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Abstract

The aim of this audit was to review current practice within a rural mental health service area on the monitoring and documentation of side effects of antipsychotic depot medication. Following a review of the literature on best practice internationally, an evidence based audit tool was adapted. A sample of 60 case files, care plans and prescriptions were audited between January and May 2010. This represented 31% of the total number of service users receiving depot injections in the mental health service region (n=181). The audit results revealed that most service users had an annual documented medical review and a documented prescription. However, only 5 (8%) case notes examined had documentation recorded describing the condition of the injection site and alternation of the injection site was recorded in only 28 (47%) case notes. No case notes examined had written consent to commence treatment recorded, and only 3 (5%) of case notes had documented that information on the depot injection and side effects was given. In 57 (95%) of case notes no documentation of recorded information on the depot and on side effects was given. Documentation of physical observations and tests revealed that 58% of cases had full blood count, liver function tests, thyroid function tests and fasting lipids recorded. All other tests (i.e. temperature, pulse, respirations, blood pressure, ECG) were recorded in less than 50% of cases. Prolactin levels were not recorded in any case. The lack of written consent was partly attributed to lack of recording of consent. The failure to monitor and record some

blood tests was partly attributed to a lack of clarity regarding whose responsibility it was. A standardised checklist has been developed as a result of the audit and this will be introduced by all teams across the service.

Key words: audit, depot antipsychotics, side effects

Background

Depot antipsychotic medication was developed as an additional method of drug delivery in the 1960s in order to promote concordance with medication taking, reduce relapse rates and improve functioning in individuals with a diagnosis of schizophrenia (Marland & Sharkey 1999). The potential benefits of depot medication are cited as improving treatment adherence, early detection of relapse and reduction in hospitalization, along with a reduced risk of accidental or deliberate overdosing. Furthermore, depots are reported as providing a more consistent drug delivery (Patel & David 2005).

Prescribing guidelines advocate for choice and joint decision making between service users and their clinician, based on informed discussion of benefits and side effects of the medication (NICE 2002). It is recommended that atypical and typical antipsychotics should not be prescribed concurrently except for short periods to cover changeover of medication (Nice 2002, American Psychiatric Association 2006, Taylor *et al.* 2009). However, it is estimated that up to 40% of people with schizophrenia take two or more antipsychotics (Canales *et al.* 1999). Guidelines also acknowledge that high doses of antipsychotic medications may have a limited role in the treatment of schizophrenia (NICE 2002), and the practice is strongly discouraged (Royal College of Psychiatrists 2006). In addition, anticholinergic medication should be

prescribed with caution with depot antipsychotics and the dose regularly reviewed, as they can sometimes exacerbate side effects. Moreover, Anticholinergics carry a range of side effects and have the potential to be abused (Williams 1999).

Adverse events associated with depot medication include pain at the injection site (Bloch *et al.* 2001), akathisia (Millera *et al.* 1997), sexual side effects (McCann 2000) and risk of metabolic side effects (Gumber, Abbas &Minajagi, 2010). Studies indicate that there may be a high risk of metabolic syndrome in individuals with a diagnosis of schizophrenia independent of medication; regular monitoring for abnormalities is therefore recommended (Thakore *et al.* 2002, Ryan *et al.* 2004). The international Diabetes Federation characterises metabolic syndrome as having central obesity with waist circumference greater than 40 inches in males and greater than 36 inches in females and two of the following: raised triglycerides, reduced high density lipid cholesterol, raised blood pressure, raised plasma fasting glucose (International Diabetes Federation 2006).

A collaborative recovery focused practice is paramount. Nurses play a key role in educating service users on the benefits and side effects of medications; this supports informed decision making regarding accepting the medications (NHS Plymouth 2009). The administering of depot medication is also an important aspect of this role (Gray 2007). Administration of depot medication is reported as a therapeutic nursing intervention facilitating the development of the relationship between nurse and service user as well as providing a forum where psychosocial and clinical issues can be addressed in a collaborative manner (Phillips & McCann 2007). Opportunities to engage in health promotion and deliver holistic nursing care can be seized upon

at each administration of the depot. In addition, assessing for side effects supported by the use of evidence based rating scales is recommended (Morrison *et al.* 2001, Jordan *et al.* 2002). Furthermore, ensuring patient safety must always be of the highest priority. Avoiding errors is achieved by ensuring another nurse checks the medication for injection before it is administered, and ensuring that a current prescription is in place (UKPPG 2009).

Structured information giving to service users taking antipsychotic medication is advocated. The basis of consent to treatment is contingent on the service users having adequate information offered in an accessible medium supporting the notion of partnership working (Campbell 1996). This information provision has been found to improve concordance with treatment (Chaplin & Kent 1998). Good record keeping and adhering to documentation standards is seen as essential for safe service users' outcomes and supports good nursing practice (Bowler *et al.* 2000). However, an audit of psychiatric case notes in relation to antipsychotic medication and information giving in the UK found lack of provision of such information in over half of the case notes audited, and where information was provided it was on an *ad hoc* basis (Bowler *et al.* 2000).

Aims and objectives of the audit

The purpose of this audit was to evaluate the monitoring of side effects of depot antipsychotic medication prescribed to service users in an Irish rural mental health service area with the aim of improving and standardising practice across the region. This region offers an adult mental health service to a rural population of approximately 110,000 in Ireland. The area is served by four general adult mental health teams, and three specialist teams (i.e. a rehabilitation team, psychiatry of later life team, and Intellectual Disability team).

Methods

A sub working group of a interdisciplinary Clinical Audit Steering Group in the region consisting of an Advanced Nurse Practitioner (ANP) in mental health, a senior pharmacist, a clinical nurse manager, an assistant director of nursing, a medical registrar and a consultant psychiatrist developed the audit plan. Formal approval for audit in the service is provided by senior management.

Because the study was classified as audit, ethical approval from the regional health service ethics committee was not required. However, audit governance was followed and no personal data was collated that would identify individuals or breach confidentiality.

A literature review was initially undertaken to determine international best practice guidelines on the prescribing, administration and monitoring of depot antipsychotic medication. A standard of documentation was then developed on which the audit tool was based (Table 1).

The audit tool used was an adapted version of the Prescribing Observatory for Mental Health (POMH-UK) clinical audit tool for monitoring the side effects of depot antipsychotic medication. The audit tool included questions on physical parameters and a biochemical test that can indicate a diagnosis of metabolic syndrome (by evaluating waist circumference, blood lipids, and blood pressure and fasting glucose). The audit tool also included a checklist for

documentation of evidence for the monitoring of side effects of depot antipsychotic medication, including the service user's consent for each injection, a six monthly prescription in the service user's file, and the condition of the injection site. Moreover, the tool sought evidence of site rotation, whether a reliable scale that measures neuroleptic-induced parkinsonism was used, whether an antipsychotic side effect rating scale was used and monitoring of sexual and menstrual side effects.

Table 1

Standard for audit of documentation of the monitoring of side effects of depot antipsychotic medication

<ul style="list-style-type: none">• Documentation of informed consent at commencement of treatment and annually thereafter.• Documentation of continued consent at each administration of injection.• Documentation of six monthly prescription• Documentation of condition of injection site and evidence of site rotation at each injection• Documentation of annual medical review.• Documentation of evidence of use of Glasgow Antipsychotic Scale and the Simpson Angus Scale to monitor side effects.• Documentary evidence of physical side effects monitoring• Documentary evidence of sexual and menstrual side effect monitoring
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The sample of case notes, care plans and prescriptions audited was 60. Two sampling strategies were used. A disproportionate stratified random sampling was used to select ten service users'

notes from each of the four community mental health teams within the health service region, and from the intellectual disability service (n=50). Convenience sampling was used with the remainder all of the service users receiving depot injections in the psychiatry of later life (n = 5) service and rehabilitation service (n =5). The audit was undertaken between January and May 2010.

Results

The sample of case notes, care plans and prescriptions audited was 60 (32 male and 28 female) (Table 2). This represented 31% of the total number of service users receiving depot injections in the mental health service region (n=181).

Table 2: Age range of audited service users

18-25: Number =1 (1 %)
26-35: Number = 6 (10 %)
36-45: Number = 9 (15%)
46-55: Number = 15 (25%)
56-65: Number = 16 (27%)
65 and over: 13 = (22%)

The sample audited had a range of diagnoses, as follows: schizophrenia, schizo-affective disorder, bipolar affective disorder, depression, alcoholic hallucinosis, and autism. The majority of depot injections were administered on home visits (29/60), 12 were administered at the nursing clinic, 4 at the day hospital, 4 at the day centre, 9 on the hospital ward, 1 at a training centre and 1 in a community residence. 56 (93%) of case notes had an annual medical review

documented and 4 (7%) did not. 65% of case notes examined had a documented prescription and 45% had none. Only 5 (8%) case notes examined had documentation recorded describing the condition of the injection site, while 55 (92%) had no recorded documentation of the injection site condition. Alternation of the injection site was recorded in 28 (47%) case notes. No recorded documentation of alternation of injection site was evident in 32 (53%) case notes.

Regarding service users' consent, no case notes examined had written consent to commence treatment recorded. 24 (42%) of case notes had documented verbal/non verbal consent to continue treatment recorded and 35 (58%) had no documentation of this. Only 3 (5%) of case notes had documented that information on the depot injection and side effects was given. 57 (95%) of case notes had no documentation of information on depot and side effects given.

The administration of additional medications was also audited. 39 (65%) of the sample were being administered additional antipsychotics and 21 (35%) were not. One service user was taking three oral anti psychotic medicines, 13 were taking two oral anti psychotic and 25 service users were taking one anti psychotic. 36 (60%) were taking anticholinergics and 24 (40%) were not.

Documentation of physical observations and tests revealed that 58% of cases had a full blood count, liver function tests, thyroid function tests and fasting lipids recorded. All other tests (i.e. temperature, pulse, respirations, blood pressure, ECG) were recorded in less than 50% of cases. Prolactin level was not recorded in any case.

Side effects were not recorded in 37 (72%) of cases. Two of the Community Mental Health Teams were monitoring and recording side effects using locally developed checklists derived from the literature in 15 (25%) of the cases. These checklists were informed by the findings and recommendations of studies on the subject topic undertaken by Jordan *et al.* (1999) and Jordan, *et al.* (2002). There were no side effects in 17 (28%) of cases and side effects were present in 8 (13%). No physical examination to assess side effects was recorded in 58 (97%) of cases. Only 2 (3%) of cases had a recorded physical examination of side effects. Weight was recorded in 32 (53%) of cases, but waist circumference was not measured or recorded in any case. No assessment of sexual side effects or menstrual irregularities was recorded.

In 18% of cases there was documentation to say that movement disorders were not present on assessment. In the remaining 82% of the sample there was no documentation to say that a movement disorder was assessed.

Discussion

The audit results reveal the need for a consistent approach to the assessment of side effects and movement disorders using valid and reliable assessment scales and the need for adequate information for service users and their carers. The need to gain service users' consent has also been highlighted. In addition, the gap in prescribing and medical reviews requires addressing.

While locally developed checklists scales were used in 25% of the case notes examined, this percentage is low when considering the popularity of using an evidenced based tool in practice

for example the LUNSERS (e.g. Kim & Kim 2009, McCann *et al* 2009, Kim & Byun 2010, Hwang *et al.* 2010). LUNSERS is a self report scale used to assess the level of side effects experienced by individuals prescribed antipsychotic medication (Walker & MacAulay, (2005). However it is considered too lengthy and some one word terms used in the scale may be unclear to patients (Waddell & Taylor 2008). Simple checklists are promoted as possibly the most effective clinical intervention for improving service (Millar *et al* 1999). In view of this and the copyright status of the LUNSERS scale, the audit committee are now promoting the use of the Glasgow anti psychotic side effects scale (GASS). The GASS takes only five minutes to complete and has shown a strong level of agreement with the LUNSERS (Waddell & Taylor 2008). It also has good construct validity and good re-test reliability and uses plain everyday English (Waddell & Taylor 2008). Moreover it is available freely in the public domain for use.

The audit results also reveal that no scale was used in the assessment of movement disorders arising from anti psychotic medicines among service users. The committee are now promoting the use of the Simpson Angus Scale (SAI) (Simpson & Angus 1970). This rating scale has the advantage of being quick and simple to complete (Waddell & Taylor 2009). It is also valid and reliable and the most widely used scale for drug induced Parkinsonism (Knol *et al.* 2010) and is also available in the public domain. It has been agreed that these two scales (i.e. The GASS and SAI) could be completed annually or when a need for medication adjustment is required and at any time if deemed necessary by the clinician.

The audit revealed that one person was on three oral anti psychotics along with a depot. It is

widely recommended that a person should only be on one antipsychotic alone and the combination of typical and atypical antipsychotics should not be used except when transferring from one to another (Patel & David, 2005). The audit did not check doses of depot or equivalence in oral medication, and it may have been the case that some people were on a lower dose of the depot and additional oral medication. Nevertheless, the group agreed that it was good practice to ensure that the reason for poly pharmacy was documented.

The lack of written consent to commence treatment was attributed to this not being a mandatory requirement in the prescribing guidelines. However, as a service it is seen as best practice to obtain formal written consent at commencement and annually thereafter. Oral consent will be determined at each administration of depot injection and recoded in case notes. This is currently the practice with Clozapine treatment. Service users sign a specially designed form when commencing Clozapine. This practice should be standard for other anti psychotics too. Due to the low percentage in the provision of information to service users, the committee propose accessing user friendly information leaflets available from the Royal College of Psychiatrists (www.Rcpsych.ac.uk) to support making informed choices.

The low incidence of assessment and recording of blood pressure and weight has resulted in the group recommending that the current local monitoring checklist used for Clozapine be modified for use with antipsychotic drugs. Prolactin level will also be assessed and recorded on the new form that will be adopted. An increase in serum prolactin increases the risk of sexual dysfunction among men and women taking anti psychotics (Rettenbacher *et al.* 2010). Furthermore Higgins

(2007) reports a lack of emphasis on the impact of drugs on sexuality reported in nursing literature where emphasis is placed on extra pyramidal symptoms side effects.

The lack of evidence for prescription in 35% of cases was attributed to the current book of prescriptions used which does not facilitate placing a copy in the notes. However no depot medication is dispensed from the hospital pharmacy without a current prescription. In future it is mandatory that a copy of the prescription is also filed in the case notes.

Many service users express fears about taking anti psychotic medication (Brad *et al.* 2010) and they value the time health professionals spend on monitoring their physical health. The audit results prompted discussion among the team on whether it is the responsibility of the GP or the Mental Health Service team for monitoring blood tests and ECGs. For instance, in some of the Community Mental Health Teams ECGs were being read by the doctors on the team and advice sought from a cardiologist where appropriate. It was agreed that the standard should be that the results of a blood test are available in the chart and it was the responsibility of the key worker to ensure this happens.

The audit team have met and discussed the findings, and standards were agreed by the group (Table 3). A checklist is being developed to monitor for the onset of metabolic disorder, assessing its physical and biochemical criteria as per best practice guidelines.

Table 3 Standard for documentation of the monitoring of side effects of depot antipsychotic medication (post audit)

- Documentation of informed consent, signed at commencement of treatment and at annual medical review.
- Documentation of continued consent, recorded each time an injection is given.
- Documentation of six monthly prescriptions, with a copy of a prescription in the patients chart.
- Documentation of condition of injection site and evidence of site rotation at each injection, recorded in the case notes.
- Documentation of annual medical review. Recorded in the casenotes, including Simpson Angus Rating Scale.
- Documentation of evidence of monitoring FBC, LFT, Fasting Glucose, Fasting Lipids, Prolactin, Weight and waist circumference at 3 months and annually thereafter.
- Documentary evidence of physical side effects monitoring, using GASS annually.

Limitations

There are a number of limitations with this audit. There were no in-house service practice guidelines for the delivery of care for service users prescribed antipsychotic medication. This led to the finding of variations in documentation across the service regarding the monitoring of blood tests, physical examination, use of scales and prescription files. Secondly, the sampling techniques used means that the case notes audited may not be representative of the total sample. Finally, observer bias is an issue due to the amount of documentation audited posing a difficulty to ensure that data was not missed.

Conclusions

While many aspects of the audit highlighted deficiencies in the monitoring and recording of side effects of depot antipsychotic medication, some other areas of practice revealed encouraging results. The study showed that the majority of individuals (93%) had an annual medical review. Blood monitoring showed an average of 58% of the sample were monitored with the exception of prolactin monitoring. While documented prescriptions were available in 65% of the sample, pharmacy policy necessitates no medication can be dispensed without a current prescription.

The audit highlighted the need for improved clinical documentation. Improvement needs to be undertaken in the areas of information provision and informed consent. Fundamental to collaborative practice is the nurse-patient relationship and this must be nurtured at all times. There is also a need to use evidence based rating scales to assess side effects, movement disorder, sexual and menstrual irregularities, as well as discomfort at injection site.

Finally, consumer feedback is essential in service improvement and care delivery. Gray (2007) supports the practice of measuring patient satisfaction with their experience of receiving depot treatment. This approach will be incorporated into future care delivery. It is envisaged that the new standard developed will be implemented by all clinicians within all multidisciplinary team across the region.

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