

# Controlling Heart Failure in Massachusetts

## I. Heart Failure in Massachusetts: Prevalence, Outcomes & Costs.

Heart failure (HF) is a major human and financial problem in Massachusetts (MA) as it is in the rest of the US (U.S.). Table 1, below, summarizes the critical statistics related to HF in MA. The population of Massachusetts (MA) is 6.4 million and, based on national statistics, 106,667 individuals in this population have heart failure (HF). Based on a mathematical model developed by CVP Diagnostics (the Company), the frequency of HF hospitalizations, deaths and costs in any population can be predicted. Using that model, 68,267 of the estimated 106,667 HF patients in MA will have abnormally elevated LVEDPs which will lead to 28,672 hospitalizations and 10,240 deaths along with care-costs of \$802.8M annually.

**Table 1. Critical HF Statistics in MA**

Population	6.4M*
Number of HF Patients	106,667
HF Patients with LVEDPs >20 mmHg	68,267
Annual Hospitalizations	28,672
Annual Deaths	10,240
Annual Care-Costs	\$802.8M

\*M, million

**Abnormally Elevated LVEDP Levels Drive All HF Outcomes & Costs** HF is a chronic condition characterized by progressive shortness of breath and frequent hospitalizations. After hospital discharge, 44% of HF patients are re-admitted within six months. The major cause of declining quality of life and frequent hospitalizations is thought to be unrecognized expansion of intravascular fluid volume and abnormally elevated left ventricular end-diastolic pressure (LVEDP).

**Efficacy of HF Management In MA Must Be Assured** For more than 60 years, the treatment of HF patients in the US has been guided by clinical assessment (patient history and physical exam). Recent reports indicate that replacement of clinical assessment with hemodynamic monitoring could reduce hospitalizations by more than 50%. Since thousands of HF patients are hospitalized or die each year in MA while managed by clinical assessment, assuring that the management of HF is as effective as possible is critically important to HF patients and their care providers in MA.

**New Monitor Evaluates Efficacy of Clinical Assessment for Management of HF Patients in MA** A new monitor, the VeriCor® monitor, was recently cleared by the US FDA as “essentially equivalent” in accuracy for LVEDP to catheters used to measure LVEDPs in-hospital ICUs. “LVEDP” stands for “left ventricular end-diastolic pressure”, the pressure of blood entering the heart from the lungs. Abnormally elevated LVEDP levels drive virtually all negative HF outcomes and costs.

CVP Diagnostics developed the first noninvasive ICU-caliber monitor, the VeriCor® monitor and the VeriCor® monitor went on to provide dramatic new insights into the causes and control of heart failure.

New scientific evidence indicates that the VeriCor® monitor could revolutionize HF care in the US and reduce HF deaths, hospitalizations and costs dramatically.

To date, the VeriCor® monitor has shown:

- (i) clinical assessment, the gold standard for the management of heart failure patients for more than 60 years, is ineffective;
- (ii) the ineffectiveness of clinical assessment leads directly to most heart failure deaths, hospitalizations and costs;
- (iii) replacing clinical assessment with the VeriCor® monitor has been shown to reduce HF hospitalizations and care-costs by more than 80% while also reducing heart failure deaths by more than 60%;
- (iv) replacing clinical assessment with the VeriCor® monitor could control heart failure deaths, hospitalizations and costs in every state in the US.

The following sections describe and quantify the potential benefits of the VeriCor® monitor in the US.

## **II. MA Study Shows Clinical Assessment Fails to Control HF Deaths, Hospitalizations & Costs**

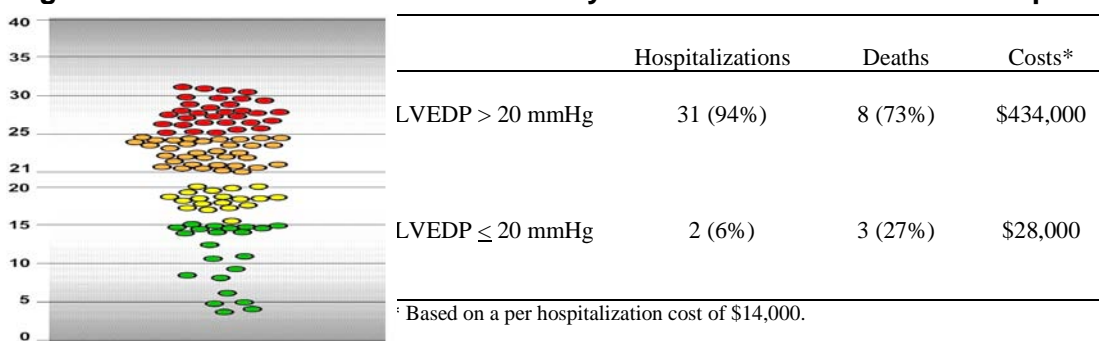
**Critical Evaluation of Clinical Assessment Carried Out in Boston** Clinical assessment has been the "gold standard" for the management of HF patients in the US for more than 60 years. Although cardiologists and other care providers have long believed that clinical assessment is effective for the management of HF patients, the reliability of clinical assessment for controlling LVEDP levels and keeping HF hospitalizations, deaths and costs at a minimum had never been documented. The Company sponsored the first-ever evaluation of clinical assessment and the results of that evaluation are presented below.

*While the evaluation was carried out in Boston, the results should be reasonably representative of the status and prognosis of HF patients across the state and across the US since virtually all HF patients in the US are managed by clinical assessment.*

**Ineffectiveness of Clinical Assessment Causes Most HF Hospitalizations, Deaths & Costs** A detailed discussion of the first evaluation of the efficacy of clinical assessment was included in an earlier report, i.e., *Revolutionizing Heart Failure Care In Connecticut*. Figure 1, below, shows that clinical assessment failed to maintain LVEDPs in the normal/near-normal range in 74 (64%) of 115 ambulatory HF patients. As a result, there were 33 hospitalizations in the 12 month follow-up period and 31 of the 33 (94%) hospitalizations occurred in patients with elevated LVEDP levels.

In addition, there were 11 deaths in the follow-up period and 8 of the 11 (73%) occurred in patients with abnormally elevated LVEDP levels (LVEDP range, 21 to 34 mmHg). Finally, care-costs were \$434,000 in patients with elevated LVEDPs and \$28,000 in patients with LVEDPs in the normal-near normal range ( $\leq 20$  mmHg).

**Figure 1. 115 LVEDP Levels in Ambulatory HF Patients & 1-Year Follow-Up**



**Comment.** These findings indicate that clinical assessment is ineffective for the control of HF outcomes and costs. Since the treatment of virtually all of the 106,667 HF patients in MA is guided by clinical assessment, these results are likely representative of the status and prognosis of HF patients across MA.

**Conclusion.** Management of HF in MA is ineffective and should be supplemented or replaced by treatment guided by monitoring with the VeriCor® monitor.

### III. Will Replacing Clinical Assessment With Hemodynamic Monitoring Reduce HF Outcomes & Costs in MA?

Replacing clinical assessment with the IHM (Implanted Hemodynamic Monitor, Medtronic Corp.) for the treatment of ambulatory HF patients reduced hospitalizations dramatically. As shown in Table 2, 32 HF hospitalizations occurred in a 6-month period in which clinical assessment guided treatment. Clinical assessment was then replaced by the IHM to guide treatment. In the next 6-months, there were 15 hospitalizations, a reduction of 53% that was statistically significant ( $p < 0.05$ ).

**Table 2. IHM Impact On Hospitalizations**

	6 Months Prior to IHM	6 Months Post IHM	% Reduction	p-value
HF Hospitalizations	32	15	53 %	0.05

**Comment.** *In view of the failures of clinical assessment to control LVEDP levels and outcomes in HF patients shown in Figure 1 and the impact of replacing clinical assessment with monitoring provided by the IHM, it is reasonable to conclude that clinical assessment alone may no longer be acceptable for the management of HF patients and should be supplemented or replaced by hemodynamic monitoring with the VeriCor® monitor to guide treatment.*

**LVEDP Levels Are A Major Determinant of Prognosis In HF Patients.** Levels of LVEDP (left ventricular end-diastolic pressure, the most reliable indicator of the presence and severity of HF) now appear to be the primary determinant of the prognosis of HF patients. Earlier scientific publications by CVP Diagnostics have shown that most HF hospitalizations and deaths occur in patients with abnormally elevated LVEDP levels. While LVEDPs are maintained in the normal/near-normal range ( $\leq 20$  mmHg), hospitalizations and deaths in HF patients are infrequent to rare. As LVEDP levels increase into the abnormally elevated range ( $>20$  mmHg) hospitalizations, deaths and costs increase dramatically.

*To control HF in MA, LVEDP levels must be maintained in the normal/near-normal range.*

#### IV. Monitoring Levels & Costs of Identifying Patients in Need of Monitoring In MA

**Preparing For & Implementing Comprehensive HF Monitoring In MA** To implement an effective monitoring program for HF patients in MA, priority must be given to the identification of patients with abnormally elevated LVEDPs that put them at-risk for hospitalization and death. The 4 items identified below indicate the monitoring targets and the costs for implementing each step.

**1. Screening HF Patients to Identify Those in Need of Monitoring.** To identify patients at-risk for hospitalization and death because of abnormally elevated LVEDP levels, LVEDP levels must be measured in all 106,667 HF patients in MA to identify the 68,267 with elevated LVEDP levels. With a per-test cost of \$150, the measurement of LVEDP levels in 106,667 patients in MA will cost \$16 million.

**2. Controlling LVEDPs in Patients with Abnormally Elevated LVEDPs.** To reduce abnormally elevated LVEDPs in 68,267 HF patients with elevated LVEDPs, LVEDP levels must be measured weekly for 6 weeks while treatment to reduce high LVEDP levels is provided. The total number of LVEDP measurements for this 6-week period will be 409,602 and costs will be \$61.4 million.

**3. Maintaining LVEDP Levels in Normal/Near-Normal Range.** To assure that LVEDP levels are maintained in the normal/near-normal range, monthly measurements of LVEDP will be made for six months for a total of 409,602 measurements at a cost of \$61.4 million.

**4. Quarterly Monitoring to Maintain LVEDP Levels in Normal/Near-Normal Range.** Once stabilized with the LVEDP in the normal/near-normal range, most HF patients can be maintained at this level with quarterly monitoring. This will require measurement of LVEDP four times a year in 68,267 patients for a total of 273,068 VeriCor® monitor measurements at a cost of \$41 million.

The total number of tests and costs of testing with the VeriCor® monitor are shown below.

**Table 3. Number & Costs of VeriCor® Monitor Measurements in Year 1 of Monitoring Program**

Measurements	LVEDP Measurements (No) (N)	Costs of LVEDP (\$)
1. Screening	106,667	\$16M
2. Controlling	409,602	\$61.4M
3. Maintaining	68,267	\$10.2M
4. Monitoring	273,068	\$41.0
<b>Totals</b>	<b>857,604</b>	<b>\$128.6M</b>

**Do Treatment Benefits Justify Costs of Monitoring?** The total number of measurements needed to control LVEDP levels is expected to be 857,604 at a cost of \$128.6 million.

*Expected benefits of the comprehensive VeriCor® monitoring in terms of savings in HF care-costs as well as reductions in deaths and hospitalizations are presented below.*

## V. Cost-Benefit Projections of Replacing Clinical Assessment with the VeriCor® Monitor To Control HF Outcomes & Costs

There are an estimated 28,672 HF hospitalizations and 10,240 HF deaths annually with clinical assessment along with care-costs of \$802.8 million (Table 1). Replacing clinical assessment with the VeriCor® monitor to guide the treatment of HF patients is expected to reduce HF outcomes and care-costs by at least 50%.

These reductions are expected to prevent 14,331 hospitalizations and 5,120 deaths while saving \$401.3 million (Table 4).

**Table 4. Replacing Clinical Assessment With VeriCor® Monitor Will Reduce HF Outcomes & Costs By 50% In MA**

	Clinical Assessment	VeriCor® Monitor	Reductions/Savings
HF Hospitalizations	28,672	14,331	14,331
HF Deaths	10,240	5,120	5,120
HF Care-Costs	\$802.5M	\$401.3M	\$401.3M

**Comment.** A 50% reduction in HF hospitalizations will reduce hospitalizations by 14,331 a year while reductions in HF deaths of 50% will reduce deaths by 5,120 (Table 4, lines 1 & 2).

A 50% reduction in "HF Care-Costs" will reduce costs by \$401.3 million a year, saving \$401.3 million a year (Table 4, line 3).

## VI. Cost-Benefit Analysis of Impact of Monitoring HF Patients in MA With VeriCor® Monitor

**Costs of Monitoring to Control HF in MA.** As shown in Table 3, controlling LVEDP levels in HF patients in MA in Year 1 of a VeriCor® monitoring program will require 819,204 LVEDP measurements at a cost of \$138.8 million.

In Year 2, since the costs of "Screening" and "Controlling" HF will no longer be necessary, only the costs of "Maintaining" LVEDPs at a cost of \$10.2 million and "Monitoring" treatment at a cost of \$41 million will remain, the costs of controlling HF in Year 2 and thereafter will be \$51.2 million.

**Expected Reductions In HF Hospitalizations, Deaths & Costs With VeriCor® Monitor in MA.** Replacing clinical assessment with the VeriCor® monitor could reduce HF outcomes and costs by at least 50%. With a 50% reduction, HF hospitalizations could be reduced by 14,331 a year, deaths could be reduced by 5,120 a year and annual care-costs could be reduced by \$401.3 million (Table 4).

**Net Reductions In HF Care-Costs With VeriCor® Monitor In MA.** As shown in Table 4, annual cost-savings with the VeriCor® monitor are expected to be \$401.3 million. The total annual costs of the VeriCor® monitoring program in MA in Year 1 are \$128.6 million (Table 2). Net cost-savings for the VeriCor® monitoring program in Year 1 can be projected by subtracting the costs of the monitoring program (\$128.6 million) from annual cost savings, i.e., \$401.3 million minus \$128.6 million. Thus, annual "net cost-savings" in Year 1 would be \$272.7 million.

In Year 2 and thereafter, assuming annual savings would continue at about \$401.3 million, the costs of monitoring would be \$51.2 million because the costs for “Screening” and “Controlling” (Table 3) would no longer be necessary. Thus, “net cost-savings” in Year 2 to be expected to be \$401.3 million minus \$51.2 million, or \$350.1 million.

**Conclusion.** *With major reductions in HF hospitalizations (14,331 a year) and deaths (5,120 a year) each year and annual net cost-savings of \$272.7 million in Year 1 and \$350.1 million in Year 2 and thereafter, a comprehensive VeriCor® monitoring program for HF patients in MA could be cost-effective while also being highly effective in human and medical terms.*