



East Lancashire Health Economy  
Medicines Management Board

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## **Low Strength Antipsychotic Prescribing in Dementia: A GP Resource Pack**

## Foreword

Antipsychotics are being prescribed to manage the behavioural and psychological symptoms associated with dementia (BPSD), however the clinical evidence shows limited effectiveness and this practice also threatens patient safety due to the increased risks of stroke, other cerebrovascular problems and death amongst older people.

**There are an estimated 1800 excess deaths and 1620 cerebrovascular accidents each year as a result of the prescription of antipsychotics to people with dementia.**

Based on this clinical evidence, the National Institute for Clinical Excellence (NICE) has made clear that antipsychotics should be only used **as a last resort in severe cases or where there is the risk of harm to the patient or others**. Also that when indicated, regular reviews should be carried out when they are prescribed with a view to reduce or discontinue prescriptions whenever possible.

ELMMB appreciates that GPs often take on prescribing of antipsychotics which have been initiated by specialists during a secondary care admission. We appreciate these are challenging for GPs to manage, as there is often limited background information as to the indication for prescribing or monitoring arrangements.

We hope that with the aid of this pack GPs will feel confident to review any remaining antipsychotic prescribing in dementia patients within their practices. It should be noted that it is usually straightforward for GPs to carry out discontinuation or reduction and that **70% of patients have no worsening of symptoms when antipsychotics are discontinued**.

# GUIDELINE

## 1. Introduction

- 1.1 Behavioural and psychological symptoms of dementia (BPSD) include a range of non-cognitive symptoms, such as apathy, anxiety, depression, agitation, aggression, delusions and hallucinations, wandering, incontinence, altered eating habits, sexual disinhibition, shouting, hoarding, repeated questioning and sleep disturbances.
- 1.2 It is important for clinicians to try and identify a cause for the above symptoms and manage these using non-pharmacological measures (see later) rather than resorting to drugs to treat the symptoms.
- 1.3 Low strength antipsychotics are sometimes prescribed to treat BPSD but produce only limited benefits and are associated with an increased risk of stroke and mortality, as well as other serious adverse events such as sedation, extrapyramidal side effects, dehydration, falls, chest infections and accelerated cognitive decline.
- 1.4 **Evidence for use:** Systematic reviews have analysed the clinical effectiveness of antipsychotics in people with dementia. These analyses are based on 18 placebo controlled randomised trials, most of which were conducted over a 10-13 week period. However, many of these trials have not been published in full. The evidence for benefit is not equal for all antipsychotics. The best evidence base exists for risperidone for use for aggression symptoms only where trials showed a modest short term benefit.
- 1.5 Reducing inappropriate prescribing of antipsychotic medication for people with dementia is an urgent national priority and has been an increasing concern over the past few years.
- 1.6 In 2004, the CSM reported an apparent 2 to 3 fold increase in risk of cerebrovascular event in people with dementia prescribed olanzapine and risperidone.
- 1.7 In 2005 it became apparent that no antipsychotic was safer than any other when it was reported a 1.7 fold increase in mortality with the typicals due to heart failure, sudden death and pneumonia.
- 1.8 [The 2006 NICE guideline](#) recommends the use of pharmacological intervention in the first instance **only** if the patient is severely distressed or there is an immediate risk of harm to the person or others. The National Dementia Strategy advocates only the appropriate use of antipsychotic medication for people with dementia.
- 1.9 In his 2009 'Time for Action' report Banerjee states that across the country 180,000 people are being treated with antipsychotics of which 36,000 will derive benefit but an additional 1,600 cerebrovascular effects (of which half are severe) and 1,800 deaths will occur sooner than would be expected. In conclusion the report states that the potential harms of antipsychotic use in dementia patients (including increased cerebrovascular events and mortality) outweigh the benefits.
- 1.10 If the above figures are extrapolated to apply to just Greater Manchester this would equal approximately **75 extra deaths** and **68 extra strokes** each year, solely attributable to use of these drugs in dementia patients.
- 1.11 National data sets show use is mostly off-licence: either prescriptions of antipsychotics such as quetiapine, olanzapine, aripiprazole, and haloperidol without a licence indication or the use of risperidone outside the strict licence indication (i.e. use>6 weeks). In addition, audits have shown

that at least 62% of dementia patients are prescribed atypical antipsychotics for **six months** or more.

- 1.12 Despite the considerable work in this area, prescribing data still shows higher than England average of low strength antipsychotic prescribing across Greater Manchester.

## 2. Managing a patient with BPSD – non pharmacological treatments

- 2.1 Many different factors may be associated with behavioural problems in patients with dementia these are outlined in the table below:

<b>Physical Illness</b>	poorly controlled pain diabetes with impaired glucose metabolism dehydration hypoxia electrolyte disturbances heart failure delirium
<b>Environmental factors</b>	noisy and over stimulating environments social isolation visual and auditory sensory impairments
<b>Prescribed medicines</b>	These may cause psychotic symptoms in elderly during use or on withdrawal: Benzodiazepines Anti-Parkinson drugs – LDopa, procyclidine Anti-arrhythmics – digoxin, propranolol Anti-inflammatories – aspirin, indomethacin Anticonvulsants – carbamazepine, phenytoin Steroids - prednisolone

- 2.2 Challenging behaviours may be a way of communicating an unmet need.
- 2.3 Clinicians will need to be aware of and address the above factors before doing anything else; this should include taking a history of the problem, having the behaviour described by the carer/team and discussing current and past behaviour with the carer/team.
- 2.4 The PAIN approach should be applied. Manage or treat any contributory factors. If the patient is not eating or drinking adequately initiate a food and fluid chart, and check that they are not over-sedated, or have dental problems e.g. ill-fitting dentures, candida infection. Pain is one of the most common causes of BPSD
- P** Physical problems e.g. infection, pain  
**A** Activity related e.g. dressing, washing  
**I** Iatrogenic e.g. side effects of drugs such as anti-cholinergics  
**N** Noise and other environmental factors e.g. lighting, lack of stimulation.
- 2.5 Involve the person/carers/staff in developing an ongoing person-centred care plan to address individual needs.

- 2.6 An analysis should be made of whether the behaviour (e.g. reversal of sleep–wake cycle so that the person with dementia is awake at night) is a problem primarily for the person with dementia, or for their carers (be they paid carers or family carers).
- 2.7 For mild to moderate BPSD, watchful waiting or non-pharmacological interventions should be tried first.
- 2.8 Identify factors that improve BPSD e.g. music, dance, aromatherapy, cognitive stimulation, massage, multisensory stimulation, exercise, creative therapies, animal assisted therapies. Consider available options and tailor activities to individual preferences, skills and abilities.
- 2.9 All treatable causes should be treated with the correct specific treatment (e.g. antibiotics for infection).
- 2.10 Be alert for and treat any coexisting emotional disorders (e.g. depression and/or anxiety and sleep disturbances)
- 2.11 Decide and record what symptom/behaviour you are treating, set up a system for monitoring it (e.g. using simple charts completed by nursing staff or carer), and monitor and record side-effects closely (sedation, stiffness, tremor, mobility problems).
- 2.12 Antipsychotic treatment should only be considered if the above options have not reduced symptoms to a manageable level.

### 3. Appropriate use of antipsychotics in people with dementia

#### Considerations for New Prescriptions.

***NB GPs should not initiate new antipsychotic prescriptions in patients with dementia as this is a red indication on the Red, Amber and Green traffic light list.***

- 3.1 There is limited evidence for the pharmacological management of BPSD.
- 3.2 There is a high rate of spontaneous recovery (or placebo effect) in trials, so watchful waiting may be useful in the case of less severe problems since up to half of all cases may be self-limiting.
- 3.3 For most people with dementia, the risk of harm of antipsychotic treatment outweighs the likelihood of benefit, therefore they should not be considered as first-line treatment options except in circumstances of extreme risk and harm.
- 3.4 Antipsychotics should also be used with caution in Parkinson's disease and dementia with Lewy bodies. There is a high risk of severe neuroleptic sensitivity reactions (such as severe extrapyramidal symptoms; or acute, severe physical deterioration)
- 3.5 Risperidone is the only licensed antipsychotic, with moderate evidence base for aggression and should therefore be the first line choice. It should only be used in people with dementia who have pre-existing psychotic disorders or severe aggression. The lowest dose for the shortest time period should be used; it is licensed for 6 weeks use and should be prescribed for no more than 12 weeks.
- 3.6 Other antipsychotics should not be prescribed for people with dementia. Exceptions should be made only when the individual has a pre-existing psychotic disorder independent of a diagnosis of dementia.
- 3.7 **The decision to prescribe should be made by a specialist** and only after a careful risk assessment, particularly cerebrovascular risk (taking into account age, hypertension, diabetes, smoking, atrial fibrillation and previous stroke).
- 3.8 Prior to initiation the specialist must discuss risks and benefits with patient/relative/carer, the indication for the prescription, alternatives considered and plans for review, reduction and cessation. If use is unlicensed then consent should be obtained. All discussions about risks and benefits of use must be clearly documented.
- 3.8 Prescriptions for antipsychotics should be time limited and reviewed against target symptoms and side effects. Once initiated continuation should be reviewed 1-2 monthly and reduction or cessation actively considered at each review.
- 3.9 There is growing evidence that acetylcholinesterase inhibitors or memantine may delay the onset of BPSD, providing additional benefit to using these currently available treatment options. Use in this way is outside of NICE guidance but it is licensed. If used, it is important to ensure that the target symptoms are identified and there is a plan for review and discontinuation if there is no response to treatment.

## **Reviewing patients already prescribed an antipsychotic**

- 3.9 As there are already people with dementia on antipsychotics in primary care, GPs have a key role to play in reviewing these patients with a view to stopping treatment if appropriate. Where antipsychotics are already prescribed for BPSD, all healthcare professionals should question the need for long-term use.
- 3.10 All patients with dementia currently on antipsychotics for behavioural problems who have not had a trial discontinuation in the last 3 months should have the antipsychotic reviewed and stopped to assess the risks and benefits of continued treatment unless:
- The antipsychotic was prescribed for a pre-existing condition prior to a diagnosis of dementia, e.g. bipolar disorder or psychotic depression.
  - The patient is under regular review by a specialist for behavioural problems. This does not include reviews solely planned to assess the on-going benefits of prescribing cholinesterase inhibitors (e.g. donepezil) or memantine to delay cognitive decline.
  - There is a detailed care plan in place for ongoing antipsychotic use.
- 3.11 There may be some patients with undiagnosed dementia prescribed antipsychotics that need reviewing. Consider running a report on patients on an antipsychotic to discover those that do not have a linked diagnosis requiring antipsychotics.
- 3.12 If the patient is under regular review by secondary care for behavioural problems then responsibility for reviewing and reducing or stopping the antipsychotic lies with secondary care, otherwise this should be undertaken by the patient's GP.
- 3.13 It is recommended that when reviewing a number of patients in a care home, that the stopping of treatment is staggered and those patients considered to be the most likely to not need the antipsychotic are stopped first, to give the home confidence in the process.
- 3.14 If a decision is made to reduce or stop an antipsychotic carers, should be involved in the decision and supported through the process.
- 3.15 It should be noted that **70% of patients have no worsening of symptoms when antipsychotics are discontinued.**
- 3.16 The risk of recurrence of BPSD after discontinuation is more likely if:
- Previous discontinuation has caused symptoms to return
  - The person currently has severe symptoms
- 3.17 If the person is receiving a "low dose" then proceed directly with discontinuation and monitoring

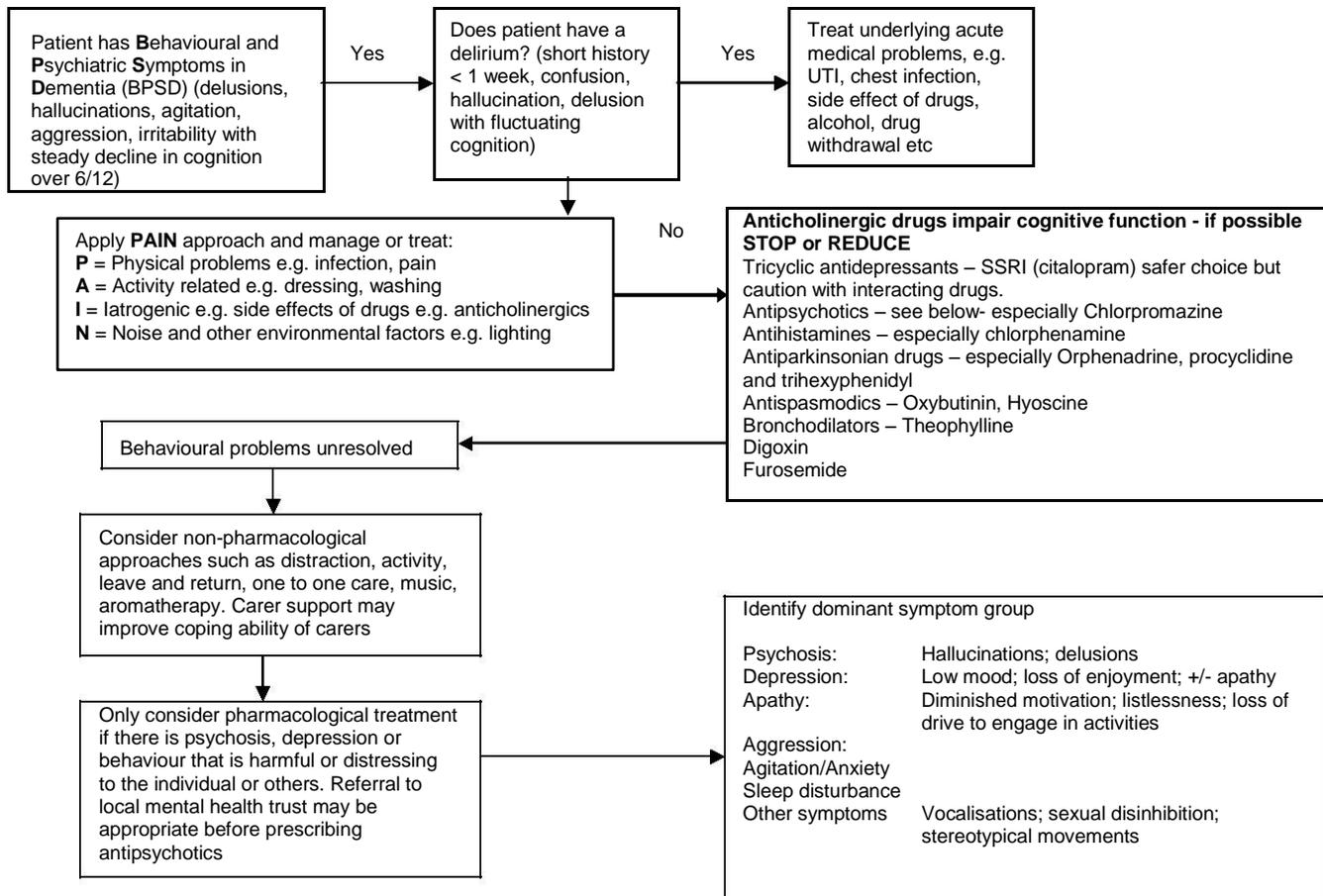
<b>Antipsychotic</b>	<b>Suggested daily "Low Dose"*</b>
<b>Aripiprazole</b>	<5 mg
<b>Olanzapine</b>	<2.5 mg
<b>Quetiapine</b>	<50 mg
<b>Risperidone</b>	<500 microgram
<b>Haloperidol</b>	<500 microgram
<b>Amisulpride</b>	<50 mg
<b>*Suggested "low dose", but consult the BNF first</b>	

- 3.18 **If the person is receiving a higher dose**, taper the dose over one month:
- Reduce to half dose for two weeks
  - GP review at two weeks
  - Discontinue immediately after a further two weeks
- 3.19 Review every stage of dose reduction to evaluate patient response.
- 3.20 **In some cases it may be necessary to withdraw the drug more slowly, particularly if symptoms reappear.**
- Implement small decreases in dose (ensure dose reduction is possible with strengths available), one step down at a time.
  - Where the anti-psychotic is given more than once daily, **decrease** only one dose to start with, choosing the dose where patient is likely to be least affected.
  - Allow sufficient time for the patient to adapt to the new dose (usually 1-2 weeks) before considering the next small reduction in dose.
  - When the lowest dose has been achieved on a daily basis then administer on alternate days before stopping completely.
- 3.21 If the patient is difficult to manage or BPSD returns seek advice from local mental health trusts.

## 4. Summary Flow Chart

### MANAGING BEHAVIOUR PROBLEMS IN PATIENTS WITH DEMENTIA

Adapted from pathway developed by NHS Peterborough and NHS Cambridgeshire.



#### General guidelines for the prescription of antipsychotic drugs in dementia

If the patient you are seeing is not known to the Dementia Service consider a referral. This will enable prompt assessment for appropriate non-pharmacological treatment and for cholinesterase Inhibitor therapy

Remember that depression and anxiety are common in dementia and it is often safer to use an antidepressant as a first line treatment before considering antipsychotic medication.

Care should be taken to avoid using antipsychotic drugs in people with Parkinson's disease/ Lewy Body dementia

Where antipsychotics are already prescribed for BPSD, all healthcare professionals should question the need for long-term use.

When possible, before prescribing an antipsychotic drug for someone with dementia, the risks and benefits should be discussed with relatives and/or care staff. It is important to inform relatives and carers if the antipsychotic drug being prescribed is not licensed for the treatment of behavioural problems in dementia. If you do decide to prescribe "off licence" ensure you clearly record your reasons for doing so in the clinical notes.

There are several risks associated with the use of antipsychotic drugs in dementia. They can cause sedation, increase the risk of falls; increase the risk of cerebrovascular events and sudden death. The long term use of such drugs can accelerate cognitive decline.

The only product licensed for the treatment of behavioural problems in dementia is risperidone. It is licensed for short term treatment of up to 6 weeks in patients unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others.

## 5. Tools to support review in primary care

### Antipsychotics in Dementia – Review Checklist

Adapted from NHS South West Yorkshire Partnership

Patient Name:	
Date of Birth:	
Antipsychotic prescribed and dose	

#### Background information:

Have cerebrovascular risk factors been assessed?	YES / NO
Has there been a baseline assessment of cognitive function?	YES / NO
Have the target symptoms (that the medication should be improving) been identified, quantified and documented? e.g. Hallucinations	YES / NO
Was antipsychotic treatment indicated? (*)	YES / NO
Were the risks / benefits of treatment discussed with the patient and / or carer & documented in the notes?	YES / NO
Have baseline measurements been carried out? (see table 2)	YES / NO
Has discontinuation been attempted previously?	YES / NO
Does the patient have an individual care plan?	YES / NO
Has a date for review of treatment been set?	YES / NO

\* **Antipsychotics should not be used for mild to moderate non-cognitive symptoms.** Medication for non-cognitive symptoms or behaviour that challenges should only be considered as a first-line option **if there is severe distress or an immediate risk of harm to the person with dementia or others.**

#### Ongoing review of treatment

Date of the review	
Current antipsychotic and dose	
Have target symptoms been assessed (for therapeutic response) and been clearly documented? e.g. Hallucinations	YES / NO
Has cognitive function been assessed (for decline)?	YES / NO
Has the patient been assessed for antipsychotic side effects / adverse effects? (E.g. mobility, falls, sedation, extra pyramidal symptoms, BP and pulse, blood glucose, infection, anticholinergic S/Es, weight & central obesity. In patients with DLB monitor for severe untoward neuroleptic sensitivity reactions)	YES / NO
Is antipsychotic to be continued?	YES <sup>†</sup> / NO

<sup>†</sup> If YES, document reason why in the notes and discuss with patient and/or carers. Set another date for review.

**Table 1: Assessment of patient with non-cognitive symptoms.**

Assess patient early to identify factors that may influence behaviour. Include:-

<b>Physical Health</b>	Suitable physical examination Any acute medical problems i.e. delirium Exclude infection (especially UTI) Exclude possible undetected pain or discomfort Is patient dehydrated? Any chronic disease that may have become unstable or relapsed?
<b>Mental Health</b>	Assess for anxiety and depression
<b>Side-effects of medication</b>	What medication is the patient on? Assess for side-effects of medication (including acetylcholinesterase inhibitors). Has any new medication recently been started?
<b>Psychosocial factors</b>	Individual biography Religious beliefs, spiritual and cultural identity Against who is the aggression directed? Is there a reason? Physical environmental factors. Is the patient bored? Behavioural and functional analysis in conjunction with carers and care workers

**Table 2: Baseline measurements before initiating Risperidone**

Risperidone is the only antipsychotic licensed for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others.

**NB- If baseline measurements are not carried out before initiating risperidone and a side-effect develops it will be difficult to decide whether the effect was due to risperidone or if it was already there.**

	<b>Baseline</b>	<b>After initiation of risperidone</b>
<b>Body weight</b>	✓	at 3 months then yearly
<b>Serum U&amp;E's</b>	✓	Yearly
<b>FBC</b>	✓	Yearly
<b>Plasma glucose</b>	✓	at 4 – 6 months then yearly
<b>Blood pressure and pulse</b>	✓	monitor frequently during dose titration
<b>ECG</b>	✓	Where possible, then monitor after dose changes and if there is evidence of other risk factors such as relevant personal/family history, co-prescription of drugs that prolong QT interval or lower potassium
<b>Prolactin</b>	✓	at 6 months then yearly
<b>LFTs</b>	✓	Yearly
<b>Creatinine Phosphokinase</b>	✓	measure again only if Neuroleptic Malignant Syndrome suspected

## Patient information:

- A leaflet for patients / carer's and a guide for health and social care professionals can be found at [www.alzheimers.org.uk/antipsychotics](http://www.alzheimers.org.uk/antipsychotics)
- The Use of Antipsychotics in Dementia – Information for Patients and their Carers  
<http://www.1000livesplus.wales.nhs.uk/sitesplus/documents/1011/%283%29antipsychotic%20leaflet.pdf>
- The Dementia Action Alliance's call to action on the use of antipsychotic drugs for people with dementia. [http://www.institute.nhs.uk/qipp/calls\\_to\\_action/Dementia\\_and\\_antipsychotic\\_drugs.html](http://www.institute.nhs.uk/qipp/calls_to_action/Dementia_and_antipsychotic_drugs.html)
- Social Care Institute for Excellence (SCIE) has a dementia gateway for people who work with people with dementia. <http://www.scie.org.uk/publications/dementia/index.asp>
- Dementia UK is a charity committed to improving quality of life for all people affected by dementia. <http://www.dementiauk.org>

## Example patient information letter:

- Example of letter to care home, carer or patient regarding the need to review antipsychotics in dementia patients: <http://www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/Meds-use-and-safety/Service-deliv-and-devel/Mental-health/Antipsychotic-Medicines-Audit-and-Reduction-Tool-Vs1/>

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5. Drugs and Therapeutics Bulletin: Vol 45 No 11 November 2007 – How safe is antipsychotics in dementia? ([www.dtb.bmj.com](http://www.dtb.bmj.com) )
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8. Government response to Professor Sube Banerjee's report on the prescribing of anti-psychotic drugs to people with dementia: 12 November 2009 ([http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_108303](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_108303))
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