All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

CEPP National Audit – Antipsychotics in Dementia

December 2018

This document has been prepared by a multiprofessional collaborative group, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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1.0 BACKGROUND

The behavioural and psychological symptoms of dementia (BPSDs) are commonplace amongst people with dementia, with more than 90% experiencing at least one BPSD during the course of their condition[1]. Psychological, or non-cognitive, symptoms include psychosis (hallucinations and/or delusions), agitation, and anxiety; behavioural symptoms include wandering, shouting, aggression, and repeated questioning. These behavioural symptoms can often be viewed as an attempt to communicate an unmet need, rather than as direct symptoms of dementia[2]. Antipsychotics have frequently been used to manage BPSD, however as psychosis is relatively rare in dementia compared with the absolute level of antipsychotic prescribing, it is clear that these medications are being prescribed to deal with BPSD in a more general sense for behavioural symptoms[1].

In 2009, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a Drug Safety Update highlighting the clear increased risk of stroke and small increased risk of death associated with the use of antipsychotics in elderly people with dementia[3]. In the same year, the government-commissioned Banerjee Report, *The use of antipsychotic medication for people with dementia: Time for action*, noted that the high level of use of antipsychotics in patients with dementia meant that the potential benefit of their use in specific cases was likely to be outweighed by the adverse effects of their use in general[1]. The report also highlighted that antipsychotics were estimated to cause approximately 1,800 deaths and 1,620 cerebrovascular adverse events in people with dementia in the UK annually, and estimated that around two thirds of antipsychotic prescriptions for the treatment of dementia may be inappropriate[1]. In addition, for people with dementia with Lewy bodies or Parkinson's disease dementia, antipsychotics can worsen the motor features of the condition, and in some cases cause severe antipsychotic sensitivity reactions[4].

Despite the risks of adverse events with antipsychotics being well known and it being almost a decade since the Banerjee Report was published, an inquiry and subsequent report by the National Assembly for Wales's Health, Social Care and Sport Committee in 2018, *Use of antipsychotic medication in care homes,* noted that significant concerns about the inappropriate use of antipsychotics still remain[5]. The report contains 11 recommendations, including:

- Recommendation 1. The Welsh Government should ensure that, within 12 months, all health boards are collecting and publishing standardised data on the use of antipsychotic medication in care homes.
- Recommendation 2. The Welsh Government should ensure that, within 12 months, all health boards are fully compliant with NICE guidelines on dementia, which advise against the use of any antipsychotics for non-cognitive symptoms or challenging behaviour of dementia unless the person is severely distressed or there is an immediate risk of harm to them or others.
- Recommendation 4. We recommend the introduction of mandatory three monthly medication reviews for people with dementia who have been prescribed antipsychotic medication, with a view to reducing or stopping the medication following the first review where possible[5].

These recommendations have been 'Accepted, in principle' by Welsh Government[6]. In addition, the *Dementia Action Plan for Wales 2018–2022* includes the following high-level performance measures for health boards: '*Reduction in the percentage of people with a diagnosis of dementia prescribed antipsychotic medications and a reduction in duration of treatment*'[7].

The 2018 NICE Guideline, *Dementia: assessment, management and support for people living with dementia and their carers*, states that people with dementia with non-cognitive symptoms of agitation, aggression, distress and psychosis should only be offered antipsychotics if they are at risk of harming themselves or others, or they are

experiencing agitation, hallucinations or delusions that are causing them severe distress[4]. Where an antipsychotic for the treatment of non-cognitive symptoms is offered, NICE recommends that this is following a full discussion with the person with dementia and/or carers about the benefits and harms[4].

Two antipsychotics are currently licensed in the UK for the indications above, these are risperidone and haloperidol. The marketing authorisation for risperidone only covers 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 where there is a risk of harm to self or others[8]. The marketing authorisation for haloperidol only covers treatment of persistent aggression and psychotic symptoms in people with moderate to severe Alzheimer's dementia and vascular dementia when non-pharmacological treatments have failed and when there is a risk of harm to self or others. It is noted in its Summary of Product Characteristics that the need for continued treatment must be reassessed after no more than 6 weeks[9].

Outside of these specific groups, use of other antipsychotic medicines is therefore unlicensed or off-label. When prescribing unlicensed or off-label medicines, the prescriber should follow relevant professional guidance, taking full responsibility for the decision with informed consent having been obtained and documented[4].

NICE guidance states that antipsychotics are used at the lowest effective dose, for the shortest possible time, and that the person is reviewed at least every 6 weeks to check whether they still need the medication. Treatment with antipsychotics should be stopped if the person is not getting a clear ongoing benefit from taking them, and after discussion with the person taking them and their family members or carers (as appropriate)[4].

Swansea University have developed a tool to enable nursing professionals to undertake a structured approach to the monitoring of medicines for mental health, including antipsychotics. The Adverse Drug Reaction (ADRe) Profile[10] facilitates the identification of adverse drug reactions experienced by patients in care homes, with suggestions for an appropriate course of action where issues are identified. The report *Use of antipsychotic medication in care homes* cites the ADRe profile as an example of 'good practice' as it has been shown to reduce the use of sedative medicines, including antipsychotics, in care homes[5].

1.1 Therapeutic Priorities and Clinical Effectiveness Prescribing Programme

This audit has been developed to support local prescribing initiatives as part of the Clinical Effectiveness Prescribing Programme (CEPP), as well as providing a national picture on antipsychotic prescribing in Wales. The audit also supports recommendations made in the Welsh Government's *Dementia Action Plan for Wales 2018–2022* and the National Assembly for Wales's Health, Social Care and Sport Committee report, *Use of antipsychotic medication in care homes.*

2.0 DATA COLLECTION

2.1 Aim

The aim of this audit is to ensure appropriate prescribing of antipsychotics in patients aged 65 years and over with a diagnosis of dementia.

2.2 Objectives

1. To ensure that antipsychotic prescribing in patients aged 65 years and over, with a diagnosis of dementia, is in line with NICE guidance.
2. To identify patients who may require a review of their antipsychotic prescription.

2.3 Setting standards

Setting standards is difficult, and reasonable targets for some of the criteria will vary depending on many factors. Completion of the audit to obtain baseline data may assist in setting more appropriate standards in future, though re-auditing (i.e. completion of the audit cycle outlined here) should demonstrate movement towards the currently suggested standards.

In addition to recommending that compliance with NICE guidance as a whole is audited, the National Assembly's inquiry into the use of antipsychotics in care homes also made the recommendation of introducing mandatory three-monthly medication reviews for people with dementia who have been prescribed an antipsychotic[5]. This recommendation has since been 'Accepted, in principle' by Welsh Government[6], and has been included here as an audit standard.

The recommendation of three-monthly medication reviews was made to align with the advice in the previous version of the NICE guideline published in November 2006; the version of the guideline that was available at the time of the inquiry. Therefore, an additional audit standard has been included here to assess compliance with recommendations made in the most recent version of the NICE guideline (published in June 2018); to carry out medication reviews every 6 weeks[4].

Auditing compliance with both three-monthly and six-weekly reviews will help demonstrate a shift towards the latter as the updated NICE guidance embeds to become routine practice, therefore standards have not been set for these criteria individually, however the combined percentage for these two standards should add up to 100%.

2.3.1 Standards

- 100% of patients have evidence of being at risk of harming themselves or others, or are experiencing agitation, hallucinations or delusions that are causing them severe distress.
- 100% of patients have documented evidence of a discussion between the healthcare professional and person with dementia/carer about the benefits and harms of treatment with an antipsychotic.
- 100% of patients prescribed an antipsychotic:
    - for three months or longer have evidence of regular three-monthly reviews.
    - for 6 weeks or longer have evidence of regular six-weekly reviews.

2.4 Method

1. Open the patient list generated by Audit+ for the Prescribing Safety Indicator—*Number of patients aged 65 years or over prescribed an antipsychotic, as a percentage of all patients aged 65 years or over*.
2. Complete the 'Data collection sheet' for all patients identified.
3. Complete the 'Data summary sheet' using the completed data collection sheet(s).
4. Discuss findings at GP/cluster meeting, and complete the 'Practice review sheet'.
5. Send the anonymised 'Data summary sheet' to awttc@wales.nhs.uk.
6. Decide on post-audit activities, i.e. patient review; refer to mental health team; change to GP practice policies/procedures for prescribing antipsychotics in dementia etc.
7. Re-audit and complete 'Data summary sheet'. Discuss findings at GP/cluster meeting.
8. Send anonymised 'Data summary sheet' to awttc@wales.nhs.uk.

If you are willing to share any examples of good practice please upload them to the *Antipsychotics in Dementia* thread on share.awttc.org.

3.0 DATA COLLECTION SHEET

Data collection sheet __ of __ GP Practice: _____ Date: _____

Baseline audit ☐ **OR** Follow-up audit ☐ Health Board: _____

Patient ID	Indication					Initiation					Benefits and harms		Dementia type	Place of residence	
	Is the antipsychotic prescribed for BPSD?* • Yes [Y] • No [N]		Is the patient on the dementia register? Please tick if Yes [Y]	Is it documented that the person with dementia is: • At risk of harming themselves or others, **or** • Experiencing agitation, hallucinations or delusions that are causing them severe distress? • Yes [Y] • No [N]		Who initiated or recommended the antipsychotic? • Secondary care mental health team [MH] • GP [GP] • Other [O] • Not recorded [NR]				Is the patient currently under the care of the Older Persons Mental Health Team? Please tick if Yes [Y]	Is there evidence of a discussion with the person with dementia / family member / carer about the benefits and harms of treatment with an antipsychotic? • Yes [Y] • No [N]		• Alzheimer's [A] • Lewy Body [LB] • Vascular [V] • Parkinson's [P] • Mixed [M] • Other dementia [O] • Not recorded [NR]	Does the person with dementia live in: • Their own home [H] • Care home [C]	
	Y	**N**	**Y**	**Y**	**N**	**MH**	**GP**	**O**	**NR**	**Y**	**Y**	**N**		**H**	**C**
1.															
2.															
3.															
4.															
5.															
6.															
7.															
8.															
9.															
10.															
Totals															

***If the antipsychotic has been prescribed for an indication other than BPSD (e.g. bipolar disorder), stop the audit for this patient**

Patient ID	Antipsychotic prescribed	Duration of treatment							Treatment reviews							Review required?	
	• [name, form, strength, dose]	Antipsychotic start date [DD/MM/YY]	• Less than 6 weeks [A] • 6 weeks – 3 months [B] • 3–6 months [C] • 6–9 months [D] • 9–12 months [E] • 12 months+ [F]						Have an appropriate number of 6-weekly antipsychotic reviews been carried out and documented since initiation or in the last 12 months (whichever is the least)? If 'Yes', please circle who carried out the review: 1° care team or 2° care team. • Yes [Y] [1° or 2° care] • No [N]			If no – have an appropriate number of 3-monthly reviews been carried out and documented since initiation or in the last 12 months (whichever is the least)? If 'Yes', please circle who carried out the review: 1° care team or 2° care team. • Yes [Y] [1° or 2° care] • No [N]			Is there evidence of a dose reduction or withdrawal attempt at the last medication review? (Irrespective of when the last review took place) Please tick if Yes [Y]	Where the answer to any question is 'No', a review is required. Does the patient require a review? • Yes [Y] • No [N] If yes, consideration should be given to stepping down or stopping treatment where appropriate, according to guidelines.	
			A	B	C	D	E	F	Y		N	Y		N	Y	Y	N
1.									1°	2°		1°	2°				
2.									1°	2°		1°	2°				
3.									1°	2°		1°	2°				
4.									1°	2°		1°	2°				
5.									1°	2°		1°	2°				
6.									1°	2°		1°	2°				
7.									1°	2°		1°	2°				
8.									1°	2°		1°	2°				
9.									1°	2°		1°	2°				
10.									1°	2°		1°	2°				
Totals																	

4.0 DATA SUMMARY SHEET

An Excel version is available here, which will automatically calculate percentages and produce graphs, enabling progress between baseline and follow up audits to be tracked.

Practice: _____ Date of audit: _____

Health Board: _____

Baseline audit ☐ **OR** Follow-up audit ☐

		Number	Percentage
A	Total number of patients generated by Prescribing Safety Indicator.		
B	Total number of patients prescribed an antipsychotic for a diagnosis other than non-cognitive symptoms/BPSD, e.g. bipolar disorder.		
C	Total number of patients suitable for audit (A-B).		**100%**

	Criterion	Number	Percentage	Standard
1. Indication				
1a.	Number of patients with evidence of being at risk of harming themselves or others, or are experiencing agitation, hallucinations, or delusions that are causing them severe distress.			**100%**
1b.	Number of patients **without** evidence of being at risk of harming themselves or others, or experiencing agitation, hallucinations or delusions that are causing them severe distress.			**0%**
1c.	Number of patients on the Dementia Register.			
2. Initiation				
2a.	Number of patients whose antipsychotic was initiated or recommended by:			
	• Secondary care mental health team			
	• GP			
	• Other			
	• Not recorded			
2b.	Number of patients currently under the care of the Older Persons Mental Health Team.			
3. Benefits and harms				
3a.	Number of patients where there is evidence of a discussion between the healthcare professional and person with dementia / family member / carer about the benefits and harms of treatment with an antipsychotic.			**100%**
3b.	Number of patients where there is **no** evidence of a discussion between the healthcare professional and person with dementia / family member / carer about the benefits and harms of treatment with an antipsychotic.			**0%**
4. Place of residence				
4a.	Number patients residing in their own home.			
4b.	Number of patients residing in a care home.			

	Criterion	Number	Percentage	Standard
5. Duration of treatment				
5.	Number of patients treated with an antipsychotic for:			
	A. Less than 6 weeks			
	B. 6 weeks – 3 months			
	C. 3–6 months			
	D. 6–9 months			
	E. 9–12 months			
	F. Longer than 12 months			
6. Treatment reviews				
6a.	Number of patients suitable for a review [total of 5B to 5F, above]			
Treatment reviews — 6-weekly reviews				
6b.	Of the patients identified in **6a**, number of patients prescribed an antipsychotic for 6 weeks or longer with evidence of an appropriate number of 6-weekly reviews.			**100%** 6b and 6c combined
6b(i).	Of the patients identified in **6b**, number of reviews carried out by primary care team.			
6b(ii).	Of the patients identified in **6b**, number of reviews carried out by secondary care team.			
Treatment reviews — 3-monthly reviews				
6c.	Of the patients identified in **6a**, number of patients prescribed an antipsychotic for 3 months or longer with evidence of an appropriate number of 3-monthly reviews.			**100%** 6b and 6c combined
6c(i).	Of the patients identified in **6c**, number of reviews carried out by primary care team.			
6c(ii).	Of the patients identified in **6c**, number of reviews carried out by secondary care team.			
Treatment reviews — no evidence of review				
6d.	Of the patients identified in **6a**, number of patients **without** evidence of an appropriate number of 6-weekly or 3-monthly reviews.			**0%**
Treatment reviews — evidence of reduction or withdrawal				
6e.	Of the patients identified in **6a**, number of patients where there is evidence of a dose reduction or withdrawal attempt at the last medication review (irrespective of when the last review took place).			
7. Review required				
7.	Of the total number of patients suitable for audit (Criterion **C**), number of patients identified as requiring an antipsychotic review.			

5.0 PRACTICE REVIEW SHEET

A. What issues have been identified as a result of carrying out this audit?

B. What discussion/activities did the practice undertake as a result of the audit? This may include discussions with secondary care colleagues.

C. What changes will be implemented as a result of this audit?

This audit was completed by:

Name(s):……Date:……

Signature(s):……...

Practice (name and address): ……

……..…

……..

……...

Health Board: ……

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