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Multidisciplinary consensus of best practice for pro re nata (PRN) psychotropic medications within acute mental health settings: a Delphi study

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Multidisciplinary consensus of best practice for pro re nata (PRN) psychotropic medications within acute mental health settings: a Delphi study

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.

Keywords: 'as required', Delphi panel, expert opinion, mental health, pro re nata (PRN), psychotropic medication

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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% and 90% of patients within inpatient mental health settings studied received PRN psychotropic medications on one or more occasions (Geffen *et al*. 2002, Curtis & Capp 2003). Psychotropic PRN drugs most frequently used in inpatient mental health settings are; anxiolytics (diazepam and lorazepam) and antipsychotics (haloperidol), followed by hypnotics and anticholinergics (Geffen *et al*. 2002, Curtis & Capp 2003). 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*. 2002, Whicher *et al*. 2003). Despite the welcomed advice regarding rapid tranquilization 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 tranquilization (National Institute of Clinical Excellence

2005), Maudsley prescribing guidelines (Taylor *et al*. 2005) and those that focus on high doses of antipsychotics (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.

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 hypothesize the outcome and effect of Russian nuclear attack on the munitions output of the USA (Dalkey & 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 because of attrition (Keeney *et al*. 2001). A minimum return of 70% per round is essential to maintain the rigour of the Delphi study (Walker & Selfe 1996, Sumison 1998). There are conflicting views of sample sizes for Delphi studies, and the numbers of participants have ranged from seven to more than 1000 (Walker & Selfe 1996, Hasson *et al*. 2000). The optimum range appears to be 7–20 respondents, with no less than seven (Linstone & Turoff 1975, Philips 2000).

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 predetermined senior clinical level within acute mental health settings, for example, Nurse Consultant specializing 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 multidisciplinary clinicians specializing in acute inpatient mental health care from three 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, College of Mental Health Pharmacists, the Association of Nurse Consultants, CSIP and the National Association of Psychiatric Intensive Care Units. 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*. 2006).

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 (Fig. 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 multidisciplinary clinical protocol. Reminders were sent a maximum of three times using a variety of media including electronic, postal and telephone contact.

Data analysis

Data were analysed using SPSS™ 13 (SPSS 2003). Ratings of items were on a 7-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 & Webb 1994). This study focused on two. First, a predetermined criterion of consensus was established as those items which received only 100% positive ratings (5, 6 or 7) without disagreement were retained (Williams & Webb 1994). After three rounds, the stability of responses for the items selected as

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?

Figure 1
Four Delphi questions. PRN, pro re nata

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 (Landis & Koch 1977) strength of agreement has been applied to these results. Values ≥0.4 have been suggested as the minimum required, and this criterion was applied to the remaining items (Hripcsak & Heitjan 2002).

Ethical issues

The study had Multi-Centre Research Ethics Committee 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.

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 complete questions about their expertness (Kennedy 2004). The panel consisted of four 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 specializing in acute inpatient care and four acute leads for the CSIP. Five panel members were not working in a current clinical role. Of the 15 not participating, eight replied, but were unable to commit because of a variety of reasons, and no response was received from the remaining seven. Non-participants included three psychiatrists, 10 nurses and two 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 randomized within the four questions and in the second round, participants were asked to rate the importance of each item on a 7-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 redistributed 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 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 1) (Hripcsak & Heitjan 2002). High kappas indicated statements where panellists did not change opinions between rounds 2 and 3.

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,

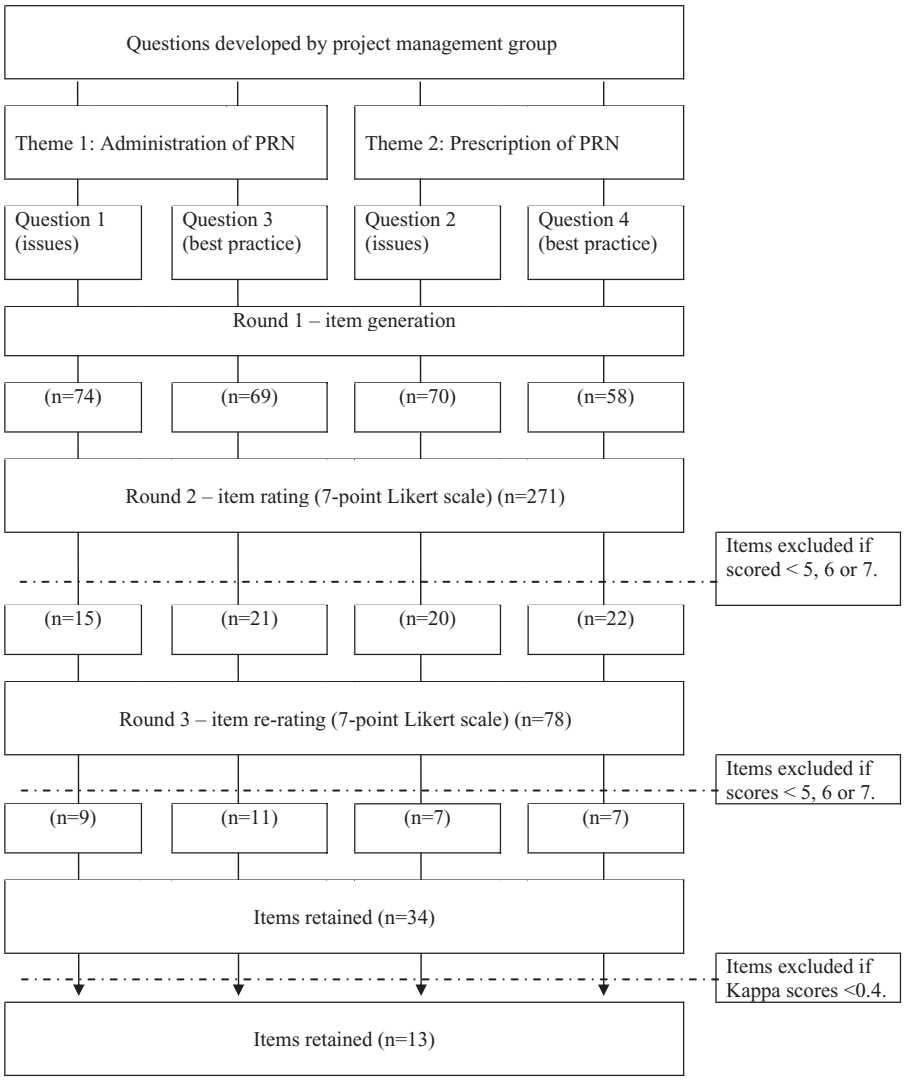

Figure 2
Flow chart of statement reductions. PRN, pro re nata

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. First that service users should be more involved in all processes associated with PRN psychotropic medications. This process should be individualized, 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, Taylor *et al.* 2005, Royal College of Psychiatrists

Table 1
Remaining 13 consensus statements after round 3

		Round 3 item scoring			Item stability (kappa statistic)				
	Statement	% 6 or 7	Mean	SD	Agreement	% agreement	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	0.00–0.86	Moderate
93	Awareness of potential side effects	77.8	6.3	0.8	16/18	88	0.78	0.48–1.00	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	0.45–1.00	Substantial
137	Consideration of side effects and additional drug interactions/allergic reactions	83.3	6.2	0.7	12/18	67	0.41	–0.04–0.85	Moderate
139	Any allergies are known, prior to administration	88.9	6.7	0.7	14/18	78	0.48	0.09–0.87	Moderate
165	Clear goals underpinning the use of PRN	88.9	6.5	0.7	13/18	72	0.46	0.07–0.85	Moderate
195	Clear description of indications	88.9	6.4	0.7	14/18	78	0.65	0.28–1.00	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	0.35–1.00	Substantial
212	Time-limited prescription of PRN medication, with regular review	94.5	6.6	0.6	13/18	72	0.53	0.12–0.94	Moderate
217	Knowledge of any advance directive(s) related to PRN medication	88.9	6.2	0.6	15/18	83	0.67	0.34–1.00	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	0.01–0.83	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	0.27–1.00	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	–0.04–0.84	Fair

PRN, pro re nata.

2006). 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 optimize the quality and importance of those items retained. The manner by which items were deleted does mean that one individual can assert a substantial effect. Of those 237 items deleted, 44.7% ($n = 106$) had been scored negatively by only one individual. This accounted for 36.8% ($n = 71$) and 81.4% ($n = 35$) of items deleted from rounds 2 and 3. This is a respected criterion for achieving consensus (Williams & Webb 1994). Those items remaining do, however, fulfil a number of the established criteria for consensus as established in the literature (Salmond 1994, O'Brien *et al*. 2003). 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 72–100%). All means for the final statements were >6 (range 6.1–6.7), 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 0.5–0.8). 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 National Health Service, CSIP and Higher Education Institution's. 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.

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 regard to these items is needed to evaluate effects within clinical practice.

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References

Baker J.A., Lovell K., Easton K., *et al.* (2006) Service users' experiences of 'as needed' psychotropic medications in acute mental healthcare settings. *Journal of Advanced Nursing* **56**, 1–9.

Baker J.A., Lovell K. & Harris N. (2007) Mental health professionals' psychotropic pro re nata (p.r.n.) medication practices in acute inpatient mental health care: a qualitative study. *General Hospital Psychiatry* **29**, 163–168.

Beech B. (2001) The Delphi approach: recent applications in health care. *Nurse Researcher* **8**, 38–48.

Bowers L. (2005) Reasons for admission and their implications for the nature of acute inpatient psychiatric nursing. *Journal of Psychiatric and Mental Health Nursing* **12**, 231–236.

Cohen J. (1960) A coefficient of agreement for nominal scales. *Educational and Psychological Measurement* **20**, 37–46.

Curtis J. & Capp K. (2003) Administration of 'as needed' psychotropic medication: a retrospective study. *International Journal of Mental Health Nursing* **12**, 229–234.

Dalkey N. & Helmer D. (1963) An experimental application of the Delphi method to the use of experts. *Management Science* **9**, 458–467.

Department of Health (2005) *New Ways of Working for Psychiatrists: Enhancing Effective, Person-Centred Services through New Ways of Working in Multidisciplinary and Multi-agency Contexts*. Department of Health, London.

Fink A., Kosecoff J., Chassin M., *et al.* (1984) Consensus methods: characteristics and guidelines for use. *American Journal of Public Health* **74**, 979–983.

Geffen J., Sorensen L., Stokes J., *et al.* (2002) Pro re nata medication for psychoses: an audit of practice in two metropolitan hospitals. *Australian and New Zealand Journal of Psychiatry* **36**, 649–656.

Hardy D., O'Brien A., Gaskin C., *et al.* (2004) Practical application of the Delphi technique in a bicultural mental health nursing study in New Zealand. *Journal of Advanced Nursing* **46**, 95–109.

Hasson F., Keeney S. & McKenna H. (2000) Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing* **32**, 1008–1115.

Hripcsak G. & Heitjan D.F. (2002) Measuring agreement in medical informatics reliability studies. *Journal of Biomedical Informatics* **35**, 99–110.

Jones M., Bennett J., Gray R., *et al.* (2005) Developing medication management capacity through mental health nurse prescribing. *Mental Health Practice* **8**, 20–23.

Keeney S., Hasson F. & McKenna H. (2001) A critical review of the Delphi panel technique as a research methodology for nursing. *International Journal of Nursing Studies* **38**, 195–200.

Kennedy H. (2004) Enhancing Delphi research: methods and results. *Journal of Advanced Nursing* **45**, 504–511.

Landis R.J. & Koch G.G. (1977) The measurement of observer agreement for catagorical data. *Biometrics* **33**, 159–174.

Linstone H.A. & Turoff M. (1975) *The Delphi Method: Techniques and Applications*. Addison-Wesley, Reading, MA.

National Institute of Clinical Excellence (2005) *Violence: The Short-Term Management of Disturbed/violent Behaviour in In-patient Psychiatric Settings and Emergency Departments*. National Institute of Clinical Excellence, London.

O'Brien A.P., O'Brien A.J., Hardy D., *et al.* (2003) The New Zealand development and trial of mental health nursing clinical indicators – a bicultural study. *International Journal of Nursing Studies* **40**, 853–861.

Philips R. (2000) New applications for the Delphi technique. *2000 Annual V.2: Consulting* **2**, 191–195.

Royal College of Psychiatrists (2006) *Consensus Statement on High-Dose Antipsychotic Medication*. Royal College of Psychiatrists, London.

Salmond S.W. (1994) Orthopaedic nursing research priorities: a Delphi study. *Orthopaedic Nursing* **13**, 31–45.

SPSS (2003) *SPSS for Windows*. SPSS Inc., Chicago, IL.

Sumison T. (1998) The Delphi technique, an adaptive research tool. *British Journal of Occupational Therapy* **61**, 153–156.

Taylor D., Paton C. & Kerwin R. (2005) *The Maudsley Prescribing Guidelines 2005–2006*. Taylor & Francis group, London.

Walker A.M. & Selfe J. (1996) The Delphi method: a useful tool for the allied health researcher. *British Journal of Therapy and Rehabilitation* **3**, 677–680.

Whicher E., Morrison M. & Douglas-Hall P. (2003) '*As Required' Medication Regimes for Seriously Mentally Ill People in Hospital*. The Cochrane Library, Oxford.

Williams P. & Webb C. (1994) The Delphi technique: a methodological discussion. *Journal of Advanced Nursing* **19**, 180–186.