

Monitoring adverse drug reactions: scales, profiles, and checklists

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Abstract

Background: Globally, adverse drug reactions (ADRs) make a substantial contribution to ill health. Introducing a systematic approach to patient surveillance could mitigate these problems. Formalized medication monitoring schedules have been proposed as one strategy to diagnose and action side-effects and the problems emanating from adverse drug reactions. To date, most developments have been linked to antipsychotic medications. Several scales, checklists, and side-effect profiles are available, including the West Wales ADR (adverse drug reaction) profile. However, relatively little work has been undertaken on the clinical validity, reliability, and sensitivity of these instruments. **Aim:** This paper describes the development of the monitoring schedule approach to medication management. It also reviews and compares the instruments available for monitoring the adverse drug reactions of antipsychotic medications. The UKU (Udvalg for Kliniske Undersogelser) scale and the West Wales ADR profile assess a broader range of physiological parameters and potential problems than other instruments. However, to be adopted in practice, such instruments must achieve a balance between clinical gain and practical cost, including the time spent in administration. **Conclusion:** Further work is needed to explore the translation of formalized ADR surveillance programmes into clinical gains and improved outcomes for clients.

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Introduction

Much has been written on the burden of disease, often at the expense of the 'burden of treatment'. The increasing prevalence of long-term illness in both the developed and the developing world should encourage health care professionals to acknowledge that the burden of treatment requires

recognition and management in its own right. However, much of this management will focus on care, rather than cure, and may be devolved to nurses, as the major caring profession.

The burden of treatment is particularly important in settings where nurses administer medications associated with a high incidence of adverse drug reactions (ADRs), such as antipsychotic medi-

cations (formerly known as neuroleptics). Chlorpromazine was the first antipsychotic introduced for the management of serious mental illness and schizophrenia, in 1952, soon followed by other phenothiazines and haloperidol. Antipsychotics, including long-acting intramuscular 'depot' injections and the atypical antipsychotics, such as olanzapine and risperidone, are now commonly administered in both specialist and generalist settings. In the developing world, the prescription of antipsychotic medications is increasing, even in the most economically deprived rural communities (Ran et al. 2001).

The wide range of possible adverse effects attributable to antipsychotics has the potential to impact on both the physical and mental health of patients. (These are listed in the profile in Appendix 1.) With many antipsychotic medications the dose range that allows effective control of the disease without causing posture and movement disorders is extremely narrow and varies with the individual (Miller 1997). Consequently, patients receiving such medications often experience distressing ADRs, including Parkinsonism, akathisia, memory loss and sedation. In addition to central nervous system side-effects, patients taking antipsychotic medication often suffer poor physical health: their cardiovascular and respiratory mortality rates and femoral neck fracture incidence are twice that of the general population (Brown 1997; Zaleon & Guthrie 1994). Also, the severe adverse drug reactions associated with antipsychotic medications may exacerbate the patients' mental distress and lead to non-compliance with medication regimens (for a first-hand account see Perry 1998). Diagnosing and managing the ADRs of antipsychotics is essential since, without intervention, some 66% of patients administered long-term antipsychotic medication develop irreversible movement and posture disorders, mainly tardive dyskinesia (Zaleon & Guthrie 1994). Therefore, every available method should be employed to evaluate the potential ADRs suffered by patients prescribed antipsychotic medications.

Recognizing and taking action on adverse reactions is an important aspect of medication management for all drugs, and templates have been published in a recent *Nursing Standard* series (e.g.

Knight & Jordan 2004). However, it is only for antipsychotics that formal monitoring instruments have been developed and investigated.

Checklists, scales, and profiles

One method of increasing the recognition of antipsychotic-induced side-effects is the introduction of checklists, scales, and side-effect profiles, implemented by a range of health care professionals or the patients themselves. One study in New York revealed that without formal surveillance programmes only 5 of 48 cases (10.4%) of tardive dyskinesia were recognized (Weiden et al. 1987). Also, regular structured medication reviews have been shown to improve the clients' quality of life (Awad et al. 1997).

The first instruments for formalizing surveillance of ADRs were developed by neurologists in the USA to assess the novel forms of Parkinsonism and tardive dyskinesias that emerged in the 1960s, in association with antipsychotic usage (Cunningham Owens 1999). These relied heavily on physical examination. Subsequently, these have been developed into scales for assessing specific posture and movement disorders, for example the Barnes scale (Barnes 1989), Simpson & Angus scale (Simpson & Angus 1970), St. Hans rating scale (Gerlach et al. 1993), the Unified Dystonia Rating Scale (UDRS) (Comella et al. 2003), and DIES (Drug-Induced Extrapiramidal Symptom) scale (Inada et al. 2003). They have been adapted for clients with learning difficulties (Kalachnik & Sprague 1993). Possibly the most widely used is the abnormal involuntary movement scale (AIMS), which is designed to detect the early signs of tardive dyskinesia (Guy 1976). It has nine separate observations on movement, including two items of global judgement, an item on patient awareness of potential ADRs, and two items on dental status. Typically, the examination takes between 10 and 12 minutes.

Other checklists, profiles, and scales assess a broader range of potential ADRs. Several global instruments are currently in use to assess ADRs and new ones are continually being developed. For example, the 'side-effect scale/checklist for antipsychotic medication' (SESCAM) is rather shorter than

the other instruments, consisting of 13 observations rated by clinicians and 12 questions (Bennett et al. 1995).

The UKU rating scale is currently the most comprehensive instrument. It assesses 48 possible ADRs, including a range of posture and movement problems, together with other physiological parameters such as heart rate and rhythm disturbances, weight changes, bowel disturbances, dermatological problems, and changes in central nervous system function (Lingjaerde et al. 1987). Similarly the DOTES (dosage record and treatment emergent symptom) scale assesses a broad range of 41 parameters including items on posture and movement, alertness, and cardiovascular, oral, nasal, bowel, and dermatological problems. These instruments compartmentalize the antimuscarinic side-effects, which are intensified in patients with HIV/AIDS.

Both the UKU and DOTES scales are intended to be implemented by trained investigators such as psychiatrists, take up to an hour to administer, and entail extracting information from medical notes. In most clinical settings these factors limit the potential for frequent use. Recently, a self-rated version of the UKU has been developed. This correlates with the traditional UKU in most areas (Spearman's $\rho = 0.48-0.66$, $P < 0.01$) except the assessment of posture and movement disorders (Spearman's $\rho = 0.09$) ($n = 63$). However, items considered unsuitable for self-assessment are excluded: physical and psychological dependence (Lindstrom et al. 2001).

The Liverpool University Neuroleptic Side-effect Rating Scale (LUNSERS) (Day et al. 1995) is designed to be self-administered. LUNSERS, like UKU, assesses a variety of parameters including those related to posture and movement, blurred vision, skin rashes, and mood and concentration disturbances; the correlation (Spearman's ρ) between the total scores for the two scales is reported to be 0.48, $P < 0.01$ ($n = 29$) (Lambert et al. 2003). However, the LUNSERS does not include any direct physiological measurements, such as weight and vital signs.

The West Wales ADR profile is designed to be implemented by nurses undertaking measurements, observations, and questioning. Like other

instruments, it includes items on posture and movement, central nervous system functioning, and autonomic disturbance. The first section is designed to be passed to prescribers with problems and changing situations highlighted. Completion entails measurement of vital signs, weight and girth, and a dietary history. Uniquely, the West Wales ADR profile has a distinct health promotion section, where problems identified can be actioned autonomously by nurses.

Pharmaceutical companies sometimes supply instruments they have developed with their promotional material for the newer, atypical drugs. Some instruments have been developed in conjunction with clinical trials for antipsychotics. Consequently, these focus on rating and scoring, to assess and compare each drug's ADRs, rather than ameliorating and addressing service users' problems. Unlike other instruments, the West Wales ADR profile has no total score, as each potential problem is considered for action individually. The focus is on direct action, such as arranging dental and optician appointments, supplying sunscreen, emollients, or mouthwashes, testing urine, and advising on diet and fluid intake. It also seeks information on all coadministered drugs. (The West Wales ADR profile and guidelines appear in the two appendices.)

Whilst there may be benefits to introducing formal ADR assessments, there is, at present, no standard for monitoring the potential ADRs of antipsychotic medications, and issues of reliability and clinical validity are rarely discussed in the literature.

Reliability and sensitivity

Clinical measurement is, by its very nature, imprecise. Therefore, several strategies are employed to assess the degree of uncertainty in clinical measurements. Reliability is variously defined as the consistency, repeatability, and stability of a test or the minimum error component of a measure (Anthony 1999; Greenhalgh 1997). In this field, reliability of an instrument may vary with clinical setting, subject, and severity of illness. Due to the unequal absorption and elimination half-lives of depot injections, and diurnal variations, plasma concentrations of antipsychotics may fluctuate, causing the client's

side-effects, particularly posture and movement disorders, to vary in severity (Zaleon & Guthrie 1994). This reduces the value of test-retest and stability measurements. In future, digital imaging may offer a more reliable strategy to assess posture and movement disorders (Buchel et al. 1995). Repeating any physiological measurements may be considered to be too intrusive and time consuming for research subjects. Immediately repeating sphygmomanometric readings is ill-advised, due to the risk of vasospasm in the limb (Jordan et al. 2002).

Lack of consistency, or agreement, for most clinical observations is a major problem (Sackett et al. 1991). Discrepancies may arise where observers have different clinical backgrounds, and therefore apply different clinical inferences to the evidence. For example, to obtain data on the West Wales ADR profile, the responses of 20 patients were recorded simultaneously by a fieldworker (SJ) and the patients' nurses. For all items on the profile, the fieldworker detected more problems than the nurses. Agreement was lowest for posture and movement disorders. The nurses knew the patients very well (in some cases for 20 years), and had become accustomed to any abnormalities and idiosyncrasies, which may have led to a redefinition of 'normalcy'; this is termed 'entrapment by prior expectation' (Sackett et al. 1991, p. 38). Where problems are suspected, the guidelines refer users to established posture and movement instruments, such as the AIMS or Barnes scales for more precise assessments. Like others, we found higher inter-rater reliability with questions than observations (Barnes 1989). Questions with a subjective element, such as those about depression and sleepiness, had the lowest agreements.

Despite their popularity, many established scales have little published data on their reliability. Although AIMS is extensively used, the inter-rater reliability, despite training, has been questioned (Bergen et al. 1988). The LUNSERS scale was reliable in a study of 50 patients (Day et al. 1995).

Inter-rater reliability is calculated for each item on an instrument, using Cohen's kappa statistic to assess the strength of agreement between two observers (Anthony 1999; Barnes 1989; Sackett et al. 1991). The value computed represents the pro-

portion of the agreement beyond that which could be attributed to chance (range 0–1) (Altman 1991). Previous work on the agreement in interpretation of physical examination findings between two observers indicates that kappa values above 0.67 are rare (Greenhalgh 1997). Available data indicate that the items on the West Wales ADR profile have moderate-to-good inter-rater reliability (ranging 0.44–1.00), and it is unlikely that such levels of agreement could have arisen by chance alone. (This data is available from authors on request.) Complete agreement when studying inter-rater reliability with instruments in this field is rarely achieved: kappa values as low as 0.29 for scale items on clients' movements and 0.34 for tongue tremor have been reported (Bergen et al. 1988).

Sensitivity is a procedure's ability to identify correctly those individuals who truly have the condition (Cassens 1987, p. 70). This assumes the existence of an objective criterion or 'gold standard' for identifying true positives for the condition. Identifying all 'true positives' may be impossible in ADR monitoring, as some reactions, such as akathisia, have a subjective element, and many others, such as 'abnormal' posture or gait, may be open to interpretation by observers. This may be compensated, in part, by recording changes when medication is introduced or changed.

Internal reliability or homogeneity of scales is usually assessed by statistical tests, such as Cronbach's alpha. However, these instruments are profiles, not scales, and therefore such tests are inappropriate (Lingjaerde et al. 1987, p. 100). Clinically, there may be no correlation between posture and movement problems and constipation, or between weight gain and orthostatic hypotension; therefore, there can be little justification for assessing correlation coefficients between these variables.

Validity

Validity has been variously defined as the relevance and appropriateness of measures and the answer to the 'So what?' question (Anthony 1999; Greenhalgh 1997). In this context, the validity of ADR checklists can only be assessed in terms of clinical outcomes. However, few studies and no randomized trials have

been published which address the clinical validity and utility of ADR checklists, scales, and profiles.

The West Wales ADR profile proved useful in practice. Its introduction with long-term users of antipsychotic medication focused the attention of healthcare professionals on ADRs and increased the number of problems actioned (Jordan 2002; Jordan et al. 2002). More work is needed to explore the hiatus between the paper scales, profiles, and checklists and clinical actions. The guidelines accompanying many instruments focus on the process, rather than the outcomes, of the assessment. Where instruments have been designed to accompany drug trials or encourage a change of medication, from the traditional to the newer antipsychotics, the anticipated clinical actions are clearly defined. However, nursing care encompasses a wider spectrum of actions, which cannot all be addressed by change in antipsychotic medication. The clinical effectiveness of restructuring nursing care to link such actions, from mouth care to weight monitoring, to formalized surveillance systems has not been fully explored, but some suggestions have been made (Morrison et al. 2000). The links between the West Wales ADR profile and clinical actions are included in the guidelines (Appendix 2).

Comparison of scales

Profiling the problems detected by each of six instruments (Table 1) compared the clinical validity and utility of the instruments used to detect ADRs. The selection of items for comparison was based on parameters described by two or more instruments, clinical judgements, and problems highlighted in the BNF (2003), and was free from commercial pressures.

Table 1 lists 43 parameters which could be assessed by a healthcare professional. The table records the number of 'hits' for each of 6 instruments currently used to assess side-effects of antipsychotic medications. A cursory examination of the table reveals that there is variation in the variety of side-effects that each scale will capture. The UKU captures the most parameters (31 out of 43), followed by the West Wales ADR profile (30), the LUNTERS (23), the SESCAM (17), the DOTES (15), and finally the AIMS (5); however, the last is restricted to

posture and movement disorders. These results are summarized in Fig. 1. It is evident that the AIMS instrument provides the most detailed description of abnormal movements. Only the West Wales ADR profile sought information on the wider aspects of health affected by antipsychotic medication, such as diet, sunscreen, and visits to dentists and opticians. While other scales (e.g. DOTES) assess blood pressure, this is the only scale to assess orthostatic hypotension by direct measurement.

Antipsychotic medications can be divided into the traditional antipsychotics, such as haloperidol and pericyazine and the atypical antipsychotics, such as olanzapine and clozapine. The two groups of drugs differ in their ADR profiles. For most patients, the most disabling ADRs associated with traditional drugs are posture and movement disorders, including irreversible tardive dyskinesia. In contrast, patients prescribed atypical drugs are more likely to experience an inner restlessness, known as akathisia, and weight gain. The difference is one of degree, as many traditional drugs can cause weight gain and posture and movement problems arise with the atypical drugs, albeit less frequently. These differences are likely to be reflected in ADR profiles. Therefore, to be valid, instruments used in practice must be as comprehensive as possible, and include the ADRs of both groups of drugs.

When considering the validity of ADR monitoring instruments, investigators should consider their provenance and potential for commercial bias, in that it would be possible to design and develop instruments which unduly favour certain products. This could be achieved by highlighting problems associated with standard therapies and traditional drugs while selectively ignoring ADRs linked to the company's own product. For example, if a company's medication were known to cause weight gain, the monitoring schedule might not require regular records of weight, as these could deter clients and professionals from using that medication.

Limitations of the checklist approach

The development of checklists, scales, and profiles has been based on observational research,

Table 1 Comparison of checklists, scales, and profiles. Comparison of six current checklists for 43 selected parameters, highlighting the problems that will be observed or missed

<i>Measurement, observation or question</i>	<i>West Wales</i>	<i>UKU</i>	<i>AIMS</i>	<i>LUNTERS</i>	<i>SESCAM</i>	<i>DOTES</i>
Heart rate	+	+	-	-	-	+
Irregular heart beat	+	+	-	+ Question only	-	+ on ECG
BP sitting	+	-	-	-	-	+
BP standing	+	-	-	-	-	-
Weight	+	+	-	+ Question only	+ Question only	+
Feet shuffling	+	+	-	-	+	-
Posture abnormal	+	+	-	+ Question only	+	-
Gait abnormal	+	-	-	-	+	-
Hand tremor	+	+	+	+ Question only	+	+
Tongue tremor	+	-	+	-	-	-
Sleepy at interview	+	+	-	-	-	-
Poor concentration	+	+	-	+	-	-
Depressed at interview	-	+	-	+	-	+
Abnormal movements	+	+	+	+ Question only	+	+
Incapacitation due to abnormal movements	-	-	+	-	-	-
Eyesight changes	+	+	-	+	+	+
Sleep changes	+	+	-	+	+	+
Increased dreaming	-	+	-	+	-	-
Memory changes	+	+	-	+	-	-
Energy changes	+	+	-	+	+	-
Emotional indifference	-	+	-	+	-	-
Mood changes	+	-	-	-	-	+
Irritability	+	+	-	+	+	-
Epileptic seizures	-	+	-	-	-	-
Bowel problems	+	+	-	+	+	+
Urination problems	+	+	-	+	+	-
Chest pain	+	-	-	-	-	-
Shortness of breath	+	+	-	-	-	-
Tooth/denture problems	+	-	+	-	-	-
Dry mouth	+	+	-	+	-	+
Increased salivation	-	+	-	+	-	+
Sore throat	+	-	-	-	-	-
Use of alcohol	+	-	-	-	-	-
Use of non-prescription medication	+	-	-	-	+	-
Compliance with medication	+	-	-	-	+	-
Orthostatic dizziness	-	+	-	+	+	+
Skin rash	-	+	-	+	+	+
Pruritus	-	+	-	-	-	-
Changes in sexual function	+	+	-	+	+	-
Dry vagina	-	+	-	-	-	-
Menstrual changes	-	+	-	+	-	-
Breast discharge	-	+	-	-	-	-
Photosensitivity	-	+	-	+	-	-

which is inherently subject to the biases, inconsistencies, and inaccuracies in the instruments, the researchers, and the clinicians. Such data cannot necessarily be transferred to settings

where the prevalence of the conditions under consideration is different (Altman 1991). The low numbers involved in many of these studies indicate that these findings must be interpreted

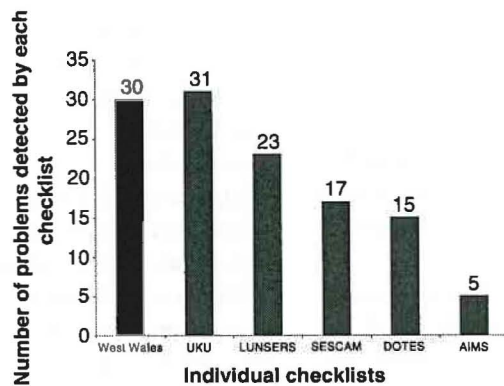


Fig. 1 Comparison of checklists.

with caution and regarded as preliminary data only.

Feasibility

An 'ideal' checklist would be simple and quick to complete, while capturing all the important clinically relevant data. Where instruments and questions are too brief, they may fail to collect useful information. For example, we found that the simple questions on 'adequate' diet and fluid intake were insufficient to elicit sufficient detail: problems emerged only with specific questioning in the follow-on health promotion section of the West Wales ADR profile. When optimizing both convenience and rigour, the needs of the patient must be balanced with the constraints of the services.

Professionals' time taken in recording all the parameters in the monitoring schedule must be taken into account. Client-administered instruments are particularly attractive in this respect. Some instruments (UKU, DOTES) require a specialist, such as a psychiatrist, for implementation, and this detracts from their feasibility in routine practice. Uniquely, the West Wales ADR profile was designed to be implemented by mental health nurses, and the guidelines have been designed to be as objective as possible to facilitate incorporation into existing pre- and postregistration education programmes (Jordan et al. 1999).

The potential stress incurred by the client during the monitoring process should be considered: a shorter instrument may well prove less stressful. We suggest that it may well be more beneficial, and equally feasible, to complete a longer profile incrementally.

Physical examinations

'Traditional nursing work' includes vital signs (BP, HR, temperature, respiration), weight, and fluid balance charts. However, it cannot be assumed that these parameters are monitored regularly in community and long-term care settings. For example, Fahey et al. (2003) report that, among patients diagnosed as hypertensive, 47% in long-term care and 15% in the community had not had blood pressure recorded in the last year. Such measurements are time-consuming. In another screening study, we found that the item most frequently omitted was the only physiological measurement required (Jordan et al. 2003). Also, without guidelines, we cannot be sure that nurses are interpreting their physiological measurements with any reference to medication administered.

Some aspects of the neurological examination are incorporated into posture and movement assessments and rating scales and nurses may be reluctant to undertake this without further training. Only the LUNSERS entails no physiological measurements, which contributes to its ease of administration.

Self-administration

Only the LUNSERS is self-administered by the clients. This has advantages in terms of health professionals' time and in ensuring a client-centred approach to monitoring. However, in the authors' experience, some clients are unable to read, are too agitated to do so, or do not have access to their reading glasses. Vision may also be compromised by the antimuscarinic effects of antipsychotic medication. Nurses also need to ensure that clients comprehend the questions, rather than assume a response set bias. (Male clients have been observed to tick the boxes indicating that menstrual irregularities are problematic.)

Ethical issues

All the checklists described here may serve to raise clients' awareness of potentially irreversible problems. It is essential that such distress be counterbalanced by the clinical gains arising from actioning adverse drug reactions and health promotion deficits.

The LUNSERS scale contains 41 items plus 10 questions which are considered invalid or 'red herring' items. The LUNSERS scale offers a rating, each item is scored 0–4, with a separate score for the 'red herring' items, designed to detect 'high scorers' or nocebo responders. However, some of the 'red herring' items could arise as a result of side-effects, for example, mouth ulcers could arise from xerostomia and runny nose from alpha blockade included by antipsychotics. This 'red herring' label could be distracting clinicians from addressing important problems, particularly dental hygiene. There is also the ethical issue of professionals informing clients that they are scoring 'side-effects' but in reality scoring another parameter, that is, 'responsivity' to questionnaires.

The way forward

ADR monitoring offers opportunities to obtain the clients' perspectives of their physical and mental health problems, and some instruments offer guidelines to address such problems. Inclusion of practical advice, which can be followed by nurses or carers, independently of prescribers, expands the opportunities to improve care. We suggest that ADR monitoring should not focus solely on the switch to newer, atypical antipsychotics.

In their seminal paper, Cochrane & Holland (1971) state that, before adoption, all assessment and screening procedures should be tested for: clinical effectiveness, accuracy, sensitivity, and specificity. Unfortunately, this is not always done. To be clinically worthwhile, monitoring with checklists, scales, profiles, and screening instruments should meet certain criteria:

- 1 Is the monitoring sufficiently sensitive to detect the clients' problems?
- 2 Once identified, can problems be treated?

- 3 Does the burden of treatment and suffering warrant the time spent in monitoring?
- 4 Can the services cope with the extra work of monitoring?
- 5 Are resources available to action any positive findings or care deficits identified?
- 6 Will positive findings be pursued?
- 7 Is the monitoring evidence-based?
- 8 Has the monitoring proved effective in prospective randomized trials?

Due to lack of resources, our work has been unable to answer many of these questions for the West Wales ADR profile. It was not always clear if resources would be available to treat the problems identified. For example, it emerged that many clients needed to see a dentist, but this would not necessarily be easy: for example, some clients in rural areas lived 50 miles from the nearest NHS dentist, a journey of 3 h by public transport. Although the nurses did not detect all the problems apparent to the researcher, it should be remembered that many of the clients had been attending the clinics regularly for a considerable time without any of these problems being actioned or passed to prescribers. Therefore, any problems detected represented an advance on existing care. However, even where both nurse and researcher found an important clinical problem, there could be no guarantee that the prescriber would, in turn, agree with their findings.

Further work is needed to explore the effectiveness of channels of communication between those monitoring the clients and medical prescribers (Jordan et al. 2002). In the UK, this will be formalized by the introduction of supplementary nurse or pharmacist prescribing, supported by clinical management plans (DoH 2003). The mechanisms for 'notification of suspected or known reactions to any medicine which may be prescribed under the plan' (paragraph 48) must be described within this documentation; however, the incorporation of ADR monitoring instruments into clinical management plans has not been investigated.

Summary and conclusions

Simple checklists are one of the most effective methods of improving patient care and medication man-

Box 1 Monitoring adverse drug reactions: implications for practice

- Wherever medications are prescribed, adverse drug reactions (ADRs) are an important cause of morbidity.
- Strategies to systematically detect and action ADRs are not always incorporated into practice. Therefore, the burden of treatment is higher than it needs to be.
- An antipsychotic ADR profile, such as that in Appendix 1, detects many previously unsuspected ADRs and physical health problems and can be incorporated into routine practice.
- The numerous omissions, imprecise nature, and practical difficulties of some instruments, together with any lack of resources to action problems identified, may detract from the usefulness of this approach.
- Further work is needed to explore the clinical effectiveness of the West Wales ADR profile in a range of settings.

agement (Leveille et al. 1998). All six instruments examined capture a range of ADRs related to the long-term use of antipsychotic medications, and all have potential to improve and standardize care. Previous studies have demonstrated that nurse-administered checklists have been effective at highlighting previously unrecognized problems related to both mental (Millar et al. 1999) and physical health (Jordan et al. 2002). However, if instruments are not assessing certain key clinical parameters, such as orthostatic hypotension, vision and diet, this will limit their clinical effectiveness in all situations. Only the West Wales ADR profile addresses these issues; while this instrument requires further development, it offers potential as a focus for nurse-led client-centred care (see Box 1).

Development of systematic strategies to alleviate the 'burden of treatment' is in its infancy. Even if checklists, profiles, and scales can be shown to be reliable, it is important to consider their clinical effectiveness and validity. The value of formally documenting ADR monitoring, and communicating these findings within multidisciplinary teams, has not been investigated: other strategies may prove to be more acceptable to stakeholders. Whether formalized surveillance by scales, profiles, or checklists can improve patient outcomes should be explored in prospective, international studies, funded from non-commercial sources.

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Appendix I West Wales ADR profile for antipsychotic medication

The purpose of this assessment is to identify any problems. The first sheet may be attached to the clinic notes and passed to the prescriber.

Observation		Comments. Please note any changes	Actions	
Heart rate	bpm			
Irregular rhythm	<u>Yes/no</u>			
BP lying/sitting	/ mmHg			
BP standing	/ mmHg			
Weight/BMI	kg kg/m ²			
Temperature	°C			
Oxygen saturation	%			
ECG	Abnormalities <u>yes/no</u>			
Potential problem		Problem worsening	Comments. If problem is worsening, state for how long this has been so.	Actions
Hand tremor	<u>Yes/no</u>	<u>Yes/no</u>		
Tongue tremor	<u>Yes/no</u>	<u>Yes/no</u>		
Feet shuffling	<u>Yes/no</u>	<u>Yes/no</u>		
Abnormal movements	<u>Yes/no</u>	<u>Yes/no</u>		
Posture abnormal	<u>Yes/no</u>	<u>Yes/no</u>		
Gait abnormal on walking	<u>Yes/no</u>	<u>Yes/no</u>		
Changes or problems with:				
Dizziness (particularly on standing)	<u>Yes/no</u>	<u>Yes/no</u>		
Injection site, e.g. pain	<u>Yes/no</u>	<u>Yes/no</u>		
Sleep problems	<u>Yes/no</u>	<u>Yes/no</u>		
Sleepy/sedated	<u>Yes/no</u>	<u>Yes/no</u>		
Memory	<u>Yes/no</u>	<u>Yes/no</u>		
Concentration	<u>Yes/no</u>	<u>Yes/no</u>		
Energy	<u>Yes/no</u>	<u>Yes/no</u>		
Mood	<u>Yes/no</u>	<u>Yes/no</u>		
Irritability or aggression	<u>Yes/no</u>	<u>Yes/no</u>		
Eyesight	<u>Yes/no</u>	<u>Yes/no</u>		
Bowel control	<u>Yes/no</u>	<u>Yes/no</u>		
Constipation	<u>Yes/no</u>	<u>Yes/no</u>		
Urination	<u>Yes/no</u>	<u>Yes/no</u>		
Reproductive health	<u>Yes/no</u>	<u>Yes/no</u>		
Chest pain	<u>Yes/no</u>	<u>Yes/no</u>		
Being short of breath	<u>Yes/no</u>	<u>Yes/no</u>		
Dry mouth/hypersalivation	<u>Yes/no</u>	<u>Yes/no</u>		
Sore throat	<u>Yes/no</u>	<u>Yes/no</u>		
Alcohol over-use	<u>Yes/no</u>	<u>Yes/no</u>		
Non-compliance with medication	<u>Yes/no</u>	<u>Yes/no</u>		
List of medicines prescribed by doctors (including GP)	None			
Other problems, not listed				

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Health promotion issues related to antipsychotic medication

Diet/intake: list everything eaten yesterday:

Breakfast
Lunch/dinner
Tea/dinner
Supper
Snacks
Number of cups of tea/coffee _____
Number of soft drinks _____

Potential problem

2 or more meals (1 cooked) eaten daily on 6 of last 7 days
Fruit eaten every day for 6 of the last 7 days
Is fluid intake at least 1.2 L per day?
Are sugar-free drinks used?
Indigestion or heartburn
Medicines used for this

Comments

No/yes
No/yes
No/yes
No/yes
No/yes
No/yes

Actions**Dentists**

Problems with teeth or dentures
Dentist visit in last 6 months
Dentist visit in last 12 months

No/yes
No/yes
No/yes

Opticians

Optician visit in last 6 months
Optician visit in last 12 months

No/yes
No/yes

Sunlight

Is sunscreen available?
Does the client apply it evenly?
Is the sunscreen adequate?
Does the client wear dark glasses in bright sunlight?

No/yes
No/yes
No/yes
No/yes

Medicines

List of medications obtained without prescriptions

None

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Appendix 2 Guidelines for assessment West Wales profile of antipsychotic adverse drug reactions

Vital signs

Observations	Comments/actions
Heart rate Irregular rhythm BP lying sitting BP standing	Normal range 55–90 beats per minute. Any irregularities or abnormalities will indicate the need for an ECG 1 min should elapse between the 2 measurements. If systolic BP falls by >10% on standing, this indicates postural hypotension. If heart rate also rises by >10%, this indicates dehydration. Hypertension is defined as >140/90, severe hypertension >115/200 mmHg (Berg 1999) ¹ .
Weight/BMI	Clients should be weighed at the same time, on the same scales, wearing the same clothes, after voiding. A change of 0.5–1 kg in 1 week or of more than 2.4 kg in 1 month is important. Weight gain should trigger blood glucose and/or thyroid assessment. Chlorpromazine, clozapine, and olanzapine have been associated with diabetic ketoacidosis. Therefore, regular measurement of blood glucose is recommended. BMI* 20–25 is ideal. <19 indicates underweight. 25–30 indicates overweight. >30 indicates obese. If no records or equipment available, clients may be asked height. The bnf.org website can then be used to calculate BMI. Waist circumference (measured above iliac crest) may be useful to assess cardiovascular risks of central obesity. This should be less than 88 cm (35 inches) in women & 102 cm (40 inches) in men. Unintentional weight loss of 2.4 kg in 1 month is significant.

Observations	Comments/actions
Temperature	Normal is $36.8 \pm 0.4^{\circ}\text{C}$. Important to obtain baseline in case neuroleptic malignant syndrome or infection develop.
Oxygen saturation if appropriate	Below 97%, contact doctor for advice. Not always reliable in heavy smokers. Useful in elderly or if respiratory or cardiac disease present. Included in tranquillization protocols. Hypoxia is an important cause of aggression, confusion, and restlessness.
ECG if possible or as guidelines advise, see BNF (2003)	Report all abnormalities. These ECG changes provide a warning that serious cardiac events may arise suddenly, without further warning signs and symptoms. QT interval may be prolonged by antipsychotic, lithium, and tricyclic therapy, excitement, hypokalaemia, hypomagnesaemia, hypocalcaemia, and eating disorders. Some people are poor metabolizers of antipsychotic medication, and vulnerable to cardiac arrhythmias. Check for these conditions, if possible. A prolonged QT interval is diagnosed if $QT > 456$ ms or 11 small squares. QT interval = start of Q to end of T. Heart block is another potential problem, particularly if clients are prescribed tricyclic antidepressants or lithium. Heart block is diagnosed if the PR interval > 200 ms or 5 small squares. PR interval = start of P to start of Q.

BNF (2003); Taylor et al. (2001).

*BMI = weight (kg)/height (m²).

*Since this paper was written, the British Hypertension Society has given new figures for severe hypertension of 7180/110 mmHg (Williams et al. 2004).

Observations and questions. For some items, it may be advisable to take a view of the last 72 h, rather than an instant assessment. If problems are worsening, this could be particularly important. We cannot always be sure of the cause of the clients' problems

Potential problem	Descriptions and actions
Hand tremor	With fingers stretched out and a sheet of paper placed on top, is the paper seen to vibrate? Vibration of more than 1 inch indicates a problem. OR Does tremor interfere with activities of daily living? For example, tying shoelaces, drinking, writing. Consider Parkinsonism and administer the St. Hans scale.
Tongue tremor	Ask client to protrude tongue gently for 30 s. Is there a fine tremor of the tongue when mouth is open? Consider tardive dyskinesia and administer the AIMS.
Feet shuffling	Involuntary movements of feet when sitting or standing. Administer Barnes akathisia scale.
Abnormal movements	Involuntary movements as if chewing or sucking. Movements of fingers or sudden jerking movements. Does client feel restless? Distinguish from mannerisms, particularly in those with learning difficulties. Administer AIMS and/or Barnes scales.
Posture abnormal	Stooping. Reduced facial expression. Consider Parkinsonism and administer the St. Hans scale.
Gait abnormal on walking	Observe the client when walking for: reduced movements (e.g. arm swings), small steps, shuffles, feet dragging, knees bent, stiffness.
Changes or problems with:	
Dizziness (particularly on standing)	Any falls or stumbles? Feeling light headed, particularly on standing for a long time or suddenly. Recheck BP lying and standing.
Injection site, e.g. pain	Injections becoming more painful or lumps forming around the injection site. Is injection 'wearing-off' early? Consider oral medication or injecting into the ventrogluteal site.
Sleep problems	Is sleep lasting 2 h more or less than at last enquiry?
Sleepy/sedated	Yawning, appears drowsy, sleeping 2+ h of daytime. Consider sleep apnoea if client is obese or is reported to snore heavily. Check oxygen saturation if client is obese.
Memory	Failing memory hampers everyday life.
Concentration	Difficulties in concentrating are hampering everyday life. Check oxygen saturation in the elderly.
Energy (lack of)	Needs to rest often. Resting/tiredness interferes with everyday life.
Mood	Expressions of 'hopelessness' 'helplessness' OR 'agitation'
Irritability or aggression	Expressions of hostility. Consider physical pain and akathisia. Check oxygen saturation
Eyesight	How close to the TV does the client need to be? Does client bump into furniture?
Bowels	Seek history of: incontinence, diarrhoea, pain, blood.

Continued

Constipation	Bowels open less than twice per week. Should be every 36 h
Urination	Seek information on: incontinence, urgency, pain/burning/blood/smell. Consider retention of urine. Test urine for UTI. If urine stream poor or hesitant, consider enlarged prostate.
Reproductive health	Seek information on: breast discomfort (gynaecomastia/galactorrhoea); menstrual irregularities; dry vagina; change in libido; erectile/ejaculatory dysfunction. Discuss with same sex nurse.
Chest pain	Associated with a need to lie down or sweating or nausea may be very serious. Arrange ECG.
Being short of breath	Client is breathless on moderate exercise, e.g. climbing stairs. Arrange ECG.
Dry mouth/hypersalivation	Causes client to drink excessively or suck sweets. Observe inside of mouth. Does it look dry? Are mouth ulcers visible? Consider mouthwashes. Is hypersalivation socially inconvenient?
Sore throat	Sudden onset. Client feels hot to the touch. Arrange urgent full blood count. Remote possibility of blood dyscrasia. Risk increased if carbamazepine is coprescribed.
Alcohol	Increase in drinking since client was last asked. More than 2 alcoholic drinks on any one occasion in the last 7 days is sufficient to cause excessive drowsiness.
Compliance with medication	Are once-daily medicines taken at the same time each day with a full glass of water? Are twice-daily medicines taken 12 h apart and thrice-daily taken 8 h apart?
List of medications prescribed by doctors (including GP)?	Check in BNF and standard reference works.

Health promotion issues related to antipsychotic medication

Potential problem	Comments/actions
Diet	
2 or more meals (1 cooked) eaten every day for 6 of the last 7 days.	Consider: Loss of appetite. Client becoming withdrawn or disturbed. Problems with eating, e.g. dentures
Fruit eaten every day for 6 of last 7 days	Guidelines recommend 5 portions (15 ounces/375 g) of fruit or vegetables daily
Is fluid intake at least 1.2 L per day?	Fluid intake minimum is 1.2 L + 1 L taken within solid food
Are sugar-free drinks used?	E.g. diet coke, lemonade
Indigestion or heartburn	Taking oral medication with milk may help
Medicines used for this	E.g. antacids, Bisodol, Rennies, Gaviscon. Avoid administration within 2 h of oral medication
Dentists	
Problems with teeth or dentures	Mouthwashes may be helpful. Chlorhexidine gluconate reduces plaque formation. Check for signs of ulceration.
Dentist visit in last 6 months	6 monthly visits recommended. Oral hygienist may be helpful.
Dentist visit in last 12 months	
Opticians	
Optician visit in last 6 months	Since clients have increased risks of eye problems, visits should be more frequent than biannual. At least yearly.
Optician visit in last 12 months	
Sunlight	
Is sunscreen available?	Does the client have access to sunscreen throughout the year? Important for all skin types.
Does the client apply it evenly?	No gaps left.
Is the sunscreen adequate?	The sunscreen should have a high factor (15+) and high stars (at least 4)
Does the client wear dark glasses in bright sunlight?	These should be sufficiently darkened.
Medicines	
List of medications obtained without prescriptions	'Cold cures', indigestion medicines, antihistamines are all likely to interact. Heavy use of paracetamol could be problematic.

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