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EXPERT CONSENSUS DECISION PATHWAY

2024 ACC Expert Consensus Decision Pathway on Practical Approaches for Arrhythmia Monitoring After Stroke

A Report of the American College of Cardiology Solution Set Oversight Committee

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1. INTRODUCTION

Stroke remains one of the leading causes of death and disability worldwide.[1] In contrast with myocardial infarction, which has a relatively uniform pathophysiology, there are numerous ischemic stroke mechanisms, necessitating a thorough evaluation to determine the cause of a stroke or transient ischemic attack (TIA) and to ensure optimal secondary stroke prevention.[2] Atrial fibrillation (AF) is the most common arrhythmia that adults experience, and its incidence increases with age. It raises the risk of stroke approximately 5-fold and is the cause of about 1 in every 7 strokes.[3] AF is often asymptomatic, and the true incidence of AF in the general population is uncertain.[4] Excluding patients with low cerebrovascular risk, the vast majority of patients who have AF benefit from prolonged anticoagulation for stroke prevention.[5,6] Current guidelines recommend treatment with anticoagulation in all patients with AF if they have had a prior stroke, and also in patients without a stroke if they have additional risk factors.[2,6-9]

The benefit of anticoagulation in patients with stroke and AF contrasts with most other stroke mechanisms, which are generally better served by antiplatelet medications. In addition to patients with stroke due to small- and large-vessel disease, there are now multiple randomized trials that suggest cryptogenic embolic stroke in the absence of AF is best managed with antiplatelet medication.[2] Ischemic strokes attributable to AF tend to be more debilitating and recurrent, necessitating a vigilant focus on accurate poststroke AF detection. Traditional methods of AF diagnosis, relying on brief intermittent electrocardiogram (ECG) recordings, often fall short in capturing transient AF episodes. Studies have demonstrated the utility of prolonged cardiac monitoring technologies in unmasking occult AF in patients with stroke, although a clear clinical benefit of monitoring has not been confirmed for future stroke prevention in poststroke patients.[10-12] An important principle of cardiac monitoring after stroke is that the longer a patient is monitored, the more often AF is detected. It becomes increasingly less likely with time, however, that AF detected long after a stroke is the proximate cause of that past event.

There are a variety of technologies that have been developed to identify AF, including continuous or intermittent ambulatory ECG monitors. Medical-grade monitors can either be attached to the skin as an external monitor or placed as an implantable cardiac monitor. There also has been rapid growth of “consumer-grade” off-the-shelf monitoring capabilities, for which the clinical application is still being established. There exists wide variability in practice among institutions and clinicians in cardiac monitoring after stroke. Guidance based on the best available evidence is needed to provide specific recommendations where possible. This includes tailoring of monitoring to each patient’s underlying risk of a clinically important arrhythmia and likelihood of informing the management and prognosis for recurrent stroke. Clarification is also needed regarding the treatment of AF detected after a stroke via monitoring vs AF detected prior to a stroke. For these reasons, an evidence- and consensus-driven standardized “clinical decision pathway” approach is needed for AF monitoring of patients following ischemic stroke. This document will address several important poststroke patient populations, including patients who are already prescribed

anticoagulation, patients with cryptogenic stroke (CS), and patients with stroke of known noncardioembolic etiology. The information should be useful to a wide variety of clinicians, including neurologists, cardiologists, and primary care physicians.

In accordance with the American College of Cardiology's (ACC) Relationships with Industry and Other Entities Policy, relevant disclosures for the writing committee and comprehensive disclosures for external peer reviewers can be found in Appendixes 1 and 2. A list of abbreviations relevant to this Expert Consensus Decision Pathway (ECDP) can be found in Appendix 3.

For additional details concerning ECDPs, please consult the Preface and Methods sections. To ensure full transparency, a comprehensive table of the writing committee's relationships with industry, including those not pertinent to this document, has been created. All these items can be found in the online Supplemental Appendix.

2. ASSUMPTIONS AND DEFINITIONS

To facilitate interpretation of the recommendations provided in this ECDP, specific assumptions were made by the writing committee, as specified.

2.1. General Clinical Assumptions

1. The principal focus of this effort, including ECDP considerations, applies to patients at risk for recurrent stroke.
2. The writing committee endorses the evidence-based approaches to AF management recommended in the 2023 AHA/ACC/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation.[6]
3. The writing committee endorses the evidence-based approaches to stroke management recommended in the 2024 AHA/ASA Guideline for the Primary Prevention of Stroke,[7] the 2019 AHA/ACC Guideline on the Primary Prevention of Cardiovascular Disease,[8] and the 2021 AHA/ASA Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack.[2]
4. These algorithms assume the treating clinician will seek input as needed from a neurologist, cardiologist, cardiac electrophysiologist, pharmacist, hematologist, or palliative care specialist to guide clinical management.
5. Shared decision making (SDM) should be utilized to ensure optimal patient care decisions are made. These decisions should jointly reflect patient preference and those of the managing clinician, especially in areas of management uncertainty.
6. This ECDP does not supersede good clinical judgment. The treating clinician should seek input as needed from relevant experts.
7. This ECDP is based on the best data currently available. New information to inform guidance is being rapidly generated. These updates (eg, trials of additional devices, inclusion of other patient populations) will influence the considerations made here. Clinicians should be careful to stay current on relevant information published after this ECDP.

2.2. Definitions

AF: A supraventricular tachyarrhythmia with uncoordinated atrial activation and consequently ineffective atrial contraction.[6]

AF burden: The time spent in AF during a specific period, reported absolutely (actual duration of the longest paroxysm) or relatively as a proportional duration of AF relative to the total duration of cardiac monitoring.[13]

AF detected after a stroke: The detection of AF after a stroke or TIA. This may provide an important diagnostic clue as to the mechanism of stroke or TIA, with possible change in therapy from antiplatelet medications to oral anticoagulation. This subgroup of AF is associated with a reduced prevalence of risk factors and is associated with a lower risk of recurrent stroke.[13]

Cardioembolic stroke: A stroke attributed to arterial occlusion from an embolus that presumably arose in the heart due to an identified high-risk source in the absence of large-vessel disease. Strokes involving >1 vascular territories generally support cardioembolic stroke.[2]

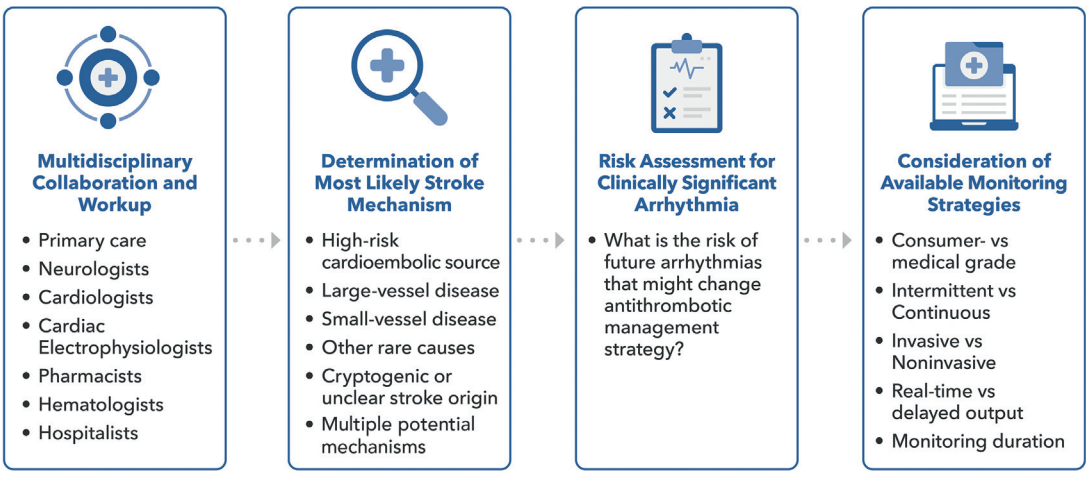
Consumer-grade monitor: Monitoring technology that may have regulatory clearance for cardiac rhythm monitoring that is purchased by a consumer without a prescription with output that is self-reported to the purchaser. Consumer-grade monitors may utilize either photoplethysmography (PPG) or direct electric recording and can be either intermittent (eg, handheld) or continuous wear with intermittent monitoring (eg, smartwatch).

CS: An ischemic stroke without an identified etiology despite a thorough diagnostic assessment. At a minimum, such assessment should include head and neck arterial imaging, echocardiography, extended cardiac rhythm monitoring, and key laboratory studies.[2]

Embolic stroke of undetermined source (ESUS): Image-confirmed nonlacunar cryptogenic ischemic stroke without proximal arterial stenosis or cardioembolic source.[14,15]

Medical-grade monitor: Monitoring technology that is approved by a regulatory body for heart rhythm monitoring, prescribed for diagnosis by a clinician, and typically reimbursable by a healthcare payer for diagnosis. This could include minimally invasive wearable devices or invasive implant devices that can provide intermittent or continuous recording.

FIGURE 1 Pathway Summary Graphic



Stroke: A neurological deficit attributed to an acute focal injury of the central nervous system by a vascular cause.[16] Ischemic stroke is defined as brain, spinal cord, or retinal cell death attributable to ischemia, based on neuropathological, neuroimaging, and/or clinical evidence of permanent injury.[17]

Stroke caused by large-artery atherosclerosis: Evidence of an ischemic stroke in the vascular distribution of a major artery with >50% stenosis of the vessel by vascular imaging. Diagnosis should exclude cardioembolic sources of stroke.[2]

Subclinical AF: Episodes of asymptomatic AF detected by intracardiac, implantable, or wearable monitors and confirmed by intracardiac electrogram or review of the recorded rhythm on an ECG.[18]

TIA: A transient episode of neurological dysfunction lasting <24 hours caused by focal brain, spinal cord, or retinal ischemia without evidence of acute infarction on imaging. [19]

3. PATHWAY SUMMARY GRAPHIC

Arrhythmia monitoring after a stroke requires three important steps (Figure 1). The first is a multidisciplinary evaluation to identify any potential mechanisms for the stroke. Ultimately, the stroke may be determined to be cryptogenic. The second step is risk assessment to determine the likelihood that a cardiac arrhythmia played a role in the stroke or may play a role in future stroke or nonstroke morbidity. The final step is choosing the optimal monitoring strategy for the patient that considers accuracy, practicality, barriers to care, and follow-up.

4. DESCRIPTION, RATIONALE, AND IMPLICATION OF PATHWAY

4.1. Adults With Stroke of Presumed Cardiac Origin Who Require Anticoagulation

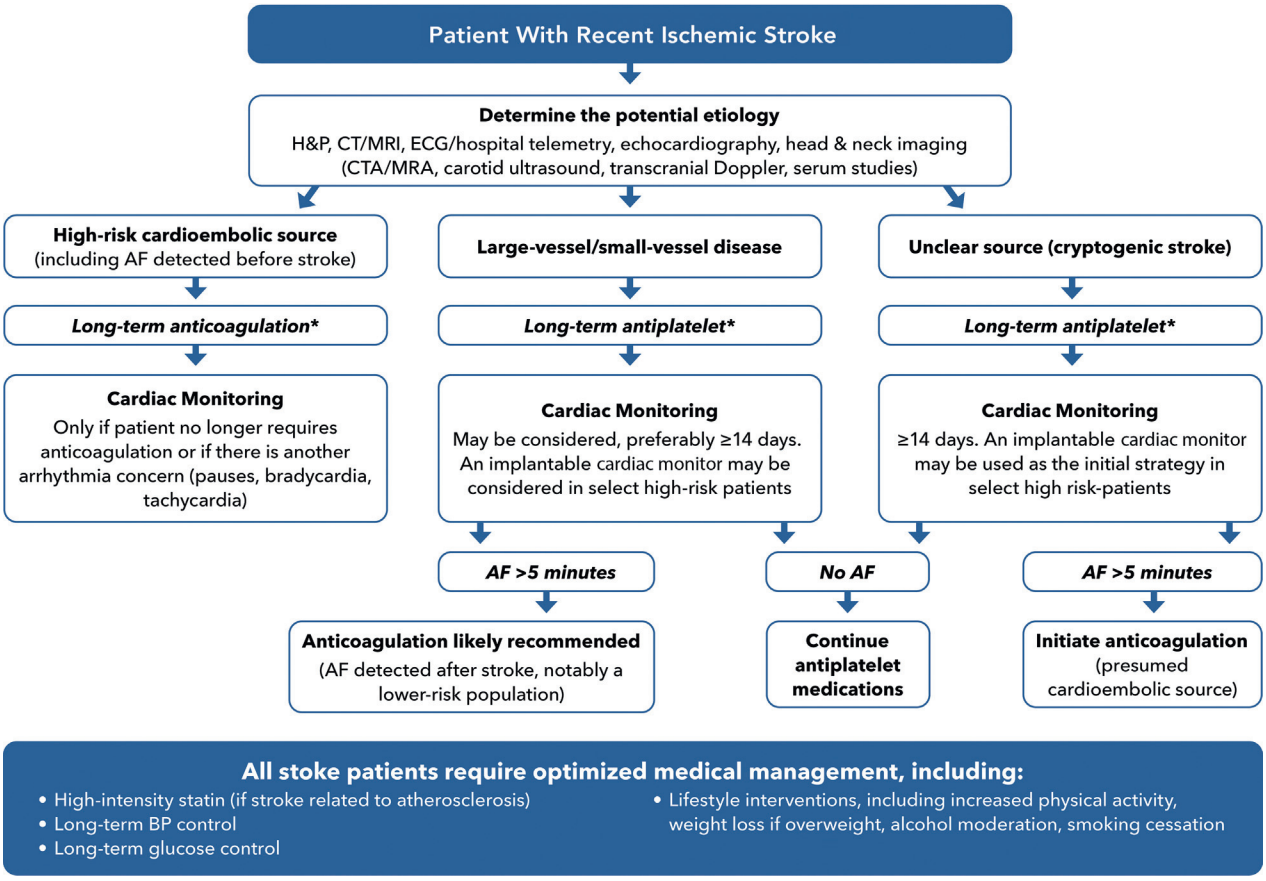
Many patients with an ischemic stroke of presumed cardiac origin require anticoagulation to reduce the risk of future events. Conditions that warrant consideration for long-term anticoagulation include AF, left atrial or left ventricular thrombus, postablation electrical isolation of the left atrial appendage, rheumatic mitral stenosis with an embolic event, mechanical heart valves, cardiac amyloidosis, left ventricular noncompaction, severely reduced ejection fraction (particularly when combined with anterior wall akinesis or dyskinesis), and the presence of a left ventricular assist device.[2,9,20] Long-term anticoagulation may also be recommended for patients with unprovoked venothromboembolism,[21] and hypercoagulable states such as malignancy[22] or antiphospholipid antibody syndrome.[23]

There are other conditions for which the future risk of stroke may decrease with time, allowing consideration for a shortened anticoagulation duration. These include left ventricular thrombus associated with transient cardiac wall motion abnormalities, AF in some patients who have undergone poststroke percutaneous left atrial appendage occlusion, postoperative AF, or AF due to a reversible cause. Future studies are required to better understand the optimal duration of anticoagulation for these patients.

4.1.1. Role for Monitoring

As shown in Figure 2, the role for rhythm monitoring in this group is limited given the verifiable evidence of a

FIGURE 2 Flowchart of Poststroke Monitoring and Treatment Strategy



Patients with recent ischemic strokes should be comprehensively evaluated for the most likely underlying cause. Determination of the etiology will guide therapeutic decisions, specifically determining the need to start oral anticoagulation vs the continuation of antiplatelet medications. *All stroke patients require optimized medical management (high-intensity statin, long-term BP control, long-term glucose control, lifestyle interventions). AF = atrial fibrillation; BP = blood pressure; CT = computed tomography; CTA = computed tomography angiography; ECG = electrocardiogram; H&P = history and physical examination; MRA = magnetic resonance angiography; MRI = magnetic resonance imaging.

cardioembolic source or other indication that necessitates persistent anticoagulation. Monitoring should be considered if there is a possibility of stopping anticoagulation or are other treatment decisions that depend on arrhythmia detection. Table 1 provides a summary of pathway recommendations.

4.2. Adults With Ischemic Stroke From Presumed Small- or Large-Vessel Disease

Ischemic stroke is a heterogeneous condition with several potential mechanisms. These include large-vessel atherosclerosis (aortic, cervical, or intracranial); small-vessel disease (which includes lacunar infarcts); and other known factors such as hypercoagulability, migraine with aura, cervical artery dissection, and sympathomimetic drug use. Most of these conditions do not typically require indefinite anticoagulation. Furthermore, the role for prolonged cardiac monitoring in this group of patients is uncertain.

Several points in favor of monitoring can be argued. First, many risk factors for large-vessel atherosclerosis and small-vessel disease overlap with risk factors for AF. These include hypertension, diabetes, obesity, smoking, excessive alcohol use, obstructive sleep apnea, and advanced age. As such, detection of AF is likely to be higher in patients with atherosclerotic or small-vessel stroke compared with that of the general population. Second, 2 stroke etiologies can coexist in the same patient.[24] For example, hemodynamically significant internal carotid artery stenosis may be present in a patient who also has AF. In these instances, discerning the stroke etiology can be challenging. Third, even if the stroke is thought to be from large- or small-vessel disease or another noncardioembolic etiology, identification of

TABLE 1 Summary of Stroke Monitoring Pathway Recommendations

	Recommendation
1.	In patients with stroke from presumed cardioembolic origin, the role for rhythm monitoring is limited, given an indication that necessitates persistent anticoagulation. Monitoring should only be considered if there is consideration of stopping anticoagulation or there are other treatment decisions that depend on arrhythmia detection.
2.	In patients with ischemic stroke from presumed small- or large-vessel disease, it is reasonable to monitor patients for 2-4 wks, with the addition of oral anticoagulation should an AF event ≥5 min be identified.
3.	In patients with ischemic stroke from presumed small- or large-vessel disease, extended monitoring with an implantable cardiac monitor may be considered especially in patients with higher risk criteria for the development of AF.
4.	In patients with ESUS, cardiac monitoring (2-4 wks) should be offered to patients if they are a candidate for long-term anticoagulation should AF be identified.
5.	An implantable monitor can be used in select patients with higher risk of post-stroke AF among those with a recent ESUS and no identified cause by external monitoring.
6.	It is reasonable to consider anticoagulation in patients with AF events ≥5 min, particularly in those with a CHA_2DS_2-VASc score ≥3 or equivalent stroke risk.
7.	Use of anticoagulation for patients with a very low burden of AF (<5 min) is not recommended without other indications.

AF = atrial fibrillation; CHA_2DS_2-VASc = congestive heart failure, hypertension, diabetes, previous stroke/ischemic attack, vascular disease, and sex; ESUS = embolic stroke of undetermined source.

intermittent AF could still have implications for long-term stroke prevention management.

Two recent studies have addressed whether patients with AF identified by an implanted device may benefit from initiation of oral anticoagulation for long-term stroke prevention even in the absence of a recent stroke. The NOAH-AFNET 6 (Non-vitamin K antagonist Oral anticoagulants in patients with Atrial High-rate episodes) study demonstrated no benefit of edoxaban vs placebo for the combined endpoint of stroke, systemic embolism, and cardiac death. In contrast, the ARTESIA (Apixaban for the Reduction of Thrombo-Embolism in Patients with Device-Detected Subclinical Atrial Fibrillation) trial, a study of device-detected AF between 6 minutes and 24 hours, reported lower rates of stroke or systemic embolism (0.78% vs 1.24% per patient-year; $P = 0.007$) among patients randomized to apixaban. A recent meta-analysis of both studies indicated that stroke and systemic embolism were consistently reduced by anticoagulation (relative risk [RR]: 0.68; CI: 0.50-0.92), although slightly higher bleeding rates were seen in the anticoagulation arms. Together, these trials suggest that treatment with anticoagulation does reduce stroke risk in patients with device-detected AF, even if there was no prior stroke.[25-27]

Arguments against screening patients with a known stroke etiology also exist. These include the fact that secondary stroke prevention treatment should focus on the most recent stroke etiology.[28] For example, patients with severe, symptomatic internal carotid artery stenosis require long-term intensive medical therapy, including an antiplatelet medication, with most patients also benefiting from early carotid revascularization. Similarly, patients with lacunar strokes due to presumed small-vessel disease require antiplatelet therapy and long-term risk factor modification.

Increased duration of monitoring has been shown to improve detection of AF, especially in populations with risk factors for AF.[29-31] A meta-analysis that evaluated 30 studies and 5,687 patients sought to evaluate the frequency of AF detected among those with stroke due to large- or small-vessel disease.[32] With short-term monitoring (maximum 7 days), AF was identified in 2.2% of individuals with large-vessel disease and 2.4% with small-vessel disease. These rates were notably lower compared with that of patients with CS, who had a 9.2% rate of AF detection. This contrasts with the largest single study to evaluate AF detection in patients with large-vessel atherosclerosis or small-vessel disease, the STROKE-AF (Stroke of Known Cause and Underlying Atrial Fibrillation) trial.[33] This industry-sponsored study was conducted at 33 centers in the United States between 2016 and 2020. Patients were eligible if they were aged ≥60 years or 50 to 59 years with ≥1 additional vascular risk factor. Patients were required to have an ischemic stroke judged by the participating physician to be due to large-vessel atherosclerosis or small-vessel disease. In total, 496 patients (mean age 67 years, 62% men) were enrolled, with 417 completing 12 months of follow-up. An implantable cardiac monitor (ICM) was placed within 10 days of the index stroke. Patients in the ICM group had a higher rate of AF detection (12.1%) compared with that of the usual care group (1.8%). The median time to detection of the first AF episode was 99 days.

In a post-hoc analysis of this trial, there was no difference in the AF detection rate in those with large-vessel atherosclerosis (11.7%) compared with those with small-vessel disease (12.6%). The median duration of the longest AF episode across the 2 groups was 88 minutes. Patients with small-vessel disease had a longer duration compared with those with large-vessel disease (267 minutes vs 44 minutes). In addition, the 2 most significant predictors of AF were history of heart failure (HF) (hazard ratio [HR]: 5.06) and left atrial enlargement (HR: 3.32), defined as left atrial size >41 mm in men or ≥39 mm in women or a left atrial volume index >28 mL/m^2 (HR: 3.32).[34] At 12 months, AF was identified in 23.4% of patients with a history of HF and/or left atrial enlargement, compared with that of 5.0% in patients with neither condition.

Recently reported cost-analysis data from the STROKE-AF trial demonstrated that monitoring was highly effective, showing a change in quality-adjusted life-years from 6.46 years to 6.63 years when an ICM was employed for long-term monitoring vs standard of care (SoC).[35] This

TABLE 2 Randomized Clinical Trials Evaluating Oral Anticoagulant Therapy in ESUS

Trial	Population	Intervention	Primary Endpoint	Findings
NAVIGATE ESUS[56,75]	Recent ESUS (7 d to 6 mo), n = 7,213	Rivaroxaban (15 mg/d) vs aspirin (100 mg/d)	Efficacy: first recurrence of ischemic or hemorrhagic stroke or systemic embolism (time-to-event analysis) Safety: major bleeding (ISTH criteria)	Median follow-up of 11 mo, with premature termination because of lack of efficacy and increased bleeding with rivaroxaban Efficacy: rivaroxaban (5.1% annualized rate) vs aspirin (4.8% annualized rate), HR: 1.07 (0.87-1.33); $P = 0.52$ Safety: rivaroxaban (1.8% annualized rate) vs aspirin (0.7% annualized rate), HR: 2.72 (1.68-4.39); $P < 0.001$ Rivaroxaban was not superior to aspirin for recurrent stroke and was associated with a higher risk of major bleeding
RE-SPECT ESUS[55]	Recent ESUS (<3 mo) with ≥1 additional vascular risk factor, n = 5,390	Dabigatran (150 or 115 mg twice/d) vs aspirin (100 mg/d)	Efficacy: first recurrence of stroke of ischemic, hemorrhagic, or unspecified type (time-to-event analysis) Safety: major bleeding (ISTH criteria)	Median follow-up of 19 mo Efficacy: dabigatran (4.1% annualized rate) vs aspirin (4.8% annualized rate), HR: 0.84 (0.68-1.03); $P = 0.10$ Safety: dabigatran (1.4% annualized rate) vs aspirin (1.2% annualized rate), HR: 1.19 (0.85-1.66); dabigatran was associated with a significantly greater rate of clinically relevant nonmajor bleeding (1.6% vs 0.9%, HR: 1.73 [1.17-2.54]) Dabigatran was not superior to aspirin for recurrent stroke; there was not a higher risk of major bleeding but there was a higher rate of clinically relevant nonmajor bleeding
ARCADIA[58,61]	Recent ESUS (≤120 d) with evidence of atrial cardiomyopathy, n = 1,015	Apixaban (5 mg or 2.5 twice/d) vs aspirin (81 mg/d)	Efficacy: first recurrence of stroke of any type Safety: symptomatic intracranial bleeding and major bleeding other than intracranial bleeding	Mean follow-up of 1.8 years, with premature termination because of lack of efficacy Efficacy: apixaban (4.4%) vs aspirin (4.4%); HR: 1.00 (0.65-1.55) Safety: apixaban (0 cases) vs aspirin (7 cases) for intracranial bleeding; apixaban vs aspirin for major bleeding (HR: 1.02 [0.29-3.51]) Apixaban was not superior to aspirin for recurrent stroke and was associated with a similar risk of bleeding
ATTICUS[57,59,60]	Recent ESUS (≤7 d) with ≥1 risk factor for cardiac embolism (left atrium size >45 mm, spontaneous echo contrast in the LAA, LAA flow velocity ≤0.2 m/s, PFO, CHA_2DS_2-VASc score ≥4), n = 352	Apixaban (5 mg or 2.5 twice/d) vs aspirin (100 mg/d)	Efficacy: ≥1 new ischemic lesion identified by FLAIR and/or DWI MRI at 12 mo compared with that of the baseline MRI Safety: major and clinically relevant nonmajor bleeding (ISTH criteria)	There was premature termination because of lack of efficacy Efficacy: apixaban (13.6%) vs aspirin (16.0%); $P = 0.57$ Safety: apixaban vs aspirin; P = NS Apixaban was not superior to aspirin for new ischemic lesions by MRI with a similar risk of bleeding

ARCADIA = Atrial Cardiopathy and Antithrombotic Drugs in Prevention After Cryptogenic Stroke; ATTICUS = Apixaban for Treatment of Embolic Stroke of Undetermined Source; CHA_2DS_2-VASc = congestive heart failure, hypertension, diabetes, previous stroke/ischemic attack, vascular disease, and sex; DWI = diffusion weight imaging; ESUS = embolic stroke of undetermined source; FLAIR = fluid attenuated inversion recovery; HR = hazard ratio; ISTH = International Society on Thrombosis and Haemostasis; LAA = left atrial appendage; MRI = magnetic resonance imaging; NAVIGATE ESUS = Rivaroxaban Versus Aspirin in Secondary Prevention of Stroke and Prevention of Systemic Embolism in Patients With Recent Embolic Stroke of Undetermined Source; NS = not significant; PFO = patent foramen ovale; RE-SPECT ESUS = Randomized, Double-Blind, Evaluation in Secondary Stroke Prevention Comparing the Efficacy and Safety of the Oral Thrombin Inhibitor Dabigatran Etexilate Versus Acetylsalicylic Acid in Patients With Embolic Stroke of Undetermined Source.

equated to an incremental cost overall per quality-adjusted life-year of $37,760 compared with that of SoC. This ratio was improved to $22,016 per quality-adjusted life-year when risk criteria were utilized to identify the subset of patients with the highest AF risk. This lends support to the use of a risk-scoring algorithm to help better stratify patients at higher risks of AF poststroke who may qualify for long-term monitoring.

Beyond large-vessel atherosclerosis and small-vessel disease, other conditions linked with stroke may increase the risk of AF. One such factor is illicit or recreational drug use. A study using a statewide database in California identified individuals that received care in an emergency department and analyzed the relationship between illicit drug use and documentation of AF during the next 12 months.[36] An increased rate of AF was noted among those that used methamphetamines (HR, 1.86), cocaine (HR, 1.61), opiates (HR, 1.74), and cannabis (HR, 1.35). A meta-analysis of 7 prospective studies shows that alcohol consumption, even at moderate intakes, is a risk factor for AF.[37] In a prospective, randomized study, abstinence from alcohol has been shown to reduce AF recurrences in regular drinkers who have a history of AF.[38] These findings raise the question as to whether screening for AF should be performed in patients with stroke that use these substances.

4.2.1. Role for Monitoring

It is reasonable to monitor select patients with a recent ischemic stroke attributed to small- or large-vessel

disease. The minimal duration of monitoring is uncertain, although 2 to 4 weeks is preferred. A longer-lasting implantable monitor can be used initially or in select patients with higher risk of poststroke AF if initial external monitoring is unrevealing (**Figure 2**). If a meaningful burden of AF is identified, it is likely that antiplatelet therapy would be replaced with an anticoagulant given prior studies of primary stroke prevention in high-risk individuals with AF and the 2 recently published studies of device-detected AF showing stroke risk reduction with anticoagulation. Cost-effectiveness data from STROKE-AF also show some advantage of extended monitoring, especially when utilized in the subset of patients who have other clinical risk factors for AF (**Figure 2**).[35] These patients include those with a history of HF and/or left atrial enlargement or an elevated poststroke AF risk score (CHASE-LESS score [Coronary, HF, Age, stroke SEverity, LipidEmia, Sugar, prior Stroke]), as discussed in Section 4.4. Additional studies are needed to focus on those patients most likely to benefit from monitoring. **Table 1** provides a summary of pathway recommendations.

4.3. Adults With Ischemic Stroke and Unclear Source

Despite standard and complete evaluation, up to 40% of ischemic strokes may not have an identified underlying etiology.[39] CS and ESUS have been used to describe this condition but are somewhat different entities.

First introduced in 1984[40] and later redefined in 1993[41] and 2016,[42] the term CS refers to cerebral infarction not attributable to a definite source of cardiac embolism, atherosclerosis involving large arteries, or disease involving small arteries despite extensive cardiovascular and laboratory evaluation.[43] The term ESUS represents a subset of CS with infarct size and distribution that suggests it was the result of embolization.[15] ESUS constitutes an important subgroup, accounting for approximately 17% of all ischemic strokes[14] and one-half of CS.[2] Patients with ESUS tend to be younger, have a lower frequency of traditional cardiovascular risk factors, and often present with milder symptoms.[14] The rate of stroke recurrence among individuals with this condition, however, is appreciable, approximating 4% to 5% per year.[14,44] Accordingly, there is a need to define its optimal treatment.

Among the many etiologies that may underlie ESUS (eg, unrecognized aortic atheroma, paradoxical embolism, valvular heart disease, thrombophilia, subocclusive arterial disease, vasculopathy), cardioembolism from occult AF has received increased attention, and this possibility may support long-term monitoring. Various studies have identified AF in up to 30% of patients with CS when long-term heart rhythm monitoring is performed.[11] Multiple lines of evidence have called into question, however, the direct and causal link between AF and ESUS. First, uncertainty still exists as to the requisite burden of AF required to increase stroke risk and the specific thresholds for this (eg, total time in AF, number of episodes, duration of episodes). Most cutoffs for AF burden have been empirically derived and the stroke risk associated with brief AF episodes (<5 to 6 minutes) remains largely unknown.[45]

There have been conflicting data regarding the temporal association of AF with the stroke itself. Whereas several studies have indicated a relationship with preceding evidence of AF prior to the stroke,[46-50] other studies have shown a temporal discordance, with absence of AF on cardiac implantable electronic devices in the months leading up to a stroke.[50] Finally, subclinical AF lasting ≥5 minutes has been observed at similar rates in older adults with and without a history of stroke.[51]

AF has also been identified in patients with stroke resulting from different etiologies beyond ESUS. In the Find-$AF_{RANDOMISED}$ (Finding Atrial Fibrillation in Stroke—Randomized Evaluation of Enhanced and Prolonged Holter Monitoring) trial, considerable overlap was noted in the rate of Holter monitor-detected AF between those with ESUS and other nonembolic stroke types.[52] The STROKE-AF study similarly demonstrated a significantly increased rate of AF detected by an ICM among individuals with prior large- or small-vessel strokes.[33,53]

In addition, patients with ESUS generally have less severe strokes compared with those resulting from cardioembolism. In the Athens Stroke Registry, National Institutes of Health Stroke Scale scores were lower among individuals with ESUS compared with those resulting from cardioembolism.[54] Similar findings were noted in the NAVIGATE-ESUS (Rivaroxaban Versus Aspirin in Secondary Prevention of Stroke and Prevention of Systemic Embolism in Patients With Recent Embolic Stroke of Undetermined Source) trial and the RE-SPECT ESUS (Randomized, Double-Blind, Evaluation in Secondary Stroke Prevention Comparing the Efficacy and Safety of the Oral Thrombin Inhibitor Dabigatran Etexilate Versus Acetylsalicylic Acid in Patients With Embolic Stroke of Undetermined Source) trials, where enrolled patients had low National Institutes of Health Stroke Scale scores.[55,56]

To date, multiple studies of patients with ESUS have failed to demonstrate reduced risk of recurrent stroke with an oral anticoagulant compared with that of antiplatelet therapy (**Table 2**).[55-61] It should be noted that several of these studies were stopped prematurely due to lack of effect, individuals with known AF were excluded, and only ≤24 hours of heart rhythm monitoring was required for enrollment in most cases. These findings have prompted some to question whether the concept of ESUS should be re-examined,[62,63] with the belief that it likely reflects a more diverse condition that warrants a

more tailored treatment approach.[64] Regardless, the findings from the ESUS trials suggest that unselected anticoagulation is not beneficial, and thus evaluating for AF is appropriate to select which patients are likely to benefit from anticoagulation.

Important additional considerations in patients with ESUS include the following: 1) most AF detected by prolonged monitoring after stroke may have a lower stroke risk compared with that of AF known to exist prior to stroke[12,65]; 2) other embolic sources beyond AF may underlie observed strokes[44,63]; 3) white (platelet-rich) rather than red (erythrocyte-rich) thrombi may predominate in some patients with ESUS[66]; and 4) increasing age,[67] clinical variables (obesity, presence of hypertension, valvular heart disease, HF, peripheral arterial disease, coronary artery disease),[68] laboratory test results (elevated N-terminal pro-brain natriuretic peptide [NT-proBNP],[68] ECG parameters (PR interval, P-wave index and dispersion, interatrial block, and P-wave terminal force),[69,70] imaging findings (infarcts in both hemispheres or multiple locations in 1 territory),[71,72] and risk scores[73] may all help to more optimally inform screening for AF.

Although there remains some uncertainty regarding the cause and effect relationship of ESUS and AF, the 2021 AHA/ASA Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack recommends that individuals identified to have AF be started on an oral anticoagulant to reduce the risk of recurrent stroke (Class 1, Level of Evidence: B recommendation).[2] In addition, the guideline notes that it is reasonable for individuals with CS (with or without ESUS) to undergo the following: 1) echocardiography to evaluate for possible cardiac sources of embolism (Class 2a, Level of Evidence: B recommendation); and 2) long-term cardiac rhythm monitoring to detect intermittent AF (Class 2a, Level of Evidence: B recommendation).[2] The guideline further notes that it might be reasonable for individuals with ESUS to undergo transesophageal echocardiography, cardiac computed tomography, or cardiac magnetic resonance imaging to identify possible cardioaortic sources for cerebral embolism (Class 2b, Level of Evidence: C recommendation).[2] Implicit in these recommendations, however, is the need to further clarify the optimal duration of heart rhythm monitoring, the clinical significance of brief episodes of AF, and who is most likely to benefit from such testing.[2,62]

More recently, the 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation notes that that is reasonable for individuals with stroke or TIA of undetermined cause to undergo initial cardiac monitoring and, if needed, extended monitoring with an ICM to improve detection of AF (Class 2a, Level of Evidence: B recommendation).[6] Furthermore, among those with device-detected atrial high-rate episodes lasting: 1) ≥24 hours with a CHA_2DS_2-VASc (congestive HF, hypertension, diabetes, previous stroke/ischemic attack, vascular disease, and sex) score ≥2 or equivalent stroke risk, initiation of oral anticoagulation is reasonable (Class 2a, Level of Evidence: A recommendation); 2) 5 minutes to 24 hours with a CHA_2DS_2-VASc score ≥3 or equivalent stroke risk, initiation of oral anticoagulation may be reasonable (Class 2b, Level of Evidence: B recommendation) within an SDM framework that considers episode duration and individual patient risk; and 3) <5 minutes without another indication for oral anticoagulation, initiation of oral anticoagulation should not be performed (Class 3, Level of Evidence: B recommendation).

4.3.1. Role for Monitoring

As recommended in current guidelines from a variety of professional societies, prolonged cardiac monitoring should be offered to patients with recent ESUS if they are felt to be a candidate for long-term anticoagulation should AF be identified. The minimal duration of monitoring is uncertain, although 2 to 4 weeks is reasonable. A longer-lasting implantable monitor can be used initially or in select patients with higher risk of poststroke AF if initial external monitoring is unrevealing (**Figure 2**). There is likely a reduced role for short-term 24- to 48-hour monitoring in this population given the lower yield, although results from the AF-SPICE (Atrial Fibrillation Screening Post Ischemic Cerebrovascular Events) protocol will provide additional information.[74] Use of anticoagulation in patients with a very low burden of AF (<5 minutes) is of uncertain benefit at this time, and is not recommended without other indications. It is reasonable to consider anticoagulation in patients with AF events ≥5 minutes, particularly in those with a CHA_2DS_2-VASc score ≥3 or equivalent stroke risk.[6] **Table 1** provides a summary of pathway recommendations.

4.4. Poststroke Risk Assessment for Atrial Arrhythmias

As mentioned previously, AF has been noted in up to 30% of patients after CS and 12.1% with large- or small-vessel strokes.[11,33] To better determine which patients warrant monitoring and for how long to monitor, several poststroke risk scoring systems have been developed to help identify patients at higher risk for atrial arrhythmias that may contribute to future strokes. Several such risk scores (**Table 3**) have been proposed, including AS5F (age, stroke severity, National Institutes of Health Stroke Scale score >5), C_2HEST (coronary artery disease or chronic obstructive pulmonary disease, hypertension, elderly, systolic HF, thyroid disease), $CHADS_2$ (congestive HF, hypertension, age, diabetes, previous stroke [2 points]) CHA_2DS_2-VASc, CHASE-LESS, HATCH (Hypertension, Age, Transient ischemic attack or stroke, Chronic obstructive

TABLE 3 AF Risk Scores Validated in Poststroke Patients

Risk Score	Component	C-Statistic in Validation
AS5F[81]	Age: 0.76 points/y, stroke severity NIHSS ≤5 = 9 points, NIHSS >5 = 21 points	0.689
C_2HEST[82]	C_2: CAD/COPD (1 point each); H: hypertension (1 point); E: elderly (age ≥75 y, 2 points); S: systolic HF (2 points); and T: thyroid disease (hyperthyroidism, 1 point)	0.734 (poststroke)
$CHADS_2$[83]	Congestive HF, hypertension, age ≥75 y, and diabetes, each given 1 point; and a history of TIA or stroke given 2 points	0.700
CHA_2DS_2-VASc[83]	Congestive HF, hypertension, age ≥75 y (doubled), diabetes, stroke/TIA (doubled), vascular disease, age 65-75 y, and sex category (female)	0.706
CHASE-LESS[78]	CAD (1 point), congestive HF (1 point), age (1 point for every 10 y), stroke severity (NIHSS; 1 point for 6-13 and 4 points for ≥14), hyperlipidemia (−1 point), diabetes (−1 point), and prior history of stroke or TIA (−1 point)	0.732
HATCH[84]	2 points for either a history of TIA/stroke or HF, respectively; 1 point for hypertension, age >75 y, or COPD, respectively	0.653
HAVOC[73]	4 points for congestive HF, 2 points for each of hypertension, age ≥75 y, valvular disease, and CAD, and 1 point for each of peripheral vascular disease and obesity (body mass index >30 kg/m^2)	0.687
Re-CHARGE-AF[85]	5-y predictive model includes the variables of age, race, height, weight, systolic and diastolic blood pressure, current smoking, use of antihypertensive medication, diabetes, history of myocardial infarction, and HF	0.64

AS5F = age, stroke severity, NIHSS score >5; CAD = coronary artery disease; C_2HEST = coronary artery disease or chronic obstructive pulmonary disease, hypertension, elderly, systolic heart failure, thyroid disease; $CHADS_2$ = congestive heart failure, hypertension, age, diabetes, previous stroke (2 points); CHA_2DS_2-VASc = congestive heart failure, hypertension, diabetes, previous stroke/ischemic attack, vascular disease, and sex; CHASE-LESS = Coronary, Heart failure, Age, stroke SEverity, - LipidEmia, Sugar, prior Stroke; COPD = chronic obstructive pulmonary disease; HATCH = Hypertension, Age, Transient ischemic attack or stroke, Chronic obstructive pulmonary disease, and Heart failure; HAVOC = Hypertension, Age, Valvular heart disease, Obesity, Congestive heart failure, and coronary artery disease; HF = heart failure; NIHSS = National Institutes of Health Stroke Scale; Re-CHARGE-AF = Refitted Model for the Cohorts for Heart and Aging Research in Genomic Epidemiology for Atrial Fibrillation; TIA = transient ischemic attack.

pulmonary disease, and HF), HAVOC (Hypertension, Age, Valvular heart disease, Obesity, congestive HF, and Coronary artery disease), and Re-CHARGE-AF (Refitted Model for the Cohorts for Heart and Aging Research in Genomic Epidemiology for AF). In the Taiwanese Stroke Registry validation study, the AS5F and CHASE-LESS scores seemed to show the highest correlation with future AF risk with C-statistics of 0.730 and 0.741, respectively.[76] A machine learning algorithm was also recently validated for poststroke prediction of AF with a C-statistic of 0.77.[77] Validation studies, however, have typically shown lower rates of detected AF poststroke given shorter monitoring times. Common to both the AS5F and the CHASE-LESS score are age as well as National Institutes of Health Stroke Scale. The CHASE-LESS score also includes coronary heart disease, HF, and age with negative points for hypercholesterolemia, diabetes, and prior stroke.[78]

Other specific ECG and echocardiographic markers of atrial cardiomyopathy have also been proposed as possible future predictors of AF. These include increased atrial and ventricular automaticity, P-wave terminal force in ECG lead V_1, increased left atrial size or volume, decreased left atrial function, and automaticity AF[79] as noted per the STROKE-AF trial.[34] Although showing no benefit with anticoagulation in the absence of AF, the ARCADIA (AtRial Cardiopathy and Antithrombotic Drugs In prevention After cryptogenic stroke) trial did show an association between specific atrial cardiomyopathy criteria and onset of AF. These criteria included P-wave terminal force in ECG lead V_1 >5,000 mcV·ms, serum N-terminal pro-brain natriuretic peptide >250 pg/mL, or left atrial diameter index ≥3 cm/m^2.[80] Utilization of these criteria and scoring systems could be a means to help determine when long-term monitoring with an ICM needs to be considered.

4.5. Medical-Grade Monitors: Monitoring Devices Available and Utility in Detection and Treatment of AF for Stroke Prevention

Detection of AF has become an essential part of poststroke care to elucidate a potential cause of stroke and to optimize secondary stroke prevention with select use of long-term oral anticoagulation. Currently, long-term cardiac rhythm monitoring is a Class 2a indication for the detection of silent AF in poststroke patients in both the 2023 AHA/ACC/ACCP/HRS Guideline for the Diagnosis and Management of Patients With Atrial Fibrillation[6] and the 2021 AHA/ASA Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack.[2,9]

Both medical- and consumer-grade (direct-to-consumer) digital devices for cardiac rhythm monitoring are available. The U.S. Food and Drug Administration (FDA) defines a medical device as those "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals." Medical-grade devices require regulatory clearance by the FDA in advance of marketing and in follow-up to rigorous scientific review. These devices are also subject to postmarket regulation, including device reporting, postmarket approval and/or post-market surveillance studies, along with device tracking to ensure safety and efficacy.[86,87] In contrast, some consumer-grade devices considered low-risk or for

TABLE 4 Medical-Grade External Cardiac Rhythm Monitoring Devices

Device	Technology	Sensor	Number of ECG Channels	Duration of Monitoring	Single-Use/ Reusable	Rhythm Monitoring	FDA Class/ 510(k) Number
FibriCheck® (FibriCheck, Belgium)[88]	PPG Smartphone mApp	Smartphone camera	N/A	Long-term, intermittent use	Reusable	Asynchronous	II/K173872
BodyGuardian™ MINI (Boston Scientific, Inc)[89-94]	Ambulatory ECG patch options: ± electrodes, ± 1-4 wires	2 integrated or 2-5 standard ECG electrodes	1-3	15-d continuous	Single-use	Asynchronous	II/K182030
BodyGuardian™ MINI PLUS Mobile Cardiac Telemetry (Boston Scientific, Inc)[89-94]	Ambulatory ECG patch options: ± electrodes, ± 1-4 wires	2 integrated or 2-5 standard ECG electrodes	1-3	30-d continuous	Single-use	Wireless near real-time telemetry (cloud)	II/K182030
Cardea SOLO (Cardiac Insight, Inc)[95-98]	Ambulatory ECG patch	2 integrated electrodes	1	7-d continuous	Single-use	Asynchronous	II/K162503
CardioSTAT (Incentia Inc)[99-101]	Ambulatory ECG patch	2 integrated electrodes	1	14-d continuous	Single-use	Asynchronous	II/K223049
Carnation Ambulatory Monitor (CAM®) Patch (BardyDx, Inc/Baxter, Inc)[102-105]	Ambulatory ECG patch	2 integrated electrodes	1	7- to 14-d continuous	Single-use	Asynchronous	II/K210036
Nuubo30[106]	Wearable ECG textile	4 integrated electrodes	3	30-d continuous	Single-use	Asynchronous	II/K173461
Philips Extended Wear Holter Monitoring (formerly BioTelemetry, Inc)[107]	ePatch™: Ambulatory ECG patch FLEX™: Chest device + 1 wire Lead-wire option: wired device	ePatch: 2 integrated electrodes FLEX: 2 standard ECG electrodes Wired: 3 standard ECG electrodes	1-2	ePatch:14-d continuous FLEX: 14-d continuous Wired: 3- to 5-d continuous	Single-use	Asynchronous	II/K171410
Philips Mobile Cardiac Telemetry (MCOT) Patch (formerly BioTelemetry, Inc)[107]	Ambulatory ECG patch	3 integrated electrodes	2	30-d continuous	Single-use	Wireless near real-time telemetry (cloud)	II/K153473
Zio AT® (iRhythm, Inc)[108]	Ambulatory ECG patch	2 integrated electrodes	1	14-d continuous	Single-use	Wireless near real-time telemetry (cloud)	II/K163512
Zio® XT (iRhythm, Inc)[108]	Ambulatory ECG patch	2 integrated electrodes	1	14-d continuous	Single-use	Asynchronous	II/K123119

ECG = electrocardiogram; FDA = U.S. Food and Drug Administration; N/A = not applicable; PPG = photoplethysmography.

"general wellness" may not be subject to such rigorous (if any) FDA regulation.

Medical-grade cardiac rhythm monitors require a prescription. In general, these devices fall into 2 categories based on the type of technology used to detect heart rate and rhythm: PPG- or electrode-based devices (Table 4).

4.5.1. PPG-Based Devices

PPG devices use optical sensors to measure heart rate with additional algorithms to further obtain heart rhythm. Blood volume changes at the skin surface are measured and additional software algorithms analyze variations between individual pulse waves to differentiate normal from irregular rhythm.[109] The ubiquity of smartphones with built-in light sources (flash) and photodetectors (camera) have allowed for widespread availability of consumer-grade smartphone applications (apps) for heart rate detection; PPG technology is also widely used in fitness bands and smartwatches for the same purpose.[110,111] These will be discussed in the next section. PPG heart rate detection has long been used in medical-grade devices, such as pulse oximeters; however, in general, PPG devices have not been used in isolation to make the diagnosis of AF, as they: 1) are highly subject to motion artifact; 2) provide intermittent, rather than continuous monitoring; and 3) do not generate an ECG tracing.[111] Clinician overread and rhythm confirmation via a traditional ECG are required.[111] Currently, the only PPG-based AF detection software that is both European Commission (CE)-marked and FDA-cleared as a medical device is the FibriCheck (Flanders, Belgium) smartphone app.[112] Of the 93% of studied patients with verifiable rhythms, this clinically validated app has a reported AF detection sensitivity and specificity of 96% and 97%,

respectively.[113,114] It has been used to support ongoing, comprehensive management of patients with AF in >6,000 patients in Europe.[115-117] Use of this smartphone app in the United States requires prescription; however, it has not been specifically studied to detect paroxysmal AF in the poststroke population.

4.5.2. ECG-Based Devices

Wearable ECG monitors

Wearable ambulatory ECG monitors have evolved from the low-storage, cumbersome, multicomponent devices of the 1970s. Current ambulatory ECG monitors are more inconspicuous, generally single-use, self-adhesive, and often rechargeable, with longer storage capability and wireless data transmission, allowing for a better user experience.[111] Devices range from 2 electrodes that allow the ability to obtain a single-lead ECG, to multiple electrodes that allow for ≥2 diagnostic ECG channels. Importantly, electrode-based, wearable ambulatory ECG monitors can provide continuous ECG monitoring for up to 30 days, with mobile cardiac telemetry options offering near real-time detection and assessment of cardiac arrhythmias (**Table 4**).[118,119] Limitations with these devices relate mainly to the following: 1) relatively short monitoring periods as a result of limited data storage and battery life; 2) suboptimal durability; and 3) intolerance to skin adhesives.[111]

The diagnostic yield of AF detection has been shown to increase with more continuous ambulatory patch ECGs and mobile cardiac telemetry.[120,121] In the randomized SCREEN-AF (Screening for Atrial Fibrillation) trial, continuous monitoring via a 14-day ambulatory ECG patch had a 10-fold higher rate of AF detection compared with that of SoC in those ≥75 years of age with a CHA_2DS_2-VASC ≥2 (5.3% vs 0.5%; $P < 0.001$).[122] The randomized mSToPS (mHealth Screening To Prevent Strokes) trial also found that 14-day ambulatory ECG patch monitoring had higher AF detection compared with that of routine care in a similar population (3.9% vs 0.9% at 4 months and 11.4% vs 7.7% at 3 years; $P < 0.01$).[123,124] Findings have been similar in studies of poststroke patients. The randomized EMBRACE (30-Day Cardiac Event Monitor Belt for Recording Atrial Fibrillation after a Cerebral Ischemic Event) (30-day event monitor vs 24-hour Holter ECG), Find-$AF_{RANDOMISED}$ (10-day ECG monitor vs 24-hour Holter), and EPACS (Early Prolonged Ambulatory Cardiac monitoring in Stroke) (14-day patch ECG vs 24-hour Holter) trials all found that AF detection improved significantly with longer-term or more continuous ambulatory ECG monitoring (16.1% vs 3.2%; $P < 0.001$ for EMBRACE; 14% vs 5%; $P = 0.002$ for Find-$AF_{RANDOMISED}$; and 16.3% vs 2.1%; $P < 0.02$ for EPACS, respectively).[52,122,125] Specific types of ambulatory ECG devices may also be more cost-effective than others. A retrospective cohort study found that a single-use 14-day ambulatory patch ECG monitor (iRhythm Technologies, Inc) had higher diagnostic yield, lesser need risk for repeat testing, and generally lowest overall healthcare resource utilization when compared with that of 24- to 48-hour Holter monitoring, along with other long-term cardiac monitors, event recorders, and mobile cardiac telemetry.[126]

Implantable cardiac rhythm monitors

With battery longevity varying between 3 and 5.5 years, ICMs provide the longest duration of continuous single-lead ECG cardiac rhythm monitoring. ICMs have an AF detection yield of approximately 12% to 16% at 1 year, up to 22.8% at 24 months, and 28.5% at 36 months (**Table 5**).[11,127-130] These devices have significantly decreased in size with time, and implantation involves a minimally invasive outpatient procedure. ECG data can be wirelessly transmitted for daily remote interpretation.[131] Many also have handheld symptom triggers to allow for improved symptom-rhythm correlation. ICMs can have high false-positive rates for AF detection (up to 55% in some studies), mostly due to noise and premature atrial or ventricular contractions.[132,133] Recent recommendations for proper programming in combination with enhanced algorithms have helped to address this issue.[131,134] In one study, the addition of artificial intelligence algorithms to ICMs improved positive predictive value of AF detection from 53.9% to 74.5% ($P < 0.001$),[135] and up to 98.5% by another study.[136] Adjudication of false-positive results require overreading by a provider leading to an increased number of alarms per day. In addition to AI, remote reprogramming of these device has also been shown to reduce the number of provider alarms from 0.13 to 0.03 (Medtronic LINQ II) and 0.15 to 0.01 (Boston Scientific LUX-Dx) median alerts per day without adverse clinical events.[137]

4.5.3. Role of ICMs in AF Detection

The Class 2a guideline recommendation for the detection of subclinical AF poststroke with ICMs was informed by the 2014 randomized CRYSTAL-AF (Cryptogenic Stroke and Underlying Atrial Fibrillation) trial, which found that AF detection was significantly higher in patients with CS monitored with ICM vs SoC (8.9% vs 1.4%; HR: 6.4; $P < 0.001$ at 6 months; 12.4% vs 2.0% at 12 months; HR: 7.3; $P < 0.001$; 30.0% vs 3.0% at 36 months; HR: 8.8; $P < 0.001$).[2,9,11] It should be noted that episodes of AF were frequently asymptomatic (74% in the ICM group and 33% in the control group) in the first 6 months after enrollment in the CRYSTAL-AF trial.[11] Since then, 2 other randomized trials have confirmed the findings of the CRYSTAL-AF trial. The 2021 PER DIEM (Effect of Implantable vs Prolonged External Electrocardiographic Monitoring on Atrial Fibrillation Detection in Patients With Ischemic Stroke) study randomized 300 patients with ischemic

TABLE 5 Medical-Grade Implantable Cardiac Monitor Devices: FDA-Cleared, Clinically Studied, Commonly Prescribed

Name	Characteristic	Sensitivity for AF	PPV for AF	Battery Life	Remote Monitoring	Remote Reprogramming	MRI	Size
Medtronic (Minneapolis, Minnesota, USA) LINQ II™[138]	Titanium with polymer heading; current version uses AI algorithm before sending	99%	88.2% (with enhanced AI)	4.5 y	2 monitoring options – one with Bluetooth to mobile app on mobile device; second option via traditional home communicator	Online platform allows clinical team to reprogram device parameters through the app	Yes (≤3-T)	3.4 g; 8 × 45.1 × 4.2 mm
Boston Scientific (Marlborough, Massachusetts, USA) LUX-Dx II/II+™[136]	Titanium with polymer header; magnet initiates communication between device and app; II+ with AI algorithm before sending	97.6%-100%	79.1%-98.5%	3 y	Mobile application transmits to server; patients record symptomatic events (mobile device or clinical assistant)	Online platform allows clinical team to reprogram device parameters through the app	Yes (≤3-T) (external magnet and clinical app not MRI conditional)	3.0 g; 7.2 × 44.8 × 4 mm
Abbott (Chicago, Illinois, USA) Confirm Rx™/ Assert-IQ™[139]	Parylene coating; faster transmission time compared with loop recorders; Assert-IQ with additional AI algorithm before sending; Assert-IQ with HR tracking with and without activity	97.2%	93.7%	2 y (Confirm Rx); 3 y (Assert-IQ); 6 y (Assert-IQ EL+)	Bluetooth-integrated symptom recording system via mobile app to mobile device	Online platform allows clinical team to reprogram device parameters through the app	Yes (≤1.5-T for Confirm Rx; ≤3-T for Assert-IQ)	3.0 g; 9.5 × 49 × 3.1 mm (Confirm Rx); 9.4 × 46.5 × 3.1 mm (Assert)
Biotronik (Berlin, Germany) Biomonitor III/ IIIm[140]	Silicone coating; device has greatest distance between second electrode and device for long-sensing vector, Biomonitor IIIm allows remote monitoring of fever and other parameters	95.4 ± 13.3%	76.3 ± 38.7%	5.5 y	Data sent via home transmitter to home monitoring service	Device can be reprogrammed or customized during in-office visits	Yes, 1.5- or 3-T	4.0 g; 8.6 x 77.5 x 4.6 mm

AF = atrial fibrillation; AI = artificial intelligence; FDA = U.S. Food and Drug Administration; HR = heart rate; PPV = positive predictive value; MRI = magnetic resonance imaging; T = Tesla.

stroke to ICM vs external loop recorder; ICMs significantly outperformed external loop recorders in AF detection at 12 months (15.3% vs 4.7%; $P = 0.003$).[141] The multicenter randomized STROKE-AF trial compared ICM vs local usual care, including 12-lead ECGs, Holter monitoring, telemetry, or event recorders in nearly 500 patients with large- or small-vessel stroke; AF detection was significantly higher in the ICM group than the patch monitor group (12.1% vs 1.8%; HR: 7.4; $P < 0.001$).[33] A meta-analysis of three randomized clinical trials [RCTs]) comparing ICM with that of control subjects (the latter of which included Holter, event monitoring, or mobile telemetry) after ischemic stroke demonstrated a 12-month AF detection of 13% in the ICM group and 2.4% in the control group (odds ratio [OR]: 5.75; [95% CI: 3.24-10.18]; $P < 0.00001$).[142] Another recent meta-analysis of 5 RCTs and 3 observational studies that included 2,994 patients undergoing cardiac poststroke rhythm monitoring after a stroke again confirmed higher AF detection in patients receiving prolonged cardiac monitoring, with the ICM subgroup specifically having a higher likelihood of AF detection than wearable external monitors.[143]

4.5.4. Role of ICMs in Guiding Anticoagulation

Whether the AF detected by long-term cardiac monitoring results in a change in stroke outcome remains to be seen. The previously mentioned meta-analysis found that while long-term rhythm monitoring was associated with a lower risk of recurrent stroke in observational studies (RR: 0.29 [95% CI: 0.15-0.59]), this was not true for RCTs (RR: 0.72 [95% CI: 0.49-1.07]).[143] The more recent LOOP (Implantable Loop Recorder Detection of Atrial Fibrillation to Prevent Stroke) trial randomized 6,004 patients >70 to 90 years of age with AF risk factors but no history of AF to

either ICM or usual care. Although 3-fold more patients in the ICM than control group were diagnosed with AF lasting >6 minutes (31.8% vs 12.2%, median follow-up 39.3 months; $P < 0.0001$) and were subsequently started on oral anticoagulation (29.7% vs 13.1%; $P < 0.0001$), there were no significant differences in bleeding between groups or reduction in stroke or systemic embolism (5.6% vs 4.5%, median follow-up 64.5 months; HR: 0.80; $P = 0.11$).[144] A subsequent post-hoc analysis of the LOOP trial showed no statistically significant reduction in disabling or lethal stroke with ICMs (HR: 0.69 [95% CI: 0.44-1.09]; $P = 0.11$), with subgroup analyses also showing no benefit in patients with prior stroke (HR: 1.13; [95% CI: 0.54-2.32]; $P = 0.75$) or prior stroke, TIA, or systemic embolism (HR: 0.98 [95% CI: 0.51-1.88]; $P = 0.96$).[145] However, there were several limitations to this study. The time to event curves overlapped during the first 2 to 3 years, then diverged with increased events rates in the control group during longer follow-up. In a prespecified sensitivity analysis of primary outcome that included only participants receiving their assigned intervention (ICM or control) for ≥3 years or until AF detection, death, or the primary outcome, there was a significant reduction in stroke or systemic embolism per protocol analysis (3.9% in ICM group vs 5.6% control; HR: 0.75; [95% CI: 0.56-1.00]; $P = 0.047$). Detection of AF was significantly higher than anticipated in the control group. In addition, AF detected in the control group may have been of longer duration than in the ICM group, and the 6-minute diagnostic threshold used in the study may be lower than AF diagnosed by usual care. These factors may have reduced the stroke risk associated with shorter episodes detected in the ICM group, increasing the likelihood that this study was underpowered. Whereas the NOAH-AFNET 6 study concluded no reduction in the combination of stroke or death when anticoagulating AF events across 6 minutes, the more recent ARTESIA trial and a combined meta-analysis of both trials demonstrated reduced rates of stroke or systemic embolism with treatment of device-detected events.[26] The ongoing SAFFO (Detection of Silent Atrial Fibrillation aFter Ischemic StrOke) prospective, multicenter, RCT exploring the effects of ICM in secondary stroke prevention, the Find-AF2 study, and a subanalysis of ARTESIA patients who had previous strokes should also provide additional insights.[146,147]

4.5.5. Current Guidelines

Current ACC/AHA/ACCP/HRS guidelines provide a Class 2a recommendation stating that in patients with stroke or TIA of undetermined cause, initial cardiac monitoring and, if needed, extended monitoring with an ICM are reasonable to improve detection of AF.[6] The European Society of Cardiology guidelines recommend monitoring for AF using a short-term ECG recording for at least the first 24 hours, followed by continuous ECG monitoring for ≥72 hours in patients with acute ischemic stroke or TIA and without previously known AF (Class 1 recommendation).[148] Further, in selected stroke patients without previously known AF, additional long-term noninvasive ECG monitors or ICMs to detect AF should be considered to detect AF (Class 2a recommendation).[148] Current guideline recommendations regarding treatment of AF detected by implanted devices are also shown in **Table 3**.

4.6. Consumer Monitors

4.6.1. Discussion of Consumer Devices Available

Consumer devices are playing an increasing role in health management, although their utility is limited by questionable data quality and a potentially overwhelming quantity of data.[149] Devices equipped with ECG capabilities, either independently or in combination with PPG technology, are superior in determining the heart rhythm.[150] Many of the PPG and ECG devices have the notable limitation of requiring direct skin contact for accurate readings, which can be challenging with wearable devices, particularly during exercise. Although options like chest straps, medical earbuds, smart rings, and even smart clothing are available, they are less popular among consumers compared with smartwatches and handheld ECG devices.

Several smartwatches and handheld ECG devices can detect AF (**Table 6**). Currently available smartwatches that have FDA 510(k) clearance for this indication include devices made by Apple (Apple Inc), Fitbit (Google Fitbit), Samsung (Samsung Electronics), Google, and Withings. These devices utilize both PPG and ECG capabilities to identify irregular rhythms. It is important to highlight that not all smartwatches have ECG functionality and that the largest trials to date using wearable devices for the detection of AF used PPG-based software without ECG capability.[151-153] Even when ECG functionality is utilized, it requires active measurement by the wearer. Passive utilization by PPG is only sampled a few times per every 2 hours.[154] Most studies evaluating wearable devices (Apple Heart Study, Health eHeart Study, Fitbit Study, Apple Watch 4 Study) excluded inconclusive tracings from their analysis, which may bias the reported sensitivity and specificity of these devices. Additionally, most studies of wearable devices were validated in patients who were in their 40s and 50s. When head-to-head comparisons of 5 common wearables were performed, the sensitivity and specificity of the devices was lower than manufacturer reports.[155]

Importantly, there are no prospective studies that have demonstrated the ability of wearable devices to improve clinical outcomes in patients with a prior ischemic stroke, although ongoing research is seeking to evaluate this.[164]

TABLE 6 Consumer-Grade Cardiac Rhythm Monitoring Devices. FDA-Cleared, Clinically Studied, Commonly Utilized

Device	Technology	Sensor	Monitoring	FDA Class/510(k) Number
Apple Watch Series 4-7 (Apple Inc, Cupertino, California, USA)[153,156]	Smartwatch	PPG and ECG	Intermittent sampling (PPG) and spot-check (ECG)	K213971 (PPG) K201525 (ECG)
Fitbit Sense (Google Fitbit, San Francisco, California, USA)[152,157]	Smartwatch	PPG and ECG	Intermittent sampling (PPG) and spot-check (ECG)	K200948
Samsung Galaxy Watch 2, 3 (Samsung Electronics, Suwon-si, South Korea)[155,158,159]	Smartwatch	PPG and ECG	Intermittent sampling (PPG) and spot-check (ECG)	
Google Verily Study Watch (Google, Mountain View, California, USA)[160]	Smartwatch	PPG and ECG	Intermittent sampling (PPG) and spot-check (ECG)	K182456
Withings ScanWatch, Move ECG (Withings, Issy-les-Moulineaux, France)[158,161,162]	Smartwatch	PPG and ECG	Intermittent sampling (PPG) and spot-check (ECG)	K201456
KardiaMobile® (AliveCor, Mountain View, California, USA)[163]	Handheld ECG device	ECG	On-demand Spot-check	K211668

ECG = electrocardiogram; FDA = U.S. Food and Drug Administration; PPG = photoplethysmography.

Currently available handheld ECG devices include the KardiaMobile device (AliveCor), which has regulatory clearance in the United States and the Zenicor device (Zenicor), which has regulatory clearance in Europe. These handheld devices may be utilized for occasional rhythm checks. Sustained surveillance may not be practical, and short but clinically significant episodes of AF may not be detected.

Currently, medical-grade monitors, including patch ECGs, ICMs, and the 12-lead ECG, remain the gold standard for the detection of AF. Although patients and their clinicians may choose to utilize consumer-grade devices for ambulatory monitoring after an ischemic stroke, they must be aware of the limitations. Wearable devices must be periodically charged and therefore cannot be worn 24 hours per day. Current models do not provide continuous rhythm monitoring by PPG or by ECG. Monitoring is intermittent and is only performed when the patient is at rest. AF recognition algorithms are limited to certain heart rate ranges. Additionally, atrial flutter often creates a regular rhythm, which may not be detected by the PPG tachogram notification algorithm. Finally, because motion artifact and suboptimal fidelity remain issues with recordings from these devices, tracings still require physician interpretation because automated diagnoses may be inaccurate.[111,155]

4.6.2. Situations When Consumer Monitoring Devices May Be Helpful

Although medical-grade monitoring is the SoC for patients with prior CS, there are several cases where consumer monitors may be useful. These include patients who cannot tolerate an external cardiac monitor and refuse an implantable one, or when access to medical-grade monitors or clinicians qualified to interpret them is limited. Consumer monitoring may also provide a long-term method of following symptomatic or asymptomatic arrhythmias once medical-grade monitoring has been completed.

4.6.3. Engagement and Empowerment

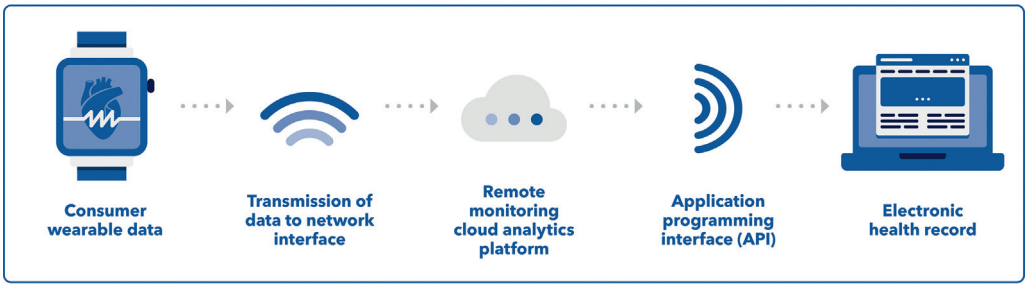
Patient empowerment is the ability for patients to be responsible for one's own healthcare, change in symptoms, and self-management facilitated by members of the clinical team. A recent analysis showed that the use of mobile health technologies may help assist poststroke patients collectively with self-management and self-care.[165] Successful use of consumer-grade devices requires a partnership between clinicians and patients and a shared plan for the incorporation of digital healthcare.[111] Ideally, the use of consumer devices may decrease the need for office visits and ECGs, especially whether recordings are transmitted through electronic medical records for review.

4.6.4. Behavior Changes and Risk Factor Modifications

Clinical correlation with consumer-grade devices allows patients to recognize arrhythmia triggers, which can facilitate risk-factor modification and medication adherence. The I-STOP-AFib (Individualized Studies of Triggers of Paroxysmal Atrial Fibrillation) randomized study showed a reduction in AF events detected by a smartphone mobile application when patients changed behaviors they viewed as triggers (adjusted RR: 0.60; $P < 0.001$).[166] This may help lead to reduced emergency and urgent care visits.

Consumer monitoring devices provide an opportunity for ongoing arrhythmia surveillance for patients with a history of stroke. Given that consumer PPG sampling algorithms are not intended to detect AF episodes <30 minutes, medical-grade external and internal monitoring devices remain the gold standard.[153] Consumer

FIGURE 3 Process of Integrating Patient-Level Data Into the Electronic Health Record



Integration of patient-level data from a consumer monitor requires the following: 1) electronic transmission of data to a network interface; 2) movement and evaluation by a cloud analytics platform; 3) conversion into an application programming interface; followed by 4) storage in the electronic health record.

devices do provide patients with additional real-time monitoring that is more convenient, assists with more timely diagnosis, and promotes long-term patient engagement.

4.6.5. Situations When Consumer Monitoring Devices May Not Be Helpful

There are limitations to consumer monitoring devices that may make them less helpful in certain clinical situations.[149] Unfortunately, these devices are not readily available to all patients. For example, patients with cognitive impairments, especially those after a stroke, may not be able to utilize these technologies. Also of great importance is that many patients cannot afford the device or smartphone that is often required.

For clinicians, it has become increasingly cumbersome to monitor and verify these devices given the lack of supportive databases or staff to interpret, report, and manage the data. Although we have seen early adoption by some cardiologists and many cardiac electrophysiologists, uptake within primary care remains low.[167]

Despite broad acceptance by consumers in purchasing these devices, device ECG outputs can be suboptimal with indeterminate results that are difficult for clinicians to interpret.[155] Consumers should receive guidance on both the best type of device to purchase and the most effective way to utilize it. Effective use involves education in interpreting results and how to manage detected arrhythmias.[168]

False alarms are a serious concern, which may lead to unnecessary anxiety, additional testing, and treatment.[169] Conversely, false-negatives may lead to false reassurance. Individuals may equate normal rhythms with a healthy heart.

Although consumer monitoring devices are a great advancement in healthcare, they are putting additional strain on limited healthcare resources. They are also at times contributing to increased patient anxiety and unnecessary testing.[131] Finally, the cost of these devices may lead to healthcare disparities in care, especially in patients who may be at highest risk.[170]

4.6.6. Integration of Outputs From Consumer Devices Into the Electronic Health Record and to the Practitioner

The current U.S. market for consumer monitoring devices is growing rapidly, with a projection to reach $383.5 billion by 2032 (up from $95.7 billion in 2022).[171] With this shift to remote monitoring technology comes the issue of processing and allowing meaningful clinical use of raw data collected at the patient level. While existing platforms may allow a patient to send a PDF file to be uploaded into the electronic health record (EHR), more seamless data transmission is desired. Integration of patient data into the EHR is a 3-step process requiring a consumer monitor that collects the patient data, a network interface that enables transfer of the data to a remote monitoring cloud analytics platform (where raw data are processed by a third party), and an application programming interface, which enables access of the data for clinical management.[172] Application programming interfaces bridge the gap between the clinician and third parties by providing a common interface that enables the exchange of data through automated and predictable processes across various computer systems.[173-175] Given variability in EHR platforms, the wide variety of consumer applications available, and concern for patient safety and quality, the Office of the National Coordinator for Health Information Technology (IT) enacted the 21st Century Cures Act, which integrates third-party apps within EHRs by requiring developers to adopt secure application programming interfaces using the Health Level Seven Fast Healthcare Interoperability Resources

data exchange standards. Additionally, The Office of the National Coordinator for Health IT implemented key provisions of the Cures Act to advance interoperability and support the access, exchange, and use of electronic health information, including the Office of the National Coordinator for Health IT Health IT Certification Program certification criterion and funding the Substitutable Medical Apps & Reusable Technology (SMART) program.[176] These programs were designed to allow a flexible healthcare IT ecosystem to foster innovation, consumer choice, and product scalability.[174]

Unfortunately, the transfer process depicted (**Figure 3**) requires extensive infrastructure, along with administrative and personnel support. Decisions regarding which consumer devices will be integrated into the EHR are institution-specific, requiring extensive data agreements. To circumvent this issue, many consumer wearable devices have settled for patient-facing platforms that allow patients to print ECG recordings and other salient data, providing them to clinicians during office visits. This process assumes that the patient can navigate smartphone technology and has access to the necessary technological and financial resources. Considerations should also be made for the burdens placed on patients with lower health literacy. Thus, thoughtful consideration toward patient preferences and circumstances should be a key element in the clinical management process.

4.6.7. How to Integrate Consumer Monitoring Outputs Into SDM

More choices for healthcare monitoring do not necessarily translate to better utility for clinical management or decision making.[177] There is a complex interconnection between individual social context, consumer health beliefs, patient perception of information accuracy, and perceived usefulness of consumer monitoring devices, with the latter having a significant impact on integrating findings into long-term healthcare decision making.[177] Given that there are a variety of mechanisms that contribute to stroke, discussion on the integrity of data collected through use of consumer devices, implications for clinical management, and potential limitations should be addressed. Legislation such as The U.S. Affordable Care Act integrated SDM by way of decision aids into routine clinical care, along with the Centers for Medicare & Medicaid Services, which in certain instances, mandated their use for reimbursement as a central component of value-based care.[178] It is imperative that clinicians engage in SDM with patients when discussing options for post-stroke monitoring and subsequent management strategies. In this context, SDM should be understood as engaging patients as collaborators to determine a clinical approach that responds well to their situation (improves clinical outcomes), makes practical sense (is feasible in the lives of the patient), makes intellectual sense (relies on evidence-based medicine), and makes emotional sense (for each patient the plan feels like the right thing to do).[178-182] There are a multitude of approaches available to clinicians to incorporate SDM, including professional development and education utilizing the Agency for Healthcare Research and Quality's Seek Health Activate Reach Evaluate (SHARE) approach, education on therapeutic communication, incorporation of patient decision aids, and use of trained decision coaches.[178,182] Several SDM aids exist to support anticoagulation choice in the setting of confirmed AF/atrial flutter.[183] Given that patients with low health literacy and numeracy may have difficulty understanding numerical risk/benefit information, clinicians should incorporate the use of a decision aid that includes diagrams or icon arrays.[178] There is an opportunity for integration of SDM into consumer wearable applications on both the clinician- and patient-facing sides, with some applications currently supporting a summary of the SDM process, including risk calculations that patients can present to their cardiologists.

4.7. Conclusion

With the publication of recently updated and new stroke and AF guidelines, there is growing consensus on the role of cardiac rhythm monitoring in patients after a stroke that is informed by outcomes of several recent landmark trials. Although improved monitoring leads to improved detection of arrhythmia after a stroke, there remains less clarity on the effect this detection has on secondary stroke prevention. Given the variety of heart rhythm monitoring devices available in both the medical and consumer space, a consistent approach to understanding, interpreting, and handling device data will be key in guiding future utilization.

PRESIDENT AND STAFF

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APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2024 ACC EXPERT CONSENSUS DECISION PATHWAY ON PRACTICAL APPROACHES FOR ARRHYTHMIA MONITORING AFTER STROKE

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ACC = American College of Cardiology; AHA = American Heart Association; AMA = American Medical Association; JAMA = *Journal of the American Medical Association;* CDRH = Center for Devices and Radiological Health; EP = electrophysiology; FDA = U.S. Food and Drug Administration.

APPENDIX 3. ABBREVIATIONS

ACC = American College of Cardiology
ACCP = American College of Clinical Pharmacy
AF = atrial fibrillation
AHA = American Heart Association
ASA = American Stroke Association
CHA_2DS_2-VASc = congestive heart failure, hypertension, diabetes, previous stroke/ischemic attack, vascular disease, and sex
CHASE-LESS = Coronary, Heart failure, Age, stroke SEverity, LipidEmia, Sugar, prior Stroke
CS = cryptogenic stroke
ECG = electrocardiogram
ECDP = expert consensus decision pathway
EHR = electronic health record
ESUS = embolic stroke of underdetermined source
FDA = U.S. Food and Drug Administration
HF = heart failure
HR = hazard ratio
HRS = Heart Rhythm Society
ICM = insertable cardiac monitor
PPG = photoplethysmography
RCT = randomized clinical trial
RR = relative risk
SDM = shared decision making
SoC = standard of care
TIA = transient ischemic attack