Does Home Monitoring Heart Failure Care Improve Patient Outcomes?

Home Monitoring Should Be the Central Element in an Effective Program of Heart Failure Disease Management

Marvin A. Konstam, MD

Heart failure (HF) is a major and growing public health problem in the United States. On the basis of current trajectories, it has been estimated that, over the next 20 years, the prevalence of HF will increase by 25%, from 2.8% to 3.5% of the population (Figure 1). The increased prevalence may be expected to contribute to an increase in annual direct medical costs from the present estimate of $24.7 billion to approximately $77.7 billion, in 2008 dollars. At the same time, indirect costs—that is, costs related to lost productivity due to morbidity and mortality—may be expected to increase from $9.7 to $17.4 billion. If current legislative and regulatory efforts are successful at expanding healthcare access while improving affordability, systematic approaches must be developed and implemented to drive cost-effectiveness. The management of patients with HF will be front and center in efforts to achieve this goal. Although many questions remain, extensive research performed to date indicates that certain disease management interventions cost-effectively improve clinical outcomes in patients with HF. Home monitoring—providing continuity of patient assessment and care beyond the hospital and conventional ambulatory settings—has been central among the elements of these programs.

Heart Failure Disease Management and Home Monitoring

Home monitoring has been integral to most HF disease management programs, with demonstrable clinical benefit in randomized, controlled trials. A proposal for categorizing the generic components of disease management programs may be applied to define the elements of a HF program as 1) optimizing treatment prescriptions; 2) patient and caregiver education—including adherence to medication and dietary recommendations, self-monitoring, and connectivity to a healthcare provider; and 3) ongoing monitoring and responsiveness to the patient’s condition.

Properly constructed approaches to home monitoring drive or support each of these disease management components by focusing on far more than mere acquisition of physiological data. A systemic approach to home monitoring provides for continual reconsideration of optimal medication prescription and continual reinforcement of patient and caregiver education. Longitudinal interaction with the home monitoring provider can be a key element in driving patient adherence, which may persist long after active monitoring has been withdrawn.

Unlike prescribing a drug or implanting a device, the success of a disease management intervention depends not merely on its implementation, but also on attention to its operational details. Desai et al described the sequence of steps needed to derive clinical benefit from a home monitoring program. These include 1) patient transmission of physiological data; 2) data retrieval and analysis; 3) prescription of an appropriate treatment response; 4) patient contact to implement the prescription; and 5) continued monitoring for response and revised intervention. Table 1 delineates the variables that must be considered in implementing a home monitoring program. The disease

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The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

This article is Part I of a 2-part article. Part II appears on p 828.

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(Circulation. 2012;125:820-827.)

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Circulation is available at http://circ.ahajournals.org

DOI: 10.1161/CIRCULATIONAHA.111.031161
management approaches used in clinical trials generally incorporated several elements, making it difficult to dissect the specific contribution of home monitoring, per se. Nevertheless, assuming that the optimal system characteristics can be identified, it is self-evident that ongoing monitoring of a patient’s condition and expeditiously responding with appropriate treatment will improve on patient outcomes that can be achieved through the conventional approach of intermittent ambulatory visits.

Evidence for the Effectiveness of Home Monitoring

In 1995, Rich et al reported the first randomized, controlled trial supporting the effectiveness of disease management in patients recently hospitalized with HF and considered high risk for readmission. The population was elderly (≥70 years old), predominantly female, and hypertensive. The authors used a 90-day, nurse-directed, multidisciplinary intervention including intensive dietary assessment and instruction, medication review, individualized home visits, and telephone contacts for monitoring and reinforcement of education directed toward medication and dietary adherence. The intervention group had a trend toward improvement in the primary end point of readmission-free survival (P=0.09), driven by 44% and 56% reductions in the total number of all-cause (P=0.02) (Figure 2) and HF readmissions (P=0.04), respectively. Health-related quality-of-life scores improved significantly more in the treatment than in the control group (P=0.001). The treatment was estimated to reduce the average overall 90-day per-patient cost of care by $460.

Publication of the study by Rich et al represented a transformational event for the field of HF management. It demonstrated that a disease management initiative incorporating a robust, interdisciplinary home monitoring component, through which patient education was reinforced and changes in clinical condition triggered rapid adjustments in medical treatment, could substantially and cost-effectively improve clinical outcomes and health-related quality of life. Several key elements likely contributed to this trial’s success, notably greater prescription of, and adherence to, medical treatments compared with the control group. All subsequently published literature helps us to clarify the characteristics of patient populations that most stand to benefit and the disease management components that most contribute to that benefit.

A meta-analysis of remote telemonitoring analyzed results of 14 randomized controlled trials of remote monitoring, comprising either telemetering, structured telephone support, or both, enrolling 4264 patients with HF. Overall, HF-related readmissions were reduced by 21% (95% confidence intervals [CI], 11%–31%) and mortality was reduced

Table 1. Variables to Consider in Implementing a Home Monitoring Program

<table>
<thead>
<tr>
<th>Characteristics of the population that stands to benefit</th>
</tr>
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<tbody>
<tr>
<td>Physiological parameters to monitor</td>
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<tr>
<td>Modality and technology deployed</td>
</tr>
<tr>
<td>Personnel system for monitoring, communicating, and intervening</td>
</tr>
<tr>
<td>Nature of interventional response</td>
</tr>
<tr>
<td>Duration of monitoring and active intervention</td>
</tr>
</tbody>
</table>

Figure 1. Twenty-year projections for United States heart failure prevalence and associated direct medical costs based on current trends. Adapted from Heidenreich et al with permission of the publisher.

Figure 2. Impact of a heart failure disease management intervention on freedom from hospital readmission. Reprinted from Rich et al with permission of the publisher. Copyright ©Massachusetts Medical Society, 1995.
by 20% (8% to 31%). In a subsequent expanded Cochrane review and meta-analysis, these same authors found similar benefits on HF-related hospitalizations among 16 studies (5613 participants) evaluating structured telephone support and 11 studies (2710 participants) evaluating automated telemonitoring (Table 2). The mortality benefit was more evident within the telemonitoring trials (relative risk [RR], 0.66; 0.54–0.81; *P* <0.0001) than within the telephone support trials (RR, 0.88; 0.76–1.01; *P* =0.08).

### Benefits on Mortality

Particularly noteworthy are 2 trials demonstrating reduction in all-cause mortality. Goldberg et al enrolled 280 patients hospitalized with New York Heart Association (NYHA) class III or IV HF. In contrast to the study by Rich et al, entry required left ventricular ejection fraction (LVEF) ≤35%, mean age was 59±15 years, and 68% were male. All patients were under the care of cardiologists experienced in HF management and most were enrolled at centers with dedicated HF management programs. All patients received education, including dietary advice, and recommendations to monitor daily weight, clinical signs, and symptoms and to report any changes to a physician. For patients randomized to the disease management intervention, trained nurses reviewed outputs from an electronic scale and an individualized symptom-response system and reported any changes beyond individualized, prespecified limits to the physician for intervention. Importantly, compliance to the automated monitoring system was 98.5%. Over a mean follow-up of 169±51 days, although improvement in the primary end point of 180-day hospital readmission did not reach statistical significance, there was a 56% reduction in the percentage of patients who died within the intervention group, compared with the control group during this time (18.4% versus 8.0%; hazard ratio 0.40; *P*<0.003).

Cleland et al randomized 426 patients with recent HF hospitalization and LVEF <40% to either automated home telemonitoring, nurse telephone support, or usual care (ratio 2:2:1). Entry required at least one higher-risk marker: prior hospitalization within the preceding 2 years, LVEF <25%, or furosemide dose ≥100 mg/d, or equivalent. Patients were enrolled at hospitals that did not already have a specialized HF management program. All patients received an individualized management plan, including appropriate medications, with implementation among usual care patients performed by the patient’s primary care physician. The telephone support group received monthly calls by a HF nurse specialist who assessed symptoms and medical regimen, provided advice to the primary care provider, and was available for incoming patient calls. The telemonitoring group underwent twice-daily weight, blood pressure, and cardiac rhythm monitoring via an automated home system. In the event of parameters falling outside predefined limits, nurse monitors initiated a guideline-driven intervention either directly or through the primary care physician. Of the patients, 81% demonstrated >80% compliance with at least 1 daily measurement. The study demonstrated a nonsignificant, progressive trend toward reduction in the primary end point of percentage of days lost due to death or hospitalization over 240 days, comparing the usual care (19.5%), telephone support (15.9%), and telemonitoring (12.7%) groups. However, 1-year mortality was significantly reduced in both the telephone support (27%) and telemonitoring (29%) groups, compared with the usual care group (45%) (*P*=0.032) (Figure 3).

These 2 studies importantly advance beyond the observations of Rich et al by 1) extending observed benefit to

### Table 2. Meta-Analysis Findings Delineating the Impact of Telephone-Based and Telemonitoring-Based Home Monitoring Programs on Key End Points

<table>
<thead>
<tr>
<th>End Point</th>
<th>Events per 1000</th>
<th>RR (95% CI)</th>
<th><em>P</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telephone</td>
<td>112</td>
<td>127</td>
<td>0.88 (0.76–1.01)</td>
</tr>
<tr>
<td>Telemonitor</td>
<td>102</td>
<td>154</td>
<td>0.66 (0.54–0.81)</td>
</tr>
<tr>
<td>HF hospitalization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telephone</td>
<td>164</td>
<td>213</td>
<td>0.77 (0.68–0.87)</td>
</tr>
<tr>
<td>Telemonitor</td>
<td>225</td>
<td>285</td>
<td>0.79 (0.67–0.94)</td>
</tr>
<tr>
<td>All-cause hospitalization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telephone</td>
<td>379</td>
<td>412</td>
<td>0.92 (0.85–0.99)</td>
</tr>
<tr>
<td>Telemonitor</td>
<td>474</td>
<td>521</td>
<td>0.91 (0.84–0.99)</td>
</tr>
</tbody>
</table>

Adapted from Inglis et al with permission of the publisher. CI indicates 95% confidence interval; RR, relative risk; and HF, heart failure.

Figure 3. Survival of patients randomized to usual care compared with those randomized to receive a heart failure home monitoring intervention using either a telephone-based or automated telemonitoring-based approach. Reprinted from Cleland et al with permission of the publisher. Copyright ©Elsevier, 2005.
younger populations and those with reduced LVEF; 2) pointing to a specific benefit of home-based monitoring, because the level of background medical care and of initial educational efforts were high in control groups (particularly in Goldberg et al); and 3) suggesting a benefit of home monitoring on all-cause mortality.

Benefits on Readmission
Hospitalization is, by far, the single largest healthcare cost driver among patients with HF, accounting for approximately 60% of the direct costs associated with this condition.11 As a key marker of disease activity and progression, HF hospitalization rate is also a principal outcome measure in most major clinical trials evaluating HF treatment strategies. It is no surprise, then, that HF disease management intervention strategies have focused on rehospitalization rates as a major indicator of the program’s success. The principal findings within the seminal investigation by Rich et al6 were reductions in all-cause and HF-related rehospitalizations. Most (although not all: see below) subsequent randomized clinical trials of programs incorporating home monitoring efforts have demonstrated a reduction in HF-related rehospitalization rates.8

We conducted a randomized, controlled trial across academic and community-based sites, enrolling patients with both reduced and preserved (30% of the population) LVEF, hospitalized for HF, examining the impact of a HF disease management program on the primary end point of HF readmissions.12 The centerpiece of the intervention was a 90-day program of nurse-driven, telephone-based home monitoring incorporating all the elements later articulated by Desai et al.5 Nurses who made initial patient contact soon after hospitalization continued in the monitoring and interventional processes throughout the program. They interfaced directly with the patients’ primary care providers and had regular and continuous support and advice from a HF specialist medical director. Notably, both groups received appropriate medical care, with 90% and 63% of the control group receiving angiotensin converting enzyme (ACE) inhibitors/angiotensin receptor blockers (ARBs) and β-blockers, respectively, at baseline. HF hospitalizations per patient-year alive occurred at rates of 0.55±0.15 versus 1.14±0.22 (mean±SE), respectively, in 97 patients randomized to the intervention versus 103 patients randomized to usual care (relative risk 0.48; P=0.027). This effect was associated with between-group relative risks of 0.54 and 0.64 for HF-related and all cardiovascular-related hospital days per patient-year alive (both P<0.001).

The GESICA Investigators randomized 1518 ambulatory patients with stable HF to an intervention consisting of education, counseling, and nurse-telephone monitoring or to usual care.13 Over an average follow-up of 16 months, patients randomized to the intervention experienced a relative risk reduction of 20% (3%–34%; P=0.026) in the primary end point of death or HF hospitalization, an effect principally driven by 29% relative risk reduction for HF hospitalizations (P=0.005).

The impact of monitoring, per se, on rehospitalization may be difficult to distinguish from that of patient education. Krumholz et al14 demonstrated a reduction in the rate of death or readmission among 44 patients randomized to an intervention focusing on patient education, compared with 44 controls (RR, 0.69; 0.52–0.92; P=0.01). It may be difficult to assign this benefit exclusively to education because the nurses performing frequent calls to reinforce education were also able to detect changes in clinical condition and recommend physician consultation. As a number of authors15,16 have pointed out, the key to achieving clinical benefit, including reduced hospitalization rates, from a disease management program may be the implementation of patient-centered care—ie, enlisting the patient’s direct participation in his or her own care through both education and involvement in the monitoring and intervention process.

Not surprisingly, the impact of HF disease management interventions, including home monitoring initiatives, has often tended to be more evident for HF-related hospitalization than for all-cause hospitalizations. Treatment assessment, educational efforts, and approaches for monitoring and treatment response in these programs have focused on HF as a condition, and the staff implementing and directing these efforts are usually expert in this particular area. However, approximately 50% of rehospitalizations after a HF hospitalization are generally coded as non—HF-related.12,17 A number of the controlled trials have displayed a lesser risk reduction for all-cause hospitalizations,12,13,17 suggesting a possible excess of hospitalizations for other causes. Such an excess may actually speak to a benefit to patients, reflecting detection of related or nonrelated remediable conditions, such as active myocardial ischemia, renal functional impairment, or noncardiovascular conditions, attention to which may obviate longer-term morbidity and mortality.

Not every study has demonstrated the above-mentioned reduction in HF hospitalization rates.17,18,19 Notably, Chaudhry et al17 showed no benefit on the primary end point of death or all-cause readmission over 180 days or on any of the secondary end points, including HF readmission, among 1653 recently hospitalized patients randomized to usual care or an interactive telephone-based system allowing clinical review of daily information regarding symptoms and body weight. As discussed by a number of commentators,5,15,20,21 including the study authors themselves, the negative findings of this well-designed and well-constructed clinical trial provide much insight into the elements of a home monitoring-based HF disease management program contributing to clinical benefit. The intervention seemed to lack several of the elements elucidated by Desai et al.5 Across the 33 US practice sites enrolling patients, there was no standardized management structure connected to the monitoring effort. Practices did not necessarily possess the resources, including sufficient clinical expertise among staff, to implement a full disease management effort with direct patient communication and a standardized response and management algorithm. Clinical
responses to monitoring variances were not systematically documented. As the authors point out, patient and caregiver education, including instruction in self-management, was not integrated into the communication strategies of the nurse monitors. Of the patients, 14% never used the telemonitoring system, and by the final study week, only 55% of patients were using it ≥3 times per week. These points illustrate that monitoring alone is insufficient to improve clinical outcome. Rather, the system must be leveraged to achieve a continuum of education, clinical observation, treatment response, and continued monitoring, with careful attention to patient adherence both to the monitoring process itself and to treatment prescription. Importantly, home monitoring programs are most effective if they drive patient-centered care,$^{22,23}$ enabling and recruiting patients into direct involvement in their own care process.$^{5,15,16,20}$

**Benefits on Health-Related Quality of Life**

Among the 30 studies summarized in a recent review,$^8$ 16 analyzed health-related quality of life. Of these 16 studies, 9 reported significant improvement in patients randomized to the intervention compared with controls. Six of 9 telephone-based interventions and 3 of 7 automated telemonitoring interventions demonstrated quality-of-life benefit. We examined the relative effects of 2 HF disease management interventions and showed no incremental benefit on health-related quality of life, measured by using the Minnesota Living with Heart Failure Questionnaire, for patients randomized to an intervention containing automated telemonitoring versus those receiving a previously validated telephone-based program.$^{24}$ It is possible that the nurse interaction associated with telephone-based monitoring is a key factor in achieving improvement in health-related quality of life and that automated telemonitoring achieves no further impact on this metric or may even detract from this benefit if it diminishes nurse-patient interaction.

**Benefits on Healthcare Cost and Cost-Effectiveness**

It should be anticipated that the reduction in hospitalization rates achieved with HF disease management programs incorporating home monitoring will translate into significant savings within this category of cost, the largest contributor to overall direct costs among patients with HF. In considering the financial impact of a disease management intervention, analysis of net direct healthcare costs must account for both differences (intervention versus control) in usual costs and adherence manifested the greatest long-term clinical benefit, providing insight into the elements that drive sustained improvement after monitoring is discontinued. Rich et al$^6$ demonstrated persistent reduction in HF readmissions within the intervention group, compared with the control group (80 versus 57, $P=0.08$), over the 9 months after discontinuation of the active monitoring program. Patients randomized to the disease management intervention showed improved medication adherence as a byproduct of the program,$^28$ which likely contributed to the sustained clinical benefit. Similarly, over 3 years after completion of their primary trial, Ferrante et al$^4$ showed persistent reduction in death or HF hospitalization among patients randomized to their education, counseling, and nurse-telephone monitoring intervention. Patients showing the greatest improvement in adherence manifested the greatest long-term clinical benefit, principally a reduction in HF hospitalizations. We specifically tested the durability of our disease management program and found no sustained benefit after completion of our 3-month intervention.$^{13}$ However, our control population was extremely well managed, including continued educational reinforcement regarding medical adherence from their primary care providers. The common theme of these observations seems to be that, beyond the clinical outcome benefit achieved during active home monitoring, there may be
sustained outcome improvement if patient adherence and self-efficacy occurs as a byproduct of the home monitoring effort.

Role of Technologies

Technological adjuncts to home monitoring may be divided into 1) noninvasive telemonitoring systems automating the acquisition, storage, retrieval, and analysis of manually available clinical and physiological data such as body weight, vital signs, and symptoms; and 2) more complex and/or invasive systems acquiring information such as pulmonary artery pressure, cardiac output, or lung impedance, which may facilitate detection of early signs of decompensation.29–31 Either option, or a combination of the two, may be justified if it improves either the clinical outcomes or the cost-effectiveness associated with a telephone-based system alone.

In the study by Cleland et al,19 there was a nonsignificant trend toward incremental benefit in the primary end point of percentage of days lost due to death or hospitalization for patients randomized to telemonitoring of weight, blood pressure, and cardiac rhythm compared with those receiving telephone-based monitoring alone. Both interventions reduced mortality to a similar degree compared with usual care. We compared a similar telemonitoring system to a previously validated program of nurse-telephone-based monitoring and intervention and found that use of the telemonitoring system further improved the primary end point of HF hospitalizations.32 However, there was no further benefit in all-cause hospitalization or in quality of life34 derived from the telemonitoring intervention relative to the telephone-based program.

The Cochrane meta-analysis8 showed almost identical benefits of telephone-based versus telemonitoring interventions, compared with usual care, on HF-related and all-cause hospitalization but suggested a greater benefit on mortality for the telemonitoring approaches. There was no evidence of incremental benefit on quality of life through the use of telemonitoring. Even assuming equivalent outcome benefit, telemonitoring technology has the potential to improve on the cost-effectiveness of a telephone-based approach if the incremental technology cost can be overridden by reduced personnel cost through a larger case load per nurse manager.

A number of invasive systems have been investigated with the aim of achieving earlier, more systematized detection of hemodynamic decompensation.30,31 Abraham et al31 demonstrated reduction in the rate of HF hospitalizations at 6 months (hazard ratio 0.70; CI, 0.60–0.84; P<0.0001) for patients with prior hospitalization and NYHA class III HF, randomized to undergo home hemodynamic monitoring using an implanted pulmonary artery sensor, compared with patients receiving “standard of care management.” This study confirms the value of a home monitoring program. The specific incremental value of the implantable monitoring device is difficult to discern in the absence of an alternative systematized home monitoring program within the control group. Any monitoring device, implantable or otherwise, will only be as good as the contribution it provides within a comprehensive disease management program. The role of implantable monitoring devices in improving clinical outcomes and cost-effectiveness of care, compared with less-invasive approaches to home monitoring, remains to be clarified.

Significance

Given the enormous and growing burden of morbidity, mortality, and healthcare cost associated with HF, it is imperative that we 1) identify new approaches to prevent this condition and 2) perfect and implement systems of care that can deliver proven treatments and continuously manage patients in the interest of cost-effective improvement of healthcare outcomes. Home monitoring represents a critical component of comprehensive disease management programs, which are well established to achieve this latter goal, particularly when implemented in patients with recent hospitalization.

Home monitoring is likely to facilitate improved performance on the recently popularized 30-day rehospitalization metric, which is projected to soon carry significant financial incentives and penalties from both Medicare and commercial payers. This metric is limited and flawed because it overly incentivizes avoidance of early readmissions, necessary or not, and provides no incentives for sustaining management programs beyond the 30-day window. It may incentivize transition to hospice designation, an intervention that may or may not be appropriate for a particular patient. Importantly, it fails to account for the competing risk of death. The need for a more sustained clinical management approach will likely drive further evolution of the reimbursement model, including bundled payments for patient populations with chronic diseases such as HF, better aligning the interests of patients, payers, and providers. Such models will drive implementation of care delivery initiatives with demonstrable long-term clinical benefit, such as home monitoring and comprehensive HF disease management.

Conclusions

Home monitoring represents a key element of effective HF disease management programs. Clinical trial evidence, in aggregate, demonstrates that such programs improve clinical outcomes, particularly for patients with recent HF hospitalization. Benefits observed in various clinical trials include reduced hospitalization rates, particularly HF-related hospitalizations, reduced all-cause mortality, and improved health-related quality of life. Where cost analyses have been performed, these interventions have been found to be highly cost-effective and, depending on the cost of the overall intervention, may also be cost-saving. Various noninvasive and invasive telemonitoring technologies facilitate home monitoring, but more work is needed to clarify the incremental value of these technologies in further driving cost-effective outcome improvement. Careful examination of home monitoring programs explored across various clinical
trials indicates that, to be effective, home monitoring must be incorporated into a structured sequence of events, driving appropriate therapeutic responses to changes in clinical status. Home monitoring programs seem to be most effective in driving long-term outcome benefit when they reinforce patient education toward medical adherence and patient self-efficacy.

Sources of Funding

None.

Disclosures

Dr Konstam has served as a consultant for Cardiomecema.

References

Konstam makes a compelling case that comprehensive, nurse-directed, multidisciplinary disease management can contribute to substantial reductions in heart failure-associated morbidity and mortality. However, the best approach to operationalizing this concept in clinical practice, particularly for patients out of reach of specialized heart failure centers, remains unclear. Although some form of longitudinal patient surveillance is undoubtedly important, data from recent clinical trials suggests that current home monitoring approaches, emphasizing continuous tracking of trends in weight, symptoms, and vital signs, do not enhance the efficacy of routine heart failure management. The lack of a clear relationship between the intensity of home monitoring and improvement in patient outcomes may be evidence that other components of disease management (education, prescription of appropriate medications, counseling regarding adherence) are the critical determinants of success, but it is also possible that the wrong signals are being tracked. Implantable hemodynamic monitors offer the potential for earlier detection of clinical deterioration and intervention to prevent heart failure hospitalization. However, we agree that leveraging even these next-generation home monitoring approaches to benefit patients requires that they be deployed within a broader framework capable of linking detected variances to timely and effective corrective action, closing the feedback loop between patients and their providers. Because it may not be practical to provide comprehensive disease management to the entirety of the burgeoning heart failure population, continued exploration of more focused, scalable interventions to enhance patient self-efficacy and improve clinical outcomes is essential.
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Circulation. 2012;125:820-827
doi: 10.1161/CIRCULATIONAHA.111.031161
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2012 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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