Post-Embolic Rhythm Detection with Implantable versus External Monitoring (PER DIEM) Pilot Feasibility Study

Protocol/version #:	4.0
Current Version Date:	February 22, 2016
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Trial Registration ClinicalTrials.gov Identifier: NCT02428140

Summary of PERDIEM study protocol changes

Version	Date Approved	Changes from the previous version
1.0	Jan 29, 2015	**Original protocol**
2.0	March 18, 2015	**Changes from v1.0** -inclusion minimum age changed from 50 to 18 years old -added requirement for at least 1 ECG as part of the etiologic workup -excluded patients with workup that included >48 hours of external ECG monitoring -allowed the inclusion of patients with transient deficits if CT/MRI showed evidence of infarction -removed plan for MRI scan at baseline and 12 months -removed cognitive testing from study visits -changed study visit schedule from 90 days and 1 year to 30 days, 6 months, 12 months
3.0	August 4, 2015	**Changes from v2.0** -changed inclusion to specify that patients must be enrolled within 6 months of the index event
4.0	Feb 22, 2016	**Changes from v3.0** -changed study visits from exclusively clinic-based to allow either clinic **or telephone study** visits -changed exclusion from "any condition with an indication for anticoagulation" to "any condition with **an evidence-based indication** for long term OAC"
4.0r	April 26, 2016	**Changes from v4.0** -the device adjudication process and the study AF reporting document were amended to the protocol -the primary outcome was defined as definite atrial fibrillation lasting 2 minutes or more, including atrial flutter [a] - removed the statement that the primary outcome requires a change in antithrombotic medication [b]

[a] The decision to change the study endpoint to **definite AF lasting 2 minutes or more, including atrial flutter** was finalized by the steering committee on April 26, 2016, before the adjudication of any device data. The change was made due to technical limitations of the AF detection algorithm for the Medtronic LINQ implantable loop recorder studied. The shortest time over which the LINQ device can make a reliable assessment for AF is 2 minutes. The new endpoint was indicated in an adjudication document that was attached to the protocol

[b] There was consensus from study investigators that 2 minutes or longer of **definite AF** in the setting of a recent stroke was likely to always be clinically actionable. The requirement for a change in antithrombotic medication was felt redundant and removed from the endpoint description.

List of Abbreviations

ADC	apparent diffusion coefficient
AF	atrial fibrillation
CRF	case report form
CT	computerized tomography
CTA	computerized tomography angiogram
DWI	diffusion-weighted imaging
ECG	electrocardiogram
ELR	external loop recorder
FLAIR	fluid-attenuated inversion recovery
GRE	gradient recalled echo
ICD	implantable cardiac defibrillator
ILR	implantable loop recorder
MRA	magnetic resonance angiogram
MRI	magnetic resonance imaging
OAC	oral anticoagulant
OCSP	Oxfordshire Classification of Stroke Program
REB	research ethics board
TIA	transient ischemic attack
TOAST	Test of Orgaran in Stroke Trial

1.0 BACKGROUND AND RATIONALE

Stroke is a leading cause of death and disability worldwide. In Canada, there are approximately 38,000 ischemic stroke admissions to hospital per year with an average annual cost estimated at 2.8 billion dollars.(1) Cardiac embolism is the cause of approximately 25% of ischemic strokes(2) with majority of these due to atrial fibrillation (AF).(3) Cardio-embolic stroke event rates are projected to rise in the next three decades, as the prevalence of AF increases with an aging population. The diagnosis of AF in stroke patients is particularly important since it typically results in prescription of antiplatelet to oral anticoagulant (OAC) therapies(4) that have been shown to reduce the risk of recurrent stroke by up to 63%.(5)

AF can be difficult to detect as it is often intermittent (paroxysmal) and most patients are asymptomatic.(6) In 25-30% of ischemic strokes no cause is established despite thorough diagnostic workup (cryptogenic stroke). Undiagnosed paroxysmal AF has been hypothesized to be the cause of a substantial proportion of cryptogenic strokes. Furthermore, determining TIA/stroke etiology is imperfect and often is complicated by the presence of coexisting causes.(7) It is likely that a sizable number of patients in whom a TIA/stroke has been attributed to an abnormality other than AF (non-cryptogenic stroke) will have AF detected if adequately investigated with prolonged ECG monitoring.(8)

Given superiority of OAC therapy in secondary stroke prevention in AF, detection of paroxysmal AF in in all regardless of putative mechanism is of particular clinical relevance. Intermittent ambulatory electrocardiographic (ECG) assessment (Holter) is typically used for detection of paroxysmal AF after a stroke. However, this approach has a very low diagnostic yield in detecting a clinically actionable ECG diagnosis (4%-6%).(9) Cardiac ultrasound (echocardiography) is also routinely ordered after a stroke, but has a diagnostic yield of only 1% and rarely alters clinical management.

It is typical for a patient to undergo multiple ECGs, Holters and an echocardiogram after a stroke at significant cost (> $1,000), but low diagnostic yield (< 5%).

The question of whether prolonged ECG monitoring with an external event triggered external loop recorder (ELR) can improve the detection of paroxysmal AF after cryptogenic stroke was addressed in the recently completed EMBRACE trial.(10) In EMBRACE, paroxysmal AF (> 30 seconds) was detected in 16% of stroke patients compared to only 3% with a repeat 24 hour Holter. It is not known whether even more prolonged ECG recording will increase the diagnostic yield further. However, it is likely that extended monitoring will identify a greater number of patients with paroxysmal AF given the infrequent nature of AF. Nonetheless, this is being addressed in the CRYSTAL-AF trial in which stroke patients undergo 12 months of continuous rhythm monitoring using a surgically implanted subcutaneous implantable ECG monitor termed implantable loop recorder (ILR).(11)

ECG monitoring has evolved greatly. While 24 to 48-hour recordings were once the only option, with the EMBRACE and CRYSTAL-AF trials we expect extended ECG monitoring will become the standard of care in the work-up of patients with embolic stroke. Yet the ideal target stroke patient population and the most cost-effective strategy to translate these clinical trials into practice remains unclear.

Long-term external recorders offer the potential to detect AF at a modest increase in cost but they suffer from three limitations; namely signal quality, compliance, and time delays in getting the diagnostic information to clinicians. The other option for long-term ECG monitoring is an ILR device. For example, the Medtronic LINQ REVEAL is a new miniaturized recorder that can be implanted in the outpatient clinic setting and is associated with minimal risks. It is linked to a wireless remote monitoring system, allowing long-term high quality ECG recordings and the capacity for early detection of AF and implementation of augmented antiplatelet or OAC where appropriate. This system is equipped with remote cardiac rhythm monitoring, where the collection of device data occurs in the patient's home with minimal patient interaction (i.e., wireless transmission). Cardiac rhythm data are then uploaded to a secure site for review, and appropriate intervention. ILR has disadvantages; specifically they are invasive, non-reusable and carry a significant upfront cost. While ILR may provide a more comprehensive estimate of the total burden of AF the clinical relevance is unclear. Furthermore, there are no data on the relative cost-effectiveness of ILR versus an ELR for the diagnostic work-up after a stroke.

Whether the additional cost of an ILR is warranted, the relative diagnostic accuracy of external versus internal ECG assessment, compliance with external ECG monitoring, as well as the costs related to prolonged ELR versus ILR assessments balanced with potential reduction in recurrent stroke with early targeted OAC therapy are all important and unanswered questions which this aspect a pivotal trial will address. The pilot phase will assess whether a pivotal trial is warranted and collect important interim data

2.0 STUDY OBJECTIVES

The aim of the pilot is to assess feasibility of a pivotal trial. If successful, we will proceed with a pivotal trial assessing cost-effectiveness. The pilot will assess feasibility in terms of recruitment, data collection, and rates of clinically actionable rhythm detection; that is identification of an atrial arrhythmia that results in initiation of additional anti-platelet or OAC therapy as per usual clinical practice. Unlike prior studies, this trial will include stroke/TIA patients without known AF with both cryptogenic and known stroke mechanisms.

2.1 Hypotheses:

1. Both strategies are feasible and can be implemented in a large geographic region (Alberta).
2. The implantable loop recorder (ILR) plus remote monitoring will diagnose more paroxysmal AF / atrial flutter and provide better assessment of the total burden of

AF resulting in a greater proportion of patients started on an OAC versus the external loop recorder (ELR) strategy.

3.0 METHODS

3.1 Study Design: Randomized, open label trial comparing two different extended ECG monitoring strategies for the detection of paroxysmal AF / atrial flutter after ischemic stroke or transient ischemic attack (TIA).

3.2 Selections of Subjects

Inclusion Criteria:

1. Informed consent from the patient
2. Age ≥ 18 years
3. Diagnosis of the index event* made by a stroke specialist of an acute ischemic stroke or TIA occurring within the last 6 months. The event must be either:
   i) arterial ischemic stroke confirmed by neuroimaging; or ii) transient ischemic attack with DWI positive lesion on MRI
4. The patient is expected to survive at least 6 months
5. At least one 12-lead ECG has already been obtained as part of the routine clinical post-stroke/TIA work-up, and no ECGs have shown any episodes of atrial fibrillation or atrial flutter
6. The patient is being actively investigated for the etiology of the stroke/TIA event and additional cardiac monitoring is desired to screen further for the possibility of occult paroxysmal atrial fibrillation/flutter

Exclusion Criteria:

1. Previously documented atrial fibrillation/flutter.
2. Planned carotid endarterectomy or carotid artery stenting within 90 days.
3. Any condition for which there is already an evidenced-based indication for long term OAC.
4. Pacemaker or ICD device that would allow for detection of AF / atrial flutter.
5. Work-up for stroke that has already included extended (>48 hours) external ECG.
6. Stroke and/or comorbid illness will prevent completion of planned follow-up assessments.

3.3 Study Enrollment Process

The study will be conducted over 24-30 months. A total of 300 patients will be recruited during from inpatient stroke units and stroke prevention clinics at the Foothills Medical Centre, University of Alberta Hospitals, and Grey Nuns Community Hospital using standard of care screening methods. Eligible patients will be randomized in a 1:1 ratio to receive either an ILR coupled with remote monitoring for 12 months versus an ELR for 30 days. A centralized web based randomization process will be used. Patients will be randomized in

small, variable block sizes. Both groups of patients will receive the best standard of care for secondary stroke prevention based on the Canadian best practices guidelines.(12)

Monitoring with ELR for 30 days
The ELR group will be fitted with a battery operated SpiderFlash-t (Sorin Group, USA) auto-triggered ELR and will be provided with a diary to track total hours worn per day and any clinical symptoms.

ILR with remote monitoring for 12 months
The ILR plus remote monitoring group will have a Health Canada approved Medtronic Reveal LINQ device surgically implanted. This is a miniaturized recorder about the size of a clip on a pen (44.8 mm x 7.2 mm x 4.0mm) (Figure 1a). It can be readily inserted in a procedure room with a very low risk of complications. It will be linked to a wireless (cellular) remote monitoring system (MyCareLink) (Figure 1b).

3.4 Study Assessments (see Appendix I)

Baseline Visit (Day 0)
During this visit patients will be assessed for eligibility. Demographic information, medical history, vitals, height, weight, antithrombotic medication, diagnosis of stroke subtype (using the Oxfordshire Classification of Stroke Program; OCSP), etiology (using the Test of Orgaran in Stroke Trial (TOAST) criteria)(13), and a calculation to determine stroke risk related to atrial fibrillation (CHA2Ds2-VASC) will be collected and recorded in a case report form (CRF). Baseline stroke severity (NIHSS), health status (EQ-5D), and global disability (modified Rankin scale using structure interview)(15) will also be completed. The results of etiologic investigations performed prior to enrolment and as part of clinical care including Holter monitor, echocardiography, neuroimaging (CT and/or MRI) and vascular imaging will be collected.

Patients who are randomized to receive 30-day cardiac event monitoring will be asked to complete a patient diary on a daily basis to monitor the daily number of hours the monitor is worn.

Day 30 (± 7 days)
This visit will be used to collect information about etiologic investigations related to the index stroke completed since the baseline visit. The study physician will determine if there has been any new stroke / TIA and cardiac events, new diagnoses of atrial fibrillation, and changes in medications including antithrombotic agents. In patients with the ILR the implantation site will be examined. In addition, patients will have vital signs completed and an ECG.

6 month (± 2 weeks) Follow-Up
This visit may be completed by Telephone call or in clinic. During this visit subject detailed review of medical history. Blood pressure and pulse will be obtained at this visit. EQ-5D and modified Rankin will be repeated. New diagnosis of atrial fibrillation, stroke / TIA,

cardiac events and current antithrombotic medications will be recorded. 12-lead ECG will be obtained.

If the visit is completed via the phone: Blood Pressure and Pulse will be obtained if the subject has a home Blood pressure cuff, otherwise this will not be collected. The EQ-5D will be completed over the phone and the caller will record the subject's response. The subject will be asked to go for an ECG after the call has been completed.

1 and 2 year (± 4 weeks) Follow-Up
This visit will be conducted by telephone. Patients will be contacted to collect data about any new diagnosis of atrial fibrillation, stroke / TIA, cardiac events and changes in antithrombotic medications.

4.0 STUDY OUTCOMES

Primary Outcome

The primary outcome will be the rate of detection of an atrial arrhythmia (AF / atrial flutter) that results in initiation of additional anti-platelet or OAC therapy as per usual clinical practice.

Secondary Outcomes:

1. Recruitment rates.
2. Compliance with assigned therapy (accept ILR, conduct at least 80% of ELR assessments)
3. Time to detection of first episode of atrial fibrillation / atrial flutter ≥ 30 seconds.
4. Costs for all cardiac and non-cardiac investigations related to etiologic workup of index stroke / TIA.
5. Total duration of any detected atrial fibrillation / atrial flutter.
6. Study related adverse events / serious adverse events.
7. Clinical recurrence of ischemic stroke / TIA, death, hemorrhagic stroke, major adverse bleeding, or death.
8. Association between baseline clinical characteristics (e.g. comorbidities, burden of supraventricular ectopy on Holter, left atrial dimension) and subsequent detection of AF

OUTCOME REPORT
If a subject experience any of the following a outcome report is to be completed following:

- New TIA – complete GUSTO
- New Ischemic Stroke – complete TOAST
- Intracranial Hemorrhage- Complete Intracranial Hemorrhage classification

- Other Bleeding event- complete GUSTO
- Newly Diagnosed Atrial Fibrillation/Atrial Flutter

Assessment of Adverse Events
All serious adverse events (per GCP guidelines) will be reported and described using the MEDRA classification and categorized as related or unrelated to the treatment strategy.

5.0 STATISTICAL METHODS

Sample Size and Power Calculation
A total of 300 patients will be randomized in the pilot phase. This sample size reflects 8% inflation for cross over (2% with either strategy) and loss to follow-up (5% in each group). This sample size provides 85% power to assess a clear difference in rates of atrial arrhythmia (AF / atrial flutter) that results in initiation of additional anti-platelet or OAC therapy between the two strategies (two- sided alpha of 5%). This estimate is based on the following assumptions:

1. Equal allocation (1:1) to ELR for 30 days vs. ILR plus remote monitoring for 12 months.
2. 10% rate of AF / atrial flutter that results in initiation of additional anti-platelet or OAC therapy in the ELR and 20% rate of this endpoint in the ILR plus remote monitoring group.

This estimate was derived using the Two Independent Proportions (Null Case) Power Analysis estimation method (PASS 2012).

6.0 Informed Consent Process

All participants will be given detailed oral and written information about the trial. Consent forms describing in detail the study intervention, study procedures and risks will be given to each participant and written documentation of informed consent is required prior to starting study medication/intervention. Participants must sign an informed consent document that has been approved by a participating centre's REB prior to any procedures being done specifically for the trial. Each participant should have sufficient opportunity to discuss the study and consider the information in the consent process prior to agreeing to participate. Participants may withdraw consent at any time during the course of the trial. The informed consent form will be signed and dated by the participant and the person who conducted the informed consent discussion. The original signed informed consent form will be retained in the participant's study files and a copy of the signed form will be provided to the participant.

7.0 Participant Confidentiality

All subject related information including Case Report Forms, evaluation forms, reports, etc. will be kept strictly confidential. All records will be kept in a secure, locked location and only research staff will have access to the records. Subjects will be identified only by means of a coded number specific to each subject. All computerized databases will identify subjects by numeric codes only, and will be password protected.

8.0 Data Management Responsibilities

Electronic data capture (REDCap: http://project-redcap.org/) will be used for this trial, meaning that all CRF data will be entered in electronic forms at the investigational site. Authorized study site personnel designated by the Investigator will complete data collection. Appropriate training and security measures will be completed with the Investigator and all authorized study site personnel prior to the study being initiated and any data being entered into the system for any study subjects. The study data will be housed on a secure in-house server and study documents will be retained for up to 25 years after completion of the study, or as required by Health Canada.

9.0 Source Documents and Access to Source Data/Documents

Each site must maintain appropriate medical and research records for this trial and regulatory/institutional requirements for the protection of confidentiality of study subjects. Source documentation should support the data collected on the CRF's. The Principal Investigator is responsible for assuring that the data collected are complete, accurate, and recorded in a timely manner. Access to the source documentation will be as per regulatory/institutional guidelines.

References:

1. Mittmann N, Seung SJ, Hill MD, Phillips SJ, Hachinski V, Coté R, et al. Impact of disability status on ischemic stroke costs in Canada in the first year. The Canadian Journal of Neurological Sciences. 2012;39(6):793-800.
2. Grau AJ, Weimar C, Buggle F, Heinrich A, Goertler M, Neumaier S, et al. Risk factors, outcome, and treatment in subtypes of ischemic stroke: the German stroke data bank. Stroke. 2001;32(11):2559-66.
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4. Furie KL, Kasner SE, Adams RJ, Albers GW, Bush RL, Fagan SC, et al. Guidelines for the prevention of stroke in patients with stroke or transient ischemic attack a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2011;42(1):227-76.
5. Connolly SJ, Eikelboom J, Joyner C, Diener H-C, Hart R, Golitsyn S, et al. Apixaban in patients with atrial fibrillation. New England Journal of Medicine. 2011;364(9):806-17.
6. Savelieva I, Camm AJ. Clinical relevance of silent atrial fibrillation: prevalence, prognosis, quality of life, and management. Journal of interventional cardiac electrophysiology. 2000;4(2):369-82.
7. Bogousslavsky J, Cachin C, Regli F, Despland P-A, Van Melle G, Kappenberger L. Cardiac sources of embolism and cerebral infarction—clinical consequences and vascular concomitants The Lausanne Stroke Registry. Neurology. 1991;41(6):855-.
8. Rabinstein AA, Fugate JE, Mandrekar J, Burns JD, Seet RC, Dupont SA, et al. Paroxysmal atrial fibrillation in cryptogenic stroke: a case-control study. Journal of stroke and cerebrovascular diseases : the official journal of National Stroke Association. 2013;22(8):1405-11.
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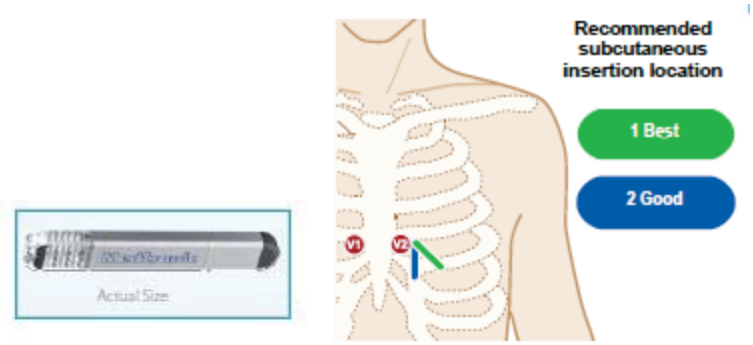
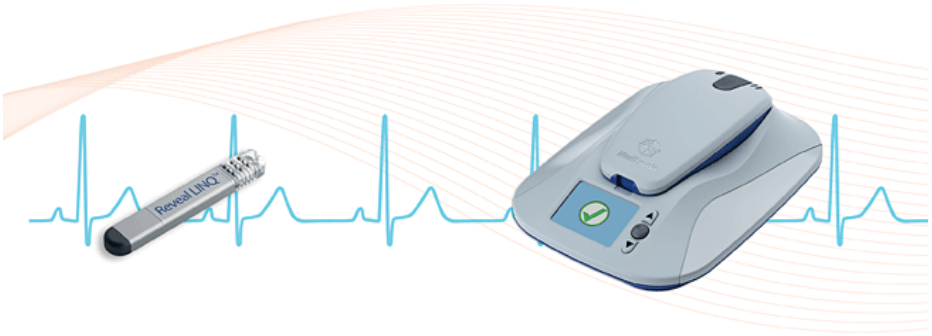
11. Sinha A-M, Diener H-C, Morillo CA, Sanna T, Bernstein RA, Di Lazzaro V, et al. Cryptogenic Stroke and underlying Atrial Fibrillation (CRYSTAL AF): design and rationale. American heart journal. 2010;160(1):36-41. e1.
12. Coutts S, Kelloway L. Stroke prevention. CANADIAN BEST PRACTICE RECOMMENDATIONS FOR STROKE CARE. 2012.
13. Adams HP, Bendixen BH, Kappelle LJ, Biller J, Love BB, Gordon DL, et al. Classification of subtype of acute ischemic stroke. Definitions for use in a multicenter clinical trial. TOAST. Trial of Org 10172 in Acute Stroke Treatment. Stroke. 1993;24(1):35-41..
15. Quinn TJ, Dawson J, Walters MR, Lees KR. Functional outcome measures in contemporary stroke trials. International Journal of Stroke. 2009;4(3):200-5.

Figure 1.

a) Reveal LINQ implanted cardiac monitor (actual size) and typical insertion site



b) MyCareLink wireless patient monitor



Appendix I: Schedule of Assessments

	Pre-study (routine clinical studies)	Baseline (Day 0)	Day 30 (±1 week)	6 months (± 2 weeks)	12 months +/- 4 weeks (telephone)	24 month +/-4 weeks (telephone)
Holter (optional)	X	*Reports collected*				
Echo (optional)	X	*Reports collected*				
Neuroimaging (CT or MRI)	X	*Reports collected*				
Vascular Imaging (CTA/MRA/doppler)	X	*Reports collected*				
ECG	X	*Reports collected*	X	X		
Informed consent, randomization		X				
Demographics		X				
Medical History		X			X	X
Vital signs		X*	X	X		
Antithrombotic and thrombolytic therapy		X	X	X	X	X
NIHSS		X				
CHA2DS2-VASc		X				
TIA/Stroke Subtype / Etiology (OCSS/TOAST)		X				
Modified Rankin		X		X		
EQ-5D		X		X		
Adverse event assessment		X	X	X	X	X
New stroke/TIA, cardiac events		X	X	X	X	X
Return monitor / compliance diary			X			

*Height and weight will be obtained at this visit only.

Appendix II: Oxfordshire Classification of Stroke Subtype

Oxfordshire Community Stroke Project Classification

TAC — Total Anterior Circulation Stroke

LAC — Lacunar Stroke

PAC — Partial Anterior Circulation Stroke

POC — Posterior Circulation Stroke

Code last letter as follows:

(S) — Syndrome: Indeterminate pathogenesis, prior to imaging (e.g., TACS)

(I) — Infarct (e.g., TACI)

(H)— Hemorrhage (e.g., TACH)

References

Bamford J, Sandercock P, Dennis M, Burn J, Warlow C. "Classification and natural history of clinically identifiable subtypes of cerebral infarction."
Lancet 22;337(8756):1521-6, 1991.

"How well does the Oxfordshire Community Stroke Project classification predict the site and size of the infarct on brain imaging?"
J Neurol Neurosurg Psychiatry 2000;68:558-562.

Appendix III: TOAST Classification for Etiological Stroke/TIA Diagnosis

For classification of the most likely cause of the index ischemic stroke or TIA event, the TOAST (Trial of ORG 10172 in Acute Stroke Treatment) criteria will be used. This classification should be completed by the enrolling study physician at baseline and at the 90-day follow-up.

The 5 major categories of the TOAST classification are as follows:

- large-artery atherosclerosis, including large-artery thrombosis and artery-to-artery embolism
- cardioembolism
- small-artery occlusion
- stroke of other determined cause
- stroke of undetermined cause.

For strokes of undetermined origin, 1 of 2 explanations is needed: (1) no cause was found despite an extensive evaluation or (2) a most likely cause could not be determined because more than 1 plausible cause was found.

The subtype definitions will be based on risk factor profiles, clinical features, and results of diagnostic tests. Diagnostic tests will include brain imaging, vascular imaging, ECG/Holter, and echocardiography.

Reference:

Goldstein LB, Jones MR, Matchar DB et al. Improving the reliability of stroke subgroup classification using the Trial of ORG 10172 in Acute Stroke Treatment (TOAST) criteria. Stroke 2001 May;32(5):1091-8.

Appendix IV: Modified Rankin Scale

Modified Rankin Scale Structured Interview (MRSSI)

0 = No symptoms at all; no limitations and no symptoms.

1 = No significant disability; symptoms present but not other limitations. Question: Does the person have difficulty reading or writing, difficulty speaking or finding the right word, problems with balance or coordination, visual problems, numbness (face, arms, legs, hands, feet), loss of movement (face, arms, legs, hands, feet), difficulty with swallowing, or other symptom resulting from stroke?

2 = Slight disability; limitations in participation in usual social roles, but independent for ADL. Questions: Has there been a change in the person's ability to work or look after others if these were roles before stroke? Has there been a change in the person's ability to participate in previous social and leisure activities? Has the person had problems with relationships or become isolated?

3 = Moderate disability; need for assistance with some instrumental ADL but not basic ADL. Question: Is assistance essential for preparing a simple meal, doing household chores, looking after money, shopping, or traveling locally?

4 = Moderately severe disability; need for assistance with some basic ADL, but not requiring constant care. Question: Is assistance essential for eating, using the toilet, daily hygiene, or walking?

5 = Severe disability; someone needs to be available at all times; care may be provided by either a trained or an untrained caregiver. Question: Does the person require constant care?

References

*Wilson, L. J. T., Harendran, A., Grant, M., Baird, T., Schultz, U. G. R., Muir, K. W., Bone, I. (2002). Improving the assessment of outcomes in stroke: Use of a structured interview to assign grades on the Modified Rankin Scale. Stroke, 33, 22432246.

PER DIEM Device Rhythm Adjudication Process (Instructions for Cardiac Device Nurses)

Calgary Device Nurses

Designated Cardiologists
Dr. Russell Quinn

Dr. Derek Exner

Process

1.0 ILR Device nurse checks on PER DIEM Carelink Clinic for Alerts MWF
2.0 Sends an email message to the designated adjudicating MD using the Rhythm template in the body of the email.(copy and paste or as a template*)
3.0 The e-mail message should have a standard subject line: "Rhythm Adjudication: <Subject number> <Alert/transmission date (YY/MM/DD)>"*
4.0 Naming Convention will be for Calgary patients FMC-study number (delete clinic number 45 as this is misleading): For Edmonton patients GNH-study number (we need the site prefixes as the study numbers are randomized per site and not for the whole study)
5.0 The designated MD will have 2 business days to respond
6.0 If there is no response to the email, the ILR device nurse will send a reminder email
7.0 As soon as the response is received the ILR nurse will send report to the Study Coordinators with a copy to the PI (Dr. Buck)

ILR Device Capabilities/Troubleshooting

1. Shortest duration of AF that Reveal LINQ can store is 2 minutes.

2. An "AF Alert" does not mean that the rhythm is definitely AF – this needs confirmed by a Cardiologist.

3. For PER DIEM the LINQ device is programmed to store AF Episodes with a duration of 2 minutes and longer. The nominal setting for Reason for Monitoring: Cryptogenic Stroke is "all episodes". Threshold Options are All Episodes, 6,10,20,60 minutes. For Cryptogenic stroke-use "all episodes".

4. When a patient is transferred from one clinic to another all of the device data is transferred. Care Alerts settings are not transferred from one clinic to another. They are set at the Root or Parent Clinic level. You can retrieve previous episodes by checking the episode tab.

5. The volume of Event Reports can be reduce by tailoring your Care Alerts to your patient population. You can reduce the duplication of episode review by marking the episode as reviewed under the Episode Tab.

6. If an Event Report for AF is received with "No Data Available" – please request that the patient send a manual transmission. This situation can occur with AF episodes <10 minutes in devices purchased prior to March 7, 2016.

7. You can reduce your false positives for under-sensing or over-sensing by reprogramming the LINQ device.

Please review the attached PDF file, indicate your responses below by marking with an "X" or highlighting the relevant answer and send your response within 2 business days of receipt to the sender.

1. Rhythm diagnosis (select one):

---- No Atrial Fib/Aflutter
---- Atrial Fib/Aflutter Possible
---- Atrial Fib/Aflutter Definite/ High Probability

Identify event number(s) containing definite AF:_____
Duration of longest episode: _____

2. Other significant arrhythmia(s) (select all that apply):

---- HR<40
---- HR>140
---- Sustained ventricular tachycardia / ventricular fibrillation
---- Complete heart block
---- Pause ≥5 s
---- Other, describe:_____

Identify event number(s) containing significant arrhythmia:_____

3. Quality of ECG recording (select one):

---- Excellent, atrial activity clearly visible or clearly absent
---- Moderate, atrial activity not reliably seen but rhythm interpretation possible on basis of R-R intervals alone
---- Poor, excessive noise, loss of contact

4. Request second reading by another cardiologist

---- Yes ---- No