

Policy for Clinical Physiologist performing Implantable Loop Recorder (ILR) Procedures

October 2018

DOCUMENT PROFILE

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CONTENTS LIST:

1. Introduction	Page 3
1.1 Rationale	
1.2 Scope	
1.3 Principles	
2. Policy / Guideline purpose	Page 5
3. Procedure	Page 5
3.1 Training and Competency	
3.2 Indemnity	
3.3 Accountability	
3.4 Audit	
3.5 Costs	
4. Development and consultation process	Page 7
5. Reference documents	Page 7
6. Glossary of terms	Page 8
7. Implementation plan	Page 8
8. Appendices	Page 8
Appendix 1 Standard Operating Procedure (SOP)	
Appendix 2 Torbay Hospital costings	

1. INTRODUCTION

1.1 Rationale

The Implantable Loop recorder (ILR) has been shown to be a powerful diagnostic tool for the diagnosis of unexplained recurrent syncope, unexplained episodes of palpitations and in long term-monitoring of patients at risk for or with documented atrial fibrillation (AF).

The existing ILR service in Jersey, introduced in 2010, has cemented itself as an important, unique and innovative diagnostic service in the wider cardiac and arrhythmia services setting.

Syncope: Syncope affects up to half the population in the UK at some point in their lives. Defined as spontaneous loss of consciousness with complete recovery, there are various causes, including cardiovascular disorders (which are the most common), neurological conditions such as epilepsy, and psychogenic attacks.

The diagnosis of the underlying cause of syncope is often inaccurate, inefficient and delayed. ILR's have provide extended rhythm monitoring for patients with syncope in whom a diagnosis of cardiac arrhythmia is suspected. (Nice guidelines)

Palpitations: ILR's also have an important role in the evaluation of patients with recurrent unexplained episodes of palpitations. In patients with infrequent episodes, short term ambulatory monitoring often fails to establish a diagnosis. The use of ILR's in this type of patients is safe, cost effective and has a high diagnostic yield. (Giada et al 2007)

Atrial Fibrillation: ILR's can provide long-term ECG monitoring in patients at risk for or with documented AF with improved AF detection algorithms reducing false positive outcomes. (Hindricks et al 2010)

The Future: ILR's may come to play an important role in cryptogenic stroke patients. The CRYSTAL-AF study is currently prospectively investigating whether ILR's improve the diagnostic yield over short-term ambulatory external ECG recording techniques in this patient population.

Finally, multiple trials are currently underway to assess the clinical utility of ILR's in patients who have undergone ablation of AF, using AF Burden for clinical treatment. Nice Guidelines, Medtech Innovation briefing published 16-02-18 stating 'Superior results: The ILR shows significantly higher rates of AF detection in cryptogenic stroke patients with 12.4% detection rate compared with conventional ECG monitoring with 2.0% after 12 months.

1.2 Scope

All patients who may benefit from an ILR implantation to aid their diagnosis or treatment and management options.

These patients will be assessed by the Cardiology team (medical or specialist nursing staff) and if it is considered that an ILR is required. The consultant cardiologist will review the patient's details and refer them to the Clinical Investigation Department (CID) using the ILR referral form. (Standard Operating procedure - Appendix 1)

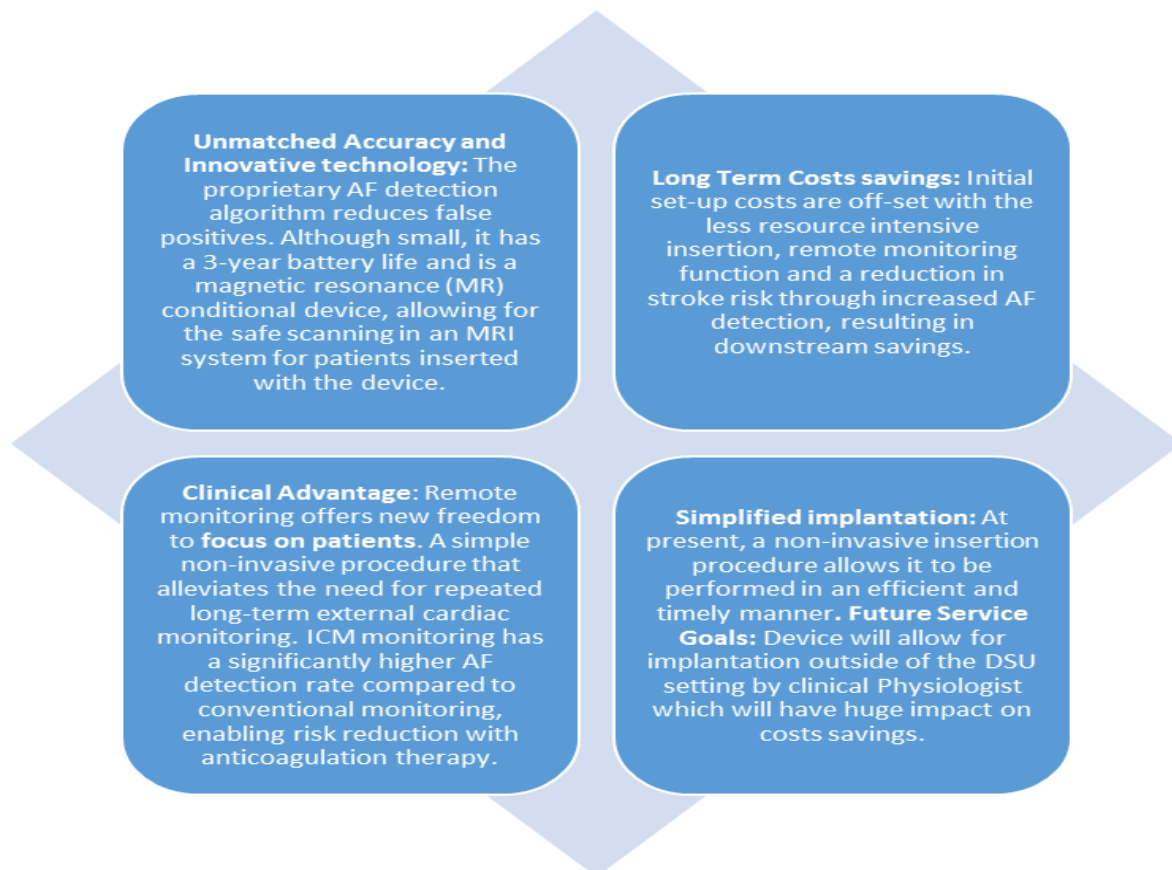
1.3 Principles

Historically, ILR procedures have been undertaken by cardiology consultants in Theatre settings. In Jersey, one cardiac consultant is responsible for all Cardiac Device implantation, the majority of which are performed in the Day Surgery Unit (DSU). Over the last 5-6 years there has been a rise in the number of other health professionals, such as Clinical Physiologists implanting these devices. In Centre's including Torbay and South Devon NHS trust, Central Manchester University NHS hospitals, St Thomas's Hospital, London and others.

Improvements identified and anticipated as a result of the implementation include;

- Increased flexibility and access to the service
- Provision of more cost effective service
- Continuity of care for the patient with skilled personnel
- Improving skill mix of necessary staff
- Streamlined referral and booking system
- Single point of expertise for patients and other health professionals
- Release of nursing and medical staff for other duties
- Release of time for Theatres/DSU for more necessary surgical operations

Advantages and benefits of ILR implantation



2. POLICY / GUIDELINE PURPOSE

Aim is to allow the Clinical Physiologist (CP) to acquire the knowledge and skills to widen their scope of professional practice to undertake implantation of ILR

3. CORPORATE PROCEDURE

Training and competency

The CP will be trained to perform the procedure by the consultant cardiologist, Dr AR Mitchell, although other agreed off site training may be necessary to obtain the number of implantations required for competency. The standard operating procedure (SOP) and associated forms for sign off by the consultant cardiologist can be found in the Appendix.

1. Theory and practice

- Video demonstration of procedure
- Practical demonstration from manufacturer
- Use of demonstration kits to practice procedure

2. Observations

- Observation of trained and experienced implanter (locally/offsite) – 10 procedures

3. Practical – direct supervision

- Demonstration and sign off of attached competencies
- Includes review of notes, consent, patient preparation and procedure.
- Minimum 20 procedures undertaken successfully and signed off by Consultant cardiologist

4. Indirect supervision

- Further 10 procedures undertaken without direct supervision but for review with the Consultant cardiologist, with a completed log book.

Indemnity

On approval of this document and following competency assessment of the CP, States of Jersey, Hospital and community services will provide vicarious liability for the performance of ILR procedures providing the practice is within the agreed protocols.

Accountability

It is understood that the ultimate responsibility is on the CP to determine their own individual competence and also be prepared to refuse to undertake a task if this competence is not possessed.

The referring Consultant Cardiologist will remain responsible for the medical management of the patient.

The prescription and administration of Lidocaine 1% local anaesthetic by the CP will be covered under the “patient specific authorisation to administer signed by a prescriber” – The request for the lidocaine will be generated by the CP and signed by the Consultant cardiologist or prescribing member of the Jersey Heart Team prior to each procedure and specific to the individual patient.

Audit

An ILR log book will be completed for each procedure in order to audit the CP service and to identify any further training and development needs, or procedural changes.

Costs

Estimated cost savings comparing CP led ILR service to a consultant led service have indicated a benefit of approximately £660 per implant (Torbay Trust – Appendix 2)

4. DEVELOPMENT AND CONSULTATION PROCESS

4.1 Consultation Schedule

Name and Title of Individual	Date Consulted
J Le Masurier, Infection control	June 2018
K Pitcher, Senior Clinical Physiologist	
A Norman, Principal Clinical Physiologist	
Dr A R Mitchell, Consultant Cardiologist	September 2018

Name of Committee/Group	Date of Committee / Group meeting
Cardiology Services	September 2018
Clinical Support Services	September 2018

5. REFERENCE DOCUMENTS

BHRS Standards for insertion, follow up and explant of implantable loop recorders (ILR's) by non-medical staff -

Reveal Insertable Cardiac Monitor Information

<http://www.medtronic.com/patients/fainting/device/our-insertable-cardiac-monitors/reveal-ling-icm/>

Edvardsson N, et al: PICTURE Study Investigators. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry. *Europace*. 2011 Feb;13(2):262-90.

Gersak B, Pernat A, Robic B, Sinkovec M. *Low rate of atrial fibrillation recurrence verified by implantable loop recorder monitoring following a convergent epicardial and endocardial ablation of atrial fibrillation. J Cardiovasc Electrophysiol*. 2012 Oct. 23(10):1059-66.)

Giada F, Gulizia M, Francese M, et al. *Recurrent unexplained palpitations (RUP) study comparison of implantable loop recorder versus conventional diagnostic strategy. J Am Coll Cardiol*. Epub Apr 30, 2007; May 15, 2007. 49(19):1951-6.)

Hindricks G, Pokushalov E, Urban L, et al. *Performance of a new leadless implantable cardiac monitor in detecting and quantifying atrial fibrillation. Results of the XPECT trial. Circ. Arrhythm. Electrophysiol.* 2010. DOI:10.1161/CIRCEP.109.877852.)

NICE clinical Guideline 139: Prevention and control of healthcare associated infections in primary and community care; March 2012
<https://www.nice.org.uk/Guidance/CG139>

NICE Transient Loss of Consciousness management in Adults and young people, Clinical Guideline 109, August 2010
<http://www.nice.org.uk/Guidance/CG109>

States Of Jersey Universal Infection Control Precautions (UICP), July 2015. HSS-PP-IC-0129-03

6. GLOSSARY OF TERMS / KEYWORDS AND PHRASES

ILR – Implantable Loop Recorder
 CP – Clinical Physiologist
 AF – Atrial Fibrillation
 DSU – Day Surgery Unit
 CID – Clinical Investigation Department

7. IMPLEMENTATION PLAN

Following ratification of this document by the Cardiology services meeting, the CP will undertake all the necessary competencies as identified previously and detailed in the SOP requirements in the Appendix. Upon completion of all the required pre procedure training, supervised implantation will begin and following the agreed number of successful procedures the CP will establish the CP implantation programme for ILR's.

Action	Responsible Officer	Timeframe
ILS	Resuscitation Officer	Current
ANTT	On-Line learning	3 months
Lidocaine	Prescriber- Cardiology team	3 months
Documentation	K Pitcher	Current
Sub Cut Injection training	Nurse Education	1 month
Implants - supervised	Dr A R Mitchell	Competency based
Implants unsupervised	Dr A R Mitchell	6 months

9. APPENDICES

Appendix 1: Standard Operating Procedure (SOP) - Jersey.
 Appendix 2: Cost benefit analysis – Torbay Trust