NORFOLK & SUFFOLK SPECIAL ALLOCATION SCHEME (SAS) LOCAL POLICY ON MANAGING HIGH RISK MEDICINES

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OPERATIONAL POLICY SUMMARY

To provide guidance, when supporting individuals to take and look after their medicines effectively and safely; when receiving continuing primary care, through the Norfolk, Suffolk & North Essex Special Allocation Scheme (SAS).

The Trust monitors the implementation of and compliance with this operational policy in the following ways;

This policy will be monitored by the Medicines Management Team according to a three year rolling, medicines management audit programme.

Services	Applicable	Comments
Mental Health & Learning Disability	✓	

The Director responsible for monitoring and reviewing this policy is the Executive Nurse

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1.0 INTRODUCTION

1.1 The Norfolk, Suffolk & North Essex Special Allocation Scheme (SAS) is for patients who have been subject to immediate removal (due to violence or the threat of violence) from a practice's patient list. The aim is to provide a safe and stable environment for the patient to receive continuing primary care services, addressing any underlying causes of aggressive behaviour and providing a safe environment for the individuals involved in delivering that treatment.

1.2 When prescribing for adults (18 years old and over) in the community, it is important that healthcare professionals ensure that individuals are supported to take and look after their medicines effectively and safely (NICE NG67). This policy provides key steps healthcare professionals should take when supporting such individuals.

2.0 OBJECTIVES

The Policy Aims To Support:

- **CQC Outcome 4**: Care and welfare of people who use services – People should get safe and appropriate care that meets their needs and supports their rights.
- **CQC Outcome 9**: Management of medicines – People should be given the medicines they need when they need them, and in a safe way.

3.0 GLOSSARY

High Risk Medicines: High risk medicines are medicines that are most likely to cause significant harm to patients even when used as intended. These may be medicines with narrow therapeutic range or with serious side effects when administered incorrectly e.g. incorrect dose.

4.0 PRESCRIBING OF HIGH RISK MEDICINES

4.1 The Norfolk, Suffolk & North Essex SAS will prescribe all medicines as deemed clinically necessary for patients, taking into account NICE Guidance and the formulary of the relevant local CCG. Prescriptions should generally be written generically to ensure cost effective prescribing where possible. It is expected normal quantities will be for 28 days.

4.2 When prescribing, suitable arrangements must be in place for monitoring, follow up and review; taking into account the patients' needs and any risks arising from medicines.

4.3 Reviewing medicines will be particularly important where:

- Patients may be at risk, for example, patients who are frail or have multiple illnesses
- Medicines have potentially serious or common side effects
- The patient is prescribed a controlled or other medicine that is commonly abused or misused
- The BNF or other authoritative clinical guidance recommends blood tests or monitoring at regular intervals

4.4 As with any prescription, an agreement should be reached with the patient on which medicines are appropriate, and how their condition will be managed, including a date for review. It should be clear why regular reviews are important, and the patient should made aware of what they should do if they:

- Suffer side effects or adverse reactions, or
- Stop taking their medicines before the agreed review date

4.5 At each review, confirmation must be sought that the patient is taking their medicines as directed, that the medicines are still needed, are dose appropriate, effective, and tolerated. This may be particularly important following a hospital stay, or changes to medicines following a hospital visit.

4.6 Clear records of these discussions must be made.

4.7 **PRESCRIBING OF INSULIN**

4.7.1 Errors in the administration of insulin are common. To address this, the National Patient Safety Agency (NPSA) has produced two patient safety alerts:

4.7.2 NPSA/2010/RRR013(51) All regular and single insulin (bolus) doses should be measured and administered using an insulin syringe or commercial insulin pen device. Intravenous syringes must never be used for insulin administration. The term ‘units’ should be used in all contexts. Abbreviations, such as ‘U’ or ‘IU’ must never be used.

4.7.3 NPSA/2011/PSA003(52) When prescribing insulin the NPSA recommends:

- Offering the use of an insulin passport to record information on the insulin products they use
- Providing a patient information booklet which describes known error-prone situations and actions that may cause harm and enforce the benefits of using the insulin passport to minimise these risks

- Recording the patient's decision of whether or not to use the passport offered to them (the patient's passport status) in medical notes.

- Assisting patients in completion of therapy details in the insulin passport, specifically in how to describe their insulin products so that there is no ambiguity in what they are using

- Instructing patients to present their insulin passport when visiting all healthcare professionals

4.7.4 More details can be found at www.nrls.npsa.nhs.uk

4.7.5 Cutaneous amyloidosis at the injection site has been reported[8] in patients using insulin and this may affect glycaemic control. Remind patients to rotate injection sites within the same body region.

Advice for healthcare professionals[8]:

• injection of insulin (all types) can lead to deposits of amyloid protein under the skin (cutaneous amyloidosis) at the injection site

• cutaneous amyloidosis interferes with insulin absorption, and administration of insulin at an affected site can affect glycaemic control

• remind patients to rotate injection sites within the same body region to reduce or prevent the risk of cutaneous amyloidosis and other skin reactions (for example, lipodystrophy)

• consider cutaneous amyloidosis as a differential diagnosis to lipodystrophy when a patient presents with subcutaneous lumps at an insulin injection site

• advise patients:

  - that insulin may not work very well if they inject into an affected 'lumpy' area

  - to contact their doctor if they are currently injecting insulin into a 'lumpy' area before changing injection site since a sudden change may result in hypoglycaemia

  - to monitor carefully blood glucose after a change in injection site and that dose adjustment of insulin or other antidiabetic medication may be needed

• report serious adverse drug reactions associated with insulin to the Yellow Card Scheme

4.8 PRESCRIBING OF LOW MOLECULAR WEIGHT HEPARIN (LMWH)

4.8.1 The dose of LMWH depends on the patient's current weight, renal function and its clinical indication. Overdosing increases the risk of bleeding and under dosing increases the risk of a further thromboembolic event.

The NPSA (NPSA/2010/RRR014)(53) recommends:

- A patient's weight is used as the basis for calculating the required treatment dose of LMWH. The weight must be accurately recorded in kilograms (kg) on the inpatient medication chart (when in use) and clinical record. Patients should be weighed at the start of therapy and, where applicable, during treatment.

- Renal function is considered when prescribing treatment doses of LMWHs. The renal function test should not delay initiation of the first dose but every effort must be made to base subsequent dosing on these results.

- Dose calculation tools are available for a range of body weights, specific clinical indications and LMWH products, and that consideration is given to rationalising the range of LMWH products used in the organisation.

- Essential information such as dose, weight, renal function, indication and duration of treatment is communicated at transfers of care (e.g. by discharge letters) and used to ensure that future doses are safe.

- Dosing checks based on patient information are made by healthcare professionals who review, dispense or administer LMWHs when this information is readily available to them.

- System improvements should be demonstrated through the collection and review of data, such as incident reports, clinical pharmacy interventions, audit or other relevant outcome measures.

Further information can be found at www.nrls.npsa.nhs.uk

4.9 PRESCRIBING OF LITHIUM

4.9.1 Some patients taking lithium have been harmed because they have not had their dosage adjusted based on recommended regular blood tests. If patients are not informed of the known side effects or symptoms of toxicity, they cannot manage their lithium therapy safely.

4.9.2 Regular blood tests are important; linked to adjustment of dose as necessary. Clinically significant alterations in lithium blood levels occur with commonly prescribed and over-the counter medicines.

4.9.3 The blood level of lithium is dependent on kidney function and lithium has the potential to interfere with kidney (renal) and thyroid functions.

4.9.4 The NPSA (NPSA/2009/PSA005)(54) recommends:

- Patients prescribed lithium are monitored in accordance with NICE guidance

- There are reliable systems to ensure blood test results are communicated between laboratories and primary care and specialist prescribers.

- At the start of lithium therapy and throughout their treatment patients receive appropriate on-going verbal and written information and a record book to track lithium blood levels and relevant clinical tests*

- Prescribers and community pharmacists check that blood tests are monitored regularly and that it is safe to issue a repeat prescription and/or dispense the prescribed lithium

- Systems are in place to identify and deal with medicines that might adversely interact with lithium therapy

*The NPSA has developed a patient information booklet, lithium alert card and record book for tracking blood tests.

4.10 PRESCRIBING OF METHOTREXATE

4.10.1 Oral methotrexate is a safe and effective medication if taken at the right dose and with appropriate monitoring. However, very occasionally problems with taking the medication can cause serious harm and even death. Two thirds of all incidents result from the wrong dose being prescribed, and a fifth are linked to poor monitoring.

4.10.2 The NPSA produced advice in 2004 “Towards the safer use of oral methotrexate”(55) and then a Patient Safety Alert(56) in 2006:

- Information on the risks and benefits of oral methotrexate should be given to the patient. Confirmation of the patient’s understanding and consent should be sought, baseline tests conducted, monitoring schedule explained, and patient-held monitoring booklet issued.

- For NHS organisations with Shared Care Guidelines, the following issues should be addressed:

    - clarity of prescribing and monitoring responsibilities
    - how often blood tests will be conducted and in which location
    - which clinician will be responsible for receipt and review of the results
    - who will communicate any necessary dosage changes to the patient and the GP

- who will record test results on the patient-held monitoring booklet

- NHS organisations without Shared Care Guidelines must make similar appropriate arrangements. The British Society for Rheumatology (BSR) has published guidelines on the monitoring of disease modifying drugs, including oral methotrexate, which may be a useful source of information.

- All prescribers must avoid the use of 'as directed' in prescribing – a specific dose must be applied to each prescription. Bear in mind that patients often understand their dose by the number of tablets they take rather than 'mg'. The required quantity and frequency of dose should be regularly discussed with the patient.

- Repeat prescriptions should be retained separately for prescriber review prior to authorising. It may help to change the printer driver software so that it shades the prescription signature space on FP10/WP10 to alert the prescriber to this high-risk drug. Be aware of patients who attend with symptoms such as breathlessness, dry persistent cough, vomiting or diarrhoea, as these can be signs of oral methotrexate toxicity or intolerance.

- Handwritten prescriptions and discharge summary information must be complete, legible and include the form, strength, dose and directions in full.

- Consideration needs to be given to the duration of supply and frequency of issue of repeat prescriptions for methotrexate. Ideally patients should not be given more than a four week supply

- A check should be carried out to ensure necessary monitoring is conducted prior to issuing or re-authorising repeat prescriptions.

Further information can be found at
www.nrls.npsa.nhs.uk and http://www.hscboard.hscni.net/publications/search/

4.10.3 The MHRA published[8] further safety guidance in 2020. Methotrexate should only be prescribed by healthcare professionals who are fully aware of the benefits and risks of treatment and who have all necessary prescribing competence.

The advice aims to reduce risk of fatal overdose due to inadvertent daily instead of weekly dosing, for autoimmune diseases and some cancer therapy. These new measures have been implemented to prompt healthcare professionals to record the day of the week for intake and to remind patients of the dosing schedule and the risks of overdose.

Advice for prescribers:

• before prescribing methotrexate, make sure that the patient is able to understand and comply with once-weekly dosing
• confirm with the patient which day of the week they take their methotrexate
• remind the patient and their caregivers of the potentially fatal risk of accidental overdose if methotrexate is taken more frequently than once a week; specifically, that it should not be taken daily
• advise patients of the need to promptly seek medical advice if they think they have taken too much

4.11 PRESCRIBING OF WARFARIN

4.11.1 Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harms and admissions to hospitals. Managing the risks associated with anticoagulants can reduce the chance of patients being harmed in the future.

4.11.2 The NPSA issued a Safety Alert NPSA/2007/17(57) and gave the following advice to GPs:

- Ensure that before issuing a repeat prescription for anticoagulant medication, check that the patient's INR is being monitored regularly and that it is at a safe level for the repeat prescription to be issued. The easiest way to do this is to ask to see the patient-held INR record, which may be in the form of a single printed sheet, a small booklet or another format used locally.

- Ensure that if a patient who is already on oral anticoagulants is co-prescribed one or more clinically significant interacting medicines, that arrangements are made for additional INR blood tests, and that the anticoagulant clinic is made aware that an interacting medicine has been prescribed. The patient may be empowered to ensure this happens in appropriate cases

- Ensure that doses are expressed in mg and not in number of tablets

- Review and, where necessary, update any sections of clinical procedures and protocols that relate to parts of the anticoagulant care pathway for which they or their staff take responsibility

- Ensure that all dose changes, originated by the surgery, for patients in care homes are confirmed in writing

- Ensure that patients on anticoagulant therapy have received appropriate verbal and written information at the start of their therapy, and when necessary throughout their treatment. In practice, this means making sure that patients have received a 'yellow book' and ensuring that they (or their carers) fully understand its contents

- Participate in an annual audit of anticoagulant services

4.11.3 Further information can be found at www.nrls.npsa.nhs.uk

4.12 DIRECT ORAL ANTICOAGULANTS (DOACs)

4.12.1 Direct Oral Anticoagulants (DOACs), previously known as Novel Oral Anticoagulants (NOACs); offer an alternative option to warfarin, in the management of patients with thromboembolism (VTE) and non-valvular AF.

4.12.2 NICE has issued Technology Appraisals (TA) for dabigatran (Pradaxa®), rivaroxaban (Xarelto®▼), apixaban (Eliquis®▼) and edoxaban (Lixiana® ▼) for the prevention of stroke and systemic embolism in non-valvular atrial fibrillation (TA249, TA256, TA275 and TA355).

4.12.3 One advantage of DOACs over warfarin is the lack of any requirement to regular monitor clotting parameters, with consequent dosage adjustment. This is because DOACs are given as fixed once or twice daily regimens. However, they are all dependent on the kidney for excretion, and may require dose modification depending on the patient's renal function.

4.12.4 An incorrect DOAC dose may have important efficacy and safety implications:

- Using a lower dose when patients do not meet the criteria for dose reduction may increase the risk of embolic events and result in potentially preventable strokes

- Using a higher dose where the renal function indicates that a dose reduction is necessary, may increase the risk of bleeding[1, 2, 3, 4]

4.12.5 The risk of developing kidney disease also increases with age, so DOACs are likely to be prescribed for a substantial number of patients who will require dosage adjustment. Regular monitoring to identify and address the consequences of any deterioration in kidney function over time is important.

4.12.6 Renal function should be assessed at baseline in all patients starting a DOAC. Although no specific recommendations are made by manufacturers on the frequency of monitoring, the importance of monitoring renal function was highlighted by the MHRA as early as 2012.[5]

4.12.7 The BNF currently advises that dosage adjustments for DOACs should be based on CrCL. The licensed doses for all DOACs also currently use CrCL to estimate renal function. Dosages are given in the manufacturers' summary of product characteristics.

4.12.8 The current consensus is that renal function should be assessed at least once a year.[6] More frequent monitoring is required in clinical situations where renal function may declines and in patients with impaired renal function at baseline.

4.13 AMIODARONE

4.13.1 Amiodarone has an important place in the treatment of severe cardiac rhythm disorders, where other treatments either cannot be used or have failed. It has

potential major toxicity and its use requires monitoring both clinically and via laboratory testing.[7]

4.13.2 If in exceptional circumstances there is a clinical need for amiodarone to be prescribed, this should be undertaken in a co-operation arrangement with a multi-disciplinary team and/or other healthcare professional. It must be initiated by a specialist and only continued under a local agreement for patients where other treatments cannot be used, have failed, or is in line with NICE Guidance CG180.

4.14 OPIOIDS

4.14.1 Good practice in prescribing opioid medicines for pain should reflect fundamental principles in prescribing generally. The decision to prescribe is underpinned by applying best professional practice; understanding the condition, the patient and their context, and understanding the clinical use of the drug.

4.14.2 Initiating, tapering or stopping opioid medicines should be managed in agreement with the patient and all members of their healthcare team.

4.14.3 The Faculty of Pain Medicine (FPM) in collaboration with Public Health England (PHE) provides information to support a safe and effective prescribing decision. The key principles from this information include:

- Opioids are very good analgesics for acute pain and for pain at the end of life but there is little evidence that they are helpful for long term pain
- A small proportion of people may obtain good pain relief with opioids in the long-term if the dose can be kept low and especially if their use is intermittent (however it is difficult to identify these people at the point of opioid initiation)
- The risk of harm increases substantially at doses above an oral morphine equivalent of 120mg/day, but there is no increased benefit: tapering or stopping high dose opioids needs careful planning and collaboration
- If a patient has pain that remains severe despite opioid treatment it means they are not working and should be stopped, even if no other treatment is available
- Chronic pain is very complex and if patients have refractory and disabling symptoms, particularly if they are on high opioid doses, a very detailed assessment of the many emotional influences on their pain experience is essential

4.14.4 Further information can be found at: https://fpm.ac.uk/opioids-aware

4.14.5 MHRA published new recommendations[8] in 2020 following a review of the risks of dependence and addiction associated with prolonged use of opioid medicines for non-cancer pain. Before prescribing opioids, discuss with the patient the risks and features of tolerance, dependence, and addiction, and agree together a treatment strategy and plan for end of treatment.

Advice for healthcare professionals:

• opioid medicines (opioids) provide relief from serious short-term pain; however long-term use in non-cancer pain (longer than 3 months) carries an increased risk of dependence and addiction

• discuss with patients that prolonged use of opioids may lead to drug dependence and addiction, even at therapeutic doses – warnings have been added to the labels (packaging) of UK opioid medicines to support patient awareness

• before starting treatment with opioids, agree with the patient a treatment strategy and plan for end of treatment

• explain the risks of tolerance and potentially fatal unintentional overdose, and counsel patients and caregivers on signs and symptoms of opioid overdose to be aware of (see opioids safety information leaflet [9])

• provide regular monitoring and support especially to individuals at increased risk, such as those with current or past history of substance use disorder (including alcohol misuse) or mental health disorder

• at the end of treatment, taper dosage slowly to reduce the risk of withdrawal effects associated with sudden cessation of opioids; tapering from a high dose may take weeks or months

• consider the possibility of hyperalgesia if a patient on long-term opioid therapy presents with increased sensitivity to pain

• consult the latest advice and warnings for opioids during pregnancy in the product information and in clinical resources

• report suspected dependence or addiction to any medicine, including to an opioid, via the Yellow Card scheme

Resources:

Faculty of pain medicine of the Royal College of Anaesthetists. Opioids aware. [10]

Healthcare Improvement Scotland / SIGN. Management of chronic pain. [11]

4.15 **FENTANYL PATCHES**

4.15.1 **Transdermal fentanyl patches for non-cancer pain: do not use in opioid-naive patients**

Following a review of the risks associated with use of opioid medicines for non-cancer pain, the Commission on Human Medicines has recommended that fentanyl transdermal patches are contraindicated in opioid-naive patients in the UK [8].

Advice for healthcare professionals:

• Fentanyl is a potent opioid – a 12 microgram (µg) per hour fentanyl patch equates to daily doses of oral morphine of up to 45mg a day

• do not use fentanyl patches in opioid-naive patients

• use other analgesics and other opioid medicines (opioids) for non-cancer pain before prescribing fentanyl patches

• if prescribing fentanyl patches, remind patients of the importance of:

o not exceeding the prescribed dose

o following the correct frequency of patch application, avoiding touching the adhesive side of patches, and washing hands after application

o not cutting patches and avoiding exposure of patches to heat including via hot water (bath, shower)

o ensuring that old patches are removed before applying a new one

o following instructions for safe storage and properly disposing of used patches or patches that are not needed; it is particularly important to keep patches out of sight and reach of children at all times

• make patients and caregivers aware of the signs and symptoms of fentanyl overdose and advise them to seek medical attention immediately (by dialling 999 and requesting an ambulance) if overdose is suspected

• remind patients that long-term use of opioids in non-cancer pain (longer than 3 months) carries an increased risk of dependence and addiction, even at therapeutic doses; before starting treatment with opioids, agree with the patient a treatment strategy and plan for end of treatment

• report suspected adverse drug reactions, including dependence, accidental exposure, or overdose associated with fentanyl patches, via the Yellow Card scheme

5 REPORTING ADVERSE DRUG/ DEVICE AND OTHER PATIENT SAFETY INCIDENTS

5.1 Patients must be protected from risks of harm posed by prescribing, administrations and other medicines related errors. Early, routine reporting of adverse reactions, incidents and near misses involving medicines and devices can allow performance and systems issues to be investigated and lessons learned. Reports must be made in accordance to local clinical governance procedures.

5.2 The Medicines and Healthcare products Regulatory Agency (MHRA) must be informed about:

- Serious suspected adverse reactions to all medicines and all reactions to products marked with a Black Triangle in the BNF and elsewhere using the Yellow Card Scheme

- Patients should be provided with information about how they can report suspected side effects directly to the MHRA

5.3 All serious patient safety incidents should be reported through local clinical governance arrangements.

6 MANAGEMENT OF HIGH RISK MEDICINES

6.1 A patient's medicines support needs must be reviewed as part of the overall assessment of their needs and preferences for care and treatment. As far as possible, patients should manage their medicines themselves.

6.2 Responsibility for ordering, transporting, storing, administering and disposing of medicines usually stays with the patient and/or their family members, or carers (if this has been agreed with the patient). However, if it has been agreed that a social care provider is responsible, effective medicines management systems must be in place.

6.3 When a patient is assessed to be at risk because of unsecured access to their medicines, confirmation must be sought that for example social care providers have agreed with the patient and/or their family members, or carers, whether secure home storage is needed, for example, in a lockable cupboard (NICE NG67).

6.4 Robust processes must be in place to ensure there is safe access to medicines e.g. Controlled Drugs (CDs), where social care providers are responsible for storage.

6.5 Measures should be put in place to enable individuals who require support with medication in community settings to receive this from suitably trained and competent staff; for example, patients may need support with medicines administration procedures, which might require registered nursing input.

6.6 Where support is required for the use of medicines, the following should be considered:

a. What medicines the patient uses and when

b. Why and how they take the medicines

c. How they manage and store the medicines

d. What help they need e.g. devices to help administer the medicines

e. Possible changes to their ability to make decisions about their medicines.

f. What might affect the type, amount or timing of support the individual needs e.g. 'when required' medicines, medicines needed at a particular time, devices used to help administer the medicines

g. Use of over-the-counter medicines, herbal medicines or nutritional supplements

h. Who will order, collect and/or deliver the medicines

6.7 Clear records of the discussion and any decisions made in relation to these issues must be made in the patient's care record and/or personal plan

6.8 Roles and responsibilities must be clarified in relation to the provision of support with medication:

a. General practices should record details of each patient's medicines support needs and who to contact about their medicines (the patient or a named contact) in their medical record, when notified that a patient is receiving medicines support from a social care provider

b. Health professionals should encourage social care practitioners to seek advice about medicines from people with specialist experience, such as the prescriber, a pharmacist or another health professional, when it is needed

c. Health professionals should provide ongoing advice and support about a patient's medicines and check if any changes or extra support may be helpful

6.9 Regular review and rationalisation of treatment should be conducted to ensure the patient's medicines and medicines support needs are met, to thus enable desired outcomes to be achieved:

a. A timely review should be conducted to ensure that any support provided is appropriate to the patient's ability and needs

b. A structured patient centred approach to polypharmacy should be adopted, where applicable

c. Changes to a patient's medicines must be communicated by informing the patient or their named contact, providing written instructions of the change, issuing a new prescription as necessary, informing the patient's community pharmacy where needed; in agreement with the patient and or their named contact or carer

d. Where verbal changes are made in order to avoid treatment delays, written instructions should be provided as soon as possible and the written confirmation sent by an agreed method

6.10 Patients and/or their carers should be advised of the following with regards to the storage of Controlled Drugs (CDs):

a. CDs should be kept securely as possible, prescribers should perform a risk assessment with regards to the potential for misuse of CDs. This risk assessment should be uploaded onto the patient's notes. Where concerns are identified the prescriber should formulate a plan to manage any issues identified

b. Patients and carers should be encouraged to store CDs in the original dispensed labelled boxes, keeping different strengths physically separated, especially injectable morphine and diamorphine, to minimise risk of accidental preparation and administration of a wrong dose

c. All medicines should be kept in one location to avoid them being mislaid

d. Prescribers should explain that CDs are potentially dangerous and vulnerable to misuse, and that a drug which is appropriate to the particular needs of a patient might be a temptation or a danger to others, and that it

should be looked after accordingly. Any such discussions or conversations must be documented clearly in the patient's record

e. Prescribed drugs including CDs are the property of the patient and remain so even after death. It is illegal for anyone to possess CDs that have not been prescribed for them. Relatives/carers should be advised that it is illegal to possess the CDs and that all CDs should be returned to a community pharmacy for safe destruction; whether that is because of discontinuation of the CD or due to the death of the patient

7 REVIEW AND MONITORING

7.1 Compliance with key elements of the Norfolk & Suffolk Special Allocation Scheme local policy on managing high risk medicines, is monitored through a programme of regular quarterly and six-monthly audits conducted by the pharmacy staff.

7.2 The findings of these audits, and recommendations for action, are presented to the Medicines Management Group. Where re-audit identifies a lack of progress, the findings and recommendations are escalated to the appropriate senior managers and/or committees.

7.3 The Medicines Management Group is a sub-committee of the Clinical Governance & Quality Sub-Committee. The activity of the Medicines Management Group is reported in the Medicines Management Annual Report which is presented to the Quality Committee, a sub-committee of the Trust Board.

7.4 The Risk Management department collates details of all incidents involving the prescribing and administration of medication. Reports of these are available to the Chief Pharmacist and Medication Safety Officer (MSO). A summary report of medication-related incidents is a quarterly standing item on the agenda of the Medicines Management Group.

7.5 Compliance with training will be monitored by the Workforce Development and Training department

8 REFERENCE TO OTHER TRUST POLICIES/PROCEDURES

CLPG13-MH & LD Procedural Guidelines for the Safe and Secure Handling of Medicines in Mental Health Services.

Section 21: High Risk Medicines Formulary and Prescribing Guidelines.

9.0 BIBLIOGRAPHY

1. Schwartz, J. 2016. Potential Effect of Substituting Estimate Glomerular Filtration Rate for Estimated Creatinine Clearance of Dosing of Direct Acting Oral Anticoagulants. *J Am Geriat Soc*. **64**(10), pp.1996-2002.

2. MacCallum, P. Mathur, R. Hull, S. 2013. Patient safety and estimation of renal function in patients prescribed new oral anticoagulants for stroke prevention in atrial fibrillation: a cross sectional study. *BMJ Open*. **3**.

3. Steinberg, B. Shrader, P. Thomas, L. 2016. Off label dosing of non-vitamin K antagonist oral anticoagulation and adverse outcomes. *The Orbit II AF registry JACC.* **68**, pp. 2597-2604.

4. Yao, X. Shah, ND. Sangaralingham, LR. 2017. Non-vitamin K antagonist oral anticoagulation dosing in patients with atrial fibrillation and renal dysfunction. *JACC*. **69**(23), pp. 2779-2790.

5. MHRA. (2012) Dabigatran (Pradaxa▼): risk of serious haemorrhage. https://www.gov.uk/drug-safety-update/dabigatran-pradaxa-risk-of-serious-haemorrhage

6. Steffen, J. Verhamme, P. Potpara, T. 2018. The 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation. *EH*. pp.1-64

7. NHS England. 2019. Items which should not routinely be prescribed in primary care: Guidance for CCGs Version 2. https://www.england.nhs.uk/wp-content/uploads/2019/08/items-which-should-not-routinely-be-prescribed-in-primary-care-v2.1.pdf

8. Drug Safety Update volume 14, issue 2: September 2020

9. Opioid medicines and the risk of addiction. Safety leaflet on opioid medicines to help patients and their families reduce the risks of harm. https://www.gov.uk/guidance/opioid-medicines-and-the-risk-of-addiction

10. Faculty of pain medicine of the Royal College of Anaesthetists. Terminology and prevalance. https://fpm.ac.uk/opioids-aware-opioids-addiction/terminology-and-prevalence

11. Management of chronic pain. Healthcare Improvement Scotland / SIGN. https://www.sign.ac.uk/our-guidelines/management-of-chronic-pain/

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