Guide to Using Psychotropic Medication to Manage Behaviour Problems among Adults with Intellectual Disability

Technical Document

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UNIVERSITY OF BIRMINGHAM   The Royal College of Psychiatrists *Let Wisdom Guide*   MENCAP *Understanding learning disability*

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Technical Document Section 1: Introduction, Background and Development of the Guideline

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Executive summary

Some adults with a learning disability display behaviour problems. Behaviour problems in this context are defined as socially unacceptable behaviour that causes distress, harm or disadvantage to the person himself or herself, or to other people or property, and usually requires some intervention. Terms such as 'challenging behaviour', 'behaviour disorder', and 'behaviour difficulty' have also been used. Examples of problem behaviours include verbal aggression and physical aggression to self (self-injurious behaviour, SIB), others or property.

This guide has been produced to provide advice to people who are considering prescribing medication to manage behaviour problems among adults with a learning disability. The development of the guideline has followed the National Institute for Health and Clinical Excellence (NICE) guideline development methods (2004) and has been assessed by the internationally accepted 'Appraisal of Guidelines for Research and Evaluation' (AGREE, 2001) criteria for guideline development.

The guidance represents the view of the Guideline Development Group (GDG). The GDG considered the evidence available and consulted widely before writing this document. The recommendations in the guide reflect the principles laid down in the Valuing People Strategy from the Department of Health (2001). Health professionals are expected to take it into account when exercising their clinical judgment. However, the guide does not override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual situation. Such decisions must be taken after careful consideration of all the possible benefits and potential risks involved with the intervention.

This guide does not consider in any detail the indications for choosing specific medication to manage behaviour problems among adults with a learning disability. Rather, it provides recommendations for clinical practice surrounding the use of medication to manage behaviour problems among people who are aged 18 years and over and who have a learning disability. All relevant medication and related issues are considered. This guide should facilitate the care process and improve the way that behaviour problems are managed. This should lead to a better quality of life for people with a learning disability.

The guide has identified several key principles that should always underpin the prescribing of medication in this field. One such principle is that all prescribing should follow a thorough assessment and formulation. A proper assessment and formulation will often require input from a number of disciplines and from families and carers. Indeed, this guide endorses the use of interdisciplinary input and working throughout all stages of the care

process, from the assessment and formulation of the treatment plan, to the initiation of treatment and monitoring of the management options.

Furthermore, input from the person with a learning disability and their families and carers is also identified as a key principle of practice. This input should continue at every stage of the care process. In order to allow the person with a learning disability to provide input into their management plan, it is important to share information in a way that they understand. Communication issues are identified as an important factor to consider when prescribing medication in this field. Therefore, additional time and effort and innovative methods may be required on the part of the prescriber to fully communicate the management plan to the person with a learning disability and/ or their family and carers. Moreover, communication issues need to be considered regarding information sharing with other relevant professionals involved in the care of the individual to ensure that information about the management plan is effectively and accurately communicated in a timely manner to all the members of the care team.

The use of interdisciplinary working with effective communication and information sharing can facilitate prescribing within Person-Centred Planning. Furthermore, the input of the person with a learning disability, their family and carers is essential when prescribing within person-centred planning. The guide recommends that managing behaviours must always take place within person-centred planning, meaning that it should be driven by the person themselves to ensure that healthcare provision is directed by what is important to the individual.

In alliance with the thorough assessment and formulation, the monitoring of the effectiveness of interventions should also be thorough and carried out at regular intervals. The guide recommends the use of objective outcome measures as well as subjective self and carer reports. Furthermore, the monitoring process should inform the formulation and management plan which should be re-evaluated at each stage of monitoring. Underlying the careful monitoring and assessment process should be the aim to prescribe medication, if necessary, at the lowest possible dose and for the minimum duration. In addition, non-medication management strategies and the withdrawal of medication should always be considered at regular intervals.

The guide acknowledges that the implementation of the recommendations may have resource implications and therefore guidance on how to implement the recommendations is offered (see Section 2). It is suggested that organisations that are involved in caring for adults with a learning disability for whom medication is either prescribed or considered to manage behaviour problems ensure that the systems and resources are in place to allow the recommendations to be implemented.

The process of guideline development involved the completion of a comprehensive systematic review examining the evidence base for the effectiveness of medication in the management of behaviour problems in adults with a learning disability. The systematic review utilised a large-scale

electronic database search, hand searching and cross-referencing. The search was split into separate searches for seven different medication classes (antipsychotics, antidepressants, opioid antagonists, mood stabilisers and antiepileptic medications, antianxiety medications including beta-blockers and benzodiazepines, psychostimulants, and vitamins and others). Strict inclusion and exclusion criteria were established to assist in the identification of relevant articles. All articles that addressed the effectiveness of any psychotropic medication in the management of any behaviour problem in adults, or any randomised controlled trials with children, with a learning disability were included in the review. Those studies that assessed the effects of medication on the symptoms of a diagnosed psychiatric illness were excluded as the intention was to probe the effects of medication on behaviour problems per se. The relevant papers were subsequently summarised to provide an overview of the current evidence for each medication (see Section 3).

The results of the systematic review indicate that there is a general paucity of good quality evidence to support the use of most psychotropic medication in the management of behaviour problems in adults with a learning disability. There appears to be adequate evidence from randomised controlled trials with adults, but mainly with children with and without autism, that risperidone is effective in the management of behaviour problems for this population. However, the emergence of adverse effects such as somnolence and weight gain may give cause for concern. Nonetheless, long-term follow up studies with children provide some reassurance to suggest that by and large these side effects are short lasting and tolerable.

The results for the antidepressants search suggest that the evidence base is rather equivocal and primarily based on prospective or retrospective case studies. Overall, an average of less than half of the cohort studied showed an improvement in behaviour with the rest showing no improvement or deterioration. The most pronounced effect of antidepressants on behavioural problems emerged where anxiety or obsessive compulsive symptoms were prominent. Again, concern was highlighted over the emergence of adverse events with the medication making the behaviour worse in some cases.

Similarly, there is some evidence to support the use of some mood stabilisers and antiepileptics in the management of behaviour problems. Small case study based evidence indicates that sodium valproate, carbamazepine and topiramate may be effective. Furthermore, there is some evidence to support the use of lithium, however, the outcome measures used were of questionable validity.

Equivocal evidence also currently exists for opioid antagonists with some studies showing better results on large doses and others on small doses. There is currently no evidence available to support the use of antianxiety medication, psychostimulants, or vitamins. However, it is important to recognise that lack of evidence of effectiveness does not imply that there is evidence that these medications are ineffective.

In response to the concern over the high rate of prescription of psychotropic medications in the area and with the dearth of good quality evidence to support their use, withdrawal studies have attempted to study the withdrawal of long prescribed medication in the field. Such withdrawal studies suggest that in approximately one third of cases, medication can be successfully withdrawn with no re-emergence of the behaviour problems. In approximately another one third of cases, a reduction in dose can be achieved and in one third of cases, no reduction in dose can be achieved.

Background to the guideline

Commissioning of the guideline

The project was funded by the Big Lottery Fund and was managed by MENCAP. The University of Birmingham on behalf of the Learning Disability Faculty and the College Research and Training Unit of the Royal College of Psychiatrists has developed a clear set of guidelines for clinicians, service users and carers on the use of medication for the management of behaviour problems in adults with a learning disability. This project was undertaken to enhance the welfare, reduce social exclusion, and improve the quality of life for people with a learning disability, their families and carers.

Analysis of need for the guideline

The prevalence of all levels of a learning disability (IQ less than 70) is 20–30 per 1000 of the general population of all ages, and the prevalence of a moderate and severe learning disability (IQ less than 50) is between 3 and 4 per 1000 (Fryers, 2000).

The rate of behaviour problems is high among those who have a learning disability. This is a major public health concern because approximately 2.5% of the general population has a learning disability. This also causes major suffering for the patients and burden for the carers. In a recent epidemiological study of a population based sample, Deb et al (2001a) found evidence of functional psychiatric illness among 14.4% (95% Confidence Interval 7.4-21.4%) of adults who have a mild to moderate learning disability. In the same population, (but including adults with a severe, moderate and mild learning disability) 60.4% showed behaviour problems of any severity (Deb et al, 2001b) and 11% showed severe challenging behaviour. Furthermore, 23% showed aggression, 24% self-injurious behaviour, 36% temper tantrums, 26% overactivity, 29% screaming, and 12% showed destructiveness. Similar rates are shown in another epidemiological survey in the UK (Smith et al, 1996). Behaviour problem in this context is defined as socially unacceptable behaviour that causes distress, harm or disadvantage to the person themselves or to other people or property, and usually requires some form of intervention. Terms such as 'challenging behaviour', 'behaviour disorder', and 'behaviour difficulty' have also been used.

Examples of behaviour problems include:

- Physical and verbal aggression towards other people.
- Physical harm and damage towards property.
- Self-harm and self-mutilation.
- Withdrawal, restricted socialisation, hyperactivity and stereotypical movements.

The cost of managing behaviour problems in adults who have a learning disability is considerable (approximate estimate of a minimum of £50-140 million per annum) because severe aggression in people with a learning disability often leads to a breakdown in community care and consequent admission to hospital with or without a secure environment. People with a learning disability are often excluded from mainstream services. The chances of social isolation increase markedly when learning disability is compounded with behaviour problems. It is therefore of utmost importance that appropriate national good practice guidelines for the medication management of behaviour problems in adults with a learning disability are developed. We envisage that the development of such a guideline will ultimately aid in the process of integration of people with a learning disability within the wider society.

It has been reported that between 20 and 45% of people with a learning disability are on antipsychotic medication, of which 14-30% are taking these to control behaviour problems (Deb and Fraser, 1994). Clarke et al. (1990) showed that 36% of adults with a learning disability who did not have a diagnosis of psychiatric illness also received psychotropic medication. Many medications including beta-blockers, antidepressants (including Selective Serotonin Reuptake Inhibitors (SSRIs)), lithium, anti-epileptics (such as sodium valproate and carbamazepine), naltrexone, and antipsychotics have been used for the management of behaviour problems per se in people with a learning disability (see reviews by Deb & Weston, 2000; Santosh & Baird, 1999). The use of psychotropic medication in people with a learning disability is as common in community settings as it is in institutional settings.

There is a widespread concern among professionals and caregivers of people with a learning disability regarding the use of medication for the treatment of behaviour problems in people with a learning disability in the absence of a diagnosed psychiatric illness. It is widely believed that there should be stringent criteria and a framework within which these medications should be used. Furthermore, their use should be monitored regularly, and if and when appropriate, these medications should be withdrawn rather than used for an indefinite period.

To date no guideline has previously been developed in the United Kingdom specifically covering the use of medications for behaviour problems in people with a learning disability. The National Institute for Health and Clinical Excellence (NICE) has been commissioned to develop many other guidelines on medication management but there are no plans in the near future to develop guidelines in this area. It is therefore necessary to develop a national clinical guideline in this area.

Guideline development process

The guideline development process utilised the guideline development criteria set up by the National Institute for Health and Clinical Excellence (NICE; 2004). This involved an initial scoping exercise, setting up of a Guideline Development Group (GDG) (see Appendix 1), and the formation of a

stakeholder group list (see Appendix 1). The initial scoping meeting was held on 3rd March 2004. This produced the 'Scope' for the project. The 'Scope' was subsequently circulated among stakeholder groups for their comments, amended in light of the comments received, and finalised by the GDG.

The GDG met monthly at the Conference Park in the University of Birmingham, UK over a period of 18 months. A second scoping meeting was held on 16th May 2005. In their first meeting, the GDG discussed a clinical care pathway for a virtual adult with a learning disability who lived in a community setting and had developed behaviour problems. This allowed the GDG to develop pathways for referral, assessment and treatment. The treatment pathway is broadly divided into the following treatment phases 'initiation', 'monitoring' and 'discontinuation'. The assessment pathway is broadly divided into 'Behaviour', 'Medical', 'Psychological/ Psychiatric' and 'Social' issues. This provided the framework for developing the guideline.

The GDG has recognised the importance of the recently published guideline by the British Psychological Society (BPS, 2004) on psychological interventions for the management of challenging behaviour among persons with a learning disability. The current guideline should be used in conjunction with the BPS guideline.

The project team, in conjunction with an Information Specialist and a Health Economist, has carried out a systematic review of the evidence on medication efficacy in the treatment of behaviour problems in adults with a learning disability, under the guidance of the GDG. The GDG has advised about search terms, databases, time scale, and inclusion/ exclusion criteria. It was decided that the review would be restricted to papers published from 1990 onwards. However, any relevant randomised controlled trials (RCTs) before that date have also been included as have other papers found through a hand search of relevant journals and cross-referencing.

The GDG has decided that unlike NICE, they will consider non-RCT studies, as good quality RCTs are rare in this field. However, the GDG has taken a conscious decision to limit papers for the systematic review to only those that have included 10 or more participants in their study. The GDG recognises the arbitrary nature of this cut-off but feels this is the most pragmatic way to address the difficult issue of conducting a systematic review in this area.

Initially the GDG advised on carrying out a literature review of 'systematic reviews' in the field, which revealed only three relevant systematic reviews. Therefore, the GDG further advised on carrying out a literature review of original papers combining all categories of medication in the same search. After scrutinising the initial search, the GDG advised to carry out systematic reviews according to individual medication groups, which revealed more relevant studies than compared with the initial search. The GDG therefore advised the systematic reviewers to use the latest literature search as the basis of the systematic review. The medication groups that were explored included: antipsychotics, antidepressants, mood stabilisers including antiepileptics and lithium, anxiolytics including beta-blockers, opioid

antagonists such as naltrexone, psychostimulants, and vitamins/ diets or other supplements that may have been considered for use in the present context. Where necessary, the GDG advised collecting supplementary data from studies carried out in related groups such as children with a learning disability, however only good quality RCT data have been assimilated from these sources in order to assist with the decision-making. The papers identified for inclusion were assessed for their methodological rigour based on a number of criteria to determine the validity of the results. Furthermore, these studies were graded according to the established hierarchy used by NICE (see Section 3 for full details on the systematic review).

The GDG made recommendations based on the available evidence from the systematic review. As the GDG discovered, there is a paucity of good quality evidence in the field and so decided to carry out an exercise of consensus gathering using similar methodology as that employed by Aman et al. (2000) using a modified 'Delphi' technique. The findings of this consensus exercise are included in the guideline (see Section 4).

The GDG also supervised a multi-centre audit involving the practice of clinicians in prescribing medication for the management of behaviour problems in adults with a learning disability. The audit assessed clinicians' practice against the audit questions that are included in the Quick Reference Guide. The results of this preliminary audit are reported in the guideline (see Section 6). The GDG envisage that a larger multi-centre audit along similar lines will be conducted in the future once the guideline is fully disseminated. The College Research and Training Unit (CRTU) at the Royal College of Psychiatrists is likely to play a prominent role in this audit.

The GDG also advised the Health Economist to produce data related to this area. It has become clear that there is no evidence available in this area and the methodology is fraught with difficulty. The GDG has therefore decided not to attempt to carry out a 'cost effective analysis' but simply to report the possible treatment costs and costs for possible consequences associated with a lack of treatment. However, the health economics data cannot demonstrate a causal relationship between the latter two issues. Real life case scenarios were used in order to make the health economics data more practicable. This is reported in the guideline (see Section 7).

The relevant part of the draft guideline and the consensus questionnaire were circulated among the Consultants and Specialist Registrars in the Learning Disability Faculty of the Royal College of Psychiatrists for their comments (over 250 members). The former was also circulated among stakeholder groups for their comments. The draft guideline was amended in the light of comments received (see Appendix 2 for a summary table of comments received and how these were subsequently addressed by the GDG).

Carer advice came primarily from the carer members of the GDG. It was difficult to find a General Practitioner (GP) member for the GDG; therefore, a psychiatrist who is also an ex-GP provided input. The 'People First' group in Staffordshire provided regular service users' input and advice to the guideline.

We have used a standardised, validated quality control criteria 'Appraisal of Guidelines for Research and Evaluation' (AGREE, 2001) instrument for assessment of the guideline and the process of its development (see Section 8 for details of the assessment).

Once finalised, three versions of the guideline (as per NICE criteria), have been published; a technical guideline, a quick reference guide (QRG), and an easy read guide.

The guideline has been disseminated through 7 regional launch conferences throughout the United Kingdom (see Section 8 for further details on the dissemination of the guideline). Furthermore, data has been presented at various national and international conferences, and published in various peer-reviewed journals. The guideline website has also been hyperlinked with various relevant organisations' websites.

Guideline development group

A guideline development group (GDG) developed the recommendations for the guideline. The GDG comprised a multidisciplinary forum of professionals and carers that are involved in or have in-depth knowledge of the care of adults with a learning disability. The GDG represented the following groups:

- Carers
- Nurses
- Psychiatrists (with a special interest in people with a learning disability)
- General practitioners
- Clinical Psychologists
- Pharmacists
- Social Workers
- NHS Management
- Health Economists
- Systematic reviewers & Information Specialists
- Researchers and administrative staff from the University of Birmingham.

(A list of the GDG members is included in Appendix 1 of this section.)
The GDG members have met 18 times between May 2004 and November 2005. Most of the GDG submitted a declaration of interest.

Stakeholder groups

The GDG has received comments on the scope and the draft guideline from a group of stakeholders (see Appendix 1 for list of stakeholders). The draft guideline was circulated among the consultant members of the Learning Disability Faculty of the Royal College of Psychiatrists in the United Kingdom and the stakeholder groups for comments. The GDG has considered comments received from the above groups before finalising the guideline (see Appendix 2 for a table of comments received and action taken).

Service user input

The People First (Staffs) group has provided the service users input to the guideline. Initially a Community Nurse Manager in Staffordshire who is the advisor to the People First (Staffs) liaised with the group. He translated information in a user-friendly fashion for presentation to the group. The following are the main themes that the group recommended:

- The prescriber should spend as much time as is necessary with the service user during consultations
- If there is not enough time available during the consultation, another appropriate professional should discuss the treatment plan with the service user outside the medical consultation allowing adequate time
- When appropriate the prescriber should speak to the service user directly as much as possible
- The prescriber should explain to the service user the treatment plan including its positive and negative effects
- The prescriber should provide information to the service user in an accessible format
- The service user should agree with the treatment plan if s/he has the capacity to give informed consent
- The service user should not be the last in the queue for medical consultation.

Scope of the guideline

Clinical questions covered by the guideline

- To develop a pathway relating to the assessment and treatment, including efficient monitoring and withdrawal, of the use of medication for the management of behaviour problems in adults with a learning disability.

Audience for the guideline

- All healthcare professionals involved in prescribing medication for the management of behaviour problems among adults with a learning disability.
- All those who are involved in the management of behaviour problems among adults with a learning disability.
- All those who are involved in any aspect of care for adults with a learning disability and behaviour problems.
- Service users.
- Families and carers of adults with a learning disability and behaviour problems.
- Other groups involved in managing, providing (NHS and independent organisations), and commissioning services for adults with a learning disability and behaviour problems.

Criteria addressed by this guideline

Individuals
- All people 18 years of age and older with a learning disability and behaviour problems.

Settings
- Any setting where this group exhibits behaviour problems.

Interventions and related topics covered
- All medications, supplements, diets and vitamins used for the management of behaviour problems among adults with a learning disability.

Interventions not covered
- Although reference will be made to non-medication based interventions, such as behaviour management (for example, positive behaviour support)

and psychological therapies, details of evidence relating to these managements will not be presented in this guideline. Instead, readers are referred to the British Psychological Society's (BPS) guideline on challenging behaviours (2004).

- This guideline will not address electro convulsive therapy (ECT) and complementary therapies.
- This guideline will not cover treatment options for psychiatric disorders among people with a learning disability in the absence of behaviour problems or where a behaviour problem is secondary to a psychiatric disorder and the primary aim of prescription is to treat the psychiatric disorder per se which may or may not have an effect on the associated behaviour problem.

Aims of the guideline

- To develop a set of recommendations to form a framework for the medication management of adults with a learning disability and behaviour problems based on the best evidence available.
- To identify gaps in the evidence.
- To identify and assess the clinical implications of the medication management of adults with behaviour problems and a learning disability.
- To develop a set of auditable criteria for the implementation and monitoring of the recommendations of the guideline.
- To improve the quality of care and endorse health gain for adults with a learning disability.

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Appendix 1: Individuals and organisations involved in developing this guideline

The project was funded by the Big Lottery Fund and managed by MENCAP. The University of Birmingham Neuropsychiatry and Intellectual Disabilities Research Group was commissioned to carry out this project. Professor Shoumitro Deb led the project on behalf of the Learning Disability Faculty of the Royal College of Psychiatrists. This document is editorially independent from the funding body and does not represent the views of that organisation.

Guideline development group (GDG) members

Professor Shoumitro Deb (Clinical Professor of Neuropsychiatry and Intellectual Disabilities, University of Birmingham; Project Lead)
Dr. Suzanne Robinson (Health Economist)
Dr. Gill Bell (representing General Practitioners)
Dr. David Branford (Pharmacist with special interest in Learning Disabilities)
Mrs. Miriam Wilcher (Pharmacist with special interest in Learning Disabilities)
Dr. David Clarke (Consultant Psychiatrist in Learning Disabilities)
Dr. Ashok Roy (Consultant Psychiatrist in Learning Disabilities and Medical Director)
Dr. Sabyasachi Bhaumik (Consultant Psychiatrist in Learning Disabilities)
Mrs. Linda Woodcock (Parent Carer/ Autism West Midlands)
Mrs. Florence Simon (Health Service Manager for Learning Disabilities Services)
Mrs. Caroline Lee (Approved Social Worker specialising in Learning Disabilities)
Dr. Biza Stenfert Kroese (Consultant Clinical Psychologist in Learning Disabilities)
Ms. Caron Thomas (Consultant Nurse specialising in Learning Disabilities and Acting Clinical Director)
Dr. Rob Chaplin (Consultant in General Adult Psychiatry and Learning Disability Lead in the College Research and Training Unit in the Royal College of Psychiatrists)
Mr. Chris Dale (Nurse Advisor to People First Self-Advocacy Group)
Mr. Ray Smart (Parent, Carer/ MENCAP)

Project team (University of Birmingham)

Dr. Rivashni Soni (Project Manager)
Miss Laure Lenotre (Systematic reviewer & Information specialist)
Miss Gemma Unwin (Research Associate)
Miss Sundip Sohanpal (Research Associate)
Miss Louisa Strain (Research Secretary)
Mr. Jarvey Moss (Research Secretary)
Ms Zaida Parveen (Research Secretary)

Steering group members

Professor Paul Lelliott (Director of the College Research and Training Unit of the Royal College of Psychiatrists)
Mr. David Condon (Head of Campaigns and Policy, Mencap)
Professor Gregory O'Brien (Chair of the Learning Disability Faculty of the Royal College of Psychiatrists)
Mr. Brian McGinnis (Learning Disabilities Advisor, Mencap, Retired)

Stakeholder organisations

Association for Real Change (ARC)
Association of Community Health Councils for England
Association of Directors of Social Services
Association of the British Pharmaceuticals Industry
AstraZeneca PLC
Audit Commission
Autism West Midlands
Autistic People Against Neuroleptic Abuse (APANA)
Aventis
British Association for Psychopharmacology
British Association for Social Work
British Council of Disabled People (BCODP)
British Institute of Learning Disabilities (BILD)
British Medical Association
British Psychological Society
Carers UK
College of Mental Health Pharmacists
College of Occupational Therapists
College Research and Training Unit, The Royal College of Psychiatrists
Commission for Social Care Inspection (CSCI)
Community Practitioners' and Health Visitors' Association
Department of Health (DoH)
Elfrida Society
General Social Care Council
GlaxoSmithKline
HASCAS
Healthcare Commission
Independent Healthcare Forum
Institute for Health Research, Lancaster University
Institute of Quality Assurance (IQA)
Janssen-Cilag Limited
Lilly
Lundbeck
Medicine and Healthcare Products Regulatory Agency
MENCAP
MENCAP (Birmingham)
Mental Health Act Commission
Mental Health Nurses Association (MNHA)

Mental Health Providers Forum
National Autistic Society
National Coordinating Centre for Health Technology
National Institute for Health and Clinical Excellence (NICE)
National Institute for Mental Health in England (NIMHE)
National Network for Learning Disability Nurses
National Patient Safety Agency
National Prescribing Centre
National Public Health Service for Wales
NHS Centre for Reviews and Dissemination (CRD)
NHS Confederation
NHS Direct Online
NHS Quality Improvement Scotland
Norah Fry Research Centre
Novartis Pharmaceuticals UK Ltd
Nursing and Midwifery Council (NMC)
Partnership Boards
People First (Staffs)
Pfizer
Primary Care Network
Princess Royal Trust for Carers
Psychopharmacology Special Interest Group
Rethink
Royal College of General Practitioners
Royal College of Nursing
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Speech and Language Therapists
Royal Pharmaceutical Society of Great Britain
Royal Society of Medicine
Sanofi-Synthelabo
School of Health and Related Research (ScHARR)
Scottish Assembly Government
Social Care Institute for Excellence
Strategic Health Authority (Birmingham & the Black Country)
Strategic Health Authority (Shropshire & Staffordshire)
Strategic Health Authority (West Midlands, South)
Surrey Place Centre, Canada
The Foundation for People with Learning Disabilities
The Mental Health Foundation
Tizard Centre, University of Kent
United Kingdom Home Care Commission
United Kingdom Psychiatric Pharmacy Group
Valuing People
Valuing People Support Team
Welsh Assembly Government
Welsh Centre for Learning Disabilities, Cardiff University
White Top Centre, Dundee University
Widgit Rebus
Zito Trust

Appendix 2: Summary of comments received and action taken from external review

The following table provides a brief summary of the comments that were received from stakeholders and members of the Royal College of Psychiatrists' Learning Disability Faculty during the external review of the draft guideline.

Comment	Action Decided
I think that it is rather too long. It takes the form of a text book while I would have thought that it should be more flexible, so it can be used by MDT members et al.	Going to have a shorter version (quick reference guide). Also reduce long paragraphs to bullet points.
Bullet points at the end of each chapter would be useful.	Bullet points to be added.
The goal is to identify the underlying cause so as to be able to use the medications more judiciously. Currently drugs are most often used to manage behaviour disturbances not infrequently because the resources are not available to conduct comprehensive assessments so as to determine the underlying cause.	Make explicit reference to drugs not being prescribed as compensation for the lack of other services, and non-drug treatment should always be considered.
I thought there could be more mention of the interdisciplinary team and in particular the contributions from speech/ language/ communication therapists and occupational therapists.	Include separate sections on multi disciplinary team working and information sharing.
Who assesses and continues to monitor target behaviours against which medication trials are being conducted? With persons with very challenging behaviours not infrequently a series of medication trials and on-going review of psychiatric and medical diagnoses is required and this can all become very overwhelming in terms of data unless there is someone competent to mange this. In general terms I think it is this infrastructure capacity and expertise to assess, review, trial of intervention, assess, review, another trial etc that eventually results in a successful outcome. Most often this infrastructure is inadequately present or totally absent.	Include reference to: 1) Key/ contact person identified through HAP/ CPA/ CP/ PCP can complete regular, objective assessments. 2) Suggested use of validated scale: will include review in guideline if possible. 3) Not expecting prescriber to do all assessments - can share responsibility with other teams.
Bottom of page 19: Comments could imply that drug treatment works- this still has to be demonstrated.	Wording to be changed.
Page 24: guideline development group - I see	Add to stakeholders list:

no mention of speech/ language/ communication and OTs. Perhaps these folk might be asked to comment on the draft?	British Association of Occupational Therapists and British Association of Speech and Language Therapists (draft guideline sent to these organisation for comment).
Reference to the 'prescriber' whom I again assume is the psychiatrist- but the psychiatrist is really only competent to assess in his/ her area of expertise i.e. 'psychiatric disorders' on page 33. For the most part I do not think the average generic psychiatrist in LD can adequately assess physical conditions and disabilities, medical conditions, seizure disorders, genetic issues, sensory impairments and impact of etc although he/she can provide leadership in ensuring these are adequately assessed and help develop such assessment services in his/her patch. Perhaps the strengths and limitation of the psychiatric role in LD needs to be clarified in this context.	Clarify: When assessment is beyond remit of professional capabilities, should refer to other professionals, but must make some basic assessments along the lines described. Also, emphasise in multidisciplinary input to the assessment.
Reference to all that 'prescriber' is going to do. Surely a comment here about the role of the interdisciplinary team rather than this being seen as a purely medical/ doctor intervention- which is not/ should not be if one is truly conducting a trial of intervention/ medication following an interdisciplinary assessment. Continued interdisciplinary reviews are particularly needed where underlying cause of the behaviour disturbance is still elusive and it is only through intervention trial (including medication) that an underlying cause may become clearer. On a slightly separate note, multi and inter disciplinary team work is actually quite difficult to mange well and perhaps a comment in the document about such work and the challenges involved might be made- while difficult, it has been my experience that interdisciplinary teamwork is absolutely essential in addressing the most challenging of behaviours.	No action needed: Already dealt with - inserting heading and explanation of multi and inter disciplinary work. Particular, emphasised it is part of interdisciplinary work and added in the beginning under general principles.
Treatment Plans and Reaction Strategies'- all very laudable goals but would not be easily achieved in present work setting or time allocated to clinical practice.	No action needed: All points discussed and decided upon that they should remain the same as all examples of best/ ideal practice.

Page 40 and 41: Points (a)-(r) in my experience would require adequate infrastructure support within a team structure to be possible- is this generally available up and down the country- or if not would a comment here on the required infrastructure be helpful. Many clinicians/ psychiatrists in poorly supported settings may easily feel overwhelmed and even clinically inadequate reading this.	No action needed: Discussed and decided upon that they are all good general principles. In addition, implementation points added to suggest organisations, such as NHS Trusts, are responsible for ensuring that the resources are available to implement the guidance.
Clinicians under pressure to use psychotropic medication should depend on careful consideration.	No action needed: Reason for guideline
Many situations where clinicians may feel under pressure or consider prescribing (AJMR list not relevant to executive summary indeed delete paragraph 2).	List deleted and Executive Summary edited.
Major comment: the font size is awful - almost unreadable it's so small (and yes I have had my eye sight checked regularly). Suggest you change it to 12 font.	No action needed: Guideline to be published in larger font.
Poly-prescribing, pg 42 this section does not specifically state that it refers to the polyprescribing specifically for problem behaviours… Suggest: spell it out that you're referring to just the prescribing for the problem behaviours.	Clarify as per advice: Add in definition of poly-prescribing. Now clarified that poly-prescrbing is meant in relation to one indication.
The guideline describes best practice in an ideal world and with well-resourced CLDTs. This is not the real world and I often have to make treatment decisions based on immediate concerns with the primary aim of preventing deterioration in the situation. This reality needs to be included in the document, long stating that in areas where resources do not allow guideline to be followed the responsibility lies with the commissioners and NOT clinicians.	Clarify: That assessments in emergency situations needs to be as thorough as possible and that a complete assessment be executed as soon as possible. Also, implementation points to be included that are directed to the NHS and independent service provider organisations.
Not sure sufficient psychiatrists to provide the number of second opinions that will be required	Wording to be changed. Second opinions to be obtained where relevant and necessary.
There is a training issue to ensure people use guidelines. I am not sure services have sufficient resources to carry out such detailed audits.	Training to be applied through dissemination and conferences- add words to this effect in dissemination section. In addition, implementation points to be

	added.
In the glossary it may be helpful to define "behaviour disorder".	Behaviour problem is now defined in the QRG and technical guide.
The intervention pathway is confusing, needs to be a clear statement of whether or not people with learning disabilities and behaviour disorder should be on care programme approach. I believe they should and this is the best framework, other plans confuse the issue.	Decided that it does not have to be a CPA but should be one of the options (CP, HAP, CPA, PCP) to ensure good monitoring.
The section on 6.5.1 and 6.5.1.2 and 6.5.1.3 is too wordy. It may be more user friendly to do clinical examples with flow charts to illustrate.	No action needed: Already dealt with. Going to reduce/ bullet point lengthy sections.
Needs a summary version, maybe one for clinicians, patients carers, GP's.	No action needed: Already dealt with. Going to have a Quick Reference Guide.
Worth referencing (key references) e.g. RCT's etc	No action needed: Systematic review section will have details of all pertinent studies in the field.
If audited: over 30 audit targets would have to be met which would be unreasonable. Better to identify a smaller number (max 10) key standards to aim for, these may then be met.	Audit questions are streamlined and the number of audit points has been reduced.
I am unclear how the causes of challenging behaviours are classified	Already addressed by recommendations. Not within remit.
Review of less than 28 days after stopping medication seems too soon.	No action needed: Already re-worded. Now has no specific time limit.
Pages 10-14- layout is poor, need to get rid of excessive underlining, use of colour? Executive summary is ok, in terms of summarising evidence, but if it is indeed a summary, could do with bullet points/ numbered brief statements, so that in actual fact, this could be used as a simple audit tool.	Look at layout and amend if necessary. Executive summary to be amended. Quick Reference Guide will provide brief summary.
Assessment Pathway (page 27-36) is too lengthy- most of this information is common sense, headings could be used in version for e.g. psychiatrists, could use longer version if information is for nurses etc.	No action needed: Already changed to bullet points with additional, separate extended section.
The intervention pathway/ CPA - description of CPA/ HAP etc is unnecessary- CPA is not up and running yet in Wales.	No action needed: Majority of responders appreciate this section. Also

	the section has been streamlined.
PRN prescribing, if needs to be included, should be on a separate page. High dose drugs needs to be separate.	No action needed: Already moved to a separate section at the end.
Audit Criteria (page 51)- is physical exam necessary to fulfil audit criteria? Cannot audit what investigations were carried out before prescription as will be different for different individuals. Rationale/ target behaviour can be one question.	No action needed: Also auditing medications prescribed. Rationale and target behaviour are addressed as different concepts. Physical examinations and investigations are added as 'when appropriate'.
Use bullet points. Too wordy in places, found myself sifting through 52 pages to obtain approximately 6 pages of 'nitty gritty'- need to make core take-home message easy to find (e.g. pages 15/16, 38-42, 47, 48, 52-52) Also- References, assume they are in full guideline. Different versions for patients, carers, doctors etc? To be used as 'line' document, need to get down to no more than 15 pages similar to NICE layout.	No action needed: Already amending to include more bullet points and an executive summary. Also, references included in full guideline. Three versions to be published, full, quick and service user.
I see you have not restricted your guideline to England and Wales. Legislation here will be rather different after next Wednesday but I do not think this will affect your guideline.	No action needed: Not within scope to identify specific legislation.
Would like to suggest that the term medicine/medication be used in preference to "drug/s". The former has more positive associations while the latter is now frequently reserved for the abuse/misuse arena and has somewhat negative connotations.	No action needed: Already decided to change term.
Administration of drugs requires excellent communication for PWLD and full attention will have to be given to the training needs of prescribing clinicians.	No action needed: Guideline addresses training issue in implementation points.
Key Priorities for Implementation… I feel that these recommendations are too loose and have no connection with the purpose of DATABID. Surely the recommendation should be related to all the stages of medicine use in LD i.e. prescribing, drug choice, review, pathology testing, and stopping.	Implementation points have been revised thoroughly.
4. Background to the Guideline. I think much	Section has been revised and

of sections 4.1 and 4.2 need rewriting.	streamlined.
Good reminder that formulation should include a risk assessment.	No action needed.
Treatment plan. Whilst I fully support minimum effective dose and ongoing consideration of withdrawal, I prefer think in terms of optimum minimum period of time necessary where drug treatment is of clear and proven benefit.	No action needed.
Page 39 (issues to consider (h))- good idea in principle but I would question the feasibility of ST and M/ LT plans at time of prescribing, at least until efficacy tested.	No action needed: Decided that treatment plans serve as a useful reminder to clinicians of their initial treatment intentions. The time frame to define short, medium and long term have been revised.
PRN prescribing - does there need to be an extra entry about the use of prn in community settings- needs a clear prn protocol- possibly drawn up and monitored by community nursing/ psychology colleagues?	Details added to prn section.
Page 47 (monitoring of treatment)- agree with time scales of follow up in general, apart from setting a minimum of 28 days for first follow up. I usually initiate treatment in GP and is often a delay, my first follow up may therefore be longer- users/ carers know to contact earlier if any problems arise.	No action needed, already dealt with. The specification of strict time scale (i.e. 28 days) is now omitted.
The draft guidelines document is excellent overall and addresses the majority of key dimensions that underpin a high quality set of guidelines- a) of development, b) context, c) content application. The authors have also consulted comprehensively with an optimum group of stakeholders, experts and clinicians, which is commendable. The end result would be a much-needed final document for PWLD.	No action needed.
The general guidelines are extensive and very useful in this specific group of people who are referred to psychiatrists (unreadable) definite psychiatric disorder is difficult to be diagnosed. At the moment there are no such guidelines locally and we have only the Maudsley guidelines, which cover this aspect of our practice only very, very briefly.	No action needed.
Very laudable, but too long and repetitive to be very 'user-friendly'. Summary/ flow charts in various sections	No action needed: Plans to streamline document and produce 3 versions

would help.	including the QRG.
Comprehensive and needed guideline. Would be helpful to have more specific mention of autistic spectrum disorder and problem behaviours.	If time allows, include a section on autistic spectrum disorder. Also if resources allow, will review evidence of interventions within this group.
These are common sense guidelines and a necessary checklist. Problem with guideline committees can be a tendency to prepare a voluminous document (unconsciously fortifying that a lot of work has been done) and then that document becomes redundant. For guidelines to be of any clinical use in longevity, brevity is the key. I feel overall, a good document.	No action needed: Plan to have quick reference guide version. Also produced separate A4 and A5 posters that are included in the QRG with bullet points for audit and main recommendations so that clinicians can put them up on their clinic/ office wall for quick reference.
The enclosed guideline is comprehensive but dense. I would prefer to see a more user-friendly version to go on the clinic wall- probably in graphical form, e.g. a flow chart.	Posters with summaries to be inserted into quick reference guide and available on the website.
Useful guidance and "gold standard" to aim for. Cannot always do everything suggested, especially after initial consultation or in emergency situations.	No action needed: Already stressed in guideline that it details aspects of best practice.
I approve of the guidelines. The use of a rating scale/ direct recording of behaviour is an essential requirement. Failure to obtain a baseline makes it impossible to judge benefit and means the patient may be exposed to an unlicensed drug with side effects whilst deriving no benefit. This approach forces the prescriber to make a decision about effectiveness.	Noted that objectivity needs to be applied to outcome measures when judging the effectiveness of a clinical trial.
It cannot be emphasised enough that there may be environmental remedies available which may cause a dramatic improvement in behaviour i.e. meaningful daytime activities, trained and experienced staff. If this is what a person requires we should resist prescribing unless these issue are also addressed.	No action needed: The importance of non-medication based interventions and a thorough assessment of causes and consequences of problem behaviours are already highlighted in the document.