

Editorial

Use of medication for challenging behaviour in people with intellectual disability

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**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.

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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.

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