Policy:

MD 011 - Rapid Tranquillisation Policy and Guidelines for Inpatient Wards

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Policy version and advice on document history, availability and storage
This is version 6.1 of this policy and replaces version 6.
This version was reviewed and updated as part of an on-going policy document review process.

This policy will be available to all staff via the Sheffield Health & Social Care NHS Foundation Trust Intranet and on the Trust's website. The previous version will be removed from the Intranet and Trust website and archived. Word and pdf copies of the current and the previous version of this policy are available via the Director of Corporate Governance.

Any printed copies of the previous version (V6) should be destroyed and if a hard copy is required, it should be replaced with this version.

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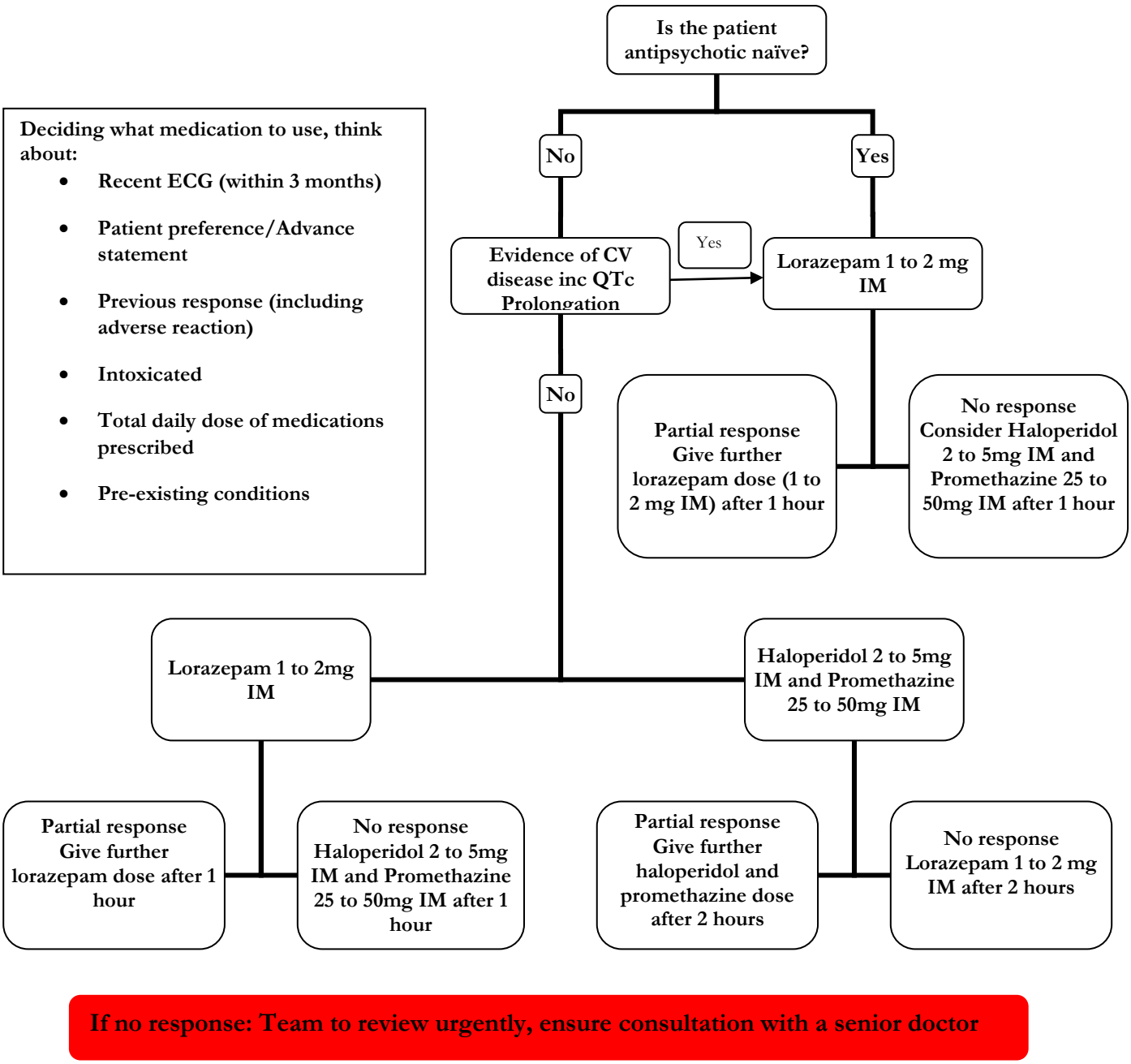
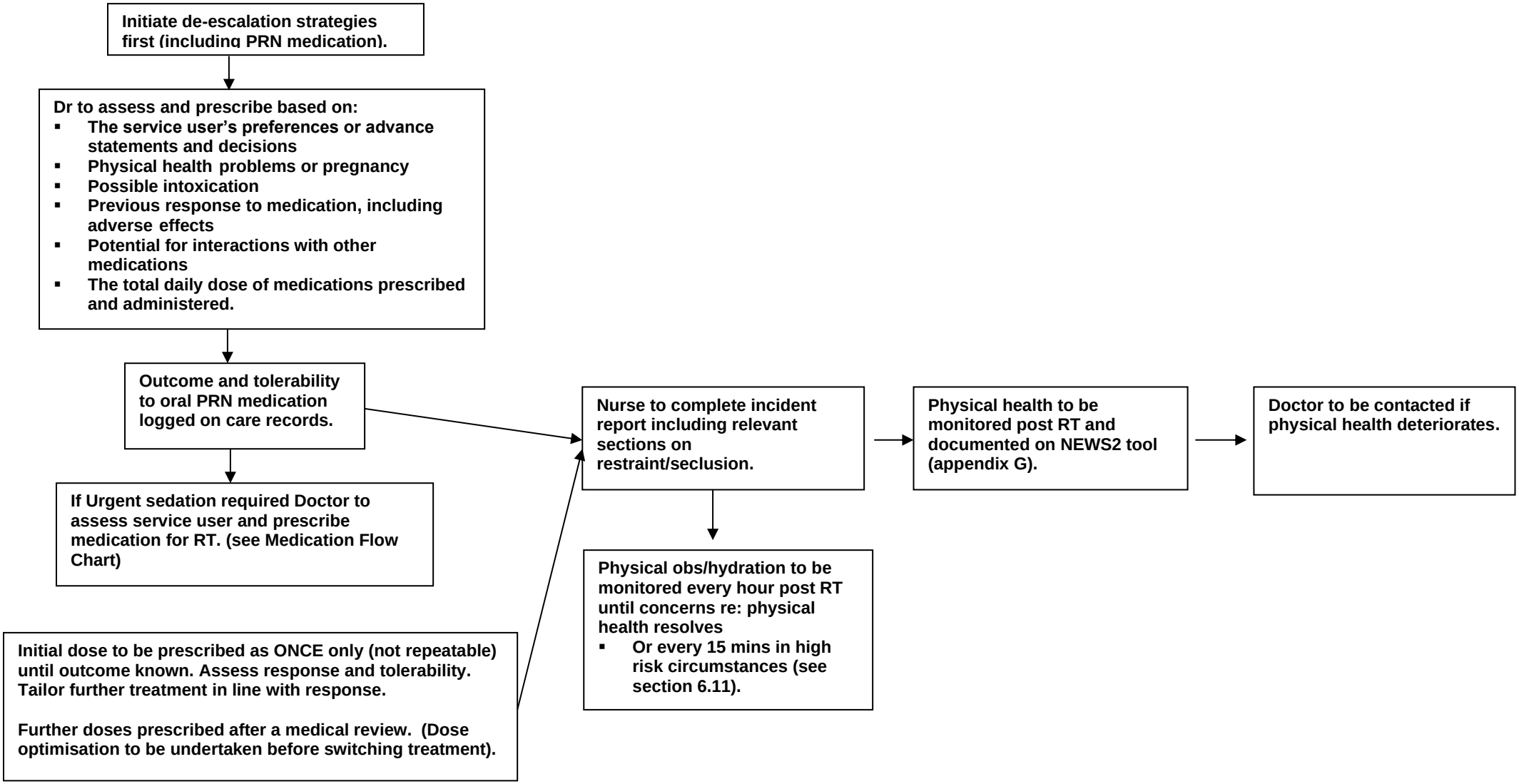


If no response: Team to review urgently, ensure consultation with a senior doctor

Flowchart – Rapid Tranquillisation Algorithm



Summary: medication for rapid tranquillisation adults (18-65yrs)

Medication	Time to peak plasma concentration	Dose	Approx. plasma half-life	Notes
Lorazepam injection (SPC)	60 to 90 min	**1-2mg** Dose can be repeated after 1 hour up to 4mg in 24 hours	12 to 16 hours	**If there is insufficient information to guide the choice of medication for rapid tranquillisation, or the service user has not taken antipsychotic medication before, intramuscular lorazepam is generally first line.** **Exceptionally and with documented rationale up to 6mg in 24 hours maybe used.**
Promethazine injection	2 to 3 hours	**25-50mg** Dose can be repeated after 2 hours Max dose 100mg in 24 hours	5 to 14 hours	**NICE recommend intramuscular promethazine combined with intramuscular haloperidol.** **When IM haloperidol is combined with IM promethazine there is some suggestion that risk of movement-related side effects may be reduced**
Haloperidol injection (SPC)	15 to 60 min	**2-5mg** Dose can be repeated after 2 hour Max dose 12mg in 24 hours	10 to 36 hours	**A baseline ECG is recommended before intramuscular dosing.** **Haloperidol should be avoided if there is any evidence of or significant risk factors for cardiovascular disease.** **If an ECG has not been obtained prior to administering intramuscular haloperidol, an ECG should be carried out at the earliest opportunity.** ***The BNF states a maximum dose of 20mg for oral and intramuscular haloperidol in 24 hours.*** ***However oral and intramuscular doses are not bioequivalent (5mg oral equates to 3mg intramuscular).*** ***SHSC recommends a maximum dose of 12mg in 24 hours.*** **Post-rapid tranquillisation patients should closely monitored for side effects, particularly extrapyramidal side effects (parkinsonism, acute dystonia etc.). Procyclidine oral/IM should be available if required.**

1. Introduction

The management of disturbed and potentially dangerous behaviour, with due regard for the safety and dignity of service users and safety of staff, is an important part of the daily work of the Sheffield Health and Social Care NHS Trust. In addition to environmental, physical and psychological management, the appropriate use of medication may be required. Other non-pharmacological interventions, including de-escalation should always be considered. Restrictive interventions including rapid tranquillisation should only be used in a way that respects human rights (Mental Health Act 1983 Code of Practice (MHACoP) 2015 (26.2)).

This policy covers the use of medication for rapid tranquillisation. The decision to prescribe/administer medication urgently or against the will of the individual should be based on decisions made in line with current legislation:

- Mental Health Act (1983)
- Mental capacity Act (2005)

Drug treatment that is not urgent requires informed consent or administration under the relevant sections of the Mental Health Act (1983). The aim of rapid tranquillisation is not to treat the underlying psychiatric condition and is not to induce sleep or unconsciousness. The service user should be sedated but still be able to participate in further assessment and treatment.

Rapid tranquillisation in this policy refers to the use of medication by the parenteral route (usually intramuscular or, exceptionally, intravenous) and when urgent sedation with medication is needed. A broader definition is captured in section 3 – but for the purposes of the policy RT refers to the use of medication via the injectable routes.

The process of prescribing and administration RT should be clear and transparent. Service users should be encouraged to participate in post incident reviews, and staff should record service user's preferences as part of their advanced statements.

2. Scope

The guidance within this policy applies to all staff who advise, prescribe or administer medication for the control of disturbed behaviour. It may impact on any service user being treated as an inpatient.

This guidance does not cover the non-pharmacological related management of disturbed or challenging behaviour.

3. Definitions

Rapid tranquillisation (RT) – In this policy, RT, refers to the use of medication by the parenteral route (usually intramuscular or, exceptionally, intravenous) if oral medication is not possible or appropriate and urgent sedation with medication is needed.

Rapid tranquillisation refers to the use of medication to calm or lightly sedate an individual to reduce the risk of harm to self or others and to reduce agitation and aggression.

PRN (when required medication) Within this policy PRN refers to the use of medication as part of a strategy to de-escalate or prevent situations that may lead to violence or aggression. The use of oral medication (PRN) may be considered as part of a strategy to de-escalate or prevent situations that may lead to violence and aggression.

Violence and aggression - A range of behaviours or actions that can result in harm, hurt or injury to another person, regardless of whether the violence or aggression is physically or verbally expressed, physical harm is sustained or the intention is clear.

Advance statement - A written statement that conveys a person's preferences, wishes, beliefs and values about their future treatment and care. An advance statement is not legally binding.

De-escalation - The use of techniques (including verbal and non-verbal communication skills) aimed at defusing anger and averting aggression PRN medication can be used as part of a de-escalation strategy but PRN medication used alone is not de-escalation.

4. Purpose

During an acute illness, some service users can become behaviourally disturbed to the extent that they or others may be at risk of harm. The use of medication as rapid tranquillisation is risky and may be distressing for service users.
People with mental health problems are at increased risk of coronary heart disease, cerebrovascular disease, diabetes, epilepsy and respiratory disease; all of which can be exacerbated by the effects of manual restrain and RT.
RT should be used in a way that ensures the safety of service users. Monitoring physical health during and after manual restraint/RT is paramount

This policy is based on NICE Guidance: NG10 Violence and aggression: short-term management in mental health, health and community settings (NICE 2015). This policy will ensure that the standards set down by these NICE guidelines are met within the Trust.

The purpose of this policy is to ensure the safe and appropriate use of RT within the trust.

5. Duties

All staff

When dealing with medicines, all staff should follow the relevant SHSCT medicines related policies, procedures and where applicable their own professional body's code of practice. This will also apply to all staff employed by the Trust or any staff working or seconded to work within the Trust. Staff must act within the scope of their own competencies and professional standards.

Any health care professional choosing to deviate from these standards will be expected to do so knowingly and be able to justify their course of action to their peers. Adherence to these standards should be the norm.

- All staff that have any involvement with medicines are expected to work within their own sphere of competencies.
- All staff should be are aware of and have access to medicines management / medicine optimisation policies and procedures.

Clinical guidelines are recommendations for the care of individuals by healthcare professionals that are based on the best available evidence. Guidelines assist the practice of healthcare professionals, but do not replace their knowledge and skills.

All staff that are likely to become involved in the use of medicines as part of this policy should ensure that they are familiar with the drugs used, the dose ranges and any relative – or absolute contraindications.

Managers

- To ensure their staff attend relevant mandatory training courses associated with this policy
- To ensure their staff have access to all the current Trust policies and procedures relating to medicines.
- To support staff through the appraisal process and training required to ensure they are working within their medicine related competencies

Pharmacists

To participate in and support the processes of medicines management throughout the Trust and across organisational boundaries. This will include providing advice to all SHSCT staff including cultural & adaptations for service users with special needs.

Chief Pharmacist

Responsible for medicines management/medicines optimisation throughout the Trust. This does not alter the professional responsibilities or duty of care of any other healthcare professional when dealing with medicines.

Medicines Optimisation Committee

To provide multidisciplinary advice, guidance and where necessary assurance on medicines management (medicines optimisation) throughout the Trust.

Medicines Safety Group

To support the medicines safety officer and improve the quality and learning from medicines related incidents in order to prevent harm.

CD Accountable officer

To protect the service users and the wider public from harm associated with controlled drugs prescribed by relevant people.
To provide assurance that sound systems of governance relating to controlled drugs are in operation throughout the Trust.
To share information in order to prevent harm from controlled drugs by relevant people.

Trust Board

The Trust is expected to make sufficient resources available to enable the accountable officer to discharge his/her responsibilities as accountable officer for the Trust (relates to drugs controlled under the Misuse of Drugs Act). The Trust board must also be assured of medicines optimisation processes within the Trust.

6. Process

6.1 General

- Always seek advice of a senior colleague/consultant when unsure.
- Service users should only receive RT after an assessment of risk and when it has been established that the risk of not doing so is greater than the risks of the intervention (i.e. a proportionate response).
- The immediate safety of the service user, staff or others is of prime concern. RT should not be used for the sole purpose of protecting property.
- RT should only be considered if de-escalation strategies (including oral PRN medications) have been tried - or felt to be inappropriate.
- Other non-pharmacological interventions should be considered, for example increasing the level of observations of the service user, increasing the level of staffing, changing the service users setting, this may include transfer to a more secure setting. Seclusion could also be considered as a last resort.
- It is vital that the assessing doctor obtains as much history as possible from the service user and other sources before medication is prescribed or administered, as the opportunity to make a diagnosis may be lost if the service user is sedated before an understanding of their mental state is reached.
- Non-psychiatric causes of behavioural disturbance should be considered and managed accordingly e.g. hypoglycaemia, delirium, and drug / alcohol intoxication.
- The service user should be informed that RT is going to be administered and why (this should be clearly documented in the clinical notes).
- If possible the service user should be given the opportunity to make an informed choice by way of an advance statement if they are admitted to an in-service user unit and RT is considered to be possible at some stage of their admission.
- The dose of medication prescribed and administered should be individualised.
- Preferred intramuscular injection site is usually the gluteal muscle.

6.2 Prevention of violence and aggression

When prescribing oral PRN medication as part of a strategy to de-escalate or prevent situations that may lead to violence and aggression:

- A multidisciplinary team (MDT) should develop and document an individualised pharmacological strategy for using routine and PRN medication to calm, relax, tranquillise or sedate service users who are at risk of violence and aggression as soon as possible after admission to an inpatient psychiatric unit.
- PRN medication should not routinely or automatically be prescribed on admission.
- PRN medication should be tailored to an individual needs (this should include discussion with the service user if possible).
- When multiple PRN medications are prescribed for the same indication, ensure there is clarity about the rationale and the circumstance in which each PRN medication may be used and this is clearly stated in the care plan.
- The multidisciplinary team should review the pharmacological strategy and the use of medication for the prevention and/or management of violence at least once a week and more frequently if events are escalating and restrictive interventions are being planned or used.

Medication choice for prevention of violence (oral therapy as part of de-escalation strategy)

Adult doses
Lorazepam 1mg to 2mg orally PRN up to 4mg in 24hrs.
BNF maximum dose 4mg in 24 hours. However, trust policy recognises higher doses may sometimes be required up to 6mg in 24hrs.

If lorazepam is ineffective consider alternatives e.g. oral promethazine 25mg to 50mg 2hrly up to 100mg in 24hrs, haloperidol 2mg to 5mg 2hrly up to 20mg in 24hrs.

Adolescents (particularly those who are antipsychotic naive) and the elderly are likely to be more sensitive to the side effects of the medication.
Doses appropriate to the age group should be prescribed (see section 6.5 and Section 6.6 respectively).

6.3 Rapid Tranquillisation (injectable treatment)

Medication Choice
When deciding which medication to use, take into account:

- The service user's preferences or advance statements and decisions
- Pre-existing physical health problems or pregnancy
- Possible intoxication
- Previous response to these medications, including adverse effects
- Potential for interactions with other medications
- The total daily dose of medications prescribed and administered.

In the absence of specific treatment choices above – follow the treatment guidelines below.

If rapid tranquillisation is being used, a senior doctor should review all medication at least once a day. The service user's care plan should be discussed in the next multidisciplinary meeting or sooner if appropriate for discussion of long term management.

The review should be recorded and include:

- Clarification of target symptoms
- The likely timescale for response to medication
- The total daily dose of medication, prescribed and administered, including PRN medication
- The number of and reason for any missed doses
- Therapeutic response
- The emergence of unwanted effects.
- After an episode of disturbed behaviour the service user should still be assessed and the treatment plan reviewed to check if suitable to manage any further episodes.

Intramuscular haloperidol should be avoided in the absence of a baseline ECG.
If there is evidence of QTc prolongation, cardiovascular disease, electrolyte abnormalities or the patient is known to be prescribed other medications that can cause QTc prolongation, intramuscular haloperidol should be avoided and intramuscular lorazepam used instead.

Maximum daily dose must be clearly stated on the prescription and does not inadvertently exceed the maximum daily dose stated in the British National Formulary (BNF) when combined with the person's regular dose, PRN dose and dose for rapid tranquillisation.
The combined total dose of antipsychotic (i.e. haloperidol + one or more additional antipsychotic) should not exceed 100% BNF maximum limits.

Only exceed the BNF maximum recommended doses (including combined PRN dose, the standard dose and dose for rapid tranquillisation) if this is planned to achieve an agreed therapeutic goal, documented and carried out under the direction of the responsible clinician (RC).
Patients are at greater risk of developing side effects and complications, additional monitoring is required when exceeding BNF maximum doses, see section 6.9.

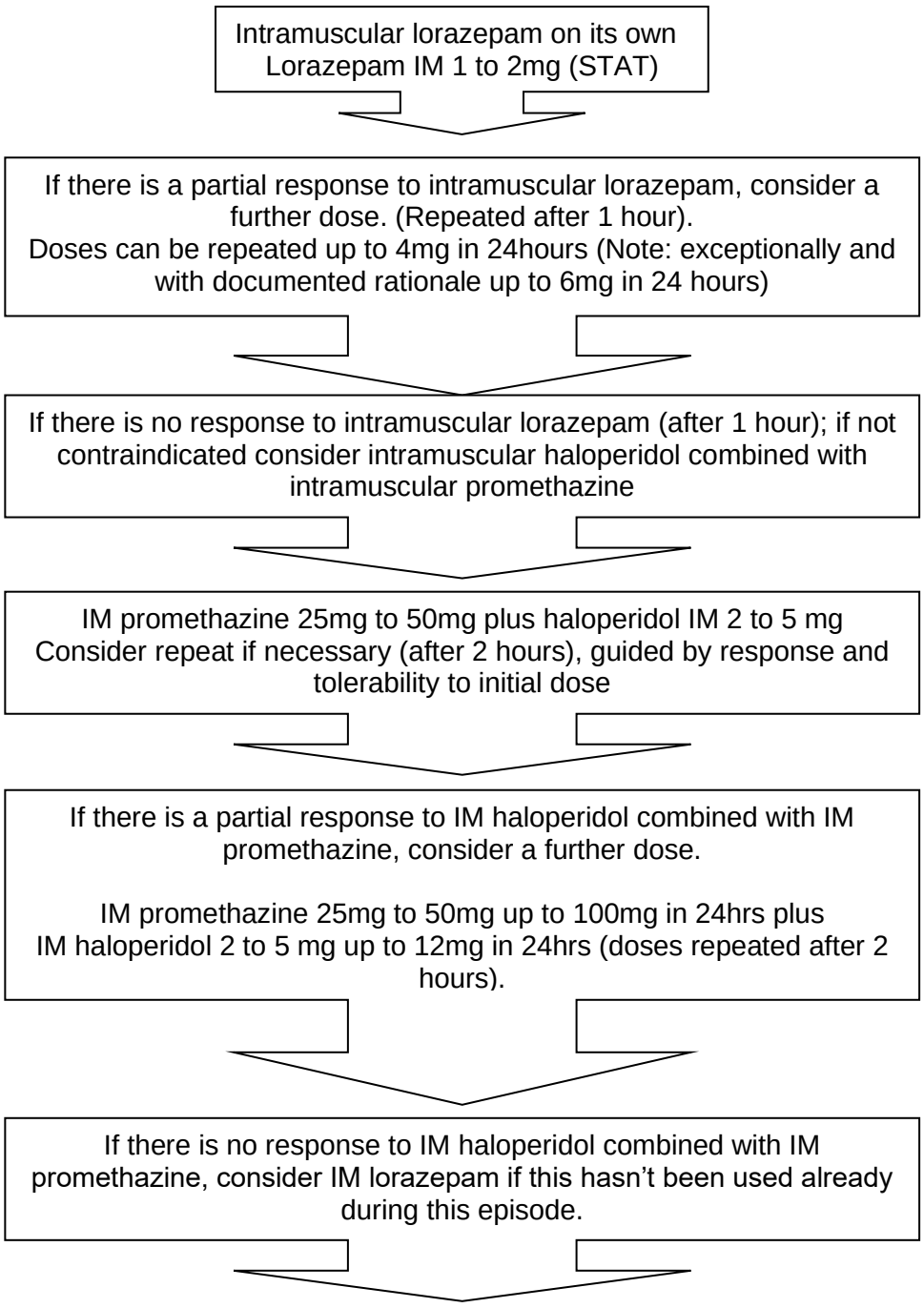
Seclusion
Be aware of and be prepared to address any complications associated with rapid tranquillisation e.g.

- ensure the service user is observed within eyesight by a trained staff member.
- undertake a risk assessment and consider ending the seclusion when rapid tranquillisation has taken effect.

6.4 Adults (service users aged 18 to 65 years old)

If there is insufficient information to guide the choice of medication for rapid tranquillisation, or the service user has not taken antipsychotic medication before, use intramuscular lorazepam.

When prescribing medication for use in rapid tranquillisation, write the initial prescription as a single dose to manage an episode of violence. This should not be repeated until the effect of the initial dose has been reviewed.



If IM lorazepam has already been used, discuss management options with the team involving a Senior Doctor and a Specialist Pharmacist (if available). Seek a second opinion if needed.

6.5 Administration Guidelines

The Intramuscular Route

The intramuscular route delivers medication into a well-perfused muscle. The vascularity of the muscle tissue aids the rapid absorption of medication. This provides a rapid systemic action.

Needles should be long enough to penetrate the muscle. For intramuscular injections the most common sizes used in adults are 21 gauge (green) and 23 gauge (blue) with a length of 25mm (1 inch) or 38mm (1½ inches) long, length used should be based on an individual patient assessment. If a patient has a lot of adipose tissue, a longer needle should be used. Intramuscular injections should to given at a 90-degree angle to ensure the needle enters into the muscle and reduces pain. Following insertion of the needle, aspiration should be performed to ensure a blood vessel is not being penetrated. In the event of blood being aspirated the procedure should be started again with a new safer sharp needle. Intramuscular injections usually require the removal of some clothing to access the appropriate injection site.

Rapid tranquillisation medication is not emergency lifesaving medication and should not be administered through clothing.

Rapid tranquillisation medication should be administered via the following IM routes using appropriate injection technique.

Medication	**Considered site of administration**
Haloperidol	Dorsogluteal/Ventrogluteal
Lorazepam	Dorsogluteal/Ventrogluteal
Promethazine	Dorsogluteal/Ventrogluteal

On occasions the lateral thigh (Vastus lateralis) may be considered for IM injection but this site is not custom and practice. Administration to this site is painful. Using this site would need an MDT decision with appropriate reasons for this route and recorded in the collaborative care plan.

Dilution information

Lorazepam should be mixed 1:1 with water for injection before injecting. The following table provides injection volumes for delivering various doses of lorazepam once diluted.

Dose of lorazepam required	Volume of undiluted (lorazepam (4mg/mL)	Volume of Water from injection
0.5	0.125mL	0.125mL
1.0	0.25mL	0.25mL
2.0	0.5mL	0.5mL

Infection Prevention and Control considerations

- Hypodermic needles are sterile and therefore if being inserted through clothing there is the possibility of clothing fibres or contamination being entered into the skin (it is no longer a sterile procedure)
- The healthcare worker (HCW) administering the injection cannot visualise the injection site prior to administration, during or site observation following administration
- Skin should be visibly clean prior to an injection – visual check prior to administration unable to be performed if wearing clothing
- Clothing may blunt/damage the needle
- Injecting through clothing means the HCW is unable to stabilise the injection site ready for injecting
- The full depth of the needle won't penetrate the skin due to the fabric being in the way

Note:

It is best practice for ONE nurse to carry out the whole procedure for an individual supported by a colleague to assist in checking that the medication is correct.

6.6 Special Treatment Groups - Older Adults

The doses of medication required in the older adult group will be less than those required for the general adult population.

Similar principles as for adult service users should be applied. Particular care should be given to co-existing medical states and prescribed medication, the risk of accumulation of sedatives and the possibility of delirium. Non-pharmacological factors must always be considered.

For acute behavioural disturbances in the elderly when urgent sedation is required to prevent injury or harm consider first line:

- Lorazepam 500micrograms to 1mg IM should be used and repeated not more frequently than every 1 hours (maximum 2 mg in 24 hours).

An initial single dose should be prescribed to allow assessment of response or side effects. Further prescriptions should be considered after assessing the response to initial dose. High doses of benzodiazepines can cause respiratory depression and should be avoided in service users who have significant respiratory impairment.

If IM lorazepam is ineffective and RT is necessary and not contraindicated consider:

- Promethazine IM 12.5mg plus haloperidol IM 500micrgrams to - 1mg.
  Repeat if necessary according to response and tolerability no more frequently than every 2 hours (promethazine maximum 50mg in 24 hours. Haloperidol maximum 5mg in 24 hours).

Doses prescribed above this regimen should be discussed with a senior doctor and the rationale documented in the patients records.

The dose of haloperidol is a critical factor when determining the likelihood of severe adverse effects. If haloperidol is not tolerated or inappropriate discuss alternative options with the Consultant Psychiatrist and specialist SHSC pharmacist.

The use of antipsychotics is cautioned in elderly service users with dementia. An increased risk of stroke has been implicated with all antipsychotics. The balance of risks and benefit should be considered before prescribing antipsychotic drugs for elderly service users.

Antipsychotics should therefore, only be prescribed for use in service users when the use is considered a proportionate response to the risks – https://www.nice.org.uk/guidance/ng97

Promethazine has anticholinergic effect such as dry mouth, blurred vision, urinary retention and constipation. Cognition can also be impaired. Particular care should also be taken in those patients with dementia or learning disability.

6.7 Special Treatment Groups - Learning Disability

The doses of medication required in learning disability group will be less than those required for the general adult population.

Similar principles as for adult service users should be applied. Non-pharmacological factors must always be considered.

Disinhibition is more likely to occur in organic brain disease including learning disabilities. For acute behavioural disturbances in learning disability when urgent sedation is required to prevent injury or harm consider first line:

- Lorazepam 500micrograms to 1mg IM should be used and repeated not more frequently than every 1 hours (maximum 2 mg in 24 hours).

If IM lorazepam is ineffective and RT is necessary and not contraindicated consider:

- Promethazine IM 12.5mg plus haloperidol IM 3-5mg. Repeat if necessary according to response and tolerability no more frequently than every 2 hours (promethazine maximum 50mg in 24 hours. Haloperidol maximum 12mg in 24 hours).

Promethazine has anticholinergic effect such as dry mouth, blurred vision, urinary retention and constipation. Cognition can also be impaired. Particular care should also be taken in those patients with dementia or learning disability.

Olanzapine IM is also another option (only after >1-hour post lorazepam IM). Dose 5 -10mg (max 10mg/24 hours) see section 6.9 for further information.

6.8 Special Treatment Group - Adolescent service users

In practice this only refers to adolescent service users aged 16 or 17 who may be admitted to adult acute wards if they are unable to access adolescent services.

Prior to starting drug treatment it is very important to exclude non-psychiatric causes such as organic disease, psychological disturbance e.g. anger and anxiety, intoxication or withdrawal states.

In all cases the minimum effective dose of medication should be used. BNF maximum doses should only be exceeded in extreme circumstances and with the advice of a Consultant Child & Adolescent Psychiatrist.

Oral medication as part of a de-escalation
The drugs used in adolescents should follow the guidance as for the adult service users however, lower doses may be needed.

For Rapid Tranquillisation:
Lorazepam 1mg to 2mg repeated after 1hr if required, up to a maximum of 4mg in 24 hours. (Treatment recommended by NICE)
If ineffective or unsuccessful consider promethazine 25 to 50mg 2hrly up to maximum of 100mg daily and haloperidol 2 to 5mg (maximum daily dose 12mg) repeat after 2hr if required. (Note – Off-label use)

6.9 Zuclopenthixol acetate (Acuphase)

Acuphase /Zuclopenthixol acetate is not suitable for rapid tranquillisation and should not be used for acutely disturbed patients.
Please see SHSC Guidelines: Use of zuclopenthixol acetate injection (Clopixol Acuphase®) for further guidance.

6.10 Olanzapine IM

Olanzapine IM is an option that can be considered for a patient, if haloperidol is contra-indicated and lorazepam is not suitable or effective. This must be agreed by a senior doctor, and a senior pharmacist. Olanzapine IM is unlicensed in the UK. A dose of 5 -10mg is recommended max dose is 20mg, minimum 2 hours between doses. For older adults a starting dose of 2.5mg, max 10mg. Maximum 3 doses per 24 hours and up to a maximum 3 consecutive days only. Onset of action is 15-30minutes.

Monitoring is the same as discussed in section 6.11.

Lorazepam IM cannot be prescribed alongside olanzapine IM due to the increased risk of respiratory depression. If oral lorazepam is required, it must be administered 1 hour before or after administration of olanzapine IM.

Promethazine IM should also not be given at the same time as olanzapine IM.

6.11 Aripiprazole IM

Aripiprazole IM is not recommended in rapid tranquillisation in the Trust. The reason for this is it is not recommended by NICE. Aripiprazole is a dopamine 2 partial agonist. Evidence shows IM aripiprazole can cause increased agitation initially.

6.12 Monitoring

After rapid tranquillisation, the service user should be monitored. The response to medication and any emergent side effects documented in care records.
Ensure the service user is observed within eyesight by a trained staff member post RT.

The following physical health observations should be monitored and recorded every hour until there are no concerns about their physical health status (physical observations within range or agreed with a doctor).

Pulse
Blood pressure
Respiratory rate/O2 saturation
Temperature
Level of hydration
Level of consciousness

In high risk circumstance monitoring should be increase to every 15 minutes – this includes situations where:

- BNF maximum dose has been exceeded
- The service user appears to be asleep or sedated or has taken illicit drugs or alcohol
- The service user has a pre-existing physical health problem or has experienced any harm as a result of any restrictive intervention.

Physical Health observations/ monitoring should be documented on the trust agreed national early warning scoring tool (NEWS2) (Appendix G).
Post administration clinical response and side effects should be documented in the patient's Insight care records.

If monitoring of vital stats is not possible the service user should be monitored closely via the ALERT monitoring system (covered in the basic and immediate life support training).

(A) AIRWAY	Is the airway clear? Is the person able to speak – if so their airway is clear. Is the breathing noisy – coming from the throat?
(B) Breathing	Can you see the chest rising? Can you see if rising equally? Is breathing noisy – coming from the chest? Count the patients respiratory rate
(C) Circulation	Can pulse oximetry be used? Has the person's colour changed – blue lips or finger tips? Monitor the service user's temperature.
(D) Disability	(AVPU) Alert, responds to Voice, responds to Pain and Unresponsive.

Any abnormalities or concerns identified during the physical observations or rapid deterioration in physical presentation should be discussed with a doctor urgently and/or an ambulance called if the doctor will be delayed attending.

A baseline ECG is recommended before intramuscular dosing of haloperidol.
If an ECG has not been obtained prior to administering intramuscular haloperidol, an ECG should be carried out at the earliest opportunity. The risks and benefits of using haloperidol without an ECG should be considered on a case by case basis.
Its use without a prior ECG may be off-label. – Summary of Products Characteristics (SPC) states - A baseline ECG is recommended before intramuscular dosing. During therapy, the need for ECG monitoring for QTc interval prolongation and for ventricular arrhythmias must be assessed in all patients, but continuous ECG monitoring is recommended for repeated intramuscular doses.

Staff should have access to resuscitation equipment including: an automatic external defibrillator, a bag valve mask, oxygen, cannulas, intravenous fluids, suction and first-line resuscitation medications (Refer to the Trust resuscitation Policy).
Ward staff should check equipment and emergency tray on a weekly basis.
In addition pharmacy staff will also check the emergency trays during the ward top up process.
Opened or out of date emergency trays need to be re-ordered from pharmacy as soon as possible.

Staff should be trained in immediate life support and a doctor trained to use resuscitation equipment should be immediately available to attend an emergency if restrictive interventions might be used.

If the service users respiratory rate drops below 10/min due to benzodiazepine administration staff should call an ambulance immediately and **unless contra indicated *Flumazenil*** should be given by staff trained in its use (As this is administered via the intravenous route – This should be a doctor)

Repeated doses may be required as it is short acting see current BNF and SPC for further dosing details (see Appendix H). Flumazenil is best avoided in epileptic service users, due to the risk of inducing seizures – start mechanical ventilation instead.
Resuscitation equipment and medication, including flumazenil, must be available and easily accessible to all staff likely to use medication to manage behavioural disturbance. Staff should be familiar with their use.

If the service user, is in seclusion and falls asleep then seclusion should be ended, and the service users vital signs monitored more closely.

6.13 Incident Review

After using RT and when the risks of harm have been contained, conduct an immediate post-incident debrief, including a nurse and a doctor, to identify and address physical harm to service users or staff, ongoing risks and the emotional impact on service users and staff, including witnesses.
This should review the factors that contributed to an incident that led to the use of RT so that any factors can be addressed quickly to reduce the likelihood of a further incident. The care plan should be amended accordingly.

The service user involved should have the opportunity to discuss the incident in a supportive environment with a member of staff or an advocate or carer. Offer the service user the opportunity to write their perspective of the event in their clinical notes.

As the administration of parenteral medication under restraint is restrictive practice an incident form should be completed.

6.14 Legal Aspects

- If administering medication against the service user's wishes then their legal status must be taken in to account. Longer-term detained service users may fall within the remit of the MHA 1983 (see Richard Jones, Mental Health Act Manual 11th Ed, Part 4 – Consent to Treatment pp 289-341). Informal service users and service users subject to shorter term detention under the MHA are not covered by Part 4 MHA and 'common law' provision usually applies to them. However, if treatment is in the best interests of an informal service user who is lacking capacity, the provisions of the Mental Capacity Act 2005 apply.
- Detained service users – longer-term: For this group of service users (Sections 2; 3; 36; 37 or 37/41; 38; 45a; 47 or 47/49; 48 or 48/49) the provisions of Section 58 MHA apply; i.e. if it less than 3 months since medicine was first administered, RT can be administered even if it is against the service user's will – Sec 58(1b) - 'the 3-month rule'.
- If it is more than 3 months since medicine was first administered, treatment against the service user's will requires that the medication intended for RT is included on the certificate (Sec 58 (3b) – Form T3) provided by the Second Opinion Appointed Doctor (SOAD)
- Urgent treatment not included on the SOAD certificate requires authorisation under Section 62.
- NB – service users with capacity who have consented to their treatment under Sec 58 (3a) – Form T2 - may withdraw their consent at any time. Therefore, even if the medication intended for RT is included on their certificate, it would be unlawful to

proceed if they refused. Urgent treatment for these service users would require authorisation under Section 62

- Informal Service users and service users subject to shorter-term detention (Sections 4; 5; 35; 135 and 136): There is a general [common law] power to take such steps as are reasonably necessary and proportionate to protect others from immediate risk of significant harm whether or not the service user lacks capacity to make decisions for himself. (See Richard Jones, Mental Health Act Manual 11th Ed Appendix A – p957). Therefore RT may be administered under the common law where there is an immediate need to do so.
- NB – informal service users who lack capacity may be treated under the provisions of the Mental Capacity Act 2005 if to do so is in the service user's best interests. Please refer to the Trust 'best interest decisions' form on the Intranet.

Service users recalled to hospital under a Community Treatment Order (CTO). RT can be administered, against the service user's will if necessary under the following circumstances:

- The SOAD certificate under Part 4A MHA includes in the section for medication to be used on recall the medicines intended for RT: or
- Supervised Community Treatment began less than 1 month ago; or
- It is less than 3 months since medicine was first administered in this period of detention – Sec 58 (1b); or
- A part 4 SOAD certificate is put in place – Sec 58 (3b)
- The treatment is urgent - Sec 62

Service users who have had their CTO revoked: RT can be administered, against the service user's will if necessary, under either:

- Sec 58 (3b) – where the medication intended for RT is included on the SOAD certificate (Sec 58 (3b) – Form T3): or
- As urgent treatment under Sec 62.
- NB - there is no new '3-month rule' period when an order is revoked.

7. Dissemination, storage and archiving (Control)

The policy should be disseminated through the trust clinical governance structures, supported where possible by pharmacists within clinical teams and if available the directorate lead pharmacists.

The policy will be available for all staff on the Trust Intranet via the Rapid Tranquillisation guidelines policy link and the Pharmacy site.

RT policy version 6 will be archived in Pharmacy.
Reference to the policy will be included in the Junior Doctor Induction process and mandatory RT training sessions.
Dissemination of the policy will be through the mandatory training sessions on pharmacological aspects of rapid tranquillisation and any relevant learning from incidents processes.

8. Training and other resource implications

All staff will be trained in accordance with the requirements as set out in the Trust's Training Needs Analysis.

- Before newly qualified nursing staff can administer medication for rapid tranquillisation they should receive training in Rapid Tranquillisation as part of their induction process.

- All qualified nursing staff who administers medication for rapid tranquillisation should have regular appropriate training and should be updated no less frequently than every 3 years.
- It is the responsibility of the ward manager to ensure that staff have received the relevant training and are deemed competent in the Rapid Tranquillisation process.

All prescribers should have regular appropriate training if likely to prescribe medication for rapid tranquillisation. This training should be updated no less frequently than every 3 years.

The details of the policy will be included in the Junior Doctor Induction process and the training sessions on the pharmacological aspects of Rapid Tranquillisation.
The administration of flumazenil requires staff to be competent to administer this drug through the IV route.

Not covered in this policy
Staff must be trained in how to assess and manage potential and actual violence, using de-escalation techniques, restraint, seclusion and rapid tranquillisation. Refer to:

- Aggression and Violence: Respectful Response and Reduction Policy.
- Seclusion and Longer Term Segregation
- Staff must be trained to use and maintain the techniques and equipment required to undertake cardiopulmonary resuscitation (refer to Resuscitation Policy).

9. Audit, monitoring and review

The prescribing and use of drugs for rapid tranquillisation (RT) is routinely monitored by Pharmacists working in individual teams (where available). Where pharmacists are not part of teams where rapid tranquillisation is used, these issues should be monitored through each team's governance framework.

The trust wide weekly/monthly review of restrictive practice will include all incidents of RT reported through the trust incident system. The Trust will participate in the POMH topic on RT (Topic 16a).

Monitoring Compliance Template						
Minimum Requirement	Process for Monitoring	Responsible Individual/ group/ committee	Frequency of Monitoring	Review of Results process (e.g. who does this?)	Responsible Individual/group/ committee for action plan development	Responsible Individual/group/ committee for action plan monitoring and implementation
Duties	*Exception reporting through incident review plus individual appraisal process*	*Serious incidents reviewed as part of Trust SUI system. For individuals relevant line manager*	Ongoing	Incident Review Panel	In line with incident policy http://xct/images/stories/documents/ policies/APPROVED/IncidentPolicy. pdf for individuals line management responsibility	Governance group & line management for individuals
Prescribing guidelines for rapid tranquillisation	In addition to exception reporting through incident review (RT) is routinely monitored by Pharmacists working in individual teams (where available). Where pharmacists are not part of teams where rapid tranquillisation is used, these issues should be monitored through each team's governance framework Audits including POMH high doe & combination as well as ad hoc audits from staff	Prescribers responsible for prescribing in line with trust policy for RT	Ongoing	Outcomes of ad hoc audits & POMH high dose & Combination presented to quality improvement group, and medicines management committee	Chief Pharmacist supported by pharmacy team	Directorates
How Observations are recorded including timeframes when service users have received rapid tranquillisation	In line with NICE guidance (violence) and EWS tool. .	Risk dept	On receipt of monitoring form	Risk dept	Risk dept. with directorates	Directorates monitoring process
How the organisation trains staff in line with the training needs analysis	Attendance at pharmacy training events – On line training also shortly to become available	Directorate line management structure to ensure attendance at training events	On-going – Post incident review also captures details of staff medicines related training	Expectation that training is covered as part of clinical supervision and post incident debrief. There may be the option for scrutiny & monitoring of the performance of staff through	Through directorates supported by directorate pharmacists and training dept.	Directorates supported by lead pharmacists and training dept.

				the proposed on line training module.		

The policy will be reviewed in March 2022 (i.e. before July 2022), unless any changes are made sooner in line with changes to national guidance.

10. Implementation plan

Implementation should be through directorate governance systems and supported by pharmacists in clinical teams where available.

Action / Task	Responsible Person	Deadline	Progress update
New policy to be uploaded onto the Intranet and Trust website.	Director of Corporate Governance	Within 5 working days of finalisation	
A communication will be issued to all staff via the Communication Digest immediately following publication.	Director of Corporate Governance	Within 5 working days of issue	
A communication will be sent to Education, Training and Development to review training provision.	Director of Corporate Governance	Within 5 working days of issue	

11. Links to other policies, standards and legislation (associated documents)

Aggression and Violence Policy: Respectful Response and Reduction.
Practice Guidance for the Implementation of the Mental Capacity Act 2005
Mental Capacity Act Deprivation of Liberty Safeguards (DoLS)
Medicines Management Policy
Mental Health Act (1983)
Resuscitation Policy
Incident Reporting and Investigation Policy
Observation of Inservice users Policy
Physical Health Care Policy
Resuscitation Policy
Seclusion Policy

Any links to other policies/documents that become out of date or inoperative should be to the Chief Pharmacist.

In situations where access to a key document of reference is lost staff should contact SHSC Pharmacy, or their line manager for advice.

12. Contact details

Title	*Name*	*Phone*	*Email*
Chief Pharmacist	Abiola Allinson	0114 271 8630	Abiola.allinson@shsc.nhs.uk

13. References

NICE: NG10 Violence and aggression: short-term management in mental health, health and community settings (May 2015)
British National Formulary (https://www.medicinescomplete.com/mc/)
British National Formulary for Children (https://www.medicinescomplete.com/mc/)
PhVWP Assessment report - Antipsychotics and cerebrovascular accident (Sept 2005) (http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con2024914.pdf accessed May 2019

Department of Health (2015) Mental Health Act 1983: Code of Practice. London; The Stationery Office). Available at: https://www.gov.uk/government/publications/code-of-practice-mental-health-act-1983. Last accessed on May 2019.

Appendix A – Version Control and Amendment Log

Version No.	Type of Change	Date	Description of change(s)
1	Policy creation	Oct 2006	Previous guidance in operation updated to policy status in line with NICE
2	Review on expiry of policy	Dec 2008	
3	Review on expiry of policy	Feb 2010	
4	Review on expiry of policy	Sept 2012	
5	Review on expiry of policy and updated NICE guidance	Oct 2016	Reviewed in line with updated NICE violence guidelines.
6	Review on expiry of policy	June 2022	
6.1	Clarity on information	October 2020 – April 2021	Amendment in flow diagram, information on administration, further information on olanzapine and aripiprazole use within RT. Addition of LD section.

Appendix B – Dissemination Record

Version	Date on website (intranet and internet)	Date of "all SHSC staff" email	Any other promotion/ dissemination (include dates)
1.0	Oct 2006		
2.0	Dec 2008		
3.2	Feb 2010		
4.0	Sept 2012		
5.0	Nov 2016	Nov 2016 via Communications Digest	
6.0			

Appendix C – Stage One Equality Impact Assessment Form

Equality Impact Assessment Process for Policies Developed Under the Policy on Policies

Stage 1 – Complete draft policy

Stage 2 – **Relevance** - Is the policy potentially relevant to equality i.e. will this policy potentially impact on staff, patients or the public? If **NO** – No further action required – please sign and date the following statement. If **YES –** proceed to stage 3

This policy does not impact on staff, patients or the public (insert name and date)

Stage 3 – **Policy Screening** - Public authorities are legally required to have 'due regard' to eliminating discrimination , advancing equal opportunity and fostering good relations , in relation to people who share certain 'protected characteristics' and those that do not. The following table should be used to consider this and inform changes to the policy (indicate yes/no/ don't know and note reasons). Please see the SHSC Guidance on equality impact assessment for examples and detailed advice. This is available by logging-on to the Intranet first and then following this link https://nww.xct.nhs.uk/widget.php?wdg=wdg_general_info&page=464

	Does any aspect of this policy actually or potentially discriminate against this group?	**Can equality of opportunity for this group be improved through this policy or changes to this policy?**	**Can this policy be amended so that it works to enhance relations between people in this group and people not in this group?**
AGE	**No**	**Intentionally doesn't cover under 16's**	**N/A – Trust services don't cover this age range**
DISABILITY	**No**		
GENDER REASSIGNMENT	**No**		
PREGNANCY AND MATERNITY	**No – care needed with prescribing. Benefits v risks decisions needed and referral to specialist services**		
RACE	**No. Use based on clinical need.**		
RELIGION OR BELIEF	**No**		
SEX	**No**		
SEXUAL ORIENTATION	**No**		

Stage 4 – **Policy Revision** - Make amendments to the policy or identify any remedial action required (action should be noted in the policy implementation plan section) Please delete as appropriate: no changes made.

Impact Assessment Completed by (insert name and date) Abiola Allinson 05/06/2019

Appendix D - Human Rights Act Assessment Form and Flowchart

You need to be confident that no aspect of this policy breaches a person's Human Rights. You can assume that if a policy is directly based on a law or national policy it will not therefore breach Human Rights.

If the policy or any procedures in the policy, are based on a local decision which impact on individuals, then you will need to make sure their human rights are not breached. To do this, you will need to refer to the more detailed guidance that is available on the SHSC web site
http://www.justice.gov.uk/downloads/human-rights/act-studyguide.pdf
(Relevant sections numbers are referenced in grey boxes on diagram) and work through the flow chart on the next page.

1. Is your policy based on and in line with the current law (including case law) or policy?

X **Yes. No further action needed.**

☐ **Work through the flow diagram over the page and then answer questions 2 and 3 below.**

2. On completion of flow diagram – is further action needed?

X **No, no further action needed.**

☐ **Yes, go to question 3**

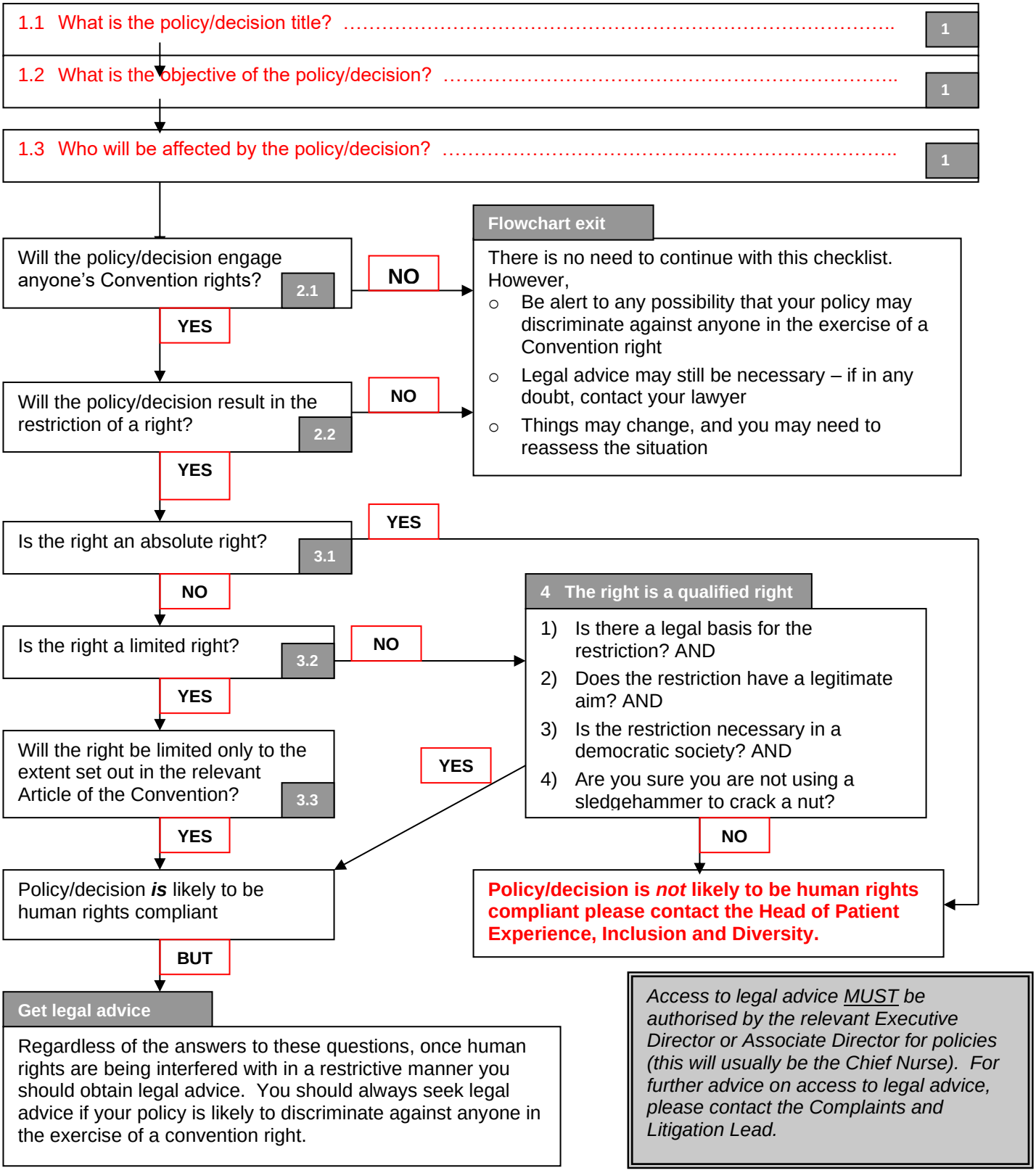
3. Complete the table below to provide details of the actions required

Action required	By what date	Responsible Person

Human Rights Assessment Flow Chart

Complete text answers in boxes 1.1 – 1.3 and highlight your path through the flowchart by filling the YES/NO boxes red (do this by clicking on the YES/NO text boxes and then from the Format menu on the toolbar, choose 'Format Text Box' and choose red from the Fill colour option).

Once the flowchart is completed, return to the previous page to complete the Human Rights Act Assessment Form.



Appendix E – Development, Consultation and Verification

Minor Amendments February 2021
Amendment in flow diagram, information on administration, further information on olanzapine and aripiprazole use within RT. Addition of Learning Disability (LD) section. Consultation with LD Pharmacist – Winola Chio, and Catriona Murray (Consultant Psychiatrist)

Minor amendments October 2020.
Amended flow chart. Additional information regards administration details, including not to administer via the lateral thigh and not through clothing.
Minor amendments May and June 2019
Notification of maximum dose of lorazepam as 4mg in 24 hours and administration above this should be in exceptional circumstances and rationale recorded on Insight
Removal of zuclopenthixol acetate (Acuphase) information and signposting to Acuphase guidelines
Review of formatting and minor typographical errors
Maximum dose of IM haloperidol kept at 12mg due bioavailability as compared to oral therapy (Note BNF. Daily maximum dose is given parity with oral at 20mg in 24 hours)
Administration of flumazenil only by doctors competent to do so.

First updated draft generated Feb 2016
Chief Pharmacist Review – Minor amendment to reflect NICE guidance NG10
SHSC Pharmacists review

- recommended greater emphasis on the need for dose optimisation before switching treatments.(L Scott)
- S Kirby sought clarification of dosing for older adults and adolescents.

Submitted to Restricted interventions group for comment August 2016.

Older Adult Psychiatrists recommended lower initial doses of promethazine IM. Doses reduced to 12.5mg. Dr Atter requested clarification of the term “concern” re: monitoring. This was considered a subjective term. Policy updated – “concern” removed and clearer guidance added.

This policy has been updated in line with NICE clinical guidelines for the management of violence and aggression in mental health settings (2015) (NG10).
(https://www.nice.org.uk/guidance/ng10/resources/violence-and-aggression-shortterm-management-in-mental-health-health-and-community-settings-1837264712389)

Updated details

- Definition -Rapid tranquillisation Use of medication by the parenteral route (usually intramuscular or, exceptionally, intravenous) if oral medication is not possible or appropriate and urgent sedation with medication is needed.
- Oral medication (PRN) is an option to be used as part of strategies to de-escalate or prevent situations that may lead to violence.
- Flow chart – easy read/algorithm added.
- Links to Aggression and Violence: Respectful Response and Reduction Policy and Seclusion and Longer Term Segregation added
- Moderate disturbance/aripiprazole IM removed.
- Duties – reference to KSF processes removed. Support through training added.
- Electronic incident report form and restraint form added.
- Physical health monitoring form added (post RT/restraint)
- Reference to physical health policy / Early warning score.
- Physical health monitoring – updated in line with NICE NG10 guidance. Process of checking physical health equipment every week
- Old Appendix E removed – IM midazolam removed.
- Treatment guidelines updated – Service user choice/advance statement or previous good outcome first line consideration. IM lorazepam as first option if service user unknown. IM

Promethazine combined with IM haloperidol as alternative. IM haloperidol alone or in combination with IM lorazepam not first line consideration.
- Initial management of violence. Prescribe RT as a single dose, which should not be repeated until the outcome of the initial dose has been reviewed.
- Review of RT by Senior Doctor daily if RT continued.
- Medical Director details updated.

Verified by Medicines Management Committee on 9 September 2016.

31st Oct 2016 – Emphasis was added in the introduction section to capture the change of the definition for Rapid Tranquillisation within the policy (use of injectable medicines).
Broader definition of Rapid Tranquillisation added to include the use of medicines for the purpose of de-escalation (Mental Health Act Code of Practice 2015). Added to definitions section.
Interim Chief Pharmacist details updated.

Added to general points (6.1)
- Preferred intramuscular injection site is usually the gluteal muscle.

Appendix F –Policies Checklist

Please use this as a checklist for policy completion. The style and format of policies should follow the Policy template which can be downloaded on the intranet (also shown at Appendix G within the Policy).

1. Cover sheet X☐

All policies must have a cover sheet which includes:

- The Trust name and logo ☐X
- The title of the policy (in large font size as detailed in the template) ☐X
- Executive or Associate Director lead for the policy ☐X
- The policy author and lead ☐X
- The implementation lead (to receive feedback on the implementation) ☐X
- Date of initial draft policy ☐X
- Date of consultation ☐X
- Date of verification ☐X
- Date of ratification ☐X
- Date of issue ☐X
- Ratifying body ☐X
- Date for review ☐X
- Target audience ☐X
- Document type ☐X
- Document status ☐X
- Keywords ☐X
- Policy version and advice on availability and storage ☐X

2. Contents page

3. Flowchart ☐X

4. Introduction ☐X

5. Scope ☐X

6. Definitions ☐X

7. Purpose ☐X

8. Duties ☐X

9. Process ☐X

10. Dissemination, storage and archiving (control) ☐X

11. Training and other resource implications ☐X

12. Audit, monitoring and review ☐X

This section should describe how the implementation and impact of the policy will be monitored and audited and when it will be reviewed. It should include timescales and frequency of audits. It must include the monitoring template as shown in the policy template (example below).

Monitoring Compliance Template						
Minimum Requirement	Process for Monitoring	Responsible Individual/ group/ committee	Frequency of Monitoring	Review of Results process (e.g. who does this?)	Responsible Individual/group/ committee for action plan development	Responsible Individual/group/ committee for action plan monitoring and implementation
A) Describe which aspect this is monitoring?	e.g. Review, audit	e.g. Education & Training Steering Group	e.g. Annual	e.g. Quality Assurance Committee	e.g. Education & Training Steering Group	e.g. Quality Assurance Committee

☐X

13. Implementation plan

14. Links to other policies (associated documents) ☐X

15. Contact details ☐X

16. References ☐X

17. Version control and amendment log (Appendix A) ☐X

18. Dissemination Record (Appendix B) ☐X

19. Equality Impact Assessment Form (Appendix C) ☐X

20. Human Rights Act Assessment Checklist (Appendix D) ☐X

21. Policy development and consultation process (Appendix E) ☐X

22. Policy Checklist (Appendix F) ☐X

Appendix G

For physical health monitoring;
All physical health monitoring observations should be recorded on the trust agreed early warning scoring tool (NEWS2) available on the wards and in the physical health policy.

Appendix H

USE OF FLUMAZENIL

Indications
Complete or partial reversal of the central sedative effects of benzodiazepines. It will also block the effects of non-benzodiazepines which act on the benzodiazepine receptor e.g. zopiclone. It should be given if the respiratory rate falls below 10/minute, unless contraindicated (see below).

If flumazenil needs to be administered an ambulance should be called. The administration of flumazenil within the Trust is intended as a short term action so the service user can be maintained until an ambulance arrives. **(It is administered via the intravenous route and should be only be given by a doctor competent with the use of the medication**)

Dosage and method of administration
Adults
Initial dose 200micrograms by intravenous injection over 15 seconds If desired level of consciousness is not achieved within 60 seconds:

Further dose(s) 100micrograms by slow intravenous injection, repeated at 60 second intervals up to a maximum of 1mg total dose.

Elderly
No specific data. This population is more sensitive to benzodiazepine effects and they should be treated with caution.
Children - No specific data. Use only if potential benefits outweigh risks.

Keep the service user under close observation until all possible central benzodiazepine effects have subsided, bearing in mind the half-life of the benzodiazepine.

Contraindications
- With hypersensitivity to the active substance or any of the excipients
- Who have been administered benzodiazepines for the treatment of a potentially life-threatening condition (e.g. increased intracranial pressure or status epilepticus).
- In mixed intoxications with benzodiazepines and tricyclic and/or tetracyclic antidepressants, the toxicity of the antidepressants can be masked by protective benzodiazepine effects.
- In the presence of autonomic (anticholinergic), neurological (motor abnormalities) or cardiovascular symptoms of severe intoxication with tricyclic's/tetracyclics, Flumazenil should not be used to reverse benzodiazepine effects

Cautions
Not recommended in epileptic service users who have received benzodiazepines for a prolonged period (possible convulsions).
Service users with head injury (possible convulsions or altered cerebral blood flow).
Service users who have taken benzodiazepines at high dose or for a prolonged time (withdrawal symptoms).

Undesirable effects
If service users awake too rapidly, they may become agitated, anxious or fearful.
Benzodiazepine withdrawal symptoms, e.g. anxiety, tachycardia, dizziness, sweating.
Panic attacks in service users with a history of panic disorder.
Very rarely, seizures have been reported.
Hypersensitivity reactions have been reported very rarely (taken from Flumazenil SPC).