Enhancing the use of 'as required' (PRN) medication in acute mental health wards: the development and testing of a good practice manual.

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Abstract

Background

Pro re nata (PRN) psychotropic medication is regularly prescribed and administered in inpatient mental health care. Approximately 80% of inpatients receive PRN psychotropic medications during an admission. The most frequently administered PRN medications are benzodiazepines and typical antipsychotics. The use of antipsychotic medications as PRN contributes to polypharmacy, high doses and potentially dangerous drug interactions. Previous research into this area has mainly been retrospective analysis of case notes, and has been hampered by poor quality and imprecise documentation. A Cochrane review concluded that PRN as a clinical intervention does not have a robust evidence-base.

Aims

The aim of this study was to contribute to improving the practice of prescribing and administering psychotropic PRN medication in acute mental health wards through the development and testing of a good practice manual.

Methods

This thesis employs a two phase design based on the Medical Research Council's complex intervention framework. The first phase developed a good practice manual. Four studies contributed to this, which included a literature review (best-evidence synthesis), interviews with the multi-disciplinary team (n=59) and service users (n=22), and a Delphi study with experts (n=18). The second phase used a pre-post test design to undertake an exploratory and acceptability trial of the manual.

Results

In phase one (theory and modelling phase) nine themes of good practice emerged. These were: a) considering the patient (knowledge, preferences and choices); b) improving prescription quality; c) PRN as part of the clinical management plan; d) evaluating the effects and side effects of PRN; e) frequent review of PRN; f) enhanced documentation by the MDT; g) preventing distress when using PRN; h) PRN as a last resort encouraging the use of non-pharmacological interventions; and i) additional training and education is required for all clinical staff.

In phase two (the exploratory and acceptability trial) 28 of 35 patients received 484 doses of PRN in the 10 week period. Patients had a mean of 3.6 prescriptions of 14 different PRN medications in 34 different dose combinations prescribed. Medication errors beyond poor quality of prescribing occurred in 23 of the 35 patients (65.7%). Prescription quality improved following the introduction of the intervention but quality of nursing notes reduced. Acceptability of the manual to both nursing and medical staff was high.

Conclusions

This thesis demonstrates a systematic and rigorous mixed method approach to the development and testing of a good practice manual designed to enhance the use of PRN psychotropic medication.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Copyright

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Dedications

I dedicate this to Toni - I love you very much and couldn't have done this without you. And of course Myla, Zac and new arrival Hattie who give me so much love and happiness.

List of associated publications and conference presentations not referred to in the thesis.

National Psychiatric Nursing Research Conference (Sept 2007) Methodological symposium – The Delphi study. Oxford.

Mixed Methods Conference (2007) A mixed methods approach to developing and testing a manual to enhance the use of psychotropic PRN medication. Fitzwilliam College, Cambridge.

European Academy of Nursing Science (2005, 2006, 2007) Enhancing the use of 'as required/extra' (PRN) medication within acute mental health settings. Poster and presentations, PhD summer schools at York, Maastrict and Manchester.

Manchester Mental Health and Social Care Trust (2006) Enhancing the use of 'as required/extra' (PRN) medication within acute mental health settings. Effectiveness day. Wythenshaw Hospital, Manchester.

World University Network (WUN) Postgraduate mental health nursing seminars (2006) Enhancing the use of 'as required/extra' (PRN) medication within acute mental health settings. http://www.wun.ac.uk/mentalhealthnursing/

Consortium for Health Care Research (2004, 2005, 2006) Enhancing the use of 'as required/extra' (PRN) medication within acute mental health settings, Windsor.

National Psychiatric Nursing Research Conference (2006) Service users' experiences of PRN 'as needed' medication within acute mental health settings. Poster presentation, Oxford.

The Author

I qualified as a Mental Health Nurse in 1995 and completed my Bachelor of Nursing (hons) degree in 1996, my dissertation explored homelessness and mental health. At this point I started working for what has now become Pennine Care NHS Trust in a variety of inpatient settings, including acute and low secure rehabilitation. Between 1997 and 2000, I completed a part-time MSc in Psychosocial Interventions at the University of Sheffield; my dissertation explored the experiences of service users with mood disorders. In 2001, I was seconded to The University of Manchester to design and implement training for acute mental health workers (Richards et al. 2003). At this time I studied for an MPhil (2001/2), which developed a measurement tool to explore the attitudes of acute mental health nurses '*Attitudes Towards Acute Mental Health*' scale (Baker et al. 2005). This scale is increasingly being recognised as a primary tool of choice and is being used in a variety of international settings.

In 2003, after a number of year's part-time secondment to The University of Manchester, I was appointed Lecturer in Mental Health Nursing. Since September 2004 I have been employed as a Health Foundation research fellow, undertaking an externally funded PhD. The fellowship is highly competitive and prestigious with only one pre-doctorial award being funded in 2004. In addition to the United Kingdom doctorial study, I am collaborating with The University of Wollongong (Associate Professor J Curtis) and James Cook University (Professor K Usher), Australia, in several funded complimentary studies of PRN. I have been involved in the establishing the World Universities Network for Mental Health Nursing and organized a seminar series for post-graduate mental health students. I have also successfully participated in the European Academy of Nursing Science PhD Summer School. I continue to maintain good links with the NHS by supporting research in the clinical area. I have published over 20 articles relating to mental health nursing with a focus on inpatient care and research methodology.

Abbreviations

British National Formulary	BNF
Care Services Improvement Partnership	CSIP
Chief Nursing Officer	CNO
Child and Adolescent Mental Health Services	CAMHS
College of Mental Health Pharmacists	CMHP
Computer Assisted Qualitative Data Analysis Software	CAQDAS
Consolidated Standards of Reporting Trials	CONSORT
Extra pyramidal side effects	EPSE
Higher Education Institution	HEI
Intra-Muscular	IM
Medical Research Council	MRC
Medium Secure Unit	MSU
Multi Centre Research Ethics Committee	MREC
Multi-disciplinary team	MDT
National Service Framework	NSF
National Association of Psychiatric Intensive Care Units	NAPICU
National Institute of Clinical Excellence	NICE
Nominal Group Technique	NGT
Patient Group Directives	PGD
Patient Safety Incidents	PSIs
Prescribing Observatory for Mental Health (UK)	POMH-UK
Pro re nata	PRN
Psychiatric Intensive Care Units	PICU
Quality of Reporting of Meta-analysis	QUORUM
Randomised Controlled Trial	RCT
Research and Development	RAND
Senior House Officer	SHO
Specialist Registrar	SpR
United Kingdom	UK
United Kingdom Psychiatric Pharmacy Group	UKPPG

Chapter 1 Introduction

This thesis is presented in the 'PhD by alternative methods' format. It describes a series of studies which culminated in the development and testing of a good practice manual designed to enhance the use of pro re nata (PRN) psychotropic medication in acute mental health wards (Figure 1.1). Acute mental health wards provide a place of safety for service users who are experiencing a mental health emergency, are at a high level of risk and/or are in crisis. They provide a specialist setting for the assessment and treatment of both mental and physical health needs (Bowers 2005). The thesis is structured as follows. This introduction (Chapter 1) provides a broad rationale and outline of this thesis. Chapter 2 provides the background to the study and examines the relevant issues of acute mental health wards and psychotropic medication. Chapter 3 details the methodological underpinnings and rationale for the studies undertaken. Chapters 5-8 detail the studies undertaken and are presented as the following papers:

Study 1 Baker JA, Lovell K and Harris N (in press) Administration of psychotropic pro re nata (PRN) medication in adult inpatient mental health settings: a best-evidence synthesis review. *Journal of Clinical Nursing*.

Study 2 Baker JA, Lovell K, Harris N, and Campbell M (2007) Multi-disciplinary consensus of best practice for pro re nata (PRN) psychotropic medications usage within acute mental health settings – a Delphi study. *Journal of Psychiatric and Mental Health Nursing,* **14**, 478-484.

Study 3 Baker JA, Lovell K, and Harris N (2007) Mental health professionals' psychotropic pro re nata (PRN) medication practices in acute inpatient mental health care: a qualitative study. *General Hospital Psychiatry*, **29**, 163–168.

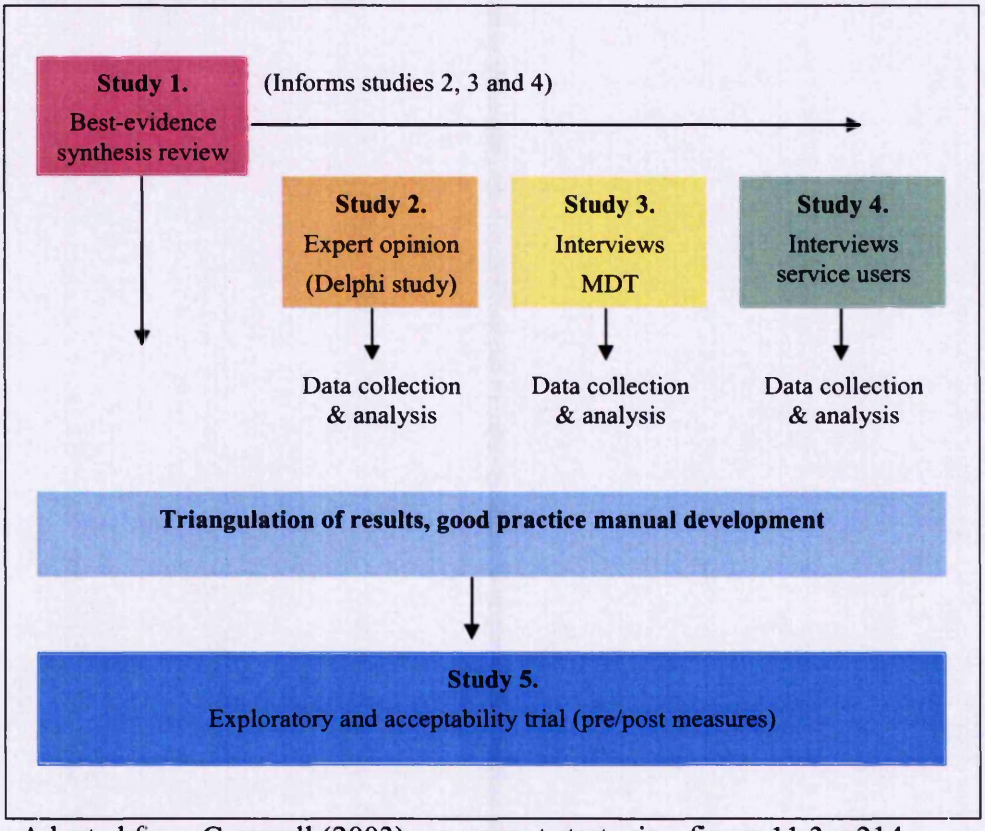
Study 4 Baker JA, Lovell K, Easton K, and Harris N (2006) Service Users' experiences of 'as needed' psychotropic medications in acute mental healthcare settings. *Journal of Advanced Nursing*, **56**(4), 354–362.

Study 5 Baker JA, Lovell K and Harris N (to be submitted) The impact of a good practice manual on professional practice associated with psychotropic PRN in acute mental health wards: An exploratory study.

Those studies which have been published are presented as the version accepted for publication to reduce editorial influences on the work. Each study has been written as

per journal specifications[1]. The first study (Chapter 4) describes a literature review (a best-evidence synthesis) of utilisation studies of PRN psychotropic medication in inpatient mental health settings. Study two details a Delphi study of expert consensus on good practice for the prescribing and administering of PRN psychotropic medicines (Chapter 5). The next two studies (Chapters 6 and 7) establish a picture of current PRN practice as a result of semi-structured interviews with members of the multi-disciplinary team (MDT) and service users. These interviews allowed clinicians and service users to generate ideas for good practice based on their experiences. The fifth and final study (Chapter 8) details an exploratory and acceptability trial of the good practice manual generated by the four previous studies (Chapters 4-7). The thesis concludes (Chapter 9) with a summary of the studies, their limitations, clinical implications, and makes recommendations for future research.

Figure 1.1: Framework for development and testing of the good practice manual and structure of the thesis.



Adapted from Creswell (2003) concurrent strategies, figure 11.3, p214.

[1] To improve the consistency of this thesis the style of referencing and abbreviations have been standardised throughout.

1.1 PRN psychotropic medication

PRN has Latin origins (pro re nata) and is often translated to mean 'as occasions arise', 'as needed', 'as required' or 'whenever necessary'. It is commonly used in many health settings to provide drugs or doses in addition to regularly prescribed medicines. Psychotropic refers broadly to medicines which influence mental state (Usher et al. 2001).

PRN psychotropic medications are frequently used in acute mental health wards. Approximately 2.4 million doses of psychotropic PRN are administered in acute mental health wards in England every year[2]. Up to 80% of service users will receive PRN during their hospital stay (Curtis and Capp 2003, Hales and Gudjonsson 2004, Thapa et al. 2003, Voirol et al. 1999, Walker 1991). The groups of drugs most commonly used as PRN are antipsychotics, anxiolytics, hypnotics and anticholinergics. Although, PRN psychotropic drugs are prescribed by doctors, they are administered at the discretion of mental health nurses for a range of reasons including: agitation; symptom distress; insomnia; in occasions of violence and aggression; and at the request of service users (Usher et al. 2001). A recent systematic review conducted on behalf of the Cochrane Library, which compared PRN with regular medication for the treatment of psychotic symptoms concluded that:

'This common current practice has no support from randomised trials. Current practice is based on clinical experience and habit rather than high quality evidence.... and is therefore difficult to justify.'

Whicher et al. (2003) p1.

[2] Conservative estimate based on the Author's assumption of 13,000 acute mental health beds, median 2 week stay of which 70% will receive 10 doses.

1.2 Rationale for studying PRN psychotropic medications

'More insidious than seclusion, and often more damaging to the patient's welfare and to ward morale, was the repeated and excessive use of sedating drugs.... Before 1943 the practice at the hospital was to leave orders [PRN] on evening rounds for heavy doses of barbiturates to be administered during the night in the event of restlessness, disturbed behaviour, or sleeplessness....The staff learned that most mental patients tolerated barbiturates poorly, that the repeated use of such sedation even in small doses tends to intoxicate them, blunt their finer sensibilities, reduce their integration and control, and lead to a more rather than a less disturbed ward.'

Greenblatt et al. (1955) p81.

'Our findings indicate that the use of PRN orders may expose psychiatric inservice users to unnecessary psychotropic medications. Given the objective of regulatory bodies to minimise the use of 'chemical restraints' in the population of vulnerable patients, these findings have important policy implications.'

Thapa et al. (2003) p1286.

Interest in the topic of PRN psychotropic medications emerged from clinical experience in a variety of inpatient mental health settings. Observations of prescribing and administration habits suggested that these were often influenced by clinician's beliefs and knowledge about medicines, their interactions and relationship with individual service users, and the clinical team. PRN could on occasions be problematic; either used excessively or minimally depending on these variables. The use of typical antipsychotics as PRN contributes to polypharmacy, high doses and dangerous drug interactions (Davies et al. 2007, Geffen et al. 2002b, Milton et al. 1998, Royal College of Psychiatrists 2006, Thapa et al. 2003). This is clearly an issue of concern. PRN therefore warranted further research with the aim of improving its use.

1.3 Aims and objectives of this study

Enhancing the use of PRN psychotropic medications through the development of a good practice manual clearly requires the understanding of complex clinical situations prior to the developing and testing of an intervention designed to change practice. The study is guided by the Medical Research Council (MRC) framework for designing and evaluating complex interventions (Medical Research Council 2000). As briefly outlined in the background the current state of knowledge in this area is poor and limited.

1.3.1 Aim

The aim of this study was to contribute to improving the practice of prescribing and administering psychotropic PRN medication in acute mental health wards by developing and testing the effects and acceptability of a good practice manual.

1.3.2 Objectives

Phase 1 (Theoretical and modelling phases of MRC framework)

- To conduct a literature review of the utilisation of PRN psychotropic medication (Study 1).
- To explore current practice (strengths and weakness) from the perspectives of experts (Study 2), the MDT (Study 3) and service users (Study 4).
- To triangulate findings into an intervention (good practice manual).

Phase 2 (Exploratory trial phase of MRC framework)

- To determine the effects of the good practice manual on clinical practice (Study 5).
- To determine acceptability of the good practice manual by the MDT (Study 5).

1.4 Developing a complex intervention to enhance the use of PRN psychotropic medications

There are numerous complexities associated with the use of PRN psychotropic medications in acute mental health wards, including the decisions about what to prescribe and when to administer. These decisions do not occur in isolation, combining the influence of doctors, nurses and service users. The development and testing of an intervention (a good practice manual) to improve this process requires careful design and the mixing of a variety of methods (Blackwood 2006, Campbell et al. 2000, Campbell et al. 2007, Oakley et al. 2006).

The MRC framework provides clear guidance on developing complex interventions[3] (Campbell et al. 2000, Medical Research Council 2000). This useful framework has five clear stages (theoretical, modelling, exploratory trial, definitive and long-term implementation). This framework incrementally guides researchers towards a randomised controlled trial (RCT), at the same time it offers flexibility in intervention development. For example, depending on existing knowledge researchers may not need to start at the beginning of the model (Medical Research Council 2000). This thesis focuses on the first three stages of the framework; theoretical and modelling (phase 1 objectives) and exploratory trial (phase 2 objectives). The MRC framework is discussed in more detail in Chapter 3.

[3] 'Complex interventions are built from a number of components.....include behaviours, parameters of behaviours, and methods of organising and delivering these behaviours. It is not easy to precisely define the 'active ingredient' of a complex intervention.' Medical Research Council (2000) p2.

1.5 Conclusions: The development and evaluation of a good practice manual which aims to enhance the use of PRN psychotropic medication

PRN psychotropic medications are a frequently used clinical intervention in acute mental health wards. Limited research has been conducted on this complex intervention. This thesis aims to develop and test best practice principles for PRN psychotropic medications developed from combining evidence from several related studies. The research associated with this thesis has specific challenges. The use of PRN psychotropic medications in acute mental health wards occurs in the absence of a clear diagnostic framework. They are prescribed and administered as part of a MDT intervention and therefore the manual should enhance the practice of all disciplines. Furthermore, the manual needs to be clinically relevant with few, if any inclusion or exclusion criteria. It will need to draw on the best available evidence; in the absence of which, new evidence should be sought. This should encompass '*evidence informed practice*' (Glasziou 2005) reflecting the values of both staff and service users. Most importantly, the manual should be developed and evaluated in a rigorous manner in this instance using the MRC framework for complex interventions the outcome of which will inform future randomised controlled trials.

Chapter 2 Background

This chapter provides the background of this thesis. It focuses on two issues pertinent to the aims and objectives of the research. The first section focuses on acute mental health wards. It briefly outlines the current literature for this clinical setting, which includes published concerns, the role of acute wards, and recent relevant mental health policy. The second section focuses on psychotropic medicines, principally antipsychotics and benzodiazepines, the evidence-base and their use in acute mental health wards.

2.1 Acute mental health wards

The United Kingdom (UK) has 5.8 mental health beds per 10,000 of the population (World Health Organisation 2005). Inpatient mental health services provide approximately 170,000 admissions a year (Bosanquet et al. 2006). Figures from 2005-6 suggest that 47,400 of these are detained under the Mental Health Act (Office of National Statistics 2007). There are approximately 13,000 acute mental health beds located in 492 acute mental health wards in 85 Mental Health Trusts (The Sainsbury Centre for Mental Health 2005a, Warner 2005).

Mental health expenditure accounts for 10% of all health spending in the UK (World Health Organisation 2005). Acute mental health wards are the most expensive component accounting for 40% of the mental health resource (The Mental Health Foundation 2005). Even with this significant proportion of expenditure there is a continued perception that acute mental health wards remain the '*Cinderella*' of mental health services. Recent figures suggest that spending per admission has risen by 48% since the year 2000. This has been attributed to falling numbers of admissions and an investment of £600 million between the years 1999-00 to 2003-4 (Bosanquet et al. 2006). However, Quirk and Lelliott (2001) suggest that increased pressure in acute mental health wards caused by the reduction of beds has resulted in the loss of economies of scale, therefore increasing the cost of services.

Improving the quality of care on acute mental health wards has, and continues to be a priority for modern mental health policy makers (Bowles and Jones 2005). Acute mental health wards remain a target of policy initiatives to improve the quality of care as part of the National Service Framework (NSF) for Mental Health (Department of Health 2004). The recent Chief Nursing Officer (CNO) Review of Mental Health Nursing targeted acute mental health wards (one of seventeen recommendations) and fourteen suggestions were made to help improve the quality of care (Department of Health 2006).

'Inpatient units provide care for those people who are most acutely unwell, who experience high levels of distress and who cannot be care for within their own homes or other community settings. Meeting such needs presents enormous challenges to staff and requires high levels of skill and commitment. Service users have frequently expressed concern at some aspects of the service provided (DH, 2002b) [(Department of Health 2002)]. Some common challenges arise from a lack of therapeutic activities, limited time spent in direct contact between qualified MHNs [Mental Health Nurses] and service users, problems in retaining staff, frequent absconsions from unlocked wards, a threat of violence and negative public and professional views of inpatient care.'

Department of Health (2006) p40.

2.1.1 The nature of acute mental health wards

It is commonly suggested that the inpatient population is largely composed of those with serious and enduring mental illnesses (Power et al. 1998, Sainsbury Centre for Mental Health, 1998). There is a perception that acute mental health wards have high levels of young men with serious and enduring mental health problems (psychotic disorders), co-morbid substance misuse and disturbed behaviour being admitted to them. Reports continue to describe a discouraging picture of acute mental health wards and criticise their ability to deliver safe, sound and supportive care (Channel 4 2006, Clarke and Flanagan 2003, Clarke 2004, National Patient Safety Agency 2004, Standing Nursing and Midwifery Advisory Committee 1999, The Sainsbury Centre for Mental Health 1997, 1998, 2005b). Acute mental health wards are frequently described as:

i) overcrowded, due to 100% average occupancy and poor ward design (Department of Health 2002, Mind 2005, The Sainsbury Centre for Mental Health 2005a);

ii) un-therapeutic, (Department of Health 2002, Mind 2005, The Sainsbury Centre for Mental Health 2005a);

iii) violent and aggressive, wards are seen as having high levels or perceived high levels of violence caused by pressures brought about by reduction in beds (de-institutionalisation) and the focusing of services towards risk management (Quirk and Lelliott 2001, Quirk et al. 2004);

iv) populated with a group of service users which are perceived as becoming increasingly ill (higher levels of detention under the Mental Health Act) and shorter stays (median length of stay of between 13 to 15 days) (Bartlett et al. 2001, Priest et al. 1995, Thompson et al. 2004);

v) concentrated in a diminishing resource (reduced numbers of beds) (Cleary 2004, Quirk and Lelliott 2001).

Quirk et al. (2006) described acute mental health wards as: mundane, boring but busy places; where service users were contained in cramped conditions and their movements restricted; where rapid turnover of staff and service users was common; and where drug misuse frequently occurred. To manage some of these difficulties security measures noticeably increased: doors were locked; nurses guarded ward entrances; and high numbers of service users were placed on high levels of observations (Hall 2004, Quirk et al. 2006). Despite these criticisms some service users do report satisfactory, positive and safe experiences associated with aspects of care in acute mental health wards (Howard et al. 2003, Johansson and Lundman 2002, Kuosmanen et al. 2006, Quirk et al. 2004).

2.1.2 Summary acute mental health wards

Acute mental health wards have frequently been criticised because they are overcrowded, disturbed and violent places with few therapeutic activities on offer. Despite the attention of policy makers, reports continue to highlight the inadequacies of care provided in these settings.

2.2 Psychotropic medication

Psychotropic medications are the main treatment option in acute mental health wards. The role of psychotropic medication in this setting is multi-functional: it improves mental health and reduces positive symptoms of psychosis (Harris et al. 2002); decreases arousal particularly to stress and stimulation; and is used in the reduction and management of violence and aggression. Accordingly, these medicines have an important role in acute mental health wards (Bowers 2005) and are routinely seen as the treatment of choice, with most service users admitted to acute mental health wards receiving them (Paton and Lelliott 2004). The Healthcare Commission (2007) recently estimated that 91% of inpatients were taking two or more medicines for either mental or physical health problems. A review of case notes and interviews with 255 inpatient admissions by Abas et al. (2003) identified restarting medication as the most frequently occurring reason for admission (n=117, 46%). Furthermore, research has identified that medication is perceived as a '*central task*' by the MDT in acute mental health wards (Bowers et al. 2005). Issues relating to the administration of medication account for nearly a quarter (21.7%) of the time nurses are in contact with service users, and nearly 10% of their total time (data collected between 7am and 6pm) (Whittington and McLaughlin 2000). The two groups of psychotropic medication most frequently used as PRN are antipsychotics and benzodiazepines; these groups of drugs are discussed in more detail (Bernard and Littlejohn 2000, Curtis et al. in press, Curtis and Capp 2003, Geffen et al. 2002b, Hales and Gudjonsson 2004, McKenzie et al. 1999, Usher et al. 2001).

2.2.1 Antipsychotic medication

Antipsychotic medication was introduced in the early 1950s (Stip 2002, Whitaker 2004). These first generation drugs (typical antipychotics) can be grouped into phenothiazines, butyrophenones, thioxanthines, and diphenylbutylpiperines. In the late 1950s a second generation of drugs commonly referred to as atypical antipsychotics were synthesized, of which Clozaril was the first (Spiegel 2003). They were defined as atypical due to the reduced frequency of extra-pyramidal side-effects (EPSEs) (Stip 2002). More recently, a third generation of antipsychotic drugs has emerged (aripiprazole). For the purpose of this thesis these drugs have been grouped

with second generation ones and are referred to as atypical antipsychotics. The anti-psychiatry movement has continually critiqued the effectiveness of all psychotropic drugs, particularly antipsychotics (Breggin 1993). Antipsychotics in particular continue to be a controversial treatment option and Mosher et al. (2004), in their chapter *'Drug companies and Schizophrenia'* provides a useful summary of recent issues and debates, Figure 2.1.

Figure 2.1: Neuroleptic drugs: proven and mythological effects.

Neuroleptic drugs: proven and mythological effects
Proven effects 1. Reduce the 'positive' (externally expressed) symptoms of 'schizophrenia' 2. Shorten, overall, hospital stays 3. Usually reduce readmission rates 4. Produce serious, often permanent, iatrogenic diseases like tardive dyskinesia 5. Revitalised interest in Schizophrenia 6. Produce enormous corporate profits
Mythological effects 1. Responsible for depopulation of psychiatric hospitals – 'deinstitutionalisation' 2. Improve long-term recovery rates for 'schizophrenia' 3. Enhance learning of new coping skills 4. Address the aetiology of 'schizophrenia' 5. Readmission rates would be nearly zero if drug compliance were assured

From Mosher et al. (2004) p116, table 10.1.

There is considerable evidence for the effectiveness of all antipsychotic medications in reducing positive psychotic symptoms and having a calming mechanism (Joint Formulary Committee 2006, Spiegel 2003). Additionally, there is evidence that atypical antipsychotic medication is as efficacious as typical antipsychotic preparations (National Institute of Clinical Excellence 2002a). Conversely, Stip (2002) argues that the reduction in positive symptoms reported in drugs trials is not definitive evidence that they work well. Despite advances in antipsychotic medications in recent decades, none have been demonstrated to cause remission of schizophrenia (Stip 2002). Furthermore, about a third of service users have no response to any antipsychotic medication (Conley and Buchanan 1997, Helliwell 1999, Karow and Lambert 2003) with Whitaker (2004) suggesting that:

'In the real world, up to 30% of hospitalized patients do not respond to neuroleptics. Among those who do and are discharged, more than one-third relapse within the next 12 months and need to be rehospitalised, even though they reliably take their medications. Thus, fewer than 50% of people who suffer a schizophrenic breakdown respond to standard neuroleptic [antipsychotic] and remain relapse-free for as long as a year.....' (p9).

The evidence for negative symptoms is less clear, although some literature implies that atypical antipsychotics are more effective. A systematic review completed by Geddes et al. (2000) found no difference between atypical and typical antipsychotic medication. Only Clozaril has been shown to be more effective than other antipsychotic preparations (National Institute of Clinical Excellence 2002a). Atypical antipsychotic medications are recommended for either first episode psychosis or in individuals who experience unbearable side effects from typical antipsychotics (National Institute of Clinical Excellence 2002b). It is widely accepted that antipsychotic medications are the treatment of choice during an acute episode, especially for those with psychotic disorders (National Institute of Clinical Excellence 2002b, Waraich et al. 2002). However, recently published studies on the Soteria project which tested an alternative to routine inpatient care, suggests that not using antipsychotic medication has a more favourable outcome for the treatment of first episode psychosis (Bola and Mosher 2003).

2.2.1.1 High doses and Polypharmacy[4]

The practice of prescribing high doses and/or polypharmacy of antipsychotic medication is not recommended (Harrington et al. 2002b, Joint Formulary Committee 2006, Karow and Lambert 2003, National Institute of Clinical Excellence 2005). Indeed, one study suggests that long-term exposure to multiple antipsychotic medications leads to premature death (RR 2.50 [95% CI 1.46-4.30]) (Joukamma et al. 2006). It has been contended that in those individuals with severe symptoms clinicians may prescribe multiple antipsychotic medications in an attempt to avoid high dose of one particular antipsychotic (Biancosinoa et al. 2005).

[4] Polypharmacy in this thesis is defined as the use of two or more antipsychotics at the same time. High doses are defined by the British National Formulary (BNF) limits. High doses in polypharmacy, doses can be calculated in two ways either as 'chlorpromazine equivalents' (maximum dose 1000mg per day), or as percentages of BNF limits for each drug added together (Royal College of Psychiatrist 2006).

A number of UK studies have examined the prevalence of high dose and polypharmacy in antipsychotic prescribing (Chaplin and McGuigan 1996, Krasucki and McFarlane 1996, Newton et al. 1996, Warner et al. 1995, Yorston and Pinney 1997). These studies found the prescription of high doses ranged from 2% to 42.4%. These studies were conducted around the time of the introduction of Royal College of Psychiatrists consensus statement about high-dose prescribing (Thompson 1994). A further study, which evaluated the impact of this statement, identified that PRN prescriptions substantially increased the number of service users prescribed high dose antipsychotics although only around 5% of these prescriptions were actually used (Milton et al. 1998).

A UK study of 3,132 service users in 47 Mental Health Trusts, (two thirds of whom were on acute mental health wards), found 20% (n=613) were prescribed doses higher than the British National Formulary (BNF) limit (Harrington et al. 2002b). Prescriptions for PRN antipsychotics accounted for up to half of these potentially high doses. Nearly half (48%, n=1,487) were prescribed more than one antipsychotic. There was considerable variation between services of high doses (range 0 to 50%) and polypharmacy (range 12 to 71%) of antipsychotic medication (Harrington et al. 2002a). The authors speculated that variations in case mix attributed for these differences. Further analysis revealed that age, gender, detention under the Mental Health Act and ward setting (rehabilitation and forensic rather then acute) increased antipsychotic polypharmacy, high dose prescribing and administration (Lelliott et al. 2002). Antipsychotic polypharmacy was found to be the most important factor in causing high doses (Lelliott et al. 2002). These studies used cross-sectional surveys of inpatient populations which potentially over-estimates the prevalence of both high doses and polypharmacy (Harrington et al. 2002b, Royal College of Psychiatrists 2006).

Based on these studies the Royal College of Psychiatry estimates that approximately one quarter of inpatients are prescribed high doses of antipsychotic medication. They attribute these high doses to the effects of polypharmacy, but also suggest that PRN significantly contributes to this (Royal College of Psychiatrists 2006). However, a

recent audit of prescribing practices of acute wards and psychiatric intensive care units (PICUs) in 32 Mental Health Trusts in the UK as part of the Prescribing Observatory for Mental Health UK (POMH-UK)[5] identified levels higher than Royal Colleges' estimates for high doses (36%, range 17 to 71%), multiple antipsychotic medications (43%, range 0 to 70%) and the co-prescribing of first and second generation antipsychotic medications (31%, range 0 to 56%) (Healthcare Commission 2007). Results from the first topic audit cycle suggest that there has been minimal impact on either high doses or polypharmacy prescribing of antipsychotic medication despite a multi-faceted intervention (Paton 2007). The intervention consisted of a clinical workbook (adapted from a previous trial (Thompson et al. 2005)), stickers on prescription cards, posters, workshops, and individual feedback to prescribers. Pre-post data from 32 Mental Health Trusts identified that 27% (n=945) patients were prescribed (or received) high dose antipsychotics, this compared with 24% (n=893) after the intervention (Paton 2007). The role of PRN was not discussed in these findings.

2.2.2 Benzodiazepine medication

The use of benzodiazepines in acute mental health wards is widespread. They were originally developed from Chlorpromazine and have been used in clinical practice since the early 1960s (Rogers et al. 2007). They are most commonly used for their sedating properties (Spiegel 2003). As clinicians have attempted to reduce dependency on older typical antipsychotics there has been an increased reliance on benzodiazepines, such as lorazapam and diazepam, in acute mental health care (Paton et al. 2000, Power et al. 1998, Richardson and Joseph 2001). Benzodiazepines are also commonly used as an adjunct to antipsychotic medications (Richardson and Joseph 2001). This contrasts with clinical practice in the community were the use of

[5] POMH-UK was established in March 2005 by Health Foundation funding. It aims to monitor and improve the prescribing of psychotropic medicines in relation to best practice. Five topics have been identified: i) topic 1, high dose and combination antipsychotics prescribed on adult acute and psychiatric intensive care wards (PICU)(Oct 2005-Apr 2007); ii) topic 2, monitoring the physical health of Assertive Outreach Team patients who are prescribed antipsychotics (Oct 2005 – May 2007); iii) topic 3, high dose and combination antipsychotics prescribed on forensic wards; iv) topic 4, benchmarking anti-dementia prescribing; v) topic 5, the prescribing of high dose and combination antipsychotics on adult acute and PICU wards.

benzodiazepines has been seen as problematic (Rogers et al. 2007). Lorazepam is often cited as the benzodiazepine drug of choice, especially when intra-muscular (IM) medication is required, because other benzodiazepine, for example diazepam, has erratic IM absorption (McAllister-Williams and Ferrier 2002). There are a range of sides effects associated with their use, most notably re-bound anxiety or insomnia, disturbed behaviour and in severe cases, respiratory depression and toxicity (with long half-life drugs) (Spiegel 2003, Stahl 2000). A paper by Duxbury and Baker (2004) which further describes benzodiazepines and their role in acute mental health wards has been included in the appendices (Appendix 1).

2.2.3 Related literature from studies in emergency psychiatry, and comparisons trials for the management of aggression

'On one occasion a patient practised 'Kung fu moves' in the smoking room. A nurse held down his arm and warned that 'if he did not calm down he would be given PRN.''

Ryan and Bowers (2005) p697.

Given the limitations of the evidence-base for PRN psychotropic medication (Whicher et al. 2003), trials in emergency psychiatry and comparisons studies of medicines for the management of aggression provides additional information on drugs which are commonly used as PRN. Benzodiazepines (lorazepam, diazepam and midazolam) and antipsychotics (haloperidol, droperidol, olanzapine, ziprasidone) are most commonly used drugs in these studies. In these trials drugs have been administered as either single doses or in combinations aiming to reduce behavioural disturbances, including; aggression, acute psychosis or mania. There has been renewed research interest in this area as older typical antipsychotics (droperidol and thioridazine) have been withdrawn and atypical antipsychotics introduced (De Fruyt and Demyttenaere 2004).

2.2.3.1 Acute psychosis

A number of systematic reviews have been conducted on behalf of Cochrane (Belgamwar and Fenton 2005, Carpenter et al. 2004, Gibson et al. 2004, Gillies et al.

2005, Waraich et al. 2002) and in other institutions (De Fruyt and Demyttenaere 2004, Goedhard et al. 2006) of treatments for acute psychosis. The Cochrane reviews have concluded that there is insufficient evidence to support the use of: benzodiazepines either alone or in combination with antipsychotic drugs (Gillies et al. 2005); clotiapine (Carpenter et al. 2004); and zuclopenthixol acetate (Gibson et al. 2004) in acute phases of psychotic illness. Although there is limited evidence of the effectiveness of olanzapine, the authors concluded that there may be an ethical bias because of how the studies were funded (Belgamwar and Fenton 2005). Furthermore, the Cochrane review of haloperidol often used as the 'benchmark' treatment concluded:

'It would be understandable, however, if clinicians were cautious in prescribing doses in excess of 7.5 mg/day of haloperidol to a person with uncomplicated acute schizophrenia, and if people with schizophrenia were equally reticent to take greater doses.'

Wariach et al. (2002) pp1-2.

Another Cochrane review compared combinations of haloperidol plus promethazine for psychosis induced aggression (Huf et al. 2004) and found that this combination worked better and was safer than using benzodiazepines (lorazepam or midazolam). The authors concluded that trials of these two drugs had randomised the largest total sample of any drug in this area. Despite this finding this combination of drugs is rarely used in the UK.

2.2.3.2 Violence and aggression

Chemical or physical restraint occurs relatively frequently during an emergency admission (10-20%) (De Fruyt and Demyttenaere 2004). There is a paucity of research which focuses on clinical interventions for dealing with violence (Department of Health 2006). This potentially leads to a reliance on pharmacological interventions rather than non-pharmacological ones. A systematic review by Goedhard et al. (2006) examined randomised controlled trials for pharmacological treatment of aggression and failed to identify any strong evidence for its use. In addition, they expressed concerns about flawed study designs and subsequent generalisability of the findings. Particular concerns were: general lack of statistical power; trials of too short a duration; and a lack of consistency in outcome

measurement (Goedhard et al. 2006). They recommended that larger pragmatic (naturalistic) trials should be undertaken (Goedhard et al. 2006).

A recent UK study identified that PRN medication had the highest approval rating of eleven potential containment methods (Bowers et al. 2004). However, a study in Australia suggested that nurses were more likely to seclude service users than rely on PRN medications (Wynaden et al. 2002), and the authors proposed that this enabled the service user to maintain control, prevent unwanted effects (sedation or disinhibition), and acted as a behavioural intervention. For these staff seclusion was identified as a safer and less restrictive practice than using PRN medication (Wynaden et al. 2002). In the UK, a study found that medication was a frequent consequence of restraint, occurring 51% (n=229) of the time (Ryan and Bowers 2006). Of these 40% was given in an IM format, although unclear from the published study these medications were likely to be administered from ongoing PRN prescriptions (Ryan 2007). Further studies have identified that the use of other behavioural interventions or training staff in these reduces the frequency of assaults, the use of PRN, restraints and seclusion (Bisconer et al. 2006, Donat 2002a, 2002b, 2005). The use of observations has been found to be highly significant in the reduction of IM medication usage (Damsa et al. 2006).

2.2.3.3 Rapid tranquilisation[6]

The National Patient Safety Agency has identified four Patient Safety Incidents (PSIs) specific to acute mental health wards. These are: i) absconding; ii) self harm and suicide; iii) violence (and aggression, including sexual); iv) harm caused by seclusion, restraint or rapid tranquilisation (National Patient Safety Agency 2004). Whilst most services have clear policies for rapid tranquilisation based on guidance (National Institute of Clinical Excellence 2005), the point at which PRN becomes rapid tranquilisation is ambiguous, although often assumed to be the point at which

[6] Defined as 'the use of medication to calm/lightly sedate the service user, reduce the risk to self and/or others and achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place and allowing comprehension and response to spoken messages throughout the intervention. Although not the overt intention, it is recognised that in attempting to calm/lightly sedate the service user, rapid tranquilisation may lead to deep sedation/anaesthesia.' National Institute of Clinical Excellence (2005) p81.

parenteral methods are used (McAllister-Williams and Ferrier 2002). De Fruyt and Demyttenaere (2004) concluded their systematic review of rapid tranquilisation by suggesting that despite the high frequency of use, they were surprised by the small number of trials conducted in this area. These trials were methodologically flawed in terms of poor design, small samples, varying definitions of rapid tranquilisation, and they failed to report unwanted effects. This they argued invalidates the generalisability of the findings. Despite these criticisms findings from these trials are reflected in some clinical guidelines, with De Fruyt and Demyttenaere (2004) concluding:

'..in the face of emergency, imminent agitation or aggression where everything and everyone is out of control, clinicians will stick to personal experience and methods. Hard evidence is needed to challenge and change these 'proven habits'' (p248).

2.2.4 Service users' perceptions of medications (in inpatient settings)

The reliance on medication as the dominant treatment option has been criticised by both service users and carers (Johnson et al. 2004, Pollock et al. 2004). Ruane (2004) identified nine anti-therapeutic features of acute mental health wards, three of which relate to medication: firstly, a medication dominated approach which excludes other forms of therapies; secondly, the side effects of the medication; and thirdly, compulsory treatment. Other factors such as failure to share decision making have emerged as part of the negative experiences associated with treatment particularly medication (Brimblecombe et al. 2007, Johnson et al. 2004).

Unfortunately, trials and clinical practice rarely reflect the concerns of service users or their preference for oral and single doses of medications with only a few studies which examine users' views. One study suggested that the inpatient service users and staff have a high preference for oral preparations (Muller 2002). This contrasts with several studies which have explored service users experiences of forcibly being medicated whilst inpatients (Haglund et al. 2004, Haglund et al. 2003). A further study identified a group of service users who were so opposed to having antipsychotic medication that they would prefer physical restraint (Sheline and Nelson 1993). A recent survey by Gray et al. (2005) of community and inpatient identified that about two thirds were either satisfied or very satisfied with their treatment (68%, n=47) and

found medication beneficial (71%, n=49). However, this conflicted with the finding that more than half took medication because they had been told to (54%, n=35). They were also experiencing side effects (64%, n=44), with 34% of these deemed 'intolerable' (n=15).

Recently, there has been a considerable debate about service users and their choices about medication (Day et al. 2005, Perkins and Repper 1999). Rather than the issue being seen as one of compliance, consideration should be given to service users making an informed choice about their treatment and care (National Institute of Clinical Excellence 2002a, 2002b). Lack of information and education about medication and unwanted effects is a consistent theme emerging from user and carer surveys (Gray et al. 2005, Howard et al. 2003, Pollock et al. 2004, Ruane 2004). Information provision is more likely to occur when new treatments are initiated as it is often assumed that those who have been on treatment for a while know all about them; however, this is often not the case (Happell et al. 2002).

2.2.5 Summary medication

There is a substantial evidence for the use of both antipsychotics and benzodiazepines. They are a frequently used intervention in acute mental health wards for a range of reasons including psychosis and behavioural disturbances. PRN clearly has a substantial role in causing both high doses and polypharmacy of antipsychotic medication. However, the use of medication is frequently criticised as being the only treatment option in acute care. Information provision and choice by service users is often neglected.

Chapter 3 Methodology

'No single method or even a combination of methods can capture the whole and complex reality'

Foss and Ellefsen (2002) p244.

The use of PRN psychotropic medications in acute mental health wards is a complex clinical intervention. This chapter provides the methodological foundations for the thesis. It begins by providing an overview of the research paradigms. This is followed by a discussion of the chosen methodology and its key features. In doing so the rationale for adopting a mixed methods approach for the study becomes apparent. It then provides a description of steps required to join the data into a coherent meaningful intervention which achieves the aims and objectives. The chapter then focuses on the selection of suitable methods to answer the aims and objectives of the thesis and includes methods for reviewing the literature, gaining expert opinion and exploring current practice.

3.1 Research paradigms

Understanding how paradigmatic issues influence the research process is important. A recent nursing 'think tank' cited this issue in the top ten of all issues facing nursing (Weaver and Olson 2006). Understanding the differing research paradigms, especially those which reflect personal thinking and therefore influence research design, should improve the quality of research conducted. Homogeneity in the research process is undoubtedly important, without transparency the philosophical underpinnings of research can become hidden, this can lead to research projects becoming flawed (Creswell 2003). A clear understanding of research paradigms enables any investigation to be well structured and provides understanding of philosophical assumptions that researchers may have made (Weaver and Olson 2006).

Traditionally, research has been influenced by either quantitative or qualitative paradigms. Authors have described a number of other paradigms which have

emerged during the 20th Century including pragmatism, constructivism, and advocacy and participatory schools of thought (Creswell and Clark 2007, Tashakkori and Teddlie 1998).

3.1.1 Quantitative approach

The concept of positivism [Comte/Hume] emerged in the 18th Century (Fox et al. 1998, Richards et al. 1999, Smith 1997). During its development positivism has been refined through logical positivism [Ager/Carner] (early 20th century) to more recently being described as logical empiricism or post positivism [Kemple] (late 20th century) (Smith 1997). It aims to form generalisable laws and theories from which empirical data can be explained (Fox et al. 1998, Wilson and Butterworth 1998). The main focus of research is devised through the testing of theories and hypotheses. As such this approach is used in a diverse range of research, including the natural and social sciences (Wilson and Butterworth 1998). Experimental approaches explore cause and effect; an example of this type of research can be found in randomised controlled trials (Richards et al. 1999, Smith 1997, Wilson and Butterworth 1998). Specific methods employed include surveys, which aim to collect information about variables and experimental approaches.

3.1.2 Qualitative research

Interpretivism emerged as a direct rejection of positivism. A number of philosophical approaches can be included in a qualitative (interpretivism) approach such as naturalism, ethnography, grounded theory and phenomenology (Smith 1997, Wilson and Butterworth 1998). These approaches developed from the rejection of science and in particular positivism (Richards et al. 1999, Smith 1997). Specific methods used include observations or unstructured interviews. Method selection is often dependent upon the underlying philosophical approach adhered to (Parahoo 1997, Wilson and Butterworth 1998). A major distinction from a positivist approach can be seen in the role of the researcher. In the qualitative paradigm researchers' involvement is valued in the process (Smith 1997).

3.1.3 Pragmatism

Pragmatism is now widely regarded as the 'third paradigm' (Creswell 2003). Pragmatism is based on the principles of inclusiveness as opposed to the traditionally held views of 'incompatibility' which fuelled the paradigm wars. Pragmatists have been described as pacifists of this war, and propose that it is possible to build on the strengths of the two research traditions (compatibility thesis) thereby reducing their inherent flaws (Johnstone and Ouwuebuzie 2004, Johnstone 2004, Tashakkori and Teddlie 1998). It is closely associated with mixed methods research (Creswell and Clark 2007, Tashakkori and Teddlie 2003). Classical pragmatism emerged in the late 19th century and is closely associated with American culture (Maxcy 2003). Its founding fathers are regarded as Charles Sanders Peirce, William James, Herbert Mead and John Dewey. Later interest was re-kindled by the neo-pragmatists including Abrabham Kaplan and Richard Rorty (Johnstone and Ouwuebuzie 2004, Maxcy 2003). Kaplan's work is regarded as one of the first challenges to the ideas of incompatibility (Maxcy 2003) and enables the integration of research methods from different research paradigms:

'Thus pragmatists decide what they want to research, guided by their personal value systems; that is, they study what they think is important to study. They then study the topic in a way that is congruent with their value system, including variables and units of analysis that they feel are the most appropriate for finding an answer to their research question. They also conduct their studies in anticipation of results that are congruent with their value systems.'

Tashakkori and Teddlie (1998) p26-7.

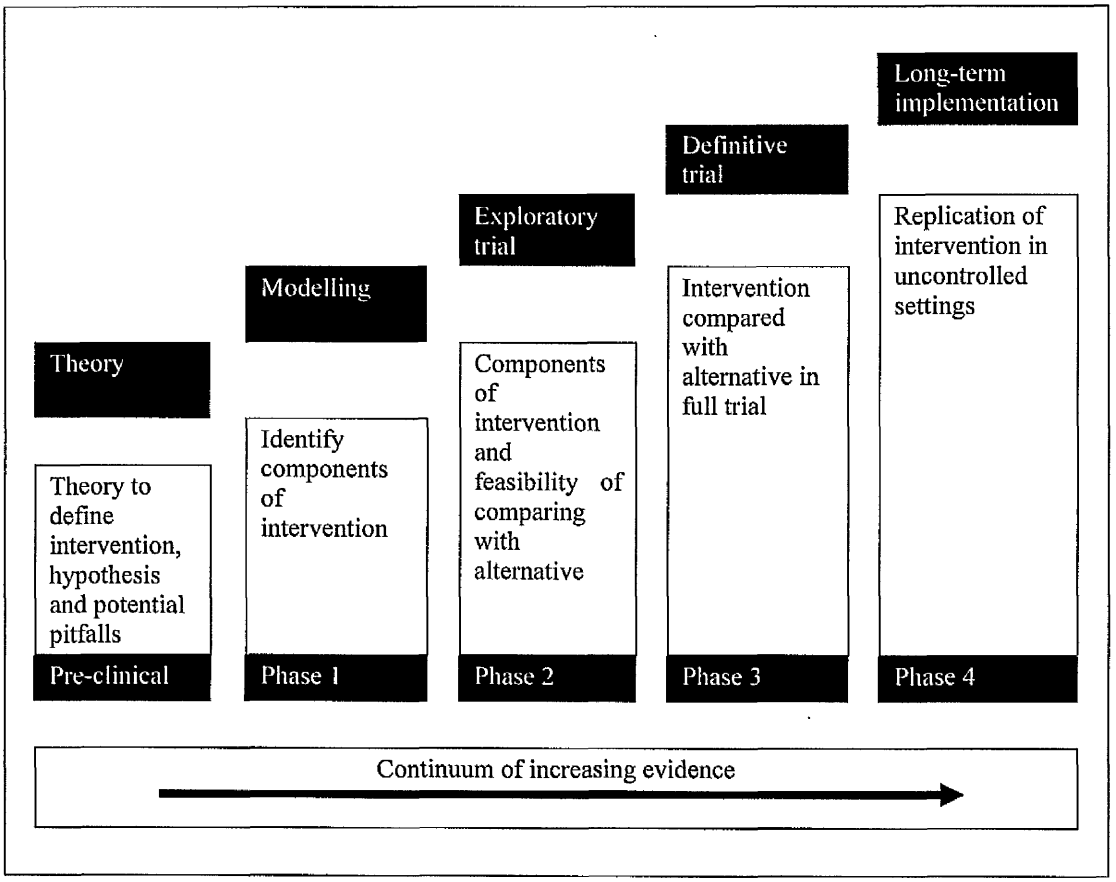
3.1.4 Research paradigms - summary

A study of PRN psychotropic medication which leads to the development of an effective good practice manual needs to take account of both the breadth (quantitative) and depth (qualitative) of current practice. Grounding the study in one of the two traditional research paradigms could make the resulting manual weaker than if both avenues had been explored. Pragmatism provides a philosophical basis for studies which use mixed methods and informed this thesis.

3.2 MRC framework for complex interventions

As stated in the introduction the MRC framework provides clear guidance on developing complex interventions (Figure 3.1) (Campbell et al. 2000, Medical Research Council 2000).

Figure 3.1: Framework for trials of complex interventions.



From Medical Research Council (2000) p3.

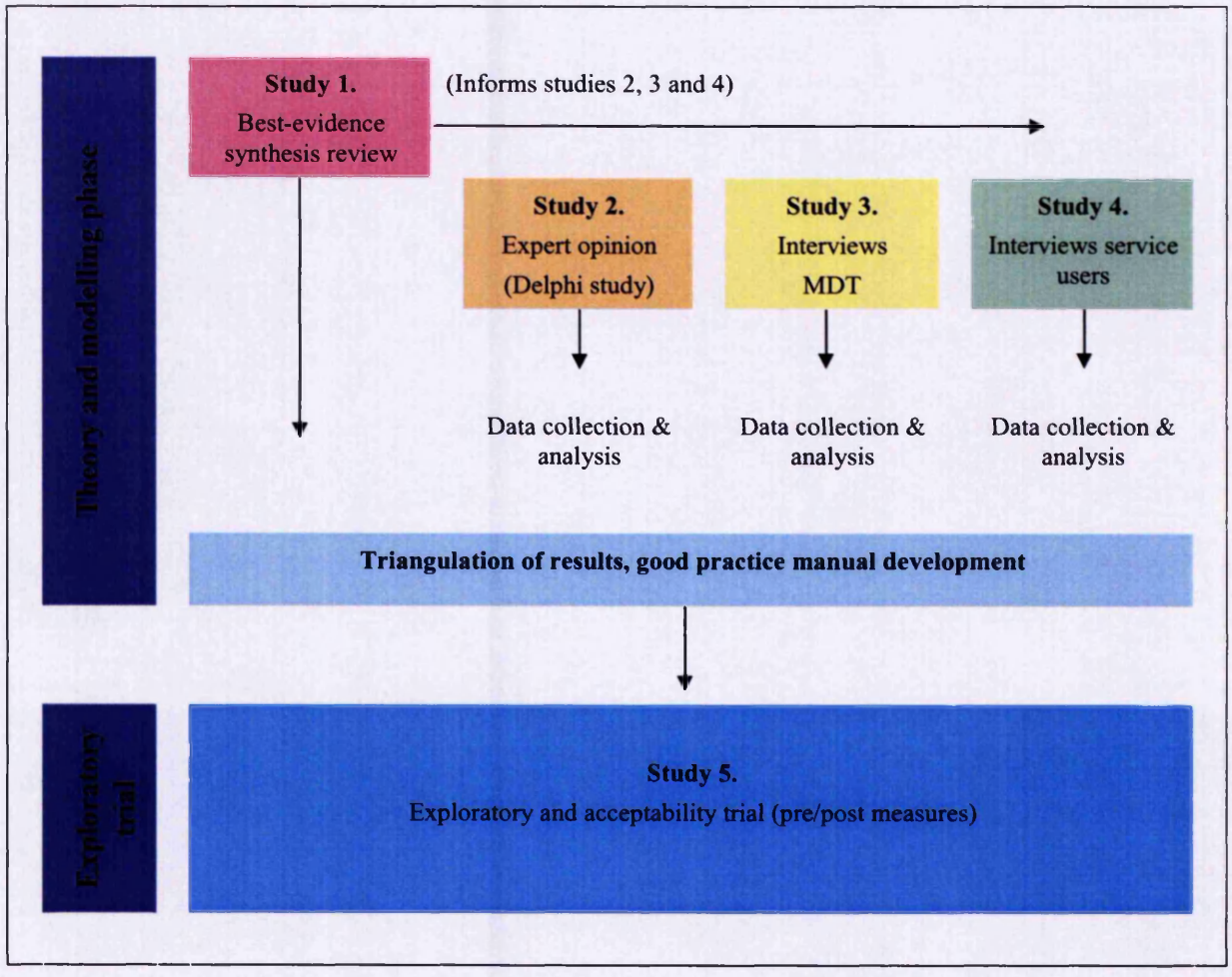
The aim of the pre-clinical phase is to develop a theoretical basis for the intervention and identify the potential effects that it may have. In the next stage modelling, importance is placed on defining and developing the intervention (Medical Research Council 2000). The MRC (2000) identifies that this is often the weakest part of most studies. The more complex the intervention the more components there are to explore. The undertaking of qualitative research has clear value at this point, although other methods such as surveys can also be used (Blackwood 2006, Medical Research Council 2000). The next stage the exploratory trial tests the intervention, potential outcomes, feasibility and acceptability of the intervention (Blackwood 2006). It also

allows the identification of variables which could be tested in larger randomised studies (Medical Research Council 2000). Figure 3.2 describes aspects of this thesis relative to these phases. Recent discussions have suggested moving this framework from a stepwise to a parallel approach; this combines the first three stages to enable understanding of the context, the problem, the interventions and methods of evaluation (Campbell et al. 2007).

However, it has been suggested that a standardised intervention used in a RCT is incompatible with the idea of 'complex systems' instead they propose there should be 'context level adaptation' (Blackwood 2006, Campbell et al. 2007). Another criticism of trials of complex interventions is their failure to consider the generalisability of interventions particularly, feasibility, acceptability and coverage (Blackwood 2006, Bonnell et al. 2006). Bonnell et al. (2006) proposes that the process of trials (including planning, delivery, uptake and context) should be rigorously evaluated with sufficient reference to the socio-demographic profiles of participants for future studies to be able to adapt the intervention.

Intentional space

Figure 3.2: Framework for development and testing of the good practice manual, and structure of the thesis with reference to the MRC complex intervention framework.



3.3 A mixed method approach; merging quantitative and qualitative methods

Mixed method designs are the inextricably linked to the development of complex interventions (Blackwood 2006). The term mixed method research should not be confused with either multimethod research studies (2 or more methods in the same paradigm) or mixed model research (which relates to statistical analysis) (Creswell and Clark 2007). For the remainder of this thesis mixed method research will be the consistently applied term to describe the approach of this study. Tashakkori and Teddle (2003) define mixed method research as studies which combine both qualitative and quantitative data in either sequential or concurrent designs. The literature reports over 40 different designs for mixed method research. It has been

suggested that these can be subsumed into six design types as a result of four design criteria (Tashakkori and Teddlie 2003). These criteria are termed: a) implementation; b) priority; c) stage of integration; and d) theoretical perspective (Creswell 2003). The interplay of these four factors is shown in Table 3.1 and will be explored in more detail in the subsequent text.

Table 3.1: Method designs by four criteria.

Design type	Implementation	Priority	Stage of integration	Theoretical perspective
Sequential explanatory	Quantitative followed by qualitative	Usually QUAN, can be QUAL or equal	Interpretation phase	May be present
Sequential exploratory	Qualitative followed by quantitative	Usually QUAL, can be QUAN or equal	Interpretation phase	May be present
Sequential transformative	Either QUAN - QUAL or QUAL - QUAN	QUAN, QUAL or equal	Interpretation phase	Definitely present (i.e. conceptual framework, advocacy, empowerment)
Concurrent triangulation	Concurrent collection of QUAN and QUAL data	Preferably equal; can be QUAN or QUAL	Interpretation phase or analysis phase	May be present
Concurrent nested	Concurrent collection of QUAN and QUAL data	QUAN or QUAL	Analysis phase	May be present
Concurrent transformative	Concurrent collection of QUAN and QUAL data	QUAN, QUAL or equal	Usually analysis phase; can be during interpretation phase	Definitely present (i.e. conceptual framework, advocacy, empowerment)

From Creswell et al. (2003) Advanced mixed methods research designs, Chapter 8, p224, in Tashakkori and Teddlie (2003) *Handbook of mixed methods in social and behavioural research,* (Key: QUAN = quantitative, QUAL = qualitative).

3.3.1 Implementation

Implementation refers to the timing or sequencing of data collection. This can be either sequential (one method followed by another) or concurrent (at the same time) (Tashakkori and Teddlie 2003). A sequential design usually involves the collection of one type of data followed by another from a different paradigm and is a preferred method for either problem exploration followed by testing (qualitative followed by quantitative), or when testing is followed by problem exploration (quantitative

followed by qualitative) (Tashakkori and Teddlie 2003). A concurrent design allows the researcher to be able to collect more than one type of data at a time (quantitative and qualitative together). Concurrent data collection enables a shorter overall data collection period and is therefore more relevant to time limited studies such as doctorial studies (Creswell et al. 2004). It also allows for the identification of similar (congruent) findings from different methods (Creswell et al. 2003). However, it can be a complicated process as it requires the researcher to be familiar with and collect different types of data at the same time.

3.3.2 Priority

Priority provides an indication which of the two methods/paradigms is more valued by the researcher (quantitative or qualitative). So are quantitative methods more important than qualitative ones or vice versa? Although rare researchers can place equal emphasis on both qualitative and quantitative data in a study (Creswell et al. 2003, Foss and Ellefsen 2002).

3.3.3 Stage of integration

This refers to the point at which the multiple methods are merged. There are four commonly cited points when integration can occur: i) research question; ii) data collection; iii) data analysis; and/or iv) interpretation (Creswell et al. 2003). Integration most commonly occurs either at the interpretation or the analysis phase.

3.3.4 Theoretical perspective

All research is influenced by theoretical perspectives, both informal (researcher's personal stances) and formal (lens) (Creswell et al. 2003). This needs to be taken account of when developing mixed methods studies.

3.3.5 Concurrent triangulation design

Taking account of the four design criteria the concurrent triangulation design is the most suitable for this study. It is the most frequently used design of mixed method

research studies and has a number of clear advantages (Creswell et al. 2003). The concurrent collection of data enables a very practical way of collecting multiple forms of data in a short time period (Creswell et al. 2004, Tashakkori and Teddlie 2003). The benefit of adopting this approach is that it allows for a comprehensive understanding of the issue of PRN psychotropic medications in acute mental health wards. The integration of data at the interpretative phase could produce a meaningful and valid manual based on combining experiences and views with best available evidence (literature review and expert opinion). However, there are some drawbacks. The collection of different types of data at the same time is complex and requires expertise in multiple methods. Care is also required with how the resulting data is compared, especially at times of disagreements (Creswell and Clark 2007, Creswell et al. 2003).

3.4 Triangulation

In the literature five types of triangulation are described. Figure 3.3 describes these in more detail. Four of these types have been attributed to Denzin (1989); data, investigator, theory, and method. A fifth type, analysis, was developed by Kimchi et al. (1991).

Figure 3.3: Five types of triangulation.

<table>
<tr><th>Types of triangulation</th><th colspan="5">Sub-types</th></tr>
<tr><td rowspan="2">Data triangulation</td><td rowspan="2">Time (same thing different times)</td><td rowspan="2">Space (same thing different sites)</td><td colspan="3">Person (different levels of the person)</td></tr>
<tr><td>Individuals</td><td>Groups</td><td>Collectives</td></tr>
<tr><td>Investigator / researcher</td><td colspan="5">Multiple researchers involved all with differing knowledge and experiences.</td></tr>
<tr><td>Theoretical / theory</td><td colspan="5">Differing theoretical backgrounds.</td></tr>
<tr><td>Methodological</td><td colspan="2">Two or more research methods at time of data collection or analysis</td><td colspan="2">Within-method - two or more research methods at time of data collection or analysis from the same paradigm</td><td>Across (or between) method. Two or more research traditions i.e. Qualitative and quantitative.</td></tr>
<tr><td>Analysis</td><td colspan="5">Two or more methods of analysis of the same data to validate.</td></tr>
<tr><td>Multiple triangulation</td><td colspan="5">The use of two or more of the above</td></tr>
</table>

From Denzin (1989) and Kimchi et al. (1991)

3.4.1 Benefits and limitations of triangulation

Redfern and Norman (1994) have identified eight strengths and limitations of triangulation, Table 3.2, many of the limitations can be associated with most research methods (Begley 1996). An additional criticism results from the varied meaning of the word 'triangulation'; this means researchers need to be explicit about process (Adami and Kiger 2005).

Table 3.2: Strengths and limitations of triangulation.

Strengths	Weaknesses
Overcome bias of single studies.	No guarantee of internal and external validity.
Increased confidence in results.	May compound sources of error.
Allows validation and development of instruments and methods (confirmation)	Methods selected may not be the right ones.
Provides an understanding of the domain.	Unit of analysis might not apply to all methods.
Ideal for complex social issues.	Cannot compensate for researcher bias.
Overcomes elite bias of naturalistic research.	Expensive.
Overcomes holistic fallacy of naturalistic research.	No use with the wrong question.
Allows divergent results to enrich explanation.	Replication difficult.

From Redfern and Norman (1994) p51-2.

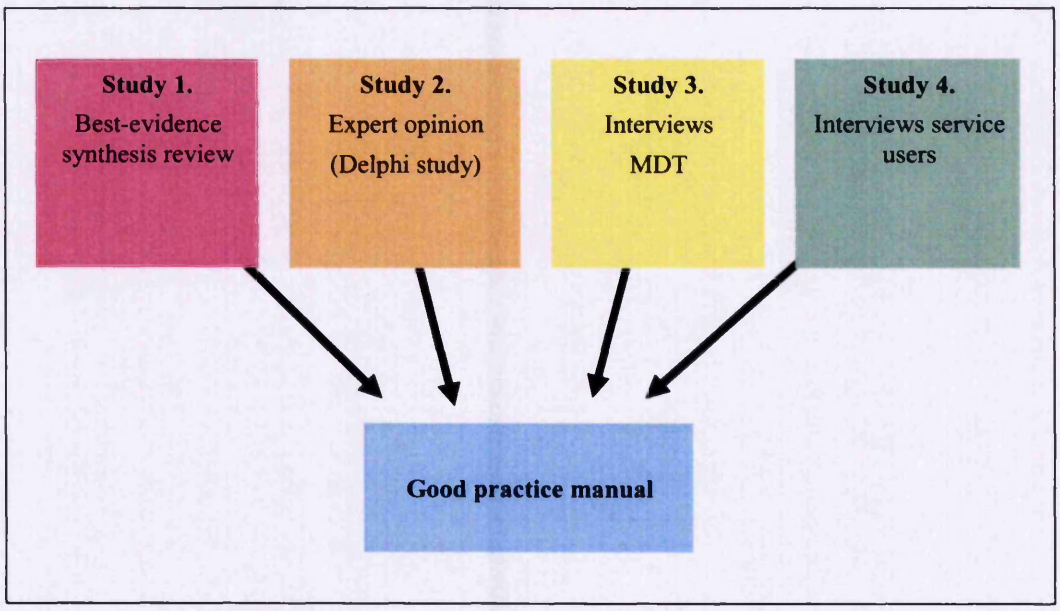
3.4.2 Triangulation used in this thesis and related studies

The development of the good practice manual via a mixed methods approach required the extraction and combination of data from several strands: (i) review of the literature; ii) clinical practice (interviews with MDT and Service Users); and, iii) expert opinion (Delphi Study) of the research. This process is displayed in Figure 3.3. Merging the data into a meaningful and clinically relevant product is undoubtedly important, but clearly required careful consideration, as there is potential for introducing bias or generating unfounded conclusions. Given the pragmatic underpinnings of this mixed method study design, triangulation appeared to the recommended process for bring the data together (Farmer et al. 2006):

'Given the projects multiple data sets and the need to generate an integrated set of findings, the aim of employing triangulation was to help ensure complementarity and test for convergence and dissonance of ideas inherent within.'

Farmer (2006) p381.

Figure 3.4: Data strands which required combining.



The study employed several different types of triangulation (multiple triangulations) to enhance the rigour, depth and breadth of resultant findings (Adami and Kiger 2005, Begley 1996). Firstly, in terms of data triangulation, the use of staff from different shifts (time), multiple sites in three different organisations (space), and different group of people including service users and the MDT (person). Triangulation at this level has traditionally been regarded as confirmatory, to cross-validate findings, although it is increasingly thought of as enabling completeness (Adami and Kiger 2005). At the investigator level the project management group and supervisors contributed differing perspectives and knowledge to the authors. Finally, at a methodological level, multiple methods of data collection and analysis were used from differing research traditions (across-method or between method) to assure convergent validity (Begley 1996).

3.5 Reflexivity

Reflexivity requires researchers to reflect on their impact on the research that they are conducting (Arber 2006). It is traditionally associated with qualitative research it is now considered to be applicable in all research (Freshwater 2005). It enables understand of the researcher's tacit knowledge and bias that they may introduce, although critiques report it encourages self-indulgence and provides a pre-determined defence against external criticism (D'Cruz et al 2007, Freshwater 2005). Experiences which have influenced me include: i). my clinical experience of working in acute mental health wards, which challenged and influenced my beliefs about how PRN psychotropic medication should be used; ii) my formal educational development, from reading 'Toxic Psychiatry' (Breggin 1993) as a student nurse to undertaking a Master's degree in psychosocial interventions iii) my personal reluctance to take medication iv) my status as a Nurse and Researcher required consideration of how to act if examples of bad or dangerous practice would occurred. One method employed throughout the study to challenge my thinking was the use of supervision and steering group meetings to discuss and ratify ideas for the direction of the research. For example, all the questions used in Studies 2, 3 and 4 were devised during steering group meetings.

3.6 Method

This section describes the rationale for the method selection in the five studies, summarised in Table 3.3. It then provides a description of the main features of the selected methods.

Table 3.3: Phase, objectives, sample, design, analysis and outcomes for the studies.

	Objectives	Study	Sample	Design	Analysis	Outcome
Phase 1 (theory and modelling phase)	To conduct a literature review of the utilisation of PRN psychotropic medication.	Study 1	27 papers	Best-evidence synthesis	Synthesis of findings	6 themes identified: - Frequency of administration - Administration in the 24 hr day - Administration associated with length and stage of admission. - Rationales for administration - Medicines administered (including route of administration) - Effects and side effects
	To explore current practice (strengths and weakness) from the perspectives of experts.	Study 2	18 multi-disciplinary experts	Delphi study	- Criterion of consensus - Stability of responses - Landis and Koch's (1977) strength of agreement	78, then 34 items and finally 13 items in 4 themes: - Increase service user focus - Improved process of prescribing and administration - Review of PRN - Monitoring of side effects
	To explore current practice (strengths and weakness) from the perspectives of the MDT.	Study 3	59 members of the MDT	Semi-structured interviews	Thematic content analysis	- Balanced usefulness. - Decision making processes. - PRN psychotropic medication as a clinical intervention. - Process issues. - Information provision and PRN psychotropic medication. - Variations in practices.
	To explore current practice (strengths and weakness) from the perspectives of service users.	Study 4	22 service users	Semi-structured interviews	Thematic content analysis	- Value of PRN - Disempowerment and control - Information and knowledge - Alternatives to PRN - The need for PRN
Phase 2 (exploratory trial)	a) To determine the pre-post effects of the good practice manual on practice (study 5);	Study 5	35 service users 11 nurses 12 doctors	Exploratory trial	Comparisons of pre-post quality (Independent sample T-tests/Mann Whitney U). Drugs administered pre-post (Chi-squared)	- 484 doses administered to 28 of 35 service users - 14 different drugs prescribed in 34 different combinations - Prescription quality increased, nursing notes reduced - Medication errors in 23 of 35 service users
	b) To determine MDT acceptability of the good practice manual (study 5).		13 of 23 consenting MDT	Questionnaire with Likert scales and open ended questions	Descriptive statistics	High levels of acceptability of the manual reported by the MDT

3.7 Study 1: Reviewing the literature on PRN psychotropic medication

A number of methods of reviewing the literature have been proposed in the literature. These include: systematic reviews; topic reviews (Griffiths and Norman 2005); clinical reviews (Vetter 2003); mini-reviews (Griffiths 2002); ground analysis approach (Glasby and Beresford 2006, Glasby and Lester 2005); and best-evidence synthesis (Slavin 1986). These will now be defined in further detail.

3.7.1 Systematic reviews

The undertaking of a systematic review of the literature is a common and highly regarded approach for reviewing the literature (with or without meta-analysis) (Sutton et al. 1998). This would provide a systematic and structured search; assessment of the quality of studies; a clear description of processes undertaken to ensure replication was possible; and a summary of the extracted data under the PICO[7] format (Griffiths 2002, Vetter 2003). However, systematic reviews are not infallible. Inaccuracies have been identified between Cochrane reviews and published study based ones and there have been disputes about conclusions reached in different systematic reviews on the same drugs, for example between National Institute of Clinical Excellence (NICE) and the Drugs and Therapeutic Bulletins on zanamivir (used in the treatment of flu (influenza)) (Vetter 2003). There are also concerns that publication bias, heterogeneity between studies, poor consensus for study quality assessment, statistical methods to explore study effects and unrefined methods of dealing with missing data could impact on the quality of systematic reviews and meta-synthesis (Sutton et al. 1998). It is reported that adopting the new Quality of Reporting of Meta-analysis (QUORUM) statements for the reporting of meta-analyses should help address some of these inadequacies (Griffiths and Norman 2005). QUORUM contains 18 items, eight of which are evidence-based, in the forms of a statement, check list and flow diagram to describe how systematic reviews should be formatted for publication (Moher et al. 1999).

[7] PICO: Participants, Intervention, Comparison, Outcomes.

3.7.2 Topic reviews

Griffiths and Norman's (2005) editorial in *International Journal of Nursing Studies* debated the value of undertaking systematic reviews, particularly in a PhD thesis, or at times when there is limited RCT evidence, or if the question is broader than a systematic review can answer. They propose that it maybe more appropriate to conduct wider more encompassing '*broad topic reviews*' which in many aspects is similar to a traditional review. This approach replaces inclusion and exclusion criteria with a '*sieving strategy*' which contains a more qualitative account of why articles were included. However, traditional literature reviews have received considerable criticism in recent years because they can be un-systematic, include outdated reviews, and present a biased account of the literature (Antman et al. 1992, Vetter 2003).

3.7.3 Clinical reviews

Vetter's (2003) editorial in *Reviews in Clinical Gerontology* provides a detailed elaboration on the differences between clinical reviews and systematic reviews. Although clinical reviews may use the similar searching strategies as systematic reviews they are less rigorous in obtaining unpublished data. Their advantage is that they are conducted often by a clinician experienced in the disorder rather than a 'technician'. This can make the findings broader, but more useful at a local or clinical level. Vetter (2003) recommends using the READER[8] algorithm for screening studies as this have been demonstrated to improve the consistency and scrutiny of studies.

3.7.4 Mini-reviews

This format has been proposed by Griffiths (2002) as a means of increasing the accessibility of literature reviews which are systematic to the nursing workforce. In essence it is a less sophisticated, shorter version of a systematic review. Less attention is given to the searching and retrieval of articles and while meta-synthesis is not undertaken, a general description of trends is presented.

[8] READER: Relevance, Education, Applicability, Discrimination and Overall Evaluation in Vetter (2003).

3.7.5 Ground analysis approach to reviewing the literature

A ground analysis approach to reviewing the literature has been proposed as a means of incorporating different types of literature to produce a broader review (Glasby and Beresford 2006, Glasby and Lester 2005). This approach undertakes a broad comprehensive search but in reviewing the literature themes are inductively identified and tested against the subsequent literature. This in effect allows more literature to be included in reviews than the tight inclusion and exclusion criterion of systematic reviews normally permits. Glasby and Beresford (2006) propose that this leads to 'knowledge-based practice', which incorporates traditional medical knowledge with practice wisdom and testimonies of service users and careers.

3.7.6 Best-evidence synthesis

The best-evidence synthesis model of reviewing literature was proposed as a means to overcome perceived flaws associated with traditional or meta-analytical reviews and which combines their strengths. This method appears particularly useful in the absence of RCT evidence, as it is acceptable to review less well designed studies:

'However, if a set of studies high in internal and external validity does not exist, we might cautiously examine the less well designed studies to see if there is adequate unbiased information to come to any conclusion.'

Slavin (1986) p6.

Slavin (1986) recommends a number of features that differentiate this method from others. This includes establishing inclusion criteria, although these should not be subjective as is common in traditional reviews (for example excluding thesis), or excluding papers with unclear effect sizes which would happen in meta-analyses. Slavin (1986) also suggests that the literature should be broadly searched. Slavin (1986) describes that the main part of the review will in essence look similar to any narrative review but be able to synthesise the evidence to:

'....answer important questions about effects of various treatments, possible conditioning or mediating variables, and so on.' (p10)

3.7.7 Summary Study 1: Reviewing the literature on PRN psychotropic medication

From exploring the various approaches for reviewing the literature the best-evidence synthesis approach offers the best method for Study 1. Given that a systematic review had been completed on PRN psychotropic medication in acute mental health settings by Cochrane (Whicher et al. 2003), this methods was rejected with its shorter version the mini-review. Although useful at the local level clinical reviews were considered less robust, particularly as there is a tendency not to search for all available published materials. Whilst the topic and ground analysis approaches were considered useful, there were, nevertheless, not as robust as the best-evidence synthesis method proposed by Slavin (1986).

3.8 Study 2: To explore current practice (strengths and weakness) from the perspectives of experts (consensus methods).

In the absence of robust evidence (RCTs or systematic reviews), alternatives are required to inform clinical and health policy decision-making. Historically decisions in healthcare were made informally. This has been criticised for a lack of scientific credibility, rationality and authority (Murphy et al. 1998). Consensus methods have been proposed as one mechanism which improves on informal group decisions (Bowling 2002, Campbell and Cantrill 2001). There are a number of approaches for building consensus (Murphy et al. 1998). Most common are: i) Delphi studies (Dalkey and Helmer 1963); ii) Nominal group technique (NGT) (Delbecq and Van de Ven 1971, Delbecq et al. 1975); and iii) Consensus development conferences or panels (Fink et al. 1984). However, Campbell and Cantrill (2001) suggest that the Research and Development (RAND) appropriateness method (otherwise known as a 'modified NGT') should be included as a consensus method instead of the NGT as they argue it is a more robust method.

Only one of these methods uses postal means to develop consensus; the Delphi study (Murphy et al. 1998). For a PhD thesis this approach has several advantages. Firstly, the Delphi study can cover large geographical areas without associated travel; it is

unlikely that experts would travel large geographical distances to attend a meeting or conference organised by a PhD student (Graham et al. 2003, Jeffery et al. 2000, Murphy et al. 1998, Philips 2000, Powell 2002). Secondly, the method is cost-effective (Hardy et al. 2004). The financial costs associated with an electronic or postal survey are relatively cheap in comparison to organising face-to-face meetings (Shannon et al. 2002). Moreover, not having face-to-face contact with other panellists also decreases the biases associated with meetings, such as personality clashes, seniority, inhibition, intimidation, or the persuasive panellist effect (peer group pressure) (Graham et al. 2003, Hardy et al. 2004, Kennedy 2004). However, this comes at a cost because it can reduce accountability leading to carelessness (Beech 1999, Duncan et al. 2004, Jeffery et al. 2000, Kennedy 2004, Mullen 2003, Powell 2002). The lack of interaction can also reduce insight and stimulation (Graham et al. 2003, Jeffery et al. 2000).

3.8.1 The Delphi method

The development of the Delphi method has been attributed to Dalkey & Helmer (1963) of the RAND Corporation. Originally sponsored by the United States Air Force, 'Project Delphi' was established during the 1950s to hypothesise the effects of Russian nuclear attack on the munitions output of the USA (Dalkey and Helmer 1963). Delphi is an established technique for determining consensus in policy issues, treatment protocols and algorithms, and developing informed judgements (Beech 2001, Graham et al. 2003, Hardy et al. 2004, Mead and Moseley 2001b). It is particularly useful when little previous research (knowledge) has been conducted or uncertainty exists (McKenna 1994, Mead and Moseley 2001a, Murphy et al. 1998, Powell 2002). In the last fifty years several different versions have been used, these have been summarised by Walker and Selfe (1996) (Figure 3.5):

Figure 3.5: Adaptations of the classic Delphi method.

Types of Delphi	Main feature
Numerical[1]	Only simple statistical analysis required.
Policy	Forecasting future issues
Historic	Concerns background to past decisions
Reactive[2]	Uses pre-generated items in round one.
Conventional[3]	Postal, round one generates items, aims for consensus.
Real-time	Electronic media, eg, using email or conference voting to provide instant feedback.
Policy	Used to produce policy options
Decisions	Respondents are stakeholders in decision making; consensus less relevant

From Walker and Selfe (1996) p677, (key: [1]= Reid (1988), [2]= McKenna (1994), [3]= Weinstein (1994)).

3.8.1.1 Key elements in designing a Delphi study

Given the variations in designs the main issues which are reported in the literature and required consideration are as follows:

a) Development of questions

Questions used in a Delphi project can either be developed by the researcher or the participants. Green and Dye (2003) and Beech (1999) both developed their own questions which were then circulated to participants. Others used open questions to generate ideas (Mullen 2003), or questions developed by participants with the aim of reducing bias (Duncan et al. 2004, Geller 1982).

b) Number of rounds

There are published examples of Delphi studies conducting between two and five rounds (Mullen 2003), although this is dependent on the type of study. Recently published examples of Delphi studies have undertaken three rounds (Duncan et al. 2004, O'Brien et al. 2003). It would appear that the number of rounds is arbitrary as it is dependent on when consensus is reached, and this can not be predetermined

(Mullen 2003). However, too many rounds will cause attrition whilst too few rounds will result in the loss of data reducing feedback and opportunities to revise ideas (Mullen 2003).

c) Sampling techniques

'It should be pointed out that a Delphi inquiry is not an opinion poll, relying on drawing a random sample from 'the population of experts'; rather, once a set of experts has been selected (regardless of how), it provides a communication device for them, that uses the conductor of the exercise as a filter in order to preserve anonymity of responses.'

Helmer (1977) p19.

Delphi studies rely on the use of non-probability sampling methods such as purposive, criterion or snowballing techniques (Hasson et al. 2000, Jeffery et al. 2000, McBride et al. 2003) and may mean that representativeness is not assured (Hasson et al. 2000).

d) Sample size

Historically, Delphi studies used small samples. The original study used only seven participants (Dalkey and Helmer 1963). Large variations of sample size have been reported, ranging from four to thousands of participants (Cantrill et al. 1996, Hasson et al. 2000, Walker et al. 2000). Samples should be more than seven, with about twenty participants being ideal (Jeffery et al. 2000, Linstone and Turoff 1975, McDonnell et al. 2005, Philips 2000), as they tend to have better responses than larger samples (Reid 1988). There is no evidence that sample sizes influence the reliability or validity of the study (Murphy et al. 1998).

e) The expert panel

Defining participants by their expertise is crucial to the undertaking of a Delphi study and a paper written by the author (Baker et al. 2006b) discusses this issue further and can be found in the appendices (Appendix 2).

f) Attrition

Preventing attrition appears key to maintaining the rigour of a Delphi study (Mullen 2003, Williams and Webb 1994). Clearly, bias can be introduced if attrition is too high and/or response rates drop below 70% per round (Mullen 2003, Sumison 1998, Walker and Selfe 1996). Several methods have been employed to reduce attrition and these include: reducing time between rounds; ensuring professional layout, with clear instructions; and providing reports between rounds (Mead and Moseley 2001b). However, attempts to reduce attrition need to be balanced with the burden of frequent reminders as this can cause a perceived reduction in anonymity and encourage dropout (Hasson et al. 2000).

g) Establishing 'consensus' in Delphi studies

There are no clear guidelines, or rules, for establishing reliable consensus in Delphi research. Instead a number of methods exist (Fink et al. 1984, Powell 2002):

i) The most common method for establishing consensus is simply defined '*percentage agreement*' (Powell 2002). Ranges cited in the literature vary from 50% to 100% (Loughlin and Moore 1979, Walker et al. 2000, Williams and Webb 1994). Percentage agreement has been criticised because it fails to take account of round by round changes or the strength of a participants agreement (Crisp et al. 1997).

ii) Scaling of responses. A number of authors have used the Likert scales combined with percentage agreement as a means of determining consensus. For example, Salmond (1994) established consensus on a seven point Likert scale as a *'very high priority'* for items rated 6 or 7 by 70%, or *'high priority'* for items rated 5, 6 or 7 for 80%. O'Brien et al. (2003) identified a criterion of 85% in two adjoining brackets as indicative of consensus, for example 1 and 2 or 2 and 3 *et cetera.*

iii) Median scores. It is recommended that the median is preferable to the mean for establishing consensus (Murphy et al. 1998). Mead (1993) established consensus as those items which had a median of four on a five point likert scale, but also included the proviso that if 23% of the panel had given no response then an item would be rejected.

iv) Reliability of agreement. Coefficient alpha is commonly used (Cronbach 1951) and it is often referred to as the standard test of inter-rater reliability or homogeneity in the literature (Lester and Pattison 2000, Taylor et al. 2001). Graham et al. (2003) used Cronbach's alpha to represent a measure of group confidence which they defined as consensus, although their research used a visual analogue scale the same test can be applied with Likert scales (Eagly and Chaiken 1993).

v) The stability of opinion between rounds (inter-rater agreement). The use of Spearman' rho or Kendal co-efficient has been recommended (Jairath and Weinstein 1994). Alternatively the stability of responses between rounds can be calculated with the kappa statistic of chance-corrected agreement (Cohen 1960). It is then possible to apply Landis and Koch's (1977) strength of agreement to the results, this categorises scores from poor (<0.0) to almost perfect (>0.81). Scores ≥0.4 have been suggested as the minimum required for agreement (Hripcsak and Heitjan 2002).

h) Statistical consensus may not represent agreement

Given the variations of methods used for determining consensus, authors propose that consensus may not be the aim of Delphi studies (Mead and Moseley 2001a, Mullen 2003). Potentially those items which achieve statistical consensus represent the safer middle ground, and are therefore less controversial (Sackman 1975). Furthermore, Sackman (1975) refers to these as *amorphous* statements, and proposes that despite high levels of consensus being obtained, this might not be 'genuine agreement'. It can be proposed that it may be more important to explore, understand and identify the differing positions, the degrees of polarisation, or whether experts and non-experts agree (Critcher and Gladstone 1998). Despite respondents not meeting, Delphi studies still exert pressures on individuals to conform to their peers (Sackman 1975). Sackmen (1975) describes the situation of giving feedback after each round as reinforcing respondent's perception of the correct answers, reducing the likelihood that differing positions, outliers, and extreme views are developed. Alternatively, Jones and Hunter (2000) recommend that outliers should be encouraged to voice their views. Linstone and Turoff (1975) critique of the Delphi methodology concluded that the failure of authors to take account of these major differences by ignoring the

dissenters could lead to their withdrawal, further skewing results (Mullen 2003). Likewise experts who change opinion in later rounds should be asked why? (Greatorex and Dexter 2000).

3.8.1.2 Summary of Study 2: To explore current practice (strengths and weakness) from the perspectives of experts

To ensure rigour of the Delphi study in the reported study, the following considerations were made. There should be at least three rounds with experts who have been clearly defined. Experts should be purposefully recruited into the study with an aim of having approximately 20 participants. Steps should be taken to ensure that attrition from the study is minimised. Consensus should encompass levels of agreement in each round and between them.

3.9 Study 3 and 4: To explore current practice (strengths and weakness) from the perspectives of the multi-disciplinary team and service users

Previous studies on PRN psychotropic medications have mainly used retrospective methods of collecting data (Usher et al. 2003). These studies have been hampered by the poor quality of documentation associated with either the prescribing or administration of PRN psychotropic medications. Alternative methods of examining current practice were necessary. Any method selected needed to be able to allow detailed exploration (depth) of clinical practice associated with the prescribing and/or administration of PRN psychotropic medication, this suggests qualitative methods (Crombie 1996). Crombie (1996) argues that method selection is crucial in determining the success and robustness of a study. The value of qualitative techniques have been highlighted particularly when developing a complex intervention where additional depth is required to explain quantitative findings, or to enable hypothesis generation (Murphy and Dingwall 1998). The Medical Research Council (2000) suggests that qualitative research has clear value in the development of complex interventions.

Four potential qualitative methods were identified: i) observations (including participant), ii) interviews, iii) focus group, iv) text/discourse analysis or conversational/video analysis (Murphy and Dingwall 1998, Pope and Mays 2000). As previously stated the documentation associated with the either the prescribing or administration of PRN psychotropic medications is poor, this would undoubtedly have hampered discourse analysis of text. This thesis briefly outlines the benefits and practicalities of conducting observations, focus groups and interviews in acute mental health wards.

3.9.1 Observations

Observations (including participant) have several advantages. It does not rely on the quality or provision of documentary evidence, and reduces biases associated with recall (Bowling 2002). The benefits of observational studies can be found in that they directly observe care (Pontin 2000b). Observations do, however, affect the behaviours of those being watched, the 'Hawthorne' effect (Pope and Mays 2000). The use of observations can be time-consuming and is often supplemented with interviews (Pontin 2000b). Access is a particular problem associated with observational studies (Pontin 2000b, Pope and Mays 2000). For the purpose of this study it was considered too challenging to undertake participant observations on acute mental health wards. This was particularly due to the ethical issue of obtaining written informed consent from all service users for observations to take place which would be both time consuming and possibly impractical. It was also considered unlikely that 'covert observations' as used by Goffman (1961), Rosenhan (1973) or in the television programme 'Dispatches' (Channel 4 2006), would receive ethical or research governance approval. The use of hidden cameras or recording equipment could not be justified.

3.9.2 Focus groups

Focus groups are considered markedly different from interviews. They provide additional depth to the resulting data as a result of the group process and dynamics (Bowling 2002). They are ideal for exploring and clarifying views, attitudes or experiences (Finch and Lewis 2003, Kitzinger 2000). Focus groups commonly

comprise of small groups of people (6-8), who meet for up to 2 hours (Finch and Lewis 2003). They can be particularly difficult to conduct with those with communication difficulties or multiple complex needs (Kitzinger 2000). They can also compromise an individual's confidentiality (Bowling 2002), with special care being required with 'captive' populations (Kitzinger 2000). Focus groups can be cumbersome and complex, require co-facilitation and could be difficult to conduct with service users on acute mental health wards (Finch and Lewis 2003, Kitzinger 2000). The practicalities of getting groups of staff or service users together without interruptions could also prove difficult (Finch and Lewis 2003). Despite these caveats, focus groups can be mutually supportive, allow discussion of 'taboo' subjects and enable participants to be more critical than individual interviews sometime allow (Kitzinger 2000).

3.9.3 Interviews

For this study, interviews were considered the best and most appropriate method for exploring current practice with both the MDT and service users. Interviews are the most frequently used qualitative method in health care research (Britten 2000, Legard et al. 2003, Newell and Burnard 2006). Interviews can be conducted at different levels from unstructured, semi-structured to highly structured. Although, qualitative interviews are often described as unstructured Britten (2000) states that this is misleading as all interviews require some structuring by the researcher. Semi-structured interviews use a set of open questions (interview schedule or topic guide) to define the area to be explored (Britten 2000, Polit and Hungler 1999). Interviews are a useful and flexible approach for gathering data, particular if the area being researched is new (Polit and Hungler 1999, Pontin 2000a). They also enable the immediate exploration of issues that arise during an interview through further questioning or probing (Pontin 2000a). However, interviews are time-consuming when face-to-face contact, travel and transcribing time is accounted for (Britten 2000, Polit and Hungler 1999, Pontin 2000a). Samples are often small and thus impact on generalisability, with 60 being regarded as the maximum for large qualitative studies (Britten 2000, Polit and Hungler 1999).

3.9.3.1 Recording and transcribing interviews

Interview data is often recorded either verbatim onto a tape recorder or as notes at the time or following the interview (Britten 2000). Although recording an interview is the preferred means, as it adds rigour, there maybe times when it should be avoided or is not possible (Britten 2000, Newell and Burnard 2006). At these times hand written notes or typing responses directly into a laptop are considered to work equally well (Bazeley 2007, Newell and Burnard 2006).

Audio recorded data often requires transcribing which has time and cost implications (Britten 2000, Pope et al. 2000). Britten (2000) estimates that each recorded hour of audio material can take approximately seven hours to transcribe. The transcripts require careful checking with the original material to ensure accuracy (Bazeley 2007, Newell and Burnard 2006). The transcribing process removes aspects of speech, such as, tones or inflections (Gibson et al. 2005, Hutchinson 2005), and if a third party does the transcribing it also removes an opportunity to be become close to the data (Bazeley 2007). To counter these flaws attempts are increasingly being made to edit or analyse digitally record data without transcribing it (Gibson et al. 2005, Hutchinson 2005). Pragmatically, the transcribing of data remains the most common option of preparing the data for analysis (Bazeley 2007).

3.9.3.2 Content analysis

'Content analysis is a research method that provides a systematic and objective means to make valid inferences from verbal, visual, or written data in order to describe and quantify specific phenomenia.'

Downe-Wamboldt (1992) p314.

Content analysis originally provided a quantitative process to describe the content of communication, over time it has expanded to include interpretations and inferences (Graneheim and Lundman 2004, Krippendorff 1980). Content analysis is the process whereby data is systematically analysed (Bowling 2002), with coding being an essential component of this process (Coffey and Atkinson 1996, Strauss and Corbin 1998). Once transcribed the data should be repeatedly read to identify themes,

categories or codes (Newell and Burnard 2006, Park et al. 2004, Pope et al. 2000). This process enables immersion in the data (Burnard 1991). 'Open coding' then identifies themes, categories or codes and is conducted 'in vivo' with continuous comparisons (comparative analysis) identifying the same codes elsewhere in the text (Pope et al. 2000, Strauss and Corbin 1998). Open coding can be conducted either line by line, paragraph by paragraph or by entire document (Strauss and Corbin 1998). Although time consuming it is preferable early in a study to conduct line by line analysis (Strauss and Corbin 1998). Over time codes are merged (collapsed) into concepts then to categories and finally themes (Burnard 1991, Strauss and Corbin 1998). Traditional methods of content analysis require the manual cutting and pasting of items, however this process can remove the person from the content (Bowling 2002, Pope et al. 2000).

3.9.3.3 Computer assisted qualitative data analysis (CAQDAS)

Given the complexities of analysing qualitative data a number of software packages have been developed to support the process, the most widely used are Atlas.Ti. and QSR Nud*ist (Barry 1998, Lewins and Silver 2004, Pope et al. 2000). Their use is becoming increasingly popular (Bowling 2002). Computer packages appear to enhance the rigour of studies by enabling a more systematic approach to the analysis of data (Bazeley 2007, Bowling 2002, Pope et al. 2000). Analysing the data electronically prevents fragmentation or de-contextualisation of the data as can happen with manual techniques (cut and paste). It also encourages proximity to the data (Lewins and Silver 2007, Pope et al. 2000). However, critics dispute this suggesting that computer assisted qualitative data analysis (CAQDAS) causes distance between the researcher and the data. Furthermore, they are seen as encouraging larger sample sizes and quantitative analysis of qualitative data as they are seen as a practical method of dealing with large datasets (Barry 1998, Bazeley 2007, Bowling 2002, Pope et al. 2000). Regardless of how sophisticated packages become, researcher skills are still required to analyse the data (Pope et al. 2000).

3.9.3.4 Ensuring Trustworthiness of the Data

Ensuring the trustworthiness associated with qualitative research requires consideration (Pope and Mays 2000). Four criteria are used to ensure the trustworthiness: credibility, dependability, confirmability, and transferability (Lincoln and Guba 1985). Credibility is described as a two part process. Firstly, are the results believable? Secondly, what steps were taken to demonstrate credibility? Credibility can be improved by the scope and depth of the data collected, the use of triangulation, identification of disconfirming evidence, researcher credibility, peer debriefing or member checking and external validation (Creswell and Clark 2007, Graneheim and Lundman 2004, Polit and Hungler 1999, Pope and Mays 2000). Both dependability (either stability of data over time/conditions or independent data analysis) and confirmability (characteristics of the data) can be assured with robust descriptions of the researchers audit trail. This includes, for example, evidence of raw data, data reduction/analysis, process notes, and drafts of final reports (Polit and Hungler 1999). Transferability is commonly defined as the generalisability of the data to other groups and settings (Graneheim and Lundman 2004, Polit and Hungler 1999). In basic terms it is about sampling and design issues (Polit and Hungler 1999). Generalisability is a judgement made by others; therefore it requires a clear description of the processes undertaken in order for a decision to be made (Graneheim and Lundman 2004, Polit and Hungler 1999).

3.9.3.5 Summary of Study 3 and 4: To explore current practice (strengths and weakness) from the perspectives the multi-disciplinary team and service users

Interviews offer a pragmatic method of collecting staff and service users experiences associated with PRN psychotropic medication. The sample, if collected purposefully, should ensure a diverse range of participants. Interviews should be semi-structured and recorded digitally to allow flexibility for analysis and storage of data and should be transcribed and analysed with the assistance of a software package.

3.10 Study 5: To determine the pre-post effects of the good practice manual on clinical practice and acceptability by the MDT

There are 16 experimental and quasi-experimental designs from which to choose when considering undertaking research which can make inferences about an intervention (Campbell and Stanley 1963). Three are considered pre-experimental, three experimental and the remaining ten are classified as quasi-experimental (Table 3.4). Each design influences how robustly inferences can be made. Twelve factors can threaten the robustness of inferences made in research, eight of these are considered internal and four external (Table 3.5) (Campbell and Stanley 1963).

3.10.1 Identifying a suitable trial design

The objective of Study 5 was to undertake an exploratory and acceptability trial of the intervention (good practice manual). The MRC (2000) describes a number of aspects which can be examined during an exploratory trial and these broadly focus on four themes. The first concentrates on the intervention. Is it possible to define or standardise the intervention? Is there evidence of this being individualised or changing over time? What levels of compliance are there with the intervention? The second enables power calculations for the main trial. The third allows the development of alternative comparative arms, for example, can a placebo be developed or is routine care the preferred option. The final area enables the researcher to test aspects of the study such as recruitment, randomisation, follow up, and/or retention.

'In Phase II, all the evidence gathered thus far is put to the test....it maybe appropriate to experiment with your intervention....Evidence can be obtained to support the theoretically expected treatment effect, to identify an appropriate control group, outcome measures, estimates of recruitment for a main trial and other requirements of such a trial.'

Medical Research Council (2000) p4.

Table 3.4: Research designs and sources of invalidity.

Design	Diagrammatic example	Sources of invalidity: Internal: History	Maturation	Testing	Instrumental	Regression	Selection	Mortality	Interaction of selection and maturation	External: Interaction of testing and X	Interaction of selection and X	Reactive arrangements	Multiple-X inferences
Pre-experimental designs (n=3)													
One-shot case study	X O	-	-				-	-			-		
One-group pre-post test	O_1 X O_2	-	-	-	-	?	+	+	-	-	-	?	
Static-group comparison	X O O	+	?	+	+	+	-	-	-		-		
True experimental designs (n=3)													
Pre-post test control group design	R O X O R O O	+	+	+	+	+	+	+	+	-	?	?	
Solomon four group design	R O X O R O O X O R O	+	+	+	+	+	+	+	+	+	?	?	
Post test-only control group design	R X O R O	+	+	+	+	+	+	+	+	+	?	?	
Quasi-experimental designs (n=10)													
Time-series design	O O O X O O O	-	+	+	?	+	+	+	+	-	?	?	
Equivalent time sample designs	X_1O X_2O X_3O	+	+	+	+	+	+	+	+	-	?	-	-
Equivalent materials sample design	M_aX_1O M_bX_0O M_cX_1O	+	+	+	+	+	+	+	+	-	?	?	-
Nonequivalent control group design	O X O O O	+	+	+	+	?	+	+	-	-	?	?	
Counterbalanced design	X_1O X_2O X_3O X_2O X_3O X_1O X_3O X_1O X_2O	+	+	+	+	+	+	+	?	?	?	?	-
Separate-sample pre-post test design	R O (X) X O	-	-	+	?	+	+	-	-	+	+	+	
Multiple time series	O O O X O O O O O O O O O	+	+	+	+	+	+	+	+	-	-	?	
Institutional cycle design	A X O_1 B_1 RO_2 X O_3 B_2 R X O_4 O_5 X	Varies dependent upon observations made											
Regression discontinuity		+	+	+	?	+	+	?	+	+	-	+	+

From Campbell and Stanley (1963), Table 1 (p178), Table 2 (p210), Table 3 (p226).
(Key: R=randomisation, O=observation, X=intervention).

Table 3.5: Common threats to the validity of inferences.

Type	Definition
Internal	
History	Events between measurements beyond the experimental variable
Maturation	Changes over time
Testing	Influence of the test on subsequent scores
Instrumental	Changes in calibration or observer scores
Regression	Influence of group selection on the basis of extreme scores
Selection bias	Selecting different respondents
Mortality	Different losses (between groups) of respondents
Interaction of selection and maturation	Effects multiple group designs mistakenly identifies experimental effect
External	
Interaction of testing and intervention	The influence of pre-testing on the intervention
Interaction of selection bias and intervention	Sample selection (for example, Site selection) may influence the intervention
Reactive arrangements	The effect of being in an experiment
Multiple-intervention inferences	Effect of multiple treatments at the same time or of prior treatment

From Campbell and Stanley (1963).

Consideration was given to which study design would be most suitable for this study. The use of a control group at this stage of the project was considered complex. Firstly, it would have required the development of a placebo intervention for staff or cluster randomisation, thus requiring more sites. There is also the potential for demoralisation of those in the control group and finally, it would be difficult to prevent those in the control group seeking their own sources of information (Medical Research Council 2000). With these considerations in mind a study using experimental designs were not considered suitable for this stage of the study. A choice was therefore required between pre-experimental and quasi-experimental designs. Three types of quasi-experimental designs are most frequently used in nursing research. These are nonequivalent control group design, after-only noneqivalent control group design (Static-group comparison), and time series design (LoBiondo-Wood and Haber 1998). Clearly a time series design would require a

lengthy period of data collection, there would also a threat to instrumental/testing validity given the multiple measures which would be taken. In order to aid the decision making process the application of algorithms for selecting research design was applied (Burns and Grove 1999, LoBiondo-Wood and Haber 1998). These identified that a pre-post (pre-experimental) design was the most suitable form. This design would enable an assessment of the intervention and method of delivery to the MDT, and an exploration of which outcome measures would be most suitable in a larger study.

3.10.1.1 Potential threats to internal/external validity of the trial

The pre-post test design is considered one of the weaker designs as it only allows control of selection and mortality (Campbell and Stanley 1963). By having only one group '*Mortality*' between groups was not considered problematic, although as can be seen in the fifth study losses of consenting staff did occur during the trial. In terms of *'Selection'* the study aimed to recruit all qualified members of nursing staff who worked on the two selected wards. For the medical staff all Consultant Psychiatrists who had or would potentially have service users on the wards were included. All Senior House Officers (SHO) and Specialist Registrars (SpRs) working in mental health were included regardless of which setting they worked. This was because the on-call system made it likely that they would prescribe PRN psychotropic medications on the two selected wards. Only unqualified nursing staff and qualified bank/agency staff were excluded from the study.

Consideration was given to those potential threats to internal/external validity which could be strengthened. To reduce '*Instrumental*' threats (particularly observer scores) all entries were audited regardless of whether staff had consented to take part in the trial. This was achieved by consenting service users separately to staff in order to access their notes. Only one person (the author) rated all the notes to remove the potential systematic bias associated with multiple raters, although there was no blindness to those which had been exposed to the intervention. Consenting staff were also asked to self-complete data collection forms which arguably removed potential observer biases.

3.10.1.2 Summary of Study 5: to determine the pre-post effects of the good practice manual on clinical practice and acceptability by the multi-disciplinary team

Given the difficulties of undertaking either an experimental or quasi-experimental study with an untested intervention the use of a pre-post test appeared to be the most suitable design as identified by study design selection algorithms. This design is clearly suitable for undertaking a phase II exploratory and acceptability study of the good practice manual as defined by the MRC framework for developing complex interventions.

3.11 Ethical and research governance issues

Awareness of ethical and research governance issues is essential for the development of good practice in research. This section details the steps taken to ensure informed consent, privacy, anonymity and confidentiality, reductions in discomfort, harm and burden, and data protection issues. The final part details Ethical Committee and research governance approval received for the study.

3.11.1 Informed consent

Informed consent is a fundamental aspect of research ethics (Ashcroft et al. 1998, Department of Health 2001b). It is widely debated in health care literature (Ashcroft et al. 1998) its origins can be traced to the Nuremberg Code, and the Declaration of Helsinki, as a means of protecting individuals from atrocities (Ashcroft et al. 1998, Brink and Wood 2001, Cassell and Young 2002, Polit and Hungler 1999). Despite the importance of informed consent in research, authors continue to debate and criticise it as a concept (Ashcroft et al. 1998, Cassell and Young 2002, Polit and Hungler 1999). Firstly, it can be impossible to provide all relevant information for complete understanding to participants. However, the alternative, limited information provision (economy of truth) is more unacceptable (Brink and Wood 2001, Edwards et al. 1998). The process of achieving informed consent can also fail. Ashcroft et al. (1998) identified six pragmatic reasons for this: i) paternalism; ii) overinterpretation; iii) social barriers; iv) language barriers; v) conceptual barriers; or vi) psychological barriers.

As the sample of service users were directly recruited from acute mental health wards special attention was paid to informed consent. Extra consideration was given to those experiencing mental distress, acute psychotic symptoms or were detained under the Mental Health Act (Department of Health 2001a, Howe et al. 2005, Roberts 2002). Despite the importance of the informed consent process, it does have the potential to be stressful and therefore cause harm (Bloch and Salzberg 2003). Any service user which the MDT or researcher identified as being unable to make informed consent were excluded from the studies. It was also deemed ethically dubious to obtain consent for participation from third parties (surrogate consent) (Bloch and Salzberg 2003, Department of Health 2001a). All potential participants were given a minimum of 48 hours to consider the information provided before being re-approached for consent. Further delays were frequently offered to enabled additional time to make decisions (Faulkner 2005). Information contained in the leaflets was verbally repeated at the time of consenting. Checks were also made at this point to ensure that information had been accessible, understandable and retained (Brink and Wood 2001, LoBiondo-Wood and Haber 1998). Opportunities were also provided to ask questions (McHaffie 2000). Written consent was required for participation in any of the studies. Although this process in itself is not proof of informed and valid consent (Department of Health 2001a).

The content of information required for potential participants has been standardised (National Patient Safety Agency and National Research Ethics Service 2007). The information leaflets for this study fulfilled these requirements and were scrutinised by the Multi-centre Research Ethics Committee (MREC). Each study associated with this thesis required variations to the information leaflet. Staff and service users received different information leaflets.

3.11.2 Privacy, anonymity and confidentiality

Anonymity refers to the complete protection of an individuals identity, where as confidentiality prevents participants being identifiable to those outside of the research team (Brink and Wood 2001, Lewis 2005, Polit and Hungler 1999). Both are important aspects of conducting ethical research which participants often want

assurances of (McHaffie 2000). Several steps were used to maintain anonymity: the locations of units used have not been identified; new codes different from consent forms were devised for publications; comments which could identified or described individuals or settings were omitted; and biographical details about individuals were not linked with quotes (Brink and Wood 2001).

To ensure confidentiality, careful consideration was given to how data should be stored. This is fundamentally important in ensuring ethical practice in research (Department of Health 2001b, The University of Manchester 2006a, 2006b). The study was informed by the Data Protection Act (1998) and Caldicott Principles (Department of Health 2003). All data was made anonymous (by coding) at the time of collection. Personal identifiable data was only recorded once; this was stored in a locked filing cabinet. Access to this filing cabinet was restricted. Other members of the research team were only given access to coded data. All data held on computers was unlinked and anonymous. Access to this data was also restricted through a secure password system. However, given that the research was conducted with a potentially vulnerable group of individuals confidentially clearly needed to be balance with risk. Participants were made aware that there maybe occasions when confidentiality would be broken, but that this would only occur after discussion with them (McHaffie 2000).

3.11.3 Discomfort, harm and burden

Research is not benign. Discussing the issue of medication may evoke painful emotions (Harrison 2003). The topic of PRN may overlap with times when forced medication (rapid tranquilisation) may be given. This experience has been linked to development post-traumatic stress disorder (McGorry et al. 1991). Participation could therefore impact on an individual's mental health (Bloch and Salzberg 2003). Care was clearly needed to prevent harming individuals. In designing this research project attempts were made to reduce burden and harm. These included: enforcing the rights of individuals (staff and service users) not to participate in the study (McHaffie 2000); providing the option to withdraw from the study at anytime; the termination of interviews when participants became distressed or stressed; allowing time after the interviews to discuss issues and feeling which may have emerge (debrief); waiting

until participants felt well enough to take part in interviews/the consenting procedure; and repeatedly checking with individuals that the research process was not detrimentally effecting them.

3.11.4 Ethical Committee and research governance approval

In order to ensure that research is ethically sound scrutiny is required (Department of Health 2001b, McHaffie 2000). This should include the submission of the research project to external validation. The use of Ethical Committees can identify ethical problems associated with research. To conduct the research associated with this thesis approval was gained from a number of sources. Ethically this included, The North-West MREC (04/MRE08/48) and The University of Manchester Ethics Committee (04277). Approval from the university ethics committee also provided indemnity insurance. Research governance approval was granted from Manchester Mental Health and Social Care Trust (099-04-HSR-BAKE); Bolton, Salford and Trafford Mental Health NHS Trust (BSTMHT 378); and Pennine Care NHS Trust (5960416).

3.12 Chapter summary

This chapter has explored the methodological underpinnings of the thesis. By using the MRC complex interventions framework to develop and test an intervention the rational for using a mixed methods approach is clear. The chapter then provides details of each of the five studies (Chapters 4-8). This includes rational for method selection, and the strengths and weakness of each approach undertaken. It concludes by highlighting some of the ethical aspects of conducting research.

Chapter 4 Study One

The administration of psychotropic pro re nata (PRN) medication in inpatient mental health settings: a best-evidence synthesis review.

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4.1 Abstract

Aims and objectives;

This paper aims to synthesise published literature of drug utilisation/administration studies of pro re nata (PRN) psychotropic medications in mental health wards. The study employed a best-evidence synthesis review design.

Background (stating what is already known about this topic);

The administration of psychotropic PRN medications is a frequently used clinical intervention in mental health wards. PRN contributes to exposing patients to high doses of antipsychotic medication. Despite the frequent use of PRN there is limited evidence of their effectiveness.

Conclusions (stating what this study adds to the topic);

Six major themes emerged from the literature: i) frequency of administration; ii) administration during the 24 hour day; iii) administration associated with length and stage of admission; iv) rationales for administration; v) medicines administered (including route of administration); and vi) effects and side effects of the medicines administered.

Relevance to clinical practice;

Overall findings indicate that the administration of psychotropic PRN varies radically and appears to be influenced by many variables. Patients are most likely to receive a benzodiazepine or typical antipsychotic as PRN. PRN is an important and under researched clinical intervention used in mental health wards.

4.2 Introduction

This study aims to synthesise drug utilisations studies of pro re nata (PRN) psychotropic medications in inpatient mental health settings. PRN medications are used to allow for the administration of additional medication and are used widely in healthcare. Patients (approximately 80%) are likely to receive PRN psychotropic medications whilst in mental health wards (Curtis and Capp 2003, Geffen et al. 2002b). The most frequently used PRN psychotropic drugs are; antipsychotics,

anxiolytics, hypnotics and anticholinergics. Significantly, PRN antipsychotic medications have been implicated in exposing patients to high doses and polypharmacy (Milton et al. 1998, Royal College of Psychiatrists 2006).

Three key literature reviews have added to the knowledge base of PRN medication. Of the three reviews, two were systematic reviews (Demczar and Levin 1996, Whicher et al. 2003) and the third a literature review (Usher et al. 2003). Whicher et al. (2003) published a Cochrane systematic review of PRN psychotropic medications in acute mental health settings. They concluded that there is no *high quality evidence (due to an absence of high quality randomised controlled studies)* regarding the effectiveness of PRN psychotropic medications. Demczar and Levin (1996) conducted a systematic review of the clinical value of atypical antipsychotic medications as PRN. They concluded practice should continue to use typical antipsychotic with benzodiazepines rather than atypicals. The literature review focussed on the administration of PRN psychotropic medications (Usher et al. 2003) and concluded that the research which had been conducted was inadequate. However, limitations with these reviews are that have either have devised strategies which in effect rejected current knowledge by only including RCT evidence (Demczar and Levin 1996, Whicher et al. 2003) or failed to provide detailed accounts of their search strategy including inclusion/exclusion criteria (Usher et al. 2003). Given the methodological difficulties associate with the above, a more encompassing and thematic review of the literature is clearly required, one which synthesises the current evidence (Glasby and Beresford 2006, Glasby and Lester 2005, Slavin 1986).

4.3 Aim

The aim of this review was to examine and synthesise published literature of the administration (utilisation) of PRN psychotropic medications in mental health wards. This included frequency of administration, administration over the 24 hr day, rationales for administration, the medicines administered (including route of administration) and the effects and side effects that PRN psychotropic medications have. This review forms part of, and informed, a funded programme of research on PRN psychotropic medications in mental health settings culminating in the

development and testing of a good practice manual to enhance the use of PRN psychotropic medication.

4.4 Method

A best-evidence synthesis review method was used (Slavin 1986). The search strategy was defined as *'studies with a primary focus on the administration/utilisation of psychotropic PRN in a mental health ward setting'*. Three 'facets' related to the question were identified as text terms, described in Table 4.1 (Khan et al. 2001), when available database subject headings were matched with them. The primary search was conducted in September 2005. Inclusion and exclusion criteria were established prior to searching and were deliberately kept broad to maximise identification of literature. Inclusion was limited to PRN psychotropic medication, inpatients of mental health services[9], with no diagnostic criteria or age limit being applied. All English language study designs and published materials were included and no date restrictions were applied.

Table 4.1: Three facets and text terms used in the search strategy.

Facets	Search terms
PRN	'as required', 'as needed', 'as indicated', p.r.n., PRN, pro re nata, 'on demand'.
Medication	Prescriptions, administration, medicine, medication, medication systems, psychotropic, antipsychotic agents, neuroleptic, benzodiazepine, hypnotics, physician's practice patterns, drug therapy, antidepressant drug, sedatives, tranquilisers, drug administration schedules.
Inpatients	Inpatients, mental health, acute, ward, hospital, hospital units, psychiatric, acute, schizophrenia, psychiatric nursing, mental disorders, bipolar disorder, substance related disorder, depression, forensic.

[9] The decision taken to search for and include all inpatient facilities was based on a number of factors. Firstly, previous reviews had not been limited to acute mental health wards (Whicher al 2003, Usher et al. 2003). Secondly, to focus exclusively on acute mental health wards in the UK would severely limit the review to the work of Gray and colleagues. Thirdly, a number of studies combined data from acute mental health wards and other inpatient settings such as rehabilitation. Finally, discussions with colleagues in Australia suggested that PRN was an internationally occurring clinical problem.

Databases searched included: MEDLINE (1966 - September 2005); Cumulative Index to Nursing and Allied Health Literature (1982 - September 2005); PsycINFO (1967 - September 2005), Embase (1980 - September 2005); British Nursing Index (1985 - September 2005); Database of Abstracts Reviews of Effectiveness; The Cochrane Library; The University of Manchester library databases including thesis searching and books; Siegel (Grey literature); and Questia (Web library). References (n=9823) were exported directly into Reference Manager (Thomson I. S. I. ResearchSoft 2004). Duplicate studies were deleted (n=2222). The resulting study titles and abstracts (where available) were screened for suitability (n=7601). For those studies which met the inclusion/exclusion criteria reference lists were hand searched by the lead author (JAB) to identify any additional unidentified material.

There are difficulties associated with establishing the quality of the included studies. Glasby and Bereford (2006) dispute the application of hierarchies of evidence in literature reviews as it leads to the rejection of knowledge. However, given that most studies collected retrospective data from single sites generalisations to the wider inpatient population are difficult. Samples were also conveniently recruited from populations of patients during a given month or period of time. Cross sectional surveys of this kind are considered weak in the hierarchy of evidence (Greenhalgh et al. 2005). Although they are clearly a sensible design to provide further understanding of the administration of PRN in mental health ward settings.

4.5 Results

27 studies met the inclusion, exclusion criteria and have contributed to this literature review. One author repeated data published in one paper in a second (Gray et al. 1997, Gray et al. 1996), the earlier study has been included in this review. The main characteristics of the included studies can be found in Table 4.2. Most studies used retrospective case note analysis (n= 19), only three used prospective methods, and the remainder were literature reviews or discussion articles (n=5). Two studies formed postgraduate theses (Grice 1997, Stratton-Powell 2001). The majority of studies focused on adult inpatient settings (n=15) including forensic (n=2), or child and

adolescent mental health services (CAMHS) inpatient settings (n=4). Samples were frequently selected by convenience and ranged from 44 to 973 participants.

Table 4.2: Studies included in the review.

Author	Date	Country	Setting	Sample size	Study design
Ayd	1985	USA	Discussion study & hypothetical case study		
Bernard & Littlejohn	2000	UK	CAMHS	500 consecutive admissions	Cross-sectional
Blair & Ramones	1998	USA	Discussion study of both inpatient & community		
Craig & Bracken	1995	USA	Acute	All inpatients during a one month period (n=973)	Cross-sectional
Craven et al.	1987	Canada	Acute	Convenience sample of 100 consecutive admissions	Cross-sectional
Curtis & Capp	2003	Australia	PICU	54 in-patient files reviewed (convenience sample)	Cross-sectional
Demczar & Levin	1996	USA	Systematic Literature review of atypical antipsychotic medication		
Evans & Scipo	1980	USA	CAMHS	47 adolescents (convenience sample)	Prospective, repeated measures
Fishel et al.	1994	USA	Acute/PICU	Comparison of PRN administrations between 2 sites. Samples, all discharge patients in one month from one site n=54, 1 in 3 patients from the other (n=55).	Cross-sectional
Garrison et al.	1990	USA	CAMHS	99 consecutive admissions	Prospective, repeated measures
Geffen et al.	2002	Australia	Acute	Convenience sample of 85 consecutive admissions	Cross-sectional
Gray et al.	1996	UK	Acute	44 inpatients (convenience sample)	Cross-sectional
Grice	1997	USA	Acute	71 patients	Cross-sectional
Hales & Gudjonsson	2004	UK	Forensic setting (MSU)	All inpatients admissions 1995-2000 (convenience sample)	Cross-sectional
Mason & Dewolfe	1974	USA	Veterans hospital	Convenience sample of all inpatients (n=241)	Cross-sectional
McKenzie et al.	1999	Australia	Acute/Rehab units	Convenience sample of discharged patients (n=122)	Cross-sectional
McLaren et al.	1990	UK	Forensic setting (MSU)	Convenience sample of all inpatients during 3 months (n=32)	Cross-sectional
Perlman & Hogber	1977	USA	Acute	Convenience sample of all inpatients during 6 months	Cross-sectional
Petti et al.	2003	USA	CAMHS	Convenience sample of those receiving PRN 42/57.	Repeated measures

Author	Date	Country	Setting	Sample size	Study design
Stratton-Powell	2001	UK	Acute & PICU	Convenience sample	Cross-sectional
Thapa et al.	2003	USA	Acute	Convenience sample of all admissions. Pre-post test design.	Cross-sectional
Usher et al.	2001	Australia	Acute	Convenience sample of all admissions during one month (n=90).	Cross-sectional
Usher et al.	2003	Australia	Literature review		
Voirol et al.	1999	Switzerland	Acute & PICU	Convenience sample (n=55)	Cross-sectional
Vitiello et al.	1987	USA	CAMHS	Convenience sample of all admissions during six months (n=49).	Cross-sectional
Walker et al.	1991	USA	Acute	Convenience sample of all new admissions (n=132).	Cross-sectional
Whicher et al.	2003	UK	Systematic Literature review for Cochrane review.		

Data were extracted and grouped into themes for comparison (Glasby and Lester 2005). This process resulted in the emergence of six major themes:

- Frequency of administration
- Administration in the 24 hr day
- Administration associated with length and stage of admission.
- Rationales for administration
- Medicines administered (including route of administration)
- Effects and side effects

4.5.1 Frequency of administration

Administration of PRN psychotropic medication to the inpatient population varied from 22.9% to 100% of patients (Gray et al. 1996, McKenzie et al. 1999). The Gray et al. (1996) study included all administered PRN medications including analgesia, which undoubtedly influenced their findings. The most frequently cited range of administration of psychotropic PRN medications to the inpatient population was between 70% and 80% (Curtis and Capp 2003, Hales and Gudjonsson 2004, Thapa et al. 2003, Voirol et al. 1999, Walker 1991). The next commonest reported range was

80% to 90% of all inpatients (Craven et al. 1987, Geffen et al. 2002b, Vitiello et al. 1987).

Wide variations in the number of doses individuals received were reported, means varied from 2.4 (Walker 1991) to 25.7 doses (Vitiello et al. 1987). The Walker (1991) study occurred in a medium secure (forensic) unit (MSU) and Vitiello (1987) in a long-term child and adolescent mental health service (CAMHS). Four international studies of PRN usage in acute mental health settings in Australia, Canada and the UK reported means of between 10 and 12 administrations per individual (Craven et al. 1987, Curtis and Capp 2003, Geffen et al. 2002b, Gray et al. 1996).

4.5.2 High users of PRN

It is reported in some studies that a small percentage of patients receive a disproportionately high number of PRN administrations. In McKenzie et al. (1999) study three patients received an average of 45.3 administrations per individual, or 9% (n=136) of the total doses administered. Three other studies have also identified that a small number of patients received ≥40 administrations each (McLaren et al. 1990, Thapa et al. 2003, Vitiello et al. 1987). Only one study made comparisons between these high and low PRN users (Craig and Bracken 1995).

4.5.3 Administration during the 24 hour day

Administration of PRN is most likely to occur during the evening and night, from 6pm onwards (Bernard and Littlejohn 2000, Craven et al. 1987, Stratton-Powell 2001, Usher et al. 2001). For example, Gray et al. (1996) identified that 10% of all PRN administered was during a 15 minute time period (22:00 hrs to 22:15 hrs). Although additional peaks have been reported in the morning (Curtis and Capp 2003, Stratton-Powell 2001), at other regular medication and meal times (Gray et al. 1996, McLaren et al. 1990, Stratton-Powell 2001). Perlman and Hogber (1977) research hypothesised that the evening peaks of demand for PRN medication could be attributed to visiting hours and the stress associated with this. When the medication times were changed

(drug rounds occurred 2 hours earlier) as part of the research project a significant reduction in the use of psychotropic PRN occurred (Perlman and Hogber 1977).

4.5.4 Administration associated with length and stage of admission

PRN psychotropic medications are likely to be administered in the first four days of admission (Curtis and Capp 2003, Geffen et al. 2002b, Gray et al. 1996, McKenzie et al. 1999, Usher et al. 2001). Both McKenzie (1999) and Fishel et al. (1994) reported that 80% of patients received PRN psychotropic medication during the first four days of admission. Gray et al. (1996) and Usher et al. (2001) identified that 38.4% and 51.5% of the total doses of PRN administered occurred during this period. Some reported data suggested that the highest usage can be on the day of admission (Curtis and Capp 2003, Fishel et al. 1994). Further, Hales and Gudjonsson (2004) found 74% (n=31) of patients were prescribed PRN routinely on admission. They reported that there was minimal evidence of risk assessment (29%, n=12), and poor documentation (19%, n=6) in the case notes for these individuals.

There does appear to be an additional peak for those who remain in hospital for longer periods of time. For example, Usher et al. (2001) identified that administrations after 15 days accounted for 12.31% of the total doses given; Mason and Dewolfe (1974) identified 15% after 14 days. An additional peak was identified by Bernard and Littlehorn (2000) who found that admissions longer than 28 days were significantly associated with receiving PRN ($p<.001$).

4.5.5 Documented reasons for the administration of PRN psychotropic medications

Diverse reasons are documented by nurses as the rationale for administering PRN psychotropic medication (Table 3). For example, Fischel et al. (1994) identified thirty-two different documented reasons for the administration of PRN psychotropic medications, most commonly cited were agitation, insomnia and patient request. Unfortunately the literature does not expand on what medications or why these extra medications are requested so frequently by patients.

Agitation is commonly cited as the rationale for both the prescription and administration of PRN medication, and accounts for between 12.3% (Usher et al. 2001) to 100% of the rationale (Kaplan and Busner 1997). In one study agitation was the sole indication for use, but PRN was administered for behaviour which was defined in the case notes as worried and/or anxious in 50% of the cases (Petti et al. 2003). Craven et al. (1987) reported similar findings in regards to a single indication of agitation in the prescriptions but identified that those with a diagnosis of personality disorder received a greater number/percentage of administrations relative to prescriptions.

It has been proposed that a major role of psychotropic PRN is to control anti-social behaviour. Garrison et al. (1990) study with children/adolescents and violence identified that in 31.8% (n=282) violent cases PRN medication was used, the most frequent intervention was containment (59.8%). There were two significant associations identified that of age, older received more PRN than younger children ($p<0.001$) and if that attack was against a member of nursing staff ($p<0.05$). Another project identified the administration of PRN in 36% (n=783) of violent cases, this study was conducted in a forensic setting (medium secure unit), the administration most commonly co-occurred with restraint (Gudjonsson et al. 2000).

Intentional space

Table 4.3: Documented reasons for the administration of PRN psychotropic medications.

Source	Themes								
	Patient request	Insomnia	Agitation	Aspects of Aggression	Restlessness	Psychotic symptoms	Anxiety	Rational not documented	Comments & Misc.
Mason and Dewolfe (1974)			28.1%	11.6% assaultiveness 10.8% hostility 5.4% destructiveness	19.7% overactivity			4.6%	Others (14.7%, n=38).
Winstead et al. (1974)				4% anger at others			38%		Others (15%), attention seeking behaviour (7%), ward tension (7%), 29% undefined.
Craven et al. (1987)			29%					9%	
Vitiello et al. (1987)	1.5%	15%		16.5% aggression 9% aggression to peers					Unco-operativeness (45%, n=569), self injurious behaviour (7%, n=88).
McLaren (1990)	27%			32.7% containing verbal/ physical aggression 13.3% actual injury to others) 24.7% prevent physical aggression					15 others (9.9%), relieve distress (32.7%, n=49).
Fischel et al. (1994) State and Medical settings		9%	37.6%	3.9% loud/ restless/agitated		4.5% delusions	6.7%	20.2%	32 different reasons for 178 administrations
		32.8%	21.6%				4.8%	7.2%	16 different reasons for 250 administrations Insomnia/anxiety (13.2%, n=33), withdrawal (7.6%, n=19).
Gray et al. (1996)	19.8%		11.3%						14 different reasons for 19 drugs given. EPSE (11%), pain (17.9%).
Grice (1997)	24.2%			22.6% aggression 8.1% stop pattern of escalation	24.2% increased physical movements	8.1% hallucinations			Others (12.8%).
Kaplan and Busner (1997)		2% to 9%	91% to 100%						In three settings state, private and county.
McKenzie et al. (1999)	20%	5.8%	18%	4.4% verbal/physical aggression				31.6%	
Usher et al. (2001)	36.5%	25%	12.3%		5.6%		13.1%	23.9%	No reason (36.9%).
Geffen et al. (2002b)		17%	49%			15%		41%	
Petti et al. (2003)	30%								10% of patients assisted with the decision.
Curtis and Capp (2003)	15%	10.2%	19%		6.2%	10.4% hallucinations/ thought disorder		38.6%	

4.5.6 Medicines administered

Drugs which were typically administered as PRN are benzodiazepines, antipsychotics, hypnotics and antihistamines (Blair and Ramones 1998, McKenzie et al. 1999). Most frequently used in adult mental health services are typical antipsychotic and benzodiazepines (Table 4.4). CAMHS also use sedative antihistamines (Vitiello et al. 1987). A number of drugs reported in PRN studies have in recent years been discontinued in the UK; this includes thioridazine (melleril), trifluoperazine (stelazine) and droperidol (dropletan). The increasing focus on atypical antipsychotic medications for regular treatments has yet to emerge as an effective PRN treatment in the literature. Although dated the systematic literature review of atypical antipsychotic medication for use as PRN concluded:

'The risk-to-benefit ratio is not acceptable in using the atypical antipsychotic agents on a PRN basis. There are documented safety and efficacy data that support the use of the typical antipsychotic agents such as chlorpromazine, or haloperidol in combination with lorazepam, on a p.r.n. [PRN] basis. These latter choices are also more cost-effective.'

Demczar and Levin (1996) p145.

4.5.7 Route of administration

Oral administration of PRN is the most frequently cited route of administration with ranges reported from 77.1% (Gray et al. 1996) to 94.2% (Curtis and Capp 2003). Recently published literature indicates intra-muscular (IM) usage of between 5-12% (Bernard and Littlejohn 2000, Curtis and Capp 2003, Stratton-Powell 2001, Voirol et al. 1999). Although one study, published over thirty years ago had reported IM use at 45% of the medication administered (Mason and Dewolfe, 1974). The literature indicates that violence towards staff results in higher doses of medications administered in an IM format when compared to violence towards other patients (Vitiello et al. 1987).

Table 4.4: Administration of PRN psychotropic medications – classified by pharmaceutical drug names (ordered highest to lowest).

Author	PRN psychotropic medications administered.					Comment
Mason and Dewolfe (1974)	Chlorpromazine (83%, n=201)	Thioridazine (7%, n=15)				Other (only antipsychotics) 10%, (n=25).
Evans and Scipo (1980)	Thioridazine* (90%)	Chlorpromazine (10%)				
Craven et al. (1987)	Sedative-hypnotics (45%)	Antipsychotics (32%)	Anticholinergics (17%)			6% unaccounted for.
Vitiello (1987)	Sedative antihistamines (54%, n=683)	Chloral hydrate (17%, n=214)	Chlorpromazine (5.8%, n=139),	Haloperidol (5.43%, n=130),	Diazepam (4%, n=51)	Thioridazine* (1.01%, n=24), benztropine (1%, n=12, others (3%).
Garrison et al. (1990)	Thioridazine* (68.1%)	Lorazepam (10.3%).	Chlorpromazine (9.6%)			Remaining 12% includes haloperidol, diphenhydramine, and benztropine.
Fischel et al. (1994) State and Medical settings	Lorazepam (72%)	Choral hydrate (11.8%)	Hydroxyzine (6.7%)			Remaining 9% contained many drugs including haloperidol.
	Lorazepam (34%)	Diphenhydramine (Benadryl) (22%)	Chlorpromazine (11%)	Trazodone (7%)	Diazepam (4%)	Remaining 19%.contained many drugs.
Gray et al. (1996)	Procyclidine (16.4%, n=73)	Lorazepam (16.4%, n=62)	Ibuprofen ** (12.1%, n=54)	Diazepam (11%, n=49)	Droperidol* (10.1%, n=45)	High frequency of anticholinergics given.
Grice (1997)	Lorazepam (48.4%, n=60)	Hydoxyzine (25%, n=31)	Haldol (8.9%, n=11)	Thorazine (4.8%, n=6)	Thiothixene (2.4%, n=3)	A total of 13 different medications were given.
McKenzie et al. (1999)	Temazepam (27.8%, n=383)	Diazepam (22.6%, n=311)	Chlorpromazine (21.8%, n=299)	Clonazepam (6.5%, n=90)		Other (10 drugs + other (0.1%)) = 21% Not documented (0.3%)
Bernard and Littlejohn (2000)	Combination of Chlorpromazine and Chloral Hydrate (84%; n=1704)	Chloral Hydrate (5.1%; n=110)	Chlorpromazine (3%, n=61)			8% unaccounted for.
Usher et al. (2001)	Temazepam (25.7%, n=69)	Thioridazine* (22%, n=59)	Diazepam (20.5%, n=55)	Clonazepam (19%, n=51)	Chlorpromazine (5.6%, n=5.6)	Other (including haloperidol) (n=19, 7.1%).
Geffen et al. (2002b)	Diazepam (22.4%, n=91)	Haloperidol (16.7%, n=68)	Benztropine (15.0%, n=61)	Temazepam (12.3%, n=50)	Chlorpromazine (10.8%, n=44)	9 other drugs accounted for 22.7% (n=92).
Curtis and Capp (2003)	Diazepam (43%)	Chlorpromazine (32.4%)	Benztropine (22%)			2.6% unaccounted for.
Hales and Gudjonsson (2004)	Combination of Antipsychotic and Benzodiazepines (48%, n=20)	Sodium Amytal (5%, n=2)				Prescriptions only accounted for.

(Key: *thioridazine and droperidol are no longer used in UK, **non psychotropic drugs).

4.5.8 A measure of effectiveness

Few studies have attempted to examine the effectiveness of PRN psychotropic medications. Documented reported effectiveness extracted from retrospective studies ranged from 32% to 80%. Geffen et al. (2002b) merged the different reports of 'effectiveness' to propose a tentative rate of effectiveness in 76% of cases. However, these data were extracted from the third of cases in which effects were documented. In 64% of all cases there was no notation of effectiveness. Only one study collected cumulative data to evaluate the effectiveness of PRN medication (McLaren et al. 1990). In 41% to 64% of administrations no record of the PRN effects were recorded in the documentation (Curtis and Capp 2003, Geffen et al. 2002b). A similar difficulty is associated with reports of ineffectiveness; ranges in the literature were from 3.7% (Usher et al. 2001) to 20% (McLaren et al. 1990).

4.5.9 Side effects associated with the administration of PRN psychotropic medications

Only three studies reviewed undertook any evaluation of side effects associated with the use of PRN. Two studies reported the documentation of side effects (Vitiello et al. 1987, Walker 1991); the third Bernard and Littlejohn (2000) explored the issue but were unable to identify any documented evidence of side effects. In one study, side effects were recorded as sleepiness (n=14) and acute dystonia (n=3) (Vitiello et al. 1987). Vitiello et al. (1987) suggested that the dystonia only occurred with PRN haloperidol usage. Walker (1991) identified that in 6% of cases adverse side effects were reported.

4.6 Discussion

This study has reviewed and synthesised published drug utilisation studies of the administration of PRN psychotropic medications. Several issues have emerged which clinical staff and researchers need to consider further to enhance practice in this area. Firstly, the routine prescribing of PRN allows the administration of PRN early in a patient's admission. This is concerning given the difficulty of ensuring a rigorous and reliable multi-disciplinary assessment at this point (Gray et al. 1996, Hales and

Gudjonsson 2004). Hales and Gudjonsson (2004) research was conducted with a population who had probably had previous contact with mental health services and therefore pharmacological treatment. However, there are additional risks for those patients who are treatment naïve, unknown to services or would require a drug free assessment period.

Secondly, PRN continues to be prescribed and administered for complex phenomenon like agitation. Numerous authors have highlighted the imprecise and ill-defined nature of this phenomenon in clinical practice (Ayd 1985, Craven et al. 1987, Gray et al. 1996, Kaplan and Busner 1997, Usher et al. 2003). Given the difficulties associated with defining agitation, its assessment in clinical practice is undoubtedly complex. In prescriptions which have an indication for use of agitation evidence suggests that PRN will be administered for alternate reasons by nurses (Craven et al. 1987). This may provide evidence of a labelling or stigma influencing nurses' administration of PRN psychotropic medications or that regular treatment is less effective, or they are more challenging in their behaviour.

Thirdly, there appears to be a continued reliance on typical antipsychotic medications. These drugs cause numerous potential severe and dangerous side effects (Harris et al. 2002). Despite patients being prescribed atypical antipsychotic medication as regular medication, in two thirds of cases patients will receive additional typical antipsychotics as PRN (Geffen et al. 2002b). Given that atypical antipsychotics are often prescribed to reduce the incidence of extra-pyramidal side effects (EPSE), the co-prescription typical antipsychotic as PRN results in polypharmacy which exposes patients to more complex side effect profiles. Geffen et al. (2002b) identified significant ($p<0.001$) medication-related morbidity in those receiving either PRN antipsychotic or benzodiazepines when compared with those on just regular medications. Wider evidence suggests the long-term mixing of atypical and typical antipsychotic medications exacerbates side effects and has long-term health implications (Joukamma et al. 2006). Furthermore, in sudden deaths in mental health services the issue of medication is a recurring theme. There has been no identified discussion as to the role of PRN medication in this process. This represents an area

where significant research is needed. Thapa et al. (2003) concluded their study by stating:

'Our findings indicate that the use of PRN orders may expose psychiatric inservice users to unnecessary psychotropic medications. Given the objective of regulatory bodies to minimise the use of 'chemical restraints' in the population of vulnerable patients, these findings have important policy implications.'

Thapa et al. (2003) p1286.

Finally, there are inherent difficulties in assessing the side effects related to the administering one dose of antipsychotic medication, but the failure to monitor side effects generally is an issue for inpatient mental health settings (Standing Nursing and Midwifery Advisory Committee 1999). In a worst case scenario a patient could display a side-effect such as akathisia (restlessness, inner tension, emotional unease) which could be defined as agitation. This could result in the patient being administered additional doses of typical antipsychotic medication thereby worsening the patient's side effects.

4.7 Limitations

The review is based on the synthesis of published articles from many different countries during the last 30 years which have focused on the administration/utilisation of PRN psychotropic medications. It is clear that practice is influenced by geographical location and time. Medications not used in one country may have continued to be used in others, for example, lorazepam is rarely used in Australia but is frequently used in the UK. Excluding non-English articles may have reduced the quality of the literature identified. Most authors describe the absence of or poor documentation hampering the reliability of their studies. This has undoubtedly affected this review. Focusing on the administration (utilisation studies) of PRN psychotropic medication might have excluded important information about the prescribing practices of psychiatrists.

4.8 Conclusions

The administration of psychotropic PRN varies widely and appears to be influenced by many factors. PRN is most frequently given to patients at the time when clinical services know least about them, for example, early in an admission, and often because of poorly defined phenomenon such as agitation. Patients are most likely to receive a benzodiazepine or typical antipsychotic as PRN. Typical antipsychotic PRN undoubtedly contributes to antipsychotic polypharmacy and high doses that individuals may receive. The quality of the retrospective research of case notes has been hampered by the poor quality and imprecise documentation regarding the administrations of PRN medications. PRN is an important and under researched clinical intervention used in inpatient mental health services. Further research in this area should particularly focus of patient's experiences associated with PRN; particularly why they request it and what benefits does this offer them. The decision making processes associated with administering PRN psychotropic medications is clearly under-researched. Finally, additional research needs to explore both pharmacological and non-pharmacological alternatives to PRN psychotropic medication as well as an exploration of the effectiveness and side effects associated with its use.

4.9 Recently published PRN literature not included in study 1

Two studies have been recently published which have not been included in Study 1. They provide additional evidence about PRN psychotropic medications.

4.9.1 Goedhard et al. (2007)

Goedhard et al. (2007) conducted an observational study exploring incidence density rations (IDRs) for PRN psychotropic medications. Data was collected for eight months on 130 patients on 3 long-stay wards (forensic, learning disabilities and CAHMs). They identified that aggressive patients used more psychotropic (higher doses and polypharmacy) and somatic PRN medications. They concluded that the practice remains confusing as a significant proportion of PRN was used outside of the incidents.

4.9.2 Thomas et al. (2006)

Thomas et al. (2006) compared the introduction of an activity programme (nurse led) on the frequency of PRN administration. The study identified that the activity programme significantly reduced the PRN use in one of the wards ($p=0.002$), but not the other.

Chapter 5 Study Two

Multi-disciplinary consensus of best practice for pro re nata (PRN) psychotropic medications within acute mental health settings – a Delphi study.

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5.1 Abstract

There is a limited evidence-base for the use of pro re nata (PRN) 'as required' psychotropic medication within acute mental health settings. This study aimed to explore expert opinion concerning issues and best practice for the prescribing and administration of psychotropic PRN medications within acute inpatient mental health settings. Eighteen experts participated in three Delphi rounds of a modified Delphi panel to establish consensus. A total of 271 items were initially generated from four questions. As a result of the consensus process the number of items retained reduced to 78, then 34 items and finally 13 items. Clinicians' practice could be informed by the 13 recommendations established by the Delphi panel. Further research is required to establish the clinical effectiveness of these recommendations.

Key words: Pro re nata (PRN), 'as required', psychotropic medication, Delphi panel, expert opinion, mental health.

Declaration of interest: JAB is supported by the Health Foundation via The Health Foundation Nursing and Allied Health Professions scheme.

5.2 Introduction

Psychotropic medication provides the mainstay of mental health treatment in secondary care settings and is especially important within acute inpatient mental health settings (Bowers 2005). Pro re nata (PRN) or 'as required' medication is a commonly used adjunct to routine prescribed medication. Internationally, between 70%-90% of patients within inpatient mental health settings studied received PRN psychotropic medications on one or more occasions (Curtis and Capp 2003, Geffen et al. 2002b). Psychotropic PRN drugs most frequently used in inpatient mental health settings are; anxiolytics (diazepam and lorazepam) and antipsychotics (haloperidol), followed by hypnotics and anticholinergics (Curtis and Capp 2003, Geffen et al. 2002b). Despite the importance placed on medication and the frequency of its use, the clinical effectiveness of psychotropic PRN medication in acute mental health

settings has yet to be established (Geffen et al. 2002b, Whicher et al. 2003). Despite the welcomed advice regarding rapid tranquilisation and high dose antipsychotic medication there remains an absence of guidelines which specifically address the processes associated with the prescribing and administration of PRN psychotropic medication. For example, recently published clinical guidelines for rapid tranquilisation (National Institute of Clinical Excellence 2005), Maudsley prescribing guidelines (Taylor et al. 2005) and those which focus on high doses of antipsychotic (Royal College of Psychiatrists 2006) (CR138) largely excluded the PRN process. The aim of the study was to develop consensus for points to improve the prescribing and administration of PRN psychotropic medication. Delphi studies are an established technique for determining consensus particularly when little is known about the topic area (Hardy et al. 2004). This study is part of a larger study which aims to enhance the use of PRN psychotropic medications through the development and testing of a clinical protocol.

5.3 Delphi Panel Technique – Method

The Delphi study development has been attributed to Dalkey & Helmer (1963) of the Research and Development (RAND) Corporation. Their initial project was to predict and hypothesise the outcome and effect of Russian nuclear attack on the munitions output of the USA (Dalkey and Helmer 1963). This method now has a 50 year history and has been widely used in health and social care research (Beech 2001, Keeney et al. 2001). The issue which requires consensus is sent to participants whose role it is to generate solutions statements. These are then returned either through mail or electronic means and collated centrally. All solutions are redistributed to all participants for an agreement rating on a Likert scale (a round). The Delphi continues to operate this round by round approach until a predetermined consensus is established. It is recommended that no more than three rounds should be attempted due to attrition (Keeney et al. 2001). A minimum return of 70% per round is essential to maintain the rigour of the Delphi study (Sumison 1998, Walker and Selfe 1996). There are conflicting views of sample sizes for Delphi studies, numbers of participants have ranged from 7 to 1000s (Hasson et al. 2000, Walker and Selfe 1996).

The optimum range appears to be between 7 and 20 respondents, with no less than 7 (Linstone and Turoff 1975, Philips 2000).

5.3.1 Participants

This Delphi study focused on 'expert' opinion to reach consensus on the issues and best practice for the prescription and administration of PRN psychotropic medication within acute inpatient mental health settings. Panellists were selected on the basis of 'perceived expertness' as demonstrated by combinations of the following factors:

1. Professional background (medicine, nursing, and pharmacy);
2. Employment at a pre-determined senior clinical level within acute mental health settings, for example Nurse Consultant specialising in acute inpatient mental health care;
3. Publications or contributions to discussions of PRN psychotropic medication.
4. Held a position of influence which had an acute care focus, for example, acute care lead for Care Services Improvement Partnership (CSIP) regions;
5. Recommended by a professional/pressure group for example, Royal College of Psychiatrists;
6. Members of the Delphi panel could also recommend panellists, if they fulfilled the established criteria.

Panellists were identified through published literature and recommendations of the project management group. The project management group consisted of a range of multi-disciplinary clinicians specialising in acute inpatient mental health care from 3 local Mental Health Trusts and academic staff. Additionally a number of professional groups were contacted for recommendations of experts. Groups contacted included: the Royal College of Psychiatrists; United Kingdom Psychiatric Pharmacy Group (UKPPG); College of Mental Health Pharmacists (CMHP); the Association of Nurse Consultants; CSIP; and the National Association of Psychiatric Intensive Care Units (NAPICU). Service users were excluded from this study because of the complexities associated with the identification of expert user's view. Service user's views of psychotropic PRN medication are of paramount importance but were collected in a separate study (Baker et al. 2006a).

A three round Delphi process was used. Data were collected in 2004-2005. The participants were asked to generate a maximum of five statements to four questions (Figure 5.1) established via the project management group. The aim of the questions was to identify points of good practice or areas where practice could be improved to enhance the use of PRN in acute mental health settings. These points were to be incorporated into a multi-disciplinary clinical protocol. Reminders were sent a maximum of three times using a variety of media including electronic, postal and telephone contact.

Figure 5.1: Four Delphi questions.

1) What do you consider the most important issues for the **prescription** of PRN in current practice within acute inpatient mental health settings?
2) What do you consider the most important issues for the **administration** of PRN in current practice within acute inpatient mental health settings?
3) What do you consider the most important features that would constitute best practice in the **prescription** of PRN within acute inpatient mental health settings?
4) What do you consider the most important features that would constitute best practice in the **administration** of PRN within acute inpatient mental health settings?

5.3.2 Data analysis

Data were analysed using SPSS^{TM} 13 (SPSS 2003). Ratings of items were on a seven point Likert scale (coding, 7-1: very important to very unimportant). There are many reported methods for establishing statistical consensus in Delphi studies (Fink et al. 1984, Williams and Webb 1994). This study focused on two. Firstly, a pre-determined criterion of consensus was established as those items which received only 100% positive ratings (5, 6 or 7) without disagreement were retained (Williams and Webb 1994). After three rounds the stability of responses for the items selected as representing consensus was calculated using the kappa statistic of chance-corrected agreement (Cohen 1960) to measure agreement within panellists between rounds 2 and 3. Landis and Koch's (1977) strength of agreement has been applied to these results. Values ≥ 0.4 have been suggested as the minimum required, this criterion were applied to the remaining items (Hripcsak and Heitjan 2002).

5.3.3 Ethical issues

The study had Multi-Centre Research Ethics Committee (MREC) and The University of Manchester ethical approval. All participants were anonymous to each other during the research process. Initial invitations and information sheets were sent through the post and included consent forms to be completed and returned prior to inclusion in the study.

5.4 Results

Thirty-three persons were identified as experts according to the established criteria. Eighteen (56%) agreed to participate and returned the signed consent form. In addition, respondents were asked to completed questions about their expertness (Kennedy 2004). The panel consisted of 4 psychiatrists, 13 nurses and a pharmacist. All described having a policy-influencing component to their role and six identified themselves as influencing policy nationally. Sixteen were employed in a role specifically related to acute mental health settings, had conducted research in this area and were members of a variety of professional groups. Over half the group had published either about acute mental health settings (n=10) or medication (n=12). The nurses included eight Nurse Consultants specialising in acute inpatient care and four acute leads for the Care Services Improvement Partnership (CSIP). Five panel members were not working in a current clinical role. Of the 15 not participating, eight replied, but were unable to commit due to a variety of reasons, and no response was received from the remaining seven. Non-participants included 3 psychiatrists, 10 nurses and 2 pharmacists.

Sixteen participants (89%) responded in the first round, producing a total of 271 statements to the four questions. No exclusion criteria or attempts to remove duplicate statements were applied to these statements. The order of items was randomised within the four questions and in the second round, participants were asked to rate the importance of each item on a seven point Likert scale (coding, 7-1: very important to very unimportant).

All 18 participants returned the round 2 questionnaire. Any item which received a rating 5, 6 or 7 without disagreement (including Neutral votes) was retained for the next round. Examples of those questions deleted which received least support include; '*prescriptions based on staffing needs*', '*use of force and associated risks*', '*copious documentation*' and '*patients may become drug seeking, requesting PRN when they know that it is available*'. In the final round, 78 items (29% of the original 271 items) remained which were re-distributed to the 18 panellists for re-rating. Previous scores were not sent to participants. All 18 panellists returned the final round questionnaire. Means for these items ranged from 5.9 (SD 1.1) to 6.7 (SD 0.5). Thirty-four consensus items were retained, accounting for 13% of original statements. Figure 5.2 demonstrates this process of item reduction.

Agreement for items as measured by kappas varied from 'poor' (n=4) to 'substantial' (n=6), and 13 items achieved the benchmark of kappa ≥0.4 were retained (Table 5.1), (Hripcsak and Heitjan 2002). High kappas indicated statements where panellists did not change opinions between rounds 2 and 3.

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Figure 5.2: Flow chart of statement reductions.

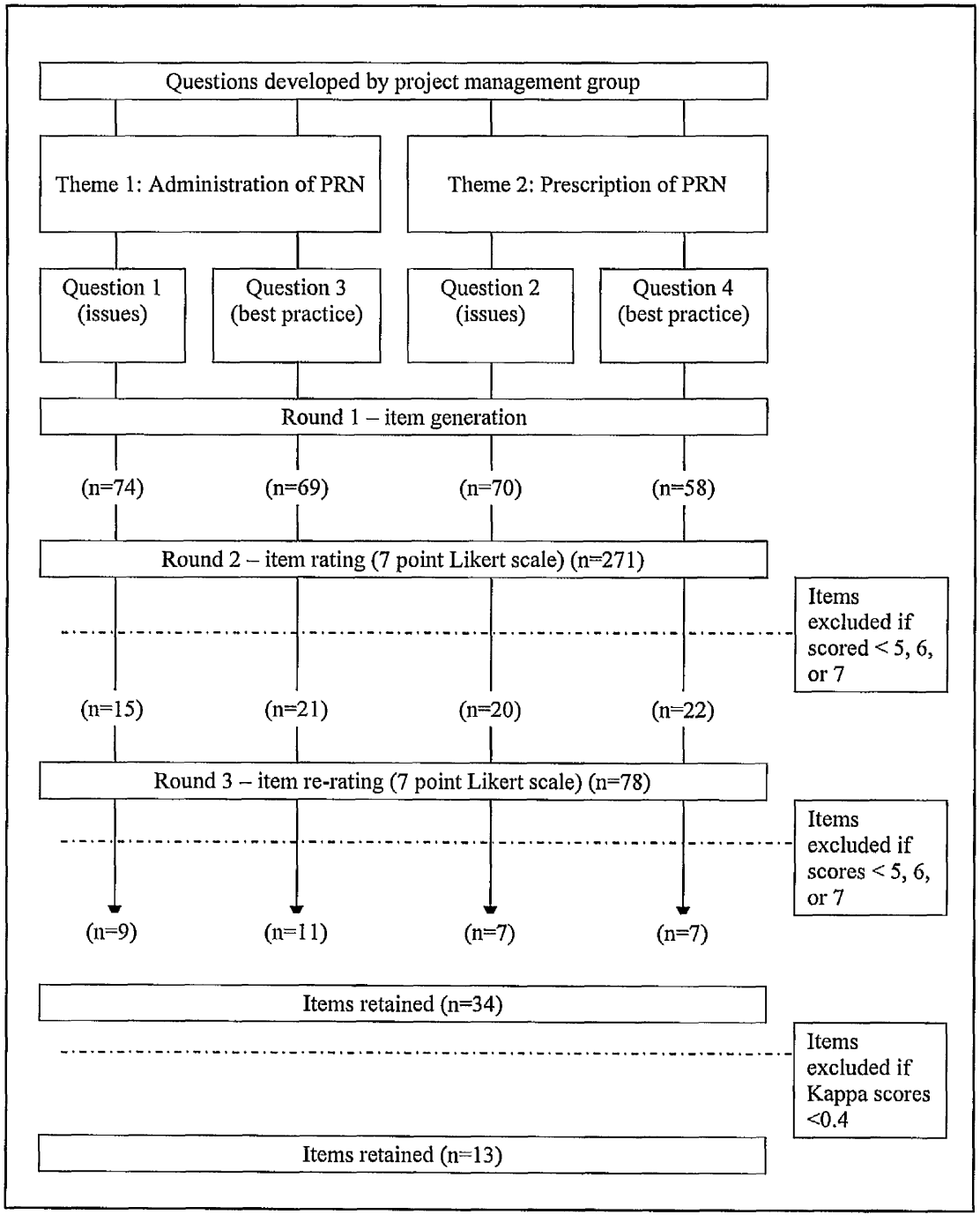

Table 5.1: Remaining 13 consensus statements after round 3.

	Statement	Round 3 item scoring			Item stability (Kappa statistic)				
		% 6 or 7	Mean	Std. D	Agree-ment	% agree-ment	Kappa	95% CI for kappa	Strength of agreement
23	Clear focus as the purpose of PRN medication.	94.4	6.5	0.6	13/18	72%	0.43	0.00 to 0.86	Moderate
93	Awareness of potential side effects.	77.8	6.3	0.8	16/18	88%	0.78	0.48 to 1.00	Substantial
102	To ensure indication for which administered matches that for which prescribed (e.g. benzodiazepine for disturbed behaviour, not for mild anxiety/dependence).	94.4	6.4	0.6	15/18	83%	0.76	0.45 to 1.00	Substantial
137	Consideration of side effects and additional drug interactions / allergic reactions.	83.3	6.2	0.7	12/18	67%	0.41	-0.04 to 0.85	Moderate
139	Any allergies are known, prior to administration.	88.9	6.7	0.7	14/18	78%	0.48	0.09 to 0.87	Moderate
165	Clear goals underpinning the use of PRN.	88.9	6.5	0.7	13/18	72%	0.46	0.07 to 0.85	Moderate
195	Clear description of indications.	88.9	6.4	0.7	14/18	78%	0.65	0.28 to 1.00	Substantial
211	Joint decision making about the prescription wherever possible – including translating/agreeing the rational/indication for the prescription into the language of/with the service user.	83.3	6.2	0.7	15/18	83%	0.68	0.35 to 1.00	Substantial
212	Time limited prescription of PRN medication, with regular review.	94.5	6.6	0.6	13/18	72%	0.53	0.12 to 0.94	Moderate
217	Knowledge of any advance directive(s) related to PRN medication.	88.9	6.2	0.6	15/18	83%	0.67	0.34 to 1.00	Substantial
223	Clear documentation of the circumstances leading to the administration of PRN medication and any beneficial or detrimental effect it had on behaviour.	100	6.5	0.5	12/18	67%	0.42	0.01 to 0.83	Moderate
228	Regular and systematic evaluation of the use and effects of PRN medication for individual service users and the service.	88.9	6.3	0.7	14/18	78%	0.64	0.27 to 1.00	Substantial
230	The rational should be communicated to the service user as well as information about any perceived risks, their questions answered and their consent sought.	94.4	6.6	0.6	13/18	72%	0.40	-0.04 to 0.84	Fair

5.5 Discussion

The study aimed to establish expert consensus for improving practice for the prescription and administration of PRN psychotropic medication. As a result of the Delphi process, 271 items initially generated were reduced to 13 consensus statements. The items retained represented the current issues and directions for improving practice for the prescription and administration of PRN psychotropic medications within acute inpatient mental health care.

The consensus statements converge into four key themes. Firstly that service users should be more involved in all processes associated with PRN psychotropic medications. This process should be individualised, involves joint decision making, negotiation and where possible takes account of advance directives and preferences. The current practice of routinely prescribing haloperidol and lorazepam does not reflect these principles (Baker et al. 2007). The second theme focuses on the process of prescribing and administering PRN medication. This process should clearly be based on assessment, leading to a clear proactive indication for use in the prescription. When nurses administer PRN medication this should be for reason it was prescribed as is suggested in statement 102. Therefore indications for use need to be clear and agreed by all. Prescriptions should also be time limited thus encouraging the process of review (third theme). This review should include evaluation of effectiveness and treatments and takes account of service user's experiences of taking PRN medication. The final theme concerns the side effects associated with PRN medication. Staff need to develop knowledge and awareness about potential side effects prior to using PRN medications.

There are clear overlaps between those items that are retained and current policy and literature. For example, side effect monitoring, avoidance of high doses and polypharmacy have all featured in recent service user or professional campaigns (National Institute of Clinical Excellence 2005, Royal College of Psychiatrists 2006, Taylor et al. 2005). Further research is clearly needed to test the impact of these statements on clinical practice.

Many methods have been employed to establish statistical consensus within Delphi panels. The method chosen pre-panel aimed to optimise the quality and importance of those items retained and identified items which all panellists agreed to (consensus) (Williams and Webb). Of those 237 items deleted, 44.7% (n=106) received one negative score, the remainder received multiple negative scores. Single negative scores accounted for 36.8% (n=71) and 81.4% (n=35) of items deleted from round 2 and 3. The manner by which items were deleted does mean that an individual could assert a substantial effect but establishing consensus at 100% is however a respected criterion for achieving consensus of all participants (Williams and Webb 1994). Williams and Webb (1994) also propose that this method prevents the use of arbitrary or vague definitions of 'high' levels of consensus being claimed. Those items remaining do however fulfil a number of the established criteria for consensus as established in the literature (O'Brien et al. 2003, Salmond 1994). Salmond (1994) indicated items should be regarded as a '*very high priority*' if more than 70% of the sample scored them a 6 or 7 on the likert scale. All items retained in this study met this criterion (range 72% to 100%). All means for the final statements were >6, (range 6.1 to 6.7), but all means for the 78 round 2 statements were also >6. All standard deviations for the 34 items retained after round 3 were <1 (range 0.5 to 0.8). O'Brien et al. (O'Brien et al. 2003) identified a criterion of 85% within two point bracket on the Likert scales as indicative of consensus, for example ratings 6 and/or 7. Twenty-eight items retained fulfilled these criteria, while six did not (S5 (72%), S28 (78%), S67 (78%), S93 (78%), S99 (78%), S162 (72%)).

Finally, the majority of the sample was from the nursing profession. However, they occupy key roles within the NHS, Care Services Improvement Partnership (CSIP) and Higher Education Institutions (HEIs). Nursing accounted for 79% of the sample, this figure being representative of the estimated 80% of the workforce (Department of Health 2005). There is increasing evidence of nurse prescribing within acute mental health settings which will undoubtedly influence PRN prescribing (Jones et al. 2005). The authors did attempt to gain expert representation from other professions. The response rate of 56% could be considered low, but more importantly there was no attrition during the study.

5.6 Conclusion

Given the limited evidence base for psychotropic PRN medication within inpatient acute mental health settings, the development of an evidence-base is undoubtedly important. This study provides recommendations to inform clinical practice. The Delphi method was useful for distilling items generated by experts. These items provide useful and practical guidance for prescribers and administrators of PRN psychotropic medications. Further analysis and research in regards to these items is needed to evaluate effects within clinical practice.

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Chapter 6 Study Three

Mental health professionals' psychotropic pro re nata (PRN) medication practices in acute inpatient mental health care: A qualitative study.

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6.1 Abstract

Objective: To explore mental health professionals' common clinical practices associated with the prescription and administration of PRN psychotropic medication within acute inpatient mental health settings.

Method: A convenience sample of 59 mental health professionals participated in face-to-face semi structured interviews exploring their PRN psychotropic medication practices in acute mental health settings in a large city in the United Kingdom in 2005. Thematic content analysis was carried out.

Results: Mental health professionals identified a number of themes associated with their clinical practices. These included a balanced usefulness of PRN psychotropic medications, factors which influenced their decision- making and use of PRN as a clinical intervention, and widespread variations in clinical practices. These findings have important implications on how PRN psychotropic medications use differs between individuals, professional groups and organisations within acute inpatient mental health settings.

Declaration of Interest: None. Funding detailed in Acknowledgements.

Key words Treatment experiences, pro re nata, PRN, 'as required', psychotropic medication, acute mental health.

6.2 Introduction

Pro re nata (PRN) psychotropic medications are widely used in acute inpatient mental health care and up to 80% of patients receive them during their hospital stay (Curtis and Capp 2003, Hales and Gudjonsson 2004, Thapa et al. 2003, Voirol et al. 1999, Walker 1991). In the United Kingdom (UK) psychotropic PRN drugs are frequently prescribed by doctors on admission (Hales and Gudjonsson 2004) though the use of 'now orders' or 'stat' doses occurs less often. PRN psychotropic medication contributes to polypharmacy and high doses of antipsychotic medications (Geffen et al. 2002b, Milton et al. 1998, Thapa et al. 2003). A recent systematic review

conducted on behalf of the Cochrane library found a paucity of studies and concluded that use of PRN psychotropic medications is based on 'clinical experience and habit rather than high quality evidence' (Whicher et al. 2003).

Few studies have examined mental health professionals' experiences, habits and views of PRN psychotropic medication. Those which have identify marked differences in knowledge, beliefs and attitudes between nursing and medical staff (Geffen et al. 2002a, Hagman et al. 1990). A more detailed account of the processes associated with the prescribing and administration of PRN psychotropic medications is required because of the high frequency of use and associated adverse effects. An improved understanding could enable educators and researchers to influence and change current practice. We aimed to explore the views of mental health professionals clinical practices associated with the prescription and administration of PRN psychotropic medication in acute inpatient mental health settings.

6.3 Method (sampling, material, analysis)

6.3.1 Sampling

Participants were mental health professionals employed in acute inpatient mental health care and involved in the prescribing, dispensing or administration of PRN psychotropic medications (medical, pharmacy and nursing staff). The sample was recruited from 4 sites in 3 Mental Health Trusts in the North West of England. Purposive stratified sampling (Silverman 2001, 2005) by professional group and grade was used to select a cross sample of 50-60 health care professionals. Recruitment to the study differed with each professional group. For the medical staff, contact was made via all Medical Directors and education/training events for senior house officers (2 out of 4 sites). For nurses, recruitment was organised through service or individual ward managers. Pharmacists were approached individually. All potential participants were given an information sheet detailing the study. Informed consent was obtained prior to participants taking part.

6.3.2 Procedure

Interviews were guided by a semi-structured interview schedule. The schedule was devised from a previously conducted systematic literature review of the topic, with its scope being further defined and clarified through the study steering group. Questions on the interview schedule included: a critique of the advantages and disadvantages of PRN psychotropic medication; the perceived value of it as a clinical intervention; and the decision-making and process issues associated with prescribing practice and administration of PRN psychotropic medication. The interviews were conducted in the participants' work setting between April and July 2005, and lasted between 18 and 74 minutes. A total of 1,690:47 minutes of digitally recorded audio data was gathered with individual interviews lasting between 18 and 74 minutes.

6.3.3 Ethical approval

North West Multi-Centre Research Ethics Committee (MREC) approval and research governance approval for the three NHS Trusts was obtained.

6.3.4 Data analysis

All interviews were conducted by the lead author (JAB). The interviews were digitally recorded and transcribed verbatim, and following the study protocol the quality and representativeness of these transcriptions were independently checked by a second researcher. All transcripts were individually coded for emergent themes using the constant comparative method (Strauss and Corbin 1998). The codes in each interview were subsequently compared across the data set until generated properties and themes became saturated and no new codes emerged. This process was supported by the use of ATLAS.ti software (Muhr 2005). Quotations from participants are used to illustrate the emergent major themes.

6.4 Results

Sixty-one members of staff expressed an interest in participating in the study. Two (a staff nurse and a specialist registrar) withdrew prior to interview. Fifty-nine mental health professionals working in acute inpatient mental health care therefore

participated in the study. Thirty-four participants were individually interviewed, twenty-two as pairs, and one group consisted of three members. Mental health professionals interviewed included psychiatrists (n=16), mental health nurses and assistants (n=38), and pharmacists (n=5). The sample was diverse in terms of age, ethnicity and grade of participants. Staff on average had worked eight years in mental health (mean 8.0, median 6, range 0.1 to 31yrs) with six of these years in acute inpatient mental health care (mean 6.0, median 4, range 0.1 to 25 yrs).

Major themes which emerged from the analysis were:

a) Balanced usefulness.

b) Decision making processes.

c) PRN psychotropic medication as a clinical intervention.

d) Process issues.

e) Information provision and PRN psychotropic medication.

f) Variations in practices.

6.4.1 Balanced usefulness

The advantages of PRN psychotropic medication focused on relieving distress (28 extracts), preventing (17 extracts) and managing violence (17 extracts). Another sub-theme focused on 'removing doctors from the process' (19 extracts). There was an underlying assumption that this would lead to safer and improved patient care. This sub-theme re-emerged in answers to a number of questions in the interviews:

It can be the nurse's decision about medication. You don't have to wait for the doctor. It's safer, than obviously waiting for a doctor to come up and prescribe the medication.

Senior Staff Nurse (A)

You don't have to bleep the doctor all the time to get things prescribed.

Senior House Officer (A)

Disadvantages focused on the perceived misuse of PRN, either by nursing staff (giving too much or too quickly) or by patients. Misuses represented over half (56%,

64 extracts) of all cited disadvantages of PRN. A second sub-theme focused on the poor quality prescriptions of PRN psychotropic medication. Cited examples included generally poorly written and insufficient or absence of indication for use:

B: I think there's inherent dangers in PRN because although it's prescribed by a doctor, the actual giving it is the nurse's decision. Nobody in this hospital would do that, but there could be a danger of overmedicating somebody.

C: And there can also be a danger, where nursing staff could use it rather quickly, rather than using other alternative techniques.

Senior Staff Nurses (B/C)

Overall a 'balanced usefulness' was reported, with answers focusing on safety (14 extracts), prevention and reduction of distress (11 extracts), but only as a last resort (8 extracts).

6.4.2 Decision making processes

Decisions to prescribe PRN psychotropic medication were often based on patient history, mental state and risk assessment. It was suggested that certain psychotropic medications (haloperidol and lorazepam) were routinely prescribed as PRN, regardless of these factors:

When people are admitted it is still common practice to put lorazepam and haloperidol down without even an assessment. It's just there because that's what we do.

Ward Manager (A)

You can bet the 23 patients we have got in here, the majority are written up for PRN and it will all be lorazepam and haloperidol.

Nursing Assistant (A)

Nurses' decisions to administer PRN psychotropic medication were influenced by safety (15 extracts), knowledge of the patient (12 extracts) and levels of patient distress (8 extracts). Nearly all staff (n=51, 86.6%) reported that nurses influenced the PRN prescribing practices of medical staff. Nurses were undoubtedly aware of this influence and targeted junior medical staff for the 'correct prescriptions'. Often,

this implied higher doses of typical antipsychotics and, on occasions, prescriptions for acuphase (zuclopenthixol acetate):

I am not going to argue with too many of the consultants but some of the junior doctors, you may try to influence them on what the level (dose) they prescribe.

Staff Nurse (D)

In contrast, only two nurses reported that their decision to administer PRN psychotropic medication was influenced by medical staff. Half of all mental health professionals reported their decision to prescribe or administer PRN psychotropic medication was influenced by patient preferences:

Well there aren't that many drugs and to be honest when they are acutely unwell, the patient, as I see them, aren't in a position to make an informed choice.

Consultant Psychiatrist (A)

You quite often medicate people with haloperidol and they say, "Whatever you do don't give me haloperidol. It's a horrible drug, it causes me side effects. Use anything but haloperidol." But we don't even ask. I think one of the things that we don't do that we should do is talk to the patients about how they manage their own crisis and the role of PRN within that. We never do that on admission do we?

Ward Manager (B)

6.4.3 PRN psychotropic medication as a clinical intervention

Forty-two (71%) of the 59 mental health professionals had encountered times when PRN was used for reasons different to the prescribed indication for use. Explanations for this were to provide sedation (11 extracts), alleviate distress (8 extracts) and to prevent '*bothering*' the doctor (5 extracts):

If somebody comes to you and they're not actually agitated, but they're saying I'm hearing voices and feel a bit disturbed, then that's a different reason from what they're prescribed, but it's a valid reason to be giving it them. If somebody said to me I'm hearing voices, I'm feeling quite troubled, then I'd just give them haloperidol or olanzapine. I wouldn't use the benzos with it that would be the difference.

Staff Nurse (E)

Perhaps on occasions, not often, medication is used to deal with somebody's behaviour rather than to treat somebody's mental state.

Charge Nurse (A)

Fifty-seven (97%) of the mental health professionals could identify times when PRN psychotropic medication had been used when preferable alternatives existed. They attributed lack of alternatives to limited skills (10 extracts) and clinical experience (7 extracts), pressure of time (6 extracts) or low/inadequate staffing levels (6 extracts). Twenty-two alternatives were proposed to PRN, the most commonly cited being i) spending more time with nursing staff (23 extracts), ii) anxiety management (21 extracts), iii) de-esculation (11 extracts) and iv) distraction (11 extracts). Time, staffing and experience were cited as reasons why this was unlikely to happen.

Despite a range of non-pharmacological alternatives to PRN, participants implied that it was regularly used as a 'first resort'. This was essentially because other factors prevent the use of non-pharmacological interventions 'the pressure cooker of acute wards'. An alternative explanation proposed was the downward prioritisation of therapeutic activity in acute inpatient mental health settings:

I would say during the day, yes, when the ward has been like flat out, 100 miles an hour, you give that one [patient] *2 milligrams* [lorazepam]. *Just really to sort of quieten them down, go out the way, and relax. I think we're all guilty of that and we'd be lying if we said differently.*

Staff Nurse (F)

Sometimes it's far easier to just give someone a couple of tablets that make them a bit more chilled out and calms them down and shuts them up, than actually spending that hour or so time with someone that they might need.

Staff Nurse (G)

I think that sometimes it's used; it can be used as an excuse not to engage in any real therapeutic dialogue with a patient.

Ward Manager (C)

Therapeutic time is seen as less important than perhaps answering the phone or dealing with the next crisis.

Ward manager (D)

6.4.4 Process issue

Two thirds suggested that PRN psychotropic medications were given at regular medication round times. Reasons for this included convenience (i.e. when the medication trolley was open and patients asked), or because it was the only time during the shift when qualified nurses saw the patients.

The interviewees suggested that all medication was reviewed at the ward round and implied this *probably* included PRN psychotropic medication. The review process of PRN psychotropic medications appeared vague, and participants felt that reviews which included PRN were infrequent. A clear trigger for review was when nursing staff identified an 'issue'. Most commonly cited was when additional doses of PRN psychotropic medications were needed or if staff had concerns that the patient was an 'addict'. Benzodiazepines in particular appeared to trigger this response which appeared to be dichotomous; that of being 'good when we (the nurses) say they are' and 'bad when you (the patient) ask for them'. To a lesser extent, the other drug that triggered this response was procyclidine:

Some are just addicted to benzos [benzodiazepines]. The only problem we have with PRN medication is with benzos. People who have genuinely been hearing voices will ask for the haloperidol - I am hearing voices. People who ask for benzos are quite addicted to them. Those people who ask for PRN medication, they'll come and ask for pills, rather than lorazepam.

Staff Nurse (G)

They come up to the office and say 'I haven't had my Lorazepam'. If they are talking about a time since they had their lorazepam, they probably don't need it. They probably want it.

Pharmacist (A)

I have seen a patient who has come to the nursing office and they are already on clozapine augmented with risperidone. They are on quite a lot of antipsychotics. He's quite a calm guy and he just came up and said "I am still having trouble with my hallucinations". The nurse goes and gives him a PRN dose of risperidone and says 'This will make you feel better'. I just thought no, it won't.

Pharmacist (B)

6.4.5 Information provision and PRN psychotropic medication

Half of the mental health professionals reported providing some information about PRN psychotropic medications to patients, although the content of this was often limited. For the most part patients only appeared to receive additional information if they asked. Information provision was particularly scarce in relation to side-effects. This information was often only given when staff did not want the patient to take a particular medication:

I am not convinced that all the time patients are fully aware or educated about the reasons for taking PRN.

Ward Manager (E)

We won't tell them side effects without them asking. It's an experiential thing. I mean if we went through every possibility. You went through every side effect that they are going to have. They are going to say I don't want that.

Staff Nurse (D)

You would give them more information about the medication that you want them to take, and only sort of give the negative side of other tablets that you didn't want them to take.

Charge Nurse (D)

6.4.6 Variations in practices

Interviewees alluded to a number of variations in the practices of individual staff, wards and organisations. These reflect individual and organisational differences in the clinical practices of prescribing and administering PRN psychotropic medication:

Now in ..... where I worked previously if I had administered that dose of medication I would have got severely disciplined.

Ward Manager (B)

I think when people are restrained they are always given i.m [intra-muscular] medication and I have no idea whether you always need to give i.m. medication, because I have only been qualified seven months. I am aware that other trusts don't necessarily give i.m. medication every time someone is restrained.

Staff Nurse (H)

There was also the impression that a sub-group of nurses administer more PRN psychotropic medications - the 'old school.' This perception often, although not exclusively, centred on members of night staff:

You get it on nights. You get certain night nurses and the team know who they are. They say so and so are on tonight. It will be a quite night then.

Ward Manager (B)

That's my pet hate, coming in, in the morning and 'Oh well they had 1mg of lorazepam'.

Staff Nurse (G)

Nurses suggested that those who had experienced an adverse event (i.e had been assaulted) or who frequently secluded patients were significantly more likely to administer PRN medication (Grice 1997). Thus, an aspect of administrating PRN psychotropic medications appears to have a punitive element:

There have been times where there's been assault on the ward. I bet if we look back at times when we've given IM medications, say there's been a fight between a patient and another patient, or – or there's been a fight between a patient and a member of staff. I reckon that medication is given more often when a member of staff's been assaulted than another patient. There's a fine line between managing the behaviours and knocking someone out with PRN. I think that can happen. That it can be used punitively.

Staff Nurse (G)

Finally, the act of prescribing PRN psychotropic medication appeared not to be related primarily to individual clinical need but more often to providing nursing staff with reassurance:

They just feel unsafe, often they'll say 'the weekend's coming up so can I have some such and such on the PRN side?' and I think it helps for them to feel that that's there. Although at the back of my head I'm sometimes thinking 'I would very much prefer to leave it and if the patient needed it, they'd see the doctor, the SHO (Senior House Officer), and then the SHO would prescribe appropriately', but I think that's often not possible.

Consultant (B)

6.5 Discussion

To the authors' knowledge, this study provides the first exploration of mental health professionals' perceptions and experiences of the prescription and administration of PRN psychotropic medication within acute inpatient mental health care. It provides further evidence of the clearly defined differences between medical and nursing beliefs and knowledge in regards to PRN medication (Geffen et al. 2002a). The clinical responsibility for PRN psychotropic medications appears to have been segregated from that of regular prescriptions. The findings suggest that there is less emphasis on information provision, education of patients and review of PRN medications than with regularly prescribed medication. The findings indicate that there was a failure to review PRN medications exposing patients to potentially dangerous and distressing circumstances of receiving high doses, side effects and polypharmacy of antipsychotic drugs. Given the increased mortality associated with multiple neuroleptic drugs (Joukamma et al. 2006), PRN is clearly an area which warrantes further attention. Trials which compare different drug or dosing regimes and the impact on these dangerous effects are clearly required. The ongoing Prescribing Observatory for Mental Health – (POMH-UK) organised by the Royal College of Psychiatrists should contribute to the understanding of this problem.

It is concerning that PRN were so frequently given when non-pharmacological interventions could be used. A previous study which stopped PRN prescriptions in favour of 'now' orders identified a reduction in the frequency of drug administrations without a subsequent increase in adverse events. They concluded that PRN prescriptions result in patients receiving unneeded psychotropic medications (Thapa et al. 2003). Studies which have introduced behavioural systems and interventions have been shown to reduce the use of PRN medications (Donat 2002a, 2005). Additional research is clearly required to test the effectiveness of, and barriers to, using non-pharmacological interventions as alternatives to PRN in acute inpatient mental health care.

The PRN process potentially allows nurses to make decisions which are usually made by doctors, including those of dose, frequency, and route of administration (Usher et

al. 2003). This process places a large amount of responsibility on the nurse who must be able to distinguish between side-effects and disturbances that are pathological in origin. It is questionable how long mental health professionals can abdicate responsibility for these decisions (Geffen et al. 2002a). Previous research and guidance has identified a poor knowledge base of staff working within acute mental health settings in regards to medication issues (Department of Health 2002, Geffen et al. 2002a, Standing Nursing and Midwifery Advisory Committee 1999, Usher et al. 2001). Few studies have explored this phenomena but those that have found that staff generally lack knowledge about antipsychotic drug side-effects and do not assess patients in a systematic manner (Bennett et al. 1995). The international development of non-medical prescribing especially in acute inpatient mental health care could further complicate this process. Regardless of which profession prescribes PRN medications, systems need to be implemented which monitor the process and encourage clinicans to regularly review the administration and prescribing of PRN psychotropic medications.

6.6 Limitations

A limitation of this study relates to the self-selected sample of mental health workers who took part in the interviews. However, the sample does include a diverse range of participants in terms of their experience and professional group. Whilst the study may include an over representation of mental health nurses in comparison to psychiatrists and pharmacists, this is representative of the workforce in acute inpatient mental health care. Consequently, the findings may not be immediately transferable to the wider multi-disciplinary team, although, we would argue, they remain of significance.

6.7 Conclusions

The findings suggest that the adminstration processes surrounding PRN psychotropic medication is complex and differs between individuals, professional groups and organisations. Attention is needed to ensure that these processes are critically examined and that PRN does not become the domain of a single professional group. There is evidence of abdication of clinical responsibility from all professionals which

undoubtedly contributes to high doses and polypharmacy that patients experience whilst exposed to acute in-patient mental health care. Further research is warranted in this area, particularly that which explores the blurred area between PRN and rapid tranquilisation. The development of an evidence-base and further testing of alternative non-pharmacological interventions to PRN psychotropic medication is also merited.

Intentional space

Chapter 7 Study Four

Service Users' experiences of 'as needed' pro re nata (PRN) psychotropic medications in acute mental healthcare settings.

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7.1 Abstract

Aims: This study reports a study which aimed to explore service users' views and experiences of the processes associated with the prescription and administration of as needed (PRN) psychotropic medications within acute mental health settings.

Background: Few studies have explored the use of as needed (PRN) medication within acute mental healthcare settings. As needed psychotropic medication are frequently requested by service users. The literature is unclear as to why service users request as needed psychotropic medications or their experiences of such treatments.

Method: A convenience sample of 22 in-patients participated in face-to-face semi-structured interviews exploring their treatment experiences of as needed (PRN) psychotropic medication within acute mental health settings in a large city in the United Kingdom in 2005. Thematic content analysis was carried out.

Results: Interviewees highlighted the value of as needed (PRN) medications. However, the process associated with their use was perceived as confusing and stigmatising. Service users had limited understanding of and felt unsupported in attempts to use alternatives to as needed (PRN) medications. Additionally, the decision-making and information-giving processes were unclear to them which raise the issue of power and control within acute mental health settings.

Conclusions: Nurses should take account of the issues of power and control when administering as needed (PRN) medication. The provision of adequate treatment information should be a priority to enable informed choices to be made about as needed (PRN) medication.

Keywords: In-patients, patient experiences, pro re nata (PRN), 'as needed', psychotropic medication, acute mental health care, nursing, interviews

What is already known on this topic?

- Although service users request as needed medication there is a limited understanding of their experiences associated with this treatment.
- Research of as needed psychotropic medications is limited.

What this study adds?

- Service users see the value of as needed medications but have limited understanding of their use and of the alternatives.
- The process associated with the use of as needed medication is perceived as confusing, and stigmatising.
- Nurses need to provide service users' information and treatment choices about as needed medication.

7.2 Introduction

Psychotropic medication is the mainstay of secondary care mental health treatment, and is especially important within inpatient mental health settings (Bowers 2005). 'As needed' or pro re nata (PRN) psychotropic medication is a common adjunct to routinely prescribed medication within mental health services. Drugs from the antipsychotic and anxiolytic therapeutic groups are often prescribed for the same indication and are used interchangeably. As needed medication is frequently used, with several Australian studies estimating use by approximately 80% of patients (Curtis and Capp 2003, Geffen et al. 2002b). These drugs are administered at the discretion of mental health nurses for a range of reasons including agitation, symptom distress, insomnia, in occasions of violence and aggression and at the request of service user (Usher et al. 2001). In both the United Kingdom (UK) and Australia retrospective data indicates between 20-37% of as needed medication is administered due to requests by the service user (Gray et al. 1996, Usher 2001). This would appear to contradict the anti-medication stance of '*survivor movements*' (Wells 2004). The literature does not explain why extra medications are so frequently requested by service users or describe their associated experiences.

A survey in the United States of America (USA) showed that 50% of adolescents receiving treatment for mental health problems agreed that as needed medication was 'best thing for them', although 30% also suggested that viable alternatives existed (Petti et al. 2003). However, another USA study identified that a proportion of service users were so opposed to antipsychotic medications that they would rather be restrained or secluded (Sheline and Nelson 1993). Another qualitative study of medication use in acute inpatient care identified few positive comments about psychotropic medications (Goodwin et al. 1999).

Limited research has been conducted of service users' experiences and perceptions associated with psychotropic medications (Happell et al. 2004) and especially of as needed medication (Usher et al. 2003). In the UK the National Institute of Clinical Excellence guidelines for dealing with violence and aggression refer to service user concerns about antipsychotic medication (National Institute of Clinical Excellence 2005). Further exploration of service user experiences of these drugs, many of which are prescribed as needed, is recommended and particular reference is made to haloperidol (National Institute of Clinical Excellence 2005). There is therefore an urgent need to explore inpatient user experiences of the process associated with being prescribed and administered as needed psychotropic medications.

7.3 The study

7.3.1 Aim

The aim of the study was to explore service users' views and experiences of the processes associated with the prescription and administration of as needed psychotropic medications within acute mental health settings. This study forms part of a larger study of as needed psychotropic medications within acute inpatient settings.

7.3.2 Design

The study design was qualitative. Semi-structured interviews were carried out with a convenience sample of in-patients in three Mental Health Trusts in Greater Manchester to explore their views and experiences of as needed medication.

7.3.3 Participants

Twenty-seven service users expressed an interest in taking part in interviews. Five of these were not interviewed. Two were on leave of absence on the arranged day, two refused to participate and one service user was considered by the researcher, following discussion with the multi-disciplinary team, as being unable to consent. Twenty-two service users participated in individual interviews.

7.3.4 Data collection

Interviews were conducted on acute mental health wards by the first author (JAB) between May and June 2005. Interviews were conducted with patients in private rooms on the ward in which they were resident. The interviews were guided by a semi-structured schedule consisting of 20 open-ended questions (Figure 7.1). The content of the questions was derived from a systematic literature review and an advisory group that consisted of clinicians (nurse consultant, practice development nurse, modern matron and a pharmacist) and academics. The final draft was sent for external review by an independent service user led research group (The Merit Project). Modifications were made to the schedule following this external review. Digital audio recordings were made of all interviews. Demographic details of the participants were also collected.

7.3.5 Ethical considerations

Ethical approval was obtained from the North West Multi-Centre Research Ethics Committee and research governance committees for each of the three NHS Trusts involved in the project. Participants received £10 expenses for taking part. Participants were recruited to the study via posters displayed on all acute wards within the four sites in three Mental Health Trusts within the Greater Manchester area. The

posters asked for participants who were inpatients, had received as needed medication and who were willing to talk about their experiences. Willing participants were asked to approach nursing staff for an information leaflet. At this point an information leaflet was provided to them. Before the researcher approached potential participants they were given 48 hours to consider their involvement in the study. Prior to the interview the researcher reiterated the purpose of the trial, discussed any concerns and questions, informed participants of the anonymity of their responses and obtained written consent.

Figure 7.1: Semi-structured interview guide for service users.

What do you understanding about the term 'when required'/'PRN'/'extra' medication?
What are the advantages/good things about PRN medications within acute mental health settings?
What are the disadvantages/bad things about PRN medications within acute mental health settings?
In your opinion are there any issues for the prescribing of PRN or the way you receive (administration) of PRN medication within hospital?
Do you see PRN medication as a useful or helpful intervention within hospital?
- Why is this?
What influences your decision to ask for a PRN medication?
How do *Doctors/or Nurses* influence this?
Have you received extra medication without asking what has happened?
At these times how much choice did you feel you had?
Have you ever taken PRN when didn't feel you needed it?
What suggestions would you make to improve the process of getting PRN medication?
Are there times when PRN is used to help the management of the ward?
- What factors influence this?
How does knowing that PRN is available aid you help you?
Are there times when you have been given PRN when other things would have been more appropriate (but not possible)?
What other things do you think would be a useful alternative to PRN?
- What prevents these from being utilised?
Could you image an acute ward which operated without PRN medications, what would it be like?
The literature suggests that PRN is often given at normal medication times, why do you think this is?
How much information is provided with extra medication?
Could you describe occasions when there have been disagreements within your care team about PRN medications?
If you were to think of best practice or improving the use of PRN medication what would be different?

7.3.6 Data analysis

Interviews were digitally recorded and transcribed verbatim by the first author. Independent analysis was carried out by two of the authors (JAB and KE). Comparative analysis of transcripts was undertaken using thematic content analysis (Strauss and Corbin 1998). This involved coding of the data and used both open and in-vivo techniques. Once codes were established they were then merged into more substantial categories, and labelled (Strauss and Corbin 1998). This allowed themes to emerge out of, rather than being imposed on the data (Curtis and Harrison 2001). The process was facilitated by the use of a dedicated computer qualitative data processing software 'ATLAS.ti' (Muhr 2005), thus enhancing the rigour associated with data analysis (Pope et al. 2000).

7.4 Results

All interviewees had received as needed medication whilst in hospital; of these 21 had received psychotropic as needed medications. The interviews generated 406 minutes of recorded data (Range 05:55 to 41:52 minutes; mean 18:27 minutes; median 16:14 minutes). Two interviews were terminated, one due to deterioration in mental health, the other at the participant's request. The sample was diverse in terms of gender, age, diagnosis, ethnicity and Mental Health Act status (Table 7.1). The interviews of those detained under the Mental Health Act were generally shorter (mean 17:20) than informal service users (mean 21:51). There were no discernable differences in the answers of those detained and those who were informal. The results described refer to the themes extracted as a result of the analysis of transcripts.

Table 7.1: Socio-demographic details of participants.

Characteristic	Number of participants (n=22)
Gender	
Male	14
Female	8
Age Range	
20-24	3
25-29	2
30-34	3
35-39	5
40-44	1
45-49	3
50-54	5
Ethnicity	
White British	19
Black British	2
Asian	1
Diagnosis	
Schizophrenia	8
Psychotic Depression	2
Depression	3
Bipolar Disorder	7
Alcohol	1
Anorexia	1
Mental Health Act (1983) status	
Section 3	13
Section 2	1
Informal	8

7.4.1 Perceived value of as needed medication

Service users valued the use of as needed medication, with the majority of participants (n=19, 86%) suggesting it was useful or helpful to them. Benefits were flexibility, availability and a calming effect:

It is valuable - it is valuable to us as mental health patients. (Patient 7).

I think PRN [as needed medication], *as and when required is an excellent way of summing it up. I think it's an ideal situation. Hopefully, those that haven't already realised that will do soon.* (Patient 20).

When you are quite poorly and feeling bad your mind just will not shut up, and if you can shut your mind up for a while, that is part of the healing process. I think these types of drugs they give you now do that. (Patient 5).

The value attributed to as needed medication by service users appeared to be greater during the initial days of an admission. However, as well as suggesting that as needed medication was valuable service users suggested that prolonged use could prohibit the use of other coping strategies or lead to dependency:

It's a difficult one because when you are feeling quite poorly it does give quite a quick relief and perhaps then gives you the opportunity to recover. The down side of it is you become reliant on them and ask for them, perhaps when some other method like breathing exercises, diversion or going for a walk may have been the alternative. So you can become reliant on it. But I have to say in fairness to all the hospitals I have been in, they are not given out like sweets. (Patient 5).

The effects and side effects of some drugs made them preferable as compared with others. There was an interesting contrast between lorazepam and haloperidol: the *'little blue tablets'* (lorazepam) seemed to be experienced more favourably than other drugs such as haloperidol. This is consistent with anecdotal evidence that benzodiazepines and hypnotics can be more acceptable and therefore more frequently requested by service users (Duxbury and Baker 2004).

The availability of as needed psychotropic medications appeared to foster feelings of control. Service users felt empowered by having the opportunity to decide about the timing and dose of extra medication, enabling them to feel more in control of their symptoms:

When I felt obviously my body needed something to boost my coping capabilities. I have been able to ask for it rather than it is given at 2 o'clock. Yes, having the control has made me feel a lot more happy and comfortable. (Patient 4).

Well I think that I am my own best doctor. So now that I have been diagnosed, I believe that I am going to be the best judge of when I take my medicine and that's as and when required. I guess it's up to me to decide what dosage and when I take it. It makes me feel like I am in control. (Patient 20).

7.4.2 Disempowerment and control

However, participants reported that the process associated with the use of as needed medication was confusing and stigmatising. Service users expressed anger, frustration and embarrassment at 'refusals' of medication that they had requested. Refusal of requests for as needed medication could be seen as disempowering, particularly in the absence of explanation by nursing staff:

Extra medication, I see many, many times people asking for it and not getting it. It seems to be when you ask for it you don't get it, when don't want it you get it. (Patient 1).

The staff have the power over the patients, mainly to do with the PRN [as needed medication] *because they can give it you at will. It's not like prescribed at a certain time to actually give it you. So they can just do it [give it] whenever they feel like. They have too much power.* (Patient 9).

For like a good half an hour after that [refusal] *I got a lot worse and that's when like I said I feel [felt] threatened and paranoid and I lashed out. Punished the walls, head butted the wardrobe. And they come in and said "What's the matter?" What's the matter, and I have told them. They said "Is there anything you want?" I said, "Well I come to see you and you refused it me, so there's no point." They will usually go away or sit outside your door for a bit, you know, to see how you are.* (Patient 15).

Participants suggested that the embarrassment associated with such encounters is exacerbated in public areas such as the smoke room or lounge, which could be humiliating. It could also be difficult for service users when staff initiated the offer of as needed medication, especially at times when they did not feel it was needed or warranted. This problem was more likely to happen when participants were being aggressive or causing a disturbance. The medication could be seen as a tool to control the ward:

It shouldn't be called PRN [as needed medication], *I know that. Cause it's embarrassing when you ask for it, PRN* [as needed medication], *it's horrible when you get rejected. You should take the patients aside, to stop the embarrassment.* (Patient 19).

I think that what ever happens when medication is taken I think it should be taken to [in] *the medicine room. I don't think it's right when say I was sat in the living room, watching the Simpsons on telly or something, I don't think it's right if the actual nursing staff come with the tablets and say take this. I don't think that's very professional, it's not private then.* (Patient 7).

Although participants disapproved of forced medication they appeared to hold no grudges towards staff, and felt these steps were necessary to control '*others*' for the well-being and recovery of all patients. Interestingly, this view was reported about '*others*' who were unwell and causing disturbances, rarely about participants' own treatment:

I have seen patients get injections when they are causing problems. I had it once myself. They just held me down and gave me an injection. I didn't really want that, they should have asked me. (Patient 3).

I have actually noticed, that some patients are offered PRN [as needed medication] *more than others who are not considered as dangerous, perhaps, in the mind of the member of staff. I have learnt to behave myself.* (Patient 9).

Medication is used as a tool. There are no bars on the windows. There are no straight jackets any more, as in one flew over the cuckoos nest. Medication is the new tool. Medication solves problems, it knocks people out. Because a quiet patient, is an easy patient. Whilst you are sleeping, the staff can get on with the study work. (Patient 1).

I'm sure they are given a little bit of extra [as needed medication] *to quiet things down to make life healthy for everybody else because it's the snowball effect isn't it.* (Patient 16).

Yes, I have had a disagreement before, one of the male nurses. I had gone and asked for it [as needed medication] *at the same time I was having normal medication. Like at half past ten to go to sleep, and I asked for the diazepam. He says you can have the diazepam or you can have your normal medication but you are not having both. So I said I thought this was supposed to be PRN* [as needed medication]*! He got a bit confused. It ended up in bit of an argument. To the point where I have spat me* [my] *dummy out and said I won't have anything then and stormed out of the room. That's only happened the once.* (Patient 15).

Forced medication and the view that medication could be administered in order to manage the ward safely could lead them to conclude they had no control over whether

or not they receive this extra medication. Thus the use of as needed medication could have the effect of reducing the autonomy of service users. Participants indicated that aggressive or noisy patients were often given medication that quietens them down, further emphasising the control dynamic of users' experience. They depended upon decisions made by staff; including when medications were prescribed or administered, and did not always receive it when they requested it, highlighting a power imbalance between staff and patients. However, some service users suggested that '*others*' played the system in order to get extra medication. The implication was that some individuals abused as needed medications especially lorazepam (Benzodiazepines) and procyclidine. This could be seen as attempts to regain control over the system:

But you never know who's like just playing the card or the ticket to enable to just get the extra medication. (Patient 15).

They think that they need it or it's just to give them bit of extra buzz. They have just gone and basically abused the system. (Patient 16).

7.4.3 Information and knowledge

Service users indicated a lack of education regarding their as needed medication. They lacked knowledge about its purpose, how often they could have it, or indeed whether it had actually been prescribed for them. Some commented on the fact that they had not been informed that they were on any as needed medication. The implication was that the doctors deliberately did this to prevent misuse. Over half (n=17, 53%) of the respondents noted they received very little information about as needed medications:

I just took it. I didn't know what it was. She just gave us (me) a cup of water and said here you are, take this, and then about 10, 15 minutes later I went back to bed and went to sleep. (Patient 22).

All they do, they bring you in, show you your room and then they leave you alone. They don't give you a thorough introduction as to being on the ward. What PRN [as needed medication] *is. They don't say to you first of all if you get out of hand we will give you PRN* [as needed medication]. (Patient 9).

However, seven of these participants stated they were not concerned about their lack of information either because they trusted the staff, staff were qualified to make decisions for them or had taken as needed medication before without concern.

However the presence of these beliefs appeared to undermine feelings of self-sufficiency:

I am not well up [informed] *on the effects of the different tablets. I have no idea. I just trust the doctors.* (Patient 10).

I might have had a couple of sheets on it at some stage but as I needed it I've never really been worried about it. (Patient 3).

Participants who believed they had acquired sufficient knowledge noted this was mainly due to the fact they had been assertive or took control of investigating the medication for themselves:

They don't tell you - you are on it. The reason why I knew why I was on medication was because of my drug sheet, and I'd seen something written down. You know what wasn't being given to me and I said "What is that?" (Patient 6).

Well a lot of people say you need to read the leaflet. To see about the possible side effects of any drugs. I always read the leaflet because I think it's important that you know what's in it. What is happening to your body or what could happen in the future, but not everybody is like that. Some people just open the box throw it [the leaflet] away. They just take it, which is a shame really. (Patient 21).

7.4.4 Alternatives to as needed medication

Participants identified alternatives to as needed medication (n=10), including talking (including counselling) and recreational activities such as painting and exercise. However few had tried them because of a perceived lack of support or opportunity to employ alternatives to as needed medication. Participants suggested that supported diversional activities offered most benefit. Nurses were seen as an important but a distant source of support for the development of alternative strategies to prevent reliance on as needed medication. Participants linked perceived resource limitations, particularly staffing, and failure to try alternative coping strategies, implying that as needed medication was used instead of nurses spending therapeutic time with patients:

Well first and foremost it can't be altered at this particular moment in time, due to the fact that it's under funded - the NHS. It's understaffed, due to that, and they are throwing more and more flipping study work. They can't cope with what they have

already got at the moment, so it's only going to get worse before it gets better. (Patient 1).

I think that they could sit down and have a chat with you, but they are that busy and they are running around. They can only speak to you for a few seconds, you know and that's it. And you get yourself all worked up. They haven't got the time to sit and talk to you properly. (Patient 22).

Yes, my name nurse has come up with a strategy on a little piece of study, like to relax, to help me get to sleep. I have tried to follow that, and to be honest with you some parts require a bit of patience and I am not really a patient person. At the moment that is not really working for me. (Patient 15).

7.4.5 The need for as needed medication

The value of as needed psychotropic medications was further reinforced when service users were asked to describe a ward where this was not available. Most (n=12) described the absence of as needed as having dire consequence - *'bedlam'*. Only two participants did not agree that a ward without as needed medication would be a negative development (n = 20):

I think everyone would be running around like a mad bull. (Patient 17).

Like I say for me I couldn't really imagine it from my point of view but from what I have seen I suppose it would be like not far short of Broadmoor. (Patient 15).

However a number of service users indicated that the environment of modern acute mental health units increased the requirement for as needed medication compared with traditional mental health units with larger grounds '*asylums*':

I think it would have to be a different sort of hospital really because everyone tends to get mixed up in here together. It would have to be very, very open place, I suppose like the old fashioned ones with grounds and things. (Patient 3).

7.5 Discussion

Power and control were prominent concepts that emerged in the accounts of the service users. These concepts have previously been identified in research within psychiatry and more specifically acute inpatient care (Hall 2004, Walton 2000), especially in relation to medication issues (Haglund et al. 2003, 2004). Other authors highlight the related concept of coercion (Bindman et al. 2005, Lind et al. 2004, Olofsson et al. 1998). Power relationships in the administration of as needed medication may reflect judgements about an individual's capacity to make a valid treatment decision. Nurses may believe that service users lack capacity to make reasonable decisions about the need for medication (Breeze 1998). However, denying service users the right to be involved in treatment decisions can have negative repercussions both in administration of effective pharmacological treatment and also on therapeutic relationships with health care staff.

The use of forced medication and failure to inform service users about treatment options can be expected to undermine their feelings of control. However, Haglund et al's (2003, 2004) observations of nursing practice within an acute mental health ward in Sweden, disputed that coercion occurred during the administration of as needed medication. However these observations were made on voluntarily admitted service users within one context. She hypothesised that asking for as needed medication provided an opportunity to gain additional time with nursing staff. However, a recent study in the UK by the Royal College of Psychiatry and Healthcare Commission (2005) identified 48 percent of service users had experienced threats by staff associated with medication. Service users may not be able to act out an appropriate 'sick role' within acute mental health settings if they are not voluntarily seeking help or perceived as having the capacity to 'get better' (Breeze and Repper 1998).

Furthermore, for some people the feeling of coercion can lead to a perception of threat to their personal freedom. This has implications for their care and management in the acute setting and beyond, especially in terms of adherence with prescribed medication (Moore et al. 2000). Coercion is clearly opposed to a recovery philosophy; a concept that reflects a person's ability to engage in a process which re-takes control and

responsibility over their lives. It has been identified that service users find the use of medication a helpful strategy in moving forward in this process (Faulkner and Layzell 2000). A major aim of medication management is to develop the person's self-efficacy in managing their pharmacological treatment. A person's subjective experience of medication and the quality of relationships with the acute care team (Day et al. 2005) can have a profound effect on service users' attitudes towards treatment and adherence to medication.

Participants suggested that one advantage of as needed medication is that it increases their feelings of control over their illness, and may in fact afford them a sense of competence that has been lost within society. This sense of control can be enhanced by developing the concept of concordance within acute care settings. It describes the therapeutic relationship between the service user, prescriber and care team and reflects a collaborative process. This results in a negotiated agreement between the service user and a health care professional which determines whether, when and how medicines are to be taken. An alliance in healthcare is required in which practitioners recognise the authority of service users in medication decision-making. Concordance has been criticised (Marinker and Shaw 2003). However, it embodies the principles of informed consent that service users understand the consequences of and agree to take a prescribed medication regimen. Refusing, enforcing, or failing to inform services users about medication may decrease their ability to recover from episodes.

Information provision is of fundamental importance to enable users to make informed choices about their treatment options. Access to treatment information is a fundamental right for all those in hospital, especially those detained under the mental health act (National Institute of Clinical Excellence 2005). The finding of poor information provision to service users is consistent with other studies (Goodwin et al. 1999, Happell et al. 2004, Paton and Esop 2005, Pollock et al. 2004). However successful education of inpatients about their medication has been demonstrated (Kavanagh et al. 2003).

7.6 Study limitations

A major limitation associated with this research relates to the sample. The views and experiences of a self-selected sample may differ in important ways from other acute mental health service users. Those willing to talk about their experiences may hold more favourable views of medication. Additionally, the participants interviewed were all inpatients and some of them were detained under the Mental Health Act which may influence findings (Haglund et al. 2003). There are major difficulties in recruiting inpatients into research. These include concerns about consent, especially with those detained under the Mental Health Act, or those experiencing acute psychotic symptoms (Howe et al. 2005), and the burden and stress associated with participation in research, which can potentially impact on an individual's mental health (Bloch and Salzberg 2003). These factors may have prevented some service users from taking part. However, the sample does include a diverse range of service users in terms of their ages, experiences, gender, diagnosis and ethnicity, and were recruited four different inpatient units, in the Greater Manchester area. While these findings may not be transferable to the wider inpatient population, the views expressed did appear to present a balanced appraisal of the benefits and costs to service users of as needed medication.

7.7 Conclusion

It would appear that service users can find as needed medication useful and helpful when handled with sensitivity and clarity about its purpose. Their preferences about treatment may not be accounted for by mental health practitioners. There can be power struggles between nurses and service users associated with the administration of as needed medication. Nurses need to take account of these issues when they consider whether or not to administer as needed psychotropic medications. Further research is required to explore service users' perception of pharmacological treatments and experiences associated with receiving medication whilst in hospital and how nurses can better provide information and treatment choices to inpatients within mental health settings.

Chapter 8 Study Five

The impact of good practice manual on professional practice associated with psychotropic PRN in acute mental health wards: An exploratory study.

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To be submitted

8.1 Abstract

Background: As required or pro re nata (PRN) psychotropic medicines are frequently used in acute mental health wards. PRN is known to contribute to polypharmacy and high doses of antipsychotic medication. Few studies have attempted to improve clinician's use of these potentially harmful drugs.

Aims: The objectives of the study were to develop, determine the impact and acceptability of a good practice manual on prescribing and administration practices of PRN psychotropic medication in acute mental health wards.

Design: The study used a pre-post exploratory design with two acute mental health wards in the NW of England.

Results: Over the total trial period of 10 weeks, 28 of 35 patients received 484 doses of PRN. Patients had a mean of 3.6 prescriptions of 14 different PRN medications in 34 different dose combinations prescribed. Medication errors beyond poor quality of prescribing occurred in 23 of the 35 patients (65.7%). Prescription quality improved following the introduction of the intervention but quality of nursing notes reduced. Acceptability of the manual to both nursing and medical staff was high.

Conclusion: The introduction of the manual appeared to influence some of the practices associated with the prescribing and administration of PRN psychotropic medications. Further, larger, more robust studies are required in this area. In particular research is required to identify the reasons why professionals continue to rely so heavily on using PRN medication.

Key Words: PRN (pro re nata) prescribing, inpatient, psychotropic, clinical psychiatry

Declaration of Interest: None. Funding detailed in Acknowledgements.

8.2 Introduction

Pro re nata (PRN) psychotropic medication is regularly prescribed and administered in inpatient mental health care. Approximately 80% of inpatients receive PRN psychotropic medications during admission (Curtis and Capp 2003, Geffen et al. 2002b). Findings suggest that the administration of psychotropic PRN varies widely and is influenced by diverse factors. The most frequently administered PRN medications are benzodiazepines and typical antipsychotics (Blair and Ramones 1998, McKenzie et al. 1999). PRN is most often given early in a patient's admission, at a time when the service potentially knows least about them (Curtis and Capp 2003, Geffen et al. 2002b, Gray et al. 1996, McKenzie et al. 1999, Usher et al. 2001). The use of antipsychotic medications as PRN contributes to polypharmacy, high doses and dangerous drug interactions (Davies et al. 2007, Royal College of Psychiatrists 2006). Previous research into this area has mainly been retrospective, and has been hampered by poor quality and imprecise documentation of both prescription and administrations of PRN medications (Usher et al. 2003). A Cochrane review concluded that PRN as a clinical intervention does not have a robust evidence-base (Whicher et al. 2003). Few studies have used prospective methods to improve the use of PRN psychotropic medications (Donat 2002a, 2005, Garrison et al. 1990, Thapa et al. 2003). Prospectively designed studies which aim to enhance the evidence-base practice associated with the prescription and administration of psychotropic PRN medications are clearly needed.

Despite an increasing evidence-base in mental health, services fail to implement evidence-based practice (Drake et al. 2003, Torrey et al. 2001). For example, despite the development of treatment algorithms and protocols, psychiatrists continue to prescribe psychotropic medication outside effective dose ranges (Drake et al. 2003, Mueser et al. 2003, Torrey et al. 2001). Treatments are used in the absence of a robust evidence-base, for example, benzodiazepines in the treatment of schizophrenia (Volz et al. 2007), or the use of PRN psychotropic medications (Whicher et al. 2003). Findings from the 'National evidence-based practice project' suggest that the quality of the strategy correlates with the success of the implementation (Drake et al. 2003,

Torrey et al. 2001). It has been found that success of the intervention is enhanced if it reflects the concerns or values of the practitioners it is targeting (Drake et al. 2003).

This study aimed to develop and evaluate a good practice manual designed to improve clinical practice in the prescribing and administration of PRN psychotropic medication in acute mental health settings.

8.3 Methods

8.3.1 Aims of the study

The aims of the study were threefold:

i) Develop a good practice manual of prescribing and administration of PRN psychotropic medications for use in acute mental health wards.

ii) Conduct a 10 week pre-post exploratory study to examine the effects of the good practice manual on clinical practice.

iii) To examine acceptability of the good practice manual.

8.3.2 Developing an evidence-based intervention

Previous studies conducted as part of the MRC complex interventions framework (pre-clinical and modelling phases) (Medical Research Council 2000) established PRN prescribing and administration habits of psychotropic medication through a narrative literature review; interviews with the MDT and patients; and a Delphi study with experts (references removed to blind manuscript). This phase ran concurrently and data were analysed independently. Summaries of this data were provided to the project management group and clinical staff from local Mental Health Trusts. Triangulation of this data identified common themes during a one day consensus exercise. This process led to the identification of nine themes for inclusion in the manual all aimed at improving practice, Figure 8.1. Recommended strategies designed to improving staff uptake of the evidence-based practice were included, such as quotes from staff and patients; clinical examples; summaries of the previously collected data; a comprehensive bibliography; and outline of the research project

(Drake et al. 2001, Drake et al. 2003, Mueser et al. 2003, Torrey et al. 2001). These and the themes were integrated into a 43 page (A5) colour manual.

Figure 8.1: Nine principles of good practice.

I. Considering the patient (knowledge, preferences and choices);
II. Improving prescription quality;
III. PRN as part of the clinical management plan;
IV. Evaluating the effects and side effects of PRN;
V. Frequent review of PRN;
VI. Enhanced documentation by the MDT;
VII. Preventing distress when using PRN;
VIII. PRN as a last resort encouraging the use of non-pharmacological interventions;
IX. Additional training and education is required for all clinical staff.

8.3.3 Study Design

A pre-post exploratory study of two acute mental health wards (38 beds) in the North West of England, UK. The study ran for 10 weeks, data were collected 4 weeks prior and following the introduction of the manual. A two week period occurred in the middle of the study to allow for staff to become accustomed with, and adopted the principles in manual into their clinical practice. In consenting to take part in the study staff explicitly agreed to use the manual in their clinical practice. The manuals were accompanied by a letter which re-iterated this point.

8.3.4 Sampling

Given that data were being collected about patient's, prescriptions and administration habits it was necessary to recruit patients, nurses (administrators) and doctors (prescribers). Nursing and medical staff from the two wards were invited to participate in the study, two weeks before the start date. Patients were deemed eligible if they were inpatients on the two wards involved in the study, or became admitted or transferred to these wards during the study period and were capable of making informed consent. Those who were discharged or transferred from the wards before consent was obtained were excluded.

8.3.5 Outcome data

Three strands of data were collected:

(1) The prescription and administration of psychotropic PRN was monitored by weekly audits of nursing notes and prescription sheets. Separate eight point quality rating scales were devised and applied to prescription sheets and nursing notes. One point was award for each criteria, all criteria are summarised in Tables 8.2 (nursing notes) and 8.3 (prescription sheets);

(2) Decision making, consenting staff were asked to complete an additional form which explored reasons why psychotropic PRN had been prescribed or administered, and what processes occurred at the time. For example, discussions with the clinical team, information provision to the patient, and alternative non-pharmacological interventions;

(3) Acceptability, at the end of the trial participating staff was asked to evaluate the manual by postal questionnaire.

8.3.6 Ethical issues

Multi-centre research ethics committee (MREC) and research governance approval was obtained for the study. Consideration was given to obtaining informed consent of participants (Bloch and Salzberg 2003, Department of Health 2001a, Howe et al. 2005). The study received full support at a Trust (Research Governance and Medicines Management Committee) and local level (Service Manager, Medical Directors, Ward Managers and Lead Pharmacist) for the study.

8.3.7 Data Analysis

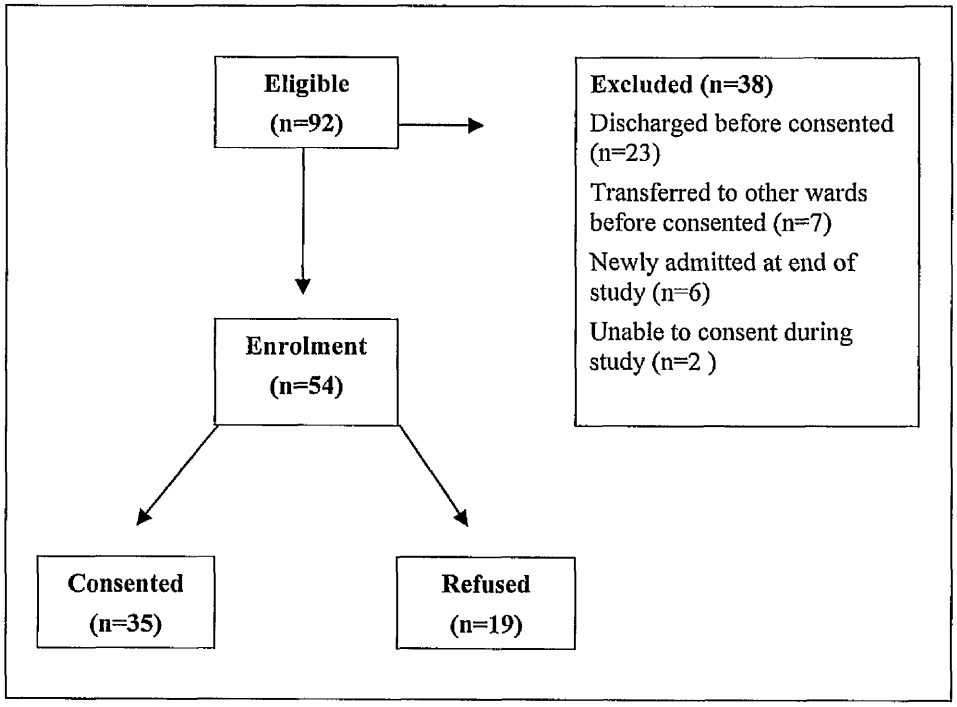
Data were entered into SPSS for comparative analysis (SPSS 2003). The administration of PRN was considered an independent event. Comparisons between the pre-post quality of nursing notes, prescriptions and educational provision were made with between group tests (Independent sample T-tests/Mann Whitney U). Groups of drugs administered were also compared pre-post (Chi-squared).

8.4 Results

8.4.1 Participants

Of the doctors (n=18) and nurses (n=18) who staffed the two acute mental health wards, 12 doctors (66.6%) (5 Consultants, 3 SpRs, 4 SHOs) and 11 nurses (61.1%) (4 senior nurses, 7 junior members of staff) agreed to take part in the study. Of the 92 eligible patients, 54 (58.7%) were approached to enrol, and of these, 35 (66.7%) consented, (Figure 8.2). Data is presented in two ways, firstly, for the total study period (10 weeks), and secondly, to explore the pre-post findings of the trial.

Figure 8.2: Patient recruitment and consenting.



Adapted from the CONSORT diagram (Altman et al. 2001).

8.4.2 Clinical practice associated with PRN

Over the total study period (ten weeks) 28 of the 35 patients received 484 doses of psychotropic PRN (mean 17.3, range 1-64) (Table 8.1). Three patients received in excess of 50 doses of PRN during this period and seven patients did not have PRN administered. The type of drugs administered (benzodiazepines, antipsychotics and hypnotics) changed significantly during the study (chi-square = 34.30, df = 3, $p < 0.001$). Most drugs (80.4%, n=389) were administered on their own, however, 12

different combinations of drugs were given on 47 occasions. Combinations of haloperidol and lorazepam accounted for the majority of these. Patients had on average 3.6 prescriptions for PRN psychotropic medications. Fourteen different psychotropic drugs were prescribed in 34 different dose combinations. There were seven different indications for use; '*agitation*' was written in eight different variations and accounted for 71.5% of all prescriptions. Nearly, 75% of prescriptions for antipsychotic medication would (if taken) have contributed to polypharmacy (76.1%, n=35). The prescribed maximum doses of antipsychotic PRN were greater than or equal to British National Formulary limits 46 times (36.5%) (Joint Formulary Committee 2006).

Intentional space

Table 8.1: Breakdown of drugs administered by group during the study.

Drug groups	Drugs	Dose	Stage of trial			
			Pre (4 weeks)	Change Period (2 weeks)	Post (4 weeks)	Total (10 weeks)
Benzodiazepines	Lorazepam (n=283, 51.8%)	0.5 mg	1	0	0	1
		1 mg	15	2	16	33
		2 mg	77	52	67	196
		4 mg	10	2	4	16
	Loprazolam (n=19, 3.5%)	1 mg	0	0	19	19
	Diazepam (n=32, 5.9%)	2 mg	0	0	2	2
		4 mg	0	0	2	2
		5 mg	12	4	7	23
		10mg	2	0	1	3
	Nitrazepam (n=8, 1.5%)	5 mg	6	2	0	8
Benzodiazepines as a % of all drugs administered during period			**123 (71.5%)**	**62 (61.4%)**	**118 (55.9%)**	**303 (62.6%)**
Antipsychotics	Olanzapine (n=6, 1.1%)	5 mg	5	0	1	6
		10mg	3	1	0	4
	Haloperidol (n=82, 15.0%)	2 mg	1	1	0	2
		5 mg	22	17	17	56
		10mg	1	3	5	9
	Zuclopenthixol (oral) (n=10, 1.8%)	10mg	0	0	10	10
	Levomepromazine (methotrimperazine) (n=6, 1.1%)	50 mg	3	1	0	4
		100 mg	2	0	0	2
Antipsychotics as a % of all drugs administered during period			**37 (21.5%)**	**23 (22.8%)**	**33 (15.6%)**	**93 (19.2%)**
Hypnotics	Zopiclone (n=89, 16.3%)	7.5 mg	12	16	43	71
		3.75 mg	0	0	17	17
Hypnotics as a % of all drugs administered during period			**12 (7.0)**	**16 (15.8%)**	**60 (28.4%)**	**88 (18.2%)**
Total doses administered			**172**	**101**	**211**	**484**

8.4.3 Quality of nursing notes

The mean quality score for all available nursing notes reduced significantly from 1.5 (pre) to 0.98 (post) during the study ($U = 13517.0$, $p < 0.001$) (Table 8.2) and non-

documentation of PRN administration increased after the introduction of the manual. In total administration of PRN was not documented in 38.2% (n=185) of all occasions (including the change period). There was no documented evidence of side effect monitoring for any dose of PRN administered during the study. Drugs used as night sedation, zopiclone (0.8), nitrazepam (0.6), and loprazolam (0.3), had lower mean quality scores than other psychotropic medications, such as olanzapine (2.3), methotrimeprazine (1.8), haloperidol (1.6), and lorazepam (1.4).

Table 8.2: Overall quality of nursing notes (pre-post) based on the entries for the administration of 378 doses of PRN.

Quality criteria for nursing notes		Stage of trial			
		Pre (n=167)		Post (n=211)	
		n	(%)	n	(%)
PRN was administered	Yes	123	(73.7)	93	(44.1)
	No	44	(26.3)	118	(55.9)
Rationale to administration	Yes	67	(40.1)	65	(30.8)
	No	100	(59.9)	146	(69.2)
Link to care plan	Yes	6	(3.6)	1	(0.5)
	No	161	(96.4)	210	(99.5)
Route	Yes	10	(6.0)	7	(3.3)
	No	157	(94.0)	204	(96.7)
Information provided to patient	Yes	1	(0.6)	0	-
	No	166	(99.4)	211	(100)
Alternative interventions explained or tried	Yes	3	(1.8)	1	(0.5)
	No	164	(98.2)	210	(99.5)
Effect	Yes	32	(19.2)	41	(19.4)
	No	135	(80.8)	170	(80.6)
Evaluation of side effects	Yes	0	-	0	-
	No	167	(100)	211	(100)
Quality scores	0	44	(26.3)	118	(56.0)
	1	38	(22.8)	20	(9.5)
	2	59	(35.3)	36	(17.1)
	3	20	(12.0)	32	(15.2)
	4	4	(2.4)	5	(2.4)
	5	2	(1.2)	0	-
Mean score for nursing notes		1.5 (sd 1.1)		1.0 (sd 1.2)	

8.4.4 Quality of prescription sheets

The mean prescription quality increased but not significantly ($t = 1.38$, $df = 72$, $p = 0.172$), (Table 8.3).

Table 8.3: Prescribing quality criteria based on 74 prescriptions of PRN psychotropic medications.

Quality criteria for prescriptions		Stage of trial			
		Pre (n=41)		Post (n=33)	
		n	(%)	n	(%)
Single route	Yes	24	(58.5)	27	(81.8)
	No	17	(41.5)	6	(18.2)
Review/expiry date	Yes	-	-	1	(3.0)
	No	41	(100)	32	(97.0)
Total dose 24 hours	Yes	35	(85.4)	31	(93.9)
	No	6	(14.6)	2	(6.1)
Dose non ranged	Yes	12	(29.3)	11	(33.3)
	No	29	(70.7)	22	(66.6)
Indication for use	Yes	40	(97.6)	33	(100)
	No	1	(2.4)	-	-
Correct name	Yes	41	(100)	33	(100)
	No	-	-	-	-
Polypharmacy	Yes	7	(17.1)	11	(33.3)
	No	34	(82.9)	22	(66.6)
Time between doses	Yes	6	(14.6)	19	(57.6)
	No	19	(46.3)	6	(18.2)
	Other e.g. *bd*	16	(39.0)	8	(24.3)
Quality scores	1-3	-	-	-	-
	4	1	(2.4)	2	(6.1)
	5	19	(46.3)	11	(33.3)
	6	19	(46.3)	13	(39.4)
	7	2	(4.8)	6	(18.2)
	8	-	-	1	(3.0)
Mean score for prescriptions		5.5 (sd 0.6)		5.8 (sd 0.9)	

8.4.5 Decision making

During the study period data were obtained from consenting staff about their decision making processes. Nursing staff completed 89 forms (58 pre, 31 post) at the time of administration of PRN. The provision of patient education increased significantly after the manuals introduction ($t = -2.17$, $df = 98$, $p = 0.032$), (Table 8.4).

Table 8.4: Educational provision to patients, data collected from 89 forms, of which 106 drugs were administered (missing data: pre n=4, post n=2).

Information provision/education did you tell the patient about PRN (includes check with the patient and they already knew)		Pre (58 forms/ 63 drugs)		Post (31 forms/ 37 drugs)	
		n	(%)	n	(%)
Provision of education at time of administration	yes	61	(96.8)	37	(100)
	no	2	(3.2)	-	
Name of drug	yes	56	(88.9)	37	(100)
	no	7	(11.1)	-	
Side effects	yes	12	(19)	8	(21.6)
	no	51	(81)	29	(78.4)
The dose	yes	45	(71.4)	31	(83.8)
	no	18	(28.6)	6	(16.2)
Rational for administration	yes	44	(69.8)	32	(86.5)
	no	19	(30.2)	5	(13.5)
Maximum dose per day	yes	3	(4.7)	6	(16.2)
	no	60	(95.2)	31	(83.8)
Effects of the drug	yes	34	(54)	21	(56.7)
	no	29	(46)	16	(43.2)
Mean score		3.0 (sd 1.4)		3.7 (1.0)	
Recorded use of non-pharmacological interventions		38/58	(65.5)	22/31	(70.9)

8.4.6 Medication errors associated with the prescription and administration of PRN

Medication errors beyond poor quality of prescribing occurred in 23 of the 35 patients (65.7%). Examples include:

i) on two occasions prescriptions were found when the same drug was prescribed twice as PRN;

ii) a prescription not being correctly stopped resulted in the administering of the same drug from two identical prescriptions;

iii) the co-prescribing of PRN procyclidine with atypical antipsychotics, and in one case oxygen with benzodiazepines;

iv) a patient who received two different antipsychotics regularly was prescribed a further two for use as PRN;

v) failure to stop PRN olanzapine as regular dose increased beyond 20 mg per day resulted in a patient receiving a daily dose of 30 mg of olanzapine.

Administration medication errors broadly fitted into two themes. Firstly, five patients were given drugs at doses different to that which was prescribed; all doses administered were lower than prescribed doses. The second area related to poor documentation (n=11), inconsistencies between the treatment sheet and the nursing notes. For example, the recording of one drug having been given in the treatment sheet but a different drug was recorded in the nursing notes. Other examples of poor documentation included recording a PRN had been given to one patient when it had actually been administered to another patient.

8.4.7 Acceptability

Thirteen members of staff completed the postal evaluation (56.5%); a further participant (excluded from the analysis) replied but stated that they had not read the manual. All staff agreed the manual was well organised and contained helpful information. Most (n=12) agreed that design of the manual was an appropriate level, linked theory to practice, and was clear and understandable in presentation. Ten

would recommend the manual to others and nine agreed the manual had changed their practice.

8.5 Discussion

The paper provides further evidence of the widespread reliance on PRN psychotropic medications in acute mental health wards. There was frequent use of PRN psychotropic medications for the consenting population (mean 13.8 doses). However, no assumption can be made about the total doses of PRN psychotropic medications administered to all patients during the ten week period. Those consenting could have received higher doses of PRN. Alternatively, this could indicate a reliance on medications in the two wards studied, or that the wards were particularly busy/disturbed. Previous international studies of PRN use in acute inpatient mental health units in Australia, Canada and the U.K, reported means of between 10 and 12 administrations per individual (Craven et al. 1987, Curtis and Capp 2003, Geffen et al. 2002b, Gray et al. 1996). Benzodiazepines accounted for 62.8% (n=343) of all drugs administered. Lorazapam (n=283 administrations), accounted for 51.8% of all drugs administered; 78% (n=221) of lorazepam administered was given at 2mg (40.4% of all drugs). The use of one drug appeared to change pre-post; 65.8% of the zopiclone administered occurred in the post phase of the trial. This may have influenced the quality scores in nursing notes.

An average of 3.6 prescriptions of psychotropic medication is above the quality indicators established for multiple PRN prescriptions and recent studies (Davies et al. 2007, Paton and Lelliott 2004). The research process identified a significant number of medication errors which were related solely to the prescription and administration of PRN psychotropic medications. Of most concern was that there appeared to be no organisational systems for identifying these potentially harmful errors by the clinical team. Previous evidence suggests that PRN prescriptions are of poorer quality than regular prescriptions (Nirodi and Mitchell 2002), and that there has been limited research of medication errors in mental health services (Maidment et al. 2006). These results highlight a lack of uniformity in the prescriptions of PRN psychotropic medications which could contribute to misunderstandings and potential errors

(Maidment et al. 2006). There is clearly need further research and audits of medication errors in mental health services which include PRN medications, these studies need to evaluate the impact of improved prescribing practices on medication error and rates of drug administration.

Few of the studies findings could identify change associated with the introduction of the manual despite staff reporting that it had influenced their practice. There were a number of complexities that were encountered during the trial; these undoubtedly influenced the recruitment of nursing staff and their continued motivation during the study. This included staff being deployed and re-deployed to other wards during the study period. Furthermore, staff that had consented or been pivotal in establishing the research project left the unit during the trial period. The regular use of qualified bank/agency staff that was not consented may have affected the quality of the notes. One of the wards was designated for decoration which resulted in the wards being moved, during which time uncompleted audit forms were temporarily misplaced. Likewise there were difficulties associated with accessing the medical staff, including rotation onto nights, staff on annual leave or who had exams during the consenting period. An attendance of medical staff at arranged meetings was limited.

8.6 Limitations

A weakness associated with the study concerns examining the overall impact of a manual to which only half the staff and a third of patients consent to. Rather than focusing the study on those who had received the manual, total ward quality was focused on. This decision was taken pragmatically because of the potential for contamination of information sharing amongst staff. Secondly, the person completing the nursing notes at the end of the shift may not have administered the PRN medication. The authors' intention has been to conduct this exploratory study prior to conducting a larger controlled trial. Future studies need to focus on either recruiting the whole clinical team, the randomisation of staff or coding all entries and administrations of PRN relative to their participation (or not) in the trial. The use of additional data collection forms proved problematic. Whilst few were completed by

the medical staff, a significant number where not completed by nurses each time they administered a PRN medication.

8.7 Conclusions

The manual was perceived favourably by the MDT. Despite them indicating that it had changed their clinical practice there is limited evidence that it impacted on either the prescription or administration of PRN psychotropic medications. A sustained intervention which is multi-faceted may bring about more clinical change. Larger, more robust and innovative studies of how to bring about change are clearly required. The addition of qualitative data on why staff continue to rely on pharmacological interventions would be a useful adjunct.

Intentional space

Chapter 9 Discussion and Conclusions

This thesis demonstrates a systematic and rigorous mixed method approach to the development and testing of a good practice manual designed to enhance the use of PRN psychotropic medication based on the MRC framework for developing complex interventions (Medical Research Council 2000). By adopting the PhD by alternative methods approach studies included in the thesis have been subjected to an external peer review process. This final chapter provides a brief summary of the results, strengths and weaknesses of the overall study, clinical recommendations from the research and for future research.

9.1 Statement of principle findings

9.1.1 Study 1

Study 1 (Chapter 4) provides a best-evidence synthesis review of utilisation studies of PRN psychotropic medication in inpatient mental health wards. The process of conducting this literature review summarised previous research and informed the ideas and thinking for the subsequent parts of the research process. Six major themes emerged from the literature: i) frequency of administration to patients; ii) administration during the 24 hour day; iii) administration associated with length and stage of admission; iv) rationales for administration; v) medicines administered (including route of administration); and vi) the effects and side effects of the medicines administered.

9.1.2 Study 2

Study 2 (Chapter 5) developed consensus expert opinion of good practice for the prescription and administration of PRN psychotropic medications by using a modified Delphi panel. Eighteen experts participated in the study. This reduced a total of 271 items to 78, then 34 items and finally 13 items. These 13 items converged into four key themes: i) that service users should be more involved in all processes associated with PRN psychotropic medications; ii) improvements to the process of prescribing

and administering PRN medication; iii) that there should be a clear process of review; and iv) staff need to develop knowledge and awareness about potential side effects prior to using PRN medications.

9.1.3 Study 3

Study 3 (Chapter 6) established a picture of current practice as a result of semi-structured interviews conducted with the MDT. Interviews with 59 mental health professionals explored their PRN psychotropic medication practices in acute mental health wards. Thematic content analysis identified a number of themes associated with their clinical practice. These included a balanced usefulness of PRN psychotropic medications, factors which influenced their decision-making and use of PRN as a clinical intervention, and widespread variations in clinical practices. The findings highlighted how PRN psychotropic medications use differs between individuals, professional groups and organisations in acute mental health wards.

9.1.4 Study 4

Study 4 (Chapter 7) explored the experiences of services users and PRN psychotropic medication in acute mental health wards using qualitative interviews. A convenience sample of 22 in-patients participated in semi-structured interviews. Thematic content analysis was undertaken and a number of themes identified. Interviewees highlighted the value of PRN medications. However, the process associated with their use was perceived as confusing and stigmatising. Service users had limited understanding of and felt unsupported in attempts to use alternatives to PRN medications. Additionally, the decision-making and information-giving processes were unclear to them raising the issue of power and control in acute mental health wards.

9.1.5 Development of the good practice manual

The undertaking of these four research projects enabled a comprehensive understanding of the previously conducted research, current clinical practice and expert opinion on the use of PRN psychotropic medication in acute mental health wards. The combining of these streams of data into one good practice manual ensures

confidence in the nine principles of good practice established. These principles were combined with a range of strategies designed to improving staff uptake of the manual. This included quotes from staff and patients; clinical examples; summaries of the previously collected data; a comprehensive bibliography; and outline of the research project (Drake et al. 2001, Drake et al. 2003, Mueser et al. 2003, Torrey et al. 2001). A copy of the good practice manual can be found in the appendices (Appendix 3).

9.1.6 Study 5

Study 5 (Chapter 8) detailed an exploratory and acceptability study of the good practicel manual. The study used a pre-post exploratory design of 10 weeks duration in two acute mental health wards in the NW of England. Eleven nurses (4 senior nurses, 7 junior members of staff) and twelve doctors (5 Consultants, 3 SpRs, and 4 SHOs) and thirty-five service users agreed to take part in the study. In the total trial period 484 doses of PRN were administered to 28 of 35 service users. Service users had a mean of 3.6 prescriptions of 14 different PRN medications in 34 different dose combinations prescribed. Medication errors beyond poor quality of prescribing occurred in 23 of the 35 service users (65.7%). Prescription quality improved following the introduction of the intervention but quality of nursing notes reduced. Acceptability of the manual to both nursing and medical staff was high.

9.2 Additional research conducted outside the focus of this thesis on PRN psychotropic medication

Two further funded studies have been undertaken in this topic area and although they have not formed chapters of this thesis they demonstrate further development of new knowledge in the area of PRN psychotropic medication. The author has been involved in these studies at the design phase, as a co-applicant on the grants, in the analysis, and in the production of the final reports.

9.2.1 Curtis, Baker and Reid (2007)

This funded study was conducted in collaboration with The University of Wollongong, Australia (Curtis *et al*, (2007) (Appendix 4)) and modified the study designed of Curtis and Capp (2003). The study used a retrospective chart audit (one month duration) of inpatients in a 20 bed acute mental health ward in New South Wales, Australia. The focus of the study was to explore the use of non-pharmacological interventions at the time of PRN administration. Forty-seven service users (73.4%) received PRN medication at least once during the study. A total of 309 doses of PRN medication were administered. For nearly three quarters (73%) of PRN medication administrations there was no documented evidence of other non-pharmacological therapeutic interventions occurring either before or afterwards. On 41 occasions, combinations of antipsychotic and benzodiazepines were administered. Eleven service users received 10 or more administrations of PRN medication; in total this group received 46.4% of all PRN medications administered (n=143). Twenty-three service users received documented face to face counselling at least once around the time of the administrations. Limited evidence could be identified of the use of alternative therapeutic interventions either prior to (n=73, 27.2%) or after (n=16, 6%) the administration of PRN psychotropic medication. The study was hampered by the overall poor quality of notes.

9.2.2 Usher, Holmes, Baker, and Stocks (2007)

The second study funded by the Queensland Nursing Council, was conducted in collaboration with James Cook University, Townsville, Australia. The study aimed to enhance understanding of MDT clinical decision making of PRN psychotropic medication (Usher et al. 2007). The study design included semi-structured interviewing, participant observation, and retrospective review of case notes. Twenty-five semi-structured interviews were conducted with staff in a variety of settings (acute, secure and rehabilitation mental health wards) were conducted. Each interview was digitally recorded and transcribed verbatim, with a mean length of 45 minutes (minimum = 26 minutes, maximum = 71 minutes). No observational data were obtained from the secure or acute mental health wards. Although observations occurred in the rehabilitation setting, no PRN was administered. The retrospective

case note analysis was conducted in an acute setting for a 24 hour period. The study identified that clinical staff recognised the need for up-to-date information about medications; however, this was exclusively met by drug company representatives. Participants recognised the potential for the abuse of PRN prescriptions and their comments suggested that this was something they had experienced at times. Nurses also acknowledged the potential for misunderstanding PRN prescriptions, but were clear that if there was any uncertainty they would contact the medical officer and seek clarification. Recommendations from the research included the development of in-service education on psychotropic medications and PRN for mental health nurses, and the undertaking of an extensive review of PRN prescription and administration compared to best practice guidelines.

9.3 Strengths and weaknesses of studies 1-5

The focus of the research concerned the use of PRN psychotropic medications in acute mental health wards. Acute mental health wards are only part of the total inpatient service provision which uses PRN medications which includes CAMHs, forensic, rehabilitation and older people services. Concerns have been expressed about the prescribing and administration of PRN psychotropic medications in these settings (Draper et al. 2001, Goedhard et al. 2007, Hales and Gudjonsson 2004, Kaplan and Busner 1997, McLaren et al. 1990, Vitiello et al. 1991, Walker 1991). To have limited the research to one setting and a population aged between 16 and 65 restricts the generalisability of the findings.

The research was centred in Greater Manchester in the North West of England. Three Mental Health Trusts participated in the study, although this was predominantly in the early stages. Recruitment for the interview participants only occurred in four of a potential eleven sites. The final study (Chapter 8) occurred in only two wards in one site in one Mental Health Trust. To centre the research in one geographical location may restrict the generalisability of the findings. These units are situated in densely populated areas, with high levels of deprivation. Manchester is ranked 7th highest in the UK Index of Multiple Deprivation (Department of Environment Transport and Regions 2000). This could have influenced a variety of factors associated with the

findings, such as, an increased reliance on pharmacological interventions, differing attitudes towards medications generally, and higher levels of service user need.

These studies successfully demonstrate the use of a mixed methods approach for developing a complex intervention in acute mental health wards. Dissemination of the findings from the studies has occurred through publications and presentations at a variety of conferences. Influencing policy at local and national levels is an important aspect of the research. Summaries of findings and the manual have been disseminated through research governance committees, in-house conferences and medicines management committees of the Trusts involved in the research. At a national level findings have been directly fed into *'Good Practice Guidelines – The prescribing, administration and recording of 'as required' medication'* by the Mental Welfare Commission, Scotland, and to POMH- UK, led by the Royal College of Psychiatry. The manual will also be made available through the virtual ward (CSIP) to enable all clinical staff access to it.

9.4 Recommendations from the research

As a result of the research several recommendations have emerged:

9.4.1 Implications for practice

- The role of psychotropic PRN medications in acute mental health wards needs to be considered. It continues to be used as a first line clinical intervention in acute mental health wards, but alternative non-pharmacological interventions should be considered, tried and tested (Studies 2-5).

- Prescriptions of PRN psychotropic medications directly influence the administration practices of nursing staff. Improving prescription quality as defined in Study 5, p143, will undoubtedly improve nurses' administration.

- Clinical responsibility for PRN medications should be seen as a multi-professional issue, one which is monitored by all involved. The abdication of professional responsibility (Study 3) clearly prevents MDT reviews of PRN psychotropic medication.

- Policies for rapid tranquilisation need to take account of the role of PRN medication in this and clearly define the differences between PRN and rapid tranquilisation.

- Medication errors associated with the prescribing and administration of medicines in inpatient mental health settings is clearly an issue of concern (Study 5). Mental Health Trusts need to ensure that systems are in place to identify, monitor and learn from these errors.

- The quality of documentation continues to be problematic (Study 1 & 5). Consideration should be given to improving documentation and MDT care planning with particular reference to PRN psychotropic medication.

Educators need to consider the findings of the studies. There are several findings which might be addressed through improved education at pre and post registration levels.

- Staff require skills in being able to deliver education and information to service users about all aspects of treatment including medication and side effects (Studies 1-5).

- Staff require knowledge of psychotropic medications and the principles of medication management (Studies 1, 3, 4).

9.5 Recommendations for future research

A number of recommendations for future research can be made:

- Studies should test further interventions strategies for promoting staff uptake of the manual. These studies could either combine interventions or compare the impact of differing interventions, such as training verses clinical supervision. Studies should be larger with a focus on understanding the impact on total teams, wards or units, and should explore issues which prevent evidence-based practice from being adopted by clinical staff in acute mental health wards.

- The clinical effectiveness of PRN psychotropic medications requires further exploration. Studies which evaluate the effectiveness and side effects of drugs used as PRN are clearly needed (Study 1, 5).

- Alternatives to prescribing PRN should be tested, including trials of Patient Group Directives (PGDs) and/or Stat doses and/or Nurse Prescribing verses PRN prescriptions to explore whether these reduce the use of psychotropic medication without subsequent increases in distress, violence, restraint or seclusion.

- The effectiveness of alterative non-pharmacological interventions to PRN psychotropic medications needs to be explored. For example, does an intervention which aims to promote sleep lead to a reduction in the use of PRN night sedation.

- Large prospective surveys of PRN prescribing and administration are still required.

- Studies which monitor the frequency of medication errors associated with prescribing and administration of PRN psychotropic medications and trials of systems designed to reduce these errors will potentially improve patient safety.

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The use and nursing management of benzodiazepines in acute, mental health inpatient care: a discussion

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The use and nursing management of benzodiazepines in acute, mental health inpatient care: a discussion

The use of medication in acute mental health is common practice however, there is a lack of research into all aspects of pharmacology within inpatient settings. This paper explores the specific use of benzodiazepines and areas of potential mismanagement. A number of priorities for investigation are raised and implications for nursing roles and responsibilities discussed.

Keywords: benzodiazepines, inpatients, medication, nursing management

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Introduction

The incidence of mental illness is reportedly very common in this country. It is suggested that at any one time one in six people of working age have a mental health problem, most often anxiety and depression (NHS Centre for Reviews & Dissemination 2001). In many instances, treatment involves the use of medication. The poor management of psychotropic medication by nurses, however, has become an increasing area of concern. Whilst criticisms levelled at community nurses and inadequate training programmes are more recently evident (Gray *et al.* 2003), the true extent of deficits in the inpatient psychiatric setting have not been explored in any great detail. Furthermore, any work up till now has tended to focus upon the use of neuroleptic treatment and little attention afforded to the increasing administration of benzodiazepines. This is despite the fact that Gray *et al.* (1997) have reported that temazepam and diazepam are the most utilized PRN medication.

In order to highlight some concerns about the mismanagement of anxiolytics in acute inpatient psychiatry, the following discussional paper is offered. This paper endeavours to raise awareness about this problem and identify an agenda for potential areas of research. This includes the use of benzodiazepines in the acute mental health setting, where they are most commonly employed and providing a decrease in arousal, an adjunct to neuroleptics or for rapid/continual sedation, is largely the focus. This can be problematic from a nursing perspective, the implications of which will be explored.

Background

Acute inpatient psychiatry

With the push to close the asylums and move towards a community model of care over the last three decades, the inpatient environment has undoubtedly become a neglected provision. This is true for both patients and nursing staff alike. It is reported that the former experience substandard care whilst the latter receive limited support or direction about fundamental practices and principles. It has been suggested in fact, that the role of the mental health nurse is somewhat of an anomaly that continues to be eroded, poorly respected or indeed in many instances undefined (Gournay 2001). Criticisms concerning care delivery within the acute inpatient setting abound and a number of

recent documents have highlighted the same (DoH 2002). The most significant include the NSF (DoH 1999); NHS Plan (DoH 2000), Acute Concerns (SNMAC 1999) and a review of the effectiveness of current mental health services (NHS Centre for Reviews & Dissemination 2001). Each identify inadequate resources, poor staff training and subsequent concerns regarding the role and skills of the mental health nurse. In response, the DoH (2002) has suggested that there is a need to improve the therapeutic environment of in-patient services and associated relationships. The mismanagement of medication is a recurring theme. This often includes concerns regarding patient compliance, the overuse of polypharmacological approaches and insufficient knowledge about administration, interactions, preferences and side-effects. The limited involvement and exploration of the patient perspective on this matter is also under great scrutiny. Indeed criticisms surrounding the management of medication and information giving are prominent among users' sources of dissatisfaction within psychiatric services (Jordan *et al.* 1999).

Medication management

With regards to medication, the nurses' role is central to the administration of both prescribed and 'as required' medication (PRN). In fact it could be argued that the decision to treat patients with an array of psychotropic drugs is and should be at the heart of mental nursing and taken very seriously as a therapeutic nursing as opposed to medical intervention. The nurse after all is the one who is in a key position to deliver, monitor and report upon patient progress in response to treatment. Furthermore, it maybe that nurses influence the decisions of doctors in the prescription of certain types of drugs and particularly in provisions made for the standard prescription of 'PRN' irrespective of symptomology. If this is the case, prescribing and administration patterns warrant detailed investigation and the need for in-depth training in this area is paramount. The content of many pre- and post-registration nurse training programmes in this country have rarely delivered modules that identify medication management as a integral part of nursing practice (Gray *et al.* 2003). This is compounded by poor guidance on 'PRN' medication in the majority of existing mental health nursing textbooks (Szczensy & Miller 2003).

Irrespective of the more general difficulties associated with medication, the suggested over prescribing and mismanagement of benzodiazepines within acute mental health care is of particular concern. This problem has attracted little attention and if as suggested, trends are correct and these drugs are commonly administered in the acute inpatient setting, then a number of factors may be attributed (Usher *et al.* 2001). For example, a shift in the present profile of the inpatient, a suggested rise in the incidence of patient aggression, protocols for drug regimes and rapid tranquillization, and poor or non-existent local policies (Wright *et al.* 2000). Furthermore and as already highlighted, deficits in nursing observational, therapeutic and communication skills that may lead to reliance upon drugs of this nature, to manage as oppose to treat patients, prevail (Duxbury 2002).

The use of benzodiazepines – treatment or behaviour management

A product of the 20th century, benzodiazepines were thought to be an innovative treatment to manage the common problem of anxiety or so-called 'neurotic disorders.' The 1950s saw psychiatric nurses becoming more involved in medical treatment particularly the administration of drugs (Nolan 1993). Today, there continues to be widespread use of benzodiazepines within acute mental health settings. However, these are most commonly relied upon for their sedative properties, and or in rapid tranquillization to contain disturbed behaviour, distress or agitation. Classes of medication usually employed in this way are antipsychotics and benzodiazepines (Usher *et al.* 2003, Whicher *et al.* 2003).

Ongoing debate about the need for reduced dependency on older typical neuroleptics has arguably contributed to an increased reliance on the use of benzodiazepines as a drug of first choice (Power *et al.* 1998, Paton *et al.* 2000, Richardson & Joseph 2001). Lorazepam and diazepam are particularly used for such purposes. This has been precipitated by the recommended withdrawal of neuroleptics such as droperidol and thioridazine (Breckenridge 2000, CSM 2001), and concerns about the sedative effects of more atypical neuroleptics (Usher *et al.* 2001). Lorazepam is often cited as the preferred benzodiazepine especially when intramuscular medication is required. This is because diazepam's intramuscular absorption is erratic (McAllister-Williams & Ferrier 2002). Furthermore, it is argued that lorazepam has an additional advantage over diazepam in that it is a potent drug with a fast acting sedative effect and a short half-life.

Benzodiazepines are also commonly utilized as an adjunct to neuroleptic medication (Richardson & Joseph 2001). This presents a new set of challenges. For example, care is needed in the use of benzodiazepines with clients on Clozapine (RCP 1997). Conversely, it is suggested that the combined use of haloperidol and lorazepam is safe. It is also recommended that within appropriate dose ranges this combination is very effective for rapid tranquillization (RCP 1997, NICE 2002). Furthermore, it is reported that

service users prefer medication to alternatives such as seclusion and/or restraint (RCP 1998). Anecdotally, it is common for patients to express a preference for lorazepam over other drugs. This may also be the result of a reduction in extra-pyramidal side-effects (E.P.S.E.) or the addictive properties of benzodiazepines [JFC 2003].

Benzodiazepines: action, effect and side-effects

Part of the concerns over the reported high incidence of the use of these drugs is their complexity and associated action and effects, which in turn may be poorly understood by nurses. Benzodiazepines exert an enhancing effect on Gamma-aminobutyric acid activity (G.A.B.A.) within the brains receptors. This activity accounts for nearly 40% of all neurons within the brain and works by inhibiting/quietening the brains excitatory neurotransmitters. However Benzodiazepines do not exclusively interact with G.A.B.A. Gamma-aminobutyric acid also influences dopamine-mediated transmissions and could therefore have a direct antipsychotic effect (Stimmel 1996, Geffen *et al.* 2002).

Ashton (2002) suggests:

> As a consequence of the enhancement of G.A.B.A.'s inhibitory activity caused by benzodiazepines, the brain's output of excitatory neurotransmitters, including norepinephrine (Noradrenaline), serotonin, acety choline and dopamine is reduced. Such excitatory neurotransmitters are responsible for alertness, memory, muscle tone and co-ordination, emotional responses, endocrine functions . . . other benzodiazepine receptors not linked to G.A.B.A., are present in the kidney, colon, blood cells and adrenal cortex. (p. 6)

Given the vast and diverse G.A.B.A. neurons within the brain, the side-effects of benzodiazepines are hardly surprising. These can include sedation, respiratory depression/arrest, memory impairment/loss, and difficulties with co-ordination, muscle weakness, confusion, and paradoxical increases in violence and disinhibition (Ashton 2002, JFC 2003). This is in addition to tolerance that can occur rapidly and rebound anxiety and insomnia. Benzodiazepines are metabolized in the liver, but at markedly different rates. For example, half-life's can range from 5 (chlordiazepoxide) to 100 h (diazepam). Some benzodiazepine metabolites remain active for long periods of time within the system (Ashton 2002). This has clinical implications for the elderly or those with pre-existing liver damage such as alcoholics who will metabolize drugs more slowly. Subsequently, the need for knowledge about the administration of drugs of this nature becomes clear.

In addition to combined neuroleptic regimes and associated effects it is also common practice in acute mental health units to supplement pharmacological drug routines with night sedation. In a study by Usher *et al.* (2001) Temazepam accounted for 25.7% of 'PRN' administered. Insomnia was the common indicator. However tolerance to night sedatives is known to develop very quickly within 1–2 weeks (Ashton 2002). Given this, even more so with medium to long-term use, care is needed in the prescription of benzodiazepines at night. In fact, in some instances, sleep itself becomes affected with a reduction in REM sleep. Furthermore, the use of night sedation is often at the exclusion of alternatives underpinned by the principles of good sleep hygiene (Duxbury 1994).

The issue of tolerance and withdrawal is very real and rarely taken seriously. Given the time delay between the commencement of neuroleptics and their clinical effectiveness, reliance on benzodiazepines in the short to medium term has become standard practice. This can equate to weeks for some clients (Paton *et al.* 2000), despite advice that they are indicated for the short-term only, for example, 2–4 weeks (JFC 2003). Subsequently, without care, long-term use of benzodiazepines can lead to problems of tolerance and in some instances the development of addiction. In a recent study by De las Cuevas *et al.* (2003) dependence was identified in 47% of those on benzodiazepine therapy for more than 1 month. Women and those over the age of 40 were at significantly higher risk. Summers & Brown (1998) have reported that 20% of those administered benzodiazepines whilst in hospital continue to need them on discharge. Even for those prescribed on a short-term basis, physical and psychological withdrawal can be a problem. Effects can last for 3 weeks and up to 1 year in some instances of severe dependency after discontinuation (JFC 2003). Given the high doses often used within inpatient settings it still remains uncommon practice to gradually withdrawal patients from Benzodiazepines as recommended (i.e. an eighth of the dose every 2 weeks). It is more common to rapidly reduce the dose before discharge. Ashton (2002) recommends that this should not be the case and that withdrawal regimes should be facilitated using diazepam as opposed to other benzodiazepines. This is particularly important given the high risks associated with shorter acting or more potent drugs such as lorazepam and Temazepam (Ashton 2002; JFC 2003).

The more recent use of benzodiazepines to rapidly tranquillize patients when aggressive has also become an area of concern. Anecdotal evidence suggests that high doses of lorazepam IM are frequently given, the implications of which are vast. NICE (2002) suggests that oral medication should always be offered first and that the majority of service users do not in fact require rapid tranquillization. Whilst the total recommended daily dose for lorazepam is 4 mg (JFC 2003), the RCP (1998) suggest using the lowest

possible dose. Clinical practice suggests that doses in excess of these guidelines are regularly utilized.

> It is argued that the mainstay of pharmacological rapid tranquillization should be parenteral benzodiazepines used with due care. (McAllister-Williams & Ferrier 2002, p. 485)

How far routine clinical practice reflects this approach still needs to be established.

Despite some recent endorsement for rapid tranquillization, there remains a scarcity of research in this area, with the exception of some limited drug trials (McAllister-Williams & Ferrier 2002). The ethics and evidence base for undertaking this course of action therefore continues to be under scrutiny. This is especially true when one considers the dangers associated with this approach. When used, medication is often given at such high doses that rather than sedating or decreasing the arousal of a client it may in fact lead to disinhibition, over sedation, damage to therapeutic relationships and in severe cases loss of consciousness (RCP 1998, NICE 2002). Respiratory depression or arrest can also occur. As such, Flumazenil an antagonist of benzodiazepines should be available within every inpatient setting, although the administration of such can only be given IV requiring medical intervention (RCP 1997, NICE 2002). This excludes the risks associated with the combined use of neuroleptics including cardiac complications. Limited training for staff in dealing with effects of this nature compounds the situation. Skills are required in CPR, monitoring blood pressure, pulse and respiratory rate, and a detailed understanding of the cardio-respiratory effects of drugs (RCP 1997, NICE 2002).

Despite the potential difficulties outlined, benzodiazepines can have several benefits and are suitable for a number of clinical indications. Most commonly as discussed, they are used for anxiety, night sedation and to reduce arousal. They are also valuable in treating convulsions. However it has also been reported that benzodiazepines can cause an increase in the clinical features they are often employed to reduce. For example, behavioural disinhibition (Bond 1998, Paton 2002), irritability, aggression and over excitement (JFC 2003). Debate about efficacy continues and research is ongoing in this area.

Administration and nursing responsibilities

Whilst service users with serious mental illness are commonly prescribed medication of this nature, it remains unclear as to who is responsible for monitoring the effects and potential side-effects highlighted (Jordan *et al.* 1999). Given the complexity of the types of drugs provided, the nursing role in the administration of benzodiazepines is paramount. Presently it seems that there are a number of problems in this area in particular monitoring polypharmacology and the use of 'PRN medication'. Patients for instance, are often prescribed and given different types of benzodiazepines concurrently.

The administration of 'as required' medication is particularly controversial but has received limited attention or investigation (Usher *et al.* 2001). Benzodiazepines are probably the most commonly utilized PRN within acute inpatient mental health settings. Usher *et al.* (2001) have reported that 65 percent of medication dispensed in this way are benzodiazepines. Whilst this retrospective study was Australian, it seems that findings may also be applied to the UK.

PRN practices continue on an ad hoc basis and rely upon the experience and judgement of the nurse. There is no trial based evidence as to the effectiveness of this type of pseudo prescribing (Whicher *et al.* 2003) yet those who are prescribed PRN benzodiazepines are likely to receive them (Paton *et al.* 2000). Given the paucity of research in this area a number of questions remain unanswered including the type and incidence of prescription patterns and reasons for administration. Alternative interventions and evidence based therapeutic interventions may in fact, be more appropriate in certain instances.

Implications for practice and research

Whilst indeed a vast array of issues may arise from the difficulties associated with the nurses' potential role as 'medication therapist and manager', the multiple use of benzodiazepines in present practice is of very real concern. Little work has been done to examine or even more importantly address this area or any subsequent implications, for example, the cost to the individual and/or organization. Implications could be extensive particularly as criticisms have already been levelled at the poor management of patients in existing acute inpatient provisions (DoH 2002).

Above all it is essential that the rationales given by nurses about the use of varied prescribed standard and 'PRN' medication are examined. Greater exploration of the use of benzodiazepines is of particular importance given the high incidence of administration by nurses. Firstly, however, it needs to be determined how, when, why and by whom these decisions are made? Usher *et al.* (2001) report that there is a lack of clarity surrounding the administration of PRN psychotropic medication, confusion surrounding decision-making processes related to this intervention and cases of poor documentation. Furthermore they recognize that this area is lacking in contemporary literature. Gray *et al.* (1997) suggest that further research be undertaken to determine whether patients requesting medication, in particular, have been assessed by

nurses before the administration of PRN. This is said to be linked to nurses' knowledge of the medications, their attitudes towards the patient and the patient condition (Usher *et al.* 2001). However, whilst mental health nurses claim their training has adequately prepared them for the task of administration, research suggests that this is not always the case (Usher *et al.* 2001). There is, instead, some evidence that existing mental health nurse education programmes may not be adequately preparing their students to deal with issues relating to drugs prescribed for those with serious mental illness (Jordan *et al.* 1999). Subsequently, concerns prevail about the reasons for their administration underpinned by a suggested inadequate knowledge of both the medications given and clinical symptoms observed. Calls for more stringent training as a result are on the increase (Gray *et al.* 2003). Furthermore, the fundamental nursing skill of medication therapist should be advocated as an integral part of the mental health nursing role in the inpatient psychiatric setting. This requires targeted training about the dose, accuracy, safety and efficacy of medication including provisions for choice and acceptability.

The research agenda in this complex and essential area of care is clearly vast. The role of the nurse in the administration of standard and PRN medication whilst poorly defined, is central to this form of intervention and warrants greater investigation. A recent systematic review has highlighted this very point finding that no randomized trials comparing 'as required medication' to regular regimens of the same drug have been identified to date (Whicher *et al.* 2003). The decision making process employed by nurses when managing medication is undetermined to any great extent before or after targeted training programmes. Indeed, one could argue that until we establish variables that do and should determine the nursing decision to administer medication, training cannot be planned, delivered or evaluated accordingly.

There remain many areas of mental health service delivery that are yet to be examined particularly in the inpatient setting (NHS Centre for Reviews & Dissemination 2001). Undertaking reviews will not only help to inform us of the evidence available, but also assist in making recommendations for future primary research. Given increasing concerns about polypharmacology, the poor monitoring of benzodiazepines, potential interactions and a lack of research in the inpatient area, a need for the evaluation of the nursing role in this area must be at the centre of future investigation. Only then can we begin to monitor and work towards the effective administration of 'PRN' psychotropic medication to inpatients with enduring mental illness. Subsequently, the efficacy of this approach can be determined. The management of medication must be high on the agenda irrespective of specific drug used, but relevant to those commonly employed in practice.

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How expert are the experts? An exploration of the concept of 'expert' within Delphi panel techniques

The use of the term 'expert' occurs widely in healthcare research, in the context of national guidelines and consensus methods for the development of clinical protocols. Within consensus methods of research, especially Delphi panel techniques, the use of 'experts' is fundamental to reliability. Yet literature fails to debate the practicalities of defining 'experts' for use within Delphi panel research. This paper, by John Baker and colleagues, draws on methodological literature and discusses the concepts and elements of 'experts'. It concludes with recommendations for researchers to ensure rigor in selecting experts for future Delphi research

Key words
- Delphi panel
- expert opinion
- healthcare research
- consensus methods

Introduction

The term 'expert opinion' is widely used within the NHS. Expert opinion is commonly sought in the development of clinical protocols; for example, National Institute for Health and Clinical Excellence (NICE) guidelines and in the provision of evidence within inquiries into adverse incidents. The use of experts is a defining feature of consensus methods of research. This paper draws on methodological review papers and recently published Delphi

research papers to explore the concept of the 'expert' within Delphi panel techniques. It discusses the inherent qualities required in defining an expert and how different types of Delphi panels and sampling techniques can influence the definition and therefore the choice of experts. The paper concludes by summarising the main elements required to improve the rigor and validity of the use of experts within Delphi research.

The development of the Delphi method has been attributed to Dalkey and Helmer (1963) of the RAND Corporation (Jeffery *et al* 2000, Keeney *et al* 2001, Mead and Moseley 2001, McBride *et al* 2003, Reid 1988), although the conceptual roots can be traced further back in time. It is reported that the concept originated in the legend of the Greek Delphi oracle, a Homeric poem to Apollo. The oracle utilised a number of informants to deliver the 'truth', enhanced as a result of data from many sources (Kennedy 2004). During the 1950s, the United States Air Force sponsored the 'Project Delphi', which was established to predict the outcome of a hypothetical Russian nuclear attack on the munitions output of the US (Dalkey and Helmer 1963). Dalkey and Helmer (1963) devised this methodology based on the notion that it would allow participants (n=7) to make considered independent opinions leading to reliable conclusions. Following this, the technique became widely utilised within future forecasting. As a methodology it now has a 50-year history, emerging from north American usage in commerce and government to recent and widespread history in healthcare settings and social research, and is increasingly used by nurses (Beech 2001, Keeney *et al* 2001). A pivotal component of this type of research is the identification of a 'panel of experts'.

Since inception the reliance on experts within consensus research has been controversial. In the original studies there is no account of how or why experts were chosen, or the specific standards for selection of panellists (Dalkey and Helmer 1963). One of the panellists was so knowledgeable they also provided 'expert' advice to the researchers on the methodology. A major criticism has been a failure to account for the choice or definitions of experts. Indeed, Sackman's (1975) critique of the Delphi methodology listed the unconvincing definition of expert as one of ten major flaws in the Delphi method. In addition the quality of panellist has reduced over time. By 1975

panellists' level of expertise was already reduced to the level of informed individuals (Linstone and Turoff 1975).

There continues to be a paucity of literature regarding the concept of experts (Mullen 2003, Walker and Selfe 1996). Crisp *et al* (1999) criticised researchers for the cursory attention they have paid to the concept of experts, suggesting that the concept has not been properly defined in the literature as a result. This has been further complicated as the classical Delphi has been adapted to include many hybrids such as 'modified', 'realtime' and 'policy' Delphis (Kenney *et al* 2001).

Why use experts?

The rationale for using Delphi techniques is clear: they form an established method for determining consensus on best policy (Beech 2001). In addition Graham *et al* (2003) state that the technique's feasibility makes it ideal in areas where consensus is lacking, for treatment protocols and for other 'best practices' where agreement is desirable. Mead and Moseley (2001) suggest that it is particularly useful in areas of limited previous work, policy making or to develop practice guidelines, and Hardy *et al* (2004) state that it is 'particularly useful when there is little knowledge or uncertainty surrounding the area being investigated'.

Experts provide an accessible source of information that can be quickly harnessed to gain opinion. They can often provide knowledge when more traditional research has not been undertaken. This, arguably, ensures high content, face-to-face and concurrent validity (Beech 2001, Sharkey and Sharples 2001).

Defining an 'expert'

The dictionary definition of an expert is 'a person who is very knowledgeable about or skilful in a particular area' (Soanes and Stevenson 2003). Despite significant criticism in the literature over the last ten years about Delphi as a methodology, there remains little consensus as to who is an expert. Such a lack of clarity has resulted in wide variations in definitions (Keeney *et al* 2001, McKenna 1994, Reid 1998, Williams and Webb 1994). Parenté and Anderson-Parenté (1987) concluded that there were no guidelines for defin-

ing an expert or evidence that using experts increased the accuracy of a Delphi study.

However, despite this there have been some attempts to define experts within the construct of Delphi studies. Mead and Moseley (2001) state that experts can be defined in a number of ways, such as their position in a hierarchy, public acknowledgement or as recommended by other participants in a study. Crisp *et al* (1999) suggest that the use of the word 'expert' may be inappropriate and suggest the term 'informed advocates' be used instead. This, they argue, is because few panels truly consist of experts. However, a critical review of the Delphi method by Keeney *et al* (2001) cites a range of definitions of 'expert' including 'informed individual', 'specialist in the field' or 'someone who has knowledge about a specific subject'.

It would appear that there is limited consensus as to what an expert is. It may not be about who they are but what attributes they possess. An expert should be a representative of their professional group, with either sufficient expertise not to be disputed or the power required to instigate the findings (Fink *et al* 1984). However, too narrow a definition of expert reduces the potential sample size available (Duncan *et al* 2004). Key themes have emerged from these numerous definitions of expert, including knowledge and experience, and ability to influence policy (Cantrill *et al* 1996, Keeney *et al* 2001, Kennedy 2004). Further expansion of these key characteristics is vital in making an informed choice about expertise.

Knowledge

One characteristic through which experts are often defined is knowledge. This can manifest in many different attributes, such as a professional qualification or registration. The possession of a qualification means that an individual has achieved a certain predefined knowledge and experience base. Many authors cite a professional qualification in their definition of 'expertise' (Hardy *et al* 2004, Williams and Webb 1994). There are clear advantages in defining a level of knowledge, which should enable the researcher to have some consistency of knowledge within the panel. However, Crisp *et al* (1999) propose that registered qualifications are not consistent with expertise, drawing on the example of developing research priorities. They state that while a registered

nurse would be unable to define research priorities they would be able to identify areas where they have practical difficulties.

Indeed individuals can be in possession of knowledge without clinical experience. Keeney *et al* (2001) describe further criticism of the use of 'experts' who are defined by knowledge alone, suggesting that knowledge does not equal expertise. Knowledge can be demonstrated in ways other than a professional qualification; for example, possessing a higher degree in a specific area may increase the credibility of an expert. It would seem that an honours degree, with increasing and widening participation, should no longer be used as a defining point.

The authoring of materials such as books or peer-reviewed articles may demonstrate knowledge within an area and this has been utilised as a criterion for selecting an expert. Duncan *et al* (2004) selected individuals who had 'published treatment manuals or used them in published research' – this was the main criterion for their expertise. Graham *et al* (2003) selected participants on the basis of a minimum number of 'quality' papers published within the last three years with 'at least one paper in a peer-reviewed medical journal'. Other researchers have identified individuals that they feel are knowledgeable within the area (Jeffery *et al* 2000, McBride *et al* 2003, Mead and Moseley 2001, Philips 2000).

Care is needed, however, in ensuring that experts who are known personally to the researcher are not invited (Murphy *et al* 1998). This can cause difficulties when experts come from a small group of individuals who know each other. More controversial is to ask potential panellists to rate their own expertise (Mullen 2003). The effect on the results of those who rated themselves as high or expert compared to those who self-rated as non-expert needs to be established. Finally, Duffield (1989) discusses a case-weighting of expertness. This was, however, dismissed as an unworkable idea but it could prove invaluable for researchers to request potential experts' CVs in order to judge their expertise.

But a major criticism of the recruitment of experts is their potential for bias: participants with specific and cutting-edge knowledge in an area may have a vested interest in preventing research taking place or in manipulating the results (Keeney *et al* 2001). The expression of conflict of interest should be a

requirement of any potential panellists. Another danger in utilising experts in the development of clinical protocols is that those participating may possess knowledge but be very distant from clinical practice and therefore unable to articulate to practice their theory and/or knowledge (Sharkey and Sharples 2001). Caution is, however, required as experts should not be judged on their representativeness but on their quality (Powell 2003).

Experience

In many papers one inclusion criterion often cited to justify expertise is the establishment of a predetermined level of experience. This is often linked with a professional qualification (knowledge) and it is often specified that an individual should have worked within an area for a certain length of time (Hardy *et al* 2004, Jeffery *et al* 2000). Again, caution is clearly required: it is tenuous to suggest that a certain number of years' experience means that an individual can be considered an expert. It may also be impossible to predict whether the individual will posses the necessary attitude, knowledge or skills if years of experience is the sole criterion upon which they are judged. No research has been identified that explores any evaluation of the nature of an individual's experience and their resultant level of expertise. It is proposed that clinical practice may enable a healthcare professional to make valuable observations based on this experience. Evidence is currently unavailable as to whether working within a good organisation would provide better observations than working in a bad one.

However, experience as a criterion is important when applied to those other than 'professional experts'. Delphi research often concentrates on professional (qualification and experience) expertise but clearly this does not fit with national policy on involving users of services. Indeed, having a professional qualification often precludes service user involvement, despite services users' knowledge and experiences. The inclusion of patients or service users within an expert panel provides valuable insights and is undoubtedly important (Sumsion 1998, Cantrill *et al* 1996, Fink *et al* 1984). Within the literature several authors have stated that service users have been included as experts if they have so many years of experience (Hardy *et al* 2004) or experience of, for example, an operation (Mead and Moseley 2001).

The inclusion of service users based on a predetermined number of years' experience is arguably difficult to justify. And it remains debatable – and controversial – whether service users can add additional validity to an expert panel dealing with technical information or expert opinion based on knowledge prerequisites. Care is required, however, as there is potential for service users' views to become marginalised very quickly as they may not share the same language of the professionals. Given that no two people share the same experience, if research is looking for commonality then this is harder to justify within a panel, although wide-ranging experience and viewpoints are essential in maximising the findings of a Delphi panel. Alternative methods of ensuring service users' viewpoints are encompassed include ratifying the findings, triangulating the results or utilising a different research modality. Arguably a minimum requirement would be to conduct further verification studies with service users to establish 'credibility' (Walker *et al* 2000).

Policy influence

A number of papers have cited positions such as nurse consultant or chief executive as part of a definition of expertise, or positions within key organisations including NICE, the Department of Health or pressure groups. Graham *et al* (2003) included 'opinion makers within national organisations' as a criterion for their study. Service users and carers are a vital component of any Delphi project aiming to target policy (Mullen 2003).

Homogenous or heterogeneous?

A major discussion within the literature is the debate about homogenous or heterogeneous samples. These appear to have a major influence on the resultant definitions of expert that researchers have utilised, as the two types of sample require very different sample sizes. In using a homogenous sample, a narrow definition of expert can be applied. Unfortunately this will reduce the potential sample size available (Duncan *et al* 2004). However, it could ensure that 'true' experts will be identified. The other extreme results in large, all-encompassing heterogeneous samples. The definition of 'experts' therefore influences the sample size necessary to ensure validity of the result.

Recent researchers have all suggested the need for heterogeneity of samples that include those from diverse settings (Hardy *et al* 2004, Mead and Moseley 2001, Mullen 2003, Powell 2003). The belief that this approach is somehow better for the validity of the findings is widely cited (Mead and Moseley, 2001). Heterogeneous groups appear to be selected because if they agree then the findings must be worthwhile (Mead and Moseley 2001). However, the dangers of adopting this approach are rarely discussed. Agreement may be on the more trivial or non-relevant points because this is the only consensus the panel can reach. Additionally, the larger the samples the further from the original Delphi concept researchers stray. The original study was conducted with seven experts, and consensus suggests that the most reliable samples for Delphi studies should be small – fewer than 20 participants (Jeffery *et al* 2000, Mullen 2003, Philips 2000). This is very difficult to achieve with a large heterogeneous sample.

Panels may not need experts

Sackman's (1975) major critique of Delphi panels maintains that expert and non-expert panels make little difference to outcomes, especially in relation to forecasting or evaluating social phenomena. It may be proposed that outcomes would be similar regardless of panel make-up. Two pieces of research have been identified that evaluate this claim. Walker (1994) made a direct comparison of two panels. One panel consisted of physiotherapist researchers and the other newly of qualified physiotherapists. Similar findings were reported between the two groups and the researcher concluded that the level of expertness required was uncertain. Secondly Duffield (1993) explored the responses of two comparable expert panels: 93 per cent were accepted or rejected by both panels. This, it is proposed, was indicative of the reliability of an expert panel regardless of participants.

Follow-up of non-respondents

As with other survey methodologies, if those that do not participate are different from the sample there is potential bias in the findings. Limited research has attempted to establish whether some experts are more likely to participate, whether there is a reason for this and what the effect is on the results. McKee *et al* (1991) questioned the representativeness of members

within expert panels. A sample of 503 doctors was selected: 246 (48.9 per cent) replied, and 166 (33 per cent) said they would participate. Those not willing to take part were asked why. The researchers found no significant difference between those who willing and unwilling to take part, in relation to time since qualification, specialty, sex, higher degree, or whether the doctor was a UK graduate. The only significant difference was that consultants with an appointment in a teaching hospital were less likely to take part. The authors suggested that the differences could be due to mailing factors. They concluded that expert panels were very similar in characteristics to their colleagues but were unable to identify further research in this area.

Future research

In order to increase the robustness of future research, defining the notion of expert is of vital importance. Work is also required to examine and refine selection criteria.

It could be proposed that there is a need for a consensus exercise to determine a hierarchy of expertness similar to present hierarchies of research. Perhaps expert panels could receive star ratings based on clear and consistent criteria. Hierarchy of language could accompany this so that not all panels are termed 'expert'. How an expert is defined not only influences the make-up of a panel but also affects the sample size needed to make the research reliable. To the authors' knowledge no research has compared a panel of professionals to one of service users. If panels are to be heterogeneous and include a diverse range of participants such undertakings are important. Likewise, it appears rare for researchers to compare directly or include members of different disciplines within the same panel.

Conclusions

This paper discusses the notion of expert within Delphi panel research. It is clear that experts are multi-faceted and there will continue to be difficulties in defining and justifying their selection. As Sumsion (1998) states: 'Consideration of these options reveals that there is no ready answer and it becomes the responsibility of each researcher to choose the most appropriate group of experts and defend that choice.'

Table 1. Aid for researchers to explore the conceptualisation of an 'expert'

1. What is your definition of an 'expert'?
2. What type of Delphi is being utilised and what effect has this exerted on choice of expert?
3. What sample are you aiming for (homogenous or heterogeneous)?
4. How has the sampling method influenced your choice of experts (snowballing etc)?
5. What are your inclusion criteria, with justification for inclusion (Walker and Selfe 1996)?
6. What are your exclusion criteria, with justification for exclusion (Walker and Selfe 1996)?
7. How do you define knowledge? What level is required and how can this be identified?
8. How do you define experience? What level is required and how can this be identified? If experience has been defined through x number of years, is this defendable?
9. How do service users/carers/patients feature within the study? If excluded, why and how will their views be taken into account?
10. Were non-participants followed up? (Mullen 2003)
11. Within publications each expert needs to be clearly labelled. Walker *et al* (2000) defined their sample in terms such as 'non-funding GP' and 'academic' to enable expertness to be understood.

Table 1 shows an aid that is intended to help potential researchers to discuss, choose and, more importantly, defend their decisions for the selection or rejection of experts. Until clear consensus appears within the literature, researchers need to be able to justify their decisions in order for readers to ascertain the expertness of the panel. Current literature fails to defend the pros and cons of the expertness of a panel selection.

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FEATURE ARTICLE

Exploration of therapeutic interventions that accompany the administration of p.r.n. ('as required') psychotropic medication within acute mental health settings: A retrospective study

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ABSTRACT: *Within acute mental health settings, pro re nata (p.r.n.) 'as required' medication is a widely used adjunct to regular treatment plans, and is administered at the discretion of a registered nurse. However, there is concern that some orders may benefit staff more than patients by providing a 'quick fix' to compensate for inadequate therapeutic programmes. Previous authors assert that p.r.n. medication administration should not be the first line of action, but should be used when other less invasive interventions such as de-escalation, talking, or separation from the group are unsuccessful. This project explored the occurrence of p.r.n. medication administration and the type of alternative therapeutic interventions that are documented as accompanying its administration. A retrospective 1-month chart audit was undertaken for a cohort of inpatients in a 20-bed mental health facility attached to a regional hospital in New South Wales, Australia. Forty-seven patients (73.4%) received p.r.n. medication at least once, with a total of 309 doses of p.r.n. medication administered during this time. There were wide variations in the documented rationales, and for nearly three-quarters (73%) of p.r.n. medication administrations, no other therapeutic intervention was documented as occurring prior to administration.*

KEY WORDS: *'as required', medication, mental health nursing,* pro re nata *(p.r.n.), psychiatric, therapeutic intervention.*

INTRODUCTION/BACKGROUND

Within acute inpatient mental health settings, *pro re nata* (p.r.n.) 'as required' medication is a widely used adjunct to regular treatment plans. Studies have estimated that between 70% and 80% of psychiatric inpatients receive p.r.n. psychotropic medication during their stay (Curtis & Capp 2003; Hales & Gudjonsson 2004; Thapa *et al.* 2003; Voirol *et al.* 1999). As opposed to standard scheduled medications, p.r.n. orders are written by a doctor but administered at the discretion of a registered nurse. Psychotropic p.r.n. medications are most frequently administered for agitation, insomnia, at service user request and to reduce distressing symptoms (Curtis & Capp 2003; Usher *et al.* 2001).

Psychiatric nurses have traditionally relied on seclusion, physical restraint, and p.r.n. medication for effective management of awkward and disruptive situations (Campbell & Simpson 1986). P.r.n. medication has usually been considered a preferable, less invasive

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alternative to physical restraint for severely agitated patients. While it has been championed as a strategy to reduce physical restraint rates, some argue that reliance has merely been switched to 'chemical restraint' (Currier 2003; Donat 2005), with intramuscular injection considered particularly invasive in some cultures. Furthermore, sedation can interfere with development of the daily living and coping skills needed to function outside the inpatient setting, and the reliance on benzodiazepines as a p.r.n. option can create a physical addiction (Donat 2005), acting as a positive reinforcer for the behaviour in some patients. This is particularly relevant as a history of substance abuse is a factor known to be associated with increased risk of aggression in psychiatric patients (Barlow *et al.* 2000).

Previous discussions of p.r.n. medications have only briefly mentioned the process of trying alternative therapeutic interventions first: Duxbury and Baker (2004) state that alternative and evidence-based therapeutic interventions may be more appropriate than p.r.n. medication in some circumstances. Usher and Luck (2004) state in a review that p.r.n. medication should not the first line of action, but is the treatment strategy when other less invasive interventions such as de-escalation, talking, or separation from the group are unsuccessful. De-escalation skills refer to a combination of understanding environmental reasons for aggression, risk assessment, and verbal and non-verbal strategies for calming a situation. For example, these might include: remain calm, appear in control but avoid appearing confrontational, maintain non-invasive eye contact, use reflective listening to acknowledge the person's concerns or emotions, and convey that you want to help the person to find a solution (Sookoo 2004).

Geffen *et al.* (2002) conducted a written questionnaire with nurses (and doctors) in two inpatient psychiatric units, which included a specific section on alternatives to p.r.n. medication. The most commonly cited responses were counselling, distraction, time out, relaxation, and cognitive behaviour therapy, with significantly more alternatives cited for the treatment of agitation than psychotic symptoms. Nurses reported, in the week prior to the survey, using alternatives to p.r.n. medication for agitation on an average of 21.7 occasions, and for psychotic symptoms, 17.7 occasions. This fits with Fagan-Pryor *et al.*'s (1994) assertion that nurses do differentiate between behaviours, reflecting differentiation of the seriousness of aggression, and that they do not merely respond in a stereotypical manner. However, a review by Daffern and Howells (2002) argued that the type and number of interventions selected were inconsistent, and influenced by a number of factors including diagnosis, age, ethnicity, and whether the victim of aggression was a nurse or patient. Senior nurses in Geffen *et al.*'s (2002) study were found to cite more alternatives than junior staff while Bowers *et al.* (2004) identified that p.r.n. medication received the highest levels of approval by student nurses as a method of containment. Another study of how staff use their time (Higgins *et al.* 1999) concluded that more experienced and qualified staff spend the least time in face-to-face contact with patients.

The administration of p.r.n. medication is clearly necessary, yet some orders may benefit staff more than patients (Thapa *et al.* 2003) by providing a 'quick fix' to compensate for inadequate therapeutic programmes. A crucial study by Thapa *et al.* (2003) compared outcomes in psychiatric units where standing p.r.n. medication orders were regular practice, and when they were disallowed by hospital policy with only one-off 'now' orders permitted. In the latter, there were fewer incidents of seclusion, restraint, and physical aggression despite the fact that unscheduled medications almost halved – suggesting that many psychiatric patients may be exposed to unnecessary psychotropic medications. However, the study did not report whether any particular therapeutic interventions were used in place of p.r.n. medication. In another study where patients were allowed to choose future strategies to manage agitation or anger, staff interaction (talking and/or walking with staff) was highlighted as the most commonly favoured method (49%), while only 11% favoured medication (Sullivan *et al.* 2005).

However, with the advent of modern pharmacological interventions, there has been less discussion and interest in other therapeutic skills within acute inpatient mental health care. The literature highlights this lack of therapeutic activity (Cleary 2004; Standing Nursing Midwifery Advisory Council 1999). Fourie *et al.* (2005) found that although nurses did perceive the therapeutic role to be their most important role, it was a role they were often prevented from performing. As Cleary *et al.* (1999) states, the nursing ward is structured so that 'something always comes up' to replace nurse–patient interaction. In an observational study of 23 nurses from three acute admission wards, which explored the allocation of time in an acute psychiatric setting, it was found that approximately 6.75% of nurses' work time was reported to be devoted to potentially psychotherapeutic interaction, with non-patient contact activities taking over 57% of work time (Whittington & McLaughlin 2000). Supporting this finding, Bee *et al.* (2006) in their study identified that only 4.5% of nursing time was spent in therapeutic activities.

Issues pertaining to staffing (such as the use of agency staff) may mean that staff are not sufficiently skilled to engage in therapeutic interaction (Geffen *et al.* 2002). Additionally, a conflicting paradigm of control is present in many mental health units, in which nurses perceive their role to be chiefly characterized by 'custodial' style surveillance and policing, and responding to rule-breaking (Hall 2004). In close-observation areas, some authors have described a situation where an imperative to provide a low stimulation environment translates into no therapeutic intervention or activities of any sort (O'Brien & Cole 2004).

Overall, the literature is plentiful regarding what therapeutic activities could be used in acute mental health settings (Baker 2000; Gagner-Tjellesen *et al.* 2001; McCann & Bowers 2005), but there is much less information on what is actually taking place in standard situations. The literature in general (not including Cleary 2004) recommends that nursing staff be encouraged to move from a crisis mode into a proactive mode, yet these 'best practice models' do not represent the reality of most inpatient settings. Importantly, despite the repeated use of p.r.n. medications and the compelling findings of Thapa *et al.* (2003), there has been no systematic analysis of the *reactive* processes surrounding the time of p.r.n. administration such as the time taken to obtain p.r.n. orders when none were prescribed previously. This is perhaps not surprising given the lack of adequate documentation of p.r.n. medication administration itself (Curtis & Capp 2003). Duxbury and Baker (2004) state that it is essential that the rationales given by nurses for its use be examined: 'it needs to be determined how, when, why and by whom the decisions are made' (p. 665). Integral to this is a knowledge of whether and what type of alternative interventions are tried prior to and in conjunction with p.r.n. medication. Until what is actually happening is understood, nurse training in the administration of p.r.n. medication cannot be planned, delivered, and evaluated accordingly (Duxbury & Baker 2004).

This project aims to provide an enhanced understanding of the type of therapeutic interventions that are actually used within acute mental health settings, with a focus on those associated with administration of p.r.n. medication. Given the difficulties associated with extracting data from case notes, times of p.r.n. administration obtained from treatment sheets should provide a pragmatic link with entries within case notes. The project will use these specific time points to identify any therapeutic interventions that are commonly documented prior to and in conjunction with p.r.n. medication.

Aim

The aim of the study was to provide further information on the use of p.r.n. psychotropic medications and their association with other therapeutic interventions within acute inpatient care.

METHOD

A retrospective chart audit was undertaken for a cohort of inpatients in a 20-bed mental health facility in an acute admission unit attached to a regional hospital in New South Wales, Australia. The study included current patients as well as those newly admitted during the month of February 2005. This type of research, a retrospective audit, where both the proposed cause and proposed effect have already occurred, is well documented (Campbell & Stanley 1963; Schneider *et al.* 2003). A research assistant manually reviewed and extracted data from both patients' case-notes and medication charts, matching information for date and time of p.r.n. administration. Additionally, data were collected on gender, age, birthplace and ethnicity, diagnosis, admission date, and legal status. P.r.n. medication administration data were recorded as follows: date, time, type of drug, dose, route, rationale for administration, effect, and pre- and post-intervention data. The data were entered and analysed in SPSS version 12.0 (SPSS Inc., Chicago, IL, USA).

Ethical issues

Ethics approval was obtained from Human Research Ethics Committee of the University of Wollongong and the relevant Area Health Service, in line with the National Health and Medical Research Council guidelines. To comply with ethical requirements, the research assistant was a clinical nurse specialist who worked in the unit and had access to the information in the normal course of work. Patients themselves were not contacted and all information was de-identified before it was provided to the Chief Investigators. Ethical permission stipulated the time frame; data were not collected for periods of time that patients were transferred to other wards, or remained inpatients past this point. Fifty-two patients were admitted and 12 patients were already inpatients on the ward during this period.

RESULTS

A total of 64 files were reviewed. Forty-seven patients (73.4%) received p.r.n. psychotropic medication at least once during the month of February and 17 patients

TABLE 1: *Sample demographics*

Theme	p.r.n. receivers ($n = 47$)	p.r.n. non-receivers ($n = 17$)
Gender		
Male	26	9
Female	21	8
Ethnicity		
Australian	39	13
Aboriginal Australian	3	0
European	4	2
Asian	1	1
American	0	1
Mental Health Act		
Voluntary	20	8
S29 – mentally disordered	27	9
Age range		
<19	5	3
20–29	9	3
30–39	12	5
40–49	15	3
50+	6	3
Diagnosis		
Depression	9	5
Schizophrenia	9	4
Suicidal	8	4
Bipolar affective disorder	5	2
Personality disorder	5	0
Psychosis	4	0
Generalized anxiety disorder	1	1
Post-traumatic stress disorder	2	0
Situational crisis	2	0
Schizoaffective disorder	1	1
Dementia	1	0

p.r.n., *pro re nata* 'as required'.

TABLE 2: *All drugs administered by therapeutic group*

Type of drug	n	Drug dose (mg) Range	Mean
Benzodiazepines ($n = 188$, 60.8%)			
Diazepam	142	5–20	9.2
Temazepam	22	10–20	13.8
Midazolam	9	5–10	8.3
Alprazolam	2	<1†	N/A
Clonazepam	9	N/A	1
Nitrazepam	4	N/A	5
Atypical antipsychotic ($n = 31$, 10%)			
Onlanzapine (Zyprexa)	23	5–10	8.2
Risperidone	2	<1†–1	N/A
Quetiapine	6	20–100	48.3
Typical antipsychotic ($n = 87$, 28.1%)			
Zuclopenthixol acetate	2	N/A	100
Chlorpromazine	85	50–200	104.8
Other ($n = 2$, 0.6%)			
Benzotropine	2	N/A	1
Missing data ($n = 1$, 0.3%)	1		
Total	309		

†Recorded as <1 mg. N/A, not applicable.

(26.6%) received none. The demographics of the total sample are described in Table 1. Eleven diagnoses were present, with patients having on average two diagnoses (range one to four). A common additional label mentioned within diagnosis was substance misuse (32.8%, $n = 21$). There were also a surprising number of patients who were listed as having suicidal thoughts or having attempted suicide (37.5%, $n = 24$).

A total of 309 psychotropic medications were administered on 268 occasions during the audit period. On 41 occasions, combinations of antipsychotic and benzodiazepines were administered. For those who were given p.r.n. medication, the mean number of administrations per individual was 6.6. Eleven patients received 10 or more administrations of p.r.n. medication; in total this small group received 143 administrations of p.r.n. medication – representing 46.4% of all p.r.n. medications administered. All of those 11 were involuntary (S29) patients, and 9 out of the 11 were female. A further five patients spent time on a locked high-security observation unit attached to another ward but none of the high-administration patients were included in that group (and data were not collected for the patients while on that unit).

On the majority of occasions when p.r.n. medication was administered, it was given orally (93.3%; $n = 250$), and the remainder via intramuscular injection (6.3%; $n = 17$). A breakdown of the p.r.n. psychotropic drugs administered can be found in Table 2. Of the total administration occasions, 55.2% were benzodiazepines on their own, 28.7% were antipsychotics on their own, and 15.3% combined benzodiazepines with an antipsychotic. Seventeen patients were administered multiple drugs at least once. On these occasions, Diazepam (5–10 mg) was the most likely adjunct to antipsychotic medications (80%, $n = 33$). As expected, there was a significant difference ($P = 0.04$) in the number of administrations of p.r.n. medication between those detained (S29) (mean = 5.56) and voluntary patients (mean = 2.42).

There were variations in the occasions of p.r.n. medication administration during the 24-hour day. Half of the administrations of p.r.n. medication occurred during the evening shift from 3 PM to 11 PM (50.0%, $n = 134$), followed by the morning from 7 AM to 3 PM (28.0%, $n = 75$), and finally the night shift from 11 PM to 7 AM (20.9%, $n = 56$; three cases of missing data). Fifty-one administra-

TABLE 3: *Rationale for administration of p.r.n.*

Rationale	Frequency (*n*)	Per cent
Agitation, anger, aggression	35	13.1
Psychotic symptoms†	31	11.6
For sleep	28	10.4
Elevated, upset, anxious	16	5.6
Patient request, demanding medication	13	4.9
Irritable, unsettled, restless	12	4.5
Alcohol withdrawal	11	4.1
Self-harm	5	1.9
Nightmares	2	0.7
Doctors instruction	1	0.4
Not stated	114	42.5
Total	268	100

†Includes hallucinations, delusions, and thought disorder. p.r.n., *pro re nata* 'as required'.

tions of p.r.n. medication (19%) were given in a 30-min period from 21:00 to 21:30; this coincided with a regular medication period. There appeared to be no substantial differences between particular days of the week (range of 11.6% on Thursday to 16.4% on Wednesday). On average, 9.6 administrations of p.r.n. medication occurred per day (range 4 (1.5%) to 17 (6.3%)). There were wide variations in the documented rationales for the administration of p.r.n. medication (Table 3).

Documented statements pertaining to therapeutic interventions around the occasion of the administration of p.r.n. medications were categorized and have been summarized in Table 4. Only 28% of occasions where p.r.n. medications were administered had any additional (pre or post) intervention been documented. Twenty-three patients received documented face-to-face counselling at least once around the time of the administrations. Occasions on which both p.r.n. antipsychotics and benzodiazepines were given were more likely to be accompanied by some documented alternative intervention than those on which the corresponding single drugs were given: 46% ($n = 41$) of the administrations compared with 22% and 30% ($n = 77$ and 148, respectively). When a rationale for the administration of p.r.n. medication was stated ($n = 154$), additional therapeutic interventions were more likely to be mentioned for: hallucinatory/psychotic/delusional/thought-disordered behaviour (18/31 cases); agitated/angry/aggressive behaviour (21/35); elevated/upset/anxious behaviour (12/15); and sleep (13/28). For all other rationales combined (see Table 3), only a small number of cases (8/43) had an alternative documented, and when no rationale was documented, no intervention was stated (3/114).

In 38.8% ($n = 104$) of occasions when p.r.n. medication was administered, an effect was documented; however, the evaluations were vague. The most frequently recorded effect was 'Nil' (8.6%, $n = 23$) followed by 'Sleep' (6.3%, $n = 17$), 'Little/some effect' (4.9%; $n = 13$), and finally 'Waiting for effect' (3.0%; $n = 8$).

DISCUSSION

This study provides a better understanding of the

- Variables associated with p.r.n. medication administration
- Alternative therapeutic practices that accompany p.r.n. medication administration
- Documentation process

Importantly, the data provide further evidence of a reliance on p.r.n. medications in acute mental health settings. The findings presented are similar to other previously published studies (Curtis & Capp 2003; Geffen *et al.* 2002; Gray *et al.* 1996; McKenzie *et al.* 1999; Usher *et al.* 2001) with nearly three-quarters of study patients receiving p.r.n. medication. In this study, documented patient request for p.r.n. medication was relatively low at 4.9% of all administrations (the previous literature suggests that this rationale accounts for at least one-fifth of administrations). At least 10% of the administrations p.r.n. medication were given to aid sleep, although the focus of this study is on the management of acute agitation, psychotic symptoms, and aggression. There appears to be a continued reliance on Chlorpromazine and Diazepam as drugs of choice. Chlorpromazine was used despite the fact that according to Geffen *et al.* (2002), the first-line p.r.n. agents should be benzodiazepines, even for acute psychoses, as they are better tolerated. In this study, the most common dose of p.r.n. Chlorpromazine was 100 mg even though Chlorpromazine is known to be most effective when given at doses of between 50 mg twice daily and 100 mg four times daily (Healy 2002).

Limited evidence could be identified of the use of alternative therapeutic interventions either prior to ($n = 73$, 27.2%) or after ($n = 16$, 6%) the administration of p.r.n. psychotropic medication. P.r.n. medication should be seen as one of the last resorts after other interventions have been tried; however, this was not documented as being the case in 72.8% of cases. While many nursing staff might consider it preferable to give p.r.n. medication early rather than physically restrain a person later, the lack of documentation of alternative interventions could imply that p.r.n. medication is currently the primary intervention within acute inpatient care. Alternative interventions such as face-to-face counselling were more likely to

TABLE 4: *Evidence of therapeutic interventions before and after the administration of p.r.n. medication*

	Before		After	
Intervention	Frequency (*n*)	Per cent	Frequency (*n*)	Per cent
Face to face (including counselling and talking)	46	17.2	4	1.5
Distraction	12	4.5	1	0.4
Seclusion (including time out)	11	4.1	3	1.1
Practical assistance	2	0.8	4	1.5
Observation	1	0.4	1	0.4
Review by doctor	1	0.4	–	–
Relaxation	–	–	1	0.4
Additional p.r.n.	–	–	1	0.4
Other	–	–	1	0.4
None recorded	195	72.8	252	94
Total	268		268	

–, no incidence; p.r.n., *pro re nata* 'as required'.

be given in more 'difficult' situations where a combination of antipsychotic and benzodiazepine was seen to be warranted – although it is unknown whether this represents a bias as to when alternative interventions get documented.

The quality of the therapeutic interventions that are identified also requires further examination. The evidence base for 'face-to-face' contact with mental health nurses requires further exploration, as it was the most frequently used intervention, accounting for 63% of the total therapeutic interventions before the administration of p.r.n. medications. However, the value of such 'face-to-face' interventions may be difficult to validate as much of 'face-to-face' time may be diluted by tasks such as administration of medication, admissions, discharges, taking patients to appointment, and so on. Little is known about the therapeutic content or value of face-to-face time. The use of seclusion was documented as occurring very rarely alongside p.r.n. medication administration, but it did occur and was counted in this study as an 'alternative' intervention. It should be noted that some efforts to reduce seclusion and physical restraint have included p.r.n. medication as a preferred means of handling difficult behaviour (Sullivan *et al.* 2005).

Improved guidelines may need to be developed regarding the process of administering p.r.n. medication and the way that it is prescribed, as well as alternatives that could be tried prior to resorting to an intervention using p.r.n. medication. Surprisingly, considering how often p.r.n. medication is used, there is practically no emphasis given to it in textbooks – for example, in a common Australian textbook *Psychiatric and Mental Health Nursing* (Elder *et al.* 2005), there is less than a page devoted to p.r.n. administration. Mental health staff training in medication practice in general is poor and is consistent with the 'medication alliance' literature (Byrne *et al.* 2004; Coombs *et al.* 2003). The seclusion and restraint programme revision implemented by Taxis (2002) provides a good example of how to execute training programmes on alternative strategies (focusing on de-escalation skills, diversional activities, and so on) and begin an overall paradigm shift emphasizing collaboration, empowerment, and ethical clinical practice.

In addition to compulsory staff training, Donat (2005) emphasizes the value of establishing behavioural plans to reduce future p.r.n. medication use such as: organizational support in the form of effective oversight of junior staff, access to expert behavioural consultants, the involvement of key clinical administrators in case reviews, and lowering of thresholds for case reviews (e.g. over three p.r.n. medication administrations a week). The outlined procedure is valuable if an individual patient is receiving multiple administrations of p.r.n. medication, although a one-off acute situation may still require p.r.n. medication when other standard strategies have been unsuccessful. Donat (2002) does acknowledge however that alternatives initially sound 'naïve and idealistic to overworked and frustrated direct care staff members who are trying desperately to keep their environment from getting out of control' (p. 34).

This paper provides additional information about the administration habits of nursing staff. Broadly, documentation is poor considering that progress notes are legal documents. The lack of documentation is consistent with that of O'Brien and Cole (2004) who studied critical incidents and seclusion in a close observation area. Their data showed that during an index month, seclusion was used on 42 occasions, but in 29 of these events there were no alternative therapeutic nursing interventions documented in the patient medical records. Counselling was mentioned once, limit setting was mentioned three times,

encouraging the patient to rest was mentioned twice, and p.r.n. medication was administered alongside seclusion seven times. The authors concluded that the critical incident forms 'provided so little descriptive data that to use them for statistical research to . . . improve care would be impossible' (p. 93).

The authors of this study believe that alternative interventions are being practised by mental health nurses, but that they are not being documented as frequently as they occur. There is accountability associated with medication and seclusion but not for other therapeutic interventions and, given that it is not mandatory to document 'talking' interventions, it is likely that alternative therapeutic interventions are being administered (either in place of or prior to p.r.n. medication) but remain undocumented in a busy ward environment. Supporting this assertion is the fact that alternative interventions were far more likely to be documented when a rationale for the p.r.n. medication administration was documented – and the latter disturbingly happened for only 57.5% of administrations. Furthermore, pre-interventions may be more likely to be documented than post-interventions. The data highlight the fact that nurses may not appreciate the importance and therapeutic benefit of other interventions, instead seeing them as a more standard aspect of their work. Cleary (2004) comments that we need to make visible what the nurse does to create a therapeutic atmosphere, as nurses take for granted their knowledge, skills, and expertise. Better documentation of other interventions, if they are used, may assist this process.

Nurses may need more training on the words needed to describe patient interaction; a tick-a-box sticker could be useful to implement this. For example, 'talking to patient' might be changed to 'spending 1:1 time exploring family issues'. However, Whittington and McLaughlin (2000) acknowledged the difficulty in coding the nurse activity categories 'individual therapy' and 'social conversation'. They defined 'individual therapy events' as occasions when nurses were consciously intending to be supportive, to counsel, to listen actively to patients' accounts of their feelings or difficulties, or to discuss treatment procedures and events. In contrast, 'social conversation activities' were defined as occasions on which nurses had discussions with patients that they might have had with anyone, such as those about the weather.

The findings have implications for nursing education in a comprehensive programme where most people do not undertake postgraduate study in the mental health area. It would appear that allowing or encouraging practising mental health nurses to rely on p.r.n. medication as the main treatment strategy may be doing these workers a disservice with regard to their skill base. This may be the only skill that they possess and therefore educators may need to ensure that training on therapeutic interventions is included in undergraduate clinical subjects. Furthermore, Area Health Services may need to take responsibility to up-skill their staff.

LIMITATIONS

A major limitation associated with this study is its reliance on retrospective data collection – previous studies that have used the same method of data collection have highlighted the poor level of documentation. Despite this problem, the data are important and relevant, as they represent the normal conditions in which staff obtain information and how patients are treated. It should be noted that our data were based on 1 month only and did not reflect the total admission time of the patient (i.e. data were not analysed for the administration of p.r.n. medication prior to or after the month of February); furthermore, no data were available on those transferred to other wards within that month.

In addition, there are limitations in using a quantitative approach to explore therapeutic interventions. This approach only allows for documented responses and anecdotal evidence suggests that many nurses do engage in therapeutic activities on a one-to-one basis, but these are not documented. Further research needs to be undertaken in this area and, in recognizing these limitations, further research using a qualitative approach is planned.

Other limitations of this study include the fact that it only focused on points of time when p.r.n. medication is administered. Unfortunately, no comment can be made regarding therapeutic activity that occurred when p.r.n. medication has *not* been administered, including activity that successfully avoided the need for p.r.n. medication. The study data also needs to be considered in the context of the total patient medication picture as p.r.n. medication does not constitute all of the patient's daily medication. Additionally, this study only investigated the administration of p.r.n. medication at one site. Due to ethical reasons, this study did not obtain information about whether any particular nurses or teams administered p.r.n. medication more readily than others. However, the research assistant found no surface evidence of this being an important factor.

CONCLUSION

The clinical implications of these findings are potentially serious – are mental health patients only getting part of

the treatment array available, and are we teaching patients and nurses to rely on medication as a quick fix rather than teaching individual techniques to recognize and cope with symptoms? Further research needs to use observational studies to disentangle the two important issues of which interventions are actually used and which are documented. A qualitative study of the use of therapeutic interventions from staff and patient perspectives, using semistructured interviews that are informed by the present study's findings, would be valuable to further the understanding of this important topic. Finally, further research on the effectiveness of staff training in alternatives to p.r.n. medication is necessary to achieve the ultimate goal of reducing reliance on this intervention method.

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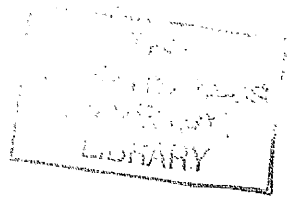


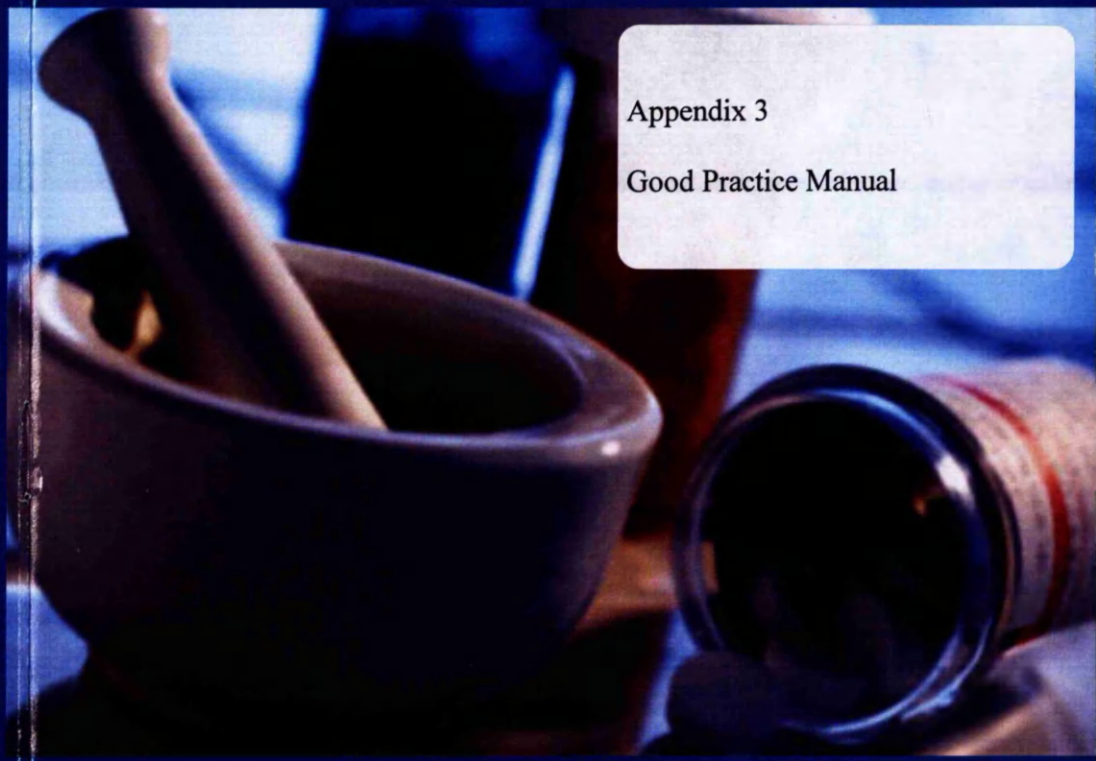
MANCHESTER 1824

The University of Manchester

Enhancing the use of 'as required'/'extra' (p.r.n.) medication within acute mental health settings

Good practice guidelines

Support manual



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Contents:

Introduction:

This manual describes the good practice principles for PRN medication which we are hoping you will adopt onto the ward.

The principles of prescribing and administering PRN described in this manual are already custom and practice for many clinicians in Greater Manchester. It is hoped that this research will act as a prompt for all clinicians to improve on what they already do well, maintain areas of good practice and for some staff provide new knowledge and skills for how they utilise PRN medication. The study will also evaluate the benefits and difficulties of using these principles in practice.

- Section 1 describes an outline and background of the study.
- Section 2 highlights the 9 principles of PRN medication and provides more detail on how to adhere to these principles.
- Section 3 details this study which aims to evaluate the key principles
- Section 4 describes some of the research that has been conducted on PRN.

This project forms the final part of PhD study and is funded by the Health Foundation, which is an independent charity.

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Summary

This manual provides supplementary information on the 9 good practice points to enhance the use of PRN psychotropic medication.

This part of the study aims to explore what impact and how feasible these good practice points are in clinical practice.

If you have any questions or would like to discuss the protocol further please contact

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Glossary:

Administration:	The process by which nursing staff give PRN medication to patients.
Atypical:	Refers to 'new' antipsychotic medication which produces less EPSE side effects
Delphi:	A research method which builds consensus (agreement) amongst experts in the topic area, in this case PRN medication[1,2].
Dispensing:	The process by which pharmacy staff issues medications to the ward.
LUNSER:	A rating scale for antipsychotic side effects.
PRN:	Pro re nata, the latin phrase for as needed medication. This medication which once prescribed can be administered to patients at the nurse's discretion
Polypharmacy	Two or more antipsychotic medication at the same time.
Psychotropic:	Medications which influence mental state[3].
Systematic literature review:	The process of reviewing previous research papers to make sense of the literature

Study Aim:

To identify, devise and test a clinical protocol for the enhanced use of psychotropic PRN medication within acute mental health settings.

Study Progress:

This part of the study focuses on the testing and evaluation of the clinical protocol. Previous parts of the study which have informed the principles of good practice are:

- A systematic literature review
- A study with experts
- Interviews with multi-disciplinary team
- Interviews with patients

Summaries of the findings from these four parts can be found later in the manual (Section 4).

Nine key principles have been extracted and confirmed by a project group. This group contained multi-disciplinary representation from the three Mental Health Trusts involved in the data collection and staff from the University of Manchester.

We hope that you will adopt these 9 KEY PRINCIPLES.

What do patients think about PRN?

PRN medications are frequently requested by patients. The literature is unclear as to why patients request PRN psychotropic medications or their experiences of such treatments. A convenience sample of 22 inpatients participated in face-to-face semi-structured interviews exploring their treatment experiences of PRN psychotropic medication within acute mental health settings. Thematic content analysis was carried out.

Interviewees highlighted the value of PRN medications. However, the process associated with their use was perceived as confusing and stigmatising. Patients had limited understanding of and felt unsupported in attempts to use alternatives to PRN medications. Additionally, the decision-making and information-giving processes were unclear to them which raise the issue of power and control within acute mental health settings.

Nurses should take account of the issues of power and control when administering PRN medication. The provision of adequate treatment information should be a priority to enable informed choices to be made about PRN medication.

The interviews findings with patients are due to be published in the Journal of Advanced Nursing.

What do nurses, psychiatrists and pharmacists think about PRN?

- The interviewees suggested that all medication was reviewed at ward round and this probably included PRN. Although there was some suggestion that this review did not occur often enough. The other trigger for review was when nurses felt there was an issue, such as the patient needing more medications.
- Nearly half of the MDT reported providing some information about PRN to patients. Although this was limited in content. There was a suggestion that if patients asked for information they would be more likely to receive it. These discussions with patients were particularly limited in regards to side effects.
- Whilst there is availability of alternatives to PRN. PRN has become a first resort option, because other factors prevent the use of non-pharmacological interventions for example, resourcing issues.
- The interviews highlight a lack of clinical responsibility for PRN medications. Accountability for the process seemed unclear.
- The 'Old school give more', the impression that there is a sub group of nurses who give more PRN medications. Whether this is based on clinical experience or lack of alternative intervention skills was unsure.
- PRN vs Rapid Tranquilisation, it appears unclear in clinical practice when RT starts, this has implications for clinical protocols.

Background:

Psychotropic medication provides the mainstay of treatment within secondary care mental health settings and is especially important within acute inpatient mental health settings [4].

Pro re nata (PRN) or 'as required' medication is a commonly used adjunct to routinely prescribed medication. Between 70%-90% of patients within inpatient mental health settings studied received PRN psychotropic medications on one or more occasions [5 6].

Psychotropic PRN drugs most frequently used in inpatient mental health settings are; anxiolytics (diazepam and lorazepam) and antipsychotics (haloperidol and chlorpromazine), followed by hypnotics and anticholinergics [5 6]. Despite the importance placed on medication and the frequency of its use, there is no clear evidence of the effectiveness of PRN medication [6 7].

There have been recent publications focusing on the use of antipsychotics, particularly rapid tranquillisation [8-10]. However, there are a lack of guidelines on the prescription and administration of PRN psychotropic medication.

Some staff working in acute settings have a poor knowledge and understanding of medication issues, which often relates to lack of training and commonly held beliefs about what medication to administer and when [3 8-10].

There are also differences between medical and nursing beliefs and knowledge in regards to PRN medication [11 9].

The level of documentation and assessment/observation of patients before and after administration of PRN medication has also been of concern [3 12].

Medication management training within recent years has tended to focus on community settings [13 14]. Given the high use of medication on inpatients settings and high level of clinical decision making required when administering PRN, it is important to provide acute mental health staff with training about medication [10].

Prerequisites for practice:

- This clinical protocol is designed to be used within adult inpatient mental health settings.
- It builds on existing good clinical practice and evidence drawn from staff within Manchester.
- It should not replace clinical judgement, but is designed to enhance the use of PRN psychotropic medications.
- Clinicians remain professionally accountable for prescribing [15] or administering [16 17] PRN psychotropic medications.
- It is assumed that staff using the protocol are knowledgeable about the patients that they are treating.
- The protocol is intended to be used when psychotropic PRN medication is being prescribed and/or administered.
- These principles supplement existing Pennine Care NHS Trust policies for example, Rapid Tranquilisation.

What do nurses, psychiatrists and pharmacists think about PRN?

- Recommendations for improving the decision making process were training (n=15), experience (n=9) and guidelines (n=9).
- 71% (n=42) of the MDT had encountered times when PRN was used for different reasons than prescribed (indication for use). Most cited were sedation (n=11), to alleviate distress (n=8) and to prevent 'bothering' the doctor (n=5).
- PRN provides a back up/safety net/last resort (n=30) and removes doctors from the process (n=17).
- Dispute as to whether PRN used to manage the ward (n=17) those who felt it was commented on the ability to reduce ward arousal (n=22).
- 57 (97%) members of the MDT could identify times when PRN had been used when alternatives would have been preferable, mainly due to limited skills (n=10), experience (n=7), pressures of time (n=6) and low staffing levels (n=6).
- 22 alternatives were proposed to PRN, the most commonly cited were spending more time with nursing staff (n=23), anxiety management (n=21), de-escalation (n=11) and distraction (n=11). Again time, staffing and experience was cited as reasons why this hadn't happened.
- A proportion could imagine an acute ward without PRN. Most suggested a ward without PRN would be chaotic, stressful for patient and staff and unsafe. To prevent this wards would need more staff (n=16) and changes to the environment (n=9).
- A third suggested that PRN wasn't given at regular times. The other (two thirds) suggested that was either connivance, the trolley acted as a prompt for patients, or this was the only time when qualified nurses would see the patients.

What do nurses, psychiatrists and pharmacists think about PRN?

Fifty-nine members of the MDT participated in interviews. Nurses (included unqualified) accounted for 64.4% (n=38) of the sample, Pharmacy (n=5, 8.5%) and Psychiatrists (n=16, 27.1%). The most frequently occurring themes have been included within this summary.

- Advantages focused on relieving distress (n=28), preventing (n=17) and managing violence (n=17).
- Another theme focused on the removal of doctors from the process (n=19).
- Disadvantages focused on themes of misuse either by nursing staff (giving too much, too quickly) or patients, followed by issues about the quality of prescriptions.
- A 'balanced usefulness' was reported, answers focused on safety (n=14), prevention of distress (n=11), but as a last resort (n=8).
- Decisions to prescribe were based on patient history, mental state, and risk assessment. There was the suggestion that PRN was routinely prescribed.
- Decisions to administer were based on safety (n=15), user knowledge (n=12) and levels of distress (n=8).
- 86.6% (n=51) of doctors are influenced by nursing staff, nurses are aware of this influence. Only 6% of nurses reported being influenced by Doctors. About half of the MDT is influenced by User preferences.

The 9 principles of good practice:

We hope that you and your service will adopt these principles of good practice. We plan to undertake detailed research to measure their impact on practice. Broadly they can be described as:

1. Remaining focused on the patient
2. Prescription quality
3. PRN as part of the clinical management plan
4. Evaluating the use and effect of PRN
5. PRN requires frequent review
6. Enhanced documentation by the Multi-disciplinary team
7. Preventing distress when using PRN
8. PRN as a last resort
9. Training and education in the use of PRN for all clinical staff

These 9 principles are discussed in further detail in the following pages.

1. Remaining focused on the patient

Patients have
- Preferences (including advanced directives),
- Knowledge,
- Preferred choices,
- Limited control,

The prescribing and administration of PRN should be a negotiated process, involving the doctor, nurse, patient and where relevant carers or advocates

PRN continues to be routinely prescribed when a patient is first admitted, often with limited or no discussion of their preferences or choices. Patients express frustration at not being involved in these decisions. Only half of all mental health professionals report that their decision to prescribe or administer PRN psychotropic medication being influenced by patients. The following quotes from various professionals and patients highlight this:

You quite often medicate people with haloperidol and they say 'Whatever you do don't give me haloperidol. It's a horrible drug it causes me side effects. Use anything but haloperidol.' But we don't even ask.

Ward Manager

Well there aren't that many drugs and to be honest when they are acutely unwell, the patients, as I see them aren't in a position to make an informed choice.

Consultant Psychiatrist

What do experts think about PRN?

The experts were asked to answer questions based on good practice for the prescribing and administration of PRN psychotropic medications. Eighteen experts participated in three Delphi rounds to establish consensus (agreement). Data were collected in 2004-2005.

A total of 271 items were initially generated to four questions posed. As a result of the process this reduced to 78, then 34 items, which concentrated on six themes.

i. Patients should be involved in all decision making processes associated with PRN medications. This process should be individualised, involve negotiation and where possible advance directives, and provide a clear rationale for the use of PRN medication.

ii. The second focused on the process of prescribing and administering PRN medication. This process should be based on assessment, with a clear proactive indication for use both within the prescription and at the point of administration. This process also requires documentation. Prescriptions should also be correctly written, time limited, and ensure that total doses are less than BNF guidelines.

iii. A clear and established process of review which includes evaluation of effectiveness and treatments.

iv. Side effects associated with PRN medication should be monitored, taking account of possible interactions and previous allergies.

v. Alternatives interventions should be encouraged, especially at times of restraint.

vi. There is a need to improve the knowledge of staff.

The findings of the Delphi study is due to be published in the Journal of Mental Health.

What do we know about PRN medication?

Patient Issues:

- The main reason for administering PRN is 'request by patient' range 20-37% [3 25 50 56].
- Lack of research focused on patients and PRN [12].
- Some would prefer restraint/seclusion rather than have antipsychotic medications [18].
- There is a great deal of wider literature concerning patients negative experiences of psychotropic medication and acute inpatient mental health settings.

What do experts think about PRN?

A sample of experts was selected on the basis of 'perceived expertness' as demonstrated by combinations of the following factors:

- Professional background.
- Employment at a pre-determined senior clinical / expert level within acute mental health settings.
- Publications or contributions to discussions of PRN psychotropic medication.
- Recommended by a professional group for example, Royal College of Psychiatrists.

1. Remaining focused on the patient

In the U.S. a study identified that a proportion of patients are so opposed to antipsychotic medications that they would rather be restrained or secluded than receive it [18].

Information on medication that is made available to patients is often reported as poor. This is especially the case with PRN medications. Members of the MDT have acknowledged they are at times selective in the information they provide and to whom, especially in relation to side effects:

I am not convinced that all the time patients are fully aware or educated about the reasons for taking PRN.
Ward Manager

We won't tell them side effects without them asking.
Staff Nurse

You would give them more information about the medication that you want them to take, and only sort of give the negative side of other tablets that you didn't want them to take.
Charge Nurse

Clinical staff are obviously concerned that providing patients with such information may impact on whether they take the medication or not. However, it needs to be remembered that all inpatients have a fundamental right to this information, especially those detained under the Mental Health Act [19]. Honesty and transparency in what we do as clinicians is a crucial part of working collaboratively with patients. This has been found to increase concordance and treatment outcomes [20 21]. Patients report little control over the prescribing or administration of PRN medications. They are unsure when they are entitled to it and for what reasons.

1. Remaining focused on the patient

The staff have the power over the patients, mainly to do with the PRN because they can give it you at will. It's not prescribed at a certain time to actually give it you. So they can just give it whenever they feel like. They have too much power.

Patient

PRACTICAL TIP

Ask the patient how they would like to use PRN medication?

Why not implement this within their clinical management plan?

PRACTICAL TIP

Does the patient have sufficient knowledge of medication to choose which one they would prefer?

PRACTICAL TIP

Talk the patient through their medication chart, maybe give them a copy or write down the medication they are prescribed, what it is used for and when they would benefit from that particular PRN. This discussion can then lead on to giving the patient more information about their medication including side effects.

What do we know about PRN medication?

Administration issues:

- Approximately 80% of inpatients receive psychotropic PRN medications [5 6].
- 'Agitation' (12 to 100%) and 'insomnia' (15 to 25%) are commonly cited reasons for the administration of PRN, (with patient request).
- PRN is most likely to be given out evening to night time (>50%) [3 22 24 31].
- PRN is more likely to be given out in the beginning of the week [3 5 22 52].
- PRN is most likely to be given out within the first 4 days of admission [3 5 6 25 50].
- There is a sub-group of people who continue to have PRN [31].
- There is a sub-group of people who have numerous administrations of PRN [27 29 43 50 53].
- PRN medication is often administered at the same times as regularly prescribed medication (>50%) [22].
- Typical antipsychotics and benzodiazepines are most likely to be administered PRN [3 5 6 43 50]. CAMHs also use antihistamines [24 28 51].
- Where there is a choice of dose, the higher one is more likely to be chosen [22].
- 5-12% of PRN is administered IM [5 22 31 54 55].
- Effectiveness of PRN ranged from 32% to 80%. Effectiveness is an ill defined concept with only one study attempting to evaluate effectiveness of PRN [29].
- No systematic recording of side effects/negative effects associated with PRN. Only 3 studies attempted to identify side effects of PRN.

Prescribing issues:

- The prescribing aspect of PRN is crucial [42].
- PRN is routinely prescribed on admission which can lead to a failure of assessment and documentation [43].
- PRN contributes to high doses– 31% of total antipsychotic dose, 28% of total benzodiazepine dose, these are often hidden [44 6].
- PRN contributes to polypharmacy. 64% of those on an atypical will have a typical prescribed PRN [6]. 76% prescribed and received 2+ antipsychotic [6].
- The clinical justification for either high doses or polypharmacy is criticised [34].
- Single prescriptions continue to offer O/IM routes against recommendations [45].
- Prescriptions are often incomplete or vague, for example statements such as 'agitation' are regularly cited as indications for use [6 24 30]
- Overall review of PRN is lacking, review dates are not established [23 46]. USA studies describe the positive effects of automatic stop dates, one off doses (STAT) vs PRN, and improving behavioural interventions [27 47-49].
- Typical antipsychotics and benzodiazepines are most likely to be prescribed PRN [3 5 6 43 50]. CAMHs also use antihistamines for sedation [24 28 51].
- Nurses are prescribing by proxy [9].

Prescriptions for PRN medication need to be correctly written, with specific attention to:

- Drug name
- Appropriate indication for use
- Non-ranged dose
- Total daily dose to be administered
- Signed
- Single route per prescription
- Polypharmacy
- Within appropriate limits, for example, BNF
- Considered limiting the length of the prescription (Expiry/review or stopping date)

Correct prescriptions form the basis of good practice and undoubtedly influence administration habits of nursing staff. The Royal Colleges of Psychiatry and Nursing, Midwifery Council have produced numerous good practice documents for prescribing and administration of medications [15 16 17].

Prescriptions should be written to ensure total daily doses of a drug can be calculated. Prescriptions should not contain dose ranges or multiple routes of administration (e.g. oral/im). This is because there are different rates of absorption of a drug depending on the route it is administered. This results in different amounts or dosages of the drug being absorbed and so effects the daily total of medication given. For example, the recommended maximum daily ORAL dose for Haloperidol is 30mg, but only 18mg intra-muscularly. Where dose ranges are prescribed evidence suggests the maximum will usually be administered without reviewing its effectiveness [22].

Indications for use tend to use jargon, for example *agitation* or *severe agitation*. Agitation is an imprecise and ill-defined term [12 23-26]. Interview data suggests these words mean different things to different professional groups.

The evidence suggests that without a time limit or stop date, prescriptions can continue until discharge. Examples have been provided of patients being discharged home with PRN medications which they had not been receiving whilst in hospital. A time limited prescription has been found to encourage medication reviews and improved regular prescribing practices. A study which implemented STAT doses instead of PRN prescriptions identified a significant reduction in the use of PRN [27]. They also found that restraint, seclusion, physical aggression also decreased without a subsequent increase in regular doses, they concluded that PRN exposed patients to unnecessary psychotropic medication.

PRACTICAL TIP

i). Avoid routinely prescribing PRN medications of haloperidol and lorazepam.

ii). Remember to do separate prescription for each route of administration and avoid dosage variations.

iii). Doctors and nurses should remind one another about good quality prescriptions as it saves time in the long run, and reduces the risk of medication errors.

This section includes summaries of data collected which has informed the 9 key principles. This includes the systematic literature review, a Delphi project with experts, interviews with multi-disciplinary team and patients.

What do we know about PRN medication?

The systematic literature review examined all written materials of psychotropic PRN medications within inpatient mental health settings published in the last 30 years. Fifty two documents were included within the systematic literature review. These originated from a variety of countries. Most studies focused on adult inpatient settings including forensic, although a few focused on child and adolescent (CAMHs) inpatient settings. The following is a summary of the findings from this review.

Wider/MDT issues:

- There is no robust research evidence to support the use of PRN [7].
- Lack of documentation is a major theme which has hampered all case note analysis studies of PRN
- There is a poor knowledge base associated with PRN medications. There are clear differences between the knowledge and preferences between doctors and nurses [9 11]. Differences also occur between the MDT and Patients. PRN is rarely taught and does not appear in text books [41].

Project Supervision

Supervision of the project is provided by Professor K Lovell (The University of Manchester) and Dr N Harris (Consultant Nurse/Lecturer, Manchester Mental Health and Social Care Trust).
Additional support has been received from a project steering group which includes clinical and management representation from the 3 mental health trusts in Greater Manchester:

- Manchester Mental Health and Social Care NHS Trust
- Pennine Care NHS Trust
- Bolton, Salford and Trafford Mental Health Trust)

3. PRN in a clinical management plan.

The use of psychotropic PRN medications should form part of the patient's clinical management plan. This has the advantage of providing:

- A rationale (considered thought) for its use
- A coherent clinical plan for PRN
- Makes PRN use explicit
- Prevents PRN prescriptions being hidden
- Ensures the use of PRN is managed by the MDT
- Facilitates dialogue with the patient

PRACTICAL TIPS

Is the use of PRN clear within the care plan?

Has the patient seen and agreed to the care plan?

Have you given a copy of this plan to the patient?

Is this process documented?

4. Evaluation of use.

PRN medications should be regularly monitored for:
- Effectiveness
- Side effects

There is no *high quality evidence* of the effectiveness of PRN medication[7]. This was attributed to a lack of robust research evidence. There are a number studies which have reported the effects of PRN medication. These studies report effectiveness from 32% [28] to 80% [29]. The imprecise definitions of effectiveness mean that these figures should be viewed with extreme caution. The evidence cited as indicative of 'effectiveness' is often drawn from documented terms such as *'settled'*. These terms are incredibly ambiguous.

There are difficulties associated with measuring the side effects of PRN medication. This is because they are rarely given in isolation. Only three studies have undertaken any evaluation of side effects associated with PRN usage [28 30 31]. Side effect monitoring within inpatient settings is consistently reported as poor [10]. However it is clear that mixing atypical and typical antipsychotic medications exacerbate side effects and have long term health implications [32 6].

Ethical issues

- Special attention is paid to
  - Informed consent [38] especially with those detained under the Mental Health Act, or those experiencing acute psychotic symptoms [39].
  - The burden and stress associated with participation in research, which can potentially impact on an individual's mental health [40]
- All participants have the right to withdrawal from the study.
- Any patients which the multi-disciplinary team or researcher have identified as being unable to make informed consent will be excluded from the study.

Dissemination of findings

The outcomes from the project will be a validated, patient-focused clinical protocol and training package for staff working within acute mental health settings. The protocol and package will be disseminated through:

- The NHS Trusts mental health trusts in Greater Manchester where different stages of the research project have been conducted.
- Care Services Improvement Partnerships (National Institute of Mental Health England).
- Publications of findings and methodology in papers in professional and academic journals and at conferences.
- The development of a one day feedback conference.
- A full report will be submitted to the Health Foundation, the supporter of the research project.
- A short report will also be published on a website to enable wider access.

Approval for research

This research project has been scrutinised by two ethical committees, the North West Multi-centre research ethics committee (ref: 04/MRE08/48) and The University of Manchester ethics committee (ref: 04277). The research project has also been assessed by the research governance committees of Manchester Mental Health and Social Care NHS Trust, Pennine Care NHS Trust, and Bolton, Salford and Trafford Mental Health NHS Trust.

All groups have favourably reviewed this study.

Ethical issues

- All participants involved in the study will be given an invitation letter and an information leaflet.
- Having received study information 48 hours delay must occur before an individual can be recruited into the study.
- All data will be anonymous and will not be traceable to individuals.
- The author is aware of the burden associated with research and will endorse the rights of patients and staff not to participate in the research.
- Participants have a right to receive a report on the outcomes should they request it.

4. Evaluation of use.

PRACTICAL TIP

When administering a PRN medication what is the effect that is required?

Evidence suggests that if there is a dose range you will give the higher dose – Why is this?

How do you know that 3mg of lorazepam isn't as effective as 4mg?

PRACTICAL TIP

Try undertaking a rating scale such as LUNSERS to establish side effects that are being experienced [33].

5. PRN requires frequent review.

Review should be:

- By the multi-disciplinary team
- Regular and consistent
- Triggered with excess *(should form part of the regular prescription)* or no use *(should be stopped)*

and take account of patient's views

Clinical staff suggested that all medication is reviewed at ward round and this *probably* included PRN psychotropic medication. The review process of PRN psychotropic medications appears vague. Interviewees implied that review of PRN medication did not occur often enough. The only clear trigger for review is when nursing staff identified an 'issue'.

Regular review of PRN medication is one of the recommendations of the Royal College of Psychiatrist recent consensus statement on high dose antipsychotic medication [34].

PRACTICAL TIPS

i. Ensure PRN medication is reviewed at every ward round and that this is documented.

ii. Stop dates help to reinforce the review process.

Dissemination of the clinical protocol with inpatient staff.

This manual details the key principles with expanded content drawn from previously collected data. Posters summarising the key principles will be distributed to the wards for display in pertinent areas. Training in the principles will also be provided. This will be offered to all Medical and Nursing staff working within the selected wards. Training would be compressed into short slots (max. 30 minutes) to enable use of handovers, SHO training, consultants meetings. The focus of the training will concentrate on dealing with stigma and challenging unfounded beliefs about PRN medication. Spare copies of this manual will be made available for the wards.

Figure 1: Research project timeframe.

Week	W/C	Site
1	4th Sept	Consenting*
2	11th Sept	Consenting*
3	18th Sept	Data Collection (1)
4	25th Sept	Data Collection (1)
5	2nd Oct	Data Collection (1)
6	9th Oct	Data Collection (1)
7	16th Oct	Implementation & Training
8	23rd Oct	Implementation & Training
9	30th Oct	Data Collection (2)
10	6th Nov	Data Collection (2)
11	13th Nov	Data Collection (2)
12	20th Nov	Data Collection (2)
13	27th Nov	Interviews, patients (n=2), MDT (n=5)
14	4th Dec	Interviews, patients (n=2), MDT (n=5)

Aim 2.

Semi-structured interviews will explore the acceptability, usefulness and impact of the implementation of the clinical protocol on practice. This will include patients and members of the MDT (n=15), stratified by professional groups, experience and sites.

6. Enhanced documentation by the Multi-disciplinary team MDT

Documentation of PRN psychotropic medications is scarce regardless of discipline.

The majority of studies reviewed have reported the poor (mostly absent) multi-disciplinary documentation in relation to prescribing and administrating PRN medication, for example:

40% of notes do not record why PRN has been administered[5,6].

64% of notes do not record outcome of PRN[6].

PRACTICAL TIP

Try to improve on your documentation. An entry such as 'PRN given, settled' provides little clinically relevant information. An improved entry may read:

Patient approached. Observed to be pacing, sweating, aroused and verbally describing this irritability. Patient described increased feelings of agitation. 2mg of lorazepam PRN administered orally at 18:10pm at the patient's request. Effects of PRN reviewed 60 minutes later, patient describes and observed to be less aroused, feeling calmer.

7. PRN processes cause patients distress

The administration of PRN can adversely affect the patient's:

- Privacy
- Confidentiality
- Dignity

and cause Stigma

Patients describe these issues for both the prescribing and administration processes of PRN medication:

It shouldn't be called PRN, I know that. 'Cause it's embarrassing when you ask for it, PRN , it's horrible when you get rejected. You should take the patients aside, to stop the embarrassment.

Patient

I think that whatever happens when medication is taken I think it should be taken to the medicine room. I don't think it's right when, say, I was sat in the living room, watching the Simpsons on telly or something, I don't think it's right if the actual nursing staff come with the tablets and say, 'Take this.' I don't think that's very professional, it's not private then.

Patient

PRACTICAL TIP

Location is particularly important; offering tablets or discussing medication with patients in corridors and communal areas increases the stigma and reduces the dignity that they experience. It also makes confidential discussion and further assessment difficult.

What is happening now?

This final stage of the research project has two objectives.

1. **To test the effect associated with the nine principles of good practice of PRN psychotropic medication.**
2. **To test the merits and difficulties of implementing clinical guidelines within acute inpatient mental health settings.**

The implementation of the clinical protocol will be evaluated by a pre-post test design, with data being collected at multiple time points (weekly) throughout the study. Figure 1, details the timeframe of *Implementation & Training* associated with the project which commences on the 4th September 2006.

Aim 1.

Measures will be taken for 4 weeks before and after the *Implementation & Training point.* Data collected will include:

1. A pre-post measure of knowledge and attitudes for all consenting staff [9].
2. Collection of additional data associated with either the prescribing or administration of PRN medication.
3. Audit of case notes at weekly intervals for 4 week prior to and post the *Implementation & Training* point.
4. Evaluation of training materials.

Patient's value time and support from mental health professionals. Patients also benefit from developing coping strategies which they can take with them when they leave hospital. Post-discharge, patients may not have access to PRN medication, nor support from staff as required. This makes it crucial to identify and use alternative non-pharmacological interventions wherever possible. PRN should be the last resort.

97% of mental health practitioners interviewed could identify times when PRN had been used when alternatives would have been preferable. This was due to a variety of reasons including limited skills, experience, pressures of time and low staffing levels.

Numerous alternative non-pharmacological interventions to PRN were proposed. The most commonly cited were spending more time with nursing staff, anxiety management, de-escalation and distraction.

PRACTICAL TIP

Each time you are about to prescribe or administer PRN medication what are the alternatives that could be tried?

Why not recommend one of these and then evaluate its impact.

3. All patients get addicted to benzodiazepines.

Staff express concerns about patients being addicted to benzodiazepines.

> *Some are just addicted to benzos. The only problem we have with PRN medication is with benzos. People who have genuinely been hearing voices will ask for the haloperidol. People who ask for benzos are quite addicted to them. Those people who ask for PRN medication, they'll come and ask for pills, rather than lorazepam.*
>
> *Staff Nurse*

> *They come up to the office and say "I haven't had my Lorazepam". If they are talking about a time since they had their lorazepam, they probably don't need it. They probably want it.*
>
> *Pharmacist*

If patients are only offered PRN when they are distressed it is not surprising that many start asking for it when they feel they need it. There is no evidence to support the belief this constitutes addiction.

4. Dosing associated with Lorazepam.

1mg of Lorazepam is equivalent to 10mg of Diazepam [37]. Whilst they have different half-lives (time the drug remains in the body) it would be very rare to administer or prescribe 40mg of Diazepam in one dose.

5. Polypharmacy/High Doses

PRN contributes to Polypharmacy and High doses of antipsychotic medication. Both have been attributed to worse health outcomes [32 34]

PRACTICAL TIP

Can you think of any other myths relating to PRN medication?

What can you do to challenge these?

Additional training covering PRN medication is required, this should focus on:

- Drug knowledge (nurses, doctors, patients and carers)
- Side effects
- Beliefs and attitudes.

Evidence suggests that mental health staff's knowledge of psychotropic medications is at times limited and individuals may hold negative attitudes towards the role and use of PRN medication. Whilst this represents a wider issue there will be some training provided within this research project. The next section of this manual detail some commonly held beliefs about PRN.

Examples of attitudes affecting the administration of PRN medication include staff concerns that the patient was an 'addict' for using PRN. In particular the use of PRN benzodiazepines results in nurses believing they are:

'good when we (the nurses) say they are'

'bad when you (the patient) ask for them'.

The lack of documentation and clear rationales supporting the use of PRN perpetuate these myths.

PRACTICAL TIP:

Dispel the myths relating to PRN try to ensure that new staff/students are taught about PRN medications.

9. Training and educational for all

Some common myths:

1. **The more antipsychotic you give the greater the effect (high doses)**

Antipsychotic medications work by blockading Dopamine receptors, they are very effective in doing this. Recent guidance suggests that doses of less than 10mg achieve this:

"It would be understandable, however, if clinicians were cautious in prescribing doses in excess of 7.5 mg/day of haloperidol to a person with uncomplicated acute schizophrenia[35]."

2. **PRN antipsychotic medications are good for immediate reduction in psychotic symptoms like voices.**

Antipsychotic medication can take many weeks to work on psychotic symptoms. PRN antipsychotic medication for 'voices' reduces arousal but is unlikely to have an immediate effect on voices.

I have seen patients who has come to the nursing office and they are already on clozapine augmented with risperidone. They are already on quite a lot of antipsychotics. A calm guy just came up and said "I am still having trouble with my hallucinations". The nurse goes and gives him a PRN dose of risperidone and says "This will make you feel better". I just thought no, it won't.

Pharmacist

Antipsychotic medication is often given as a PRN because of its sedative effect yet this is a side effect and as such is not recommended[36]. Sedation is easier to achieve with other drugs such as benzodiazepines and anti-histamines, which do not produce as many unpleasant side effects.