

**WEARABLE CARDIOVERTER DEFIBRILLATOR FOR PATIENTS AT RISK  
FOR SUDDEN CARDIAC ARREST**  
*A Technology Assessment*

**INTRODUCTION**

The California Technology Assessment Forum (CTAF) is asked to review the scientific evidence for the use of a wearable cardioverter defibrillator (WCD) for patients at risk for sudden cardiac arrest and who are not candidates for or refuse an implantable cardioverter defibrillator (ICD). This assessment reviews the peer reviewed, published trials of the only FDA approved WCD (the Zoll Lifecor LifeVest, [www.zoll.com](http://www.zoll.com)).

**BACKGROUND**

Sudden cardiac death (SCD), defined as deaths attributable to a cardiac etiology occurring less than one hour from a sudden, terminal event in a previously stable patient, is a significant public health problem accounting for 50% of all cardiac mortality in the United States<sup>1, 2</sup>. Two-thirds of these deaths are in persons with no known cardiac history or with a history of heart disease but considered to be low risk. It is estimated that SCD is responsible for 200,000 to 450,000 deaths per year in the United States<sup>3</sup> or one new event every two minutes<sup>4</sup>. Most SCD occurs outside of the hospital (in fact, most commonly in the home)<sup>4</sup> and despite the fact that most of these persons have potentially reversible arrhythmias, very few (1% to 5%) survive to hospital discharge<sup>5, 6</sup>. Prior studies have suggested that there is a direct correlation between time to defibrillation and survival<sup>3</sup>. Experts estimate that for each minute of ventricular fibrillation survival is reduced by ten percent<sup>7</sup>.

Ventricular fibrillation (VF) is the most common underlying electrophysiological (EP) disturbance in persons with SCD, but rapid ventricular tachycardia (VT) and bradyarrhythmias such as electromechanical dissociation have also been described<sup>1</sup>. Coronary artery disease is the most common underlying medical condition leading to SCD, in addition to acquired or inherited cardiomyopathies, diseases of the aorta, primary electrophysiological processes and other conditions such as toxic ingestions or electrolyte

disturbances. Other risk factors include history of diabetes mellitus, smoking, sedentary lifestyle and male gender. Patients are at increased risk of SCD following an acute myocardial infarction (MI), with the greatest risk being six to 18 months following the acute event. Risk of SCD increases with the extent of damage to the myocardium as can be assessed through measurement of the ejection fraction.

Approaches to prevention of SCD include standard pharmacotherapy such as ACE inhibitors, beta blockers and statins; anti-arrhythmic therapy; and placement of an ICD in selected patients. Two large studies have shown a reduction in mortality with use of an ICD in primary prevention for patients with congestive heart failure (CHF)<sup>8, 9</sup>. Although both studies had large relative risk reductions, they had much smaller absolute risk reductions and experts have attempted to identify which at-risk patients would most benefit from ICD placement. Various risk factors have been identified, such as ischemic heart disease, decreased left ventricular ejection fraction, and structural heart disease, and various risk stratification testing procedures have been proposed, such as standard and signal average electrocardiogram (EKG) and EP testing with programmed electrical stimulation in the EP lab. However, these tests may fail to identify a substantial portion of high-risk patients, as well as falsely predict increased risk in patients who never experience SCD. In a meta-analysis, no single method appeared to perform better than the others; however, a stepwise use of non-invasive methods, followed by an invasive EP study was able to stratify the majority (92%) of the patients<sup>10</sup>.

### **Lifecor LifeVest™**

According to the manufacturer, the current LifeVest™ system is the third generation wearable defibrillator ([www.lifecor.com](http://www.lifecor.com)). Unlike an ICD, the LifeVest™ is worn outside the body and consists of several main components: a lightweight garment worn under the patient's clothing to hold the device components; an electrode belt with sensing electrodes to continuously monitor the patient's heart and therapy electrodes for delivering a shock; a monitor and alarm module. If a life-threatening ventricular tachyarrhythmia is detected, the device alerts the patient with visual, audible and tactile alarms prior to delivering a shock, and thus allows a conscious patient to disarm the

device so that a shock is not delivered to a conscious patient. If the patient is unconscious, the device releases a gel over the therapy electrodes and delivers a biphasic electrical shock (calibrated to the patient's rhythm disturbance) to restore normal rhythm. It generally takes 20 seconds for the monitor to detect a serious arrhythmia and up to 60 seconds to deliver a shock of 75 to 150 joules. Up to five shocks can be delivered for each dysrhythmia. A web based data storage and retrieval system allows physicians to access patient data stored in the database.

Potential patient groups who may benefit from the LifeVest™ technology are those at high risk for SCD but who are not candidates for or refuse an ICD; this may include: post- MI patients with complications, cardiac surgery patients with complications, heart-transplant waiting list patients, advanced heart-failure patients, patients undergoing drug loading with potentially pro-arrhythmic medications, patients who need an ICD but have a condition that prevents or delays surgery (such as an infected ICD pocket), and patients who do not want to undergo surgery or have an implant ([www.lifecor.com](http://www.lifecor.com)). In the Food and Drug Administration (FDA) pivotal trial, the two patient populations included for study were: 1) patients waiting for a heart transplant or with equivalent cardiac status (New York Heart Association Class III or IV heart failure and an ejection fraction (EF) below 30 percent; and 2) acute MI patients and those immediately following a coronary artery bypass graft procedure who had experienced ventricular fibrillation or tachycardia within the first 48 hours or a left ventricular EF of less than 30 percent. Contraindications to use of the WCD include: 1) patient already has an ICD implanted and operating; 2) has a vision or hearing problem that interferes with hearing or reading the WCD messages; 3) takes medication that interferes with reacting to the WCD alarm; 4) unable or not willing to continuously wear the WCD; 5) childbearing age and not attempting to prevent pregnancy ([www.lifecor.com](http://www.lifecor.com)).

## TECHNOLOGY ASSESSMENT (TA)

**TA Criterion 1:           The technology must have final approval from the appropriate government regulatory bodies.**

The LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System (Zoll Lifecor, Inc., Pittsburgh, PA) received FDA premarket approval through the PMA process on December 18, 2001. The device is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator.

**TA criterion 1 is met.**

**TA Criterion 2:           The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.**

The Medline database, EMBASE, Cochrane clinical trials and reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words “wearable cardioverter defibrillator”, “wearable defibrillator”, “wearable automated defibrillator”, and “LifeVest™” from 1966 to December 2008. The bibliographies of systematic reviews and key articles were manually searched for additional references. Abstracts of citations were reviewed and all relevant articles reviewed in full.

The published, peer reviewed literature of the wearable cardioverter defibrillator consists of uncontrolled case series and case reports and one multicenter prospective trial (Feldman 2004) that served as the pivotal clinical trial for FDA approval of the device in 2001. The main outcomes assessed included ability of the LifeVest to successfully detect and treat potentially lethal ventricular arrhythmias in various groups of high-risk ambulatory patients, the ability of the LifeVest to deliver biphasic rather than monophasic shocks, and the ability of the LifeVest to accurately identify VF. Secondary outcomes included the rate of unnecessary shocks, the acceptability and comfort of the LifeVest and adverse reactions associated with the vest.

Overall, the limited scientific evidence does not permit conclusions concerning the effectiveness of the WCD regarding health outcomes for persons at risk of SCD. The current evidence is limited to one combined pivotal trial<sup>11</sup> with a precursor device and a small number of events. A confirmatory multi-center cohort study examining the impact of the WCD on mortality and quality of life in patients who meet criteria for but are unable (or perhaps unwilling) to have an ICD is needed before definitive conclusions can be made regarding its safety and effectiveness in the general population. In this population of patients who clearly meet current criteria for ICD it would not be appropriate to demand level 1 evidence (i.e. from a randomized clinical trial (RCT) before a determination can be made regarding efficacy and safety of the device. However, for patients who do not meet current criteria for an ICD but are considered to be at risk for SCD (for example, patients s/p acute MI with reduced EF) a RCT of WCD compared with AED or no treatment with mortality outcome data is recommended before the safety and efficacy of the device can be evaluated for use in clinical practice.

41 additional references were reviewed, but did not meet criteria for inclusion in this assessment. (References 23 -63).

**Level of evidence: 4, 5**

**TA Criterion 2 is not met.**

**TA Criterion 3: The technology must improve net health outcomes.**

Auricchio (1998) report on a small study in Germany in which 15 survivors of sudden cardiac arrest (SCA) due to VT/VF were fitted with a monophasic first generation WCD and then underwent EP testing prior to hospital discharge<sup>12</sup>. Five patients already had an ICD that was inactivated during the study. An episode of VF was successfully induced in ten of the 15 patients and the WCD correctly identified and successfully terminated the induced VT/VF in nine of the ten arrhythmias with a single

230-joule shock. In the one unsuccessful attempt, the electrodes had been inadvertently disconnected.

Reek (2003) report on a study conducted in Germany in 12 patients undergoing EPS testing for VF<sup>13</sup>. The study aim was to determine whether the LifeVest could effectively deliver a biphasic rather than monophasic shock. They found that induced VF was successfully terminated in 22 episodes with a single 70 or 100 joule biphasic shock. They conclude however, that the WCD should be programmed to deliver the maximum output of 150 joules when used in ambulatory patients.

Feldman (2004) report on a prospective, non-randomized multi-center trail (the WEARIT and BIROAD studies) designed to assess the safety and efficacy of a WCD in treating ventricular tachyarrhythmias in patients between 18 and 75 years of age at high risk for SCA but not eligible for an ICD or receipt of an ICD would be delayed for several months<sup>11</sup>. Historical controls of emergency medical services and SCA survivorship and reports of ICD unnecessary shock frequency were used to establish outcome criterion. These studies began as separate studies at 18 centers in the US and one cite in Germany but were combined at the request of the FDA. The WEARIT study enrolled patients with New York Heart Association (NYHA) functional Class III or IV heart failure and EF of < 0.30, including patients on a heart transplant list. The BIROAD study enrolled patients with a recent MI complicated by VT within 48 hours of the event, and/or an EF of 0.30 three days after the infarct or an episode of syncope or SCA at least 48 hours after an MI but not candidates for an ICD. Other patients enrolled in BIROAD included: 1) patients with VT/VF, SCA or syncope within 48 hours of coronary artery bypass grafting (CABG) but unable to receive an ICD; 2) EF < 0.30 at least three days after CABG; 3) ICD candidates not expected to receive a device for at least four months and 5) met criteria for ICD but refused implantation. Patients were excluded from both studies if they were unable to use or wear the device, were DNR, participating in another clinical trial, were not seen daily by a caregiver or had a non-cardiac terminal illness. The study device used a monophasic wave form with a maximum output of 285 joules. The primary study endpoint was successful resuscitation in at least 25% of events at a

confidence level of 90% and power of at least 50%. The comparison rate of 25% success was obtained by comparison to historical controls of patients who called 911 after SCA. All data were reviewed by an independent monitoring board. A total of 298 patients were enrolled (177 in WEARIT and 112 in BIROAD) when the study was terminated upon meeting the safety and efficacy endpoints. The participants were 82% male with an average age of 55 years and average EF of 23%. Overall, six successful defibrillations were observed in eight attempts for an estimated success rate of 69%.<sup>1</sup> Of the two unsuccessful attempts, the patients had inadvertently reversed the leads in both cases; one patient and the other were successfully resuscitated with an external defibrillator.<sup>2</sup> Two successful defibrillations occurred in the WEARIT patients (both in the same patient) and four successful defibrillations were reported in the BIROAD patients (two of these four were also in the same patient). They reported that six unnecessary shocks were delivered over a total of 901 months of use for a rate of 0.67% per month or eight percent per year of patient use. Five sudden deaths occurred in study participants who were not wearing the device at the time. Overall, 65 of the 289 subjects withdrew due to “comfort or lifestyle issues”, three additional withdrew due to adverse reactions and 46 patients received an ICD during the course of the study (most commonly as a result of increased ventricular arrhythmias). Seventeen patients complained of skin rash and itching associated with the device. One of 17 patients enrolled who met criteria for ICD use received an appropriate and successful shock from the WCD. The authors point out that the indications for ICD implantation have since expanded so that some of these patients would have been offered an ICD initially.

### **Patient Safety**

In the FDA pivotal trial, 12 deaths were reported in the 289 patients enrolled. One death was considered device related. In this instance, the patient experienced a ventricular arrhythmia that was detected by the device but the device failed to deliver a shock due to incorrect placement of the front therapy electrode (The device has been modified to prevent incorrect electrode placement).

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<sup>1</sup> The FDA Summary of Safety and Effectiveness Data states that the device successfully treated 5 of 7 correctly diagnosed SCA events.

<sup>2</sup> The device has been redesigned so that lead reversal is no longer possible.

Seven patients died at home while not wearing the device and four died in the hospital. Other device related adverse events in this trial included skin rashes in 5.9% (17 patients), inappropriate defibrillation in two percent, and pacemaker interaction in one patient.

Lapage (2008) report on a fatal device to device interaction between a WCD and a unipolar ventricular pacemaker in an 18 year old patient on a cardiac transplantation list for a failing Fontan circulation<sup>14</sup>. The patient had refused ICD placement and presented with cardiac arrest when the WCD failed to discharge due to artifacts from the unipolar ventricular pacemaker. Such interactions have also been reported between pacemakers and ICDs<sup>15</sup> (.

In sum, the published peer reviewed literature of the WCD in clinical practice is limited to a single combined pivotal trial. This study (Feldman 2004) suggests that the WCD appears to be effective and safe as a cardioverter for resolving VT/VF in appropriate patients; however the overall number of events in this trial was small and the generalizability of the findings limited. Misuse of the device can lead to death and a subset of patients (22%) withdrew from the study citing comfort and lifestyle” issues. Another large multi-center confirmatory study is needed to evaluate the WCD for use in select populations in the context of FDA and current clinical indications with careful ascertainment of appropriate outcomes of safety, morbidity and mortality and quality of life.

### **Ongoing Clinical Trials of WCD**

One RCT, the “Vest Prevention of Early Sudden Death and PREDiction of ICD Therapies” ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)), is currently enrolling patients at more than 20 centers in the United States to evaluate the effectiveness of the LifeVest in preventing death from arrhythmia in patients in the two months after an MI. Patients will be randomized to receive the LifeVest or usual care with the primary outcome being all cause mortality at two to three months; non fatal cardiovascular events, VF/VT, compliance, quality of life, and cost will also be assessed. In the second part of the study, participants will be followed for up to eight years after receiving an ICD or Reveal monitor with the primary outcome being the occurrence of ventricular arrhythmias to improve the methods for predicting which patients will most benefit from an ICD.

**TA criterion 3 is not met.**

**TA Criterion 4: The technology must be as beneficial as any established alternatives.**

The main potential alternatives to the Wearable Cardioverter Defibrillator are the automatic external defibrillator (AED), the ICD, antiarrhythmic drugs, surgical or transcatheter ablation and sudden cardiac arrest treatment by emergency medical services (EMS - generally activated by calling 911). Cardiac transplantation may be the ultimate alternative for some patients. Implantable cardioverter defibrillators (ICDs) were first implanted in humans in 1980. Since that time, scores of devices have been implanted, and the indications for the use of ICDs continue to be defined and expanded by clinical trials. The main indications for ICDs currently are for secondary prevention in patients with prior episodes of resuscitated VT or VF and with sustained hemodynamically unstable VT (not within 48 hours of an acute MI); for patients with sustained VT and structural heart disease; for primary prevention in patients with prior MI and impaired EF and for patients with cardiomyopathy and impaired EF. Two large studies, the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), have shown a reduction in mortality with use of ICD in primary prevention for patients with CHF<sup>8, 9</sup>. Although both studies had large relative risk reductions, they had much smaller absolute risk reductions and experts have attempted to identify which at-risk patients would most benefit from ICD placement. Having an ICD is not risk-free. Initial implantation requires anesthesia and a dye load, carrying risks with both of these as well as the risk of a wound infection<sup>16</sup>. In addition, inappropriate shocks may and can negatively impact quality of life. It has been estimated that for every 100 patients receiving an ICD approximately seven to eight will be saved by the device, the rest will experience an inappropriate shock or other complications or will not have the ICD fire at all<sup>17</sup>.

Several studies have found improved patient outcomes with use of the AED in public locations such as airports and casinos<sup>18-21</sup>. A clinical review concluded that use of AEDs

by first responders and lay-persons reduces time to defibrillation and improves survival in persons with SCA<sup>6</sup>. It is estimated, however, that 70% of sudden cardiac arrests occur at home. AEDs are available for home use but this requires that someone be available to witness the event and are capable of using the AED rapidly and accurately. A recent study found that in survivors of MI at risk for SCA but who were not candidates for ICD, a home AED did not significantly improve survival<sup>22</sup>. Whether the WCD can improve outcomes in these patients is the major aim of an ongoing RCT.

Cardiac ablation involves localizing and selectively ablating abnormal conduction pathways percutaneously via catheter or less commonly during surgery. If successful, this procedure generally obviates the need for a WCD or ICD. While an important option for some patients with known or at risk for malignant VT/VF, this procedure will rarely be used as a potential alternative to WCD.

In sum, the ICD is the gold standard treatment for patients at risk for SCA/SCD who meet the current, evidence based guidelines for use. The WCD has been approved by the FDA for patients who are not candidates for an ICD because of medical contraindications or who refuse an ICD. To date, the WCD has not been shown to be as effective as the ICD in treatment of patients who would have otherwise qualified for one. While a head to head trial of WCD and ICD is not the appropriate standard, the current literature is insufficient to conclude if the WCD should be offered to patients as an alternative to the ICD when use of an ICD is not feasible.

**TA criterion 4 is not met.**

**TA Criterion 5:           The improvement must be attainable outside of the investigational setting.**

The peer reviewed, published data are not sufficient to conclude that the efficacy and safety of the WCD has been established in the investigational setting, let alone under conditions of usual medical practice.

**TA criterion 5 is not met.**

## **CONCLUSION**

SCA and death is a significant public health issue that is not adequately addressed by current medical, pharmacological or technological treatments. More than 160,000 out of hospital cardiac arrests occur in the US every year<sup>22</sup>. The WCD is a promising new technology that has the potential to ameliorate the risk of SCD in two major types of patients; 1) those who qualify for a permanent ICD but are unable or unwilling to have one implanted immediately (i.e. as a bridge to a permanent device), and 2) those felt to be at risk for SCA/SCD but who do not currently qualify for a permanent ICD or for whom the ICD may not be needed long term (e.g. patients immediately s/p acute MI or as a bridge to transplantation for patients awaiting cardiac transplant). Current FDA approval states that the Lifecor LifeVest (WCD) is indicated for adult patients at risk for sudden cardiac arrest and are not candidates for or refuse an ICD.

The existing peer reviewed literature consists of a single study (Feldman 2004) that found that use of the WCD was feasible in a heterogeneous population of patients in detecting and treating VT/VF<sup>11</sup>. It found that in patients with a variety of indications including as a bridge to cardiac transplant and in patients temporarily at risk for malignant ventricular arrhythmias (e.g. after MI or CABG) and who used the device for up to four months or until implantation of a permanent ICD, the WCD detected and successfully treated six of eight episodes of VT/VF. There were six unnecessary shocks delivered. This pivotal trial reported only short-term outcomes and did not examine the impact of the WCD on overall mortality compared with the current gold standard ICD or other alternatives such as the AED. Prior studies of ICDs have proven their effectiveness in reducing mortality for patients with life threatening ventricular arrhythmias and for those who previously survived SCA. Future studies of the WCD must examine the device's impact on overall mortality in selected patient populations.

It is unknown how many patients at risk for SCD refuse a permanent ICD and how compliant these patients would be with a WCD. In addition, the number of patients who are unable to receive an ICD or had the ICD removed because of infection or any other medical

contraindication to ICD implantation is presumed to be small. And most patients felt to be too sick to receive an ICD would be unlikely to benefit from long term from use of a WCD. It is difficult to draw definitive conclusions about the efficacy and safety of the WCD in these patient populations from the current peer reviewed literature.

The FDA indications state that the WCD is an appropriate alternative for patients at risk for SCD but who are unable or unwilling to have an ICD. Since it is known that most SCA/SCD that occur outside of the hospital take place at home<sup>4</sup>, this would suggest that the AED would be an effective intervention for patients at risk for SCD and a reasonable alternative to the WCD for these indications. To date, no trial has compared outcomes of the WCD with the AED

While overall the WCD appears to be safe, two patients died due to improper device set-up in the pivotal trial and almost one fourth of patients withdrew from the study due to discomfort or other lifestyle reasons. The WCD has since been redesigned to avoid improper use and to ease discomfort; whether this newest generation of the LifeVest can improve on these outcomes has not been studied in a clinical trial.

The WCD appears to be a potentially useful device for those patients who are at risk for sudden cardiac death but who are unable to receive an ICD or may not require a permanent ICD. Limited data from existing peer-reviewed literature is not adequate to address this question. Data from the ongoing RCT will help address some of the gaps in the current evidence.

### **DRAFT RECOMMENDATION**

It is recommended that the use of a wearable cardioverter defibrillator (WCD) for patients at risk for sudden cardiac arrest and who are not candidates for or refuse an implantable cardioverter defibrillator (ICD) *does not* meet CTAF TA criteria 2-5 for efficacy and improvement in health outcomes.

**March 11, 2009**

This is the first CTAF assessment of this technology.

## RECOMMENDATIONS OF OTHERS

### BLUE CROSS BLUE SHIELD ASSOCIATION (BCBSA)

The BCBSA Technology Evaluation Center (TEC) has not conducted a formal assessment of this technology.

### CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

In the absence of a CMS NCD, policy decisions for the Automat External Defibrillator are determined by local carriers. Noridian Administrative Services provides access to this technology in California and several other states.

### AMERICAN COLLEGE OF CARDIOLOGY, CALIFORNIA CHAPTER (CA ACC)

The CA ACC has been invited to provide an opinion regarding the use of this technology. A representative will be attending the meeting.

**ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death** was published in the Journal of the American College of Cardiology in 2006. The report was developed in Collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. The Wearable Automatic Defibrillator is mentioned on page e271 6.5.3. Wearable Automatic Defibrillator. The guidelines are not specific as to the use of this device.

**ABBREVIATIONS USED**

CTAF	California Technology Assessment Forum
WCD	Wearable cardioverter defibrillator
ICD	Implantable cardioverter defibrillator
SCD	Sudden cardiac death
VF	Ventricular fibrillation
VT	Ventricular tachycardia
MI	Myocardial infarction
EP	Electrophysiologic
CHF	Congestive heart failure
EKG	Electrocardiogram
FDA	Food and Drug Administration
DARE	Database of Abstracts of Reviews of Effects
RCT	Randomized clinical trial
SCA	Sudden cardiac arrest
NYHA	New York Heart Association
EF	Ejection fraction
CABG	Coronary artery bypass grafting
AED	Automatic external defibrillator
EMS	Emergency medical services
MADIT-II	Multicenter Automatic Defibrillator Implantation Trial II
SCD-HeFT	Sudden Cardiac Death in Heart Failure Trial

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