

# Clinic Site Preparation for a PSSV

- You are the SC/ CRC for a Heart Failure clinic located in Springfield, OH
- Your site has been approached by Zoll Medical the makers of LifeVest to conduct an SQV.
- Your site visit is scheduled for Wed, 23 Sep 2020 at 6 PM
- You are required to provide site capabilities information to support a study for acute decompensated Heart failure
- All site files and study synopsis is provided in a separate cover.
- You will provide site population data and discuss site questionnaire information to support your site capabilities.

# Site Staff

- PI- Dr. Pradeep Gujja
- Sub-I – Dr. Mohammed Aktar
- Sub-I – Dr. Mohammad S. Ashraf
- Sub-I – Avindar Gupta
- Sub-I – Dr. Lolita Randawar

# Site Location

- Mercy Health- Springfield Heart 100 W. McCreight Ave. 2<sup>nd</sup> Floor. Springfield, OH
- [www.mercy.com](http://www.mercy.com)

## PSSV Discussion with PI

- Site Heart failure population
  - Recruitment efforts during COVID-19
  - Structure of Heart Failure Clinic
  - How does PI delegate clinical staff to a study
  - How many MD support the PI
  - How will PI identify Patients
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- What is the hospital policy to use arrhythmia data provided by Zoll in the management of HF patients, are there hospital restrictions to download clinical reports
  - Will the PI allocate time to review the weekly report and delegate SC to call the patient?
  - How does the PI manage AEs

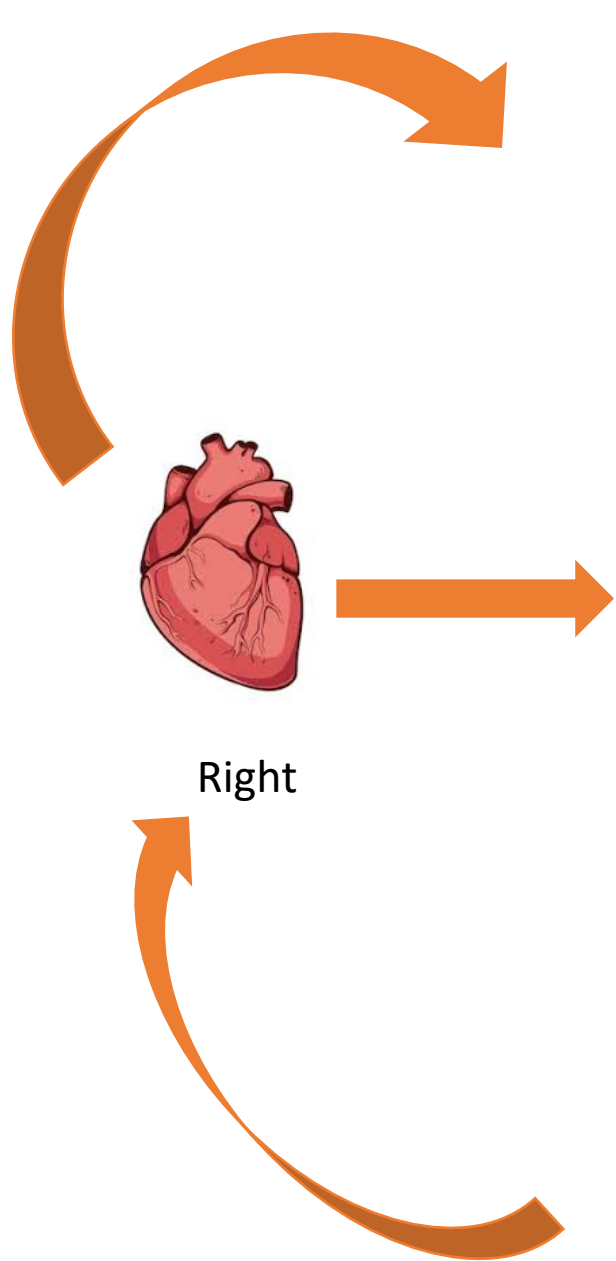
## PSSV Discussion with PI

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# Acute Decompensated Heart Failure

- HF (systolic or diastolic) can result from any structural or functional impairment of ventricular filling or ejection of blood
- LVEF
- HFrEF - Clin Dx of HF < 40%
- HFpEF – Clin Dx of > 40-50% with abnormal LV diastolic function
- Pulmonary congestion is an acute increase in extravascular lung water EVLW and a common manifestation of ADHF.
- The worsening of HF symptoms with fluid build up in the lungs can lead to symptoms listed
- Population in the US is > 5 million with over 650,000 Dx annually.
- 50% of patients die within 5 years of Dx.
- Cost is >\$30B annually
- Dyspnea- difficulty breathing
- Swollen legs and feet
- Fatigue
- Acute respiratory distress
- Hospitalization
- If patient is not properly monitored, 50% of patients die within 6 months of Dx.

RV heart failure causes fluid back-up in the RV when the pump breaks, causing venous distention, confusion in the brain. Fluid back-up in the periphery, causing jugular venous distention, peripheral edema,



Brain – altered mental status due to low flow state of blood flow

Fluid will back-up to the lungs causing dyspnea on exertion, shortness of breath, orthopnea

LV heart failure (reduced systolic EF) causes fluid to back-up. Blood cannot flow to the brain causing confusion.



Right

Left

Fluid build up occurs in the lower limbs because peripheral edema of and bowel fills with fluid causing malabsorption-belly ache



Kidney

Reduced LVHF will also produce a S3 heart sound on examination using a stethoscope. Reduced blood flow to the kidney causes renal failure

## Management of ADHF

- Volume Overload
  - Flash Pulmonary edema from uncontrolled hypertension
  - Atrial Fibrillation
  - Hypotension
  - Reduced organ perfusion from reduced cardiac output leading to shock from low oxygen
- 
- For most of these patients lifestyle modifications such as diet and weight loss has not been successful due to sedentary lifestyles
  - Poor management of dietary discretion
  - Possible medication non-compliance.
  - The heart muscles (wall of the ventricles) become very weak from working overtime to pump enough blood and supply the entire body with oxygen



## How to Diagnose ADHF Pathophysiology

- Chest- x-ray – will show cardiomegaly – enlargement of the heart
- Pulmonary edema- left heart is backing up fluid into the pulmonary circulation.
- BNP value – Brain Natriuretic Peptide: a blood test that shows the ventricles releases proteins into the bloodstream due to the stress of the overworked muscles. It is higher if you have CHF.
- Echocardiography- gold standard- will show Systolic HF- dilated; Diastolic HF- constricted; MI, or other type of pathology
- Cardiac Catheterization – will determine any other underlying pathology

## Management of ADHF

- Therapy goals are to manage the triggers of this disease and relieve symptoms
- For most of these patient, lifestyle modifications such as, diet and weight loss has not been successful due to sedentary lifestyles
- Poor management of dietary discretion.
- Possible medication non-compliance.

# Class of CHF- NYHA functional Class

- Stage A- high risk with no structural heart disease
  - Stage B – structural disease but no HF symptoms
  - Stage C – Structural Heart disease with prior HF symptoms
  - Stage D - Refractory and require durable mechanical support
- Class
  - Class I
  - Class I-III
  - Class IV

# Management of CHF

- Is determine by what class of CHF the patient has and to minimize the risk factor, regardless of the class, all MD follow ;
- Diabetes – Put them on insulin
- HBP – hypertensive meds
- High cholesterol – put them on statins
- COPD- put them on a CPAP
- Reduce Na<sup>+</sup> intake and H<sub>2</sub>O intake; high Na causes the body to retain water.

# Management of CHF

- Our focus is on NYHF Class IV patients that require some form of mechanical support and monitoring post hospitalization.
- Despite improvement with medical therapy, the readmissions of these patients pose a significant burden to the healthcare system.
- The Zoll MicroCor device monitors ADHF patients who have been admitted and require post-hospitalization monitoring.
- Outpatient monitoring and lung impedance management can significantly reduce repeat hospitalization, therefore reducing the healthcare burden.

# Management of CHF

- The SC will work with the CRA to provide site capabilities information to manage this study.
- Good luck everyone!

