Standard Operating Procedure (SOP), study of the implementation of a stroke prevention initiative through structured Atrial Fibrillation (AF), Blood Pressure (BP) and Smoking risk detection in Cork Kerry Community Healthcare.

Introduction to the SOP

This SOP has been designed for GP's participating in the structured AF, BP and smoking risk detection study in the North Lee catchment area of Cork city. Each of the steps in the SOP is to be followed by each participating GP. It is important that all participants use the same procedure in the recording of all clinical measurements as defined in the SOP to ensure continuity and consistency. GP's must provide a copy of their medical indemnity before recruitment of participants.

1. Participation in the Study

Each GP is to complete and sign the MOU, by way of consenting to participate in the study and to complete an agreed number of patient consultations. The GP is to advise the patient that there may be a qualitative interview in relation to the study and note if they would be prepared to be interviewed.

2. Recruiting the Patient

2.1 The GP is to explain the nature of the study to the patient and provide the patient with an information leaflet, which is provided.

2.2 If the patient agrees to participate in the study, the patient is to complete and sign the standard consent from provided by the researchers.

2.3 The GP must explain all of the risks of screening to the patient including the risk of false negative or false positive.

2.4 The GP must explain that the screening test and equipment has been provided by the HSE and that the research component run by UCC is collecting data on the test (but UCC is not responsible for the test).

Note

The GP is to record the findings on the Clinical Report Form (CRF) which can be provided in either hard or in soft (electronic) copy and is attached.

Public Health clinical and risk guidance for GP practices to be followed, Health Protection Surveillance Centre guidance for GP primary care settings is available here: https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/primarycareguidance/

3. The Screening Visit

The GP is to:

3.1 Completing the CRF

3.1.1 Complete a clinical report form (CRF) for each participating patient recruited into the study. Record the local GP/practice number, patient/file number, age, date of screening and gender, and please note any existing Atrial Fibrillation condition i.e. Y/N. If yes exclude the patient from the study.

3.1.2 Record the patient's weight in kilogrammes (KG).

3.1.3 Record the patient's height in metres.

3.1.4 Record the patient's BMI (kg/m^2).

3.1.5 Record the patient's relevant past medical history ie cardiology, diabetes or stroke history.

3.1.6 Record the patient's current medications.

3.2 Smoking risk detection

3.2.1 Ask the patient about their smoking status i.e. current smoker, ex-smoker, or never smoked.

3.2.2 Record their smoking status on the CRF.

3.2.3 If the patient is identified as a smoker assess their readiness to quit and offer them the appropriate supports.

3.3 Atrial fibrillation screening using a Kardia Mobile device

3.3.1 Initial set up of Kardia Mobile device (once-off prior to beginning patient contact)

3.3.1.1 Decide where to locate the Kardia device i.e. directly on your mobile phone or on your mobile phone case? The Kardia logo should have the K closest to the top of your device.
3.3.1.2 Search your mobile phone or laptop or the like and download the Kardia phone app.
3.3.1.3 Create a Kardia account to access, print and save ECG (Echocardiograph) recordings.
3.3.1.4 Add a passcode (PIN or touch ID) to your device for an added layer of security.

3.3.2 Taking a reading using Kardia Mobile device

3.3.2.1 Disconnect all chargers, headphones or other accessories from your mobile phone before taking an ECG reading.
3.3.2.2 If the patient is wearing hearing aids, please ask the patient to turn them off before taking a reading.
3.3.2.3 Clean the electrodes with an alcohol-based sanitiser before taking a reading.
3.3.2.4 Using your device, launch the Kardia app.
3.3.2.5 From home screen choose "Record your ECG" or "Add resting HR".
3.3.2.6 Ask the patient to rest 2 or more fingers on the Kardia mobile device with their right hand on one electrode and left on the other. The recording will begin automatically when the patient has made good contact with the electrodes. If the reading is successful, an analysis of the ECG will be displayed immediately after recording.
3.3.2.7 Clean the electrodes with an alcohol-based anti-bacterial sanitiser after taking a reading.
3.3.2.8 Add or record a personalised tag or a note following a reading, as desired or not. Personalised tags or notes can also be added in the history screen by choosing "edit" from the drop-down menu.
3.3.2.9 Review the ECG in the history screen which can be emailed, shared or sent for analysis.
3.3.2.10 Record ECG results on the CRF.

3.4 Standardised 12 lead ECG in patients with screen diagnosed AF

3.4.1 If the ECG reading is AF positive, perform a 12 lead ECG.
3.4.2 Place 4 limb lead electrodes over medial aspect of extremities distally, right arm, left arm, right leg, left leg. Ensure electrodes are placed on flat non-muscular areas of the body.
3.4.3 Place 6 precordial electrodes, chest, V1-V6, using bony landmarks to identify proper placement.
3.4.4 Remove the patient cable from the machine and place it beside the patient on their abdomen and attach each lead wire to the correct electrode.
3.4.5 Instruct the patient to lie still ahead of recording.
3.4.6 Record the 12 lead ECG.
3.4.7 Remove the electrodes and cleanse the patient's skin to remove any adhesive.
3.4.8 Record the results of 12 lead ECG on CRF.
3.4.9 Newly diagnosed cases of AF to be provided with the Irish Heart Foundation booklet 'Live Well with Atrial Fibrillation', provided.

3.5 Monitoring Blood Pressure (BP)

3.5.1 Take the patient's blood pressure using a calibrated sphygmomanometer 3 x times.
3.5.2 Ensure use of the correct cuff size before proceeding.
3.5.3 Ensure the patient is seated with their back supported, arms at heart level with feet flat on the ground and legs uncrossed and ask the patient to loosen any tight clothing.
3.5.4 Ensure the patient has not engaged in any strenuous activity or smoking is the last 30 minutes. If the patient has engaged in strenuous activity or smoking, please wait at least 30 minutes before BP is measured.
3.5.5 Begin measuring BP 5 minutes after resting the patient on the patient's right arm, if the left arm is used please note same.
3.5.6 Place the bladder over the brachial artery directly on the inside of the arm of the cuff's lower border i.e. approximately 2.5 cm above the antecubital crease.
3.5.7 Rotate the patient's arm so the palm is facing upwards.
3.5.8 Ask the patient to remain still and to refrain from talking during the BP reading.
3.5.9 Switch-on the apparatus and record the displayed measurement.
3.5.10 Repeat the measurement a further 2 x times if first measurement is above 140/90 mmHg.
3.5.11 Record the average of the last two measurements on the CRF.
3.5.12 Record on CRF if this is a new or existing diagnosis of BP.

Callanan A, *et al*. *BMJ Open* 2022; 12:e054324. doi: 10.1136/bmjopen-2021-054324

3.5.13 Treatment of hypertension should follow the ESH-ESC hypertension guidelines https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Arterial-Hypertension-Management-of

3.5.14 Risks and benefits of treatment must be fully explained to patients by the GP in the normal way.

3.5.14.1 Ensure device is appropriately disinfected with an alcohol-based anti-bacterial sanitiser before and after use.

3.6 Monitoring Blood Pressure in patients with AF

3.6.1 Most automatic devices are not validated for BP measurement in patients with AF and will record the highest individual systolic pressure wave form rather than an average of several cardiac cycles. This will lead to overestimation of BP.

3.6.2 In patients with confirmed AF blood pressure should be measured using an aneroid or mercury sphygmomanometer and auscultation recording the first Korotkoff sound as the systolic as the systolic pressure and the fifth Korotkoff sound (or fourth sound if the fifth is not detectable) as per traditional blood pressure measurement.

3.6.3 Risks and benefits of treatment must be fully explained to patients by the GP in the normal way.

4 Oral Anticoagulation (OAC) in patients with newly diagnosed AF

4.1 If a patient has a positive Kardia Mobile reading and a positive 12 lead ECG then consider commencing an anticoagulation regime. Patient consent to OAC is important outlining the risks and benefits.

4.2 Where a decision is made to initiate OAC early initiation is recommended.

4.3 CHA2DS2VASc and HAS-BLED are important considerations. The Keele Anticoagulation Therapy Decision Support Tool https://www.anticoagulation-dst.co.uk/ can be used to guide anticoagulation decisions.

4.4 Appropriate blood testing of renal function should be undertaken.

4.5 A small number of patients may be especially complex, and the input of a specialist cardiologist may be sought.

4.6 Risks and benefits of treatment must be fully explained to patients by the GP in the normal way.

5 ECHO cardiography in AF

5.1 Refer all newly diagnosed AF patients for echo. This referral can be sent to Mallow Primary Care Centre. If the patient prefers, they can choose to make a private appointment.

6 Cardiology referral in newly diagnosed AF

6.1 Should a cardiology referral be considered the patient may opt attend their current cardiologist, opt to attend a private cardiologist or opt to attend Professor David Kerins in Mercy University Hospital.

7 Patient recruitment and remuneration

7.1 Ensure the clinical report form (CRF) is completed in full.

7.2 Once a patient has been reviewed the CRF should be completed in full and anonymised.

7.3 CRFs should be returned to the research team at UCC (c/o Ms Aileen Callanan, School of Public Health, Western Gateway Building, Western Road, Cork).

7.4 Payment in the sum of €80 per completed CRF will be made upon receipt of completed CRFs up to a maximum of 85 patients (in the first instance). Payment will be made in December 2020 once an invoice has been received from practices for all completed CRFs.

7.5 Recruitment will be reviewed in late December at which point practices will be advised if there is scope for further patient recruitment.

8 Time lines and deliverables

8.1 Practices seeking to join the study must return the letter accompanying this Standard Operation Procedure duly signed; the Memorandum of Understanding; and a copy of their Medical Indemnity confirmation prior to commencement of patient recruitment.

8.2 Upon receipt of this documentation practices will be informed of their inclusion in the study and assigned a practice study number

8.3 Practices are to return all completed CRFs, up to a maximum of 80, by December 2020 in the first instance. At that point recruitment levels will be reviewed by the research team and a further directive regarding the next phase of recruitment will be issued.

Amendment

8.4 Participant withdrawal

8.4.1 In the event of a participant withdrawing from the study the participant or practice should contact the study team via email aileen.callanan@ucc.ie

8.4.2 The study team will identify the participants documentation from the study and dispose of accordingly under data protection regulations.

8.4.3 All data pertaining to that individual will be removed from the study.

8.4.4 The study team will confirm the withdrawal via email to the participant and/or the individual once it has been complete.