CORRESPONDENCE

Telemonitoring in Patients with Heart Failure

TO THE EDITOR: In their article on the Telemonitoring to Improve Heart Failure Outcomes (Tele-HF) trial (ClinicalTrials.gov number, NCT00303212), Chaudhry et al. (Dec. 9 issue)[1] report neutral effectiveness of remote telemonitoring in patients with heart failure, in contrast to the results of a previous meta-analysis.[2] Most studies have focused on patient-reported data. The risk is information overload for and noncompliance by health care professionals. In the present study, 14% of the patients did not use the intervention, and 45% of the patients did not adhere to the intervention. The World Health Organization[3] has identified patient-centered care[4] as a core component in quality health care in the 21st century, and we suggest that patient-centered care will increase the effectiveness of telemonitoring. Telemonitoring needs to focus on patients' self-care instead of reporting data.[5] Given the progressive nature of chronic heart failure and the need for extensive management of the illness, it is important that professionals and patients develop a partnership to achieve commonly agreed-on goals. How was this partnership achieved in the Tele-HF study? We suggest that modern mobile-phone technology can advance person-centered telemonitoring.

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No potential conflict of interest relevant to this letter was reported.

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3. Preparing a health care workforce for the 21st century: the challenge of chronic conditions. Geneva: World Health Organization, 2005. (http://whqlibdoc.who.int/publications/2005/9241562803.pdf.)
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5. Cleland JG, Ekman I. Enlisting the help of the largest health care workforce — patients. JAMA 2010;304:1383-4.

TO THE EDITOR: Chaudhry et al. suggest that enhanced support in the use of a telephone-based interactive voice-response system for patients recently discharged after worsening heart failure does not improve outcomes. This finding is broadly consistent with previous systematic reviews of telephone support[1] and contrasts with the substantial effect observed with home telemonitoring of vital signs in similar populations.[1] The treatment of patients in the control group was excellent, but unrepresentative of usual clinical care and not inferior to the treatment of patients receiving enhanced support. Monitoring alone is unlikely to improve outcomes but may do so when it improves prescription of or adherence to lifesaving treatments. Given enough resources, traditional methods for delivering care may render an interactive voice-response system or a home telemonitoring system ineffective. Nonetheless, there may be more cost-efficient approaches to ensuring quality care.[2]

Informal post hoc addition of these data to our recent meta-analysis of telephone support[1] does not substantially alter the point estimates for death from any cause or heart-failure–related

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hospitalizations, but it does nullify the small benefit in hospitalizations for any cause, which may not be reduced by a heart-failure–focused intervention.[1]

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1. Inglis SC, Clark RA, McAlister FA, et al. Structured telephone support or telemonitoring programmes for patients with chronic heart failure. Cochrane Database Syst Rev 2010;8:CD007228.
2. Cleland JGF, Lewinter C, Goode KM. Telemonitoring for heart failure: the only feasible option for good universal care? Eur J Heart Fail 2009;11:227-8.

TO THE EDITOR: The study by Chaudhry and colleagues showing that telemonitoring did not improve outcomes among patients hospitalized for heart failure has several shortcomings. In other major studies, well-designed home telemonitoring programs that used more advanced forms of technology to support patient education and health care for patients with congestive heart failure have been shown to be successful in reducing unnecessary hospitalizations. These systems require daily, real-time monitoring of physiological data, direct patient feedback and coaching, and a high level of patient–clinician interaction to achieve positive results. The findings of Chaudhry et al. reflect the lack of an effective, comprehensive intervention combined with an intention-to-treat evaluation model that is best reserved for clinical trials that do not involve ongoing provider–patient interaction. In addition, patients who were not using the program at the end of the evaluation period were counted in the results. From our collective experience, the study's negative findings are due to an inadequate intervention and the design of the study itself and should not be taken as a denunciation of telemonitoring systems that enable patients to manage their chronic illnesses effectively.

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THE AUTHORS REPLY: Efforts to enable patients' self-care are critical in achieving improved outcomes. The telemonitoring intervention we selected promoted active, daily self-care by requiring patients to weigh themselves, assess their symptoms, and report their clinical status. All telemonitoring variances (denoting possible heart-failure decompensation) triggered telephone calls from clinicians to discuss clinical status, potential triggers of worsening status (including nonadherence to diet and medication), and therapeutic strategies. In this way, patients' self-care efforts were individually supported as needed.

Swedberg et al. point out the risk of noncompliance by clinicians overwhelmed by information from telemonitoring. We required documentation of clinicians' actions in response to each variance, which we reviewed every 2 to 3 weeks to ensure adherence during the study period. Therefore, we can confidently state that clinicians did not ignore the telemonitoring data. Furthermore, considerable resources were dedicated to optimizing patients' engagement with telemonitoring, including individual counseling for patients who were not using the system. Thus, adherence rates in this trial probably represent the best-case scenario, which is difficult to replicate in real-world clinical practice.

Inglis et al. highlight previous studies on telemonitoring in heart failure. A notable challenge in interpreting data from their meta-analysis[1] is the variable methodologic quality of the studies included, many of which were also of small size and performed at single sites. In contrast, Tele-HF is the largest and among the most methodologically rigorous studies of telemonitoring (using telephone support) for heart failure. Our negative findings should serve as a cautionary tale not to put too much weight on the pooling of small, methodologically weak studies. Further, the high

event rate in usual care (>50% of the patients were rehospitalized or died) does not support the suggestion that these patients received a standard of excellent care unrepresentative of that seen in clinical practice.

Everett et al. suggest that our results should not lead to a complete rejection of telemonitoring for heart failure, since the intervention was not sufficiently potent. The intervention we selected consisted of daily reporting of symptoms and body weight, with timely review and management by the cardiology practice team that was clinically responsible for managing each patient's heart failure. Notably, our findings were consistent with a recently reported, high-quality German study of an even more intensive telemonitoring intervention,[2] in which clinicians provided real-time responses to symptoms of heart failure and physiological data 24 hours a day, 7 days a week. Finally, our use of an intention-to-treat analysis is consistent with the standard scientific approach to evaluating the benefit of an intervention for a population at risk.

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Since publication of their article, the authors report no further potential conflict of interest.

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Teriparatide and Osseous Regeneration in the Jaw

TO THE EDITOR: Bashutski et al. (Dec. 16 issue)[1] report markedly improved alveolar bone regeneration after periodontal surgery plus teriparatide therapy as compared with placebo. In an accompanying editorial, Grey[2] notes that the trial reported on by Bashutski and colleagues has provided preliminary evidence of enhanced benefit in comparison with standard care, but he notes the need for larger and longer additional trials to compare various treatment regimens. We are writing to highlight the findings of a previously reported pilot trial in which adjunctive treatment with locally delivered, controlled-release chlorhexidine resulted in a marked improvement in bone regeneration after periodontal surgery.[3] Interestingly, the number of patients in each treatment group in both trials was almost identical, although the surgical approach differed in the earlier trial, which involved a standard regenerative approach with the use of a graft and an occlusive membrane. Thus, comparison of the magnitude of the responses is not appropriate. We think it is important that any comparative trial protocols include a treatment group that includes surgical therapy plus the adjunctive use of a locally delivered, controlled-release antimicrobial agent.

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Dr. Finkelman reports owning stock in AstraZeneca Pharmaceuticals. No other potential conflict of interest relevant to this letter was reported.

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2. Grey A. Teriparatide for bone loss in the jaw. N Engl J Med 2010;363:2458-9.
3. Reddy MS, Jeffcoat MK, Geurs NC, et al. Efficacy of controlled-release subgingival chlorhexidine to enhance periodontal regeneration. J Periodontol 2003;74:411-9.

THE AUTHORS REPLY: As Finkelman and Reddy indicate, local antimicrobials could be valuable adjuncts for periodontal procedures to regenerate bone. Our study was designed to determine the effects of teriparatide on a periodontal standard-of-care treatment. Thus, we used controls accepted in published guidelines for trials of osteoporosis drugs[1] along with a standard control for outcomes of periodontal surgery.[2] We acknowledge that the selection of controls for clinical trials of bone-active agents is controversial.[3] Our investigation focused on the evaluation of an anabolic agent to promote bone regeneration coupled with surgery and avoided confounding effects of chemotherapeutic agents or devices such as bone grafts or cell-occlusive barriers on wound repair. Further, according to the position