

# TEN-HMS Study Demonstrates Clinical and Financial Efficacy of Home Telemonitoring

*The world's first large-scale, randomized prospective telemonitoring trial showed that home-based telemonitoring reduced the number of days spent in hospital by 26% and led to an overall 10% cost savings compared to nurse telephone support. Home Telemonitoring also significantly improved survival rates relative to usual care and led to high levels of patient satisfaction.<sup>1</sup>*

### **Background:**

Heart Disease Management is an important topic to world health leaders because of the high mortality rate and significant expense of treating congestive heart failure (CHF). CHF is the leading cause of hospital admissions for people over 65 in the United States, and the hospital readmission rate for this population is approximately 44% within a six-month period.<sup>2</sup> According to the American Heart Association's 2003 *Heart and Stroke Statistical Update*, heart failure patient care will cost \$24.3 billion in 2003 alone<sup>3</sup> – with hospitalization accounting for nearly 70% of this expense.<sup>4</sup> Treating high-risk heart failure patients is estimated to cost 1-2% of the total health care budget in U.S. and in Europe.<sup>5</sup>

90% of heart failure cases can be treated with a combination of drugs, diet and lifestyle changes,<sup>6</sup> yet as many as one out of five CHF hospital admissions result from patients' non-compliance with AHCPR guidelines for diet and medication.<sup>7</sup> The intent of

home-based telemonitoring is to promote patient self-care through education, so that patients get in the habit of self-monitoring and are empowered to play a more active role in their own health care management and variation in diuretic intake. The telemonitoring service used in this study, provided by Philips Medical Systems, allows patients to take vital sign measurements in their homes using automated wireless devices. The information is then transmitted via telephone line to a secure web server, so that care managers can review the current status of their patients, assist in the titration of therapy and aid in discharge planning – allowing for earlier intervention and crisis prevention, rather than crisis management.

### **TEN-HMS Study Parameters:**

Sponsored in part by the European Commission under the Trans-European Network initiative, the Home-Care Management Systems study (TEN-HMS) was the first large-scale randomized prospective clinical trial to determine if home-based telemonitoring services for heart failure patients could reduce hospitalizations and improve patient well being while reducing the overall cost of care. To provide proof of concept to European insurance companies and national health care systems, the trial was structured to compare home telemonitoring to nurse telephone intervention, given the high mortality rates and health care costs of providing only usual care to Heart Failure patients.<sup>8</sup>

The Philips logo, consisting of the word "PHILIPS" in a bold, blue, sans-serif font.

Led by Professor John GF Cleland, Department of Cardiology at the University of Hull (UK) and Editor in Chief of the European Journal of Heart Failure, the study involved twelve leading medical centers in the Netherlands, Germany and the UK. Statisticians at the Swiss Institute of Medical Informatics and Biostatistics (IMIB) analyzed the data collected from participating hospitals. The study consortium also included Philips Medical Systems, manufacturer of the home telemonitoring service, and national health care foundations and consultancies across Europe.

The TEN-HMS trial took place between January 2000 and July 2002. In total, 426 heart failure patients with left ventricular systolic dysfunction were randomized to one of three groups:

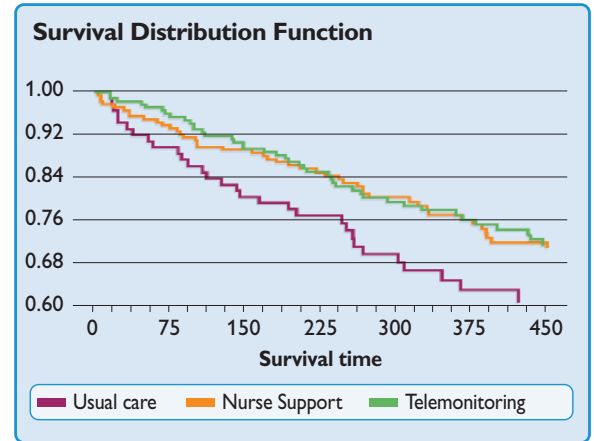
- The control group received ‘Usual Care’ with specialist advice and a management plan delivered by their primary care physician.
- The first intervention group received ‘Nurse Telephone Support’ – with patient care supplemented by monthly telephone contact from a nurse-specialist, as well as patient-initiated “as needed” phone calls.
- The second intervention group received ‘Home Telemonitoring’ – which consisted of nurse telephone support plus patient twice-daily self-measurement of weight, heart rate, blood pressure and ECG, with the data automatically transmitted to their care provider.

Almost all patients in the study had a minimum of 240 days in the trial, with an average follow-up of 480 days, equating to a cumulative 205,000 patient-days. See the Appendix for information on criteria selection and specifics on the intervention groups.

### TEN-HMS Study Results:

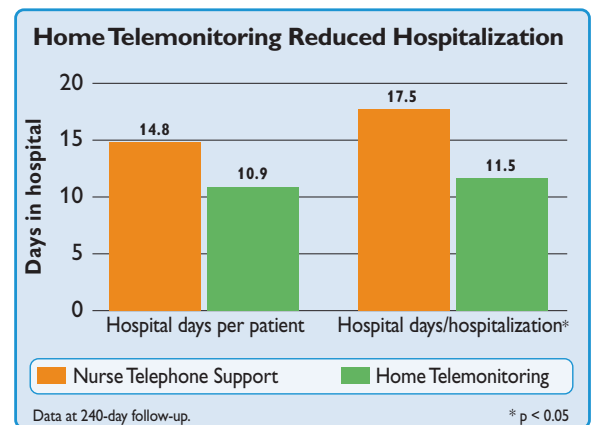
**Survival rates were substantially better for patients receiving Home Telemonitoring or Nurse Telephone Support as compared to Usual Care.**

Home Telemonitoring and Nurse Telephone Support led to significantly lower mortality rates across the entire time period of the TEN-HMS study, compared to patients receiving care through traditional means. At 360-day follow-up, Usual Care patients on average lived 263 days, whereas Home Telemonitoring and Nurse Telephone Support patients survived 303 and 307 days, respectively. 27% fewer patients died after 240-day follow-up in the Home Telemonitoring group compared to those receiving Usual Care.



**Home Telemonitoring patients spent 26% fewer days in hospital than patients receiving only Nurse Telephone Support, due to significantly shorter hospital stays per admission.**

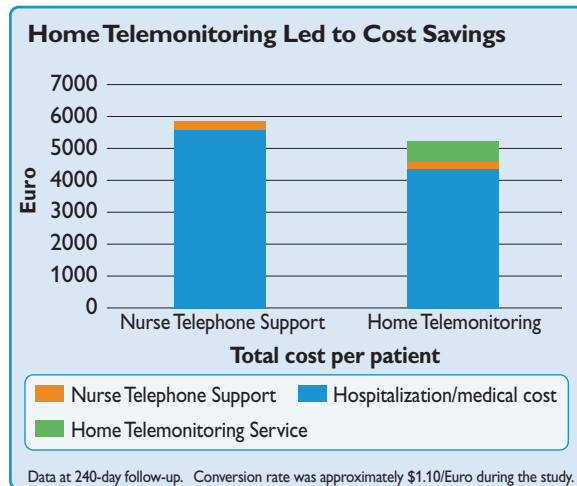
Home Telemonitoring led to an average 3.9-day reduction in hospital days per patient, measured at 240 days follow-up. For the approximately 50% of patients hospitalized, there was a 6.0-day or 34% decrease in Length of Stay for patients in the Home Telemonitoring group. Note that statistically valid comparisons between the Usual Care control group and either intervention group cannot be made for total hospital days or length of stay because of the much greater mortality rate of patients receiving Usual Care.



**Home Telemonitoring led to a 10% cost savings over Nurse Telephone Support.**

Program costs were calculated using a bottom-up approach with hospitalization expenses specific to each of the three countries, and data for days alive observed in each country, measured at 240-day follow-up. The results were then averaged across the three countries. Cost calculations show that there

is a 10% overall savings per patient for the Home Telemonitoring group (including the cost of the telemonitoring service and nurse calling program).



**10% overall cost savings for Home Telemonitoring versus Nurse Telephone Support.**

**20% lower hospitalization/medical costs for HTM vs. NTS (excluding cost of monitoring).**

**Cost Calculation Details:**

- Nurse Telephone Support cost 28 Euro per patient per month<sup>9</sup>
- Home Telemonitoring cost 99 Euro per patient per month
- Hospitalization/Medical Cost includes:  
country-specific hospital costs/day depending on the ward (GVV, ICU or CCU) + Doctor or Specialist consultations (depending on if GP or Specialist and if office appointment or home visit); cost did not include rehab or medication.<sup>10</sup>
- Total Cost of Program = Hospitalization/Medical Cost + Cost of Nurse Telephone Support or Home Telemonitoring

**Home Telemonitoring generated an overall program ROI of 2.1 relative to Nurse Telephone Support.**

Using the following formula to calculate ROI for a disease management program:<sup>11</sup>

$$\text{Return on Investment} = \frac{\text{Gross Savings}}{\text{Program Fees}} = \frac{\text{incremental cost savings per patient}}{\text{additional cost per patient for telemonitoring}} = 2.1$$

This calculation results in an ROI of 2.1 for the Home Telemonitoring program compared to Nurse Telephone Support, calculated as the hospitalization cost saved per patient (1,101 Euro) divided by the additional cost of Telemonitoring per patient (518 Euro) over the 240-day follow-up period. In other words, for every Euro invested in implementing a Home Telemonitoring program, one can expect to return 2.1 Euro in cost savings as compared to nurse telephone support.

**Home Telemonitoring led to high patient satisfaction.**

Patients in the Home Telemonitoring group also reported positive feedback about their care. 88% of these patients felt “safer or much safer” about their health as a result of taking their own vital signs measurements twice daily and knowing that their status was being reviewed by a medical professional. 95% had a “very good or good” overall impression about their home telemonitoring experience. One patient commented, “Having monitoring is very reassuring. Knowing that someone is checking my health twice a day makes me feel safer. Not having to go to see the doctor or having to wait at home for the doctor or nurse to come makes it very convenient for me.”

**TEN-HMS Summary Findings:**

The TEN-HMS study demonstrated the clinical efficacy and cost savings potential of Home Telemonitoring as a means of supplementing more traditional care for managing Heart Failure patients. Home Telemonitoring not only improved survival rates by 15% over Usual Care, but also led to a 26% reduction in hospital days per patient compared to Nurse Telephone Support. This resulted in a 10% overall cost savings for the Home Telemonitoring program relative to Nurse Telephone Support and a Return on Investment of 2.1 (at 240-day follow-up).

As the lead clinical investigator, Professor John GF Cleland, stated in his press conference at the XXIV Congress of the European Society of Cardiology on September 2nd, 2002, “the TEN-HMS trial has, for the first time, scientifically proven that Telemonitoring can reduce the number of days a patient spends in hospital.” These findings should pave the way for more healthcare organizations to consider using Home Telemonitoring as a cost-effective means of improving clinical outcomes and increasing patient satisfaction while managing the hospitalization expense of their Heart Failure programs.

## Appendix: TEN-HMS Protocol

- **Major inclusion/exclusion criteria:**
  - CHF (NYHA II-IV)
  - Discharge from hospital after an admission for heart failure within the previous 6 weeks
  - LV systolic dysfunction (LVEF < 40%) and dilatation (30 mm/m<sup>2</sup>)
  - Treatment with loop diuretics (furosemide > 40 mg/d or equiv.)
  - At least one prior admission in the last 2 years, or if not, LVEF < 25% or furosemide dose > 100 mg/day
  - Able to give informed consent and comply with protocol
  - Not routinely attending hospital more than once per week
- **Interventions: (randomized 1:2:2)**
  - Usual Care (UC): 85 patients
    - Patient management plan delivered principally by the primary care physician (PCP), with usual support from the hospital
    - Included Clinic Visit every 4 months
  - Nurse Telephone Support (NTS): 173 patients
    - Patient management plan delivered by PCP, supplemented with monthly telephone contact from a nurse (est. 60% were HF specialist nurses)
    - Patients also had the ability to call the nurse as needed
    - Included Clinic Visit every 4 months + Nurse Telephone Call every month
  - Home Telemonitoring (HTM): 168 patients
    - Patient management plan primarily implemented by home telemonitoring, which consisted of twice-daily patient self-measurement of weight, heart rate, ECG, and blood pressure (using devices that transmitted information directly, via a telephone link, to a secure server)
    - Included Clinic Visit every 4 months + Nurse Telephone Call every month + Home Telemonitoring twice per day

	UC	NTS	HTM
Number of patients	85	173	168
Mean Age	68	67	67
Mean EF [%]	24	25	25
Gender % Male	82	72	80
NYHA % Class III	42	31	26
NYHA % Class IV	4	8	8
Hosp adm. 24 months prior Random	2.4	2.7	2.6
Mean Weight [kg]	80	75	77
Median NT-proBNP [pmol/l]	273 (n=70)	344 (n=140)	458 (n=131)

(In comparison of plasma NT-proBNP, the COPERNICUS study, which compared carvedilol and placebo in patients with chronic severe heart failure, had Median values of 319pmol/L and 331pmol/L respectively.)<sup>12</sup>

### Footnotes:

- 1 Cleland John GF, Balk Aggie, Janssens, Uwe, et al. Non-Invasive Home Telemonitoring for Patients with Heart Failure at High Risk of Recurrent Admission and Death: The Trans-European Network – Home-Care Management Systems study (TEN-HMS), publication pending. Data in this paper are based on the TEN-HMS summary by John GF Cleland.
- 2 Krumholz HM, Parent EM, et al. Readmission after hospitalization for congestive heart failure among Medicare beneficiaries. Arch Int. Med. 1997; 157: 99-104.
- 3 Economic Cost of Cardiovascular Diseases, 2003 Heart and Stroke Statistical Update, American Heart Association; 40.
- 4 McMurray JJ, Petrie MC, Murdoch DR, et al. Clinical epidemiology of heart failure: public and private health burden. Eur. Heart J. 1998; 19: 9-16.
- 5 McMurray JJ, Stewart S, et al. The burden of heart failure. Eur. Heart J. Supplements 2002, Vol. 4 (Suppl. D); D50-D58
- 6 Meyer TE, Shreve P, et al. Two and Half Year Experience Using “Telemedicine Solutions” for Heart Failure Patients, University of Massachusetts Memorial Health Center, Division of Cardiology, Heart Failure Wellness Center.
- 7 “A cross-sectional study of 435 patients admitted with CHF suggested that 21% of hospital admissions for heart failure are precipitated by diet and medication noncompliance.” Quality of care for patients hospitalized with heart failure at academic medical centers. AM Heart J. 1999; 137(6): 1028-1034
- 8 McMurray JJ, Stewart S, et al. The burden of heart failure. Eur. Heart J. Supplements 2002, Vol. 4 (Suppl. D); D50-D58
- 9 Stewart S, McMurray JJ, et al. An economic analysis of specialist heart failure nurse management in the U.K. Eur. Heart J. 2002; 23: 1371-1378
- 10 S. Stewart, The current cost of heart failure to the NHS in the UK, Eur. J. of HF, 4 (2002); Reduced cost with bisoprolol treatment for heart failure, Eur. Heart J. 2001; 22: 1021-1031; Oostenbrink JB, Koopmanschap MA, Rutten FF. Standardisation of cost: the Dutch manual for costing in economic evaluations. Parmaconomics 2002; 20(7): 443-54
- 11 Stone RE. Playing disease management numbers games. Dis. Mgt. Health Outcomes 1999 Dec; 6 (6): 343-348
- 12 Parker M, Coats AJ, Fowler MB et al. (Carvedilol Prospective Randomized Cumulative Survival Study Group) Effect of Carvedilol on survival in severe chronic heart failure. N Engl J. Med. 2001 May 31: 344(22): 1651-8



**Philips Medical Systems is part of Royal Philips Electronics**

<http://www.medical.philips.com/goto/telemonitoring>

medical@philips.com

© Philips Medical Systems North America Corporation 2003

Philips Medical Systems  
3000 Minuteman Road  
Andover, MA 01810-1085  
(978) 687-1501

All rights are reserved. Reproduction in whole or in part is prohibited without the prior written consent of the copyright holder.

Philips Medical Systems reserves the right to make changes in specifications or to discontinue any product at any time without notice or obligation and will not be liable for any consequences resulting from the use of this publication.

September, 2003  
4522 981 84971