B-SAFE Study





The B-SAFE Study & AF Decision Support Tool

About the B-SAFE study

There is potential to decrease the burden from stroke and cardiovascular disease in NZ by improving prevention. With this aim the National Cardiac and Stroke Networks teamed up with General Practice to develop a new tool and management approach aimed to optimize the management atrial fibrillation in primary care.

We are now inviting general practices to participate in B-SAFE or the 'Biomarkers for Stroke Prevention in Atrial Fibrillation using Electronic decision support (EDS)' study. The study, which is funded by the Health Research Council of NZ and approved by the Health and Disability Ethics Committee (HDEC), will compare an Electronic Decision Support (EDS) tool with usual care. It will also evaluate the utility of cardiac biomarkers (BNP and troponin) in guiding management of atrial fibrillation.

We will randomize practices to one of three groups: (1) usual care, (2) access to the EDS using current clinical guidelines, (3) access to an enhanced EDS that incorporates the results of a single blood test when providing management advice. All treatment decisions remain at the discretion of the treating GP.

Practices who agree to participate will be provided with the B-SAFE EDS tool as part of MedTech. We estimate each practice will have on average 30 suitable patients. We aim to complete the EDS for approximately 3000 patients in all and anticipate that this will take about 6 to 12 months. Practices initially randomized to the 'usual care' group will have access to the EDS tools after 6 months, and then have the opportunity to be randomized to the other groups.

The study is designed to minimize impact on busy GP practices. The EDS tool is concise and takes just a few minutes to complete. The tool will provide an individualized check list for anticoagulation, steps to reduce bleeding risk, and advice on heart rate control and overall cardiovascular risk management.

BPAC will work with each practice to extract a list of patients with known atrial fibrillation. If requested BPAC can also send an invitation letter to patients you agree are suitable for inclusion. The patient information sheets are attached for your information. We will provide funding to practices who take part in the study. There is additional funding for patients in the biomarker group who require an additional visit.

B-SAFE study flow

The study is designed to be very straight forward and minimize the impact on busy GP practices, and follows the steps below:

- 1. Invitation to participate and GPs return expressions of interest and training preference
- 2. Webinar, telephone or in person meetings to discuss study
- 3. Practice agrees to participate
- 4. Practice provided with access to electronic decision support tool (delayed 6 months for some practices)
- 5. Eligible patients with AF identified by BPAC from electronic medical records
- 6. Practice randomised and informed whether clinical or biomarker decision tool
- 7. Consent obtained from patients. EDS completed. Treatment adjusted by GP if appropriate
- 8. For biomarker practices only
 - a. Blood test arranged for consenting patients
 - b. Results returned to practice
 - c. Additional clinic visit considered and treatment adjusted by GP if appropriate
- 9. Using anonymised data outcomes sourced from national health databases

We greatly appreciate your contribution to this study and value your questions and feedback. You can contact us at **b-safe@bestpractice.org.nz**

Getting Started

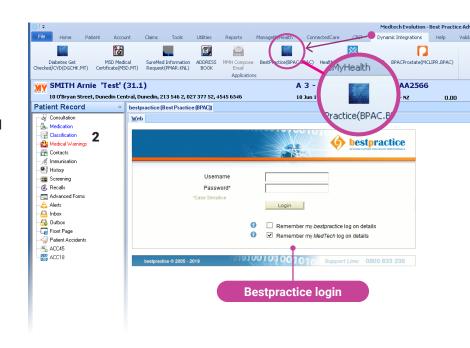


For Medtech-32:

With your patient with AF open, click on the **bestpractice icon** on the top tool bar. This will open the *bestpractice* module.



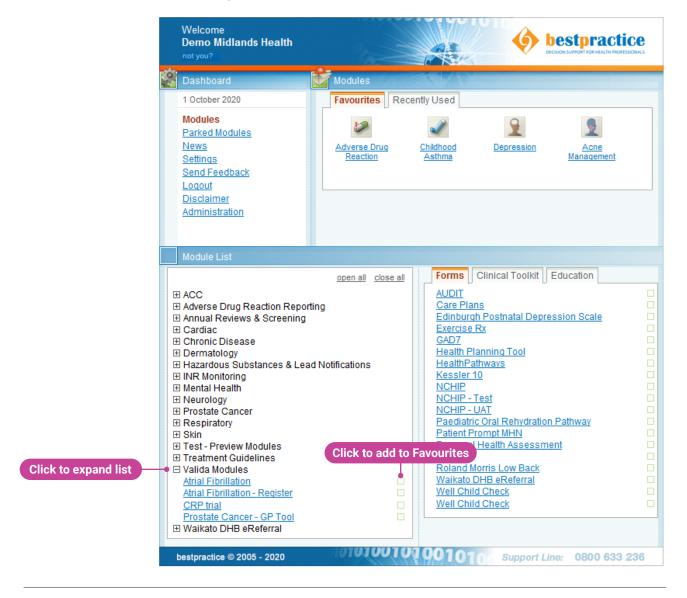
- For Medtech Evolution:
 With your patient with AF open, select the Dynamic
 Integrations tab from the top menu bar and then click on the bestpractice icon. This will open the bestpractice module.
- If asked, enter your
 Username and Password
 and then click login.



Finding the AF Study Tools



In the Modules List click on the plus symbol \boxplus beside Valida Modules to expand this list. Click on Atrial Fibrillation to open the Atrial Fibrillation tool or Atrial Fibrillation – Register to open the AF Register Tool. You can also add a shortcut to the AF modules in the favourites list. Do this by clicking on the box \square beside Atrial Fibrillation or Atrial Fibrillation – Register .



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The Atrial Fibrillation module is part of the Valida Modules so you may be asked to enter your Username and Password again. Use the same Username and Password as you did in step 3 and then click login.



Using the AF Register Tool



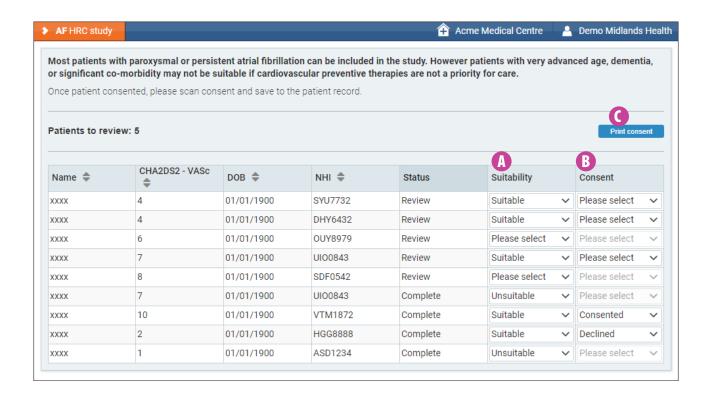
The AF Register tool displays a list of potentially suitable AF patients to be enrolled in the "B-SAFE" Trial.

There could be a number of reasons why a patient may not be suitable for the study, therefore the practice should validate whether this list is correct by indicating on the tool (A) for each patient whether they are **Suitable** or **Unsuitable** for the study.

Once an AF patient has been indicated as **Suitable** the patient can be approached to consent to being part of the study and requested to have an AF consultation using the AF Decision Support Tool. Use the Register **B** to record **Consented** and **Declined** consents.

Selecting **Print consent** opens a print version of the patient consent form, which details the purpose of the research, information about the study, benefit and risks, and provides the ability to record consent from the patient that de-identified information from their medical records can be used for research to evaluate the electronic decision support tool for AF.

The study will provide funding for practices who take part in the study, based on the number of patients who have recorded consent using the **AF register tool** and had a consultation using the **AF decision support tool**.



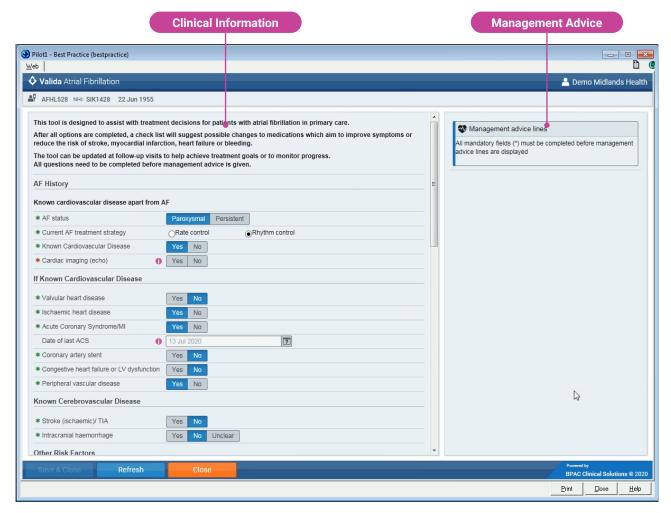
Using the AF Tool

For this example, we have selected a patient who is Female, 65 years of age, with AF and a history of cardiovascular disease. This patient is currently taking warfarin and cilazapril.





The AF tool is divided into two parts. On the right-hand-side are **management advice lines**. On the left-hand side is a form where you **enter clinical information** about the patient.



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- Note that some of **the form has already been pre-filled** with information taken directly from the practice management system.
- *
- Fields marked with an asterisk are mandatory and must all be completed before management advice lines are displayed. When completed the asterisk will change colour from red * to green *.
- **Some fields also have additional help** which you can view by hovering over the magenta information symbol **(**).
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Scroll down and continue to fill in the form. When you have answered the last question on medication the tool will automatically generate management advice lines on the right-hand-side panel.

Management advice



Each management advice line is colour coded. **Red for urgent** recommendations. **Orange for recommendations that require further attention** and **green for non-urgent** recommendations.





In last section of the tool, **Management Advice and Supplementary Study Material** you will asked if you followed the recommended advice. If your answer is **No** you will be asked for your reasons why. Select this from the dropdown list.

Once all mandatory form fields have been completed the "Save & Close" button will become active. Clicking this button will save the form back to the PMS, and become part of the Patient's record. The AF module form will then close.

Further information:

For more information about the AF Decision support tool see the Bpac Clinical Solutions website:



