



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number:	TER355
Topic:	Wearable cardioverter defibrillators for people at risk of cardiac death
Summary of findings:	<p>Wearable cardioverter defibrillators (WCDs) may help manage the risk of sudden cardiac death in populations where other treatment approaches cannot be immediately provided.</p> <p>We identified one systematic review that identified a number of studies examining the effectiveness of WCDs. The review included one randomised controlled trial that trialled WCDs for people awaiting implantable cardioverter defibrillators. This study found that WCDs did not to reduce arrhythmia-related mortality but did appear to reduce overall mortality compared to discharge home under standard care. Other studies included in the systematic review supported these findings.</p> <p>We also identified two economic evaluations of WCD for populations who have had awaiting implantable cardioverter defibrillators removed due to complications. These studies suggest that use of WCD may be cost-effective.</p> <p>There are key uncertainties around use of WCD, including whether there may be differing effectiveness across at risk populations, how they would fit into current pathways in Wales, and why reductions in overall but not arrhythmia-related mortality are seen. A fuller review is likely to be able to address these issues.</p>

Introduction and aims

Wearable cardioverter defibrillators (WCDs) are garments with inbuilt monitors and electrodes that can detect problematic heart rhythms and act as a defibrillator to deliver a treatment shock. They can be worn under clothing in direct contact with the skin and can be removed when needed, for example to bathe. WCDs are designed for patients who are at risk of sudden cardiac death and are usually used as a temporary solution while longer-term treatment decisions are planned. The LifeVest device was highlighted by the topic proposer and appears to be the most widely used type of WCD.

Health Technology Wales researchers searched for evidence on the effectiveness of wearables cardioverter defibrillators, including LifeVest and other similar devices.

Evidence overview

Health technology assessments and guidance

We did not identify any guidelines or guidance from the UK or other settings.

Evidence reviews

We identified one systematic narrative review that aimed to examine the effectiveness and safety of WCDs (Aidelsburger et al. 2020).

The review identified one randomised controlled trial (RCT), one non-randomised controlled trial and 44 uncontrolled studies. The RCT recruited 2,303 patients who were at risk of sudden cardiac death and may be eligible for an implantable cardioverter defibrillator (ICD) due to a recent myocardial infarction and reduced ejection fraction from 108 centres across Europe and the United States. Patients were randomised to WCD or standard care and followed-up over three months to assess reduction in mortality and other outcomes. The RCT reports that for the primary outcome of arrhythmia-related mortality, there did not appear to be differences (WCD, 1.6% versus control, 2.4%, relative risk [RR] = 0.67, 95% confidence interval [CI] 0.37 to 1.21). However, overall mortality did appear to be reduced in the WCD arm (WCD, 3.1% versus control, 4.9%, RR = 0.64, 95% CI 0.43 to 0.98) and outcomes from other studies support reductions in overall mortality. Findings from all study types suggest that appropriate shocks are likely to be successful in converting heart rhythm (range 75% to 100%) and the number of inappropriate shocks is acceptable (range 0.6% to 14.2%) and does not lead to significant harm. Non-randomised studies included in Aidelsburger et al. (2020) appear to have different populations to the RCT but the review does not report this clearly and does not consider whether effectiveness may differ.

Economic evaluations

We also identified two economic evaluations on WCDs (Boriani et al. 2021, Jiang et al. 2019). Both of these evaluations focused on populations where an ICD had had to be removed due to infection and could not be immediately replaced. No randomised trials were available to inform clinical parameters in these evaluations.

Boriani et al. (2021) used a cost-minimisation approach comparing discharge from hospital after ICD explant to a month-long period low intensity inpatient stay. The model was based on a hypothetical cohort of patients with mean age 61 in the Italian setting. They report that discharge with ICD is cost saving compared to inpatient stay. In sensitivity analyses, discharge with WCD remains cost saving if the cost of WCD and inpatient stay within a plausible range were used.

Jiang et al. (2019) used a cost-utility for a similar population based in China but added discharge without WCD as a third comparator. They report that discharge with WCD was associated with higher

quality-adjusted life years (QALYs: 3.099) compared to discharge without WCD (QALYs: 3.0132) and inpatient stay (QALYs: 3.0553). When costs were considered, the cost-effectiveness of WCD was heavily dependent on its cost but would likely to be cost-effective at a WCD cost of USD \$72 per day or lower.

Primary studies

We did not identify any RCTs or non-randomised controlled trials published since the Aidelsburger et al. (2020) review.

Areas of uncertainty

There are several populations at risk of sudden cardiac death that WCD could be used for. We were only able to identify randomised evidence for populations awaiting an ICD and it is unclear whether these findings would be generalisable to other groups and whether long-term use for some populations would be feasible. The Aidelsburger et al. (2020) review included non-randomised evidence for other populations and a fuller review may be able to explore these issues.

Identified studies and economic evaluations used varying comparators. There is uncertainty about whether these comparators would change according to the included population and how relevant they would be to the Welsh settings. For populations awaiting ICD or after explant, it is unclear how widely these devices are used in Wales and how the eligible population relates to the study populations.

It is unclear why an intervention aimed at preventing arrhythmia-related mortality did not reduce this outcome in the RCT but did reduce overall mortality. There is some suggestion in the literature that this could be due to other changes in compliance associated with randomisation to the WCD arm or a change in response from services to those not randomised to the WCD arm (i.e. reduced time to ICD implantation). This issue could be explored further during a fuller review.

Literature search results

Health technology assessments and guidance
No relevant health technology assessments or guidance identified.
Evidence reviews and economic evaluations
Aidelsburger et al. (2020). Effectiveness, efficacy, and safety of wearable cardioverter-defibrillators in the treatment of sudden cardiac arrest – Results from a health technology assessment. <i>International Journal of Technology Assessment in Health Care</i> , 36, 363-371. https://doi.org/10.1017/S0266462320000379
Boriani et a. (2021). Cost-minimization analysis of a wearable cardioverter defibrillator in adult patients undergoing ICD explant procedures: Clinical and economic implications. <i>Clinical Cardiology</i> , 44, 1497-1505. https://dx.doi.org/10.1002%2Fclc.23709
Jiang et al. (2019). Potential cost-effectiveness of wearable cardioverter-defibrillator for patients with implantable cardioverter-defibrillator explant in a high-income city of China. <i>Journal of Cardiovascular Electrophysiology</i> , 30, 2387-2396. https://doi.org/10.1111/jce.14153
Individual studies
No additional relevant primary studies identified.
Ongoing research
No ongoing trials identified.

Date of search:	April 2022
Concepts used:	LifeVest, wearable cardioverter defibrillator, WCD