

Revolutionizing Heart Failure Care in Connecticut

I. Current Status of Heart Failure in Connecticut

Heart failure (HF) affects 5 million Americans, has a mortality rate of 50% in 5-years and the estimated total cost of HF in the US (U.S.) for 2008 is projected to be \$34.8 billion. Despite new drugs and other advances, HF deaths in CT and the US have increased steadily over the past 20 years, and will continue to increase as the population ages.

The annual economic burden of HF for CT is approximately \$280 million with HF hospitalizations being the primary contributor. During 2005, there were an estimated 9,519 HF hospitalizations at a cost of \$140 million in CT (Table 1). Medicare was the expected payer in 66% of these hospitalizations while private insurers, patients and other sources paid the rest of the costs.

Table 1. Heart Failure Deaths, Hospitalizations and Costs in Connecticut

Heart Failure Deaths	3,134
Heart Failure Hospitalizations	9,519 ¹
Hospitalization Costs	\$140 million ²
Total Heart Failure Costs	\$280 million

¹Office of Health Care Access, CT Department of Public Health.

²Average HF hospitalization cost is \$14,706 per CT Department of Public Health.

Abnormally Elevated LVEDP Levels Drive All HF Outcomes & Costs. HF is a chronic condition characterized by progressive shortness of breath and declining quality of life. Many HF patients suffer repeated episodes of increasing shortness of breath, many of which require hospitalization. Within 6 months of hospital discharge, as many as 44% of hospitalized HF patients are re-hospitalized. The major cause of declining quality of life and frequent hospitalizations/re-hospitalizations is the unrecognized accumulation of fluid.

The excess fluid increases LVEDP (left ventricular end-diastolic pressure, the pressure of blood entering the heart from the lungs) which, in turn, increases shortness of breath as fluid in the air sacs of the lung blocks the absorption of oxygen and ultimately leads to death.

Limited Efficacy of "Gold Standard" for HF Management. Clinical assessment (patient history and physical exam) manages virtually all HF patients in CT and throughout the US. Clinical assessment, however, cannot detect abnormally elevated LVEDP levels and has never been evaluated for the control of HF deaths and hospitalizations because a technology capable of measuring LVEDP levels in ambulatory HF patients managed by clinical assessment has not been available.

New Noninvasive ICU-Caliber Monitor Can Overcome Limitations of Clinical Assessment.

Recently, a noninvasive ICU-caliber monitor, the VeriCor[®] monitor, became available and was cleared by the US FDA as "essentially equivalent in accuracy" for LVEDP to the catheters used to monitor LVEDP levels in HF patients in hospital ICUs. The VeriCor[®] monitor has since measured LVEDP levels in 115 HF patients in the greater Boston area to determine:

1. the sensitivity of the physical findings of clinical assessment for the detection of abnormally elevated LVEDP levels;
2. the relationship of abnormally elevated LVEDP levels to subsequent HF deaths, hospitalizations and costs.

The surprising results are presented below.

II. Physical Signs of Clinical Assessment Fail to Identify HF Patients with Abnormally Elevated LVEDP Levels

For more than 60 years, clinical assessment has been the "gold standard" for the management of HF patients in CT. The emergence of the noninvasive VeriCor[®] monitor made it possible to evaluate clinical assessment for the first time. In this section, the sensitivity of clinical assessment for abnormally elevated LVEDP levels will be evaluated and, in the next section, the results of the first analysis of the relationship of LVEDP levels to HF deaths, hospitalizations and costs will be presented.

Sensitivity of Clinical Assessment for Abnormally Elevated LVEDP Levels. As noted above, clinical assessment manages the treatment of virtually all HF patients in CT. Clinical assessment, however, is entirely dependent upon the presence of the physical findings of HF, i.e., rales (crackles over the lung fields on stethoscopic examination indicating fluid in the airways), jugular venous distention (JVD) and edema (abnormal accumulation of fluid especially in the lower legs) to identify HF patients at increased risk for death and hospitalization because of abnormally elevated LVEDP levels, i.e., LVEDPs >20 mm Hg.

The VeriCor[®] monitor determined the frequency with which these physical findings of HF were present in 74 patients with abnormally elevated LVEDP levels (mean 25 mmHg; range 21-34 mmHg) and the results are shown in Table 2.

Table 2. Sensitivity of Rales, JVD & Edema for Abnormally Elevated LVEDPs* in 74 HF Patients

	Rales		JVD		Pedal Edema	
	N	%	N	%	N	%
Absent	59	80%	53	72%	42	57%

*LVEDPs >20 mmHg

Comment. The results shown in Table 2 indicate that, in a group of HF patients with abnormally elevated LVEDP levels, physical findings were absent in 57% or more, i.e., rales were absent in 80%, JVD was absent in 72% and edema was absent in 57%. The impact on subsequent HF deaths and hospitalizations and the inability of clinical assessment to identify HF patients in need of more aggressive treatment is examined in the next section.

III. Failure of Clinical Assessment Causes Most HF Deaths, Hospitalizations & Costs

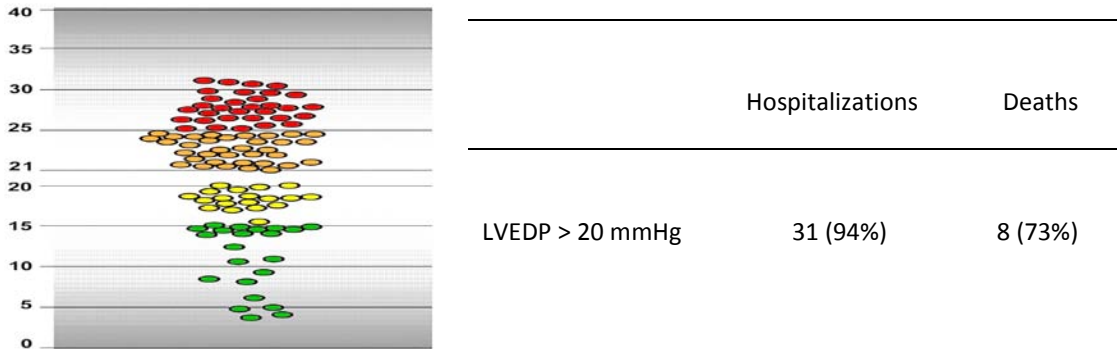
An evaluation of the relationship between LVEDP level and subsequent HF deaths and hospitalizations in ambulatory HF patients was not possible until the advent of the noninvasive VeriCor® monitor. As noted above, the physical findings that allow clinical assessment to recognize HF patients in need of more aggressive treatment were absent in 57 to 80% of patients with abnormally elevated LVEDP levels (>20 mmHg).

In this section, the relationship between LVEDP level and subsequent HF death and hospitalization will be presented.

First Noninvasive ICU-Caliber Monitor Shows Elevated LVEDPs Drive HF Deaths, Hospitalizations & Costs. The VeriCor® monitor measured LVEDP levels in a population of 115 ambulatory HF patients considered to be "stable", i.e., relatively symptom-free and with few or no physical signs of HF. LVEDP levels are displayed in Figure 1. Of the 115 patients, 74 (64%, upper panel) had abnormally elevated LVEDPs while LVEDPs were in the normal/near-normal range (≤ 20 mmHg, lower panel) in only 41 (36%).

More importantly, there were 11 deaths and 33 hospitalizations in the subsequent 12 months and 8 (73%) of the 11 deaths and 31 (94%) of the 33 hospitalizations occurred in patients with abnormally elevated LVEDP levels.

Figure 1. LVEDP Levels in 115 Ambulatory Heart Failure Patients



Comment. Since clinical assessment is the same in CT as it is in Boston, the relationship between LVEDP levels and subsequent HF deaths and hospitalizations in CT can be expected to be comparable to those in the greater Boston area.

CONCLUSION. These data provide two important insights into HF control:

1. Clinical assessment alone is no longer acceptable for the management of HF;
2. VeriCor® monitor-mediated treatment could reduce negative HF outcomes.

IV. Scientific Evidence Indicates Replacing Clinical Assessment with Hemodynamic Monitoring to Guide Treatment of HF Patients Will Reduce HF Outcomes

The replacement of clinical assessment with the IHM (Implanted Hemodynamic Monitor, Medtronic Corp.) for the treatment of ambulatory HF patients reduced hospitalizations dramatically. As shown in Table 3, below, 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 3. IHM Impact on HF Hospitalizations in Patients Managed by Clinical Assessment

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

*The IHM requires chest surgery and will not be acceptable to the vast majority of HF patients.

Comment. Now that it is clear that abnormally elevated LVEDP levels are responsible for the large majority of HF hospitalizations and deaths (Figure 1) and that hemodynamic monitoring can reduce HF outcomes (IHM) by more than 50%, it is reasonable to assume that the more accurate VeriCor® monitor could also reduce HF outcomes by more than 50%. With abnormally elevated LVEDPs apparently responsible for more than 90% of HF hospitalizations and more than 70% of HF deaths (Figure 1) and very likely the vast majority of HF costs, it is important to examine the potential benefits and cost-effectiveness of a comprehensive HF monitoring program in CT.

V. Quantifying Monitoring Needs & Costs of A Comprehensive HF Monitoring Program In CT

Objective of Comprehensive HF Monitoring in CT. The objective of a comprehensive HF monitoring program in CT is to identify HF patients with abnormally elevated LVEDP levels, reduce elevated LVEDPs and maintain them in the normal/near-normal range (≤ 20 mmHg).

This section will estimate the number of LVEDP measurements likely to be needed to identify HF patients with abnormally elevated LVEDPs and to reduce abnormally elevated LVEDPs as needed.

To permit cost-effectiveness projections, the costs of monitoring will also be estimated so that, when the potential benefits of the monitoring program are considered in one of the following sections, a reasonable indication of the potential human benefits can be considered in view of the costs needed to achieve those benefits.

Costs of Physician Oversight of HF Monitoring Program. Once LVEDP measurements have been performed, the patient's physician will be notified of the LVEDP level and will make treatment decisions based on the test results and the patient's condition. A reasonable cost for physician compensation could be built into the current \$150 per test cost or an alternative means of physician compensation will need to be identified.

A. Monitoring Needs & Costs in Year 1

Preparing For Comprehensive HF Monitoring in CT. The following three steps indicate how an effective HF monitoring program can be implemented in CT. Three monitoring targets are identified below, along with the number and costs of LVEDP measurements needed to reduce abnormally elevated LVEDPs to the normal/near-normal range in the targeted populations.

- 1. Screening HF Patients to Identify Those in Need of Monitoring.** To identify patients at-risk for hospitalization and death, LVEDP levels must be measured in all 56,661 HF patients in CT to identify those with elevated LVEDPs. At a per-test cost of \$150, these measurements will cost \$8.5 million. The estimated 20,400 patients with LVEDPs in the normal/near-normal range will enter the LVEDP maintenance program (# 3, below) while the estimated 36,261 patients with elevated LVEDPs will enter a program to reduce elevated LVEDPs (# 2, below).
- 2. Controlling LVEDPs in Patients with Abnormally Elevated LVEDPs.** To safely reduce abnormally elevated LVEDPs in 36,261 HF patients will require weekly LVEDP measurements for a period of six weeks. The total number of LVEDP measurements for this 6-week period will be just under 218,000 and the costs are expected to be \$32.7 million.
- 3. Quarterly Monitoring to Maintain LVEDP Levels in Normal/Near-Normal Range.** Once LVEDP levels are stabilized in or close to 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 all 56,661 HF patients which will require 226,644 VeriCor® monitor measurements at a cost of \$34 million.

As shown under "Costs" in Table 4-A, costs will be \$75.2 million for 501,305 (under "LVEDPs") VeriCor® measurements of LVEDP. Payments to physicians for guiding treatment have not yet been determined and will need to be added to the \$75.2 million in Table 4-A.

Table 4-A. Number & Costs of LVEDP Measurements in Year 1 of HF Monitoring Program in CT

Steps to HF Control	Patients (N)	LVEDPs	Costs
		(N)	(\$)
1. Identify HF Patients With LVEDPs >20 mmHg	56,661	56,661	\$8.5M
2. Controlling Elevated LVEDPs	36,263*	218,000	\$32.7M
3. Maintaining LVEDPs in Target Range	56,661	226,644	\$34M
Total		501,305	\$75.2M

*It is estimated that 64% of HF population will have LVEDP > 20 mmHg, i.e., 36,263.

Comment. Thus, the total costs of the monitoring program in Year 1 will be \$75.2 million for 501,305 VeriCor® monitor measurements of LVEDP plus the cost of payments to the physicians providing the treatment decisions which are yet to be determined.

B. Monitoring Levels & Costs in Year 2

Costs of Monitoring in Year 2. Since Steps 1 & 2 will only be necessary in Year 1, only Step 3 will be required in Year 2 and thereafter. Thus, as shown in Table 4-B, 226,644 LVEDP measurements at a cost of \$34M will be required to maintain LVEDP levels in the normal/near-normal range after Year 1.

Table 4-B. Costs of HF Monitoring in CT in Year 2

	Patients (N)	LVEDPs (N)	Monitoring Costs (\$)
Maintaining LVEDPs in Target Range	56,661	226,644	\$34M
Total		226,644	\$34M

VI. Projected Annual Impact of VeriCor® Monitor on HF Outcomes & Cost Savings in CT

As shown in Part IV, above, hemodynamic monitoring (IHM) reduced hospitalizations by more than 50%. Because the VeriCor® monitor is significantly more accurate than the IHM for LVEDP, it is likely that the VeriCor® monitor could not only achieve a 50% reduction in hospitalizations but could achieve reductions of 70 to 80%. Pending the results of ongoing studies and for the purposes of this presentation, however, projected reductions in HF outcomes with VeriCor® replacement of clinical assessment will be limited to 50%.

Reductions In LVEDPs Will Reduce Deaths & Costs As Well As Hospitalizations. Since the VeriCor[®] monitor has shown (Figure 1) that abnormally elevated LVEDP levels not only drive HF hospitalizations but also deaths and costs, it is expected that reductions in elevated LVEDPs will reduce deaths and costs as well as hospitalizations (as shown in Section 4). Accordingly, projections of outcome reductions of 50% in HF deaths and costs as well as hospitalizations are included in the analyses below.

Impact of 50% Reductions On Annual Deaths & Hospitalizations in CT. As shown under "Treatment Guided by Clinical Assessment" in Table 5, there are an estimated 3,134 HF deaths each year in CT. A 50% reduction in HF deaths would reduce deaths to 1,567 a year (Table 5, under "Treatment Guided by VeriCor[®] monitor"), for a reduction of 1,567 deaths a year. There are also 9,519 HF hospitalizations a year in CT and a reduction of 50% would reduce hospitalizations to 4,760 a year, a reduction of 4,760 hospitalizations a year.

Impact of 50% Reduction on "All HF Costs" Each Year In CT. As shown at line 3 of Table 5, annual costs of hospitalizations are \$140 million a year in CT. A 50% reduction would decrease costs to \$70 million a year, saving \$70 million a year. "All HF Costs" in CT are estimated to be \$280 million a year (Table 5, line 4). A reduction of 50% would reduce "All HF Costs" from \$280 million a year to \$140 million a year, saving \$140 million a year in CT.

Table 5. Reductions (50%) In Deaths, Hospitalizations & Costs with VeriCor[®] In CT

	Treatment Guided by Clinical Assessment*	Treatment Guided by VeriCor [®] Monitor *	Net Reductions & Cost Savings
Deaths	3,134	1,567	1,567
HF Hospitalizations	9,519*	4,760	4,760
Hospitalization Costs	\$140M**	\$70M	\$70M
All HF Costs	\$280M	\$140M	\$140M

*CT Department of Public Health. **Average hospitalization cost in CT, \$14,706.

Projected Impact In Year 1 Of Replacing Clinical Assessment With VeriCor® Monitor To Guide Heart Failure Treatment in CT. If the projected annual reductions of 50% in HF deaths & hospitalizations are achieved, 1,567 deaths and 4,760 hospitalizations would be prevented and care-costs would be reduced by 50% from \$280 million to \$140 million a year.

VII. Cost-Benefit Analysis of Comprehensive HF Monitoring Program in CT

Year 1. Cost Savings with Comprehensive HF Monitoring in CT. As shown in Table 5, “All HF Costs” in Year 1 while clinical assessment guides the management of HF are estimated to be \$280M. After a 50% reduction in these costs, all HF care-costs would be \$140 million (line 4, Table 5). Thus, savings in “All HF Costs” of \$140 million are shown in Table 5 and in Table 6 under “**Year 1**” at “All Costs of Monitoring Program”.

At "All Costs of Monitoring Program" in Table 6 for Year 1, all costs of the monitoring program are shown to be \$75.2 million. When these costs are subtracted from the \$140 million savings in "All HF Costs" in Table 5 which are seen as “Savings in HF Care Costs” in Table 6, net savings are expected to be \$64.8 million in Year 1.

Year 2. Cost Savings with Comprehensive HF Monitoring in CT. In Year 2, it is expected that "Savings in HF Care Costs” should remain about the same as they were in Year 1, i.e., \$140 million. “All Costs of Monitoring”, however, will be reduced to \$34 million because all of the monitoring costs that had been necessary to identify the HF population that would need continuous monitoring had already been identified. As a result, net savings in Year 2 and thereafter are expected to be \$106 million a year.

Table 6. Net Savings in Year 1 & 2 with HF Monitoring

	Year 1	Year 2
Savings in HF Care Costs	\$140M	\$140M
All Costs of Monitoring Program	\$75.2M	\$34M
Net Savings	\$64.8M	\$106M

Comment. It is expected that replacement of clinical assessment with the VeriCor® monitor will prevent 1,567 deaths and 4,760 hospitalizations while reducing heart failure care-costs by \$140 million a year. When “All Costs of Monitoring Program” (\$75.2 million in Year 1) are subtracted from “Savings in HF Care Costs”, “Net Savings” are expected to be \$64.8 million.

In “Year 2”, “Savings in HF Care Costs” are expected to be \$140 million while “All Costs of Monitoring Program” are expected to be \$34 million. “Net Savings” in Year 2 and thereafter are expected to be \$106 million a year.

VIII. Summary & Conclusions

The Treatment of Heart Failure Patients In Connecticut Is Ineffective. The treatment of HF patients in Connecticut is ineffective because clinical assessment is ineffective.

Supplementing clinical assessment with the VeriCor® monitor will overcome the limitations of clinical assessment and could reduce deaths from 3,134 to 1,567 a year, sparing HF patients and their families 1,567 deaths a year. Hospitalizations could be reduced from 9,159 to 4,760, a reduction in 4,760 hospitalizations a year in CT (Table 5).

Financial Benefits of VeriCor® Monitor-Guided Treatment of HF Patients in CT. As shown in Table 6, by the end of Year 1 of comprehensive treatment of HF patients guided by the VeriCor® monitor, net cost-savings could reach \$64.8 million a year and are expected to reach \$106 million a year in Year 2 and thereafter.

Quality-of-Life Impact. While quality of life evaluations were not part of this study, major reductions in hospitalizations and deaths may be the best evidence that quality-of-life of HF patients in CT would be improved significantly by a comprehensive HF monitoring program using the VeriCor® monitor.

Conclusion. A comprehensive VeriCor® monitor-guided HF treatment program could dramatically reduce HF deaths, hospitalizations and costs each year in CT and be cost-effective.