



Wearable Cardioverter Defibrillator - Adult - Inpatient/Ambulatory/Emergency Department Clinical Practice Guideline

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Introduction

The wearable cardioverter-defibrillator (WCD) is an external device capable of automatic detection and treatment of ventricular tachycardia (VT) or ventricular fibrillation (VF). In cases where the need for an implantable cardioverter defibrillator (ICD) to decrease sudden cardiac death (SCD) risk is not fully established (pending medical optimization for heart failure, soon after revascularization following a myocardial infarction, or with a cardiomyopathy that may be reversible) or in cases where ICD implantation is deferred (e.g., ongoing infection), a WCD may be an acceptable alternative for the prevention of sudden cardiac death.

The evidence to support routine use of WCDs is evolving and current evidence does not support routine use of WCDs in most patients. A WCD should be considered only after a comprehensive and shared decision-making discussion between provider and patient, highlighting the potential effects of the device and some of its limitations (lack of robust evidence, in rare cases the failure to restore a normal rhythm, and daily challenges of wearing the vest, etc.)

Scope

Intended User(s): Physicians, Advanced Practice Providers, Registered Nurses, Nurse case managers

Objective(s): To outline best practices for prescribing a wearable cardioverter defibrillator, management of UW Health patients with a WCD in the inpatient and outpatient settings, and what to do if a non-UW Health patient with a WCD has an event at a UW Health facility.

Target Population: Patients age 18 years or older who may qualify for a WCD or already wear one.

Clinical Questions Considered:

- When is a WCD indicated for a patient?
- Should the wearable cardioverter defibrillator be worn when a patient is admitted to a UW Health hospital?
- When should manufacturer default settings be changed on the WCD?

How Does a Wearable Cardioverter Defibrillator Work

The WCD is an external device that continuously monitors the patient's heart with its electrodes to detect life-threatening abnormal heart rhythms. If a life-threatening rhythm is detected, the device alerts the patient for 1 minute prior to delivering a treatment shock, allowing a conscious/awake patient to delay the shock. If the patient becomes unconscious, a blue gel is released over the therapy electrodes and delivers an electrical shock to restore normal rhythm. This "event" from detecting arrhythmia to automatically delivering treatment shock, usually occurs in less than a minute.

If the device cannot detect electrocardiogram (ECG) or it has delivered the maximum number of treatments, it will prompt for bystander help if the patient is unresponsive. Cardiopulmonary resuscitation (CPR) can be performed if the device is not speaking/ broadcasting and WCD removed. If an external defibrillator is available and WCD removed, the individual can be monitored/treated with external equipment. To remove the WCD, first pull out the battery and then remove the vest from the patient.

Recommendations

Indications for a Wearable Cardioverter Defibrillator

According to the 2016 American Heart Association (AHA) Science Advisory, the use of a wearable cardioverter defibrillator is reasonable when:¹

- There is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in implantable cardioverter defibrillator (ICD) care such as infection. *(AHA Class IIa, LOE C)*
- It is used as a bridge to more definitive therapy such as cardiac transplantation. *(AHA Class IIa, LOE C)*
- There is concern about a heightened risk of sudden cardiac death (SCD) that may resolve over time or with treatment of left ventricular dysfunction; for example, in
 - Ischemic heart disease with recent revascularization
 - Newly diagnosed non-ischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy
 - Secondary cardiomyopathy (tachycardia mediated, thyroid mediated etc.) in which the underlying case is treatable *(AHA Class IIb, LOE C)*

In addition, per the AHA Science Advisory, a WCD should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive > 6 months. *(AHA Class III: No benefit, LOE C)¹*

Table 1. When a Wearable Cardioverter Defibrillator May be Indicated

WCD indicated	<ul style="list-style-type: none"> • Interruption in/transient contraindication for in implanted/permanent device care • Bridge for cardiac transplant or ICD • Increased risk of sudden cardiac death that may resolve over time or with treatment
WCD is NOT indicated	<ul style="list-style-type: none"> • Life expectancy < 6 months

Patients with Increased Risk for Sudden Cardiac Death Post-MI and The VEST Trial

The 2016 AHA Science Advisory on WCD states that a WCD, may be “used as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 days of a myocardial infarction (MI).”¹ Since the Advisory’s publication, the results of the Vest Prevention of Early Sudden Death Trial (i.e., VEST trial) results were published.²

The VEST Trial evaluated the efficacy of a WCD in post-MI setting with a LVEF < 35% in reducing SCD. This trial enrolled and randomized 2,302 patients in an open label 2:1 fashion to optimal medical therapy (OMT) and WCD versus OMT. The trial did not show a decrease in sudden cardiac death in the WCD treatment arm in the 90 days follow-up period compared to the control arm.²

There were limitations to the VEST trial. The trial was likely underpowered and compliance with the use of the device declined over the course of the study (81% at randomization and 41% at 90 days). Patient deterrents to wearing the device included frequent device alarms,

inappropriate shocks, skin irritation, and emotional distress. The majority of deaths in the WCD and OMT arm also occurred when the WCD device was not being worn.²

Patient-Provider Discussion

The recommendation and decision to place a WCD is a complex one that currently lacks strong randomized controlled evidence to guide therapy. Post-MI patients with LV dysfunction are a particularly challenging patient population. Although the VEST trial did not show a clear benefit, these patients are at increased risk for sudden cardiac death, particularly in the first 30 days post-MI (incidence of 2.3% if EF < 30%).³ Other clinical characteristics that could potentially heighten this risk should also be considered on a case-by-case basis (e.g., incomplete revascularization, greater myocardial damage, hemodynamic compromise at presentation, and ventricular arrhythmias on telemetry monitoring).

Patients must be educated on their cardiac disease, risk of SCD, and the potential benefits of the WCD; this should be addressed with a thorough discussion between a patient and their provider. Patients must also be informed of the lack of direct evidence of benefit in patients immediately post-MI and the potential drawbacks and limitations of the WCD device, including how to properly wear the device and maintain it. Patients unfit or unwilling to manage the WCD should not be prescribed the device.⁴ (*UW Health Very low quality of evidence, S recommendation*)

Ordering a Wearable Cardioverter Defibrillator

Ordering and Authorizing Provider

Only UW Health Cardiology attendings or advanced practice providers should order a WCD for a patient. (*UW Health Very low quality of evidence, S recommendation*) Physicians in training (i.e., residents and fellows) should not order the device to streamline insurance billing. (*UW Health Very low quality of evidence, S recommendation*) Note: the provider should determine that the patient will be able to wear and maintain the WCD and abort shocks as indicated.

When possible, that the ordering and authorizing provider be the same individual. (*UW Health Very low quality of evidence, S recommendation*)

It is the responsibility of the ordering provider to ensure that a follow-up plan with Cardiology is in place for the patient. The patient should follow-up with a Cardiology provider within 6-12 weeks after the WCD is obtained. (*UW Health Very low quality of evidence, C recommendation*)

Additional information on how to order a WCD such as an overview of the process and medical documentation needed for device approval can be found in [Appendix A](#) and [Appendix B](#).

Manufacturer Device Settings

It is recommended that when ordering a WCD from an inpatient setting using the Health Link order, ventricular tachycardia heart rate threshold be requested as 190 bpm and the ventricular fibrillation heart rate threshold be requested as 220 bpm. (*UW Health Very low quality of evidence, C recommendation*) If the WCD is being ordered in the outpatient setting via manufacturer form, device-default settings may be used (i.e., ventricular tachycardia heart rate threshold 150 bpm and the ventricular fibrillation heart rate threshold 200 bpm.) (*UW Health Very low quality of evidence, C recommendation*)

Questions regarding the operation of the WCD equipment should be directed to the WCD manufacturer.

Management of Patient with a WCD Admitted to University Hospital and Outpatient Settings

If a patient with a WCD is admitted to a UW Health hospital (including the Emergency Department), the following is recommended:

- The WCD should not be worn and the patient should be placed on continuous cardiac rhythm monitoring (i.e., place order for continuous monitoring.) ⁵(*UW Health Low quality of evidence, S recommendation*)
- Continuous cardiac rhythm monitoring should not be interrupted or discontinued without approval from an attending physician. (*UW Health Low quality of evidence, S recommendation*)
- Patient is accompanied by a nurse when leaving the unit (*UW Health Low quality of evidence, S recommendation*)
- Patient is informed that WCD batteries must be charged and on hospital premises 24 hours prior to anticipated discharge from an inpatient unit. (*UW Health Low quality of evidence, S recommendation*)
 - UW Health does not have any ownership of the WCD.
 - WCD may be secured and stored for the duration of the patient's inpatient stay or the patient may opt to have the WCD stored at home/with family.
 - If kept on-site at hospital, WCD should be treated and documented as part of patients' belongings.

Upon admission to an inpatient unit, it is also recommended to contact the UW Health's WCD manufacturer representative to notify them of the patient's admission, in case the manufacturer's assistance is needed for device upkeep during admission. (*UW Health Low quality of evidence, S recommendation*)

If the patient chooses to wear the WCD during his/her hospital stay, staff involved with the patient's care ought to be aware of device alerts and how to remove the WCD if necessary (see **Table 2. First Responder Information**) (*UW Health Low quality of evidence, S recommendation*)

Table 2. First Responder Information

- | |
|---|
| <ul style="list-style-type: none">• Gong alert (single tone): Not part of treatment sequence; indicates device attention needed• Siren alert (two tone): Device cannot detect ECG, delivered maximum number of treatments or about to treat patient• CPR may be performed when WCD is worn if device is not broadcasting "Press response buttons to delay treatment," or "Bystanders do not interfere." <u>Individuals can get shocked by the WCD while a treatment shock is being delivered.</u>• To remove WCD: Pull out device battery first then unbuckle garment from patient. |
|---|

A patient with a WCD may not be discharged from the hospital without the WCD charged and present (i.e., patient wearing charged WCD when leaving the hospital.) (*UW Health Low quality of evidence, S recommendation*)

When discharging a patient with a new WCD, a plan is needed for patient follow-up regarding this device. ⁶ (*UW Health Low quality of evidence, S recommendation*)

Management of Patient at a UW Health Outpatient Facility

If a patient with a wearable cardioverter defibrillator presents to a UW Health outpatient facility, the patient should be placed on continuous cardiac monitoring, if available. If continuous cardiac monitoring is NOT feasible/available, the WCD should be worn by the patient and NOT removed. (*UW Health Low quality of evidence, S recommendation*) Any questions or concerns regarding necessity of cardiac monitoring for outpatient procedures should be directed to the ordering provider for the patient's WCD or patient's cardiologist.

Persons with a WCD at Visiting UW Health Hospital or Clinic

It is possible for individuals wearing a WCD to be onsite at a UW Health hospital or clinic (e.g., visiting a family member admitted, accompanying a patient to a clinic appointment.) If a two-tone siren alert occurs on such an individual, it is recommended to follow the prompts from the WCD and call a code blue (*UW Health Low quality of evidence, S recommendation*).

Following an event, the individual may become a UW Health patient. Questions related to the indications or needs for the WCD should be directed to the initial ordering provider. If the ordering provider cannot be determined, contacting the WCD manufacturer may be helpful. If the ordering provider cannot be contacted, questions regarding the indication or need for the WCD can be directed to the Electrophysiology (EP) Consult Service.

Disclaimer

Clinical practice guidelines assist clinicians by providing a framework for the evaluation and treatment of patients. This guideline outlines the preferred approach for most patients. It is not intended to replace a clinician's judgment or to establish a protocol for all patients. It is understood that some patients will not fit the clinical condition contemplated by a guideline and that a guideline will rarely establish the only appropriate approach to a problem.

Methodology

Development Process

Each guideline is reviewed and updated a minimum of every 3 years. All guidelines are developed using the guiding principles, standard processes, and styling outlined in the UW Health Clinical Practice Guideline Resource Guide. This includes expectations for workgroup composition and recruitment strategies, disclosure and management of conflict of interest for participating workgroup members, literature review techniques, evidence grading resources, required approval bodies, and suggestions for communication and implementation.

Methods Used to Collect the Evidence:

The following criteria were used by the guideline author(s) and workgroup members to conduct electronic database searches in the collection of evidence for review.

Literature Sources:

- Electronic database search (e.g., PubMed)

Time Period: October 2018 to April 2019

Search terms: wearable cardioverter defibrillator, vest prevention.

Methods to Select the Evidence:

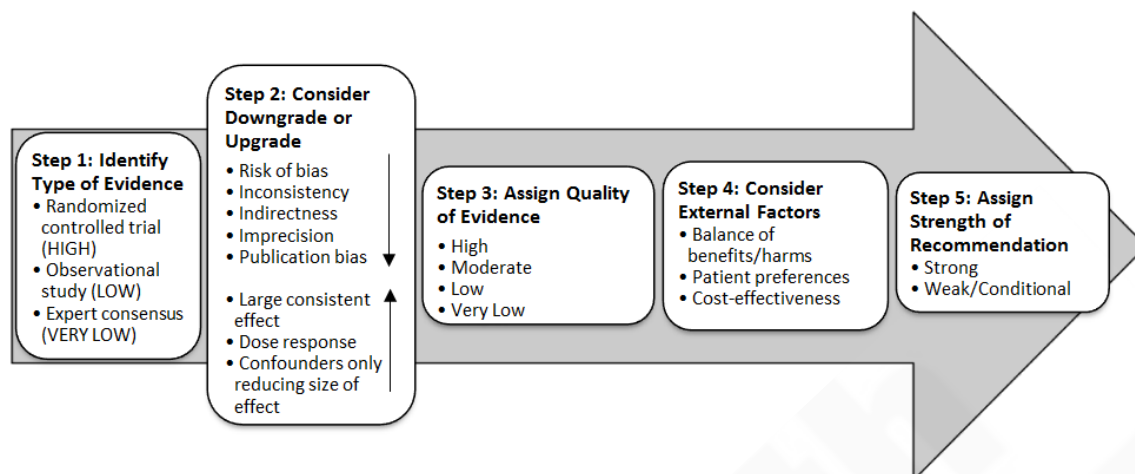
Literary sources were selected with the following criteria in thought: English language, subject age (i.e., age > 18 years), publication in a MEDLINE core clinical journal and strength of expert opinion (e.g., national or international society statement).

Methods Used to Assess the Quality of the Evidence/Strength of the Recommendations:

Recommendations developed by external organizations maintained the evidence grade assigned within the original source document and were adopted for use at UW Health.

Internally developed recommendations, or those adopted from external sources without an assigned evidence grade, were evaluated by the guideline workgroup using an algorithm adapted from the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology (see **Figure 1**).

Figure 1. GRADE Methodology adapted by UW Health



Rating Scheme for the Strength of the Evidence/Recommendations:

GRADE Ranking of Evidence

High	We are confident that the effect in the study reflects the actual effect.
Moderate	We are quite confident that the effect in the study is close to the true effect, but it is also possible it is substantially different.
Low	The true effect may differ significantly from the estimate.
Very Low	The true effect is likely to be substantially different from the estimated effect.

GRADE Ratings for Recommendations For or Against Practice

Strong (S)	Generally should be performed (i.e., the net benefit of the treatment is clear, patient values and circumstances are unlikely to affect the decision.)
Conditional (C)	May be reasonable to perform (i.e., may be conditional upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented.)

American Heart Association Classification Recommendation Grading Scheme

		SIZE OF TREATMENT EFFECT				
		CLASS I <i>Benefit >>> Risk</i> Procedure/Treatment SHOULD be performed/administered	CLASS IIa <i>Benefit >> Risk</i> Additional studies with <i>focused objectives needed</i> IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb <i>Benefit ≥ Risk</i> Additional studies with <i>broad objectives needed; additional registry data would be helpful</i> Procedure/Treatment MAY BE CONSIDERED	CLASS III <i>No Benefit or CLASS III Harm</i>	
				Procedure/ Test	Treatment	
				COR III: No benefit	No Proven Benefit	
				COR III: Harm	Excess Cost w/o Benefit or Harmful Harmful to Patients	
ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	<ul style="list-style-type: none"> Recommendation that procedure or treatment is useful/effective Sufficient evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> Recommendation in favor of treatment or procedure being useful/effective Some conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> Recommendation's usefulness/efficacy less well established Greater conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> Recommendation that procedure or treatment is not useful/effective and may be harmful Sufficient evidence from multiple randomized trials or meta-analyses 	
	LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	<ul style="list-style-type: none"> Recommendation that procedure or treatment is useful/effective Evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> Recommendation in favor of treatment or procedure being useful/effective Some conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> Recommendation's usefulness/efficacy less well established Greater conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> Recommendation that procedure or treatment is not useful/effective and may be harmful Evidence from single randomized trial or nonrandomized studies 	
	LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	<ul style="list-style-type: none"> Recommendation that procedure or treatment is useful/effective Only expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> Recommendation in favor of treatment or procedure being useful/effective Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> Recommendation's usefulness/efficacy less well established Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> Recommendation that procedure or treatment is not useful/effective and may be harmful Only expert opinion, case studies, or standard of care 	
Suggested phrases for writing recommendations		should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit is not recommended is not indicated should not be performed/administered/other is not useful/beneficial/effective	COR III: Harm potentially harmful causes harm associated with excess morbidity/mortality should not be performed/administered/other
Comparative effectiveness phrases ¹		treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B			

Recognition of Potential Health Care Disparities: None identified.

Collateral Tools & Resources

The following collateral tools and resources support staff execution and performance of the evidence-based guideline recommendations in everyday clinical practice.

Metrics

- % of patients with a WCD admitted to University Hospital who chose to wear WCD during admission
- % of patients with WCD ordered by a non-cardiology provider
- % of patients with WCD ordered in Health Link with “Other” indication selected

Guidelines

1. Heart Failure – Adult – Inpatient/Ambulatory

Order Sets & Smart Sets

No order set or smart set available however order panel “Request for Wearable Defibrillator Panel” is available in Health Link.

Patient Resources

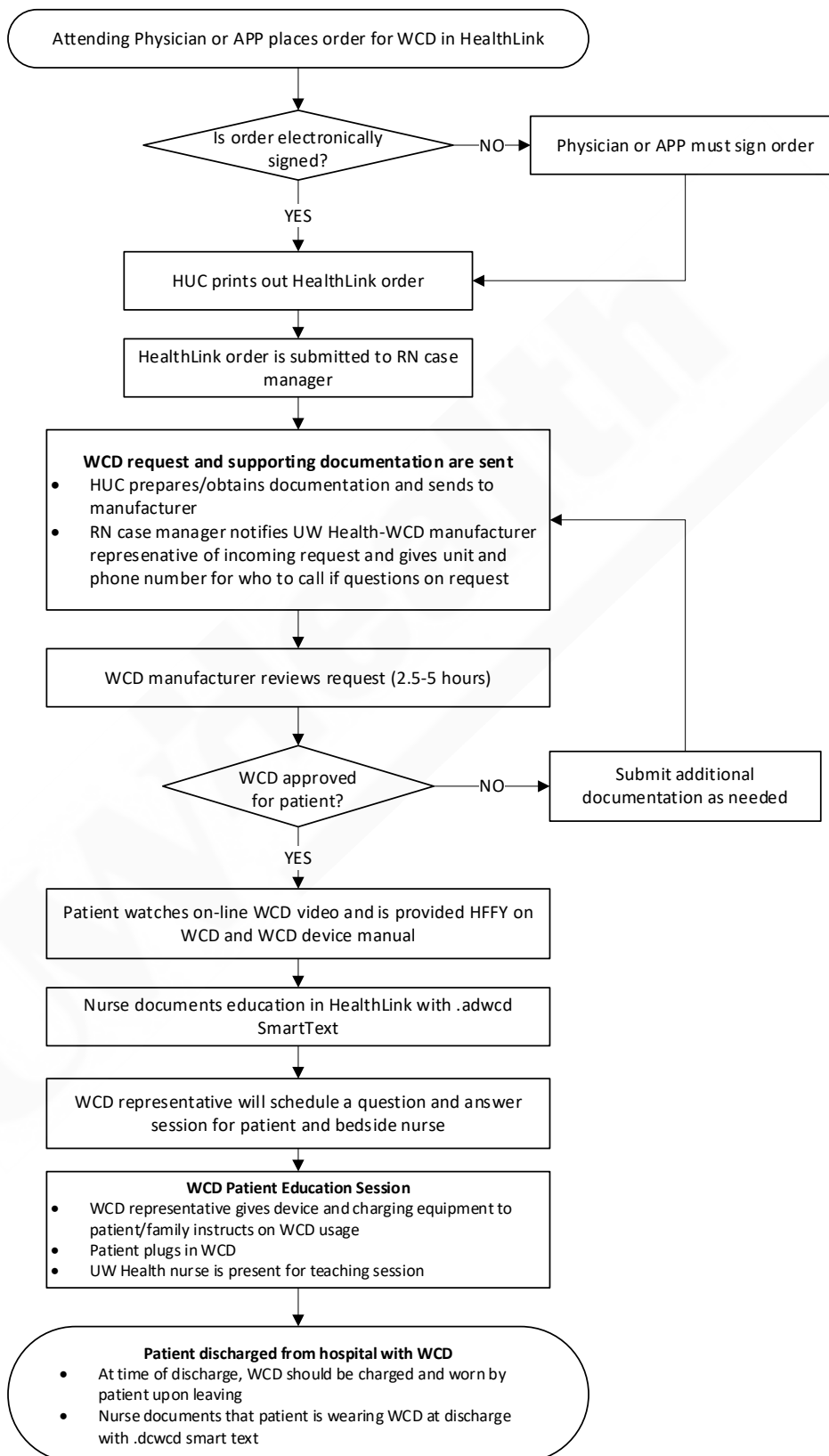
1. Health Facts For You #8032: Wearable Cardioverter Defibrillator (WCD)

Policies

1. UWHC Policy 5.1.13: Defibrillation by BLS/ACLS/PALS Trained and Qualified Nurses and Clinical Exercise Physiologists
2. UWHC Policy 5.1.15: Maintaining and Securing the Emergency Response Carts, Defibrillators, and Automated External Defibrillators (AED)
3. UWHC Policy 5.1.16: Emergency Response Teams (Adult and Pediatric)

Appendix A. Steps to Prescribing/Ordering a WCD for Admitted Patient

WCD Ordering for Admitted Patient at University Hospital



Appendix B. Checklist for ordering a wearable cardioverter defibrillator

Checklist for ordering a wearable cardioverter defibrillator
Documents to send
<input type="checkbox"/> Cover sheet with contact information managing WCD request
<input type="checkbox"/> Patient Demographics sheet that includes: <ul style="list-style-type: none">○ patient name○ date of birth○ home address○ last four digits of Social Security number○ insurance information (Insurer, Member ID, Group #)
<input type="checkbox"/> Print out Health Link WCD order, electronically signed by ordering/authorizing provider (if patient currently admitted)
<input type="checkbox"/> Zoll LifeVest® form filled out and signed and dated by ordering/authorizing provider (if outpatient)
<i>**Physician or advanced practice provider must date the form when signing- date cannot be pre-entered by anyone else!**</i>
<input type="checkbox"/> Patient documentation that includes: <ul style="list-style-type: none">○ note from ordering provider within the past 6 months○ note from a cardiologist within the past 6 months○ admission Health & Physical (H&P) progress note○ progress note that includes indication for WCD○ most recent documentation of LVEF (e.g., ECHO, cardio MRI)○ most recent catheter lab report (if available)
<i>All notes must be signed either manually (signed and dated by author) or electronically signed. Unsigned notes from the electronic medical record WILL NOT be accepted.</i>
Contact WCD manufacturer
<input type="checkbox"/> Send WCD request to device manufacturer by fax 1-866-567-7615 or by email LifeVest.Order@zoll.com.
<input type="checkbox"/> Notify UW Health- WCD manufacturer representative of incoming new request

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