# JOURNAL ARTICLES SUBMITTED BY MASS GENERAL BRIGHAM IN SUPPORT OF THE PERFORMANCE IMPROVEMENT PLAN PROPOSAL DATED SEPTEMBER 20, 2022

The following journal articles were submitted to the HPC by Mass General Brigham in support of the Performance Improvement Plan Proposal dated September 20, 2022.

In accordance with its regulations, the HPC will approve Mass General Brigham's proposed PIP if it finds that it is reasonably likely to successfully address the underlying cause(s) of Mass General Brigham's cost growth and if it has a reasonable expectation that Mass General Brigham will be capable of successfully implementing the proposed PIP.

The final PIP is subject to change and will be posted to the HPC's website upon approval.

For more information on this process, see the PIP webpage and the Mass General Brigham Live PIP Tracker.

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1. A Cost-Effectiveness Analysis of Cardiology eConsults for Medicaid Patients
2. Hospital-at-Home Interventions vs In-Hospital Stay for Patients With Chronic Disease Who Present to the Emergency Department: A Systematic Review and Meta-analysis
3. Alternative Strategies to Inpatient Hospitalization for Acute Medical Conditions: A Systematic Review
4. "Hospital at home" versus hospital care in patients with exacerbations of chronic obstructive pulmonary disease: prospective randomised controlled trial
5. Early Supported Discharge/Hospital At Home For Acute Exacerbation of Chronic Obstructive Pulmonary Disease: A Review and Meta-Analysis
6. Early Supported Discharge/Hospital At Home For Acute Exacerbation of Chronic Obstructive Pulmonary Disease: A Review and Meta-Analysis
7. Home treatment of COPD exacerbation selected by DECAF score: a non-inferiority, randomised controlled trial and economic evaluation
8. Home hospitalisation of exacerbated chronic obstructive pulmonary disease patients
9. Bending The Spending Curve by Altering Care Delivery Patterns: The Role of Care Management Within A Pioneer ACO
10. Hospital-Level Care at Home for Acutely Ill Adults: a Pilot Randomized Controlled Trial
11. Hospital-Level Care at Home for Acutely Ill Adults: A Randomized Controlled Trial
12. 'Hospital at home' care model as an effective alternative in the management of decompensated chronic heart failure
13. Early experiences with cardiology electronic consults: A systematic review
14. Electronic Consultations in Allergy/Immunology
15. Trends in Ambulatory Electronic Consultations During the COVID-19 Pandemic

# A Cost-Effectiveness Analysis of Cardiology eConsults for Medicaid Patients

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## ABSTRACT

**OBJECTIVES:** To evaluate the cost-effectiveness of electronic consultations (eConsults) for cardiology compared with traditional face-to-face consults.

**STUDY DESIGN:** Cost-effectiveness analysis for a subset of Medicaid-insured patients in a cluster-randomized trial of eConsults versus the traditional face-to-face consultation process in a statewide federally qualified health center.

**METHODS:** A total of 369 Medicaid patients were referred for cardiology consultations by primary care providers who were randomly assigned to use either eConsults or their usual face-to-face referral process. Primary care providers in the eConsult arm transmitted consults to cardiologists using a secure peer-to-peer communication platform in an electronic health record. Intention-to-treat analysis was used to assess the total cost of care and cost across 7 categories: inpatient, outpatient, emergency department, pharmacy, labs, cardiac procedures, and "all other." Costs are from the payer's perspective.

**RESULTS:** Six months after the cardiology consult, patients in the eConsult group had significantly lower mean unadjusted total costs by $655 per patient, or lower mean costs by $466 per patient when adjusted for non-normality, compared with those in the face-to-face arm. The eConsult group had a significantly lower cost by $81 per patient in the outpatient cardiac procedures category.

**CONCLUSIONS:** These findings suggest that eConsults are associated with total cost savings to payers due principally to reductions in the cost of cardiac outpatient procedures.

*Am J Manag Care*. 2018;24(1):e9-e16

Many initiatives aimed at transforming primary care have concentrated on the development of patient-centered medical homes, with emphasis on elements including the adoption of electronic health records (EHRs), multidisciplinary team-based care, and care coordination. Fewer efforts have been directed at improving the interface between primary care providers (PCPs) and specialists in the outpatient setting.[1-3] This gap is notable given the significant clinical importance and financial impact of the PCP–specialist relationship. Outpatient specialty visits represent a disproportionate source of year-over-year increases in healthcare expenditures,[4,5] with research suggesting that a typical PCP interacts with more than 200 specialists in a year.[6] Such financial considerations are increasingly important as payment reform gains momentum across the country and stimulates experimentation with novel reimbursement arrangements. Additionally, the proliferation and adoption of new technologies, including EHRs and secure health information exchanges, are creating fertile conditions for improving the interface between specialists and PCPs.



Electronic consultations (eConsults) are non–face-to-face (F2F) consultations between a PCP and a specialist that utilize secure messaging to exchange information. Unlike electronic referral systems that link primary care practices with specialty providers for F2F appointment triage, eConsults provide a virtual consultation by the specialist after clinical information sent by the PCP is reviewed and returned with recommendations, which potentially eliminates the need for the patient to be seen in person by the specialist. Health systems that implemented eConsults have improved specialty access, reduced wait times,[7] and decreased F2F consultations between 9% and 51% depending on setting and specialty.[8-14] However, few studies have evaluated the effects of PCP access to a secure eConsult platform on total healthcare expenditures. Findings using retrospective data from an eConsult program in Canada suggest the potential for cost savings,[15,16] but these studies were not randomized and did not evaluate the impact on total cost of care. The reduction in F2F visits with specialists

**TAKEAWAY POINTS**

Electronic consultations (eConsults) improve access, timeliness, and coordination of care compared with traditional face-to-face consultations. Findings from this study suggest that the use of eConsults is associated with cost savings to payers due principally to reductions in the cost of cardiac outpatient procedures.

- The implications of cost savings demonstrated in this study are important for state Medicaid agencies and other health systems seeking new ways to improve access and quality while reducing cost.
- Policy changes that support the use of eConsults could result in significant savings to the Medicaid program in a relatively short time frame.

is a potential source of cost savings to payers, but these savings could be offset by an increase in primary care costs and the cost of administering an eConsult program. We recently published results of a cluster-randomized controlled trial of eConsults for cardiology in a statewide federally qualified health center (FQHC) in Connecticut[14] that demonstrate significant improvements in access and timeliness of care with a reduction in cardiology utilization. In this article, we report the impact of the intervention on cost for the subset of Medicaid-insured patients in this trial.

# METHODS

## Setting

Community Health Center, Inc, (CHCI) is a statewide multisite FQHC providing comprehensive primary medical, behavioral, and dental care to medically underserved patients in Connecticut. CHCI delivers care in 13 primary care clinics as well as in numerous school-based and homeless shelter–based facilities. All sites use an integrated EHR. Patients receive primary medical care from internists, family physicians, pediatricians, nurse practitioners, and physician assistants. Most of CHCI's practice sites refer to hospitals and specialists within their neighboring communities or to large regional academic medical centers. During the study, more than 60% of CHCI's patients were racial/ethnic minorities, more than 90% had incomes at or below 200% of the federal poverty level, more than 60% had state Medicaid insurance, and almost 25% were uninsured.

## Study Design

Complete details of the design and methods of the trial have been published.[14] Briefly, the intervention period for the eConsult study was between August 1, 2012, and June 30, 2013, and involved 590 patients and 36 providers from CHCI and 3 cardiologists from the University of Connecticut Health Center (UCHC). All consenting PCPs were assigned to the intervention (eConsult) or control (F2F) arm using 1:1 blocked randomization at the level of the PCP. No other parameters were used. There were no significant differences in site of practice between the intervention and control sites. All providers at all practices accepted all patients regardless of insurance status.

Intervention providers used eConsults for all nonurgent cardiology referrals except for patients who had an established relationship with a cardiologist. Determination of urgency was at the discretion of the PCP. The eConsult option was a function embedded in the EHR that allowed direct electronic communication between the PCP and the cardiologist. The eConsult included a specific question and relevant documentation, such as a brief clinical history, electrocardiograms, medication lists, laboratory and procedure results, and progress notes. A referral coordinator managed the eConsult process. The participating cardiologist received an email notification each time an eConsult was submitted, retrieved the eConsult from a secure Web portal, and responded within 2 business days. Their responses generally provided answers to PCPs' questions and included other relevant suggestions, such as additional laboratory readings/tests or therapeutic trials prior to a subsequent consult, or occasionally a recommendation for a F2F visit. When a F2F consultation was recommended, providers and patients were free to choose any cardiologist accepting FQHC referrals in the service area. Providers in the control group sent all cardiology consults via the traditional F2F referral process at CHCI (**Figure**). The institutional review board of CHCI approved the study.

## Data Sources

The economic analysis used demographic information for participating PCPs and their patients from CHCI's practice management system and Medicaid paid claims data between August 8, 2011, and February 21, 2014.

## Statistical Analysis

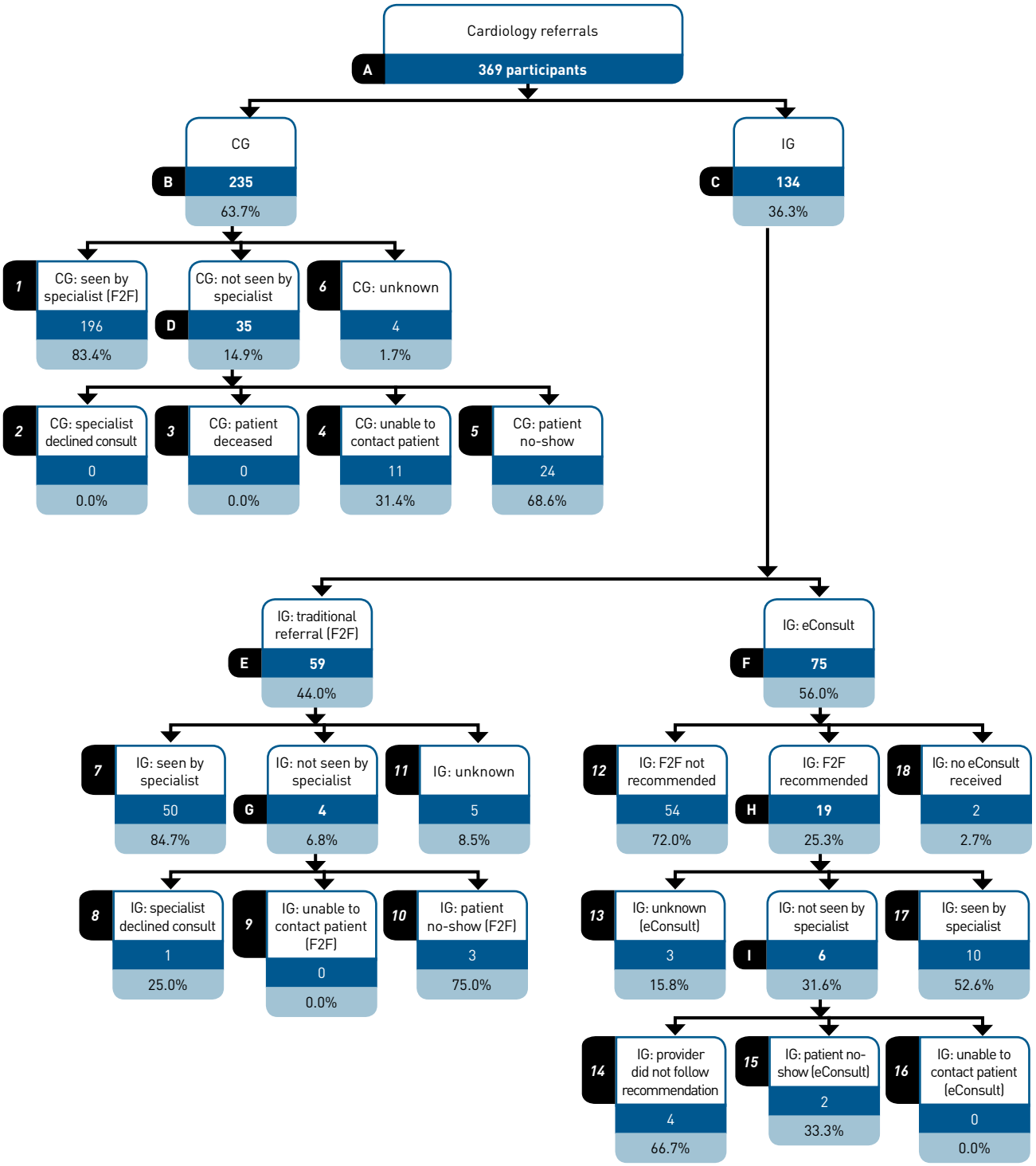
Three types of analysis were conducted: 1) an intention-to-treat (ITT) analysis, 2) an analysis of actual treatment (AT) received, and 3) a sensitivity analysis.

In the ITT analysis (Group B vs C in the Figure), all claims from patients in the PCP intervention and control arms were counted in their respective groups regardless of provider's or patient's adherence to their assigned consultation arm.

In the AT analysis, patients were grouped based on actual consultation choice (eConsult vs F2F), regardless of the provider's assigned group. This second analysis regrouped claims of patients of intervention PCPs who were reassigned to a F2F consult as per the study protocol (B+E vs F in the Figure). This analysis presents the postrandomization ("real-world") provider referral behavior.

The sensitivity analysis used 3 hypothetical fee combinations. All combinations were tested for the ITT and AT scenarios. In

**FIGURE.** Consort Diagram of Randomized Assignment to Conditions and Received Treatment[a,b]




CG indicates control group; F2F, face-to-face; IG, intervention group.

[a]Bold numbers in dark blue boxes indicate sums from lower tier (denoted by letters in black tabs).

[b]Numbers in italics in black tabs are Consort Diagram Codes.

**TABLE 1.** Cost Categories

| Cost Category | Comments |
|---|---|
| Total costs | Includes all nonduplicative cost categories. |
| Inpatient admissions | Includes all admissions to hospitals regardless of diagnosis. This category includes all patients seen in the ED and later admitted to the hospital. A subset of this category is cardiac admissions, defined as admissions with a principal cardiac diagnosis. |
| ED | Includes all ED visits that were not converted to inpatient admissions. A subset of this category is ED patients with a potential cardiac chief complaint, such as chest pain or syncope, who were later discharged. |
| All outpatient visits | All provider office visits including specialists other than cardiology. This category excludes outpatient procedure-related cardiology visits (see below). |
| Total prescriptions | Includes inpatient and outpatient prescriptions. |
| Labs | All outpatient tests (predominantly blood tests) performed at clinics or independent laboratory facilities. |
| Cardiac outpatient treatment or diagnostic tests | Includes cardiac invasive and noninvasive outpatient tests and procedures, such as echocardiograms, cardiac catheterizations, coronary artery stent placement, nuclear cardiac imaging, Holter monitors, etc. |
| All other | This represents a small fraction of claims that could not be attributed to any of the above categories. Residual claims are an artifact of the cost categorization logic and the way claims were coded or later modified by the payer. |

ED indicates emergency department.

addition to the $25 eConsult fee charged for this study, we used $185 per visit for F2F visits and $45 per visit for eConsults. The latter 2 reimbursement rates correspond to the average commercial reimbursement rate for a 30-minute new patient F2F office consultation in the same zip code as the UCHC and a cost-based estimate for eConsults, respectively.[17,18]

Cost items were segregated into the categories shown in **Table 1**. Baseline costs were established by evaluating all claims for 180 days preceding the cardiology consult request. Cost analysis for the intervention period was based on claims inclusive of the date of the referral and the following 180 days. All claims included a 3-month lag. Extreme costs were not truncated.

All cost analyses were performed from the payer's (Connecticut Medicaid) perspective. Transportation costs paid for by Medicaid for F2F visits were not included. At the time of the study, Medicaid did not reimburse for eConsults and therefore payment was not reflected in the claims extracts. All analyses included a $25 fee for each eConsult visit paid to the cardiologist by CHCI. Cardiology F2F new visits (Current Procedural Technology code, 99243) were reimbursed by Medicaid at their customary rate of $66. Any costs borne by PCPs (eg, additional time spent creating and reviewing eConsults), specialists (eg, lost revenue from "no-shows"), or patients (eg, co-pays, unpaid time off work, or out-of-pocket transportation costs) were not included.

Healthcare costs are typically not normally distributed (ie, they are skewed),[19] resulting in the distributions of repeated cost variables being "pulled up" toward a higher mean by a few extreme scores. Several statistical paths were followed to ensure that comparisons of changes in costs between F2F and eConsult patients yielded robust results.

Baseline and intervention costs were assessed across 7 categories (inpatient, emergency department, outpatient, pharmacy, labs, cardiac procedures, and all other) for departure from normality. Then, non-normal cost changes were modeled using Mplus version 7.4 software (Muthén & Muthén; Los Angeles, California).[20,21] Its skew-*t* estimation method allows for direct comparisons of means without the need to truncate scores, by estimating 2 parameters beyond mean and variance, namely the skewness and *t* degrees of freedom for extreme scores (to model "thick-tailed" distributions).[22]

Patient demographic characteristics and raw baseline costs were first evaluated for baseline equivalency. This was followed by analyses of differences between the non-normality–adjusted means of the cost changes (ie, change scores adjusted for baseline values).[23,24] All results are reported as the test of differences in changes between cost categories from the baseline to intervention periods for the total cost. Amounts paid in 2013, 2014, and 2015 were converted to 2016 dollars. All claims categories (ie, cardiac and noncardiac) were included in the analysis.

## RESULTS

Thirty-six PCPs participated in the trial; 19 were randomly assigned to the control group and 17 to the intervention group. Characteristics of the PCPs in both groups were balanced, with no statistically significant differences in age, clinical experience, gender, race/ethnicity, or primary care specialty (**Table 2**).

During the study period, these participating PCPs initiated 590 adult cardiology consults. Of those, 369 patients had Medicaid insurance continuously for the duration of the study and were pooled for this comparative cost analysis.

The number of Medicaid patients in each group included 235 (64%) in the F2F group and 134 (34%) in the eConsult group. A portion of this difference was accounted for by the fact that 2 providers in the intervention group dropped out of the study at the outset and 2 additional intervention providers left the health center before completion of the study. Patient demographic and clinical

characteristics are shown in Table 3. There were no significant demographic differences between the 2 groups. Clinically, rates of smoking and diabetes were similar in both groups, as were average blood pressure, body mass index, cholesterol level, and composite cardiovascular risk as measured by the Framingham Risk Score.[25] The average total cost of care for the 6-month period prior to the referral date was $4102 in the control group and $4667 in the intervention group ($P = .650$ for difference).

The Figure shows the distribution of patients and the flow of patient referrals included in this analysis. Of the 134 consults in the intervention group, 59 (44%) were sent directly for a F2F visit due to the perceived urgency of the referral or the existence of an established relationship with a cardiologist. Seventy-five consults (56%) were referred to the reviewing cardiologist. Fifty-four (72%) of these eConsults contained advice for management in primary care and a recommendation that a F2F visit was unnecessary. Nineteen (25%) of the eConsults recommended a F2F visit by the patient, of whom 10 (53%) completed a visit and 9 (47%) did not (the PCP did not order a F2F visit for 4 patients, 2 were no-shows, and the status of the 3 remaining patients was unknown). Two patients (3%) referred for an eConsult did not receive it, 1 due to technical problems and 1 for an unknown reason.

Of the 235 patients in the control group, 196 (83%) had a F2F visit with a cardiologist, 35 (15%) were not seen, and the status of 4 (2%) patients was unknown. Of the 35 patients who were not seen, 24 were no-shows (10% of those patients who were originally referred).

**TABLE 2.** Demographic Characteristics of Primary Care Providers

| Provider Characteristics | Intervention (n = 17) | Control (n = 19) |
|---|---|---|
| Age, years, mean (SD) | 37.3 (7.5) | 40.5 (10.1) |
| Years in practice, mean (SD) | 6.1 (7.2) | 10.1 (9.6) |
| Female gender, n (%) | 13 (76) | 12 (63) |
| Race, n (%) | | |
| Asian | 3 (18) | 5 (26) |
| Black | 3 (18) | 2 (11) |
| Hispanic | 0 (0) | 1 (5) |
| White | 11 (65) | 11 (58) |
| Provider specialty, n (%) | | |
| Family medicine physician | 8 (47) | 13 (68) |
| Internal medicine physician | 3 (18) | 1 (5) |
| Nurse practitioner/physician assistant | 6 (35) | 5 (26) |

**TABLE 3.** Patient Demographic and Clinical Characteristics

| Patient Characteristics | Intervention (n = 134) | Control (n = 235) |
|---|---|---|
| Age, years, mean (SD) | 51 (14) | 53 (13) |
| Female gender, n (%) | 76 (57) | 144 (61) |
| Race, n (%) | | |
| Black | 24 (18) | 29 (12) |
| Hispanic | 38 (28) | 99 (42) |
| White | 55 (31) | 84 (36) |
| Other | 17 (13) | 23 (10) |
| Clinical characteristics | | |
| Current every day smoker, n (%) | 36 (28) | 67 (29) |
| Former smoker, n (%) | 26 (20) | 49 (21) |
| Never smoker, n (%) | 45 (35) | 100 (43) |
| Body mass index, mean (SD) | 31.9 (9.2) | 31.6 (8.0) |
| Total cholesterol (mg/dL), mean (SD) | 192.6 (55.1) | 186.3 (42.3) |
| Diagnosis of diabetes, n (%) | 39 (30) | 69 (29) |
| Framingham Risk Score, mean (SD) | 13.4 (10.1) | 13.5 (10.1) |

Table 4 shows the ITT unadjusted and adjusted means[20,26] for all cost categories in both arms of the study. For 6 months following the request for the cardiology consult, patients referred by providers in the eConsult arm had a mean unadjusted total cost of care that was $652 per patient lower than that of patients referred by providers in the F2F group. After adjusting for skewness, *t* shape, and baseline differences, overall cost in the eConsult group was $466 per patient lower than in the F2F group.

Further analysis demonstrated that the number of claims for cardiac testing, total claims, and the total cost diverged between treatment and control groups immediately following initiation of the cardiology consult, with higher rates in the control group, suggesting that the observed differences were in fact the result of differences in utilization.

Although a portion of the cost difference between the 2 groups can be attributed to the difference in cost between an eConsult and a F2F visit ($25 vs $66 for this study), this difference accounted for only a small part of the actual observed savings. Even after applying a $66 charge to all patients in the eConsult arm, including for those not seen F2F, the savings were still significant ($433; $P = .032$); the AT analysis (75 patients in eConsult vs 296 in F2F) showed savings of $550 per patient ($P = .084$).

A sensitivity analysis further demonstrates the potential cost savings with various reimbursement rates for eConsults and F2F

**TABLE 4.** Average Cost Changes Per Patient by Expense Category and Unadjusted and Adjusted Means

| | Unadjusted Mean Changes[a] | | | Adjusted Mean Changes[b] | | | |
|---|---|---|---|---|---|---|---|
| Cost Changes Baseline/Intervention (Δ) | Control (n = 235) | Intervention (n = 134) | Difference[c] Control/ Intervention | Control (n = 235) | Intervention (n = 134) | Difference[c] Control/ Intervention | *P* |
| ΔInpatient | $692 | $37 | –$655 | $692 | $37 | –$655 | .227[d] |
| ΔOutpatient[e] | $102 | $139 | $37 | $102 | $152 | $51 | .660[d] |
| ΔEmergency department | –$15 | $13 | $28 | -$15 | $13 | $28 | .181[d] |
| ΔLabs | $36 | $45 | $9 | $36 | $45 | $9 | .319[d] |
| ΔCardiac procedures | $167 | $86 | –$81 | $167 | $86 | **–$81** | .001[d] |
| ΔPharmacy | –$93 | $205 | $298 | –$2079 | –$2144 | –$65 | .809 |
| ΔResidual claims | –$1600 | –$2341 | –$741 | $5540 | $3554 | **–$1986** | .046 |
| ΔTotal costs[e] | $508 | –$144 | –$625 | –$3963 (SE, $76) | –$4429 (SE, $182) | **–$466** (SE, $201) | .021 |

SE indicates standard error.
[a]Controlled for baseline costs.
[b]Controlled for baseline costs, skewness, and *t* shape.
[c]Negative difference indicates savings in treated versus controls. Significant savings in **bold**.
[d]Estimation problems existed for all skew, *t*, and skew-*t* models, hence normal mixture estimates are reported.
[e]A $25 eConsult additional fee was added to the treated group only.

visits. Case scenario 1 (ITT eConsult, $45; F2F, $66.40) showed a reduction in total adjusted savings for eConsults of $450 (*P* = .025). In case scenario 2 (ITT eConsult, $25; F2F, $185), the adjusted savings was $557 (*P* = .006). In case scenario 3 (ITT eConsult $45; F2F, $185), the adjusted savings was $541 per patient (*P* = .007).

## DISCUSSION

Inadequate access to specialty services among Medicaid beneficiaries is a well-recognized barrier to optimal health outcomes and a contributing factor to healthcare disparities.[27-29] Previous studies have demonstrated that eConsults improve access by reducing referral waiting times,[8,30] but until now, the economic impact of giving practicing PCPs access to a secure, efficient eConsult platform to enhance their interactions with specialists was unknown. The results of our analysis show for the first time that when PCPs are given an option to use eConsults for Medicaid beneficiaries, the total costs and the cost of outpatient cardiac tests and procedures at 6 months are significantly lower, by $466 and $81, respectively, compared with the traditional F2F approach. Although we randomized providers, rather than patients, baseline data demonstrate that patients in both PCP groups were similar in demographics, cost of care, and clinical characteristics. In addition, there were no differences between providers in the 2 treatment arms or in their sites of practice. This relatively rapid decline in cost (6 months) is unusual in health services studies. Moreover, the results suggested that, given the conservatism inherent in the ITT or "as randomized" method, the analysis may underestimate savings with eConsults compared with the "as treated" case scenario. Our secondary analysis using the as treated scenario confirmed significant savings of $93 per patient for cardiac tests and procedures and a favorable trend of $533 for overall costs. This analysis should give confidence to payers looking for innovative delivery models that reduce costs and improve access, timeliness, and convenience for patients and specialists alike.

At the outset, a hypothetical explanation for potential savings with eConsults was based on more timely initiation of a treatment plan and reduced duplication of tests and procedures. Our study was not able to elucidate the impact of considerable improvements in timeliness on cost of care, but it did demonstrate a net reduction in overall outpatient procedures. This finding is a direct result of the redesigned process itself, rather than individual provider behaviors, suggesting that this transformation is potentially durable.

Our analysis was conservative, as it only evaluated claims-related costs from the payer perspective and did not evaluate other plausible sources of cost savings. For example, many Medicaid patients receive reimbursement for transportation to F2F appointments. The claims file did not include payments related to patient transportation, but those unmeasured cost savings in the eConsult group accrued to Medicaid.

There were several additional potential cost implications to the PCP. The use of eConsults reduced the administrative work of scheduling F2F consults and coordinating F2F visits with patients, which could have staffing implications. Some safety-net health centers invest significant resources not only in scheduling specialty visits for their patients, but also in providing extra support to help patients overcome financial, transportation, and other logistical barriers to reduce the likelihood of a no-show.[31]

The eConsult workflow used in this project required little additional work or training on behalf of the PCP. Consults were

routed via the eConsult system by a referral coordinator who was responsible for managing the consult process. Any additional work for providers reviewing and implementing eConsult treatment recommendations was likely offset by a reduction in the work required to address and manage complaints while patients were waiting for their F2F visit.

The impact of this intervention on costs to patients was also not considered in this analysis. One study from Canada has demonstrated that cost savings to patients may be significant[16] due to avoided transportation costs and lost productivity and wages from taking uncompensated time off from work. These potential benefits associated with the eConsult represent unmeasured but potentially important cost savings that accrued to patients in this study.

One final cost savings to specialists (but not to payers) that was not measured in our study was the potential reduction in no-show rates in the F2F group. Reducing the number of F2F visits and only sending those patients who truly require one may also reduce rates of costly no-shows. Of the 235 patients in the F2F group, 35 (15%) patients never saw the cardiologist and 24 (10%) were confirmed no-shows. No-shows are not only costly to the specialist, but missing appointments also means forfeiting needed input on the patient's care. This can result in costly complications later on that may have been preventable.

### Limitations

This study had several limitations. The short 6-month duration of follow-up may have resulted in an inability to detect any seasonal cost variations. It is also possible that shorter-term cost savings resulted in cost increases at a later date. In addition, the focus on a single specialty precludes generalizing these findings to other specialties. Many eConsult systems provide access to a wide range of specialties for which the cost implications are unknown. Also, this evaluation only included patients with Medicaid, which precludes drawing broader conclusions on the impact of eConsults for the uninsured or for patients with Medicare or private insurance, as Medicaid costs are significantly different from those of other payers.

## CONCLUSIONS

We conducted the first randomized controlled trial of eConsults for cardiology and demonstrated that they resulted in reduced total healthcare costs for Medicaid members' care. The implications of the cost savings demonstrated in this study are important for state Medicaid agencies and other health systems seeking new ways to improve access and quality while reducing cost. Policy changes that support the use of eConsults as a new service modality could result in significant savings to the Medicaid program in a relatively short time frame. However, sustaining eConsult programs will require changes in reimbursement policies, either by authorizing payments for eConsults on a fee-for-service basis or by increasing the opportunities for primary care and specialty providers to share in the savings that accrue from more efficient and effective care. Future studies should examine the cost–benefit balance of eConsults for multiple specialties and in more diverse settings to further inform these policy changes as well as which changes in costs trigger changes in other costs. Longer follow-up will also be useful to determine the durability of savings realized in the short term. ■

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***Source of Funding:*** Connecticut Health Foundation.

***Author Disclosures:*** Dr Villagra is president of Health & Technology Vector, which signed a contract with CeCN, an eConsult company, after completion of this work. Dr Olayiwola began work for an eConsult company in March 2017, well after this work was completed. The remaining authors report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

***Authorship Information:*** Concept and design (DA, IZ, JV, JNO); acquisition of data (DA, VV); analysis and interpretation of data (DA, VV, EC, AH, JV); drafting of the manuscript (DA, VV, EC, IZ, AH); critical revision of the manuscript for important intellectual content (DA, VV, EC, IZ, AH, JV, JNO); statistical analysis (DA, VV, EC, AH); provision of patients or study materials (DA); obtaining funding (DA, JNO); administrative, technical, or logistic support (DA, JNO); and supervision (DA).

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# Hospital-at-Home Interventions vs In-Hospital Stay for Patients With Chronic Disease Who Present to the Emergency Department

## A Systematic Review and Meta-analysis

Geneviève Arsenault-Lapierre, PhD; Mary Henein, MSc; Dina Gaid, PhD; Mélanie Le Berre, MSc; Genevieve Gore, MLIS; Isabelle Vedel, MD, PhD


## Abstract

**IMPORTANCE** Hospitalizations are costly and may lead to adverse events; hospital-at-home interventions could be a substitute for in-hospital stays, particularly for patients with chronic diseases who use health services more than other patients. Despite showing promising results, heterogeneity in past systematic reviews remains high.

**OBJECTIVE** To systematically review and assess the association between patient outcomes and hospital-at-home interventions as a substitute for in-hospital stay for community-dwelling patients with a chronic disease who present to the emergency department and are offered at least 1 home visit from a nurse and/or physician.

**DATA SOURCES** Databases were searched from date of inception to March 4, 2019. The databases were Ovid MEDLINE, Ovid Embase, Ovid PsycINFO, CINAHL, Health Technology Assessment, the Cochrane Library, OVID Allied and Complementary Medicine Database, the World Health Organization International Clinical Trials Registry Platform, and ClinicalTrials.gov.

**STUDY SELECTION** Randomized clinical trials in which the experimental group received hospital-at-home interventions and the control group received the usual in-hospital care. Patients were 18 years or older with a chronic disease who presented to the emergency department and received home visits from a nurse or physician.

**DATA EXTRACTION AND SYNTHESIS** Risk of bias was assessed, and a meta-analysis was conducted for outcomes that were reported by at least 2 studies using comparable measures. Risk ratios (RRs) were reported for binary outcomes and mean differences for continuous outcomes. Narrative synthesis was performed for other outcomes.

**MAIN OUTCOMES AND MEASURES** Outcomes of interest were patient outcomes, which included mortality, long-term care admission, readmission, length of treatment, out-of-pocket costs, depression and anxiety, quality of life, patient satisfaction, caregiver stress, cognitive status, nutrition, morbidity due to hospitalization, functional status, and neurological deficits.

**RESULTS** Nine studies were included, providing data on 959 participants (median age, 71.0 years [interquartile range, 70.0-79.9 years]; 613 men [63.9%]; 346 women [36.1%]). Mortality did not differ between the hospital-at-home and the in-hospital care groups (RR, 0.84; 95% CI, 0.61-1.15; $I^2$ = 0%). Risk of readmission was lower (RR, 0.74; 95% CI, 0.57-0.95; $I^2$ = 31%) and length of treatment was longer in the hospital-at-home group than in the in-hospital group (mean difference, 5.45 days; 95% CI, 1.91-8.97 days; $I^2$ = 87%). In addition, the hospital-at-home group had a lower risk of long-term care admission than the in-hospital care group (RR, 0.16; 95% CI, 0.03-0.74; $I^2$ = 0%).


*(continued)*

## Key Points

**Question** Are hospital-at-home interventions consisting of, at minimum, home visits from nurses or physicians associated with better patient outcomes for adult patients with a chronic disease who present to an emergency department?

**Findings** This systematic review of 9 randomized clinical trial studies, including 959 adult patients with a chronic disease, found that although patients receiving hospital-at-home care had an average length of treatment of 5.4 days longer than that of in-hospital patients and a similar mortality risk, they had a lower risk for readmission by 26% and a lower risk for long-term care admission relative to the in-hospital group. Patients who received hospital-at-home care also had lower depression and anxiety scores than patients receiving in-hospital care, but there was no difference in functional status.

**Meaning** This systematic review provides further evidence that hospital-at-home interventions with at least 1 home visit from a nurse or physician may be a promising substitute to in-hospital care, especially for patients with chronic diseases who present to the emergency department.

+ Invited Commentary

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

*Abstract (continued)*

Patients who received hospital-at-home interventions had lower depression and anxiety than those who remained in-hospital, but there was no difference in functional status. Other patient outcomes showed mixed results.

**CONCLUSIONS AND RELEVANCE** The results of this systematic review and meta-analysis suggest that hospital-at-home interventions represent a viable substitute to an in-hospital stay for patients with chronic diseases who present to the emergency department and who have at least 1 visit from a nurse or physician. Although the heterogeneity of the findings remained high for some outcomes, particularly for length of treatment, the heterogeneity of this study was comparable to that of past reviews and further explored.

*JAMA Network Open.* 2021;4(6):e2111568. doi:10.1001/jamanetworkopen.2021.11568

## Introduction

Hospitalization is associated with adverse events, nosocomial infections, delirium, and even death[1-5] and represents important costs for the health care system.[6-8] Furthermore, patients may prefer being cared for at home.[9,10] Thus, alternatives to hospitalization have been considered.

Hospital-at-home (HaH) interventions were developed to reduce health risks for patients and costs for the system.[11] These interventions consist of treatment delivered to patients who present with an acute condition; a health care professional provides this treatment in the patient's home for a condition that would normally require hospitalization.[12-14] In other words, HaH is the delivery of hospital-level care in patients' homes as a substitute for an in-hospital stay.[15] Services usually include monitoring, face-to-face clinical care from nurses and physicians, diagnostic testing (eg, laboratory investigations, electrocardiograms, and radiography), and treatment (eg, intravenous medication) in patients' homes.[15]

Hospital-at-home interventions have attracted widespread interest. A meta-review of HaH interventions has demonstrated its association with better health outcomes and system costs in patients with acute conditions.[16] However, systematic reviews on complex interventions, like HaH, suffer from high heterogeneity, thereby hindering conclusions made from meta-analyses.[17]

One source of this heterogeneity may be the variability of pooled studies with various interventions and populations.[17] Systematic reviews often do not distinguish between early discharge[18] and a substitute for the in-hospital stay altogether.[11,19] Previous systematic reviews also pooled studies recruiting patients from various entry points (the community, emergency department [ED], and/or during an in-hospital stay).[20] However, the reasons patients choose to go to the ED rather than visiting their physician vary, one of these being perceived urgency and health care needs.[21]

The interventions' key components also varied in the systematic reviews, including home visits, phone access, or coordination with home-based services, all of which may influence heterogeneity. Home visits offer an invaluable opportunity to better understand the needs of patients. When carried out by physicians or by nurses collaborating closely with physicians, home visits could provide care that is more consistent with in-hospital care than providing only hospital equipment at home (eg, intravenous therapy) or coordinating home-based services (eg, nurse visits from community services). Furthermore, home visits have been identified as a key component of transitional care and HaH interventions in older patients with chronic diseases.[22]

Hospital-at-home interventions may be particularly fitting for patients with chronic diseases, as these patients tend to use health services more frequently.[23-29] Systematic reviews on HaH interventions are usually focused on acute conditions or specific chronic diseases (eg, chronic obstructive pulmonary disease [COPD]) and rarely examine the association of HaH on health outcomes across multiple chronic diseases. Specifically, examining patients with chronic diseases (in

consideration of their higher service use than those without chronic diseases) could reduce heterogeneity.

The safety of HaH in terms of patient outcomes, such as mortality and readmission, has been demonstrated.[16] However, other patient outcomes (eg, patients' satisfaction, caregiver stress, and out-of-pocket costs) remain inconsistent or unexplored in systematic reviews. In a previous meta-review,[16] 3 of 6 reviews showed an association between HaH and patient satisfaction, 2 showed no difference, and 1 did not compare patient satisfaction between groups. The reviews that demonstrated an association included studies with various acute conditions, whereas the reviews on specific chronic diseases did not show significant associations.

Given the continuously growing interest in HaH interventions and the high heterogeneity of these complex interventions, it is important to systematically review the literature and assess the association between patient outcomes and HaH interventions considering intervention and population specifics.

The objective of our study was to assess the association between better patient outcomes and HaH interventions aimed at avoiding an in-hospital stay, which included home visits by nurses and/or physicians, for patients with chronic diseases who presented to the ED.

## Methods

### Eligibility Criteria of Included Studies

We conducted a systematic review of the literature guided by the Cochrane Handbook[30] and the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guideline.[31] To be included, studies had to be randomized clinical trials (RCTs) that were published in peer-reviewed journals and compared care received in an experimental group (HaH group) with a control group (in-hospital stay group). Hospital-at-home interventions consisted of at least 1 home visit by nurses and/or physicians who provided treatment that would have otherwise been received in the hospital, and in-hospital care consisted of treatment received by patients during an in-hospital stay. To be included, studies had to report at least 1 outcome relating to patients (ie, patient outcomes): clinical (eg, mortality, quality of life, patient or caregiver satisfaction with care, and complications); use of health services (eg, readmission to hospital, out-of-pocket costs); and process (eg, length of treatment). System costs were not considered, because the focus was on patient outcomes. Previous systematic reviews showed that system costs are lower for HaH than for the control group.[16] Patients included in both groups had to have a chronic disease. Other exclusion criteria are listed in eAppendix 1 in the Supplement. This study did not require institutional review board approval nor was patient consent required, as the systematic review used published, publicly available data.

### Search Strategy, Study Selection, and Data Collection

Three authors (G.A.L., I.V., D.G.) and a health science librarian (G.G.) designed and performed a 3-concept search on March 4, 2019, in 9 databases: Ovid MEDLINE, Ovid Embase, Ovid PsycINFO, CINAHL, Health Technology Assessment, the Cochrane Library, OVID Allied and Complementary Medicine Database, the World Health Organization International Clinical Trials Registry Platform, and ClinicalTrials.gov (**Figure 1**). The search strategy is outlined in eAppendix 1 in the Supplement.

After removal of duplicates, 2 independent reviewers (D.G., M.H.) screened titles and abstracts, and then they assessed full-text records of potentially eligible studies. Disagreements were resolved by 2 additional reviewers (G.A.L., I.V.). A structured extraction form was developed and piloted on a sample of articles. Data extraction was completed by 1 reviewer (M.H.) and reviewed by a second reviewer (D.G.). Discrepancies were resolved by 2 additional reviewers (G.A.L., I.V.).

Descriptive data were collected for patient characteristics (number of patients, age, proportion of women in each group), characteristics of the interventions, and study design (eg, length of

follow-up, home visits by nurses or physicians). The definition of each outcome is provided in eAppendix 1 in the Supplement.

## Risk of Bias

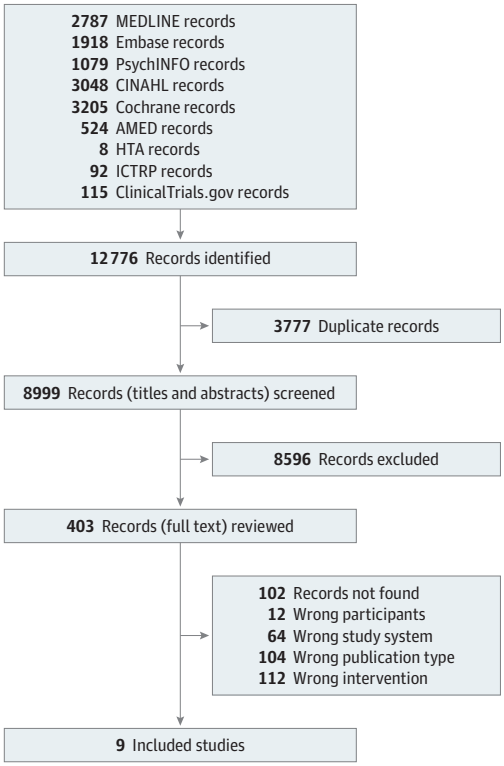
Two reviewers (D.G., M.H.) assessed the risk of bias using criteria from the Cochrane Handbook.[30] Disagreements were resolved by 2 other reviewers (G.A.L., I.V.). Efforts were made to obtain more information and data (and reduce heterogeneity) by contacting the authors directly, as per Godard-Sebillotte et al.[32] Details are given in eAppendix 1 in the Supplement.

## Synthesis of Outcomes

Descriptive statistics were conducted on continuous and categorical data, including counts, proportion, CI, mean, median, and SD as appropriate. Meta-analyses were conducted on comparable outcomes measured by at least 2 studies. For binary data, we calculated pooled risk ratio (RR) and 95% CIs. For continuous data, we calculated mean differences and 95% CIs. In both cases, we used a random-effects model to incorporate heterogeneity. Where needed, data transformation was performed (eAppendix 2 in the Supplement). The number of observations used in the meta-analyses was the number of patients at baseline (ie, displayed in flowchart or characteristic table). A 2-sided *P* value less than .05 and a 95% CI that did not cross 1 (RR) or 0 (mean difference) were considered statistically significant. We reported $I^2$ estimates of heterogeneity. Statistical analyses were performed using the statistical software R, version 1.2.1335 (RStudio Team) and package meta.

We performed sensitivity analyses to assess the robustness of results for each outcome based on suspected modifiers: individual chronic diseases, different follow-up periods, reasons for readmission, sample size, and age of participants. Sensitivity analyses are described in eTables 1 to 4 and eFigures 1 to 3 in the Supplement.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Flowchart




Search was conducted from the earliest record to March 4, 2019. AMED indicates Allied and Complementary Medicine Database; HTA, Health Technology Assessment; ICTRP, International Clinical Trials Registry Platform.

We performed post hoc subgroup analyses to verify whether specific components of the interventions were associated with different results, and we explored reasons for any remaining heterogeneity. We regrouped studies based on home visits by nurses and/or physicians and assessed the magnitude of the association for each outcome.

Outcomes that were not amenable to meta-analysis (eg, reported by 1 study or measured using different tools) were synthesized narratively.[33] Justifications for performing narrative synthesis are found in eTable 1 in the Supplement.

## Results

### Study Selection

The search identified 8999 records; 8595 were excluded based on title and abstract screening. The remaining 405 records were considered in full text. Of these, 396 records were excluded because the design, publication type, participants, or intervention did not satisfy our criteria or because full text was missing. Reasons for exclusions and the study flowchart are found in Figure 1.

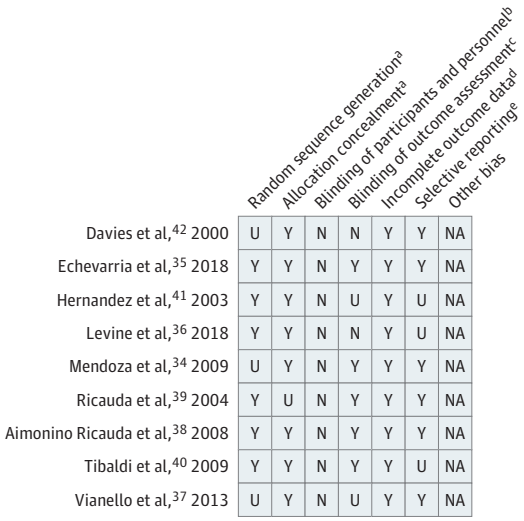
### Risk of Bias

We used a 5-criteria of risk of bias appraisal tool (blinding the participants was not possible). Eight studies explicitly concealed allocation from study personnel, 5 studies blinded outcome assessment, 6 studies described random sequence generation, 9 studies presented attrition data, and 6 studies reported complete outcome data. Risk of bias appraisal is presented in **Figure 2**. Results of efforts to obtain more information and data are described in eAppendix 1 in the Supplement.

### Study Participants and Intervention Characteristics

Nine studies[34-42] were included, providing data on 959 participants (median age, 71.0 years [interquartile range (IQR), 70.0-79.9 years]; 613 men [63.9%] and 346 women [36.1%]) with chronic diseases randomized to either the HaH group or the in-hospital group (**Table 1**; eAppendix 3 in the Supplement). Median population size was 104 patients (IQR, 71-120 patients) with a median of 52 patients (IQR in HaH group, 37-60 patients vs IQR in in-hospital group, 38-58 patients).[43] The HaH and in-hospital groups had similar characteristics, except that there were more women in the HaH group than in the in-hospital group (207 of 513 [40.4%] vs 139 of 446 [31.2%], respectively). The

Figure 2. Risk of Bias Quality Appraisal Results




Risk of bias was conducted according to the Cochrane Handbook; N indicates no; NA, not applicable; U, unknown; Y, yes.

[a] Selection bias.

[b] Performance bias.

[c] Detection bias.

[d] Attrition bias.

[e] Reporting bias.

study year ranged from 2000 to 2018 and were from 4 different countries (4 studies out of 9 [44.4%] were from Italy).

All studies included home visits by nurses, and 5 studies[34,36,38-40] included home visits by nurses and/or physicians (all were hospital or HaH team staff). Additional intervention components included phone access and availability (7 studies[35-40]), patient and caregiver education (3 studies[38,40,41]), social services (4 studies[39-42]), and household support (2 studies[35,41]). Some studies included additional staff on their HaH team, such as social workers (3 studies[38-40]), respiratory therapists (2 studies[35,37]), occupational therapists (2 studies[35,39]), physiotherapists (4 studies[35,38-40]), dieticians (1 study[39]), speech therapists (1 study[39]), and pharmacists (1 study[35]). The median follow-up period was 3 months (IQR, 2-6 months) varying from 1 to 12 months.

## Results of Meta-analyses

Outcomes analyzed via meta-analysis were mortality (all 9 studies[34-42]), readmission (7 studies[34-36,38,40-42]), length of treatment (5 studies[34,35,38-40]), and long-term care admission (3 studies[38-40]). For all outcomes, we used the longest follow-up period, because intermediate time points were not amenable to meta-analysis. Although 2 studies[35,42] provided more than 1 time point data for mortality (14 and 90 days), 1 study[35] counted 0 mortality at 14 days for both groups, making it not amenable to meta-analysis. Forest plots are presented in eAppendix 4 in the Supplement.

Table 1. Characteristics of Included Studies for HaH and In-Hospital Groups

| Source | Design | Patient illness | What and who is involved in the HaH intervention | Outcomes measured | HaH group characteristics[a] | In-hospital group characteristics |
|---|---|---|---|---|---|---|
| Mendoza et al,[34] 2009 Spain | Prospective randomized controlled trial | CHF | Home visits by internal medicine specialist and nurse. Other HCP involved: not specified | Mortality; readmission; functional status; quality of life. Length[b,c] of follow-up: 12 mo | 37 patients; mean age 78 y; 51% women | 34 patients; mean age 80 y; 29% women |
| Ricauda et al,[38] 2008 Italy | Prospective randomized controlled single-blind | COPD | Home visits by physicians and nurses. Other HCP involved: geriatricians, physiotherapists, social worker, and counselor | Mortality; morbidity; readmission; depression, functional status, nutritional status, cognitive status; quality of life; caregiver stress; satisfaction. Length of follow-up: 6 mo | 52 patients; mean age 80 y; 44% women | 52 patients; mean age 79 y; 25% women |
| Ricauda et al,[39] 2004 Italy | Randomized, controlled, single-blind trial | Ischemic Stroke | Home visit by nurse, physician, and physical therapist. Other HCP involved: geriatricians, dietitians, physiotherapists, speech therapists, occupational therapists, psychologists, and social workers | Mortality; functional impairment; depression; morbidity; length of treatment; readmission; neurologic deficit. Length of follow-up: 6 mo | 60 patients; median age 83 y; 62% women | 60 patients; median age 80 y; 48% women |
| Tibaldi et al,[40] 2009 Italy | Prospective, single-blind, randomized controlled trial | CHF | Home visits by physician and nurse. Other HCP involved: geriatricians, physiotherapists, social worker, and counselor | Mortality; morbidity readmission; length of treatment; caregiver stress. Length of follow-up: 6 mo | 48 patients; mean age 82 y; 54% women | 53 patients; mean age 80 y; 43% women |
| Levine et al,[36] 2018 United States | Randomized controlled trial | CHF, COPD, or asthma | Home visits by general internist and nurse. Other HCP involved: not specified | Mortality; length of treatment; readmission; morbidity; satisfaction. Length of follow-up: 1 mo | 9 patients; median age 65 y; 22% women | 11 patients; median age 60 y; 73% women |
| Davies et al,[42] 2000 England | Prospective Randomized controlled trial | COPD | Home visits by nurses. Other HCP involved: hospital respiratory physician | Mortality; readmission; quality of life. Length of follow-up: 3 mo | 100 patients; mean age 70 y; 55% women | 50 patients; mean age 70 y; 40% women |
| Vianello et al,[37] 2013 Italy | Prospective Randomized Controlled trial | Neuromuscular disease | Home visit by district nurse, respiratory therapist, or pulmonologist. Other HCP involved: general physician, and trained caregiver | Mortality. Length of follow-up: 3 mo | 26 patients; mean age 45 y; 35% women | 27 patients; mean age 47 y; 11% women |
| Hernandez et al,[41] 2003 Spain | Randomized controlled trial | COPD | Home visit by respiratory nurse. Other HCP involved: respiratory physician | Quality of life; mortality; readmission. Length of follow-up: 2 mo | 121 patients; mean age 71 y; 3% women | 101 patients; mean age 71 y; 3% women |
| Echevarria et al,[35] 2018 England | Noninferiority randomized controlled trial | COPD | Home visits by respiratory specialist nurse. Other HCP involved: respiratory consultant, pharmacist, occupational therapist, physiotherapist, and social support | Mortality; readmission; depression and anxiety; quality of life; length of treatment. Length of follow-up: 3 mo | 60 patients; mean age 71 y; 53% women | 58 patients; mean age 69 y; 52% women |

Abbreviations: CHF, chronic heart failure; COPD, chronic obstructive pulmonary disease; HaH, hospital-at-home; HCP, health care professional.

[a] Number of patients counted at baseline.

[b] Length of treatment defined as number of days in HaH for the experimental group and the number of in-hospital days for the control group.

[c] Length of follow-up was defined as the number of months for which outcome data was collected for both HaH and in-hospital groups.

There was no significant difference between the HaH and in-hospital groups in mortality (RR, 0.84; 95% CI, 0.61-1.15). There was a lower risk for readmission in the HaH group than in the in-hospital group (RR, 0.74; 95% CI, 0.57-0.95). Length of treatment was significantly longer in the HaH group than in the in-hospital group (mean difference, 5.4 days; 95% CI, 1.9-9.0 days). There was a statistically significantly lower risk of long-term care admission in the HaH group than in the in-hospital group (RR, 0.16; 95% CI, 0.03-0.74) (**Table 2**; eAppendix 4 in the Supplement). Heterogeneity ($I^2$) was 0% for mortality and long-term care admission, 31% for readmission, and 87% for length of treatment (eAppendix 4 in the Supplement).

We analyzed individual chronic diseases in sensitivity analyses and did not find a significant difference between the HaH and in-hospital groups in readmission for patients with only COPD or chronic heart failure (CHF). However, the direction of the associations and magnitude remained comparable. Similarly, we did not find a significant difference between the HaH and in-hospital groups in length of treatment for patients with only CHF, although the direction and magnitude of the associations remained comparable. When considering various lengths of follow-up periods in sensitivity analyses, we did not find a significant difference between the HaH and in-hospital groups on readmission at 3-month follow-up. All other sensitivity analyses (age, population size, and reasons for readmission) yielded similar results as the original analyses.

We performed post hoc subgroup analyses on specific components of the intervention (home visits by nurses and/or physicians). The 4 studies[35,37,41,42] in which home visits were performed by nurses alone did not seem to differ from the 5 studies[34,36,38-40] in which home visits were performed by nurses and physicians. The magnitude of the RR estimates for mortality in studies with physician visits ranged from 0.6 to 1.12, whereas that of nurses-only studies ranged from 0.6 to 0.97. Two nurses-only studies reported on readmission, with RR estimates of 0.74 and 1.09, whereas that of studies with physicians visits ranged from 0.31 to 0.81. This analysis was not conducted on length of treatment because only 1 nurse-only study reported on this outcome, with similar results in both groups.

## Narrative Synthesis

Outcomes synthesized narratively included anxiety and depression, quality of life, patient satisfaction, caregiver stress, cognitive status, nutrition, morbidity due to hospitalization, functional status, and neurological deficits. Most outcomes were measured at longest follow-up period, except for 1 study,[35] which reported intermediate time points at 14 days for anxiety and quality-of-life outcomes. Results are presented in **Table 3** and eAppendix 3 in the Supplement.

All 3 studies[35,38,39] looking at anxiety and depression reported that it improved more in the HaH group than the in-hospital group. Five studies that evaluated quality of life reported mixed findings:

Table 2. Meta-analysis Comparing HaH and In-Hospital Groups

| Outcome | HaH group | In-hospital group | Risk ratio or mean difference (95% CI) | 95% Prediction interval | *P* value |
|---|---|---|---|---|---|
| Mortality | | | | | |
| No. of observations | 513 | 446 | 0.84 (0.61 to 1.15) | 0.57 to 1.24 | .28 |
| No. of events (%) | 57 (11.1) | 63 (14.1) | | | |
| Readmission | | | | | |
| No. of observations | 427 | 359 | 0.74 (0.57 to 0.95)[a] | 0.41 to 1.32 | .02 |
| No. of events (%) | 123 (28.8) | 139 (38.7) | | | |
| Length of treatment | | | | | |
| No. of observations | 257 | 257 | 5.45 (1.91 to 8.98)[a] | −7.30 to 18.19 | .003 |
| Mean (SD), d | 18 (12.6) | 11 (6.9) | | | |
| Long-term care admission | | | | | |
| No. of observations | 160 | 165 | 0.16 (0.03 to 0.74)[a] | NA | .02 |
| No. of events (%) | 1 (0.6) | 16 (9.7) | | | |

Abbreviations: HaH, hospital-at-home; NA, not applicable.

[a] Significant result.

3 studies[35,38,41] found that it improved more in the HaH group than in the in-hospital group, and 2 studies[34,41] found no difference. Three studies that evaluated patient satisfaction reported mixed results: 1 study[41] found a higher patient satisfaction in the HaH group than in the in-hospital group, whereas 2 studies[36,38] showed no difference. Two studies that evaluated caregiver stress reported mixed results: one[40] found higher stress at admission that decreased at discharge in the HaH group, whereas caregiver stress did not change in the in-hospital group. The other study[38] found no difference. All 3 studies that evaluated functional status found no difference between the groups.[34,38,39] No study reported out-of-pocket costs for patients or caregivers, and 4 studies[36,38-40] that evaluated morbidity due to hospitalization reported mixed results.

Table 3. Summary of Outcomes Synthesized Narratively

| Variable | Measurement tools or outcomes | Study conclusions |
|---|---|---|
| Cognitive status | Mini Mental State Exam[38] | No difference |
| Nutrition | Mini Nutritional Assessment Tool[38] | No difference |
| Patient satisfaction | Unidentified questionnaire[38] | No difference |
| | "Patient experience" as measured by a composite score including 2 tools: Care Transition Measure 3 and Picker Patient Experience and 2 questions: whether participant recommend the hospital and how they rate their global experience[36] | No difference |
| | Unidentified questionnaire[41] | Slightly higher in HaH patients compared to in-hospital patients |
| | Single question to assess whether the patient would prefer HaH[35] | Both HaH and in-hospital patients preferred or would have preferred HaH |
| Morbidity due to hospitalization | Morbidity (ie, urinary tract infections, catheterization, falls, delirium, pressure sores)[38] | Less urinary tract infections in the HaH group compared to the in-hospital group; no other differences |
| | Respiratory infections and urinary tract infections[39] | No difference |
| | Adverse events[36] | One adverse event in the in-hospital patients compared with none in the HaH patients |
| | Morbidity (infections, delirium, bed sores, deep vein thrombosis, and falls)[40] | Slightly lower in HaH patients compared with in-hospital patients (not statistically significant) |
| Caregiver stress | Relative Stress Scale[38,40] | One study[38] found no difference in the change between in-hospital and HaH patients. The other study[40] found caregiver stress of HaH patients decreased at discharge, but was higher at admission |
| Anxiety and depression | Hospital Anxiety and Depression Scale[35] | HaH patients showed improvement for anxiety at 14 d, not at 90 d, follow-up whereas in-hospital patients worsened |
| | Geriatric Depression Scale[38,39] | More improvement in HaH patients compared with in-hospital patients |
| Quality of life | Short Form Health Surveys-36[34]and 12[41] | No difference |
| | Nottingham Health Profile[38] | More improvement in HaH patients compared with in-hospital patients |
| | St George's Respiratory Questionnaire[41,42] | One study[42] found no difference. The other study[41] found that HaH patients improved more than in-hospital patients |
| | EuroQuality of Life Instrument 5D-5L[35] | More improvement in HaH and in-hospital patients at 14 d; no difference at 90 d |
| Functional status | Barthel Index[34] | No difference |
| | Katz Instrument for Activities of Daily Living and Lawton Instrumental Activities of Daily Living[38] | No difference in either instruments |
| | 7-item Functional Impairment Measure and Activities of Daily Living[39] | No difference in either instruments |
| Neurologic deficit | Canadian Neurological scale[39] | No difference |
| | National Institutes Health Stroke Scale score[39] | No difference |

Abbreviation: HaH, hospital-at-home.

## Discussion

In this systematic review and meta-analysis, study results suggest that patients with chronic diseases who presented to the ED and were treated with HaH interventions had a lower risk of hospital readmission and long-term care admission than those who received in-hospital care. We found no difference in mortality between the 2 groups, but we found that length of treatment was longer in the HaH group than in the in-hospital group. Taken together, our findings suggest that for patients with chronic diseases who present to the ED, HaH interventions may be as safe as hospitalization (with no difference in mortality) and a preferred alternative (with lower risk of readmission). Furthermore, we found that HaH intervention may be associated with better anxiety and depression scores but not with functional status.

The results of our meta-analysis are consistent with those of other systematic reviews that found lower risk of readmission[19,44] and no difference in risk of mortality.[15,45] Since the writing of our manuscript, a new RCT was published and reported similar results.[46]

The results from our narrative synthesis for lower anxiety and depression were also similar to previous systematic reviews.[15,20] Although another review article that evaluated various medical conditions has shown better patient satisfaction for HaH interventions than that of their control,[16] we found mixed results. This was probably due to the variety of assessment tools measuring different concepts of satisfaction.

Although costs related to the health care system have been shown to be lower for HaH interventions than for in-hospital care,[16] none of the studies in our review reported out-of-pocket costs. It is possible that in HaH interventions, some costs are transferred to patients and caregivers.[47,48] Considering the longer length of treatment in the HaH group, it will be important to assess out-of-pocket costs in future studies.

### Recommendations for Future Studies

Our results suggest various ways that future RCTs on HaH interventions may improve. First, more RCTs should evaluate the association between patient outcomes and HaH intervention in patients with chronic disease who present to the ED by using standard outcomes and measurements. It will be important to report out-of-pocket costs to gain a better understanding of what HaH interventions actually cost, especially given the longer length of treatment experienced in the HaH patient group. Randomized clinical trials should clearly define their interventions and report on process outcomes to allow further exploration of factors that may contribute to different results. Finally, studies should also consider sex-based bias in these HaH studies.

### Limitations

This study has some limitations, particularly regarding potential sources of heterogeneity. Despite efforts to reduce heterogeneity by selecting studies with specific intervention components (hospital avoidance, recruitment from the ED, home visits by nurses or physicians) and specific patient characteristics (chronic diseases), we still observed high heterogeneity, especially for length of treatment. The heterogeneity in our meta-analyses was similar to what was found in other reviews, where it varied between 0% and 1%[15,44,49,50] for mortality, between 17% and 45%[15,44,49,50] for readmission, and 88% for length of treatment.[15] The heterogeneity of our findings may be explained by other characteristics related to the intervention, population, and outcomes, as well as the context in which the interventions were implemented and the studies conducted.[17]

Despite selecting specific components of the interventions, variations remained across studies in terms of home visits by hospital or HaH team nurses alone or by nurses and physicians. However, the magnitude of the association in studies with or without physician home visits did not appear to differ, especially for mortality and readmission. Other components of the interventions varied across studies (eg, phone calls, other health professional consultations, home support, education) and may contribute to heterogeneity. Further studies should explore other components of interventions.

Variations in the patients' characteristics may have contributed to the heterogeneity of our findings. Although most of the patients included had either COPD or CHF (4 studies included only patients with COPD, and 2 studies included only patients with CHF), sensitivity analyses limited to either COPD or CHF no longer yielded a significant association in terms of readmission and length of treatment. Although the significance is different in the sensitivity analyses compared with that of the original analyses, the direction and magnitude of the associations remained comparable. This difference in significance may have been due to the small number of studies in the sensitivity analyses. Pooling studies conducted with patients with different chronic diseases may not be sufficient to reduce variability in the patients' characteristics, especially considering the various clinical criteria for admission owing to the specifics of the patients' diseases. Only 1 RCT evaluated patients with different chronic diseases. However, there is an intrinsic interest in monitoring this population of patients, because they are high users of health services compared with patients without chronic diseases.[26,28,51]

Most patients in our review were older; removing the 1 study with younger patients did not alter our results. Women were underrepresented in our study compared with the proportion of older women globally. Furthermore, the proportion of women varied between studies as well as within studies. This may have been an important source of heterogeneity, because men use hospital services more than women.[52] Further research regarding these findings is needed.

The operationalization of outcomes poses challenges to all systematic reviews; ours was no exception. This was especially true for the length of treatment. It was the only process outcome in our study, but it was neither clearly defined nor referred to consistently (eg, length of stay, length of treatment, time to recovery). Systematic reviews often do not report the pooled results for length of treatment for these reasons. We pooled the length of treatment in our paper nonetheless, as we think that this high heterogeneity is not a sufficient rationale, especially in the context of complex interventions such as HaH.[17]

Considering process outcomes is important in the evaluation of interventions because it allows for the exploration and explanation of underlying factors associated with the success or lack thereof of an intervention.[53] Process outcomes may provide valuable information on the heterogeneity between and within studies. We found that the HaH group experienced a longer length of treatment than the in-hospital group. This is important to note, as one likely benefit of HaH is the smoother transition between hospital and home. In fact, many components of HaH are similar to transitional care interventions, such as multidisciplinary approaches and close monitoring, which have been shown to reduce readmission in patients with chronic diseases.[22,54] Our efforts to obtain clarification for this outcome were answered by 1 study.[35]

Other possible variations in outcomes consisted of differing follow-up periods. Our sensitivity analyses suggest that among studies with a 3-month follow-up, there was no longer a significant difference in hospital readmission between the HaH and in-hospital groups. This sensitivity analysis was limited to only 2 studies[35,42] and will require future studies.

Another source of heterogeneity concerns the context in which the HaH interventions were implemented and the context in which the studies were conducted. We found a wide range in publication year (2000 to 2018) and country of origin (many from Italy). In future studies, this variability in contexts should be analyzed further, as hospitals and available technologies have evolved considerably over time and are unique to specific contexts.

Overall, the small number of studies in our review limits a deeper examination of heterogeneity. However, we conducted random-effects models to incorporate this heterogeneity. Neither selecting studies with specific intervention components nor looking at specific patient characteristics seemed to change our findings' statistical heterogeneity. However, we generated hypotheses for heterogeneity based on variations in interventions, population characteristics, outcome definitions, and study context.

## Conclusions

The results of our systematic review support the use of HaH interventions in people with chronic disease. Given the current global COVID-19 pandemic wherein risk of infectious disease spread is a major concern, especially for patients with chronic diseases, HaH may be considered as a viable alternative to hospitalization.[55]

### ARTICLE INFORMATION

**Accepted for Publication:** April 1, 2021.

**Published:** June 8, 2021. doi:10.1001/jamanetworkopen.2021.11568



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*Administrative, technical, or material support:* Gaid, Le Berre, Vedel.

*Supervision:* Arsenault-Lapierre, Gaid, Vedel.

**Conflict of Interest Disclosures:** None reported.

**Funding/Support:** This study was funded by grant VR5-172692 from the Canadian Institute of Health Research (Dr Vedel).

**Role of the Funder/Sponsor:** The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

**Additional Contributions:** We thank our team members for their input on our meta-analysis (Claire Godard-Sebillotte, MD, PhD, and Nadia Sourial, MD). We thank Quan Nha Hong, PhD, for advising us on the selection of articles. We also thank Hao Zhang, PhD candidate, and Ana Maria Campbell, BSc, for helping us read and screen articles that the authors could not. Finally, we would like to thank Juliette Champoux-Pellegrin for help with general edits to our manuscript. No one received financial compensation for their contributions.

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**SUPPLEMENT.**

JAMA Internal Medicine | Review

# Alternative Strategies to Inpatient Hospitalization for Acute Medical Conditions
## A Systematic Review

Jared Conley, MD, PhD, MPH; Colin W. O'Brien, BS; Bruce A. Leff, MD; Shari Bolen, MD, MPH; Donna Zulman, MD, MS

**IMPORTANCE** Determining innovative approaches that better align health needs to the appropriate setting of care remains a key priority for the transformation of US health care; however, to our knowledge, no comprehensive assessment exists of alternative management strategies to hospital admission for acute medical conditions.

**OBJECTIVE** To examine the effectiveness, safety, and cost of managing acute medical conditions in settings outside of a hospital inpatient unit.

**EVIDENCE REVIEW** MEDLINE, Scopus, CINAHL, and the Cochrane Database of Systematic Reviews (January 1995 to February 2016) were searched for English-language systematic reviews that evaluated alternative management strategies to hospital admission. Two investigators extracted data independently on trial design, eligibility criteria, clinical outcomes, patient experience, and health care costs. The quality of each review was assessed using the revised AMSTAR tool (R-AMSTAR) and the strength of evidence from primary studies was graded according to the Oxford Centre for Evidence-Based Medicine.

**FINDINGS** Twenty-five systematic reviews (representing 123 primary studies) met inclusion criteria. For outpatient management strategies, several acute medical conditions had no significant difference in mortality, disease-specific outcomes, or patient satisfaction compared with inpatient admission. For quick diagnostic units, the evidence was more limited but did demonstrate low mortality rates and high patient satisfaction. For hospital-at-home, a variety of acute medical conditions had mortality rates, disease-specific outcomes, and patient and caregiver satisfaction that were either improved or no different compared with inpatient admission. For observation units, several acute medical conditions were found to have no difference in mortality, a decreased length of stay, and improved patient satisfaction compared to inpatient admission; results for some conditions were more limited. Across all alternative management strategies, cost data were heterogeneous but showed near-universal savings when assessed.

**CONCLUSIONS AND RELEVANCE** For low-risk patients with a range of acute medical conditions, evidence suggests that alternative management strategies to inpatient care can achieve comparable clinical outcomes and patient satisfaction at lower costs. Further study and application of such opportunities for health system redesign is warranted.

*JAMA Intern Med*. 2016;176(11):1693-1702. doi:10.1001/jamainternmed.2016.5974
Published online October 3, 2016.

Supplemental content

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The US health care system is in the midst of transformation as it seeks to improve the health outcomes of populations and individual patients at an affordable cost. One important area of redesign is identifying the best management setting for the diagnosis and/or treatment of acute medical conditions—particularly as it relates to hospital-based care, which accounts for the largest share of total US health care costs (32.4% in 2014).[1] Conventionally, many acute medical conditions have been managed in a hospital inpatient setting; however, innovative care delivery models are challenging the status quo, often with the support of biotechnological advancement. These newer approaches suggest that safe, alternative management strategies exist that obviate the need for inpatient admission.[2-4]

These management approaches are currently organized into 4 models of care delivery: (1) outpatient management—emergency department (ED) or clinic workup and treatment with close outpatient follow-up; (2) quick diagnostic units (QDUs)—organized clinics that obtain rapid diagnoses for serious illnesses (eg, malignant neoplasm); (3) hospital-at-home (HaH)—evaluation in the ED or clinic, followed by delivery of inpatient-level care within the patient's home[3,5]; and (4) observation units—protocol-driven management for up to 24 to 48 hours within a dedicated space with subsequent discharge for outpatient follow-up.[4] Most of these models of care have been in various phases of development for decades (albeit with notable spread to additional conditions in recent years); QDUs, however, were devised more recently in the mid-2000s.

To date, several systematic reviews of alternative management strategies have been completed; however, the scope of these reviews have been limited to either a single condition or a single strategy. Therefore, we sought to comprehensively review all pertinent systematic reviews to better characterize the state of the science of these alternative management strategies—with regard to their ability to safely achieve high-quality clinical outcomes, greater patient satisfaction, and lower cost.

### Key Points

**Question** Can patients with acute medical conditions conventionally managed through hospitalization be treated in alternative management strategies, while maintaining similar or improved health outcomes, patient satisfaction, and costs?

**Findings** Evidence demonstrates that a range of acute medical conditions can be safely treated without hospitalization, at lower cost, and with neutral-to-positive impact on patient satisfaction. Further robust evaluation is warranted for some conditions and alternative management strategies.

**Meaning** In the management of acute medical conditions conventionally requiring hospital admission, opportunities for health system redesign exist that enable better alignment of health needs with the appropriate setting of care.

## Methods

We searched MEDLINE, Scopus, CINAHL, and the Cochrane Database of Systematic Reviews (January 1, 1995, to February 4, 2016) for systematic reviews that examined the use of alternative management strategies. Our search strategy made use of various combinations of terms for alternative care delivery settings and management strategies, and was limited by "systematic review" and English language (see eMethods in the Supplement). We also manually reviewed the references of the included studies, reached out to subject-matter experts, and searched relevant gray literature.

We defined the following a priori inclusion criteria: (1) evaluated 1 or more acute medical condition(s) conventionally managed in an inpatient hospital unit; (2) focused on evaluating the efficacy or effectiveness of managing such a condition using an alternative management strategy that avoided hospital admission; (3) reviewed at least 2 studies, either randomized clinical trials (RCTs) or observational studies;and (4) evaluated adults 18 years or older. We excluded studies of "early-discharge" management strategies and studies focusing exclusively on obstetric, surgical, and psychiatric populations. When feasible, we also excluded "early-discharge" data from within qualified reviews that assessed multiple different management strategies. For the review process, titles were reviewed by 1 author and abstracts and full-text articles were reviewed independently by 2 authors (J.C., C.O.). Disagreements regarding inclusion in the final review were resolved through discussion or by seeking consensus with a third reviewer (D.Z.). Data extraction was performed independently by 2 reviewers (J.C., C.O.). The methodological quality of each systematic review was evaluated by one reviewer (C.O.) using the R-AMSTAR checklist[6] and verified by a second reviewer (J.C.). The strength of evidence from each primary study was graded according to the Oxford Centre for Evidence-Based Medicine levels of evidence by 2 reviewers independently (J.C., C.O.), with discrepancies resolved through discussion.[7]

## Results

Out of 18 113 articles meeting search criteria, there were 25 systematic reviews—representing 123 unique primary studies—that met all eligibility criteria and were included for data abstraction (see eFigure and eTable 1 in the Supplement).[8-32] For evidence synthesis, 3 systematic reviews[30-32] were ultimately not used given their lack of unique primary studies owing to more updated systematic reviews.

**Table 1** describes the general characteristics of each included systematic review. For outpatient management, there were 11 qualifying systematic reviews that examined pulmonary embolism (PE) (n = 4),[8-11] deep vein thrombosis (DVT) (n = 1),[12] chemotherapy-induced febrile neutropenia (CIFN) (n = 2),[13,14] community-acquired pneumonia (CAP) (n = 1),[15] pneumothorax (n = 1),[16] renal colic (n = 1),[18] and diverticulitis (n = 1).[17] For QDUs, there was 1 qualifying systematic review that evaluated malignant neoplasms and a variety of other clinical conditions.[19] For HaH, there were 6 qualifying systematic reviews that examined acute exacerbations of heart failure (n = 1)[20] and chronic obstructive pulmonary disease (COPD) (n = 2),[24,25] as well as a variety of other clinical conditions (n = 3).[21-23] For observation units, there were 4 qualifying systematic reviews that examined multiple clinical conditions (n = 3),[26-28] as well as chest pain individually (n = 1).[29]

Patient eligibility varied across studies. For outpatient management and observation units, patients qualified for lower-intensity management strategies if they were identified as low-risk based on

Table 1. Characteristics and Quality of the Systematic Reviews

| Strategy and Condition | Systematic Review | Relevant Studies, No.[a] | Study Design (No.) | Relevant Primary Studies by Evidence Level | R-AMSTAR Quality Rating (44 Points Total) |
|---|---|---|---|---|---|
| Outpatient management | | | | | |
| PE | Zondag et al,[8] 2013 | 14 | RCT (3), observational (11) | 1 Level 1b study, 2 level 1b− studies, 11 level 4 studies | Moderate (32) |
| | Piran et al,[9] 2013 | 9 | RCT (3), observational (6) | 1 Level 1b study, 2 level 1b− studies, 6 level 4 studies | High (35) |
| | Vinson et al,[10] 2012 | 8 | RCT (2), observational (6) | 1 Level 1b study, 1 level 1b− study, 1 level 2b study, 5 level 4 studies | High (35) |
| | Squizzato et al,[11] 2009 | 8 | RCT (1), observational (7) | 1 Level 1b− study, 7 level 4 studies | Moderate (30) |
| CIFN | Mamtani and Conlon,[13] 2014 | 3 | RCT (2), observational (1) | 1 Level 1b study, 1 level 1b− study, 1 level 4 study | Low (23) |
| | Carstensen and Sørensen,[14] 2008 | 9 | RCT (4), observational (5) | 4 Level 1b− studies, 5 level 4 studies | Low (23) |
| CAP | Chalmers et al,[15] 2011 | 6 | RCT (3), observational (3) | 1 Level 1b− study, 4 level 2b studies, 1 level 4 studies | High (36) |
| Pneumothorax | Brims and Maskell,[16] 2013 | 13 | RCT (1), observational (12) | 1 Level 2b study, 12 level 4 studies | Moderate (31) |
| DVT | Lane and Harrison,[12] 2000 | 4 | Observational (4) | 4 Level 4 studies | Low (21) |
| Diverticulitis | Jackson and Hammond,[17] 2014 | 7 | Observational (7) | 1 Level 2b study, 6 level 4 studies | Moderate (31) |
| Renal colic | Stewart ,[18] 2012 | 3 | Observational (3) | 3 Level 4 studies | Low (21) |
| QDU | | | | | |
| Various medical conditions (eg, malignant neoplasm, unexplained anemia) | Gupta et al,[19] 2014 | 5 | Observational (5) | 1 Level 2b study, 4 level 4 studies | Moderate (31) |
| HaH | | | | | |
| Heart failure exacerbation | Qaddoura et al,[20] 2015 | 5 | RCT (3), observational (2) | 2 Level 1b− studies, 1 level 2b study, 2 level 4 studies | High (40) |
| Various medical conditions (eg, pneumonia, urosepsis, cellulitis) | Varney et al,[21] 2014 | 16 | RCT (9), observational (7) | 5 Level 1b− studies, 3 level 2b studies, 1 level 2c study, 7 level 4 studies | Moderate (32) |
| | Caplan,[22] 2012 | 26 | RCT (26) | 19 Level 1b− studies, 6 level 2b studies, 1 level 4 study | Moderate (31) |
| | Shepperd et al,[23] 2009 | 11 | RCT (11) | 7 Level 1b− studies, 3 level 2b studies, 1 level 4 study | High (35) |
| COPD exacerbation | Jeppesen et al,[24] 2012 | 8 | RCT (8) | 5 Level 1b− studies, 2 level 2b studies, 1 level 4 study | High (40) |
| | McCurdy,[25] 2012 | 2 | RCT (2) | 2 Level 1b− studies | Moderate (31) |
| Observation unit | | | | | |
| Various medical conditions (eg, chest pain, atrial fibrillation, asthma) | Galipeau et al,[26] 2015 | 5 | RCT (5) | 4 Level 1b− studies, 1 level 2b study | High (40) |
| Chest pain, asthma | Daly et al,[27] 2003 | 4 | RCT (4) | 1 Level 1b− study, 3 level 1b studies | Moderate (27) |
| Various medical conditions (eg, asthma, COPD, pyelonephritis) | Cooke et al,[28] 2003 | 7 | RCT (2), observational (5) | 1 Level 1b− study, 1 level 1b study, 5 level 4 studies | Low (21) |
| Chest pain | Goodacre,[29] 2000 | 9 | RCT (4), observational (5) | 4 Level 1b− studies, 1 level 2b study, 4 level 4 studies | Low (24) |

Abbreviations: CAP, community-acquired pneumonia; CIFN, chemotherapy-induced febrile neutropenia; COPD, chronic obstructive pulmonary disease; DVT, deep vein thrombosis; HaH, hospital-at-home; PE, pulmonary embolism; QDU, quick diagnostic unit; R-AMSTAR, revised AMSTAR tool; RCT, randomized clinical trial.

[a] In some cases, primary studies appeared in more than 1 review within the same clinical category (see eTable 3 in the Supplement for more details).

clinical and social criteria. For HaH, individuals met home management criteria if they required inpatient care for a qualifying condition, had adequate home circumstances, and accepted this form of acute management.

In general, the methodological quality of the systematic reviews was moderate with an average R-AMSTAR score of 31 out of 44 (Table 1 and eTable 2 in the Supplement). Systematic reviews focusing on outpatient management and HaH were given the highest quality ratings. The main area of weakness for these systematic reviews was a failure to report potential publication bias, along with a limited amount of meta-analyses for outpatient reviews. Systematic reviews focusing on observation unit settings had additional limitations owing to inadequate search comprehensiveness, incomplete reporting of publication bias, and limited quality assessment—with the exception of the most recent review.[26] The strength of evidence from primary studies was varied. For outpatient management and QDUs, most of the evidence came from level 4 observational studies (often owing to a lack of inpatient

comparison), along with some level 1b and 2b studies. For HaH, the evidence largely came from level 1b and 2b RCTs. For observation units, evidence came from a mix of level 1b and 4 studies (Table 1 and eTable 3 in the Supplement).

## Outpatient Management

### Clinical Outcomes

Compared with hospitalization, outpatient management (after appropriate ED or clinic workup) demonstrated no significant differences in mortality for low-risk PE, CIFN, and CAP.[8,9,13-15] For low-risk DVT and pneumothorax, no inpatient comparison data were available, but overall mortality rates were less than 1.2%.[12,16] No mortality data were available in the renal colic or diverticulitis systematic reviews, likely owing to the lower acuity of these conditions.[17,18] Return hospitalization rates (ie, admissions following outpatient management or readmissions following inpatient management) were reported in reviews of diverticulitis (3.4%) and CIFN (14%-21%), but were compared across outpatient and inpatient management only for CAP (no significant difference).[13-15,17] Additional disease-specific outcomes demonstrated overall low complication rates with no significant differences between outpatient and inpatient management (**Table 2**).

### Patient and Caregiver Experience

Patient and caregiver satisfaction with outpatient management was high for all conditions that evaluated these outcomes (DVT, PE, CAP). Although there was limited evidence comparing outpatient vs inpatient management strategies, studies of PE and CAP suggest no significant differences in satisfaction (**Table 3**).[10,12,15]

### Costs

The 2 systematic reviews (on pneumothorax and diverticulitis) that assessed the financial impact of outpatient vs inpatient management suggest significant cost savings (Table 3).[16,17]

## Quick Diagnostic Units

### Clinical Outcomes

Data on mortality were limited in this care model; there was no comparison to inpatient admission, but 1 large prospective trial of 4170 patients showed a mortality rate of 0.3%. Return hospitalization rates (ie, necessary admissions following QDU management) varied from 3% to 10%. Time from initial contact to diagnosis ranged from 6 to 11 days across each QDU cohort (Table 2).[19]

### Patient and Caregiver Experience

Patient satisfaction with the QDU model was high among all studies that evaluated this metric. Notably, 1 primary study found that when compared with inpatient admission, 88% preferred QDU-based care. Two other studies, which did not have inpatient comparison groups, reported very high satisfaction with QDU care (95%-97% of patients) (Table 3).[19]

### Costs

Two primary studies demonstrated savings of $2353 to $3304 per patient for those in the QDU model compared with inpatient matched controls. Another study showed a potential economic saving of 4.5 inpatient beds per day but did not include specific cost-savings data (Table 3).[19]

## Hospital-at-Home

### Clinical Outcomes

Across many acute medical conditions (including heart failure and COPD exacerbations, cellulitis, CAP, PE, and stroke), 4 reviews[20,21,24,25] showed no significant difference in mortality in HaH management compared with conventional inpatient admission, while 2 reviews[22,23] showed a significant decrease in mortality in HAH management. Return hospitalization rates (ie, admissions following HaH or readmissions following inpatient management) were found to be unchanged,[20,21,23,25] except in 1 review of COPD exacerbations and another review of various medical conditions, where HaH was associated with lower return hospitalization rates.[22,24] Additional patient outcomes demonstrated no significant differences in functional ability, quality of life, or disease-specific outcomes for all reviews, except 1 in which HaH management of exacerbations of heart failure demonstrated significantly improved health-related quality of life (Table 2).[20]

### Patient and Caregiver Experience

Hospital-at-home management was associated with higher patient satisfaction in the 3 reviews[21-23] of multiple conditions, while no significant difference was seen in patients with COPD exacerbations.[24,25] A review on HaH for heart failure exacerbations showed high patient satisfaction (96%); however, there was no inpatient comparison group.[20] Evidence on caregiver satisfaction was limited to data from 4 reviews[21-24] and showed modest but significantly higher satisfaction for all conditions except COPD, for which caregiver satisfaction was unchanged (Table 3).

### Costs

One meta-analysis of 5 studies covering several clinical conditions found that HaH saved an average of just under $2000 per patient when compared with inpatient management.[22] Two other systematic reviews also covering various clinical conditions found statistically significant cost savings for HaH, but these reviews excluded costs of informal and related care.[21,23] A review of HaH for exacerbations of heart failure showed unanimous short-term savings across 3 studies; follow-up costs at 1 year were significantly lower in 1 study and nonsignificantly lower in another[20,24] (Table 3).

## Observation Unit

### Clinical Outcomes

Mortality data in observation unit management were evaluated for asthma, chest pain, and atrial fibrillation and found no difference between intervention and inpatient admission groups.[26,29] Return hospitalization rates (ie, admissions following observation unit care or readmissions following inpatient management) were found to be significantly lower in 1 primary study of chest pain observation units, while 2 other primary studies reported a nonsignificant increase for chest pain units.[26,29] Other disease-specific outcomes were found to be either equal or improved in observation units compared with hospital admission (Table 2).

### Patient and Caregiver Experience

Observation units were associated with increased patient satisfaction when compared with inpatient management strategies.[26-28] None of the reviews examined family or caregiver satisfaction with observation units (Table 3).

Table 2. Clinical Outcomes of Alternative Management Strategies

| Strategy and Condition | Systematic Review | Mortality | | Return Hospital Admissions | | Additional Clinical Outcomes |
|---|---|---|---|---|---|---|
| | | Summary | Details | Summary | Details | |
| Outpatient management | | | | | | |
| PE | Zondag et al,[8] 2013 | ↔ | 1.94% In outpatients (13 studies; 95% CI, 0.79-4.84) and 0.74% in inpatients (5 studies; 95% CI, 0.04-11.14) | NA | NR | Major bleeding risk in outpatients was 0.97% (12 studies; 95% CI, 0.58-1.59) and in inpatients was 1.04% (5 studies; 95% CI, 0.39-2.75); recurrent VTE risk in outpatients was 1.70% (13 studies; 95% CI, 0.92-3.12) and in inpatients was 1.18% (4 studies; 95% CI, 0.16-8.14) |
| | Piran et al,[9] 2013 | ↔ | 1.58% In outpatients (9 studies; 95% CI, 0.71-2.80) and 3.67% in inpatients (2 studies; 95% CI, 0.02-15.15) | NA | NR | Recurrent VTE risk in outpatients was 1.47% (9 studies; 95% CI, 0.47-3.0), major bleeding was 0.81% (9 studies; 95% CI, 0.37-1.42) and fatal ICH was 0.29% (9 studies; 95% CI, 0.06-0.68) |
| | Squizzato et al,[11] 2009 | NA | 0% At 7-10 d in outpatients (3 studies); VTE-related mortality at 3-13 mo occurred in 1 outpatient, owing to major bleeding (7 studies), and no inpatients (2 studies) | NA | NR | Recurrent VTE at 7-10 d in outpatients was 0%-1.5% and major bleeding was 0%-2.3% (3 studies); recurrent VTE at 3-13 mo in outpatients ranged from 0% to 8.7% and major bleeding was 0%-2.7% (7 studies); recurrent VTE ranged from 3.2% to 9.3% in inpatients, and there was no major bleeding (3 studies) |
| CIFN | Mamtani and Conlon,[13] 2014 | ↔ | No difference in mortality between outpatient and inpatient groups (2 RCTs); 0% in both groups in a retrospective study | NA | 17%-21% In outpatients (3 studies) | Success rate in outpatient oral therapy was 89.5% and in inpatient IV therapy was 91% in an RCT; initial response to treatment in outpatients was 81% and in inpatients was 80% in a retrospective study |
| | Carstensen and Sørensen,[14] 2008 | ↔ | No significant difference between outpatients and inpatients (3 studies) | NA | 14% In outpatients (9 studies). | Treatment response in outpatients was not inferior to inpatients, regardless of antibiotic administration route |
| CAP | Chalmers et al,[15] 2011 | ↔ | OR for outpatients compared with inpatients was 0.83 (6 studies; 95% CI, 0.59-1.17) | ↔ | OR for outpatients compared with inpatients was 1.08 (6 studies; 95% CI, 0.82-1.42) | Return to work and usual activities did not differ between inpatients and outpatients (2 studies); there was also no difference between health-related QOL (2 studies) |
| Pneumothorax | Brims and Maskell,[16] 2013 | NA | 0% in outpatients (13 studies) | NA | NR | Successful treatment using Heimlich valve was 77.9% in outpatients (13 studies; 95% CI, 75.2%-80.4%) |
| DVT | Lane and Harrison,[12] 2000 | NA | 1.1% VTE-related mortality in one study, no VTE related death in another (2 studies) | NA | NR | DVT recurrence ranged from 0% to 5.6% (4 studies) |
| Diverticulitis | Jackson and Hammond,[17] 2014 | NA | NR | NA | 3.4% In outpatients (7 studies) | 4 Days of oral therapy resulted in resolution of symptoms in 95% of outpatients (1 study) |
| Renal colic | Stewart,[18] 2012 | NA | NR | NA | NR | Incidence of complications was 0% (3 studies); proportion of patients able to be safely discharged home ranged from 33% to 75% (2 studies); 54% of patients were discharged in another study |
| QDU | | | | | | |
| Various medical conditions (eg, malignant neoplasm, unexplained anemia) | Gupta et al,[19] 2014 | NA | 0.3% In QDU cohort (1 study) | NA | 3%-10% In QDU cohort (3 studies) | Time from initial contact to diagnosis ranged from 6 to 11 d (5 studies); the most common final diagnosis was malignant neoplasm; range, 15% to 30% of diagnoses (4 studies) |

(continued)

Table 2. Clinical Outcomes of Alternative Management Strategies (continued)

| Strategy and Condition | Systematic Review | Mortality | | Return Hospital Admissions | | Additional Clinical Outcomes |
|---|---|---|---|---|---|---|
| | | Summary | Details | Summary | Details | |
| HaH | | | | | | |
| Heart failure | Qaddoura et al,[20] 2015 | ↔ | RR for HaH compared with inpatients was 0.94 (3 studies; 95% CI, 0.67-1.32); mortality was 3.8% in HaH and 9.7% in inpatients in a prospective cohort study ($P < .05$) | ↔ | RR for HaH compared with inpatients was 0.68 in RCTs (2 studies; 95% CI, 0.42-1.09); return admissions were significantly lower in prospective cohort trials (2 studies) | Health-related QOL was significantly improved at 6 mo, standard mean difference in HaH was −0.31 (2 studies; 95% CI, −0.45 to −0.18); this measure was also improved at 12 mo in another study |
| Various medical conditions (eg, pneumonia, urosepsis, cellulitis) | Varney et al,[21] 2014 | ↔ | No difference between HaH and inpatient care (5 studies) | ↔ | No difference between HaH and inpatient in RCTs (3 studies); 0%-15% in observational studies (5 studies) | Clinical outcomes (4 studies), QOL (3 studies) and adverse events or complications (3 studies) did not differ between HaH and inpatient care |
| Various medical conditions (eg, COPD, stroke, pulmonary embolism) | Caplan et al,[22] 2012 | ↓ | OR for HaH compared with inpatients was 0.79 (23 studies; 95% CI, 0.65-0.97) | ↓ | OR for HaH compared with inpatients was 0.76 (18 studies; 95% CI, 0.60-0.97) | NR |
| Various medical conditions (eg, COPD, stroke, cellulitis, pneumonia) | Shepperd et al,[23] 2009 | ↓ | Hazard ratio for HaH compared with inpatients at 3 mo was 0.77 (5 studies; 95% CI, 0.54-1.09); at 6 mo it was 0.62 (3 studies; 95% CI, 0.45-0.87) | ↔ | RR for HaH compared with inpatients was 1.35 (5 studies; 95% CI, 0.97-1.87); patient-level meta-analysis had hazard ratio of 1.49 (3 studies; 95% CI, 0.96-2.33) | Functional ability was not significantly different at 3, 6, and 12 mo between HaH and inpatient groups (5 studies); QOL measurements did not differ (3 studies) |
| COPD | Jeppesen et al,[24] 2012 | ↔ | RR for HaH compared with inpatients was 0.65 (7 studies; 95% CI 0.40-1.04) | ↓ | RR for HaH compared with inpatients was 0.76 (8 studies; 95% CI, 0.59-0.99) | FEV1 in HaH compared with inpatients had standardized mean difference of 0.13 (3 studies; 95% CI, −0.10 to 0.36) |
| | McCurdy,[25] 2012 | ↔ | RR for HaH compared with inpatients was 0.85 (2 studies; 95% CI, 0.45-1.62) | ↔ | RR for HaH compared with inpatients was 0.79 (2 studies; 95% CI, 0.43-1.45) | Mean percentage predicted FEV1 after bronchodilator use was 36% in HaH compared with 35% in inpatients (1 study) |
| Observation unit | | | | | | |
| Various medical conditions (eg, chest pain, atrial fibrillation, asthma) | Galipeau et al,[26] 2015 | ↔ | 0% In observation units and inpatients (4 studies) | ↔ | 8% In short stay unit and 23% in inpatients in 1 study ($P = .03$) and no difference in another study | No adverse events in 2 studies and no difference in adverse events between observation units and inpatients in a third study; length of stay was shorter in short stay units (4 studies) |
| Chest pain, asthma | Daly et al,[27] 2003 | NA | NR | NA | NR | No difference in cardiac events between a chest pain unit and inpatients (1 study); peak flow and relapse-free survival was equivalent in an asthma observation unit compared with inpatients (1 study) |
| Various medical conditions (eg, asthma, COPD, pyelonephritis) | Cooke et al,[28] 2003 | NA | NR | ↔ | No difference in an asthma observation unit compared with inpatients (1 study); no change in admissions with an asthma observation unit in another study | NR |
| Chest pain | Goodacre,[29] 2000 | ↔ | No significant difference between observation unit and inpatients (5 studies) | ↔ | 6.1%-8% For observation units and 4.2%-4.5% for inpatients, with no significant difference between groups (2 studies) | Acute myocardial infarction (range, 0%-4.9%) and did not differ between observation unit and inpatient management |

Abbreviations: CAP, community-acquired pneumonia; CIFN, chemotherapy-induced febrile neutropenia; COPD, chronic obstructive pulmonary disease; DVT, deep vein thrombosis; FEV1, forced expiratory volume in 1 second; HaH, hospital-at-home; ICH, intracranial hemorrhage; IV, intravenous; NA, no available evidence, or no inpatient control group with which to compare the intervention; NR, not reported; OR, odds ratio; PE, pulmonary embolism; QDU, quick diagnostic unit; QOL, quality of life; RR, risk ratio; VTE, venous thromboembolism; ↔, outcome did not differ between intervention group and inpatient control group; ↓ outcome was decreased in intervention group compared with inpatient control group.

Table 3. Patient Satisfaction and Costs of Care of Alternative Management Strategies

| Strategy and Condition | Systematic Review | Patient Satisfaction | | Costs of Care | |
|---|---|---|---|---|---|
| | | Summary | Details | Summary | Details[a] |
| Outpatient management | | | | | |
| Pulmonary embolism | Vinson et al,[10] 2012 | ↔ | No difference between inpatient and outpatients in 1 RCT ($P$ = .39); more inpatients preferred home therapy than outpatients preferred inpatient care | NA | NR |
| CAP | Chalmers et al,[15] 2011 | ↔ | OR of outpatients compared with inpatients was 1.21 (3 studies; 95% CI, 0.97-1.49) | NA | NR |
| Pneumothorax | Brims and Maskell,[16] 2013 | NA | NR | ↓ | Use of Heimlich valve in outpatients compared with intracostal catheter use in inpatients resulted in cost ratios of 1:3.5 and 1:5 (2 studies; 2006, 1980) |
| Deep vein thrombosis | Lane and Harrison,[12] 2000 | NA | 91% Of outpatients were pleased with home treatment (1 study) | NA | NR |
| Diverticulitis | Jackson and Hammond,[17] 2014 | NA | NR | ↓ | 35.0%-83.0% Cost savings in outpatients (4 studies; 2009, 2006, 2002) |
| QDU | | | | | |
| Various medical conditions (eg, malignant neoplasm, unexplained anemia) | Gupta et al,[19] 2014 | NA | Preference for QDU care over hospitalization was 88% (1 study); 95%-97% of patients in 2 other studies reported very high satisfaction with QDU care | ↓ | $2353-$3304 Per patient cost savings in the QDUs (2 studies; 2012, 2001) |
| HaH | | | | | |
| Heart failure | Qaddoura et al,[20] 2015 | NA | 96% Of patients were very satisfied or satisfied with HaH care (1 study) | ↓ | Significantly reduced costs in outpatients in RCTs (3 studies; 2008, 2007, 2005); costs at 12 mo remained significantly lower in 1 RCT and were lower in another RCT but not statistically significant |
| Various medical conditions (eg, pneumonia, urosepsis, cellulitis) | Varney et al,[21] 2014 | ↑ | Satisfaction was greater in HaH compared with inpatients in RCTs (3 studies); 1 RCT reported high HaH satisfaction; 95% of patients were satisfied in observational studies (2 studies) | ↓ | Significantly reduced costs in HaH in RCTs (3 studies; 2000, 1997); other studies reported savings without a $P$ value (2 studies; 1999, 1998) |
| Various medical conditions (eg, COPD, stroke, pulmonary embolism) | Caplan,[22] 2012 | ↑ | Satisfaction was greater in HaH compared with inpatients in all but 1 study, in which satisfaction was equal (10 studies) | ↓ | Cost savings favored HaH with mean difference of −1821.69 in RCTs (5 studies; 2008; 95% CI, −2591.89 to −1051.49) |
| Various medical conditions (eg, COPD, stroke, cellulitis, pneumonia) | Shepperd et al,[23] 2008 | ↑ | Higher satisfaction in HaH compared with inpatients: cellulitis ($P$ < .001) and CAP (40% more); elderly patients with various medical conditions also reported significantly higher satisfaction in HaH (2 studies); in 1 study, 6% of patient refused HaH care | ↓ | Significant and nonsignificant cost savings were found in HaH when compared with inpatient care (6 studies; 2003, 2000, 1998, 1996) |
| COPD | Jeppesen et al,[24] 2012 | ↔ | Risk ratio of HaH compared with inpatients was 1.06 (2 studies; 95% CI, 0.96-1.17) | ↓ | Significant reduction in direct costs for HaH in 2 studies, and 1 other study showed a trend toward lower cost without significance (3 studies; 2005, 2000) |
| | McCurdy,[25] 2012 | ↔ | 95% Of patients completely satisfied with care in HaH (1 study); 94% of patients in HaH and 88% of inpatients rated care as very good/excellent (1 study) | NA | NR |

(continued)

### Costs

Chest pain observation units resulted in cost-savings ranging from $567 to $1873 per patient compared with conventional inpatient management.[29] Two other reviews[26,28] of observation unit use for a variety of medical conditions found reduced costs. Limited evidence was available for observation unit management of asthma (1 primary study)—it showed the mean (SD) observation unit costs of $1203 ($1344) compared with inpatient costs of $2247 ($1110) (Table 3).[27]

## Discussion

Understanding the safety, efficacy, and costs of managing acute medical conditions in alternative care delivery settings to inpatient admission is critically important as the US health care system attempts to identify affordable mechanisms for improving individual patient and population health. In our study of alternative management strategies for acute medical conditions conventionally thought

Table 3. Patient Satisfaction and Costs of Care of Alternative Management Strategies (continued)

| Strategy and Condition | Systematic Review | Patient Satisfaction | | Costs of Care | |
|---|---|---|---|---|---|
| | | Summary | Details | Summary | Details[a] |
| Observation unit | | | | | |
| Various medical conditions (eg, chest pain, atrial fibrillation, asthma) | Galipeau et al,[26] 2015 | ↑ | Satisfaction was significantly higher in observation units compared with inpatients in RCTs (2 studies) | ↓ | Significantly lower costs in observation units compared with inpatients in RCTs, 1 of which reported no difference in total revenue (3 studies; 2014) |
| Chest pain, asthma | Daly et al,[27] 2003 | ↑ | Satisfaction was higher in a chest pain unit compared with inpatients in an RCT (1 study); satisfaction was higher in another RCT comparing an asthma observation unit to inpatients (1 study) | ↔ | Observation unit costs were $1203 ± $1344 compared with mean (SD) inpatient care costs of $2247 ($1110) (1 study; 1998) |
| Various medical conditions (eg, asthma, COPD, pyelonephritis) | Cooke et al,[28] 2003 | ↑ | An asthma RCT showed the observation unit scored higher on all 7 care satisfaction measures and significantly greater for 4 measures (1 study) | ↓ | Cost savings in observation units compared with inpatients for chest pain, asthma, abdominal trauma (4 studies;1988, 1986, 1984, 1980); another study on asthma found no savings (1 study; 1990) |
| Chest pain | Goodacre, 2000[29] | ↑ | Satisfaction was higher in chest pain observation unit compared with inpatients (1 study) | ↓ | Cost savings in observation units ranged from $567-$1873 (7 studies; 1991-1996, 1988) |

Abbreviations: CAP, community-acquired pneumonia; COPD, chronic obstructive pulmonary disorder; HaH, hospital-at-home; NA, no available evidence, or no inpatient control group with which to compare the intervention; NR, not reported; OR, odds ratio; QDU, quick diagnosis unit; RCT, randomized clinical trial. ↔ Outcome did not differ between intervention group and inpatient control group. ↓ Outcome was decreased in intervention group compared with inpatient control group. ↑Outcome was increased in intervention group compared with inpatient control group.

[a] The year of cost estimates are reported for each study. (In the limited cases where this was not provided, we reported the last year of patient enrollment.)

to require inpatient admission, we found moderate evidence of opportunities for safe and effective health system redesign, although further evaluation is required in some cases. For outpatient management strategies, several acute medical conditions showed no significant difference in mortality, disease-specific outcomes, patient satisfaction—and also showed significant cost savings. For QDUs, the evidence was more limited but did show low mortality rates, high patient satisfaction, and lower costs than inpatient admission. For HaH management, a variety of acute medical conditions demonstrated mortality rates, disease-specific outcomes, and patient and caregiver satisfaction that were either improved or no different compared with inpatient admission; costs were universally lower. Finally, for observation units, several acute medical conditions were found to have no difference in mortality, a decreased length of stay, as well as improved patient satisfaction. Results for other acute medical conditions in observation unit settings were more limited, but costs were generally lower. Across all these alternative management strategies, the 1 notable exception to equal or improved outcomes was return hospitalizations for QDUs and outpatient management of CIFN, highlighting the need for improved low-risk stratification and strict return precautions when used. It should also be noted that, as a result of the Medicare Readmissions Reduction Program, hospital readmissions for Medicare patients have slightly decreased since its introduction, which might further affect this finding.[33]

Recommendations from guideline documents are consistent with our findings.[34-38] Despite the promise of alternative management strategies, the overall uptake remains low in many parts of the United States[39,40] and internationally.[41] In the United States, this is likely due, in part, to residual fee-for-service models, in which hospitals potentially lose revenue by delivering care in lower-cost settings. However, with the recent uptake of risk-sharing models of care delivery (eg, accountable care organizations, bundled payments) that are structured to better coordinate care across inpatient and outpatient settings, these alternative management strategies are likely to appeal to patients, clinicians, and organizational leadership alike.

With our unit of analysis being systematic reviews, a limited number of recent primary studies are not included in this review and deserve mention. Recent studies on outpatient management of diverticulitis,[42] pneumothorax,[43] HaH for respiratory infections in patients with neuromuscular disease,[44] and a QDU for unexplained peripheral lymphadenopathy[45] reached similar conclusions to those found in our study. As for observation unit management, with the most recent systematic review evaluating only RCTs,[26] several recent prospective cohort studies have not been included in the systematic reviews to date. A narrative review by Baugh et al,[46] however, corroborates our findings and adds further conditions (eg, transient ischemic attack, heart failure exacerbations) that show promising results regarding safety and efficacy. Another study[47] performed a systematic review that focused solely on the cost of observation unit management vs hospitalization and showed an average cost savings of $1572 per patient and the estimated potential for $3.1 billion in annual savings if observation units were implemented more broadly in the United States.

There are some limitations of this review. First, as noted herein, the evidence for some alternative management strategies (with the exception of HaH) is moderate owing to the lack of significant level 1 evidence; as such, some caution should be used to interpret these results. However, high-quality observational studies are important for analyzing these alternative management strategies, especially for rare events such as mortality and serious complications—where carrying out a sufficiently powered RCT may be impractical. Second, the interventions themselves often differed considerably within each management strategy (outpatient, QDU, HaH, and observation unit). Unlike a device or drug intervention, health care process interventions often have to be adapted to each particular setting and

are, by nature, more varied. Nonetheless, this should not deter clinicians, researchers, and policymakers from drawing appropriate conclusions about the overall efficacy of such interventions. As stated by Shepperd et al,[23] the external validity of these findings is limited less by the challenge to define the exact intervention—a common difficulty in other trials of complex interventions—and more by the identification of the eligible populations for these newer management strategies. In addition, it speaks to their broad feasibility, as adaptations to each unique intervention setting (eg, in terms of population size and wealth) did not result in different overall outcomes. Third, the countries represented in these systematic reviews were diverse, and it is important to account for relevant differences in health care delivery systems when assessing US or global applicability.[48] Such differences, however, should not inappropriately restrict what Mulley[49] refers to as "cross-border learnings"—the ability to adapt and adopt the best practices of nations beyond our own.

Our review highlights several opportunities for future research. For conditions and management strategies with limited level 1 evidence, additional evaluation is needed to validate findings from low-quality RCTs and observational studies. There is also a critical need to determine optimal patient eligibility for alternative management strategies. For many conditions, clinician experts and innovators have thoughtfully developed eligibility criteria for each condition/strategy (including social factors, such as home support and distance from hospital), but certain risk-stratifying algorithms require further evaluation and validation.

## Conclusions

Our findings of alternative management strategies for low-risk patients with acute medical conditions conventionally treated via hospitalization suggest that safe and effective care can be achieved in lower cost settings with positive or neutral impact on patient satisfaction. Further examination with RCT and high-quality comparative observational studies for some conditions and models of care is warranted.


### ARTICLE INFORMATION

**Accepted for Publication:** August 14, 2016.

**Published Online:** October 3, 2016. doi:10.1001/jamainternmed.2016.5974



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**Author Contributions:** Dr Conley had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
*Concept and design:* All authors.
*Acquisition, analysis, or interpretation of data:* All authors.
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*Critical revision of the manuscript for important intellectual content:* All authors.
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*Study supervision:* Leff, Bolen, Zulman.

**Conflict of Interest Disclosures:** None reported.

**Funding/Support:** This work was supported by Stanford University (Dr Conley and Mr O'Brien), the Levy Foundation (Dr Conley), and a VA Health Services Research and Development Service career development award (Dr Zulman).

**Role of the Funder/Sponsor:** The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

**Additional Contributions:** We thank Arnold Milstein, MD, MPH (professor of medicine and director of the Clinical Excellence Research Center, Stanford University School of Medicine); Duncan Neuhauser, MBA, MHA, PhD (professor emeritus of medicine, family medicine, and organizational behavior, Case Western Reserve University School of Medicine); Kurt Stange, MD, PhD (professor of family medicine, epidemiology and biostatistics, oncology, and sociology at Case Western Reserve University School of Medicine); and Lucy Kalanithi, MD (clinical assistant professor of medicine, Stanford University School of Medicine), for their insightful contributions to this research study. They were not compensated for their assistance.


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# "Hospital at home" versus hospital care in patients with exacerbations of chronic obstructive pulmonary disease: prospective randomised controlled trial

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## Abstract

**Objectives** To compare "hospital at home" and hospital care as an inpatient in acute exacerbations of chronic obstructive pulmonary disease.

**Design** Prospective randomised controlled trial with three months' follow up.

**Setting** University teaching hospital offering secondary care service to 350 000 patients.

**Patients** Selected patients with an exacerbation of chronic obstructive pulmonary disease where hospital admission had been recommended after medical assessment.

**Interventions** Nurse administered home care was provided as an alternative to inpatient admission.

**Main outcome measures** Readmission rates at two weeks and three months, changes in forced expiratory volume in one second ($FEV_1$) from baseline at these times and mortality.

**Results** 583 patients with chronic obstructive pulmonary disease referred for admission were assessed. 192 met the criteria for home care, and 42 refused to enter the trial. 100 were randomised to home care and 50 to hospital care. On admission, $FEV_1$ after use of a bronchodilator was 36.1% (95% confidence interval 2.4% to 69.8%) predicted in home care and 35.1% (6.3% to 63.9%) predicted in hospital care. No significant difference was found in $FEV_1$ after use of a bronchodilator at two weeks (42.6%, 3.4% to 81.8% versus 42.1%, 5.1% to 79.1%) or three months (41.5%, 8.2% to 74.8% versus 41.9%, 6.2% to 77.6%) between the groups. 37% of patients receiving home care and 34% receiving hospital care were readmitted at three months. No significant difference was found in mortality between the groups at three months (9% versus 8%).

**Conclusions** Hospital at home care is a practical alternative to emergency admission in selected patients with exacerbations of chronic obstructive pulmonary disease.


## Introduction

Exacerbations of chronic obstructive pulmonary disease are the commonest cause of admission to hospital due to respiratory conditions, amounting to 1250 cases per year in our teaching hospital. This has a major economic impact and is an important factor contributing to pressures for beds in winter.[1] Mortality from these episodes is closely related to the degree of hypercapnia and acidosis at admission and to the presence of non-respiratory comorbidities.[2–4] As many patients presently admitted to hospital do not have these features it may be possible to manage them equally well outside the hospital environment.

Initial attempts at community care for exacerbations of chronic obstructive pulmonary disease have produced mixed results, but the studies were small and the protocols more suited to extended community care than to managing the acute episode.[5 6] An alternative approach has been reported by Gravil et al who enrolled 962 patients with chronic obstructive pulmonary disease in an open study of hospital based supported discharge to the community.[7] They found no greater morbidity in patients cared for at home, although there was a significant readmission rate (12%) in this group. This approach has been taken up enthusiastically throughout the United Kingdom,[8] and it is being actively investigated in Barcelona and Palma, Majorca. Randomised controlled trials of this type of intervention have not, however, been reported.

We hypothesised that selected patients currently admitted with exacerbations of chronic obstructive pulmonary disease could safely be cared for at home with sufficient support. In this trial, patients accepted for hospital admission with exacerbations of chronic obstructive pulmonary disease were intercepted in the accident and emergency department by the Acute Chest Triage Rapid Intervention Team (ACTRITE).

## Patients and methods

### Assignment

*Patients*—The diagnosis of chronic obstructive pulmonary disease was based on standard criteria.[9] An exacerbation was defined as increased breathlessness and an increase in at least two of the following symptoms for 24 hours or more: cough frequency or severity, sputum volume or purulence, and wheeze. The inclusion and exclusion criteria (table 1) were recorded on a set proforma. Patients gave written informed consent. The study was approved by the district ethics committee.

*Assessments*—Three whole time equivalent specialist nurses based in the accident and emergency depart-

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*BMJ* 2000;321:1265–8

**Table 1** Inclusion and exclusion criteria for randomisation

| Inclusion criteria | Exclusion criteria |
|---|---|
| $FEV_1$ <80% predicted | Personal history of asthma |
| $FEV_1$/FVC ratio <70% | Marked use of accessory muscles |
| Minimental state score >7 | Suspected underlying malignancy on chest *x* ray film |
| Pulse rate <100 beats/minute | Pneumothorax or pneumonia |
| Systolic blood pressure >100 mmHg | Uncontrolled left ventricular failure |
| pH >7.35 | Acute changes on an electrocardiogram |
| $pO_2$ >7.3 kPa | Requirement for full time nursing care |
| $pCO_2$ <8 kPa | Requirement for intravenous therapy |
| Total white cell count 4-20×$10^9$/l | |

**Table 2** Baseline characteristics. Values are means (SDs) unless stated otherwise

| Characteristic | Home care (n=100) | Hospital care (n=50) |
|---|---|---|
| Age (years) | 70 (8) | 70 (8) |
| Sex: | | |
| Male | 45 | 30 |
| Female | 55 | 20 |
| Smoking history: | | |
| No of current smokers | 34 | 19 |
| No of ex-smokers | 60 | 30 |
| No of non-smokers | 6 | 1 |
| Pack years | 41 (31) | 43 (24) |
| Prebronchodilator $FEV_1$ (litres) | 0.71 (0.33) | 0.65 (0.21) |
| Postbronchodilator $FEV_1$ (litres) | 0.82 (0.37) | 0.76 (0.28) |
| % predicted postbronchodilator $FEV_1$ | 36.1 (17.2) | 35.1 (14.7) |
| Respiratory rate (breaths/minute) | 24 (4) | 23 (4) |
| Arterial blood gases*: | | |
| pH† | 7.4 (0.05) | 7.39 (0.04) |
| $pO_2$ (kPa) | 9.7 (2.9) | 9.0 (1.2) |
| $pCO_2$ (kPa) | 5.2 (1.0) | 5.2 (0.8) |

$FEV_1$, forced expiratory volume in one second.
*Arterial blood gas measurements were obtained in all patients, but in only 61 patients in home care group and 26 in hospital admission group were measurements recorded on air. These data are recorded here.
†Geometric mean.

ment assessed patients seven days a week from 8 am to 6 pm. All were state registered nurses, and all had further training in the care of patients with chronic obstructive pulmonary disease. A doctor from the hospital respiratory team agreed management and entry into the trial. Patients were randomised in a ratio of 2:1 for "hospital at home" or hospital admission, using blinded sealed envelopes. On the basis of Scottish data and an earlier pilot[10] we chose a study size with 90% power to detect a 25% difference between the admission rates at three months in the two groups.[7 8]

### Protocol

*Study design*

*Period of exacerbation*—Patients were escorted home by one of the specialist nurses. Patients' general practitioners were faxed to inform them of patients being randomised to hospital at home care. Social support was immediately available if required. Nebulised ipratropium bromide and salbutamol with a compressor, oral prednisolone for 10 days, and antibiotics for five days were prescribed. Nurses visited the patients mornings and evenings for three days and thereafter at the discretion of the nurses. Evening and night cover was provided with the agreement of pre-existing services by district nurses. If progress was unsatisfactory the nurse or patient could trigger admission. Inpatients received the same drugs, with all other management being at the discretion of the ward team. Clinical responsibility for the patients remained with the hospital respiratory physicians until the exacerbations had resolved. At day 14 the forced expiratory volume in one second ($FEV_1$) was measured in all patients after the use of a bronchodilator, and these measurements were repeated at three months.

*Principal outcomes* were the number of subsequent admissions to hospital during the first two weeks of home care, the number of admissions to hospital in the three months after this period, and changes in $FEV_1$ after the use of a bronchodilator. Secondly we examined health status in a subgroup of those randomised to the two treatment arms.

*Health related quality of life*—A random subgroup of 90 patients completed a St George's respiratory questionnaire during the first week of the exacerbation. Fifty of these completed a second such questionnaire at three months. All questionnaires were administered by the specialist nurses.

*Statistical analysis*—Data are presented as means (95% confidence intervals) unless otherwise stated. We used paired and unpaired *t* tests to compare data within and between the groups respectively for parametric data, and we used $\chi^2$ tests for non-parametric data. Data were analysed with Microstat version 1 and Microsoft Excel 97. All data have been analysed on an intention to treat basis.

## Results

### Patient flow and follow up

Overall, 583 patients were assessed from February 1998 to August 1999, of whom 192 met the entry criteria (figure). Forty two patients declined to take part and were admitted to hospital, leaving 150 patients. One hundred patients were randomised to hospital at home and 50 to hospital admission. The baseline characteristics of the patients in each group did not differ (table 2). Most patients had severe chronic obstructive pulmonary disease on British Thoracic Society criteria.[9] At randomisation, 47 patients lived alone, 89 with a partner, 11 with their offspring, and three were "other." No difference was found between the groups.

Fifty five patients (37%) had started a course of high dose oral corticosteroids and 75 (50%) had started oral antibiotics within 2 or 3 days of randomisation, as prescribed by their general practitioners. No difference was found between these patients and the others for $FEV_1$ after the use of a bronchodilator, duration of hospital or home care, or distribution between the treatment arms. Table 3 shows other concurrent treatment.

### Analysis

*Home care*

Exacerbations were treated successfully at home in 91 patients. Nine required admission within 14 days of randomisation (figure). These nine did not differ in age, smoking habit, or social support from the others but their percentage predicted $FEV_1$ after the use of a bronchodilator at randomisation was lower (24.9%, 9.0% to 40.8% versus 35.0%, 0.9% to 69.1%; P = 0.004). Two patients died within 14 days of randomisation; both developed pneumonia which was not present clinically or radiographically at the time of randomisation.

Twenty four patients cared for at home required social referral, with a median of 20 hours' care (interquartile range 12-28 hours). Fifteen patients were

provided with home help for cleaning and shopping, eight with assistance for washing and dressing, nine with meals on wheels, five with night sitters, and three with day and night sitters. Patients had a mean of 11 (SD 3) home visits, and exacerbations settled within 14 days in 96 patients. Three patients were loaned an oxygen concentrator, all others receiving the standard treatment outlined above.

*Hospital admission*—Of the 50 patients randomised to hospital admission the median stay was 5 days (interquartile range 4-7 days), and there were no deaths. Three patients admitted were referred for increased social support at the time of discharge.

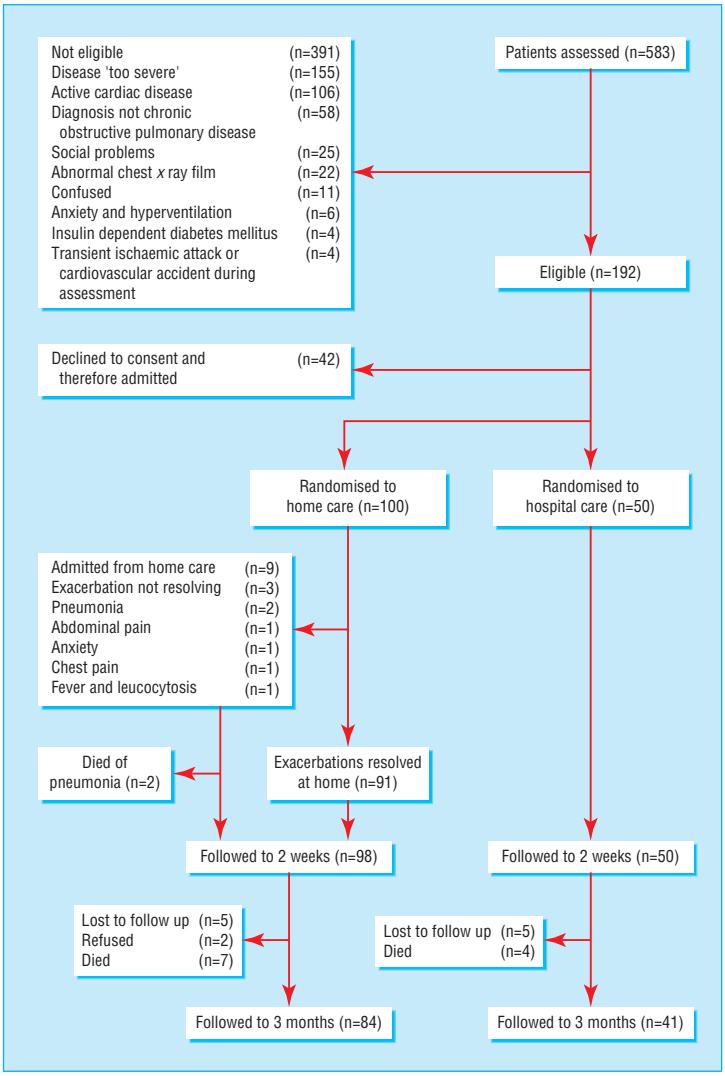
*Follow up*

*Two weeks—The mean percentage predicted FEV*$_1$ after the use of a bronchodilator in the home care group was 42.6% (13.4% to 81.8%). No patient had called their general practitioner during the exacerbation. The mean percentage predicted FEV$_1$ after the use of a bronchodilator for those admitted was 42.1% (5.1% to 79.1%).

*Three months*—The mean percentage predicted FEV$_1$ after the use of a bronchodilator was 41.5% (8.2% to 74.8%) in the home care group and 41.9% (6.2% to 77.6%) in the hospital group. Readmission rates were similar between the groups despite the early readmissions from the home care group, most being due to further exacerbations (table 4). There was no significant difference in mortality between the groups (table 4).

*Health related quality of life*

Of the 90 patients who completed St George's respiratory questionnaires during the exacerbation, total scores were higher in the 32 readmitted within three months (mean 77.1 (SD 15.9)) compared with the 58 not readmitted (67.4 (18.4); P = 0.012). Data from repeat St George's respiratory questionnaires were available in 50 of 90 patients at three months; 34 received home care and 16 hospital care. Mean initial scores in the home care group were 71.5 (43.4 to 99.6) and in the hospital group were 71.0 (43.4 to 98.6). At three months there was no difference in the scores either from admission or between the groups. The score in the home care group had decreased by a mean of 0.48 (SD 16.92) and in those admitted to hospital by 3.13 (14.02).




Trial profile

**Table 3** Participant's treatment at assessment. Values are numbers (percentages) of participants

| Treatment | Home care (n=100) | Hospital care (n=50) |
|---|---|---|
| Inhaled β agonist | 94 (94) | 45 (90) |
| Inhaled anticholinergic | 53 (53) | 31 (62) |
| Inhaled corticosteroid | 75 (75) | 42 (84) |
| Oral corticosteroid | 36 (36) | 19 (38) |
| Antibiotic | 56 (56) | 19 (38) |
| Nebulised bronchodilators | 29 (29) | 11 (22) |
| Theophylline | 23 (23) | 10 (20) |
| Long acting inhaled β agonist | 18 (18) | 10 (20) |
| Oxygen cylinder | 10 (10) | 6 (12) |
| Long term oxygen therapy | 4 (4) | 3 (6) |

**Table 4** Data at three months. Values are numbers (percentages) unless stated otherwise

| Characteristic | Home care | Hospital care |
|---|---|---|
| Mean (SD) change in postbronchodilator FEV$_1$ (litres) | 0.11 (0.34) | 0.14 (0.32) |
| Cause of readmission: | | |
| Exacerbation of chronic obstructive pulmonary disease | 31 (31) | 16 (32) |
| Other | 6 (6) | 1 (2) |
| Total | 37 (37) | 17 (34) |
| Mortality | 9 (9) | 4 (8) |

## Discussion

As chronic obstructive pulmonary disease progresses the effects of intercurrent viral and bacterial infection[11] are more difficult to manage by simply intensifying routine medical treatment, and several factors, including hypoxaemia and limited social support, have been suggested as indicators for admission to hospital.[9] Previous studies of "hospital at home" care have reported small numbers of poorly characterised cases or have used sustained intervention over several months to reduce admission rather than addressing the specific problem of the care of patients with acute exacerbations of symptoms who would otherwise be admitted to hospital.[5,6] This is the first prospective randomised study to show that hospital at home run from the accident and emergency department and not involving an overnight hospital stay is as effective as

## What is already known on this topic

A large number of patients with acute exacerbations of chronic obstructive pulmonary disease currently require inpatient management

A proportion of patients does not have major comorbidities or respiratory failure but needs a level of support requiring inpatient care

## What this study adds

Nursed based assessment in the accident and emergency department may identify a cohort of patients who, given adequate support, could be managed in the community

Hospital at home care for selected patients otherwise requiring admission is safe and practicable in exacerbations of chronic obstructive pulmonary disease

conventional hospital management in some exacerbations of chronic obstructive pulmonary disease.

The two randomised groups were well matched for age, at admission $FEV_1$ after the use of a bronchodilator and initial treatment. They were more severe, as assessed by spirometry, than those in other recent studies of exacerbations of chronic obstructive pulmonary disease in the United Kingdom but were selected to be relatively normocapnic and not acidotic.[5 12] The two deaths were due to pneumonia and were not secondary to respiratory failure complicating chronic obstructive pulmonary disease. This supports the use of our selection criteria when contrasted with an overall mortality of 14% in unselected patients.[13] The encouraging results of the study are that it may be possible to relax the inclusion criteria, particularly with regard to hypoxaemia in the absence of hypercapnia as this could be corrected by supplying patients with oxygen at home.

Unlike previous reports, patients eligible for our study had been referred for hospital admission either by their general practitioner or by an emergency physician. Randomisation occurred in the accident and emergency department without a preliminary overnight stay. We followed our patients for three months and found no differences in mortality, admission rates, or health status between the groups at this time. Since the trial has ended only 17 of 116 (15%) patients eligible for home care have refused to be managed at home.

Like others, we could not prospectively identify patients failing at home, although as a group they had worse initial $FEV_1$ after the use of a bronchodilator. No combination of clinical or objective assessments identified the two patients who developed pneumonia at home after their initial normal chest *x* ray film and who died. The number of early admissions in the home care group, however, does justify our policy of relatively intensive home monitoring. We obtained a measurement of health status at the time of randomisation in almost two thirds of our patients. In keeping with previous data, we found that individuals with higher total scores on the St George's respiratory questionnaire were significantly more likely to be readmitted to hospital in the next three months.[7]

Only one third of patients assessed proved suitable for inclusion in our protocol. This reflects the high incidence of other diseases and the presence of major respiratory acidosis and important social problems, all of which merit hospital care. We believe that hospital assessment is necessary to exclude major comorbidities and to perform radiographic and blood gas analysis. Although this intervention in exacerbations of chronic obstructive pulmonary disease meeting our criteria has proved to be safe and acceptable, it is unlikely that all patients can be managed in this way and a significant provision for those who are admitted will continue to be needed.

Now knowing the readmission rates in each group, we would need over 3000 patients to show a 5% difference in readmission between the groups, which is beyond the scope of a single centre. Given the satisfactory resolution of most of the exacerbations at home we believe that further study should be directed at examining the optimal number of home visits, the impact of the availability of immediate social support, and cost benefit issues. We did attempt to study patient satisfaction in a subset of our population, but administrative problems precluded an adequate sample size. The 17 patients, however, were satisfied with home care.

Our study shows that home care organised directly from the accident and emergency department is a practical alternative to emergency admission in properly selected patients with exacerbations of chronic obstructive pulmonary disease.

We thank A Shaw for supporting the case for a randomised controlled trial, S Callaghan for helping to set up the Acute Triage Rapid Intervention Team, A Townsend-Rose for assessing and managing many of the patients, and S White for statistical advice.

Contributors: LD, PMAC, and RMA were involved in the planning of the service and study. LD and MW collated and analysed the data. SB led the team of specialist nurses, and MW and LD undertook the medical assessments of the patients. LD, PMAC, and RMA interpreted the results and wrote the paper. RMA will act as guarantor for the paper.

Funding: North Mersey Community (NHS) Trust and University of Liverpool.

Competing interests: None declared.

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*(Accepted 29 September 2000)*

COPD: Journal of Chronic Obstructive Pulmonary Disease

ISSN: 1541-2555 (Print) 1541-2563 (Online) Journal homepage: https://www.tandfonline.com/loi/icop20

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**To cite this article:** Carlos Echevarria, Karen Brewin, Hazel Horobin, Andrew Bryant, Sally Corbett, John Steer & Stephen C. Bourke (2016) Early Supported Discharge/Hospital At Home For Acute Exacerbation of Chronic Obstructive Pulmonary Disease: A Review and Meta-Analysis, COPD: Journal of Chronic Obstructive Pulmonary Disease, 13:4, 523-533, DOI: 10.3109/15412555.2015.1067885

**To link to this article:** https://doi.org/10.3109/15412555.2015.1067885

Published online: 08 Feb 2016.

COPD: JOURNAL OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE
2016, VOL. 13, NO. 4, 523–533
http://dx.doi.org/10.3109/15412555.2015.1067885

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REVIEW

# Early Supported Discharge/Hospital At Home For Acute Exacerbation of Chronic Obstructive Pulmonary Disease: A Review and Meta-Analysis

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**ABSTRACT**

A systematic review and meta-analysis was performed to assess the safety, efficacy and cost of Early Supported Discharge (ESD) and Hospital at Home (HAH) compared to Usual Care (UC) for patients with acute exacerbation of COPD (AECOPD). The structure of ESD/HAH schemes was reviewed, and analyses performed assuming return to hospital during the acute period (prior to discharge from home treatment) was, and was not, considered a readmission. The pre-defined search strategy completed in November 2014 included electronic databases (Medline, Embase, Amed, BNI, Cinahl and HMIC), libraries, current trials registers, national organisations, key respiratory journals, key author contact and grey literature. Randomised controlled trials (RCTs) comparing ESD/HAH to UC in patients admitted with AECOPD, or attending the emergency department and triaged for admission, were included. Outcome measures were mortality, all-cause readmissions to 6 months and cost. Eight RCTs were identified; seven reported mortality and readmissions. The structure of ESD/HAH schemes, particularly selection criteria applied and level of support provided, varied considerably. Compared to UC, ESD/HAH showed a trend towards lower mortality ($RR_{MH} = 0.66$; 95% CI 0.40–1.09, $p = 0.10$). If return to hospital during the acute period was not considered a readmission, ESD/HAH was associated with fewer readmissions ($RR_{MH} = 0.74$, 95% CI: 0.60–0.90, $p = 0.003$), but if considered a readmission, the benefit was lost ($RR_{MH} = 0.84$; 95% CI 0.69–1.01, $p = 0.07$). Costs were lower for ESD/HAH than UC. ESD/HAH is safe in selected patients with an AECOPD. Further research is required to define optimal criteria to guide patient selection and models of care.

**ARTICLE HISTORY**
Received 28 March 2015
Accepted 28 June 2015

**KEYWORDS**
COPD; Hospital at Home; mortality; readmission; cost

## Introduction

The burden of chronic obstructive pulmonary disease (COPD) is increasing and is predicted to be the fourth-leading cause of death and seventh-leading cause of disability-adjusted life years worldwide by 2030 (1). In the United Kingdom (UK), patients with acute exacerbations of COPD (AECOPD) account for one in eight emergency hospital admissions (2), and have high in-hospital mortality (7.7%) and 90-day readmission (~33%) rates (3). The estimated annual healthcare cost of COPD is: 38.6 billion Euros in the European Union; 49.4 billion dollars in the United States (4); and £817.5 million (5) to £982 million (6) in the United Kingdom, of which 30% to 50% is due to inpatient care.

Hospital at Home (HAH) "provides active treatment by health care professionals in the patient's home for a condition that would require acute hospital inpatient care" (7). Early Supported Discharge (ESD) (8–10) aims to shorten length of stay. However, the definition of HAH and ESD varies across healthcare systems; in some settings HAH refers exclusively to admission avoidance (11), whilst elsewhere HAH simply implies a higher level of care than ESD (12). In published RCTs in COPD, the terms HAH and ESD are variably used to refer to similar services, and individual studies often include schemes aimed at both admission avoidance and shortening length of stay. Such schemes also vary substantially in the level of clinical and social support provided. Loan equipment, such as oxygen concentrators and nebulisers, is typically available and patients are supported by visiting respiratory specialist nurses, with medical supervision.

Some services will provide intravenous therapy and short-term social services input. ESD/HAH may encourage greater mobility and independence, and should include education on self-management, which may improve outcomes. Contrary to national guidelines, most hospitals in the United Kingdom do not offer ESD/HAH (3). In AECOPD, previous meta-analyses concluded that ESD/HAH is safe (13–15). Two recent meta-analyses were published at similar times, but differed in their conclusions in regard to readmission risk, reflecting differences in trial selection and interpretation of the event rates and risk of bias (15, 16).

It is advised that treatment reviews and meta-analyses are updated bi-annually (17). Our meta-analysis includes an RCT published subsequent to earlier reports and compares the efficacy of ESD/HAH to usual care with respect to mortality, readmission and cost. We describe how the benefit of ESD/HAH

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depends on whether return to hospital during the period of acute care is considered a readmission. In contrast to other studies, in our primary analysis we excluded patients lost to follow-up. Including such patients assumes their event rate is zero and introduces bias, particularly when there are substantial differences in the proportion lost to follow-up between arms. Some RCTs included patients who did not present through accident and emergency (A&E) departments (or equivalent) (18) or were not triaged for admission at the time of randomisation (i.e., patients in UC were discharged directly from A&E) (19). Such patients are likely to be experiencing milder exacerbations and may have been well enough for immediate discharge from A&E; to ensure consistency and avoid bias they have been excluded.

We also review the structure of ESD/HAH schemes, and assess costs, whilst recognising the problems of comparing cost across different countries and healthcare structures.

## Materials and Methods

### Selection criteria and outcome measures

RCTs of ESD/HAH compared to UC in patients with a primary diagnosis of AECOPD, triaged for admission, were considered for inclusion. Studies were only included if, without ESD/HAH, all patients would have been admitted; patients could receive ESD/HAH directly from A&E provided this criterion was met. The reported outcomes are: number of patients experiencing one or more readmissions, mortality and cost.

### Search strategy and selection of studies

The pre-planned search strategy included combining search terms COPD, pulmonary disease, lung disease, respiratory disease, airway disease, airway obstruction, airflow limitation, hospital at home, home care, home base, home support, early supported discharge, early discharge, hospitalisation, hospital base, hospital care, usual care and acute care. Searches using all available date ranges were conducted on databases including Medline, Embase, Amed, Cinahl and HMIC and in web-based libraries (e.g., British Library, United States National Library of Medicine and Institute of Health Economics), relevant national organisations (e.g., National Institute for Health and Clinical Excellence (NICE), BTS, Global Initiative for Chronic Obstructive Lung Disease) and current research registers (e.g., Clinical Trials Register, Current Controlled Trials Register, Centre for Health Economics). Hand-searching of relevant journals was performed to ensure abstracts and conference proceedings were retrieved and the bibliography of each trial was screened to identify any additional RCTs not retrieved in the initial search. All searches were completed by November 2014. Abstracts were screened and, if potentially eligible, full papers reviewed. All reports identified were independently assessed by three reviewers (CE, KB, SB). Disagreements were resolved with discussion.

### Methodological quality assessment (Risk of bias)

Bias was assessed and reported using The Cochrane Collaboration six core risks of bias (20). Bias was assessed independently by at least 2 authors for all trials (CE, KB, SB).

### Data extraction

Data were extracted onto a data abstraction table. When available, characteristics of the trial (e.g., author, year of publication and journal citation, country, setting, design, methodology), study population (e.g., total number enrolled, patient characteristics, age, other important baseline characteristics), interventions (ESD/HAH and UC details), risk of bias in trials, duration of follow-up and outcomes (including outcome definition, unit of measurement) were recorded. Where possible, all data extracted were those relevant to an intention-to-treat analysis. The time points at which outcomes were collected and reported were noted. All authors were contacted to clarify reported data.

### Statistical analysis

Trials with similar outcome measures were pooled in meta-analyses. For time to event (hospital readmission) data, it was not possible to extract the log of the hazard ratio [log(HR)] and its standard error from trial reports or approximate using the methods of Parmar et al. (21). Consequently, we analysed readmission outcomes at the specific time points reported to estimate the risk ratio (RR). A fixed effect risk ratio was calculated for each trial using the Mantel–Haenszel approach ($RR_{MH}$) and these were pooled in sub-groups of trials with similar durations of follow-up. Fixed effect models were chosen (unless otherwise stated) as most trials were similar in methodology, setting and population.

Ninety-five percent confidence intervals (CI) were calculated for the summary effect size and $P < 0.05$ was deemed statistically significant. Heterogeneity between trials was assessed by visual inspection of forest plots and estimation of the percentage heterogeneity between trials that cannot be ascribed to sampling variation (22). If there was evidence of substantial heterogeneity, potential reasons for this were assessed.

## Results

From the literature search, 1,689 references were screened. Including hand-searching, we identified 52 unique references that were retrieved in full. Eight RCTs were included, all published within the last 15 years. The majority of excluded studies were not RCTs or did not involve a comparison of ESD/HAH and usual care (see Figure 1). Seven RCTs (8–10, 12, 23–25) were included in the mortality and readmissions review. Four trials included a cost analysis (9, 23, 26, 27). One RCT published separate clinical (10) and cost (27) analyses.

### Description of selected studies

Four RCTs were conducted in the UK (8, 9, 12, 24), two in the Netherlands (10, 25, 27), one in Australia (26) and one in Italy (23). The inclusion and exclusion criteria are summarised in Table 1. All trials randomised patients to ESD/HAH or UC and provided some description of the ESD/HAH service offered. Clinical responsibility for patients in the ESD/HAH arm remained with the hospital team until discharge from the scheme, with the exception of one trial in which the General

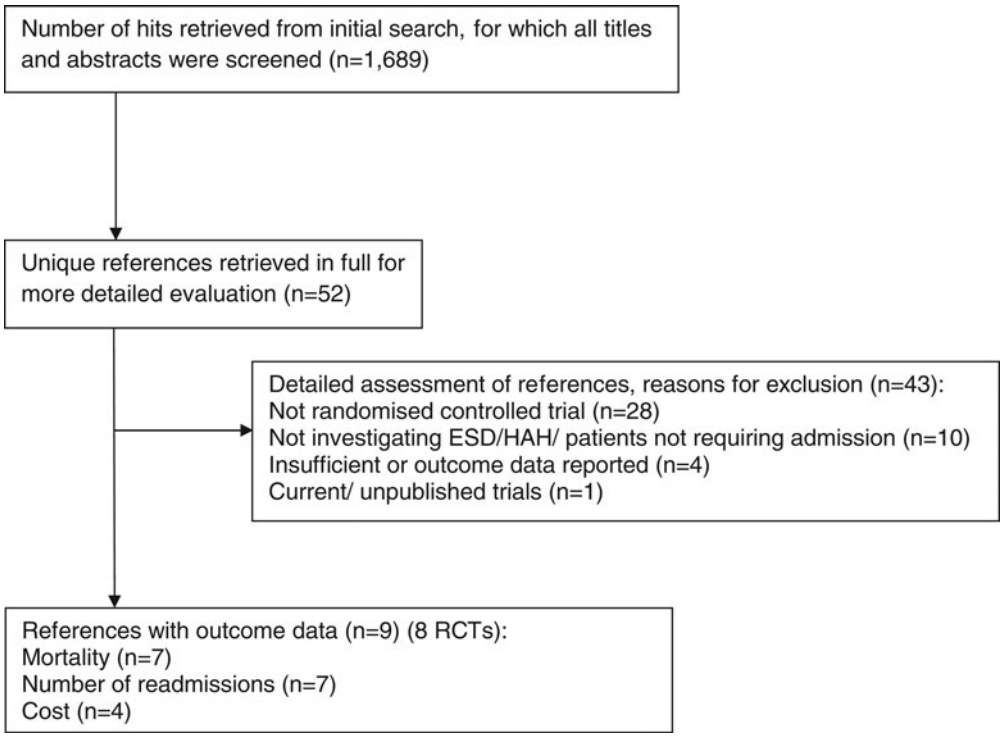


**Figure 1.** Result of the search strategy and reasons for excluding trials from the review.

Practitioner provided care out-of-hours and for "other medical problems" (8). Reported outcomes include mortality (8–10, 12, 23–25), readmissions (8–10, 12, 23–25), cost (9, 23, 26, 27), length of in-hospital stay for UC (8, 9, 12, 24, 25) and ESD/HAH (8, 23, 25), total length of care (in hospital and at home) for ESD/HAH (8, 9, 12, 23, 25), patient preference (9, 12) and service satisfaction (9, 12, 23, 26).

### *Methodological quality of included studies*

Seven trials (8–10, 12, 23–25) reported the method of randomisation. Two trials (9, 10) employed computer-generated random numbers and three trials used random numbers (8, 23, 25). Four trials reported allocation concealment using sealed envelopes (10, 12, 24, 25).

Blinding of participants and treating clinicians is not possible. Only one RCT was single blind (Ricauda et al.) (23); clinicians who performed baseline assessments and the researcher assessing outcomes were unaware of allocation. For subjective outcomes (e.g., quality of life) the risk of bias was considered moderate for Ricauda et al., and high in the remaining trials. Mortality is an objective outcome with low risk of bias regardless of blinding (20). Readmission was regarded as objective in the Cochrane 2012 meta-analysis (15). On balance, we agree, although subjective influences may affect patient behaviour.

Six trials (8–10, 12, 23, 24) included patients who were lost to follow-up, withdrew consent or were excluded from analysis (e.g., due to incorrect diagnosis). In total, 726 and 688 patients were included in the mortality and readmission analyses, respectively. The baseline characteristics of patients and risk of bias, other than blinding, in the included trials are shown in Table 2. The recruitment process and structure of ESD/HAH services outlined in Table 3. Readmission and mortality rates are shown in Table 4.

### *Organisational structure of ESD/HAH schemes*

Two trials offered ESD/HAH from Monday to Friday only (8, 9) and two trials provided a 7-day service (23, 24). Utens et al. (10), Nicholson et al. (26) and Ojoo et al. (12) provided telephone support 7 days a week, but it is unclear if patients were visited at the weekends. Patients were recruited from the A&E department (23, 24, 26), or from general or speciality wards (8–10, 12, 25).

In most trials, patients returned home within 24 (9, 23, 24) to 48 (12, 25) hours of hospital admission. Patients were usually visited at home within 24 hours of discharge (8–10, 23, 24), though Nicholson et al. (26) and Nissen et al. (25) were unclear in this regard.

Most ESD/HAH services involved home visits from hospital-based nurses with respiratory experience, but not physicians (8, 9, 12, 24). In one trial of patients aged 75 years and over, home visits were performed by both geriatricians and nurses; although not respiratory specialists, they are experienced in delivering HAH treatment (23). In other trials, visits were performed by "generic community nurses" (10) or community based nurses and General Practitioners (26). Within most ESD/HAH services, the nurses could obtain medical advice from respiratory physicians (8, 9, 24, 26).

Out of hours support varied, and included district nurses (24), out of hours GP (8), the on call respiratory team/ medical chest unit/ respiratory ward (9, 12, 28), or the HAH team (which included nurses and physicians) (23); in one study this information was unclear (25). Five trials (8, 9, 23–25) reported the number of home visits, which ranged from a mean of 2.6

**Table 1.** Inclusion and exclusion criteria for trials included in the mortality and readmission analysis

| Study | Additional AECOPD inclusion criteria | Exclusion criteria | | |
|---|---|---|---|---|
| | | Clinical indices | Co-morbidities | Demographic and social |
| Cotton 2000 | Not reported | Acidaemia ($H^+ > 45$ nM); Pneumonia or lung cancer on CXR | Other medical conditions, including: Chest pain suggesting MI or PE; Anaemia; Gastrointestinal or endocrine disorders; Musculoskeletal disease; Nausea, vomiting and dehydration | Non-Glasgow resident; Homeless or Hostel dwellers; Unable to consent; No telephone; Discharge already planned; Primary social admission |
| Davies 2000 | $FEV_1 < 80\%$ predicted; $FEV_1/FVC < 70\%$; HR < 100, SBP >100; pH > 7.35, $PaO_2 > 7.3$; $PaCO_2 < 8$; WCC 4–20 × 10 g/l; MMSS>7 | Marked use of accessory muscles; Uncontrolled LVF; Acute changes on echocardiogram; Need for intravenous therapy; Suspected malignancy, pneumothorax, or pneumonia on CXR | Asthma | Require full-time nursing care |
| Skwarska 2000 | Not reported | Impaired LOC or acute confusion pH < 7.35; Acute changes on CXR | Other serious medical conditions, e.g., Ischaemic cardiac pain; Cardiac failure | Social reasons |
| Ojoo 2002 | $FEV_1/FVC < 70\%$; Previous $FEV_1$ reversibility to salbutamol < 15%. | Acidosis or new type 2 respiratory failure; Cor pulmonale; Acute changes on CXR | Concomitant medical conditions requiring medical admission. | Age >18; no telephone; Resident >15 miles from hospital; Poor home support or lives alone |
| Nissen 2007 | $FEV_1 < 80\%$; $FEV_1/FVC < 70\%$ with lack of reversibility 30 mins after bronchodilator therapy $PaO_2 > 7.3$ | Need for intravenous therapy; Need for NIV or ventilation; ECG changes; Pneumonia on CXR | Unstable heart failure; Confusion; Other severe medical disorder | Inadequate social conditions; No telephone; Lives outside the hospital area; Previously participated in the study; Participant in another study |
| Ricauda 2008 | Not reported | $PaO_2 < 6.7$; pH < 7.35 or > 7.55; Suspected PE or MI; MMSS < 14 (severe dementia) | Severe renal impairment; Cancer (not skin); Hepatic failure | No family or social support; Age < 75; no telephone; Living outside catchment area |
| Utens 2012 | 10 pack-years of smoking | Impaired LOC or acute confusion; Indication for admission to ICU or NIV; Acute ECG changes; pneumonia on CXR By day 3: no decrease in physical complaints IV therapy or newly prescribed oxygen therapy; BM ≥ 15 mmol/l (and unable to self-regulate) | Major uncontrolled co-morbidity including heart failure and malignancy Mental disability including dementia; Active alcohol and/or drug abuse | Age < 40; Lives outside care region; Inability to understand; Lack of home care By day 3, independent toileting</TB> |

Key: AECOPD – Acute exacerbation of chronic obstructive pulmonary disease; $FEV_1$ – forced expiratory volume in 1 second; MMSS – Mini mental state score; $FEV_1/FVC$ – $FEV_1$/forced vital capacity; HR – heart rate; SBP – systolic blood pressure; $PaO_2$ - partial pressure of oxygen in arterial blood; $PaCO_2$ – partial pressure of carbon dioxide in arterial blood; WCC – white cell count; LOC – level of consciousness; LVF – left ventricular failure; CXR – chest X-ray; MI – myocardial infarction; PE – pulmonary embolus; ICU – intensive care unit; NIV – non-invasive ventilation.

visits (25), to 14.1 visits from nurses and 9.9 visits from geriatricians (23). The trial with the least number of nurse home visits also offered a telephone support service. The mean (SD) number of telephone calls from patient to nurse was 0.76 (1.34) and from nurse to patient was 1.56 (1.31).

Two trials offered patient and carer education (12, 23), including recognition and management of AECOPD, to the ESD/HAH group only. Other support offered includes social support (23, 24), physiotherapy (23, 25), and counselling and occupational therapy (23).

## Mortality

Meta-analysis of seven RCTs (8–10, 12, 23–25), assessing 726 participants showed a trend towards lower risk of death within 2 to 6 months favouring ESD/HAH ($RR_{MH} = 0.66$, 95% CI: 0.40–1.09, $p = 0.10$) (Figure 2). The percentage of the variability in effect estimates due to heterogeneity rather than sampling error (chance) was not important ($I^2 = 0\%$).

The results using a random effects model were similar ($RR_{MH} = 0.67$, 95% CI: 0.40–1.11, $p = 0.12$), which suggests a small amount of between trial variation. To investigate the possibility of publication bias, the analysis was performed only including the largest trials, which did not reduce the treatment effect but widened the confidence interval (0.60, 95% CI: 0.28–1.25, $p = 0.29$) (9, 10, 24). We performed a sensitivity analysis excluding the trial with the most select population (patients aged 75 and over) ($RR_{MH} = 0.60$, 95% CI: 0.32–1.16, $p = 0.13$) (23). Finally, the analysis was repeated including all patients lost to follow-up (assuming zero event rate) to allow comparison to previous meta-analyses, which adopted this approach ($RR_{MH} = 0.67$, 95% CI: 0.41–1.10, $p = 0.11$) (15, 16).

## Readmissions

Meta-analysis of seven RCTs (8–10, 12, 23–25), assessing 688 participants, assuming return to hospital during ESD/HAH was not a readmission, showed ESD/HAH was associated with a lower risk of readmission within 2 to 6 months than UC ($RR_{MH} = 0.74$, 95% CI: 0.60–0.90, $p = 0.003$). This, and the time periods for readmission, are shown in Figure 3. The percentage of the variability in effect estimates that was due to het-

**Table 2.** Baseline characteristics of patients and risks of bias in trials included in the mortality and readmission analysis

| Study | Number of patients | Age | $FEV_1$ | $PaO_2$ | $PaCO_2$ | Risks of bias | |
|---|---|---|---|---|---|---|---|
| Cotton 2000 | ESD/HAH<br>UC | 41<br>40 | 65.7 (1.6)∗<br>68.0 (1.2)∗ | 0.95(0.08) 41 (3)∗%<br>0.94(0.06) 44 (3)∗% | 8.5 (0.4)∗<br>9.2 (0.4)∗ | 6.0 (0.3)∗<br>5.5 (0.2)∗ | Follow-up method varied. Some patients had face-to-face contact, others did not. More withdrawals in ESD/HAH.> |
| Davies 2000 | ESD/HAH<br>UC | 100<br>50 | 70(8)<br>70(8) | 0.82(0.37) 36.1(17.2)%<br>0.76(0.28) 35.1(14.7)% post bd | 9.7 (2.9)<br>9.0 (1.2) | 5.2 (1.0)<br>5.2 (0.8) | Methods of sequence generation and follow-up not reported. Higher rate lost to follow-up in usual care group. |
| Skwarska 2000 | ESD/HAH<br>UC | 122<br>62 | 68.5<br>69.9 | 0.77<br>0.66 | >7 (91.6%)<br>>7 (90%) | Not reported<br>Not reported | Allocation concealment unclear.<br>Unequal proportions lost to follow-up. |
| Oojo 2002 | ESD/HAH<br>UC | 30<br>30 | 69.7<br>70.1 | 1.0 (0.38)<br>0.85 (0.34) | Not reported<br>Not reported | Not reported<br>Not reported | Random sequence generation method not reported. |
| Nissen 2007 | ESD/HAH<br>UC | 22<br>22 | 69 (10.3)<br>69 (10.1) | 1.5 at admission 40.1 (17.7)%<br>1.4 at admission 33.7 (10.0)% | 9.2 (1.4)<br>8.9 (1.3) | 5.5 (0.7)<br>5.5 (0.81) | Sequence generation not described in article; author confirmed sealed envelopes were used. |
| Ricauda 2008 | ESD/HAH<br>UC | 52<br>52 | 80.1 (3.2)<br>79.2 (3.1) | 0.92(0.4)<br>1.04(0.5) | 9.2 (2.5)<br>8.7 (1.9) | 5.9 (1.6)<br>6.1 (1.6) | Education only provided within the ESD/HAH arm. |
| Utens 2012 | ESD/HAH<br>UC | 70<br>69 | 68.3 (10.3)<br>67.8 (11.3) | Not reported<br>Not reported | 9.0 (1.1)<br>9.4 (1.8) | 5.2 (0.7)<br>5.0 (0.8) | Unequal proportions of patients lost to follow-up. |

Values are given as means (standard deviations). Key: ∗ – standard error; † – 8 weeks post discharge; $FEV_1$ – forced expiratory volume in 1 second; $PaO_2$ – partial pressure of oxygen in arterial blood; $PaCO_2$ – partial pressure of carbon dioxide in arterial blood; ESD/HAH – early supported discharge/ hospital at home; UC – usual care; bd – bronchodilator.

erogeneity rather than chance was $I^2 = 26\%$. An analysis with random effects was similar ($RR_{MH} = 0.72$, 95% CI: 0.57–0.92, $p = 0.010$).

The results were not robust to a sensitivity analysis that excluded the trial of Aimonino Ricauda et al. (23), in which patients were limited by age (greater or equal to 75 years) ($RR_{MH} = 0.83$, 95% CI: 0.65–1.05, $p = 0.11$, $I^2 = 0\%$).

The benefit was also not seen when including all trials with return to hospital during the period care within ESD/HAH classed as a readmission ($RR_{MH} = 0.84$; 95% CI 0.69–1.01, $p = 0.07$) (Figure 4).

Finally, the analysis was repeated including patients lost to follow-up. Once again ESD/HAH was associated with fewer readmissions ($RR_{MH} = 0.75$, 95% CI: 0.61–0.93, $p = 0.007$), but not if return to hospital during ESD/HAH was considered a readmission ($RR_{MH} = 0.88$ 95% CI: 0.72–1.07, $p = 0.21$).

### *Service costs*

Three trials performed cost analyses (9, 23, 26), and one trial performed cost-effectiveness and cost utility analysis (27). There is substantial variation in the costs that were included in the analyses, and how these costs were assessed.

Although the trials were conducted in different countries with different healthcare systems, the cost per episode of healthcare associated with ESD/HAH was consistently lower than UC (UK ESD/HAH = £877, UC = £1753 (9); Italy ESD/HAH = ∃1,175.9, UC = ∃1,390.9 (23); Netherlands ESD/HAH = €1,219, UC = €1,463 (27); and Australia ESD/HAH = Aus∃745, UC = Aus∃2543) (26).

Only one trial assessed costs beyond the acute event; both healthcare and societal costs were reported over three months (27). Healthcare costs for the acute period (the period receiving in hospital or home treatment)) and the acute and follow-up periods combined (ESD/HAH = €4,129, UC = €4,297) marginally favoured ESD/HAH. However, during the follow-up period alone, usual care was less expensive (ESD/HAH = €2,910, UC = €2,834). The largest costs during the follow-up period were due to community nursing and readmissions. Readmission costs were equal in both arms (€941), however in the usual care arm a larger proportion of patients were lost to follow-up. This may have underestimated the readmission cost in UC by underestimating the readmission rate. UC patients had a marginally lower mean change in their Clinical COPD questionnaire, reflecting a smaller deterioration in symptoms.

The UC group had marginally higher QALYs, though the difference was small and statistically non-significant. Therefore, from a healthcare perspective HAH was associated with a savings per QALY lost of €31,111. This is not consistent with other studies that tend to show improved quality of life with ESD/HAH though do not report in-depth economic evaluations. When costs from a societal perspective were also considered, including formal and informal carer costs and production losses for the patient, over the acute and follow-up periods combined, ESD/HAH was more expensive than UC (ESD/HAH = €6,304, UC = €5,395).

## Discussion

### *Principal findings*

Compared to UC, ESD/HAH was associated with a trend towards lower mortality in trials reporting outcome between 2 and 6 months after discharge from hospital or ESD/HAH.

ESD/HAH was associated with a lower rate of all-cause readmission than UC at 2 to 6 months provided all trials were included and that return to hospital during the period of acute care within ESD/HAH was not considered a readmission. Of

**Table 3.** Recruitment process and structure of care for ESD/ HAH services in trials

| Study | ESD/ HAH recruitment structure | | | Structure of ESD/ HAH services | |
|---|---|---|---|---|---|
| | When? | Where from? | Who by? | Intervention | Additional services provided |
| Cotton 2000 | Monday to Friday mornings Discharge next working day after recruitment | Medical Wards | Respiratory specialist nurse, respiratory middle grade doctor | Nurse visited morning after discharge and then as required: median 11 visits over median 24 days. GP out of hours care. | Nebulised bronchodilators, oxygen cylinders. (Additional social support or community physiotherapy not provided). |
| Davies 2000 | Monday to Sunday 08.00 to 18.00 | Accident and Emergency | Respiratory specialist nurse; Respiratory Doctor | Nurse escorted home, visited mornings and evenings for first 3 days, then as required: mean (SD) 11 (3) home visits. District nurse cover evenings and overnight. | Social support (cleaning, shopping, W&D, MOW, day and night-sitters). Nebulised bronchodilators, oxygen concentrator. |
| Skwarska 2000 | Monday to Friday 09.00 to 17.00 | Accident and Emergency; Medical Admissions Unit | Medical Registrar; Acute Respiratory Assessment Service; Respiratory Consultant | Nurse visited next day and then 2–3-day intervals: mean 3.8 nurse visits. Weekly meeting with consultant. Medical advice available daily from on-call respiratory team | Nebulised bronchodilators, oxygen concentrator. |
| Ojoo 2002 | Monday to Thursday 09.00 to 17.00 Discharge within 48hrs | Medical Chest Unit | Respiratory outreach nurses | Nurses complete daily progress and symptoms score charts. The medical chest unit were available out of hours by phone. | Oxygen therapy and nebulised bronchodilators. |
| Nissen 2007 | Discharged from hospital within 48 hours of admission | Not reported | Project nurses | Chest physiotherapy (assumed provided in hospital). Mean 2.6 (1–6) home visits; mean 1.5 hours nurse visit; mean 2.1 (0–6) phone contacts; mean phone time 15 mins; average time per patient = 4 hours 15 mins. | Oxygen therapy. No additional social support. |
| Ricauda 2008 | Monday to Sunday. Mean time in emergency department =15.5 hrs | Emergency department | Not reported | 3 Geriatricians, 13 nurses, 3 physiotherapists, 1 social worker, 1 counsellor. Daily meetings. 7 day service. Physician and nurse visit day after discharge, then daily nurse visit (mean = 14.1) and physician visit every 2–3 days (mean = 9.9). | Oxygen therapy, nebulised bronchodilators, intravenous antibiotics and steroids. |
| Utens 2012 | Screened for inclusion day 1. Randomised day 3 of admission, home on day 4 | Not reported | Community nurses; Respiratory Physician | Community nurses visited or contacted patient at least once daily on day of discharge and for 3 consecutive days. | 24-hour telephone access to hospital respiratory ward for emergencies.</TB> |

Key: GP – General Practitioner; W&D – washing and dressing; MOW – meals on wheels.

importance, the trial by Aimonino Ricauda et al. (23) was age restrictive, education was only routinely provided in the ESD/HAH arm and there was a high event rate in the UC arm (after correction for age and co-morbidity).

If this trial is excluded from the analysis, the difference in readmission rates is no longer significant. However, this trial (23) provides strong evidence that patients aged 75 and over may be safely included in ESD/HAH schemes. Most patients hospitalised with AECOPD are elderly (3) and older patients are most at risk of readmission (29), and death (29–31).

Conceptually, if patients receiving ESD/HAH remain fully under the care of the specialist hospital based team, return to hospital during the period of acute care may be regarded as a transfer to a higher level of care within the same episode, rather than a readmission. This may also be of interest to commissioners and inform service tariffs. Whilst the distinction between HAH and ESD is blurred, return to hospital during a period of ESD is more typically regarded as a readmission. Regardless of the service description and level of care provided, the patient and their carers may regard return to hospital as a failure of ESD/HAH and the event as a readmission, which may have a negative impact on quality of life and service satisfaction. If this approach is adopted, readmission rates were similar for ESD/HAH and UC.

Compared to UC, ESD/HAH is associated with a shorter in-hospital stay, although the total period of care tends to be longer. This does not necessarily mean that patients receiving ESD/HAH are kept under review unnecessarily. Pressures to reduce length of stay in hospital may have led to patients being discharged earlier than is optimal. If return to hospital is regarded as a readmission, this favours UC because UC patients cannot be 'readmitted' during their inpatient stay. Conversely, as the total period of care is longer in ESD/HAH, and the risk of readmission is highest in the early discharge period, not defining return to hospital as a readmission may favour ESD/HAH. In common with earlier reviews (15, 16), we estimate that 23% of patients could be safely treated at home.

Service costs relating to health during the initial treatment phase favour ESD/HAH over UC. For most studies, a description and breakdown of the cost calculations are not provided. Due to this, and heterogeneity of studies, identifying the most cost-effective model is not possible. Goossens et al. (27) provide a detailed cost analysis, and when considering health and social costs combined, ESD/HAH is more expensive. In this

**Table 4.** Readmission and mortality rate in trials.

| Study | Readmitted / at-risk patients | | Died / at-risk patients | | Notes | Further information provided by author? | Lost to follow-up? |
|---|---|---|---|---|---|---|---|
| | ESD/HAH | UC | ESD/HAH | UC | | | |
| Cotton 2000 | 12 / 41 **12 / 41** | 12 / 40 | 1 / 41 | 2 / 40 | Readmission and mortality data analysis as reported in study. | Clarification on definition of readmission, and exclusions and withdrawals. | Nil reported |
| Davies 2000 | 35 / 93 **37 / 95** | 17/ 45 | 9 / 95 | 4 / 45 | Two patients died within 14 days in ESD/HAH, both developed pneumonia, not visible on admission CXR, and returned to hospital before death. Denominator reduced in ESD/HAH and UC for patients with missing data for readmission and mortality. | Confirmed 14-day period defined as the period of acute care and additional details regarding mortality. | 5 in ESD/HAH 5 in UC |
| Skwarska 2000 | 27 / 108 **39 / 120** | 21 / 61 | 4 / 122 | 7 / 62 | In UC one patient died in acute period so removed from denominator for readmission. In ESD/HAH, twelve patients readmitted during hospital at home period, who were not analysed as readmissions so subtracted. | Mortality and readmission data confirmed with author. On review of the data, author confirmed that two patients in ESD/HAH were not included in the readmission analysis (subtracted from denominator). | Nil reported |
| Ojoo 2002 | 9 / 27 **11 / 29** | 12 / 27 | 1 / 27 | 3 / 27 | In UC readmission rate reported as 44.4% (12/27). ESD/HAH readmission rate 33.3%. As 27 followed up, number of events = 9. Of three patients excluded from ESD/HAH analysis, authors report two patients returned to hospital during ESD/HAH. | No. | 3 in ESD/HAH 3 in UC |
| Nissen 2007 | 4 / 22 **6 / 22** | 8 / 22 | 1 / 22 | 0 / 22 | No deaths during the acute period. No patients lost to follow-up. | Detailed information provided on readmission and return to hospital data. Two patients who were admitted during ESD/HAH were included in the analysis, and were not readmitted during follow-up, so denominator not adjusted. | Nil reported |
| Ricauda 2008 | 17 / 41 **20 / 41** | 34 / 39 | 9 / 50 | 12 / 51 | Three patients returned to hospital during ESD/HAH, not termed readmissions. Unable to clarify if these 3 patients were readmitted during follow-up period. | No. | 2 in ESD/HAH 1 in UC. |
| Utens 2012 | 17 / 66 **18 / 66** | 17 / 56 | 1 / 66 | 1 / 56 | Patients died during the follow-up period, not acute period, so denominator not adjusted. | Detailed information provided on follow-up. UC- of 16 lost to follow-up, 3 known to be readmitted. ESD/HAH- of 6 lost to follow-up, 2 known to be readmitted prior to being "lost". | 4 in ESD/HAH 13 in UC |

In some instances, patients who returned to hospital during EDS/HAH were not included in the authors' analysis, so they have been removed from both the numerator and denominator. Patients who died during the acute period are not at risk of readmission and have been removed. The numbers in bold (readmission column) describe readmissions including return to hospital during ESD/HAH. Patients who were lost to follow-up have been removed.

study all patients spent three days in hospital, and so this model is closer to ESD than HAH, and the results may have been different if the patients had returned home soon after admission or hospital admission was avoided. Patient preference favours ESD/HAH over UC, whilst service satisfaction appears to be similar although further robust trials are required.

### *Strengths and weaknesses of meta-analysis and comparison of included studies*

This review and meta-analysis has provided an up-to-date analysis of ESD/HAH compared to UC for AECOPD and includes a trial (10) not published at the time of previous reviews (15, 16). We employed a comprehensive search strategy and contacted the corresponding authors to verify data when necessary.

The included trials were conducted in different countries with different healthcare systems. The diagnostic criteria for AECOPD were similar, but there were important variations in inclusion criteria and the structure and organisation of ESD/HAH services. Some trials did not offer enrolment at the weekends (8, 9, 12), reducing both the cost of, and the number of patients who could access, ESD/HAH. In two trials (23, 24) patients were recruited directly from A&E or the Emergency Department, facilitating quicker discharge home, whilst in other trials (8–10, 12, 25) patients were recruited from wards, allowing a period of stabilisation and observation as an inpatient. It is likely that offering both pathways, tailored to the individual patient, would optimise costs and the proportion of patients suitable to access the service.

The structure of ESD/HAH services varied, including the healthcare professionals involved, the number of home visits, telephone support, access to medical services such as home oxygen, and provision of temporary social support. Differences in selection criteria and service structure may, in part, explain the striking variation in the level of support provided in the ESD/HAH arm; the mean number of home visits ranged from 2.6 nurse visits (25) to 14.1 nurse and 9.9 physician home visits (23).

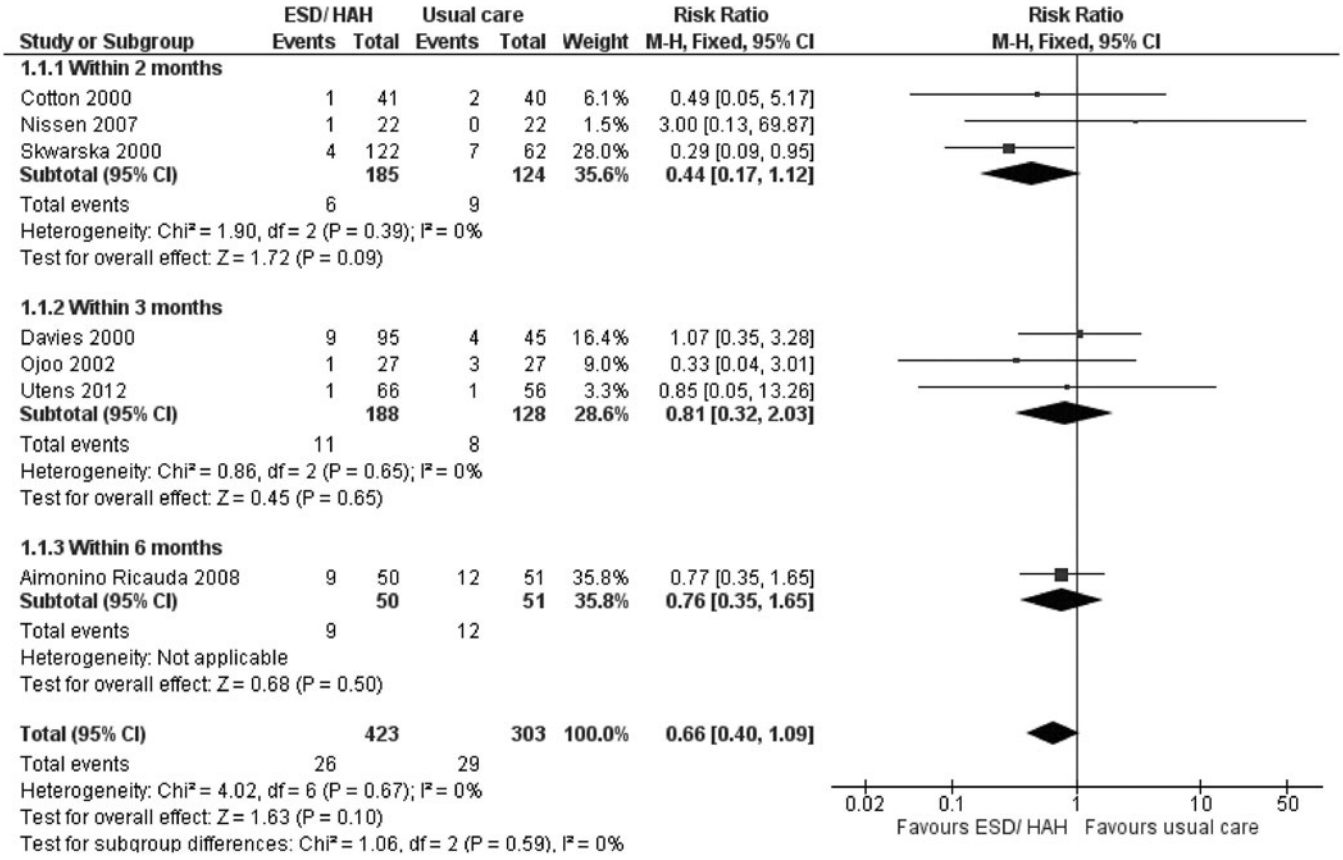


**Figure 2.** Forest plot comparing ESD/HAH versus UC for mortality.

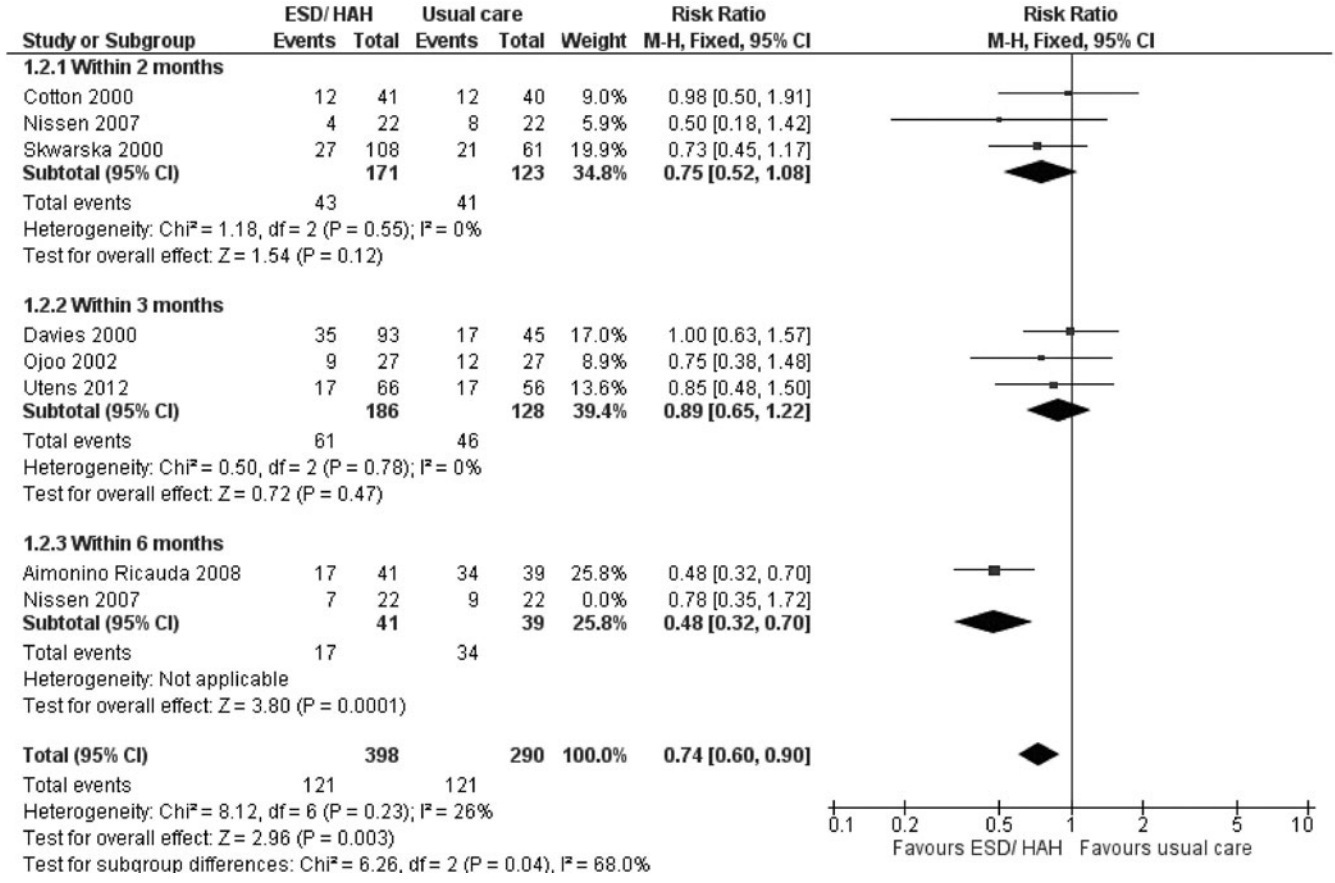


**Figure 3.** Forest plot comparing ESD/HAH versus UC for proportion of readmissions with return to hospital not classed as a readmission.

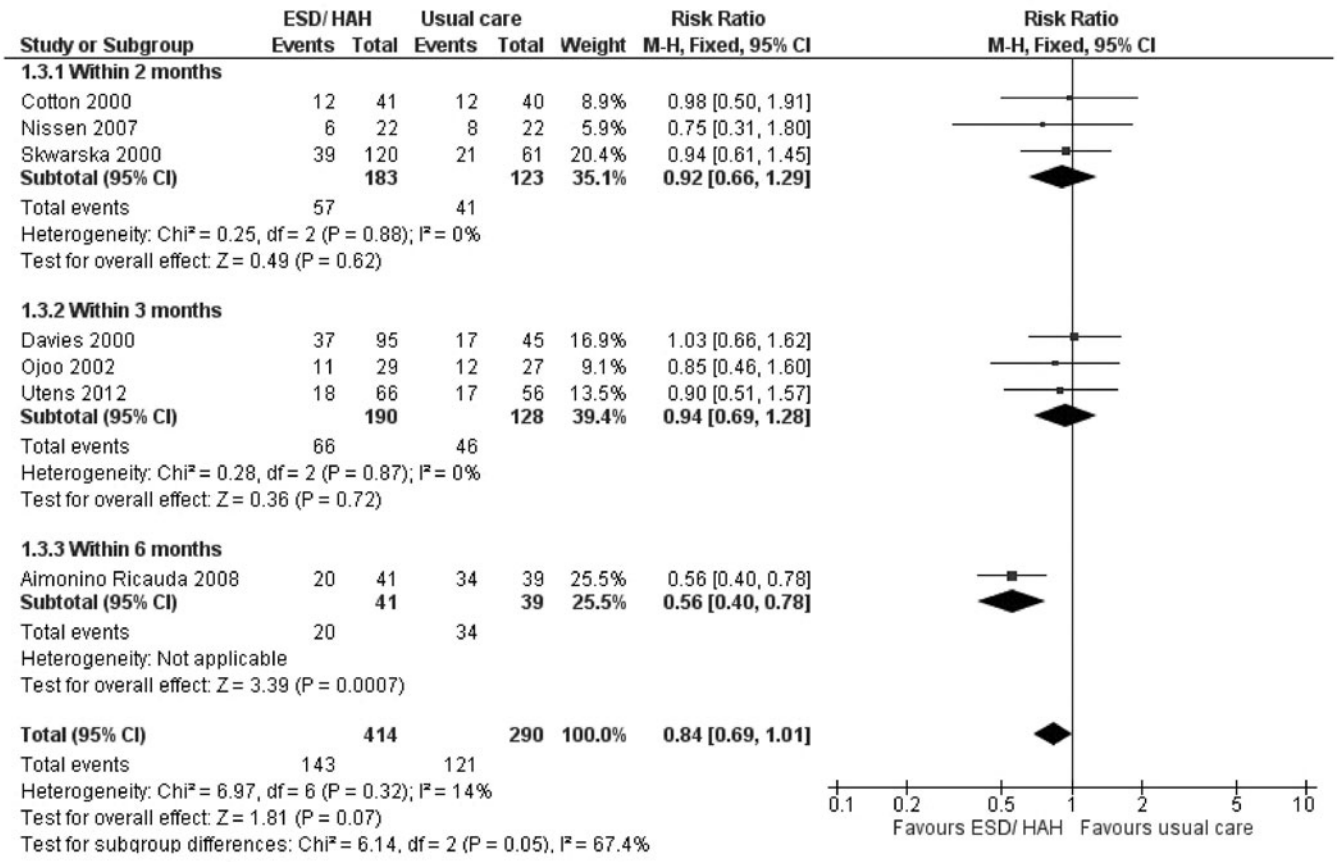


**Figure 4.** Forest plot comparing ESD/HAH versus UC for proportion of readmissions including return to hospital as a readmission.

Amongst patients with AECOPD who require in-hospital or ESD/HAH treatment, those with more severe exacerbations and/or poor performance status may require greater clinical and social support at home. A more comprehensive service, offering frequent visits from professionals, home oxygen therapy and temporary social services if required, will allow inclusion of a broader spectrum of patients. Although this will increase the cost of ESD/HAH, it may still be less expensive than UC.

In some trials there were differences in the elements of care provided in each arm. For example, in one trial, education, including exacerbation self-management, was provided to patients and carers in the ESD/HAH group, but not to the UC group (23).

The period of follow-up varied; this influenced the event rate. To address this, we initially planned to analyse results using hazard ratios, but the data required were not available and could not be estimated using Parmar's methods (21); therefore, risk ratios were calculated.

Differentiating between ESD and HAH is challenging, and in this review we have considered both together. HAH is an appropriate term for patients that have their entire episode treated at home, without admission. The term HAH is also used in some healthcare systems for patients who are assessed in the medical admission unit and return home for treatment the same day or the following morning if admitted overnight.

For patients who deteriorate at home, during the period of care under ESD/HAH, an overnight stay in hospital is often defined as a readmission. However, equally this may be considered an escalation in level care within a single acute episode, and alternatively defined as "return to hospital." We have analysed the data separately, where possible, to reflect this variation. Some patients may have a brief assessment in an emergency department or ambulatory setting without an overnight stay; this would typically not be considered a readmission, and we consider that the RCTs described were consistent in this respect.

## *Comparison with previous meta-analyses*

### *Trial selection*

Two meta-analyses comparing ESD/HAH and UC published in 2012 came to different conclusions with regards to outcome. Jeppesen et al. (15) reported moderate quality evidence that ESD/HAH was associated with lower readmission risk than UC (RR 0.65, 95% CI 0.59–0.99, p = 0.04) (15), which was further strengthened following exclusion of the trial deemed to have the highest risk of bias (CI 0.58 to 0.91; p = 0.006), and moderate evidence of a trend towards a reduction in mortality. In contrast, McCurdy (16) found no significant difference in readmission and mortality rates. The evidence was regarded as low to very low in quality, with a need for further research.

We did not include the study by Nicholson et al. (26), which primarily compares costs, in our meta-analysis of readmission. We shared the concerns reported by Jeppesen et al., which is why they excluded this paper in a sensitivity analysis. Nicholson et al. may have included patients referred by the outpatient

department. No information was provided on baseline function, the randomisation process, allocation concealment, mortality or readmissions. Data on readmissions was obtained at the time of the Cochrane review, but the period of follow-up is unclear. In the ESD/HAH arm the risk ratio for readmission was high compared to other trials (8, 9, 12, 19, 24), however due to the small number of subjects, the confidence intervals are wide (RR = 2.77, 95% CI:0.69 to 11.17).

We excluded Hernandez et al. (19), which was included by Cochrane, because patients attending A&E with an AECOPD without the need for admission were considered eligible; 38.6% of the patients in the UC arm were discharged directly from A&E. A similar proportion of those treated within ESD/HAH would be expected to not otherwise require admission, thus this structure of care does not meet the definition of ESD/HAH for all included patients. Whether or not this group of patients benefit from home support is of importance, but is not the subject of this review.

### *Patient events*

McCurdy differs from Jeppesen et al. (15) in the number of events because McCurdy classes return to the hospital during ESD/HAH as a readmission. Neither adjusted their analyses for patients who die prior to discharge, yet such patients are not at risk of readmission.

McCurdy discusses the issues surrounding missing data, but, like Cochrane, did not make any adjustment in the analysis. Both performed an intention to treat analysis, but included those patients lost to follow-up in whom outcome data was not available. This assumes their event rate is zero, though other RCTs suggest that patients with missing data have a higher event rate than the population with complete data (32). The ideal approach to missing data is multiple imputation, but this requires raw trial data.

We analysed readmission rates with and without return to hospital counting as a readmission and with and without patients lost to follow-up. We are grateful to all authors who clarified data.

### *Implications for clinicians and policymakers*

AECOPD are associated with substantial morbidity, mortality and healthcare costs. It is imperative that clinically and cost effective methods to reduce admissions and readmissions are considered and implemented. In selected patients presenting with AECOPD, ESD/HAH schemes substantially reduce length of stay, with similar or lower mortality and readmission rates compared to conventional inpatient care. Despite this, many Trusts currently do not offer such services.

## Future research

We recommend that future RCTs of ESD/HAH clearly define readmission, and provide data on patients who return to hospital during ESD/HAH and whether these same patients are readmitted during the follow-up period.

The optimal selection criteria and structure of care for ESD/HAH services is unclear. Selection of patients should be based on their chance of surviving the acute episode, among other factors. The application of a robust prognostic tool for use in AECOPD would potentially be very useful in this respect (33). It is likely that a tailored approach to ESD/HAH, depending on the clinical and social dependency and performance status of each patient would be most efficient. Compared to basic ESD/HAH schemes primarily reliant on specialist respiratory nurses, multi-disciplinary interventions including higher levels of clinical support, temporary social support and input from occupational therapists and physiotherapists may allow a broader spectrum of patients to access ESD/HAH.

Incorporating services such as early pulmonary rehabilitation and education for both patients and carers within ESD/HAH is likely to confer additional benefits. The clinical outcomes and costs associated with different models of ESD/HAH warrant further study. A better understanding of patients, carers and clinicians views of ESD/HAH may help inform the refinement and expansion of these services. Cost analyses should be based on actual costs rather than tariff and include all direct and indirect costs, including temporary social care, primary care and readmission costs. ESD/HAH schemes may foster greater independence and reduce the risk of subsequent readmission, particularly if combined with education, including self-management. Consequently, ESD/HAH could be provided for readmissions as well as the index admission, and costs analysed across all episodes.

## Declaration of Interest Statement

There is no financial, personal, academic, employment, consultancy, ownership or intellectual conflicts of interest to be declared. No sponsorship was received for conducting this review. The authors alone are responsible for the content and writing of the paper.

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ORIGINAL ARTICLE

# Home treatment of COPD exacerbation selected by DECAF score: a non-inferiority, randomised controlled trial and economic evaluation

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► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/thoraxjnl-2017-211197).

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Received 24 October 2017
Revised 27 February 2018
Accepted 19 March 2018
Published Online First 21 April 2018

## ABSTRACT

**Background** Previous models of Hospital at Home (HAH) for COPD exacerbation (ECOPD) were limited by the lack of a reliable prognostic score to guide patient selection. Approximately 50% of hospitalised patients have a low mortality risk by DECAF, thus are potentially suitable.

**Methods** In a non-inferiority randomised controlled trial, 118 patients admitted with a low-risk ECOPD (DECAF 0 or 1) were recruited to HAH or usual care (UC). The primary outcome was health and social costs at 90 days.

**Results** Mean 90-day costs were £1016 lower in HAH, but the one-sided 95% CI crossed the non-inferiority limit of £150 (CI −2343 to 312). Savings were primarily due to reduced hospital bed days: HAH=1 (IQR 1–7), UC=5 (IQR 2–12) (P=0.001). Length of stay during the index admission in UC was only 3 days, which was 2 days shorter than expected. Based on quality-adjusted life years, the probability of HAH being cost-effective was 90%. There was one death within 90 days in each arm, readmission rates were similar and 90% of patients preferred HAH for subsequent ECOPD.

**Conclusion** HAH selected by low-risk DECAF score was safe, clinically effective, cost-effective, and preferred by most patients. Compared with earlier models, selection is simpler and approximately twice as many patients are eligible. The introduction of DECAF was associated with a fall in UC length of stay without adverse outcome, supporting use of DECAF to direct early discharge.

**Trial registration number** Registered prospectively ISRCTN29082260.

## Key messages

### What is the key question?

► In patients with an exacerbation of COPD triaged for admission, is Hospital at Home directed by low-risk DECAF score (0 or 1) clinically effective and cost-effective compared with usual inpatient care?

### What is the bottom line?

► Hospital at Home directed by DECAF is safe, clinically effective, cost-effective, and preferred by 90% of patients. This model simplifies selection for Hospital at Home, while approximately doubling the proportion of patients considered eligible compared with previous studies.

### Why read on?

► The potential clinical and financial benefits of widespread implementation of Hospital at Home directed by DECAF are large, especially given that exacerbation of COPD is the second most common reason for hospital admission.

## INTRODUCTION

Hospital at Home (HAH) treats patients in their home for a condition that would otherwise require hospital admission.[1] The British Thoracic Society,[2] the National Institute for Health and Care Excellence (NICE)[3] and the joint European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines[4] endorse HAH services for patients with COPD exacerbation (ECOPD) and recommend that selection for such services is based on low acute mortality risk. Previous randomised controlled trials (RCTs) of domiciliary care for patients with ECOPD had extensive and inconsistent inclusion and exclusion criteria, partly due to the previous lack of a reliable prognostic score to direct selection of low-risk patients.[5] The pressing need for prospective research to define optimal criteria for patient selection for HAH has been highlighted.[4]

The DECAF score is a robust predictor of inpatient mortality in patients admitted with ECOPD.[6 7] It has shown consistent, strong performance in 2645 patients across three cohorts with an area under the receiver operator curve of 0.82–0.86. Of importance, it is simple to score at the bedside using indices routinely available on admission (table 1). The 2014 UK COPD audit report recommends routine documentation of DECAF indices on admission.[8]

Approximately 50% of hospitalised patients have a DECAF score of 0 or 1, which is associated with a low in-hospital mortality risk (1%–1.4%). Selection for HAH by DECAF offers the potential to more than double the proportion of eligible patients compared with earlier models,[5] while simplifying the selection process. As ECOPD is one of the most common reasons for hospital admission, this represents a large absolute number of patients that could be treated with HAH, but the effect on cost and outcome is unknown.

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**To cite:** Echevarria C, Gray J, Hartley T, *et al*. *Thorax* 2018;**73**:713–722.

**Table 1** DECAF score

| DECAF score | | Circle |
|---|---|---|
| D* | eMRC**D** 5a (too breathless to leave the house unassisted but independent in washing and/or dressing) | 1 |
| | eMRC**D** 5b (t oo breathless to leave the house unassisted and requires help with washing and dressing) | 2 |
| E | **E**osinopaenia (eosinophils <0.05×10$^9$/L) | 1 |
| C | CXR **C**onsolidation | 1 |
| A† | Moderate or severe **A**cidaemia (pH<7.3) | 1 |
| F | Atrial **F**ibrillation (including history of paroxysmal AF) | 1 |
| | Total: | |

*Breathlessness assessed on a good day within the last 3 months, not breathlessness during an exacerbation/on admission.
†If a blood gas has not been performed, provided oxygen saturation breathing room air is greater than 92%, acidaemia can be assumed not to score. Please refer to the DECAF validation study for detailed instructions on scoring.[7]
AF, atrial fibrillation; CXR, chest radiograph; eMRCD, extended Medical Research Council Dyspnoea score.

Accurate prediction of outcome may direct treatment choices and improve outcomes[9]; however, clinical judgement alone is suboptimal.[10] Before prognostic scores are adopted in routine practice, clinical impact studies assessing outcomes and cost-effectiveness are recommended, although these are seldom performed.[9] We have undertaken an RCT with an economic evaluation (cost-effectiveness analysis) comparing HAH with usual care (UC) in patients admitted with a low-risk ECOPD selected by DECAF score. The trial examined whether, within a non-inferiority limit of £150, the total health and social care costs up to 90 days associated with HAH are the same or less than those from UC. Clinical outcomes included length of hospital stay (LOHS), readmission rates, mortality and health-related quality of life.

## METHODS

### Study design and patients

In a non-inferiority RCT, eligible patients with a low-risk (DECAF 0–1) ECOPD[11] admitted to one of three hospitals within one Trust underwent 1:1 allocation to HAH or UC and were followed for 90 days from presentation. In the UK healthcare system, a National Health Service Trust is an organisation that serves a geographical region, in this instance a socioeconomically diverse urban and rural population, with the largest geographical footprint in England. The COPD population has high rates of social deprivation and comorbidity.[7 8] Ninety days was chosen for the primary outcome because this is the key risk period for readmission.[12]

Eligibility criteria included low mortality risk (DECAF 0–1), age 35 years or older, 10 or more smoking pack-years, and pre-existing or admission obstructive spirometry.[11] Inpatient spirometry was only performed in individuals with a pre-existing COPD diagnosis where confirmatory spirometry was unavailable (eg, inaccessible general practitioner (GP) records on weekends) or in those with a high pretest probability of a new diagnosis of COPD. Patients were excluded if they had an illness (other than COPD) likely to limit survival to less than 1 year, were on long-term ventilation, had a coexistent secondary diagnosis necessitating admission, were assessed more than one overnight stay after admission or could not provide written informed consent. Patients were not eligible to enter the trial from the emergency department to ensure only admitted patients were included.

**Table 2** Minimisation indices

| | | | |
|---|---|---|---|
| ABG (management pathway) | $PaCO_2$ ≤6 + pH ≥7.35 | $PaCO_2$ >6 + pH ≥7.35 | pH <7.35 |
| Hospital admissions in the previous year | 0 | 1 | 2 or more |
| Prior social care (private or social services) | None | Social care | |
| eMRCD score | 1–4 | 5a | |
| Cerebrovascular disease | Yes | No | |

ABG, arterial blood gas; eMRCD score, Extended Medical Research Council Dyspnoea score.

All patients who met the entry criteria were offered participation, including DECAF 1 patients with coexistent pneumonia or acidaemia. All patients were analysed in their original allocated group, even if the consultant decided that an HAH patient should stay in the hospital. Baseline data were collected prior to treatment allocation. In the HAH arm, patients readmitted during follow-up with a low-risk ECOPD were offered HAH while all other readmissions were managed according to UC.

### Randomisation and masking

Allocation to HAH or UC was based on 1:1 randomisation, performed by minimisation[13] (table 2) undertaken by an external, independent agency (sealedenvelope.com). Individual patients had a 30% chance of allocation purely by random number sequence; the researchers were blind to the method of allocation for individual patients. For the primary cost analysis, the health economist was blinded to group allocation.

### Procedures

#### HAH treatment

HAH treatment replaces all or most of the hospital admission and requires that patients are not sufficiently well for discharge, resulting in a more unwell population than seen in early supported discharge (ESD) services.

In our HAH model, patients were admitted to hospital, identified as low risk by DECAF, and then returned home under the care of the hospital respiratory team, usually within 24 hours of admission. The HAH treatment period ended when the respiratory specialist nurse (RSN) and consultant deemed that the patient was sufficiently well for discharge to the care of the GP, typically after 5 days.

Patients received once or twice daily visits from an RSN, under remote supervision from a respiratory consultant. An emergency contact number allowed patients to contact the team 24 hours a day, 7 days a week. Physiological parameters were monitored daily and blood sampling (including arterial blood gas analysis) taken as required. Oral and intravenous therapies, acute controlled oxygen therapy, physiotherapy, psychology, occupational therapy and formal social care were available at home.

Patients randomised to HAH could return home immediately provided the initial arterial pH was 7.35 or more and $PaCO_2$ was 6 kPa or less. Patients with $PaCO_2$ greater than 6 kPa without acidaemia could return home after one overnight stay in hospital, provided they were not deteriorating. Patients with acidaemia could return home the day that followed resolution of the acidaemia and, if initiated, once non-invasive ventilation was complete. This 'ABG management pathway' was included as one of the minimisation indices.

Return to hospital during HAH was not considered a readmission, but rather an increase in level of care. If return to hospital

during HAH were considered a readmission, this could create bias because patients in UC are hospitalised and therefore not exposed to the risk of readmission.

Further details of the HAH service are available in the HAH manual and review sheets in online supplementary files 1, 2 and 3. The manual has been updated following service feedback, but the interventions and procedures are unchanged from those used in the trial.

### Usual care

This included usual measures to ensure the prompt discharge of patients with ECOPD, such as supported discharge by RSNs. Based on local data from 492 patients scoring DECAF 0 or 1 prior to the trial, we anticipated that the median LOHS would be 5 days. The decision to discharge patients in the UC group was made by the attending clinician.

## Outcomes

The primary outcome was the total cost of health and formal social care over 90 days from presentation, costed from a UK health and social care perspective. The secondary outcomes were survival, readmission rate, total bed days over 90 days and cost-effectiveness, using the EuroQuality of life instrument (EQ-5D-5L) quality-adjusted life year (QALY) measured at baseline, 14 and 90 days,[14] patient preference for HAH or UC (as a binary question at 14 days), COPD exacerbations, Hospital Anxiety and Depression Scale scores (HADS), and COPD Assessment Tool (CAT) scores.

All costs, unless stated otherwise, were recorded at the patient level by multiplying patient-level resource use by the appropriate unit cost, and the average costs per treatment arm were subsequently estimated. Data collection was the same in both arms, except for resource collection during HAH treatment ('HAH visits and travel time' and 'telephone call costs'). All visiting health and social care staff recorded time spent with the patient and travel time, including interactions outside of usual work hours. This was triangulated with a time and motion study performed by RSNs in a subpopulation of HAH patients.

Patients in both arms maintained a diary of all health and social care visits and attendances, and were phoned every 2 weeks to prompt completion and collect data. These data were cross-referenced with primary, secondary and social care records to provide costs for 'formal social care', 'home visits after discharge' and 'A+E and outpatient appointments'. Additional consent was gained for remote monitoring of health and social records if the patient withdrew from the trial, allowing complete data capture.

For primary care, resource use included all medications, GP appointments, and home visits by doctors and allied healthcare professionals.

Secondary care inpatient costs considered specific to DECAF 0–1 patients were costed at the patient level. This included inpatient healthcare reviews, medications, laboratory and diagnostic costs, oxygen use, non-invasive ventilation use and LOHS. All 'inpatient healthcare reviews' were recorded, including those by doctors, specialist nurse and physiotherapists; this was costed based on the seniority of the individual and the amount of time spent with the patient. Where unavailable, the time spent with the patient was estimated based on the type of encounter (such as 'physiotherapy chest clearance') and the average time taken for similar encounters; all assumptions were the same across both arms, and assumptions regarding the type of encounter were performed blind to group allocation.

**Table 3** Key unit costs

| Type of unit cost | Source | Cost (£) |
|---|---|---|
| A+E attendance | NHS reference costs 2015 | 90.2–377.9 |
| Outpatient clinics | NHS reference costs 2015 | 39.7–215.4 |
| Respiratory clinic | NHS reference costs 2015 | 165.9 |
| Bed days, admissions unit | Healthcare Trust | 294.9 per day |
| Bed days, medical ward | Healthcare Trust | 246.2 per day |
| Bed days, rehabilitation ward | Healthcare Trust | 168.8 per day |
| Doctor, consultant time | PSSRU unit costs of health+social care 2015 | 153 per hour |
| Doctor, registrar time | PSSRU unit costs of health+social care 2015 | 68.4–75 per hour |
| Doctor, F1–ST2 | PSSRU unit costs of health+social care 2015 | 42.5–67 per hour |
| Respiratory specialist nurse | PSSRU unit costs of health+social care 2015 | 46.2–68.6 per hour |
| Physiotherapy | PSSRU unit costs of health+social care 2015 | 39.2–49.5 per hour |

A+E, accident and emergency; NHS, National Health Service; PSSRU, personal social services research unit.

The remaining inpatient costs are those that we expected would be similar between patients and/or were not possible to separate out at the patient level, for which an average bed day cost was calculated. The cost of a day on a ward was costed using data from the Trust's finance department. This included running costs (including catering, laundry, gas and electricity), staff costs (such as support staff), equipment (medical, surgical and non-medical) and associated services (such as phlebotomy). These costs were not patient-specific and were assumed the same regardless of patients' characteristics. This was performed separately to give a cost for the admissions unit, medical ward and rehabilitation ward.

All outpatient visits and accident and emergency attendances were recorded.

Social care resource use, including formal social care and equipment costs, was obtained from individual social care records.

Unit costs were obtained from a variety of national and local sources and are reported in online supplementary file 4 for the financial year 2015 (£), with key unit costs shown in table 3.

## Statistical analysis

The primary outcome was the mean difference between HAH and UC in total health and social care costs over 90 days. HAH was deemed non-inferior to UC if the upper limit of the one-sided 95% CI for the primary outcome was less than the non-inferiority limit. CIs were calculated with 1000 bootstrap replications. For the breakdown in costs (table 7), two-sided 95% CIs were calculated.

The non-inferiority limit and the power calculation were based on the best available data, which were limited to health costs for the index admission. Based on tariff costs received by the Trust for 373 patients admitted with DECAF 0–1 ECOPD, the estimated SD of costs was £1143, and HAH costs were estimated as £470 less expensive per patient compared with UC. One hundred and eighteen patients were required to be 90% sure that the upper limit of a one-sided 95% CI would be below the non-inferiority limit of £150, if the true difference in costs were 0.[15] This threshold was discussed with hospital managers,

who confirmed that if HAH was £150 more expensive than UC this would not prevent them from financially supporting the implementation of HAH services.

The outcome measure used in the economic analysis was the QALY. Health-related quality of life was assessed using the EQ-5D-5L questionnaire, which is valid and responsive in COPD,[16] and a standard algorithm was used to obtain utility scores.[17] The QALY was obtained by linear regression estimation, controlling for intervention groups and baseline utility using the area under the curve approach (individual QALYs were calculated by taking the mean value between measurements and multiplying this with time).[18] The cost-effectiveness plane and a cost-effectiveness acceptability curve were derived from the joint distribution of incremental costs and incremental QALYs using non-parametric bootstrapping of the observed data.

Bed days were compared using Mann-Whitney U test with a two-sided P value of $<0.05$ regarded as significant. Primary analyses were performed with complete case analysis. A sensitivity analysis was performed using multiple imputation, with missing data assumed to be missing at random, to create five data sets[19] using the Markov chain Monte Carlo method. All baseline patient characteristics and outcomes were included in the imputation model. Data were analysed using IBM SPSS V.22 statistics and Stata V.14. Patients allocated to HAH who received UC treatment were analysed in their original allocation group as per the intention-to-treat principle. In a prespecified safety analysis, deaths and readmissions were reported per protocol.

The funders had no role in data collection, analysis or in writing of the report. During the review process, we agreed to make our prespecified cost outcome the primary measure, replacing total bed days over 90 days.

## RESULTS

Emergency hospital admissions from June 2014 to January 2016 were reviewed to ensure all patients with ECOPD were identified. Of note, 64 patients with a DECAF 0–1 ECOPD were planned for same-day discharge before eligibility assessment and were not included because HAH is not indicated for those who are sufficiently well for discharge. Of 207 DECAF 0 or 1 ECOPD assessed for eligibility, 120 were randomised. Two patients who did not meet the eligibility criteria were randomised in error and were not included in the primary analysis. In both instances, this was recognised and the patients were removed within 30 min of randomisation. Three patients were randomised to HAH, but were intentionally treated by UC, and were analysed in their original allocation as per the intention-to-treat principle (see figure 1). Groups were well matched with respect to minimisation indices (table 4).

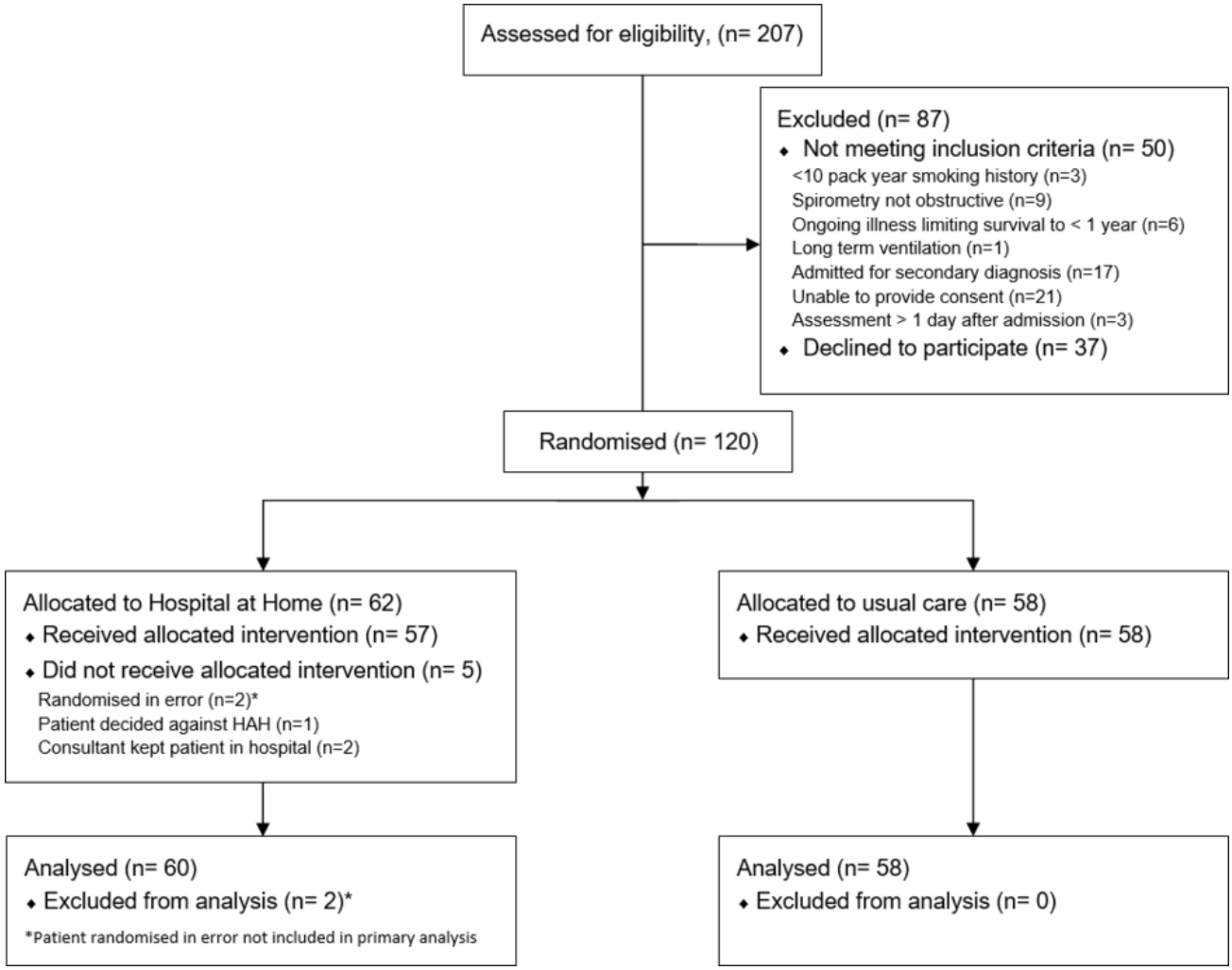


**Figure 1** CONSORT diagram. CONSORT, Consolidated Standards of Reporting Trials; HAH, Hospital at Home.

**Table 4** Baseline characteristics of patients

| | HAH, n=60 | UC, n=58 |
|---|---|---|
| DECAF indices | | |
| DECAF score 1, n (%) | 43 (71.7) | 31 (53.4) |
| eMRCD dyspnoea score 5a, n (%) repeat below | 12 (20) | 9 (15.5) |
| Eosinopaenia, % | 15 (25) | 8 (13.8) |
| CXR consolidation, % | 15 (25) | 9 (15.5) |
| Acidaemia (pH <7.30), % | 1 (1.7) | 0 |
| Atrial fibrillation, % | 0 | 0 |
| Minimisation indices | | |
| ABG management, pH <7.35 / $PCO_2$ >6 pH ≥7.35, % | 7 (11.7) / 40 (66.7) | 8 (13.8) / 38 (65.5) |
| Hospital admissions in the previous year 1 / 2, % | 12 (20) / 21 (35) | 12 (20.7) / 19 (32.8) |
| Prior social care, % | 3 (5) | 1 (1.7) |
| Cerebrovascular disease, % | 9 (15) | 9 (15.5) |
| Sociodemographics | | |
| Age, years* | 71.0 (9.6) | 68.7 (10.5) |
| Female, % | 32 (53.3) | 30 (51.7) |
| Smoking pack-years, n† | 45 (35–50) | 44 (30–60) |
| Current smoking, % | 27 (45) | 25 (43.1) |
| Reporting no qualifications on leaving school, % | 46 (76.7) | 41 (70.7) |
| Most frequently reported family income per year, £† | 5200–10 399 | 10 400–15 599 |
| Markers of disease severity | | |
| $FEV_1$% predicted* | 45.5 (18.4) | 42.1 (16.3) |
| LTOT prior to admission, % | 7 (11.7) | 2 (3.4) |
| Cor pulmonale, % | 11 (18.3) | 5 (8.6) |
| Comorbidity | | |
| IHD, % | 14 (23.3) | 12 (20.7) |
| Diabetes, % | 8 (13.3) | 5 (8.6) |
| LVD, % | 1 (1.7) | 3 (5.2) |
| Anxiety, % | 9 (15.0) | 3 (5.2) |
| Depression, % | 12 (20.0) | 9 (15.5) |
| Admission clinical data | | |
| Respiratory rate, per minute* | 25 (4.5) | 26 (5.1) |
| Pulse rate, per minute* | 103.9 (19.6) | 104.9 (15.4) |
| sBP, mm Hg* | 140.8 (21.1) | 145.1 (24.3 |
| dBP, mm Hg* | 77.3 (12.2) | 80.9 (14.5) |
| Temperature, °C† | 36.6 (36.2–37.3) | 36.5 (36.1–37.1) |
| Oxygen saturation† | 92 (89–94) | 92 (88.5–95) |
| Discoloured sputum, % | 43 (71.7) | 33 (56.9) |
| Arterial blood gas values | | |
| pH† | 7.42 (7.39–7.45) | 7.42 (7.38–7.44) |
| $PaO_2$, kPa† | 7.6 (7.2–9.3) | 7.9 (7.2–10.2) |
| $PaCO_2$, kPa† | 5.5 (5–6.25) | 5.3 (4.8–6.6) |
| $HCO_3$, mmol/L* | 27.1 (4.3) | 27.3 (4.7) |
| pH <7.35, % | 7 (11.7) | 8 (13.8) |
| Baseline outcome measures | | |
| Utility score (EQ-5D-5L), n* | 0.517 (0.268) | 0.501 (0.243) |
| Hospital Anxiety and Depression Scale score A / D, n† | 6 (4–10.25) / 7 (4–9) | 7 (4–10) / 5 (2–8.25) |
| COPD Assessment Tool, n† | 28.5 (21.75–33) | 27 (23–32.25) |
| Treatment | | |
| ECOPD treatment prior to admissions, % | 32 (53.3) | 26 (44.8) |

*Mean (SD).
†Median (IQR).
A/D, anxiety/depression; ABG, arterial blood gas; CXR, chest radiograph; dBP, diastolic blood pressure; ECOPD, COPD exacerbation; eMRCD, extended Medical Research Council Dyspnoea score; EQ-5D-5L, EuroQuality of life; HAH, Hospital at Home; $HCO_3$, bicarbonate; IHD, ischaemic heart disease; LTOT, long-term oxygen therapy; LVD, left ventricular dysfunction; sBP, systolic blood pressure; UC, usual care.

## Clinical outcomes

There were no deaths in the acute period (within 14 days) in either arm. Within 90 days, there was one death in each arm. There was a statistically significant reduction in bed days over 90 days in those treated with HAH (HAH=1, IQR 1–7 compared with UC=5, IQR 2–12; P=0.001). Readmission rates were similar in both arms, with 22 (36.7%) in HAH and 23 (39.7%) in UC (table 5).

At 14 days, 90% of patients across both arms stated they would prefer HAH treatment during future exacerbations of similar severity (HAH=54 of 60; UC=51 of 57). In the prespecified,

**Table 5** Mortality, length of stay, readmission, appointments and social care, and treatment preference outcome

| | HAH, n=60 | UC, n=58 |
|---|---|---|
| Death at 14 days, n (%) | 0 (0) | 0 (0) |
| Death at 90 days, n (%) | 1 (1.7) | 1 (1.7) |
| Length of hospital stay at 90 days, median (IQR) | 1 (1–7) | 5 (2–12)* |
| Length of hospital stay at 90 days, mean (SD) | 6.1 (9.7) | 10.3 (15.8) |
| Length of hospital stay (index admission), median (IQR) | 1 (1–1) | 3 (2–4.25) |
| Length of hospital stay (index admission), mean (SD) | 1.2 (2.1) | 4.1 (4.6) |
| Length of stay within HAH, median (IQR) | 4 (2–5) | NA |
| Patients with one or more hospital readmissions, n (%) | 22 (36.7) | 23 (39.7) |
| Patients with one or more A+E attendances post discharge, n (%) | 29 (48.3) | 26 (44.8) |
| Patients with one or more GP attendances post discharge, n (%) | 26 (43.3) | 30 (51.7) |
| Patients with one or more secondary care appointments, n (%) | 48 (80.0) | 41 (70.7) |
| Patients with a social care package post discharge, n (%) | 7 (11.7) | 5 (8.6) |
| Stated preference for HAH care day 14, n (%) | 54 (90.0) | 51 (87.9) |

*P=0.001 using Mann-Whitney. For bed days over 90 days, based on length of stay from 373 patients, 116 patients were needed to detect a difference of 4.7 days with 90% power assuming a type 1 error rate of 5% in a superiority analysis.
A+E, accident and emergency; GP, general practitioner; HAH, Hospital at Home; NA, not applicable; UC, usual care.

**Table 6** Changes in quality of life and HADS scores from baseline

| | HAH | | | UC | | |
|---|---|---|---|---|---|---|
| | Unit change* | % MCID† | Missing | Unit change | % MCID | Missing |
| HADS-A 14-day (IQR) | −1.0 (−3 to 1.75) | 48.3 | 0 | 0.5 (−3 to 2) | 33.9 | 2 |
| HADS-A 90-day (IQR) | 0 (−2 to 3) | 33.3 | 6 | 0 (−3 to 2) | 38.2 | 3 |
| HADS-D 14-day (IQR) | −1.0 (−3 to 1) | 38.3 | 0 | 0 (−2 to 3) | 26.8 | 2 |
| HADS-D 90-day (IQR) | −0.5 (−3 to 1.25) | 37.0 | 6 | 0 (−2 to 3) | 27.3 | 3 |
| CAT 14-day (IQR) | −4.0 (−9.5 to 0) | 61.7 | 0 | −3.0 (−7 to 1) | 57.9 | 1 |
| CAT 90-day (IQR) | −3.0 (−8 to 1) | 51.9 | 6 | −1.0 (−6 to 1) | 36.4 | 3 |
| Utility 14-day (EQ-5D-5L) (SD) | 0.091 (0.249) | 56.7 | 0 | 0.055 (0.316) | 49.1 | 1 |
| Utility 90-day (EQ-5D-5L) (SD) | 0.003 (0.287) | 43.9 | 3 | 0.007 (0.338) | 41.1 | 2 |

*Values are median, except utility which is mean. Unit change is the difference in absolute values between follow-up and baseline. Improvements in health status are negative for HADS and CAT, and positive for utility scores.
†The percentage of patients who improved by an MCID, which is 1.5 for HADS-A and HADS-D,[21] 2 for CAT and 0.051 for the EQ-5D-5L.[20]
CAT, COPD Assessment Tool; EQ-5d-5L, Euro Quality of life instrument; HADS, Hospital Anxiety and Depression Scale; HAH, Hospital at Home; MCID, minimally clinically important difference; UC, usual care.

per-protocol safety analysis, deaths were unchanged (one in each arm at 90 days), and there were 21 of 57 (36.8%) readmissions in HAH and 23 in 58 (39.7%) in UC. Table 6 shows the change in quality of life scores from baseline at 14 days and 90 days as the unit change and as the per cent of patients who improved by a minimally clinically important difference (MCID). Further data on utility scores are available in online supplementary table e10.

For HADS and CAT, negative values represent improvements in health from baseline, while for utility scores, positive values represent improvements from baseline. The improvements in health status in HAH compared with UC were clinically meaningful for HADS-anxiety score at 14 days and CAT at 90 days, but this could be a chance finding.[20 21] On multiple imputation the difference in the benefit of CAT at 90 days was 1.5, but the utility score at 14 days was 0.51, which is above the MCID (online supplementary table e11).

### Cost and cost-effectiveness analysis

The mean health and formal social care cost over 90 days was £1016 lower in HAH than in UC. However, there was wide variation in costs and the one-sided 95% CI crossed both the no effect limit (0) and the prespecified non-inferiority limit of £150 (figure 2, 'UC=3 days': CI −2343 to 312). The cost difference and distribution were substantially greater than anticipated, and so a post-hoc analysis was performed with an adjusted non-inferiority limit of £340,[15] which was achieved (see figure 2 and the Discussion section).

During the index admission, the median LOHS in UC was 3 days, which was 2 days less than expected[7] and greater than seen in most UK hospitals for unselected ECOPD.[8] We performed a prespecified sensitivity analysis to assess the effect of LOHS in UC during the index admission on health and formal social care costs. One additional bed day without medical staffing costs would increase the mean cost difference to −£1262 with a one sided 95th percentile of £66, achieving the prespecified non-inferiority limit of £150. Two bed days would have been −£1508 with a one-sided 95th percentile of −£180.

The difference in cost was primarily related to inpatient and formal social services costs (table 7). The costs of the index admission alone are shown in online supplementary table e12. Total QALY scores were non-significantly higher in HAH compared with UC. The mean total QALYs (SD) adjusted for baseline utility were 0.138 (0.052) for HAH and 0.133 (0.052) for UC, giving a small difference of 0.005 (95% CI −0.14 to 0.25). Unadjusted and Multiple Imputation (MI) analyses of QALYs are shown in online supplementary table e10. The probability of HAH being cost-effective compared with UC was 90% at the NICE threshold of £30 000 per QALY. This is the proportion of dots beneath the diagonal line in figure 3A, and is represented by the vertical line in figure 3B. HAH was both cheaper

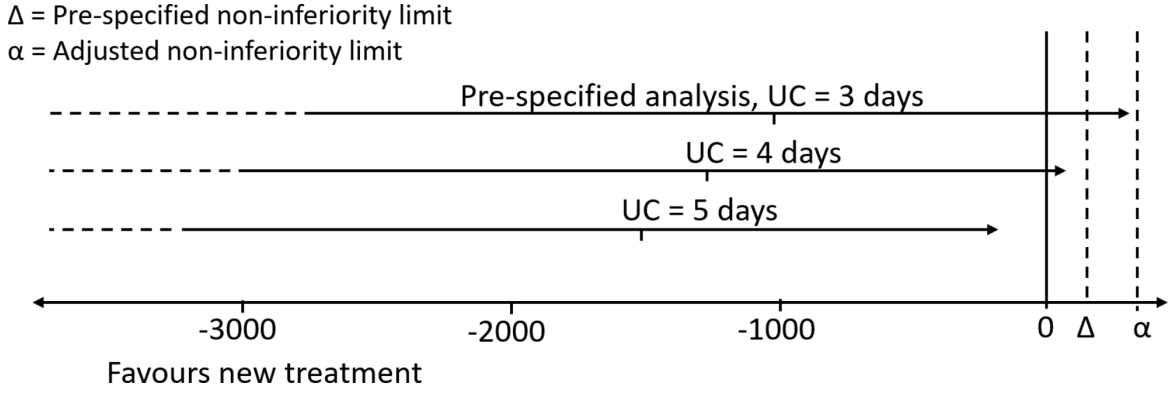


**Figure 2** Length of stay and cost difference (£) between HAH and UC. One-sided CIs for the mean difference in 90-day health and social care costs between UC and HAH are shown for the trial population (UC=3 days) and the sensitivity analysis adjusting for a longer hospital stay in UC (UC=4 days and UC=5 days); Δ=£150, α=£340. HAH, Hospital at Home; UC, usual care.

**Table 7** Health and formal social care average costs at 90 days

| Overall costs | HAH, £ (SD) | UC, £ (SD) | Bootstrapped mean difference (£) | Bootstrapped 95% CI* of cost difference |
|---|---|---|---|---|
| Health and formal social care | 3857.8 (3199.6) | 4873.5 (5631.1) | −1015.7 | −2735.5 to 644.8 |
| Healthcare | 3819.2 (3135.0) | 4755.8 (5525.4) | −936.6 | −2645.4 to 709.9 |
| Oxygen therapy | 38.4 (68.4) | 18.3 (53.7) | 20.1 | −1.73 to 42.0 |
| Medication | 422.5 (275.2) | 458.9 (331.4) | −36.4 | −150.1 to 75.7 |
| Hospital costs | | | | |
| Bed stay | 1540.8 (2000.7) | 2775.2 (4129.6) | −1234.4 | −2524.8 to −82.0 |
| Inpatient healthcare review | 417.7 (399.1) | 514.3 (650.7) | −96.7 | −288.4 to 96.4 |
| Laboratory and diagnostic tests | 375.1 (383.8) | 358.7 (422.4) | 16.4 | −128.1 to 169.1 |
| NIV costs | 44.4 (261.0) | 158.2 (436.2) | −113.8 | −255.4 to 8.12 |
| HAH costs | | | | |
| HAH visits and travel time† | 383.9 (276.0) | 0.0 (0.0) | 383.9 | 319.2 to 455.3 |
| Telephone calls costs | 5.8 (14.2) | 5.4 (10.8) | 0.5 | −3.57 to 5.33 |
| Community costs | | | | |
| Formal social care | 38.6 (173.1) | 117.7 (711.0) | −79.0 | −299.2 to 55.2 |
| Home visits after discharge | 43.7 (87.7) | 39.2 (55.7) | 4.5 | −19.2 to 31.8 |
| A+E and outpatient appointments | 546.8 (347.5) | 427.6 (394.9) | 119.2 | −22.6 to 243.0 |

*The 95% CI in the table is two-sided (0.025 to 0.975), calculated with the bootstrap approach. For health and formal social care (the primary outcome), the one-sided 95% CI (0.95) was £312.
†55% of time on HAH visits was spent with the patient (45% on travel time).
A+E, accident and emergency; HAH, Hospital at Home; NIV, non-invasive ventilation; UC, usual care.

and more effective for most patients treated (74% probability). Similar results were seen using multiple imputation (online supplementary figure E1). Of note, the Cost Effectiveness plane shows high uncertainty around the incremental cost difference, although little uncertainty around the incremental effectiveness estimates.

### HAH and inpatient interactions

Of the 60 patients allocated to HAH, 53 (88.3%) had a 0 or 1 day stay. Most patients incurring an overnight stay were admitted in the afternoon or evening. The period of HAH lasted a median of 4 (IQR 2–5) days per episode. Including travel time, healthcare professionals spent a median of 7.2 hours (IQR 4.7–10.8) on

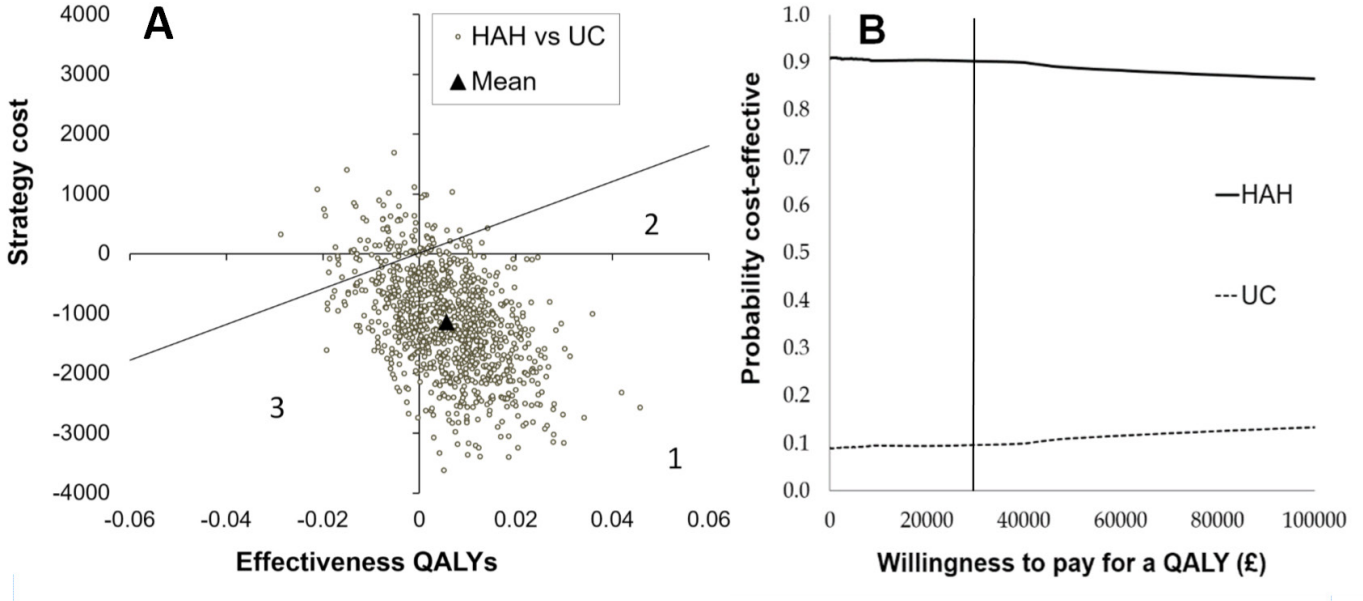


**Figure 3** Cost-effectiveness plane (A) and cost-effectiveness acceptability curve (B). The cost-effectiveness plane for HAH and UC, with the diagonal line representing the NICE cut-off at £30 000 per QALY. Area 1=HAH cheaper and more effective; area 2=HAH more effective and more expensive but less than the NICE cut-off; and area 3=UC is more effective but more expensive and exceeds the NICE cut-off. (B) The probability of cost-effectiveness is shown over a range of willingness to pay for a QALY, to inform decisions to accept or reject new technologies. There is a 90% probability HAH will be cost-effective at the NICE threshold (vertical line). HAH, Hospital at Home; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year; UC, usual care.

home visits per HAH spell (median RSN visits=7.1 hours, IQR 4.4–10.1). There were 342 visits for 57 episodes: RSN=327, physiotherapy=13, psychology=1 and respiratory support worker=1. During HAH, two patients returned to hospital for assessment (which included a respiratory consultant review, repeat chest radiograph and blood testing) and returned home the same day. One patient returned to hospital and stayed overnight before returning home to complete their HAH spell.

The number of inpatient interactions with any healthcare worker was 1158 for HAH (1500 including inpatient interactions, or 25 interactions per patient) and 1558 for UC (or 27 interactions per patient). In part, the increased numbers of inpatient interactions for UC were due to reviews by doctors and physiotherapists (see online supplementary table e13).

### Patients declining participation

As part of an audit of practice, the baseline characteristics of patients who declined to participate in the HAH study were reviewed. Patients who declined enrolment were not more unwell than study participants based on comorbidity and measures of disease severity (online supplementary table e14).

## DISCUSSION

In an economic evaluation, HAH selected by DECAF was more cost-effective than UC, primarily driven by a fivefold reduction in median hospital bed days over 90 days, with a small non-significant difference in QALYs favouring HAH. The percentage of patients improving by the MCID was numerically higher in HAH compared with UC for seven of eight outcomes measuring health status.

The potential cost savings are substantial as ECOPD is one of the most common reasons for hospital admission and up to 50% of patients are potentially eligible (DECAF 0–1). In both arms, there were no deaths within the acute period, and readmission rates over 90 days were comparable in intention-to-treat and per-protocol analyses. Crucially, 90% of patients across both arms stated they would prefer HAH to UC for future exacerbations of similar severity. The DECAF score allows low-risk patients to be identified quickly and safely using indices routinely captured on admission, facilitating replication of our model of HAH. This meets the major research need identified by the ERS/ATS to better define patient selection criteria for HAH.[4] Of importance, use of DECAF was associated with reduction in LOHS within UC of at least 2 days, without adverse outcome. This supports use of a low-risk DECAF score to select patients for early discharge, which may be implemented in advance of establishing a full HAH clinical service.

This study has several strengths. We assessed the impact of using the DECAF score to direct HAH treatment, replicating how we anticipate the tool will be used in clinical practice. Such implementation studies are extremely rare despite being strongly recommended.[9] We performed a detailed and extensive cost analysis, recording all important aspects of health and social care with low rates of missing data. We included several important measures of health status which the ERS/ATS reported is lacking in previous studies,[4] and methods of patient allocation and handling of missing data were robust. Patients were randomised by minimisation, which ensures excellent balance for selected prognostic indices.[13 22] The likelihood of allocation to an intervention is influenced by the current distribution of subjects and weighted minimisation indices. To avoid potential selection bias, 30% of allocations were by simple randomisation and the researchers were blinded to the allocation process, performed by an independent agency. The HAH service included all members of the usual multidisciplinary team and important aspects of care such as smoking cessation, inhaler training, breathing exercises and the offer of early pulmonary rehabilitation.

One of the key limitations of the study was the choice of £150 as the non-inferiority limit, which meant that HAH did not meet the chosen non-inferiority limit. First, this occurred because the data were only available for a single admission, and not for the primary outcome of total health and social care cost over 90 days. The actual mean total cost over 90 days in UC was far higher than anticipated at £4874, so a non-inferiority limit of £150 was overly conservative. It is usual in non-inferiority studies to choose a margin that reflects the largest loss that would be acceptable.[23] In the context of a higher mean difference, a larger non-inferiority limit is appropriate. Non-inferiority limits should be based on statistical reasoning and clinical judgement. In our post-hoc analysis a non-inferiority limit to £340 was selected. Statistically, we chose this value as it is one-third of the cost difference between arms, which is the same ratio as the original non-inferiority limit and estimated cost difference. The acceptability of this non-inferiority limit is confirmed by the fact that this model of HAH has subsequently been commissioned. Second, the cost difference between HAH and UC may have been affected by a reduction in LOHS in UC. The number of patients unsuitable for HAH (because they already had same-day discharge plans) was larger than expected, resulting in a more unwell and costly study population. This should have resulted in an increased median LOHS in UC, but it was 2 days lower than expected. Non-exclusion of more unwell patients with longer LOHS could theoretically account for this. However, this is unlikely as the short stay group (n=64) was larger than the excluded group (n=50), and would have had a bigger impact on the median value. Furthermore, those who declined participation in the study were not more unwell than study participants. The most likely explanation is that the use of the DECAF score and study participation reduced LOHS. Only UC patients expressed disappointment with their allocated arm, knowledge of participation may have influenced clinician behaviour and bed pressures may have exerted additional influence.

Despite a large proportion of patients improving by the MCID (table 6), baseline and 90-day follow-up quality of life scores were similar across the whole population. This apparent discrepancy may be explained by worsening health status in those who were readmitted. In those who suffered an overall deterioration in utility score at 90 days, the proportion with one or more admissions was 2.5-fold higher.

The results of the study require validation in other healthcare systems. The structure of care, including availability of ESD, differed between sites and the DECAF score has previously effectively identified low-risk patients in six different hospitals, with different populations and structures of care.[7] This supports the generalisability of the results to other UK hospitals. Some hospitals may currently lack the nursing infrastructure to deliver HAH selected by DECAF, but investment is justified as there is a 90% chance of this model being cost-effective at both the NICE and commonly cited US thresholds, with further possible cost savings through reduced LOHS in UC. Training costs of nurses were included in our analysis. Finally, 90-day follow-up was selected because this is the critical time period for readmission,[12] although a longer time period of up to 1 year may have been preferable to identify a difference in readmission rates between groups.

Meta-analyses of previous studies considered HAH and ESD together. These showed that HAH/ESD report reduced readmission rates and a trend towards a lower mortality with limited evidence for an effect on health-related quality of life.[5 24] Three

studies performed cost analyses showing that HAH/ESD was less expensive.[25–27] Goossens[28] and others performed a detailed economic evaluation: at 3 months HAH/ESD was €168 less expensive than UC from a healthcare perspective, but €908 more expensive when societal costs were included. These previous studies are primarily of ESD services rather than HAH, and comparison with our study should be guarded. For example, in the study by Goossens and others, length of stay in the ESD treatment arm was the same as our UC arm.

Previous studies of HAH/ESD had extensive eligibility criteria to identify suitable, low-risk patients and typically excluded those with coexistent pneumonia and acidaemia on blood gas.[25 26 29–33] Ordinarily, clinicians would be reluctant to allow these patients into HAH/ESD services, but we treated such patients successfully with no difference in mortality between groups. This result is consistent with findings from the DECAF derivation and validation study, which showed that patients with a low-risk DECAF score and pneumonia or acidaemia had a low acute mortality risk.[6 7]

This RCT shows that HAH selected by low-risk DECAF score is safe, clinically effective, preferred by most patients and cost-effective compared with UC in this clinical setting. DECAF has proven a robust tool in the gold standard of derivation, validation and implementation studies, and can be used in clinical practice to select low-risk patients for HAH services. Based on this result, our commissioners and the Trust have agreed to the implementation of a full clinical service.

**Acknowledgements** We are grateful to Victoria Ferguson for her invaluable contribution with data collection, data management and the coordination of patient visits. We thank Peter Fenwick and Amy Loveland for their contribution to the screening and recruitment of patients, and Teresa Gibson for her input to the trial management group as an expert patient. Invaluable statistical support was provided by Nick Steen and Colin Muirhead. We acknowledge all the hard work of the respiratory specialist nurses and respiratory consultants at Northumbria NHS Healthcare Trust, without whom the trial could not have been delivered. We thank those that attended the Hospital at Home implementation group meetings from various services, including occupational therapy (Beryl Osbourne), social services (Eleanor Binks and Sheila Pearson), physiotherapy (Karen Brewin and Elizabeth Hardingham), respiratory specialist nurses (Elizabeth Norman and her team), respiratory consultants, pharmacy (Nicola Harker) and hospital management (Anne Kennedy, Deborah Freake, Patrick Garner and Robert Willers). We thank the members of the Data Monitoring Committee (Rodney Hughes, Nick S Hopkinson and Niall Anderson), the Trial Steering Committee (Nicholas Hart, Jennifer Quint, Jadwiga Wedzicha, Patrick Murphy and Robert Rutherford) and Belfast Clinical Trials Unit (Roisin Boyle). Most of all, we are grateful to the participants for their time in contributing to the study.

**Contributors** SCB conceived the study and was chief investigator with overall responsibility for the management of the study. SCB, CE, JG and GJG were responsible for the study design, protocol and obtaining funding. AJS, JS and JM contributed to trial design. CE, SCB, and JG wrote the statistical analysis plan, with statistical input from Colin Muirhead. CE and TH recruited patients and collated data. CE and JG performed statistical analyses. CE drafted the original manuscript, and all authors helped write the final version.

**Funding** This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0213-30105). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. Funding was also provided by the Northumbria Healthcare NHS Foundation Trust Teaching and Research Fellowship Programme.

**Competing interests** SCB reports grants from NIHR: Research for Patient Benefit Programme, during the conduct of the study; HTA funding, grants from Philips Respironics and Pfizer Open Air, personal fees from Pfizer and AstraZeneca, outside the submitted work. JG reports grants from NIHR Research for Patient Benefit, during the conduct of the study. CE, GJG, TH, AJS and JS have no competing interests to declare.

**Patient consent** Obtained.

**Ethics approval** Ethics approval was provided by the NRES Committee North East Sunderland (3/NE/0275). All participants gave informed consent before taking part in the study.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** For any requests for data sharing, please contact the corresponding author.



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Eur Respir J 2003; 21: 58–67
DOI: 10.1183/09031936.03.00015603
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European Respiratory Journal
ISSN 0903-1936

# Home hospitalisation of exacerbated chronic obstructive pulmonary disease patients

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*Home hospitalisation of exacerbated chronic obstructive pulmonary disease patients. C. Hernandez, A. Casas, J. Escarrabill, J. Alonso, J. Puig-Junoy, E. Farrero, G. Vilagut, B. Collvinent, R. Rodriguez-Roisin, J. Roca, and partners of the CHRONIC project. ©ERS Journals Ltd 2003.*

**ABSTRACT: It was postulated that home hospitalisation (HH) of selected chronic obstructive pulmonary disease (COPD) exacerbations admitted at the emergency room (ER) could facilitate a better outcome than conventional hospitalisation.**

**To this end, 222 COPD patients (3.2% female; 71±10 yrs (mean±SD)) were randomly assigned to HH (n=121) or conventional care (n=101). During HH, integrated care was delivered by a specialised nurse with the patient's free-phone access to the nurse ensured for an 8-week follow-up period.**

**Mortality (HH: 4.1%; controls: 6.9%) and hospital readmissions (HH: 0.24±0.57; controls: 0.38±0.70) were similar in both groups. However, at the end of the follow-up period, HH patients showed: 1) a lower rate of ER visits (0.13±0.43 *versus* 0.31±0.62); and 2) a noticeable improvement of quality of life (Δ St George's Respiratory Questionnaire (SGRQ), -6.9 *versus* -2.4). Furthermore, a higher percentage of patients had a better knowledge of the disease (58% *versus* 27%), a better self-management of their condition (81% *versus* 48%), and the patient's satisfaction was greater. The average overall direct cost per HH patient was 62% of the costs of conventional care, essentially due to fewer days of inpatient hospitalisation (1.7±2.3 *versus* 4.2±4.1 days).**

**A comprehensive home care intervention in selected chronic obstructive pulmonary disease exacerbations appears as cost effective. The home hospitalisation intervention generates better outcomes at lower costs than conventional care.**

*Eur Respir J 2003; 21: 58–67.*

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Keywords: Chronic obstructive pulmonary disease, healthcare costs, healthcare services, home care, hospitalisation

Received: February 21 2002
Accepted after revision: July 26 2002

Supported by Grants AATM 8/02/99 from the Agencia d'Avaluació de Tecnología Mèdica; FIS 98/0052-01 from the Fondo de Investigaciones Sanitarias; SEPAR 1998; CHRONIC project (IST-1999/12158) from the European Union (DG XIII); and, Comissionat per a Universitats i Recerca de la Generalitat de Catalunya (1999-SGR-00228). A. Casas was a predoctoral research fellow supported by CHRONIC and grant-in-aid by ESTEVE group.

Chronic respiratory diseases are an important burden on healthcare systems worldwide [1] that is expected to increase over the forthcoming 2 decades [2], particularly due to chronic obstructive pulmonary disease (COPD). Winter outbreaks of COPD exacerbations mostly occurring in elderly people with concurrent chronic comorbidities often generate dramatic increases in hospital emergency room admissions with subsequent dysfunctions in the healthcare system. It is estimated that hospitalisations of COPD exacerbations represent ~70% of the overall costs associated with the management of the disease [3].

A first feasibility analysis of home-based services to prevent conventional hospitalisations of COPD exacerbations was reported in 1999 by GRAVIL *et al.* [4]. Three subsequent controlled trials [5–7] also conducted in the UK have demonstrated both safety and cost reduction when these types of services were applied to selected COPD patients. It is worth noting, however, that none of these studies or the most recent report by SALA *et al.* [8] showed higher efficacy than conventional hospitalisation in terms of prevention of short-term relapses.

The present investigation was conducted on COPD exacerbations admitted at the emergency room of two tertiary hospitals in the Barcelona area. It was postulated that home hospitalisation with free patient phone access to a specialised nurse should generate a better outcome at lower direct costs than inpatient hospitalisation. Namely: 1) a lower rate of emergency room (ER) relapses; 2) a greater improvement of health-related quality of life (HRQL); and 3) better patient self-management of the disease.

The clinical trial was performed as a preliminary

step prior to the setting of a technological platform that includes a web-based call centre as one of the core elements [9].

## Methods

### *Study groups*

Over a 1-yr period (1st November 1999 to 1st November 2000), 222 patients with COPD exacerbations were included in the study among those admitted at the ER of two tertiary hospitals, Hospital Clínic and Hospital de Bellvitge of Barcelona, Spain. The two primary criteria for inclusion in the study were COPD exacerbation as a major cause of referral to the ER [10] and absence of any criteria for imperative hospitalisation as stated by the British Thoracic Society (BTS) guidelines [11] (*i.e.*, acute chest radiograph changes, acute confusion, impaired level of consciousness, and arterial pH <7.35). All COPD exacerbations admitted at the ER on weekdays (Monday to Friday, from 09:00 am to 04:00 pm) during the study period (n=629) were screened by a specialised respiratory team (one chest physician and one nurse) in each hospital. As displayed in the study profile (fig. 1), 220 patients (35%) showing one of the following exclusion criteria were not considered candidates for the programme: 1) not living in the healthcare area or admitted from a nursing home (11.5%, n=72); 2) lung cancer and other advanced neoplasms (5.9%, n=37); 3) extremely poor social conditions (5.2%, n=33); 4) severe neurological or cardiac comorbidities (4.8%, n=30); 5) illiteracy (4.8%, n=30); and 6) no phone at home (2.8%, n=18). One-hundred and sixty-five (26.2%) of the 629 screened patients required imperative hospitalisation. Up to 244 patients (38.8%) were considered eligible for the study, but 22 subjects (3.5%) did not sign the informed consent after full explanation of the characteristics of the protocol. The remaining 222 patients (35.3%) were blindly assigned using a set of computer-generated random numbers in a 1:1 ratio either to the treatment group (home-based hospitalisation (HH)) or to the control group (conventional care). One of the hospitals (Hospital Clínic) used a 2:1 randomisation ratio during the first 3 months of the study, which explains the difference in number between the two groups (HH: 121 patients; conventional care: 101 patients).

### *Home hospitalisation intervention*

Only patients assigned to HH were assessed by a specialised team. The characteristics of the intervention are summarised in the Appendix. The HH intervention had three main objectives: 1) an immediate or early discharge from the hospital was encouraged by the specialised team aiming to either avoid or reduce the length of inpatient hospitalisation; 2) a

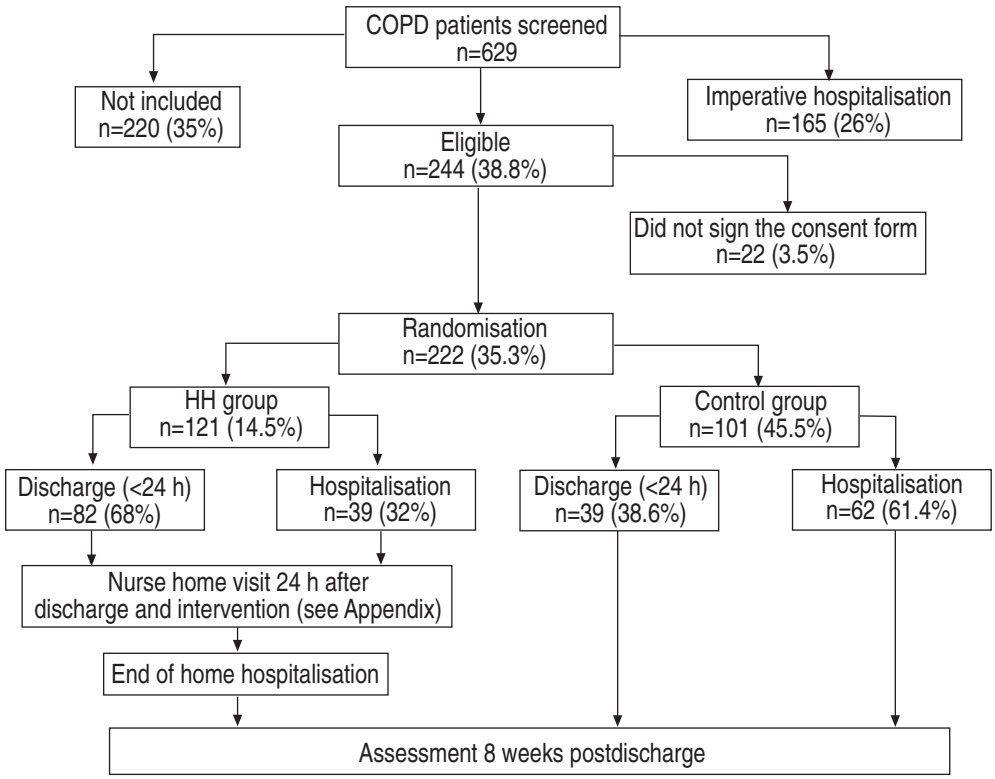


Fig. 1. – Study profile. From the 629 patients screened, 26% (n=165) required imperative hospitalisation [11] while up to 35% (n=220) were not eligible (see text). The remaining 244 patients (38.8%) were candidates for the study, but 22 patients (3.5%) did not sign the consent form. Two-hundred and twenty-two patients were included (home hospitalisation: 121 and conventional care: 101). COPD: chronic obstructive pulmonary disease; HH: home hospitalisation.

comprehensive therapeutic approach was tailored on an individual basis, according to the needs detected by the specialised team; and 3) patient support by a skilled respiratory nurse either through home visits or free-phone consultation was ensured during the 8-week follow-up period. For each HH patient, a first home visit was scheduled by the nurse within 24 h after discharge. The length of the home hospitalisation was set by the respiratory nurse. A maximum of five nurse visits at home were permitted during the 8-week follow-up period, but patient's phone calls to the nurse were not limited in number. The intervention was considered to be a failure if one of the two following events occurred: the patient relapsed and required referral to the ER; or >5 nurse visits at home were needed during the follow-up period. In both circumstances, the patients were analysed in the study but they were not considered for a new randomisation (*i.e.* when attended at the ER for the relapse).

Standard pharmacological treatment was used following COPD guidelines of the Spanish Respiratory Society (SEPAR) [10] during HH and conventional care. Nonpharmacological interventions for HH patients, summarised in the Appendix, were performed following specific guidelines [12]. Fragility factors that might facilitate COPD exacerbations were arbitrarily defined by consensus of the research team pre-hoc: 1) severity of pulmonary disease (hypercapnia, cor pulmonale); 2) active comorbidities; 3) poor knowledge of the disease; 4) poor compliance with treatment; 5) inadequate skills for the administration of inhaled therapy; 6) low level of social support; and 7) anxiety and/or depression. All of these factors were evaluated both at the initial assessment and then at completion of the follow-up using standard questionnaires, as described below. The response to therapy at home was evaluated by the nurse, based on clinical judgment plus measurements of vital signs and pulse oximetry (Monitor Pulsox$^{TM}$-$^{3i}$; Minolta, AVL Medical Instruments AG, Osaka, Japan). Arterial blood sampling at home for respiratory gases was performed if needed. The nurse's phone access to the physician at the hospital for remote supervision was ensured. Assessment of the progress of the active patients as well as decisions on potential changes in treatment prescription was done during weekly meetings of the specialised team.

### *Conventional care group*

Patients included in the conventional care group (controls) were evaluated by the attending physician at the ER who decided either on inpatient hospital admission or discharge. Pharmacological prescriptions followed the standard protocols of the centres involved in the study which were similar in the two groups (HH and controls) [10], but the support of a specialised nurse at the ER and at home was not provided for controls. At discharge, the patient was usually supervised by the primary care physician who was not aware of the protocol.

### *Initial assessment and evaluation 8 weeks after discharge*

Initial assessment at admission to the study was identical for both groups patients and included evaluation of the BTS [11] criteria of severity of the exacerbation and blind administration of a questionnaire, described in detail elsewhere [13], about: 1) risk factors for exacerbation (vaccination, smoking habits, comorbidities); 2) HRQL status during the previous year (St George's Respiratory Questionnaire (SGRQ) [14] and Short-Form 12-item survey (SF-12) [15]); 3) history of previous exacerbations (1 yr) requiring inpatient hospitalisations and/or ER admissions evaluated, at least, by questionnaire and, at the most, also by examination of individual clinical records; 4) clinical features of the current exacerbation; 5) fragility factors; and 6) treatment, including compliance, observed skills for administration of inhaled drugs, and rehabilitation at home. Home rehabilitation included interventions, such as manoeuvres to facilitate sputum clearance, nutrition recommendations and skeletal muscle exercise of both upper and lower limbs. Vital signs, chest radiograph films and arterial blood gases were obtained in all patients on admission.

After the 8-week follow-up period, the same questionnaires were administered again to the two groups. In addition, a detailed list of questions on the utilisation of healthcare resources during this period was included. Forced spirometry, chest radiograph films and arterial blood gases were also obtained. A questionnaire to evaluate patient's satisfaction was also blindly administered.

### *Healthcare costs*

Costs were calculated for each group from the perspective of the public insurer, such that, the cost analysis was restricted to direct healthcare costs. Other resources implied in the programme, such as patient labour time and informal care, were not evaluated in this study.

First, the relevant categories to be considered in order to estimate cost at patient level were identified: 1) length of hospital stay (days of initial hospitalisation plus days during hospital readmissions); 2) ER visits not requiring admission to the hospital; 3) hospital outpatient visits to specialists; 4) primary care physician visits; 5) visits for social support; 6) nurse visits at home; 7) treatment prescriptions; 8) phone calls; and 9) transportation services. Data on use of categories were obtained for each patient during the follow-up period.

A second step was the valuation of resource use. The total cost for each category was calculated as the product of the number of events multiplied by the unit cost per event (*i.e.* hospitalisation costs were calculated as days in hospital including initial stay plus readmissions multiplied by the average hospitalisation cost per day). Unit costs are expressed as year 2000 prices using Euros (€) as the monetary unit in the European Union. Costs for nurse visits at home, drug

prescriptions, phone calls and transportation services were directly calculated using information about labour cost, market prices, including value added tax, and overhead costs. Hospital unit costs per hospital stay and visits were not available in the hospitals participating in the study. Instead, average specifically observed tariffs for COPD patients in a public insurance company covering the civil servants of the City Council of Barcelona (PAMEM) were used. These tariffs are mainly paid to public and nonprofit hospitals, and have a close relationship with the real costs. In fact, tariffs represent an adequate basis for cost estimates, given that the present authors' interest is in the financial costs for third party insurers [16].

### *Statistical analysis*

Results are expressed as mean±SD or as percentages in the corresponding categories. Comparisons between the two study groups on admission and 8 weeks after discharge and changes during the follow-up period were performed using independent t-tests, a nonparametric test (Mann-Whitney U-test) or the Chi-squared test. Changes within each group were assessed using t-test or nonparametric Wilcoxon test for paired samples. Statistical significance was accepted at $p<0.05$.

## Results

### *Assessment on first emergency room admission*

Patients of the HH group and controls showed similar characteristics on ER admission (table 1). HRQL was also similar (SGRQ total score, 58±17 *versus* 59±20, HH and conventional care, respectively; SF-12 physical, 36±8 *versus* 34±8; and, SF-12 mental, 44±12 *versus* 44±13, respectively). No differences between groups were observed in knowledge of the disease and in self-management of the chronic condition (fig. 2). On average, the two groups showed a relatively acceptable compliance to oral therapy (79% of the patients), inhaled therapy (66%), and long-term oxygen therapy (82%). However, they showed poor results in knowledge of the disease (only 20% of the patients were fully aware of their disorder), appropriate inhalation technique (26%), and rehabilitation therapy at home (10%). Forced spirometric measurements at week 8 after discharge did not show differences between the two groups (table 1).

### *Outcomes*

Five patients (4.1%) in the HH group and 7 controls (6.9%) died during the 8-week follow-up period (table 2). The rate of hospital readmissions during this period was ~25%, with no differences between

Table 1. – Baseline characteristics of the study groups

| | Home hospitalisation | Conventional Care | Total |
|---|---|---|---|
| Subjects n (% female) | 121 (3.3) | 101 (3.0) | 222 (3.2) |
| Age yrs | 71.0±9.9 | 70.5±9.4 | 70.8±9.7 |
| Respiratory rate·min$^{-1}$ | 26.9±6.0 | 26.8±5.9 | 26.8±5.9 |
| Dyspnoea score (VAS) | 6.1±3.1 | 6.2±3.3 | 6.2±3.2 |
| Risk factors | | | |
| Influenza vaccination % | 66.1 | 65.3 | 65.8 |
| Current smokers % | 27.3 | 17.8 | 23.0 |
| Comorbidities % | 93.4 | 96.0 | 94.6 |
| Number of comorbid conditions | 2.9±1.8 | 3.1±1.6 | 3.1±1.7 |
| Exacerbations requiring in-hospital admission (previous year) | | | |
| Subjects % | 40.8 | 40.6 | 40.7 |
| Number of episodes | 0.7±1.2 | 0.9±1.4 | 0.8±1.2 |
| Oxygen therapy at home | | | |
| Patients % | 12.4 | 18.8 | 15.3 |
| Arterial blood gases (on admission) | | | |
| $F_{I,O_2}$ | 21.7±1.4 | 22.1±2.3 | 21.9±1.8 |
| pH | 7.4±0.04 | 7.4±0.3 | 7.4±0.2 |
| $P_{a,O_2}$ | 65.0±13.6 | 64.7±16.4 | 64.9±14.9 |
| $P_{a,CO_2}$ | 42.7±7.5 | 43.8±8.9 | 43.2±8.2 |
| Blood sampling at $F_{I,O_2}$=0.21 % patients | 77.6 | 72.6 | 75.4 |
| $P_{a,O_2}$ breathing $F_{I,O_2}$=0.21 | 63.2±10.5 | 62.9±13.9 | 63.1±12.1 |
| Forced spirometry (at 8 weeks of follow-up) | | | |
| FVC L (% pred) | 2.4±0.9 (64) | 2.2±0.9 (60) | 2.3±0.9 (62) |
| $FEV_1$ L (% pred) | 1.2±0.6 (43) | 1.1±0.4 (41) | 1.1±0.5 (42) |
| $FEV_1$/FVC % | 50±13.3 | 50±13.1 | 50±13.2 |

Results are expressed either as mean±SD or as a percentage of subjects in the corresponding category. Total: combined data of the two groups; VAS: visual analogue scale for scoring dyspnoea; $F_{I,O_2}$: inspiratory oxygen fraction; pH: arterial pH; $P_{a,O_2}$: oxygen tension in arterial blood; $P_{a,CO_2}$: carbon dioxide tension in arterial blood; FVC: forced vital capacity; pred: predicted; $FEV_1$: forced expiratory volume in one second; $FEV_1$/FVC: ratio, expressed as an actual value.

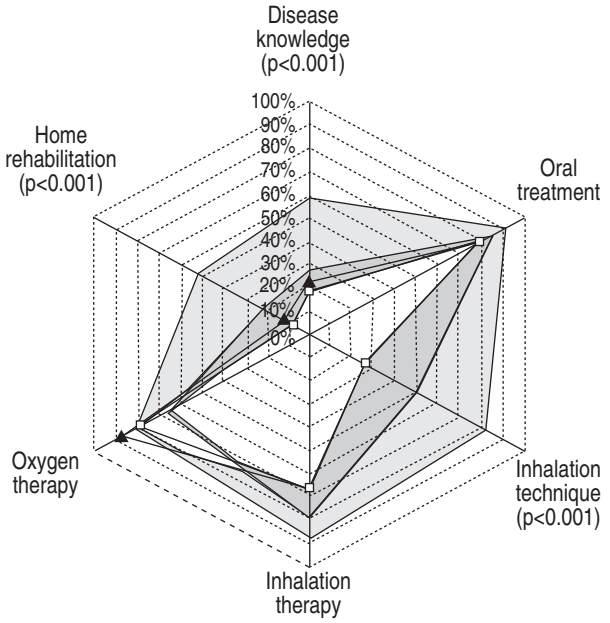


Fig. 2. – Knowledge of the disease and self-management of the chronic condition. Results are expressed as per cent of patients. On admission (inner limits: home hospitalisation (HH): ▲; controls: □), no differences were seen in any of the six dimensions of the graph. No changes in the control group (dark grey area) were seen during the 8-week follow-up period, but marked beneficial effects were detected in the HH group (light grey area).

groups. In the control group, however, the rate of relapses requiring new ER admission without subsequent hospital readmissions almost doubled the figure shown by the HH patients ($p<0.05$). As indicated in table 2, the HH group showed higher improvement in HRQL and higher satisfaction than the control group after the 8-week follow-up period. Furthermore, a higher percentage of patients in the HH group (fig. 2) had a substantial improvement in knowledge of the disease (HH 58% *versus* 27% for controls, $p<0.01$), compliance on inhalation technique (HH 81% *versus* 48% for controls, $p<0.001$), and rehabilitation at home (HH 51% *versus* 21% for controls, $p<0.01$).

### *Characteristics of inpatient hospitalisation*

Up to 68% of HH patients were discharged from ER without requiring hospitalisation (<24 h) compared to 39% of the control patients ($p<0.001$; table 2). Consequently, the length of hospitalisation was also significantly lower in the HH group than in controls (1.7 *versus* 4.2 days, respectively; $p<0.001$). Hospitalisation for >3 days was required in 48% of controls but only 17% of HH patients. Characteristics of inpatient hospitalisation in the two groups are reported in table 2. The average length of the stay in the hospitalised patients of the control group was 8.1 days.

Table 2. – Main outcomes of the study and characteristics of the initial inpatient hospitalisation

| | Home hospitalisation | Conventional care | p-value |
|---|---|---|---|
| Clinical outcomes (8-week follow-up) | | | |
| Inpatient hospital readmissions | | | |
| Patients n (%) | 23 (20.0) | 26 (27.7) | |
| Number of episodes | 0.24±0.57 | 0.38±0.70 | |
| Emergency room readmissions | | | |
| Patients n (%) | 11 (9.6) | 21 (22.3) | 0.02[#] |
| Number of episodes | 0.13±0.43 | 0.31±0.62 | 0.01[¶] |
| Deaths n (%) | 5 (4.1) | 7 (6.9) | |
| Health-related quality of life (8-week follow-up) | | | |
| Mean ΔSGRQ score | | | |
| Total | -6.9 | -2.4 | 0.05[+] |
| Symptoms | -8.7 | -8.4 | |
| Activity | -4.8 | -0.09 | |
| Impact | -7.6 | -1.9 | 0.03[+] |
| Mean ΔSF-12 score | | | |
| Physical | 1.7 | 1.9 | |
| Mental | 2.0 | -0.05 | |
| Patient's satisfaction | | | |
| Mean score | 8.0 | 7.5 | 0.03[¶] |
| Inpatient hospitalisation | | | |
| % of patients hospitalised | | | |
| <1 day % | 67.8 | 38.6 | <0.001[#] |
| 2 days % | 5.8 | 4.0 | |
| 3 days % | 9.9 | 9.9 | |
| >3 days % | 16.5 | 47.5 | |
| Days of hospitalisation | 1.71±2.33 [0–11] | 4.15±4.10 [0–16] | <0.001[¶] |

Results are expressed either as mean±SD or as a percentage of subjects in the corresponding category. Minimum and maximum values are expressed in square brackets. SGRQ: St George's Respiratory Questionnaire; SF-12: Short-Form 12-item survey. [#]: Chi-squared test; [¶]: Mann-Whitney U nonparametric test for independent samples; [+]: t-test for comparison of two independent samples.

In the HH group, the average length of the home-based hospitalisation was 3.56 days (1–14 days). During the 8-week follow-up period, the number of nurse visits at home was 1.66±1.03 (range, 0–4) and the number of nurse phone calls to patients was 1.56±1.31 (0–6). Likewise, the number of patients′ phone calls to the nurse was 0.76±1.34 (0–9), such that the overall number of phone calls was 2.33±2.05 (0–10).

As indicated in table 3, the control group showed a higher average cost per patient than the HH group in terms of length of hospitalisation and ER visits. Conversely, the control group displayed lower costs for prescription than HH. During the follow-up period, no differences between the two groups were seen in the use of the following three categories: visits to primary care physician, transportation, and social support. The average overall healthcare cost per patient in the HH group was only 62% of the average cost calculated for control patients (€1,255 *versus* €2,033; p= 0.003).

## Discussion

The present study indicates that home hospitalisation as described in the Appendix generated better outcomes than conventional care of COPD exacerbations. Better outcomes with HH included: 1) lower hospitalisation rates; 2) lower rates of short-term relapses requiring ER admissions; 3) clinically relevant improvement in HRQL, as assessed by the SGRQ [17]; 4) a higher degree of patient satisfaction; and 5) an important positive impact on knowledge of the disease and on patient self-management of the chronic condition.

The results were obtained with a rather modest use of the resources allocated to home support. Only a small portion of the five potential nurse visits was used (on average 1.7 nurse visits at home) during the 2-month follow-up period. Despite the free-phone access that was ensured to all patients, the average number of patients′ phone calls to the nurse was only 0.76. Somewhat unexpectedly, the study shows that home hospitalisation was less costly than conventional care. The average overall costs per HH patient were substantially lower than in conventional care, essentially due to fewer days of inpatient hospitalisation. Slightly higher costs in the HH group were only observed in prescriptions that were due to both oxygen therapy and nebuliser therapy, because these two treatments were part of the inpatient hospitalisation costs in a substantial portion of the control group.

While all previous studies assessing either home hospitalisation or early discharge [5–8] have essentially shown that the approach is safe, this is the first report that clearly demonstrates the beneficial effects of the intervention compared with conventional care of COPD exacerbations. The present study also indicates that improvement of the outcomes can be associated with a reduction of direct costs. Like other reports [5–8], the present study confirms that home hospitalisation is suitable only in a subset of exacerbations that must be selected at the hospital after proper assessment by a specialised team.

### *Internal validity of the trial*

The validity of the assignment process for either HH or conventional care was ensured by both the generation of the allocation sequence by a random

Table 3. – Average direct cost per patient for the two study groups

| Categories | Costs per category € | Home hospitalisation | | Conventional care | | p-value[#] |
|---|---|---|---|---|---|---|
| | | No. of events/ patients | Cost per patient € | No. of events/ patients | Cost per patient € | |
| Inpatient hospital stay | 220.62 | 495/77 | 941.40 | 765/81 | 1795.47 | <0.001 |
| ER visits | 79.71 | 15/11 | 10.31 | 29/21 | 24.59 | 0.01 |
| Outpatient visits | 39.85 | 16/12 | 5.49 | 52/14 | 22.04 | |
| Primary care physician visits | 47.48 | 20/6 | 8.19 | 15/8 | 7.57 | |
| Social support visits | 18.75 | 10/3 | 1.62 | 11/4 | 2.19 | |
| Nurse home visit | 25.34 | 192/101 | 41.94 | | | |
| Prescriptions | | | 217.21 | | 172.06 | 0.001 |
| Phone calls: | | | | | | |
| Patient to nurse | | 88/46 | | | | |
| Nurse to patient | | 182/96 | | | | |
| Total | 9.02 | 270/99 | 20.99 | | | |
| Transport | 6.01 | 154/77 | 7.97 | 150/61 | 9.59 | |
| Average direct cost per patient (95% CI) | | | 1255.12 (978.54–1568.04) | | 2033.51 (1547.05–2556.81) | 0.003 |

Costs are expressed in Euros (€) at year 2000 prices. Cost per category indicates the estimated average unit cost (*i.e.* cost of one day of inpatient hospitalisation). Number of events/patients is the number of units of the corresponding category and number of active patients in that category, respectively. The average cost per patient for a given category normalised by group size was calculated as the product of the unit cost per category (one event) multiplied by the number of events divided by the total number of patients in the group (home hospitalisation, n=116 or conventional care (controls), n=94, dead patients were not taken into account in the calculation). CI: confidence interval. [#]: Mann-Whitney U nonparametric test.

process and preventing any foreknowledge of the treatment assignments by the specialised team that implemented the allocation sequence [18]. As described in the Methods section, one of the hospitals (Hospital Clínic) transiently used a 2:1 randomisation ratio as a conservative approach to ensure an adequate number of HH patients. This strategy provoked a lack of equilibrium in the number of patients assigned to each group (HH: 121; controls: 101), but does not seem to compromise the comparability between the two groups, as shown by the similar results obtained in the assessment on admission.

Since missing data represented <2% of the study group, it can be considered that the aims of the follow-up analysis were fully achieved. It is worth noting, however, that the relatively short follow-up planned in the study might have reduced the impact of the positive effects shown by educational intervention (fig. 2). The pivotal effects of education on self-management of asthma have been widely demonstrated in recent years [19, 20] and evidence of this has recently been reported for COPD patients [21]. The present study identifies this area as a key field for the development of future guidelines for chronic respiratory diseases.

In the economical analysis, the limitation of self-reported use of healthcare resources was partially palliated by the evaluation of the clinical records of the patients. An excellent correlation between the two scores was observed. The economic evaluation performed in the context of this randomised controlled trial was designed to ask the following question: does substituting hospital-at-home care for hospital care in COPD exacerbations result in a lower cost to the health service?

This economic evaluation may be affected by two main limitations. First, the perspective of the evaluation was that of the public healthcare insurer, excluding nonhealthcare costs. In this study, formal (paid work) or informal (unpaid work and leisure time) care for exacerbated COPD patients were not evaluated. Notwithstanding, a previous randomised controlled trial comparing hospital-at-home care with inpatient care [22] reported that carers' expenses made up a small proportion of total costs and inclusion of these costs did not alter the results.

A second limitation of the economic evaluation is that average costs were used to evaluate hospital care. In fact, hospital resources released for the care of other patients may be less than the final average cost when patients are nearing the end of their hospital stay and therefore require less resource intensity (marginal cost). It has been argued that the existence of fixed hospital costs amplifies the value of any potential savings resulting from a reduction in bed-days [23].

However, marginal costs estimated as the short-run variable costs are not appropriate to evaluate the costs (or savings) that would be associated with the provision of new hospital services in the long-term [24]. From the theoretical point of view, average costs may appropriately represent the value of freed resources, assuming that patients can be admitted to empty beds. Even so, a sensitivity analysis was performed assuming that resources released by home hospitalisation intervention (days of hospital) would be either 75% or 50% of the average cost. Under both assumptions, it was found that the average cost per patient in the HH group was lower than the cost calculated for control patients. It may therefore be asserted that using marginal cost to evaluate resources does not result in home hospitalisation being more costly than conventional care for exacerbated COPD patients.

### *External validity*

The positive outcomes obtained in the study probably reflect the combined effects of the comprehensive home care intervention (Appendix) undertaken in this trial. It is worth noting, however, that while the reduction of ER readmissions in the HH group was clear, the impact on short-term hospital readmissions was rather modest, as seen in other reports [5].

It is remarkable that the results of the present study fully substantiate and amplify the message given by studies [5, 6] carried out in the UK, despite noticeable country differences in terms of interactions between primary care and tertiary hospitals. While in Barcelona, ~70% of the ER admissions in tertiary hospitals for COPD exacerbations corresponded with self-referrals [25]. This figure falls to ~30% on average in the UK and as low as 1% in the report by SKWARSKA *et al.* [5]. The present results seem to support the notion that the efficacy of HH is not dependent on the specificities of the healthcare system if the logistics of the home care services are fully managed by the hospital. Whether this type of setting should be recommended or not is still controversial. Alternatively, a distributed model based on a close collaboration between healthcare levels [26, 27] has been suggested, as discussed below.

Although the current investigation purposely followed general aspects of the study profile reported by SKWARSKA *et al.* [5], a proper comparative analysis between the two studies is difficult because of several factors. First, differences in the healthcare systems are not negligible as alluded to above. Second, the Scottish patients were randomised after ER doctors had already decided on hospital admission, which was not the case in the present study. This factor might have resulted in a selection of more severe patients in the two groups (HH and controls) in [5] as compared to the present study. It can be speculated that the clear beneficial effects described in the present investigation (not seen in [5]) might be because patients in Barcelona had less severe exacerbations. It is worth noting that UK studies [4–7] on different modalities of home hospitalisation consistently showed, on average, lower $FEV_1$, higher SGRQ scores and lower rates of autoreferrals to ERs of tertiary hospitals than in studies carried out in Spain [8, 13], suggesting that sicker patients were attending in UK hospitals. This is probably due to country differences in the interactions between healthcare levels.

It can be concluded, however, that an assignment bias was not present in these two studies. Moreover, the patients of the present study showed similar characteristics to those reported by studies on

exacerbated COPD patients admitted in the ER of tertiary hospitals in Spain [8, 13].

There is controversy regarding the effects of hospital-at-home schemes on costs for COPD patients. Two randomised controlled trials [22, 23] reported that hospital-at-home significantly increased healthcare costs for COPD patients. The two trials, however, analysed a very small sample of patients whose severity of illness was not delineated.

The economic evaluation of home hospitalisation in the current study clearly reported cost savings. As stated in the Results section, savings may be mainly attributed to the reduction in the length of stay for patients in the HH programme. The magnitude of this reduction in the present study is enough to compensate the increase in the costs corresponding to the HH programme. In this sense, the present results confirm the importance of the impact of the intervention on the use of this resource for COPD patients in the economic evaluation of home care programmes as the sensitivity analysis of Shepperd *et al.* [22] indicated.

### *Implications for healthcare policy*

The search for healthcare services meeting the needs of chronically ill people [26, 27] has recently generated the so-called chronic care model [28]. These authors propose a patient-centred approach, with special emphasis on shared care arrangements across the healthcare system (between specialised care at the hospital and primary care) and within the multidisciplinary primary care team. Key features of the model [28] are the development of innovative home-based services with involvement of patients (and caregivers) as partners in the management of the disease.

A key challenge in the development of such new services is a redefinition of the roles and skills of the specialised nurses and physiotherapists [29, 30]. The interactions of these allied healthcare professionals with physicians should be re-examined. Adequate standardisation of procedures is also needed. In this new setting, there is an important role for the use of information technologies, facilitating the interactions between healthcare levels and the development of novel educational tools.

It can be concluded that home hospitalisation of selected chronic obstructive pulmonary disease exacerbations generates better outcomes at lower costs than conventional care. The data of the present study suggests that managerial aspects of exacerbated chronic obstructive pulmonary disease patients must be revisited. Home-based services (home hospitalisation or home support) should be taken as part of the continuum of care in chronically ill patients. Despite the promising results of these new approaches in the treatment of chronic obstructive pulmonary disease exacerbations, prevention of early relapses after discharge is still an important challenge. The present study prompts the need for the deployment of this type of intervention as a regular healthcare service for exacerbated chronic obstructive pulmonary disease patients under the frame of a properly designed cost-effectiveness analysis.

## Appendix: Description of the intervention in the home hospitalisation group

Assessment on ER admission by the specialised team

1. Characteristics of the exacerbation, comorbidities, and response to treatment at the ER
   - 1.1. Baseline conditions of the patient (duration 1.5 h): a) health-related quality of life; b) healthcare resources in the previous year; c) fragility risk factors; and knowledge of the disease and compliance to therapy.
   - 1.2. Decision on discharge from the ER or after a short period of inpatient hospitalisation based on 1.1. and 1.2.

2. Treatment at discharge
   - 2.1 Pharmacological therapy of COPD and comorbidities
   - 2.2. Nonpharmacological treatment (duration 2 h): a) education on knowledge of the disease; adherence to treatment; and recognition/prevention of triggers of exacerbation; b) selection of appropriate equipment at home; training on administration of pharmacological treatment; c) smoking cessation; d) patient empowerment on daily life activities: hygiene, dressing, household tasks; leisure activities; breathing exercises; and, skeletal muscle activity; e) nutrition recommendations; and f) socialisation and changes in lifestyle.

3. Home hospitalisation and 8-week follow-up
   - 3.1. First nurse visit at home at 24 h (duration 1 h)
     a) Assessment of the response to pharmacological treatment
     b) Introduction of changes under remote physician′s supervision
     c) On-site assessment of fragility factors
     d) Action plan revisited and education reinforced
   - 3.2. Eight-week follow-up
     a) Number of home visits and duration of HH were decided by the nurse
     b) Patient free-phone access to the nurse was ensured
     c) Nurse phone calls to patient to reinforce the action plan
   - 3.3. Failure of the programme
     a) More than five nurse home visits during the 8-week follow-up
     b) New problem requiring ER admission

4. Assessment after 8-week follow-up (see text)

***Acknowledgements.*** The authors are grateful to A. Alonso, J.A. Barberà, E. Sala, E. Gavela, and the nurses I. Fernandez and

C. Fornas, from the Hospital Clínic (Barcelona, Spain) for their support during the study and in the preparation of the manuscript. The authors also acknowledge the support of N. Celorrio and nurse M. Maderal from the Hospital de Bellvitge (Barcelona, Spain) for their valuable contribution. The authors are indebted to R. Santed from the IMIM for his job in the preparation of the database, and thank J.M. Marín, from the Hospital Miguel Servet (Zaragoza, Spain) for his collaboration in the design of the protocol. Finally, the authors are grateful to all of the following partners of the CHRONIC project. CSC, Barcelona: A. Alonso, J.A. Montero, J. Pastor and B. Sifre; UPM, Madrid, Spain: F. del Pozo, P. de Toledo, S. Jiménez; CESTEL, Madrid: F. Ortiz, L. Mena, M. Godoy, J. Luís Sirera; CSIC-CNM, Barcelona: J. Aguiló, L. Sánchez, A. Guimerà; SMS, Milano, Italy: A. Falco, D. Balconi; SMS, Madrid: B. Andrés, J.J. Moratillas; ICP, Milano: A. Mattiussi, A. Antonini (Parkinson Center); MC, Milano: C. Castiglioni, E. Battaglia; TILAB, Turín, Italy: F. Moggio, M. Mercinelli; KUL, Leuven, Belgium: M. Decramer, T. Troosters, W. Droogne, F. Van de Werf; EW, Paris, France: P. Sylvester, N. Pougetoux; ALAMO, Madrid: M.A. García Matatoros, A. Marcus; UB, Barcelona: R. Farré; ECOMIT, Barcelona: C. Céinos.

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DOI: 10.1377/hlthaff.2016.0922
HEALTH AFFAIRS 36,
NO. 5 (2017): 876–884


By John Hsu, Mary Price, Christine Vogeli, Richard Brand, Michael E. Chernew, Sreekanth K. Chaguturu, Eric Weil, and Timothy G. Ferris

# Bending The Spending Curve By Altering Care Delivery Patterns: The Role Of Care Management Within A Pioneer ACO

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**ABSTRACT** **Accountable care organizations (ACOs) appear to lower medical spending, but there is little information on how they do so. We examined the impact of patient participation in a Pioneer ACO and its care management program on rates of emergency department (ED) visits and hospitalizations and on Medicare spending. We used data for the period 2009–14, exploiting naturally staggered program entry to create concurrent controls to help isolate the program effects. The care management program (the ACO's primary intervention) targeted beneficiaries with elevated but modifiable risks for future spending. ACO participation had a modest effect on spending, in line with previous estimates. Participation in the care management program was associated with substantial reductions in rates for hospitalizations and both all and nonemergency ED visits, as well as Medicare spending, when compared to preparticipation levels and to rates and spending for a concurrent sample of beneficiaries who were eligible for but had not yet started the program. Rates of ED visits and hospitalizations were reduced by 6 percent and 8 percent, respectively, and Medicare spending was reduced by 6 percent. Targeting beneficiaries with modifiable high risks and shifting care away from the ED represent viable mechanisms for altering spending within ACOs.**

Health care delivery in the United States is undergoing an intensive period of experimentation, using changes in payment policies to induce changes in the delivery system. Increasingly, payers such as Medicare are adopting payment alternatives—including accountable care organizations (ACOs)—to fee-for-service reimbursement that involve the sharing of financial risk between payers and providers.[1]

The hope is that these alternative payment models will alter care delivery and thereby slow medical spending growth. Several studies have found that Medicare ACOs appear to be associated with modestly lower spending growth, compared to what would have been expected in the absence of ACOs, but that spending does not decrease, compared to previous levels.[2–6] There is limited information on how ACOs might lower spending.[7,8]

Understanding how changes might be occurring is critical for several reasons. First, and perhaps most important, many individual providers and provider organizations are in the early stages of deciding whether to join an ACO or to progress to more advanced permutations of ACOs in which they would share both profits and losses. Therefore, they would likely benefit from information on the strategies and

mechanisms that have or haven't worked among advanced ACOs.

Second, information on the mechanisms that underlie spending reductions could provide information on the likely sustainability of change. Some observers have expressed doubts about the feasibility of achieving savings by improving care or its delivery among Medicare beneficiaries.[9] Moreover, if ACOs reduce spending primarily through lowering the cost of an input (for example, using less expensive imaging centers), then the spending change could represent a one-time event. This type of reduction changes the level of spending once but does not alter the growth in spending on health care. Alternatively, if ACOs alter the utilization rate of services such as imaging, then spending reduction might be more likely to be sustainable.[10,11]

Third, evidence supporting a deliberate strategy would increase the plausibility of the overall ACO findings, given the difficulty of isolating the effects of any single policy in an environment with multiple ongoing changes. For example, identifying a valid control group for ACO studies represents a major challenge when there are multiple concurrent changes within health care. Evidence of this type could further inform policy making—for example, guiding refinements to the ACO program or incentives that support (or not) targeting high-risk beneficiaries, particularly in future iterations of Medicare's payment changes.

We used a combination of health system and Medicare data to examine the primary care improvement and cost reduction strategy of a large Pioneer ACO in the Partners HealthCare System.

## Background

Before the start of the Pioneer ACO program, one of the main hospitals within the Partners HealthCare System, Massachusetts General Hospital, had participated in the Medicare Care Management for High Cost Beneficiaries Demonstration and had developed an intensive care management program.[12] The study ACO extended this program throughout the Partners HealthCare System with no changes to the basic structure of the program, except for centralizing operations.

The care management program represented the ACO's primary strategy for achieving its contractual cost and quality goals under the Pioneer ACO program. The ACO employed no other contemporaneous, systematic programs. Specifically, the care management program identified beneficiaries who first appeared likely to be at high risk for future spending and then selected the subset of this group whose costs appeared to be modifiable,[13] using information from each beneficiary's primary care physician. These beneficiaries with elevated but potentially modifiable risks for future spending were eligible for the care management program.

Determination of program eligibility occurred at the beginning of each year, but entry into the program for each year's eligible participants was staggered over a period longer than twelve months because of capacity constraints. This fortuitous design created a natural experiment in which we used the timing of program entry to examine the impact of the care management program on utilization and spending, while controlling for contemporaneous influences on beneficiary experience. Specifically, we compared each beneficiary's experience after joining the care management program to his or her experience before joining it, and we used the experience of beneficiaries who entered the program at different times as contemporaneous controls.

We used a similar approach to examine the impact on utilization and spending of beneficiary alignment with the Partners ACO. As part of the Pioneer ACO program, each year the Centers for Medicare and Medicaid Services (CMS) aligned beneficiaries with an ACO to define the population for which the ACO and CMS shared risk; beneficiaries were not required or incentivized to receive care from the ACO. Beneficiary alignment took effect at the beginning of 2012 and the beginning of 2013. We compared each beneficiary's experience during the year he or she was initially aligned with the ACO to his or her experience before alignment, and we used the experience of subjects aligned later as contemporaneous controls.

We hypothesized that rates of emergency department (ED) visits and hospitalizations would decline over time with greater exposure to the care management program (in other words, that there would be a dose response). We also hypothesized that spending would increase initially as unmet needs were addressed but then decline in response to the program's effects.

## Study Data And Methods

We used Medicare claims data for the period 2009–14 sent from CMS to the Partners ACO. Our ACO study group included all Medicare beneficiaries who were initially aligned with the Partners ACO in 2012 or 2013. We excluded beneficiaries who were initially aligned in 2014, because of the limited follow-up time available. To assess the association between ACO exposure time and the outcomes, we tracked the number of months that each beneficiary had been aligned.

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Our care management program study population included beneficiaries who had been identified in any year between 2012 and 2014 by their primary care physicians as having potentially modifiable elevated risks for future spending and chose to participate in the care management program. Because of capacity constraints, only 33 percent of identified beneficiaries had participated in the program by the end of 2014. The care management program started with an initial assessment of each beneficiary by the care manager; because the care managers had limited capacity, the assessments (that is, program initiations) were staggered throughout the year. We tracked the number of months that each eligible beneficiary was in the program, to assess the association between length of program exposure and the outcomes. We excluded subjects who had not been assessed by the end of 2014. While our study included only those who participated in the program, we examined all beneficiaries who were eligible to participate—including those who chose not to do so—in sensitivity analyses. Additional details about the program and the selection process have been published previously.[13–16]

**TIME-STABLE AND TIME-CHANGING COVARIATES** To analyze changes within each beneficiary over time, we used models with patient-level fixed effects. In these types of models, any unobserved characteristics of people that do not change over time cancel out and essentially drop out of the model. Thus, this approach controls for any time-stable characteristics that could affect the outcome but are difficult to measure and therefore are not specified in models.

We controlled for time-varying covariates, including changes in comorbidity levels and entry into hospice, nursing home, or other institutional care. To control for comorbidities, we used CMS–Hierarchical Condition Categories, which are prospective risk scores used to pay Medicare Advantage plans. These risk scores use inpatient and outpatient diagnostic information from the previous twelve months to predict spending risk in the next calendar year.[17]

**OUTCOMES** We examined ACO and care management program effects on all hospitalizations, all ED visits, and the subset of ED visits for nonemergency conditions (medical conditions amenable to care in a doctor's office or urgent care facility)—which we identified using a previously validated algorithm.[18] The primary analysis focused on ED visits for conditions with at least a 50 percent probability of being nonemergency or amenable to outpatient care; we varied this threshold in sensitivity analyses.

We analyzed care management program effects on total Medicare Parts A and B spending for all beneficiaries in the study and on total spending including prescription drugs for the subset of beneficiaries who received drug coverage through Part D.

**Our findings provide evidence to support the expansion of successful programs.**

**ANALYSES** Our main analysis followed a difference-in-differences design, with individual-level fixed effects. We conducted two categories of analyses: an examination of the association between ACO alignment and the outcomes, and an examination of the association between participation in the care management program and the outcomes. For each category, we exploited the staggered start dates that naturally created concurrent control groups whose members received their care in the same system. Preprogram trends in the outcomes were similar across the comparison groups, which satisfied the assumption of parallel historical trends required by a difference-in-differences analysis.

We compared beneficiaries who were first aligned to the ACO in 2012 to those who were first aligned in 2013. We also compared beneficiaries who started the care management program in a given month to those who started in subsequent months, controlling for the amount of exposure to the ACO or to the care management program. Analyses that used these exposure variables enabled us to test our hypotheses that rates of ED visits and hospitalizations would decline over time with greater exposure to the program and that spending might increase initially before decreasing as program effects manifested themselves.

We used negative binomial models for analyses of ED visit and hospitalization rates and linear models for analyses of spending. All models used fixed effects estimation methods to account for unmeasured time-stable patient-level effects. The models adjusted for year, month within a given year, and time-changing risk scores.

The data supplied from CMS to the ACO did not specify the exact date of initial eligibility for Medicare, so we used 2009 as that date, to provide the most conservative estimate of any potential findings. We tested alternative dates, such as the first claim date, in our sensitivity analyses. In these analyses, we also tested several alterna-

tive definitions for other variables and other analytic models. All findings of the main analyses were similar to those across the sensitivity analyses.

**LIMITATIONS** There were several limitations to our analyses. First, assignment to the ACO and the care management program was nonrandom, so there could be potential selection bias from unmeasured time-changing covariates. We assumed that if such unmeasured potential confounders existed, their distribution would be similar across our comparison groups and would not bias the findings. Preprogram outcome trends were similar across comparison groups, which provided some assurance that any unmeasured confounders were evenly distributed.

Second, care managers had considerable latitude in their workflow, including when they first assessed beneficiaries who were newly eligible for the care management program. Thus, it is possible that care managers preferentially entered the sickest patients into the care management program first. If this were the case, it could bias the analyses toward a null result, as the true program effect might be smaller than the difference in severity between earlier versus later entrants. Similarly, if assignment to the program reflected a transient change in a beneficiary's clinical condition, regression to the mean could result in an overstatement of the program effect. An examination of beneficiaries' risk scores did not find any differences across entry times, which mitigated concerns about nonrandom entry into the program.

Third, we assumed that there were no interactions among time-stable confounders. We also assumed that if there was an interaction between the intervention and a beneficiary trait, the proportion of beneficiaries with the trait was constant across the comparison groups. While these are important assumptions, the direction of any potential bias is unclear.

Fourth, the analyses occurred within a single ACO—albeit one of the largest in the country and one that includes multiple hospitals and thousands of physicians. In addition, the process of determining eligibility for the care management program involved physicians' input into the mutability of patients' risk for high levels of future spending. Results could vary in different settings and with different approaches to care management eligibility.

Fifth, the study did not examine differential effects within subgroups of beneficiaries, such as those who were dually eligible for Medicare and Medicaid, members of racial or ethnic minority groups, or people living in poorer areas or farther away from the ACO. It is possible that the effects of either the ACO or the care management program could differ between the members of these groups and other beneficiaries, depending on the structure of the ACO and on beneficiaries' level of care before being aligned with the ACO.[6,19]

Finally, the analyses also focused on Medicare spending but did not assess total spending, including program costs. To our knowledge, no other study of ACOs has included program costs in its analysis.

## Study Results

**BASELINE TRAITS** We found significant differences with respect to a number of baseline traits within both the ACO and the care management program study groups (Exhibit 1). For example, beneficiaries who were initially aligned with the ACO in 2012 were older than those aligned in 2013 (72.8 versus 72.1 years, respectively) but had lower risk scores (1.1 versus 1.2, respectively).

**EMERGENCY DEPARTMENT VISIT RATES** Exhibit 2 shows rates of visits to the ED associated with participation in the ACO and participation in the care management program, relative to the rates of nonparticipants (the relative rates for nonemergency ED visits are shown in online Appendix Exhibit A1).[20] Overall participation in the ACO was associated with lower ED visit rates, both for all ED visits (91 percent of the rates of nonparticipants) and for nonemergency visits (86 percent). As beneficiaries' length of participation in the ACO increased, the rate of ED visits—both overall and nonemergency visits—declined in stepwise fashion.

Overall participation in the care management program was also associated with reductions in ED visit rates: Participants' rates for all ED visits were 94 percent of the rates for nonparticipants and, for nonemergency visits, 88 percent (Exhibit 2 and Appendix Exhibit A1).[20] Additionally, having spent more time in the program was associated with greater reductions in ED visit rates.

**HOSPITALIZATION RATES** There was no significant association between overall ACO participation and hospitalization rates (Exhibit 3). However, there was a significant association between participation in the ACO for up to six months and an increase in hospitalization rates, as we originally hypothesized: Participants' overall hospitalization rates were 105 percent of the rates of nonparticipants. By month seven this associated increase became statistically indistinguishable from no change in hospitalization rates (data not shown).

Participants' rates for hospitalizations were 92 percent of the rates for nonparticipants. Again, hospitalization rates increased initially

**EXHIBIT 1**

**Baseline traits of Partners HealthCare System beneficiaries by year of ACO alignment and year of entry into the ACO's care management program, for those in the program**

| | Initial ACO alignment year | | Year of entry into the care management program | | |
|---|---|---|---|---|---|
| | 2012 | 2013 | 2012 | 2013 | 2014 |
| Number of beneficiaries | 42,417 | 19,649 | 2,143 | 1,917 | 760 |
| Mean age (years) | 72.8**** | 72.1**** | 74.3 | 74.5 | 74.8 |
| Female | 60.6% | 59.9% | 58.9%* | 62.4%* | 61.2%* |
| Race | | | | | |
| White | 89.0%**** | 89.0%**** | 89.1%**** | 86.1%**** | 93.6%**** |
| Black | 5.1 | 4.5 | 5.8 | 8.4 | 4.0 |
| Other | 5.9 | 6.5 | 5.1 | 5.5 | 2.5 |
| Eligible for Medicare based on age | 80.5%** | 79.7%** | 73.4%** | 70.8%** | 75.7%** |
| Mean CMS-HCC score | 1.1**** | 1.2**** | 2.4**** | 2.5**** | 2.6**** |
| Dually eligible for Medicare and Medicaid | 19.8%**** | 21.4%**** | 24.4%**** | 30.7%**** | 24.6%**** |

**SOURCE** Authors' analyses of Medicare alignment and claims data for Partners HealthCare System and of the accountable care organization's (ACO's) care management program data. **NOTES** For ACO participation, baseline refers to the initial alignment year. For participation in the care management program, baseline refers to the year of entry into the program. The Centers for Medicare and Medicaid Services–Hierarchical Condition Category (CMS-HCC) score is a diagnosis-based risk adjustment score that CMS uses for payment (range: 0.12–13.467). Significance refers to statistical significance of observed differences in either the initial ACO alignment year or the year of entry into the care management program. *$p < 0.10$ **$p < 0.05$ ***$p < 0.001$

after program entry and then declined in a stepwise fashion with increasing length of exposure. The increase was not significant, but the subsequent declines were.

**MEDICARE SPENDING** Overall participation in the ACO was associated with a reduction in Medicare spending of $14 per participant per month (Exhibit 4), a decline of 2 percent. This association was not significantly different from no change, but the magnitude of the decline was comparable to estimates in previous studies.[2,3] The associations between length of ACO participation and reduced Medicare spending were significant.

Overall participation in the care management program was associated with a reduction in Medicare spending of $101 per participant per month, a decline of 6 percent. The spending reductions increased with longer program exposure, in a stepwise fashion. All associations were significant except that between spending and program participation in the first six months.

## Discussion

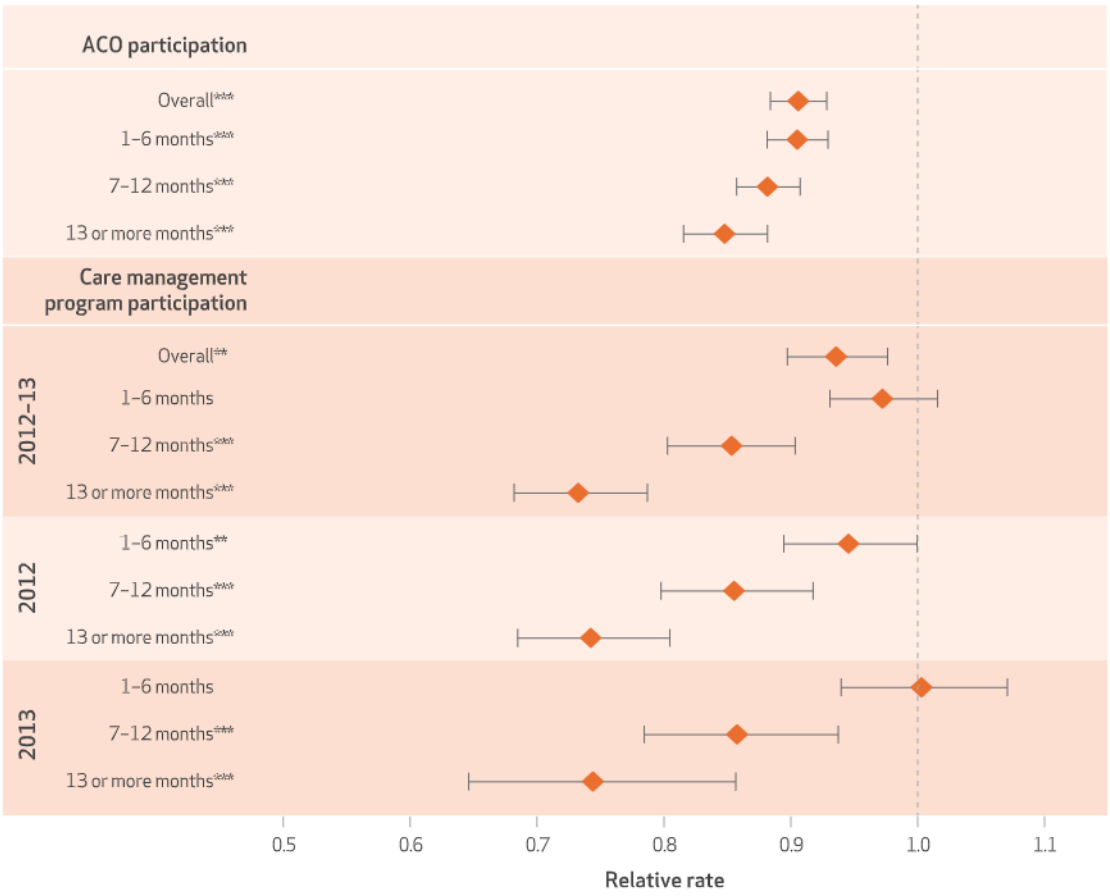
To our knowledge, this is the first detailed empirical examination of how a Pioneer ACO altered utilization and spending for its aligned Medicare beneficiaries. There were modest overall ACO spending reductions, with magnitudes comparable to those of all ACOs as described in other published reports and generally consistent with the assessment of the Partners ACO by CMS. For example, J. Michael McWilliams and coauthors found a 1.2 percent reduction in spending associated with joining an ACO,[2] David Nyweide and colleagues found a 3.8 percent reduction,[3] and the Government Accountability Office[21] and we found a 2 percent reduction. L&M Policy Research (as part of its contract with CMS) found a $20 reduction in spending per month,[22] compared to $14 in our study. Corroborating the findings of spending effects is critically important, as all studies of ACOs face major challenges in finding valid control groups for their analyses.

Our major overall finding is that participating in an ACO and a care management program lowered utilization and spending. The dose-response pattern further supports the validity of this finding: ED visits decreased relatively quickly, particularly for conditions amenable to outpatient care, while hospitalization rates increased initially before decreasing. The analyses also found similar statistically significant spending changes associated with overall ACO participation.

We found similar results for overall participation in the care management program and participation over time. There were sizable reductions in overall ED visits soon after program entry, particularly for conditions amenable to outpatient care. The reductions in hospitalization rates were associated with being in the program for a longer period of time but not with brief exposures to the program, as we originally hypothesized. Overall, this study's findings on the effects of care management were consistent

**EXHIBIT 2**

**Emergency department visit rates associated with participation in the Partners HealthCare System ACO and its care management program, overall and by length of participation**




**SOURCE** Authors' analyses of Medicare alignment and claims data for Partners HealthCare System and of the accountable care organization's (ACO's) care management program data. **NOTES** The exhibit shows the effects of participation in separate difference-in-differences models of ACO participation (overall and by number of months) and of care management program participation (for 2012–13: overall and by number of months; and for each year of eligibility by number of months of eligibility). The effects are shown as the differences between the changes over time in the rate of ED visits for participants once exposed to ACO (or care management program) participation and the changes over time in the rate for participants not exposed to participation. The error bars indicate 95 percent confidence intervals. Regressions included individual-level fixed effects (to isolate within-person changes) and adjusted for changes in risk scores and the year that the ACO identified the subject as being eligible for the care management program, thus exploiting the staggered program entry over time across subjects. $^{**}p < 0.05$ $^{***}p < 0.01$

with those of the Medicare Care Management for High Cost Beneficiaries Demonstration, which was the forerunner of the program we analyzed.[12]

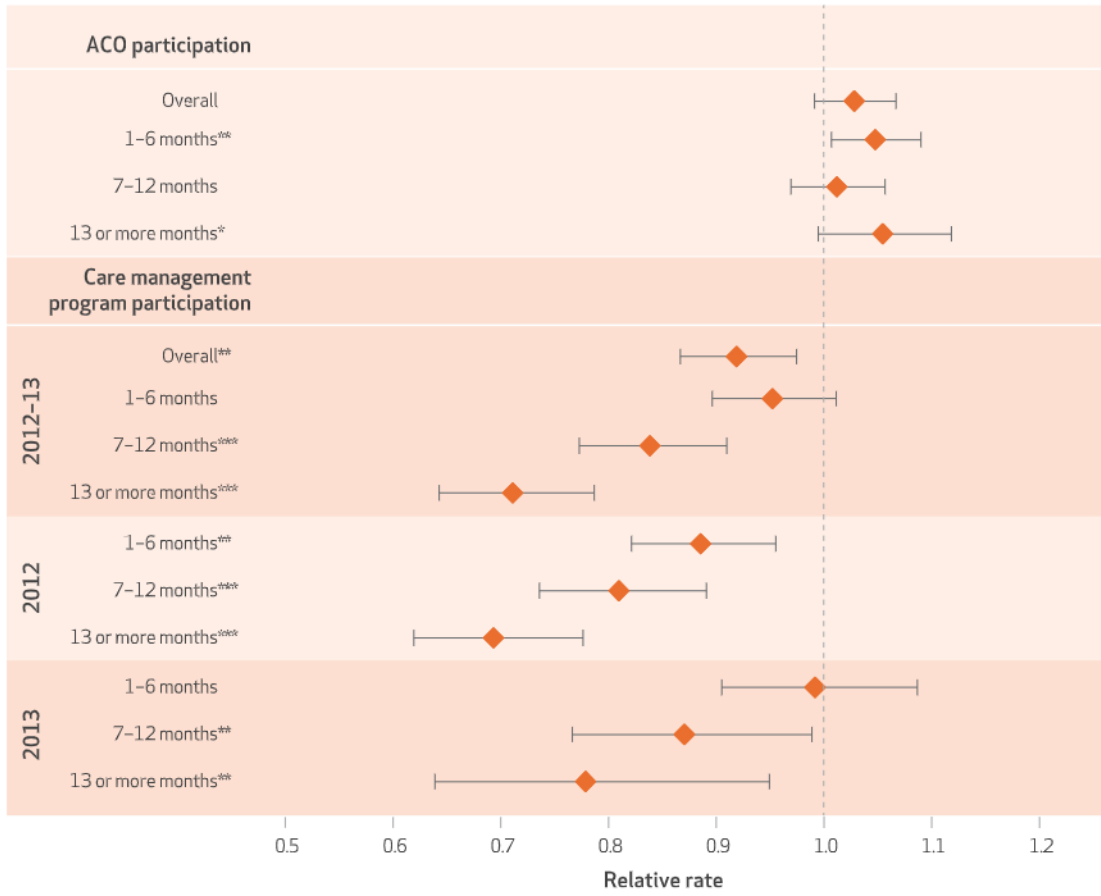
Our findings are promising for several reasons. First, they point toward a potential mechanism responsible for the national findings of reductions in spending growth associated with ACOs. Specifically, targeting beneficiaries with high risks that their primary care physicians believe are modifiable appears to be a viable strategy, as opposed to more diffuse strategies that target broader ACO populations.

Two components of the ACO were specifically designed to decrease visits to the ED: giving beneficiaries alternative ways to talk with providers when needed and encouraging beneficiaries to use lower-intensity sites of care, such as urgent care centers, when appropriate. The subsequent changes were not one-time cost shifts but changes in the site of care and reductions in use rates, which increased the likelihood that these changes will be sustainable over time.

Second, our findings provide evidence to support the expansion of successful programs. Even though one of the sites in this study had performed successfully in the Medicare Care Management for High Cost Beneficiaries Demonstration, there was initial uncertainty about whether the care management program could be expanded to some very different sites and remain effective. For example, several of the additional sites within the ACO included commu-

**EXHIBIT 3**

**Hospitalization rates associated with participation in the Partners HealthCare System ACO and its care management program, overall and by length of participation**



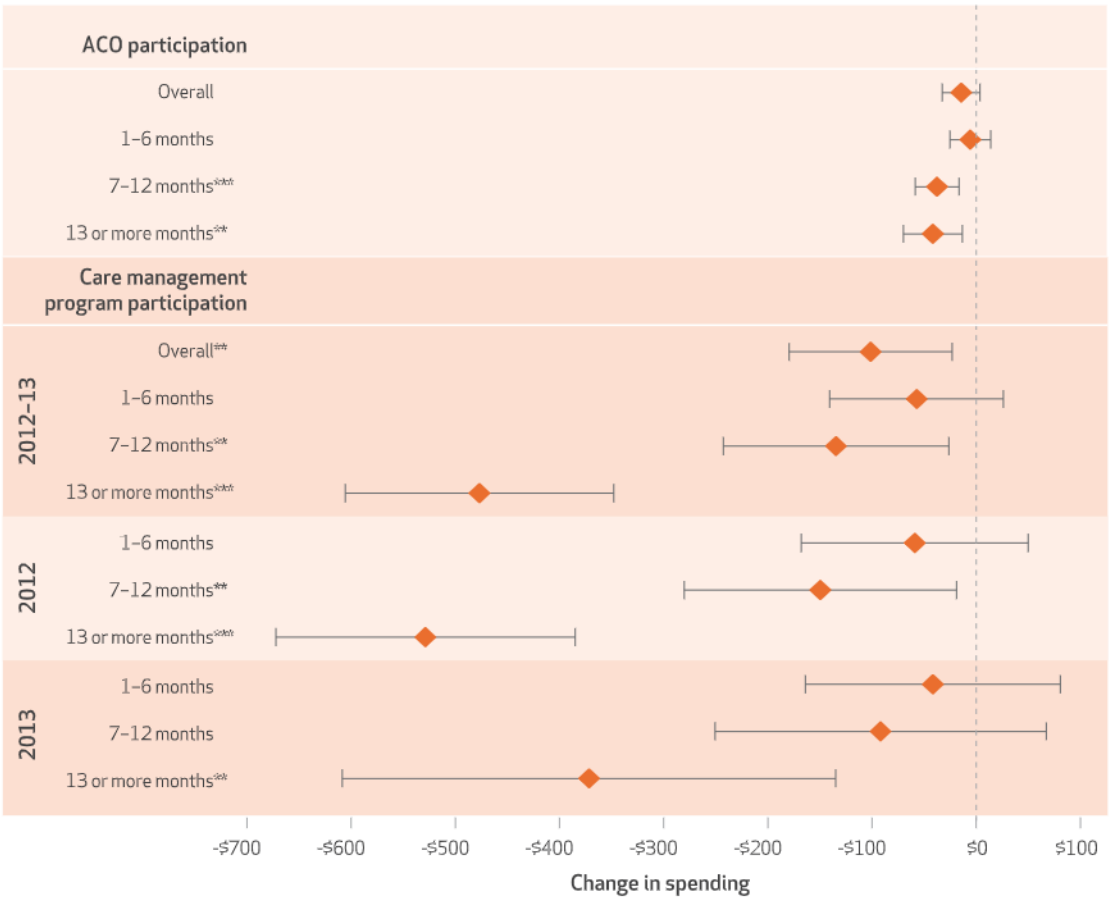

**SOURCE** Authors' analyses of Medicare alignment and claims data for Partners HealthCare System and of the accountable care organization's (ACO's) care management program data. **NOTES** The exhibit shows the effects of participation in separate difference-in-differences models of ACO participation (overall and by number of months) and of care management program participation (for 2012–13: overall and by number of months; and for each year of eligibility by number of months of eligibility). The effects are shown as the differences between the changes over time in the rate of hospitalizations for participants once exposed to ACO (or care management program) participation and the changes over time in the rate for participants not exposed to participation. The error bars indicate 95 percent confidence intervals. Regression details are in the Exhibit 2 Notes. *$p < 0.10$ **$p < 0.05$ ***$p < 0.01$

nity-based physicians affiliated with smaller hospitals that had different practice patterns and workflows, compared to the demonstration site. The Partners ACO's care management program was shown to be scalable. Scalability of programs, the next logical goal after efficacy, is particularly important as Medicare expects alternative payment models, including the ACO model, to account for 50 percent of all Medicare spending by 2018.[23]

Finally, our findings show that altering care delivery takes time. The early effects of both the ACO and the care management program were modest, with reductions in utilization and spending becoming larger with beneficiaries' greater exposure to the ACO or the program. In any given patient population, there will be a mixture of unmet needs and opportunities for efficiency. This implies that it could take time and investment before even efficacious programs achieve clinical or financial payoffs, particularly if there was substantial unmet need in the target population before the program started or if the clinical benefits take time to manifest themselves. This is important for Medicare as a whole, for ACOs that are making investment decisions, and for beneficiaries who ultimately bear most of the costs and receive most of the benefits. Previous work[14] has found a substantial amount of turnover within the ACO beneficiary population. Our findings reinforce the importance of using policy solutions to reduce population turnover, such as requiring beneficiaries to join ACOs (instead of simply being aligned with

**EXHIBIT 4**

**Changes in per participant monthly Medicare spending associated with participation in the Partners HealthCare ACO and its care management program, overall and by length of participation**




**SOURCE** Authors' analyses of Medicare alignment and claims data for Partners HealthCare System and of the accountable care organization's (ACO's) care management program data. **NOTES** The exhibit shows the effects of ACO participation, in separate difference-in-differences models of participation (overall and by number of months), and of care management program participation (for 2012–13: overall and by number of months; and for each year of eligibility by number of months of eligibility). The effects are shown as the differences between the changes over time in spending for participants once exposed to ACO (or care management program) participation and the changes over time in the rate for participants not exposed to participation. The error bars indicate 95 percent confidence intervals. Regression details are in the Exhibit 2 Notes. $^{**}p < 0.05$ $^{***}p < 0.01$

them) and remain there for minimum periods of time.

## Conclusion

The United States is in the midst of a large national experiment in which changes in payment policy are intended to alter the health care system and thereby reduce medical spending growth. Early findings (here and in the literature) suggest that ACOs can generate modest spending reductions, relative to what would have been spent without ACOs.[2,3] This study provides some evidence of how one large and successful Pioneer ACO appears to have achieved its stated savings—through an integrated care management program with narrowly targeted beneficiaries. Overall, our findings provide evidence of the effects of payment system changes that are still ongoing, while also demonstrating the importance of giving the changes time to take hold and show results over the long term. ■

The manuscript was originally presented as a late-breaking abstract at the AcademyHealth Annual Research Meeting, Boston, Massachusetts, on June 28, 2016. John Hsu, Mary Price, Christine Vogeli, Sreekanth Chaguturu, Eric Weil, and Timothy Ferris all work within the Partners HealthCare System, which has a large Pioneer ACO (Massachusetts General Hospital and Brigham and Women's Hospital are both part of the Partners HealthCare System).

## NOTES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# Hospital-Level Care at Home for Acutely Ill Adults: a Pilot Randomized Controlled Trial

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***BACKGROUND:*** Hospitals are standard of care for acute illness, but hospitals can be unsafe, uncomfortable, and expensive. Providing substitutive hospital-level care in a patient's home potentially reduces cost while maintaining or improving quality, safety, and patient experience, although evidence from randomized controlled trials in the US is lacking.
***OBJECTIVE:*** Determine if home hospital care reduces cost while maintaining quality, safety, and patient experience.
***DESIGN:*** Randomized controlled trial.
***PARTICIPANTS:*** Adults admitted via the emergency department with any infection or exacerbation of heart failure, chronic obstructive pulmonary disease, or asthma.
***INTERVENTION:*** Home hospital care, including nurse and physician home visits, intravenous medications, continuous monitoring, video communication, and point-of-care testing.
***MAIN MEASURES:*** Primary outcome was direct cost of the acute care episode. Secondary outcomes included utilization, 30-day cost, physical activity, and patient experience.
***KEY RESULTS:*** Nine patients were randomized to home, 11 to usual care. Median direct cost of the acute care episode for home patients was 52% (IQR, 28%; $p = 0.05$) lower than for control patients. During the care episode, home patients had fewer laboratory orders (median per admission: 6 vs. 19; $p < 0.01$) and less often received consultations (0% vs. 27%; $p = 0.04$). Home patients were more physically active (median minutes, 209 vs. 78; $p < 0.01$), with a trend toward more sleep. No adverse events occurred in home patients, one occurred in control patients. Median direct cost for the acute care plus 30-day post-discharge period for home patients was 67% (IQR, 77%; $p < 0.01$) lower, with trends toward less use of home-care services (22% vs. 55%; $p = 0.08$) and fewer readmissions (11% vs. 36%; $p = 0.32$). Patient experience was similar in both groups.
***CONCLUSIONS:*** The use of substitutive home-hospitalization compared to in-hospital usual care reduced cost and utilization and improved physical activity. No significant differences in quality, safety, and patient experience were noted, with more definitive results awaiting a larger trial.
**Trial Registration** NCT02864420.

*KEY WORDS:* home hospital; hospital at home; hospital alternative; home-based care.

J Gen Intern Med 33(5):729–36
DOI: 10.1007/s11606-018-4307-z


***Electronic supplementary material*** *The online version of this article (https://doi.org/10.1007/s11606-018-4307-z) contains supplementary material, which is available to authorized users.*

*Received May 8, 2017*
*Revised October 24, 2017*
*Accepted December 18, 2017*
*Published online February 6, 2018*

## INTRODUCTION

Hospitals are the standard of care for acute illness in the US, but hospital care is expensive and often unsafe, particularly for older individuals.[1] While admitted, 20% suffer delirium,[2] over 5% contract hospital-acquired infections,[3] and many lose functional status that is never regained.[4] Timely access to inpatient care is often poor: many hospital wards are typically over 100% capacity, and emergency department (ED) waits can be protracted. Moreover, hospital care is increasingly costly, accounting for about one-third of total medical expenditures, and is a leading cause of patient debt.[5]

A "home hospital" is home-based provision of acute services usually associated with the traditional inpatient hospital setting.[6] Prior work suggests home hospital care can reduce cost, maintain quality and safety, and improve patient experience for selected acutely ill adults who require traditional hospital-level care.[7–15] While home hospital care is familiar in several developed countries,[16] only two non-randomized studies have been conducted in the US.

We sought to demonstrate the cost, safety, quality, and patient experience of substitutive hospital-level care in the home through a pilot randomized controlled trial.

## METHODS

### Study Design

This investigator-initiated study was approved by the Partners HealthCare Human Research Committee as more than

minimal risk human subject research. It was registered at clinicaltrials.gov, record NCT02864420. All participants provided written informed consent. None of the study's commercial vendors participated in design, analysis, interpretation, preparation, review, or approval.

We performed a randomized controlled trial at Brigham and Women's Hospital (BWH, an academic medical center) and Brigham and Women's Faulkner Hospital (a community hospital) between September 12, 2016, and November 13, 2016. Faulkner hospital was added in the last 3 weeks of the study to increase sample size.

## Participants

Participants were recruited in the ED. Participants were initially pre-screened by a research assistant to ensure they were adults, were not presenting for trauma or psychiatric evaluation, and lived within our catchment area. After the decision by the ED attending was made to admit a patient, s/he would call the triage attending as per usual protocol to discuss admission. If the patient at hand met inclusion and had no exclusion criteria, and the ED attending was in agreement, then the admission could be held so the home hospital team could assess the patient for eligibility, interest, and consent (Fig. 1). The goal of enrollment was minimal disruption to the ED, for which we tracked various process measures (online eTable 1), demonstrating minimal delays in the ED because of the study protocol.

## Inclusion and Exclusion Criteria

Participants were eligible for home hospital if they resided within our catchment area, had capacity to consent, were 18 years old or older, and had a primary diagnosis of any infection, heart failure exacerbation, COPD exacerbation, or asthma exacerbation.

Participants were ineligible to enroll if they were undomiciled, lacked utilities, were in police custody, screened positive for domestic violence,[17] or resided in a facility that provided on-site medical care. Participants were also ineligible if peripheral intravenous access could not be obtained in the ED, they required routine administration of intravenous narcotics, they had an acute concomitant condition (e.g., hemorrhage), they could not independently ambulate to a bedside commode, or, as deemed by the home hospital attending, they were likely to require a procedure not available in the home hospital program (e.g., computed tomography, endoscopy, surgery). Patients were also excluded if they were considered at high risk for clinical deterioration based on already validated general and disease-specific risk algorithms (online eAppendix 1). No exclusion was made based on insurance status.

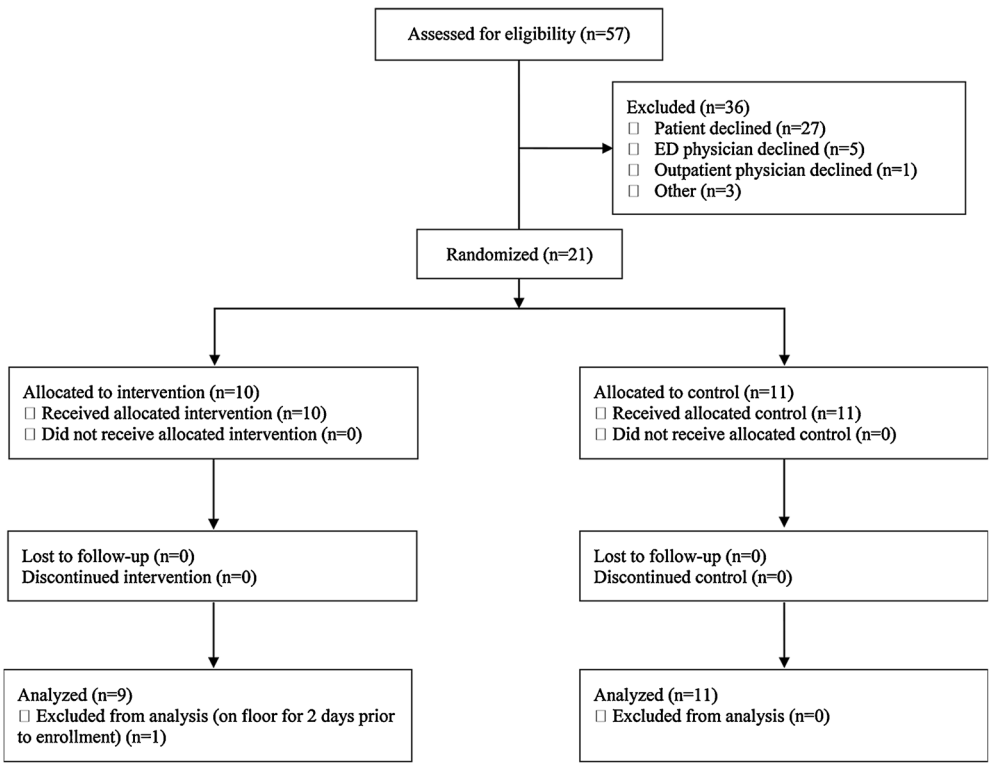


**Fig. 1 Participant flow. The Consolidated Standards of Reporting Trials flow diagram. One patient in the home group was excluded from analysis. This patient was a pre-specified "n of one" attempt at a separate model of early transfer to home hospital after stabilization in the traditional hospital**

**Table 1 Baseline Patient Characteristics**

| | Home ($n = 9$) | Control ($n = 11$) | p* |
|---|---|---|---|
| Age, years, median (IQR) | 65 (28) | 60 (29) | 0.49 |
| Female, n (%) | 2 (22) | 8 (73) | 0.07 |
| Race/ethnicity, n (%) | | | 0.84 |
| White | 4 (44) | 5 (45) | |
| Latino | 4 (44) | 3 (27) | |
| Black | 1 (11) | 3 (27) | |
| Partner status, n (%) | | | 0.41 |
| Partnered | 5 (56) | 6 (55) | |
| Divorced/widowed | 3 (33) | 3 (27) | |
| Single | 1 (11) | 2 (18) | |
| Primary language, n (%) | | | 0.62 |
| English | 6 (67) | 9 (82) | |
| Spanish | 3 (33) | 2 (18) | |
| Insurance, n (%) | | | 0.17 |
| Private | 6 (67) | 3 (27) | |
| Medicare | 3 (33) | 5 (45) | |
| Medicaid | 0 | 3 (27) | |
| Education, n (%) | | | 0.06 |
| > 4-year college | 3 (33) | 1 (9) | |
| 4-year college | 1 (11) | 6 (55) | |
| < 4-year college | 1 (11) | 3 (27) | |
| High school | 1 (11) | 1 (9) | |
| < High school | 3 (33) | 0 | |
| Employment, n (%) | | | 0.33 |
| Employed | 5 (56) | 4 (36) | |
| Unemployed | 0 | 3 (27) | |
| Retired | 4 (44) | 4 (36) | |
| Cigarette smoking, n (%) | | | 0.55 |
| Never | 4 (44) | 3 (27) | |
| Current | 0 | 2 (18) | |
| Prior | 5 (56) | 6 (55) | |
| PRISMA (0–7), median (IQR) | 2 (1) | 3 (3) | 0.86 |
| Ascertain dementia-8 (0–8), median (IQR) | 0 (0) | 1 (3) | 0.08 |
| Health literacy (4–20), median (IQR)† | 20 (7) | 18 (10) | 0.57 |
| Medication count, median (IQR) | 8 (13) | 10 (14) | 0.93 |
| Comorbidity count, median (IQR)‡ | 7 (7) | 6 (7) | 0.14 |
| Code status: Full code, n (%) | 6 (67) | 10 (91) | 0.28 |
| Yes, surprised if died in 1 year, n (%) | 5 (56) | 8 (73) | 0.64 |
| EuroQol VAS (0–100), median (IQR) | 75 (10) | 65 (25) | 0.05 |
| ADLs (0–6), median (IQR) | 6 (0) | 5 (2) | 0.07 |
| IADLs (0–8), median (IQR) | 8 (2) | 5 (5) | 0.34 |
| PHQ-2 (0–6), median (IQR) | 0 (0) | 2 (4) | 0.04 |
| PROMIS emotional support (4–20), median (IQR) | 20 (2) | 20 (1) | 0.93 |
| Hospital admission in last 6 months, n (%) | 4 (44) | 4 (36) | 1 |
| Emergency department visit in last 6 months, n (%) | 5 (56) | 3 (27) | 0.36 |

*Abbreviations: ADLs, activities of daily living; IADLs, instrumental activities of daily living; IQR, interquartile range; PHQ-2, Patient Health Quesitonnaire-2 (measure of depression); PRISMA, Program of Research to Integrate Services for the Maintenance of Autonomy (measure of frailty); PROMIS, Patient-Reported Outcomes Measurement Information System; VAS, visual analog scale*

**Wilcoxon rank-sum test for continuous variables and Fisher exact test for categorical variables*

*†Brief health literacy screener, 4–12: limited; 13–16: marginal; 17–20: adequate*

*‡Count of patient's chronic comorbidities*

## Randomization

After meeting criteria and providing written informed consent, participants were randomized to usual care admission or home hospital admission by research study staff. Randomization was stratified by condition with randomly selected block sizes between 4 and 6 with allocation concealment via sealed envelopes. Given the nature of the study, blinding of patients, study staff, and physicians was not possible.

## Intervention

All patients received at a minimum one daily visit from an attending general internist and two daily visits from a home health registered nurse, with additional visits performed as needed. Also tailored to patient need, participants could receive medical meals and the services of a home health aide, social worker, physical therapist, and/or occupational therapist.

Home hospital could provide oxygen therapy, respiratory therapies (e.g., nebulizer), intravenous medications via infusion pump (Smiths Medical, St. Paul, MN), in-home radiology, and point-of-care blood diagnostics. All patients had continuous monitoring of heart rate, respiratory rate, telemetry, movement, falls, and sleep via a small skin patch (physIQ, Chicago, IL; VitalConnect, San Jose, CA). Monitoring was performed through machine-based algorithms, and clinical staff reviewed any alarms produced by these algorithms as part of their clinical care. Participants communicated with their home hospital team via telephone, encrypted video, and encrypted short message service (Everbridge, Burlington, MA). The physician was available 24 hours a day for urgent issues and visits. Criteria for discharge were by design left to the discretion of the home hospital attending. We mandated no treatment pathways or algorithms. Follow-up after discharge was by design no different than usual care.

Participants randomized to the control group received usual care in the hospital, also from an attending general internist, with the addition of the aforementioned skin patch (placed while in the ED). Hospital staff was unaware of the patch's purpose.

## Data Sources and Outcomes

For both groups, we interviewed patients on admission, at discharge, and at 30-days post-discharge. On admission, patients reported their sociodemographics (Table 1) and completed assessments of frailty (PRISMA-7; > 2 indicates frailty),[18] cognitive impairment (Ascertain Dementia-8; > 1 indicates cognitive impairment),[19] depression (Patient Health Questionnaire-2; > 2 indicates depression),[20] emotional support (PROMIS Emotional Support 4a; > 17 indicates better than average support),[21] health literacy (BRIEF health literacy screening tool; > 17 indicates adequate literacy),[22] quality of life (EuroQol Visual Analogue Scale),[23] and functional status scores [activities of daily living (ADLs) and instrumental activities of daily living (IADLs)]. We supplemented sociodemographic data with the hospitals' electronic health record (EHR) for items such as insurance status.

Our primary outcome was direct cost of the acute care episode, calculated as the sum of non-physician labor, supplies, monitoring equipment, medications, labs,

radiology, and transport directly attributed to the patient's care (online eAppendix 2). Both groups used an identical cost calculation, except for transport (not applicable to the hospital group) and non-physician labor. In the home group, we multiplied non-physician labor hours by the hourly direct rate to obtain cost; in the control group, we multiplied non-physician labor hours by the hourly unit-based direct rate (this is our institution's best-practice in estimating labor and derived directly from their internal accounting system). Administrative costs are considered indirect costs and were not included.

We did not include physician labor because this is customarily separate from traditional hospital costs, and BWH does not utilize a direct care model such as home hospital (e.g., physicians at BWH always work with residents or physician assistants). The attending physician-to-patient ratios for home hospital and BWH are capped at 1:4 and 1:16, respectively. However, the BWH attending physician is assisted by 3 daytime and 2 night-time residents, in effect requiring more physicians per patient than in home hospital. In addition, at nearby academic medical centers that do have direct care models (i.e., no resident or mid-level provider assistance), attendings typically see eight patients and still require overnight attending coverage.

We secondarily studied utilization, safety, quality, and patient experience during the acute care episode. Utilization measures included laboratory orders, radiology studies, consultations, and length of stay, all derived from the EHR (Table 2). Safety measures included adverse events (e.g., falls and standard hospital-acquired conditions), delirium (captured by the Confusion Assessment Method,[2] already documented every 8 h at BWH as part of usual care), and the unexpected return to hospital rate (intervention arm only; Table 3). Quality measures included pertinent Center for Medicare and Medicaid Services (CMS) inpatient quality measures (e.g., angiotensin-converting enzyme inhibitor in a patient with heart failure of reduced ejection fraction), pain scores, physical activity [exertion (any movement at least as vigorous as slow walking, 0.02 g's), steps, and upright posture], and sleep. All measures were derived from the EHR, except falls, physical activity, and sleep, which were observed via the skin patch. We considered hospital-acquired disability to be any reduction in a patient's ADLs or IADLs between admission and discharge.[24] Patient experience measures included the Care Transitions Measure (CTM) 3, Picker patient experience questionnaire,[25] recommending the hospital experience, and global experience (Table 4). Experience measures were recorded during the 30-day interview.

We additionally measured cost and utilization in the 30-day post-discharge period using the same cost-accounting method. We tracked readmissions, ED visits, primary care visits, and specialist visits. As we only had access to records from Partners HealthCare (the health system that includes BWH), we asked participants whether they received any health care outside of our health system and added those to the cost estimates. This occurred in only two patients who received a single primary care visit each outside of Partners.

**Table 2 Patient Utilization**

| Measure | Home (n = 9) | Control (n = 11) | p* |
|---|---|---|---|
| Length of stay, median days (IQR) | 3 (1) | 3 (3) | 0.79 |
| IV medication during admission, n (%) | 6 (67) | 9 (82) | 0.62 |
| Imaging during admission, n (%) | 1 (11) | 5 (45) | 0.16 |
| Consultant session during admission, n (%) | 0 (0) | 5 (45) | 0.04 |
| Lab orders per admission, median (IQR) | 6 (6) | 19 (22) | < 0.01 |
| PT/OT session during admission, n (%) | 1 (11) | 3 (27) | 0.59 |
| Disposition, n (%) | | | 0.08 |
| Routine | 7 (78) | 5 (45) | |
| Home Health | 2 (22) | 6 (55) | |
| Primary care visit by 14 days post-discharge, n (%) | 7 (78) | 4 (36) | 0.09 |
| 30-day readmission, n (%) | 1 (11) | 4 (36) | 0.32 |
| 30-day ED presentation, n (%) | 1 (11) | 2 (18) | 1 |

*Wilcoxon rank-sum test for continuous variables and Fisher exact test for categorical variables*
*Abbreviations: ED, emergency department; IV, intravenous; OT, occupational therapy; PT, physical therapy*

**Table 3 Patient Safety**

| Measure, n (%) | Home (n = 9) | Control (n = 11) |
|---|---|---|
| Fall | 0 (0) | 0 (0) |
| Delirium | 0 (0) | 0 (0) |
| DVT/PE | 0 (0) | 0 (0) |
| New pressure ulcer | 0 (0) | 0 (0) |
| Thrombophlebitis at peripheral IV site | 0 (0) | 0 (0) |
| CAUTI | 0 (0) | 0 (0) |
| Clostridium difficile | 0 (0) | 0 (0) |
| New MRSA | 0 (0) | 0 (0) |
| New arrhythmia | 0 (0) | 0 (0) |
| Hypokalemia | 0 (0) | 0 (0) |
| Acute kidney injury | 0 (0) | 1 (9) |
| Transfer back to hospital | 0 (0) | n/a |
| Mortality during admission | 0 (0) | 0 (0) |
| > 3 medications added to medication list | 0 (0) | 1 (9) |
| 30-day mortality | 0 (0) | 0 (0) |

*Abbreviations: CAUTI, catheter-associated urinary tract infection; DVT/PE, deep venous thromboembolism/pulmonary embolism; IV, intravenous; MRSA, methicillin-resistant Staphylococcus aureus; n/a, not applicable*

## Sample Size Considerations

From previous quasi-experimental data, home hospital reduced the payer (not provider) cost of admission by 20–30% with baseline payments of $7480 (SD $8112).[7, 8] To achieve at least 80% power with a type I error rate of 5%, we required 30 patients per arm to detect a 60% relative reduction in costs. While this was an optimistic effect size based on the literature,

**Table 4 Quality, Physical Activity, and Experience**

| Measure | Home (n = 9) | Control (n = 11) | p* |
|---|---|---|---|
| Quality of care† | | | |
| Pain score (0–10), median (IQR) | 1.5 (4) | 1.4 (4.9) | 1 |
| Inappropriate medication use, n (%) | 0 (0) | 1 (9) | 1 |
| Foley use, n (%) | 0 (0) | 0 (0) | 1 |
| Restraint use, n (%) | 0 (0) | 0 (0) | 1 |
| Activity each day | | | |
| Physical activity, minutes, median (IQR) | 209 (90) | 78 (44) | < 0.01 |
| Sleep, hours, median (IQR) | 5.4 (1.9) | 4.1 (3.0) | 0.33 |
| Steps, median (IQR)‡ | 1820 (3300) | 159 (508) | 0.06 |
| Upright posture, hours, median (IQR) | 4.8 (1.4) | 2.7 (1.8) | < 0.01 |
| Patient experience | | | |
| Care transitions measure-3 (3–12), median (IQR) | 12 (0) | 12 (3) | 0.21 |
| Picker questionnaire (0–15), median (IQR) | 15 (4) | 13 (4) | 0.18 |
| Global satisfaction (0–10), median (IQR)§ | 10 (1) | 10 (2) | 0.67 |
| Recommend hospital (0–4), median (IQR)‖ | 4 (0) | 4 (0) | 1 |

*Abbreviations: ADLs, activities of daily living; ED, emergency department; IADLs, instrumental activities of daily living; IQR, interquartile range; IV, intravenous; OT, occupational therapy; PT, physical therapy*

**Wilcoxon rank-sum test for continuous variables and Fisher exact test for categorical variables*

*†Standard inpatient quality measures for pneumonia and heart failure (e.g., beta blocker for heart failure with reduced ejection fraction, smoking cessation counseling) were achieved equally in both groups and are omitted because of space constraints*

*‡Two older patients in the home group shuffled while walking, resulting in a step count of almost zero being registered. These outliers drove the large IQR*

*§Scale: 0 = the worst possible hospital; 10 = the best possible hospital*

*‖Scale: 0 = definitely would not recommend; 4 = definitely would recommend*

we anticipated smaller variance based on our local data and randomized design.

We had limited funding and could only continue our pilot for at most 2.25 months. Thus, irrespective of enrollment, we a priori planned to stop the pilot when funds were depleted.

## Statistical Methods

Given our small sample size and, in the case of cost, skewed data, we used non-parametric tests to compare home hospital and usual care, presenting results as median and interquartile range (IQR). We compared characteristics of participants in both groups with the Wilcoxon rank-sum test for continuous variables and the Fisher exact test for dichotomous and categorical variables. We present cost data as percent change from control given the sensitive nature of these data.

All tests for significance used a two-sided $p$ value of 0.05. We performed all analyses in SAS v9.4 (Cary, NC, USA).

# RESULTS

## Patient Characteristics

A total of 57 patients were assessed for entry into the study; 21 were enrolled and randomized (Figure; details of those declined/lost, online eTable 2). Twenty-seven patients declined enrollment; six physicians declined to allow their patients to enroll. All patients enrolled received their allocated treatment and were followed until 30-days post discharge. One patient in the home group was excluded from analysis. This patient was a pre-specified "n of one" attempt at a separate model of early transfer to home hospital after stabilization in the traditional hospital. As a result, this patient had been in the hospital for 2 full days prior to enrollment. While we learned valuable lessons about this model, this patient is not comparable to the other home hospital patients.

The nine patients randomized home had a median age of 65 years (IQR, 28), 22% were female, 44% White, and 56% partnered (Table 1). Most (67%) spoke English as their primary language, 67% had private insurance, 56% were employed, and 33% had less than a high school education. The 11 patients randomized to control were not statistically different, although they trended toward younger (median age 60 years [IQR 29]), more often female (73%), more English-speaking (82%), less privately insured (27%), more educated (55% with college degree), and more unemployed (27%).

Patients' clinical characteristics were similar between groups (Table 1). In the home group, patients had mild frailty (2/7 [IQR, 2]), unlikely dementia and depression (AD-8 0/8 [IQR, 0], PHQ2 0/6 [IQR, 0]), excellent functional status (ADLs 6/6 [IQR, 0] and IADLs 8/8 [IQR, 2]), high health literacy (19.5 [IQR, 7]), and excellent social support (20/20 [IQR, 2]). Patients reported moderately high quality of life (75/100 [IQR, 10]. Patients in the control group had significantly more depression.

Despite reassuring self-reported characteristics, patients in both groups were chronically ill and frequently used care. In the last 6 months, 44% of home group patients had been admitted; 56% had visited the ED. Home group patients had seven (IQR, 7) chronic comorbidities and took eight (IQR, 13) chronic medications.

## Cost and Utilization

Median direct cost of the acute care episode for home patients was 52% (IQR, 28%; $p = 0.05$) lower than for control patients.

Median length of stay was 3.0 days in both groups ($p = 0.8$; Table 2). During the care episode, home patients had fewer laboratory orders (6 vs. 19; $p < 0.01$) and received consultations less often (0% vs. 27%; $p = 0.04$), with a trend toward less imaging. Each day, home patients received a median of one physician visit (range: 1 to 3) and two nurse visits (range: 2 to 4).

Median direct costs for the acute care plus 30-day post-discharge period for home patients was 67% (IQR, 77%; $p < 0.01$) lower, with non-significant trends toward less use of home health services, fewer readmissions, and improved follow-up with their primary care clinicians within 14 days of discharge (Table 2).

## Safety, Quality, and Activity

No adverse safety events and no transfers back to hospital occurred in home patients (Table 3). One control patient had nosocomial acute kidney injury. Neither group used indwelling urinary catheters or restraints.

Pain scores were similar in both groups (Table 3). Both groups were similarly provided pneumococcal vaccination, influenza vaccination, smoking cessation counseling, and the CMS heart failure measures (e.g., beta blocker for heart failure with reduced ejection fraction) when applicable.

Home patients had more minutes of physical activity per day (median minutes, 209 [IQR, 90] vs. 78 [IQR, 44]; $p < 0.01$), spent more time upright (median hours per day, 4.8 [IQR, 1.4] vs. 2.7 [IQR, 1.8]; $p < 0.01$), and had a trend toward more sleep (Table 4).

There was a trend toward more hospital acquired disability in the control group: ADLs and IADLs were respectively worse at discharge in 9% and 18% of the control group vs. 0% and 0% of the home group.

## Patient Experience

Patients in the home and control group reported high global satisfaction and would always recommend their experience to others (Table 4). Home patients had a trend toward better Picker experience scores.

# DISCUSSION

In this small two-site pilot study, providing care to acutely ill adults at home compared to the traditional hospital reduced cost, decreased utilization, and improved physical activity, without appreciably changing quality, safety, or patient experience. We also observed trends toward reduced hospital-acquired disability, readmission, and disposition to home health services among home hospital patients.

The goal of the home hospital model is to get the "right care to the right patient at the right time." Home hospital reduces cost, for example, because it reduces nursing labor (similar patient:nurse ratio, but 2 visits at home versus 24 h care in the hospital), reduces utilization (fewer laboratory draws and consultations), likely improves follow-up with primary care, and possibly reduces readmission (online eAppendix 2 for cost details). It delivers care in a more patient-centered manner: patients can be surrounded by their family and friends, eat their own food, move around in their own home, and sleep in their own bed, with the supports of the home hospital team. The home is also an ideal place to empower patients and caregivers around self-management during and after the episode. Performing medication reconciliation with the medicine cabinet in sight and dietary education in a patient's kitchen are powerful touch points. Discharge without home health or in a timely manner was also likely facilitated, as the home hospital team had greater confidence in a patient's ability to function at home because they were already in the home setting.

To our knowledge, this is the first randomized controlled trial of home hospital performed in the US. Importantly, what constitutes a "home hospital" is highly variable both nationally and internationally.[26, 27] Our model involves a physician in the home, delivers twice-daily nurse visits and 24-h physician coverage, provides acute care similar to that received in a traditional hospital to acutely ill patients who otherwise would have been admitted, and offers cutting edge connectivity (continuous monitoring, video, and texting). This differs from most home-based models in its ability to handle high patient acuity and enmesh physician medical decision-making with a patient-tailored care team. Careful patient selection also minimized risk.

Previous work corroborates our findings. Others providing substitutive care to acutely ill patients have shown reduced cost (20–30%) and decreased utilization, all while maintaining or improving on quality, safety, and patient experience.[7, 8] Two randomized controlled trials in Italy for patients presenting with COPD and heart failure exacerbations echo these findings and demonstrated reductions in readmission.[9, 28] An older randomized controlled trial in Australia found a 51% reduction in cost.[13, 29] Our findings regarding physical activity build on other work.[15, 24] Our study included patients of a somewhat younger median age than others.

Our study has limitations. First, our small sample size resulted in unequal groups and insufficient ability to adjust for some clinically important differences between them. In a larger trial, we would expect these differences to be decreased. Second, the small sample size left us underpowered to detect significant differences for many of our secondary outcomes. However, this study was designed as a pilot, and it is notable that even with our small sample size we were able to detect statistically significant differences in our primary outcome and several secondary outcomes because of the large effect sizes. Third, we only recruited from two, albeit distinct sites, limiting generalizability. For example, our cost calculations may be less valid at an institution with different staffing structures and patient to clinician ratios. Fourth, 63% of patients declined to participate, approximately the inverse of prior work (online eTable 2).[7] This was likely due to our robust randomization scheme, which only allowed us to approach patients just

before "rolling upstairs," a time when most patients had already mentally prepared for traditional admission. It may also be reflective of a patient culture that is not yet comfortable with home hospitalization. On the other hand, this approach greatly minimized selection bias between the enrolled patients in the two arms of the study.

## CONCLUSIONS

Despite important incremental improvements in traditional hospitals, the structure and care delivered are still very reminiscent of hospitals 50 years ago. Some hospital structures have persisted for over 100 years. Reimagining the best place to care for select acutely ill adults holds enormous potential.

This randomized controlled pilot of substitutive home hospital care demonstrates improvements in cost, utilization, and physical activity while likely maintaining quality, safety, and experience, with more definitive results awaiting a larger trial.

***Acknowledgements:*** *The authors would like to acknowledge the home hospital clinicians who cared for the home hospital patients. The authors also graciously acknowledge the various departments at Brigham Health who were instrumental to the success of the home hospital program: Cardiology, Emergency Medicine, General Internal Medicine and Primary Care, Hospital Medicine, Pharmacy, Laboratory, and Population Health.*

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***Compliance with Ethical Standards:***

***Prior Presentations:*** *Society of General Internal Medicine—national conference; Washington, DC, 2017. Awarded Lipkin Award.*

***Conflicts of Interest:*** *The authors declare that they do not have a conflict of interest.*

***Financial Support:*** *Partners HealthCare Population Health Management provided funding support for the home hospital clinical program. Dr. Levine received funding support from an Institutional National Research Service Award from (T32HP10251) and the Ryoichi Sasakawa Fellowship Fund.*
*The NIH had no role in the design and conduct of the study; the collection, management, analysis, and interpretation of the data; or the preparation, review, or approval of the manuscript.*

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Annals of Internal Medicine ORIGINAL RESEARCH

# Hospital-Level Care at Home for Acutely Ill Adults

## A Randomized Controlled Trial

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**Background:** Substitutive hospital-level care in a patient's home may reduce cost, health care use, and readmissions while improving patient experience, although evidence from randomized controlled trials in the United States is lacking.

**Objective:** To compare outcomes of home hospital versus usual hospital care for patients requiring admission.

**Design:** Randomized controlled trial. (ClinicalTrials.gov: NCT03203759)

**Setting:** Academic medical center and community hospital.

**Patients:** 91 adults (43 home and 48 control) admitted via the emergency department with selected acute conditions.

**Intervention:** Acute care at home, including nurse and physician home visits, intravenous medications, remote monitoring, video communication, and point-of-care testing.

**Measurements:** The primary outcome was the total direct cost of the acute care episode (sum of costs for nonphysician labor, supplies, medications, and diagnostic tests). Secondary outcomes included health care use and physical activity during the acute care episode and at 30 days.

**Results:** The adjusted mean cost of the acute care episode was 38% (95% CI, 24% to 49%) lower for home patients than control patients. Compared with usual care patients, home patients had fewer laboratory orders (median per admission, 3 vs. 15), imaging studies (median, 14% vs. 44%), and consultations (median, 2% vs. 31%). Home patients spent a smaller proportion of the day sedentary (median, 12% vs. 23%) or lying down (median, 18% vs. 55%) and were readmitted less frequently within 30 days (7% vs. 23%).

**Limitation:** The study involved 2 sites, a small number of home physicians, and a small sample of highly selected patients (with a 63% refusal rate among potentially eligible patients); these factors may limit generalizability.

**Conclusion:** Substitutive home hospitalization reduced cost, health care use, and readmissions while increasing physical activity compared with usual hospital care.

**Primary Funding Source:** Partners HealthCare Center for Population Health and internal departmental funds.

*Ann Intern Med.* 2020;172:77-85. doi:10.7326/M19-0600 **Annals.org**
For author affiliations, see end of text.
This article was published at Annals.org on 17 December 2019.

Hospitals are the standard of care for acute illness in the United States, but inpatient care is expensive—accounting for about one third of total medical expenditures (1)—and may be unsafe, particularly for older persons (2). Timely access to inpatient care is often poor: Hospital wards are typically at capacity, and average emergency department (ED) waits can be more than 6 hours (3). After hospital discharge, many patients have "posthospital syndrome," due in part to such factors as deconditioning and sleep deprivation (4), and almost 20% of Medicare patients are readmitted within 30 days of discharge (5).

A "home hospital" is the home-based provision of acute care services usually associated with the traditional inpatient hospital (6). Prior work suggests that home hospital care can reduce cost, maintain quality and safety, and improve patient experience for selected acutely ill adults who require traditional hospital-level care (7–16). Home hospital care is already provided in several developed countries, such as Australia and Spain (17, 18), but few nonrandomized studies have been done in the United States (7, 8, 16). We published the first pilot randomized controlled trial in the United States (19). Given the strong potential for confounding and bias in nonrandomized evaluations of substitutive care, we sought to strengthen the evidence base by replicating our prior trial with more patients.

## METHODS

### Design Overview

We performed a parallel-design, randomized controlled trial in which participants were randomly allocated to home hospital care (intervention) or traditional hospital care (control). We enrolled participants between 12 June 2017 and 16 January 2018; follow-up ended on 17 February 2018. Patients, study staff, and physicians were not blinded to allocation status. This internally funded study was stopped early (after enrolling 91 patients) in light of local operational needs to quickly increase home hospital capacity after positive interim outcomes were presented to hospital leadership. The trial protocol (**Supplement**, available at Annals.org) was approved by the Partners HealthCare institutional review board and registered at ClinicalTrials.gov (NCT03203759). All participants provided written informed consent before randomization.

### Setting and Participants

Adult participants were recruited in the ED at Brigham and Women's Hospital (an academic medical

**See also:**

Editorial comment . . . . . 145

*Web-Only*
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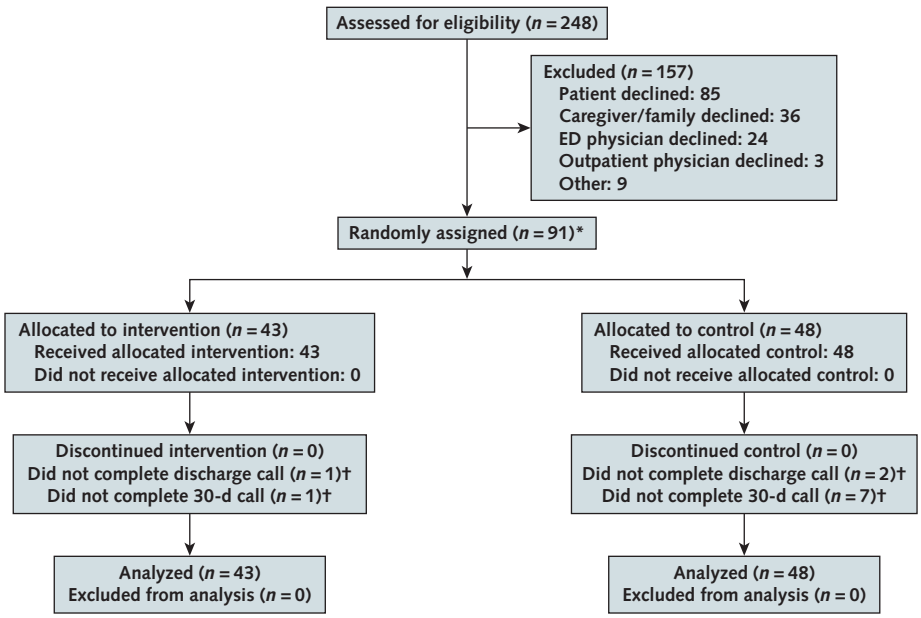
***Figure.*** Study flow diagram.




ED = emergency department.
* Enrollment was stopped after 91 patients (76% of intended) were enrolled.
† Not completing a discharge call required estimation of postdischarge health care use through the electronic health record and incurred missing values for patient experience measures.

center) and Brigham and Women's Faulkner Hospital (a community hospital). A research assistant prescreened patients to ensure that they were not presenting for trauma or psychiatric evaluation and did not live outside the catchment area. After the ED attending physician decided to admit a patient, he or she would call the triage hospitalist as per usual protocol. If these physicians agreed that the patient met preliminary inclusion criteria, the home hospital team assessed the patient for eligibility, interest, and consent (Figure). All hospital-based attending physicians received education on the trial and its inclusion criteria. One goal of enrollment was minimal disruption to the ED; our tracking of various process measures (Appendix Table 1, available at Annals.org) showed minimal delay in the ED due to the intervention.

Participants were eligible for home hospital care if they resided within a 5-mile catchment area; had the capacity to consent (or could assent with the consent of a health care proxy who was physically present); were aged 18 years or older; and had a primary diagnosis of any infection, heart failure exacerbation, chronic obstructive pulmonary disease exacerbation, asthma exacerbation, or selected other conditions (Appendix Table 2, available at Annals.org). Patients were excluded if they resided in a long-term care or rehabilitation facility, required routine administration of controlled substances, required more than the assistance of 1 person to reach a bedside commode, or were considered to be at high risk for clinical deterioration on the basis of validated general and disease-specific risk algorithms (Appendix Table 2). Patients were not excluded on the basis of insurance status or living alone.

## Randomization and Interventions

Eligible participants who provided informed consent were randomly assigned to usual care or home hospital by study staff. Randomization was stratified by infection, heart failure, chronic obstructive pulmonary disease or asthma, and other diagnosis; block sizes between 4 and 6 were randomly selected, and allocation was concealed via sealed opaque envelopes. An outside statistician generated the randomization using SAS (SAS Institute).

All patients received at least 1 daily visit from an attending general internist and 2 daily visits from a home health registered nurse (Partners HealthCare at Home), with additional visits as needed. If necessary, participants could receive medical meals (Community Servings, Boston, Massachusetts) and the services of a home health aide, social worker, physical therapist, or occupational therapist (Partners HealthCare at Home). Selected specialists could be consulted via telemedicine as needed. Eight nurses (7 women; mean experience, 15 years) worked the week's day shifts. Five general internists (2 women; mean time since residency, 1 year; 3 were hospitalists at Brigham and Women's Hospital) rotated on 7-day shifts. Training involved a 1-day didactic course and several days of shadowing physicians experienced in home medicine.

The home hospital service could provide respiratory therapies (such as oxygen), intravenous medications via infusion pump (Smiths Medical), in-home radiology, and

point-of-care blood diagnostics (Abbott Laboratories). All patients had continuous monitoring of temperature, heart rate, respiratory rate, telemetry, movement, and falls via a small skin patch (VitalConnect). This monitoring was done through machine-based algorithms, which produced alarms for review by both nurse and physician (delivered to their smartphones). Participants communicated with their home hospital team via telephone, encrypted video, and encrypted short message service (Everbridge). The home hospital attending physician was available 24 hours a day for urgent issues and visits. He or she made decisions about when patients were ready to be discharged and postdischarge plans. We did not mandate the use of treatment pathways or algorithms for the home hospital group.

Participants randomly assigned to the control group received usual care in the hospital from an attending general internist (usually a hospitalist) or cardiologist. These physicians typically worked a 7- to 14-day rotation with additional coverage from residents or physician assistants during the day and night (admitting patients, entering orders, and responding to nursing concerns). The aforementioned skin patch (placed while in the ED) tracked patient movement; hospital staff were unaware of the patch's purpose.

### Outcomes and Follow-up

For both groups, study staff interviewed patients on admission, at discharge, and 30 days after discharge. On admission, patients reported sociodemographic characteristics and completed assessments of frailty (20), cognitive impairment (21), depression (22), emotional support (23), health literacy (24), quality of life (25), and functional status (26). Staff collected information from the electronic health record (EHR) on such items as insurance status.

Our primary outcome was the "direct cost" of the acute care episode, hereafter referred to simply as "cost." Physician labor (all attending physicians, residents, and physician assistants) was excluded from cost calculations because its cost is customarily separate from traditional facility billing and revenue. Thus, we calculated cost by summing the costs of nonphysician labor, supplies, monitoring equipment, medications, laboratory orders, radiology studies, and transport related to each patient's care during the hospitalization (**Appendix Table 3**, available at Annals.org). Both groups used an identical cost calculation, except for transport (not applicable to the control group), nonphysician labor, and case management. In the home group, we multiplied nonphysician labor hours by the appropriate hourly direct rate, including fringe benefits and travel time, to obtain cost; in the control group, we used nonphysician labor cost as reported in our institution's internal cost-accounting system that includes direct labor and fringe benefits on a patient level. Case management cost appears only in the home group because case management was done directly by the home hospital team but its cost to the hospital cannot be reliably allotted to a specific patient.

The costs of items that were paid for by the institution but are not necessarily directly applicable to a specific patient (for example, executive salaries) were not included in either group.

We secondarily studied health care use, physical activity, patient experience, safety, and quality during the acute care episode (**Appendix 1**, available at Annals.org). Health care use comprised laboratory orders, radiology studies, consultations, and length of stay. Physical activity was evaluated via time sedentary (<0.1 $m/s^2$) and time lying down. Patient experience measures were the 3-item Care Transitions Measure (27), the 15-item Picker patient experience questionnaire (28), whether the patient would recommend the hospital, and global experience; all were based on the 30-day postdischarge interview. Safety comprised inappropriate medications (29) and delirium (30). All measures were derived from the EHR or patients, except physical activity, which was observed via the skin patch.

We also measured cost and health care use in the 30 days after discharge using the same cost-accounting method. We tracked readmissions, distinct ED visits, primary care visits, and specialist visits. In addition to EHR records from all Partners HealthCare facilities (the health system that includes both study hospitals) and the Care Everywhere system that joins all institutions that use the Epic EHR, we asked participants during the 30-day postdischarge interview whether they had received any health care outside our system and added those visits to the cost estimates. This occurred in only 2 patients, who each received a single primary care visit outside Partners HealthCare. Costs for these 2 visits were extrapolated using similar visits from Brigham and Women's Hospital. If patients could not be reached 30 days after discharge (8 total patients, 1 in the home group and 7 in the control group), we used EHR data alone to estimate health care use and readmission rates and did not measure patient experience.

### Statistical Analysis

To have an adequate sample size for the primary outcome and some secondary outcomes, we originally intended to enroll 120 patients. We first estimated the sample size needed to detect the 52% reduction in the cost of an acute care episode that we had observed in our pilot study (19). We required 19 patients per group to detect this difference with 90% power using a 2-sided $\alpha$ level of 0.05. Increasing the intended sample size to 60 patients per group allowed us to detect a smaller effect in the primary outcome and differences in some secondary outcomes. We did not account for multiple comparisons, and we report secondary outcomes descriptively only.

We present descriptive data with counts and percentages, means and 95% CIs, or medians and interquartile ranges, as appropriate. We first present unadjusted outcomes. For our primary outcome (cost), we did prespecified adjustment for sex, age, race/ethnicity, education, discharge diagnosis, and comorbid condition count (31). We used a generalized linear model assuming a $\gamma$ distribution with a log link, given the skewed nature of cost

data. Because our cost analysis takes the perspective of the hospital, we also did a sensitivity analysis that included physician labor in cost (Appendix 2, available at Annals.org). We present cost data as the percentage of change from control (rather than absolute difference) because of the sensitive nature of these data. All tests for significance used a 2-sided *P* value of 0.05. We did all analyses in SAS, version 9.4 (SAS Institute).

### Role of the Funding Source

The Partners HealthCare Center for Population Health funded the operational aspects of the clinical care team. The Center had no role in design, data collection, analysis, or the decision to submit the manuscript for publication. The Center gave comments on the manuscript. Internal departmental funds supported the evaluation efforts.

## RESULTS

### Patient Characteristics

Of the 248 patients who were screened for eligibility, 91 were enrolled and randomly assigned to a group (Figure; Appendix Table 4 [available at Annals.org] shows details of those who declined). In an unadjusted bivariate comparison, patients who declined to participate were more often female. All randomly assigned patients received their allocated treatment.

At baseline, patients were generally frail and chronically ill; were frequent users of hospital care; and had excellent emotional support, fair health literacy, fair health-related quality of life, and functional status limitations (Table 1). Approximately 25% of each group lived alone. Patients in the control group were younger, more often black, and less often insured through Medicare. They more often had full code status (that is, a desire for full resuscitation) and were less likely to have a home health aide; physicians more often would have been surprised if they had died within 1 year. The 2 groups had similar proportions of patients in the prespecified blocked strata (that is, broad categories) of infection, heart disease, respiratory disease, and other. Within the infection category, home patients had more pneumonia, more skin or soft tissue infection, and less diverticulitis than control patients.

### Cost and Health Care Use

Mean unadjusted cost of the acute care episode was 41% lower for home patients than control patients ($P < 0.001$). Adjusted mean cost was 38% lower (95% CI, 24% to 49% lower; $P < 0.001$) (Table 2).

Mean unadjusted length of stay was 4.5 days (CI, 3.9 to 5.0 days) for home patients versus 3.8 days (CI, 3.3 to 4.4 days) for control patients. During the care episode, home patients had less imaging (median percentage of patients, 14% vs. 44%), had fewer laboratory orders (median per admission, 3 vs. 15 orders), and less often received consultations (median percentage of patients, 2% vs. 31%) (Table 3).

Mean unadjusted cost for the hospitalization and 30-day postdischarge period combined was 41% lower for home patients. Mean adjusted cost was 36% (CI, 20% to 49%) lower, with reduced use of home health services, more use of home hospice, and better follow-up with primary care (Table 2).

In a secondary analysis that included physician cost using the number of patients per physician in each group, adjusted cost of the acute care episode was 19% (CI, 4% to 31%) lower in the home group and adjusted cost of the acute and 30-day postdischarge period was 25% (CI, 10% to 38%) lower (Appendix 2).

Home patients were less often readmitted within 30 days after discharge (7% vs. 23%).

### Safety, Quality, and Activity

Nine percent of home patients and 15% of control patients had a safety event (Table 4; Appendix Table 5 [available at Annals.org]). None of the home patients required emergency medical services or were transferred back to the hospital during their acute care episode. Pain scores (Table 4) and frequency of delirium (Appendix Table 5) were similar between groups. No home patients and 10% of control patients received inappropriate medications.

Home patients were less often sedentary (median percentage of day, 12% vs. 23%) and spent less of the day lying down (median percentage of day, 18% vs. 55%) (Table 4). Decrements in functional status at discharge and 30 days after discharge were considerable but seemed similar between groups (Table 4).

### Patient Experience

Patients in both groups reported high global satisfaction with care (median score, 10 of 10 in home group vs. 9 of 10 in control group) and readiness to transition care from acute care (median score, 12 of 12 in home group vs. 11 of 12 in control group) (Table 4). Both groups would recommend their acute care experience (4 of 4; interquartile range, 0) and had high Picker patient experience scores (14 of 15; interquartile range, 2).

## DISCUSSION

In this randomized controlled trial of acutely ill adults requiring hospital admission, home hospital care reduced cost, decreased health care use and 30-day readmissions, and improved physical activity compared with traditional hospital care without appreciable differences in quality, safety, or patient experience.

The home hospital model aims to get the right care to the right patient at the right time in the right place. However, the definition of "home hospital" varies widely both nationally and internationally (32, 33). Our model involved physician home visits with 24-hour physician coverage, twice-daily nurse visits, and home-based treatments to provide acutely ill patients with care similar to that received in a traditional hospital. It also offered cutting-edge connectivity (continuous monitoring, 24-hour access to video and texting, and virtual consultations), which makes it different from many home-based models in its ability to handle high patient acuity and include a high degree of medical decision making by physicians. Careful patient selection also minimized risk.

***Table 1.*** Baseline Patient Characteristics*

| Characteristic | Home (*n* = 43) | Control (*n* = 48) |
|---|---|---|
| Median age (IQR), *y* | 80 (19) | 72 (23) |
| Female sex | 15 (35) | 18 (38) |
| Race/ethnicity | | |
| White | 24 (56) | 22 (46) |
| Black | 6 (14) | 14 (29) |
| Hispanic/Latino | 8 (19) | 8 (17) |
| Asian | 4 (9) | 2 (4) |
| Other | 0 (0) | 2 (4) |
| Partner status | | |
| Partnered | 16 (37) | 18 (38) |
| Divorced | 8 (19) | 5 (10) |
| Widowed | 9 (21) | 6 (13) |
| Single, never partnered | 10 (23) | 18 (38) |
| Other | 0 (0) | 1 (2) |
| Lived alone | 11 (26) | 12 (25) |
| Primary language | | |
| English | 31 (72) | 38 (79) |
| Spanish | 8 (19) | 6 (13) |
| Insurance | | |
| Private | 6 (14) | 7 (15) |
| Medicare | 21 (49) | 17 (35) |
| Medicaid | 4 (9) | 5 (10) |
| Medicare and Medicaid | 12 (28) | 17 (35) |
| None | 0 (0) | 2 (4) |
| Education† | | |
| Less than high school | 15 (35) | 15 (32) |
| High school | 7 (16) | 14 (30) |
| <4-y college | 6 (14) | 6 (13) |
| 4-y college | 7 (16) | 7 (15) |
| >4-y college | 8 (19) | 5 (11) |
| Employment† | | |
| Employed | 11 (26) | 10 (21) |
| Unemployed | 2 (5) | 7 (15) |
| Retired | 30 (70) | 30 (64) |
| Cigarette smoking | | |
| Never | 21 (49) | 28 (58) |
| Current | 6 (14) | 6 (13) |
| Prior | 16 (37) | 14 (29) |
| Median PRISMA frailty score (IQR)‡ | 4 (3) | 3 (3) |
| Median comorbid condition count (IQR), *n*§ | 4 (3) | 3 (3) |
| Admitted to hospital in past 6 mo | 15 (35) | 18 (38) |
| Visited ED in past 6 mo | 17 (40) | 15 (31) |
| Median 8-Item Interview to Differentiate Aging and Dementia score (IQR)‖ | 1 (4) | 2 (4) |
| Median PHQ-2 score (IQR)¶ | 0 (3) | 0 (3) |
| Median PROMIS emotional support score (IQR)** | 20 (0) | 20 (0) |
| Median Brief Health Literacy Screening Tool score (IQR)†† | 13 (12) | 13 (11) |
| Mean EuroQol VAS score (95% CI)‡‡ | 56 (50–62) | 61 (54–68) |
| Median ADLs on admission (IQR), *n*§§ | 6 (5) | 6 (3) |
| Median IADLs on admission (IQR), *n*‖‖ | 4 (7) | 6 (6) |
| Full code status | 27 (63) | 43 (90) |
| Physician would be surprised if patient died within 1 y¶¶ | 21 (51) | 33 (69) |
| Mean outpatient medications (95% CI), *n* | 13 (10–15) | 12 (10–14) |
| Had home health aide | 17 (40) | 10 (21) |
| Diagnosis*** | | |
| Infection | 23 (53) | 22 (46) |
| Pneumonia | 11 (26) | 10 (21) |
| Skin/soft tissue infection | 8 (19) | 3 (6) |
| Complicated urinary tract infection/pyelonephritis | 4 (9) | 4 (8) |
| Diverticulitis | 0 (0) | 5 (10) |
| Heart failure | 7 (16) | 8 (17) |
| Airway disease | 6 (14) | 7 (15) |
| Asthma | 1 (2) | 2 (4) |
| Chronic obstructive pulmonary disease | 5 (12) | 5 (10) |

*Continued on following page*

*Table 1*–Continued

| Characteristic | Home (*n* = 43) | Control (*n* = 48) |
|---|---|---|
| Other | 7 (16) | 11 (23) |
| Diabetes complication | 2 (5) | 4 (8) |
| End of life | 1 (2) | 1 (2) |
| Hypertensive urgency | 2 (5) | 0 (0) |
| Anticoagulation need | 1 (2) | 4 (8) |
| Gout exacerbation | 1 (2) | 0 (0) |
| Other | 0 (0) | 2 (4) |

ADL = activity of daily living; ED = emergency department; IADL = instrumental ADL; IQR = interquartile range; PHQ-2 = Patient Health Questionnaire 2; PRISMA = Program of Research to Integrate the Services for the Maintenance of Autonomy; PROMIS = Patient-Reported Outcomes Measurement Information System; VAS = visual analogue scale.
* Values are numbers (percentages) unless otherwise indicated. Percentages may not sum to 100 due to rounding.
† Data missing for 1 control patient.
‡ Range, 0–7, where scores >2 indicate frailty.
§ Count of the patient's chronic comorbid conditions, out of the 20 conditions considered chronic by the Health and Human Services Office of the Assistant Secretary of Health (31).
‖ Range, 0–8, where scores >1 indicate cognitive impairment.
¶ Range, 0–6, where scores >2 indicate depression.
** Range, 4–20, where scores >17 indicate better-than-average emotional support.
†† Range, 4–20, where scores of 4–12 indicate limited health literacy, scores of 13–16 indicate marginal health literacy, and scores of 17–20 indicate adequate health literacy.
‡‡ Range, 0–100.
§§ Range, 0–6.
‖‖ Range, 0–8.
¶¶ Data missing for 2 home patients.
*** Block-randomized at the level of infection, heart failure, airway disease, and other.

Home hospital care may reduce cost because it delivers a combination of remote and in-person care that reduces nursing labor (similar patient–nurse ratio, but 2 visits at home vs. 24-hour care in the hospital), use of ancillary services and consultations, and readmissions. It may also deliver care in a more patient-centered manner: Patients can be surrounded by their family and friends, eat their own food, move around in their own home, and sleep in their own bed (without being awakened multiple times per night), all with the support of the home hospital team.

The reduction in readmission rate is particularly notable, especially given the magnitude of effect and the inability of many transitional care interventions to influence this outcome (34). Perhaps patients who receive acute care at home are less likely to develop "posthospital syndrome" because they sleep better; eat better; walk more; and become less deconditioned, malnourished, and sedated (4). Discharge planning may also be more effective at home because it occurs where patients and caregivers will be carrying out postdischarge tasks and can be tailored to the home environment. The first hypothesis is only partly supported by our results: Home patients were more active than but had functional status reductions similar to control patients, perhaps because of limitations in functional status measurement tools. Other components of these hypotheses were not specifically tested in this study and require further research.

This work builds substantially on our pilot study and corroborates previous work. Others providing home hospital care to acutely ill patients have shown reduced cost and decreased health care use while maintaining or improving quality, safety, and patient experience (7, 8). A randomized controlled trial in Australia found a 51% reduction in cost (13, 35). Few studies have measured 30-day postdischarge cost, and our reporting of unadjusted and log-adjusted mean is conservative when the sizable portion of patients readmitted in the control group is con-

*Table 2.* Relative Cost of Home Hospital Care to Traditional Hospital Care

| Cost | Without Physician Labor | | With Physician Labor* | |
|---|---|---|---|---|
| | Relative Reduction, % | *P* Value | Relative Reduction, % | *P* Value |
| **Acute care episode** | | | | |
| Unadjusted cost† | 41 | <0.001 | 16 | 0.075 |
| Adjusted mean cost (95% CI)‡ | 38 (24–49) | <0.001 | 19 (4–31) | 0.017 |
| **Acute care episode and 30 d after acute care episode** | | | | |
| Unadjusted cost† | 41 | <0.001 | 29 | 0.007 |
| Adjusted mean cost (95% CI)‡ | 36 (20–49) | <0.001 | 25 (10–38) | <0.001 |

* Appendix 1 (available at Annals.org) shows physician cost modeling. Model shown assumes actual mean number of patients per physician.
† Percentage of change in mean cost is calculated as [(control cost − home cost) ÷ (control cost)] × 100%. If percentage of change is negative, control group costs less; if percentage of change is positive, home group costs less.
‡ From a generalized linear model with a γ distribution and a log link that adjusted for sex, age, race/ethnicity, education, discharge diagnosis, and comorbid condition count.

*Table 3.* Patient Health Care Use*

| Measure | Home (*n* = 43) | Control (*n* = 48) |
|---|---|---|
| **During acute care episode** | | |
| Mean length of stay (95% CI), *d* | 4.5 (3.9–5.0) | 3.8 (3.3–4.4) |
| Intravenous medication during admission | 30 (70) | 39 (81) |
| Imaging during admission | 6 (14) | 21 (44) |
| Median laboratory orders per admission (IQR), *n* | 3 (5) | 15 (15) |
| Consultant session during admission | 1 (2) | 15 (31) |
| Physical or occupational therapy session during admission | 0 (0) | 8 (17) |
| Disposition | | |
| Routine | 28 (65) | 32 (67) |
| Home health | 10 (23) | 15 (31) |
| Home hospice | 4 (9) | 1 (2) |
| Other | 1 (2) | 0 (0) |
| **30 d after acute care episode** | | |
| Primary care visit ≤14 d after discharge† | 22 (55) | 19 (42) |
| 30-d readmission† | 3 (7) | 11 (23) |
| For same condition as index hospitalization, *n/N*‡ | 1/3 | 6/11 |
| 30-d ED presentation† | 3 (7) | 6 (13) |

ED = emergency department; IQR = interquartile range.
* Values are numbers (percentages) unless otherwise indicated. Percentages may not sum to 100 due to rounding.
† For 1 home patient and 7 control patients, these data were evaluated via medical record review only because the patients could not be reached for the 30-d telephone call.
‡ Out of all readmitted patients in each study group.

sidered. Federman and colleagues (16) recently showed reduced readmissions in a quasi-experimental home hospital study. Two randomized controlled trials in Italy for patients presenting with exacerbation of chronic obstructive pulmonary disease or heart failure had similar findings to ours and showed reduced readmissions (9, 36). Our findings regarding physical activity corroborate other work (15, 37).

*Table 4.* Quality, Physical Activity, Functional Status, and Experience*

| Measure | Home (*n* = 43) | Control (*n* = 48) |
|---|---|---|
| **Quality of care†** | | |
| Any safety event‡ | 4 (9) | 7 (15) |
| Median pain score (IQR)§ | 0 (1) | 0 (3) |
| Inappropriate medication use‖ | 0 (0) | 5 (10) |
| Urinary catheter use | 0 (0) | 2 (4) |
| Restraint use | 0 (0) | 0 (0) |
| **Activity each day** | | |
| Median percentage of day sedentary (IQR) | 12 (15) | 23 (23) |
| Median percentage of day lying down (IQR) | 18 (32) | 55 (66) |
| **Functional status** | | |
| IADLs worse: admission to discharge¶ | 11 (26) | 14 (31) |
| IADLs worse: admission to 30 d after discharge** | 14 (37) | 13 (34) |
| ADLs worse: admission to discharge¶ | 6 (14) | 6 (13) |
| ADLs worse: admission to 30 d after discharge** | 4 (11) | 6 (16) |
| **Patient experience** | | |
| Median global satisfaction score (IQR)**†† | 10 (1) | 9 (1) |
| Median 3-item Care Transitions Measure score (IQR)¶‡‡ | 12 (1) | 11 (3) |
| Median recommendation of hospital (IQR)**§§ | 4 (0) | 4 (0) |
| Median Picker patient experience questionnaire score (IQR)‖‖ | 14 (2) | 14 (3) |

ADL = activity of daily living; IADL = instrumental ADL; IQR = interquartile range.
* Values are numbers (percentages) unless otherwise indicated.
† Standard inpatient quality measures for pneumonia and heart failure (e.g., β-blocker for heart failure with reduced ejection fraction, or smoking cessation counseling) were achieved equally in both groups (data not shown).
‡ Appendix Table 5 (available at Annals.org) shows detailed safety events.
§ Range, 0–10.
‖ Using the updated Beers Criteria (29).
¶ For 1 home patient and 3 control patients, these data are missing.
** For 1 home patient and 10 control patients, these data are missing.
†† Range, 0–10, where 0 indicates the worst possible hospital and 10 the best possible hospital.
‡‡ Range, 3–12.
§§ Range, 0–4, where 0 indicates "definitely would not recommend" and 4 indicates "definitely would recommend."
‖‖ Range, 0–15.

Unlike other studies, we found similar rates of delirium, changes in functional status, and length of stay between groups (7, 8, 16). Perhaps some patients will become delirious because of their severity of illness or frailty regardless of the location of their care; however, it is possible that the home hospital team better identified delirium or that delirium resolved more quickly at home. This issue requires further investigation. Regarding length of stay, clinicians may have experienced less pressure to discharge patients from acute care in the home, but this did not result in higher cost and may have contributed to lower readmission rates. We were surprised to observe similar decrements in functional status in both groups despite improved physical activity in home patients. Perhaps a more nuanced tool is required to capture differences in functional status, or perhaps the reduced use of physical and occupational therapy in the home group counteracted the increased physical activity. Alternately, home hospitalization may be insufficient to counteract the negative effect of acute illness on functional status.

Our study has limitations. First, we recruited from only 2 sites, and only 5 physicians delivered the home hospital intervention, limiting the generalizability of our findings. Our cost calculations may be less valid at an institution with different nurse staffing structures, and we cannot exclude the possibility that at least some of the results are due to a small number of clinicians delivering exceptional care. However, our academic center has a high standard of care overall. Second, our study was stopped early to facilitate local operational needs ("rollout" of the intervention to as many patients as possible). Third, our eligibility criteria included a broad list of conditions so that we could enroll patients typically admitted to the general medical service and meet our sample size estimate; this approach limited our ability to examine condition-specific outcomes. Furthermore, patients were carefully selected for lower risk for clinical deterioration, which limits the generalizability of our findings. Fourth, a substantial proportion (63%) of patients did not enroll—approximately the inverse of prior work (7)—mostly because patients and families declined to participate. This was likely due to our randomization scheme, which allowed us to approach patients only just before "rolling upstairs," a time when most patients had already mentally prepared for traditional admission. However, few differences existed between those who did and did not choose to enroll (**Appendix Table 4**). Fifth, our study was small and does not allow us to exclude an increase in patient safety events with home hospital. Finally, our prespecified primary outcome excluded physician cost to mirror hospital payment structures; however, our secondary analysis included physician cost and had similar, albeit attenuated, findings. We also could not report revenue.

Compared with traditional hospital care, home hospital care for acutely ill adults reduced cost, decreased health care use and 30-day readmissions, and improved physical activity. Reimagining the best place to care for selected acutely ill adults holds enormous potential. Further work is needed to better understand the conditions and illness severity of patients who could be successfully cared for at home; new technologies we might deploy; and more efficient workflows that may optimize home-based teams and allow for expansion, both on a small scale and at a regional or national level. If scaled, home hospital teams could transform how acute care is delivered in the United States, with potential improvements in cost, health care use, and readmissions.

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Presented in part at the Society of General Internal Medicine Annual Meeting, Denver, Colorado, 11–14 April 2018.

**Acknowledgment:** The authors thank the home hospital clinicians who cared for the home hospital patients; John Orav, PhD, for his insightful comments on a prior draft of the manuscript; and various departments at Brigham Health that were instrumental to the success of the home hospital program: Cardiology, Emergency Medicine, General Internal Medicine and Primary Care, Hospital Medicine Unit, Pharmacy, Laboratory, and Population Health.

**Financial Support:** By the Partners HealthCare Center for Population Health and internal departmental funds.

**Disclosures:** Dr. Levine reports grants from Biofourmis outside the submitted work. Dr. Blanchfield reports consulting income from Verily, GreyBird Ventures, and Atlas5D outside the submitted work. Dr. Schnipper reports grants from Mallinckrodt Pharmaceuticals and Portola Pharmaceuticals outside the submitted work. Authors not named here have disclosed no conflicts of interest. Disclosures can also be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M19-0600.

**Data Sharing Statement:** The authors have indicated that they will not be sharing data.

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## Appendix 1: Additional Secondary Outcomes

Safety measures included routinely reported adverse events (such as falls and hospital-acquired conditions), delirium (captured by the Confusion Assessment Method, [38] documented every 8 hours for control patients as part of usual care and twice daily for home patients), and the unexpected return to hospital rate (intervention group only). Appendix Table 5 lists these and other safety measures.

Quality measures included pertinent inpatient quality measures from the Centers for Medicare & Medicaid Services (for example, angiotensin-converting enzyme inhibitor in a patient with heart failure with reduced ejection fraction), pain scores, and inappropriate medication use (using updated Beers Criteria). We considered hospital-acquired disability to be any reduction in a patient's activities of daily living or instrumental activities of daily living between admission and discharge (37).

Appendix Table 6 lists the various secondary and exploratory outcomes that we do not present in this article.

## Appendix 2: Cost Calculation Sensitivity Analyses, Including Physician Labor

Brigham and Women's Hospital (BWH) does not use a direct care model like home hospital (that is, physicians at BWH always work with residents or physician assistants). The attending physician–patient ratios for home hospital and BWH are capped at 1:4 and 1:16, respectively. However, the BWH daytime attending physician is assisted by a nocturnist and 3 daytime, 2 twilight, and 2 nighttime residents, or by physician assistant equivalents; in effect, this requires more physicians per patient than home hospital. In addition, at nearby academic medical centers that do have direct care models (that is, no assistance from a resident or advanced practice provider), attending physicians typically see 8 patients and still require overnight attending coverage.

To calculate the direct cost of physician care per patient in the control group, we obtained confidential data from the hospital medicine unit at BWH. For each hospital role (attending daytime physician, attending nocturnist, physician assistant, and resident physician), we obtained the following data: starting salary, salary with fringe benefits, shifts per year, patient load, and full-time equivalents required for load. From these data, we calculated cost per year, cost per day, and cost per patient per day.

To calculate cost per patient, we multiplied the patient's length of stay by cost per patient per day.

To calculate the direct cost of physician care per patient in the home group, we obtained the same data noted earlier from our own records. Because the home hospital service was operating at less than its fully envisioned capacity, it did not fully leverage the physician's time. We therefore did a sensitivity analysis modeling the physician's efficiency. We started with the census (that is, patient count per physician) at which the home hospital team was able to operate during the study (current census, 3.5). We also considered that a low census would be 2 patients (for example, under conditions of low enrollment). Finally, we are planning to increase the physician's census to 8 in the near term and wanted to model this planned efficiency of 8:

Low physician efficiency: census = 2
Current physician efficiency: census = 3.5
Planned physician efficiency: census = 8

In Appendix Table 7, we present the same cost calculation methodology as in the main analysis, with the addition of physician cost. Adjustment was exactly as described in the article.

*Appendix Table 1.* Operational Process Measures

| Process Measure | Home ($n$ = 43) | Control ($n$ = 48) |
|---|---|---|
| Mean time from admission decision to assessment by research assistant (95% CI), *min* | 11 (0–25) | 12 (4–20) |
| Mean time from research assistant assessment to completed enrollment (95% CI), *min* | 29 (21–36) | 27 (21–36) |
| Mean time from completed enrollment to dismissal from ED (95% CI), *min* | 66 (54–78) | 54 (28–80) |

ED = emergency department.

*Appendix Table 2.* Detailed Inclusion and Exclusion Criteria

**Inclusion**

- Clinical
  - Aged ≥18 y
  - Primary or possible diagnosis of any infection, heart failure exacerbation, COPD exacerbation, asthma exacerbation, chronic kidney disease requiring diuresis, diabetes and its complications, gout exacerbation, hypertensive urgency, previously diagnosed atrial fibrillation with rapid ventricular response, anticoagulation needs (e.g., venous thromboembolism), or a patient at the end of life who desires only medical management

**Exclusion**

- Social
  - Not domiciled
  - No working heat (October–April), no working air conditioning if forecast >27 °C (June–September), or no running water
  - Receiving methadone requiring daily pickup of medication
  - In police custody
  - Resides in facility that provides onsite medical care (e.g., skilled-nursing facility)
  - Domestic violence screen positive (39)
- Clinical
  - Acute delirium, as determined by the Confusion Assessment Method
  - Cannot establish peripheral access in ED
  - Secondary condition: active nonmelanoma/prostate cancer, end-stage renal disease, acute myocardial infarction, acute cerebral vascular accident, or acute hemorrhage
  - Primary diagnosis requires multiple or routine administrations of controlled substances for pain control
  - Cannot independently ambulate to bedside commode
  - As deemed by on-call physician, patient likely to require any of the following procedures: computed tomography, magnetic resonance imaging, endoscopic procedure, blood transfusion, cardiac stress test, or surgery
  - For pneumonia:
    - Most recent CURB-65 score >3 (40)
    - Most recent SMRT-CO score >2 (41)
    - Absence of clear infiltrate on imaging
    - Cavitary lesion on imaging
    - Pulmonary effusion of unknown etiology
    - Oxygen saturation <90% despite 5 L of oxygen
  - For heart failure:
    - Has a left ventricular assist device
    - GWTG-HF (42) (>10% in-hospital mortality) or ADHERE (43) (high risk or intermediate risk 1)
    - Severe pulmonary hypertension
  - For complicated urinary tract infection:
    - Absence of pyuria
    - Most recent qSOFA score >1 (44)
  - For other infection:
    - Most recent qSOFA score >1 (44)
  - For COPD:
    - BAP-65 score >3
  - For asthma:
    - Peak expiratory flow <50% of normal: exercise caution
  - For diabetes and its complications:
    - Requires IV insulin
  - For hypertensive urgency:
    - Systolic blood pressure >190 mm Hg
    - Evidence of end-stage organ damage
  - For atrial fibrillation with rapid ventricular response:
    - Likely to require cardioversion
    - New atrial fibrillation with rapid ventricular response
    - Unstable blood pressure, respiratory rate, or oxygenation
    - Despite IV $\beta$ and/or calcium-channel blockade in the ED, HR remains >125 beats/min and systolic blood pressure remains different from baseline
    - <1 h has elapsed with HR <125 beats/min and systolic blood pressure similar to or higher than baseline

ADHERE = Acute Decompensated Heart Failure National Registry; BAP-65 = elevated Blood urea nitrogen, Altered mental status, Pulse >109 beats/min, and age >65 y; COPD = chronic obstructive pulmonary disease; CURB-65 = Confusion, Urea, Respiratory rate, Blood pressure, and age ≥65 y; ED = emergency department; GWTG-HF = American Heart Association Get With the Guidelines–Heart Failure; HR = heart rate; IV = intravenous; qSOFA = quick Sequential [Sepsis-related] Organ Failure Assessment; SMRT-CO = Systolic blood pressure, Multilobar chest radiography involvement, Respiratory rate, Tachycardia, Confusion, and Oxygenation.

*Appendix Table 3.* Cost Calculation Details*

| Cost Type | Home | Control |
|---|---|---|
| **Labor (including fringe benefits)** | | |
| Nurse | X | X |
| Aide | X | X |
| Occupational therapist | X | X |
| Physical therapist | X | X |
| Social worker | X | X |
| Nurse-level case management/care coordination | X | – |
| **Supplies** | | |
| IV care | X | X |
| Wound care | X | X |
| Dressings | X | X |
| Oxygen | X | X |
| Nebulizer | X | X |
| Monitoring equipment | X | X |
| Communication equipment | X | – |
| Food | X | X |
| Other | X | X |
| **Medications** | X | X |
| **Diagnostics** | | |
| Imaging | | |
| Facility-based | X | X |
| Point-of-care | X | – |
| Laboratory tests | | |
| Facility-based | X | X |
| Point-of-care | X | X |
| **Transport** | | |
| Patient | X | – |
| RN | X | – |
| Parking | X | – |

IV = intravenous; RN = registered nurse.
* We calculated cost by summing all of the various cost streams for each group where an "X" is marked.

*Appendix Table 4.* Characteristics of Patients Who Declined to Enroll*

| Characteristic | Home (*n* = 43) | Control (*n* = 48) | Declined (*n* = 157) |
|---|---|---|---|
| **Median age (IQR), *y*** | 80 (19) | 72 (23) | 74 (24) |
| **Female sex** | 15 (35) | 18 (38) | 107 (68) |
| **Race/ethnicity** | | | |
| White | 24 (56) | 22 (46) | 76 (48) |
| Black | 6 (14) | 14 (29) | 34 (22) |
| Hispanic/Latino | 8 (19) | 8 (17) | 40 (25) |
| Asian | 4 (9) | 2 (4) | 4 (3) |
| Other | 0 (0) | 2 (4) | 2 (1) |
| **Primary language** | | | |
| English | 31 (72) | 38 (79) | 121 (77) |
| Spanish | 8 (19) | 6 (13) | 28 (18) |
| **Insurance** | | | |
| Private | 6 (14) | 7 (15) | 37 (24) |
| Medicare | 21 (49) | 17 (35) | 83 (53) |
| Medicaid | 4 (9) | 5 (10) | 6 (4) |
| Medicare and Medicaid | 12 (28) | 17 (35) | 29 (18) |
| None | 0 (0) | 2 (4) | 2 (1) |
| **Admitted to hospital in past 6 mo** | 15 (35) | 18 (38) | 79 (50) |
| **Visited ED in past 6 mo** | 17 (40) | 15 (31) | 63 (40) |

ED = emergency department; IQR = interquartile range.
* Values are numbers (percentages) unless otherwise indicated.

*Appendix Table 5.* Patient Safety*

| Measure | Home (*n* = 43) | Control (*n* = 48) |
|---|---|---|
| Fall | 1 (2) | 0 (0) |
| Delirium | 3 (7) | 4 (8) |
| DVT/PE | 0 (0) | 0 (0) |
| New pressure ulcer | 0 (0) | 0 (0) |
| Thrombophlebitis at peripheral IV site | 0 (0) | 0 (0) |
| CAUTI | 0 (0) | 0 (0) |
| New *Clostridium difficile* | 0 (0) | 1 (2) |
| New MRSA | 0 (0) | 1 (2) |
| New arrhythmia | 0 (0) | 0 (0) |
| Hypokalemia | 1 (2) | 1 (2) |
| Acute kidney injury | 1 (2) | 2 (4) |
| Transfer back to hospital | 0 (0) | NA |
| Death (unplanned) during admission | 0 (0) | 0 (0) |
| Death (unplanned) ≤30 d after discharge | 0 (0) | 1 (2) |
| Death (all-cause) during admission | 0 (0) | 0 (0) |
| Death (all-cause) ≤30 d after discharge | 3 (7) | 2 (4) |

CAUTI = catheter-associated urinary tract infection; DVT/PE = deep venous thrombosis/pulmonary embolism; IV = intravenous; MRSA = methicillin-resistant *Staphylococcus aureus*; NA = not applicable.
* Values are numbers (percentages).

*Appendix Table 6.* Plan for Additional Variables

| Measure | Secondary or Exploratory | Reason Not Included |
|---|---|---|
| Direct margin | Secondary | Sensitive data |
| Direct margin, modeled with backfill | Secondary | Sensitive data |
| Total reimbursement, 30 d after discharge | Exploratory | Sensitive data |
| Intravenous fluids, days | Exploratory | Will present in a follow-up manuscript |
| Intravenous diuretics, days | Exploratory | Will present in a follow-up manuscript |
| Intravenous antibiotics, days | Exploratory | Will present in a follow-up manuscript |
| Oxygen requirement, days | Exploratory | Will present in a follow-up manuscript |
| Nebulizer treatment, days | Exploratory | Will present in a follow-up manuscript |
| Skilled-nursing facility use, days | Exploratory | Will present in a follow-up manuscript |
| Home health use, days | Exploratory | Will present in a follow-up manuscript |
| Hours of sleep per day | Secondary | Will present in a follow-up manuscript |
| Hours of sleep per night | Exploratory | Will present in a follow-up manuscript |
| Hours of activity per day | Secondary | Will present in a follow-up manuscript |
| Hours of activity per night | Exploratory | Will present in a follow-up manuscript |
| Hours of sitting upright per day | Secondary | Will present in a follow-up manuscript |
| Hours of sitting upright per night | Exploratory | Will present in a follow-up manuscript |
| Daily steps | Secondary | Will present in a follow-up manuscript |
| Pneumococcal vaccination, if appropriate | Exploratory | Less clinically impactful |
| Influenza vaccination, if appropriate | Exploratory | Less clinically impactful |
| Smoking cessation counseling, if appropriate | Exploratory | Less clinically impactful |
| Evaluation of EF scheduled or completed if not done within 1 y | Exploratory | Less clinically impactful |
| Angiotensin-converting enzyme inhibitor or angiotensin-receptor blocker for HFrEF (EF <40%) | Exploratory | Less clinically impactful |
| $\beta$-Blocker for HFrEF (EF <40%) | Exploratory | Less clinically impactful |
| Aldosterone antagonist for HFrEF (EF <40%) | Exploratory | Less clinically impactful |
| Lipid-lowering medication for coronary artery disease, peripheral vascular disease, cerebrovascular accident, or diabetes | Exploratory | Less clinically impactful |
| Smoking status after discharge | Exploratory | Less clinically impactful |
| >3 medications added to medication list | Exploratory | Will present in a follow-up manuscript |
| EuroQol 5D-5L | Secondary | Will present in a follow-up manuscript |
| Short-Form 1 | Secondary | Will present in a follow-up manuscript |
| Walk around ward/home | Exploratory | Will present in a follow-up manuscript |
| Get to (noncommode) bathroom | Exploratory | Will present in a follow-up manuscript |
| Walk 1 flight of stairs | Exploratory | Will present in a follow-up manuscript |
| Visit with friends/family | Exploratory | Will present in a follow-up manuscript |
| Walk outside around home | Exploratory | Will present in a follow-up manuscript |
| Go shopping | Exploratory | Will present in a follow-up manuscript |
| Qualitative interviews | Exploratory | Will present in a follow-up manuscript |
| RN–patient ratio | Exploratory | Will present in a follow-up manuscript |
| Number of RN visits | Exploratory | Will present in a follow-up manuscript |
| Number of "on-call" physician interactions (video or telephone) | Exploratory | Will present in a follow-up manuscript |
| Number of "on-call" physician in-person visits | Exploratory | Will present in a follow-up manuscript |
| Duration of first RN visit | Exploratory | Will present in a follow-up manuscript |
| Duration of subsequent RN visit | Exploratory | Will present in a follow-up manuscript |
| Clinician focus group | Exploratory | Will present in a follow-up manuscript |

EF = ejection fraction; HFrEF = heart failure of reduced EF; RN = registered nurse.

*Appendix Table 7.* Sensitivity Analysis Including Physician Cost

| Cost | Low Efficiency | | Current Efficiency | | Planned Efficiency | |
|---|---|---|---|---|---|---|
| | Relative Reduction, % | *P* Value | Relative Reduction, % | *P* Value | Relative Reduction, % | *P* Value |
| **Acute care episode** | | | | | | |
| Unadjusted mean cost* | −15 | 0.96 | 16 | 0.075 | 34 | <0.001 |
| Adjusted mean cost (95% CI)† | −5 (−24 to 11) | 0.54 | 19 (4 to 31) | 0.017 | 37 (25 to 47) | <0.001 |
| **Acute care episode and 30 d after acute care episode** | | | | | | |
| Unadjusted mean cost* | 16 | 0.056 | 29 | 0.007 | 39 | <0.001 |
| Adjusted mean cost (95% CI)† | 12 (−5 to 27) | 0.15 | 25 (10 to 38) | >0.001 | 35 (22 to 47) | <0.001 |

* Percentage of change in mean cost is calculated as [(control cost − home cost) ÷ (control cost)] × 100%. If percentage of change is negative, control group costs less; if percentage of change is positive, home group costs less.
† From a generalized linear model with a γ distribution and a log link that adjusted for sex, age, race/ethnicity, education, discharge diagnosis, and comorbid condition count.

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European Journal of Heart Failure (2009) **11**, 1208–1213
doi:10.1093/eurjhf/hfp143

# 'Hospital at home' care model as an effective alternative in the management of decompensated chronic heart failure

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*Received 30 March 2009; revised 30 June 2009; accepted 30 August 2009; online publish-ahead-of-print 29 October 2009*

**Aims** The 'Hospital at home' (HaH) model avoids hospital admission by transferring healthcare and treatment to the patient's home. We aimed to compare the effectiveness and direct healthcare costs of treating elderly patients with decompensated heart failure (HF) using HaH care vs. inpatient hospital care (IHC) in a cardiology unit.

**Methods and results** Eighty patients aged over 65 years who presented at the emergency department with decompensated HF were randomly assigned to IHC or HaH. All patients were studied for 1 year. Seventy-one patients completed the study, of these 34 were admitted to cardiology and 37 received HaH care. No significant differences were found in baseline characteristics, including comorbidity, functional status, and health-related quality of life. Clinical outcomes were similar after initial admission and also after the 12 months of follow-up. Death or re-admission due to HF or another cardiovascular event occurred in 19 patients in IHC and 20 in HaH ($P = 0.88$). Changes in functional status and health-related quality of life over the follow-up period were not significantly different. The average cost of the initial admission was 4502 $\pm$ 2153€ in IHC and 2541 $\pm$ 1334€ in HaH ($P < 0.001$). During 12 months of follow-up, the average expenditure was 4619 $\pm$ 7679€ and 3425 $\pm$ 4948€ ($P = 0.83$) respectively.

**Conclusion** Hospital at home care allows an important reduction in the costs during the index episode compared with hospital care, whilst maintaining similar outcomes with respect to cardiovascular mortality and morbidity and quality of life at 1 year follow-up.

**Keywords** Hospital at home • Effectiveness • Healthcare cost • Heart failure

## Introduction

Chronic heart failure (HF) remains a major and growing public health problem in industrialized nations. Its high prevalence in the general population and its increasing incidence, related to ageing of the population and to the increasing survival rates of those suffering from chronic diseases such as ischaemic heart disease, have led it to be considered a true epidemic.[1] In a recent demographic study in Spanish people aged over 45 years, 1776 individuals were evaluated for the presence of HF by their primary care physician, with the subsequent confirmation of the diagnosis by a cardiologist. Results showed that the prevalence of HF was estimated to be 7–8%, similar in men and women, and increasing with age up to 16% in those aged over 75.[2] In Spain, the cost of a hospital stay for patients with HF is 421.25 Euros/day, with an increase of 71% in the number hospital admissions for CHF and 29–59% of re-admissions in the first 6 months after hospitalization.[3]

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Heart failure is associated with high morbidity and mortality and with frequent hospital re-admissions, it is the most common cause of hospitalization in people aged over 65 years. Heart failure consumes more than 2% of the health care budget in many European countries, up to 70% of which is due to the costs related to hospitalization.[4,5] In Spain, CHF is the most common cause of hospitalization in people over 65 and it is also the cause of 11% of cardiovascular deaths in men and 19% in women.[6]

In this setting, the 2008 guidelines of the European Society of Cardiology[5] recommend the implementation of management programmes for patients with HF (Class I, level A), in an attempt to improve medical care while reducing costs. Basically, the two most widely accepted programmes are HF clinics and home-based care programmes. Both start during admission or just after discharge, and rely on the work of specialized nurses.

However, the possibility of avoiding hospital admission by transferring hospital care, including physicians, to the patient's home ['hospital at home' (HaH)] has been proposed recently.[7,8] Health economic perspectives and information about health-related quality of life[9] have been considered, but studies on this type of management of HF are scarce.

For this reason and following current recommendations,[10,11] we designed a study in patients suffering from worsening chronic HF eligible for hospital admission. Patients identified in the emergency department (ED) were randomly assigned to receive care at home (HaH) or as inpatients in a conventional hospital cardiology ward [inpatient hospital care (IHC)]. The aim of the study was to assess the effectiveness of HaH compared with IHC on the combined outcome of mortality, HF re-admission, or other cardiovascular event (stroke, acute coronary syndrome, and coronary revascularization) as well as the evolution of functional status and quality of life during the index episode and after 1 year of follow-up. The second aim was to compare the health expenditure on each type of care during the initial episode and after 1 year.

# Methods

## Study design and setting

This prospective, randomized study was performed in Txagorritxu University Hospital, Vitoria-Gasteiz, Spain, which has a catchment population of around 250 000 people. Among other departments, the hospital has a HaH unit, which is staffed by six physicians and eight nurses. The study was approved by the hospital's Ethics and Clinical Research Committee and informed written consent was required from all patients.

Patients aged $\geq$65 years with a confirmed diagnosis of HF performed at least 12 months prior to the study, who were in New York Heart Association (NYHA) functional class II or III prior to the current acute exacerbation, were eligible to participate in the study. All patients attended the ED due to a deterioration in HF symptoms and were diagnosed with decompensated chronic HF on the basis of: worsened dyspnoea and/or worsened pulmonary or systemic congestion. All inclusion and exclusion criteria are listed in *Table 1*.

A monitoring committee approved inclusion of the patients in the study and validated all clinical events.

**Table 1 Inclusion and exclusion criteria**

| |
|---|
| Inclusion criteria |
| Patient of 65 years and over |
| With diagnosis and prognosis evaluation of HF since at least 12 months prior to the study |
| NYHA functional class II or III before coming to ED due to exacerbation |
| Exclusion criteria |
| Admitted in the preceding 2 months for deterioration of HF or acute coronary syndrome |
| Presence of severe symptoms such as sudden worsening of HF |
| Poor prognosis factors (haemodynamic instability, severe arrhythmia, baseline creatinine above 2.5 mg/dL) |
| No response to treatment in the ED |
| Active cancer, severe dementia, or any other disease at an advanced stage indicating life expectancy of less than 6 months |
| Acute psychiatric diseases, active alcoholism |
| Active pulmonary tuberculosis |
| Those living in a psycho-geriatric institution |
| No guarantee of all-day supervision |
| Absence of a telephone at home or living more than 10 km from the hospital |

## Study procedure

All included patients sought care at the ED on their own initiative or were referred by primary care physicians. When the ED doctors diagnosed decompensation of CHF and identified the patient as a potential candidate for the study based on the eligibility criteria, the doctor responsible for recruiting patients into the study was called. The study doctor attended the ED whenever she was required, to confirm the diagnosis of CHF decompensation, check inclusion and exclusion criteria, provide information and to ask the patient for consent to participate. Once the patient had signed the informed consent form, they were randomly assigned (1:1) to one of the intervention groups according to an externally generated sequence, which was hidden from the clinicians until the patient had given consent to participate.

## Interventions

### Inpatient hospital care (IHC)

Patients were admitted to the hospital, cardiology ward and were managed by the usual staff of cardiology specialists and nurses, in accordance with guideline recommendations.

### Hospital at home (HaH)

Patients allocated to this group had the characteristics of the HaH unit explained to them while they were still in ED. They were also given an information sheet with contact telephone numbers. Within 12–24 h of the visit to the ED, patients received scheduled and, if necessary, urgent visits to their homes from an internal medicine specialist and a nurse, who were members of the staff of the HaH unit. In case of deterioration occurring outside the working hours of the unit (from 8 am to 9 pm every day of the year), patients and family were instructed to call 112, Emergencies Services, explaining that they were patients under the supervision of the HaH unit. Apart from the nursing and clinical evaluation, samples were taken for laboratory tests and ECGs were performed in patient's home when necessary.

Performance of X-ray and echocardiography at hospital was equally as accessible for HaH patients as for in-patients. As a general rule, all patients were visited daily by a specialist nurse. Patients were visited by a physician daily or every other day depending on their clinical condition. Treatment in HaH finished with referral to primary care after recovery or, in case of deterioration or no response to treatment, with transfer to the cardiology ward.

### Follow-up

After the initial admission (intervention), patients were followed up by their primary care physician, who was not aware of the study. A physician or a nurse from the study team contacted each patient at months 1, 3, 6, and 12 to record events such as death, new admissions, or visits to the ED, the cardiologist, or the primary care physician. Blood tests, including NT-proBNP, and re-evaluation of functional status and health-related quality of life were performed at month 12.

## Data collection

Baseline variables and clinical data from the index episode that caused admission to the ED were recorded, as well as cardiovascular history with special reference to the number of hospital admissions during the previous year. Blood samples for assessment of NT-proBNP (N-terminal pro-brain natriuretic peptide) levels were drawn in all patients at the ED. Comorbidity was estimated using the Charlson index.[12] Functional status and health-related quality of life prior to decompensation were estimated using the Barthel index[13] and the SF-36 questionnaire,[14] respectively. Left ventricular ejection fraction was measured by echocardiography. Heart failure with preserved ejection fraction was considered ejection fraction $\geq$45%.

### Effectiveness variables

The following were considered effectiveness variables: necessity to transfer the patient from HaH to IHC during the first admission, mortality due to any cause, re-admission due to HF, or another cardiovascular event (stroke, acute coronary syndrome, and coronary revascularization) during 1 year of follow-up. Variations in functional status (Barthel index) and health-related quality of life (SF-36), since first admission up to 12 months later were also studied.

### Cost variables

The following costs were collected for the initial admissions, either to HaH or to cardiology: cost of the stay, medication, diagnostic tests (electrocardiography, echocardiography, laboratory tests, and chest X-ray), consumables, and transport.

The health resources used during follow-up which were included in the study costings were: visits to HF clinic, primary care physician or ED, as well as re-admissions.

Cost estimation was based on compensation charged by the Basque Health Service-Osakidetza for hospital stays, visits, and diagnostic tests.[15] Expenditure on pharmaceuticals and consumables was calculated using the reference prices from the hospital's pharmacy service and purchasing department, respectively. For re-hospitalizations, in both the HaH and IHC groups, the cost of the admission was estimated assuming the average cost per day incurred during the first admission for each group.

## Statistics

In order to detect real differences of 2000€ or more between the two groups with respect to the overall costs associated with hospital admission, a sample size of 37 patients per group was estimated, with a power of 80% and type I error of 5%. Making provision for losses, it was decided to recruit 40 patients per group.

Comparisons between groups were performed using the $\chi^2$ test (categorical variables) and the Student's *t*-test (continuous variables) or, where necessary, the Mann–Whitney non-parametric test. Variation in quality of life and functional status during the follow-up period was compared with analysis of covariance, in order to take basal determinations into account. A significance level of $\alpha = 0.05$ was chosen for the analysis, and SPSS statistical package for Windows version 15.0 was used.

# Results

Between May 2006 and March 2007, 80 patients were included in the study. Nine patients (seven allocated to IHC arm and two to HaH) were withdrawn from the study as follows: three withdrew consent, three due to occurrence of extra-cardiac disease that made follow-up impracticable, and three on the recommendation of the monitoring committee).

Seventy-one patients completed the study, of these 34 were admitted to cardiology and 37 to HaH. No significant differences were found in baseline characteristics, including comorbidity, functional status, and health-related quality of life (*Table 2*). Clinical outcomes were similar after initial admission and also after 12 months of follow-up; death or re-admission due to HF or another cardiovascular event occurred in 19 patients in IHC and in 20 in HaH ($P = 0.88$). Changes in functional status and health-related quality of life after the follow-up did not show significant differences. The average cost of initial admission was 4502 $\pm$ 2153€ in IHC and 2541 $\pm$ 1334€ in HaH ($P < 0.001$). Over the 12 months after intervention, the average expenditure was 4619 $\pm$ 7679 and 3425 $\pm$ 4948€ ($P = 0.83$), respectively.

## Effectiveness

Results of clinical effectiveness of both models of care are shown in *Table 3*. No deaths or transfers from HaH to IHC occurred during initial admission. During the 12 months after the intervention, five patients died, three from the IHC group and two from the HaH group ($P = 0.6$). During the same period, incidence of the combined outcome of mortality, re-admission because of HF, or another cardiovascular event was similar in both arms: 19 patients in the IHC group and 20 of the HaH patients. Comparison of the incidence of new admissions due exclusively to new CHF decompensations shows no differences either: in the IHC group, 17 patients (50%) generated 29 new admissions to cardiology and 2 to HaH. Fifteen (40%) of the patients initially treated in the HaH group generated 32 new admissions, 25 to cardiology and 7 to HaH. That is, a total of 32 patients (45%) were re-admitted generating 63 admissions (1.9 re-admission per patient). The variation in quality of life (SF36, physical and mental components) and functional evaluation (Barthel index) was similar in both groups.

## Costs

The average cost of admission for the episode of HF that initiated inclusion in the study was lower for HaH (2541 $\pm$ 1334€ compared with 4502 $\pm$ 2153€; $P < 0.001$) than for IHC (*Table 4*). This reduction was mainly due to the lower average cost of

**Table 2 Baseline demographics and clinical characteristics of the study population**

| | Inpatient hospital care | Hospital at home | *P*-value |
|---|---|---|---|
| No. of patients | 34 | 37 | |
| Women, *n* (%) | 10 (29.4) | 19 (51.4) | 0.06 |
| Age, mean ± SD[a] | 79.9 ± 6.3 | 78.1 ± 6.2 | 0.20 |
| Admissions for HF in previous year | 0.41 ± 0.86 | 0.65 ± 0.86 | 0.13 |
| $O_2$ saturation in ED | 91.4 ± 5.2 | 93.2 ± 4.6 | 0.12 |
| Functional Class NYHA II, *n* (%) | 23 (67.6) | 19 (51.4) | |
| Functional Class NYHA III, *n* (%) | 11 (32.4) | 18 (48.6) | 0.16 |
| Atrial fibrillation, *n* (%) | 16 (47) | 21 (56.8) | 0.49 |
| LVEF ≥ 45%, *n* (%) | 24 (70) | 23 (62.1) | |
| LVEF < 45%, *n* (%) | 10 (29.4) | 14 (37.8) | 0.13 |
| NT-proBNP (pg/mL) | 4056 ± 5352 | 3864 ± 3720 | 0.86 |
| Charlson index | 2.1 ± 1.3 | 2.5 ± 1.5 | 0.35 |
| Chronic obstructive pulmonary dis. | 10 (29.4) | 13 (35.1) | 0.61 |
| Diabetes mellitus | 12 (35.3) | 11 (29.7) | 0.62 |
| Renal failure | 8 (23.5) | 12 (32.4) | 0.41 |
| Cancer | 4 (11.8) | 3 (8.1) | 0.7 |
| Non-severe dementia | 1 (2.7) | 2 (5.4) | 1 |
| Hypercholesterolaemia | 12 (35.3) | 17 (45.9) | 0.36 |
| Hypertension | 30 (88.2) | 31 (83.8) | 0.74 |
| Barthel index | 78.1 ± 19.1 | 85.5 ± 12.7 | 0.06 |
| SF-36 physical component | 30.6 ± 7.1 | 31.1 ± 8.8 | 0.78 |
| SF-36 mental component | 42.1 ± 10.2 | 42.7 ± 12.1 | 0.81 |

[a]Values are means ± SD, unless otherwise indicated.
HF, heart failure; ED, emergency department; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal pro-brain natriuretic peptide.

**Table 3 Clinical outcomes and change in quality of life at 1 year follow-up**

| | Inpatient hospital care | Hospital at home | *P*-value |
|---|---|---|---|
| Mortality, *n* (%) | 3 (8.8) | 2 (5.4) | 0.67 |
| Re-admission for heart failure, *n* (%) | 17 (50.0) | 15 (40.5) | 0.42 |
| Combined clinical outcome[a], *n* (%) | 19 (55.9) | 20 (54.1) | 0.88 |
| Variation in Barthel index at 1 year | 4.7 (−2.2; 11.5) | 4.0 (−0.9; 8.9) | 0.21[b] |
| Idem in SF-36 physical component | 2.2 (−1.9; 6.4) | 3.6 (−0.5; 7.7) | 0.47[b] |
| Idem in SF-36 mental component | 2.8 (−2.4; 8.0) | 4.0 (−0.9; 8.9) | 0.38[b] |

[a]Combined clinical outcome: mortality, re-admission for heart failure, or another cardiovascular event (stroke, acute coronary syndrome, coronary revascularization).
[b]ANCOVA, adjusted to basal levels.

**Table 4 Costs (in Euros) of the index episode**

| | Inpatient hospital care | Hospital at home | *P*-value |
|---|---|---|---|
| Average stay (days) | 7.9 ± 3.0 | 10.9 ± 5.9 | 0.01 |
| Cost of stay | 3771 ± 1912 | 1991 ± 1159 | <0.001 |
| Expenditure on pharmaceuticals | 38.7 ± 37.3 | 45.3 ± 41.1 | 0.52 |
| Cost of investigations | 598 ± 454 | 408 ± 173 | <0.001 |
| Consumables | 19.9 ± 17.2 | 6.4 ± 3.3 | <0.001 |
| Cost of transport | 75 ± 214 | 90 ± 217 | 0.05 |
| Total cost per episode | 4502 ± 2153 | 2541 ± 1334 | <0.001 |

stays, despite the average stay being shorter in IHC. In HaH, the amount spent on investigations and consumables was smaller. The particulars of this lower use of investigations are as follows: fewer electrocardiography (1.3 ± 0.6 vs. 3.4 ± 2; $P < 0.001$), fewer echocardiography (0.4 ± 0.5 vs. 0.9 ± 0.4; $P < 0.001$), fewer thorax radiography (1.2 ± 0.7 vs. 2 ± 0.6; $P < 0.001$), and fewer laboratory test (3.5 ± 1.5 vs. 4.9 ± 1.9; $P < 0.001$).

No significant differences were found in the overall cost per patient during follow-up, nor in the cost due to re-admissions, primary care physicians, or ED visits (*Table 5*).

# Discussion

Our study demonstrates that for patients with decompensated chronic HF, the HaH model of healthcare, with physicians and nurses undertaking visits to the patient's home, obtains similar results to IHC in the cardiology unit with respect to clinical events and quality of life at 1 year, while incurring lower overall costs.

Heart failure still has high rates of mortality and morbidity, despite the therapeutic advances made in recent years. Heart failure especially affects older patients, it is associated with a progressive deterioration in quality of life with frequent admissions to hospital. Patients in our study presented a mortality rate of 7% in the first year, with a re-admission rate of 45%, even though the 32 patients re-admitted accounted for 63 rehospitalizations, corresponding to an average of 2 re-admissions per patient. Considering that the mean age of our patients was 80 and that this age group is especially vulnerable to the adverse effects related to staying in hospital,[16] it seems necessary to find alternatives to traditional hospital admission for patients with worsening HF. In fact, several clinical trials have demonstrated a reduction in the rate of re-admissions,[17–19] and even a reduction in mortality[20] with no increase in costs[5] with a multidisciplinary home-based intervention.

**Table 5 Average costs (in Euros) per patient during the follow-up**

| | Inpatient hospital care | Hospital at home | *P*-value[a] |
|---|---|---|---|
| Cost per patient in new admissions to IHC | 4348 ± 7387 | 2809 ± 4416 | 0.45 |
| Cost per patient in new admissions to HaH | 125 ± 513 | 441 ± 1193 | 0.11 |
| Cost per patient in visits to PC, HFC, and ED | 146 ± 103 | 175 ± 127 | 0.35 |
| Total cost during follow-up per patient | 4619 ± 7679 | 3425 ± 4948 | 0.83 |

IHC, in hospital care; HaH, hospital at home; PC, primary care; HFC, heart failure clinic or cardiology outpatient clinic; ED, emergency department.
[a]Mann–Whitney test.

These findings have been confirmed in several meta-analyses reviewing different programmes for the management of HF.[21,22] In general, these programmes are initiated after hospitalization and have a multidisciplinary approach frequently led by HF nurses. However, the latest large clinical trial published,[23] regarded as definitive study on the subject, shows disappointing results on the role of nurses specialized in management of patients with HF. In these HF management programmes, physician consultations either take place over the phone or patients attend the HF clinic, the physicians do not visit the patient's home. In contrast, in our study, physician home visits were performed regularly.

A more recent and, in a sense, more innovative healthcare model is to avoid hospital admissions by transferring hospital care to the patient's home. This is the so-called HaH model of which there are several variations.[24] One model consists of a hospital unit with physicians and nurses going to the patient's home to provide the necessary care, including intravenous medication, laboratory tests, etc. This is the model that has been applied in the current study, as our hospital has a HaH unit with more than 15 years of experience.[25] Initial results from this type of care are encouraging.[25] In a recent meta-analysis[8] which included five clinical trials with patients suffering from different non-cardiac diseases, the most striking result was a reduction in mortality rates at 6 months of follow-up, with a non-statistically significant increase in hospital re-admissions and a reduction in costs.

We have not found many studies of the HaH model that only include patients suffering from HF. Leff *et al.*[7] investigated a subgroup of patients with HF, together with patients showing an exacerbation of chronic pulmonary disease or cellulitis. The study found a lower incidence of complications with a reduction in expenditure of 32% during admission. The reduction of costs during the index admission in our study was 44%, related mainly to the lower expenditure on hospital stays. Furthermore, there were also savings in the HaH group due to the lower rate of investigations and use of consumables (*Table 4*).

A study by Patel *et al.*[9] included patients with decompensated HF transferred to HaH after just 7–34 h of in-hospital treatment. Although only 31 patients were included, this excellent study provides a health economic perspective, gives detailed information about health-related quality of life by evaluating quality adjusted life years (QALYs) and supplies data about clinical evolution during 12 months of follow-up. Patel *et al.*'s model is based on nurses visits, but patients in the study stayed longer in hospital: 7–34 h in the ED or ward. A 1 year follow-up was carried out and quality of life was also assessed, although with a lower number of patients. Results were similar to ours when comparing the HaH model with the traditional one: no differences were found in clinical outcomes or quality of life, but a considerable reduction in cost of care was achieved. It would be interesting to investigate if similar results could also be achieved with shorter stays in HaH, since that would generate bigger cost savings.

## Limitations

The total costs of a disease are derived from the sum of direct, indirect, and intangible costs. The latter two, including loss of income and travel costs for relatives, as well as non-quantifiable costs derived from physical and emotional deterioration and care given by relatives and the community, have not been estimated in the present study. The number of patients in our study was small although we included more patients than others,[9] and the patient numbers conformed to the required sample size estimated before the start of the study. On the other hand, our findings are not applicable to all HF patients, but only to those fulfilling the inclusion and exclusion criteria specified for the study. These results should be confirmed in larger prospective trials.

## Conclusions

The HaH care model avoids traditional hospital admission for patients with decompensated chronic HF with no significant differences in clinical and functional outcomes at 1 year of follow-up, but with a substantial reduction in direct costs, more than 40% in the index episode.

## Acknowledgements

We would like to express our gratitude to Roche Laboratories, to the cardiology and HaH nurses, and to the pharmacy (Carlos Martinez), emergency, and laboratory departments as well as the finance unit (Jon Gonzalez de Garibay) from Txagorritxu Hospital for their collaboration.

**Conflict of interest:** none declared.

## Funding

This study was financed with a grant from the Caja Vital Kutxa.

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# Early experiences with cardiology electronic consults: A systematic review

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**Background** Many health systems have begun implementing electronic consultation programs. The clinical and financial impact of these programs in cardiology and the potential for more widespread adoption remains unknown.

**Objectives** To systematically review the current literature related to electronic consultation in cardiology.

**Methods** Following the PRISMA guidelines, we conducted a systematic review in August 2018 of English literature. We searched PubMed, the Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases for studies related to electronic consultation in cardiology.

**Results** A total of 21 studies were included. Two of the studies were randomized controlled trials, 16 were quantitative studies with defined endpoints, and 3 were qualitative descriptions. Most studies were conducted in the United States and Canada. The available literature suggests cardiology e-consult programs can be implemented in different practice settings, have good patient and provider satisfaction, deliver greater and timelier access to outpatient cardiac care, and do so in a cost saving fashion. While studies suggest cardiology e-consultation is safe, there are no studies evaluating hard clinical outcomes.

**Conclusions** Cardiology e-consults appear to be a promising tool for increasing access to outpatient cardiac care. Further investigation is required to evaluate the effects of cardiology electronic consultation on the quality of care.

**Condensed abstract** Here we present the first systematic review of electronic consultation in cardiology. The available literature suggests cardiology e-consult programs can be implemented in different practice settings, have good patient and provider satisfaction, deliver greater and timelier access to outpatient cardiac care, and do so in a cost saving fashion. While studies suggest cardiology e-consultation is safe, there are no studies evaluating hard clinical outcomes. Overall, cardiology e-consults appear to be a promising tool for increasing access to outpatient cardiac care. Further investigation is required to evaluate the effects of cardiology electronic consultation on the quality of care. (Am Heart J 2019;215:139-46.)

Health care costs in the United States continue to rise, currently accounting for nearly 18% of gross domestic product, or $3.3 trillion.[1] Cardiovascular care makes up over $300 billion of that figure annually, with some forecasting an increase to $1 trillion by 2030.[2,3] One contributor to rising healthcare costs is increasing demand for outpatient specialty care and consultation.[4] From 1999 to 2009, the absolute number of specialty referrals in the US more than doubled, further constraining limited ambulatory care capacity and increasing costs.[5] A predicted shortage of specialist and subspecialist physicians in the coming decades will exacerbate this supply-demand mismatch.[6] Furthermore, some studies classify up to 65% of specialty referrals as inappropriate and providers complain of disjointed communication resulting in lower quality care, extra testing, and increased costs.[7-9]

In addition, government, commercial insurers, and employer payers are all increasingly focused on delivering value-oriented care for beneficiaries, putting pressure on specialists to deliver more cost-effective outpatient care. Many policy initiatives including the establishment of ACOs, bundled payments, meaningful use requirements, and quality reporting are all designed to shift towards value-based care.[10,11] Several health systems have responded to these pressures by using electronic medical record platforms to facilitate access to specialty care and advice for primary care physicians (PCPs).[12] Many of these early pilot programs were created to avoid unnecessary office visits to specialists and to provide more timely consultative

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*Funding: This work was supported by grants from the National Institutes of Health and Harvard Catalyst (KL2 TR001100) as well as the American Heart Association (18CDA34110215), both awarded to Dr. Wasfy.Conflicts of interest: none declaredAcknowledgments: none*

*Submitted March 20, 2019; accepted June 18, 2019.*

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*https://doi.org/10.1016/j.ahj.2019.06.013*

input. In that context, electronic consultations ("e-consults") have developed rapidly.

Several specialties have explored the utility of e-consults in clinical practice. The clinical and financial impact of these programs, specifically in cardiology, and the potential for more widespread adoption remains unclear. Here, we perform a systematic review in an effort to explore the early experiences with cardiology e-consults. Our objective in this review is to answer four key questions:

1. What do we know about the current design of e-consults within cardiology?
2. What experiences have providers and patients had with cardiology e-consults?
3. How do e-consults differ from traditional face-to-face with respect to the delivery of cardiac care?
4. What are the financial implications of cardiology e-consults?

## Methods

This work was supported by grants from the National Institutes of Health and Harvard Catalyst (KL2 TR001100) as well as the American Heart Association (18CDA34110215), both awarded to Dr. Wasfy. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the manuscript, and its final contents.

### Data sources

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement. We performed systematic searches in PubMed, the Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) for titles published in any year. Our initial search strategy focused on keywords for electronic consultation (ie, e-consult, virtual consult, store-and-forward) and keywords for cardiac care. Reference lists of all included titles were reviewed to supplement articles identified from the electronic search. We did not include unpublished conference abstracts in this review.

### Inclusion criteria

For the purposes of this systematic review, we defined electronic consultation using 4 basic features: 1) a communication occurs between (at least) two health care providers, 2) the communication is asynchronous, 3) the question and response occurs over a secure electronic medium and is documented as part of the official record, 4) the question and response involves a specific clinical issue. Importantly, this definition excludes other forms of electronic interaction including inpatient e-consults, electronic referrals, and the less formal "curbside" or e-mail messaging.

We originally planned to include only studies dedicated to electronic consultations in cardiology, however our initial search identified relatively few publications. This prompted us to expand our review to include those studies investigating multi-specialty electronic consult systems that clearly include cardiology. We included randomized control trials, empirical studies with defined metrics as well as more descriptive and qualitative studies. We excluded editorials, prior systematic reviews, and non-English articles.

### Article selection and data synthesis

A physician (AO) reviewed the titles and abstracts of each article identified by our search terms. Those articles that met eligibility criteria on this first screen were then reviewed in full by a physician (AO) and selected for inclusion. For articles on multi-specialty electronic consults, data extraction and review focused on the portion of the study related to cardiology electronic consultations where possible. We collected information on patient population, setting, and reported outcomes. We did not aim to report specific quantitative outcome measures, but rather to synthesize and summarize qualitative experiences and effects of cardiology electronic consultation on the quality and cost of care.

## Results

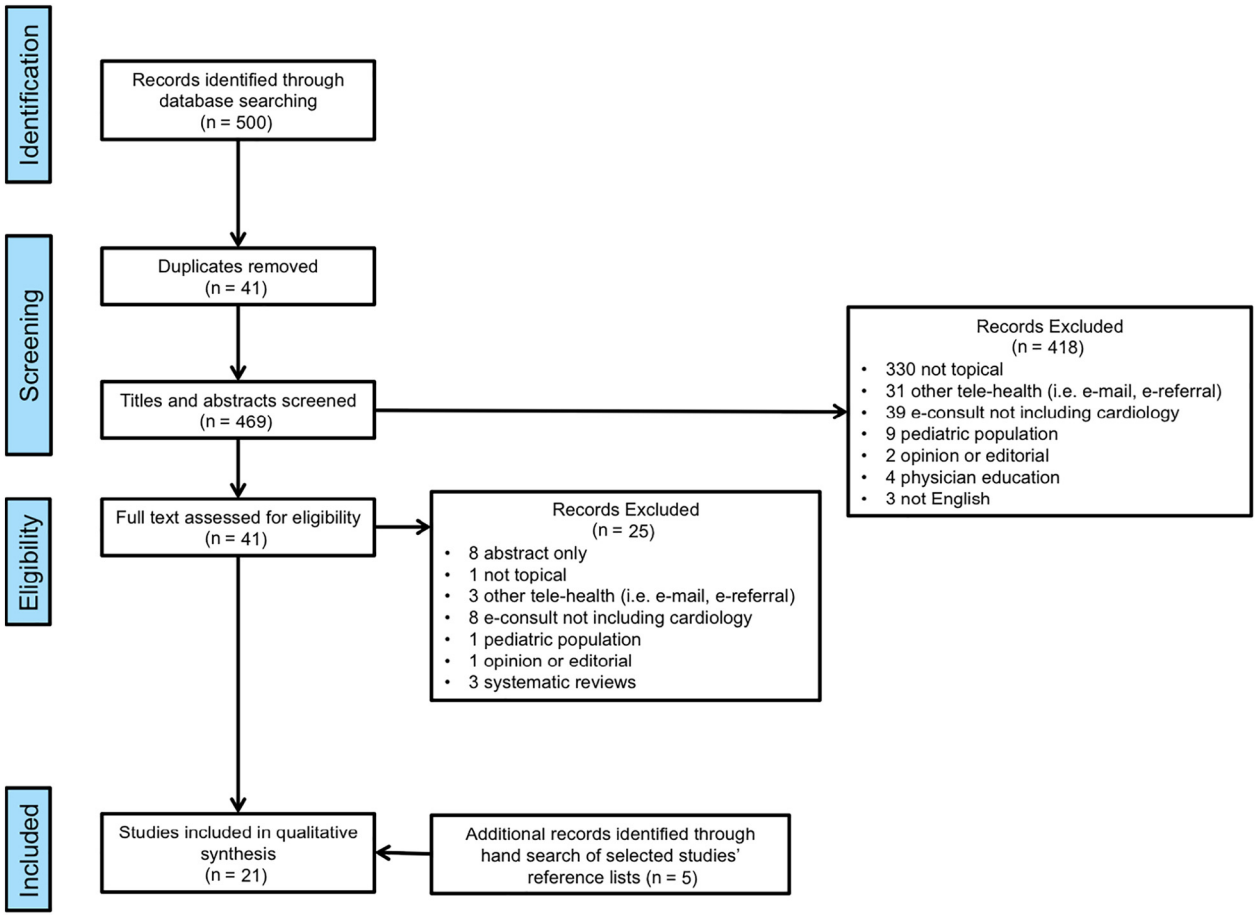
The initial database search identified 41 titles and abstracts meeting inclusion criteria. Upon review of the full-text, 16 articles were selected with an additional 5 articles identified after hand review of these studies' reference lists. The selection process is detailed in the flow diagram (Figure 1).

The 21 articles examined a variety of topics ranging from patient and provider satisfaction with e-consult systems to the impact of e-consults on the cost of care (Table I). The bulk of the literature came from a health network in Ontario, Canada (n = 13).[13-25] In the United States, published experiences with cardiology e-consults came from various single-centers including Community Health Center, Inc. (CHCI) in Connecticut,[26,27] Massachusetts General Hospital in Boston,[28-30] San Francisco General Hospital (SFGH),[31-33] and the Department of Veterans Affairs.[34] Two of the studies were randomized control trials,[26,27] 16 were quantitative studies with defined endpoints, and three were qualitative descriptions of e-consult programs. Six of the articles were focused solely on cardiology,[25-30] while the remainder examined multi-specialty e-consult programs that included cardiology. Eight of the studies took place at a single-center, while the remaining 13 investigated multi-site models. All articles were published between 2009 and 2018.

### Current design and variation in approach

Electronic consultation programs exist within diverse health systems, serving different patient populations, and utilize varied workflows and processes. Substantial

**Figure 1**




PRISMA Flow Diagram. Our systematic literature search followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement. We performed systematic searches in PubMed, the Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) for titles published in any year. One author (AO) reviewed titles and abstracts to ensure they met the pre-specified inclusion criteria. A total of 21 articles were included in the final review.

literature comes from the electronic consultation experience in the Champlain Local Health Integration Network – a regional health district in Eastern Ontario, Canada serving over 1 million patients.[17] In the United States, 2 programs have published literature specifically related to their experience with cardiology e-consult programs. The first, Massachusetts General Hospital (MGH), is a large, urban, academic medical center serving a diverse patient population.[29] The second, CHCI is a statewide, multisite federally qualified health center in Connecticut serving predominantly Medicaid patients.[26] Other well-developed e-consult programs in the United States include San Francisco Health Network, which is an academic, urban safety-net hospital and the VA, an integrated public system.

While all the programs in this review met the 4 basic features defining electronic consultation, there was variation in approach and process. The Champlain Building Access to Specialists through eConsultation (BASE) program was launched in 2009 in order to improve access to specialty care, including cardiology. The service is an independent e-consultation system built on an existing web-based platform. It allows community PCPs to voluntarily complete an electronic form when deemed clinically appropriate that is then forwarded to the appropriate, non-affiliated specialist. The system allows for iterative communication following the initial consult question. In this program, the PCP is responsible for initiating the consultation, relaying any recommendations and, finally, closing the case.[15]

SFGH has implemented an active referral management (ARM) system.[33] Under this system, primary care providers, located either in the hospital or the community, utilize a web-based portal integrated into the hospital's electronic health record (EHR) to place a consult request.

**Table I.** Characteristics of included studies

| First author (year) | Setting | Type of service | Study design | Study size | Outcomes |
|---|---|---|---|---|---|
| Anderson (2018) | USA | Cardiology | RCT | 590 patients<br>36 PCPs<br>3 Cardiologists | Total cost |
| Chittle (2015) | USA | Cardiology | Chart review | 54 patients | Patient and provider satisfaction |
| Keely (2015) | Canada | Multi-specialty | Survey | 34 specialty clinicians | Provider satisfaction |
| Kim (2009) | USA | Multi-specialty | Survey | 368 PCPs | Provider satisfaction |
| Kim-Hwang (2010) | USA | Multi-specialty | | 505 specialty clinicians | Referral appropriateness; need for and avoidability of follow-up visit |
| Liddy (2016) | Canada | Multi-specialty | Mixed methods | 3686 PCPs<br>574 NPs | E-consultation referral patterns, experience, and satisfaction based on provider type (ie NP vs PCP) |
| Liddy (2017) | Canada | Multi-specialty | Cross-sectional | 594 e-consults | E-consult response time<br>Provider satisfaction<br>Overall program cost |
| Liddy (2015) | Canada | Multi-specialty | Survey | 2052 e-consults | Provider satisfaction |
| Liddy (2016) | Canada | Multi-specialty | Cross-sectional | 1796 patients over 65yo | E-consult response time<br>Provider satisfaction<br>Need for follow-up face-to-face visit |
| Liddy (2017) | Canada | Multi-specialty | Cross-sectional | 5601 e-consults | Percentage of prompted e-consults (ie would not have otherwise been made)<br>Clinical question and process measures associated with prompted consults |
| Liddy (2018) | Canada | Multi-specialty | Cross-sectional | 14,105 e-consults | E-consult system utilization data over time |
| Liddy (2018) | Canada | Multi-specialty | Mixed methods | 28,838 e-consults | Patient and provider satisfaction<br>Cost (total system, per capita)<br>Provider adoption and utilization<br>Patient safety |
| Liddy (2016) | Canada | Multi-specialty | Economic | 3487 e-consults | Net societal cost savings |
| Liddy (2015) | Canada | Multi-specialty | Economic | 2606 e-consults | Total cost |
| Liddy (2016) | Canada | Multi-specialty | Economic simulation | 3670 e-consults | Total and per e-consult cost based on physician remuneration structure |
| Liddy (2017) | Canada | Multi-specialty | Cross-sectional | 165 patients<br>19 PCPs<br>55 specialty clinicians | Utilization statistics<br>Costing evaluation |
| McAdams (2014) | USA | Multi-specialty | Descriptive/qualitative | Not specified | Understand implementation of e-consult system at a VA health center |
| Olayiwola (2016) | USA | Cardiology | RCT | 590 patients<br>36 PCPs | Time to consultation with cardiologist<br>Completion rate of e-consult<br>Number of face-to-face visits<br>Adverse events |
| Skieth (2017) | Canada | Cardiology | Cross-sectional | 162 e-consults | Patient and provider demographic data<br>Consultative-specific data<br>Impact on provider referral patterns |
| Wasfy (2014) | USA | Cardiology | Descriptive | 78 e-consults<br>62 PCPs | Utilization statistics<br>E-consult question type<br>Provider satisfaction |
| Wasfy (2017) | USA | Cardiology | Chart review | 165 e-consults | Trends in E-consult utilization and volume<br>Safety and adverse events<br>Clinical and demographic differences in e-consults and traditional consults |

In contrast to the Champlain BASE program, all requests for specialty consultation must go through this process. Next, a clinician reviewer sorts referrals into various categories: those to be managed by the referring provider with electronic guidance and recommendations from the specialist, those requiring a face-to-face visit with the specialist, and those requiring further testing or work-up prior to either an in-person or electronic visit. The VA, which began implementing e-consults in 2011, utilizes a similar process for referrals to 50 medical specialties in over 150 medical centers and 800 community-based clinics nationwide.[34]

At Massachusetts General Hospital, the cardiology e-consult program was started in 2014. In that system, referring providers and patients together choose between a traditional face-to-face consult and an e-consult. If an e-consult is placed, the consulting cardiologist reviews available clinical data, including primary imaging data,

and provides detailed management recommendations in the EHR, which are ultimately conveyed to the patient by the PCP.[28]

These variations in design and submission workflow may have significant impact on uptake and utilization by participating providers. For example, the e-consultation program at SFGH, which is mandatory for all requests for specialty care, has experienced universal adoption by PCPs, compared to only 75% uptake in the voluntary Champlain BASE experience.[35]

## Satisfaction

E-consults have generally been associated with high levels of satisfaction among both patients and providers. Survey data from the MGH cardiology e-consult program found that 100% of patients were 'very' or 'somewhat' satisfied, while similar data from the vascular Medicine e-consult program revealed a patient satisfaction score of over 90%.[29,30] Primary care providers similarly tend to have very high levels of satisfaction. In the Champlain BASE experience, PCPs reported high value for their patients and themselves in over 90% of e-consults.[16] These high levels of satisfaction are driven by both perceived improvements in workflow (i.e. shorter wait times, convenience) and clinical care (i.e. better access to specialty input, improved communication, educational value). Specialists have also largely been satisfied with e-consultation programs. Survey data suggests improved access to specialty care, better communication between providers, and educational value for PCPs as three reasons for specialist satisfaction. In this same study, 88% of specialists felt that the e-consultation program should be expanded.[24]

## Clinical care

Important clinical differences seem to exist between traditional consults and e-consults. It appears different types of providers may have different thresholds for placing e-consults, with attending physicians being more likely than residents who are in turn more likely than physician assistants and nurse practitioners.[31] Another study comparing referral patterns of primary care physicians and nurse practitioners in a multi-specialty e-consult system found that PCPs directed a larger percentage of their consults to cardiology compared to NPs.[14] Practice environment may similarly influence likelihood for placement of an electronic consult, with physicians practicing in hospital-based clinics outnumbering community clinics in at least one study.[31] There may also be differences in the types of patients referred for electronic consultation. One study of a cardiology e-consult program found that patients who received e-consults were on average 5.1 years younger than those who received traditional consults, however, there did not appear to be gender differences.[29] Finally, the type of clinical question asked varies, with e-consults lending themselves to questions about abnormal test results or laboratory data that rely less heavily on physical examination or procedures. In two separate cardiology studies, the most common reason for an e-consult was abnormal electrocardiogram or echocardiogram findings.[27,28]

Other studies have examined the effect of cardiology electronic consultation on certain process measures. One randomized controlled trial evaluating the effects of cardiology e-consultation on wait time and access to specialty care found that the median wait time to consultation was just 5 days in the e-consult arm, compared to 24 days in the control arm. Furthermore, just 14% of patients had not seen a cardiologist within 31 days of the e-consult being placed, compared to 38 days for traditional consult requests.[27] Another study found that electronic consultation successfully improved access to specialty care for the elderly.[17] Finally, there is reason to believe that cardiology e-consultation might improve access for medically underserved patients in rural locations. While this has been seen with certain telehealth programs and may apply to electronic consultation, evidence found in these papers is currently lacking.[36]

At the time of this systematic review there are no studies evaluating definitive clinical outcomes such as mortality or myocardial infarction associated with cardiology e-consults. With that said, in both the MGH (n = 329) and the UCHC (n = 120) cardiology programs, a review of medical records did not show any evidence to suggest patients managed through electronic consultation had increased rates of adverse events; however in both instances detection of events was limited to records accessible within the system's EHR.[27,29]

## Economics and financial impact

The literature suggests that e-consults have the potential to save costs through a number of possible mechanisms. First, they are less expensive and necessitate fewer resources than traditional office visits. While the absolute cost of an e-consult is still being defined and varies based on reimbursement structure and physician specialty, one study estimated the cost per consult to be between $45 and $60.[21] The MGH experience with cardiology e-consults estimated that replacing a traditional visit with an e-consult results in overall savings in provider charges of nearly $125 (based on a cost of $52 per e-consult).[29] Second, allowing specialists to review and triage consults based on the clinical scenario may result in a reduction in avoidable specialty visits, saving face-to-face encounters for those patients who benefit most – for example pre- or post-procedure visits. In one study, in 40% of cases the PCP had originally considered a face-to-face specialty visit that was ultimately avoided as a result of e-consultation. Specific to cardiology, the VA Boston found that approximately one-third of cardiology e-consults avoided traditional referrals with a face-to-face visits.[34] In the MGH cardiology e-consult experience, only one fourth of patients who received an e-consult return to traditional cardiology care. Similarly, patients that ultimately

have a face-to-face visit with a specialist following an e-consult, may be less likely to require follow-up appointments because they receive a more extensive pre-visit work-up under the e-consult system. Finally, electronic consultation may reduce duplicative or otherwise unnecessary tests and procedures. An RCT evaluating the economic impact of the CHCI cardiology e-consult program demonstrated a net reduction in overall outpatient procedures for patients in the e-consultation arm compared to the usual care arm.[26]

A number of recent studies have attempted to estimate the overall cost consequences of electronic consults. One study evaluating a multi-specialty e-consult system in Canada estimated that e-consults led to a net societal saving of $11 per e-consult.[20] A randomized controlled trial evaluating the cost consequences of cardiology e-consults for 590 Medicaid patients concluded that cardiology e-consults reduced total healthcare costs. Specifically, giving PCP's the option to place cardiology e-consults resulted in a $466 decrease in total costs per Medicaid beneficiary compared with traditional face-to-face visits.[26]

While e-consult utilization is expanding, policy regarding reimbursement for these services continues to evolve. Examples of existing reimbursement schemes include fee-for-service, pro-rated hourly rates, workload credits, and the use of salaried physicians.[31,33] In January 2019 Centers for Medicare & Medicaid Services (CMS) introduced new Current Procedural Terminology (CPT) codes to allow direct payment to physicians for electronic consultation through Medicare.[37] Connecticut's Medicaid program has also begun reimbursing for e-consults.[38] Many commercial health insurers have also begun reimbursing for electronic consultation.[39,40] The specific reimbursement mechanism for specialists has implications for both overall cost and ease of implementation.[21] Additionally, specialist satisfaction with reimbursement structure and amount has varied.[24]

## Discussion

While cardiology e-consult programs are growing, definitive conclusions are limited by relatively short experience in a select number of diverse institutions. Early reports suggest that cardiology e-consult programs can be successfully implemented in varied practice settings with high patient and provider satisfaction. Cardiology e-consults appear to improve access to specialty care and reduce wait times. While studies suggest that e-consultation is safe, rigorously determining how e-consults affect clinical outcomes as compared to the traditional model will be essential. Other clinical outcomes besides overt adverse events, for example relief of symptoms, will be important to include in any assessment. At least initially, surveying participants and continuing to monitor for adverse events may be the most realistic way to answer this question given the high variability of clinical questions and difficulty in determining meaningful clinical endpoints in the ambulatory setting. As programs become more robust, with higher volumes, and streamlined processes, randomized-controlled trials comparing traditional and electronic-consultation with respect to clinical end points such as myocardial infarction will be important.

Understanding the financial implications of e-consults is also critical as the demand for and cost of cardiology care continues to rise. The studies reviewed in this article, including one randomized control trial, demonstrate that cardiology e-consults are associated with cost savings. However, the limited number of studies have been conducted within varied health care systems with different business models and reimbursement strategies, reducing their external validity. Lastly, finding the most appropriate time for physicians to complete e-consultations will be critical. By virtue of their design, cardiologist can perform e-consults during unanticipated gaps in time, offering increased flexibility with respect to the timing of completion.

New payment policies are requiring providers to re-think how specialty services – including cardiology – should be delivered. The organizational and reimbursement structure of policy initiatives like ACOs and bundled payments provide new incentives for providers to reduce costs.[41,42] By allowing specialists to screen appointments based on appropriateness, necessity, and urgency, while also aiding and empowering primary care physicians to more fully manage their patients without unnecessary face-to-face specialty visits, e-consults provide a compelling response to the new policy landscape.[43,44] As pointed out in a policy brief from the Commonwealth Fund, national health policy could further promote the use of e-consult technology by including it as part of the meaningful use objectives in the Health Information Technology for Economic and Clinical Health Act.[45] Finally, CMS recently issued a proposed rule that would allow separate Medicare payments for certain physician-to-physician electronic communication, such as e-consults.[37] Final approval of this rule could lead to substantial growth in cardiology e-consult programs.

## Limitations

The studies in this systematic review originated from a relatively small sample of health systems, limiting the generalizability of our findings. Our review was limited to peer-reviewed literature and therefore may have overlooked other e-consult systems and publications of interest. Finally, the majority of our studies evaluated multi-specialty e-consult systems that included cardiology. Future investigation should aim to examine quality and cost outcomes of dedicated cardiology e-consult systems.

## Conclusion

Early experience with cardiology e-consults suggests that e-consults can be successfully implemented in different practice settings with high patient and provider

satisfaction. E-consultation may be able to provide greater and timelier access for patients who require cardiology consultation. The appropriateness of individual consults and their effect on hard clinical end-points should be further evaluated to understand how cardiology e-consults influence the quality of care. Finally, cardiology e-consults appear to result in absolute cost savings. Cardiology seems well suited to lead in the further exploration and adoption of e-consults. The overall cost of care is high and access is constrained, requiring more efficient care models in the ambulatory setting. In that context, e-consults could emerge as a genuinely disruptive tool in outpatient cardiology.

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Original Article

# Electronic Consultations in Allergy/Immunology

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***What is already known about this topic?*** Electronic consultations (e-consults) provide rapid, focused, cost-effective care in other specialties but have not been studied in Allergy/Immunology.

***What does this article add to our knowledge?*** E-consults comprised 10% of all new Allergy/Immunology consults, providing efficient (11-minute completion time), rapid (<24-hour turnaround time) allergist guidance, particularly for adverse drug reaction and immunodeficiency assessments.

***How does this study impact current management guidelines?*** Many patients can be quickly helped with electronic allergist/immunologist guidance, thus reserving in-person consults for patients requiring more detailed evaluations often with specialty-specific diagnostic testing.

**BACKGROUND: Allergic condition management more often requires allergist guidance than allergy testing; necessary testing may be unavailable at initial drug allergy consultations. Electronic consultations (e-consults) provide expedited, problem-focused, potentially cost-saving care in other medical specialties, but have not yet been studied in Allergy/Immunology.**

**OBJECTIVE: To describe e-consult use at an academic allergy/immunology practice.**

**METHODS: E-consult data (August 10, 2016 through July 31, 2018) and in-person consult data (August 1, 2014 through July 31, 2018) were reviewed to determine consult volume, outcomes, indications, and timing. Referral reasons and wait times were compared with chi-square tests.**

**RESULTS: E-consults grew from 1% to 10% of all new consults, with concurrent growth in in-person consults. Of 306 completed e-consults, 41 (13.4%) made diagnostic, therapeutic, or alternative referral recommendations, with 30 (73%) recommendations followed; 183 (59.8%) patients required an in-person Allergy/Immunology consult, and only 5 (<2%) patients saw an allergist without an e-consult recommendation to do so. E-consults were used more often than in-person consults for adverse drug reactions (66% vs 9%; $P < .001$), especially penicillin allergy (132, 61% of all e-consults) and immunodeficiency (15% vs 2%; $P < .001$). Allergists completed e-consults in a median of 11 minutes, with a median turnaround time of 22 hours. E-consult implementation was associated with a decreased median in-person consult wait time (1.5 fewer calendar days; $P < .05$).**

**CONCLUSIONS: E-consults were increasingly used, particularly for historical adverse drug reactions and immunodeficiency. Implementation of an e-consult program resulted in decreased in-person wait times despite an increase in overall consult volume, supporting this model's ability to provide expedited, problem-focused care.**  **(J Allergy Clin Immunol Pract 2019;7:2594-602)**

***Key words:*** *Telehealth; E-consult; Electronic consultation; Asynchronous allergist access; Access; Adverse drug reaction; Immunodeficiency evaluation; Quality improvement*

## INTRODUCTION

Health care spending in the United States reached $3.3 trillion in 2016; nearly $665 billion was due to physician and clinical services expenditure.[1] Allergic conditions affect more

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This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sector. J.H.W. reports a career development award from the American Heart Association (18 CDA 34110215). K.G.B. discloses grant funding from the National Institutes of Health (grant no. K01AI125631), the American Academy of Allergy,Asthma and Immunology Foundation, and the MGH Claflin Distinguished Scholars Award.

Conflicts of interest: N. A. Phadke discloses spousal employment by the Chiesi Group. The rest of the authors declare that they have no relevant conflicts of interest.

Received for publication March 6, 2019; revised May 8, 2019; accepted for publication May 18, 2019.

Available online June 3, 2019.

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2213-2198



https://doi.org/10.1016/j.jaip.2019.05.039

*Abbreviations used*
*ADR- Adverse drug reaction*
*AFR- Adverse food reaction*
*E-consult- Electronic consultation*
*EHR- Electronic health record*
*IQR- Interquartile range*
*MGH- Massachusetts General Hospital*

than 50 million Americans and cost more than $18 billion annually.[2] During ragweed season, patients with allergic rhinitis lose 7% of their productivity while those not on medication lose 10%; however, $18 spent weekly on medication can manifest as a $36 weekly gain in productivity.[3] Penicillin allergy is reported by approximately 32 million Americans and results in adverse consequences for patients and costs to the health care system, but less than 0.1% of these patients see an allergist for a penicillin allergy evaluation although new multidisciplinary guidance recommends broad penicillin allergy evaluations.[4,5] Only about half of the 9% of adults who think they are food-allergic actually are, after proper allergy testing.[6] Despite the prevalence and impact of reported and true allergies, there are only about 5000 actively practicing allergists/immunologists in the United States.[7] Wait times to see an allergist often exceed the 5 days reported in 2009/2010, and in-person evaluation might cost more than $1000.[7,8] However, some allergy consults may not be necessary; patients with nonallergic symptoms associated with drugs or foods might be referred for allergy testing that is not indicated, which can leave both the allergist and the patient dissatisfied.

Electronic consultations (e-consults, a clinician-to-clinician exchange in the electronic health record [EHR]) were developed to improve specialist access and reduce unnecessary ambulatory specialist consults.[9-14] In addition to being associated with high levels of referring provider, patient, and subspecialist satisfaction, e-consults were cost-effective, with nearly $125 saved for every traditional new patient consult replaced with an e-consult.[12-17]

As health care shifts to focus on value rather than volume, novel management and health care delivery strategies often require increased spending on some services to decrease costs of others.[18-20] Telehealth is a key example. Synchronous tele-allergy services have been associated with decreased patient wait time and increased patient satisfaction, particularly for food allergy, allergic rhinitis, asthma, and urticaria; other specialties have also found telehealth evaluation methods to reduce overall health care system costs.[21-26] Comprehensive synchronous tele-allergy services, however, require patient travel to a center equipped with necessary medical supplies for examination and/or testing in addition to remote allergist doctor-to-patient engagement.[21,22,27] E-consults bypass these barriers but have not been implemented broadly or evaluated in Allergy/Immunology in the United States. We therefore sought to describe our institution's Allergy/Immunology e-consult program, including e-consult volume, outcomes, indications, and timing.

## METHODS

### E-consult description and implementation

The e-consult is an electronic, asynchronous, clinician-to-clinician (often a primary care doctor to a specialist) exchange intended to provide specialist guidance to the requesting provider for a request that is nonurgent and problem-focused and relies on information available within the EHR. There is no direct specialist-to-patient interaction. Referring providers request an e-consult using an order in the EHR that is received in the "In Basket" of designated administrators and e-consultants. Providers can request a specific e-consultant, but most requests are sent to the assigned e-consultant, typically the attending allergist supervising inpatient consults. The e-consultant asynchronously reviews EHR data and shares diagnostic and management recommendations in a brief note recorded in the EHR. The referring provider then decides which subsequent steps to take on the basis of these recommendations. If anything remains unclear, further communication with the e-consultant can occur via repeat e-consult or subsequent formal consult. All e-consults include a disclaimer statement that recommendations are based only on the information available in the EHR and that the referring provider is responsible for ongoing management (see Supplementary Text in this article's Online Repository at www.jaci-inpractice.org).

Massachusetts General Hospital (MGH) began e-consults in 2013 in Cardiology and Dermatology with the aim to reduce unnecessary ambulatory consults to specialists and improve access for the sickest patients in our complex health care system. As of January 2019, there were 47 specialty areas of service providing e-consults within MGH at a volume of nearly 10,000 e-consults per year (2018) with more than 20,000 e-consults performed to date.[9,11-13] E-consult program development was encouraged, supported, and advertised through the Massachusetts General Hospital Physicians Organization incentive programs in population health management and quality improvement.

Allergy/Immunology e-consults were launched in August 2016, initially as a pilot program for food and drug allergy, but because of early success, all indications were included by October 2016. In addition to the general e-consults offered, a specific e-consult initiative was started with Obstetrics in January 2018 to evaluate pregnant patients with penicillin allergy histories to optimize receipt of first-line beta-lactam antibiotic therapy when indicated.[5,28-30] All attending MGH allergists (n = 16) participated in e-consults; the Massachusetts General Physicians Organization encouraged completion within 3 business days (service-level expectation). Given that insurance had not yet recognized e-consults for traditional reimbursement, the Massachusetts General Physicians Organization compensated allergist e-consultants internally with a per-consult fixed rate incentive payment reflective of specialist provider effort for telehealth.

### Data periods and definitions

We reviewed ambulatory e-consults from August 10, 2016 through July 31, 2018, and ambulatory in-person consults (defined as a new patient, consult, or 60-minute established patient visit) from August 1, 2014 through July 31, 2018.

We identified e-consult outcomes, including diagnostic, therapeutic, and referral recommendations and how often such recommendations were followed by referring providers. Following recommendations was considered a binary outcome (yes/no) and was yes if at least 1 allergist recommendation was followed. Recommendations for in-person consult considered only those without a stipulation (eg, "refer for in-person consult if rash worsens" was excluded). When both diagnostic testing and in-person consult were recommended, in the absence of explicit instructions to send diagnostic testing before the consult, this was considered as in-person

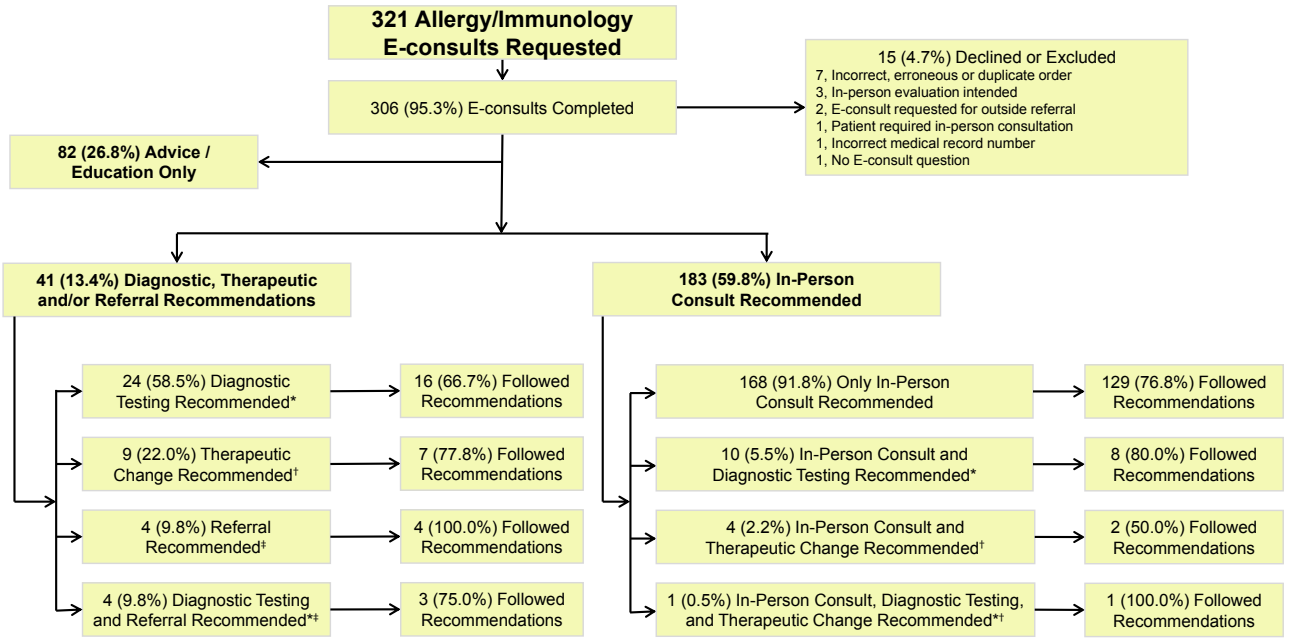


**FIGURE 1.** Allergy/Immunology E-consult outcomes. This flow chart describes all 321 e-consults ordered. E-consults were analyzed on the basis of need for in-person allergy/immunology consult (n = 183) and other diagnostic (n = 28), therapeutic (n = 9), and referral (n = 8) recommendations. Some e-consults made multiple recommendations. Recommendation percentages are out of 306 completed e-consults; recommendations followed percentages are of relevant recommendations made (eg, 66.7% is 16 of 24 diagnostic testing recommendations). *Recommended diagnostic testing included 35 recommendations for blood, urine, or stool laboratory testing, 2 drug challenge recommendations, 1 computed tomography scanning recommendation, and 1 spirometry recommendation. †Recommended treatments included 11 instances of recommending a new medication, 2 instances of recommending a different dose of a current medication, and 1 instance where both a new medication and a different dose of a current medication were recommended. ‡Other specialist referrals included dermatology, gastroenterology, hematology, infectious diseases, neuroimmunology, oral maxillofacial surgery, otolaryngology, and rheumatology.

consult recommended only. We additionally assessed the most common referring departments for e-consults.

We determined the number of completed e-consults, both as an absolute number and as a proportion of all allergy new patient consults.

We determined the indications for allergy e-consults and in-person consults. For e-consults, indications were based on the referring providers' descriptions, which were then grouped: adverse drug reaction (ADR), adverse food reaction (AFR), anaphylaxis, cutaneous (eg, rash, hives, itching, and dermatitis), eosinophilia, immunodeficiency, ocular allergy, respiratory (eg, cough, shortness of breath, and asthma), rhinitis, sinusitis, urticaria/angioedema, venom reaction, and other. For in-person consults, primary *International Classification of Diseases, Ninth and Tenth Revision* codes were used to group diagnoses similarly to the e-consults (see Table E1 in this article's Online Repository at www.jaci-inpractice.org).

Finally, we assessed e-consult completion time and turnaround time as well as wait times for in-person consults. Completion time, minutes between opening and closing the e-consult in the EHR, measured the time necessary for the reviewing allergist to provide clinical input on the basis of available data; turnaround time, hours between placement of the e-consult order and closing of e-consult, measured the time necessary for the ordering provider to receive allergist guidance. Patient wait times for in-person consults, defined as the number of calendar days between when an appointment was scheduled and when a patient was seen, were calculated by month from appointment data stored on the Tableau server at MGH.

### Statistical analysis

We present numbers with frequencies and medians with interquartile ranges (IQRs). We compared continuous variables (eg, completion time and wait time) using Wilcoxan rank sum test and frequencies (eg, consult indications) using chi-square tests. Comparative analyses were performed in SAS (version 9.4, SAS Institute Inc, Cary, NC).

### Institutional review board

The development and assessment of this e-consult program was undertaken as a Quality Improvement Initiative, and as such was not supervised by the Partners Human Research committee per its policies.

## RESULTS

### E-consult outcomes

From August 10, 2016 through July 31, 2018, there were 321 e-consults ordered, with 306 (95.3%) completed (Figure 1). Ordering providers for completed e-consults were commonly obstetricians/gynecologists (n = 133 [43.5%]), internists/internal medicine subspecialists (n = 130 [42.5%]) including infectious disease specialists (n = 12 [3.9%]), and family practitioners (n = 11 [3.6%]), but also included other allergists/

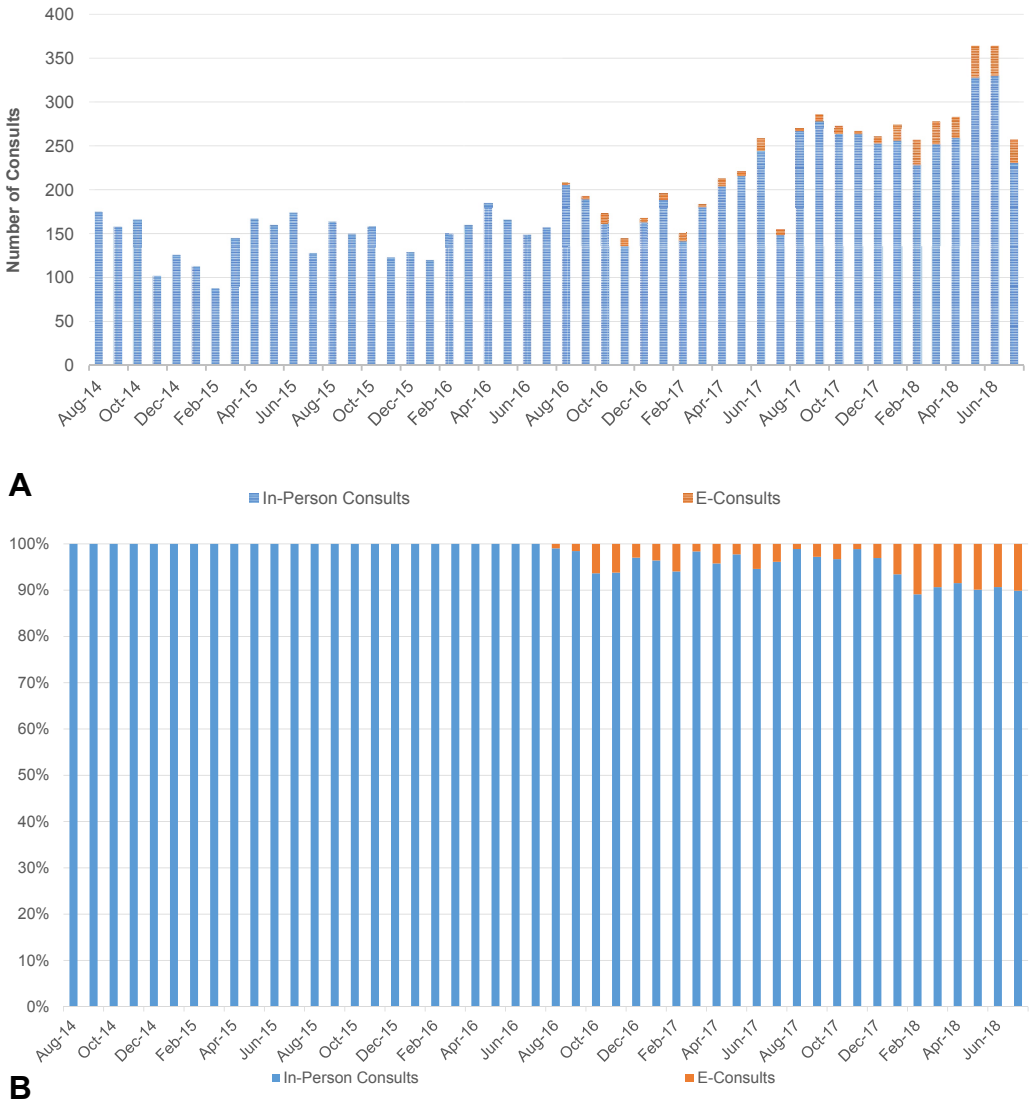


**FIGURE 2.** Trends in allergy e-consult and in-person consult volume. This bar graph shows the total in-person consults (blue) and e-consults (orange) from 2 years before the implementation of the e-consult program through the completion of our analysis. **A,** Number of e-consults. The number of e-consults increased from a median of 7 e-consults per month (August 2016-December 2017) to a median of 26 e-consults per month with the launch of the penicillin allergy testing program. Total consult volume (including ambulatory in-person consults and e-consults) continued to grow. **B,** E-consults as a proportion of all consults. E-consults initially comprised 0.9% of all consults; by July 2018, they comprised 10.1% of all new patient consults.

immunologists, rheumatologists, pulmonologists, cardiologists, gastroenterologists, medical geneticists, and pain medicine specialists. The consults from other allergists came from regional allergy practices regarding drug allergy testing.

Of the 306 completed e-consults, 183 (59.8%) recommended an in-person consult and 82 (26.8%) provided advice and education without further recommendations for diagnostic testing, therapeutic change, or subspecialist referral (Figure 1). Forty-one (13.4%) completed e-consults contained recommendations for diagnostic testing, therapeutic changes, and/or subspecialist referrals; 30 (73.2%) of these recommendations were followed. Allergists recommended only diagnostic testing as part of 24 (7.8%) completed e-consults; referring providers followed 16 (66.7%) of these diagnostic recommendations. Allergists recommended only therapeutic changes in 9 (2.9%) completed e-consults; referring providers followed 7 (77.8%) of these recommendations. Allergists recommended referral to another specialist (internal medicine subspecialist or surgeon) in 4 (1.3%) completed e-consults; referring providers made this referral in all 4 (100.0%) cases. Allergists recommended both diagnostic testing and referral to another specialist in 4 (1.3%) completed e-consults; referring providers followed these recommendations in 3 (75.0%) cases.

Of allergist-recommended in-person evaluations (n = 183; 59.8% of all completed e-consults), 140 (76.5%) were ordered. Allergists recommended in-person consult without prior diagnostic testing or therapeutic change for 168 (54.9%) patients; these recommendations were followed in 129 (76.8%) cases. Ten

**TABLE I.** Indication for electronic and in-person consults*

| Indication | E-consults (n = 306) | In-Person Consults (n = 8907) | *P* value† |
|---|---|---|---|
| ADR | 201 (65.7) | 770 (8.6) | <.001 |
| Immunodeficiency | 45 (14.7) | 186 (2.1) | <.001 |
| Urticaria/angioedema | 16 (5.2) | 1206 (13.5) | <.001 |
| AFR | 12 (3.9) | 1170 (13.1) | <.001 |
| Other | 9 (2.9) | 572 (6.4) | .01 |
| Cutaneous‡ | 8 (2.6) | 941 (10.6) | <.001 |
| Respiratory§ | 5 (1.6) | 654 (7.3) | <.001 |
| Venom reaction | 4 (1.3) | 98 (1.1) | .58 |
| Rhinitis | 3 (1.0) | 2,747 (30.8) | <.001 |
| Eosinophilia | 2 (0.7) | 45 (0.5) | .67 |
| Anaphylaxis | 1 (0.3) | 83 (0.9) | .53 |
| Sinusitis | 0 (0.0) | 308 (3.5) | <.001 |
| Ocular allergy | 0 (0.0) | 127 (1.4) | .02 |

*Data shown as n (%).
†P values calculated using $\chi^2$ test.
‡For e-consults, includes issues related to atopic dermatitis, contact dermatitis, dermatitis herpetiformis, and other types of dermatitis.
§For e-consults, includes issues related to asthma, cough, and shortness of breath.

(3.3%) e-consults recommended diagnostic testing before in-person consult; this testing was ordered in 8 (80.0%) e-consults. Four (1.3%) completed e-consults recommended a therapeutic change before in-person consultation; the therapeutic change was ordered in 2 (50.0%) cases. Allergists recommended diagnostic testing, therapeutic changes, and in-person consult for 1 patient (0.3%), in whom this recommendation was followed. Only 5 (1.6%) patients had an in-person consult that was not advised by allergy e-consult. Although these referrals were primarily for patient concern or worsening symptoms (n = 3), 1 provider requested an in-person evaluation in lieu of ordering the recommended diagnostic testing. One other patient was referred for in-person allergist evaluation when dermatology referral had been recommended for a history of sulfonamide antibiotic allergy and worsening psoriasis on a nonantibiotic sulfonamide drug.

## E-consult and in-person consult volume

There were 8907 in-person consults from August 1, 2014 through July 30, 2018. Even with e-consult implementation, in-person consult volume continued to rise during the study period (Figure 2, *A*). E-consults initially comprised 1% (n = 2) of all consults; by July 2018, e-consults comprised 10.1% (n = 26) of all consults (Figure 2, *B*). From August 2016 through December 2017, there was a median of 7 e-consults per month; with the launch of the obstetric penicillin allergy testing program in January 2018, monthly e-consults increased to a median of 26 e-consults per month, with 1 month having 36 e-consults.

## E-consult and in-person consult indications

The most common indications for completed e-consults were ADR (n = 201 [65.7%]), immunodeficiency (n = 45 [14.7%]), and urticaria/angioedema (n = 16 [5.2%]) (Table I). ADRs were primarily to antimicrobials (n = 165 [75.7%]), with penicillin antibiotic allergy questions alone comprising 132 completed e-consults (43.1%; Table II). Other common drugs included antihypertensive (n = 9 [4.1%]) and anti-inflammatory medications (n = 8 [3.7%]) as well as vaccinations (n = 6 [2.8%]). E-consults for AFRs (n = 12) were largely to specific foods (n = 3 [25%] for egg; n = 2 [16.7%] each for peanut and tree nut, and n = 1 [8.3%] each for alcohol and cow's milk), though some were nonspecific food allergy questions (Table II). Immunodeficiency evaluation requests (n = 45) were most commonly for frequent infections (n = 14 [31.1%]), IgM deficiency (n = 10 [22.2%]), and hypogammaglobulinemia (n = 8 [17.8%]) (Table II).

Of 183 e-consults where in-person evaluation was advised, 146 (79.8%) were for ADRs. Penicillin allergy evaluation programs with e-consult screening included 117 obstetric patients. Of obstetric e-consults, 101 (86.3%) patients had an allergy history requiring in-person evaluation for penicillin skin testing; 72 (71.3%) of these patients had been referred for the recommended consult at the time of this analysis. In-person evaluation was not indicated for 16 (13.7%) obstetric patients because of very low risk (medication advised to be administered by graded drug challenge) or high-risk allergy histories where the testing risks outweighed the benefits. If the 117 patients who had an e-consult guided by the obstetric penicillin allergy pathway were excluded, recommendation for in-person consult was made for 82 (43.4%) of the remaining 189 patients.

There were 8907 in-person consults with a primary diagnostic code. Of these, 2016 (22.6%) were coded under the *International Classification of Diseases, Ninth Revision* and 6891 (77.4%) were coded under the *International Classification of Diseases, Tenth Revision* billing codes. Of the primary codes billed, 2747 (30.8%) were for rhinitis, 1206 (13.5%) were for urticaria/angioedema, and 1170 (13.1%) were for AFR (Table I).

E-consults were used more frequently than in-person consults for ADR (65.7% vs 8.6%; $P < .001$) and immunodeficiency (14.7% vs 2.1%; $P < .001$; Table I). In-person consults were used more frequently for rhinitis (30.8% vs 1.0%; $P < .001$), urticaria/angioedema (13.5% vs 5.2%; $P < .001$), AFR (13.1% vs 3.9%; $P < .001$), and cutaneous reactions (10.6% vs 2.6%; $P < .001$).

## E-consult and in-person consult timing

Allergists required a median of 11 minutes (IQR, 5-25 minutes) to complete an e-consult; venom reactions, AFR, and ADR were the most quickly reviewed e-consults, whereas those for eosinophilia, anaphylaxis (n = 1), and immunodeficiency took the longest time to complete (Figure 3, *A*). Median turnaround time was 21.8 hours (IQR, 5.5-69.4 hours), with fastest turnaround time for venom reactions (5.0 hours; IQR, 4.5-8.1 hours) and longest turnaround times for eosinophilia (191.3 hours; no IQR because only 2 data points), respiratory issues (44.6 hours; IQR, 26.8-55.4 hours), and immunodeficiency (39.0 hours; IQR, 18.3-96.0 hours) (Figure 3, *B*).

The median wait time for an in-person ambulatory consult was 22 days (IQR, 20.0-24.0 days). The median wait time decreased from 22.5 days (IQR, 20.8-24.0 days) to 21 days (IQR, 19.0-23.0 days) ($P < .05$) after implementation of e-consults.

# DISCUSSION

We performed more than 300 Allergy/Immunology e-consults, a novel, asynchronous, clinician-to-clinician exchange that is nonurgent and problem-focused and relies exclusively on information available within the EHR. Although 60% of patients who received an e-consult required an in-person consult to complete diagnosis and management, all patients and referring

**TABLE II.** E-consult request detail

| | |
|---|---|
| ADR* (n = 218) | |
| Antidepressants (2 [0.9%]) | Contrast agents (3 [1.4%]) |
| Citalopram (1 [0.5%]) | Computed tomography (2 [0.9%]) |
| Nortriptyline (1 [0.5%]) | Magnetic resonance imaging (1 [0.5%]) |
| Antihypertensives (9 [4.1%]) | Diuretic agents (2 [0.9%]) |
| ACE inhibitors (6 [2.8%]) | Acetazolamide (1 [0.5%]) |
| ARB (1, 0.5%) | Furosemide (1 [0.5%]) |
| Beta-blockers (2, 0.9%) | Intravenous immunoglobulin (3 [1.4%]) |
| Anti-inflammatory medications (8 [3.7%]) | Local anesthetics (4 [1.8%]) |
| Corticosteroids (2 [0.9%]) | Benzocaine (1 [0.5%]) |
| NSAIDs (6 [2.8%]) | Lidocaine (1 [0.5%]) |
| Antimicrobial (165, 75.7%)† | Marcaine (1 [0.5%]) |
| Bacitracin (1 [0.5%]) | Procaine (1 [0.5%]) |
| Cephalosporins (7 [3.2%]) | Proton pump inhibitors (3 [1.4%]) |
| Cefazolin (2 [0.9%]) | Esomeprazole (1 [0.5%]) |
| Cefdinir (1 [0.5%]) | Lansoprazole (1 [0.5%]) |
| Cefepime (1 [0.5%]) | Omeprazole (1 [0.5%]) |
| Cephalexin (3 [1.4%]) | Vaccinations (6 [2.8%]) |
| Clofazimine (1 [0.5%]) | Influenza (2 [0.9%]) |
| Doxycycline (1 [0.5%]) | Measles (1 [0.5%])‡ |
| Fluoroquinolones (3 [1.4%]) | Pneumococcal polysaccharide vaccine (2 [0.9%]) |
| Ciprofloxacin (2 [0.9%]) | Tetanus, diphtheria, acellular pertussis (1 [0.5%]) |
| Levofloxacin (1 [0.5%]) | Other (1 [0.5%] each) |
| Gentamicin (2 [0.9%]) | Carbamazepine |
| Isoniazid (1 [0.5%]) | Diazepam |
| Macrolides (4 [1.8%]) | Diphenhydramine |
| Azithromycin (2 [0.9%]) | Hydroxychloroquine |
| Erythromycin (2 [0.9%]) | Hylan G-F 20 |
| Penicillins (132 [60.6%])† | Insulin |
| Ampicillin (1 [0.5%]) | Ferumoxytol |
| Amoxicillin (1 [0.5%]) | Opioid§ |
| Amoxicillin-clavulanate (1 [0.5%]) | Palonosetron |
| Penicillin (128 [58.7%])† | Sulfasalazine |
| Piperacillin-tazobactam (1 [0.5%]) | Tobramycin/dexamethasone ophthalmic |
| Rifampin (2 [0.9%]) | Tocilizumab |
| Sulfonamide (10 [4.6%]) | Vitamin D |
| Vancomycin (1 [0.5%]) | Multiple drug reactions (12 [5.5%]) |
| Immunodeficiency (n = 45) | |
| Frequent infections (14 [31.1%]) | Other (each 1 [2.2%]) |
| IgM deficiency (10 [22.2%]) | IgA deficiency |
| Hypogammaglobulinemia (8 [17.8%]) | Elevated IgA |
| IgG deficiency/IgG subclass deficiency (5 [11.1%]) | Complement deficiency |
| Vaccination (2 [4.4%]) | CHARGE syndrome |
| | DiGeorge syndrome |
| AFR (n = 12) | |
| Specific food | Histamine intolerance (1 [8.3%]) |
| Egg (3 [25%]) | Specific testing question |
| Peanut (2 [16.7%]) | IgE testing (1 [8.3%]) |
| Tree nut (2 [16.7%]) | Non−IgE testing (1 [8.3%]) |
| Alcohol (1 [8.3%]) | |
| Cow's milk (1 [8.3%]) | |
| Other (n = 8, each diagnosis 1 [12.5%]) | |
| Aeroallergen testing | Maxillary retention cyst |
| Fatigue | Persistently elevated IgA |
| Granulomatous lesions | Tuberculosis reactivation |
| Lower extremity edema | Vocal cord dysfunction |

*ACE*, Angiotensin-converting enzyme; *ARB*, angiotensin receptor blocker; *CHARGE*, coloboma, heart defects, atresia choanae, growth retardation, genital abnormalities, and ear abnormalities; *NSAID*, nonsteroidal anti-inflammatory drug.
*Sum of 218 is greater than 201 as 12 requests were for patients with multiple ADRs.
†Drugs/drug categories accounting for at least 10% of all ADRs.
‡Patient received measles vaccine only, not measles, mumps, rubella combination vaccine.
§Ordering provider did not specify which opioid.

providers received education, and 13% of patients received exclusively electronic guidance for diagnostic, therapeutic, or referral recommendations that were followed nearly 75% of the time. Two-third of all e-consults were for ADRs, primarily to antimicrobials/penicillin. Most e-consults were completed in about 10 minutes, and referring providers received recommendations in approximately 1 day (compared with an in-person evaluation wait time of more than 20 days). The implementation of this e-consult program was associated with persistent growth in in-person consult volume and a significant reduction in wait time of 1.5 days for in-person consults.

Indications for consults differed between e-consults and in-person consults. With the implementation of e-consults, each referring provider could choose whether to order an e-consult or an in-person consult. In-person consults were primarily ordered for rhinitis and AFRs, both diagnoses frequently requiring confirmatory skin testing that is readily available in Allergy/Immunology offices. E-consults were primarily used for historical ADRs and immunodeficiency, conditions initially assessed by history alone. ADR e-consults were driven by our institution's role as a leader in drug allergy evaluations and programs to evaluate penicillin allergy histories, specifically in obstetric patients.[28,31] Although almost all obstetric patients (86.3%) required an in-person evaluation, the e-consult replaced the initial in-person consult without testing. Because testing drugs are not readily available and mixed/diluted to the nonirritating concentrations in every Allergy/Immunology clinic, the e-consult enabled allergists to have these medications ready to perform specialized drug testing at the first in-person consult visit. Similarly, immunodeficiency evaluation patients had their first in-person Allergy/Immunology consult with relevant laboratory data already available, likely improving the productivity of the initial in-person consult and expediting the process for those who most needed more specialized immune assessments.

ADR e-consults were among the fastest for allergists to complete (10 minutes), suggesting that allergy programs that cannot address all allergic concerns via e-consult may still benefit from

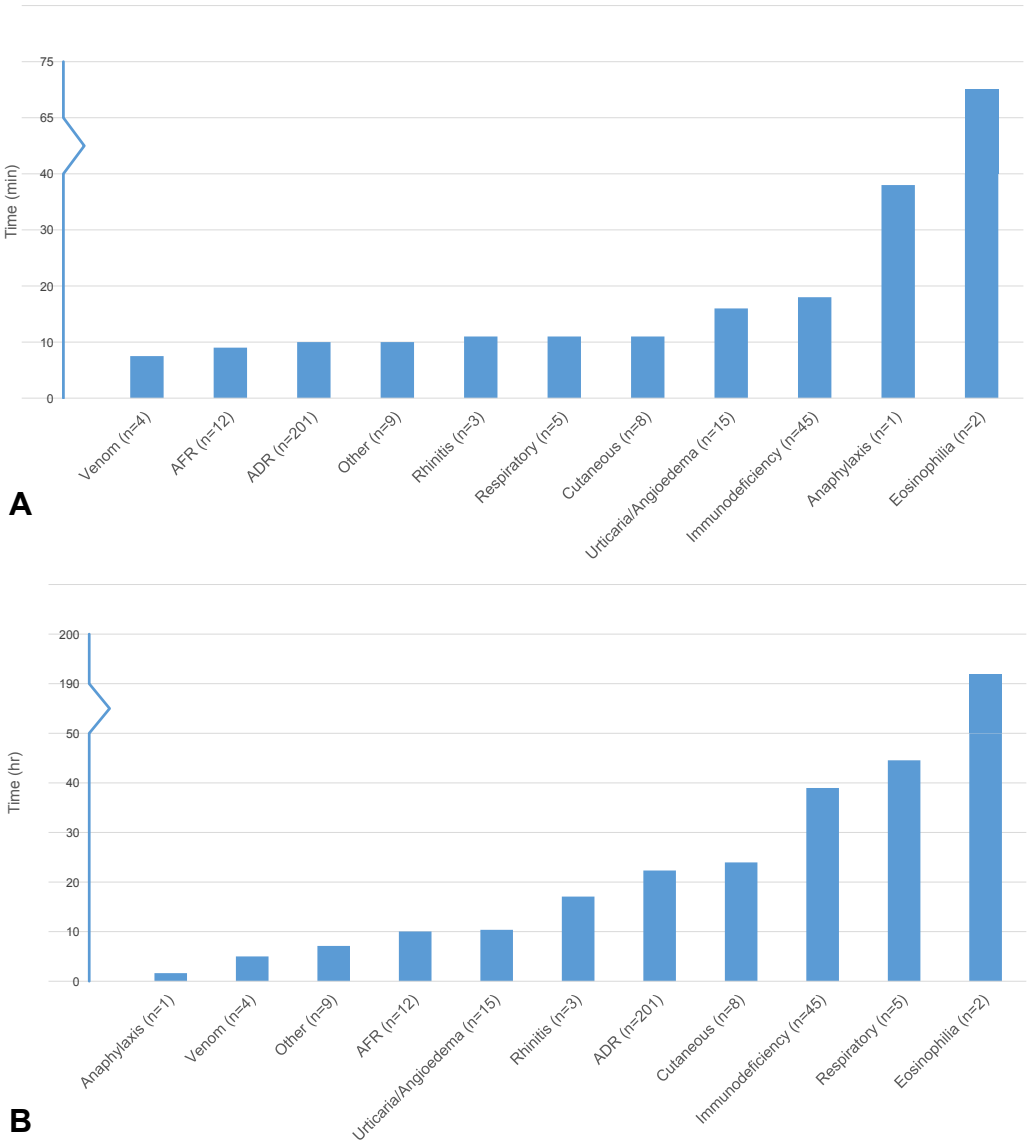


**FIGURE 3.** E-consult completion and turnaround time by indication. **A,** Median completion time (time from EHR encounter open to encounter close) was 11 minutes for all e-consults; e-consults for venom reactions, AFR, and ADR were the fastest to complete, whereas those for eosinophilia, anaphylaxis, and immunodeficiency took the most time. **B,** Median turnaround time (time from order entry to encounter close) was just under 1 day for all e-consults; this was shortest for venom and AFR and longest for eosinophilia, anaphylaxis, and immunodeficiency.

starting a drug allergy e-consult program, particularly for historical ADRs. Coupled with the implementation of standardized beta-lactam hypersensitivity pathways,[28] e-consults triage and expedite important penicillin allergy evaluations.[32-37] Immunodeficiency evaluations may also be well suited to e-consults; immunodeficiency e-consults took only about 15 minutes to complete. In addition, given that there are few centers that specialize in drug testing or immunodeficiency, e-consult—based initial evaluations may reduce (or even eliminate) long travel times for patients who live far from such centers.

E-consult referrals came not just from generalists but also from other specialists, including outside allergists/immunologists, which suggests that all providers might benefit from asynchronous allergist access using a formally EHR-documented and compensated method (replacing informal reviews, e-mails, and "curbsides"). Ultimately, e-consults reduced wait time for allergist guidance and had no impact on our growing total consult volume. Compared with the 3-week wait times for in-person consults, e-consults provided guidance to a clinical provider in hours to days. In addition, even at a large and busy academic institution like MGH where the attending physician who supervises inpatient consults also performs e-consults, e-consults were completed in a timely manner.

Subspecialist referrals cost up to twice as much as generalist visits and shift care responsibility to a specialist.[38,39] Conversely, e-consults place the onus of patient care back in the hands of the

primary care provider, which increases patient satisfaction and leads to less disjointed care, but at the cost of increasing the workload of overburdened primary care providers.[40] Nonetheless, most referring providers followed specialist e-consult recommendations and rarely (<2%) referred patients for in-person consult following an e-consult without explicit recommendation to do so. Many e-consult patients were found previously to prefer receiving subspecialist advice through the familiarity of a known provider.[12,22] There is concern that e-consults could lead to recommendations for increased testing due to inadequate available history.[24] However, only 9% of e-consults resulted in a recommendation for additional testing beyond what would have been done at an initial consult visit. Although there may be concern that e-consults create an extra encounter and associated charge without preventing an in-person consult, less than 2% of patients had a follow-up in-person consult without explicit recommendation to do so, and many in-person consults were likely more productive than they would have been otherwise because of the initial e-consult.

Our study was not designed to detect cost outcomes, but the impact of e-consults on costs is an important area of future investigation. Any cost analysis must consider patient time and travel costs, clinician time, and any differential downstream testing, medications, or referrals. One previous study estimated that 100 million electronic visits can result in $5 billion in savings for the health care system.[22,23,25] There are additional direct benefits to consider, both for specific patient populations and for all patients assessed by e-consult. E-consults are ideal for nonadherent patients and those unable to attend scheduled appointments; rather than receiving the alternative of minimal (or no) care, patients can still receive direct, focused care without the need for an additional in-person consult. All patients received specialist input more quickly than would come from waiting for an in-person consult. Referring providers also benefit from the concomitant peer-to-peer education that includes clarification and/or reassurance that a proposed plan of action is correct.[10] Indeed, more than a quarter of e-consults from allergists provided education only (no diagnostic, therapeutic, or referrals suggested). Particularly in Allergy/Immunology where nonspecialist providers receive limited education and self-report major knowledge gaps,[41,42] e-consults might improve care and reduce health care costs by preventing the ordering of large panels of unnecessary, inappropriate tests. Even for patients who ultimately require an in-person consult, the information exchanged before the consult leads to a more productive consult.[10] Future assessments of the e-consult model in a prospective, randomized, controlled fashion will better facilitate outcome and cost analyses.

Although we compared indications for e-consults to indications for in-person consults, in-person consults used billing codes, and these may not be as accurate as asking the referring provider the referral question. In addition, most ADRs and AFRs are billed with the reaction as the primary diagnosis (eg, would fall under "cutaneous," "anaphylaxis," or "urticaria/angioedema") and a drug or food code as the second diagnostic code. Thus, the in-person consult indications may underestimate drug and food allergy consults. Although this study comprised more than 300 e-consults and almost 9000 in-person consults, we present only an initial descriptive analysis of an e-consult program at a single academic Allergy/Immunology practice. Although our health care system acknowledges e-consult efforts with a flat physician fee per e-consult, these consults are, to date, not billable through traditional insurance methods, which may limit their spread. Finally, although we saw a decrease in in-person consult wait times with e-consult implementation, this decrease may not have necessarily been the result of e-consult implementation.

Given the growing supply/demand mismatch between the number of practicing allergists and patients with allergy concerns, much of the burden of allergic disease diagnosis and management falls on nonallergist clinicians. In our growingly complex health care system, a model of care that places a patient's primary care physician at the forefront of care with easy access to specialist guidance is ideal. E-consults meet this challenge, providing safe and efficient patient care in a manner that prevents unnecessary office consults and maximizes patient, referring provider, and subspecialist satisfaction. E-consults seem like an optimal form of health care delivery to consider adopting and spreading given the prevalence of large EHR networks and the minimal time effort required of providers. Promotion and proliferation of the e-consult model of care should be a priority for insurance companies, primary care providers, medical homes, patients, and allergists alike as data suggest that e-consults provide expedient, directed care, improve the quality of in-person consults, avert unnecessary in-person consults, and educate primary care doctors in a case-based relevant manner that might help curb health care spending on specialty care.

## Acknowledgment

We acknowledge Sean Gilligan for his assistance in obtaining in-person consult data.

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# Trends in Ambulatory Electronic Consultations During the COVID-19 Pandemic

J Gen Intern Med 35(10):3117–9
DOI: 10.1007/s11606-020-05878-z


## INTRODUCTION

SARS-CoV2, the virus responsible for the COVID-19 pandemic,[1] has forced rapid changes in healthcare delivery. Telehealth has previously played a role in delivering ambulatory care in the setting of similar disasters.[2] Electronic consultations (e-consults), in particular, may be an effective method of sustaining specialty consultative care while preserving social distancing and reducing demands for personal protective equipment. Hypothesizing that e-consult requests would increase during the pandemic, we sought to define COVID-19-associated changes in e-consult requests.

## METHODS

e-Consults are asynchronous clinician-to-clinician exchanges that rely on information in the patient's electronic health record (EHR). Requesting clinicians ask specific clinical questions; specialist physicians review the patient's EHR and document detailed recommendations as an EHR note (Fig. 1). Our institution, which first implemented e-consults as pilot programs in Cardiology and Dermatology,[3] has completed over 35,000 e-consults in 50 subspecialty areas and extensively studied their use.[4]

Our primary outcome was e-consult proportion, defined as e-consult volume over total consult volume (e-consult volume plus traditional ambulatory consult volume). We used an interrupted time series (IST) model to assess the effect of the pandemic on e-consult proportion. We assessed daily volumes from February 1, 2020, through April 1, 2020; the defined date of "intervention" was March 11, 2020, when Massachusetts declared a COVID-19-related state of emergency. We included weekend/holiday as a covariate to account for differences in consult requests between business days and weekends. We excluded specialty areas with less than 20 e-consult requests, specialty areas that did not offer both an active e-consult and ambulatory consult option, and psychiatry as it included some requests for behavioral health resources without a need for specialist guidance.

This work, performed for administrative purposes, was exempt from review by the Partners Healthcare Institutional Review Board (IRB) per the IRB's policies. Statistical analysis was performed using SAS, version 9.4 (SAS Institute, Inc., Cary, NC).

## RESULTS

Before March 11, 2020 ($n = 40$ days), a median of 565 ambulatory consults and 48 e-consults were requested daily. After March 11, 2020 ($n = 21$ days), a median of 144 ambulatory consults and 40 e-consults were requested daily. While both types of consult requests declined after March 11, the ambulatory consults declined more than the e-consults resulting in an increase in absolute e-consult proportion from 8.5 to 19.6%. After adjusting for weekend and secular trend, we found e-consult proportion increased by 5% (95% CI 2–7%) daily from pre-emergency declaration levels (Fig. 2).

## DISCUSSION

We describe a significant increase in e-consult utilization relative to traditional ambulatory referrals following the COVID-19-related state of emergency declaration in Massachusetts. Our results suggest that e-consults can provide a mechanism for sustaining outpatient consultative care during this pandemic.

Study limitations include the fact that these results obtained from a single Boston-based academic medical center may not be generalizable, particularly to institutions without a strong e-consult program in place. Additionally, this study design cannot assess the relative effectiveness of e-consults versus other types of virtual and in-person care delivery mechanisms.

These results suggest an increase in e-consult utilization associated with the COVID-19 pandemic in the USA. e-Consults may be a promising method of ambulatory consultative care delivery as they can potentially replace some specialty consultations in a manner that provides clinical guidance while reducing the risk of in-person visits to both patients and physicians.

**Prior Presentations** *This work has not previously been presented.*

*Received April 5, 2020*
*Accepted April 28, 2020*
*Published online May 18, 2020*

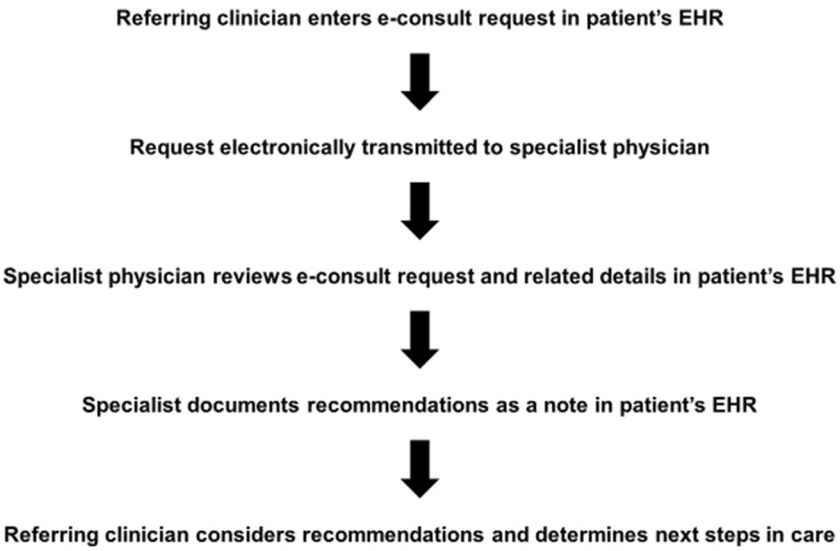


**Figure 1** e-Consult process. Referring clinicians enter a non-acute, focused clinical question into the patient's electronic health record (EHR). This question is electronically transmitted to a specialist physician who reviews the question and clinical information in the EHR and provides clinical guidance including recommendations for further diagnostic testing or therapeutic management via a note entered in the patient's EHR. The referring clinician reviews the specialist's recommendations and orders necessary testing or therapies.

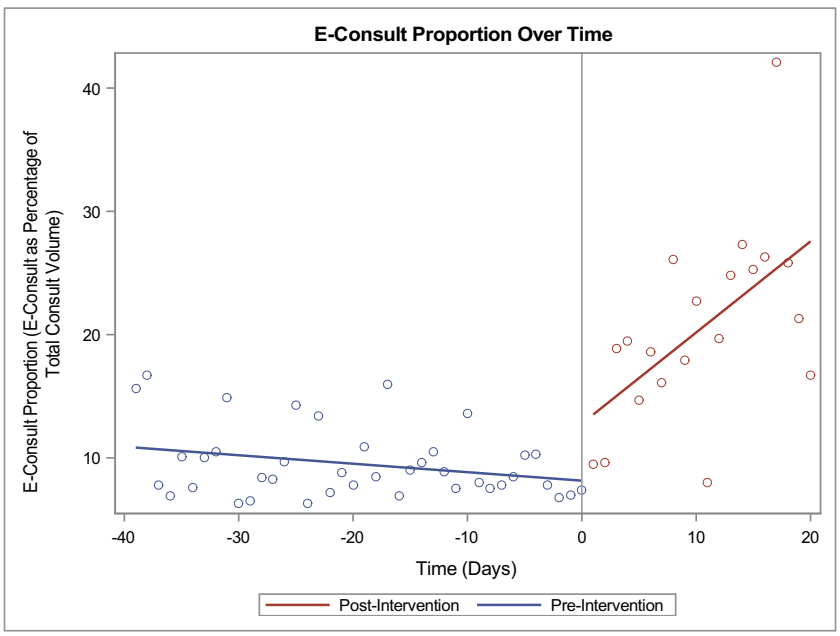


**Figure 2** e-Consult proportion over time. This figure demonstrates e-consult proportion (the e-consult proportion of total referral volume) as a function of time. The vertical line at time 0 represents the date of intervention (March 11, 2020). Points to the left of this line represent data obtained prior to this date; points to the right represent data obtained after this date. Tick marks refer to the number of days in either direction. A linear model was fitted to the pre- and post-intervention data to better demonstrate the changing trend in e-consult proportion over time.

***Acknowledgments:*** *The authors acknowledge Elizabeth Fonseca, SM, Program Director for Population Health Management, and Timothy G. Ferris, MD, MPH, Chief Executive Officer of the Massachusetts General Physicians Organization, for their support of electronic consults and other population health management efforts at Massachusetts General Hospital.*

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***Funding Information*** *e-Consults are funded internally by the Massachusetts General Physicians Organization. No additional funding was obtained for this work.*

***Compliance with Ethical Standards:***

***Conflict of Interest:*** *N.A.P. reports spousal employment by Chiesi Farmaceutici. J.H.W. reports consulting fees from Pfizer and Biotronik, career development awards from the American Heart Association (current), the National Institutes of Health (past), and Harvard Catalyst (past); honoraria from New England CEPAC for which he serves as vice chair; and travel compensation from the American College of Cardiology, academic medical centers, and academic conferences. He has additionally participated as a member on a public-private partnership convened by the U.S. Department of Health and Human Services on cardiac bundled payments. None of these relationships for either of these authors influenced the work presented here. The other authors disclose no conflicts of interest.*

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