Livewell Southwest

Rapid Tranquillisation Policy for Adults aged 18 years and over

Version No 2.5
Review: May 2017

Notice to staff using a paper copy of this guidance

The policies and procedures page of LSW intranet holds the most recent version of this document and staff must ensure that they are using the most recent guidance.

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References/Source	Sweetman, S (Ed) (2011) **Martindale: The Complete Drug Reference 37th edition.** London: Pharmaceutical Press **NICE Clinical Guideline 25**: The short-term management of disturbed/violent behaviour in in-patient psychiatric settings and emergency departments. February 2005 **NPSA Rapid Response Report**: Resuscitation in mental health and learning disability settings. Nov 2008 (NPSA2008/RRR010) Taylor D, Paton C & Kapur S (2009) **The Maudsley Prescribing Guidelines 11th Edition.** London: Informa Healthcare. Summary Of Product Characteristics(for individual drugs) accessed at medicines.org.uk
Supersedes	Rapid Tranquillisation Policy for Adults aged 18 years and over

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Document Review History

Version No.	Type of Change	Date	Originator of Change	Description of Change
1.0	Minor amendments	Sept 05	Clinical Pharmacist, Mental Health	Change of title and minor changes to wording as requested by DTC
1.1	Minor amendments	27/3/06	Clinical Pharmacist, Mental Health	Removal of referral to A&E department
1.2	Minor amendments	31/3/06	Clinical Pharmacist, Mental Health	Change of title for publication
1.3	Updated	26.11.07	Communications and Intranet Officer	Changes to author contact details and review date.
1.4	Updated	15.01.09	Communications and Intranet Officer	Review date extended.
1.5	Minor Review	24.03.09	Clinical Pharmacist, Mental Health	Updated Format Changes to Mental Health Act Info Training Requirements Changes to treatment algorithm Review date of 12 months
1.6	Minor Review	24.03.09	Clinical Pharmacist, Mental Health	Changes to Mental Health Act Info Training Requirements Changes to treatment algorithm Review date of 12 months
1.7	Major review	27.05.10	Clinical Pharmacist, Mental Health	Inclusion of adults over 65 years Changes to layout and flow diagrams Inclusion of Mental Capacity Act information
2	Ratified	17.6.10	Policy Ratification Group	Ratified.
2.1	Updated, approved at PMGG 3/6/11	25/07/11	Clinical Pharmacist, Mental Health	Addition of Aripiprazole IM and olanzapine IM following approval at Drug and Therapeutics Committee. Addition of midazolam guidelines
2.2	Published	3/8/12	Chief Pharmacist	Completion of actions agreed at PMGG and reformatted to LSW format
2.3	Review	April 2014	Chief Pharmacist	For discussion at MGG
2.4	Ratified	July 2014	Chief Pharmacist	Changes agree at MGG plus new max dose for Haloperidol
2.5	Updated	Jun 2016	A Hawke	Updated and formatted.

Rapid Tranquillisation Policy for Adults aged 18 years and over

1 Introduction

This policy has been prepared for the short-term management (up to 72hrs) of acutely disturbed mental health patients aged 18 years and over in in-patient units.

This policy is not appropriate for the management of patients under 18 years. Rapid Tranquillisation Guidelines for use in Children (12-17 years) are available on the LSW IntraNet.

This policy may be used for patients with Learning Disabilities, but extra caution should be used as these patients may be more sensitive to medication effects and side-effects.

Guidelines for the Management of Delirium and Agitated Behaviour in Older People are available via the webpage of the Plymouth and South Devon Joint Formulary.

Rapid tranquillisation should be used only when appropriate behavioural and psychological interventions have failed. It is intended to calm the patient without over-sedation, to manage extremely disturbed behaviour quickly whilst reducing the risk of harm, and to protect the patient's safety and dignity.

2 Purpose

NICE Guidance has been published for the short-term management of disturbed/violent behaviour in in-patient settings and emergency departments (CG025). However, the guidance recommends that local protocols are produced to cover all aspects of Rapid Tranquillisation.

The purpose of this policy is to give local guidance on:

- Appropriate medication choices for Rapid Tranquillisation
- How to monitor the patient following the use of medication
- Staff training requirements
- Administering medication within the legal limits of the Mental Health Act 1983

3 Duties

3.1 LSW Board, through the Safety, Quality & Performance Committee has the corporate responsibility to ensure the implementation of the policy.

3.2 The Chief Pharmacist with the assistance of the Mental Health Pharmacists has

the responsibility to draft the review of the policy, consult with all relevant parties and present to the Medicines Governance Group for ratification

3.3. The Complaints and Litigation Manager is available to advise on all legal aspects relating to the policy.

3.4 The Nurse in Charge (or Manager) of each ward/unit is responsible for:

- Ensuring all staff within their area of responsibility are aware of, understand and comply with this policy and understand the legal implications of failing to do so.

- Ensuring all staff within their area of responsibility attend regular training for Basic Life Support, Immediate Life Support (when available), use of pulse oximeters and properties of the medication used for Rapid Tranquillisation (see section 7).

3.5 Medical Staffing are responsible for ensuring junior doctors attend a session on medication used in Rapid Tranquillisation within their induction programme and for keeping a record of attendance.

3.6 The Chief Pharmacist has the responsibility for ensuring a pharmacist is available to offer teaching sessions on medication used in Rapid Tranquillisation.

3.7 Medical Staff are responsible for ensuring they are aware of, understand and comply with this policy and understand the legal implications of failing to do so and that they are up to date with the training requirements (see Section 7).

4 Definitions

BNF	British National Formulary
ECG	Electro Cardiogram
ILS	Immediate Life Support
IM medication	Medication given by intramuscular injection
NMS	Neuroleptic Malignant Syndrome
Parenteral medication	Medication given by subcutaneous, intramuscular or intravenous injection
Polypharmacy	The concomitant use of more than one drug of the same class
PRN	(Pro re nata). Medication given on a “when required” basis
QTc	Interval between points Q and T on an Electro Cardiogram (corrected for age and gender)
SCT	Supervised Community Treatment
SOAD	Second Opinion Appointed Doctor
SPC (Summary of Product Characteristics)	Published information on the licensed parameters of a medicine, required by the MHRA (Medicines and Health Regulatory Authority) for Marketing Authorisation for the product. Available at www.medicines.org.uk

5 Assessment of Patients

5.1 Taking a full history from the patient is frequently not possible in the acute situation. However the majority of patients presenting with acutely disturbed behaviour will be known to mental health services. Obtain as full a history as possible from the patient, family, old case notes and from information from colleagues, GP and police. Consult any advance directives. Try to establish:

- patient's current and past medication (prescribed and non prescribed).
- whether patient has previously been treated with antipsychotics.
- whether patient has history of severe reaction to antipsychotics e.g. dystonias, extrapyramidal side effects, neuroleptic malignant syndrome.
- if patient is taking clozapine.
- if patient has taken illicit substances or overdose.

5.2 Make a comprehensive mental state examination paying particular attention to hostility, aggression and withdrawal and their relationship to manic and psychotic symptoms.

5.3 Assess physical state, as far as possible, without exacerbating the situation. Pay attention to state of hydration.

Consider:
a) acute psychosis (may be drug induced)
b) mania
c) acute confusional state. Investigate medically and start physical treatment. Also consider the possibility of drug-induced psychosis, adverse reaction to prescribed or non-prescribed medicines, organic disorders.
d) acute stress reaction in a vulnerable individual.

5.4 Make a risk assessment and a working diagnosis and treatment plan. Document these in the patient's notes.

5.5 Document any intervention necessary to manage an individual's disturbed/violent behaviour, with reasons for the clinical decision. Consider including specific interventions in the patient's Care Plan.

5.6 Prescribers should be available for, and responsive to, requests from the patient for medication review.

5.7 **Pregnant or breast feeding women**: Wherever possible specialist provision should be made in the event that interventions for the short-term management of disturbed/violent behaviour are needed. These should be recorded in the patient's care plan.

6. Mental Health Act (MHA) Status

6.1 Informal Patients

6.1.1 If an Informal patient is resisting or aggressive and refusing treatment or threatening to leave the ward, use of Section 5(2) or 5(4) may be necessary to prevent them from leaving, although neither allows treatment without patient consent.

6.1.2 Restraint may be used to prevent harm to the patient, or for the protection of others, and can allow for removal of the patient to a safer environment (e.g. seclusion). The need for restraint may be an indicator that detention under the Mental Health Act should be considered.

6.1.3 The patient's ability to consent to treatment should be assessed at the time Rapid Tranquillisation is required. Any valid and applicable advance decision relating specifically to refusal of the proposed treatment cannot be overridden for an Informal Patient.

6.1.4 The Mental Capacity Act 2005 must be followed if a patient lacks capacity to consent to treatment. The Code of Practice for the Act can be accessed at http://www.dca.gov.uk/legal-policy/mental-capacity/mca-cp.pdf
The criteria for determining "best interests" can be found in section 5.13.

6.1.5 Everything that is done for, or on behalf of, a person who lacks capacity must be in that person's best interests and not for the benefit of staff or other patients. Restraint is only permitted if the person using it reasonably believes it is necessary to prevent harm to the incapacitated person, and the restraint used must be proportionate to the likelihood and seriousness of the harm. **It must be reasonably believed that there is no less-restrictive alternative available.**

6.1.6 If the Mental Capacity Act is used as justification for intervention, staff must have a reasonable belief that the person lacks capacity to consent to the treatment. That is, they have an impairment or disturbance of the mind or brain which means they are not able to understand information relevant to the decision, retain the information long enough to weigh it up as part of decision making and communicate their decision.

6.1.7 If Rapid Tranquillisation is used for an Informal Patient in their own best interest under the Mental Capacity Act, staff should review whether the person is deprived of their liberty on the ward/unit (and if so, they should make an application for a Deprivation of Liberty Authorisation by contacting 01752 305193).

6.1.8 If detention under the Mental Health Act is considered to be necessary the ward/A&E Department staff should contact Access to Mental Health Services during working hours and Mental Health on-call doctor at other times.

6.2 Patients to whom Part 4 of the Mental Health Act Applies

6.2.1 This applies to all patients detained under sections 2, 3, 36, 37[except 37(4)], 38, 44, 45A, 47 and 48. It also applies to patients committed to hospital under the Criminal Procedure (Insanity) Acts and to Supervised Community Treatment (SCT) patients who are recalled to hospital.

6.2.2 **For the first three months** of the patient's detention, medication for mental disorder may be administered by nursing staff under the direction of the approved clinician in charge of treatment. There is no requirement for Second Opinion Appointed Doctor (SOAD) certification, even if the patient refuses consent or is incapable of giving it.

The three month period begins when medication is first administered to the patient following detention under a section to which Part 4 applies.

6.2.3 **After the first three months**, medicine for mental disorder may be administered to a patient either:

a) with his/her capable consent – this must be recorded on statutory Form T2.

b) if the administration is authorised by a SOAD (if the patient withholds consent or is incapable of giving it) – this must be recorded on statutory Form T3.

6.2.4 In the case of a patient who has been detained and receiving medicine for at least three months it will be unlawful to administer medicine for mental disorder unless it is covered by a Form T2 or T3. The only exception to this rule is the case of **urgent treatment**, where MHA 1983 Section 62 may apply (see 6.3)

6.3 Urgent Treatment of Detained Patients

6.3.1 Under the MHA 1983, Section 62, there are some circumstances in which the approved clinician may authorise the patient's urgent treatment.

6.3.2 Section 62 Emergency Treatment applies if it is immediately necessary to do one or more of the following:

- Save the patient's life.
- Prevent a serious deterioration of the patient's condition, and the treatment does not have unfavourable physical or psychological consequences which cannot be reversed.
- Alleviate serious suffering by the patient, and the treatment does not have unfavourable physical or psychological consequences which cannot be reversed and does not entail significant physical hazard.
- Prevents patients behaving violently or being a danger to themselves or others, and the treatment represents the minimum interference necessary for that purpose and does not have unfavourable physical or psychological consequences which cannot be reversed and does not entail significant physical hazard.

6.3.3 A form must be completed every time the Approved Clinician authorises emergency treatment. Full details must also be entered in the patient's clinical records.

6.3.4 Nurses must also document the administration of the medicine and the reasons

for its use.

6.4 Supervised Community Treatment (SCT) Patients Recalled to Hospital

6.4.1 Patients who are recalled to hospital whilst on Supervised Community Treatment (SCT) may be held there for 72 hours. During this period they are subject to the provisions of Part 4 of the Act and as such require certification under section 58 for medication to be given lawfully, EXCEPT:

6.4.1.1 If the three-month period under Part 4 is yet to expire, or it is not yet a month since SCT was implemented (no certification is needed).

6.4.1.2 If the Second Opinion Approved Doctor (SOAD) explicitly authorised the administration of medication upon recall on Form CTO11.

6.4.1.3 Treatment that was already being given on the basis of a Part 4A certificate may be continued, pending compliance with section 58, if the approved clinician in charge of the treatment in question considers that discontinuing it would cause the patient serious suffering.

6.4.1.4 The approved clinician otherwise uses emergency treatment powers (section 62) to authorise treatment.

6.4.2 If none of the above exceptions can be met, a new SOAD visit should be arranged to authorise treatment. Treatment cannot be given without appropriate certification (including Section 62).

6.5 Supervised Community Treatment (SCT) Patients upon revocation of SCT

6.5.1 If the patient's SCT status is revoked they are again liable to be detained under the MHA on the section that was in place at the commencement of their SCT. However, the three month rule for administration of medication does **not** apply.

6.5.2 The points in 6.4.1 (above) may also authorise treatment upon revocation, but only for so long as it takes to arrange for appropriate certification i.e. Consent to Treatment (T2), SOAD (T3) or Section 62

7. Training

7.1 All staff involved in administering or prescribing rapid tranquillisation, or monitoring patients who have been given rapid tranquillisation, must receive ongoing competency training to a minimum of Basic Life Support (BLS). Wherever possible staff should be trained to a level of Immediate Life Support (ILS) which covers airway, cardio-pulmonary resuscitation and the use of defibrillators.

7.2 All staff involved defined in 7.1 should also be trained in the use of pulse oximeters.

7.3 Prescribers, and those administering medicines, should be familiar with and have received training and regular updates in rapid tranquillisation, including:

- properties of benzodiazepines, flumazenil (benzodiazepine antagonist), antipsychotics, antimuscarinics and antihistamines
- associated risks, including cardio-respiratory effects of the acute administration of the drugs, particularly when the patient is highly aroused, may have been misusing drugs, is dehydrated or is physically ill
- the need to titrate doses to effect

8 Emergency equipment

8.1 Consideration should be given to the close proximity of emergency equipment for effective resuscitation or treatment.

8.2 Flumazenil and procyclidine must be readily available. Only staff trained in the administration of intravenous medication may administer flumazenil. It should be available on all wards/units for use by paramedics and doctors if required.

8.3 A crash trolley should be available within 3 minutes. This should include an automatic external defibrillator, a bag valve mask, oxygen, cannulas, fluids, suction and first-line resuscitation medication.

8.4 Resuscitation equipment must be maintained and checked daily.

8.5 At all times a doctor should be available to attend an alert by staff members quickly (within 30 minutes). In some units it may be more appropriate to dial 999.

8.6 An ECG should be done on admission to hospital and as soon as possible after administration of an intramuscular antipsychotic (and see section 9.10).

9. Medication

9.1 Medication for rapid tranquillisation should be used with caution owing to the following risks:

- loss of consciousness instead of tranquillisation
- sedation with loss of alertness
- loss of airway
- cardiovascular and respiratory collapse
- interaction with medications already prescribed, or illicit drugs or alcohol
- possible damage to patient-staff relationship
- underlying coincidental physical disorders

9.2 Aim to keep doses within British National Formulary (BNF) limits and avoid polypharmacy.

9.3 If BNF limits are knowingly exceeded, record a risk-benefit analysis in the patient's notes. The monitoring of the patient is particularly important in these circumstances.

9.4 Consider all oral medication taken within the previous 24hrs as part of rapid tranquillisation, including "when required" (PRN). Where depots are prescribed consider what depot injections have been given over the previous month.

9.5 Extra care should be taken when implementing rapid tranquillisation in the following circumstances:

- presence of congenital prolonged QTc syndromes.
- the concurrent prescription or use of other medication that lengthens QTc intervals both directly or indirectly.
- the presence of certain disorders affecting metabolism, such as hypo- and hyperthermia, stress and extreme emotions, and extreme physical exertion.

9.6 Any patient needing intramuscular doses should be seen by a doctor within 24hrs of administration and their regular prescription reviewed.

9.7 When **lithium** is prescribed, consider using lorazepam with a PRN dose of the regularly prescribed antipsychotic instead of haloperidol.

9.8 **Lorazepam injection** is stored in the fridge.
Mix 1:1 with water for injections before use.
Never mix with other injections in the same syringe.

9.9 **Flumazenil** must be available to reverse the effects of benzodiazepine-induced respiratory depression.
Only staff trained in the administration of intravenous medication may administer flumazenil. It should be available on all wards/units for use by paramedics or doctors if required.

If the respiratory rate falls below 10/minute **give flumazenil 200micrograms IV over 15 seconds** and assess after 60 seconds.
If necessary, give 100micrograms every 60 seconds until desired level of consciousness is achieved. Maximum dose 1mg (1,000micrograms) in 24hrs (one initial dose and 8 subsequent doses).
Monitor respiratory rate closely as flumazenil has a short half-life and respiratory rate may recover then deteriorate again. Seizures may occur.
The dosage is unchanged in the elderly but caution should be used

9.10 **Haloperidol**

The Summary of Product Characteristics now recommends that a baseline ECG is performed prior to treatment (oral or intramuscular) in all patients, especially in the elderly and patients with a positive personal or family history of cardiac disease or abnormal findings on cardiac clinical examination. During therapy, the need for ECG monitoring (e.g. at dose escalation) should be assessed on an individual basis. Whilst on therapy the dose should be reduced if QT is prolonged, and haloperidol should be discontinued if the QTc exceeds 500ms.

It is appreciated that it is not practical to perform an ECG immediately prior to the administration of Rapid Tranquillisation, in which case the risks and benefits should be considered, bearing in mind the following information taken from the Summary of Product Characteristics for Haldol® :

In common with other neuroleptics, haloperidol has the potential to cause rare prolongation of the QT interval. Use of haloperidol is therefore contra-indicated in patients with clinically significant cardiac disorders e.g. recent acute myocardial infarction, uncompensated heart failure, arrhythmias treated with class IA and III antiarrhythmic medicinal products, QTc interval prolongation, history of ventricular arrhythmia or torsades de pointes clinically significant bradycardia, second or third degree heart block and uncorrected hypokalaemia. Haloperidol should not be used concomitantly with other QT prolonging drugs.

Very rare reports of QT prolongation and/or ventricular arrhythmias, in addition to rare reports of sudden death, have been reported with haloperidol. They may occur more frequently with high doses and in predisposed patients.

The risk-benefit of haloperidol treatment should be fully assessed before treatment is commenced and patients with risk factors for ventricular arrhythmias such as cardiac disease, family history of sudden death and/or QT prolongation, uncorrected electrolyte disturbances, subarachnoid haemorrhage, starvation or alcohol abuse should be monitored carefully (ECGs and potassium levels), particularly during the initial phase of treatment. The risk of QT prolongation and/or ventricular arrhythmias may be increased with higher doses or with parenteral use.

9.11 **Olanzapine IM injection –** licensed in the EU but not in the UK for the rapid control of agitation and disturbed behaviours in patients with schizophrenia or manic episode, when oral therapy is not appropriate. This product is now imported as an unlicensed special. Clinical trials have failed to show an increased risk of QTc prolongation above that seen with placebo, nevertheless olanzapine should be used with caution in the patient groups detailed above for haloperidol.
Due to the potential for excessive sedation, cardio-respiratory depression and in very rare cases, death, **do not give parenteral benzodiazepines within 1 hour of IM olanzapine**.
Olanzapine IM injection is approved within LSW as an alternative to Haloperidol IM injection.

9.12 **Aripiprazole IM injection –** licensed for rapid control of agitation and disturbed behaviours in patients with schizophrenia or in patients with manic episodes in Bipolar I Disorder, when oral therapy is not appropriate. In clinical trials of

aripiprazole, the incidence of QT prolongation was comparable to placebo. As with other antipsychotics, aripiprazole should be used with caution in patients with a family history of QT prolongation.
Co-administration with parenteral benzodiazepine is NOT contra-indicated but: Simultaneous administration of injectable antipsychotics and parenteral benzodiazepine may be associated with excessive sedation and cardio-respiratory depression. If parenteral benzodiazepine therapy is deemed necessary in addition to aripiprazole solution for injection, patients should be monitored for excessive sedation and for orthostatic hypotension
Aripiprazole IM injection is approved within LSW as an alternative to Haloperidol IM injection.

9.13 Oral Atypical antipsychotics – oral atypical antipsychotics are not licensed for use in rapid tranquillisation. However, use of an oral atypical antipsychotic may be useful in patients who are neuroleptic naive or who are allergic to, or have experienced an unsatisfactory level of side-effects to, haloperidol. The decision to use an atypical antipsychotic must be made by a consultant psychiatrist and recorded in the patients nursing notes. The same monitoring must be followed as for oral typical antipsychotics.

9.14 **Anticholinergic medication** must be prescribed in the appropriate form when haloperidol is used e.g.

Procyclidine usually up to 5mg orally three times daily. Maximum dose 30mg in 24hrs **or** 2-10mg intramuscular for acute dystonias, repeated if necessary after 20 minutes. Maximum dose 20mg in 24hrs.

9.15 **Promethazine** has a slow onset of action but is often an effective sedative, especially when patients are regularly prescribed/abuse benzodiazepines.
Wait 1-2 hours after injection to assess response. Maximum single intramuscular dose is 50mg, and a total maximum dose of 100mg in 24hrs.

9.16 **Clopixol Acuphase® (zuclopenthixol acetate) is not suitable for Rapid Tranquillisation due to its slow onset of action and long duration.**

However, it may be prescribed on consultant advice only, as part of a treatment plan where patients consistently refuse oral medication or need repeated intramuscular antipsychotics or lorazepam. It must not be prescribed by verbal order.
It should not be prescribed for neuroleptic-naïve patients and may be given under restraint but must not be given to a struggling patient (accidental IV bolus can be fatal). Do not give at the same time as other antipsychotics or benzodiazepines. Ensure that the patient has previously been given zuclopenthixol so that allergic and other reactions may be excluded (can have been given orally).[1]

Zuclopenthixol acetate: onset of action 2-8 hours, peaks 12-40hrs, lasts

48-72 hrs, which should give time to review therapy. Give 50-150mg (max. 100mg in the elderly) stat dose by deep IM. Repeat if necessary after 24-72hours. Maximum cumulative dose 400mg in a maximum of 4 injections over 2 weeks.

1. Reference: Maudsley Prescribing Guidelines in Psychiatry, 11th edition.

10. Data on Antipsychotic Drugs for Rapid Tranquillisation

Drug	Licensed for:	Pharmacokinetics	Dose	Common side-effects	Notes
Aripiprazole oral	Not licensed for agitated behaviour	Peak 3-5 hours Half-life 75 hours Oro-dispersible are bioequivalent to normal tablets and have same kinetics Oral solution has similar kinetics to normal tablets	No recommended dose for RT. Suggest 10-15mg, repeated up to max 30mg/24 hours (including all routes) Use a lower starting dose for 65+ years	Akathisia, tremor Dizziness Somnolence, Sedation insomnia headache blurred vision dyspepsia vomiting, nausea constipation salivary hypersecretion restlessness, anxiety	Maximum 30mg in 24 hours via all routes
Aripiprazole IM	Rapid control of agitation and disturbed behaviours in patients with schizophrenia or in patients with manic episodes in Bipolar I Disorder, when oral therapy is not appropriate.	Peak 1-3 hours Half-life 75 to146 hours	Initial dose 9.75 mg (1.3 ml), followed by a second injection after 2 hours. The effective dose range is 5.25-15 mg as a single injection. Max. 3 injections in 24 hours. Max. 30 mg in 24 hours (including all routes)	Akathisia Tremor Dizziness Somnolence insomnia sedation headache blurred vision dyspepsia vomiting, nausea constipation salivary hypersecretion restlessness anxiety	Co-administration with parenteral benzodiazepine is NOT contra-indicated but be aware of the following: Simultaneous administration of injectable antipsychotics and parenteral benzodiazepine may be associated with excessive sedation and cardiorespiratory depression. If parenteral benzodiazepine therapy is deemed necessary in addition to aripiprazole solution for injection, patients should be monitored for excessive sedation and for orthostatic hypotension

Drug	**Licensed for:**	**Pharmacokinetics**	**Dose**	**Common side-effects**	**Notes**
Haloperidol oral	Adjunct to short term management of moderate to severe psychomotor agitation, excitement, violent or dangerously impulsive behaviour	Oral: Peak 2-6 hours[2] $t_{1/2}$ 20 hours	1.5mg to 5mg (0.5-5mg in 65+ years) up to three times in 24 hours. Max. 20mg/24 hours	EPSE mental dulling or slowing down dizziness headache paradoxical effects of excitement, agitation or insomnia nausea dyspepsia Rarely: Prolonged QTc Arrhythmias	**Baseline ECG is recommended prior to treatment in all patients**, especially in the elderly and patients with a positive personal or family history of cardiac disease or abnormal findings on cardiac clinical examination. During therapy, the need for ECG monitoring should be assessed on an individual basis. The dose should be reduced if QT is prolonged, and should be discontinued if the QTc exceeds 500 ms.
Haloperidol IM		IM: Peak 20 mins $t_{1/2}$ 20 hours	2mg -5 mg (0.5mg-2.5mg in 65+ years) May be repeated every 4-8 hours Max. 12 mg in 24 hours		
Olanzapine oral	Not licensed for agitated behaviour	Peak 5-8 hours Half-life varies but around 30-36 hours (up to 52 hours in 65+ years) Oro-dispersible are bioequivalent to normal tablets and have same kinetics	No recommended dose for RT. Suggest 10mg, repeated up to max 20mg/24 hours (including all routes)	Sedation Dizziness Postural hypotension Akathisia Mild, transient anticholinergic effects	May cause significant rises in baseline fasting glucose and triglycerides during early days of treatment[3]
Olanzapine IM	Rapid control of agitation and disturbed behaviours in patients with schizophrenia or manic episode when oral therapy is not appropriate	Peak 15-45 mins $t_{1/2}$ 30-39 hours	10mg initially, then 5-10mg after 2 hours. Max 3 injections in 24 hours. Max 20mg in 24 hours (including all routes)	Hypotension Postural hypotension Bradycardia Tachycardia Syncope Injection site discomfort	**Do not give parenteral benzodiazepine within 1 hour of IM olanzapine**. If the patient has received parenteral benzodiazepine, IM olanzapine administration should only be considered after careful evaluation of clinical status and the patient should be closely

	(licensed in EU but not in UK)				monitored for excessive sedation and cardio-respiratory depression
Drug	**Licensed for:**	**Pharmacokinetics**	**Dose**	**Common side-effects**	**Notes**
Quetiapine oral (NOT XL form)	Not licensed for agitated behaviour	Peak 1.5 hours[1] Half-life 12 hours (15-18 hours in 65+ years) including active metabolite	No recommended dose for RT. Dose licensed for schizophrenia/mania is max. 50-100mg on first day (25mg in 65+ years) Could be given a higher dose if already taking quetiapine regularly	Orthostatic hypotension Dizziness Syncope Somnolence Tachycardia Dry mouth Constipation Dyspepsia	
Risperidone oral	Not licensed for agitated behaviour, but Risperdal® is indicated 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.	Peak 1-2 hours Half-life 24 hours including active metabolites (up to 33 hours in 65+ years) Oro-dispersible and liquid forms are bioequivalent to normal tablets and have same kinetics	No recommended dose for RT. Suggest 2mg initially (0.5-1mg in 65+ years), repeated as necessary. Max 6mg in 24 hours	Orthostatic hypotension EPSE Dystonia Tachycardia Headache Akathisia, agitation Dizziness Tremor Somnolence, Sedation Vision blurred Vomiting, Nausea Diarrhoea Constipation Dyspepsia Dry mouth	Limited clinical experience or trial data

[1] Sweetman, S (Ed) (2007) **Martindale: The Complete Drug Reference.** London: Pharmaceutical Press

[2] McEvoy, G (Ed) (2003) **AHFS Drug Information.** Bethesda: American Society of Health-System Pharmacists
[3] Kinon, BJ et al (2008) J Clin Psychopharmacol;28:601–607
Other information from the Summary of Product Characteristics for each drug

11. Monitoring patients following use of oral or intramuscular medication for rapid tranquillisation.

11.1 General observation

Regular physical observations (pulse, blood pressure, temperature, respiratory rate, level of consciousness and hydration) plus observations for dystonic reactions must be taken by appropriately qualified staff following use of any short-acting medication for tranquillisation.

If monitoring is not possible, due to patient's level of disturbance, then five minute visual observations should be maintained and recorded until physical observations become possible.
If the patient is sleeping, record respiratory rate, visual observations and use pulse oximeter if possible.

11.2 Observation during seclusion

Take the potential complications of rapid tranquillisation particularly seriously. Monitor the patient 'within eyesight' observation. End the seclusion when rapid tranquillisation has taken effect.

11.3 Frequency of monitoring following intramuscular medication:

Pulse
Respiratory rate
Temperature
Level of consciousness
Hydration
Every 15 minutes for first hour

Blood pressure
30 and 60 minutes after injection

THEN
All observations every 30 minutes until patient ambulatory

If patient is unrousable call ambulance and doctor

11.4 Frequency of monitoring following oral medication:

A lower frequency of observation is suitable following oral dosing. Monitor at intervals agreed by the multidisciplinary team until the patient is active again.

If, following oral administration, verbal responsiveness is lost or the patient is sedated or asleep, monitor as for parenteral administration.

11.5 Frequency of monitoring following zuclopenthixol acetate:

Monitor visually:
every half hour for the first 2 hours after administration
then every 2 hours until 12 hours after administration
then every 6 hours until 72 hrs after administration.

12. Documentation

12.1 Patients' care plans should include advice on preferred action when rapid tranquillisation is required. The daily evaluation must state what happened regarding the event.

12.2 Recording sheets must be completed and filed in the patient's notes. Patient comment is optional.

12.3 Patients should be given the opportunity to document their account of the intervention in their notes or on the monitoring sheet, which should be filed in the patient's notes.

13. Monitoring Compliance and Effectiveness

13.1 The auditing of compliance with this policy will become part of the rolling programme of clinical audits maintained by the Quality Improvement Team.

13.2 An audit should take place every 2 years (or sooner if issues or concerns arise) to monitor the following:

- Staff training
- Appropriateness of the use of Rapid Tranquillisation
- The choice of medication in a particular situation
- Adherence to the Mental Health Act
- Monitoring of patients following use of Rapid Tranquilisation
- Documentation, including Service User comments

13.3 The audit will involve examination of the notes of service users known to have received Rapid Tranquillisation in a preceding period of time (this period of time will need to be decided at the time of audit to ensure a reasonable number of patients are included)

13.4 The Mental Health Clinical Pharmacists will be responsible for reviewing the results

13.5 The results will be made available to the Quality Improvement Team , ward/unit managers and medical groups who will be responsible for ensuring any necessary action is taken

Rapid Tranquillisation Patient Monitoring Form

File in patients notes when completed

Ward **Consultant**	**Patient Name** **Hospital Number**	**Date** **Time RT started**

Trigger(s) and reason for use:	**Route used: IM ☐* Oral ☐+** ***Oral medication offered YES/NO** **+ Frequency of observations:** **Signature Date**

Time	**Temp**	**Pulse**	**B.P.**	**Resp. rate**	**Fluid intake**	**#Level of consciousness**	**Dystonic reactions**	**Initials**

Record either **1.** awake and active **3**. asleep and rousable
2. awake and calm **4**. asleep and unrousable – emergency situation

Outcome of rapid tranquillisation episode:

Signature **Date** Continue overleaf if necessary

Service user comment:

Service user did not wish to comment ☐
Signature **Date** **Time** Continue overleaf if necessary

Flumazenil and facilities for resuscitation must be readily available.

1	**Assess physical state Note drug allergies/sensitivities** **Review patient's clinical record for previous medical history and recent investigations** **Consider total antipsychotic dosage prescribed (including PRN and Depots)** **Continue to use non-pharmacological approaches throughout Rapid Tranquillisation**

2	**Offer ORAL medication**	
Lorazepam	**1mg to 2mg orally** **Wait** 45-60mins. Repeat up to twice more to **maximum dose of 4mg/24 hours** (6mg in extremis)	**Caution in respiratory depression** **Increased risk of cardio-pulmonary collapse with clozapine**
Consider adding one of the following:		
Haloperidol	**2mg to 5mg orally** **Wait** 45-60 mins. Repeat up to twice more or to **maximum dose of 20 mg/24 hours**	**Caution if no known history of antipsychotic use** **Note: Pre-treatment ECG recommended**
OR atypical antipsychotic orally:		
Aripiprazole	**10mg to 15mg orally** Repeat up to maximum 30mg/24 hours	**Consider if neuroleptic-naïve, or no known history of antipsychotic use, or history of unacceptable side-effects from typical antipsychotics** Unlicensed use – on consultant advice only
Olanzapine	**10mg orally** Repeat up to maximum 20mg/24 hours	
Quetiapine	**50mg to 100mg orally (NOT XL)**	
Risperidone	**1mg to 2mg orally** Repeat up to maximum 6mg/24 hours	

3	**Consider INTRAMUSCULAR treatment if oral medication refused or if risk continues**	
Lorazepam	**1mg to 2mg IM** Wait 30mins. Repeat up to twice more or to **maximum dose of 4mg** (6mg in extremis).	Caution in respiratory depression. Increased risk of cardio-pulmonary collapse with clozapine
Where there is a serious risk from prolonged restraint add:		
Haloperidol	**2- 5mg IM** Wait 30 mins and then repeat up to twice more. **Maximum 12mg in 24 hours**	NB: anticholinergic may be required **Note: Pre-treatment ECG recommended**
OR (but see note concerning use with parenteral benzodiazepines)		
Olanzapine	**10mg (range 5mg to 10mg) IM** Wait 2 hours and then repeat up to twice more (3 doses in all). Max. 20mg in 24 hours via any route.	**IMPORTANT: caution with benzodiazepines – see note below***
OR		
Aripiprazole	**9.75mg (range 5.25mg to 15mg) IM** Wait 2 hours and then repeat up to twice more (3 doses in all). Max. 30mg in 24 hours via any route.	

***Simultaneous injection of intramuscular olanzapine and parenteral benzodiazepine is not recommended.** If the patient is considered to need parenteral benzodiazepine treatment, this **should not be given until at least one hour after IM olanzapine** administration. If the patient has received parenteral benzodiazepine, IM olanzapine administration should only be considered after careful evaluation of clinical status, and the patient should be closely monitored for excessive sedation and cardiorespiratory depression.

4	**Other drugs**	
Promethazine Oral or IM	**50mg IM (25mg to 50mg oral)** Wait at least 60 mins Maximum dose 100mg in 24hrs.	Note slow onset of action. May be useful earlier instead of lorazepam in benzodiazepine-tolerant patients.

Guidelines for Rapid Tranquillisation in Adults age >=65 years

Flumazenil and facilities for resuscitation must be readily available.

1	**Assess physical state. Consider Delirium guidance: http://www.plymouthformulary.nhs.uk/includes/documents/Appendix-9-Management-of-acute-confusion_delirium_in-older-people-2.pdf** **Review patient's clinical record for previous medical history and recent investigations** **Note drug allergies/sensitivities** **Consider total antipsychotic dosage prescribed (including PRN and Depots)** **Continue to use non-pharmacological approaches throughout Rapid Tranquillisation** **Seek consultant advice at any stage**

2	**Offer oral medication**
Lorazepam **0.5mg – 1mg orally**	Sedation in 30-45mins, peak 1-3hrs, lasts 4-6hrs **Wait** 45-60mins. Repeat up to twice more to maximum dose of 4mg/24 hours (6mg in extremis) **Caution in respiratory depression** **Increased risk of cardio-pulmonary collapse with clozapine**
Consider adding:	
Haloperidol **0.5mg – 5mg orally**	**If known history of antipsychotic. Avoid if Lewy Body Disease suspected** Sedation 1hr, peak 4-6hr, lasts 20hrs. Wait 45-60 mins. Repeat up to twice more or to maximum dose of 15mg in 24 hours **See Policy Section 9.10 for important prescribing information**
OR	
Atypical antipsychotic orally See Policy Section 10 for drugs and dosages	**If neuroleptic-naïve, or no known history of antipsychotic use, or history of unacceptable side-effects from typical antipsychotics** Unlicensed use – on consultant advice only

3	**Oral medication refused**
Lorazepam **0.5mg-1mg IM**	Sedation in 30-45mins, peak 1-3hrs, lasts 4-6hrs Wait 30mins. Repeat up to twice more or to maximum dose of 4mg (6mg in extremis) Caution in respiratory depression Increased risk of cardio-pulmonary collapse with clozapine
Where there is a serious risk from prolonged restraint add:	
Haloperidol **0.5mg - 5mg IM**	**Avoid if Lewy Body Disease suspected** Sedation in 10 min, peaks 20-40mins, lasts 4-6hrs Wait 30 mins and then repeat up to twice more (3 doses in all to a maximum 1.5-12mg). If further doses required allow 4 hour intervals. NB: anticholinergic may be required with haloperidol **See Policy Section 9.10 for important prescribing information**

4	**In the event of inadequate response**
Seek Consultant advice and review adherence to guidelines. Possible options include:	
Promethazine oral or IM	50mg IM (25-50mg oral). Note slow onset of action. Wait at least 60 mins before assessing response. Maximum dose 100mg in 24hrs. May be useful earlier instead of lorazepam in benzodiazepine-tolerant patients.
Higher doses of lorazepam +/or haloperidol	Careful use and additional monitoring essential

Cautions:
Dose reduction needed in renal impairment, hepatic impairment, organic disorder/delirium, alcohol or drug intoxication. **Patients with Learning Disabilities** may be more sensitive to effects and side-effects of medication
Avoid: antipsychotics if Lewy Body Disease suspected. Avoid haloperidol in cardiac disease
Increased risk of NMS/neurotoxicity with haloperidol and lithium
Increased risk of cardio-pulmonary collapse with clozapine and benzodiazepines

Summary of Remedial Measures following Rapid Tranquillisation

Taken from Maudsley Prescribing Guidelines 11th Ed. 2012

Problem	Remedial measures IN ALL CASES CALL A DOCTOR
Acute dystonias Including oculogyric crises	Give **Procyclidine IM** 5-10mg. Repeat if necessary after 20 minutes. Maximum dose 20mg in 24hrs.
Reduced Respiratory Rate falls below 10 breaths/min or oxygen saturation (<90%)	**Ensure patient is not lying face down** Give oxygen, raise legs. **Give flumazenil if benzodiazepine-induced** respiratory depression suspected. If caused by any other sedative agent transfer to a medical bed and ventilate mechanically
Irregular or slow pulse <50 beats/min	Refer to specialist medical care Immediately. Call ambulance
Fall in blood pressure >30mm Hg orthostatic drop or < 50mmHg diastolic	Compare with blood pressure on admission Lie patient flat, tilt bed towards head Monitor closely.
Increased temperature Over 38^{o}C and/or increasing	Withhold antipsychotics - risk of Neuroleptic Malignant Syndrome (NMS) and possibly arrhythmias. Check creatinine kinase urgently

Guidelines for the use of flumazenil

If the respiratory rate falls below 10 per minute give flumazenil 200micrograms IV over 15 seconds and assess after 60 seconds. If necessary, give a further dose of 100micrograms over 10 seconds. Repeat every 60 seconds until desired level of consciousness is achieved
Maximum dose 1mg (1000micrograms) in 24hrs (one initial dose and 8 subsequent doses)
Monitor respiratory rate closely as flumazenil has a short half-life and respiratory rate may recover then deteriorate again
The dosage is unchanged in the elderly but caution should be used
Patients may become agitated, anxious or fearful on wakening Seizures may occur in regular benzodiazepine users
Contraindicated in patients with epilepsy who have been receiving long-term benzodiazepines
Note: if respiratory rate does not return to normal or patient is not alert after initial doses, assume that sedation is due to some other cause

Guidelines for the Administration of Midazolam IM injection

Only when Lorazepam IM injection is unavailable

This guideline should be used in conjunction with the NHS Plymouth Rapid Tranquillisation Policy. It is aimed at all clinical and medical staff who are directly involved in the management of acutely disturbed patients and the administration of rapid tranquillisation. Due to limited experience with Midazolam for Rapid Tranquillisation a doctor should attend when it is administered.

In the case of IM Lorazepam not being available the following therapeutic options should be considered:

- Wherever possible employ the use of non-pharmacological approaches and where medication is indicated encourage the patient to accept oral medication wherever possible.

- If the IM administration of a benzodiazepine is required and Lorazepam is not available, Midazolam may be considered as an alternative.

Midazolam is not licensed for the acute management of disturbed/ violent behaviour, however there are some studies to support its use in this area, and it may be considered as an alternative IM benzodiazepine to lorazepam in exceptional circumstances. In reported trials, the dose used has ranged from 2.5mg to 15mg, although it must be noted that the higher doses appear to induce sleep, whereas the aim of rapid tranquillisation is to promote a calmer state and not induce sleep or unconsciousness.

Repeated doses may lead to accumulation of midazolam and increased risk of adverse effects, including respiratory depression. Always ensure that emergency resuscitation equipment and medication (including IV flumazenil) is present before administration, and that a member of staff trained to give IV medication is available.

Patients should be monitored regularly according to the Rapid Tranquilisation Policy for excessive sedation, respiratory depression or hypotension.

There is no evidence to support the concurrent use of midazolam with antipsychotics. Concurrent administration of olanzapine IM and benzodiazepines IM is not recommended.

Following IM midazolam, anterograde amnesia of short duration may occur with the patient not remembering events that occurred during the maximum activity of the compound.

Protocol for IM Midazolam

Indication: Use in Rapid Tranquilisation **only when IM lorazepam is unavailable**

Warning: IV flumazenil and a member of staff trained to give IV medication should always be available when administering IM Benzodiazepines. The risk is thought to be greater with midazolam than lorazepam [5,6].

Preparation: Midazolam (as hydrochloride) Injection 10mg in 5ml. **This is the only strength to be use for Rapid Tranquilisation within NHS Plymouth**

Recommended dose in healthy adults 18 - 60 years:
Give 2.5mg to 5mg by deep IM injection. Always use lower dose initially. Repeat after 30 to 60 minutes if required. Maximum recommended total dose 15mg/24 hours[5].

Dose required	0.5mg	1mg	1.5mg	2mg	2.5mg	5mg
Volume required of 10mg in 5ml injection	0.25ml	0.5ml	0.75ml	1.0ml	1.25ml	2.5ml

Children / young adults 12 – 17 years:
No evidence available so not recommended

Elderly and special patient groups:
The elimination half life of midazolam may be prolonged in adults over 60 years by up to four times. Use a quarter to, half of the adult dose (e.g. 0.5mg – 2.5mg) for the elderly (>60 years) or chronically (physically) ill or debilitated patients; patients with impaired renal, hepatic or cardiac function; and patients with chronic respiratory insufficiency. **Special caution must be exercised when administering Midazolam to these patient groups.**

No Dilution Required.

Legal classification and storage
Midazolam Injection 10mg in 5ml is available from Derriford Pharmacy. It is classified as a **Schedule 3 Controlled Drug**. Trust policy (see CD SOPs[4]) requires that it must be ordered in the ward CD order book, stored in the CD cupboard and receipts and supplies entered in the CD record book.

Forms T2 and T3.
Ensure that Midazolam is covered on these forms. BNF category code for Midazolam is: 15.1.4.1

Comparison between Midazolam and Lorazepam

Property	Lorazepam[1]	Midazolam[2]
Absorption	IM injection is readily absorbed.	IM injection absorption is rapid and complete.
Time to maximum plasma concentration (T max)	60-90 minutes.	30 minutes.
Absolute bioavailability	90% [3]	90%
Elimination half-life	12-16 hours[1] (therapeutic effect lasts 4-6 hours)[1]	1.5-2.5 hours.
Excretion	Mainly renal [3]	Mainly renal
Dose	1-2mg initially. Wait 30mins. Repeat up to twice more or to maximum dose of 4mg (6mg in extremis).	2.5 to 5mg. Use lower dose initially. Repeat after 30 to 60 minutes if required. Maximum 15mg/24hours in healthy adults < 60 years
How to administer	Dilute 1:1 with water for injection or physiological saline and give IM.	No Dilution Required. Glass ampoule contains Midazolam 10mg/5mL. Draw and administer deep IM.

References:

1. Electronic Medicines Compendium. Summary of Product Characteristics for Ativan® Injection, accessed on 19/10/2010. www.emc.medicines.org.uk
2. Electronic Medicines Compendium. Summary of Product Characteristics for Hypnoval® Injection, accessed on 19/10/2010. www.emc.medicines.org.uk
3. Martindale: The Complete Drug Reference 35th edition 2007, p. 901-902
4. Plymouth Teaching Primary Care Trust HealthNET: Controlled Drug Standard Operating Procedures
5. Devon Partnership NHS Trust**:** Interim Protocol for the prescribing and administration of injectable drugs for rapid tranquillisation, when IM lorazepam is unavailable
6. National Patient Safety Alert: NPSA/2008/RRR011: Reducing the risk of overdose with midazolam injection in adults

All policies are required to be signed by the Lead Director or Assistant Director. (The policy will not be accepted onto Healthnet until signature is received.)

The proof of signature for all policies is stored in the office with the Freedom of Information Officer.

The Lead Director, Assistant Director or Head of Service approves this document and any attached appendices.

Signed: ……

Date: ……