded that pharmacists can bring about improvements in the safe and efficacious use of psychotropic medications.^[11] The review included seven studies conducted for hospital inpatients and nine studies conducted in residential aged care or outpatient settings. Since that time pharmacists and pharmacy practice researchers have developed additional community pharmacy services in speciality areas. This has corresponded with a significant increase in the volume of published research on community-based services provided by pharmacists relating to mental health. The objective of this systematic review was to specifically evaluate the impact of pharmacist delivered *community-based* services to optimise the use of medications for mental illness.

2.2 Literature search strategy

Medline (1966-April 2005), Embase (1994-April 2005), PsychInfo (1985-April 2005), Cinahl (1982-April 2005), International Pharmaceutical Abstracts (1970-April 2005) and the Cochrane Controlled Trials Register (2nd quarter 2005) were searched using text words and MeSH headings including: *pharmacy, pharmacists, pharmaceutical care, pharmaceutical services, mental disorders, mentally ill persons, depression, schizophrenia, psychotic disorders, antidepressive agents, psychotropic drugs, benzodiazepines, anxiety and antipsychotic agents*. Reference lists of retrieved articles were checked for additional studies not identified in the original database search. If the abstract clearly indicated that the study did not relate to

pharmaceutical services provided by pharmacists to optimise the use of medications for mental illness, or if the study was conducted in an acute inpatient or hospital setting, then the study was excluded at this stage.

2.3 Inclusion criteria and review procedure

Studies published in English, with a parallel control group (randomised and non-randomised) that reported the provision of services by pharmacists in community and residential aged care settings were considered. This included trials specifically conducted for individuals with a mental illness, or that reported outcomes in terms of changes to mental health symptoms, and studies of medication reviews and education initiatives to optimise the use of medications commonly prescribed for mental illness. Papers that reported pharmacists' activities as part of multidisciplinary teams were included where a pharmacist or pharmacists provided a service specifically related to optimising the use of medications for mental illness. Studies of pharmacists' interventions in residential aged care facilities were included, because community pharmacists frequently provide services to residential aged care facilities, but studies evaluating pharmacists' services in hospital inpatient or acute care settings were excluded. Studies without control groups, before and after studies, descriptive studies, results of postal surveys and qualitative interviews were excluded, as were studies to optimise medication use that did not involve a service provided by pharmacists. Each study meeting the criteria outlined above was assessed on the basis of study design, service recipient, country of origin, intervention type, number of participating pharmacists, methodological quality and outcome measurement.

2.4 Results

The literature search identified 59 papers that reported or discussed community pharmacy services to optimise the use of medications for mental illness. Twenty-two papers reported the results of studies that met the inclusion criteria for the review. Studies that met the inclusion criteria were approximately equally divided between services provided to consumers (n=10), and services provided to other health care professionals (n=12). All but one included study were conducted in developed countries, and 15 of the 22 papers were published in the last six years. Thirty-seven papers were excluded from the review for the following reasons.

Thirteen papers reported data from descriptive studies ^[43, 53-64] and nine papers reported outcomes of qualitative interviews or focus groups.^[65-73] Five papers reported results of before and after interventions or were cohort studies without parallel control groups.^[44, 74-77] Six papers reported results of postal surveys.^[78-83] Three papers presented study methods only,^[84-86] and one study was conducted by pharmacy researchers but did not report the outcomes of a service provided by pharmacists.^[87]

Papers that met the review inclusion criteria reported the outcomes of medication counselling by community pharmacists at the time of dispensing, education and monitoring activities conducted at primary care medical centres and staff model health maintenance organisations (HMOs), discharge medication counselling, and medication monitoring at a community mental health centre. Pharmacist delivered services provided to other health professionals included medication reviews and outreach education activities designed to optimise prescribing. Several medication review studies reported impacts of pharmacists' interventions in terms of changes in prescribing of medications commonly used to treat mental illness and/or changes in mental health symptoms, but were not specifically targeted to people with a mental illness. Several small studies of pharmacists' medication review activities specifically conducted for people with a mental illness did not meet the review inclusion criteria.^[43, 44, 54, 56, 58, 77]

Services provided in community pharmacies

Three papers reported results of community pharmacists' medication counselling sessions for people commencing non-tricyclic antidepressant therapy in The Netherlands.^[88-90] Intervention patients participated in three counselling sessions (lasting between 10 and 20 minutes each) and received a take-home video that emphasised the importance of medication adherence. The medication counselling sessions involved pharmacists informing patients about the appropriate use of their medication. This included providing information about the benefits of taking the medication, informing patients about potential side-effects, informing patients about the onset of action for antidepressant medications and reinforcing the need for patients to take their medication on a daily basis. At three month follow-up the intervention patients had significantly more positive drug attitudes than controls,^[88] and at six months this corresponded with significantly greater medication adherence among those patients that remained in the study.^[90] An intention to treat analysis, however, showed no significant intervention effect on medication adherence.

Medication adherence was measured using an electronic pill container that recorded the time and frequency that the cover was opened. Analysis of psychological symptoms at the six month follow-up was inconclusive, with apparent improvements in symptom scores not replicated using an alternate method of analysis.^[89] Randomisation occurred at the patient level, and neither pharmacists nor patients were blinded to their group allocation. A limitation of this method was that the same pharmacists provided services to both control and intervention patients. As the intervention studied was multifactorial, it was not clear whether the three face-to-face medication counselling sessions conducted by the pharmacists, or the “take-home” videos, were primarily responsible for changes in drug attitude, adherence and the symptoms scores observed.

Services provided at medical centres and health maintenance organisations

Four studies reported patient education and treatment monitoring services for people prescribed antidepressant medications in the United States.^[13-16] The patient education and treatment monitoring involved the pharmacists taking a medication history, providing information about the prescribed antidepressant medications, and conducting telephone and face-to-face follow-up. Two of the four studies, one controlled^[13] and the other randomised controlled,^[14] were conducted at a staff model health maintenance organisation (HMO). Pharmacists’ interventions in both studies were associated with significant improvements in adherence to antidepressant medications when calculated at the end of the six-month study periods. Medication adherence was calculated by reviewing prescription dispensing data, and reported using an intention-to-treat analysis. Both studies also demonstrated that involvement of the pharmacist was associated with a decrease in the number of visits to other primary care providers, although statistical significance was only achieved in one of the studies.^[13] The other two studies were conducted at primary care medical practices. In one study over 16,000 consecutive patients attending nine practices were screened for depression using a self administered health survey.^[16] Patients identified as having depression or dysthymia who agreed to participate in the study (n=533) were randomised to intervention or control groups. Intervention patients were significantly more likely to be taking antidepressants at the six month follow-up. Additionally, patients who were taking their antidepressants at the six month follow-up had better depression symptom scores than those who had discontinued, but the overall symptom scores between intervention and control groups were not significantly different. In the other randomised controlled study, improvements in antidepressant adherence and

depression symptom scores were similar in both intervention and control groups.^[15] In this study antidepressant adherence was measured by asking patients how many days they took their antidepressant medication in the past month.

Services provided at community mental health centres and outpatients' clinics

Three studies investigated the effect of pharmacist delivered services to community mental health centres and outpatients' clinics.^[91-93] In a controlled trial, patients' case managed by a pharmacist working at a community mental health centre in the United States had significantly better personal adjustment scores than those receiving case management from a nurse, social worker or psychologist.^[91] They were also significantly less likely to need help from other providers and rated themselves as more healthy. As part of the medication monitoring service provided, the pharmacist was allowed to adjust medication doses and dose timing, and prescribe or discontinue medications under supervision. Medication monitoring conducted by the pharmacist was estimated to cost 40% of equivalent medication monitoring conducted by the clinic psychiatrists when calculated on a per time basis. Although the pharmacist performed medication monitoring for more patients per month than the clinic psychiatrists, the pharmacist also spent longer per patient contact. This offset the overall cost savings of having a pharmacist perform the medication monitoring activities usually performed by a psychiatrist.

In a study of patients discharged home from hospital after admission for relapse of schizophrenia in Malaysia, those identified as having poor medication adherence were allocated to receive pharmacist medication counselling or standard care ^[92]. The importance of medication adherence was also reinforced by the patients' psychiatrists at follow-up visits, although it was not clear whether this applied only to intervention patients or both intervention and control patients. At the 12 month follow-up, patients who had been exposed to the intervention, and received a daily or twice daily medication treatment, had significantly fewer relapses that required hospitalisation than patients in the control group.

A study that evaluated the impact of providing mental health patients with a pharmacist generated medication care plan at the time of discharge found that patients with care plans were less likely to be readmitted to hospital than those without, however, this result was not statistically significant.^[93] Information on the medication care plans included lists of discharge medications, a summary of the patient education that was provided, and the need to assess for specific potential

adverse reactions. Community pharmacists who were provided copies of the care plans were also more likely to identify medication related problems for the discharged mental health patients than those pharmacists who were not provided copies of the care plans.

Medication review in domiciliary and residential aged care settings

Components of medication review services provided by pharmacists include comprehensive medication history taking, patient home interviews, medication regimen review, and patient education.^[94] Medication review studies described in the review were conducted for residents of aged care facilities or for those individuals living independently in the community identified to be at high risk of medication misadventure.

In a randomised controlled study of pharmacist conducted domiciliary medication reviews in the United States there were significant declines in the overall numbers and monthly cost of medications, but no significant difference in cognitive or affective functioning between the intervention and control groups.^[17] This may have been due in part to the relatively short (6 week) follow-up period. The authors noted that many patients were unwilling to follow the pharmacist's recommendations to discontinue benzodiazepines and narcotic analgesics. A randomised controlled study of a pharmacist-led multidisciplinary initiative to optimise prescribing in 15 Swedish aged care facilities resulted in a significant decline in the use of antipsychotics, benzodiazepines and antidepressants by 19%, 37% and 59% respectively in the intervention facilities.^[95] The study involved pharmacists participating in multidisciplinary team meetings with nurses, nurses' assistants and physicians at regular intervals throughout the 12-month study period. A follow-up study of the same intervention and control facilities three years later indicated the intervention facilities maintained significantly higher quality of drug use, with lower proportions of residents prescribed more than three drugs that could lead to confusion, non-recommended hypnotics and combinations of interacting drugs.^[96] Neither study reported estimates of cost or clinical outcomes. A cluster randomised controlled study of a multidisciplinary primary care intervention at a HMO in the United States included a quarterly pharmacist medication review to address the potentially inappropriate use of medications commonly prescribed for mental illness. The researchers found the intervention had no impact on depression scores and the numbers of high risk medications prescribed at the 12 week follow-up.^[18]

Two additional cluster randomised controlled studies of pharmacists' medication reviews in residential aged care facilities demonstrated significant reductions in the number and cost of medications prescribed.^[97-99] In one study 10.2% fewer residents were administered psychoactive medications and 21.3% fewer hypnotic medications.^[97] The impact of medication reviews on mortality was measured in both studies, and a significant reduction was noted in one.^[99] Despite the significant reduction in mortality, patients in the intervention facilities experienced a greater deterioration in cognitive function and behavioural disturbance than those in the control facilities.

Educational visiting to general medical practitioners

In the Netherlands, pharmacotherapy meetings to optimise prescribing are undertaken as part of routine clinical practice by groups of local community pharmacists and general medical practitioners. A cluster randomised controlled trial that involved inter-professional (pharmacotherapy) meetings to discuss prescribing of antidepressant medications resulted in a significant reduction in the prescribing of highly anticholinergic antidepressants to elderly people by 40% compared to a control group of practitioners that did not receive the prescribing support.^[100] In comparison, educational visiting (academic detailing), reduced prescribing of highly anticholinergic antidepressants by 30%.

Four additional studies evaluated the impact of pharmacists' educational visits to general medical practitioners to optimise the prescribing of benzodiazepines and other psychotropic medications commonly prescribed for mental illness.^[101-104] The two papers that reported health professional satisfaction indicated that the educational visits were acceptable and well received.^[102, 103] In a controlled trial, two types of pharmacists' educational interventions (a one-on-one presentation to prescribers with individualised feedback and a group presentation to prescribers about the use of benzodiazepines) did not produce significant changes to the prescribing of benzodiazepines at a prepaid group practice in the United States when compared to a control group that did not receive an educational intervention.^[101] An Australian cluster randomised controlled study of a pharmacist's educational visits to general medical practitioners providing services to residential care facilities detected no significant differences in the use of psychotropic medications between intervention and control facilities. The only exception was a significant increase in the use of "as required" antipsychotic medications in the intervention facilities^[102]. This differed from results of an earlier cluster randomised controlled study in the

United States that found that educational visits by a pharmacist were associated with a significant decline in prescribing of potentially inappropriate psychotropic medications in intervention facilities.^[104] Another Australian study of educational visits to general medical practitioners, conducted by three physicians and one pharmacist, reported a significant reduction in the prescribing of benzodiazepines in both intervention and control groups, but the difference between groups was not significant.^[103] The authors accounted for this overall reduction by a corresponding decline in the rate of diagnoses of anxiety and insomnia, and the possible awareness of prescribing related issues generated by asking general medical practitioners to conduct a self-audit of their prescribing.

2.5 Discussion

Given the extent of mental illness in the community and in aged care, and the fact people with mental illness frequently report concerns about their prescribed medications, services directed toward optimising the use of medications for mental illness fulfil an important public health need. As evidenced by the large number of papers excluded from this review, many studies of community pharmacy services to optimise the use of medications for mental illness have been descriptive, lacked parallel control groups or have been qualitative in nature. The controlled studies included in this review provide some evidence of the potential value of including pharmacists in mental health care across a range of settings and patient populations.

Studies included in the review utilised a range of randomisation techniques, however, the review did not attempt to characterise the quality of the randomisation beyond whether randomisation occurred at the patient, practice or residential aged care facility level. The majority of the studies involved less than five pharmacists, and 10 out of the 22 papers described interventions where just one pharmacist was involved. Studies involving small numbers of pharmacists may have good internal consistency, but the results obtained may not be generalisable to outcomes of services provided by the wider pharmacy profession. In several studies the pharmacists' interventions were components of multidisciplinary team approaches to improving mental health care. The challenge of evaluating complex and multi-factorial interventions, which by their nature depend on the context in which the intervention takes place, has been described.^[105]

Five studies assessed the impact of pharmacists' provision of medicines information and treatment monitoring for people commencing antidepressant therapy. Three of the five studies demonstrated that involvement of the pharmacist was associated with a significant improvement in medication adherence and/or medication use rates when measured using an intention to treat analysis. One further study demonstrated significant improvements in medication adherence among patients who received three pharmacist counselling sessions; however, this was not significant when measured using an intention to treat analysis. Given the high rates of antidepressant discontinuation during the first three months of treatment, pharmacists have a potentially important role in providing medicines information and conducting treatment monitoring for those patients at high risk of medication non-adherence. No studies of pharmacists' treatment monitoring for people commencing antidepressant therapy compared monitoring provided by pharmacists to monitoring conducted by other health professionals. A separate study of antidepressant treatment monitoring conducted by nurses also demonstrated improved medication adherence.^[106]

Despite people with psychotic disorders having reported unmet medicines information needs, relatively few controlled studies assessed community pharmacy services for users of antipsychotic medications. Other studies have suggested that service provision by pharmacists may be limited by not having access to patients' medical histories,^[81] a lack of specific training to counsel this patient population,^[81] and pharmacists' attitudes towards people with mental illness.^[83] Further well designed research into community pharmacy services for users of antipsychotic medications is needed before conclusions can be made about the potential of such services to reduce hospital readmission and the cost of health care.

Pharmacist conducted medication management reviews appear a valuable strategy to identify potential medication related problems among people taking medications for a mental illness. The included studies demonstrated that such reviews can reduce the numbers of potentially inappropriate psychotropic medications used for mental illness prescribed to elderly people in residential aged care settings. Only one study made the link between a reduction in psychotropic medication use and improved adherence to national prescribing guidelines.^[96] The value of pharmacist conducted medication reviews for people with mental illness may not be limited to optimising the use of mental health medications. Physical health care for people

with mental illnesses is often less than optimal, and pharmacist conducted medication reviews may be a comprehensive strategy to improve medication use for both mental and physical illnesses. The tendency among health professionals to focus solely on the management of the mental illness among people with both mental and physical illnesses has been described in the literature.^[107]

Educational visiting has been shown to modify prescribing behaviour.^[108] The reviewed studies reported pharmacists' interventions that were well received by prescribers, but produced differing results as to whether such visits were associated with changes in prescribing behaviour. This may have been because efforts to reduce prescribing of potentially inappropriate medications were not accompanied by information about alternate treatments, or because patients were reluctant to discontinue taking benzodiazepine medications. In the Dutch study that did produce a significant impact on prescribing patterns, information about the problems associated with prescribing highly anticholinergic antidepressants was accompanied by information about prescribing more appropriate antidepressant medications.^[100] Additionally, pharmacists' initiatives to improve prescribing may be most effective when both the pharmacists and general medical practitioners have an opportunity to build rapport. The practitioners involved in the Dutch study were those routinely involved in providing care to the patient populations discussed. Data presented on prescribing at these meetings were relevant and specific to the local area in which the meetings took place.

2.6 Conclusion

The review of the international literature highlights the range of pharmaceutical services provided by community pharmacists in Australia that are potentially well suited to assisting patients and prescribers optimise the use of medications for mental illness. These data show that medication counselling and treatment monitoring conducted by pharmacists can improve medication adherence among people commencing antidepressant therapy. Pharmacist conducted medication reviews and resulting recommendations to optimise medication regimens may reduce the numbers of potentially inappropriate medications for mental illness prescribed to elderly people. This review of the available published evidence supports the continued expansion of pharmaceutical service delivery to people with mental illness, but identified the need for further well-designed research in specific

areas. Future studies are needed to assess the cost-effectiveness and clinical implications of pharmacists working as members of multidisciplinary community mental health teams, and as providers of pharmaceutical services to people with psychotic disorders.



3. OVERVIEW OF METHODS

3. Overview of Methods

3.1 Ethics Approval

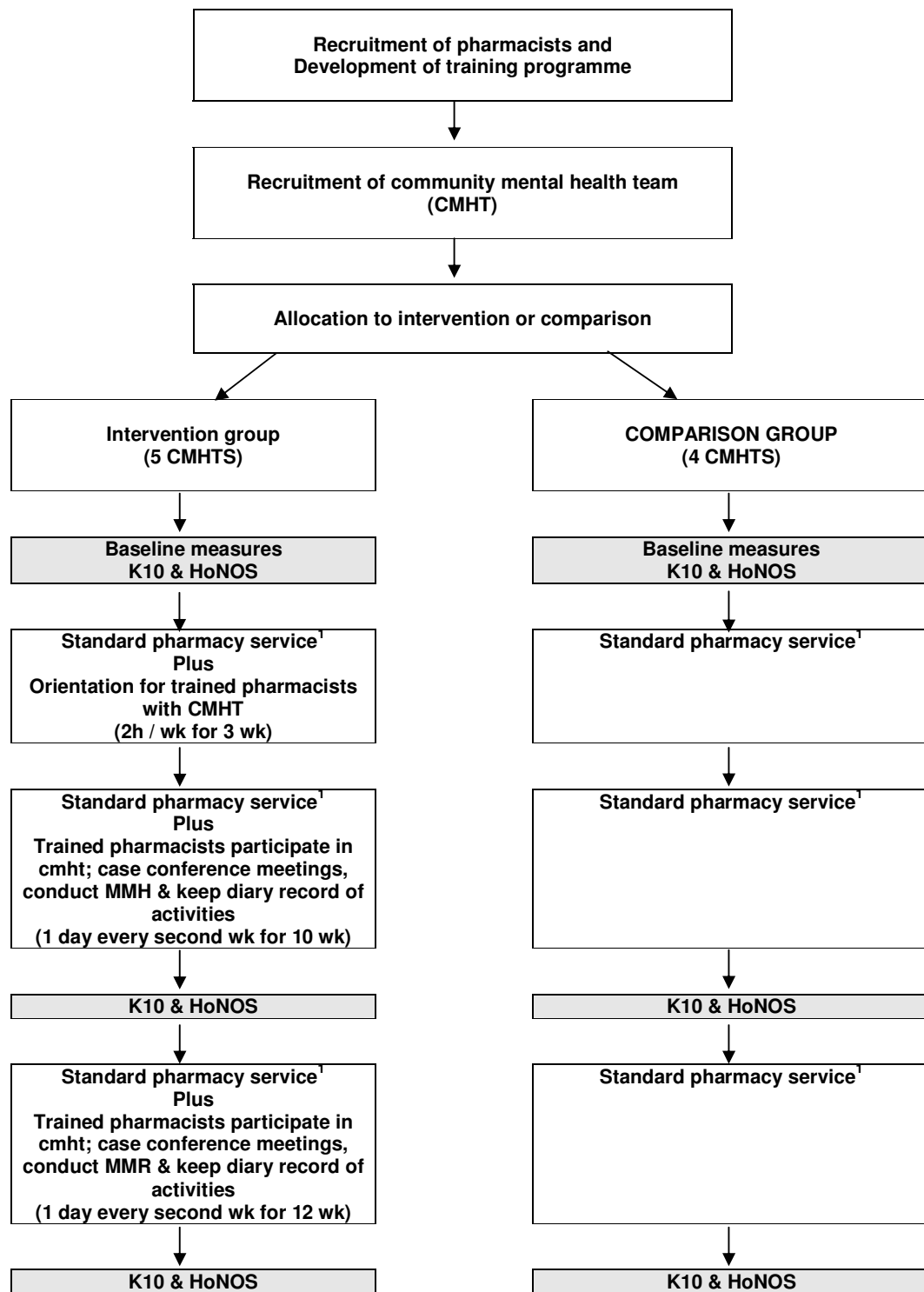
The study was approved by the following Human Ethics Committees (Appendix 1):

- Human Ethics Committee at the University of Sydney
- Northern Sydney Health Scientific Advisory Committee
- Northern Sydney Health Human Research Ethics Committee
- Sydney Clinic Management Committee
- Sydney South West Area Mental Health Advisory Committee
- Sydney South West Area Human Research Ethics Committee.

3.2 Study Design

A quasi-experimental cluster comparative design was utilised (Figure 3.1). It was anticipated at the start of the study that ten CMHTs would be recruited, with five allocated to receive standard pharmacy services plus additional input from a study pharmacist (intervention arm) and five to receive standard pharmacy services (comparison group). Nine CMHTs were subsequently recruited, with five CMHTs allocated to the intervention group, and four CMHTs allocated to the comparison group (Figure 3.1). One CMHT recruited to the comparison arm provided services through several CMHC.

Figure 3.1 Overview of study schema



¹ Standard Pharmacy Service = the distribution and supply of medications by community &/or hospital pharmacists.

MMR = medication management review

3.3 Recruitment of Study Pharmacists

Invitations for pharmacists to apply to participate in the study were circulated by the Pharmaceutical Society of Australia (NSW Branch), the Society of Hospital Pharmacists of Australia (SHPA) and the Pharmacy Guild of Australia (NSW Branch). Applications were screened and short listed applicants were interviewed. Seven pharmacists were subsequently invited to participate in the training programme. Five pharmacists were then contracted to work one day per week for the duration of the 24-week intervention. Pharmacists were paid \$AUD50/hr for interviewing clients, literature searching and preparing case notes, and \$AUD80/hr to participate in clinical case conferences. Four of the five pharmacists had previously worked in hospital pharmacy and one of the pharmacists had specialised in mental health. At the time of conducting the study, four of the five pharmacists worked primarily in community pharmacy. None of the pharmacists were pharmacy owners.

3.4 Development and Delivery of Training Package for Study Pharmacists

Four 2-hour education sessions were conducted for seven pharmacists during March 2005. Seven pharmacists, five consumer educators and one carer participated in the sessions. The sessions included both short didactic lectures and interactive discussion led by specialist pharmacists, a psychologist, a mental health nurse and a psychiatrist. In the first and fourth sessions special emphasis was placed on community pharmacists and consumer educators being able to share their experiences related to the topics presented. The consumer educators were receiving ongoing treatment for illnesses including schizophrenia, bipolar disorder, and major depression. All sessions included an opportunity for debriefing and follow-up discussion. Several of the specialist mental health pharmacists were recruited to act as mentors for the study pharmacists throughout the course of the study. Folders of evidence based mental health resource materials were prepared and provided to all study pharmacists. A detailed overview of the training package is presented in Section 5.

An email discussion group was set up to allow the study pharmacists to share their experiences with each other, and to facilitate mentoring by the specialist mental health pharmacists (There were 107 messages sent through this email discussion group over the 24 week study period). In addition, peer support meetings for the

study pharmacists were conducted. These meetings allowed for an exchange of ideas and knowledge. Study pharmacists were provided with PDAs with medication information software to support their professional activities in the community mental health centres.

3.5 Recruitment of Community Mental Health Teams

With the support of the respective Area Mental Health Services, CMHTs in the Northern Sydney Central Coast and Sydney South West Area Health Services were approached and invited to participate. Community pharmacies that supplied medicines to those CMHTs interested in participating were informed in writing about the study and invited to contribute to the planning and delivery of the intervention. CMHTs recruited to participate in the study were allocated to either the intervention or comparison group. The allocation of CMHTs to intervention or comparison groups was not random. Given the substantial time required to obtain Ethics Approval from the six human ethics and review committees, and the necessity to keep the five study pharmacists engaged with the study, the first five CMHTs recruited were allocated to the intervention group. Due to the order in which ethics approval was obtained, the five intervention CMHTs were based in the Northern Sydney and Central Coast Area Mental Health Services.

3.6 Recruitment of Clients

Case managers from each CMHT were asked to recruit clients who were receiving case management and who were taking at least one medicine for a mental illness. Other inclusion criteria were that clients were aged 18 years or older and were able to read and understand English sufficiently to provide informed consent to participate. Clients with co-morbid substance misuse or personality disorders were not excluded.

3.7 Intervention Sites

The study intervention predominantly involved the participation of trained pharmacists in clinical case conference meetings, with psychiatrists, case managers and other mental health care professionals, on a regular basis, over the intervention period, following a three week orientation (Figure 3.1).

The CMHTs also received standard pharmacy service over the study period, that is, the distribution and supply of medications by community and/or hospital pharmacists.

The pharmacists attended the mental health centre for an orientation period of two hours per week for the first three weeks. This helped facilitate the pharmacists to build rapport with the staff of the CMHT.

Pharmacists' participation in the case conference meetings provided them with an opportunity to contribute to the medication treatment planning for recruited clients. For example, the pharmacist was able to comment and advise on the quality use of medications (prescribed, non-prescription and complementary and alternative medicines) for both mental disorders and other physical comorbidities. They were also able to assist the case managers in practical aspects of medication administration and adherence and provide medication information for case managers and psychiatrists. Additionally pharmacists provided medication review services to consenting clients in the centres. Although the training programme for pharmacists focused on mental illnesses, their contribution was not restricted to the management of these conditions, and importantly included physical comorbidities such as cardiovascular disease and diabetes.

On one occasion the client's general practitioner (GP) participated in a case conference meeting. This was compatible with the MBS item number for case conferencing under the Enhanced Primary Care scheme as well as the Better Outcomes in Mental Health initiative. Articulation with external funding schemes will help to provide a financial incentive for GP participants on an on-going basis.

3.8 Comparison sites

Those CMHTs allocated to the comparison group received standard pharmacy services over the duration of the study, that is, the distribution and supply of medications by community and/or hospital pharmacists.

Baseline and post-test measures were recorded, in order to make comparisons between the groups and over time.

3.9 Evaluation Measures

A broad range of evaluation measures were used to evaluate the impact of the intervention from clinical, humanistic and economic (cost) perspectives. A combination of process and impact indicators was used. The following section is divided into quantitative evaluation measures and qualitative evaluation measures.

3.9.1 Quantitative Evaluation Measures

Clinical Measures

The importance of measuring client outcomes is outlined in Australia's National Mental Health Policy.^[109] Client outcome is defined as the effect on a patient's health status attributable to an intervention by a health professional or health service.^[109] Measuring outcomes in clients with depression and anxiety has been described as an essential component of clinical practice.^[110] The routine collection of standardised outcome assessment instruments in Australia is referred to as the National Outcomes and Casemix Collection, or NOCC.^[111] Collection of the Kessler Scale of Psychological Distress (K10) and Health of the Nation Outcomes Scales (HoNOS) is mandated under the Mental Health Outcomes and Assessment Study (MH-OAT) in New South Wales (NSW), therefore these measures formed the basis of the clinical evaluation.^[112]

Health of the Nation Outcomes Scales

The HoNOS is a clinician completed instrument to rate mental health and social and behavioural functioning (Appendix 4).^[113] The instrument consists of 12 items and four sub-scales (behaviour, impairment, symptoms and social) with each item rated on a 5 point scale, where 0=no problem and 4=severe to very severe problem.^[114] The rating period is the previous two weeks.

Kessler-10

The K10 is a ten item instrument to assess clients' level of psychological distress (Appendix 4). Respondents are asked to self-report their level of distress over the previous four weeks. Responses are scored on a 5-point Likert scale, where 1= none of the time, through to 5= all of the time.^[115] Possible scores range from 10 to 50, with scores 16-30 indicative of a one in four chance of having a current anxiety or depressive disorder and 1% chance of having made a suicide attempt.^[116]

People with scores of 30-50 are indicative of a three out of four chance of experiencing a current anxiety or depressive disorder and 6% chance of ever having made a suicide attempt.^[116]

Collection of the Kessler-10 and HoNOS measures

Case managers were asked to complete collection of the K10 and HoNOS at the time of or as soon as possible after, clients were recruited to participate in the research study (Figure 1). Thereafter, case managers were asked to complete collection of the K10 and HoNOS at thirteen weekly intervals. This was consistent with mandatory outcome assessment reporting required under the MO-OAT and NOCC.^{[111] [112]}

Economic measures

A cost analysis of the medications used by clients was undertaken. The cost was calculated in terms of daily cost to the Pharmaceutical Benefits Scheme (PBS)¹, for each client, in both the intervention and comparison groups, at baseline and follow-up. Baseline medications were considered to be those dispensed in the two months preceding the intervention. Follow-up medications were considered to be those dispensed in the final two months of the intervention period.

The following assumptions were made when calculating the total daily cost of pharmaceuticals for each client.

- (i) All medications dispensed as “when required” were costed as if they were used at the maximum recommended daily dose multiplied by 0.5.
- (ii) Medications prescribed or administered for periods of shorter than one month were costed by dividing the total unit cost by the number of days in that month.
- (iii) The daily cost of all PBS subsidised creams, metered dose inhalers, eye drops etc were calculated by assuming that one dispensing equalled one months supply. Unless otherwise indicated, it was assumed that all creams were applied daily, and therefore, constituted one dose.
- (iv) The total unit cost of injectables, including depot antipsychotic medications (usually administered fortnightly or monthly), was divided over all the total

¹ The PBS is the mechanism via which the Australian Government subsidises the cost of more than 80% prescriptions dispensed outside the State Government funded public hospital system.(www.health.gov.au)

number of days in that month. Injectables were not included when calculating the total number of medication doses.

Note that clozapine, despite being listed on the PBS, was primarily dispensed through hospital pharmacy outpatients' clinics. The cost of clozapine, therefore, was primarily incurred by the NSW State Government. For the purposes of comparison, in several cases where clozapine was dispensed through community pharmacies (and subsequently subsidised via the PBS), the cost was not included in the analysis.

The estimated monthly cost of delivering the service by study pharmacists was also computed (cost analysis). The costs included direct costs (eg pharmacist remuneration) and indirect costs (eg training programme, drug information resources). It was not possible to consider social costs or intangibles such as suicide, depression, violence, and suffering as originally planned.

Other Quantitative Evaluation Measures

Classification of medications

The Anatomical Therapeutic Chemical (ATC) Classification System was used to categorise medications taken at baseline and follow-up.^[117] This is the system recommended by the World Health Organization (WHO). All medications were classified according to one of 14 organs or systems on which they act (1st level). Nervous system medications were sub-categorised according to their pharmacological/therapeutic properties (2nd level). The medications taken by clients at baseline at follow-up, in both the intervention and comparison groups, were tabulated. Descriptive statistics were used to compare categories of medications at baseline and follow-up.

The total number of medications taken by each client at baseline and follow-up, in both the intervention and comparison group, was calculated by reviewing community pharmacy dispensing records. Where a study pharmacist identified clients to be taking non-prescription medications not documented on either the community pharmacy dispensing record or on medications' charts held at the community mental health centres, these medications were not included when calculating the number of medications taken by each client.

The total number of doses taken per day by each client, in both the intervention and comparison group, was calculated at baseline and follow-up.

Categorisation of Medication Review Findings and Recommendations

The number and type of medication review findings and recommendations were classified using the Clinical Pharmacy Activity Classification System (CPACS).^[118] The CPACS was specifically developed to classify medication review findings and recommendations, and facilitates classification of drug, patient and prescriber related issues. The CPACS can be used to classify both actual and potential drug related problems. Preliminary analysis has suggested the CPACS codes for findings and recommendations have good inter-rater reliability, with kappa values of 0.73 and 0.82 respectively.^[118] The overall frequency of each finding and recommendation was tabulated.

3.9.2 Qualitative Evaluation Measures

A variety of qualitative methods was used to undertake the process evaluation of the role of community pharmacists in a community mental health care setting (Study Objective 3) and to explore the contribution of community pharmacists to multidisciplinary treatment planning in case conferences (Study Objective 4).

Specifically, qualitative methods were used to:

- Explore the perceived role of the pharmacist in the mental health team
- Identify the perceived contribution made by the pharmacist to the mental health team and to the management of clients
- Explore the perceived benefits of providing the intervention
- Identify shortfalls in the intervention or study methodology
- Identify potential modifications to the intervention for future research
- Explore the personal outcomes of the health professionals involved in the research study

Qualitative data were collected from three major sources: the diaries kept by pharmacist participants; focus groups conducted with pharmacists, case managers and psychiatrists; and semi-structured interviews (psychiatrists). Data from these sources were triangulated.

Diary Records

Study pharmacists were asked to keep a diary for the duration of the intervention. Pharmacists were asked to record on each day they attended the community mental health centre the tasks they undertook, medication and non-medication related information provided both during and outside of case conferences, and any other interesting events that occurred.

Focus Groups

At the conclusion of the intervention four focus groups were arranged with the key health professionals, namely the pharmacists (n=1), and the case managers and the psychiatrists (n=3). The pharmacists discussed their experiences working with the community mental health teams. The other health professionals discussed their experiences of having a pharmacist involved in the centres during the intervention.

Semi-structured face-to-face interviews

Two psychiatrists who could not participate in the scheduled focus groups, provided feedback about their experiences in two face-to-face semi-structured interviews which were conducted at the conclusion of the intervention.

The interview guide for the focus groups and the semi-structured interviews contained open-ended questions (Appendix 6). The main topic areas explored were:

- The current and potential roles for the pharmacist in the centres
- The positive aspects of the intervention
- The difficulties and challenges of the intervention
- The areas of the programme that could be improved

The proceedings of focus group discussions and semi-structured interviews were audio-taped, with consent, and transcribed verbatim. Transcripts were read and thematically content analysed. Each transcript was scrutinised and words, sentences and passages were coded using the following framework:

- Professional services delivered by pharmacists
- Issues contributed by pharmacists in mental health
- Issues contributed by pharmacists outside of mental health
- Advice on technical issues
- Miscellaneous

3.10 Sample Size and Statistical Power

The sample size calculations were based on the K10 and HoNOS. A sample size of 148 clients (74 per group) was computed based on the following assumptions: significance 5%, power 80%, a two-tailed test, a mean K10 score of 26.88 units (SD=7.97) and a 4 unit change in K10 scores, a mean HoNOS score of 40 units (SD=20) and a 10 unit change in HoNOS scores, and allowing for clusters of 15 clients. Hence the recruitment target for each CMHT was 18 clients, allowing for a drop-out rate of 20% from each centre.

3.11 Data Analyses

All quantitative data was analysed using the Statistical Package for the Social Sciences (SPSS) and descriptive statistics were computed. Differences in the mean value of continuous variables were tested using t-tests, ANOVA or non-parametric equivalents. Chi squared analysis were performed to compare proportions. The level of significance was set at 5%. Face-to-face case conferences, semi-structured interviews and focus groups were audio-taped, verbatim transcripts prepared and thematically content analysed.

3.12 Null-hypotheses

1. There are no statistically significant differences in the K10 score of psychological distress or HoNOS score of functioning, between the groups, before and after the intervention.
2. There are no statistically significant differences in the number of changes in the use of medications by clients between groups, before and after the intervention.

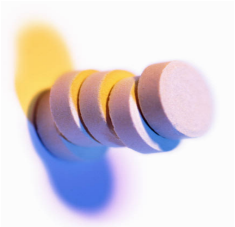
3.13 Study Limitations

1. Human ethics approval was required from numerous institutional committees including mental health specific committees. Due to the challenges and time delays in obtaining ethics approval through a number of committees, it was impossible to use a randomisation methodology in this study, as originally planned.

2. A 24 week complex intervention was chosen for this study. It is acknowledged that medium and long term benefits could not be realised within this time frame, however the immediate impact of the intervention was evaluated.
3. The collection of outcome measures in much research is problematic. The use of K10 and HoNOS was chosen based on consultation with psychiatrists and some community centres, and because the use of these instruments is mandated in New South Wales. The focus group participants explained that they would often not use these measures on clients as they can be fraught with difficulty and can, in some people's opinion, "trigger depression". For this reason, many clients did not have these data collected.
4. It was envisaged that a cost-effectiveness analysis be computed taking into consideration the cost analysis of service implementation and the consequences of it, that is, changes in the K10 and HoNOS scores. Although a statistically significant difference in the mental health of the clients in the comparison arm was detected relative to the intervention group, both groups deteriorated over time. There was no statistically significant change in the K10 scores between the groups and over time. Hence the utility of conducting a cost effectiveness analysis was deemed to be limited. Hence, a cost analysis was conducted but not a cost effectiveness analysis.
5. It was envisaged that the uptake of pharmacist medication review recommendations was to be assessed by triangulating data from community pharmacy dispensing records, following up with GPs, case managers and psychiatrists. Although this has been attempted, at the time of writing of this report, no uptake data had been forwarded to the researchers and so this key performance indicator has not been recorded in this document.
6. The case conferences that the pharmacists attended at CMHTs were audiotaped. Originally it was envisaged that transcripts from these case conferences be triangulated with data from the pharmacist's diaries. However, the large number of participants in each case conference (usually more than 10 persons), and the quality of the recordings, made it difficult to analyse the transcripts of these meetings. Hence the transcripts from the case conferences were not a valuable source of data and were not included in this report. The pharmacist's diaries provided a better source of qualitative data.
7. The estimated sample size for this study was 74 clients per group. This was based on the changes in clinical measures (K10 and HoNOS) at a power of 80% a significance level of 5% and a two-tailed test. The sample size calculation was based on a 4 unit change in K10 score and 10 unit change in HoNOS score. A 4

unit change in K10 score was selected because the probability of clients meeting current DSM-IV criterion for mental disorders has previously been described in bands of four unit changes in K10 scores.^[115] The sample size calculation factored in a 20% drop out rate due to the high rates of hospitalisation and discharge among clients from the community case management services. The final study sample of 52 in the comparison group and 63 in the intervention group reduced the power to approximately 70%. A cluster analysis was not undertaken due to the distribution of clients.

8. The recruitment process for this study was complex, with clients in the intervention group required to assess six pages of written material, which may have appeared confronting for some clients. Furthermore, the study relied on case managers (ie a third party) to identify and recruit clients into the study. This may have introduced a selection bias. It is likely that the case managers selected clients who they felt would most benefit from pharmacist intervention and/or those that would be most cooperative to a pharmacist intervention. Additionally there were statistically significant differences, at baseline, between the intervention and comparison groups in both the HoNOS and K10 scores. The quantitative results of this study therefore need to be interpreted with a degree of caution.



4. STAKEHOLDER CONSULTATION

4. Stakeholder consultation

4.1 Engagement with Key Stakeholders

Invitations to nominate representatives to participate on the study Steering Committee for this study were sent to the following organisations:

- The Pharmacy Guild of Australia (NSW Branch)
- The Pharmaceutical Society of Australia (NSW Branch)
- Schizophrenia Fellowship of New South Wales
- Northern Sydney Area Mental Health Service
- Sydney South West Area Mental Health Service

Subsequently a representative from each organisation joined the Steering Committee.

4.2 Steering Committee

The first Steering Committee meeting took place at The Faculty of Pharmacy, The University of Sydney on Monday February 1 2005 (Appendix 2). The Steering Committee was kept informed and invited to contribute feedback, via email throughout the duration of the study period.

The members of the Steering Committee were asked to and played an active role in the development of the training package for community pharmacists' participation in the case conferences at the community mental health centres. Following advice from consumer and Area Health Service representatives on the Steering Committee, a training package was developed that focused on improving the confidence and skills of the community pharmacists to communicate with people with mental illnesses. A detailed description of the development and implementation of the training package, through consultation with the above organisations, is presented in Section 5.

A final Steering Committee meeting will be conducted following submission of the Final Report. This will predominantly be for the purpose of disseminating the results of the study to the above organisations.

4.3 Other external consultation

The research team also met with Professor Ian Hickie, Executive Director, Brain and Mind Research Institute, The University of Sydney, and Associate Professor Alan Rosen, Director of Clinical Services, Royal North Shore Hospital and Community Mental Health Services, as external consultants throughout the study period.



5. TRAINING PROGRAMME

5. Development of a training package for community pharmacists' participation in case conferences for the purpose of treatment planning in mental health centres.

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5.1 Improving community care for people with mental illnesses

The World Health Organization (WHO) has estimated that as many as 450 million people worldwide suffer from a mental disorder, with one in 4 families having at least one member with a mental illness.^[1] More than 44 million people in the United States suffer a mental disorder each year, with the annual direct costs of mental illness estimated to be in excess of \$US69 billion.^[119] A similar pattern of disease burden is observed in other developed countries. Twenty percent of Canadians will personally experience a mental illness during their lifetime.^[120] In Australia, mental illness is a national disease priority area, and the leading cause of years lost due to disability.^[21, 121] Improving the quality and accessibility of community care for people with mental illnesses is an aim outlined in the recent *Inquiry into mental health services in New South Wales*.^[26] Health professionals have identified people with mental illnesses as among their most difficult patients to manage.^[45]

5.2 Community pharmacy services for people with mental illnesses

The majority of people with mental illnesses receive treatment from primary care practitioners.^[28, 122] There were over 49 million ambulatory care visits related to mental illness in the United States in 1997.^[123] As primary care health professionals, pharmacists are well placed to contribute the management of mental illness. Pharmacists have been recognized as key members of the health care workforce responsible for implementing the National Strategy for the Quality Use of Medicines in Australia, and are regarded as among the most trusted professionals.^[50, 124] The development of new community pharmacy services has expanded the opportunities for pharmacists to work collaboratively with general practitioners to provide

community mental health care. These services include domiciliary medication management review and community based multidisciplinary case conference meetings.^[125] Community pharmacists are frequently consulted for advice about medications used to treat mental illnesses.^[65-68, 78, 80] Counselling provided by community pharmacists has been demonstrated to improve adherence and attitudes to antidepressant medications.^[61, 88, 90] Pharmacists' contributions to community mental health teams have been associated with improved adherence to antipsychotic medications and a decrease in medication related side-effects.^[74-76]

The provision of medicines information by community pharmacists, however, may be limited by poor communication with people with mental illness. Finnish community pharmacists were less likely to provide medication counselling about psychotropic medications than for eight other therapeutic classes of medicines studied.^[33] Pharmacists have reported feeling more uncomfortable counselling on the use of medications used to treat mental illness than those used to treat cardiovascular conditions.^[83] British and Canadian community pharmacists have reported that their ability to provide information about antipsychotic medications is limited by a lack of training to counsel people with severe mental illnesses.^[81, 83] Dutch community pharmacists did not perceive that they have a clear role in the management of schizophrenia, despite more than 60% of people with schizophrenia and their carers indicating that they would like to receive more information about prescribed medications.^[82] People beginning courses of antidepressant medications in Britain were found to have unmet medicines information needs and consumers with mental illness in Australia have expressed their dissatisfaction with information about medications provided by their health professionals.^[31, 34]

5.3 Stakeholders in mental health education

The WHO has recognized the value of consulting with relevant stakeholders, including professional associations, community groups and advocacy organizations, when designing mental health education programs.^[126] The importance of facilitating consumer involvement in medical education, assessment and curriculum development has been described.^[127] An Australian report published in 1999, however, found that consumer and carer participation in tertiary mental health education was minimal.^[128] Institutions offering education to health professionals have typically not been accountable to recipients of health care. The second Australian National Mental Health Plan, released in 1998, recognized consumers,

families and carers as key stakeholders who must be adequately financed and resourced to influence decisions relating to service provision.^[129] Improving the delivery of mental health care services will be facilitated by close collaboration between patients' advocacy organizations, organizations responsible for mental health policy and planning, and educational institutions.

5.4 Consumer educators in mental health care

A consumer educator in mental health care is a person who has previously received mental health care and works, often on a voluntary basis, to inform and educate professionals, students and the wider community on mental illness and its effects on individuals, families and society. Similarly carers undertake this role. The consumer and carer educators work through the Schizophrenia Fellowship, a non-profit community based organization for people living with mental illness, their carers and relatives, from which they receive training and support. Australian government policy has recognized consumers with mental illness as partners in the delivery of mental health care.^[129]

The aim of this initiative was to design and conduct an interactive educational partnership between community pharmacists and consumer educators in mental health care. The specific objective of the partnership was to address the communication skills required for community pharmacists to provide pharmaceutical services to people with mental illness.

5.5 Design

Medline (1966-2004), International Pharmaceutical Abstracts (1992-2004), Embase (1992-2004) and PsychInfo (1992-2004) were searched using terms including consumer consultant, mental disorders, education, consumer participation and patient advocacy. Researchers used the outcomes of the literature search, and consulted with key stakeholders, including professional organizations representing pharmacists and patient advocacy groups, to inform the design an interactive training program involving community pharmacists and consumer educators in mental health.

The Schizophrenia Fellowship recruited the consumers and carer educator. The consumer educators employed in the education program had received training as

speakers from the Schizophrenia Fellowship. Community pharmacists who had earlier indicated their willingness to participate in a research study being conducted by the Faculty of Pharmacy were invited to participate in the educational partnership. This paper reports the qualitative evaluation of focus groups with the community pharmacists and consumers conducted as part of the educational partnership. With the consent of those present these focus groups were audio taped and content analysed.

5.6 Assessment and Results

Four 2-hour education sessions were conducted during March 2005. Seven community pharmacists, 5 consumers and one carer participated in the partnership. The sessions included both lecture style presentations and open discussions led by specialist pharmacists, a psychologist, a mental health nurse and a psychiatrist. In the first and fourth sessions special emphasis was placed on community pharmacists and consumers being able to share their experiences related to the topics presented. An important aspect of the fourth session was the debriefing and focus groups with the consumers and community pharmacists.

A key finding from the focus groups was the desire among consumers to receive more information about prescribed medications from their community pharmacist. Consumers reported that receiving more information about medicines would enable them to make informed decisions regarding their own health care, including the ability to discuss treatment options with their medical doctors. The consumers highlighted how it was important for pharmacists to provide medication counselling for the person rather than the diagnosis.

"You need to be aware that you are dealing with people. We have lives. People with mental illnesses are treated differently, but mental illness is a physical illness that occurs in the brain, just like other physical illnesses that occur in the heart."
[consumer]

"Individual pharmacists can be very selective who they relate to in their pharmacy practice, who they reach out to... they don't want any scenes in the shop... they rate you according to the drugs that they give you." [consumer]

Pharmacists discussed the barriers they perceived to providing pharmaceutical services to people with mental illness. Although pharmacists reported having the knowledge and desire to provide medicines information, several reported lacking the confidence and skills necessary to communicate effectively with people with mental illness. Many were unaware of the consumers' unmet needs for medicines information. The sessions caused the pharmacists to reflect on their own medication counselling techniques.

"It has changed my perception of how people will react to discussion...I can think of at least eight people [with mental illnesses] that I've never directly discussed their medication with." [community pharmacist]

"I won't be scared to ask 'how are you going with your medications?' It has been surprising how open people have been to share their experiences." [community pharmacist]

The consumers were enthusiastic about their participation in the partnership, the chance to speak about their experiences, and the format of the sessions.

"You are doing a training needs analysis...identifying the gaps between pharmacists and the consumer population." [consumer]

"It's good that you are doing holistic training...workshops are more personal, you can say what you feel from the heart, you can bounce ideas and brainstorm." [consumer]

The act of providing consumer education in a paid and recognized capacity was reported to be a valuable component of the consumers own treatment.

"It has been wonderful for her [daughter] to go out and share her illnesses. When I saw she was improving so well by being an advocate, I did the carer's advocacy course as well...the advocacy has been a very positive contribution towards her recovery." [carer]

5.7 Discussion

Lack of training to counsel people with mental illnesses about their medications has been cited as a barrier to service delivery, yet few mental health education programs for pharmacists have sought to address this barrier.^[81, 83] The use of consumers as educators has largely been restricted to nursing and medical education, where their contribution has been reported to be well received.^[130] Other reported advantages of using consumers are improved attitudes and a positive impact on nursing practices.^[131, 132] Although the benefits of pharmacists' membership of mental health advocacy organizations have been presented,^[133] the research team did not retrieve any published reports of consumers with mental illness being previously employed in the continuing education of community pharmacists. Mental health training programs for community pharmacists have typically focused on the indications and adverse reactions of psychotropic medications, rather than the skills required to communicate this information to consumers.

Educational interventions that allow participants to apply desired behaviours have been recognized as more effective than providing theoretical information.^[134] Role playing (with students or staff acting as patients) is frequently included in undergraduate pharmacy education, however, role playing the provision of information to people with mental illness may be perceived as too artificial to be useful. Whilst promoting interpersonal contact with people with mental illness can improve attitudes toward people with mental illness among health professionals,^[135] one study suggested that students' clinical placements at mental health centres may reinforce the "medical model orientation."^[136] This may be because students visiting psychiatric facilities observe patients receiving treatment, sometimes involuntarily, for acute exacerbations of their illness. Negative attitudes towards people with mental illnesses among health professionals has been identified as a barrier to service delivery.^[107] The educational partnership with consumers, therefore, represented a new and promising model for mental health education of community pharmacists.

The International Alliance of Patients' Organizations (IAPO) has also recognized the importance of patients learning the skills required to interact and work together with health professionals.^[137] Several consumer educators were unaware that community pharmacists were able to provide comprehensive information about prescribed medications. Barriers to consumer participation include a lack of

knowledge about the complexities of the mental health system, the mental health system being perceived as an agency of social control, and a persisting power differential between health professionals and people with mental illnesses.^[138] Strategies to improve understanding between community pharmacists and people with mental illnesses may be an important first step towards overcoming these barriers and facilitating a “concordant approach” to mental health care.

Several consumers reported that speaking about their experiences assisted their recovery. This supported earlier research that suggested the act of providing education to medical students resulted in consumer empowerment, increased self-esteem, development of new insights and an improved understanding of the doctor-patient relationship.^[139] The formation of an educational partnership, therefore, may have ongoing benefits for both groups. Although the results of this qualitative research cannot be generalized to all groups of consumers, pharmacists and pharmacy students, this case study suggested utilizing consumer educators in pharmacy education is a promising area for future research. An important aspect of the training program involved the consumer educators speaking about their own experiences. A corresponding limitation, however, was that the consumers did not attempt to represent or speak on behalf of all people with mental illness. Controlled studies are needed to assess the impact of consumer educators on pharmacists’ attitudes toward people with mental illness and their willingness to provide pharmaceutical services.

5.8 Conclusion

The educational partnership demonstrated the potential value of utilizing consumers in the education of community pharmacists. Developing a better understanding and improved communication between community pharmacists and people with mental illnesses is an important step towards improving community care for people with mental illnesses. The outcomes of the training suggest that the use of consumer educators in pharmacy education may improve the confidence of community pharmacists to discuss medication concerns with people with mental illnesses. Employing consumer educators in pharmacy education should be considered as one strategy to improve the confidence and ability of community pharmacists to communicate medicines information to people with mental illnesses. The

opportunity for consumers to provide education and speak about their experiences may aid their recovery.



6. RESULTS

6. RESULTS

4.3 Overview of Results

There were 115 clients recruited to participate in the study, 63 clients in the intervention group and 52 clients in the comparison group. Fifty-six percent of clients were female (n=64) and the mean age was 47.7 years (SD=15.8; range 18-83). Demographic characteristics of the clients in the intervention and comparison groups are outlined in Table 6.1. Nearly all clients recruited to participate in the study had a diagnosis of “chronic psychotic disorder”, “schizophrenia” or “schizoaffective disorder”.

Table 6.1 demographic characteristics of clients in the intervention and comparison groups

	Intervention group (n=63)	Comparison Group (n=52)	
Gender			
Male	26	25	NS ^a
Female	37	27	NS ^a
Age (years)	47.0	48.4	P=0.68 ^b
Number of medications (baseline) ^c	6.4	4.9	P=0.06 ^b
HoNOS (baseline) ^d	9.0	12.2	P=0.04 ^b
K10 (baseline) ^e	23.1	18.6	P=0.05 ^b

^a $\chi^2 = 0.53$, df=1, $p < 1.00$; ^b independent samples t-test

^c 26 intervention and 34 comparison clients

^d 45 intervention and 33 comparison clients

^e 28 intervention and 36 comparison clients

Of the 63 clients recruited in the intervention group, 55 received a medication review conducted by one of the five study pharmacists. One client withdrew from the study, three clients were discharged from their respective CMHTs, one client was admitted to hospital for an indefinite period, and three clients were not reviewed by one of the study pharmacists.

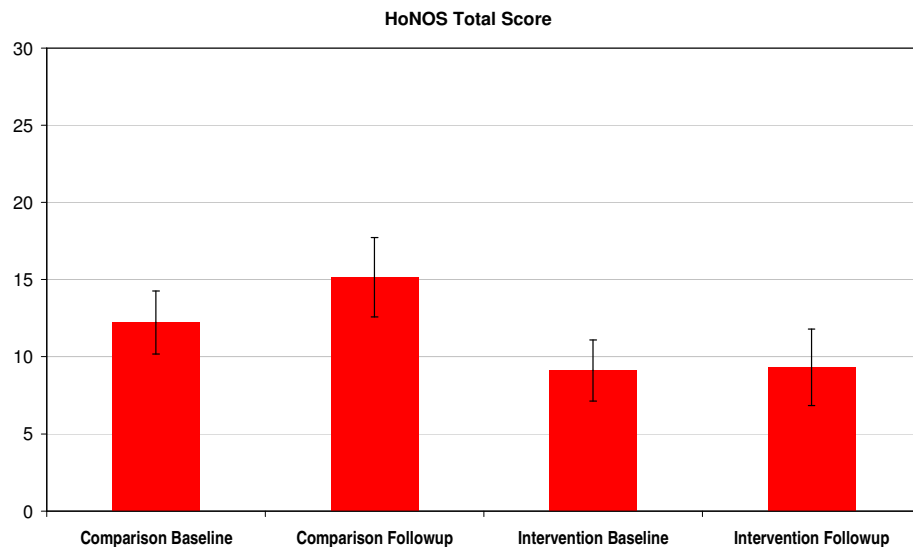
6.2 Clinical Evaluation Measures

Data for the HoNOS and K10 are reported in this section.

6.2.1 Health of the Nation Outcomes Scales

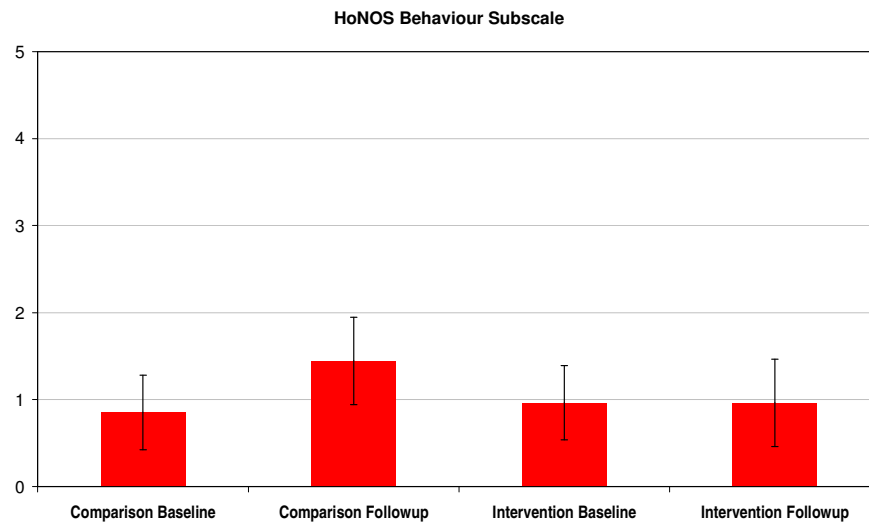
There were 27 comparison and 29 intervention clients for whom there were valid HoNOS data at two time points across the study. There were differences between the comparison and intervention groups at baseline for the HoNOS total score ($F_{(1,54)}=4.638$, $p=0.036$) and the social problem total ($F_{(1,52)}=8.168$, $p=0.006$). Each of these differences was due to the higher scores among clients in the comparison group at baseline, indicating poorer health in this group. There were no between group differences at baseline on the behaviour, impairment or symptom subscales, ($F_{(1,52)}=0.131$, $p=0.719$, $F_{(1,52)}=2.341$, $p=0.132$, $F_{(1,52)}=0.402$, $p=0.529$) respectively. There were differences on the total HoNOS score based on both the period effect, that is, the overall baseline to follow-up difference ($F_{(1,54)}=7.451$, $p=0.009$), and the group by period interaction, that is the differential effect of any intervention on the comparison and intervention groups, ($F_{(1,54)}=5.612$, $p=0.021$). Both these differences were due to the score of the comparison group rising over the course of the study. This indicated that the health of the clients in the comparison arm deteriorated more over the course of the study than the health of the clients in the intervention arm.

Figure 6.1 HoNOS Total Score



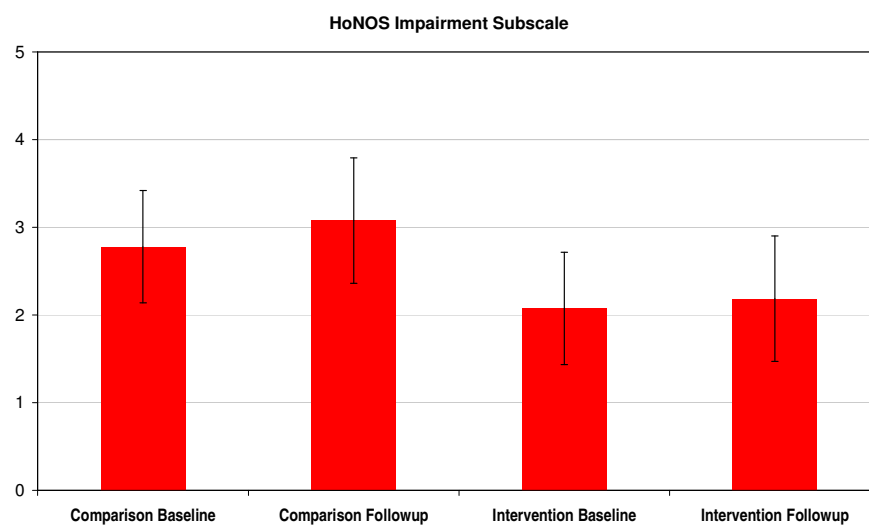
There were no differences on the behaviour subscale of the HoNOS between the control and intervention groups based on either the period or group effects ($F_{(1,52)}=2.987$, $p=0.09$, $F_{(1,52)}=2.987$, $p=0.09$) respectively.

Figure 6.2 HoNOS Behaviour Subscale



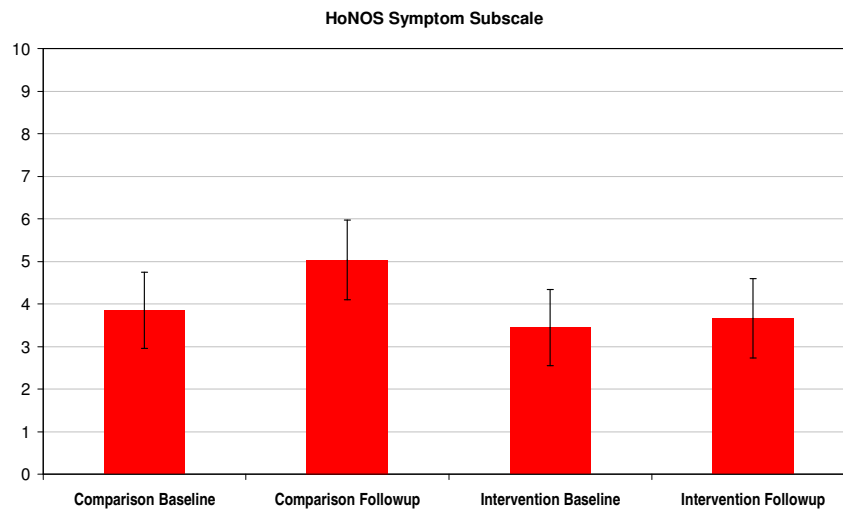
There were no differences on the impairment subscale of the HoNOS between the control and intervention groups based on either the period or group effects ($F_{(1,52)}=1.262$, $p=0.266$, $F_{(1,52)}=0.261$, $p=0.612$) respectively.

Figure 6.3 HoNOS Impairment Subscale



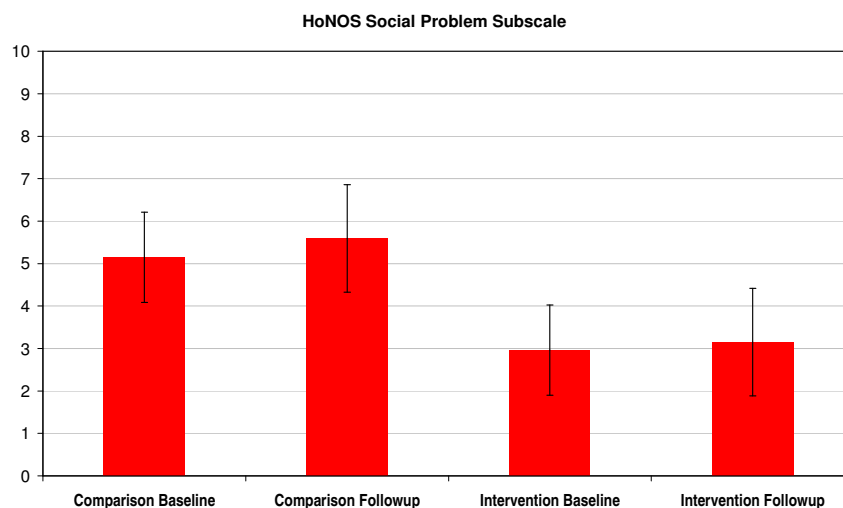
There was a difference based on the overall effect for period, but not for the group by period interaction on the symptom subscale of the HoNOS between the control and intervention groups ($F_{(1,52)}=6.598$, $p=0.013$, $F_{(1,52)}=3.089$, $p=0.085$) respectively. The significant effect for period was due to the symptom scores for both groups of patients rising during the period of the study.

Figure 6.4 HoNOS Symptom Subscale



There were no differences on the social problem subscale of the HoNOS between the control and intervention groups based on either the period or group effects ($F_{(1,52)}=0.543$, $p=0.465$, $F_{(1,52)}=0.092$, $p=0.765$) respectively.

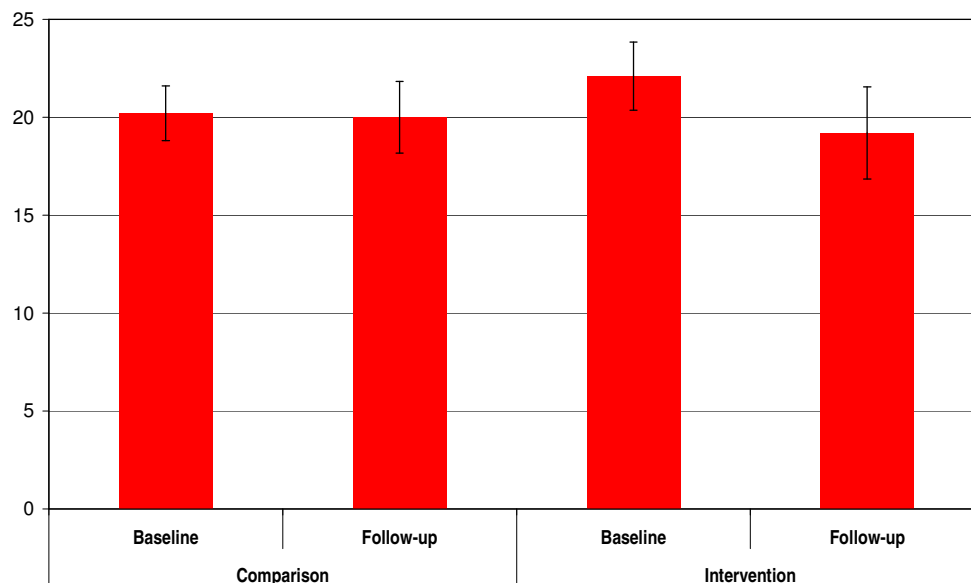
Figure 6.5 HoNOS Social Problem Subscale



6.2.2 Kessler-10

There were 30 comparison and 15 intervention clients for whom there were valid K10 data at two time points across the study period. Only means and confidence intervals for the K10 are reported because the low response rate in the intervention group prevented further statistical analysis. K10 scores decreased non-significantly in the intervention arm of the study, meaning that there was non-significant decline in psychological distress among clients in the intervention arm of the study.

Figure 6.6 Kessler-10 Scores for Intervention and Comparison Clients



6.3 Medication Numbers and Costs

Baseline and follow-up medication data from community pharmacy dispensing records were available for 26 clients in the intervention group and 34 clients in the comparison group. The medications (by ATC classification) used by clients in both intervention and comparison groups, at baseline and follow-up, are presented in Table 6.2. The mean number of medications per client in comparison group at baseline (mean = 4.9, SD = 3.2) was significantly less than the number taken by clients in the intervention group (mean = 6.5, SD = 2.5) ($F_{1,58}=4.392$, $p=0.04$) (Figure 6.7). However, both the effect of period averaged over the two groups (period effect) and the differences in the way the groups changed during the course of the study (group by period interaction effect: which is equivalent to calculating a one sample t test on the change score of the two groups) were not significant, ($F_{1,58}=2.261$, $p=0.138$ and $F_{1,58}=2.772$, $p=0.101$ respectively). The number of medications used by those in the comparison and intervention groups did not, therefore, change differentially over the course of the study. However, when the baseline (mean = 6.5, SD = 2.5) and follow-up (mean = 7.1, SD = 2.7) numbers of medications in the intervention group were compared, the number of medications used by the intervention group had increased significantly over the course of the study ($F_{1,58}=4.429$, $p=0.04$).

The mean number of antipsychotic medications taken by clients in the intervention and comparison arms was 2.0 and 1.1 respectively.

Figure 6.7 Number of medications by group over time

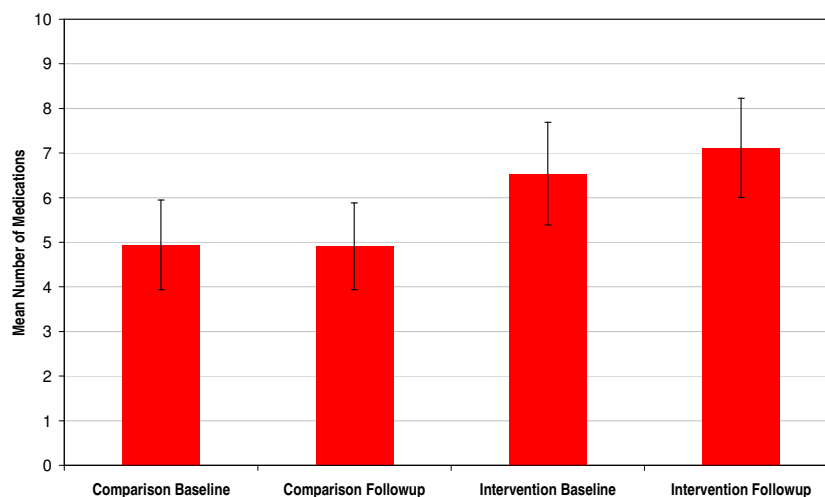


Table 6.2 Anatomical therapeutic chemical classification of medications

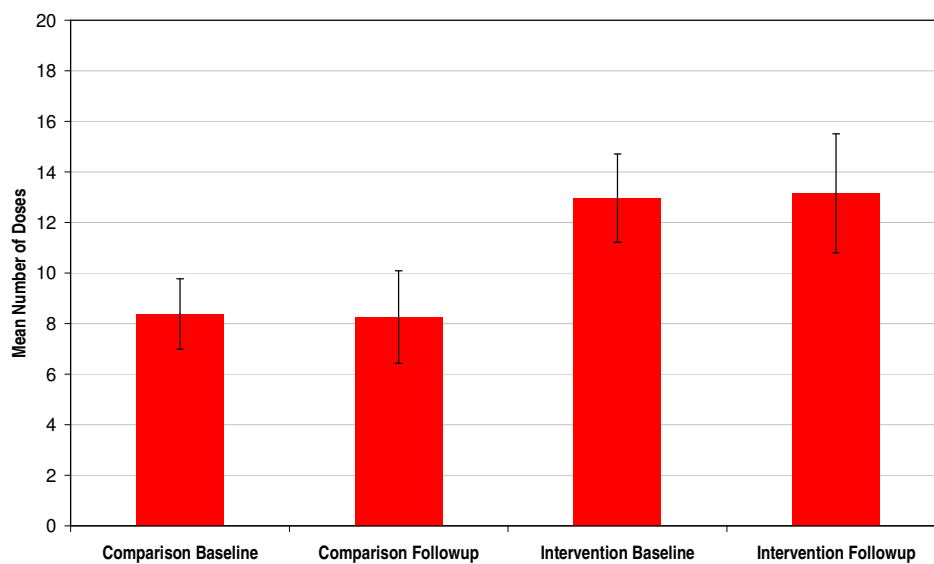
	Intervention ^a		Comparison ^b	
	Baseline	Follow-up	Baseline	Follow-Up
A Alimentary tract and metabolism	15	16	22	21
B Blood and blood forming organs	3	5	3	3
C Cardiovascular	22	28	34	32
D Dermatologicals	2	4	5	3
G Genito-urinary and sex hormones	3	3	5	4
H Systemic hormonal preparations	8	6	3	3
I Anti-infectives for systemic use	6	5	8	12
L Antineoplastic and immunomodulating agents	0	0	0	1
M Musculoskeletal system	0	0	6	3
N Nervous system	102	109	77	78
N02 Analgesics	3	3	4	5
N03 Antiepileptics	20	23	12	13
N04 Anti-parkinson drugs	4	6	4	4
N05a Antipsychotics	53	53	39	38
N05b Anxiolytics	0	0	0	0
N05c Hypnotics and sedatives	2	4	5	4
N06a Antidepressants	19	19	13	14
Other nervous system drugs	1	1	0	0
R Respiratory system	3	3	4	6
S Sensory organs	6	6	1	1
	170	185	168	167

^a sub-analysis of 26 intervention cases for which community pharmacy dispensing records were available

^b sub-analysis of 34 comparison cases for which community pharmacy dispensing records were available

The number of medication doses taken per day at baseline by the comparison group (mean = 8.4, SD = 5.4) was significantly lower than the number taken by the intervention group (mean = 13.0, SD = 6.1) ($F_{1,58}=9.416$, $p=0.003$). However neither the period effect nor the period by group interaction were statistically significant ($F_{1,58}=0.012$, $p=0.913$, $F_{1,58}=0.209$, $p=0.650$ respectively). The number of medication doses used by clients in the comparison and intervention groups did not change differentially over the course of the study. When the baseline (mean = 13.0, SD = 6.1) and follow-up (mean = 13.1, SD = 5.6) scores for the intervention group were compared, the change in the number of doses for the intervention group over the course of the study was also not significant, ($F_{1,58}=0.142$, $p=0.708$).

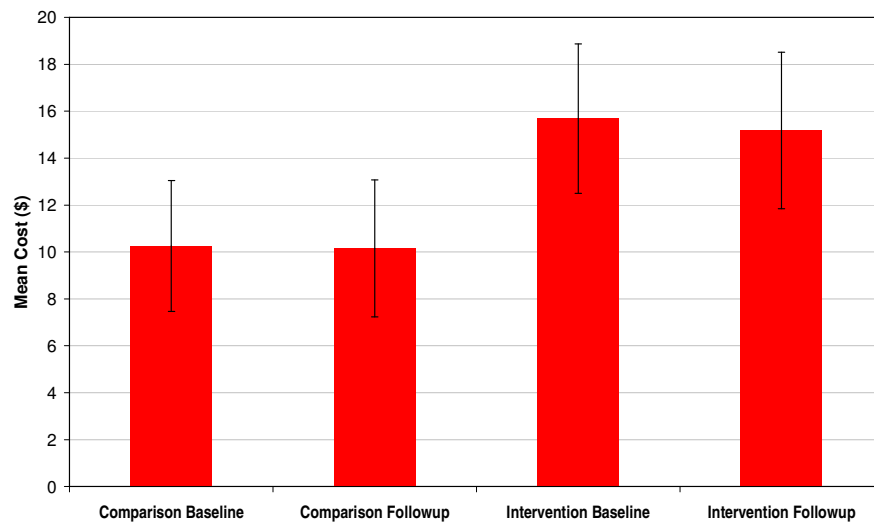
Figure 6.8 Number of doses by group over time



The daily cost of the medications taken by clients in the comparison group (mean = 9.96, SD = 7.91) was lower at baseline than clients in the intervention group (mean = 15.69, SD = 8.49) ($F_{1,58}=6.579$, $p=0.013$). There were, again, no significant differences in the period or group by period effects ($F_{1,58}=0.909$, $p=0.344$, ($F_{1,58}=0.394$, $p=0.532$ respectively). The cost of the medications used by the comparison and interventions groups did not, therefore, change differentially during the course of the study. When the baseline (mean = 15.69, SD = 8.49) and follow-up (mean = 15.16, SD = 8.77) scores for the intervention group were compared, the decline in cost for the intervention group over the course of the study was also not significant ($F_{1,58}=1.104$, $p=0.298$).

Although not statistically significant, the daily cost saving per client in the intervention arm was 0.50. This translates to \$183.63 per client per year, or \$10,099 for 55 clients in the intervention arm of the study.

Figure 6.9 Daily costs of medications by group over time



6.4 Pharmacists' Medication Review Findings and Recommendations

The most frequent findings related to suspected side effects (n=21), lack of clear indications for medication use (n=21) and lack of biochemical or pathology tests (n=19) (Table 6.3). Findings related to medications used to treat both mental and physical illnesses. The most common recommendations related to the need to provide further information about medications (n=25), the need to clarify the dose or medication regimen (n=21), to switch medications (n=19) and haematology pathology suggested (n=19) (Table 6.4).

Table 6.3 Pharmacists' Review Findings for 55 Clients in the Intervention Group

Finding	Overall frequency (n=183)	Percent of total number of findings
Drug related issues (n=120)		
Suspected side effect suffered	21	11.4
Suspected allergy suffered	2	1.1
Side effect potentially suffered	14	7.7
Drug not most appropriate	4	2.2
Dose form not most appropriate	1	0.5
Duplication of therapy	8	4.4
Contraindication	2	1.1
No clear indication for drug use	21	11.4
No drug prescribed but indication	5	2.7
Drug therapy not working	3	1.6
Dose too low or not frequent enough	2	1.1
Dose too high or too frequent	10	5.5
Length of treatment too long	6	3.2
Dose or regimen is unclear	3	1.6
Dosing schedule sub-optimal	7	3.8
Potential drug-drug interaction	11	6.0
Patient related issues (n=36)		
Wrong drug taken/administered	1	0.5
Drug not being taken as prescribed	9	4.9
Poor adherence	5	2.7
Patient is confused about regimen	5	2.7
Sub optimal administration	1	0.5
Lifestyle issue	6	3.2
Patient requires information	7	3.8
Other patient related issue	2	1.1
Prescriber related issues (n=27)		
No recent pathology or other test	19	10.4
Haematology pathology abnormal	4	2.2
Chemical pathology abnormal	4	2.2

Table 6.4 Pharmacists' Review Recommendations for 55 Clients in the Intervention Group^a

Recommendation	Overall frequency (n=182)	Percent of total number of recommendations
Drug related issues (n=96)		
Drug switch suggested	19	10.4
New drug suggested	12	6.6
Discontinue drug	12	6.6
Dose increase suggested	3	1.6
Dose decrease suggested	8	4.4
Dose form change suggested	2	1.1
Dose schedule change suggested	6	3.3
Monitor for adverse drug event	2	1.1
Clarify indication	11	6.0
Clarify drug dose or regimen	21	11.5
Patient related issues (n=37)		
Adherence aid suggested	1	0.5
Recommend take drug as prescribed	3	1.6
Instruct/clarify administration technique	3	1.6
Suggest adherence monitoring	5	2.7
Provide information / information provided	25	13.7
Prescriber related issues (n=49)		
Haematology pathology suggested	19	10.4
Chemical pathology suggested	17	9.3
Other pathology suggested	1	0.5
Diagnostic imaging suggested	3	1.6
Other monitoring by prescriber	3	1.6
Investigate indication/ diagnosis	1	0.5
Refer to another health care professional	5	2.7

^a range 0-13 recommendations per client

6.5 Economic Evaluation

An economic analysis was conducted to estimate the cost of the pharmacists' participation in the case conferences at the community mental health centres. This was done by setting pharmacists' wages at two levels (Tables 6.5 and 6.6). The first level was based on the award wage of a Pharmacist-in-Charge obtained from the Pharmacy Guild of Australia (11 June 2004). The second level was based on the wages paid to the pharmacists' to participate in this research study. Pharmacists' were paid \$80/hr to participate in the case conference meetings, and \$50/hr to prepare case notes, interview clients and research medication management reviews. This second level recognised that pharmacists' contributions in this setting required additional training and experience. The cost of one day of training per year was averaged over 12 months, as was the cost of a personal digital assistant (PDA) and corresponding medication information software.

Table 6.5 Estimated cost of service at Pharmacy Guild of Australia award wage

Aspect of service	Monthly Hours	Total monthly cost
Pharmacists' time for preparation (\$21.75 per hour)	20	\$435.00
Pharmacists' time to participate in fortnightly case conferences (\$21.75 per hour)	4	\$87.00
Personal digital assistant (PDA) (\$499/12 months)	N/A	\$41.48
Medication information software (\$165/12 months)	N/A	\$13.75
Mental health training (\$360 per year)	N/A	\$40.00
Total Monthly Cost		\$617.23

Table 6.6 Estimated cost of service at research project wages

Aspect of service	Monthly Hours	Total monthly cost
Pharmacists' time for preparation (\$50.00 per hour)	20	\$1000.00
Pharmacists' time to participate in fortnightly case conferences (\$80.00 per hour)	4	\$320.00
Personal digital assistant (PDA) (\$499/12 months)	N/A	\$41.48
Medication information software (\$165/12 months)	N/A	\$13.75
Mental health training (\$360 per year)	N/A	\$40.00
Total Monthly Cost		\$1415.23

Assuming the pharmacists spent 4 hours interviewing and researching the case notes for each client, this would allow pharmacists to review and discuss 5 clients per month. The cost per client of providing the service would range from \$123.45 to \$283.05.

6.6 Qualitative Results

A variety of qualitative methods was used to undertake a process evaluation of the role of community pharmacists in a community mental health care setting and to explore the contribution of community pharmacists to multidisciplinary treatment planning in case conferences.

6.6.1 Perceived Role of Pharmacist in Community Mental health Teams

Three diaries were submitted by study pharmacists and were analysed. Four focus groups and two interviews were conducted with various participants (Table 6.7).

Despite several attempts by the researchers to obtain the diaries from the remaining two pharmacists they were not submitted for analysis.

The perceived role of the pharmacist in the team was a key focus of the group discussions and interviews. Diary entries by the pharmacists also clearly identified a number of services provided by the pharmacists in the centres.

Table 6.7 Numbers of focus group and interview participants

Focus Group/ Interview	Case Mangers	Psychiatrists	Pharmacists
Focus Group (CMHT 1)	4	2	0
Focus Group (CMHT2)	4	1	0
Focus Group (CMHT 3 & 4)	9	0	0
Focus Group 4 (Pharmacists)	0	0	5
Interview 1 (Psychiatrist 1)	0	1	0
Interview 2 (Psychiatrist 2)	0	1	0
TOTALS	17	5	5

.Medication Information

A primary role of the study pharmacist was to provide medication related information.

"They're very involved I think...being drug information type sources." [Case manager]

It was noted by many that pharmacists were involved in providing drug information about non-psychotropic medications as well as psychotropics.

"...with non-psychotropic ones they often don't know what they are for." [Pharmacist]

"...it is more our specialty and there's often things that get passed over because they don't know a lot about non-psych meds." [Pharmacist]

Non-pharmacist focus group participants verified these points.

"Clients are on other medications we don't necessarily know, and the interactions and interrelationships of those medications are very important for their overall wellbeing, so I think it is a very important role for pharmacists here to advise us about how our drugs are going to affect their other drugs." [Psychiatrist]

Another theme that emerged relating to the provision of information by pharmacists was that it was unbiased and evidenced based. One pharmacist perceived that much of the medication related information that case managers and other members of the team had access to was provided by sales representatives from the pharmaceutical industry.

"It's good to have people there who are going to be able to gather unbiased data, because drug companies are such an influence....so it's good to have someone there who's actually able to use the resources and references to get actual facts, factual evidenced-based data." [Pharmacist]

This comment was validated in another focus group where participants echoed such sentiments, of the importance of the non-biased information the pharmacist could provide.

"Not all the drug reps have a health background....So having a pharmacist here is good for me anyway in terms of clarifying what has been said." [Case manager]

"I would consider X [the pharmacist] more objective, more helpful." [Case manager]

"It was very helpful. Most pharmaceutical reps are selling their products and don't give you any negative feedback so the objectivity is very helpful." [Case manager]

"From my point of view, I like talking to someone who I can trust, I don't trust drug company reps and I won't talk to them." [Psychiatrist]

A psychiatrist felt that another potential role of the pharmacist was the provision of drug information in an in-service/lecture style. In particular they felt this was needed by the case management staff.

"If they [case managers] were interested in having some kind of education about medications that could be helpful." [Psychiatrist]

Pharmacists noted that they saw the provision of medication related information as their main role. They did note that it was mainly provided to the team, but also they would provide medication information to the clients and their carers. Access to clients was different at each centre; hence the information provided to them would vary. One pharmacist explained that they had had a lot of contact with clients and carers.

"The parents and the family have heaps of questions about the medication and it's such a big area and they're frightened...their local pharmacy doesn't know much about it either." [Pharmacist]

Non-pharmacist team members also saw benefits from pharmacists interacting directly with clients to provide medication related information and confirm side-effect information about medications. In particular case managers felt that the clients may benefit from another person's opinion, rather than their usual doctors and case managers.

"One of the guys that I thought would benefit from the pharmacist here is a young male...he feels that he has got increasing sexual dysfunction problems....Maybe getting the point of view from the pharmacist could confirm that it may be something more."[Case manager]

"I think that is something a community pharmacist could do and do very well and contribute to the knowledge and education of our consumers about this medication and to put it in really plain language and to talk about side effects."[Psychiatrist]

It was also noted that pharmacists could have a role in counselling clients and their carers about side effects of medications, such as antipsychotic induced weight gain and hyperglycaemia. Case managers also saw there was an opportunity for the pharmacist to become more involved in running group sessions about medications for the clients.

"I know we talked about getting the pharmacist involved in the group programme...I was excited about that...I don't know why it didn't happen....I think it is something a pharmacist could do."[Case manager]

The pharmacists' diaries confirmed that the majority of the services provided by the pharmacists in the centres were to provide medication related information. This was essentially provided in three ways; to the mental health team during case conferences, to individual health professionals or clients on request, and to groups of clients, carers and health professionals in the form of talks about medications commonly prescribed to treat mental illnesses.

Additional member of the mental health team

Health professionals saw pharmacists as a member of the health care team, particularly with respect to medication.

"All the doctors and everyone is always appreciative of our help."
[Pharmacist]

"A lot of people appreciate having a professional discussion about medications....you've got lots of people who have professional discussions about diagnosis, social situations, this is an opportunity to have another person coming in, people leading discussions about medications on that kind of level." [Pharmacist]

Although it was noted by some participants that the extra member of the mental health team did not necessarily have to be filled by a person with pharmacy qualifications, it was thought that the pharmacist could fill this role because of their expert medication related knowledge.

"The pharmacist could fill that gap....There is not a lot of crossing over....Does the GP know about the psych medication? And does the psychiatrist know about the GP medication?" [Case manager]

"At the moment I go to the RN for their expert (medication) knowledge but it would be nice to have someone else to go to as well." [Case manager]

Pharmacists also perceived that to fill this role, some extra training about medications commonly prescribed for mental illness would be beneficial, as often guidelines are not adhered to for this group of clients. However, pharmacists felt that they did not need to become a "specialist pharmacist" to fulfil the role; they just required some additional information.

"Specialist knowledge, but it's something you can do, it doesn't have to be another degree" [Pharmacist]

"Extended basic pharmacy training could help with that." [Pharmacist]

The pharmacists' diaries verified this last point with pharmacists often making notes to research certain issues and then reporting the results back to the team as a whole or to individual team members.

The diaries also reflected how the pharmacists were finding their place in the team, and perhaps a little reluctant to act too independently initially. For example one pharmacist had conducted a medication review for a client and recorded that they checked with the NUM that they could send a letter to the GP.

Participation in case conferences

A major function of the pharmacists in the centres was the regular participation in case conferences. The amount of information pharmacists could give in this forum was felt to be very beneficial.

"They have a clinical meeting. You have a lot more input there, because you've probably seen more patients because you've done a review with the psych registrar." [Pharmacist]

"There was a file put together of drug information which different people asked for...it was really, really helpful...and I think because X did fit in well with the team it was easy to communicate with him, he was very approachable." [Psychiatrist]

"Participation in meetings has been really helpful." [Case manager]

The pharmacists' diaries verified the pharmacists' participation in team meetings. The three pharmacists that submitted diaries documented that they attended eight, 12 and 16 case conferences respectively over the duration of the intervention. These meetings were also classified in the diaries as "case management meetings", "handover meetings", "meetings", "clinical meetings", and "case meetings".

Provision of medication review services

Other than provide medication information, pharmacists also saw themselves as having a vital role in medication review services for mental health clients. By following the medication review process, they were able to ascertain what medications the clients were actually taking and obtain an accurate picture of their medication taking behaviour including non-psychotropic medications and over-the-counter items. Furthermore, pharmacists were able to recommend follow-up monitoring including blood tests.

"It might just be they need blood tests....they need that prompt, they need someone to say that" [Pharmacist]

The provision of the medication review service and in particular its presentation in the case conference was seen as an important new role for pharmacists. Some pharmacists perceived that by presenting the reviews it enabled other members of the team to think about things in a different light.

"I think they're very appreciative of the support...when you do a review and you do present it to them they're quite like 'Oh yeah, I hadn't thought about that' and then they have acted on things. So I think they find that role very useful from what I've found"[Pharmacist]

Some focus group participants (non-pharmacists) perceived that reviewing medications and recommending changes may be difficult for pharmacists.

"The only problem I kind of see with it, is that the pharmacists [community pharmacists] have a great deal of difficulty in saying to the doctor 'I think they're on too much medication'. There's a real problem for the pharmacist [community pharmacist] telling the doctor that they're on too much medication, or they're on not the right one, but yes they definitely do have a role." [Case manager]

A psychiatry registrar felt that the reviews were extremely helpful to prompt medication changes if needed.

"Oh yeah, extremely helpful...the temptation is often, 'oh I'm just coming here for 6 months, they must be on those medications for a reason, just leave them'. Whereas if you've got someone regularly saying 'oh look this could actually be a problem, perhaps this might actually be a better thing to do', it's...a stimulus to look at what you are doing."[Psychiatrist]

Similarly other focus group participants thought the review process was an extremely important role for the pharmacist with client benefits.

"Often the medication is considered in our care plans as an issue in terms of reducing it or increasing it and not as being tactical about it...It's quite detailed the information we got from X about why we would do something like that....that was really specific and that would form a large part of our care plan."[Case manager]

The purpose and benefits of medication review were also seen by one team as widespread and not just pertaining to doses and side effects.

"It's not just about physical health medications, mental health medications, it's about how you pack a medication, how you administer it, how you get the patient to the medication or vice versa, so yeah, it's handy I think for a team like ours in terms of support." [Case manager]

Once again the pharmacists' diaries verified the pharmacists' spent a large proportion of their time in the centres participating in medication reviews. The diaries demonstrated that a considerable amount of the pharmacists' time was taken up in arranging interviews and appointments with clients and then following the clients up after the initial interview and medication review.

Completing client medication records

Pharmacists also felt that they could help with administrative functions in the mental health centres. One pharmacist felt that there were incomplete notes and client histories due to the fact that the people compiling the records had limited medication knowledge.

"Often medication and history in the notes are quite incomplete" [Pharmacist]

"Developing a resource, folders or files...more pharmacy type service things." [Pharmacist]

In the same vain, the psychiatrists felt that improved medication histories within clients notes was a potential role for the pharmacist.

"It would be kind of handy to have somewhere in the notes as well, some kind of summary of things that have been tried and the reactions that they've had in the past as well cause that saves a lot of looking through the file for people." [Psychiatrist]

Different roles for pharmacists depending on their work setting

It became apparent during some of the focus groups that there were varying perceptions of the value of a pharmacist from different work settings. The role of the community pharmacist was often seen as very peripheral, and the dispensing of PBS medicines was often seen as their major role.

"I think community pharmacists would be more handy for PBS information"

[Case manager]

One focus group participant felt that the community pharmacist would have no role in the mental health team. This participant saw the pharmacists' only role in supplying medication.

"I've found most of the doctors here are particularly good at going through medication at some length and encouraging their client to talk about it...'do you want to increase it, decrease it, are you having any side effects?' So given all that, I can't really see how a pharmacist can help at all." [Case manager]

In contrast, team members often felt that hospital pharmacists were superior with their knowledge and could be more helpful.

"It's really different in hospital versus community setting. I mean X has a folder with all the people's treatment sheets in and he knows what they're all on...it's dealt with by the hospital pharmacy.... It's very different in a community setting...a different variety of ways to manage their medication."

[Case manager]

"X role is far more than just dispensing pills, it's about educating the staff and the consumers and picking up...contraindications and mistakes". [Case manager]

Participants from a centre where they could see a specific role for a pharmacist in the mental health team, did say that they may contact a hospital pharmacist, but having a specific pharmacist attached to the centre would be more beneficial.

“Well we do have a pharmacist in the hospital.....X provides us with our medication, X comes and does the medication sheet every couple of weeks and can be a very useful resource, but X has other areas in the hospital as well and is only part time...X doesn’t know our clients.” [Psychiatrist]

By contrast, in another centre the local community pharmacist was the pharmacist involved in the study, hence many of the clients already had some relationship with this pharmacist. The mental health team felt that this was an important part of the process and aided in the success of the programme at their centre.

“It was kind of a contributing factor to how successful it went with our team as well with the clients, especially the ones that knew X’s face and that seemed to be important.” [Case manager]

This particular pharmacist also agreed that having some background knowledge of clients aided them in the meetings.

“Often I already knew of them or knew what medications they were on from the start so it could be easier to have input than if it was someone I’d never heard of before, so that was a definite factor in it.” [Pharmacist]

6.6.2 Perceived contribution made by the pharmacist to the mental health team and to the management of clients

Information obtained from the three pharmacists’ diaries showed that the main pharmaceutical services provided in the centres could be classified as case conferences, medication review and follow up, and providing medication information to professional staff or clients. Medication talks (to clients and in-service) and providing technical information (PBS / medication prices) were secondary services provided. Appendix 8 contains the individual entries from the pharmacists’ diaries. Contributions have been classified as “mental health – provision of drug information to health care professionals”, “mental health – potential drug related problems”, “mental health – provision of drug information to clients”, and “non mental health issues”.

Case conferences

The case conferences occurred frequently (nearly weekly) in two of the centres. They appeared to take approximately one to one and a half hours each time in one centre and up to three hours in another centre. (The pharmacist had not recorded the duration of the meetings in the third centre.)

The pharmacists contributed medication related information in many ways. The mental health issues contributed (excluding medication review recommendations) were varied from general information about drug classes

“general presentation about antipsychotics”; “discussed with doctors common CYP450 drug interactions between psych and non psych meds”
[Pharmacist’s diary]

to drug specific information

“was asked to do some research on clozapine induced diabetes and if it’s possible to be reversed after ceasing the drug” [Pharmacist’s diary]

and client specific information

“discussed the likelihood of clozapine causing mictrurition in one of their patients” [Pharmacist’s diary]

Information was also provided about the non-psychotropic medications being taken by clients. Non-mental health areas included cardiovascular

“discussed changing antihypertensive due to gynecomastia” [Pharmacist’s diary]

gastrointestinal

“gave input into which PPI or statin should be used” [Pharmacist’s diary]

asthma

“participated in discussion about asthma medications” [Pharmacist’s diary]

complementary medications

“multivitamin / antioxidant use causing increased mortality” [Pharmacist’s diary]

and smoking cessation.

Pharmacists either provided information immediately during the meeting or took the query away, conducted research and presented the information at a subsequent meeting. One pharmacist prepared drug information folders for the case managers and kept it updated for the duration of the study.

Medication review and follow up

The pharmacists’ clinical contribution in medication reviews is covered in section 6.4. The diaries indicated that in some instances the pharmacists conducted their first interview with clients in their homes, in hospital or by telephone. The pharmacists often accompanied the client’s case manager for the home or hospital visits. During the client interviews the pharmacists spent time also answering client queries about their medications.

Providing medication related information to professional staff and clients

The pharmacist who participated in the least number of case conferences recorded the most medication related information questions from professional staff outside the case conference environment. All pharmacists recorded providing some form of medication related information to specific clients not recruited to the study, in addition to providing information to those recruited to the study.

Secondary services

There were a few requests for non-clinical, technical medication related information. This was generally in regard to prescribing or dispensing of medications. For example PBS requirements for prescribing a medication on authority, the “20-day rule”, the PBS safety net, provision of non-PBS items and medication costs. One pharmacist spent some time showing a new psychiatrist at the centre how to access the medication information databases on the CIAP website.

All pharmacists recorded providing formal presentations about medications used to treat mental illnesses. All pharmacists provided one or more medication information sessions for consumers and carers. One pharmacist recorded that 15 to 20 families and carers attended the session, who asked questions related to smoking in mental health (cannabis and nicotine), weight gain and sexual dysfunction. One participated in an information evening for family and friends of newly diagnosed young people. This pharmacist recorded that they presented a classification of psychotropics and their side effects. This pharmacist also attempted to run an in-house education session on antidepressants. Unfortunately the attendance was poor. The reason for this is not clear from the diary.

6.6.3 Perceived benefits of providing the intervention

Participants identified several benefits of the programme. The majority of participants explained that they felt the programme had been very successful. In particular the psychiatrists and case managers felt that the research was of great benefit to clients on multiple medications, and the comments pertaining to the role the pharmacists could play in the team were generally positive.

Increased access to medication information

Increased access to medication related information was seen to be of benefit to clients as well as case managers and psychiatrists. In particular, it was noted that the pharmacists could provide information about all medications including the non-psychotropic medications.

“The advantage of the pharmacist...we do have a generalised picture of it...we’re able to...look at overall medication regimen whereas often the doctors and the nurses they get a little bit narrow.” [Pharmacist]

One of the prescribers very much liked the idea of having the pharmacist around as part of the team.

“I find that as a person prescribing drugs here, I find the pharmacist incredibly helpful....There are always questions to ask.” [Psychiatrist]

Opportunity to explore other client details

By having a pharmacist as member of the team, other health professionals were able to ascertain more information about their clients than they might normally. In particular, case managers were sometimes able to attend medication review interviews, conducted by the pharmacists. During such interviews, details about the client and their medication taking were revealed, which the case manager would not normally have known about.

“When they’ve come along to the interviews with me...it’s given them a chance to really find out what’s going on with them as well as find out what they’re taking.” [Case manager]

Increased communication between health care professionals

Furthermore, as issues arose from medication reviews, follow-up with the clients’ general medical practitioners occurred, forging better relationships between the general practitioners, the mental health team and clients.

"It's kind of prompted them to develop a better relationship with their GP sometimes because often they don't know who their GP might be."
[Pharmacist]

A similar theme emerged in other focus groups where the potential for the pharmacist to liaise between health professionals and GPs could improve medication treatment.

"If we had a pharmacist attached to the team, it's an opportunity for the GPs who are providing medications for our patients to check on things by ringing up the pharmacist. Having access to a pharmacist and saying 'look they've come to me, I was thinking of prescribing this instead of the other thing, would that be workable?'" [Psychiatrist]

"It's just another way of linking in with the GP so it makes a bit more of a community." [Case manager]

Increased awareness and use of psychotropic guidelines

The pharmacist focus group often discussed the prescribing of psychotropics outside of the recommended guidelines. Pharmacists, although realising that there are differences in guidelines and practice, particularly in this setting, did however feel that they were able to prompt psychiatrists to at least acknowledge the current recommended guidelines.

"I think it has encouraged the psychiatrists to get back to the guidelines"
[Pharmacist]

"I think sometimes they get into this little pattern of going down this road and trying new things and they forget why they've done it. So I think they've appreciated that and hopefully will improve their prescribing habits"
[Pharmacist]

In a psychiatrist interview, they agreed that it was useful to be flagged when they were prescribing outside the guidelines

"They picked up on things like high dose...I think its fairly common, a lot of psychiatrists do actually prescribe it at a higher dose than recommended, but I think its good to sort of have that flag as well, that this is sort of in the higher range and keep an eye on it." [Psychiatrist]

Increased client satisfaction

It was perceived that the clients could also benefit from having pharmacists as part of the mental health team. Clients were able to ask the pharmacists for medication information that they may otherwise not have sourced due to a lack of time and or expertise of the other health professionals in the mental health team.

"They're unwilling to ask the psych nurse and the registrars because they say they don't have enough time and the social workers don't have as much expertise" [Pharmacist]

"I think they really liked talking about their medications to a pharmacist because often they had never done that before." [Case manager]

"I think most patients are really happy." [Case manager]

Pharmacists also believed that clients may also be more likely to adhere to therapies if they discussed their medications and gained awareness of what they were for and what to expect.

"I think it's highlighted the importance of why they're taking them and they are not just taking them every morning for fun. And things like adherence to medication as well that no one's probably ever talked to them about that."
[Case manager]

Interestingly, one psychiatrist felt that there was no use in the pharmacists speaking to the clients. In fact they thought it might stress them out talking about their medications. This comment, however, was made in the context of the pharmacist providing services for elderly clients who were resident at a community housing facility. Most clients at this facility had moderate to severe cognitive impairments.

"I don't really think it would be useful for the residents, I don't think they are really insightful enough." [Psychiatrist]

In contrast, other non-pharmacist members of a focus group felt that it was very helpful for clients to speak to the pharmacist.

"I think it's very helpful for clients to get the same information that we give them, only perhaps a bit more technical from the pharmacist....There's a lot of talk about the terrible side-effects..... Having a pharmacist add weight to the recommendations that this is necessary...is very helpful." [Case manager]

"I guess in terms of the interview...it was kind of an empowering process for the person, because they got to say what was bad about their medication....it seemed like a positive thing for them to do." [Case manager]

Members of the mental health team also felt that perhaps the clients may listen more to the pharmacist as they were perhaps new and regarded as an outsider. They questioned however, whether this objectiveness would remain once the pharmacist became an established team member.

"They see them as more objective...for some reason we get stuck into some sort of process where they think we're trying to do things to them that they don't need to have done. Whereas a pharmacist for some reason they are seen as more objective and less biased....I don't know if that would last though if he became part of the team." [Psychiatrist]

As well as clients being able to speak to the pharmacist, the changes made from the reviews were perceived to benefit some clients.

"We made some changes for a couple of people and then it seemed to be a worthwhile process for them." [Case manager]

6.6.4 Shortfalls in the intervention

Insufficient amounts of time

Although the use of pharmacists in this setting was seen as beneficial there were some shortfalls in study methodology. The intervention had pharmacists participating as members of the team for one day per week, however it was recognised by many focus group participants that this amount of time was insufficient.

"One day a week is not enough to build good rapport with the team to be able to be a member of the team, that's one of the problems." [Pharmacist]

"I had to go get myself a nametag because I had to keep telling people who I was all the time from one day to the next I had to reintroduce myself again" [Pharmacist]

"I think it would be difficult to come into a team...one day a week...I guess the comfort thing is you're part of the team,, you've been working here for a while you can speak up a lot easier than if you just come in once a week." [Case manager]

Similarly the amount of work required to be performed by the study pharmacists was difficult to complete in the time allocation of one day per week.

"Often you spend a lot of time at the centre on your one day....there was never an opportunity to actually do any of the work at the centre so it is kind of extra time on top of that. It does take a lot of work just chasing up case managers and collecting the K10s" [Pharmacist]

In contrast to the amount of time pharmacists should be involved in the centres, some other focus group participants thought that one day a week would be sufficient.

"Personally I think one day a week would be sufficient." [Case manager]

Having said this, there were some issues with the scheduling of clients for pharmacist interviews, so more than one day a week may have aided in the process of performing the reviews in a timely fashion.

"Some of my clients who I think would have really benefited couldn't make it on a Wednesday....it was very difficult to schedule appointments." [Case manager]

The duration of the study was also seen as potentially problematic. Six months to establish a new pharmacy role as well as recruit clients and perform research was perceived as being too short.

"I think with such a short-term project there was a lot of pressure on X and in some respects the team to recruit people and to get them to understand it...I think give another 6 months and if someone had had a second review....it would feel a lot more meaningful." [Case manager]

Obtaining consent and outcome measures

Another shortfall within the study that was perceived by some of the team members was obtaining client consent. There were information forms that had to be read by participants, which may have sometimes limited the number of clients recruited. Similarly the collecting of some data (K10s and HoNOS) was also perceived as difficult in the research context

"I think the only negative thing...the forms...so getting consent"

"The case managers said 'look we don't do the K10s, we hate them, it's not going to happen'."

"We don't actually do the K10s on most of our clients because we think it is contra-indicated and actually causes distress to people because it's so bloody depressing to fill in."

Focus group participants also agreed that the study was "hard to sell" to clients as it was such a new concept.

6.6.5 Potential modifications to the intervention for future research

There were comments about how the research itself could be modified as well as how the involvement of pharmacists as part of the mental health team could be improved and sustained. This section therefore is divided into the specific research improvements followed by suggestions for programme improvements

Providing more details to study participants

Some pharmacists felt that they were not prepared in the initial weeks of beginning the research.

"I felt like the lead-in, perhaps I didn't read all my stuff properly...I felt I didn't really know what I was doing...I wasted two weeks." [Pharmacist]

Although the research team made a presentation about the study at each centre at the start of the intervention, and also provided written information, some pharmacists perceived that the mental health centres were also not always well briefed on the study. This may have been because not all psychiatrists and case managers were able to attend the initial briefing. The CMHTs were also not used to having a pharmacist as part of their team, and may have taken some time to adjust to having a pharmacist on hand.

"I felt the centre didn't really know what was going on". [Pharmacist]

"It was like every time I went I was telling them what it was all about."
[Pharmacist]

A strategy suggested by the pharmacists to overcome some of these difficulties was an orientation package for each centre. This might include a power-point presentation provided by each study pharmacist. Due to the high staff turn-over at some centres it may have been beneficial to repeat the initial presentation that was offered during the intervention period.

"perhaps if the pharmacists doing the study could have just a day of orientation where maybe we could even get a presentation together.....at the first meeting and at least you've got it out of the way and they've all seen it."
[Pharmacist]

Allowing more time for study pharmacists to collect data and provide the service

As mentioned, the time-frame for data collection was tight, and many pharmacists ideally wanted to spend more time in the centre.

"I really think having someone there more than one day a week would have worked." [Pharmacist]

Pharmacists mentioned that they always had in the back of their minds the data collection. This may have prevented the pharmacists fulfilling what they perceived to be their most useful roles. The necessity to gain individual patient consent from each client that was reviewed meant that some clients who may have particularly benefited from the service were not able to be reviewed. Similarly, pharmacists spent a considerable amount of time encouraging case managers to collect the K10 and HoNOS outcome assessment instruments. There may have been other potentially more valuable tasks that could have been performed.

"You have the ability that you could do so much there, but the key thing is to have to be able to recruit patients so you always have to partly put that aside." [Pharmacist]

The duration of the study could also be lengthened to let the pharmacist have time to establish rapport with the team and clients and aid them in recruitment. One team felt that perhaps the pharmacist orientation could be passive for 1 full-time week with the team, before recruiting and performing pharmacist duties.

"A full week of the pharmacist having a passive role and attending the problems with the team, going on home visits, meeting the clients that we see, the team would become more connected with the pharmacist." [Case manager]

In the same vain, team members felt that better data could be collected in a longer study, such as monitoring medication changes over time.

Obtaining different outcome measures

As mentioned there were often issues with the collection of data such as the K10. Some participants felt that qualitative data should be collected from the clients. It was suggested that interviews immediately after the pharmacist had interviewed the client would be appropriate.

"I think a focus group is difficult for our particular client group because it's often too late. The best time to ask those questions is 5 minutes after X (the pharmacist) has finished with them. 'What did you get out of that?' It's still cognitively fresh." [Case manager]

Another case manager mentioned other quality of life outcomes measures that may be appropriate in future research. Also the collection of weight and blood sugar levels is appropriate for many of the clients on anti-psychotropic medications.

Provision of continuing education

It was noted by the pharmacists during their focus group discussions that being part of a mental health team, may require some additional education. The reasons identified for training were to do with the fact that the use of psychotropics in some of these clients were outside the standard recommended guidelines. Because of the differences in the practice-based and the evidenced-based use of medications in these client cohorts, training would be required, or pharmacists may be *"out of their depth"*.

As training resources are not readily available for practice in this area, some pharmacists agreed that exposure to this health area was important and perhaps mentoring maybe an effective strategy.

"You need to have almost a mentor who's going to teach you" [Pharmacist]

Resources for pharmacists

It was mentioned by one pharmacist that although they felt welcomed within the mental health centre, there was still no desk or computer access for them. If

pharmacists are to be fully incorporated into the health team they will need resources.

“There was me, but there wasn’t a desk at the site and I couldn’t get access to a computer, I always had to ask someone to log me in.” [Pharmacist]

The resource of time was a common theme throughout focus group discussions and interviews. Although there was debate as to whether more than one day a week was required for the service, it was certainly agreed that flexible time would be useful in conducting such a service.

“In some ways he wasn’t here enough, even though sometimes there wasn’t enough work for him to do when he was here sometimes. A bit more flexible about times would be good.” [Case manager]

Funding for pharmacists within the mental health centres

As pharmacists began to establish a role in this setting, it would be beneficial for pharmacists to be maintained in this setting. Many potential benefits may result from this intervention and funding would be required for continued work in this sector.

“They actually say ‘it’s really nice having a pharmacist here, I wish we could afford to have one all the time’. For them it all comes down to dollars” [Pharmacist]

“I think considering the numbers of people who are struggling with mental health issues that it’s appropriate for pharmaceutical industry [pharmacy profession] to start being involved. Especially for professional pharmacists who aren’t aligned with any particular brand or company and who can perhaps be very useful to clinicians.” [Psychiatrist]

As funding for pharmacists within the mental health centres may not be attainable in the short term, focus group participants suggested other ways the service could function.

"It would be really useful from my point of view to at least have access to someone over the phone. Sometimes we've got questions to ask them. They don't physically have to be there but just access to someone over the phone who is attached to the place, who knows a bit about the people would be useful." [Case manager]

It was also identified during the pharmacist focus group, that the general community pharmacist may not provide much information for this client group. Reasons for this lack of information may include social stigma, a lack of knowledge and a lack of education. Pharmacists involved in the study recommended that training programmes, perhaps with consumers, should be provided for community pharmacists.

"I think training programmes like what you held earlier on...getting them sitting there [mental health consumer educators], prompting you to start talking to them about their illness." [Pharmacist]

"I think also just information opportunities just for antipsychotic and psychotropic medications full-stop. Because I think part of the problem is if you don't feel confident in that area at all then you get put off counselling." [Pharmacist]

"The other problem is the level of information you feel you should tell them. A lot of doctors don't want the patients to know too much about the medications because they might be put-off taking them." [Pharmacist]

Defined roles for pharmacists within mental health centres

Some pharmacists felt that a specific pharmacy service in this sector should continue. It was however articulated that a defined service role was needed.

"They would really need to forge a bit more of specific duties and tasks and it would be centre specific." [Pharmacist]

In line with this theme, came the idea that pharmacists needed to be flexible and fit in with each of the centres needs. In one centre, focus group participants thought that it would be useful for the pharmacist to conduct home visits.

"Perhaps a home visit service may be possible...some of the more disabled, chronic clients of which we have a few that could go along with the case manager."[Case manager]

New roles for pharmacists

With pharmacist prescribing one of the potential new roles for pharmacists, it was recognised that mental health may be an area where this new role would be warranted. Pharmacists felt that their major role would be monitoring and making slight adjustments in therapies rather than initial prescribing duties.

"The role of the pharmacist is enormous in drug monitoring and interpretation of results...the pharmacists have the training, they've got a very good way of interpreting them and then being able to correspond those adjustments which could be quite tricky."

[Case manager]

6.6.6 Personal outcomes of the health professionals involved in the research study

Pharmacists gained professional satisfaction by being part of the study.

"I think it helps. I've had sort of a bit of background in counselling and I sort of enjoyed that side of it"[Pharmacist]

"I've definitely enjoyed what I've been doing there"[Pharmacist]

"I found it quite a change from what I normally did and I felt I got a lot out of it. I would enjoy continuing on."[Pharmacist]

In general all study participants were happy about the new service and were positive about the research and the pharmacist as a new member of mental health teams.



7. DISCUSSION

7. Discussion

This study was the first controlled study in Australia, and one of few conducted internationally, to assess a role for pharmacists as members of community mental health teams. Given that medications are central to the effective management of mental illnesses, pharmacists have a potentially important role in the management of clients suffering with these illnesses. This study examined the potential roles for pharmacists, with training, within community mental health teams, and the contribution they can make in this setting. The study evaluated a complex intervention, with pharmacists providing both client and centre specific services over the 24 week intervention period. Centre specific activities included medication information presentations for clients and their carers, whereas, client specific services included medication management review.

7.1 Quantitative Evaluation

7.1.1 Clinical Outcome Assessment

The mental health of the clients in the comparison arm, as measured by the HoNOS, deteriorated more over the course of the study than the mental health of the clients in the intervention arm. This is in contrast to previous controlled studies of pharmacists' interventions to optimise the use of medications for mental illness which have generally failed to demonstrate any impact on clinical outcomes.^[13-18] Additionally, there was a decline, though not statistically significant, in K10 scores among clients who received a pharmacists' medication review.

Due to the consenting processes required in this study, the study relied on the case managers to identify and recruit clients into the study. This added a level of complexity to the methodology as the study was reliant on a third party for recruitment, potentially introducing a selection bias. There were significant differences, at baseline, between the intervention and comparison groups in both the HoNOS and K10 scores. The differences in the HoNOS scores indicated that the comparison group had greater overall problems with mental health and social and behavioural functioning, while the K10 scores indicated that the intervention group clients had a greater chance of experiencing an anxiety or depressive disorder and a greater suicide risk. The case managers may have selected the

clients they felt would most benefit from pharmacist intervention, but also those that would be most cooperative to a pharmacist intervention. The Northern Sydney Health Human Ethics Committee also required a longer client information and consent form (six pages in total) relative to the Sydney South West Area Health Service (two pages in total). This may have impacted the type of clients who were recruited to participate in the study within the respective areas.

As such these results should be interpreted with caution. The collection rate of the K10 and HoNOS at two time points across the study was relatively low. Despite being mandated, there was strong resistance from the case managers to the use of these outcome assessment instruments in the study. This reluctance has also been voiced by psychiatrists,^[140, 141] and general practitioners.^[142] Clinical outcomes in this setting are likely to be influenced by a range of factors, of which medications were one. Although the sensitivity of the HoNOS has been described as adequate, some researchers believe that the sensitivity to change may be of a lesser magnitude in the community setting.^[114] Others have suggested the HoNOS may only be capable of detecting changes among clients with depression and anxiety.^[114] Future studies are needed to confirm the impact of the pharmacists' activities on the clinical outcomes of clients at the respective centres. Other researchers may consider using alternate outcome assessment instruments in future studies.

7.1.2 Medication numbers and costs

Clients from the intervention CMHCs were taking a greater number of medications and medication doses at baseline than those from the comparison CMHCs. Again, a possible reason may be that case managers at the intervention centres recruited clients to study who they perceived were most likely to benefit from the service. As such, case managers may have selectively recruited clients with multiple medical and medication related issues. A reason for case managers not recruiting potential clients may have been a perception that the clients' medication regimens were not complex enough to warrant discussion with the reviewing pharmacist.

The number of medications taken by clients in the intervention group increased significantly over the course of the study. This may reflect, in part, a greater recognition of the need to manage comorbid physical illnesses. Physical comorbidities account for 60% of premature deaths in people with schizophrenia.^[19]

In the 1997 Australian National Survey of Mental Health and Wellbeing, 43% of people with mental illnesses reported also suffering one or more physical illnesses.^[2] Mortality due to myocardial infarction, cardiac arrhythmias and ischaemic heart disease is higher among people with psychotic disorders than in the general population.^[19] Encouragingly, the number of cardiovascular medications taken by clients in the intervention arm increased over the course of the study, while decreasing in the comparison group. The increase in number of medications may also reflect an increase in adherence to prescribed medications with clients potentially recommencing previously prescribed but discontinued medications once the pharmacist had the opportunity to reinforce the value of the medication.

The number of nervous system medications taken by clients in the intervention arm increased slightly over the study period, and the number of antipsychotic medications remained constant. It was concerning that clients in the intervention arm were taking an average of more than two antipsychotic medications each, and an average of more than four nervous system medications, compared with the comparison group whom were taking an average of two and one antipsychotic and nervous system medications respectively. Clients taking multiple antipsychotic medications may have higher rates of hospitalisation, higher mortality and experience more frequent medication related problems when compared to people receiving antipsychotic monotherapy.^[143, 144] Once again, these may have been reasons that the case managers selected the intervention patients for pharmacist services. Pharmacists' recommendations did not appear to reduce the incidence of antipsychotic polypharmacy when measured at the conclusion of the study period. However, it is possible that many of the pharmacists' recommendations were not yet actioned by the psychiatrists, case managers or general practitioners at the time of follow-up.

The multiplicity of mental health care providers, and the difficulties experienced by some clients in accessing general practice care, may mean that recommendations made by pharmacists may take longer to be implemented than is standard for Home Medications' Reviews. Psychiatry registrars reported being uncomfortable changing clients' medications' regimens without first liaising with the consultant psychiatrist. Additionally, follow-up of clients by psychiatry registrars was made more difficult because registrars typically worked at the respective centres for periods of only six

to 12 months or less. The high incidence of antipsychotic polypharmacy among clients of CMHCs deserves further research attention.

Further, psychiatrists or psychiatry registrars did not initiate changes to medications used to treat physical illnesses, and conversely, general practitioners were not comfortable making changes to medications prescribed by the psychiatrists. Whilst these factors may have limited the number of changes that were observable in this study, they make the potential value of the medication review services provided by the pharmacists even greater. Many of the clients who participated in the intervention group had not previously received a comprehensive review of their medication regimens. In one case this resulted in clinicians discovering a client to be taking three antipsychotics concurrently, prescribed by three different medical practitioners. The potential value of the pharmacists' services needs to be assessed over a longer time period.

Given that the intervention group were taking more medications, it follows that this group was also taking more medication doses per day. Thirteen doses of medication per day is a large number to manage and generally these clients obtain some of their medications from community pharmacies in blister packs. Often the clients use more than one community pharmacy. However, it would be appropriate for clients to be encouraged to obtain their medications from their choice of just one community pharmacy. Clozapine, primarily dispensed through hospital pharmacy departments, was generally not obtained from clients' community pharmacies. Given the potential for serious adverse reactions and drug-drug interactions with clozapine, it is appropriate that clients' community pharmacists are aware that their clients are also taking this medication. Likewise, hospital pharmacists may not be aware of other medications taken by these clients when dispensing clozapine. Liaison with the clients' community and hospital pharmacies is another potential role for team pharmacists.

The pharmacists who participated in the study reviewed clients' medication regimens from a clinical rather than an economic perspective, and it is important to note that direct cost savings do not necessarily represent good value. Despite being more expensive than conventional antipsychotics, clozapine has been described as the most cost-effective treatment for schizophrenia.^[145] Other newer and more expensive atypical antipsychotics, such as olanzapine and risperidone, may be cost-

neutral, or even slightly cost-saving, when compared with older conventional antipsychotics.^[145] Treatment with olanzapine, although more expensive than haloperidol, was found to result in 13% fewer relapses.^[146] The cost effectiveness of olanzapine and risperidone may be similar, but superior to that of haloperidol, when calculated over a five year period.^[146] The cost-effectiveness of various antipsychotic medications is likely to vary according to the setting and client population. Additionally, our short study did not attempt to measure the cost of non-pharmacological treatments (including case management), or the cost of hospitalisation, both of which were likely to have been significant for this client group. Nevertheless, non-significant cost savings of \$183.63 per client per year were achieved in the intervention arm. Future studies with a larger sample size would be required to confirm whether the pharmacists' contributions to CMHTs are associated with reductions in cost of prescribed medications.

7.1.3 Types of Pharmacists' Findings and Recommendations

There were an average of three findings and recommendations made per intervention client as a result of medication review services. Adverse drug events are common among people taking psychotropic medications and, therefore, it is not surprising that the equal most frequent finding related to suspected medication side-effects. Pharmacists also identified the lack of clear indications for medication use among many clients. This may be due, in part, to the lack of routine review of clients' regimens, and the multiplicity of health care providers. Additionally, many medications were also prescribed for 'off-label' indications, and the prescribers' intentions may not have been immediately clear to the reviewing pharmacists (or other treating clinicians). Pharmacists also frequently requested clarification of a drug dose or regimen. In the qualitative analysis, the prescribers, whilst acknowledging that they often prescribed medications outside of evidence based guidelines, indicated that they appreciated the pharmacist checking the appropriateness of unusual drug indications and doses. Whilst this did not appear to result in any significant changes in prescribing this study, it is important for the quality use of medicines that prescribers be accountable for their prescribing.

The lack of haematological and chemical pathology tests probably reflected the difficulty many clients with psychotic illness experience in accessing general practice care for physical illnesses. The provision of health care for physical illnesses among

people with mental illnesses is frequently lacking.^[19] Regular monitoring of body mass index (BMI) and blood glucose is recommended for all clients taking antipsychotic medications.^[147]

Several case managers reported that their clients enjoyed the opportunity to discuss medication side-effects with the study pharmacists. People taking psychotropic medications for mental illnesses have previously reported their dissatisfaction with the quality and quantity of information about their medications provided by their health professionals.^[34] Correspondingly, pharmacists frequently recommended that clinicians provide additional information about medications to their clients.

Pharmacists also commonly recommended that clients switch medications. This may have been due to medication side-effects or perceived poor efficacy. Previous research has suggested the primary reason for antipsychotic discontinuation is poor symptom response.^[148]

7.2 Content and Process Evaluation of Pharmacists' Contributions

The role of the pharmacist in this new setting included the established services of provision of medication related information and medication review, as well as participation in case conferences, providing information talks and completing client medication records. Whilst integration of the pharmacist into the CMHT was probably more successful at some centres than others, the case managers and psychiatrists generally acknowledged the important contributions made by the pharmacist. On the whole, the pharmacists appeared to adapt into their role as a member of the team very well. However, it is interesting to note how factors, such as whether or not the pharmacists were provided with a desk or computer, made the difference of feeling fully accepted into the team or not.

The duration of this intervention was short and as such it is a credit to each of the pharmacists and the mental health teams, and perhaps reflects the degree of motivation in each of the groups, that a reasonable level of rapport and cooperation was achieved in this time. Had the duration of intervention been longer, it is reasonable to expect that the level of rapport and cooperation achieved could have been even greater.

Each pharmacist appeared to provide a slightly different balance of services in slightly different ways. For example, one pharmacist participated in fewer case conferences, yet was frequently approached by individual team members to provide medication related information. Another pharmacist chose to provide a medication information file, which was kept updated and the team acknowledged its usefulness. This shows how each pharmacist was able to adapt into the team environment and provide services where they saw a need. Although there was comment that both the pharmacists and centres felt a little unsure how to proceed initially, and asked for more guidance in any future studies, it is also important to not be too prescriptive in directing pharmacists how to provide such services. These five pharmacists have demonstrated that allowing a degree of flexibility in the pharmacists' approach, whilst taking a little time initially for the pharmacists to find their niche, can be successful.

It is interesting that there were different perceptions on the usefulness of the pharmacist from different settings, that is, hospital versus community. These perceptions could clearly be based purely on the health professionals' previous experiences of pharmacists from the different settings. In the one centre where the pharmacist providing the service was from the local community pharmacy there was clearly seen to be an advantage with the pharmacist and clients already knowing each other. It is also interesting that this research has identified that it is not necessary for pharmacists to be specialised in the area of mental health to be able to contribute to the team. Indeed it appears that having a more generalised background provides the pharmacist with an advantage and allows the pharmacist to contribute in areas, where other members of the team may not be able. It is, however, clear that placing a pharmacist with no specific training or background in mental health into a mental health team would be challenging for the pharmacist and would limit their ability to contribute fully to the team initially. Providing a small amount of training and allocating a mentor to such pharmacists would be one way of overcoming this initial difficulty.

The results show that the majority of the medication related information contributed by the pharmacists was related to psychotropic medications. However, the overall contribution included information about medications used to treat many other disease states as well as technical information, again highlighting the advantage of using a generalist pharmacist. There were clearly questions, which drew on the pharmacists' specialist knowledge of pharmacokinetics and pharmacodynamics,

demonstrating that a pharmacist is indeed appropriate in this role. The fact that pharmacists sometimes had to spend some time researching the answer to a query did not seem to be a negative factor for the health professionals. It seems reasonable that the longer the pharmacist is in the role, the less need there will be for them to have to conduct research prior to answering queries.

Although the pharmacists appeared to spend the majority of their time in the centres, there appeared to be a need for flexibility in this when providing the services. On one occasion a pharmacist was asked to accompany a case manager to see a new admission in a unit, specifically to answer any medication queries. Additionally many of the medication review interviews were conducted in the clients' homes, in hospital or over the phone. This degree of flexibility may help pharmacists to see clients who could not make it in to the centre on the day they were there.

Being involved in the information sessions for clients and carers seemed an important opportunity for the pharmacists in the study, and one that was greatly appreciated by the attendees. There currently appears to be difficulties in clients and carers obtaining this type of information from community pharmacies, perhaps due to the stigma that is still associated with mental illness and perhaps due to the amount of time that many community pharmacists may perceive would be required. The qualitative research suggested that community pharmacists could be more proactive in offering Consumer Medicines Information (CMI) to people with mental illnesses. Whilst this service proportionately took up less of the pharmacists' time in the study, it clearly was a very important area of contribution by the pharmacist, particularly from the perspective of the clients and their carers.

The perceived benefits of providing the intervention clearly outweighed the shortfalls. The intervention was seen as successful by both pharmacists and the mental health team. There was an increase in access to medication information for clients, health professionals and carers. Clients on multiple medications benefited by the pharmacist taking the time to obtain a complete list of medications and then providing an overall assessment of the medication regimen. This additional step in the routine care of clients also provided case managers with an opportunity to explore other client details. The medication review process increased communication between health care professionals, not just within the mental health team but also the client's GP and potentially their community pharmacist. The

intervention, whilst not necessarily changing prescribing, appeared to increase the prescribers' awareness and likelihood of monitoring medications where prescribing had deviated from the evidence and from accepted guidelines. The shortfalls appeared to be mainly articulated as a perceived lack of time in the centre, and the difficulties associated with obtaining client consent and collecting the outcome measures, which were research specific issues.

There appeared to be many positive outcomes for clients and health care team members. Similarly the study pharmacists seemed to enjoy providing this intervention in this specialised area.

7.3 General discussion

7.3.1 Triangulation of data (the pharmacists' roles and contributions)

The comparison of pharmacist diaries and the results of the focus groups and interviews confirm that pharmacists were able to successfully integrate into the mental health teams and provide important services in this sector. Whilst the focus of this study was in the area mental health, it is important to note that, in terms of medication use, it is dangerous to compartmentalise clients and that there is an important role for the pharmacist to review the total medication use picture when contributing in forums such as case conferences. This was confirmed in the medication reviews and the qualitative data. It was also interesting to note that the type of information pharmacists provided included that related to both psychotropic and non-psychotropic medications. It was unfortunate that the audiotapes of the case conferences were unable to be used for data analysis, however, the diaries proved a useful methodology in order to quantify the types and amounts of activities that pharmacists were performing both during case conferences and during the additional time in the centre. Although the study timeframe did not allow for follow up of medication review actions, it was encouraging to see that psychiatrists and case managers really valued the information pharmacists could provide. This innovative research has been able to explore the usefulness of the pharmacist in this setting and pave the way for more defined service roles to be established in this setting in the future.

7.3.2 Non-biased information

A common theme that was discovered through conducting the focus groups and interviews was the notion of the study pharmacists being an independent source of information in contrast to industry representatives. Mental health centres, traditionally having few dealings with pharmacists, often rely on obtaining their medication information from hospital pharmacists or pharmacy representatives. The role of the hospital pharmacist in several centres appeared to be restricted to medication supply or medication audit, and several case managers reported that the hospital pharmacist did not know their clients. It appears that several of the centres had regular visits from representatives briefing the psychiatrists and case managers on new medications or updates on indications. Many of the team members saw the representatives as presenting biased information, and were grateful for the pharmacist providing non-biased evidenced-based data. If one were looking to try to fund a pharmacist in these centres, it should be kept in mind that this person needs to remain independent of pharmaceutical companies in order to maintain such rapport with the centre and team.

7.3.3 Establishing relationships between pharmacists and centres

It is accepted that the development of successful collaborative working relationships takes time and repeated positive interactions.^[149] Due to limitations in time, the establishment of relationships between pharmacists and the teams within the CMHCs was not fully realised. However, even in the short intervention period was successful to varying degrees in all of the centres. Several factors may impact on pharmacists establishing relationships in these centres. It was interesting to note that different health care professionals had different perceptions of pharmacists, and even different perceptions of pharmacists depending on their work-place setting. For example, in some of the focus groups, the participants often reflected on their experiences with other pharmacists in the past. Several teams reported positive experiences in hospital settings with in-patient pharmacists being knowledgeable and providing relevant information. Their opinions of community pharmacists differed between individual participants with some seeing no role other than supply for a community-based pharmacist.

The teams' perceptions of the traditional roles of pharmacists would need to be explored in order to place pharmacists permanently in mental health centres and establish positive relationships. Pharmacists and team members' personalities may play a vital role in establishing this rapport, as would the demonstration of competence from the outset. Clear pre-agreed guidelines and defined pharmacist roles in the centres would also aid in the transitioning of new pharmacists into these teams. In order for this to be a sustainable model, this relationship building would be the first important step in the process. Research studies such as this can only help forge these new roles for community pharmacists.

7.3.4 Future of the service

Medication review was one of the services provided in this study. In some cases medication review services have been shown to decrease medications and costs to clients on multiple medications.^[10, 150] The outcomes of these services for clients with mental health issues are less well studied. As these cohorts of clients often have several comorbidities, review services appear to be warranted. Focus group interviews revealed that team members, pharmacists and psychiatrists felt that this was an important service pharmacists could provide to this patient cohort. Many of the team members admitted that they often did not focus on non-psychiatric specific medication and had limited knowledge of potential issues with such medications. This was where the role of the pharmacist was seen as pertinent to add a more generalist overview to the medication review procedures. This point is interesting, as many may have perceived that a specialist pharmacist may be needed for this role. After performing this research it appears that any registered pharmacist able to perform medication reviews would be appropriate, although some additional training and mentoring in this area may be of benefit initially.

Problems with funding structures for the provision of medications reviews were also mentioned in one of the focus groups. Traditionally the general practitioner initiates this service. This GP refers the client to their preferred community pharmacy and the community pharmacist or a contracted pharmacist for that business will then conduct the review. In a mental health centre, the model of service provision may need modification. Currently GPs are remunerated for referral and follow-up post review. The centres would need to establish a model for referral and funding mechanism to deal with this. Similarly, the pharmacist contracted to service a centre would need to have a funding mechanism established for payment to conduct such

a review. These issues would need to be explored in depth, once the benefits from interventions such as these are established. It became apparent from the research, that pharmacists were doing more than just medication reviews for clients. They were acting as a source of medication information for clients and team members as well as performing administrative functions such as compiling medication histories and client notes. These peripheral services were seen as an important aspect of the pharmacist's role in the mental health centres and funding for such services would need to be negotiated and established.

7.4 Limitations

The collection of outcome measures in much research is problematic. The use of K10 and HoNOS was chosen based on consultation with psychiatrists and some community centres, and because the use of these instruments is mandated in New South Wales. The focus group participants explained that they would often not use these measures on clients as they can be fraught with difficulty and can, in some people's opinion, "trigger depression". For this reason, many clients did not have these data collected. Other ideas for outcome measures that may be explored in future research include qualitative measures of client satisfaction. It was also suggested that clinical measures of blood sugar levels and weight might be appropriate. These are important issues to ensure the success of future research in order to establish outcomes and hence implement this new pharmacy role in this setting.

Due to the challenges and time delays of obtaining ethics approval through a number of committees, it was impossible to use a randomisation methodology in this study. The nature of the ethics approval required the case managers to identify and recruit the clients into the study. This may have introduced a selection bias into the sample as demonstrated by significant differences in some of the client demographics at baseline. The results of this study therefore need to be interpreted with a degree of caution.

7.5 Summary

This study has demonstrated that pharmacists can successfully integrate into mental health teams in the community setting. The study has shown that there are a number of defined services that the pharmacists can provide in this setting, including case conferencing with other team members, provision of information (to team members and clients both individually and collectively) and medication review. Through these services pharmacists can contribute to the management of clients with mental illness either directly or indirectly through the team.

Placing pharmacists in the mental health centres was well received by clients and health professionals alike. The study suggested pharmacists' may positively impact on clients' mental health outcomes, but findings should be interpreted cautiously, and require confirmation in future studies.

Clients stand to benefit from rationalisation of their medication, as well as being able to access accurate, evidenced-based medication information from an independent source. Similarly, mental health team members benefit from this information also, and can then better manage their clients particularly in the area of medication management. Pharmacists felt that their time spent in these centres was worthwhile and many thought they would like to continue to maintain their relationships with the centres.

Funding for pharmacists in this environment is an important issue to explore. Clients in this sector appear to have a need for pharmacists to aid in improving their medication management. This study has demonstrated that this intervention is feasible. Hence it may be appropriate to explore funding for these services.



8. CONCLUSION & RECOMMENDATIONS

Conclusion

This study has demonstrated that pharmacists can be successfully integrated into community mental health teams and contribute to the overall management of clients. Pharmacists' contributions to the community mental health teams were well received by psychiatrists, case managers and clients alike. Pharmacists' primary roles were to provide medication information and to review clients' medication regimens. Case managers and psychiatrists found the pharmacists' participation particularly valuable in respect of reviewing the use of medications for physical co-morbidities, and drug-drug interactions of these medications with those prescribed for mental illnesses. The overall number of medications dispensed per client, but not the number of doses or the daily cost of medications to the Pharmaceutical Benefits Scheme, increased in the intervention group. Mental health, as measured by the Health of the Nation Outcomes Scales, deteriorated in both study groups, but to a greater extent in the comparison group. Further studies of a longer duration, larger sample size and more user friendly evaluation measures are required before more definitive conclusions about the values of these services can be made.

Recommendations

1. It is recommended that further feasibility studies be conducted to explore and further define a role for pharmacists within specific community mental health teams. This may be an important precursor to the dissemination of the model prior to wider adoption by the mental health community and pharmacy profession.
2. Given the complexity of the mental health system, and the multiplicity of mental health care providers, future studies should be of longer duration, larger sample size and utilise more user-friendly evaluation measures.
3. In response to the overwhelmingly positive feedback from clients and consumer organisations, especially those involved in the education programme, additional steps should be taken to develop and consolidate links between the pharmacy profession and mental health consumer groups.
4. It is recommended that the role of consumer educators as providers of mental health pharmacy education be researched further, with a view to possible wider uptake of this model in continuing and undergraduate professional education.

5. It is recommended that community pharmacists make themselves more familiar with the structure and functions of community mental health teams that operate in their locality. Similarly, case managers and psychiatrists should be encouraged to introduce themselves to community pharmacists practicing in their area, perhaps with a view to that pharmacy or pharmacist becoming a source of information about medications for their clients.
6. It is recommended that case managers and psychiatrists encourage their clients to use one general practitioner and one community pharmacy where possible.
7. When making changes to clients' medication regimens, general practitioners, psychiatrists and case managers should be encouraged to inform the community pharmacy, and general practitioner (in cases when changes are made by the psychiatrist or case manager) or community mental health team (in cases when are changes made by general practitioners). This may help avoid the many discrepancies that were present between community mental health centre records and community pharmacy dispensing histories.
8. When conducting medication management reviews, pharmacists should use both the community mental health centre medication records and the community pharmacy dispensing histories as a basis for their findings and recommendations.
9. To meet the unmet need for information about medications it is recommended that community pharmacists be more proactive in offering Consumer Medicines Information to people with mental illnesses.
10. For the purposes of conducting reliable and routine checks for drug-drug interactions and medication appropriateness, it is recommended that community and hospital pharmacies have complete records of the medications taken by their clients. This particularly applies to the dispensing of clozapine. Community pharmacists were often unaware that clozapine was being taken by their regular clients. Conversely, hospital pharmacists may not be aware what other medications are being taken by the clients for whom they regularly dispense clozapine. In the longer term, community mental health teams should investigate having all medications, including clozapine, dispensed through one source. If through community pharmacies, then clients would be able to have their medications dispensed under the Pharmaceutical Benefits Scheme (PBS).
11. It is recommended that more formal links between hospital and community pharmacies be established. Community pharmacists were generally unaware that community mental health centres were being visited by a hospital pharmacist.



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APPENDICES



Appendix 1: Human Ethics Committee Approvals



The University of Sydney

NSW 2006 Australia

COPY
Human Research Ethics Committee
www.usyd.edu.au/ethics/human

Manager:

Gail Briody

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23 March 2005

Ms P Whitehead
 School of Pharmacy
 Curtin University of Technology
 PO Box U1987
 Perth 6845

Dear Ms Whitehead

Title: *Collaboration between community pharmacists and mental health care practitioners: a case conferencing model*
Ref No.: 7118

The Executive Committee considered your request to modify the above protocol. The Executive Committee found that there were no ethical objections to the modifications and therefore recommends approval to proceed.

The following modifications were approved:

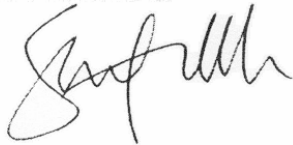
- Removal of Ms Jonine Penrose-Wall from the list of authorised personnel.
- Amendments to your contact details (see above).
- Mr Simon Bell taking responsibility for the operation of the project at the University of Sydney.
- Amendments to the Participant Information Sheets and Consent Forms.
- Community pharmacists, general practitioners and staff of the community health centers to conduct three structured (instead of four) and eight (instead of seven) semi-structured face-to-face multidisciplinary case conference meetings.

Conditions of Approval Applicable to all Projects

In order to comply with the *National Statement on Ethical Conduct in Research Involving Humans*, and in line with the Human Research Ethics Committee requirements the Chief Investigator's responsibility is to ensure that:

- (5) The Participant Information Sheet and Consent Form are to be on University of Sydney letterhead and include the full title of the research project and telephone contacts for the researchers, unless otherwise agreed by the Committee.
- (6) The following statement must appear on the bottom of the Participant Information Sheet.
Any person with concerns or complaints about the conduct of a research study can contact the Manager of Ethics Administration, University of Sydney, on (02) 9351 4811.
- (7) The standard University policy concerning storage of data and tapes should be followed. While temporary storage of data or tapes at the researcher's home or an off-campus site is acceptable during the active transcription phase of the project, permanent storage should be at a secure, University controlled site for a minimum of five years.
- (8) A progress report should be provided by the end of each year. Failure to do so will lead to withdrawal of the approval of the research protocol and re-application to the Committee must occur before recommencing. **Your first report will be due on 30 November 2004.**
- (9) A report and a copy of any published material should be provided at the completion of the Project.

Yours sincerely



Associate Professor Stewart Kellie
Chairman, Human Research Ethics Committee

Encl. Participant Information Statement (Health care professional)
 Consent form (Health care professional)
 Client Information Statement
 Client Consent form

cc: ✓ *Mr Simon Bell, Faculty of Pharmacy A15*

Northern Sydney Health

better health: from the Harbour to the Hawkesbury

ROYAL NORTH SHORE HOSPITAL
ST LEONARDS NSW AUSTRALIA 2065

June 29, 2005

Ms P Whitehead
C/- Mr Simon Bell
Faculty of Pharmacy
A15
University of Sydney NSW 2006

RESEARCH OFFICE
Level 4, Vindin House
Telephone: (02) 9926 8106
Facsimile: (02) 9926 6179

Dear Ms Whitehead,

**Re: Protocol 0504-087M — P Whitehead, T Chen, P Aslani, S Bell, J Penrose-Wall
Collaboration between community pharmacists and mental health care practitioners: a case conferencing model**

I am pleased to inform you that the Northern Sydney Health Human Research Ethics Committee approved your protocol on the above study. The approval includes:

- Client consent form version 1, dated the 24th June, 2005
- Client information sheet version 1, dated the 24th June, 2005

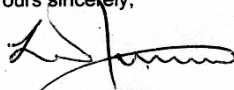
The HREC recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purpose of conducting this clinical trial.

At this time, we also remind you that, in order to comply with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia*; and in line with NSH HREC policy, the Chief Investigator is responsible to ensure that:

1. You notify the HREC at the completion of the study at this site and submit a final report (including final results) when available.
2. The HREC is notified as soon as possible of any changes to the protocol. All changes must be approved by the HREC before continuation of the research project. This includes notifying the HREC of any changes to the staff involved with the protocol.
3. All serious and unexpected adverse events are reported to the HREC within 15 working days.
4. The HREC is notified of the outcome of all submissions of this protocol to other Ethics Committees.

As at 18th May 2004, HREC approval is now valid for four (4) years from the date of the approval letter. **Your approval will therefore expire on the 30th June, 2009.** Investigators are requested to submit a progress report annually. **Your first progress report is due on the 31st October, 2005.**

Yours sincerely,



Prof Stewart Dunn
Chairperson
Human Research Ethics Committee



Appendix 2: Steering Committee



Collaboration between Community Pharmacists and Mental Health Care Practitioners

Minutes

Steering Committee Meeting

S302, February 7, 2005

The meeting was opened at 13:40

Present: Ms Kara Spiteri (Pharmaceutical Society of Australia, NSW Branch), Ms Carlene Smith (Pharmacy Guild of Australia, NSW Branch), Ms Diane Ross (Vice President, Schizophrenia Fellowship of Australia, NSW Branch), Dr Timothy Chen (Lecturer in Pharmacy Practice, The University of Sydney), Mr Simon Bell (PhD Candidate, The University of Sydney)

Apologies: Ms Louise Sharrah (Management Committee, Schizophrenia Fellowship of Australia, NSW Branch), Dr Alan Rosen (Director of Clinical Services, Royal North Shore Hospital and Community Mental Health Services), Dr Parisa Aslani (Senior Lecturer, The University of Sydney), Ms Paula Whitehead (Chief Investigator, Curtin University of Technology).

- (1) Mr Bell welcomed everybody to the meeting and thanked people for their attendance.
- (2) Mr Bell presented the main findings of a recent literature review of 51 quantitative and qualitative studies of community pharmacy services for people with mental illnesses conducted in January 2005 by the research team.
 - People with mental illnesses frequently ask community pharmacists for advice about medications used to treat mental and physical illnesses.
 - Information about medications provided by medical doctors at the time of diagnosis may not be fully absorbed and/or understood by consumers.
 - Consumers report unmet information needs and have identified potential future roles for community pharmacists in the area of providing medicines information.
 - Consumers who obtain medicines information from more than one health professional display better adherence to prescribed medication regimens than those that access information from a single source.
 - Community pharmacist medication counselling can improve adherence to antidepressant medications, especially for first time antidepressant users.
 - Community pharmacist run medication information sessions at community mental health centres have been well received by consumers and other health professionals in studies in the United Kingdom.
- (3) Mr Bell presented a short outline of the earlier case conference study (Case conferences and care plans: collaboration between community pharmacists and GPs) for people with mental illnesses, conducted by the Faculty of Pharmacy at The University of Sydney in 2003.
 - The study was conducted in the Northern Sydney and Hornsby Ku-ring-gai Ryde Divisions of General Practice from March to September 2003.
 - Twenty-six GPs and 51 community pharmacies were recruited to take part in the study. Eleven GPs referred 56 patients for pharmacist Home Medicines Review (HMR). Forty-four patients were subsequently discussed at follow-up GP-pharmacist case conference meetings.

- Most common diagnoses were depression (78%), hypertension (48%), anxiety (45%) and hypercholesterolemia (29%).
 - Pharmacists' documented 350 medication related findings and made 308 corresponding recommendations for the 44 patients.
 - For the 37 patients for which complete documentation was available, the pharmacists' recommendations were accepted by GPs in 92% in cases.
- (4) Mr Bell presented an Introduction to study "Collaboration between community pharmacists and mental health care practitioners" based on the study prospectus circulated to steering committee participants prior to the meeting.
- Ms Ross indicated that she believed that some consumers may be more willing to receive medication advice from a pharmacist than from other members of community mental health teams.
 - Ms Ross reported that there was a lack of awareness among consumers about pharmacist conducted HMRs.
 - Ms Smith agreed that there was a general lack of consumer awareness and undertook to provide the Schizophrenia Fellowship with brochures to raise awareness of the HMR service among consumers.
 - Dr Chen reported that a medicines information night he conducted at Gladesville Hospital was very well received by consumers who attended.
 - Ms Ross indicated that if people better understood how medications worked, including the risks and benefits, they may be more willing to take the medications
 - Ms Ross indicated that consumers with mental illnesses are often told contradictory and conflicting information about medications from different health professionals, and that this was distressing and confusing.
 - Dr Chen indicated that community pharmacists are now remunerated to provide Consumer Medicines Information (CMI) at the time of dispensing and this may potentially be a valuable resource for consumers with mental illnesses. Dr Chen acknowledged that one limitation was that CMI is only produced for approved medication indications and that some medications used to treat mental illnesses are used for unlicensed indications and/or in doses that exceed the maximum recommended doses.
 - Ms Ross indicated that she believed that discharge medication planning from hospital to community settings was an important role for pharmacists.
- (5) Education and training seminars for study pharmacists. Mr Bell circulated the document (Appendix A) outlining the proposed training seminars for the five study pharmacists employed to work on the study.
- Ms Spiteri indicated that she believed that many community pharmacists were unaware of the structure and type of services offered by community mental health teams.
 - Ms Ross agreed and said that community pharmacists and GPs often operate on "different planets" from community mental health teams.
 - Ms Ross indicated that she believed that it would be important for the study pharmacists to build rapport with people with mental illnesses, and that therefore use of consumer educators in the training programme was a good idea.
 - Ms Ross asked if community pharmacists who had received the training programme would be able to advertise that they have a special interest/training in mental health. She indicated that it was embarrassing and frustrating for consumers to continually have to explain themselves to different community pharmacists. She indicated that most consumers with mental illnesses only go to one pharmacy where they feel comfortable. She believed it would be a good idea for pharmacists to identify that they had a special interest in mental health.

(6) Role of consumer consultants in community mental health care and the education of health professionals

- Mr Bell indicated that based on the very successful training of community pharmacists using consumer consultants in an earlier study that it was the intention of the research team to continue with this form of training.
- Ms Ross, Ms Smith and Ms Spiteri were all supportive of the use of consumer consultants to improve the confidence of community pharmacists in providing medication counselling to consumers with mental illnesses.

(7) Other business

- Ms Smith offered to advertise the study pharmacists' positions in the Pharmacy Guild Bulletin and to pharmacists accredited to conduct HMR through an email group.
- Mr Bell explained that whilst it would be advantageous for the study pharmacists to be accredited to conduct HMR, this would not be strictly necessary because study pharmacists would be conducting medication reviews as a member of a mental health team, not performing an HMR (which can only be conducted on referral of a GP).

(8) Date and time of next meeting

- It was decided that three steering committee meetings would be held throughout the duration of the study. It was decided to hold the second steering committee meeting on Friday July 29 at 1pm at the Faculty of Pharmacy.

The meeting was closed at 2.55pm. Minutes recorded by Simon Bell

Appendix A - Outline of the Pharmacist Training Seminars

QUALITY PHARMACY PRACTICE IN MENTAL HEALTH CARE SEMINAR 1
LEAD PRESENTER: CASE MANAGER
BACKGROUND AND INTRODUCTION TO THE RESEARCH STUDY
WELCOME AND INTRODUCTION TO THE EDUCATION PROGRAMME
OUTLINE OF STRUCTURE OF MENTAL HEALTH SERVICES IN NEW SOUTH WALES. <ul style="list-style-type: none">- A CASE MANAGER WILL PRESENT ON TOPICS INCLUDING: INTENSIVE CASE MANAGEMENT, STATE AND FEDERAL FUNDING ARRANGEMENTS, AREA MENTAL HEALTH SERVICES, CRISES MANAGEMENT, AIMS AND OBJECTIVES OF COMMUNITY BASED MENTAL HEALTH CARE IN AUSTRALIA.- A CONSUMER CONSULTANT WILL PRESENT ON THEIR EXPERIENCES IN RECEIVING TREATMENT THROUGH A COMMUNITY MENTAL HEALTH TEAM.

QUALITY PHARMACY PRACTICE IN MENTAL HEALTH CARE SEMINAR 2
LEAD PRESENTER: PSYCHIATRIST
DEPRESSION, ANXIETY AND THE PSYCHOTIC DISORDERS <ul style="list-style-type: none">- A GUEST PSYCHIATRIST PRESENTER WILL DISCUSS COMMON MENTAL ILLNESSES AND THE AIMS AND OBJECTIVES OF TREATMENT.
NON-PHARMACOLOGICAL TREATMENTS FOR MENTAL ILLNESSES <ul style="list-style-type: none">- A GUEST PSYCHIATRIST/PSYCHOLOGIST PRESENTER WILL DISCUSS THE ROLE OF NON-PHARMACOLOGICAL TREATMENTS

QUALITY PHARMACY PRACTICE IN MENTAL HEALTH CARE SEMINAR 3
LEAD PRESENTER: SPECIALIST PSYCHIATRIC PHARMACIST
UPDATE AND REFRESHER ON PSYCHOTROPIC MEDICATIONS <ul style="list-style-type: none"> - A GUEST PSYCHIATRIC PHARMACIST WILL DISCUSS NEW DEVELOPMENTS IN MEDICATION TREATMENTS FOR MENTAL ILLNESSES.

QUALITY PHARMACY PRACTICE IN MENTAL HEALTH CARE SEMINAR 4
LEAD PRESENTERS: CONSUMER CONSULTANTS AND RESEARCH TEAM
INTRODUCTION TO THE ROLE PLAYS AND ROLE OF CONSUMER CONSULTANTS IN MENTAL HEALTH SERVICES. <ul style="list-style-type: none"> - FOUR CONSUMER CONSULTANTS WITH MENTAL ILLNESSES WILL CONDUCT ROLE PLAYS WITH THE STUDY PHARMACISTS, FOLLOWED BY FEEDBACK AND DISCUSSION.
INTERPROFESSIONAL COMMUNICATION IN MENTAL HEALTH TEAM CONFERENCES <ul style="list-style-type: none"> - THE RESEARCH TEAM WILL PRESENT ON MODELS OF SHARED DECISION MAKING

Appendix 3: Letters of Support

- NSW Health
- Pharmacy Defence Limited

Mr Simon Bell
Faculty of Pharmacy
Pharmacy Building A15
The University of Sydney
NSW 2006

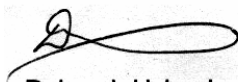
Dear Mr Bell

Re: Collaboration between community pharmacists and mental health care practitioners: a case conferencing model

Thank you for providing an update on your project. Mental health is a national health priority area. Improving the quality and accessibility of mental health services is an aim outlined in the report *Mental Health Services in New South Wales* published in December 2002 [1]. The appropriate use of medication is central to the effective management of people with mental disease. These people often display poor medication adherence and report unmet medicines information needs. The management of co-morbid mental and physical illness remains an ongoing challenge for both people with mental disorders and their health professionals.

NSW Health is enthusiastic to support initiatives designed to optimise the medication management of mental and physical illnesses for people living in the community. Following the positive outcomes of studies conducted internationally, NSW Health is keen to support local research that examines the impact of extended roles for pharmacists as members of community mental health teams. NSW Health will be following the progress and outcomes of the project "*Collaboration between community pharmacists and mental health care practitioners: a case conferencing model*" with interest.

Yours sincerely,



Deborah Hyland
Director
Workforce Development and Leadership

13.7.05

[1] Mental Health Services in New South Wales: Final Report (2002).
New South Wales Parliament
Legislative Council, Select Committee on Mental Health.



Pharmaceutical Defence Limited

A.C.N. 004 065 794 A.B.N. 51 004 065 794
New South Wales Branch

PO Box 13, Oatley NSW 2223
Telephone: (02) 9585 1705
Facsimile: (02) 9585 1713

25th October 2005

To Whom It May Concern,

This letter is confirmation of Pharmaceutical Defence Limited cover under the Terms, Conditions and Exclusions of the Policy for Pharmacists Members of Pharmaceutical Defence Limited participating in the research project:

Collaboration between community pharmacists and mental health care practitioners: a case conferencing model

This project is being carried out by the Faculty of Pharmacy, The University of Sydney under the supervision of Mr Simon Bell, Dr Timothy Chen, Ms Paula Whitehead and Dr Parisa Aslani.

The Policy carries a Professional Indemnity cover of \$20 million and Public Liability cover of \$10 million.

If any further information is required, please do not hesitate to contact the writer.

Paul Mahoney
Chairman, NSW

Appendix 4: Evaluation Measures (K10 and HONOS)

Appendix 5

Area Logo

SR1

Self Report Measures for
Adults and Older People
K10+LM

Facility Name: _____

Code: _____

Please use gummed label if available

Patient or Client Identifier: _____

Surname: _____

Other names: _____

Date of Birth: _____ Sex: _____
Male ☐ Female ☐

Address: _____

MENTAL HEALTH

Date completed: ____ / ____ / ____

Instructions

The following ten questions ask about how you have been feeling in the **last four weeks**. For each question, mark the circle under the option that best describes the amount of time you felt that way.

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
1. In the last four weeks, about how often did you feel tired out for no good reason?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. In the last four weeks, about how often did you feel nervous?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. In the last four weeks, about how often did you feel so nervous that nothing could calm you down?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. In the last four weeks, about how often did you feel hopeless?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. In the last four weeks, about how often did you feel restless or fidgety?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. In the last four weeks, about how often did you feel so restless you could not sit still?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. In the last four weeks, about how often did you feel depressed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. In the last four weeks, about how often did you feel that everything was an effort?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

please turn over the page to continue

K10+LM SELF-REPORT MEASURE (1 of 2)

Binding margin – do not write

Module SR1 v2

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
9. In the last four weeks, about how often did you feel so sad that nothing could cheer you up?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. In the last four weeks, about how often did you feel worthless?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The next few questions are about how these feelings may have affected you in the **last four weeks**.

You need not answer these questions if you answered "None of the time" to all of the ten questions about your feelings.

11. In the last four weeks, how many days were you TOTALLY UNABLE to work, study or manage your day to day activities because of these feelings?	_____ (Number of days)
12. [Aside from those days], in the last 4 weeks, HOW MANY DAYS were you able to work or study or manage your day to day activities, but had to CUT DOWN on what you did because of these feelings?	_____ (Number of days)
13. In the last 4 weeks, how many times have you seen a doctor or any other health professional about these feelings?	_____ (Number of consultations)
14. In the last 4 weeks, how often have physical health problems been the main cause of these feelings?	<div>None of the time <input type="radio"/></div> <div>A little of the time <input type="radio"/></div> <div>Some of the time <input type="radio"/></div> <div>Most of the time <input type="radio"/></div> <div>All of the time <input type="radio"/></div>

Binding margin – do not write

Thank you for completing this questionnaire.

Please return it to the staff member who asked you to complete it.

Health of the Nation Outcome Scales (HoNOS)

HoNOS rating guidelines

- Rate items in order from 1 to 12.
- Use all available information in making your rating.
- Do not include information already rated in an earlier item.
- Consider both the degree of distress the problem causes and the effect it has on behaviour
- Rate the most severe problem that occurred in the period rated.
- The rating period is generally the preceding two weeks, except at discharge from inpatient care, when it is the previous three days.
- Each item is rated on a five-point item of severity (0 to 4) as follows:

0	No problem.
1	Minor problem requiring no formal action.
2	Mild problem.
3	Problem of moderate severity.
4	Severe to very severe problem.
9	Not known or not applicable.
- As far as possible, the use of rating point 9 should be avoided, because missing data make scores less comparable over time or between settings.
- Specific information on how to rate each point on each item is provided in the Glossary.

HoNOS glossary

1 Overactive, aggressive, disruptive or agitated behaviour

Include such behaviour due to any cause, e.g., drugs, alcohol, dementia, psychosis, depression, etc.

Do not include bizarre behaviour, rated at Scale 6.

- | | |
|---|---|
| 0 | No problems of this kind during the period rated. |
| 1 | Irritability, quarrels, restlessness etc. not requiring action. |
| 2 | Includes aggressive gestures, pushing or pestering others; threats or verbal aggression; lesser damage to property (e.g., broken cup or window); marked over-activity or agitation. |
| 3 | Physically aggressive to others or animals (short of rating 4); threatening manner; more serious over-activity or destruction of property. |
| 4 | At least one serious physical attack on others or on animals; destruction of property (e.g., fire-setting); serious intimidation or obscene behaviour. |

2 Non-accidental self-injury

Do not include accidental self-injury (due e.g., to dementia or severe learning disability); the cognitive problem is rated at Scale 4 and the injury at Scale 5.

Do not include illness or injury as a direct consequence of drug or alcohol use rated at Scale 3, (e.g., cirrhosis of the liver or injury resulting from drunk driving are rated at Scale 5).

- | | |
|---|--|
| 0 | No problem of this kind during the period rated. |
|---|--|

- 1 Fleeting thoughts about ending it all, but little risk during the period rated; no self-harm.
- 2 Mild risk during period; includes non-hazardous self-harm e.g., wrist-scratching.
- 3 Moderate to serious risk of deliberate self-harm during the period rated; includes preparatory acts e.g., collecting tablets.
- 4 Serious suicidal attempt or serious deliberate self-injury during the period rated.

3 Problem drinking or drug-taking

Do not include aggressive or destructive behaviour due to alcohol or drug use, rated at Scale 1.

Do not include physical illness or disability due to alcohol or drug use, rated at Scale 5.

- 0 No problem of this kind during the period rated.
- 1 Some over-indulgence, but within social norm.
- 2 Loss of control of drinking or drug-taking; but not seriously addicted.
- 3 Marked craving or dependence on alcohol or drugs with frequent loss of control, risk taking under the influence, etc.
- 4 Incapacitated by alcohol or drug problems.

4 Cognitive problems

Include problems of memory, orientation and understanding associated with any disorder: learning disability, dementia, schizophrenia, etc.

Do not include temporary problems (e.g., hangovers) resulting from drug or alcohol use, rated at Scale 3.

- 0 No problem of this kind during the period rated.
- 1 Minor problems with memory or understanding e.g., forgets names occasionally.
- 2 Mild but definite problems, e.g., has lost way in a familiar place or failed to recognise a familiar person; sometimes mixed up about simple decisions.
- 3 Marked disorientation in time, place or person, bewildered by everyday events; speech is sometimes incoherent, mental slowing.
- 4 Severe disorientation, e.g., unable to recognise relatives, at risk of accidents, speech incomprehensible, clouding or stupor.

5 Physical illness or disability problems

Include illness or disability from any cause that limits or prevents movement, or impairs sight or hearing, or otherwise interferes with personal functioning.

Include side-effects from medication; effects of drug/alcohol use; physical disabilities resulting from accidents or self-harm associated with cognitive problems, drunk driving etc.

Do not include mental or behavioural problems rated at Scale 4.

- 0 No physical health problem during the period rated.
- 1 Minor health problem during the period (e.g., cold, non-serious fall, etc).
- 2 Physical health problem imposes mild restriction on mobility and activity.
- 3 Moderate degree of restriction on activity due to physical health problem.
- 4 Severe or complete incapacity due to physical health problem.

6 Problems associated with hallucinations and delusions

Include hallucinations and delusions irrespective of diagnosis.

Include odd and bizarre behaviour associated with hallucinations or delusions.

Do not include aggressive, destructive or overactive behaviours attributed to hallucinations or delusions, rated at Scale 1.

- 0 No evidence of hallucinations or delusions during the period rated.
- 1 Somewhat odd or eccentric beliefs not in keeping with cultural norms.
- 2 Delusions or hallucinations (e.g., voices, visions) are present, but there is little distress to patient or manifestation in bizarre behaviour, that is, moderately severe clinical problem.
- 3 Marked preoccupation with delusions or hallucinations, causing much distress and/or manifested in obviously bizarre behaviour, that is, moderately severe clinical problem.
- 4 Mental state and behaviour is seriously and adversely affected by delusions or hallucinations, with severe impact on patient.

7 Problems with depressed mood

Do not include over-activity or agitation, rated at Scale 1.

Do not include suicidal ideation or attempts, rated at Scale 2.

Do not include delusions or hallucinations, rated at Scale 6.

- 0 No problems associated with depressed mood during the period rated.
- 1 Gloomy; or minor changes in mood.
- 2 Mild but definite depression and distress: e.g., feelings of guilt; loss of self-esteem.
- 3 Depression with inappropriate self-blame, preoccupied with feelings of guilt.
- 4 Severe or very severe depression, with guilt or self-accusation.

8 Other mental and behavioural problems

Rate only the most severe clinical problem not considered at items 6 and 7 as follows: specify the type of problem by entering the appropriate letter: **A** phobic; **B** anxiety; **C** obsessive-compulsive; **D** stress; **E** dissociative; **F** somatoform; **G** eating; **H** sleep; **I** sexual; **J** other, specify.

- 0 No evidence of any of these problems during period rated.
- 1 Minor non-clinical problems.
- 2 A problem is clinically present at a mild level, e.g., patient/client has a degree of control.
- 3 Occasional severe attack or distress, with loss of control e.g., has to avoid anxiety provoking situations altogether, call in a neighbour to help, etc., that is, a moderately severe level of problem.
- 4 Severe problem dominates most activities.

9 Problems with relationships

Rate the patient's most severe problem associated with active or passive withdrawal from social relationships, and/or non-supportive, destructive or self-damaging relationships.

- 0 No significant problems during the period.
- 1 Minor non-clinical problems.
- 2 Definite problems in making or sustaining supportive relationships: patient complains and/or problems are evident to others.
- 3 Persisting major problems due to active or passive withdrawal from social relationships, and/or to relationships that provide little or no comfort or support
- 4 Severe and distressing social isolation due to inability to communicate socially and/or withdrawal from social relationships.

10 Problems with activities of daily living

Rate the overall level of functioning in activities of daily living (ADL): e.g., problems with basic activities of self-care such as eating, washing, dressing, toilet; also complex skills such as budgeting, organising where to live, occupation and recreation, mobility and use of transport, shopping, self-development, etc.

Include any lack of motivation for using self-help opportunities, since this contributes to a lower overall level of functioning.

Do not include lack of opportunities for exercising intact abilities and skills, rated at Scale 11 and Scale 12.

- 0 No problems during period rated; good ability to function in all areas.
- 1 Minor problems only e.g., untidy, disorganised.
- 2 Self-care adequate, but major lack of performance of one or more complex skills (see above).
- 3 Major problems in one or more areas of self-care (eating, washing, dressing, toilet) as well as major inability to perform several complex skills.
- 4 Severe disability or incapacity in all or nearly all areas of self-care and complex skills.

11 Problems with living conditions

Rate the overall severity of problems with the quality of living conditions and daily domestic routine.

Are the basic necessities met (heat, light, hygiene)? If so, is there help to cope with disabilities and a choice of opportunities to use skills and develop new ones?

Do not rate the level of functional disability itself, rated at Scale 10.

***NB:** Rate patient's usual accommodation. If in acute ward, rate the home accommodation. If information not obtainable, rate 9.*

- 0 Accommodation and living conditions are acceptable; helpful in keeping any disability rated at Scale 10 to the lowest level possible, and supportive of self-help.
- 1 Accommodation is reasonably acceptable although there are minor or transient problems (e.g., not ideal location, not preferred option, doesn't like food, etc).
- 2 Significant problems with one or more aspects of the accommodation and/or regime (e.g., restricted choice; staff or household have little understanding of how to limit disability, or how to help develop new or intact skills).

- 3 Distressing multiple problems with accommodation (e.g., some basic necessities absent); housing environment has minimal or no facilities to improve patient's independence.
- 4 Accommodation is unacceptable (e.g., lack of basic necessities, patient is at risk of eviction, or 'roofless', or living conditions are otherwise intolerable making patient's problems worse).

12 Problems with occupation and activities

Rate the overall level of problems with quality of day-time environment. Is there help to cope with disabilities, and opportunities for maintaining or improving occupational and recreational skills and activities? Consider factors such as stigma, lack of qualified staff, access to supportive facilities, e.g., staffing and equipment of day centres, workshops, social clubs, etc.

Do not rate the level of functional disability itself, rated at Scale 10.

NB: Rate the patient's usual situation. If in acute ward, rate activities during period before admission. If information not available, rate 9.

- 0 Patient's day-time environment is acceptable; helpful in keeping any disability rated at Scale 10 to the lowest level possible, and supportive of self-help.
- 1 Minor or temporary problems, e.g., late pension cheques, reasonable facilities available but not always at desired times etc.
- 2 Limited choice of activities, e.g., there is a lack of reasonable tolerance (e.g., unfairly refused entry to public library or baths etc.); or handicapped by lack of a permanent address; or insufficient carer or professional support; or helpful day setting available but for very limited hours.
- 3 Marked deficiency in skilled services available to help minimise level of existing disability; no opportunities to use intact skills or add new ones; unskilled care difficult to access.
- 4 Lack of any opportunity for daytime activities makes patient's problem worse.

Appendix 5: Consent Forms and Subject Information Sheets



RESEARCH STUDY INTO PHARMACISTS' PARTICIPATION IN CASE CONFERENCES

CLIENT INFORMATION SHEET

You are invited to take part in a study into "*Pharmacists' participation in case conferences*". The objective is to assess the contribution that pharmacists can make in meetings between health care professionals in your Mental Health Service. The study is being conducted by Mr Simon Bell, Ms Paula Whitehead, Dr Timothy Chen and Dr Parisa Aslani. It will also be part of a student's work towards the degree of Doctor of Philosophy (PhD) at the University of Sydney.

To participate, your case manager will ask you to complete a questionnaire (Kessler 10) twice during the study and will present your information at the regular meetings with your mental health staff. The pharmacist will provide suggestions about your medicines to ensure you can get the most benefit from them. To be able to provide this service, the pharmacist will need to have access to certain information about you. This will include the diagnoses that the doctor has made for your conditions and relevant test results. These meetings will be audio-tape recorded.

The researchers will also need information from the Health Insurance Commission (on your use of Medicare and Pharmaceutical Benefits Services). It will also include any details of hospital visits you may have had recently and medicines you may have received from any pharmacies.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants except as required by law. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study is entirely voluntary: you are not obliged to participate and - if you do participate - you can withdraw at any time, without needing to provide a reason. Whatever your decision, it will not affect your treatment at the centre in any way. If you do withdraw from the study you may request that any information already collected about you is destroyed.

When you have read this information, the researcher will discuss it with you further and answer any questions you may have. Please feel free to contact any of the following people:

Mr Simon Bell	(02) 9036 7081
Ms Paula Whitehead	(08) 9266 7369
Dr Timothy Chen	(02) 9351 4440
Dr Parisa Aslani	(02) 9351 6711

This information sheet is for you to keep.

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.
--



RESEARCH STUDY INTO PHARMACISTS' PARTICIPATION IN CASE CONFERENCES

HEALTH CARE PROFESSIONAL SUBJECT INFORMATION SHEET

You are invited to take part in a research study into "*Pharmacists' participation in case conferences*". The objective is to assess the contribution that pharmacists can make in case conference meetings between doctors, and other health care professionals in Community Mental Health Centres. The study is being conducted by Mr Simon Bell, Ms Paula Whitehead, Dr Timothy Chen and Dr Parisa Aslani, and will form the basis for the degree of Doctor of Philosophy at the University of Sydney.

If you agree to participate in this study, you will be asked to participate in case conference meetings at your local Community Mental Health Centre every fortnight for between two and four hours, over a period of 24 weeks. Each of the case conferences will be audio-tape recorded.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants except as required by law. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study is entirely voluntary: you are not obliged to participate and - if you do participate - you can withdraw at any time, without needing to provide a reason. Whatever your decision, it will not affect your relationship with medical staff at the centre. If you do withdraw from the study you may request that any information already collected about you is destroyed.

When you have read this information, the researcher will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact any of the following people:

Mr Simon Bell	(02) 9036 7081
Ms Paula Whitehead	(08) 9266 7369
Dr Timothy Chen	(02) 9351 4440
Dr Parisa Aslani	(02) 9351 6711

This information sheet is for you to keep.

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.
--



CLIENT PARTICIPANT CONSENT FORM

PHARMACISTS' PARTICIPATION IN CASE CONFERENCES

I, of
[name]

.....
[address]

Medicare number.....Date of birth.....

have read and understood the information for participants on the above named research study and
have discussed it

.....
[signature]

I am aware of the procedures involved in the study, including any inconvenience, risk, discomfort or
side effect, and of their implications.

I authorise the release of the following information, to the above project, from June 2004 to June 2006;

- Medical information from my doctor to the pharmacist providing the service for the project
- Details regarding the pharmaceutical services provided to me by my usual community pharmacists
- Pharmaceutical Benefits Scheme (PBS) data, Repatriation Pharmaceutical Benefits Scheme (RPBS) data and Medicare (MBS) data from the Health Insurance Commission and Department of Veterans Affairs (if applicable)
- Hospitalisation and treatment data from any hospitals I have received treatment from.

I understand that the project staff will have access to information about my medical service use (Medicare) and pharmaceutical use (Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme) which individually identifies me.

I freely choose to participate in this study and understand that I can withdraw without compromise at any time by contacting Mr Simon Bell on 9036-7081 or any other researcher listed on the information sheet.

I also understand that information collected about me is kept strictly confidential.

I hereby agree to participate in this research study.

Signature:

Name: **Date:**

Signature of witness:

Name of witness:

**Any person with concerns or complaints about the conduct of a research study can contact the
Manager for Ethics Administration, University of Sydney on (02) 9351 4811.**



HEALTH CARE PROFESSIONAL PARTICIPANT CONSENT FORM

PHARMACISTS' PARTICIPATION IN CASE CONFERENCES

I, of
[name]

.....
[address]

Medicare number.....Date of birth.....

have read and understood the information for participants on the above named research study and
have discussed it

.....
[signature]

I am aware of the procedures involved in the study, including any inconvenience, risk, discomfort or
side effect, and of their implications.

I freely choose to participate in this study and understand that I can withdraw without compromise at
any time by contacting Mr Simon Bell on 9036-7081 or any other researcher listed on the information
sheet.

I also understand that the research study is strictly confidential.

I hereby agree to participate in this research study.

Signature:

Name:..... **Date:**

Signature of witness:

Name of witness:

<p>Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.</p>
--



TITLE OF PROTOCOL: Collaboration between community pharmacists and mental health care practitioners: a case conferencing model

INFORMATION FOR PARTICIPANTS (*clients*)

You are invited to take part in a research study into the contribution made by pharmacists to meetings of health care professionals that routinely take place at your community mental health centre. The objective is to investigate whether pharmacists' involvement in mental health teams is associated with improvements in the safe and effective use of medications used to treat mental illness and other conditions (physical illness).

The study is being conducted by Mr Simon Bell, Dr Grenville Rose, Dr Paula Whitehead, Dr Parisa Aslani and Dr Timothy Chen at the Faculty of Pharmacy, The University of Sydney.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will be asked by your case manager to complete a questionnaire (Kessler-10) three times throughout the 24 week study period. The questionnaire takes about 5 minutes to complete each time.

In this study, community centres will be assigned to one of two groups. Centres in one group will receive standard pharmacy services. Centres in the second group will receive extra pharmacist input at case conference meetings with the other health care professionals that routinely take place at your centre. Centres in the second group will also continue to receive standard pharmacy services. The researchers will evaluate whether the additional pharmacist input helps to improve the safe and effective use of your medicines. You will know which group your community mental health centre has been assigned to.

In order to provide this service, the project pharmacists employed to work at the community mental health centre will need to access your medical and medication history. In order to evaluate the project, the research team may also request access to:

- Medical information provided by your doctor, including the completed Kessler-10 instruments.
- Details regarding your use of medications provided by your community mental health centre and local community pharmacies.
- Hospitalisation and treatment data from any hospitals you have received treatment from.

There are no disadvantages or risks envisaged with participating in this project.

The possible benefits of participating in the study are that the pharmacist will be able to provide additional information to your health professionals about the best use of the medicines you take for both mental and/or physical illnesses.

There is no risk of injuries envisaged with participating in the study.

Participation in this study will not cost you anything, nor will you be paid for participating.

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

Any new information about pharmacists' participation as members of community mental health teams that is relevant to your potential willingness to continue to participate in the study will be provided to you.

All the information collected from you for the study will be treated confidentially, and only the project pharmacist working at your community mental health centre and the researchers named above will have access to it. You may also be asked to provide consent for your GP and other health professionals to be informed that you are participating in the study.

If you do withdraw from the study you may request that any information already collected about you is destroyed. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation. Identification codes will be stored separately, away from the data.

If you require additional information after reading this information you may contact Mr Simon Bell on (02) 9036 7081 and he will answer any questions you may have. The other members of the research team may also be contacted; Dr Grenville Rose on (02) 90366382, Dr Paula Whitehead on (08) 9266 7369, Dr Parisa Aslani on (02) 9351 6711 and Dr Timothy Chen on (02) 9351 4440.

For further information you can also contact the pharmacist allocated to your community mental health centre Ms/Mr _____ on _____.

This information sheet is for you to keep.

Ethics Approval

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney South West Area Health Service. Any person with concerns or complaints about the conduct of this study should contact the Secretary on 02 9515 6766 and quote protocol number X06-0024.

Version No. : 1

Date: January 17, 2006



TITLE OF PROTOCOL: Collaboration between community pharmacists and mental health care practitioners: a case conferencing model

INFORMATION FOR PARTICIPANTS (*Pharmacists*)

You are invited to take part in a research study that will evaluate the contribution made by pharmacists to meetings of health care professionals that routinely take place at community mental health centres. The objective is to investigate whether pharmacists' involvement in mental health teams is associated with improvements in the safe and effective use of medications used to treat mental illness and other conditions (physical illness).

The study is being conducted by Mr Simon Bell, Dr Grenville Rose, Dr Paula Whitehead, Dr Parisa Aslani and Dr Timothy Chen at the Faculty of Pharmacy, The University of Sydney

If you agree to participate in this study, you will be asked to participate in case conference meetings at a local Community Mental Health Centre every fortnight for between two to four hours, over a period of 24 weeks. Each of the case conferences will be recorded using an audio tape or digital voice recorder.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information about participants except as required by law. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

You will be paid an hourly rate for your participation in the study that includes \$50/hr for the time spent preparing cases, visiting clients and collecting information, and \$80/hr for actual time spent participating in the team case conferences.

Participation in this study is voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason.

When you have read this information, Mr Simon Bell will discuss it with you and answer any questions you may have. If you would like more information at any stage please contact him on (02) 9036 7081. The other members of the research team may also be contacted; Dr Grenville Rose on (02) 90366382, Dr Paula Whitehead on (08) 9266 7369, Dr Parisa Aslani on (02) 9351 6711 and Dr Timothy Chen on (02) 9351 4440. This information sheet is for you to keep.

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney South West Area Health Service. Any person with concerns or complaints about the conduct of this study should contact the Secretary on 02 9515 6766 and quote protocol number X06-0024.

Version No. : 1
Date: January 17, 2005



TITLE OF PROTOCOL: Collaboration between community pharmacists and mental health care practitioners: a case conferencing model

INFORMATION FOR PARTICIPANTS (*Mental Health Community Centres*)

You are invited to take part in a research study into the contribution made by pharmacists to meetings of health care professionals that routinely take place at your community mental health centre. The objective is to investigate whether pharmacists' involvement in mental health teams is associated with improvements in the safe and effective use of medications used to treat mental illness and other conditions (physical illness).

The study is being conducted by Mr Simon Bell, Dr Grenville Rose, Dr Paula Whitehead, Dr Parisa Aslani and Dr Timothy Chen at The Faculty of Pharmacy, The University of Sydney.

If you agree to participate in this study, you will be asked to allow a designated pharmacist to participate in case conference meetings at your Community Mental Health Centre every fortnight for between two and four hours, over a period of 24 weeks. Each of the case conferences for those clients who have consented to participate in the study will be recorded using audio tape or digital voice recorder.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information about participants except as required by law. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study will not cost you anything, nor will you be paid.

Participation in this study is voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason.

When you have read this information, Mr Simon Bell will discuss it with you and answer any questions you may have. If you would like more information at any stage please contact him on (02) 9036 7081. The other members of the research team may also be contacted; Dr Grenville Rose on (02) 90366382, Dr Paula Whitehead on (08) 9266 7369, Dr Parisa Aslani on (02) 9351 6711 and Dr Timothy Chen on (02) 9351 4440.

This information sheet is for you to keep.

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney South West Area Health Service. Any person with concerns or complaints about the conduct of this study should contact the Secretary on 02 9515 6766 and quote protocol number X06-0024.

Version No. : 1

Date: January 17, 2006



TITLE OF PROTOCOL: *Collaboration between community pharmacists and mental health care practitioners: a case conferencing model*

PARTICIPANT CONSENT FORM (clients)

I, [name]

of
.....[address]

have read and understood the Information for Participants on the above named research study

and have discussed the study with

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I understand that my participation in this study will allow the researchers to have access to my medical record, and access to information about my medical service use and I agree to this.

My date of birth is

I freely choose to participate in this study and understand that I can withdraw at any time.

I also understand that the research study is strictly confidential.

I hereby agree to participate in this research study.

NAME:

SIGNATURE:

DATE:

NAME OF WITNESS:

SIGNATURE OF WITNESS:

Version No. : 1

Date: January 17, 2006



TITLE OF PROTOCOL: Collaboration between community pharmacists and mental health care practitioners: a case conferencing model

PARTICIPANT CONSENT FORM (Pharmacist)

I, [name]

of

.....[address]

have read and understood the Information for Health Care Provider Participants on the above named research study

and have discussed the study with

I have been made aware of the procedures involved in the study.

I understand the case conferences that I participate in may be audiotape recorded.

I hereby agree to participate in this research study.

I freely choose to participate in this study and understand that I can withdraw at any time.

I also understand that the research study is strictly confidential.

I hereby agree to participate in this research study.

NAME:

SIGNATURE:

DATE:

NAME OF WITNESS:

SIGNATURE OF

Version No. : 1

Date: January 17, 2006



TITLE OF PROTOCOL: Collaboration between community pharmacists and mental health care practitioners: a case conferencing model

PARTICIPANT CONSENT FORM (*Manger of Community Centre*)

I, [name]

of

.....
[community centre and address]

have read and understood the Information for Health Care Provider Participants on the above named research study

and have discussed the study with

I have been made aware of the procedures involved in the study.

I hereby agree that the team of the above mentioned Mental Health Community Centre that is under my management participate in this research study.

I have made this decision in consultation with the team members and I understand that I can withdraw this decision at any time and if any of the team members requests me to do so.

I also understand that the research study is strictly confidential.

NAME:

SIGNATURE:

DATE:

NAME OF WITNESS:

Version No. : 1
Date: January 17, 2006



June 24, 2005
Version 1

Client Participant Information Sheet

This participant information sheet is for you to take home. You will also be given a copy of the signed consent form for you to keep.

1. The name of the study is ***"Pharmacists' participation in case conferences"***.
2. You are being invited to participate in this study being conducted by the Faculty of Pharmacy at the University of Sydney.
3. The purpose of the study is to assess the contribution made by pharmacists to meetings of health care professionals that routinely take place in your community mental health centre. The information obtained from this study will be used to optimise the delivery of pharmacy services to community mental health centres.
4. International experience suggests that pharmacists' involvement in mental health teams is associated with improvements in the safe and effective use of medications used to treat mental illness.
5. Your community mental health centre will be randomly assigned to receive additional input from a pharmacist or to continue to receive the standard pharmacy service. You will know whether your centre has been assigned to receive additional input from a pharmacist or the standard pharmacy service.
6. Your case manager will seek your consent to participate in the study. This may be because your case manager believes that you and your health professionals would be interested to receive more information about the medicines you take. Each community mental health centre will be asked to seek consent from up to 18 consumers to participate. Ten community mental health centres in total be selected to participate in the project.
7. Your participation in this study is entirely voluntary: you are not obliged to participate. You may withdraw from the study at any time, without necessarily providing a reason. Your participation in the project will be not associated with any financial expense.
8. The study will last for 24 weeks. During the study a pharmacist will visit your community mental health centre for one day every two weeks. You will not need to be present at the community mental health centre when the pharmacist visits.

9. If you choose to take part in the study, your case manager will ask you to complete two questionnaires (Kessler 10 and HoNOS) up to three times during the study.
10. The pharmacist will provide suggestions about your medicines at meetings of health professionals that routinely occur at your community mental health centre. This is to help ensure you get the most benefit from your medicines. To be able to provide this service, the pharmacist will need to have access to certain information about you. This will include the diagnoses that the doctor has made for your conditions and relevant test results. In order to analyse the value of the pharmacists' service, these meetings will be audio-tape recorded. The researchers will also need information from the Health Insurance Commission (on your use of Medicare and Pharmaceutical Benefits Services). This may include details of hospital visits you may have had recently, and details about medicines you may have had dispensed from any pharmacies.
11. If you choose not to participate in the study, you and your community mental health centre will continue to receive the standard pharmacy service. Choosing not to participate will not affect the treatment you presently receive.
12. There are no disadvantages or risks envisaged with participating in the study.
13. The possible benefits of participating in the study are that the pharmacist will be able to provide additional information to your health professionals about the best use of the medicines you take for both mental and/or physical illnesses. This information may help you gain the most benefit from your medicines that you take.
14. If you decide to participate in the study you can withdraw at any time, without needing to provide a reason. If you do withdraw from the study you may request that any information already collected about you is destroyed. Any new information about pharmacists' participation as members of community mental health teams that is relevant to your potential willingness to continue to participate in the study will be provided to you. The researchers will assess the overall impact of this information when deciding whether or not to continue the study.
15. At the conclusion of the research project your community mental health centre will continue to receive standard pharmacy services.
16. If you have any complaints about the study then you may contact the Northern Sydney Health Patient Representative on (02) 9926 7612, or the Manager for Ethics Administration at the University of Sydney on (02) 9351 4811.
17. Your participation in the project will be kept strictly confidential. Only the pharmacist and those health professionals working at your community mental health centre will have access to your medical records, although you may also be asked to provide consent for your GP and other health professionals to be informed that you are participating in the study. All data collected as part of the study will be de-identified and stored in a secure location at The University of Sydney. Results published will be of de-identified or group data only. Audio tapes will be erased after transcription, and any names or identifying features will be erased before transcription. Identification codes will be stored separately, away from the data.

18. Feedback and results from the study will be made available through the final report published at the conclusion of the study. De-identified group data may also be published in peer reviewed journals and presented at scientific conferences.
19. The study is being conducted by Mr Simon Bell, Ms Paula Whitehead, Dr Timothy Chen and Dr Parisa Aslani from the Faculty of Pharmacy at The University of Sydney. The research is being funded by the Commonwealth Department of Health and Ageing through a research grant provided as part of the Third Community Pharmacy Agreement. Pharmacists who are participating in the research project will be paid for their time and expertise. Other health professionals working at the community mental health centres will not benefit financially from your participation in the study.
20. The study has been reviewed by the Northern Sydney Health Human Research Ethics Committee and the Human Research Ethics Committee at the University of Sydney.
21. If you require any further information about the study please contact one of the researchers listed below:

Mr Simon Bell (02) 9036 7081
Ms Paula Whitehead (08) 9266 7369
Dr Timothy Chen (02) 9351 4440
Dr Parisa Aslani (02) 9351 6711



June 24, 2005
Version 1

Client Consent Form to Participate in a Research Project

I, _____
(name of participant)

of _____
(street) (suburb/town) (state & postcode)

(Medicare number)

have been invited to participate in a research project entitled

Pharmacists' participation in case conferences

In relation to this project I have read the "Client Participant Information Sheet" and have been informed of the following points:

1. Approval for the protocol has been given by the Human Research Ethics Committee (HREC) of Northern Sydney Health
2. The aim of the project is to assess the contribution made by pharmacists to meetings of health care professionals that routinely take place in your community mental health centre.
3. The results obtained from the study may or may not be of direct benefit to my medical management.
4. The study will involve a pharmacist providing information and discussing the medications that I take at meetings of health professionals that routinely occur at my community mental health centre.
5. There are no disadvantages or risks envisaged with participating in the study.
6. My consent to participate in this project may be withdrawn at any time, without necessarily having to provide a reason.
7. Should I develop a problem which I suspect may have resulted from my involvement in this study I am aware that I may contact:

Mr Simon Bell at the University of Sydney on (02) 9036 7081.

Date: _____ Witness: _____
(Please print name)

Signature: _____ Signature: _____
(of participant) (of witness)

8. Should I have any problems or queries about the way in which the study was conducted, and I do not feel comfortable contacting the research staff, I am aware that I may contact the Northern Sydney Health Patient Representative who is an independent person within Royal North Shore Hospital on 9926 7612 or the Ethics Manager on 992 68106.
9. I can refuse to take part in this study or withdraw from it at any time without affecting my medical care.
10. I understand that participating in this study of pharmacists' contribution to community mental health teams may or may not benefit my medical treatment directly; however, my participation may assist in the development of team procedures for the future.
11. Participation in this study will not result in any extra medical and hospital costs to me.
12. All data collected as part of the study will be de-identified and stored in a secure location at The University of Sydney. Audio tapes will be erased after transcription, and any names or identifying features will be erased before transcription.
13. I consent to the collection, processing, reporting and transfer within or outside Australia of my personal and/or sensitive information for healthcare and/or medical research purposes. I authorise the release of the Pharmaceutical Benefits Scheme (PBS) data, Repatriation Pharmaceutical Benefits Scheme (RPBS) data and Medicare (MBS) data from the Health Insurance Commission and Department of Veterans Affairs for the period June 2004 to June 2006.
14. All data to be transferred by the research team during the course of the study will be de-identified, therefore not including my name, address or phone number. My information will be identified a numerical random code. Identification codes will be stored separately, away from the data.
15. If the results of my tests or information regarding my medical history are published, my identity will not be revealed. Results published will be of de-identified or group data only.
16. During the course of this study, I will be informed of any significant new findings (either good or bad) such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause me to change my mind about participating. If such new information is provided to me, my consent to participate will be re-obtained.
17. In giving my consent, I acknowledge that only the pharmacist and health professionals working at community mental health centre may examine my medical records.
18. I declare that I am over the age of 18 years.

After considering all these points, I accept the invitation to participate in this project.

I am aware that I will be given a copy of the Participant Information Sheet and Consent Form.

I also state that I have/have not participated in any other research project in the past 3 months.

If I have, the details are as follows: _____

Date: _____

Witness: _____
(Please print name)

Signature: _____
(of participant)

Signature: _____
(of witness)

Investigators confirming statement:

I have given this research subject information on the study, which in my opinion is accurate and sufficient for the subject to understand fully the nature, risks and benefits of the study, and the rights of a research subject. There has been no coercion or undue influence. I have witnessed the signing of this document by the subject.

Date: _____

Investigator's Name: _____

Investigator's Signature: _____

Withdrawal from Participation

Protocol Title: **Pharmacists' participation in case conferences**

An option should I wish to withdraw my consent to participate in the research protocol entitled above is to contact the researcher and/or return this slip. I understand that if I withdraw from the research protocol my medical care, my relationship with the Hospital and medical attendants will not be affected.

Patient's Name: _____

Patient's Signature: _____

Date: _____

Please detach the Withdrawal of Participation Section and send to Mr Simon Bell, Faculty of Pharmacy A15, The University of Sydney NSW 2006, or if I would like to speak to a member of the study investigation team I may contact Simon Bell on (02) 9036 7081.

Appendix 6: Qualitative Semi-structured Interview Guides

Focus Group / Semi-structured Interview Guide

Pharmacists

Thanks for your involvement in the study ...

We want to get some feedback on your thoughts, personal reflections, how to improve the service etc

What role should pharmacists play in mental health sector?

- How can this happen?
- What sort of knowledge / training is required?
- What role do you see yourself as having?

What were the good aspects of the study?

- New role – should pharmacists be involved?
- Profession satisfaction
- Case manager interactions – what did they get out of the study
- Patients – what did they get out of the study
- Psychiatrists – what did they get out of the study
- Knowledge – improved? What are the requirements?
- Training – what sort of requirements?

What were the difficult aspects / challenges of the study?

- Logistics
- Case manager interactions
- Patients
- Psychiatrists
- Data collection
- Knowledge / training requirements

What did you personally get out of the study?

- What did you want to get out of the study?

Would you want to continue to work in the mental health sector? Why?

What do you think the XXXX got out of the study?

- Case managers
- Psychiatrists
- Centre

How could the service be improved? How could the study be improved?

Other thoughts on the study ... pharmacists role in mental health.

Thank you.

Focus Group / Semi-structured Interview Guide

Case Managers

Thanks for your involvement in the study ...

We want to get some feedback on your thoughts, personal reflections, on the value of the contributions (if any) made by the pharmacists who participated in your CMHT

As you know, pharmacists are usually not formally involved in CMHT and in this study we attempted to explore whether or not pharmacists can contribute ...

What role should pharmacists play in mental health sector?

- How can this happen?
- Do pharmacists require additional training ... knowledge to be involved in mental health sector?
- Is there a place for pharmacists to be members of the team in a longer term sense
- Any other roles – beyond the completion of this study

What were the good aspects of the study?

- New role – should pharmacists be involved?
- What did pharmacists get out of study
- What did case managers get out of pharmacist involvement in study
- Patients – what did they get out of the study
- Psychiatrists – what did they get out of the study
- Drug knowledge – improved?

What were the difficult aspects / challenges of the studies?

- Logistics
- Pharmacist / Case manager
- Patients
- Psychiatrists
- Data collection
- Teamwork – dynamic – were there any issues?
- Knowledge / training requirements

What did you personally get out of the study?

- What did you want to get out of the study?
- Did you have / what expectations did you have?
- What about Patients? Psychiatrists? Pharmacists?

Would you want pharmacists to continue to work in the mental health sector? Why?

How could the service be improved? How could the study be improved?

Other thoughts on the study ... pharmacists role in mental health ...

Thank you.

Semi-structured Interview Guide

Psychiatrists / Other HCP

Thanks for your support of this study ...

We want to get some feedback on your thoughts, personal reflections, on the value of the contributions (if any) made by the pharmacists to the mental health sector

As you know, pharmacists are usually not formally involved in CMHTs and in this study we attempted to explore whether or not pharmacists can contribute ...

What role should pharmacists play in mental health sector?

- How can this happen?
- Do pharmacists require additional training ... knowledge to be involved in mental health sector?
- Is there a place for pharmacists to be members of the team in a longer term sense
- Any other roles – beyond the completion of this study

What were the good aspects of the study?

- New role – should pharmacists be involved?
- What did pharmacists get out of study
- What did you as a psychiatrist / case managers get out of pharmacist involvement in study
- Patients – what did they get out of the study
- Drug knowledge – can pharmacists contribute?

What were the difficult aspects / challenges of the studies?

- Logistics
- Pharmacist / Case manager / psychiatrists
- Patients
- Teamwork – dynamic – were there any issues?
- Data collection
- Knowledge / training requirements

Did you personally get anything out of the study?

- What did you want to get out of the study?
- Did you have / what expectations did you have?
- What about Patients? Case managers? Pharmacists?

Would you want pharmacists to continue to work in the mental health sector? Why?

How could the service be improved? How could the study be improved?

Other thoughts on the study ... pharmacists role in mental health ...

Thank you.

Appendix 7: Peer-reviewed Scientific Publications

Review

Open Access

Community pharmacy services to optimise the use of medications for mental illness: a systematic review

Simon Bell*¹, Andrew J McLachlan¹, Parisa Aslani¹, Paula Whitehead² and Timothy F Chen¹

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Email: Simon Bell* - simon@pharm.usyd.edu.au; Andrew J McLachlan - andrewm@pharm.usyd.edu.au;

Parisa Aslani - parisa@pharm.usyd.edu.au; Paula Whitehead - paulaw@pharm.usyd.edu.au; Timothy F Chen - timchen@pharm.usyd.edu.au

* Corresponding author

Published: 07 December 2005

Received: 20 July 2005

Australia and New Zealand Health Policy 2005, 2:29 doi:10.1186/1743-8462-2-29

Accepted: 07 December 2005

This article is available from: <http://www.anzhealthpolicy.com/content/2/1/29>

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Abstract

The objective of this systematic review was to evaluate the impact of pharmacist delivered community-based services to optimise the use of medications for mental illness. Twenty-two controlled (randomised and non-randomised) studies of pharmacists' interventions in community and residential aged care settings identified in international scientific literature were included for review. Papers were assessed for study design, service recipient, country of origin, intervention type, number of participating pharmacists, methodological quality and outcome measurement. Three studies showed that pharmacists' medication counselling and treatment monitoring can improve adherence to antidepressant medications among those commencing treatment when calculated using an intention-to-treat analysis. Four trials demonstrated that pharmacist conducted medication reviews may reduce the number of potentially inappropriate medications prescribed to those at high risk of medication misadventure. The results of this review provide some evidence that pharmacists can contribute to optimising the use of medications for mental illness in the community setting. However, more well designed studies are needed to assess the impact of pharmacists as members of community mental health teams and as providers of comprehensive medicines information to people with schizophrenia and bipolar disorder

Introduction

Mental and behavioural disorders are estimated to account for 12% of the global burden of disease [1]. More than 450 million people worldwide suffer from a diagnosable mental illness, and four of the six leading causes of years lived with disability are due to neuropsychiatric disorders [1]. Much of the burden of mental illness is managed in the community setting. In 2003–04 mental health related medications accounted for 10.9% (17.8 million) of all medications prescribed by general medical practi-

tioners in Australia [2]. Although community care offers many advantages over institutional care, community care can place extra demands on family, friends and primary health practitioners [3]. Health professionals have identified people with mental illness as among their most challenging patients to manage [4]. Improving the quality and accessibility of community care for people with mental illnesses is an aim outlined in the parliamentary report *Mental Health Services in New South Wales* [5].

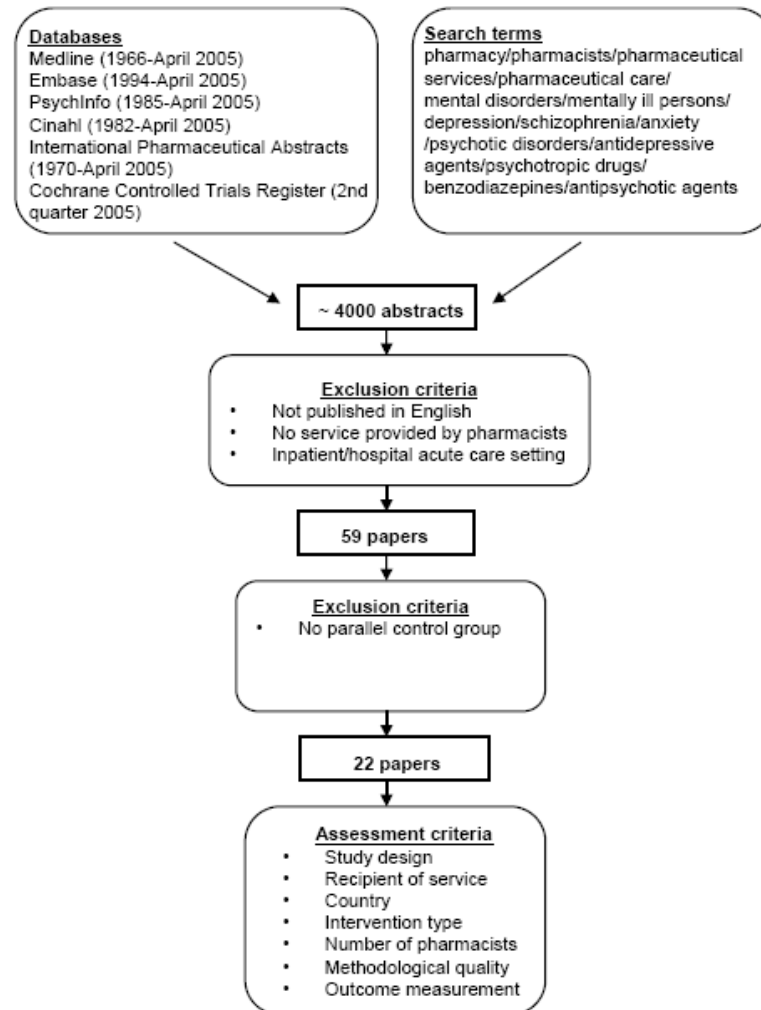


Figure 1
Literature search strategy and review procedure.

The appropriate use of medications is central to the effective management of mental illnesses, however, there is evidence that psychotropic medications are often used inappropriately [6,7]. Elderly people are especially sensitive to the effects of psychotropic medications, and may be susceptible to adverse reactions including cardiac toxicity, confusion and unwanted sedation [8]. Psychosocial problems, the emergence of side effects, and the delayed onset of action of anti-depressant medications, may be contributing factors in high rates of medication non-adherence [9,10]. Medical co-morbidity is also common, and polypharmacy increases the risk of drug-drug interactions and medication misadventure [11].

The World Health Organization (WHO) has recognised including pharmacists as active members of the health care team as one approach to improving psychotropic medication use [6]. The National Strategy for the Quality Use of Medicines in Australia highlights the importance of a multidisciplinary approach to improving medication use [12]. The development of new roles for pharmacists has expanded the opportunities for pharmacists to provide community-based services to users of psychotropic medications. The Third Community Pharmacy Agreement, signed between the Australian Government and Pharmacy Guild of Australia in 2000, provided remuneration for pharmacists in Australia to conduct medication management reviews in the community setting (referred to as 'Home Medicines Review') and to provide consumer medicine information (CMI) [13]. Residential medication management reviews, initially funded through the Second Community Pharmacy Agreement in 1995, are available to all permanent residents of accredited aged care facilities in Australia [14]. A systematic review of the role of pharmacists in mental health care, published in 2003, concluded that pharmacists can bring about improvements in the safe and efficacious use of psychotropic medications [15]. The review included seven studies conducted for hospital inpatients and nine studies conducted in residential aged care or outpatient settings. Since that time pharmacists and pharmacy practice researchers have developed additional community pharmacy services in speciality areas. This has corresponded with a significant increase in the volume of published research on community-based services provided by pharmacists relating to mental health. The objective of this systematic review was to specifically evaluate the impact of pharmacist delivered *community-based* services to optimise the use of medications for mental illness.

Methods

Literature search strategy

Medline (1966-April 2005), Embase (1994-April 2005), PsychInfo (1985-April 2005), Cinahl (1982-April 2005), International Pharmaceutical Abstracts (1970-April 2005)

and the Cochrane Controlled Trials Register (2nd quarter 2005) were searched using text words and MeSH headings including: *pharmacy, pharmacists, pharmaceutical care, pharmaceutical services, mental disorders, mentally ill persons, depression, schizophrenia, psychotic disorders, antidepressive agents, psychotropic drugs, benzodiazepines, anxiety and anti-psychotic agents*. Reference lists of retrieved articles were checked for additional studies not identified in the original database search. If the abstract clearly indicated that the study did not relate to pharmaceutical services provided by pharmacists to optimise the use of medications for mental illness, or if the study was conducted in an acute inpatient or hospital setting, then the study was excluded at this stage.

Inclusion criteria and review procedure

Studies published in English, with a parallel control group (randomised and non-randomised) that reported the provision of services by pharmacists in community and residential aged care settings were considered. This included trials specifically conducted for individuals with a mental illness, or that reported outcomes in terms of changes to mental health symptoms, and studies of medication reviews and education initiatives to optimise the use of medications commonly prescribed for mental illness. Papers that reported pharmacists' activities as part of multidisciplinary teams were included where a pharmacist or pharmacists provided a service specifically related to optimising the use of medications for mental illness. Studies of pharmacists' interventions in residential aged care facilities were included, because community pharmacists frequently provide services to residential aged care facilities, but studies evaluating pharmacists' services in hospital inpatient or acute care settings were excluded. Studies without control groups, before and after studies, descriptive studies, results of postal surveys and qualitative interviews were excluded, as were studies to optimise medication use that did not involve a service provided by pharmacists. Each study meeting the criteria outlined above was assessed on the basis of study design, service recipient, country of origin, intervention type, number of participating pharmacists, methodological quality and outcome measurement. An overview of the literature search strategy and review procedure is presented in Figure 1.

Results

The literature search identified 59 papers that reported or discussed community pharmacy services to optimise the use of medications for mental illness. Twenty-two papers reported the results of studies that met the inclusion criteria for the review. Studies that met the inclusion criteria were approximately equally divided between services provided to consumers (n = 10) (Table 1), and services provided to other health care professionals (n = 12) (Table 2).

Table 1: Services provided to consumers

Reference	Country	Design	Setting	Service	No. Ph	Sample size	Main outcome measures	Significant outcomes
Brook et al, (2003)	NL	RCT	CP	PE	19	64 Int 71 Cont	Attitudes to AD	Improved attitudes
Brook et al, (2003)	NL	RCT	CP	PE	19	64 Int 71 Cont	Depressive symptoms	Improvements in depressive symptoms (significance dependent on treatment of missing data)
Brook et al, (2005)	NL	RCT	CP	PE	19	64 Int 71 Cont	AD adherence, depressive symptoms	Improved adherence among those that completed pharmacist intervention. Intention to treat analysis no difference.
Finley et al, (2002)	USA	CT	HMO	PE/TM	2	91 Int 129 Cont	AD adherence, resource utilisation, depressive symptoms, medication switch rates, patient satisfaction.	Improved adherence, higher medication switch rates, decline in patient visits to primary care providers, improved patient satisfaction
Finley et al, (2003)	USA	RCT	HMO	PE/TM	2	75 Int 50 Cont	AD adherence, resource utilisation, depressive symptoms, patient satisfaction, medication costs.	Improved adherence, improved patient satisfaction
Capoccia et al, (2004)	USA	RCT	PCM	PE/TM	2	41 Int 33 Cont	AD adherence, resource utilisation, depressive symptoms, quality of life, patient satisfaction.	
Adler et al, (2004)	USA	RCT	PCM	PE/TM	5	268 Int 265 Cont	AD use rates, depressive symptoms.	Improved AD use rate.
Rosen et al, (1978)	USA	CT	CMH	PE/TM	1	30 Int 152 Cont	Patient well-being, patient satisfaction, quantity and cost of service provision.	Intervention patients' had higher personal adjustment scores, were 'better since coming to clinic' and less likely to need further help.
Razali et al, (1995)	Malaysia	RCT	OP	PE	1	85 Int 80 Cont	Relapses requiring hospital readmission.	Fewer relapses requiring hospitalisation in intervention group.
Shaw et al, (2000)	UK	RCT	OP	PE/CA	1	51 Int 46 Cont	Medication knowledge, medication related problems, adherence, hospital readmission.	

RCT = randomised controlled trial; CT = controlled trial; CP = community pharmacy; HMO = health maintenance organisation; PCM = primary care medical centre; CMH = community mental health centre; OP = outpatients' clinic; NL= The Netherlands; PE = patient education; TM = treatment monitoring; ca = care planning; Ph = pharmacists; Int = intervention group; Cont = control group; AD = antidepressant medication.

All but one included study were conducted in developed countries, and 15 of the 22 papers were published in the last six years. Thirty-seven papers were excluded from the review for the following reasons. Thirteen papers reported data from descriptive studies [16-28] and nine papers reported outcomes of qualitative interviews or focus groups [29-37]. Five papers reported results of before and

after interventions or were cohort studies without parallel control groups [38-42]. Six papers reported results of postal surveys [43-48]. Three papers presented study methods only [49-51], and one study was conducted by pharmacy researchers but did not report the outcomes of a service provided by pharmacists [52].

Papers that met the review inclusion criteria reported the outcomes of medication counselling by community pharmacists at the time of dispensing, education and monitoring activities conducted at primary care medical centres and staff model health maintenance organisations (HMOs), discharge medication counselling, and medication monitoring at a community mental health centre. Pharmacist delivered services provided to other health professionals included medication reviews and outreach education activities designed to optimise prescribing. Several medication review studies reported impacts of pharmacists' interventions in terms of changes in prescribing of medications commonly used to treat mental illness and/or changes in mental health symptoms, but were not specifically targeted to people with a mental illness. Several small studies of pharmacists' medication review activities specifically conducted for people with a mental illness did not meet the review inclusion criteria [17,18,20,22,41,42].

Services provided in community pharmacies

Three papers reported results of community pharmacists' medication counselling sessions for people commencing non-tricyclic antidepressant therapy in The Netherlands [53-55]. Intervention patients participated in three counselling sessions (lasting between 10 and 20 minutes each) and received a take-home video that emphasised the importance of medication adherence. The medication counselling sessions involved pharmacists informing patients about the appropriate use of their medication. This included providing information about the benefits of taking the medication, informing patients about potential side-effects, informing patients about the onset of action for antidepressant medications and reinforcing the need for patients to take their medication on a daily basis. At three month follow-up the intervention patients had significantly more positive drug attitudes than controls [53], and at six months this corresponded with significantly greater medication adherence among those patients that remained in the study [55]. An intention to treat analysis, however, showed no significant intervention effect on medication adherence. Medication adherence was measured using an electronic pill container that recorded the time and frequency that the cover was opened. Analysis of psychological symptoms at the six month follow-up was inconclusive, with apparent improvements in symptom scores not replicated using an alternate method of analysis [54]. Randomisation occurred at the patient level, and neither pharmacists nor patients were blinded to their group allocation. A limitation of this method was that the same pharmacists provided services to both control and intervention patients. As the intervention studied was multifactorial, it was not clear whether the three face-to-face medication counselling sessions conducted by the pharmacists, or the "take-home" videos, were primarily

responsible for changes in drug attitude, adherence and the symptoms scores observed.

Services provided at medical centres and health maintenance organisations

Four studies reported patient education and treatment monitoring services for people prescribed antidepressant medications in the United States [56-59]. The patient education and treatment monitoring involved the pharmacists taking a medication history, providing information about the prescribed antidepressant medications, and conducting telephone and face-to-face follow-up. Two of the four studies, one controlled [56] and the other randomised controlled [57], were conducted at a staff model health maintenance organisation (HMO). Pharmacists' interventions in both studies were associated with significant improvements in adherence to antidepressant medications when calculated at the end of the six-month study periods. Medication adherence was calculated by reviewing prescription dispensing data, and reported using an intention-to-treat analysis. Both studies also demonstrated that involvement of the pharmacist was associated with a decrease in the number of visits to other primary care providers, although statistical significance was only achieved in one of the studies [56]. The other two studies were conducted at primary care medical practices. In one study over 16,000 consecutive patients attending nine practices were screened for depression using a self administered health survey [58]. Patients identified as having depression or dysthymia who agreed to participate in the study ($n = 533$) were randomised to intervention or control groups. Intervention patients were significantly more likely to be taking antidepressants at the six month follow-up. Additionally, patients who were taking their antidepressants at the six month follow-up had better depression symptom scores than those who had discontinued, but the overall symptom scores between intervention and control groups were not significantly different. In the other randomised controlled study, improvements in antidepressant adherence and depression symptom scores were similar in both intervention and control groups [59]. In this study antidepressant adherence was measured by asking patients how many days they took their antidepressant medication in the past month.

Services provided at community mental health centres and outpatients' clinics

Three studies investigated the effect of pharmacist delivered services to community mental health centres and outpatients' clinics [60-62]. In a controlled trial, patients' case management by a pharmacist working at a community mental health centre in the United States had significantly better personal adjustment scores than those receiving case management from a nurse, social worker or psychologist [60]. They were also significantly less likely to need

help from other providers and rated themselves as more healthy. As part of the medication monitoring service provided, the pharmacist was allowed to adjust medication doses and dose timing, and prescribe or discontinue medications under supervision. Medication monitoring conducted by the pharmacist was estimated to cost 40% of equivalent medication monitoring conducted by the clinic psychiatrists when calculated on a per time basis. Although the pharmacist performed medication monitoring for more patients per month than the clinic psychiatrists, the pharmacist also spent longer per patient contact. This offset the overall cost savings of having a pharmacist perform the medication monitoring activities usually performed by a psychiatrist.

In a study of patients discharged home from hospital after admission for relapse of schizophrenia in Malaysia, those identified as having poor medication adherence were allocated to receive pharmacist medication counselling or standard care [61]. The importance of medication adherence was also reinforced by the patients' psychiatrists at follow-up visits, although it was not clear whether this applied only to intervention patients or both intervention and control patients. At the 12 month follow-up, patients who had been exposed to the intervention, and received a daily or twice daily medication treatment, had significantly fewer relapses that required hospitalisation than patients in the control group.

A study that evaluated the impact of providing mental health patients with a pharmacist generated medication care plan at the time of discharge found that patients with care plans were less likely to be readmitted to hospital than those without, however, this result was not statistically significant [62]. Information on the medication care plans included lists of discharge medications, a summary of the patient education that was provided, and the need to assess for specific potential adverse reactions. Community pharmacists who were provided copies of the care plans were also more likely to identify medication related problems for the discharged mental health patients than those pharmacists who were not provided copies of the care plans.

Medication review in domiciliary and residential aged care settings

Components of medication review services provided by pharmacists include comprehensive medication history taking, patient home interviews, medication regimen review, and patient education [63]. Medication review studies described in the review were conducted for residents of aged care facilities or for those individuals living independently in the community identified to be at high risk of medication misadventure.

In a randomised controlled study of pharmacist conducted domiciliary medication reviews in the United States there were significant declines in the overall numbers and monthly cost of medications, but no significant difference in cognitive or affective functioning between the intervention and control groups [64]. This may have been due in part to the relatively short (6 week) follow-up period. The authors noted that many patients were unwilling to follow the pharmacist's recommendations to discontinue benzodiazepines and narcotic analgesics. A randomised controlled study of a pharmacist-led multidisciplinary initiative to optimise prescribing in 15 Swedish aged care facilities resulted in a significant decline in the use of antipsychotics, benzodiazepines and antidepressants by 19%, 37% and 59% respectively in the intervention facilities [65]. The study involved pharmacists participating in multidisciplinary team meetings with nurses, nurses' assistants and physicians at regular intervals throughout the 12-month study period. A follow-up study of the same intervention and control facilities three years later indicated the intervention facilities maintained significantly higher quality of drug use, with lower proportions of residents prescribed more than three drugs that could lead to confusion, non-recommended hypnotics and combinations of interacting drugs [66]. Neither study reported estimates of cost or clinical outcomes. A cluster randomised controlled study of a multidisciplinary primary care intervention at a HMO in the United States included a quarterly pharmacist medication review to address the potentially inappropriate use of medications commonly prescribed for mental illness. The researchers found the intervention had no impact on depression scores and the numbers of high risk medications prescribed at the 12 week follow-up [67].

Two additional cluster randomised controlled studies of pharmacists' medication reviews in residential aged care facilities demonstrated significant reductions in the number and cost of medications prescribed [68-70]. In one study 10.2% fewer residents were administered psychoactive medications and 21.3% fewer hypnotic medications [68]. The impact of medication reviews on mortality was measured in both studies, and a significant reduction was noted in one [70]. Despite the significant reduction in mortality, patients in the intervention facilities experienced a greater deterioration in cognitive function and behavioural disturbance than those in the control facilities.

Educational visiting to general medical practitioners

In the Netherlands, pharmacotherapy meetings to optimise prescribing are undertaken as part of routine clinical practice by groups of local community pharmacists and general medical practitioners. A cluster randomised controlled trial of inter-professional (pharmacotherapy)

Table 2: Services provided to other health professionals

Reference	Country	Design	Setting	Service	No. Ph	Sample size	Main outcome measures	Significant Outcomes
Williams et al, (2004)	USA	RCT	GP	MR	I	63 Int 77 Cont	Physical, cognitive and affective functioning, health status, number and cost of medications.	Decrease in number and cost of medications
Schmidt et al, (1998)	Sweden	CRCT	RAC	MR	15	626 Int 1228 Cont	Incidence and quality of psychotropic medication use.	Increase in psychotropic medication use and therapeutic duplication in control group. Decrease in antipsychotic and hypnotic use in intervention group, decrease in AD use in intervention and control groups
Schmidt et al, (2000)	Sweden	CRCT	RAC	MR	15	1549 Total †	Quality of medication use (three-year follow-up).	Previous Improvements in quality of medication use sustained for specific indicators
Coleman et al, (1999)	USA	CRCT	HMO	MR	I	96 Int 73 Cont	Depressive symptoms, physical function, service utilisation, number of high risk medications, satisfaction, urinary incontinence, falls, cost.	Decrease in urinary incontinence in intervention group at 12 months. No differences between intervention and control groups at 24 months
Roberts et al, (2001)	Australia	CRCT	RAC	MR	ND	905 Int 2325 Cont	Medication use, medication cost, mortality, morbidity and resource utilisation.	Decrease in psycholeptic and benzodiazepine drug administration, decrease medication cost
Furniss et al, (2000)	UK	CRCT	RAC	MR	I	158 Int 172 Cont	Prescribing patterns, mortality, mental state, depressive symptoms, and behavioural disturbance	Decrease in mortality, decrease in number of prescribed medications, increase in behavioural disturbance
Burns et al, (2000)	UK	CRCT	RAC	MR	I	158 Int 177 Cont	Medication costs.	Decrease in medication cost
van Bijk et al, (2001)	NL	CRCT	GP	ED	37‡	70 Int 1* 52 Int 2* 68 Cont*	Prescribing of highly anticholinergic and less anticholinergic AD medications	Decrease in high anticholinergic AD use in intervention group 2. Increase in less anticholinergic AD use in intervention group 1
Hartlaub et al, (1993)	USA	CT	PPGP	ED	ND	28 Int 1* 26 Int 2* 37 Cont *	Benzodiazepine prescribing pattern	
de Burgh et al, (1995)	Australia	RCT	GP	ED	I	142 Int * 144 Cont *	Benzodiazepine prescribing pattern	Overall decline in benzodiazepine use. Differences between intervention and control groups not significant
Crotty et al, (2004)	Australia	CRCT	RAC	ED	I	381 Int 334 Cont	Fall rate, psychotropic medication use, BP, quality of life	Increase in 'as required' antipsychotic medication use in the intervention group
Avorn et al, (1992)	USA	CRCT	RAC	ED	I	431 Int 392 Cont	Psychotropic medication use, mental status, memory, anxiety, depressive symptoms, behaviour, sleep	Decrease in psychotropic medication use, decrease in inappropriateness of drug use, less cognitive decline, increase in depression scores.

CT = controlled trial; RCT = randomised controlled trial; CRCT = cluster randomised controlled trial; GP = general practice; RAC = residential aged care; PPGP = prepaid group practice; HMO = health maintenance organisation; USA = United States of America; NL = The Netherlands; MR = medication review; ED = prescribing education initiative; ND = not described in paper; Int = intervention group; Cont = control group; AD = antidepressant medication.

† Journal article reported overall number of patients (n = 1549) divided between 16 intervention and 18 control residential aged care facilities.

‡ Pharmacists participated in group discussions with physicians, discussions were led by a medical researcher.

* Reported sample size based on number of physicians that received pharmacists' educational intervention.

meetings to discuss prescribing of antidepressant medications resulted in a significant reduction in the prescribing of highly anticholinergic antidepressants to elderly people by 40% compared to a control group of practitioners that did not receive the prescribing support [71]. In comparison, educational visiting (academic detailing), reduced prescribing of highly anticholinergic antidepressants by 30%.

Four additional studies evaluated the impact of pharmacists' educational visits to general medical practitioners to optimise the prescribing of benzodiazepines and other psychotropic medications commonly prescribed for mental illness [72-75]. The two papers that reported health professional satisfaction indicated that the educational visits were acceptable and well received [73,74]. In a controlled trial, two types of pharmacists' educational interventions (a one-on-one presentation to prescribers with individualised feedback and a group presentation to prescribers about the use of benzodiazepines) did not produce significant changes to the prescribing of benzodiazepines at a prepaid group practice in the United States when compared to a control group that did not receive an educational intervention [72]. An Australian cluster randomised controlled study of a pharmacist's educational visits to general medical practitioners providing services to residential care facilities detected no significant differences in the use of psychotropic medications between intervention and control facilities. The only exception was a significant increase in the use of 'as required' antipsychotic medications in the intervention facilities [73]. This differed from results of an earlier cluster randomised controlled study in the United States that found that educational visits by a pharmacist were associated with a significant decline in prescribing of potentially inappropriate psychotropic medications in intervention facilities [75]. Another Australian study of educational visits to general medical practitioners, conducted by three physicians and one pharmacist, reported a significant reduction in the prescribing of benzodiazepines in both intervention and control groups, but the difference between groups was not significant [74]. The authors accounted for this overall reduction by a corresponding decline in the rate of diagnoses of anxiety and insomnia, and the possible awareness of prescribing related issues generated by asking general medical practitioners to conduct a self-audit of their prescribing.

Discussion

Given the extent of mental illness in the community and in aged care, and the fact people with mental illness frequently report concerns about their prescribed medications, services directed toward optimising the use of medications for mental illness fulfil an important public health need. As evidenced by the large number of papers

excluded from this review, many studies of community pharmacy services to optimise the use of medications for mental illness have been descriptive, lacked parallel control groups or have been qualitative in nature. The controlled studies included in this review provide some evidence of the potential value of including pharmacists in mental health care across a range of settings and patient populations.

Studies included in the review utilised a range of randomisation techniques, however, the review did not attempt to characterise the quality of the randomisation beyond whether randomisation occurred at the patient, practice or residential aged care facility level. The majority of the studies involved less than five pharmacists, and 10 out of the 22 papers described interventions where just one pharmacist was involved. Studies involving small numbers of pharmacists may have good internal consistency, but the results obtained may not be generalisable to outcomes of services provided by the wider pharmacy profession. In several studies the pharmacists' interventions were components of multidisciplinary team approaches to improving mental health care. The challenge of evaluating complex and multi-factorial interventions, which by their nature depend on the context in which the intervention takes place, has been described [76].

Five studies assessed the impact of pharmacists' provision of medicines information and treatment monitoring for people commencing antidepressant therapy. Three of the five studies demonstrated that involvement of the pharmacist was associated with a significant improvement in medication adherence and/or medication use rates when measured using an intention to treat analysis. One further study demonstrated significant improvements in medication adherence among patients who received three pharmacist counselling sessions; however, this was not significant when measured using an intention to treat analysis. Given the high rates of antidepressant discontinuation during the first three months of treatment, pharmacists have a potentially important role in providing medicines information and conducting treatment monitoring for those patients at high risk of medication non-adherence. No studies of pharmacists' treatment monitoring for people commencing antidepressant therapy compared monitoring provided by pharmacists to monitoring conducted by other health professionals. A separate study of antidepressant treatment monitoring conducted by nurses also demonstrated improved medication adherence [77].

Despite people with psychotic disorders having reported unmet medicines information needs, relatively few controlled studies assessed community pharmacy services for users of antipsychotic medications. Other studies have

suggested that service provision by pharmacists may be limited by not having access to patients' medical histories [46], a lack of specific training to counsel this patient population [46], and pharmacists' attitudes towards people with mental illness [48]. Further well designed research into community pharmacy services for users of antipsychotic medications is needed before conclusions can be made about the potential of such services to reduce hospital readmission and the cost of health care.

Pharmacist conducted medication management reviews appear a valuable strategy to identify potential medication related problems among people taking medications for a mental illness. The included studies demonstrated that such reviews can reduce the numbers of potentially inappropriate psychotropic medications used for mental illness prescribed to elderly people in residential aged care settings. Only one study made the link between a reduction in psychotropic medication use and improved adherence to national prescribing guidelines [66]. The value of pharmacist conducted medication reviews for people with mental illness may not be limited to optimising the use of mental health medications. Physical health care for people with mental illnesses is often less than optimal, and pharmacist conducted medication reviews may be a comprehensive strategy to improve medication use for both mental and physical illnesses. The tendency among health professionals to focus solely on the management of the mental illness among people with both mental and physical illnesses has been described in the literature [78].

Educational visiting has been shown to modify prescribing behaviour [79]. The reviewed studies reported pharmacists' interventions that were well received by prescribers, but produced differing results as to whether such visits were associated with changes in prescribing behaviour. This may have been because efforts to reduce prescribing of potentially inappropriate medications were not accompanied by information about alternate treatments, or because patients were reluctant to discontinue taking benzodiazepine medications. In the Dutch study that did produce a significant impact on prescribing patterns, information about the problems associated with prescribing highly anticholinergic antidepressants was accompanied by information about prescribing more appropriate antidepressant medications [71]. Additionally, pharmacists' initiatives to improve prescribing may be most effective when both the pharmacists and general medical practitioners have an opportunity to build rapport. The practitioners involved in the Dutch study were those routinely involved in providing care to the patient populations discussed. Data presented on prescribing at these meetings were relevant and specific to the local area in which the meetings took place.

Conclusion

The review of the international literature highlights the range of pharmaceutical services provided by community pharmacists in Australia that are potentially well suited to assisting patients and prescribers optimise the use of medications for mental illness. These data show that medication counselling and treatment monitoring conducted by pharmacists can improve medication adherence among people commencing antidepressant therapy. Pharmacist conducted medication reviews and resulting recommendations to optimise medication regimens may reduce the numbers of potentially inappropriate medications for mental illness prescribed to elderly people. This review of the available published evidence supports the continued expansion of pharmaceutical service delivery to people with mental illness, but identified the need for further well-designed research in specific areas. Future studies are needed to assess the cost-effectiveness and clinical implications of pharmacists working as members of multidisciplinary community mental health teams, and as providers of pharmaceutical services to people with psychotic disorders.

Authors' contributions

SB conducted the literature search and wrote the manuscript. AJM assisted in the literature search and in the writing of the manuscript. PA proof read drafts of the manuscript. PW and TFC participated in the conceptualisation of the review and assisted in the writing of the manuscript.

Acknowledgements

This research was funded by the Australian Government Department of Health and Ageing as part of the Third Community Pharmacy Agreement. The authors thank Dr Julija Filipovska for her assistance in compiling the manuscript.

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INSTRUCTIONAL DESIGN AND ASSESSMENT

Design and Implementation of an Educational Partnership Between Community Pharmacists and Consumer Educators in Mental Health Care

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Submitted June 7, 2005; accepted August 27, 2005; published April 17, 2006.

Objective. To design and implement an interactive education program to improve the skill and confidence of community pharmacists in providing pharmaceutical services to people with mental illnesses.

Design. A literature review was conducted and key stakeholders were consulted to design a partnership that involved community pharmacists and consumer educators. The partnership was designed so that all participants shared equal status. This facilitated mutual recognition of each others' skills.

Assessment. Four 2-hour training sessions were conducted over a 2-week period in March 2005. Seven pharmacists, 5 consumer educators, and 1 caregiver educator participated in the partnership. Pharmacists indicated that their participation caused them to reflect on their own medication counseling techniques. Consumer educators reported that speaking about their experiences aided their recovery.

Conclusion. Developing a better understanding and improved communication between community pharmacists and people with mental illnesses is an important aspect of facilitating a concordant approach to patient counseling. Implementing mental health education programs utilizing consumer educators in pharmacy schools is a promising area for further research.

Keywords: continuing education, patient counseling, community pharmacy, mental health care

INTRODUCTION

The World Health Organization (WHO) has estimated that as many as 450 million people worldwide suffer from mental disorders, with 1 in 4 families having at least 1 member with a mental illness.¹ More than 44 million people in the United States suffer a mental disorder each year, with the annual direct costs of mental illness estimated to be in excess of \$69 billion.² A similar pattern of disease burden is observed in other developed countries. Twenty percent of Canadians will personally experience a mental illness during their lifetime.³ In Australia, mental illness is a national disease priority area, and the leading cause of years lost due to disability.^{4,5} Improving the quality and accessibility of community care for people with mental illnesses is an aim outlined in the *Inquiry Into Mental Health Services in New South Wales*.⁶ Health professionals have identified the management of mental illnesses as among their most challenging therapeutic responsibilities.⁷

The majority of people with mental illnesses receive treatment from primary care practitioners.^{8,9} There were over 49 million ambulatory care visits related to mental illnesses in the United States in 1997.² As primary care health professionals, pharmacists are well placed to contribute to the management of mental illnesses. Pharmacists are key members of the health care workforce responsible for implementing the National Strategy for the Quality Use of Medicines in Australia, and are regarded as among the most trusted professionals.^{10,11} The development of new community pharmacy services has expanded the opportunities for pharmacists to work collaboratively with general practitioners to provide community mental health care. These services include domiciliary medication management review and community-based multidisciplinary case conference meetings.¹² Community pharmacists are frequently consulted for advice about medications used to treat mental illnesses.¹³⁻¹⁸ Counseling provided by community pharmacists can improve adherence and attitudes to antidepressant medications.¹⁹⁻²¹ Pharmacists' contributions to community mental health teams may improve adherence to antipsychotic medications and decrease medication-related side-effects.²²⁻²⁵

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The provision of information about medications by community pharmacists, however, may be limited by poor communication with people with mental illnesses. Finnish community pharmacists were less likely to provide directions for use of psychotropic medications than for 8 other therapeutic classes of medications studied.²⁶ Pharmacists have reported feeling more uncomfortable counseling on the use of medications used to treat mental illnesses than those used to treat cardiovascular conditions.²⁷ British and Canadian community pharmacists have reported that their ability to provide information about antipsychotic medications is limited by a lack of training to counsel people with severe mental illnesses.^{27,28} Dutch community pharmacists did not perceive that they have a clear role in the management of schizophrenia.²⁹ In the same study, however, 60% of people with schizophrenia and their caregivers indicated they would like to receive more information about prescribed medications.²⁹ People beginning courses of antidepressant medications in Britain were found to have unmet information needs, and people with mental illnesses in Australia have expressed their dissatisfaction with information about medications provided by their health professionals.^{30,31}

The WHO has recognized the value of consulting with relevant stakeholders, including professional associations, community groups, and advocacy organizations when designing mental health education programs.³² The importance of facilitating consumer involvement in medical education, assessment, and curriculum development has been described.³³ An Australian report published in 1999, however, found that consumer and caregiver participation in tertiary mental health education was minimal.³⁴ Institutions offering education to health professionals have typically not been accountable to recipients of health care. The second Australian National Mental Health Plan, released in 1998, recognized consumers, families, and caregivers as key stakeholders who must be adequately financed and resourced to influence decisions relating to service provision.³⁵ Improving the delivery of mental health care services will be facilitated by close collaboration between patient advocacy organizations, organizations responsible for mental health policy and planning, and educational institutions.

A consumer educator in mental health care is a person who has previously received mental health care and works, often on a voluntary basis, to inform and educate professionals, students, and the wider community on mental illness and its effects on individuals, families, and society. Similarly, caregivers undertake this role. The consumer and caregiver educators work through advocacy organizations, including the Schizophrenia

Fellowship of New South Wales (SFNSW), from which they receive training and support. The SFNSW is a non-profit community-based organization for people living with mental illnesses and for their caregivers and relatives. Australian government policy has recognized people with mental illnesses as partners in the delivery of mental health care.³⁵

The aim of this initiative was to design and conduct an interactive educational partnership between community pharmacists and consumer educators in mental health care. The specific objective of the partnership was to address the communication skills required for community pharmacists to provide pharmaceutical services to people with mental illnesses.

DESIGN

MEDLINE (1966-2004), International Pharmaceutical Abstracts (1992-2004), Embase (1992-2004), and PsychInfo (1992-2004) were searched using terms including *consumer consultant, mental disorders, education, consumer participation, and patient advocacy*. Researchers used the outcomes of the literature search and consulted with key stakeholders, including professional organizations representing pharmacists and patient advocacy groups, to inform the design of an interactive training program involving community pharmacists and consumer educators in mental health. The stakeholders involved in the development of the training program are outlined in Table 1.

The SFNSW recruited the consumers and caregiver educator. The consumer educators employed in the education program had received training as speakers from the SFNSW community pharmacists who had earlier indicated their willingness to participate in a research project being conducted by the Faculty of Pharmacy were invited to participate in the educational partnership. This paper reports the qualitative evaluation of focus groups with the community pharmacists and consumer educators conducted as part of the educational partnership. With the consent of those present, these focus groups were audio taped and the content was analyzed.

ASSESSMENT

Four 2-hour education sessions were conducted during March 2005. Seven community pharmacists, 5 consumers, and 1 caregiver participated in the partnership. An overview of the learning objectives and corresponding educational strategies is presented in Table 2. The sessions included both lecture style presentations and open discussions led by specialist pharmacists, a psychologist, a mental health nurse, and a psychiatrist. In the first and fourth sessions, special emphasis was placed on community

Table 1. Key Stakeholders Involved in Design of Mental Health Training Program

Stakeholder	Key Area(s) of Responsibility
Schizophrenia Fellowship of New South Wales	Nonprofit community based organization for people living with mental illnesses, their carers and relatives
Northern Sydney Area Mental Health Service	Body responsible for mental health service planning, provision, policy and evaluation in the Northern Sydney Area
Pharmaceutical Society of Australia (NSW Branch)	Professional organization representing pharmacists
Pharmacy Guild of Australia (NSW Branch)	National employers' organization representing community pharmacy owners
Faculty of Pharmacy, The University of Sydney	Education and research institution offering undergraduate and postgraduate pharmacy education

pharmacists and consumer educators being able to share their experiences related to the topics presented. An important aspect of the fourth session was the debriefing and focus groups with the consumer educators and community pharmacists.

A key finding from the focus groups was the desire among consumers to receive more information about prescribed medications from their community pharmacist. Consumer educators reported that receiving more information about medications would enable them to make informed decisions regarding their own health care, including the ability to discuss treatment options with their medical doctors. One consumer educator highlighted how it was important for pharmacists to provide medication counseling for the person rather than the diagnosis: "You

need to be aware that you are dealing with people. We have lives. People with mental illnesses are treated differently, but mental illness is a physical illness that occurs in the brain, just like other physical illnesses that occur in the heart." Another consumer educator added, "Individual pharmacists can be very selective who they relate to in their pharmacy practice, who they reach out to... they don't want any scenes in the shop... they rate you according to the drugs that they give you."

Pharmacists discussed the barriers they perceived to providing pharmaceutical services to people with mental illnesses. Although pharmacists reported having the knowledge and desire to provide information about medications, several reported lacking the confidence and skills necessary to communicate effectively with people

Table 2. Overview of Mental Health Education Program

Learning Objectives	Strategy
1. Improve awareness of structure of mental health services.	Mental health nurse manager described and discussed the structure of the mental health service in New South Wales.
2. Appreciate consumer perspectives on mental health service delivery.	Consumers, with diagnoses including depression, bipolar disorder and schizophrenia, shared their experiences of receiving treatment within the mental health system.
3. Be able to recognize the common signs and symptoms of mental illnesses.	Psychiatrist made presentation and led discussion about the common signs and symptoms of mental illnesses (including depression, anxiety, schizophrenia, schizoaffective disorder and bipolar disorder).
4. Appreciate the role of non-pharmacological strategies in the treatment of mental illnesses.	Psychologist presented overview and led discussion about non-pharmacological treatments.
5. Understand the use and context of medications in the overall treatment of mental illnesses.	Two specialist psychiatric pharmacists led discussions about medications used to treat mental illnesses.
6. Understand issues relating to drug and alcohol abuse among people with mental illnesses.	Specialist drug and alcohol pharmacist led discussion about substance abuse among people with mental illnesses.
7. Improve communication skills between community pharmacists and people with mental illnesses.	Community pharmacists interviewed consumers. The challenges of providing pharmaceutical services were discussed in a round table format.
8. Improve the attitudes of community pharmacists towards people with mental illnesses.	Consumers described their personal experiences of their mental illnesses and their interactions with community pharmacists.

with mental illnesses. Many were unaware of the consumers' unmet needs for information about medications. The sessions caused the pharmacists to reflect on their own medication counseling techniques. As one pharmacist commented, "It has changed my perception of how people will react to discussion...I can think of at least eight people [with mental illnesses] that I've never directly discussed their medication with." Another pharmacist added, "I won't be scared to ask 'how are you going with your medications?' It has been surprising how open people have been to share their experiences."

The consumer educators were enthusiastic about their participation in the partnership, the chance to speak about their experiences, and the format of the sessions. One consumer educator stated, "You are doing a training needs analysis...identifying the gaps between pharmacists and the consumer population." Another commented, "It's good that you are doing holistic training...workshops are more personal, you can say what you feel from the heart, you can bounce ideas and brainstorm."

The act of providing consumer education in a paid and recognized capacity was reported to be a valuable component of the consumer educators' own treatment. The caregiver who participated stated, "It has been wonderful for her [daughter of the caregiver] to go out and share her illnesses. When I saw she was improving so well by being an advocate, I did the carers' advocacy course as well...the advocacy has been a very positive contribution towards her recovery."

DISCUSSION

Lack of training to counsel people with mental illnesses about their medications has been cited as a barrier to service delivery, yet few mental health education programs for pharmacists have sought to address this barrier.^{27,28} The use of consumers as educators has largely been restricted to nursing and medical education, where their contribution has been reported to be well received.³⁶ Other reported advantages of using consumers are improved attitudes and a positive impact on nursing practices.^{37,38} Although the benefits of pharmacists' membership in mental health advocacy organizations have been presented,³⁹ the research team did not retrieve any published reports of people with mental illnesses being previously employed in the continuing education of community pharmacists. Mental health training programs for community pharmacists have typically focused on the indications and adverse reactions of psychotropic medications, rather than the skills required to communicate this information to consumers. Educational interventions that allow participants to apply desired behaviors have been recognized as more effective than providing theoretical information.⁴⁰ Role playing (with students or

staff acting as consumers) is frequently included in undergraduate pharmacy education; however, role playing the provision of information to people with mental illnesses may be perceived as too artificial to be useful. While promoting interpersonal contact with people with mental illnesses can improve attitudes toward people with mental illnesses,⁴¹ one study suggested that pharmacy students' clinical placements at mental health centers may reinforce the "medical model orientation."⁴² This may be because students visiting psychiatric facilities observe people receiving treatment, sometimes involuntarily, for acute exacerbations of their illness. Negative attitudes towards people with mental illnesses among health professionals has been identified as a barrier to service delivery.⁴³ The educational partnership with the consumer educators, therefore, represented a new and promising model for mental health education of community pharmacists.

The International Alliance of Patients' Organizations (IAPO) has also recognized the importance of consumers learning the skills required to interact and work together with their health professionals.⁴⁴ Several consumer educators were unaware that community pharmacists were able to provide comprehensive information about prescribed medications. Barriers to consumer participation include a lack of knowledge about the complexities of the mental health system, the mental health system being perceived as an agency of social control, and a persisting power differential between health professionals and people with mental illnesses.⁴⁵ Strategies to improve understanding between community pharmacists and people with mental illnesses may be an important first step towards overcoming these barriers and facilitating a "concordant approach" to mental health care.

Several consumer educators reported that speaking about their experiences assisted their recovery. This supported earlier research that suggested the act of providing education to medical students resulted in consumer empowerment, increased self-esteem, development of new insights, and an improved understanding of the doctor-patient relationship.⁴⁶ The formation of an educational partnership, therefore, may have ongoing benefits for both groups. Although the results of this qualitative research cannot be generalized to all groups of consumers, pharmacists, and pharmacy students, this case study suggests that utilizing consumer educators in pharmacy education is a promising area for future research. An important aspect of the training program involved the consumer educators speaking about their own experiences. A corresponding limitation, however, was that the consumers did not attempt to represent or speak on behalf of all people with mental illnesses. Controlled studies are needed to assess the impact of consumer educators on pharmacists'

attitudes toward people with mental illnesses and their willingness to provide pharmaceutical services.

CONCLUSION

The educational partnership demonstrated the potential value of utilizing consumer educators in the education of community pharmacists. Developing a better understanding and improved communication between community pharmacists and people with mental illnesses is an important step towards improving community care for people with mental illnesses. The outcomes of the training suggest that the use of consumer educators in pharmacy education may improve the confidence of community pharmacists to discuss medication concerns with people with mental illnesses. Employing consumer educators in pharmacy education should be considered as one strategy for improving the confidence and ability of community pharmacists to communicate effectively with people with mental illnesses. The opportunity for consumers to provide education and speak about their experiences may aid their recovery.

ACKNOWLEDGMENTS

This project was funded by the Australian Government Department of Health and Ageing as part of the Third Community Pharmacy Agreement. In recognition of their role as trained educators, all presenters, including the consumer educators, were paid for their time and expertise. The community pharmacists were reimbursed for the costs associated with their participation.

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Appendix 8: Pharmacist Diaries

Entries From Pharmacists' Diaries

Pharmacist 1 Contribution:
Mental Health - Provision of Drug Information to Health Care Professionals
Participated in discussion about a patient attempting to inhale and inject clozapine. Asked for my opinion on possible effects of this
Discussed likelihood of clozapine causing micturition in one of their patients
I followed this up by supplying the team with some data on this to take to a family meeting with the patient
General presentation about antipsychotics
Was asked to do some research on clozapine induced diabetes and if it's possible to be reversed after ceasing the drug
(Participated in discussion about) common side effects of antidepressants
Discussed with doctors common CYP450 drug interactions between psych and non psych meds
Discussed changing antihypertensive due to gynecomastia
Answered queries regarding which depot antipsychotics more likely to cause increase in prolactin levels with case manager and registrar
Team asked me whether overweight clients getting depot antipsychotics are actually getting absorbed if there is a lot of fat and not reaching muscle. Agreed they would not be absorbed if only reaching fat. Suggested longer needles or injecting in different spot in body eg: bum or upper arm.
Asked about effect of clozapine and depot antipsychotics and dental health because ARC patient has stained teeth and lots of dental problems
Asked about client on clozapine who has Hep C and gastroenterologist wants to know if it is safe to start him on interferon and/or Ribavirin with his schizophrenia and all of his other meds (Tritace, Zoloft, Somac, Clozapine)
Pharmacist 1 Contribution:
Mental Health – Potential drug related problem
Discussed ceasing a medication with psych Dr as it seemed unnecessary
Pharmacist 2 Contribution:
Mental Health - Provision of Drug Information to Health Care Professionals
Comparative side effects chart for atypical antipsychotics with +++ and --- etc. (Table 8.6 Psych TG)
Comment on side effects of benztropine as long-term use in conjunction with antipsychotics to counter EPSE.
PRL levels. Should routine ones be done to monitor effects of antipsychotics?
Provided team with 1) antipsychotic and adverse effects table 2) depot antipsychotic table
Email copy of ADR sheet for oral and depot meds to xx for distribution
Onset of effect, etc, etc
Avanza and Efexor for major depression
Weight gain comparison – how much, how soon
Solian and Seroquel for schizophrenia rationale
Course of atypicals if side effect profile better
Do chlorpromazine equivalent for atypicals etc
Do benzo equivalents temazepam to diazepam
Risperidone Consta – Depot → Cochrane review on efficacy
Discussed older style antipsychotics – which came first, when was first atypical antipsychotic
Oxazepam 30mg 3-4 daily – above usual dose usually once daily prn likely to exhibit benzodiazepine tolerance/ dependence
Discussed efficacy of risperidone depot
Lithium overdose – treatment, suggestions for prevention – perhaps weekly webster pack for lithium or weekly dispensing
Use of venlafaxine with olanzapine
Query dexamphetamine to cause psychosis – investigate

Did research of Risperdal Consta and dexamphetamine and psychosis
Discussed with group: Combination use of Efexor and Avanza - Maudsley guidelines suggest SSRI and mirtazapine is beneficial for refractory depression but no published guidelines for venlafaxine and mirtazapine.
Informed of changes to Efexor tabs/ caps etc
Dexamphetamine use in pts with mental illness or predisposition - journal search showed up a few letters to editor that discuss numerous case reports of dexamphetamine causing psychosis – suggest causal link
Revised availability of Efexor 37.5mg, 75mg in SR caps – remind Drs re availability for use for withdrawal or for very low dose
Held open discussion on use of Risperdal Consta. Discussed Cochrane review comparing Consta with placebo. Generally side effects are reported to be similar but case reports have shown decreased side effects. Useful in patients started on oral risperidone but who have trouble with compliance. Main concern is cost which is much more than oral tabs.
Solian and seroquel used together for patient. Mainly used seroquel at night to help with sleep - Cut out Solian
Discussed new patient – we discussed treatment options including antidepressants. Decided psychotherapy was best course of action
Enquiry to drug company regarding amount of lactose in Solian
Pharmacist 3 Contribution:
Mental Health - Provision of Drug Information to Health Care Professionals
Permission to use clozapine – legalities??
Combination of depots – No (TG)
Dr XX psych Cremorne comparative side effects of antipsychotics? TG AMH sent
Guidelines re Clopine ECHO – timing? ... Check this!
SSRIs in pregnancy ?mirtazapine
Followed up clozapine query
Consta – max dose?
Mirtazapine 15mg n sleepy – take earlier – less sedation with higher doses (TG) (increase to 30mg after one week)
Patient on Epilim, olanzapine prn - ?erectile dysfunction /? fertility – reproductive toxicity
Quetiapine od – v sleepy next day. MIC od t½ 22 hrs
Risperidone and prolactin levels female on 1-2mg for review. Menstrual irregularities. TG and AMH pages left in pigeon hole.
Discussion with XX. Pt on Solian x 400mg couple of week's deterioration – compliant?
St John's Wort and SSRI? NO!
Prepared drug info folder for case managers (AMH and TG)
Sent info re breastfeeding and olanzopine
Q: XX re changeover of antidepressants ref to TG – check for another reference
Q: raised prolactin – risk of breast cancer? Dr XX
Augmentation with clozapine 600mg for –ve symptoms another pt (PC) antipsychotic. Clozapine level 0.55. ECHO due?
Talk with XX: antipsychotic drugs in pregnancy and breastfeeding - search for recent review articles (given to Dr 12 days later)
Medline search – couple of articles re clozapine and Risperdal – get for XX
Maudsley Guidelines – XX to show at staff meeting
Discussion with Dr XX and XX re patient - implications re mental health, implications re meds - search literature and bring Wed
Check HOARC reports on w/site drug use – crystal meth, Viagra et al
Info on Consta – Risperdal Medline search, drug info files, Janssen
Spoke to XX re clozapine / ECHO policy
Naltrexone – duration of Tx – long term?
Consta info
Reference for Dr XX from Maudsley re augmentation of clozapine
Discussed a/psychs in pregnancy register with XX – would like more info
Pharmacist 1 Contribution: Mental Health – Provision of Drug Information to Clients
Talked to him (client) about new antidepressant and what to expect and side effects, etc.

Pharmacist 2 Contribution: Mental Health – Provision of Drug Information to Clients
Took trip to Cummings unit to accompany social worker to see new admission. Met with patient was to provide drug information if required. None was given as none requested.
Appointment with patient - discussed clozapine and possible side effects and other drug related issues (did not join project)
Sent info pack to XX included fact sheets from www.beyondblue.org.au on depression, stress management, alternative treatments, physical activities and depression
Pharmacist 1 Contribution: Non Mental Health Issues
Voiced concern about K levels
Asked by X about client XX and about his vitamins he is taking to 'cure his mental illness' that his mother has suggested
Gave input into which PPI or statin should be used
Participated in discussion about asthma medications
Pharmacist 2 Contribution: Non Mental Health Issues
Multivitamins especially antioxidants can shorten your life -literature search
Discussed with group: multivitamin / antioxidant use causing increased mortality (research done previously)
Cumming unit inpatients. Discussed RU486
Smoking cessation program that provides subsidy for patches? Investigate scheme
Dr XX called ... to ask re Catapres – can he prescribe it!, what qty, need authority – I answered all questions
Pharmacist 3 Contribution: Non Mental Health Issues
Ankylosing spondylitis – info fax patient