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| Enclosure No: | xx/XXXXX/xxxx0918 |
| Agenda item No: | xx – CEPP National Audit: Antipsychotics in Dementia |
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1.0 ACTION FOR CONSULTEES

Consultees are asked to consider and comment on the *CEPP National Audit: Antipsychotics in Dementia* document.

2.0 PURPOSE

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 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*.

This document is also pertinent to:

- **AWMSG Five-year Strategy 2018–2023 'Supporting prudent prescribing to obtain the best outcomes from medicines for patients in Wales':**
 - *Recommendation 3.4: Medicine-related harm*
AWMSG is committed to reducing medicine-related harm over the next five years. AWMSG will identify areas of potential harm from prescribing medications in vulnerable groups of patients and, through development of learning resources and appropriate NPIs, will encourage safe prescribing in these areas.
 - *Recommendation 4.5: National Prescribing Indicators*
AWMSG will work with health boards/trusts to develop NPIs that inform measurable improvements in the quality of healthcare and improved patient outcomes, and include audit and review activity. AWMSG is committed to using all available information technology to monitor the clinical appropriateness of the NPIs and achievement of desired outcomes.
- **National Prescribing Indicators 2018–2019**
 - *1.1 Prescribing Safety Indicators*

2.1 Process

- September 2018: Draft paper to AWPAG for comment
- October 2018: Edited paper for consultation with stakeholders identified by AWPAG
- October / November 2018: Updated paper to AWPAG for sign off
- November 2018: Updated paper presented to AWMSG Steering Committee
- December 2018: Final document presented to AWMSG for endorsement

2.2 Stakeholders

- Welsh Government
- Public Health Wales
- Royal College of General Practitioners
- Royal Pharmaceutical Society
- General Practitioners Committee Wales
- Local Medical Committees
- GPs
- Pharmacists
- Chief Pharmacists and Medicines Management teams
- Medical Directors
- Assistant Medical Directors
- Directors of Public Health
- Community Health Councils
- Patients
- Community Pharmacy Wales
- Royal College of Psychiatrists
- Alzheimer's Society

3.0 SUMMARY

It is estimated that two thirds of antipsychotic prescriptions for the treatment of dementia may be inappropriate. This is despite the increased risk of adverse events that have been associated with their use, including risk of stroke and even death. The aim of this audit is to reduce levels of inappropriate prescribing of antipsychotics in patients aged 65 years and over with a diagnosis of dementia.

This will be achieved by measuring the degree to which prescribing of antipsychotics to patients aged 65 years and over is in line with current NICE guidance, and supporting the identification of patients where it may be appropriate to reduce or discontinue their antipsychotic prescription.

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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 condition¹. 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 dementia². 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 symptoms¹.

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 dementia³. 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 general¹. 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 inappropriate¹. 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 reactions⁴.

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 remain⁵. 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 possible⁵.

These recommendations have been 'Accepted, in principle' by Welsh Government⁶. 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

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experiencing agitation, hallucinations or delusions that are causing them severe distress⁴. 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 harms⁴.

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 others⁸. 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 weeks⁹.

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 documented⁴.

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 homes⁵.

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 antipsychotic⁵. This recommendation has since been 'Accepted, in principle' by Welsh Government⁶, 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 weeks⁴.

Auditing compliance with both 3 monthly and 6 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 audited 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. Search the patient record for the antipsychotic indication. If the antipsychotic is for an indication other than BPSD, stop the audit for this patient and move on to the next.
3. Complete the data collection form for all patients appropriately identified.
4. Complete the practice summary sheet and discuss findings at GP/cluster meeting, and complete the practice review sheet.
5. Send the anonymised practice 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 practice summary sheet. Discuss findings at GP/cluster meeting.
8. Send anonymised practice summary sheet to AWTTTC.

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

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3.0 PATIENT DATA COLLECTION SHEET

Data collection sheet ___ of ___

GP Practice: _____ Date: _____

| Patient ID | Indication | | | | Initiation | | | | Benefits and harms | | Dementia type | Place of residence | | Antipsychotic prescribed |
|---------------|--|---|--|---|---|----|---|----|--|---|--|--|---|--|
| | Is the antipsychotic prescribed for BPSD?* | | Is it documented that the person with dementia is: | | Who initiated or recommended the antipsychotic? | | | | Is there evidence of a discussion with the person with dementia / family member / carer about the benefits and harms of treatment with an antipsychotic? | | <ul style="list-style-type: none"> 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: | | <ul style="list-style-type: none"> [name, form, strength, dose] |
| | Y | N | Y | N | MH | GP | O | NR | 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

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| Pt ID | Duration of treatment | | | | | Treatment reviews | | | | | | Review required? | | | |
|---------------|--|-----|-----|------|-----|---|----|---|--|----|---|--|---|---|--|
| | <3 | 3-6 | 6-9 | 9-12 | 12+ | Y | | N | Y | | N | Y | N | | |
| | <ul style="list-style-type: none"> • Less than 3 months [<3] • 3-6 months [3-6] • 6-9 months [6-9] • 9-12 months [9-12] • 12 months+ [12+] | | | | | 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. | | | 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. | | | Is there evidence of a dose reduction or withdrawal attempt at the last medication review? (Irrespective of when the last review took place) | | Where the answer to any question is 'No', a review is required. Does the patient require a review? <ul style="list-style-type: none"> • Yes [Y] • No [N] If yes, consideration should be given to stepping down or stopping treatment where appropriate, according to guidelines. | |
| | | | | | | 1° | 2° | | 1° | 2° | | | | | |
| 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 | | | | | | | | | | | | | | | |

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4.0 DATA SUMMARY SHEET

Practice: _____

Date of 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 |
|------------------------------|---|--------|------------|-------------|
| 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 a clear indication of BPSD, i.e. no evidence that the patient is at risk of harming themselves or others, or experiencing agitation, hallucinations or delusions that are causing them severe distress. | | | 0% |
| Initiation | | | | |
| 2. | Number of patients whose antipsychotic was initiated or recommended by: | | | |
| | • secondary care mental health team | | | |
| | • GP | | | |
| | • Other | | | |
| | • Not recorded | | | |
| 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% |
| Place of residence | | | | |
| 4a. | Number patients residing in their own home. | | | |
| 4b. | Number of patients residing in a care home. | | | |
| Duration of treatment | | | | |
| 5. | Number of patients treated with an antipsychotic for: | | | |
| | • Less than 3 months | | | |
| | • 3–6 months | | | |
| | • 6–9 months | | | |
| | • 9–12 months | | | |
| | • Longer than 12 months | | | |

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| | Criterion | Number | Percentage | Standard |
|--------------------------|--|--------|------------|-----------------------------------|
| Treatment reviews | | | | |
| 6a. | Number of patients prescribed an antipsychotic for 6 weeks or longer with evidence of an appropriate number of 6 weekly reviews. | | | 100% 6a and 6b combined |
| 6a(i). | Number of reviews carried out by primary care team. | | | |
| 6a(ii). | Number of reviews carried out by secondary care team. | | | |
| 6b. | Number of patients prescribed an antipsychotic for 3 months or longer with evidence of an appropriate number of 3 monthly reviews. | | | |
| 6b(i). | Number of reviews carried out by primary care team. | | | |
| 6b(ii). | Number of reviews carried out by secondary care team. | | | |
| 6c. | Number of patients where there is evidence of a dose reduction or withdrawal attempt at the last medication review. | | | |
| Review required | | | | |
| 7. | Number of patients identified as requiring an antipsychotic review. | | | |

5.0 PRACTICE REVIEW SHEET

A. What lessons did the practice learn from carrying out this audit?

B. What discussion/activities did the practice undertake as a result of the audit?

C. What changes has the practice agreed to implement as a result of this audit?

This audit was completed by:

Name(s):.....Date:.....

Signature(s):

Practice (name and address):

.....

.....

.....

6.0 REFERENCES

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