Norfolk and Waveney
Integrated Care Board

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INR point of care testing and warfarin monitoring in primary care

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Who is it aimed at and which settings?	All Norfolk and Waveney system partners, the public and patients
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Contents

1. Aims and Objectives

1.1 Aims

To ensure patients prescribed warfarin are managed safely, effectively and in a timely manner via near patient testing using the LumiraDx instrument and INRstar®.

- To reduce inequalities in access to anticoagulation management through initiation, stabilisation, monitoring, and dosing.
- To achieve optimum management of INR control and reduce drug-associated complications.
- Improve patient's experiences by seeing and treating patients in community settings.

To avoid inappropriate referrals to secondary care which are caused by a lack of timely warfarin monitoring.

1.2 Objectives

- To measure and monitor the International Normalised Ratio (INR) of patients who are prescribed warfarin therapy by their GP, independent prescriber or hospital consultant.
- To maintain the patient's INR within their therapeutic range by appropriately adjusting their warfarin dosage.
- To ensure a clinical review to determine continuing medical need for warfarin is performed annually or as appropriate and that patients no longer requiring warfarin have had treatment stopped.
- To counsel and educate patients in order for them to understand their treatment, with respect to their condition, target INR, the effects of over and under anticoagulation, diet, lifestyle and drug interactions.
- To ensure documentation is complete and accurate.
- To carry out audit procedures annually or as requested by the CCG.
- To ensure the Standard Operating Procedure (SOP) is reviewed every year and changes made accordingly.

2. Roles and Responsibilities

2.1 Primary care

- Maintain a register for all patients prescribed warfarin to include:
    - Patient's name.
    - Date of birth.

    - The indication for and duration of treatment.
    - Dose of anticoagulant.
    - Target INR.
    - Relevant clinical history, examination findings and test results.
    - Date of next appointment / Follow up arrangements from the prescriber (where appropriate).
- To measure the INR of patients registered in the service, receiving anticoagulation, using the LumiraDx instrument.
- To use the INRstar® software, along with clinical judgement, to prescribe warfarin dose.
- To work with the patient to maintain the INR within the therapeutic range by appropriately adjusting the warfarin dosage.
- To ensure relevant standard operating procedures are developed and adhered to.
- To ensure INRstar® training funded by the CCG is undertaken by relevant staff. Evidence of this training must be documented, and competencies must be satisfactory before undertaking this service.
- To use INRstar® as a robust call and recall system to ensure patient safety.
- Where appropriate, seek advice from, or refer to secondary care.
- To ensure all necessary documentation is completed as appropriate.
- To ensure both internal and external quality control tests are carried out at appropriate intervals according to manufacturer advice.
- To ensure the equipment used to deliver this service is maintained and serviced according to manufacturer advice by a suitable trained person.
- To ensure the appropriate consumables for testing INR and provision of vitamin K for over-coagulation is available in the surgery and ordered in a timely manner.
- Clinicians to carry out Continuing Professional Development (CPD) associated with anticoagulation therapy.
- To work within the parameters of the Locally Commissioned Service (LCS) framework.

2.2 Secondary Care

Secondary care will continue to initiate warfarin therapy where a clinical need is identified, for example, inpatients or those patients where anticoagulant is deemed necessary following outpatient investigations. These patients will transfer to primary care for routine warfarin

monitoring once stabilised; this is usually after 2 consecutive INR results within therapeutic range over at least one week.

A small cohort of patients may be retained for routine monitoring by secondary care but these patients will be identified by the specialist team and primary care notified.

3. Patient Criteria

3.1 Inclusion Criteria

- Dosing management of all patients aged over 18 years old prescribed warfarin will be the responsibility of the practice. Point of care testing should be undertaken on all, with the exception of Housebound patients, whose point of care testing will be undertaken by the Community Nurses (dosing will be undertaken by practice).

3.2 Exclusion Criteria

- Pregnant or breastfeeding (as warfarin is contraindicated).
- Patients aged under 18 years old.
- Patients undergoing renal dialysis (this cohort will remain under secondary care).

4. Introduction

Anticoagulant medication is used to prevent or treat thromboembolism in a variety of conditions including in patients with atrial fibrillation (AF), deep vein thrombosis (DVT), pulmonary embolism (PE) and prosthetic heart valves.

One of the most commonly used anticoagulants in the UK is warfarin. Treatment with warfarin is usually long term and requires regular monitoring due to its narrow therapeutic window and to prevent harm to the patient. Dose adjustments may be required throughout treatment; the dose is dependent upon how coagulated the blood is, assessed by the International Normalised Ratio (INR). Patients will have a target INR range depending upon the condition for which warfarin is prescribed. Deviation from this therapeutic range is associated with an increased risk of haemorrhage (if too high) or increased risk of thrombosis (if too low).

INR monitoring can be done via venous blood testing where samples are sent to the laboratory for testing or via capillary blood test via point of care testing performed in primary care. Great Yarmouth and Waveney locality is introducing point of care testing in primary care to enable eligible patients to have their INR tested and dosed in primary care

NB – Although rarely prescribed, Acenocoumarol and Phenindione also require regular INR testing and would be managed using near patient testing and INRstar.

5. Warfarin dosing and prescribing

5.1 Warfarin initiation

For patients being initiated on warfarin, please consult the Norfolk and Norwich University Hospital (NNUH) guidelines for the most appropriate loading schedule.

Warfarin is classified as a "critical medicine" as defined by the National Patient Safety Agency Rapid Response 'Report 18: Preventing fatalities from medication loading doses'. Loading doses of medicines can be complex and error prone. Incorrect use of loading doses or subsequent maintenance regimens may lead to severe harm or death.

5.2 Indication for treatment and target INR

The dose of warfarin is determined by the INR. It should be administered once daily, ideally at 5-6pm to aid compliance and to allow a dose change to be implemented on the same day as INR testing.

The target INR and duration of therapy depends on the indication for anticoagulation. The INR range is usually +/- 0.5 INR units e.g. for a target INR of 2.5 the target range is 2.0 – 3.0. For details on dosing please refer to the Norfolk and Norwich University Hospital (NNUH) guideline.

5.3 INR monitoring

Routine INR tests will be performed using the LumiraDx machine which uses a capillary blood sample. Venous blood samples should only be used in exception circumstances, for example where a venous INR test is needed to confirm a high INR result from the LumiraDx machine.

5.4 Frequency of INR testing

The frequency of INR testing varies between patients depending on their INR stability. The maximum recommended length of time between INR tests is 12 weeks (reduced to 8 weeks for those patients with a mechanical heart valve). Every patient **must** be seen at least once every 12 weeks. See appendix 1 for suggested recall periods

Recall dates will be suggested by INRstar; however, if the patient's clinical condition is unstable, or there have been alterations in other medications, the INR must be checked more frequently, and clinical judgement should override the recommended date suggested by INRstar. Although INR may be measured daily or on alternate days, on starting warfarin and following a dose change, an accurate INR can only be obtained after 3-4 days.

Patients newly prescribed warfarin and those that are less stable will require more frequent testing. This includes those patients at risk of over-coagulation (e.g., severe uncontrolled hypertension, liver disease or renal failure) or increased risk of bleeding (e.g. aged 65 years

or over, highly variable INRs, history of GI bleeding, cerebrovascular disease, serious heart disease, risk of falls etc).

Many clinical factors and drugs may affect the sensitivity of the patient to the effects of warfarin. Particular attention should be placed on checking changes in medication, food/ drink and lifestyle and the impact of these on INR. Specific warning or alert flags should be considered and added to patient records if applicable. See appendix 2 for more details.

Compliance to taking warfarin as recommended must be regularly reviewed and documented.

A robust system must be in place to ensure all DNAs (did not attends) are followed up and monitored effectively. All patients must be made aware of the importance of regularly INR monitoring to avoid adverse events. Where a patient repeatedly fails to attend for monitoring, then the risks of continuing must be reviewed against the benefits by an appropriate clinician.

5.5 Warfarin prescribing

Warfarin is always given in tablets form. Tablet strengths are as follows:

500mcg (White)*

1mg (Brown)

3mg (Blue)

5mg (Pink)

**500mcg tablets should not be prescribed as there have been errors of incorrect dosage being administered.*

Where possible patients should be routinely prescribed 1mg, 3mg and 5mg strengths to allow them to alter their dose accordingly. Specific directions for dosing should not be included on the prescription. It is recommended that the prescription states ‘dose as stated in yellow book’ ‘or dose according to INR’. All dosing instructions should be given verbally as well as written in the patient’s yellow book and/or on a computerised dosing sheet printed from INRstar.

Acenocoumarol (1mg tablets) and Phenindione (10mg, 25mg and 50mg tablets) are occasionally used in patients who cannot tolerate warfarin.

5.6 Contra-indications to anticoagulation with warfarin

This list is not exhaustive, each patient must be individually assessed for suitability, but includes:

- Haemorrhagic stroke.

- Pregnancy – particularly during weeks 6 to 12 of gestation. Women of childbearing age should be warned of the risks and counselled in the use of effective contraception methods.

5.7 Managing anticoagulation in conditions where thrombosis risk is increased

For patients with conditions such as Protein C deficiency, Protein S deficiency, Antiphospholipid syndrome and Factor V Leiden where there is an increased thrombosis risk, haematology advice may need to be sought.

6. Patient management

6.1 Patient education

It is the GP practice's responsibility to ensure that patients and/or carers have received appropriate educational counselling by the initiating GP on the risks and benefits of warfarin and anticoagulation. Patient understanding must be checked at regular intervals, including at annual review, to ensure the patient is aware of, and understands the following:

- Name of drug including tablet colours.
- Understand that the dose will vary depending on the results of their INR test.
- Target INR and range.
- Reasons for and objectives of treatment.
- Anticipated length of treatment.
- What to do in the event of a missed or wrong dose.
- Symptoms of under dose (e.g. progressive worsening of thrombotic signs or new symptoms, for example shortness of breath) and overdose and what actions to take if these occur.
- Risks and side effects of treatment including side effects and bleeding risks.
- Drug and food interactions (as per most recent BNF).
- Additional monitoring or earlier monitoring may be required in the event of changes to medication including prescribing of new medication.
- Which medications, including over the counter (OTC) and herbal/homeopathic medications that require particular care when taking warfarin.
- What to do if dental treatment or surgery is required.

- **Be provided with a 'yellow book**' and understand its contents (further supplies can be ordered via PCSE here).
- Who to contact in case of concerns.

6.2 Patient assessment for patients established on warfarin

Patients already established on warfarin should be asked to attend for an INR test on the date suggested according to their current INR dosing schedule.

Before undertaking the capillary test, the following must be checked:

- Patient identity.
- Compliance with warfarin.
- Current dose of warfarin being taken and ensure this corresponds to the most recent dosing schedule.
- Target INR range.
- If any new symptoms / problems have developed.
- Any potential side effects / unexpected bleeding.
- Any changes to medication including acute courses (e.g. antibiotics), over the counter medications and herbal/complementary medicines.
- Any lifestyle changes (e.g. diet and alcohol).
- Any changes in the patient's ability to take medicines safely (e.g. cognition, vision changes).
- Any future planned dental or surgical procedures.
- Any missed doses or extra doses.

If the patient reports any problems or changes this must be discussed with a suitable clinician.

If the practitioner has concerns at any point about the patient's ability to safely take warfarin as prescribed this must be referred to a suitable clinician.

6.3 Patients being initiated on warfarin

For patients being initiated on warfarin, a longer appointment time should be allocated so the following can be discussed:

- Patient identity.

- Reason for anticoagulation.
- Strength of tablets available and dosing.
- Target INR and range.
- Anticipated length of treatment.
- Adverse drug effects and side effects (e.g. signs of bleeding).
- Interactions (drug and food).
- How to obtain supplies of warfarin.
- Advice for dental or surgical treatment.
- Who to contact for further advice or to discuss concerns.
- Provide a Yellow book.

If the practitioner has concerns at any point about the patient's ability to safely take warfarin as prescribed this must be referred to a suitable clinician.

6.4 INR Testing

The LumraDx instrument must be set up for Near Patient Testing in accordance with the instrument's reference guide (to be kept with the instrument).

The instrument must be stored at a temperature of between 15°C and 30°C.

The instrument must only be operated on a **flat, level** surface. The air vents located at the back of the instrument must not be blocked.

For details on how to complete the testing, please refer to appendix 3 and appendix 4.

6.5 Warfarin dosing

Once the INR result has been inputted into INRstar, the program will suggest a warfarin dose to be followed until the next INR test. The suggested dose must always be considered alongside clinical judgement. If there are concerns that the dose is not suitable, the patient must be manually dosed by a suitable clinician (appendix 5).

The INR results must be recorded in INRstar as per the SOP (appendix 6) and the clinical system (SystmOne/EMIS)

6.6 Referral to GP

The practitioner running the anticoagulant clinic must refer patients to the GP or seek advice in the following circumstances.

- Any relevant new symptoms/problems that have developed.
- Any unexpected bleeding or potential side effects.
- Any problems with taking warfarin that cannot be resolved.
- Any new medicines prescribed that might interact with warfarin or increase bleed risk.
- Any relevant change in lifestyle and occupation that will affect INR control and cannot be resolved.
- Any significant changes in the patient's ability to take warfarin safely.
- The patient has not had an annual clinical review.
- Patients that "do not attend" (DNA) twice in succession or have compliance issues that cannot be resolved.

6.7 Management of bleeding and over-anticoagulation

ANY SIGNS OF BLEEDING REQUIRE MEDICAL ADVICE AND MAY NEED REFFERAAL TO SECONDARY CARE.

- Risk factors for haemorrhage increases significantly when the INR is >5.0.
- **Factors associated with higher risk of bleeding*: older age, uncontrolled hypertension; diabetes; renal or liver failure; previous gastrointestinal or cerebral bleed: use of antiplatelet medications; previous history of bleeding; postoperative.**
- Unexpected bleeding at therapeutic levels – always investigate possibility of underlying cause e.g. unsuspected renal or gastro-intestinal pathology.
- ALL patients with any active bleeding should be reviewed to determine whether these is an anatomical cause for the haemorrhage.

LumiraDx plus cannot register an INR result if it is >7.5 (range 0.8 – 7.5). The instrument will indicate if the INR is above this level and a repeat sample should be taken.

If the INR is reported as >7.5, a repeat capillary blood sample must be performed in addition to obtaining a venous blood sample to be sent to the laboratory to determine the exact INR. The patient must be referred to a GP for advice. The venous blood sample must be sent to the James Paget University Hospital the **same day and marked as urgent**. **It is vital the lab is informed the person is prescribed warfarin** – annotate this information on the ICE request. If transport has already collected it is the surgery's responsibility to ensure the sample is sent.

ACTION MUST BE TAKEN IMMEDIATELY - DO NOT WAIT for a venous INR result. If clinically appropriate, Vitamin K can be prescribed based on the capillary blood sample INR. The patient must be informed of any changes to their warfarin dosing and follow up advice (Appendix 7).

6.8 Use of Vitamin K (phytomenadione) in over-anticoagulated patients

The recommended vitamin K preparation is phytomenadione 2mg in 0.2ml ampoules to be given orally; this is off-label. Oral administration has a slower onset of action, usually within 16 to 24 hours, compared to IV administration which has a rapid onset of between 6-8 hours. Vitamin K should never be administered subcutaneously as dosing is inconsistent. Intramuscular administration should be avoided due to the risks of haematoma.

There must be a readily available stock of vitamin K (phytomenadione) at each site where point of care testing is performed. Expiry dates and stock levels must be checked weekly. Further supplies can be ordered from a community pharmacy using a signed order.

Where oral vitamin K is required, it is the GPs responsibility to administer or to direct a suitably trained clinician to administer (Appendix 8).

6.9 Head injuries

Patients presenting with head injuries who are prescribed warfarin must have an INR check as they are at great risk of haemorrhage. If there are concerns the patient must be referred to Accident and Emergency.

6.10 Dental treatment

The British Committee for Standards in Haematology (BCSH) has published guidance on the management of patients on oral anticoagulants, including those patients requiring dental surgery.

6.11 Rebooking the patient

Before the patient leaves, an appointment must be made on the clinical system for their next INR test in accordance with the testing period on INRstar® (or using clinical judgement if referral made to GP).

For patients with a mechanical heart valve, the maximum recall period on INRstar® must be set to 42 days.

The practitioner must also check with the patient they have enough warfarin to continue dosing at the current dose. If a further supply is required, a prescription should be generated following local Standard Operating Procedures.

6.12 Patient recall

At the beginning of each clinic, a search will automatically be run by INRstar® to find all outstanding warfarin monitoring and patients will be highlighted in an “overdue list”. These patients need to be followed up to check why they have not attended.

At the end of each clinic a check should be made that all patients (including home visits) have been dosed. DNA patients should attempt to be contacted. Patients who fail to attend should be phoned and offered an appointment as soon as possible; this will be determined by the urgency of re-checking the INR.

For medico-legal reasons an entry of all attempts to contact the patient should be made in the clinical record.

In extreme cases, where the patient fails to attend two or more INR checks in succession, the GP should be informed. The GP would then need to arrange to see the patient, to discuss the risks and benefits of not being monitored and a decision made as to whether to continue treatment or not.

6.13 Housebound patients

Housebound patients will have a capillary sample taken by East Coast Community Healthcare (ECCH) district nursing teams. ECCH will be responsible for ensuring the INR reading is relayed to the GP surgery promptly to ensure same day testing. The GP surgery must ensure they have a robust system in place to enable dosing to be communicated to the patient the same day.

7. Quality Control

7.1 Internal quality control

This must be performed on the first working day of each week. It involves testing control reagents with known INRs with the LumiraDx instrument. If the result is within the expected range this gives a degree of confidence that the equipment is calibrated correctly and is working accurately.

The outcome of the internal quality control must be recorded in the control log and on INRstar®.

See LumiraDx user’s manual for instructions on carrying out quality control tests. A video can also be viewed here.

7.2 External quality control

National External Quality Assurance Scheme – NEQAS - is a National scheme to monitor the accuracy of NPT instruments. This quality control test is carried out on a quarterly basis on

set dates. A control sample is sent, an INR reading obtained and returned. The practice's performance is then assessed against practices across the whole country.

8. Cleaning and disinfection of LumiraDx instrument

Cleaning and disinfection of the LumiraDx should be carried out regularly by trained staff in accordance with the manufacturer's advice. Please refer to Appendix 9.

9. Storage

When not in use, the instrument must be stored in a secure room or locked cupboard. It must be stored on a flat surface, away from direct sunlight and at a temperature of between 15°C and 30°C.

Test strips must be stored in their original container in a temperature of between 5°C and 32°C. Test strips that have past their expiry date must be discarded. Stock rotation should be in place to ensure the shortest date strips are used first.

10. Consumables

It is the surgery's responsibility to maintain and order adequate levels of all consumables required to complete near patient INR testing; this includes vitamin K for over-coagulation.

11. Training

Staff undertaking the point of care testing must have completed the initial training package provided by LumiraDx and deemed competent prior to undertaking patient appointments. This must be renewed annually.

All staff involved with the delivery of this service must have completed approved annual infection control training.

12. Audit

An annual audit will be required to be submitted to the CCG at the end of Quarter Four each year. The Practice should provide information on patient's time in therapeutic range and number of patients/occasions when patients have an INR >5 and >8.

13. Reporting near misses, incidents and serious events

These should be reported as per local procedure. INRs above 5.0 should be treated as an incident and investigated internally.

In the event of patient hospitalisation due to bleeding, this must be reported to the CCG via the medicine management team nwccg.medsqueries@nhs.net.

14. Useful links

LumiraDx training platform: Provides leaflets and videos on how to perform an INR test and internal quality test. https://www.lumiradx.com/uk-en/kc/platform-training/inr

Primary Care Support England: 'Yellow books' can be ordered by searching the terms OATBOOK - OAT Record Booklet - Oral Anticoagulant Therapy. Supplies - Primary Care Support England

Norfolk and Norwich University Hospital (NNUH) anticoagulation guidelines

15. References

Guidelines on Oral Anticoagulation with warfarin 4th edition (2011. Br J Haem: 154 (3), 311-324; www.bcshguidelines.com

National Patient Safety Agency http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/alerts/anticoagulant/

Lyall, Price. Clinical Guideline for: The Management of: Adult patients requiring anticoagulation with warfarin. Norfolk and Norwich University Hospital. 2022 Norfolk and Norwich University Hospitals NHS Foundation Trust » Adult Patients Requiring Anticoagulation with Warfarin CA2085v10 (nnuh.nhs.uk)

British National Formulary (BNF) April 2022. BNF British National Formulary - NICE

Derbyshire joint area prescribing committee: Guideline on oral anticoagulation with warfarin. Local guidance to Anticoagulation Monitoring Enhanced service specification (derbyshiremedicinesmanagement.nhs.uk)

Cambridgeshire and Peterborough CCG. Prescribing and monitoring of warfarin.

Appendix 1: Suggested recall periods during maintenance therapy (not initiation)

All patients must be seen at least every 12 weeks

One INR high	Recall in 7-14 days (stop treatment for 1 – 3 days) (maximum recall 1 week in prosthetic valve patients)
One INR low	Recall in 7 – 14 days
One INR in therapeutic range	Recall in 4 weeks
Two INRs in therapeutic range	Recall in 6 weeks
Three INRs in therapeutic range	Recall in 8 weeks (excluding prosthetic valve patients)
Four INRs in therapeutic range	Recall in 10 weeks (excluding prosthetic valve patients)
Five INRs in therapeutic range	Recall in 12 weeks (excluding prosthetic valve patients)

Patients seen after discharge from hospital with prosthetic valves may need more frequent INRs in the first few weeks (Ryan et al (1989) British Medical Journal 299, 1207-1209)

Appendix 2: Factors affecting warfarin sensitivity

Conditions that may increase warfarin sensitivity (may warrant decrease in warfarin dose)	**Conditions that may decrease warfarin sensitivity (may warrant increase in warfarin dose)**

• Hepatic dysfunction and/or jaundice
• Alcohol abuse particularly 'binge drinking'
• Congestive heart failure
• Anorexia
• Hyperthyroidism
• Acute pyrexial episode
• Reduction of dietary intake of vitamin K
• Cranberry juice / tablets
• Drugs including (but not exhaustive):
  • Allopurinol
  • NSAIDs
  • Amiodarone (marked effect)
  • Antibiotics (almost all – unpredictable effects)
  • Antifungals
  • Disulfiram
  • Tamoxifen
  • Statins
  • Thyroid hormones
  • Cimetidine
  • Antiplatelets (increased bleeds risk)
	• Hypothyroidism
	• Increase of dietary intake of vitamin K*
	• Herbal remedies including (but not exhaustive)
	  ○ St John's Wort
	  ○ Gingko Biloba
	  ○ Danshen
	• Drugs including (but not exhaustive):
	  ○ Anti-convulsant
	  ○ Barbiturates
	  ○ Rifampicin
	  ○ Oestrogen and progestogens
	  ○ Sucralfate
	
	Note: When drugs that decrease warfarin sensitivity are reduced / stopped the dose may need to be reduced to avoid over-anticoagulation

*****The following foods and supplements are rich in vitamin K (not exhaustive): dark green leafy vegetables (spinach, kale cabbage, broccoli etc); asparagus, avocado, chickpeas, egg yolks, liver, mature cheese / blue cheese, olive / rapeseed oil

Appendix 3

Example SOP 1: Preparing the LumiraDx instrument

THIS IS A SAMPLE SOP – EACH PRACTICE MUST ADAPT AS DEEMED APPROPRIATE TO ENSURE IT IS FIT FOR PURPOSE IN THEIR WORKING ENVIRONMENT

1. Switch instrument on by pressing the power button at the rear of the instrument.
2. When switched on, the instrument will perform a self-check. If an error message appears consult instrument procedural manual or manufacturer before using instrument for INR tests.
3. When prompted enter user ID and password.
4. Select 'Patient Test' on the instrument screen and enter patient details.
5. Select a test strip and check the expiry date. Discard any strips past expiry date. Note: Instrument will not accept any expired strips. Remove the strip from the foil pouch from the indicated end by tearing the triangles. **Test strips must be used within 15 minutes of removing from foil.**
6. When prompted, open the door and insert the test strip. Hold the test strip by the blue label facing upwards. Align the black rib on the strip to the instrument alignment rib and insert the strip. The instrument will sound when the strip is detected.
7. Select the sample type as 'Capillary Blood'.
8. Select 'Confirm'.
9. The instrument will heat the test strip. (Prepare patient finger for testing).

Appendix 4

Example SOP 2: Performing the INR test

THIS IS A SAMPLE SOP – EACH PRACTICE MUST ADAPT AS DEEMED APPROPRIATE TO ENSURE IT IS FIT FOR PURPOSE IN THEIR WORKING ENVIRONMENT

Local infection control and blood collections procedures must be followed at all times.

1. **Ask patient to wash and dry hands thoroughly.** Hands must be free from all oils, creams, sanitisers and/or foreign material before collecting the blood sample. The patient should wash their hands whilst the instrument is being prepared as per above.
2. **Increase blood flow**. It may be helpful to try and increase blood flow to the finger before lancing by using the following techniques:
    a. Ask the patient to rinse their hands with warm water.
    b. Ask the patient to hold their arm straight down at their side.
    c. Massage the finger from its base.
3. **Put on non-sterile disposable gloves**.
4. **Use lancet** on selected finger to obtain a blood sample. If necessary, to encourage blood flow very gently squeeze the finger from the base upwards.
5. **When prompted by the instrument apply the sample** by holding the finger and hanging the blood drop over the 'Sample Application Area' on the inserted test strip and allow the drop to touch the surface of the strip. The instrument will sound when the blood sample is detected, and a confirmation message will be displayed. Do not add any more blood to the strip.
6. **Close the instrument door.** The door must be closed within 10 seconds. Do not open the door whilst the test is in progress.
7. **INR result** will appear on the instrument screen within 3 minutes of starting the test.
    7.1 The LumiraDx instrument will not record a reading above 7.5. An error message will appear to alert (measuring range 0.8-7.5). The test must be repeated. If the second test confirms INR above 7.5, take a venous sample for lab testing and refer to a suitable clinician.

7.2 **If INR reading is greater than 4.5 REPEAT the test**. If the second result is within +/- 0.5 INR units of the original result, accept the result and refer to a GP to dose the patient.

7.3 If the second test is more than 0.5 different from the first, disregard both results. Send a venous sample for lab testing and refer to a clinician for advice. Perform an Internal Quality Control on the instrument.

7.4 If an unexpected INR result occurs (for example 50% higher or lower than expected from the patient's past history) without an explanation, repeat the test once. If there are any concerns, refer to a GP

8. **Remove test strip** and dispose along with lancet in appropriate sharps bin / clinical waste.
9. **Clean the patient's finger** with a clean tissue and applying slight pressure.
10. **Turn instrument off** by pressing the power button at the rear of the instrument for 2 seconds and tap the screen message to confirm power off.
11. **Disinfect** the instrument after each use using approved cleaning materials. The relevant SOP should be followed. Disinfectant should remain in contact for at least 5 minutes. Allow the instrument to air dry before testing the next sample.
12. **Concerns** around INR result or patient's compliance or taking of warfarin must be referred to a GP.

Appendix 5

Example SOP 3: Warfarin dosing

THIS IS A SAMPLE SOP – EACH PRACTICE MUST ADAPT AS DEEMED APPROPRIATE TO ENSURE IT IS FIT FOR PURPOSE IN THEIR WORKING ENVIRONMENT

Dosing decisions are made using INR Star alongside clinical judgement

1. Open the INRstar® program by clicking on the icon on the desktop.
2. Click on the 'Patient' box and search for patient using their surname.
3. Answer the questions on the screen.
4. Insert the current INR value and press return.
5. INRstar® will give a suggested dose and date for the next INR test. Any reasons for dose or review period adjustments should be recorded in the 'comments' section.
6. For further instructions on how to use INRstar® refer to the training module or use the 'help' function.

Appendix 6

Example SOP 4: Recording the INR result

THIS IS A SAMPLE SOP – EACH PRACTICE MUST ADAPT AS DEEMED APPROPRIATE TO ENSURE IT IS FIT FOR PURPOSE IN THEIR WORKING ENVIRONMENT

Record the relevant details of the consultation in:

1. The INRstar® 'comments' section. Open the patient on SystmOne This will automatically transfer the data into the patient's clinical record on SystmOne when the patient details are saved on INRstar®. For EMIS practices, the data will transfer without requiring the patient record to be open. This information includes:
    - INR result
    - INR target range
    - Missed doses
    - Relevant information given at each visit / education provided
    - The dose of warfarin to be taken until the next INR test
    - Date of next appointment
2. The patient's handheld record (Yellow Book). A print off from INRstar® may also be given to the patient. The following information must be documented in the Yellow Book.
    - Indication for anticoagulation
    - Duration of therapy
    - Target INR range
    - Dose of warfarin to be taken until next INR test – to be recorded in milligrams and the colour of tablets should be recorded.
    - Date of next appointment
    - Time in therapeutic range (if known)
3. A record should be made in SystmOne in the 'New Journal' consultation tab for any additional information given which has not been included in the INRstar® record. EMIS PRACTICES WILL NEED TO AMEND ACCORDINGLY

Appendix 7: Suggested management of high INR results

The below table offers guidance only. Any concerns should be discussed with secondary care.

LumiraDx is unable to record an INR value above 7.5. High INR readings require a venous sample to confirm. In the event of an INR above 7.5 **DO NOT WAIT** for the venous sample result before taking action.

INR range **Presence of bleeding**	**ACTION**
Major bleeding irrespective of INR	• **STOP warfarin** • **Urgent referral to secondary care**
INR >8.0 Minor bleeding *NB – LumiraDx will not provide an INR reading over 7.5. Obtain venous sample if result >7.5*	• **STOP warfarin** • **Refer to secondary care** (Patient likely to require IV vitamin K) • Obtain venous sample
INR >5.0 Minor bleeding	• **STOP warfarin** • **Discuss with secondary care** (Patient may require IV vitamin K)
INR>8.0 No bleeding	• **STOP warfarin** • Obtain venous blood sample for a laboratory INR • Give 1-5mg vitamin K **orally** (phytomenadione 2mg in 0.2ml IM / oral preparation). Usual dose is 2mg • Recheck INR daily via a venous blood test • Investigate cause of elevated INR – is it temporary e.g. drug interaction or permanent e.g. liver failure? • Repeat dose of vitamin K orally if INR still >8.0 after 24 hours or seek specialist advice if clinically indicated e.g. signs of bleeding or bruising • DO NOT give more than three consecutive doses of vitamin K – If INR remains >5.0 seek advice from secondary care • When INR <5.0 review need for anticoagulation • If appropriate, restart warfarin at reduced dose – 50% of previous dose
INR >4.5 – <8.0 no bleeding	• Use capillary sample result and dose via INRStar – Consider 2mg of vitamin K **orally** (phytomenadione 2mg in 0.2ml IM / oral preparation) if bleeding risk present • Restart when INR <5.0 at a reduced dose • Investigate cause of raised INR

Appendix 8

SOP 5: How to administer Vitamin K 2mg in 0.2ml orally

Phytomenadione (2mg in 0.2ml) 0.2ml ampoules should be used to manage high INR results in primary care. Although this product is licensed for several routes of administration this protocol refers to oral use. This is an off-license route of administration.

1. Check expiry date of ampoule and ensure the product is in date before use
2. Break ampoule
3. Using the oral dispenser withdraw the solution to the appropriate mark (1mg = 0.1ml or 2mg = 0.2ml)
4. Hold dispenser in patient's mouth (at the back of the tongue) and press plunger
5. Offer patient a glass of water as the solution has a very bitter taste
6. Check stock levels and reorder if only 2 ampoules remain in stock

Appendix 9

Example SOP 6: Cleaning and disinfection of LumiraDx instrument

THIS IS A SAMPLE SOP – EACH PRACTICE MUST ADAPT AS DEEMED APPROPRIATE TO ENSURE IT IS FIT FOR PURPOSE IN THEIR WORKING ENVIRONMENT

Ensuring the instrument is thoroughly and regularly cleaned and disinfected can help to minimise the risks of cross-contamination which can result in inaccurate readings.

Cleaning refers to the physical removal of dirt or other foreign material from the instrument surface.

Disinfecting is the chemical removal of harmful microorganisms from the instrument.

Further details on cleaning and disinfecting the instrument can be found here.

Cleaning the LumiraDx instrument

The instrument must be cleaned thoroughly at the end of each day that the instrument is in use, or sooner if the instrument is visibly soiled.

1. Put on non-sterile, disposable gloves.
2. Wipe the external surfaces of the instrument with a slightly damp, soft cloth. Excessive liquid may damage the instrument.
3. Dispose of cleaning materials in accordance with infection control policy.
4. Leave the instrument to air dry.
5. Sign and date the cleaning log.

Disinfecting the LumiraDx instrument

The instrument must be disinfected after each patient using approved materials. Alcohol wipes alone are not sufficient to disinfect the instrument due to the potential presence of bloodborne pathogens.

1. Put on non-sterile, disposable gloves.
2. Remove the protective screen cover.
3. Squeeze and excess liquid from disinfecting wipe or cloth. **Excessive liquid may damage the instrument.** The wipe or cloth should be slightly damp but not wet.
4. Wipe the external surfaces of the instrument whilst taking care to avoid the door hinges, test strip inlet, power cord and USB port.

5 Allow the disinfectant to remain in contact with the instrument for at **least 5 minutes** before testing the next sample.

6 Dispose of cleaning materials in accordance with infection control policy.

7 At the end of each day where the instrument is in use, the cleaning log must be signed and dated to confirm the machine has been disinfected.