

Prolonged Effects of a Home-Based Intervention in Patients With Chronic Illness

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Background: Data on the long-term benefits of non-specific disease management programs are limited. We performed a long-term follow-up of a previously published randomized trial.

Methods: We compared all-cause mortality and recurrent hospitalization during median follow-up of 7.5 years in a heterogeneous cohort of patients with chronic illness initially exposed to a multidisciplinary, home-based intervention (HBI) (n=260) or to usual postdischarge care (n=268).

Results: During follow-up, HBI had no impact on all-cause mortality (relative risk, 1.04; 95% confidence interval, 0.80-1.35) or event-free survival from death or unplanned hospitalization (relative risk, 1.03; 95% confidence interval, 0.86-1.24). Initial analysis suggested that HBI had only a marginal impact in reducing unplanned hospitalization, with 677 readmissions vs 824 for the usual care

group (mean \pm SD rate, 0.72 ± 0.96 vs 0.84 ± 1.20 readmissions/patient per year; $P = .08$). When accounting for increased hospital activity in HBI patients with chronic obstructive pulmonary disease during follow-up for 2 years, post hoc analyses showed that HBI reduced readmissions by 14% within 2 years in patients without this condition (mean \pm SD rate, 0.54 ± 0.72 vs 0.63 ± 0.88 readmission/patient per year; $P = .04$) and by 21% in all surviving patients within 3 to 8 years (mean \pm SD rate, 0.64 ± 1.26 vs 0.81 ± 1.61 readmissions/patient per year; $P = .03$). Overall, recurrent hospital costs were significantly lower (14%) in the HBI group (mean \pm SD, $\$823 \pm \1642 vs $\$960 \pm \1376 per patient per year; $P = .045$).

Conclusion: This unique study suggests that a nonspecific HBI provides long-term cost benefits in a range of chronic illnesses, except for chronic obstructive pulmonary disease.

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WITHIN PROGRESSIVELY aging Western populations, there is mounting pressure to find cost-effective ways to manage a parallel increase in the number of individuals with chronic illness (hereafter referred to as chronically ill patients) in whom recurrent hospitalization is common.¹⁻³ These patients exert the greatest pressure on health care resources and budgets. A wide range of multidisciplinary programs to manage chronic disease have been developed to provide continuity of care from the hospital to home and to provide benefits with respect to improved disease control,⁴ reduced mortality,⁵ and recurrent hospital use.^{6,7} However, careful stratification of risk for preventable and costly morbid events is required to avoid a mismatch between supply and demand for these services. Data from a large health care provider in the United States suggest that generic management of chronic disease, while improving quality of care, may not always deliver cost savings.⁸ These data emphasize the need to focus on more "malignant" conditions associated with recurrent hospitalization, poor

quality of life, and premature mortality. Meta-analyses demonstrate the potential to improve health outcomes related to congestive heart failure (CHF) cost-effectively via specifically targeted management programs.⁹ It might be argued, therefore, that successful programs should be reserved for these high-cost patients, particularly when the evidence in favor of generic programs is largely confined to studies that involve limited follow-up and the typical confounding effects of a markedly favorable response in a small proportion of high-cost patients.

Our group has previously reported the beneficial effects on morbidity and mortality at 6 months in a large cohort of chronically ill patients randomly assigned to a relatively brief but intensive, multidisciplinary home-based intervention (HBI) that was designed to improve management of chronic disease beyond the initial 6-month intervention.⁶ Subsequent analyses showed that the major short-term benefits of this intervention occurred in a subset of patients with CHF.¹⁰ A study of a more specific HBI in a different cohort of patients with CHF (n=200) confirmed the medium-¹¹ and long-term¹⁰ benefits on morbidity and mortality.

Since the original 1995-1996 study, we have prospectively followed up the residual portion of 528 chronically ill patients without an initial diagnosis of CHF. In the absence of randomized cohorts with long-term study follow-up and the prospective exclusion of high-risk patients with CHF, these data provide a unique opportunity to examine the long-term impact of management of chronic disease in a group of chronically ill patients.

We prospectively examined the null hypothesis that there will be no difference in recurrent unplanned readmissions, all-cause mortality, event-free survival (unplanned readmission or all-cause mortality), and hospital utilization rates based on exposure to a multidisciplinary HBI (n=260) or usual postdischarge care (UC) (n=268) in a heterogeneous cohort of chronically ill patients without an initial diagnosis of CHF.

METHODS

STUDY COHORT

As reported previously in greater detail,⁶ our group conducted a randomized controlled study of a multidisciplinary HBI in 762 recently hospitalized patients with a range of chronic disease states in a tertiary referral hospital in South Australia. The hospital's Ethics of Human Research Committee approved the study. Patients were included if they were admitted to a medical or surgical unit, discharged to their own home, and prescribed a medication regimen for at least 1 chronic illness. Those with a terminal malignancy were excluded. During a 12-month period commencing January 1, 1995, all 4100 medical and surgical patients (a large proportion of whom did not have a chronic illness or were discharged to institutional care) underwent screening. Overall, 906 (22%) were found to be eligible and, of these, 762 (84%) consented to participate. Patients were then randomized to UC or to HBI.

Patients underwent assessment for risk of unplanned hospitalization according to the criteria outlined in the original report.⁶ Inclusive of the 98 patients with CHF,¹¹ a total of 626 patients were prospectively identified as high risk, and 136 patients were designated as low risk. High-risk patients randomized to HBI (n=309) received the full extent of the intervention⁶ as opposed to discharge education alone for the 72 HBI patients designated as low risk.

MULTIDISCIPLINARY HBI

All HBI patients received counseling before discharge by the study nurse (S.P.) and/or hospital pharmacist in relation to their prescribed medications. High-risk patients received the following additional interventions:

- A home visit at 1 week by the study nurse and pharmacist to (1) assess the patient's physical, clinical and psychosocial status; (2) optimize home-medication management; (3) increase patient and/or caregiver vigilance for clinical deterioration; and (4) improve liaison with community-based services thereafter. As such, well-established strategies including education, counseling, and the introduction of reminder cards and medication compliance devices were used. Patients with more complex problems were referred to a community pharmacist for regular review of potential long-term problems. Patients and family members were also counseled with regard to the importance of recognizing early signs of clinical deterioration or adverse effects of medications and alerting their health care team.
- The patients' primary care physician received a comprehensive report with recommendations for remedial action and

long-term follow-up. Immediate plans for more intensive follow-up were also arranged when required. Active study follow-up lasted 6 months.

USUAL POSTDISCHARGE CARE

Patients randomized to UC were not limited in the frequency and duration of preexisting levels of health care; all patients were subject to the usual process of discharge planning and arrangement of posthospitalization care where required. All UC patients had appointments with their primary care and/or hospital physician within 2 weeks of discharge and regular community nurse visits when required.

STUDY END POINTS

During long-term study follow-up, we prospectively examined the following end points: (1) all-cause mortality; (2) the composite end point of event-free survival (all-cause mortality and/or unplanned readmission); (3) frequency, duration, and cause of recurrent hospitalization; (4) major contributors to recurrent hospitalization; and (5) hospital utilization expenditure (with the cost of the intervention as originally calculated⁶ added to HBI costs). All end points were determined in a blinded fashion.

STUDY FOLLOW-UP

Excluding those with CHF, 260 high-risk patients randomized to HBI and 268 randomized to UC were followed up for a median of 7.5 years (interquartile range, 3.3-7.3 years) after discharge. Patient morbidity status was determined after a comprehensive review of all in-patient hospital activity (via the institution's computerized data system) and individual case medical records (in-hospital and primary care clinics). These data differentiate emergency (unplanned) and prearranged (elective) admissions. Official records of the time and location of all deaths were used to compile mortality data with censoring of all patients 8 years after the recruitment of the last subject.

STATISTICAL ANALYSIS

To adjust for differences in survival and duration of follow-up, all study end points were calculated as a mean number of events per patient per year; ie, for each outcome of interest, the total number of events plus the mean \pm SD is provided. However, given the non-Gaussian distribution of all continuous endpoint data, all *P* values accompanying rate comparisons are derived from the Mann-Whitney test (2-tailed), and to determine the veracity of post hoc analyses, *P* values are derived from Mann-Whitney test comparisons of nontransformed data and unpaired *t* test of log-transformed data. To examine the independent effects of treatment mode and more than 25 baseline variables on event-free survival, all-cause mortality, and specific forms of unplanned hospitalization (eg, stroke related), we used Cox proportional hazards models (with initial entry and stepwise rejection of baseline variables at the .1 and .05 levels of significance, respectively) to derive adjusted relative risks (RRs) and 95% confidence intervals (CIs). Age- and sex-adjusted survival curves for all-cause mortality and event-free survival were also derived from these models. Consistent with a previous report of CHF-related outcomes,¹¹ we undertook a unit-specific per diem analysis of hospital utilization expenditure and adjusted these, based on official inflation rates, to year 2004-2005 equivalent costs, presented as cost per patient per year. All analyses were performed on an intention-to-treat basis according to study group assignment using SPSS for Windows (version 12.0; SPSS Inc, Chicago, Ill).

BASELINE CHARACTERISTICS

The **Table** summarizes the baseline characteristics of the study cohort according to study assignment. The 2 groups were well matched with respect to all demographic and clinical variables. As expected, most patients were prescribed multiple medications for their underlying chronic disease state(s).

EFFECT OF MULTIDISCIPLINARY HBI

Survival

During prolonged study follow-up, many patients in the UC (n=114 [43%]) and HBI (n=117 [45%]) groups died. **Figure 1** compares the age- and sex-adjusted survival curves for the 2 groups of patients. The HBI had no impact on adjusted survival rates in this cohort of patients (for all-cause mortality, RR, 1.04; 95% CI, 0.80-1.35). Advancing age, female sex, a greater number of prescribed discharge medications, and routine postdischarge home care were all associated with a significantly increased risk of death. Patients who were discharged after a discrete surgical procedure (as opposed to the specific management of their underlying chronic illness) were significantly less likely to die when adjusting for all other baseline variables.

Event-Free Survival

A total of 204 UC patients (76%) vs 212 HBI patients (82%) experienced an unplanned hospitalization or died during study follow-up. **Figure 2** compares the age- and sex-adjusted event-free survival curves for the 2 groups. The HBI also had no impact on adjusted event-free survival in this cohort of patients (RR, 1.03; 95% CI, 0.86-1.24). Advancing age, a greater number of prescribed discharge medications, and routine postdischarge home care were all associated with a significantly increased risk and recruitment from a surgical unit was associated with a significantly decreased risk of being readmitted or dying during prolonged follow-up. Greater comorbidity (as measured by the Charlson Comorbidity Index) and an unplanned hospitalization in the 6 months before study recruitment were also associated with an increased risk of this composite event during prolonged follow-up.

Unplanned Readmissions

A total of 186 UC patients (69%) vs 170 HBI patients (65%) experienced any unplanned hospitalization ($P=.23$). Overall, patients in UC accumulated a total of 824 unplanned readmissions (mean rate, 0.84 ± 1.20 readmissions/patient per year of study follow-up) and HBI patients, a total of 677 unplanned readmissions (mean rate, 0.72 ± 0.96 readmission/patient per year) ($P=.08$). **Figure 3** demonstrates that, overall, the 2 groups had a similar morbidity profile in the first 3 years of follow-up (335 UC vs 339 HBI unplanned readmissions; $P=.94$). Thereafter, surviving HBI patients (n=210) accumulated significantly fewer readmissions (429, equivalent to a mean of 0.64 ± 1.26 readmissions/patient per year)

Table. Baseline Characteristics of High-Risk Patients According to Study Assignment*

Characteristic	HBI Group (n = 260)	UC Group (n = 268)
Demographic profile		
Age, mean \pm SD, y	69 \pm 11	69 \pm 12
Male	135 (52)	135 (50)
Socioeconomic status		
Live alone	98 (38)	88 (33)
Non-English speaking	31 (12)	30 (11)
Formal home support	110 (42)	101 (38)
Clinical profile		
Preexisting treatment for chronic condition	245 (94)	251 (94)
Charlson Comorbidity Index, mean \pm SD	1.9 \pm 0.6	2.0 \pm 0.7
Days of unplanned hospitalization 6 mo before follow-up, mean \pm SD	0.4 \pm 0.7	0.5 \pm 0.6
Type of index admission		
Unplanned for a preexisting chronic illness	82 (32)	92 (34)
Unplanned for a new-onset acute illness	120 (46)	110 (41)
Category of primary diagnosis		
Cardiac disease	52 (20)	58 (22)
Respiratory disease	42 (16)	33 (12)
Orthopedic condition	41 (16)	51 (19)
Vascular disease	46 (18)	42 (16)
Other	79 (30)	84 (31)
No. of prescribed medications at discharge, mean \pm SD	4.9 \pm 2.7	4.9 \pm 2.3

Abbreviations: HBI, home-based intervention; UC, usual postdischarge care.
*Unless otherwise indicated, data are expressed as number (percentage) of patients.

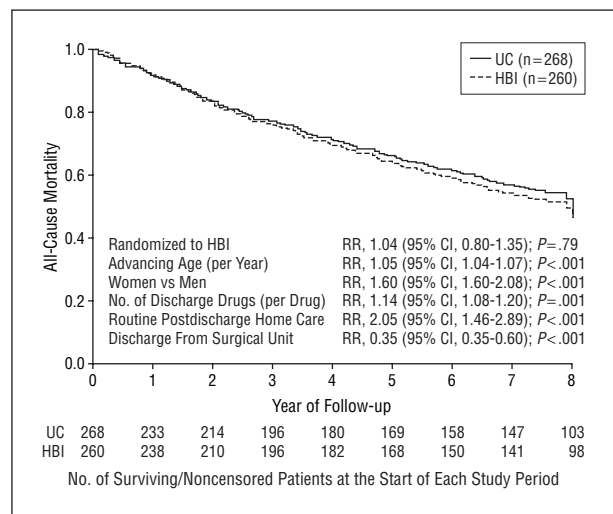


Figure 1. Comparison of long-term age- and sex-adjusted all-cause mortality according to treatment group in high-risk patients. CI indicates confidence interval; HBI, home-based intervention; RR, relative risk; and UC, usual postdischarge care.

compared with the 214 UC patients (510, equivalent to a mean of 0.81 ± 1.61 readmissions/patient per year), a 21% reduction in favor of HBI (post hoc analysis, $P=.03$; for analysis of log-transformed data, $P=.004$). Because we observed an increase in readmissions related to chronic obstructive pulmonary disease (COPD), but no other major diagnoses in the HBI group, we reexamined the rate of unplanned readmission in the remainder of the cohort (n=453). The boxed

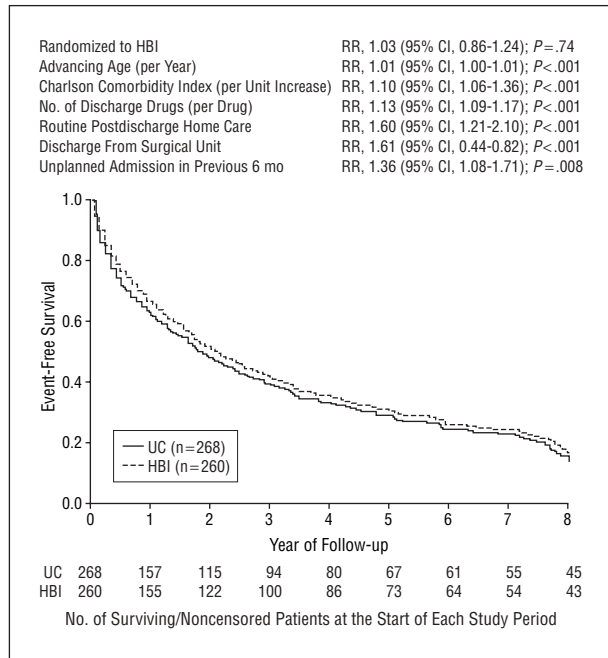


Figure 2. Comparison of long-term age- and sex-adjusted event-free survival (death or readmission) according to treatment group in high-risk patients during long-term follow-up. Abbreviations are explained in the legend to Figure 1.

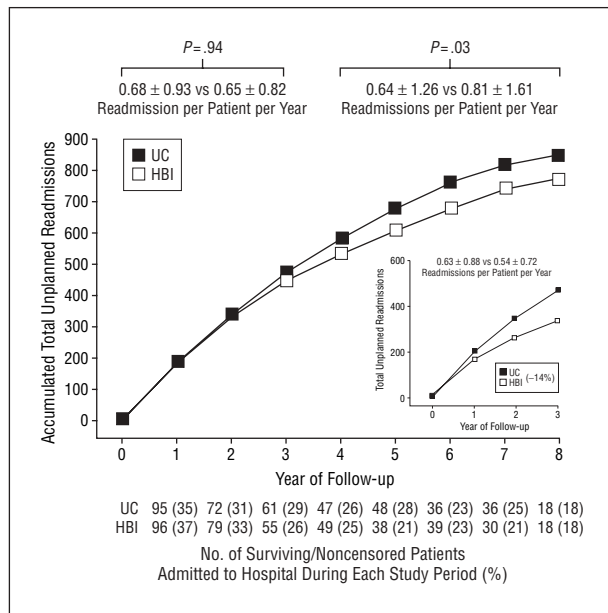


Figure 3. Comparison of accumulated total of all-cause readmissions according to treatment group in high-risk patients during long-term follow-up. Abbreviations are explained in the legend to Figure 1.

figure in Figure 3 shows that when COPD-related readmissions were excluded from the analysis of this time frame (35 and 84 readmissions in the UC and HBI groups, respectively), HBI was associated with a 14% reduction in the rate of unplanned readmission relative to UC during initial 3-year follow-up (*P* = .04, post hoc analysis; *P* < .001 for analysis of log-transformed data).

Overall, the UC group accumulated a greater number of days of hospital stay (6380 days, equivalent to a

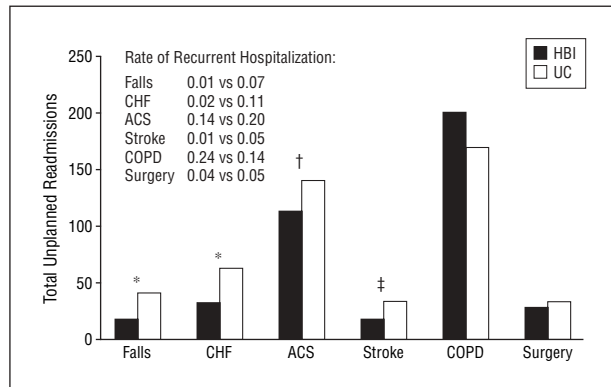


Figure 4. Comparison of the total number and frequency of unplanned hospitalizations according to treatment group in high-risk patients during long-term follow-up. The most frequent contributors are shown. ACS indicates acute coronary syndrome; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; HBI, home-based intervention; and UC, usual postdischarge care. Asterisk indicates *P* ≤ .01; dagger, *P* ≤ .05; and double dagger, *P* ≤ .001.

mean of 6.48 ± 11.56 d/patient per year) compared with the HBI group (5172 days, or a mean of 5.88 ± 10.81 d/patient per year), a nonsignificant reduction of 10% (*P* = .29). As a result of the increased hospital activity in the 3 to 8 years of follow-up, however, surviving patients in the UC group accumulated significantly more days of hospital stay during this period (2418 vs 2047 days, equivalent to a mean of 6.36 ± 12.92 vs 4.32 ± 9.60 d/patient per year), a 32% reduction (*P* = .04, post hoc analysis; *P* < .001 for analysis of log-transformed data).

On adjusted analysis, HBI patients were significantly less likely to be readmitted after a fall at home (14 vs 33 readmissions; *P* < .001; adjusted RR, 0.22; 95% CI, 0.11-0.46), an incident admission for CHF (22 vs 33 readmissions; *P* = .02; RR, 0.40; 95% CI, 0.18-0.88), stroke (13 vs 20 readmissions; *P* = .01; RR, 0.40; 95% CI, 0.17-0.80), and an acute coronary syndrome (59 vs 64 readmissions; *P* = .03; RR, 0.55; 95% CI, 0.31-0.95). Conversely, HBI was associated with a nonsignificant, increased risk of a COPD-related admission (79 HBI vs 55 UC patients, *P* = .12; RR, 1.52; 95% CI, 0.69-2.51).

Figure 4 shows a similar pattern in favor of HBI based on the frequency of recurrent readmissions associated with these conditions, with the exception of a nonsignificant increase in the rate of COPD-related readmissions (*P* = .07) and a similar rate of emergency surgical procedures. Overall, these 6 types of readmission (with >50 readmissions recorded in each category) accounted for 65% of all documented unplanned readmissions and 76% of recurrent hospital stay.

Elective Readmissions

Patients in the HBI group had more elective admissions for prescheduled surgical procedures (484 vs 425 admissions, equivalent to a mean of 0.26 ± 0.77 vs 0.16 ± 0.35 admission/patient per year; *P* = .14) and days of associated hospital stay (1681 vs 1255 days, equivalent to a mean of 0.14 ± 0.21 vs 0.05 ± 0.09 d/patient per year; *P* = .06).

Health Care Costs

Overall, the mean per diem cost of unplanned hospitalization was \$751 in the UC group compared with \$636 in the HBI group. The total cost of unplanned hospitalization was \$4.8 million (equivalent to \$902±\$1628 per patient per year) compared with \$3.3 million (equivalent to \$704±\$1273 per patient per year) in the UC and HBI groups, respectively ($P=.03$). Alternatively, the cost of elective admissions was greater in the HBI group (\$117±\$422 per patient per year) than in the UC group (\$58±\$119 per patient per year) ($P=.07$). Despite this component of increased expenditure, total hospital costs remained lower (borderline significance) in the HBI group when accounting for the cost of the initial intervention (\$823±\$1642 vs \$960±\$1376 per patient per year; $P=.045$).

COMMENT

In this unique study, we examined the impact of a non-specific, multidisciplinary HBI with respect to long-term survival and hospital utilization in a heterogeneous cohort of chronically ill patients. In the absence of expected short-term cost benefits in today's climate of limited budgets and resources, and consistent with initial observations^{10,12} and meta-analyses⁹ from our group, most of these patients would probably be denied such incremental care in favor of more obvious high-cost users (ie, those with CHF). Initially, we found that this patient cohort derived no benefits with respect to survival or unplanned hospitalization during prolonged follow-up from the additional health care they received. However, 2 clear trends emerged to suggest that the multidisciplinary HBI did confer some benefits in this regard. First, HBI obviously failed to have a positive impact on patients with COPD, which was associated with a greater rate of recurrent medium-term hospital stay. Consistent with our observations in this regard, a subsequent HBI specifically targeting patients with COPD in the same population failed to improve health outcomes.¹³ In the remainder of the cohort, we found a significant 14% reduction in unplanned hospitalizations relative to the UC group within 2 years. Second, at a stage when most of the patients with COPD had died, overall, HBI was associated with a 32% reduction in recurrent hospital stay. Alternatively, the rate of elective admissions was increased in the HBI group. However, our group¹¹ and others¹⁴ have noted a similar shift in health care utilization, postulating that this phenomenon is a healthy indicator in otherwise chronically ill patients. Notwithstanding the disappointing results in relation to COPD, overall, HBI was associated with a significantly reduced adjusted risk of being admitted for a fall, incident CHF, stroke, and an acute coronary syndrome in addition to a 14% reduction in hospital costs relative to UC, even when accounting for the initial cost of applying the intervention.

Although a recent meta-analysis of 102 studies evaluating the effectiveness of disease management programs has demonstrated the overall short- to medium-term benefits of such programs,⁴ this is to our knowledge the first study to document such long-term benefits of a disease management program in such a diverse range of chronic conditions.

What are some of the possible explanations for our findings in the absence of detailed data to describe the precise mechanisms of negative (in relation to COPD) and positive (remainder of the cohort) effects of HBI? Based on recent research, we are able to postulate why our initial intervention, examined in one of the earliest and largest studies to assess the impact of a home-based program for management of chronic disease and involving a truly multidisciplinary approach, was ultimately successful. First, the efficacy of many of the individual components applied within the cocktail of strategies that constituted the HBI (including those that improve treatment adherence rates,^{15,16} patient understanding of underlying disease processes and treatment,^{4,9} self-care behaviors,^{17,18} appropriate seeking of medical assistance in the event of clinical deterioration,¹⁹ and levels of health care surveillance in high-risk individuals^{4,9}) has since been well established in the literature. The overall benefits of patients undergoing comprehensive assessment in their own home and receiving a tailored intervention based on the results, as consistently shown by meta-analyses of HBIs,^{5,9,17,20-22} cannot be understated. It should also be noted that the universal health care system in Australia permitted us to apply a targeted intervention that would stimulate long-term strategies (eg, medical and pharmacy surveillance in the community) and therefore improve longer-term outcomes. Although these strategies appear to work as a whole, the precise mechanism of the beneficial effect of this form of intervention still remains unclear.²³ Unfortunately, given limited resources, we were unable to examine this issue specifically beyond the short-term, where we were able to document the potential for few adverse events related to prescribed treatment⁶ and improved treatment adherence. As such, a significant outcome of this study was a reduction in readmissions related to falls, a major health problem for the elderly that commonly results in hospitalization and death.²⁴ Consistent with our major focus on optimizing the benefit-risk ratio of potentially harmful medications prescribed to elderly patients ($\geq 15\%$ of hospital admissions are reported to be related to adverse drug effects^{6,25}), a recent meta-analysis of fall prevention programs demonstrated that this was an important feature of almost all beneficial programs.²⁴ However, focusing on 1 strategy is unlikely to have similar benefits for all patients, given the variation inherent in patient requirements, and further research is required to explore mechanisms of beneficial effects when a combination of strategies is applied.^{4,9,26,27}

Our apparent inability to improve health outcomes in patients with COPD (based on post hoc analyses) supports the current evidence from other randomized studies that suggest these patients are generally resistant to the otherwise beneficial effects of this type of intervention.^{28,29} In this context, it is plausible to suggest that many patients with advanced respiratory disease, unlike those with CHF,⁹ have complex needs that are beyond—and are indeed exacerbated by—strategies that promote self-care. It is likely that programs of care that place a greater emphasis on palliative support and treatments will prove to be more successful.

There are several limitations in this study that require comment. First, one of the reasons we can only speculate about the long-term effects of this HBI is that there are no direct data to confirm that recommendations made to the

patient, family members, treating physicians, and pharmacists were applied in the longer term. We have corollary evidence to support the beneficial effects of HBI in this regard from the 98 patients with CHF in the original study.¹¹ Second, patients were recruited from an area of relatively high socioeconomic deprivation and higher admission rates per capita for the region, and health care utilization and expenditure data are specific to the Australian health care system. Although preexisting evidence suggested that patients with COPD would not benefit from the HBI, we did not prospectively designate an analysis that would exclude this patient cohort, and we did not plan to examine short- and long-term effects separately. Moreover, the borderline significance of *P* values associated with our post hoc analyses imposes an important caveat on the veracity of our observations, despite their apparent clinical significance and the strength of *P* values derived from log-transformed data. Finally, given that the HBI was applied more than 8 years ago, it remains to be seen whether it would have a similar impact in today's health care environment.

CONCLUSIONS

In this unique study, we undertook long-term follow-up of a large and heterogeneous cohort of patients with chronic illnesses who were initially randomized to HBI (a program for nonspecific management of chronic disease) or to UC. An earlier report demonstrated that patients exposed to HBI experienced significantly fewer hospital admissions and fatal events during 6 months of follow-up.⁶ Subsequent analyses demonstrated that patients with CHF derived the greatest benefits from HBI in the short-¹² to medium-term.³⁰ During prolonged follow-up, HBI (with the major exception of patients with COPD) was associated with significantly fewer short- to long-term readmissions and associated hospital stay (an approximately 14% reduction). Overall, HBI was associated with significantly fewer hospital-based health care costs (the major component of health care expenditure in the chronically ill). Clearly, our results need to be validated by other randomized studies that provide prolonged follow-up of patients with chronic illness. However, at this stage, our unique study suggests that this form of intervention provides long-term cost benefits via reduced recurrent hospital stay associated with a range of chronic illnesses except COPD. In an era of competing health care demands, it reaffirms the potential for programs that manage chronic disease to improve health care outcomes in many rather than a few individuals.

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