HIGH DOSE ANTIPSYCHOTICS

(Medicines Management Reference MO5)

Policy

CONTENTS

1.0 INTRODUCTION

1.1 Robust evidence that high doses of antipsychotics are any more effective than standard doses is lacking:

- There is no evidence that high dose antipsychotics use is beneficial for patients with first episode psychosis.
- For the majority of people with acute psychotic illness the target dose for effective treatment is likely to be below the licensed maximum.
- There does not seem to be any justification in the published literature for the use of high dose antipsychotic medication for relapse prevention in schizophrenia, nor is there convincing evidence that maintaining the higher dose of antipsychotic initiated during a period of relapse provides better relapse prevention in the long term.
- There is no justification in published literature for high dose antipsychotics in the treatment of persistent aggression.
- There is no convincing evidence that antipsychotic dosage higher than the maximum licensed dose is more effective than the standard dosage for treatment resistant schizophrenia.
- There is evidence that most antipsychotic drugs are associated with a small but definite increase in the frequency of QTc prolongation, torsade de pointes and sudden cardiac death. The risk increases with higher doses.
- There is evidence that high dose antipsychotic use is detrimental to cognitive functioning.
- The efficacy of combining two or more first generation antipsychotics or adding a first generation antipsychotic to a second generation drug and vice versa has not been established, and there is evidence for an increased risk of adverse effects and pharmacokinetic interactions.

1.2 The Royal College of Psychiatrists (RCPsych) issued a consensus statement on the use of high dose antipsychotic medication (1993, updated 2014) as a result of a possible link between high doses of antipsychotics, ventricular tachycardia, sudden death and the increased incidence of side effects

1.3 The use of high dose antipsychotics should be an exceptional clinical practice, only employed when adequate trials of standard treatments, including Clozapine, have failed.

1.4 When antipsychotics are prescribed at doses above the BNF maximum dose, additional monitoring and documentation are required (as described in paragraphs 4.3 to 4.6)

2.0 DEFINITIONS

2.1 High dose antipsychotic prescribing is defined as either:

- A single antipsychotic at a dose above the BNF maximum dose
- Two or more antipsychotics that, when expressed as a percentage of their respective maximum recommended doses, and added together, result in a cumulative dose of >100%. Please refer to the Antipsychotic Dosage Ready Reckoner for further information.

2.2 ‘BNF maximum dose’ is the maximum dosage recommended in the British National Formulary (BNF) for the relevant indication and age of the patient. The dosage recommendations in the BNF largely reflect those in the manufacturer’s Summary of Product Characteristics (SmPC) however expert clinical opinion can also influence the BNF recommendations.

2.3 Prescriber: A registered doctor or registered independent/supplementary prescriber who is authorised by the Trust to prescribe to patients in the care of the Trust (see Medicines Policy and Non-Medical Prescribing Policy for further details.)

2.4 Brief Psychiatric Rating Scale (BPRS) is a rating scale which a clinician uses to measure psychiatric symptoms such as depression, anxiety, hallucinations and unusual behaviour.

2.5 The Glasgow Antipsychotic Side-effect Scale (GASS) is an easy to use self-reporting questionnaire aimed at identifying the side effects of antipsychotic medication

2.6 ‘Choice and Medication’ is an online resource providing patient information about mental health conditions and the treatments available to help make informed decisions about choosing the right medicine. The Trust portal is available here https://www.choiceandmedication.org/somerset/

3.0 ROLES and RESPONSIBILITIES

3.1 Prescribers are responsible for requirements listed in Section 4.0

3.2 Medicines management team are responsible for auditing compliance with the requirements

3.3 Clinical Directors are responsible for ensuring compliance with this policy within their services

3.4 The Medicines Oversight Group is responsible for monitoring compliance with this policy

4.0 PROCESS DESCRIPTION

4.1 Prescribers must be confident that the person has been compliant with the previous prescription directions before considering increasing the dose above the maximum BNF limits.

4.2 Any decision to prescribe high-dose antipsychotic treatment should involve an individual (and documented) risk-benefit assessment by a trained psychiatrist in consultation with the clinical team, patient and patient’s family or advocate where possible.

4.3 If a high dose is considered appropriate, the prescriber should document the target symptoms, expected response and potential side effects at the outset. Ideally, validated rating scales will be used to gauge effectiveness and side effects e.g. RiO

has the Brief Psychiatric Rating Scale (BPRS) and GASS available through the assessment menu.

4.4 Baseline tests as detailed on paragraph 4.7 should be completed before initiation of treatment above BNF maximum doses.
If an ECG or other baseline tests are not conducted, the reason for this should be clearly documented in RiO Progress Notes.
If a patient is found to have a prolonged baseline QTc interval, (men > 440 msec, women > 470 msec), halt the plan for high dose prescribing and seek further advice e.g. cardiology referral.

4.5 The following information must be included in RiO Progress Notes and should be reviewed at least annually as part of a medication review:

a) Statement clarifying why high dose is required

b) Statement clarifying why clozapine is not an option for this person if diagnosed with schizophrenia.

c) Statement clarifying that there has been a discussion with the patient to ensure that the patient understands and agrees to the treatment and appreciates as far as possible the benefits and risks of treatment including potential side effects and their consequences.

d) A summary of relevant information, leaflets, factsheets or sign-posting to online resources provided to the patient. Patients should be provided with the 'Choice & Medication' high dose leaflet prior to initiation of treatment [Available here: https://www.choiceandmedication.org/somerset/printable-leaflets/handy-fact-sheet/]

4.6 An alert must be recorded under the physical health category in RiO e.g. "Combined dose of current antipsychotic medication is above BNF limit. Extra physical monitoring required - see High dose antipsychotics section of Medicines Intranet page"

4.7 Monitoring of the patient should be completed at the following frequencies:
Base line, 1 month, 3 months, 6 months then every 6 months or after dose changes.

Test	**Recording on Rio**
Blood pressure and pulse	Assessments menu> End of bed reports> Physical observations or Medication monitoring>Cardiometabolic monitoring and intervention>Physical health/examination
GASS and Brief Psychiatric Rating Scale	Assessments menu>Rating scales
LFTs, Us&Es, FBC, HBA1c, Cholesterol, Prolactin, -	Medication monitoring>Cardiometabolic monitoring and intervention>Clinical investigations
ECG* (Base line, on dose increases and annually)	Medication monitoring>Cardiometabolic monitoring and intervention>Clinical investigations

* RCPsych CR190 recommends that ECGs should be performed every few days following initiation of high-dose antipsychotic treatment or during a period of dose escalation until steady state is achieved.

4.8 If, after 3 months, insufficient improvement has occurred or side effects emerge requiring additional medication, the dose should be decreased to the normal range (i.e. BNF maximum dose or less)

5.0 TRAINING/COMPETENCE REQUIREMENTS.

5.1 None.

6.0 MONITORING

Element of policy for monitoring	Section	Monitoring method - Information source (e.g. audit) / Measure / performance standard	Item Lead	Monitoring frequency / reporting frequency and route	Arrangements for responding to shortcomings and tracking delivery of planned actions
Appropriateness of high-dose treatment	**4.2** **4.3** **4.4**	Audit of RiO patient notes to identify completion of risk-benefit assessment with clearly defined reason for treatment and desired outcomes	Lead MH Specialist Pharmacist	Annual	Relevant Divisional Governance Groups
Annual review of patients on high-dose treatment	**4.5**	Audit of RiO patient notes for record of annual review including required statements	Lead MH Specialist Pharmacist	Annual	Relevant Divisional Governance Groups
Monitoring of patients before and during treatment	**4.2** **4.7**	Audit of RiO patient notes for documentation of monitoring at recommended frequency	Lead MH Specialist Pharmacist	Annual	Relevant Divisional Governance Groups
Termination of high-dose treatment if insufficient improvement	**4.3** **4.8**	Audit of patients initiated on high-dose treatment continued >3 months without evidence of sufficient improvement	Lead MH Specialist Pharmacist	Annual	Relevant Divisional Governance Groups

7.0 REFERENCES

DM Taylor, TRE Barnes, AH Young (2018) The Maudsley Prescribing Guidelines in Psychiatry, 13th Edition. London, Wiley-Blackwell. (“The Maudsley Guidelines”)
RCPsych CR190 Consensus Statement on High Dose Antipsychotic Medication Dec 2014

National Patient Safety agency. With safety in mind: mental health services and patient safety. July 2006.

8.0 DOCUMENT CONTROL

Document Author	Advanced Specialist Pharmacist – Mental Health		
Lead Owner	Chief Pharmacist – Head of Medicines Management		
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Applies to	Somerset Partnership NHS Foundation Trust Mental Health and Learning Disabilities, CAMHS, Old Age Psychiatric, and Psychiatric Liaison Services.	**Exclusions**	None