


PROCEDURE DOCUMENT CONTROL SHEET

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Ratification

Executive Chairman or Executive Sponsor's Signature	
Name & Job title of Executive Sponsor	Mike Wright – QHG Committee
Date Ratified	02/09/2014
Signed Paper Copy Held at:	Corporate Records Office, DMH

VERSION CONTROL TABLE

Date of Issue	Version Number	Status
Feb. 2014	1.0	Draft

TABLE OF REVISIONS

Date	Section	Revision	Author

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1 INTRODUCTION

This Procedure is intended to be used by all Clinical staff involved in the use of Telehealth/Health Call INR monitoring in Co Durham and Darlington Foundation Trust (CDDFT). It describes the process of recruiting subjects undergoing anti-coagulation therapy whereby patients self-test and provide their INR (International Normalised Ratio) reading via an automated telephone call, and then receive a further automated telephone call later that same day informing them of their dosing instructions. The procedure provides recommended recruitment definitions, strategies and activities covering the recruitment and monitoring period.

2 DEFINITION OF ROLES AND TERMS

Role	Definition
<i>Patient</i>	<i>Individual being monitored by CDDFT Warfarin service via the Health Call INR monitoring service</i>
<i>Clinic Nurse</i>	<i>Anti-coagulation nurse who is responsible for referring and monitoring patients. Advising on warfarin dosage and responding to alerts from the Health Call INR monitoring service.</i>
<i>InTechnology</i>	<i>The supplier of digital services which provides the Health Call INR monitoring software to CDDFT and the managed service.</i>
<i>Anti-coagulation</i>	<i>The therapeutic use of anti-coagulants to discourage the formation of blood clots.</i>
<i>INR</i>	<i>INR (International Normalised Ratio) is the ratio between the coagulation time of a sample of blood and the normal coagulation time, when coagulation takes place in certain standardised conditions.</i>
<i>Informed Consent</i>	<i>A process by which a subject/patient voluntarily confirms his willingness to participate in a project after having been informed of all aspects of the monitoring that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.</i>
<i>The Meter</i>	<i>The CoaguChek XS meter allows the patient to obtain blood test results on the spot, using a drop of fingertip blood as the sample. The blood drop is placed on a test strip which is inserted into the meter so that the clotting time may be measured. The result as an INR value is then displayed on the device's screen.</i>
<i>System Administrator</i>	<i>Appointed administrator who registers patient details onto Health Call INR web portal and make changes when instructed by clinic staff.</i>

3 PURPOSE

The purpose of this procedure is to outline how Health Call INR monitoring will be used by Anti-coagulation clinic staff with patients whose health condition requires monitoring of INR levels and provides the procedure to be followed.

4 DUTIES

Heads of Service and Service Managers/Team Leads

The Heads of Service and Service Managers/Team Leads are responsible for:

- Ensuring that this procedure is implemented by Anti-coagulation Nurses and identify any need for amendments in relation to service requirements
- Support the regular evaluation of the implementation and effectiveness of this procedure.
- Notify the document owner of any revisions to these procedures.
- Arranging for superseded versions of these procedures to be retained in accordance with HSC 199/053 NHS retention and disposal schedule.
- Providing advice & guidance in relation to the implementation of the procedure.
- Monitor the Health Call INR scheme.

All Nursing staff

All Anti-coagulation Clinic staff are responsible for:

- Co-operating with the development and implementation of Telehealth/Health Call INR monitoring procedures and as part of their normal duties and responsibilities.
- Identifying the need for a change in procedure as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly.
- Identifying their own training needs in respect of Health Call procedures and bringing them to the attention of their line manager.
- Attending an organised training session prior to accessing the Web portal and any subsequent updates.
- Adhere to the Trust Information Governance policy in relation to data protection.
- Patient documentation will remain with CDDFT procedures, however, it is necessary to make a brief note on the Web health portal to identify the action taken by the Anti-coagulation Nurse.
- Report any issues arising from Health Call INR monitoring to their line manager.

5 PROCEDURE FOR HEALTH CALL INR MONITORING.

5.1 Access to Health Call INR monitoring.

Health Call INR monitoring is available to patients who reside in County Durham or Darlington who require regular monitoring of their blood INR levels because of a health condition. The patient will be assessed as suitable by an Anti-coagulation Clinic Nurse, GP or Consultant and the patient will consent to being monitored. Patients will be self-testing once

they have been trained and some may require support from a carer to record their readings, an automated telephone call will ask them to enter their readings. The Anti-coagulation Clinic Nurse will be responsible for accessing the patient's readings and answers they have provided to the telephone questionnaire, this will be done through accessing the website https://portal.inhealthcare.co.uk/en_GB/ and insertion of a personal user name and password. A search for the patient is conducted and the patient 'dashboard' viewed, it is here that the details of clinical readings and completed patient questionnaire will be found.

Patient selection and Inclusion Criteria:

1. The Health Call service can be accessed by patient's over the age of 18 years and who are deemed suitable to use the service by their GP or Anti-Coagulation Nurse.
2. The patient must be able to give consent and agree to participate.
3. The patient or carer must have the ability to understand the concept of oral anticoagulation treatment and the potential risks associated with the treatment.
4. The patient or carer must have the dexterity and acuity of vision to enable them to use the device and telephone.
5. The patient must be on long term anticoagulation therapy and require regular check of INR blood level.

5.2 Referral

The Clinic Nurses will identify suitable patients for Health Call INR monitoring, and provide information about the service available. An information leaflet will be provided to patients to inform their decision to participate. Written consent will be gained from the patient and the patient's GP will be informed in writing of the patient's agreement to use Health Call INR monitoring.

A Patient Registration form is completed on enrolment of the patient, ensuring all relevant patient details are recorded (Appendix 3). This information will be held securely as per Trust data protection policy. The patient registration form is forwarded to the appointed Administrator who will register the patient on the Health Call system.

5.3 Patient training

The patient must attend two training sessions prior to starting on Health Call monitoring. If the patient requires support with blood testing, the carer/relative will also be invited to attend the training.

The patient training sessions will be provided by a suitably trained Nurse (provided by Roche Diagnostics) and the patient will be taught how to use the Meter and how the automated telephone call will work. Written information and a training DVD is provided to support the patient learning. The second session will be arranged to enable the patient to have an opportunity to practice the testing procedure at home before being observed at the follow up session to ensure they feel competent to proceed with testing. The patient will be offered any further support required.

Registration of CoaguChek meter to the patient

CoaguChek machines are registered to individual patients. During the patient training session details are recorded to ensure the patient and machine being used are identified, this information is also required by Roche Diagnostics to ensure any issues with machines can be traced and actions recorded. A warranty card is sent to Roche to provide required details, these should be sent directly to Roche via a secure postal service.

5.4 Patient Monitoring

Once the patient has attended the required training sessions and the trainer agrees they have demonstrated the required competency, they can begin the Health Call INR service. The patient will choose the times they wish to receive the automated telephone calls and a suitable day will be arranged between Monday and Thursday in agreement with the Anti-coagulation clinic. The patient can receive the telephone call to a landline or a UK registered mobile number. The patient is expected to ensure the phone line is in good working order and if a mobile is being used, there is mobile coverage. Using a mobile phone enables the patient to receive the INR monitoring service when away from home eg. on holiday or whilst at work.

The Automated telephone call.

The patient will receive two telephone calls in the same day. The first telephone call will be received at a time suitable for the patient and before 11:30am. The second telephone call will also be at a time suitable for the patient and after 15:00pm. The flexibility of the system means that the patient can have the calls to suit their individual lifestyle.

The patient will be entering their test results into the telephone key pad and also their responses to the pre-set questionnaire. Once completed the information will be relayed to the Web portal where the Clinic Nurse will be able to view the results. Alerts will be generated from the patient responses to the questions, which is received by the Clinic nurse in an email. The patient is reminded on the call when they need to contact the Clinic.

Patient dosing instructions

Warfarin Dosing of patients is completed by Clinic nurses using the DAWN computerised system, which is the current system in use within CDDFT and also this provides the patient clinical record of testing and dosing. Dosing information entered onto the Health Call Web portal by the Clinic Nurse is relayed back to the patient in a second automated telephone call, which provides the new dosing instructions and the next date the patient will be requested to test their blood. The patient is expected to respond by pressing the key pad to confirm they have heard the dosing instructions correctly and are provided with a pre-printed pad which is used as an aide-memoir for recording doses of warfarin to be taken.

5.5 Reviewing the effectiveness of Health Call monitoring

The Clinic Nurse will monitor the patient's compliance with Health Call INR monitoring and provide telephone contact from Monday to Friday for any issues arising. Sharing information received from the patient Health Call INR monitoring with the patient's GP will ensure they also have information about the patient's test results as per current practice. If the patient fails to comply with the INR monitoring and telephone calls, they will be informed that they

will be removed from the Health Call monitoring, and they will be requested to revert back to being monitored by their previous clinic arrangement.

5.6 Alerts:

A Clinical alert will be generated if a patient responds with a yes to any of the following:-

- >INR reading is outside of the parameters 0.8-8.0
- >Any bleeding symptoms
- >Any changes in medication
- >Any missed doses of warfarin

A Non-responder alert will be generated if a patient does not answer either the first or second Health Call INR automated telephone call. (The system will contact the patient at regular half hourly intervals for a maximum of three times before sending a non-responder alert).

Response of Anti-Coagulation Clinic to alerts

The Clinic Nurse will receive alerts via a system generated email and details about the alert will be viewable on the patient's record in the Web Portal. The response time is within 24 hours

The Clinical alert will be responded to by the Clinic Nurse by contacting the patient to discuss their responses and make a clinical decision as to what dosing is required. The patient is also instructed to contact the Warfarin Clinic via the automated message when inputting negative responses to the monitoring questions.

The non-responder alert will be responded to by the Clinic Nurse by contacting the patient to ask why they have not answered the call. Patients who repeatedly fail to answer may be withdrawn from the service. Clinic staff should follow their DNA (Did not attend) procedure.

5.7 Contingency planning for system failure

It is recommended that computers are compliant with Microsoft Internet Explorer version 8 or 9 and with a minimum screen resolution of 1200x 800. Any technical problems with connectivity to the Web Health Portal should be reported back to InTechnology via email support@inhealthcare.co.uk or Tel: 0845 2100440 or the Trust IT helpdesk if it is thought to be an internal problem.

System failure could occur if any part of the technology supporting Health Call fails, such as Internet access, telephone lines or digital software. It will depend on the system failure as to what course of action is taken. A Business continuity plan has been developed to include the actions to be taken by each individual/team in the Health Call system and information will be communicated to Clinic nurses so they are aware of developments and actions being taken to address faults. In the event of a medium to long term system failure, the Warfarin clinic staff would revert to previous procedures for anti-coagulation of patients.

5.8 Change of Circumstances

If the patient's circumstances change or the service is discontinued, the Anti-coagulation clinic nurse should be informed who will amend the patient information on the InHealthcare web portal. During the patient check visit to the Anticoagulation clinic, all patient details will be checked to ensure any changes are recorded eg. Address and contact details.

5.9 Discontinuation of INR monitoring

The patient is expected to return the INR monitoring equipment, if monitoring is stopped, unless the device is owned by the patient. Clinic staff should follow de-contamination guidance from Roche Diagnostics. All patient individual lancet devices will be disposed of in accordance with Infection control guidance. To enable a complete evaluation of the Health Call monitoring the system administrator will record details about the reason for removal of equipment as provided by the Clinic nurse.

5.10 Infection control and De-contamination of CoaguChek meter.

Whilst the patient is using the device it is expected that they or a representative will take responsibility for cleaning it, information is provided at the patient training session and can be found in the user manual. Patients are expected to take reasonable care of the equipment if it is on loan to prevent any damage occurring. CDDFT are not responsible for replacing the equipment if it has been damaged.

Whilst the majority of patients are on Long term warfarin and would be expected to keep the CoaguChek machine, there are occasions when the machines are returned following only short term usage. If a patient is known to have an infectious disease, guidance should be sought from CDDFT infection control team.

The patient will be provided with a sharps container to ensure used strips and lancets are not a risk to others as per CDDFT waste management policy. The sharps container will be returned by the patient to the Anti-Coagulation clinic for disposal.

CoaguChek meter disposal.

During patient testing the CoaguChek meter may come into contact with blood. Used meters therefore carry a risk of infection and will need to be cleaned appropriately if they are to be reused. Disposal of the used meters will need to be in line with the CDDFT Hazardous waste policy, unless they belong to the patient, when they will take responsibility for the disposal (refer to user manual for details).

5.11 Failure of CoaguChek machine

Any problems encountered with the CoaguChek meter following initial training and use, should be referred through the Anti-Coagulation clinic. If problems are encountered which could be a machine malfunction, patients should refer to the CoaguChek careline Tel: 0808 100 7666 or www.coaguChek.com/uk.

5.12 Patient feedback

Feedback from patients will be used to review of the Health Call INR monitoring service and will support future developments of the technology to support patient care. An annual survey will be sent to patients to seek their views on their current service.

5.13 Patient Safety and Governance

Patients being monitored by Health Call will be reviewed in the Anti-coagulation Clinic following 6 months of use and then at least annually. This will support the review of the suitability of Health Call INR for the individual patient and will also provide the quality checks of the CoaguChek machine which will be tested alongside the Clinic CoaguChek machine for accuracy. Roche advise that no other quality control checks are required for the CoaguChek XS hand held machines.

5.14 Incident reporting

Any patient safety issues should be reported using CDDFT incident reporting system Safeguard as detailed in the CDDFT Incident Management policy.

Any technical issues should be reported via telephone to InTechnology on Tel: 0845 2100440 or email support@inhealthcare.co.uk.

6 MONITORING FRAMEWORK

Monitoring Criterion	Response
Who will perform the monitoring?	Outpatient Manager
What are you monitoring?	<ul style="list-style-type: none"> a. Documented evidence of patients being monitored. b. Documented evidence of patient compliance with Health Call monitoring (answering phone calls, completion of INR test) c. Documented evidence of patient's time in therapeutic range d. All unexpected incidents reported on Safeguard in line with Trust procedures
When will the monitoring be performed?	3 monthly
How are you going to monitor?	Audit of Health Call INR monitoring
What will happen if any shortfalls are identified?	Action plan would be formulated and agreed.
Where will the results of the monitoring be reported?	Acute and Long Term Conditions Operational Group
How will the resulting action plan be progressed and monitored?	By Acute and Long Term Conditions Operational Group
How will learning take place?	Training days and updates, team meetings.

7 REFERENCES AND ASSOCIATED DOCUMENTATION

This guidance refers to and is referenced from the following documents:

- CDDFT Policy for the Development and Management of Policy and Guidance documents
- CDDFT Information Governance guidance for Projects
- CDDFT Risk Management Operational Policy
- CDDFT Risk Registering procedure
- CDDFT Incident Management Policy
- CDDFT Consent to Examination or Treatment
- CDDFT Health Records Policy
- CDDFT Information Risk Policy
- CDDFT Records Management Policy
- Confidentiality and Disclosure Policy
- Data Protection Policy
- DoH Records Management NHS Code of Practice. London. HMSO.
- DoH Information and Security NHS Code of Practice, London, HMSO.
- CDDFT Procedure – Initiation and Management of Anti-Coagulation in an outpatient setting.
- CDDFT Procedure – Anti-Coagulation Service IT system support.
- Business Continuity Plan - Anti-Coagulation Service
- CDDFT Waste disposal policy
- Cleaning guide for CoaguChek XS devices for healthcare professionals: Roche POC UK & Ireland Technical services document: clean XS v 1.0 June 2012

8 APPENDICES

- Equality Impact Assessment (For the latest EIA form please click [Here](#), this should be attached in full or embedded as a stand-alone document.
- Dissemination Plan
- Ratification Process Checklists available [here](#)

Equality Analysis / Impact Assessment

EAIA Assessment Form

v3/2013

Division/Department:

Telehealth

Title of policy, procedure, decision, project, function or service:

Procedure for Health Call INR monitoring

Lead person responsible:

Jeannie Hardy

People involved with completing this:

Tracy Murphy
Sarah Owen
Jane Haywood
Project team

Type of policy, procedure, decision, project, function or service:

Existing

New/proposed

Changed

Date Completed:

10-07-13



Step 1 – Scoping your analysis

What is the aim of your policy, procedure, project, decision, function or service and how does it relate to equality?

The procedure aims to identify how Co Durham and Darlington Anticoagulation service will manage the patients who are self-testing blood INR levels and using the telehealth service to relay test results to the Clinic and then receive warfarin dosing instructions.

Who is the policy, procedure, project, decision, function or service going to benefit and how?

The procedure will benefit patients as they are being provided with a more flexible service enabling them to have a managed service without having to travel to clinics. The procedure provides staff with a process to follow to ensure safety of patients is assured.

What barriers are there to achieving these outcomes?

Patients without access to telephone lines will not be able to self test as this is required to relay test results and medication dosages.
Patients with hearing impairment may not be able to hear the telephone messages and so currently are excluded unless they have carer or family support.
Lack of dexterity may exclude patients from accessing the service.

How will you put your policy, procedure, project, decision, function or service into practice?

Anticoagulation staff will be trained on the use of the Web portal prior to the service being used. The procedure will be circulated to staff and available on the intranet.

Does this policy link, align or conflict with any other policy, procedure, project, decision, function or service?

This procedure links with the strategic direction of increasing usage of Telehealth for those with long term health conditions. The procedure links and supports the Anticoagulation services provided by CDDFT.

Step 2 – Collecting your information

What existing information / data do you have?

The patient groups impacted on by this procedure are those requiring monitoring of blood INR levels for a variety of long term health conditions. Many of the patients are of working age or are retired well who have a flexible life style. This telehealth provision provides an enhanced service by enabling self testing of blood and remote dosing instructions being sent via a telephone line. Patients who are housebound are also being offered an opportunity to be involved in the telehealth service. The Government is supporting the drive to increase the use of technology with Long Term condition monitoring and aims to impact on 3 million lives UK wide.

Who have you consulted with?

Head of Pharmacy
 Outpatient Managers
 Warfarin clinic staff at Bishop Auckland and Darlington Memorial Hospital
 Community Nurse managers and nurses
 Patient groups using the Anticoagulation services currently

What are the gaps and how do you plan to collect what is missing?

House bound patients and those in Care Homes are currently being approached, discussions with Community nurses in progress.
 Information is being shared across CDDFT and Commissioners to inform about the services available.

Step 3 – What is the impact?

Using the information from Step 2 explain if there is an impact or potential for impact on staff or people in the community with characteristics protected under the Equality Act 2010?

Ethnicity or Race

The Telehealth INR services have been developed and are delivered in English. It is possible to request additional languages/translations from the supplier InTechnology if required. Currently no ethnicity or race issues have arisen, as the majority of the patients using the service are white British.

Sex/Gender

There is no impact on an individual patient's gender, anyone can access the service if criteria is agreed by their Nurse or Health Professional.

Age

The service is currently offered to adults, so is directly discriminating towards patients who are 18 years of age or above, this links to the current service provided by the anticoagulation clinics.

Disability

The service can be offered to anyone who is able to understand their health condition and are able to use the self-testing device and telephone. This can be done by their carer or family member if required. It can support the accessibility of the service by those disabled as they can have the service in their own home.

Religion or Belief

No one is discriminated against for their religion or belief.

Sexual Orientation

No one is discriminated against for their sexual orientation.

Marriage and Civil Partnership (applies to workforce issues only)

Not applicable

Pregnancy and Maternity

Patients are not discriminated against because of pregnancy.

Gender Reassignment

Patients are not discriminated against because of gender.

Other socially excluded groups or communities e.g. rural community, socially excluded, carers, areas of deprivation, low literacy skills etc.

The Telehealth service requires the patient to have access to a telephone, either landline or mobile. The service is designed to offer flexibility and to support access to the service remotely. The monitoring can benefit those living in rural areas as it reduces travel to hospital clinics or nurses visiting unnecessarily. The service can also be accessed by patients in their workplace or when they are on holiday.

Step 4 – What are the differences?

Are any groups affected in a different way to others as a result of the policy, procedure, project, decision, function or service?

Anticoagulation services will be available to all who are referred and require it. The Telehealth INR service provides another way for the service to be accessed. Currently limited funding is available for provision of the CoaguChek machines required by patients to use the service, however, if funding is not available, patients may be required to purchase the machine and this may prevent access to the service.

Does your policy, procedure, project, decision, function or service discriminate against anyone with characteristics protected under the Equality Act 2010?

Yes No

If yes, explain the justification for this. If it cannot be justified, how are you going to change it to remove or mitigate the affect?

Step 5 – Make a decision based on steps 2 - 4

If you are in a position to introduce the policy, procedure, project, decision, function or service? Clearly show how this has been decided.

Agreement to the service has been given by CDDFT Project Board following development of the service, also the Clinical Services and Therapeutic committee has agreed to the initial pilot to trial it and subsequent evaluation is to be completed to support ongoing use. The service has been developed with the Warfarin Clinic lead Nurse and Outpatient Manager.

If you are in a position to introduce the policy, procedure, project, decision, function or service, but still have information to collect, changes to make or actions to complete to ensure all people affected have been covered please list:

None

How are you going to monitor this policy, procedure, project or service, how often and who will be responsible?

This policy will be monitored by Outpatient Manager and Business Manager through evidence of referrals to the service, numbers using the service, evidence of patients compliance with therapeutic range of warfarin. Also any untoward incidents occurring. Feedback from patients using the service will be monitored and staff views also.

Step 6 – Completion and central collation

Once completed this Equality Analysis form must be forwarded to Jillian Wilkins, Equality and Diversity Lead. jillian.wilkins@cddft.nhs.uk and must be attached to any documentation to which it relates.

Appendix B DISSEMINATION PLAN

Policy title: Health Call INR monitoring			
Date finalised:		Dissemination Lead: Tracy Murphy Warfarin Clinic, Outpatients, BAH Tel: 01388 455525	
Proposed action to retrieve expired copies of P&G : N/A			
To be disseminated to:	How will it be disseminated: who will do and when?	Paper/Electronic	Comments
Anticoagulation nurses	Via Intranet, training sessions and team meetings	Electronic	

Dissemination record to be used once procedural document approved.

Date uploaded to Trust Intranet:

Disseminated to:	Format:	Date disseminated:	No of Copies sent:	Contact details:
Comments:				
Need to read staff list attached:	Summary points/fact sheets included for Trust wide bulletin if appropriate.		Date for all need to read staff confirmed read:	
Yes	No		April 2014	