

Editorial

Use of medication for challenging behaviour in people with intellectual disability

Gyles Glover, Sarah Bernard, David Branford, Anthony Holland and Andre Strydom

**Summary**

Medications, particularly antipsychotics, are commonly used to manage challenging behaviour in people with intellectual disability. When the behaviour does not arise from an underlying mental illness, this is commonly off-licence and evidence of efficacy is lacking. A national

audit programme would be one way to address the concerns this raises.

Declaration of interest

None.

Gyles Glover (pictured) is a public health specialist at Public Health England. He co-directs the English Learning Disabilities Observatory. Tony Holland is Professor of Learning Disabilities in the Department of Psychiatry at the University of Cambridge. David Branford was Chief Pharmacist at Derbyshire Mental Health Services NHS Trust and currently chairs the English Pharmacy Board of the Royal Pharmaceutical Society. Sarah Bernard is a consultant psychiatrist, Child and Adolescent Learning Disability Service at the South London and Maudsley NHS Foundation Trust. Andre Strydom is a reader in intellectual disabilities at University College London.

The use of medication in the treatment of people with intellectual disability who present with challenging behaviour is an emotive and contentious subject. It has been highlighted recently in the context of the appalling events at the independent hospital, Winterbourne View. The government's final report into this scandal promised two strands of work in this area: an exploration of the current state of prescribing and the possible need for a new audit (Action 45); and work with professional leadership organisations to ensure safe, appropriate and proportionate use of medicines in adults and children with intellectual disability in the future, with a particular focus on antipsychotics and antidepressants (Action 51).¹ We reflect on the use of medication in this context and propose a way in which this might better be examined.

Indications for medication in managing challenging behaviour

Best practice guidance jointly published by the Royal College of Psychiatrists, the British Psychological Society and the Royal College of Speech and Language Therapists emphasises that the term 'challenging behaviour' is not a diagnosis but a descriptor of behaviours occurring in specific contexts with many possible causes.² In some cases, challenging behaviour may arise from psychotic or affective illnesses, or be associated with attention-deficit hyperactivity disorder or severe anxiety in autism. If so, the rationale for the use of the range of psychotropic medications normally prescribed for these conditions is that they are as likely to be efficacious in people with intellectual disability as in those without. The test, even where there is diagnostic difficulty, is that as the underlying psychiatric condition is addressed, the frequency and severity of the challenging behaviour should diminish. However, the concern is that medication is commonly being prescribed without a rationale of this type, with the therapeutic target being the behaviour itself – the symptom, not the cause.³

There are very few high-quality studies of the efficacy of medication in ameliorating challenging behaviour in the long

term in the absence of mental illness, or of the nature and scale of the associated risks.⁴ A randomised trial of a typical and an atypical antipsychotic *v.* placebo for aggressive behaviour found no significant advantage for either active drug.⁵ A subsequent controlled discontinuation trial of long-term antipsychotics for behavioural problems in The Netherlands showed improved outcomes for individuals withdrawn from the medication.⁶ In the latest edition of their book *Challenging Behaviour*, Emerson & Einfeld attribute this evidence gap in part to a lack of a commercial incentive for pharmaceutical companies to undertake studies.⁴ But there are also major challenges in designing and undertaking trials capable of providing reliable evidence. Studies would need to include consideration of relevant psychosocial and other factors contributing to behaviours and the extent to which these could be and are being modified at the same time as drugs are administered. The presence or absence of major mental illness is critical but the degree of confidence with which this can be established is often limited, particularly in people with little or no verbal communication. The potential contribution of neurological abnormalities is a further important complication. Researchers would also need to resolve the likely difficulties in recruiting people with intellectual disability to such a randomised trial.

'Off-label' prescribing

In secondary care practice, antipsychotic medications are commonly used for both short- and long-term behavioural goals in people with intellectual disability.³ From a licensing perspective, short-term use to manage acute behavioural crises is within guidelines. However, although it appears to be common, long-term treatment of behaviour with such medication is 'off-label'. Other than in schizophrenia and other psychotic disorders, almost the only behaviour-related indications for the use of antipsychotics listed in the *British National Formulary*⁷ relate to short-term adjunctive management of anxiety, psychomotor agitation, excitement and violent or dangerously impulsive behaviour. 'Short-term' in this context would mean acute crises of less than 72 h duration. The situation has striking similarities to the use of antipsychotics to manage behavioural and psychological symptoms in dementia, reviewed by Banerjee for the English Department of Health.⁸

Off-label use of medications is not rare. A US study of prescribing by office-based physicians found that 21% of the prescriptions for 160 commonly used drugs were for indications not covered by Food and Drug Administration approvals.⁹ The reasons vary. In oncology, drugs are commonly used to treat

cancers other than those for which their use has been formally approved. In paediatric practice, many important drugs are not formally licensed for use in children. Largent and colleagues, exploring what constitutes responsible practice, have identified three categories of off-label prescribing – ‘Supported’, ‘Suppositional’ and ‘Investigational’ – on the basis of whether, despite the lack of formal approval, the evidence of ‘net health benefit’ is ‘moderate to high’, ‘low’ or ‘very low’.¹⁰ In England, the National Institute for Health and Care Excellence initiated a programme in 2009 to provide readily available evidence summaries for off-label usages which fall in the ‘Supported’ category (<http://www.nice.org.uk/mpc/evidencesummariesunlicensedofflabelmedicines/home.jsp>). This is unlikely to include the use of long-term antipsychotics to treat challenging behaviour in the absence of major mental illness.

In the UK, General Medical Council guidance on off-label use of medicines focuses on the responsibility on clinicians.¹¹ They are expected to assure themselves about the evidence, take responsibility for overseeing all aspects of treatment, record usage carefully and inform patients and carers fully. Essentially, clinicians are expected to shoulder the additional responsibility of using a non-established approach to clinical management.

The reasons for this extensive off-label use of antipsychotics are clear. Clinicians have to manage practical situations. They are commonly asked to intervene in situations of acute disturbance in residential care placements. Intensive and high-quality supportive or behavioural interventions may not be available and anyway might not work. The demand is usually for immediate action to manage behaviour in order to avoid placement breakdown. In these circumstances, sedative medication on an ‘as needed’ basis is an almost inevitable part of a crisis management package. Once started, longer-term use can easily follow without any clear rationale. Alternative acute behavioural management options, such as seclusion and/or restraint, also raise major ethical and legal concerns and, as recent and past enquiries have shown, if not very carefully supervised can lead to abusive practices. Such approaches would be extremely problematic in community settings and offer no long-term solution.¹²

A way to improve the evidence

Without positive action this unsatisfactory state of affairs is likely to persist. We believe that the leadership of the profession and the pharmaceutical licensing authority have a responsibility to act, following their commitments in the Winterbourne View concordat. The key requirements are first to clarify what is currently happening (the extent and patterns of prescribing and other interventions) and second to seek to establish an evidence-based consensus about what types of medication work, for whom, in what contexts and with what risks. This second task requires the development of more systematic evidence about the short- and long-term benefits, and the associated risks of the different treatment approaches, and about how these are affected by various specific features of patients’ behaviour patterns, and associated physical – particularly neurological and metabolic – characteristics.

The most obvious approach for both goals would be to establish a national audit programme, based not on small samples, but including all individuals with intellectual disability and challenging behaviour for whom National Health Service (NHS) treatment is provided. Ideally, this would be set in the context of a comprehensive clinical audit of the care of people with intellectual disability following the pattern of the National Diabetes Audit, which aims to collect information regularly about all patients in England and Wales identified as having diabetes. All clinicians (doctors, psychologists, nurses and others, in specialist

or primary care, National Health Service or independent sectors) providing relevant care for people with intellectual disability would be asked to provide the audit with details of patients’ assessment findings, the interventions used and the progress which followed. Inclusion could be based either on the nature of the problems treated (specified problem behaviours) or of the interventions given (initially antipsychotic or antidepressant medication). Wider details about each patient’s level of intellectual functioning and communication style, specific neurological abnormalities (such as the presence of epilepsy) and evidence (if any) of mental illness would be included, and a standardised rating approach would be used for describing the nature, severity and impact of behaviours. Anonymised data would be made available for study by researchers at little or no cost.

In time, an audit of this nature should develop a large national data-set, which would offer the best possible prospect of providing evidence on which to base firmer guidance on the role of medications in this difficult area.

Gyles Glover, MSc, MD, FRCPsych, FPPH, Co-Director, Learning Disabilities Team, Public Health England; **Sarah Bernard**, MD, FRCPsych, DRCOG, Child and Adolescent Learning Disability Service, South London and Maudsley NHS Foundation Trust; **David Branford**, PhD, FRPharmS, FCMHP, Chairman, English Pharmacy Board, Royal Pharmaceutical Society; **Anthony Holland**, MPhil, MRCP, FRCPsych, Diploma in Clinical Genetics, Health Foundation Chair in Learning Disabilities, Academic Department of Psychiatry, University of Cambridge; **Andre Strydom**, MSc, PhD, MRCPsych, Reader in Intellectual Disabilities, Mental Health Sciences Unit, University College London, UK.

Correspondence: Gyles Glover, Public Health England Knowledge and Intelligence Team (East), Institute of Public Health, University Forvie Site, Robinson Way, Cambridge CB2 0SR, UK. Email: Gyles.Glover@phe.gov.uk

First received 12 Jan 2014, final revision 2 Apr 2014, accepted 1 May 2014

References

- 1 Department of Health. *Transforming Care: A National Response to Winterbourne View Hospital. Department of Health Review: Final Report.* Department of Health, 2012.
- 2 Royal College of Psychiatrists, British Psychological Society, Royal College of Speech and Language Therapists. *Challenging Behaviour: A Unified Approach. Clinical and Service Guidelines for Supporting People with Learning Disabilities who are at Risk of Receiving Abusive or Restrictive Practices (College Report CR144).* Royal College of Psychiatrists, 2007.
- 3 Paton C, Flynn A, Shingleton-Smith A, McIntyre S, Bhaumik S, Rasmussen J, et al. Nature and quality of antipsychotic prescribing practice in UK psychiatry of intellectual disability services. *J Intellect Disabil Res* 2011; **55**: 665–74.
- 4 Emerson E, Einfeld SL (eds) *Pharmacotherapy.* In *Challenging Behaviour* (3rd edn): 94–101. Cambridge University Press, 2011.
- 5 Tyrer P, Oliver-Africano PC, Ahmed Z, Bouras N, Cooray S, Deb S, et al. Risperidone, haloperidol, and placebo in the treatment of aggressive challenging behaviour in patients with intellectual disability: a randomised controlled trial. *Lancet* 2008; **371**: 57–63.
- 6 De Kuijper G, Evenhuis H, Minderaa RB, Hoekstra PY. Effects of controlled discontinuation of long-term used antipsychotics for behavioural symptoms in individuals with intellectual disability. *J Intellect Disabil Res* 2014; **58**: 71–83.
- 7 Joint Formulary Committee. *British National Formulary (BNF) 67* (March–September 2014). Pharmaceutical Press, 2014.
- 8 Banerjee S. *The Use of Antipsychotic Medication for People with Dementia: Time for Action.* Department of Health, 2009.
- 9 Radley DC, Finkelstein SN, Stafford RS. Off-label prescribing among office-based physicians. *Arch Intern Med* 2006; **166**: 1021–6.
- 10 Largent EA, Miller FG, Pearson SD. Going off-label without venturing off-course. *Arch Intern Med* 2013; **169**: 1745–7.
- 11 General Medical Council. *Good Practice in Prescribing and Managing Medicines and Devices.* GMC, 2013.
- 12 Menon K, Baburaj R, Bernard S. Use of restraint for the management of challenging behaviour in children with intellectual disabilities. *Adv Ment Heal Intellect Disabil* 2012; **6**: 62–75.