

FR/ID/09

Psychotropic drug prescribing for people with intellectual disability, mental health problems and/or behaviours that challenge: practice guidelines

Faculty of Psychiatry of Intellectual Disability

FACULTY REPORT

Faculty Report FR/ID/09

April 2016

© 2016 The Royal College of Psychiatrists

The Royal College of Psychiatrists is a charity registered in England and Wales (228636) and in Scotland (SC038369).

| Contents

| | |
|---|----|
| Working group | 2 |
| Foreword | 4 |
| Executive summary and recommendations | 5 |
| Background | 7 |
| Mental health and behaviours that challenge | 9 |
| Approaches to prescribing | 10 |
| Prescribing standards and recommendations | 14 |
| Appendix 1. Self-assessment framework | 15 |
| Appendix 2. Examples of case notes | 16 |
| Appendix 3. Key resources | 20 |
| References | 21 |

Working group

Chair and Editor

Dr Regi Tharian Alexander, Consultant Psychiatrist, St John's House, PiC LDS, Norfolk and Clinical Research Lead Consultant, Leicestershire Partnership NHS Trust

Co-Editors

Dr David Branford, pharmacist expert in the field of intellectual disabilities and mental health and Previous Chair, English Pharmacy Board, Royal Pharmaceutical Society

Dr John Devapriam, Consultant Psychiatrist and Clinical Director, Leicestershire Partnership NHS Trust, National Professional Advisor (Learning Disability), Care Quality Commission and Chair, Quality Network for Learning Disability, Royal College of Psychiatrists

Members

Dr Ezhil Anand, Consultant Psychiatrist, Bradford District Care NHS Foundation Trust

Professor Sabyasachi Bhaumik, Honorary Chair, University of Leicester and Consultant Psychiatrist, Leicestershire Partnership NHS Trust

Dr Jane McCarthy, Consultant Psychiatrist, East London NHS Foundation Trust and Vice-Chair, Faculty of Psychiatry of Intellectual Disability, Royal College of Psychiatrists

Dr Ashok Roy, Consultant Psychiatrist, Coventry and Warwickshire Partnership NHS Trust and Chair, Faculty of Intellectual Disability, Royal College of Psychiatrists

Dr Rory Sheehan, Academic Clinical Fellow, Division of Psychiatry, University College London

Consultation group

Ms Kerry Barnaby, Practice Nurse (Lead for Learning Disabilities), Ancora Medical Practice, Scunthorpe

Mr Jonathan Beebee, Nurse Consultant, PBS4, Southampton

Dr Harm Boer, Consultant Forensic Psychiatrist for people with intellectual disability, Coventry and Warwickshire Partnership NHS Trust

Ms Denise Farmer, Pharmaceutical Adviser Health and Justice Commissioning, NHS England (Central and East Anglia Area Team)

Dr Michael Fitzpatrick, parent and General Practitioner

Dr Ignatius Gunaratna, Consultant Psychiatrist, PiC LD Services, Burston House, Norfolk

Dr Anjana Hari, General Practitioner, Craven Arms Medical Practice, Shropshire

Mr Ian Hulatt, Mental Health Advisor, Royal College of Nursing

Dr Thrisha John, General Practitioner, Groby Surgery, Leicester

Dr Deepa Joy, General Practitioner, Ancora Medical Practice, North Lincolnshire

Dr Theresa Joyce, National Professional Advisor for Learning Disabilities, Care Quality Commission

Ms Karina Marshall-Tate, Clinical Pathway Lead, Bethlem Royal Hospital

Dr Mary Langan, parent and Academic Consultant, Open University

Dr Paul Lelliott, Deputy Chief Inspector of Hospitals (Mental Health), Care Quality Commission

Dr Anjana Ranjit, General Practitioner, Jiggins Lane Medical Centre, Birmingham

Dr Saquib Muhammad, Consultant Psychiatrist, Leicestershire Partnership NHS Trust and Second Opinion Appointed Doctor, Care Quality Commission

Dr Raja Aezad Naseem, Speciality Registrar and locum Consultant Psychiatrist, Lexden Hospital, Colchester, Hertfordshire Partnership University NHS Foundation Trust

Dr Mini Nelson, General Practitioner, Long Stratton Medical Partnership, Norfolk

Ms Ann Norman, professional lead, Criminal Justice Nursing and Learning Disability Nursing, Royal College of Nursing

Dr Rahul Rai, Speciality Registrar, East London NHS Foundation Trust

Dr Susan Smith, Consultant Psychiatrist, Leicestershire Partnership NHS Trust and Second Opinion Appointed Doctor, Care Quality Commission

Ms Sue Stewart, parent and advisory group member of Quality Network for Learning Disabilities, Royal College of Psychiatrists

Ms Zandrea Stewart, Autism Lead, Association for Directors of Adult Social Services

Dr Jovanka Tolmac, Consultant Child and Adolescent Psychiatrist, Central and North West London NHS Foundation Trust

Dr Simon Wood, Principal Second Opinion Appointed Doctor, Care Quality Commission

Foreword

People with intellectual disabilities are as likely, or more likely, than the general population to experience mental health problems, including mental disorders such as depression and psychotic disorders. When they do, they should have the same expectation as the general population that they will receive high quality mental healthcare – whether that is a psychological therapy or medication.

If prescribed judiciously, medication can relieve mental distress and shorten an episode of depression or psychosis. However, if the wrong medication is given, or if it is given at too high a dose, or for too long or in an inappropriate combination with other medications, it can do more harm than good. The harm can range from unpleasant but time-limited symptoms such as drowsiness to effects that can be life-threatening – either in the short-term because of toxic drug effects or in the long-term because of drug effects on metabolism.

There is compelling evidence that a significant number of people with intellectual disabilities are prescribed psychotropic medication that, at best, is not helping them. In particular, there is a risk

that doctors are prescribing medication to treat behaviour that is an expression of distress or a mode of communication rather than a mental disorder. Some people with intellectual disabilities have difficulty communicating their emotional needs and preferences. Therefore, doctors have a particular responsibility to ensure that they have fully assessed a person's potential to benefit from medication before they prescribe. They must also check that the anticipated benefits have occurred after they have prescribed.

Every doctor who might prescribe psychotropic medication for people with intellectual disabilities should read this report, as should nursing staff who care for people with intellectual disability. Those responsible for commissioning should ensure that services are following the guidance. The Care Quality Commission will be paying particular attention to this aspect of prescribing in its future inspections.

Dr Paul Lelliott
*Deputy Chief Inspector
Mental Health, Care Quality Commission*

Executive summary and recommendations

There are ongoing concerns that psychotropic drugs are used inappropriately in people with intellectual disability.

This good prescribing practice guidance, aimed at primary and secondary healthcare clinicians, proposes standards for improving clinical practice in this area. It covers the prescription of any psychotropic medication, including antipsychotics, antidepressants, anxiolytics and mood stabilisers, and sets out a framework for clinicians on how to rationalise their prescribing practice and, where appropriate, taper and stop psychotropic drugs. It also serves as a resource for those providing a statutory second opinion.

Intellectual disability is a condition characterised by significant impairment of both intellectual and adaptive functioning, with onset before the age of 18.

People with an intellectual disability develop psychiatric conditions at rates similar to or higher than the general population. Recording of diagnoses can be problematic in patients who are unable to give a clear verbal account of their symptoms. In clinical practice, it can happen that a psychiatric diagnosis is recorded only when the main syndromes are present, while the narrative account of psychopathology is omitted. This clearly contributes to the problem of under-recording of psychiatric diagnoses and the inability to adequately monitor prescriptions.

A significant proportion of people with intellectual disability display 'behaviours that challenge'. This is a descriptive term and not a diagnosis. It covers a wide range of presentations and can be related to communication difficulties, environmental stressors, physical health problems, psychiatric disorders or, in many cases, a combination of these. A careful assessment of the presentation is therefore required before making decisions about treatment, particularly prescribing.

Just recording the indication for prescribing as 'behaviours that challenge' is not precise enough. All patients for whom prescribing is considered should have a full diagnostic evaluation that covers:

- the degree of intellectual disability
- the cause of intellectual disability (including syndromes, behavioural phenotypes, etc.)
- other developmental disorders (including autism spectrum disorders, hyperkinetic disorder, etc.)
- any mental illnesses, personality disorders, disorders related to substance misuse or dependence
- physical disorders (including any of the causes of the intellectual disability)
- psychosocial stressors (longstanding issues as well as recent environmental changes)
- types of behaviours that challenge.

In this diagnostic formulation, behaviour that challenges is not treated as a diagnosis *per se*, but as a presenting symptom that is placed in the context of a range of biopsychosocial factors.

Prescribers should accurately record all relevant diagnoses and, equally importantly, the narrative that underpin them.

If the diagnosis is such that there are no mental disorders and the behaviour that challenges is the result of psychosocial factors, there might be no role for prescribing other than in the very short term to alleviate a serious risk to the safety of the patient or others while other, non-pharmacological programmes are implemented to manage the behaviour.

On the other hand, if an independent mental illness or disorder is diagnosed, treatment should follow established guidelines for that condition. Medications are effective at the same doses as for those without an intellectual disability and there is no clear evidence that they have more side-effects.

However, side-effects and potential drug interactions should be monitored carefully, particularly in those with more severe degrees of intellectual disability.

Because presentations are rarely straightforward in clinical practice, there is often a combination of several symptoms and this might not clearly meet the criteria for the categorical diagnoses of a mental illness. In those cases, there should be clear identification of the affective, psychotic and behavioural symptoms or clusters of symptoms that are the target of treatment with medication. If the identified target symptoms are not improving satisfactorily within 3 months, then that drug should be tapered or stopped and other options considered. Clinicians should be aided in this process by the range of clinical guidelines that have been published.

Clinicians should be aware that although off-label prescribing is not inappropriate, unlawful or unethical in itself, it can be if not done properly. When prescribing off-label, they should follow guidelines that are published by regulatory bodies like the General Medical Council and ensure that their practice would be considered to be of an adequate standard by their peers.

The prescribing clinician should explain the proposed treatment to patients, their families and carers. This may involve providing information in an easy-to-read format, making reasonable adjustments and involving independent advocates. There should be a record of the patient's consent and capacity, any best-interests decisions, timeframes for reviews and the tapering off or stopping of drugs that are ineffective.

The tapering off or stopping of drugs that are ineffective will be aided by a careful recording of progress (or otherwise) with medication using standardised outcome measures that can be quickly and easily rated (e.g. Clinical Global Impression scale).

This report sets out four over-arching prescribing standards and makes six recommendations to inform future practice in this area. Examples of clinical case-note entries consistent with good practice and a self-assessment framework for evaluating prescribing practice are provided in the Appendices.

Standards for psychotropic drug prescribing

- The indication(s) and rationale for prescribing the psychotropic drug should be clearly stated, including whether the prescribing is off-label, polypharmacy or high dose.
- Consent-to-treatment procedures (or best-interests decision-making processes) should be followed and documented.
- There should be regular monitoring of treatment response and side-effects (preferably every 3 months or less, at a minimum every 6 months).
- Review and evaluation of the need for continuation or discontinuation of the psychotropic drug should be undertaken on a regular basis (preferably every 3 months or less, at a minimum every 6 months) or whenever there is a request from patients, carers or other professionals.

Recommendations

- 1 All psychotropic prescribing should adhere to the four prescribing standards above.
- 2 All initiations of psychotropic drugs for people with intellectual disability, whether from primary or secondary care, should be by a prescriber who is competent in the care of people with intellectual disability.
- 3 Psychotropic drug prescribing should be seen as part of a wider multidisciplinary and holistic care plan.
- 4 Regular reviews of the drugs should occur either according to NICE quality standards or when requested by the patient, carer or other professionals.
- 5 There should be a national audit on prescribing practice that takes into account all the standards mentioned above.
- 6 Regulators and commissioners should use these standards for quality checks on services.

Background

There have been concerns that psychotropic drugs, in particular antipsychotics, are used inappropriately in people with intellectual disability for the treatment of behaviours that challenge (Molyneux *et al*, 1999; Matson *et al*, 2000; Brylewski & Duggan, 2004; Tsiouris, 2010). These concerns were amplified by the Winterbourne View abuse scandal, in which the inappropriate use of psychotropic drugs was highlighted (Department of Health, 2012a,b). The Learning Disabilities Census (Health & Social Care Information Centre, 2015) raised further concerns with its finding that 72% of patients with intellectual disability in hospitals had received antipsychotic medication either regularly or as needed in the 28 days prior to census collection (compared with 73% in 2014 and 68.3% in 2013; Health & Social Care Information Centre, 2013, 2014).

As a consequence, three separate projects were completed to ascertain current practice in this field:

- an examination of prescribing of antipsychotics and antidepressants in primary care by Public Health England (PHE);
- partnership working with six project sites in England to further understand process and pathways to test new ways of working by NHS Improving Quality (NHS IQ); and
- a survey by the Care Quality Commission (CQC) of use of psychotropic drugs in people detained under the Mental Health Act 1983 (amended 2007).

The first project examined primary-care prescribing and concluded that 30 000–35 000 adults with intellectual disability are on antipsychotics, antidepressants or both without appropriate indications (Public Health England, 2015). The second examined practice within six selected secondary-care sites and concluded that, although there was some good practice, there was a need for improvement in communication with patients and families (NHS Improving Quality, 2015). The third, using data from

the Care Quality Commission (2016) relating to 945 reports on 796 patients by second opinion appointed doctors (SOADs), concluded that half of prescriptions were not for recognised indications and that limited rationale had been offered, by the provider clinicians, for the totality of the treatment plan (Care Quality Commission, 2016). Based on these documents, the conclusion was that there was robust evidence of inappropriate use of powerful drugs in people with intellectual disabilities and a 'Call for Action' was issued to improve this practice (NHS England, 2015).

In a subsequent study, a primary-care database containing the electronic health records of more than 33 000 adults with an intellectual disability from over 500 UK general practices was examined for the incidence of recorded mental illness, behaviours that challenge, and the prescription of psychotropic drugs in this group (Sheehan *et al*, 2015). It concluded that the proportion of people with intellectual disability treated with psychotropic drugs exceeded the proportion with recorded mental illness. In a reasoned commentary, the authors pointed out some of the limitations of their study. There was a possibility that the rate of recorded diagnoses in the database did not correspond to the true rate of mental illness. Free text of the electronic health record was not interrogated. As the degree of intellectual disability was not recorded, it was not possible to perform an analysis based on that factor. Finally, an inference was made that if a person had a record of challenging behaviour and was on psychotropic drugs, but had no record of mental illness, the prescription was for challenging behaviour. This might not have been the case, especially as conditions like personality disorders, substance misuse and obsessive–compulsive disorder, all of which can be associated with psychotic or affective symptoms, were not included.

Interestingly, of the 9135 patients prescribed an antipsychotic, 2362 (26%) had neither a recorded

severe mental illness nor challenging behaviour. It was found that 71% of those prescribed an antipsychotic did not have a recorded severe mental illness. While this is higher than in the general population, even in the latter, 50% of those prescribed an antipsychotic did not have a recorded severe mental illness (Marston *et al*, 2014). These findings suggest that even in the general population there is inadequate recording of the diagnosis underpinning psychotropic drug prescriptions in primary care. Notwithstanding these issues, the study's two main findings are of enormous relevance:

- the proportion of people with intellectual disability treated with psychotropic drugs exceeded the proportion with recorded mental illness;
- antipsychotics are prescribed for people with no recorded severe mental illness but behaviours that challenge.

These findings call for introspection and urgent action from prescribing clinicians, with whom the ultimate responsibility for prescribing lies.

This good prescribing practice guidance, aimed at primary and secondary healthcare clinicians, proposes standards for improving clinical practice in this area. It covers the prescription of any psychotropic medication including antipsychotics, antidepressants, anxiolytics or mood stabilisers and sets out a framework for clinicians on how to rationalise their prescribing practice and where appropriate, taper and stop psychotropic drugs. It also serves as a resource for those who are providing a statutory second opinion.

Mental health and behaviours that challenge

Intellectual disability is a condition characterised by significant impairments of both intellectual and adaptive functioning and an onset before 18 years of age (World Health Organization, 2008). The UK government uses the term 'learning disability' for this condition.

About 1–2% of the general population will have an intellectual disability (Emerson *et al*, 2011). The degree of intellectual disability is categorised as mild, moderate, severe or profound, with over 90% of those affected falling within the mild range (Department of Health, 2001).

People with an intellectual disability have a high rate of mental health comorbidity, with a point prevalence of around 30% (Cooper *et al*, 2007). They develop psychiatric conditions at rates similar to or higher than the general population (Buckles *et al*, 2013), but deficits in communication and health literacy, atypical presentations and difficulties in accessing services might mean that their conditions are under-recorded and underdiagnosed (Cooray *et al*, 2015). They also have high rates of physical health comorbidity and premature mortality (Heslop *et al*, 2013).

A significant proportion of people with intellectual disability display 'behaviours that challenge', defined as behaviours of an intensity, frequency, or duration that threaten the physical safety of the person or others or restrict access to community facilities (Emerson *et al*, 2001). It is important to recognise that the term is a socially constructed, descriptive concept and not a diagnosis (NICE, 2015a) and that it makes no inferences about the aetiology of the behaviour. It covers a very

heterogeneous group of behavioural phenomena across different degrees of intellectual disability, and the dividing line between challenging behaviour and offending behaviour is often not as clear as one would want. Presentations that range from repetitive self-injury to serious suicide attempts, from low-grade disruptive behaviour to grievously injuring someone, and from indecent exposure to rape can all come under this category. The behaviour might be related to physical health problems, communication difficulties or environmental changes and, in many cases, a combination of these. It might be unrelated to psychiatric disorder, but might also be a primary or secondary manifestation of it (Xeniditis *et al*, 2001).

The current definition of behaviours that challenge (or challenging behaviour; Emerson *et al*, 2001) is broad enough to cover acts of aggression towards people or property, self-neglect, self-harm and the risk of exploitation. It therefore seems that almost anyone who has a mental health problem that reaches the threshold of needing attention from primary- or secondary-care services would have some behaviour that challenges as one of the presenting features. It is therefore very important to tease out any underlying causes and associations of the behaviour before making decisions about treatment, particularly prescribing.

This can be a particular issue in intellectual disability, where there is often reduced formal recognition and recording of mental health problems. Therefore, the conventional good medical practice of making an accurate diagnosis might not take place, although the treatment is initiated. This issue is discussed in greater detail in the next section.

Approaches to prescribing

In people with an intellectual disability and mental health or behavioural problems, there are three broad situations in which they might come into contact with primary or secondary care:

- the presence of behaviour that challenges that is not associated with mental illness or any other mental disorder
- the presence of behaviour that challenges that is associated with symptoms that meet the diagnostic criteria for mental illness or any other mental disorders
- the presence of behaviour that challenges that is associated with some psychiatric symptoms, but these do not quite fulfil the diagnostic criteria for mental illness or any other mental disorder.

Previous guidance (Kalachnick *et al*, 1998; Rush & Frances, 2000; Deb *et al*, 2006, 2009; Bhaumik *et al*, 2015; NICE, 2015a) suggests that the most important part of psychotropic drug prescribing for this group is the need for a clear assessment before the prescribing, followed by regular review and monitoring of the prescribing. The assessment is underpinned by the clinician's awareness that, although behaviour that challenges might be the presenting symptom, it might actually be the result of another condition. This other condition might improve only with medication or might have no need for medication at all.

The assessment should include a full recording of the diagnostic formulation that covers all the below points:

- degree of intellectual disability
- cause of intellectual disability (including syndromes, behavioural phenotypes)
- other developmental disorders (including autism spectrum disorders, hyperkinetic disorder)
- any mental illnesses
- personality disorders

- disorders related to substance misuse or dependence
- physical disorders (including any of the causes of the intellectual disability)
- psychosocial stressors (long-standing issues as well as recent environmental changes)
- types of behaviours that challenge.

In this structure, behaviour that challenges is not treated as a diagnosis, but as a presenting symptom in the context of a range of biopsychosocial factors.

The recording of diagnoses can be particularly problematic in patients who are unable to give a clear verbal account of their psychopathology. Even those who do have expressive speech can find it difficult to describe their psychopathology precisely, and the clinician might have difficulty making the subtle distinction between hallucinations and pseudo-hallucinations or between overvalued ideas, obsessions and delusions. Thus, in clinical practice, it can happen that a psychiatric diagnosis is recorded only when the main syndromes are present (e.g. schizophrenia, bipolar disorder), while the narrative account of psychopathology (e.g. transient psychotic symptoms and affective lability in someone with a mild intellectual disability and a personality disorder) is omitted. This clearly contributes to the problem of under-recording of psychiatric diagnoses and to the inability to adequately monitor prescriptions.

It is clear that this is a problem not just in intellectual disability services, but also in mainstream mental health services. For example, studies have found that 71% of those with a learning disability who were prescribed an antipsychotic in primary care did not have a recorded severe mental illness (Sheehan *et al*, 2015) and 50% of the general population who were prescribed an antipsychotic in primary care also did not have a recorded severe mental illness (Marston *et al*, 2014).

As a result of this assessment and formulation, the prescriber generates what is essentially a multi-axial diagnosis.

- If the diagnosis is such that there is no mental illness or other mental disorder and the behaviour that challenges is purely the result of psychosocial factors, there might be no role for prescribing other than in the very short term to alleviate a serious risk to the safety of the patient or others while other, non-drug programmes are implemented to manage the behaviour.
- If an independent mental illness or disorder is diagnosed, treatment should follow established guidelines for that condition. Medications are effective at the same doses as for those without an intellectual disability and there is no clear evidence that they have more side-effects (Frighi *et al*, 2011). However, side-effects and potential drug interactions should be monitored carefully, particularly in those with more severe degrees of intellectual disability.
- Because presentations are rarely straightforward in clinical practice, there is often a combination of several symptoms and this might not be captured by categorical diagnosis. Therefore, there should be clear identification of the affective, psychotic and behavioural symptoms or clusters of symptoms (Bhaumik *et al*, 2015) that are the target of treatment. All psychotropic drug prescribing should target specific symptoms and, if the specific symptoms are not improving satisfactorily within 3 months, then that drug should be tapered or stopped and other options considered.

It is important, therefore, to acknowledge that the terms 'behaviour that challenges' or 'challenging behaviour' are not precise enough to be a recorded indication for prescribing. One should record all diagnoses systematically and, more importantly, with the narrative that underpin them. This will allow the prescriber to record target symptoms or syndromes, have professional time frames for evaluation and communicate that to all concerned. If prescribing at all, the clinician would want to look at immediate, short-term and long-term strategies that depend on the presentation.

NICE (2015a) offers the most comprehensive guidance to date on the prescribing of psychotropic drugs in presentations of challenging behaviour. It recommends that antipsychotic drugs be considered to manage behaviour that challenges only if:

- psychological or other interventions alone do not produce change within an agreed time; or
- treatment for any co-existing mental or physical health problem has not led to a reduction in the behaviour; or
- the risk to the person or others is very severe (for example, because of violence, aggression or self-injury).

NICE (2015a) also recommends that:

- antipsychotic drugs should be offered only in combination with psychological or other interventions
- such drugs should be initially prescribed and monitored by a specialist who should identify the target behaviour, set timelines for assessment, discuss with a patient and the family and taper off the drug based on its effectiveness.

In the absence of a clear-cut diagnosis of mental illness, clinicians sometimes arrive at a working diagnosis based on assessment and investigations. This might lead to a therapeutic trial with careful monitoring of the impact of the prescribed drugs on target symptoms and side-effects. The fundamental principle in such a trial is to consider stopping the drugs if the clinical response is not satisfactory within a reasonable time scale, if alternative, non-drug strategies are deemed to improve behaviour, or if unacceptable side-effects emerge. In that situation, a review of the diagnosis and the treatment approach should be reconsidered following the withdrawal of drugs.

In the context of the situation described above, unlicensed or off-label prescribing becomes relevant. Off-label prescribing has been a part of mainstream medical practice for several years: 65% of all paediatric prescriptions, 90% of neonatal prescriptions, a number of anti-cancer drugs and drugs used in the treatment of delirium are examples of off-label prescribing (Mason *et al*, 2012; Largent *et al*, 2013; Glover *et al*, 2014). The crucial difference with prescribing for people with an intellectual disability, as opposed to the many

other conditions described above, lies in the poor diagnostic reliability and validity of the indications and the longer length of treatment usually required. The General Medical Council (2013) has specified the responsibilities of the prescriber when recommending off-label prescribing, which include overseeing all aspects of treatment, recording use carefully and informing parents and carers. Thus, although off-label prescribing is not inappropriate, unlawful or unethical in itself, it can be if not done properly.

All prescribing clinicians should explain the proposed treatment to patients, their families and carers. This may include providing information in an easy-to-read format, making other reasonable adjustments and involving independent advocates. There should be a record of the patient's consent and capacity, any best-interests decisions, time-frames for reviews and the tapering off or stopping of drugs that are ineffective. This is particularly relevant when the prescribing is off-label.

There is an undeniable problem with repeat prescriptions and medication review. This problem highlights the need for meaningful follow-up that considers continuation or discontinuation of drugs. In this meaningful follow-up, narrative accounts of improvement (or lack of) in target symptoms or syndromes might not be enough. These narrative accounts need to be supplemented by standardised measures.

One concern often heard is that, although introducing a structured tool is ideal practice, it can seem a counsel of perfection that has no hope of being implemented. It is therefore important that the tool that is introduced is quick and easy to administer and can capture the balance between positive effects and side-effects. The Clinical Global Impression (CGI) scale (Guy, 1976) might be a very useful choice for this. It is freely available online, can be administered in a matter of minutes by a clinician who knows the patient well, and generates a summary score of improvement as well as the efficacy index. The Health of the Nation Outcome Scale (HoNOS) is another option for monitoring change over time (Royal College of Psychiatrists, 2016). Although the CGI rates the balance between therapeutic benefit and side-effects, clinicians might want to consider using additional

objective measures like the Liverpool University Neuroleptic Side Effect Rating Scale (LUNTERS) to record side-effects (www.reach4resource.co.uk/node/104). Using both narrative accounts and standardised measures in this way will help the prescriber determine objectively which drugs are ineffective and aid the process of stopping them in consultation with patients and their carers.

The issue of whether the doses required for the treatment of psychiatric conditions in those with an intellectual disability are the same as in the general population and whether they have more side-effects has been examined. The clinical consensus has been that the drugs are equally effective at the same doses as are used in the general population and there is no conclusive evidence of them having more side-effects (Frighi *et al*, 2011). Although the widely prevalent dictum of 'start low and go slow' might be relevant, particularly in those with more severe degrees of intellectual disability, it should be balanced against the risk of under-treating and adversely affecting prognosis, particularly in those with serious mental illness comorbidity.

The risk of drug–drug interactions must be considered, as many individuals with an intellectual disability are likely to be on other drugs for their associated health comorbidities. Prescribers should make sure they are aware of all the drugs the patient is receiving when prescribing.

One of the frequently heard complaints in any discussion about prescribing is about the limited evidence base. This is often related to the practical difficulties of conducting randomised, controlled trials in people with an intellectual disability. The few that have been completed (Tyrer *et al*, 2009; Ahmed *et al*, 2000; De Kuyper *et al*, 2014) are limited by the discrepancy between patients who are enrolled in research and those who are treated in clinics. To generate information that most resembles the experience of frontline clinicians and patients, large-scale naturalistic studies and national audits might be the best way forward in gathering an evidence base. This has been done in other branches of medicine and surgery, for example breast-cancer outcomes (Pereira *et al*, 2008). There have been some attempts within psychiatry for this, such as the national Prescribing Observatory for Mental Health audits. Although

these audits have generated a large database based on clinical practice, they rely on categorical diagnoses and do not record narrative accounts – for instance, the presence of psychotic symptoms that might be the indication for antipsychotic drugs, or the presence of affective lability/instability that might be the indication for mood stabilisers.

Appendix 1 contains a self-assessment template for measuring prescribing practice that covers diagnoses on multiple axes, prescribing categories, the rationale for prescribing, target symptoms and

measures of outcome. It incorporates the quality standards that have been published by NICE (2015*b*). Using this template to generate national samples could help to improve and rationalise clinical practice in this area.

Appendix 2 contains three examples of case notes showing how to record the use of psychotropic drugs and their reviews.

Appendix 3 contains a list of key resources for prescribing guidelines and other information related to prescribing.

Prescribing standards and recommendations

Initiation of psychotropic drugs should be from secondary care. If from primary care, it should be by prescribers with a special interest or expertise in this area or through shared protocols with secondary care. Monitoring and discontinuation of psychotropic drugs should follow the standards set out below. This can be done by the prescriber from primary or secondary care.

Standards for psychotropic drug prescribing

- The indication(s) and rationale for prescribing the psychotropic drug should be clearly stated, including whether the prescribing is off-label, polypharmacy or high dose.
- Consent-to-treatment procedures (or best-interests decision-making processes) should be followed and documented.
- There should be regular monitoring of treatment response and side-effects (preferably every 3 months or less, at a minimum every 6 months).
- Review and evaluation of the need for continuation or discontinuation of the psychotropic drug should be undertaken on a regular basis (preferably every 3 months or less, at a minimum every 6 months) or whenever there is a request from patients, carers or other professionals.

Recommendations

- 1 All psychotropic prescribing should adhere to the four prescribing standards described above.
- 2 All initiations of psychotropic drugs for people with intellectual disability, whether from primary or secondary care, should be by a prescriber who is competent in the care of people with intellectual disability.
- 3 Psychotropic drug prescribing should be seen as part of a wider multidisciplinary and holistic care plan.
- 4 Regular reviews of the drugs should occur either according to NICE quality standards or when requested by the patient, carer or other professionals.
- 5 There should be a national audit on prescribing practice that takes into account all the standards mentioned above.
- 6 Regulators and commissioners should use these standards for quality checks on services.

Appendix 1.

Self-assessment framework

| Standards | Key lines of enquiry | Audit standard rating |
|--|---|-----------------------|
| <p>The indication(s) and rationale for prescribing the psychotropic drug should be clearly stated, including whether the prescribing is off-label, polypharmacy or high dose</p> | <ul style="list-style-type: none"> • Is the prescribing part of a wider multidisciplinary care plan? • Is there documentation of the indication for prescribing? (This can include the diagnoses as well as the narrative account of the target symptoms.) • If the prescription is only for behaviour that challenges, are the NICE guidelines being followed? (Psychological interventions have not produced a change within an agreed time period or treatment of co-existing mental and physical conditions have not led to a reduction or risk to the person or others is very severe and drugs are offered only with psychological or other interventions.) • Is there off-label prescribing? If so, is the rationale explained? • Is there polypharmacy? If so, is the rationale explained? • Is there prescribing over <i>British National Formulary</i> maximum limits? If so, is the rationale explained? | |
| <p>Consent-to-treatment procedures (or best-interests decision-making processes) should be followed and documented</p> | <ul style="list-style-type: none"> • Is there evidence of a capacity assessment? • If the patient is deemed to lack capacity, is the best-interests process followed? • Is there evidence that the patient's views about the drug treatment are being recorded? • Is there evidence that the carers' or family members' views about the drug treatment are being recorded? • If patient is detained (e.g. under the Mental Health Act 1983), are the legal requirements around consent to treatment satisfied? | |
| <p>There should be regular monitoring of treatment response and side-effects (preferably every 3 months or less, at a minimum every 6 months)</p> | <ul style="list-style-type: none"> • Is there documentation about progress on the target symptoms for treatment? • Is there evidence of objective evaluation of treatment response (e.g. use of standardised instruments)? • Is there evidence of objective evaluation of side-effects (e.g. use of standardised instruments)? | |
| <p>Review and evaluation of the need for continuation or discontinuation of the psychotropic drug should be undertaken on a regular basis (preferably every 3 months or less, at a minimum every 6 months) or whenever there is a request from patients, carers or other professionals</p> | <ul style="list-style-type: none"> • Is there evidence of objective evaluation of treatment response (e.g. use of standardised instruments)? • Is there evidence of objective evaluation of side-effects (e.g. use of standardised instruments)? • Is there evidence of regular review of the need for continuation or discontinuation of the drug? (This includes discussion of risks and benefits with the patient and/or carer.) | |

Appendix 2.

Examples of case notes

Patient XY

- XY's clinical diagnosis is one of Mild Learning Disability (ICD-10 Code F70.1), a Rapid Cycling Bipolar Affective Disorder (ICD-10 Code F31.6), Emotionally Unstable & Dissocial Personality Disorders (ICD-10 Codes F60.3 & 60.2). He also has a 47XYY karyotype (F98.5).
- At present, XY is on two mood stabilisers (valproate 1200mg/day and lamotrigine 150mg/day), one antipsychotic (haloperidol 20mg/day) and one anti-muscarinic (procyclidine 10mg/day). On a p.r.n. basis, he takes up to 4mg of lorazepam for severe anxiety/ agitation and up to 10mg of procyclidine for EPS.
- The environmental, psychological and possible physical causes of aggression are addressed in XY's Behaviour Support Plans. His aggressive outbursts are often related to the rapid cycling mood disorder – particularly the depressive/irritable spells that last a few days at a time, as well as the impulsivity and affective instability associated with his personality disorders. These are the targets of pharmacological treatment.
- On this medication regime, his arousal and manic symptoms are under control and the affective instability though present is under a better degree of control. Although the two mood stabilisers can be considered polypharmacy, this combination has been most effective in controlling his rapid cycling mood disorder. All drugs are within the BNF maximum limits.
- XY does not report any major side-effects other than occasional tiredness, particularly when he has the p.r.n. lorazepam. He also has features of mild EPS and dyskinetic movements.
- A CGI rating was completed today and shows that he is maintaining his improvement (global improvement score 1, efficacy index 02).
- XY has a general understanding of the effects and side-effects of the drugs and the rationale for their use. He can retain that information and use it to reach a decision to accept the drugs. I consider him to continue to have the capacity to consent to the drugs. His T2 consent form was last completed on xx/xx/xxxx.
- XY knows he is treated as a consenting patient and that he is free to change his mind. He feels better on this regime and is happy to continue on it. He has been given easy-read information leaflets about the drugs and is quite able to ask questions. His drug regime is frequently explained to his nearest relative – his

father (Mr YY), who regularly attends his CPA meetings along with his care coordinator and social worker. The last such CPA was on xx/xx/xxxx.

Patient AB

- AB's clinical diagnosis is one of Mild Learning Disability (F70), Pervasive Developmental (Autistic spectrum) disorder (F84) and Schizoaffective disorder (F25). He also has a childhood history of Hyperkinetic Disorder (F90) with some symptoms persisting into adulthood.
- At present, AB's drugs regime includes clopixon 60 mg/day (antipsychotic), clonidine 150 micrograms/day (for the ADHD symptoms; treated on this from late childhood), valproate 1600 mg/day (mood stabiliser) and diazepam 10 mg/day (anxiolytic). In addition, he is on diazepam up to 10 mg/day and clopixon up to 20 mg/day as p.r.n. drugs for aggression/ agitation and procyclidine up to 10 mg/day p.r.n. for EPS.
- The environmental, psychological and possible physical causes of aggression are addressed in AB's Behaviour Support Plans. The unpredictable aggression that is often very problematic can be related to any three strands of his diagnosis, in particular to the psychotic features and mood instability associated with schizoaffective disorder.
- On this regime, his mental state is free of any pervasive depression or mood elevation and there are no clear psychotic features now. However, there are spells of him seeming to react to hallucinatory experiences although he denies this on direct questioning. Since the increase in dose of clopixon to 60 mg/day, this has been less problematic.
- Clonidine: This was prescribed for his Childhood Hyperkinetic symptoms that were persisting into adulthood. He has been on it since his previous placement and there is very little evidence of active ADHD features now. On the other hand, he seems to have constipation, a recognised side-effect of clonidine. I am therefore tapering the drug off gradually. I am reducing it in steps of 25 µg per week. A daily blood pressure chart will be maintained.
- He has features of mild EPS, but the drowsiness is much less since being on clopixon instead of clozapine. There have been complaints of constipation and I keep an eye out to make sure it is not worsened by anticholinergic drugs. AB's father has spoken to me (on xx/xx/xxxx) about how constipation might make his behaviour worse because he does not like talking about it.
- A CGI rating and HONOS have been completed today and show that he is maintaining his improvement. On the CGI, his global improvement score was 2 and the efficacy index 06.
- AB has a limited ability to understand the effects or side-effects of his drug regime and the rationale for their use. His ability to

retain that information is limited and he has little ability to weigh it in the balance and reach an informed decision. It is therefore my considered view that he lacks the capacity to consent to treatment with this psychotropic drug regime. He is treated subject to a Statutory Second Opinion and T3 Form. The T3 consent form was last completed on xx/xx/xxxx and the last Section 61 review on xx/xx/xxxx. I have explained to him today that he is treated subject to a Second Opinion although his ability to understand the processes involved is limited.

- His drug regime is frequently explained to his nearest relative – his father – both face to face and through letters. The last time that happened was on xx/xx/xxxx at AB's CPA and subsequently in a telephone call on xx/xx/xxxx.

Patient CD

- CD is a 25-year-old woman with Mild Learning Disability (ICD-10 code F70.1). Known to mental health services from the age of 13, with a range of 'challenging behaviours' and a very difficult family background of abuse and neglect, she has had a number of diagnoses mentioned in the past – some with ICD 10 codes and some without. This has included autistic tendencies, mixed disorder of conduct and emotions, depressive episodes, anxiety disorder unspecified, alcohol and substance abuse, personality difficulties and psychosis.
- After a detailed diagnostic clarification, her current diagnosis is one of a Mild Learning Disability (ICD-10 Code F70.1) and an Emotionally Unstable Personality Disorder (ICD-10 Code F60.3). At present, there is no evidence of any mental illness, although it is possible she might have had at least two depressive episodes lasting about 2–3 months in the past. When 'stressed' due to her complicated family situation, CD goes through spells that last 1–2 weeks when she will complain of 'hearing voices' telling her to harm herself, abuse alcohol and repeatedly threaten to jump off high buildings. The evaluation suggests that she does not have a chronic psychotic illness, but that these brief psychotic episodes are happening within the context of an emotionally unstable personality. She responds quickly to antipsychotic medication when this happens.
- The environmental, psychological and possible physical causes of her behavioural problems are addressed in CD's behaviour support plans. She has been offered therapy and support from the community intellectual disability team's psychology and outreach services.
- In spite of this, there are several episodes when CD acts out with aggression towards her carers in the supported living environment and makes serious attempts to self-harm, putting her and others at risk.

- My impression is that CD's predominant mood state even when she is not having major depressive disorder is one of dysphoria with her having little interest or motivation in getting engaged in various activities. This low mood was associated with mood swings and impulsive behaviours, particularly when stressed.
- Because of the persisting dysphoric symptoms and mood instability, she was started on paroxetine 20mg/day and there was improvement on these target symptoms. At present, CD is on one antidepressant (paroxetine 20mg/day). On a p.r.n. basis, she is on one anxiolytic (up to 2mg/day of lorazepam for severe anxiety/agitation. She has used this three times in the past month).
- CD does not report any major side-effects other than occasional tiredness, particularly when she has the p.r.n. lorazepam.
- CD has a general understanding of the effects and side-effects of the drugs and the rationale for their use. She can retain that information and use it to reach a decision to accept the drugs. I consider her to have the capacity to consent to the drugs. However, the prescription of the antidepressant is off-label and I have discussed this with the team, CD, her support staff in the community and her independent advocate. The family is not involved in her care because of past issues. CD knows she is treated as a consenting patient and that she is free to change her mind. She feels better on this regime and is happy to continue on it. She has been given easy-read information leaflets about the medication and is quite able to ask questions. The last review was on xx/xx/xxxx as part of her CPA.
- A CGI rating has been completed today and shows that she is maintaining her improvement for about 12 months now. (She had a global improvement score of 2 and efficacy index of 06.)
- She does continue to have 'crises', but those involved in supporting her in the community feel that these have become less in intensity and frequency than before.

Appendix 3.

Key resources

Bhaumik S, Branford D, Barrett M, *et al* (2015) *Frith Guidelines for Prescribing in Intellectual Disability*. Wiley Press.

Deb S, Kwork H, Bertelli M, *et al* (2009) International guide to prescribing psychotropic medication for the management of problem behaviours in adults with intellectual disabilities. *World Psychiatry*, **8**: 181–6.

General Medical Council (2013) *Good Practice in Prescribing and Managing Medicines and Devices*. GMC (http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp).

Guy W (ed) (1976) Clinical Global Impression (CGI). In *ECDEU Assessment Manual for Psychopharmacology*. US Department of Health, Education, and Welfare (<http://www.psywellness.com.sg/docs/CGI.pdf>).

Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS) (<http://www.reach4resource.co.uk/node/104>).

NICE (2015) *Learning Disabilities: Challenging Behaviour* (QS101). NICE (<https://www.nice.org.uk/guidance/qs101>).

NICE (2015) *Challenging Behaviour and Learning Disabilities: Prevention and Interventions for People with Learning Disabilities Whose Behaviour Challenges* (NG11). NICE (<http://www.nice.org.uk/guidance/ng11>).

Royal College of Psychiatrists (2016) *Health of the Nation Outcome Scales*. Royal College of Psychiatrists (<http://www.rcpsych.ac.uk/clinicalservice-standards/honos.aspx>).

References

- Ahmed Z, Fraser W, Kerr MP, *et al* (2000) Reducing antipsychotic medication in people with a learning disability. *British Journal of Psychiatry*, **176**: 42–6.
- Bhaumik S, Branford D, Barrett M, *et al* (2015) *Frith Guidelines for Prescribing in Intellectual Disability*. Wiley.
- Brylewski J, Duggan L (2004) Antipsychotic medication for challenging behaviour in people with learning disability. *Cochrane Database of Systematic Reviews*, **3**: CD000377.
- Buckles J, Luckasson R, Keefe E (2013) A systematic review of the prevalence of psychiatric disorders in adults with intellectual disability, 2003–2010. *Journal of Mental Health Research in Intellectual Disabilities*, **6**: 1181–207.
- Care Quality Commission (2016) *Learning Disability: Survey of Detained Patients' Medications*. CQC.
- Cooper S-A, Smiley E, Morrison J, *et al* (2007) Mental ill-health in adults with intellectual disabilities: prevalence and associated factors. *British Journal of Psychiatry*, **190**: 27–35.
- Cooray SE, Bhaumik S, Roy A, *et al* (2015) Intellectual disability and the ICD-11: towards clinical utility? *Advances in Mental Health and Intellectual Disabilities*, **9**: 3–8.
- Deb S, Clarke D, Unwin G (2006) *Using Medication to Manage Behavioural Problems in Adults with Learning Disabilities*. University of Birmingham.
- Deb S, Kwork H, Bertelli M, *et al* (2009) International guide to prescribing psychotropic medication for the management of problem behaviours in adults with intellectual disabilities. *World Psychiatry*, **8**: 181–6.
- De Kuijper G, Evenhuis H, Minderaa RB, *et al* (2014) Effects of controlled discontinuation of long-term used antipsychotics for behavioural symptoms in individuals with intellectual disability. *Journal of Intellectual Disability Research*, **58**: 71–83.
- Department of Health (2001) *Valuing People: A New Strategy for Learning Disability for the 21st Century*. Department of Health.
- Department of Health (2012a) *Department of Health Review: Winterbourne View Hospital Interim Report*. Department of Health.
- Department of Health (2012b) *Transforming Care: A National Response to Winterbourne View Hospital: Department of Health Review Final Report*. Department of Health.
- Emerson E, Kiernan C, Alborz A, *et al* (2001) The prevalence of challenging behaviours: a total population study. *Research in Developmental Disabilities*, **22**: 77–93.
- Emerson E, Hatton C, Robertson G, *et al* (2011) *People with Learning Disabilities in England 2010: Services and Support*. Improving Health and Lives Learning Disabilities Observatory.
- Frigi E, Stephenson MT, Morovat A, *et al* (2011) Safety of antipsychotics in people with intellectual disability. *British Journal of Psychiatry*, **199**: 289–95.
- General Medical Council (2013) *Good Practice in Prescribing and Managing Medicines and Devices*. GMC.
- Glover G, Bernard S, Branford D, *et al* (2014) Use of medication for challenging behaviour in people with intellectual disability. *British Journal of Psychiatry*, **205**: 6–7.
- Guy W (ed) (1976) Clinical Global Impression (CGI). In *ECDEU Assessment Manual for Psychopharmacology*. US Department of Health, Education, and

Welfare (<http://www.psywellness.com.sg/docs/CGI.pdf>).

Health & Social Care Information Centre (2013) *Learning Disabilities Census Report – England, 30th of September 2013*. HSCIC.

Health & Social Care Information Centre (2014) *Learning Disabilities Census Report – England, 30th of September 2014*. HSCIC.

Health & Social Care Information Centre (2015) *Learning Disabilities Census Report – England, 30th of September 2015*. HSCIC.

Heslop P, Blair P, Fleming P, *et al* (2013) *Confidential Inquiry into Premature Deaths of People with Learning Disabilities (CIPOLD)*. Norah Fry Research Centre.

Kalachnik JE, Leventhal BL, James DH, *et al* (1998) Guidelines for the use of psychotropic medication. In *Psychotropic Medication and Developmental Disabilities: The International Consensus Handbook* (Reiss S, Aman MG, eds): 45–72. Ohio State University.

Largent EA, Miller FG, Pearson SD (2013) Going off-label without venturing off-course. *Archives of Internal Medicine*, **169**: 1745–7.

Mason J, Pirmohamed M, Nunn T (2012) Off-label and unlicensed medicine use and adverse drug reactions in children: a narrative review of the literature. *European Journal of Clinical Pharmacology*, **68**: 21–28.

Marston L, Nazareth I, Petersen I, *et al* (2014) Prescribing of antipsychotics in UK primary care: a cohort study. *BMJ Open*, **4**: e006135.

Matson JL, Bamburg J, Mayville EA, *et al* (2000) Psychopharmacology and mental retardation – a 10 year review (1992–1999). *Research in Developmental Disabilities*, **21**: 263–96.

Molyneux B, Emerson E, Caine A (1999) Prescription of psychotropic medication to people with intellectual disabilities in primary healthcare settings. *Journal of Applied Research in Intellectual Disability*, **12**: 46–57.

NHS England (2015) *The Use of Medications in People with Learning Disabilities*. NHS England (<http://www.england.nhs.uk/2015/07/14/urgent-pledge>).

NHS Improving Quality (2015) *Winterbourne Medicines Programme: Improving the Use of Medicines in People with Learning Disabilities*. NHSIQ.

NICE (2015a) *Challenging Behaviour and Learning Disabilities: Prevention and Interventions for People with Learning Disabilities Whose Behaviour Challenges* (NG11). NICE.

NICE (2015b) *Learning Disabilities: Challenging Behaviour* (QS101). NICE (<https://www.nice.org.uk/guidance/qs101>).

Pereira J, Jeevan R, Browne J (2008) *First Annual Report of the National Mastectomy and Breast Reconstruction Audit*. Department of Health.

Public Health England (2015) *Prescribing of Psychotropic Drugs to People with Learning Disabilities and or Autism by General Practitioners in England*. PHE.

Royal College of Psychiatrists (2016) *Health of the Nation Outcome Scales*. Royal College of Psychiatrists (<http://www.rcpsych.ac.uk/clinicalservice-standards/honos.aspx>).

Rush AJ, Frances A (2000) Expert Consensus Guidelines Series: treatment of psychiatric and behavioural problems in mental retardation. *American Journal of Mental Retardation*, **105**: 159–227.

Sheehan R, Hassiotis A, Walters K, *et al* (2015) Mental illness, challenging behaviour and psychotropic drug prescribing in people with intellectual disability: UK population based cohort study. *BMJ*, **351**: 4326.

Tsiouris JA (2010) Pharmacotherapy for aggressive behaviours in persons with intellectual disabilities – treatment or mistreatment? *Journal of Intellectual Disability Research*, **54**: 1–16.

Tyrer P, Oliver-Africano P, Romeo R, *et al* (2009) Neuroleptics in the treatment of aggressive challenging behaviour that challenges for people with intellectual disabilities: a randomised controlled trial (NACHBID). *Health Technology Assessment*, **13**: iii–iv, ix–xi, 1–54.

World Health Organization (2008) *International Statistical Classification of Diseases and Related Health Problems* (ICD-10). WHO.

Xeniditis K, Russell A, Murphy D (2001) Management of people with challenging behaviour. *Advances in Psychiatric Treatment*, **7**: 109–16.

