**Table 15: Review protocol: Diagnostic accuracy of point of care devices**

| ID | Field | Content |
|---|---|---|
| 0. | PROSPERO registration number | Not registered |
| 1. | Review title | Accuracy of methods for detecting atrial fibrillation in people with cardiovascular risk factors for AF and/or symptoms suggestive of AF |
| 2. | Review question | What are the most accurate methods for detecting atrial fibrillation in people with cardiovascular risk factors for AF and/or symptoms suggestive of AF? |
| 3. | Objective | To identify the most accurate methods of detecting AF in this population in the primary care clinic.<br><br>A variety of tests have recently become available that claim to diagnose AF. The accuracy of these need to be tested.<br><br>Although each may be used in a different way (for example, some may be used at home by patients, or some may be applied in the clinic) it is important to have data on their accuracy.<br><br>Issues around two-tier testing or location of testing will not be considered in this review. This review is simply a pragmatic attempt to survey the currently available diagnostic tools and to evaluate their accuracy relative to an appropriate reference standard. Once this is known then the GC can use this information to recommend 1) the tests that can be used and 2) how or where they may be used, perhaps as part of a two-stage approach [for example a test that is found to be very sensitive but non-specific might be appropriate as a first line test to ration who goes on to more definitive (but more resource-intensive) 12 lead testing]. |
| 4. | Searches | The following databases will be searched:<br>Cochrane Central Register of Controlled Trials (CENTRAL)<br>Cochrane Database of Systematic Reviews (CDSR)<br>Embase<br>MEDLINE<br><br>Searches will be restricted by:<br>English language<br><br>Other searches:<br>None<br><br>The searches may be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion if relevant.<br><br>The full search strategies for MEDLINE database will be published in the final review. |

| ID | Field | Content |
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| 5. | Condition or domain being studied | Atrial Fibrillation |
| 6. | Population | People aged over 18 with symptoms suggestive of AF (including breathlessness, palpitations, syncope/dizziness, chest discomfort) and/or with cardiovascular risk factors for AF (including TIA, stroke, Heart Failure, hypertension, valve disease). |
| 7. | Index Test | Any point of care tests used to detect AF<br>For example (non-exhaustive list):<br>• Manual pulse checking<br>• Pulse oximeters<br>• US devices<br>• Blood pressure monitors<br>o Microlife BPM<br>o Watch BP Home A<br>• Non-portable (but non-12 lead) ECG devices<br>• Portable ECG devices<br>o My Diagnostick<br>o AliveCor Kardia<br>• Smart portable devices eg phones, watches<br>• 12 lead ECG (when gold standard is long-term loop recording – see section below)<br><br>Where the same test is used with a differing number of recordings across studies, these should be regarded as separate test strategies, and should thus be dealt with separately.<br><br>Tests using differing periods of recording will also be dealt with separately. For example, pulse oximeters for 2 minutes will be in a separate category of index test to pulse oximeters used for 1 hour, and they could be compared to each other as separate index tests. |
| 8. | Comparator/Reference standard/Confounding factors | The reference standard that is used will determine the type of AF that the measured accuracy relates to. The analyses will therefore be stratified by the reference standards used, as follows:<br><br>1. 12-lead ECG, adjudicated by an expert clinician (usually cardiologist). This will theoretically pick up all constant AF but only a small proportion of intermittent AF cases. It is therefore really only useful for determining how well an index test can pick up constant AF.<br>2. Ambulatory monitoring for >24 hrs [NB: OR ANY DEVICE THAT GIVES A LONG-TERM RECORDING]. These should pick up all forms of AF. It is therefore a useful way of determining how well as test can pick up any AF. Unfortunately, it is likely that studies using this reference standard will be rare.<br><br>NB: The ability of the tests to pick up AF vs no AF is being evaluated in this review, not the ability to differentiate between persistent and paroxysmal. |

| ID | Field | Content |
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| 9. | Types of study to be included | Cross-sectional/prospective/retrospective diagnostic studies, or any study containing a diagnostic accuracy analysis |
| 10. | Other exclusion criteria | Studies that do not report sensitivity and specificity, or insufficient data to derive these values.<br>Non-English language studies. |
| 11. | Context | N/A |
| 12. | Primary outcomes (critical outcomes) | • Sensitivity<br>• Specificity<br>• Raw data to calculate 2x2 tables to calculate sensitivity and specificity (number of true positives, true negatives, false positives and false negatives). |
| 13. | Secondary outcomes (important outcomes) | None |
| 14. | Data extraction (selection and coding) | EndNote will be used for reference management, sifting, citations and bibliographies. All references identified by the searches and from other sources will be screened for inclusion. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.<br>The full text of these potentially eligible studies will be retrieved and assessed in line with the criteria outlined above.<br>A standardised form will be used to extract data from the included studies (see Developing NICE guidelines: the manual section 6.4).<br>Data extraction will be independently quality assured by a second reviewer, discrepancies will be identified and resolved through discussion (with a third party where necessary). |
| 15. | Risk of bias (quality) assessment | Risk of bias quality assessment will be assessed using QUADAS-2.<br>Assessment will be independently quality assured by a second reviewer. Disagreements between the reviewers will be resolved by discussion, with involvement of a third party where necessary. |
| 16. | Strategy for data synthesis | Where possible data will be meta-analysed where appropriate (if at least 3 studies reporting data at the same diagnostic threshold) in WinBUGS. Summary diagnostic outcomes will be reported from the meta-analyses with their 95% confidence intervals in adapted GRADE tables. Heterogeneity will be assessed by visual inspection of the sensitivity and specificity plots and summary area under the curve (AUC) plots. Particular attention will be placed on sensitivity, determined by the committee to be the primary outcome for decision making.<br>If meta-analysis is not possible, data will be presented as individual values in adapted GRADE profile tables and plots of un-pooled sensitivity and specificity from RevMan software. |
| 17. | Analysis of sub-groups | If heterogeneity is identified, where data is available, subgroup analysis will be carried out for the following subgroups:<br>Subgroups to investigate if heterogeneity is present<br>1. Expertise of index test interpreter (clinician trained in the use of the index test, such as cardiologist/electrophysiologist versus non-electrophysiologically trained clinician (e.g. GP) versus patient/carer)<br>2. Simultaneous index and gold std vs non simultaneous |
| 18. | | ☐ Intervention |

| ID | Field | Content | | |
|---|---|---|---|---|
| | Type and method of review | ☒ | Diagnostic | |
| | | ☐ | Prognostic | |
| | | ☐ | Qualitative | |
| | | ☐ | Epidemiologic | |
| | | ☐ | Service Delivery | |
| | | ☐ | Other (please specify) | |
| 19. | Language | English | | |
| 20. | Country | England | | |
| 21. | Anticipated or actual start date | | | |
| 22. | Anticipated completion date | | | |
| 23. | Stage of review at time of this submission | Review stage | Started | Completed |
| | | Preliminary searches | ☐ | ☑ |
| | | Piloting of the study selection process | ☐ | ☑ |
| | | Formal screening of search results against eligibility criteria | ☐ | ☑ |
| | | Data extraction | ☐ | ☑ |
| | | Risk of bias (quality) assessment | ☐ | ☑ |
| | | Data analysis | ☐ | ☑ |
| 24. | Named contact | 5a. Named contact<br>National Guideline Centre<br><br>5b Named contact e-mail<br><br>5e Organisational affiliation of the review<br>National Institute for Health and Care Excellence (NICE) and the National Guideline Centre | | |
| 25. | Review team members | From the National Guideline Centre:<br>Sharon Swain<br>Mark Perry<br>Nicole Downes<br>Sophia Kemmis Betty<br>Elizabeth Pearton | | |

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| 26. | Funding sources/sponsor | This systematic review is being completed by the National Guideline Centre which receives funding from NICE. | |
| 27. | Conflicts of interest | All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline. | |
| 28. | Collaborators | Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: [NICE guideline webpage]. | |
| 29. | Other registration details | N/A | |
| 30. | Reference/URL for published protocol | | |
| 31. | Dissemination plans | NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as:<br>notifying registered stakeholders of publication<br>publicising the guideline through NICE's newsletter and alerts<br>issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.<br>[Add in any additional agree dissemination plans.] | |
| 32. | Keywords | Diagnosis, Atrial Fibrillation | |
| 33. | Details of existing review of same topic by same authors | N/A | |
| 34. | Current review status | ☐ | Ongoing |
| | | ☒ | Completed but not published |
| | | ☐ | Completed and published |
| | | ☐ | Completed, published and being updated |
| | | ☐ | Discontinued |
| 35.. | Additional information | N/A | |
| 36. | Details of final publication | www.nice.org.uk | |