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Evaluation of the Extended Medicare Care Management for High Cost Beneficiaries (CMHCB) Demonstration: VillageHealth's Key to Better Health (KTBH)

Final Report

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EVALUATION OF THE EXTENDED MEDICARE CARE MANAGEMENT FOR HIGH COST BENEFICIARIES (CMHCB) DEMONSTRATION: VILLAGEHEALTH'S KEY TO BETTER HEALTH (KTBH)

Final Report

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EXECUTIVE SUMMARY

The purpose of this report is to present the findings from RTI International's evaluation of VillageHealth's Key to Better Health (KTBH) Medicare Care Management for High Cost Beneficiaries (CMHCB) Demonstration. The principal objective of this demonstration is to test a pay-for-performance contracting model and new intervention strategies for Medicare fee-for-service (FFS) beneficiaries, who are high cost and/or who have complex chronic conditions, with the goals of reducing future costs, improving quality of care and quality of life, and improving beneficiary and provider satisfaction. The desired outcomes include a reduction in unnecessary emergency room visits and hospitalizations, improvement in evidence-based care, and avoidance of acute exacerbations and complications. In addition, this demonstration provided the opportunity to evaluate the success of the "fee at risk" contracting model, a relatively new pay-for-performance model, for the Centers for Medicare & Medicaid Services (CMS). This model provided the Phase II KTBH Demonstration with flexibility in its operations and strong incentives to keep evolving toward the outreach and intervention strategies that are the most effective in improving population-based outcomes.

The overall design of the CMHCB Demonstration follows an intent-to-treat (ITT) model, and like the other care management organizations (CMOs), the Phase II KTBH Demonstration was held at risk for its monthly management fees based on the performance of the full population of eligible beneficiaries assigned to its intervention group and as compared with all eligible beneficiaries assigned to its comparison group. Beneficiary participation in the CMHCB Demonstration was voluntary and did not change the scope, duration, or amount of Medicare FFS benefits received. All Medicare FFS benefits continued to be covered, administered, and paid for by the traditional Medicare FFS program. Beneficiaries did not pay any charge to receive CMHCB program services. On January 13, 2009, CMS announced that it was granting 3-year extensions, subject to annual renewal, for three participants in the CMHCB Demonstration that had demonstrated some success managing the care of their selected intervention beneficiaries, one of which was the Phase II KTBH Demonstration. For Phase II, two new cohorts of beneficiaries were drawn – Phase II original population, followed by a Phase II refresh.

Our evaluation focuses upon three broad domains of inquiry for the Phase II populations:

- **Implementation.** To what extent was the Phase II KTBH Demonstration able to implement its Phase II program?
- **Reach.** How well did the Phase II KTBH Demonstration engage its intended audience?
- **Effectiveness.** To what degree was the Phase II KTBH Demonstration able to improve clinical quality and health outcomes and achieve targeted cost savings?

Organizing the evaluation into these areas focuses our work on CMS' policy needs as it considers the future of population-based care management programs or other interventions in Medicare structured as pay-for-performance initiatives. We use both qualitative and quantitative

research methods to address a comprehensive set of research questions within these three broad domains of inquiry.

E.1 Scope of Implementation

VillageHealth launched its Phase II KTBH CMHCB Demonstration on August 1, 2009. VillageHealth worked with its CMS project officer and analysts from Actuarial Research Corporation (ARC) to develop a methodology for selecting the starting population for the Phase II KTBH CMHCB Demonstration. Beneficiaries had to meet the following four inclusion criteria for eligibility in the Phase II KTBH CMHCB Demonstration:

- Medicare fee-for-service beneficiaries, who had a primary residence in Nassau, Suffolk, Queens, Kings, Westchester for the end-stage renal disease (ESRD) population with the addition of Richmond, Rockland, or Bronx counties for the chronic kidney disease (CKD) population.

- High costs based on Medicare claims from July 1, 2007 through June 30, 2008 (i.e., $5,000 or more for CKD beneficiaries and $12,000 or more for ESRD beneficiaries); and

- Diagnosis of chronic kidney disease (CKD) as evidenced by at least one claim with a diagnosis code indicative of CKD of stage 3 or higher

- Beneficiaries with an ESRD flag on the Enrollment Data Base (EDB).

Beneficiaries were excluded if they had one of the following exclusion criteria for eligibility in the Phase II KTBH CMHCB Demonstration:

- Met the specific VillageHealth diagnostic criteria for exclusion, generally identifying patients with cancer;

- any transplant was an exclusion for ESRD beneficiaries; however if a CKD beneficiary had a CKD claim after their transplant claim, they were still eligible,

- reside in a nursing home (custodial care),

- institutionalized in a mental health facility,

- elected the Medicare hospice benefit, enrolled in a commercial Medicare Advantage plan, did not have both Part A and Part B Medicare coverage, had Medicare as a secondary payer, or did not have a phone number from a search of the Social Security Administration's contact information database.

The remaining beneficiaries were randomly assigned to the intervention and comparison groups at a ratio of 1 to 1. The final Phase II original population was composed of 2,945 intervention beneficiaries and 2,944 comparison beneficiaries, of which 1,500 were ESRD beneficiaries in both populations. A Phase II refresh population of 2,234 intervention beneficiaries and 2,233 comparison group beneficiaries was received by the KTBH program in

April 2010, of which about 800 were ESRD beneficiaries in both populations. Because these beneficiaries were randomized prior to the start of the demonstration, the number of beneficiaries eligible at the start of the demonstration is lower. The basic criteria for selection of the intervention and comparison Phase II refresh populations were similar to the criteria used to select the initial populations with one noted exception. Westchester County was no longer needed to reach the target ESRD population.

Of the KTBH Phase II original intervention group beneficiaries, 75% verbally consented to participate in its demonstration at some point during the intervention period, 22% refused to participate, and 2% were not contacted or unable to be located. Of the refresh intervention beneficiaries, 42% consented to participate at some point during the 11-month period. The percent that refused to participate was more than double (57%), and the percent that were not contacted or were unable to be contacted was 1%. The Phase II KTBH Demonstration ended April 30, 2011, or 21 months after initiation of the Phase II original population and 11 months after the start of the Phase II refresh population.

For Phase II, fees were reduced from $225 per beneficiary per month (PBPM) to $180 PBPM. In addition to the reduction in fees for Phase II, the reduction in the savings threshold from 5% to 2.5% for the Phase I refresh beneficiaries also applied to both Phase II populations. Participating nephrology partners in Phase II received a nominal fee of $15 PBPM (down from $25 PBPM during Phase I) in exchange for primarily providing the KTBH program with laboratory and other relevant beneficiary medical information and corresponding with the KTBH care managers. Further, VillageHealth's fee strategy was based on a literal interpretation of participation, i.e., only patients who agree to actively participate by receiving care support services via telephone and/or home visits from nursing staff are defined as program participants. Lower risk individuals who agreed to receive periodic educational mailings are classified as non-participants in terms of program fees collected. For the refresh cohorts (Phase I refresh and Phase II original and refresh), a fee was paid for the refresh beneficiaries only if they became participants.

E.2 Overview of the KTBH CMHCB Demonstration Program

VillageHealth introduced a number of changes and enhancements to its KTBH program and operations between the January 2008 (Phase I) and October 2009 (Phase II) site visits. The following is a discussion of the most notable changes to the program content and delivery process.

Changes in VillageHealth and KTBH Program Leadership. KTBH was a department of VillageHealth (formerly RMS Disease Management) that maintained its own budget, although VillageHealth funded periodic staff training out of its clinical operations budget. VillageHealth and KTBH program leadership staff changed between RTI's 2008 and 2009 site visits, including a new President/General Manager of VillageHealth, the addition of VillageHealth's Director of Strategy and Government Relations, a new Vice President of Clinical Operations who maintained oversight of the KTBH Regional Operations Manager and Nursing Team Leader. KTBH also eliminated the position of Regional Operations Director.

Addition of New Program Staff. The program hired seven new nurse care managers for the Phase II extended KTBH program to serve the ESRD population. Given that the nursing team provided care management rather than dialysis treatment, KTBH program leadership believed that it was critical for the nurses to have care management skills and the ability to coach participants, rather than to have renal experience. In addition to adding care managers, KTBH program leadership added a local social worker to conduct home visits and address the social needs of participants. The program included six telephonic nurses, 10 field nurses, a registered dietician, a pharmacist (the dietician and pharmacist served programs across VillageHealth and were not solely dedicated to the KTBH program); and two social workers (one social worker was field-based; the other was located in New Jersey and provided telephonic support). The telephonic nurses primarily worked with CKD beneficiaries whereas the field nurses typically worked with ESRD beneficiaries in the dialysis facilities or conducted home visits to CKD or ESRD beneficiaries. A Provider Relations Representative was also hired to improve the program's relationship with physicians in the community.

Collection of Beneficiary Survey Data. During Phase II, VillageHealth began administering the SF-12 Health Survey to participants in an effort to evaluate their quality of life. The survey was administered as part of the baseline assessment and was re-administered again at six months after assessment, one year after assessment, and annually thereafter. VillageHealth also administered member satisfaction surveys six months after assessment, one year after assessment, and annually thereafter. VillageHealth planned on compiling a report of the responses at the end of 2009.

Expansion of Physician Group Partners. As previously noted, the KTBH program expanded from 6 partner nephrology groups to 17 during the extension period. The program provider strategy also included providing more information to physicians through a quarterly newsletter and the KTBH program website. KTBH program staff reported that the care managers worked closely with the partner nephrologists on both outreach and beneficiary management.

Expansion of Relationships with Local Hospitals, Other Care Agencies, and Community Organizations. KTBH staff reported the care managers worked hard during Phase II to expand their relationships with hospitals, skilled nursing facilities, and rehabilitation facilities. In particular, they emphasized introducing the KTBH program to skilled nursing facilities and rehabilitation facilities in Kings County (where they had no beneficiaries in Phase I). They also worked on developing relationships with community not-for-profit agencies such as The Jewish Guild for the Blind, Parker Jewish Institute for Health Care & Rehabilitation, and Visiting Nurse Services, and reported progress in working with hospitals such as St. Frances to better coordinate discharge planning.

Termination of Service Provider Contracts and a Return to In-House Provision of Services. During Phase I, RMS contracted with Intellicare to conduct telephonic outreach to the intervention beneficiaries but KTBH staff decided to discontinue the contract in Phase II and bring outreach efforts in-house to allow the nurse care managers to make the calls and speak more directly about the potential benefits of the Phase II KTBH Demonstration. VillageHealth also terminated its subcontract with Enclara, a firm that specializes in end-of-life planning and preparation for hospice referral. In Phase I, once a KTBH program care manager made a

referral, Enclara provided telephonic or in-person support and reported the outcome of the intervention back to the KTBH program team. During Phase II, KTBH contracted with an external vendor, LifeMasters, to train their nurse care managers on speaking directly with beneficiaries about end-of-life issues. In Phase I, the KTBH program provided a Cardiocom telemonitoring scale to selected participants with heart failure, or who had been hospitalized, or who were at risk for hospitalization based on disease progression. Cardiocom's telescale is a product that electronically transmits beneficiary weight and responses to questions related to health status and self-management back to the KTBH program. In November 2007, the program switched to using Cardiocom nurses to perform the monitoring because KTBH staff felt that Cardiocom staff had greater expertise in the use of the software. During the extension period, VillageHealth scaled back their relationship with Cardiocom. The KTBH program continued to use Cardiocom scales in Phase II to capture the weight of their participants at-risk for fluid-related hospital admissions, KTBH program leadership brought the monitoring of the weights and alerts in-house to provide care managers with the ability to address potential issues in a timelier manner, particularly on weekends and holidays.

More Frequent Contact with Beneficiaries. In Phase I, beneficiaries were contacted every one, two, or three months depending on how they rated according to thirteen different factors/service intensity guidelines. In Phase II, contact with all participants was initiated by the care managers at least once every 30 days. This effort was based on the idea that more frequent, shorter contact will facilitate greater beneficiary activation. The monthly contacts allowed care managers to better monitor participants—especially with respect to recent hospitalizations whereby an opportunity may exist to potentially prevent costly readmissions. Care managers contacted beneficiaries more often if they believed it was necessary.

Availability of Classes for Beneficiaries. The KTBH program began offering in-person educational classes to participants with CKD and also created a website that provides participants with access to additional educational materials. In addition, they began inviting KTBH participants to DaVita's EMPOWER educational program session on CKD. The KTBH staff held two sessions that lasted approximately 1 ½ hours and also planned to hold subsequent regular sessions throughout their geographic area.

Provision of Additional Training for Care Managers. Site visit participants reported that VillageHealth invested heavily in additional motivational interviewing (MI) training, a client-centered, semi-directive technique used to engage participants' own intrinsic motivation to facilitate behavior change. In an effort to test the effectiveness of MI, KTBH care managers were collecting patient activation measures (PAM) to establish a baseline and planned to re-survey beneficiaries to determine the effectiveness of the care managers in increasing beneficiary activation. KTBH contracted with LifeMasters to conduct a two-day training session on end-of-life care issues with a subset of the care management team. Upon completion of the LifeMasters session, KTBH staff held 12 follow-up advanced care planning meetings. Staff also received VillageHealth-funded training on new tools and processes introduced during Phase II pertaining to vascular access planning, hospitalization admission review, medication therapy management, and fluid treatment metrics.

Availability of New Technology for Care Managers. During Phase I, the KTBH care managers used an internally developed clinical care management tool known as the Medical

Information System Technology (MIST) that allowed care managers to document information about a beneficiary's condition and care needs primarily using drop-down menus. The Nurse Panel was developed as a tool to provide a quick and easy way to access information stored in MIST. The Nurse Panel permitted the care managers to view their entire panel of beneficiaries and provided access to key clinical outcomes, recent contacts, and provider information. The Nurse Panel was part of the Phase II KTBH Demonstration's updated model for care management, Capella, which was introduced at the beginning of Phase II. Capella included new processes, tools, technology, and training for ESRD and CKD beneficiaries. It tied together clinical, operational, and technical components with the intent of enabling care managers to focus on the correct interventions with beneficiaries, standardize and simplify clinical processes, and facilitate the use of integrated technology to provide decision-making support to care managers

Expanded Clinical Focus that Includes End-Stage Renal Disease (ESRD). Phase I targeted outreach and participation of late stage CKD beneficiaries. In Phase II, engagement of CKD beneficiaries remained telephonic. The outreach to ESRD beneficiaries, however, was entirely new in Phase II since ESRD was not part of the clinical focus in Phase I. KTBH program leadership found that when a nurse had an in-person contact with an ESRD beneficiary, the beneficiary was more than twice as likely to enroll in the program. As a result, KTBH program leadership decided to send a nurse to every dialysis facility with more than two eligible beneficiaries.

E.3 Key Findings

In this section, we present key findings based upon the 21 months of Phase II KTBH Demonstration operations with the Phase II original population and 11 months with its Phase II refresh population. Our findings are based on the experience of approximately 2,700 ill Medicare beneficiaries with CKD and 2,200 beneficiaries with ESRD assigned to an intervention or a comparison group. Five key findings on participation, intensity of engagement in the KTBH program, clinical quality, health outcomes, and financial outcomes have important policy implications for CMS and future disease management or care coordination efforts among Medicare FFS beneficiaries.

Key Finding #1: During the Phase II KTBH Demonstration, VillageHealth was able to engage a variety of beneficiaries across the spectrum of health status.

Of all KTBH Phase II original intervention group beneficiaries, 75% verbally consented to participate in its demonstration at some point during the intervention period. For the Phase II KTBH Demonstration, we find that participants for more than 75% of the eligible months from the Phase II original population tended to be younger than beneficiaries who never participated (44% were less than 65 years of age compared to 39% for the nonparticipants). These are beneficiaries entitled to Medicare due to a disability. In the multivariate regression analysis, however, beneficiaries that died or were institutionalized during the demonstration were less likely to be participants, yet ESRD beneficiaries were more likely to participate.

For the Phase II refresh population, in addition to beneficiaries that died or were institutionalized during the demonstration being less likely to participate, Medicaid enrollees

were also less likely to participate. Beneficiaries with high baseline PBPM costs were a positive predictor of participation and ESRD continued to be associated with a higher likelihood of participation. These findings suggest that the Phase II KTBH Demonstration staff were able to engage beneficiaries across the spectrum of health status.

Key Finding #2: The Phase II KTBH Demonstration was not successful at targeting intervention beneficiaries at high risk of hospitalization or who had been hospitalized.

A cornerstone of the KTBH's program was health coaching interactions with care manager nurses. However, over one-half of participating Phase II original beneficiaries received no call or in-person visit from a care manager in the last 15 months of the demonstration. Everyone that did have contact had ten or more total contacts. Telephone contact was the most dominant form of contact. That being said, among the ESRD beneficiaries, nearly one-half received an in-person visit during the demonstration period. In our multivariate regression modeling of likelihood of being in a high contact versus low contact group for the Phase II original population, we found that beneficiary characteristics were not indicators of being in the high contact category. Among the baseline characteristics and demonstration period health status indicators, only having ESRD increased the likelihood of being in the high contact group while dying during the demonstration decreased that likelihood. Demonstration period acute care utilization was not a strong predictor of a high level of contact and likely reflects the challenges that the KTBH staff expressed in knowing when one of their participants had been to an emergency room or hospitalized. No other variables were found to be statistically significant.

Key Finding #3: The Phase II KTBH Demonstration had difficulty improving adherence to quality of care process measures.

We defined quality improvement for this evaluation as an increase in the rate of receipt of nine claims-derived, evidence-based process-of-care measures. Six of these measures pertain to beneficiaries with diabetes: rate of annual HbA1c testing, low-density lipoprotein cholesterol (LDL-C) screening, receipt of a retinal eye exam, medical attention for nephropathy, as well as the rate at which beneficiaries received all four of those measures, or none of those measures. Completion of a complete lipid profile was used for beneficiaries with ischemic vascular disease (IVD). We also created two ESRD-related measures applicable to the solely to the demonstration period: rate of progression to ESRD during the demonstration period, and rate of fistula/graft placement prior to initiation of dialysis among beneficiaries who initiated dialysis during the demonstration period for beneficiaries with CKD at the time of randomization. Out of nine measures, few exhibited statistically significant differences in the rate of receipt of evidence-based care between the intervention and comparison groups, and none of the significant differences were seen consistently across the Phase II original and refresh populations. Beneficiaries in the Phase II original intervention group were more likely to progress to ESRD during the demonstration period but were less likely to have a graft or fistula inserted prior to initiation of hemodialysis. Among the Phase II refresh intervention beneficiaries, we observed a positive intervention effect for nephropathy screening, reflecting a higher rate of screening during the demonstration period.

Over the course of the demonstration, the Phase II KTBH Demonstration had expected to increase rates of adherence to evidence-based care. However, during the last year of its

demonstration, we observe lower or very similar rates of adherence to the selected measures among its intervention beneficiaries relative to the comparison group beneficiaries for all measures. These findings suggest that improving or sustaining adherence to guideline concordant care in a cohort of ill Medicare FFS beneficiaries was more challenging than originally envisioned.

Key Finding #4: The Phase II KTBH Demonstration did not reduce acute care utilization as measured by rate of hospitalization, ER visits, or 90-day readmissions nor did they have any success reducing mortality.

During the course of the Phase II KTBH Demonstration, we generally observed increasing rates of all-cause and ambulatory care sensitive condition (ACSC) hospitalizations, ER visits, and 90-day readmissions in both the intervention and comparison groups and for both the Phase II original and refresh populations. We observed no statistically significant differential rates of hospitalizations or ER visits during the demonstration period relative to the baseline period for either population. Of all the 33 outcome measures reported for the Phase II original population, only two were found to be statistically significant: percent of beneficiaries with ACSC same-cause readmissions for all Phase II original beneficiaries and for the CKD group within that population. While the trend for this measure was the same for beneficiaries with ESRD, it was not statistically significant for those beneficiaries. Further, we found no differential rate of mortality between the Phase II intervention and comparison groups in either the Phase II original or Phase II refresh populations, nor by disease.

Key Finding #5: Medicare cost growth in the intervention group was not different from the rate of growth in the comparison group.

No statistically significant savings were found for the intervention in either the original or refresh samples. Costs rose $206 faster, not slower in the original intervention group (3.7% of comparison costs). The Phase II KTBH Demonstration may have performed slightly better with its refresh sample because intervention costs increased $99 slower than in the comparison group. Still, this difference was insignificant because savings needed to be $405 to be considered statistically significant.

Phase II KTBH Demonstration's intervention and comparison groups were randomly determined. We found no material imbalances across disease, severity, and other patient characteristics in the base period. Consequently, any slight differences that did exist in the subsequent base year had no material effects on our final conclusion of no significant savings.

RTI conducted analyses of savings separately for the CKD and ESRD groups. Neither disease group showed statistically significant savings due to the intervention in either the Phase II original or Phase II refresh populations.

E.4 Conclusions

Based on extensive quantitative analysis of performance, we find that the Phase II KTBH Demonstration had no success improving key processes of care, reducing acute care utilization or reducing mortality. PBPM costs rose faster in the Phase II original intervention group relative to the comparison group. Although PBPM costs rose slower in the Phase II refresh intervention

group relative to the comparison group, statistically significant savings were not achieved. The lack of program savings to offset monthly management fees and lack of any impact on other outcomes cannot justify the Phase II KTBH Demonstration model for chronically ill Medicare fee-for-service beneficiaries with CKD or ESRD on cost-effectiveness grounds.

What might explain the lack of success in the Phase II KTBH Demonstration? One explanation may be the targeting of beneficiaries at greatest risk of intensive, costly, service use (as distinct from the need for general care management). Responding to KTBH's request, CMS staff selected a very costly, complex set of Medicare beneficiaries for their intervention and comparison groups. As a result, the comparison group exhibited substantial regression-to-the-mean (RtoM) effects. While the randomized experimental design should cancel out RtoM effects and isolate a pure intervention effect, the large churning of beneficiaries from lower (higher) to higher (lower) cost groups over time adds considerable statistical noise to the test of savings. Even still, we would have considered the Phase II original intervention to be a success if it had saved 5.4% of costs. Large increases in demonstration period costs in less costly beneficiaries in the base period make it very difficult for intervention staff to target those at highest financial risk. It is much easier to target beneficiaries during the intervention period who actually incur major flare-ups and hospitalizations. Unfortunately, these beneficiaries have already incurred major expenditures by the time they receive intensive disease management services.

A second explanation may be their recruitment strategy. Given the KTBH program's high monthly management fee ($180 per month) and the population-based financial risk feature of this demonstration, engagement of 75% of the Phase II original population and less than 50% of the Phase II refresh intervention population required the Phase II KTBH Demonstration to have been extremely successful in reducing costs associated with the participating beneficiaries. The Phase II KTBH Demonstration was not successful in reducing hospitalizations during the demonstration period for the Phase II original or Phase II refresh populations. The lack of substantive improvements in acute care utilization broadly across their intervention population translated into limited financial savings. And, their targeting strategy was costly. Each contact cost was roughly $150 ($5 million in total fees divided by 33,594 contacts), higher than the national average payment amount for a face-to-face office visit with an established patient with the ***highest level of complexity*** under the Medicare Fee Schedule[1].

Lastly, a third explanation may be the model of intervention itself. Prior evaluations of Medicare care management programs that were primarily telephonic have not demonstrated savings sufficient to cover fees one-half the size of the Phase II KTBH Demonstration's fee. A cornerstone of the Phase II KTBH Demonstration was health coaching interactions with care manager nurses. However, nearly one-half of participating beneficiaries during the last 15 months of the program received no calls or in-person visits from a care manager. KTBH staff reported greater challenges recruiting CKD patients than ESRD patients because the CKD program was based on purely telephonic support. KTBH program staff estimated the bad phone number rate was greater than 30% and reported that they were unable to reach approximately 35-40% of the CKD population. Additionally, KTBH care managers felt that the inability to

[1] National non-facility price of $ 135.80 for HCPCS code 99215 for 2011.

conduct in-person visits to some dialysis facilities made it far more difficult to interact with ESRD beneficiaries, which then had to be conducted telephonically.

CHAPTER 1
INTRODUCTION TO THE EXTENDED MEDICARE CARE MANAGEMENT FOR HIGH COST BENEFICIARIES (CMHCB) DEMONSTRATION AND VILLAGEHEALTH'S PHASE II KEY TO BETTER HEALTH (KTBH) PROGRAM

1.1 Background on the CMHCB Demonstration and Evaluation

The purpose of this report is to present the findings from RTI International's evaluation of VillageHealth's Key to Better Health (KTBH) Phase II Care Management for High Cost Beneficiaries (CMHCB) Demonstration. On July 6, 2005, the Centers for Medicare & Medicaid Services (CMS) announced the selection of six organizations to operate programs in the CMHCB Demonstration. On January 13, 2009, CMS announced that it was granting 3-year extensions, subject to annual renewal, for three participants in the CMHCB Demonstration that had demonstrated some success managing the care of their selected intervention beneficiaries:

1. Robert Bosch Healthcare's (RBHC) Health Buddy® Program
2. Massachusetts General Hospital (MGH) Care Management Program (CMP)
3. VillageHealth's Key to Better Health program

These programs offer a variety of models, including "support programs for healthcare coordination, physician and nurse home visits, use of in-home monitoring devices, provider office electronic medical records, self-care and caregiver support, education and outreach, behavioral health care management, and transportation services" (CMS, 2005).

The principal objective of this demonstration is to test a pay-for-performance contracting model and new intervention strategies for Medicare fee-for-service (FFS) beneficiaries, who are high cost and/or who have complex chronic conditions, with the goals of reducing future costs, improving quality of care and quality of life, and improving beneficiary and provider satisfaction. The desired outcomes include a reduction in unnecessary emergency room visits and hospitalizations, improvement in evidence-based care, and avoidance of acute exacerbations and complications. In addition, this demonstration provides the opportunity to evaluate the success of the "fee at risk" contracting model, a relatively new pay-for-performance model, for CMS. This model provides the care management organizations (CMOs) with flexibility in their operations and strong incentives to keep evolving toward the outreach and intervention strategies that are the most effective in improving population outcomes.

The overall design of the CMHCB Demonstration follows an intent-to-treat (ITT) model, and the CMOs are held at risk for their monthly management fees based on the performance of the full population of eligible beneficiaries assigned to their intervention group and as compared with all eligible beneficiaries assigned to their comparison group. Beneficiary participation in the CMHCB Demonstration is voluntary and does not change the scope, duration, or amount of Medicare FFS benefits received. All Medicare FFS benefits continue to be covered, administered, and paid for by the traditional Medicare FFS program. Beneficiaries do not pay any charge to receive CMHCB Demonstration program services.

In Phase I, the CMOs receive from CMS a monthly administrative fee per participant, contingent on intervention group savings in Medicare payments being equal to fees paid to the CMO plus an additional 5% savings safety margin calculated as a percentage of its comparison group's Medicare payments. CMS developed the CMHCB Demonstration with considerable administrative risk as an incentive to reach assigned beneficiaries and their providers and to improve care management. To retain all of their accrued fees, the CMOs have to reduce average monthly payments by the proportion of their comparison groups' Medicare program payments that the fee comprises. In addition, to insure that savings estimates were not simply the result of random variation in estimates of claims costs, CMS required an additional 5% in savings (net savings). If the CMOs are able to achieve net savings beyond the 5% safety margin, there is also a shared savings provision with CMS according to the following percentages:

1. Savings in the 0%-5% range will be paid 100% to CMS.

2. Savings in the >5%-10% range will be paid 100% to CMO.

3. Savings in the >10%-20% range will be shared equally between CMO (50%) and CMS (50%).

4. Savings of >20% will be shared between CMO (70%) and CMS (30%).

One year after the launch of each Phase I Demonstration, CMS offered all CMOs the option of supplementing their intervention and comparison populations with additional beneficiaries to offset the impact of attrition primarily due to death. This group of beneficiaries is referred to as the "Phase I refresh" population. The CMOs are at financial risk for fees received for their Phase II refresh populations plus an additional 2.5% savings. For Phase II, a new cohort of beneficiaries were drawn – Phase II original population, followed by a Phase II refresh.

We use the chronic care model developed by Wagner (1998) as the conceptual foundation for our evaluation because the CMHCB Demonstration programs are generally provider-based care models. This chronic care model is designed to address systematic deficiencies and provides a standard framework that the area of chronic care management lacks. The model identifies six elements of a delivery system that lead to improved care for individuals with chronic conditions: the community, the health system, self-management support, delivery system design, decision support, and clinical information systems (Glasgow et al., 2001; Wagner, 2002; Wagner et al., 2001). According to the model, patients are better able to actively take part in their own care and interact productively with providers when these components are developed, leading to improved functional and clinical outcomes. Our evaluation focuses upon three broad domains of inquiry:

1. *Implementation.* To what extent were the CMOs able to implement their programs?

2. *Reach.* How well did the CMOs engage their intended audiences?

3. *Effectiveness.* To what degree were the CMOs able to improve clinical quality and health outcomes and achieve targeted cost savings?

Organizing the evaluation into these areas focuses our work on CMS' policy needs as it considers the future of population-based care management programs or other interventions in Medicare structured as pay-for-performance initiatives. We use both qualitative and quantitative research methods to address a comprehensive set of research questions within these three broad domains of inquiry.

RTI International was hired by CMS to be the evaluator of the CMHCB Demonstration and has previously conducted and reported to CMS findings from site visits to each CMO and a beneficiary survey of each CMO's intervention and comparison populations. In general, for Phase I, we made two rounds of site visits to each CMO to observe program start-up and to assess CMO implementation over time. For Phase II, RTI planned three rounds of site visits to each of the three extended CMHCB Demonstration programs to supplement our response to the key research questions. In advance of the site visits, a data collection questionnaire was sent to the sites for completion. The questionnaire enabled RTI to systematically collect information on changes to programmatic features, systems, policies, and procedures that may have occurred since the Phase I site visits. The 1–2 day site visits with administrative and clinical staff employed by the CMOs were planned for months 4–6 in year 1, months 17–19 in year 2, and months 30–32 in year 3. However, all CMOs ended their programs before the end of the 3-year period, so only 1 or 2 site visits were conducted for each CMO. RTI staff interviewed program and organizational leadership as well as clinical and program staff during each site visit. Two RTI evaluation team members participated in the 1–2 day on-site visits at each CMO location. For each site visit, we collected data through a combination of telephone interviews, in-person interviews, and secondary sources, including CMO-generated program monitoring reports.

The first Phase II site visit focused on learning about program implementation since the extension period began, performance monitoring/outcomes to date, and implementation experience/lessons learned to date. For those sites that had a second site visit, it was focused on engagement of the Phase II populations, program evolution, program monitoring/outcomes, and implementation experience/lessons learned. During the site visits, RTI met with a small number of physicians to develop an overall impression of satisfaction and experiences with the Phase II CMHCB Demonstration. The primary objectives of the interviews were to (1) assess physicians' awareness of the CMHCB Demonstration and (2) gauge their perceptions of the effectiveness of these programs.

The October 2009 site visit to VillageHealth's Key to Better Health (KTBH) program marked the third site visit trip for the program since the start of the CMHCB Demonstration, and the first during the Phase II extension period. The site visit included an in-person meeting with the management team and key staff from KTBH and VillageHealth (a subsidiary of DaVita Inc. that operated formerly under the name RMS Disease Management). The KTBH program is operated within a department of VillageHealth that maintains its own budget; however, some training activities are funded by the VillageHealth clinical operations budget. The KTBH program provides participants with services designed to slow the progression of kidney failure, effectively treat complications of kidney disease, and coordinate the smooth transition to renal replacement therapy as needed.

During this visit, two RTI evaluators met with VillageHealth and KTBH program senior management, key program staff, and the program's Medical Director, a KTBH program

nephrology practice partner. The interviews included a range of questions related to: program implementation and changes since the last site visit/since the extension period began; program monitoring/outcomes; and implementation experience/lessons learned to date. RTI also conducted a follow-up telephone conference call with the KTBH program director and analysis staff in November 2009 to discuss updated KTBH enrollment data. In January 2011, VillageHealth submitted a memo to CMS indicating their decision to terminate the KTBH program early, in April 2011. RTI conducted a closeout call with the KTBH Program Director, Director of Medical Cost Analysis, and Director of Finance in April 2011 to discuss key program changes since the October 2009 site visit, factors leading to program termination, and lessons learned.

This final report presents evaluation findings based on the full 21 months of the Phase II KTBH CMHCB Demonstration operations with its Phase II original population and 11 months with its Phase II refresh population. We start by reporting on the degree to which the KTBH program was able to engage its intervention populations. We measure degree of engagement in two ways: (1) participation rates and characteristics of participants; and (2) number and nature of contacts between the KTBH program and participating beneficiaries from encounter data provided to RTI from VillageHealth. We then report findings related to the effectiveness of the Phase II KTBH Demonstration to improve functioning and health behaviors, improve clinical quality and health outcomes, and achieve targeted cost savings.

1.2 KTBH's CMHCB Demonstration Program Design Features

1.2.1 KTBH Organizational Characteristics

VillageHealth (formerly RMS) was formed in 1996 as part of Baxter, a global medical products and services company with expertise in medical devices, pharmaceuticals and biotechnology. In 1997, VillageHealth signed its first contract to provide chronic kidney disease (CKD) care management services to Humana, which continues to be VillageHealth's largest client today. In 2002, DaVita, Inc. acquired VillageHealth, which operates the renal disease management program as a wholly owned subsidiary. The largest independent provider of dialysis services in the United States, DaVita, Inc., bought VillageHealth rather than developing its own disease management service line. DaVita, Inc. is a publicly traded company with $3 billion in annual revenue, 65% of which is obtained through contracts with Medicare and Medicaid. DaVita, Inc. provides support to almost 100,000 dialysis patients within approximately 1,250 dialysis centers in 41 states and the District of Columbia, with a staff of 28,000 teammates.

Headquartered in Vernon Hills, Illinois, near the offices of its previous owner, Baxter, VillageHealth is the largest renal disease management organization (DMO) in the country. VillageHealth was the first renal DMO to receive full National Committee for Quality Assurance accreditation in 2002, which was recently renewed for an additional 3 years. VillageHealth's staff of 178 full-time employees provides advanced care management programs in more than 25 markets throughout the U.S. DaVita also operates a Medicare Advantage Special Needs Plan in California, which is also the CMS ESRD Disease Management Demonstration Project. In addition, DaVita is collaborating with Evercare's Medicare Advantage Special Needs Plan /

CMS ESRD Demonstration Project in Georgia and Arizona, as a result of DaVita's recent acquisition of Gambro, another provider of dialysis services.

The CMHCB Demonstration serves as an important opportunity for VillageHealth to expand its government business, as well as learn about better ways to provide support for Medicare beneficiaries with CKD, a vulnerable population receiving less than optimal care from the currently fragmented health care system. VillageHealth employs a rigorous process of continuous quality improvement to ensure that lessons learned are applied to improve ongoing operations. VillageHealth enlisted the support of several partners to meet the needs of the high-cost Medicare beneficiaries served by the CMHCB program.

VillageHealth developed the "Key to Better Health" (KTBH) program to serve Medicare fee-for-service beneficiaries with CKD eligible for the CMHCB Demonstration in Suffolk, Nassau, and Queens, New York. The KTBH program was within a department of VillageHealth that maintained its own budget; however, some training activities were funded by the VillageHealth clinical operations budget. The KTBH program provided participants with services designed to slow the progression of kidney failure, effectively treat complications of kidney disease, and coordinate the smooth transition to renal replacement therapy as needed. The KTBH program drew from the core elements of VillageHealth's other disease management offerings, with adaptations to meet the needs of the older, sicker population eligible for the CMHCB Demonstration program. The core of the VillageHealth disease management program consisted of ongoing support from a team of telephone- and field-based nurse care managers/health coaches, supplemented by assistance from a pharmacist, social worker, and dietician on the program team. The goals of the Phase II KTBH Demonstration were to decrease risk of "crashing" into dialysis, reduce the number of patients who progress to end-stage renal disease (ESRD), and avoid or delay preventable hospitalizations. "Crashing" into dialysis refers to a patient going into renal failure, requiring the urgent initiation of renal replacement therapy with a catheter typically conducted in the emergency department of a hospital. This emergency procedure carries significant costs at the time of the crash, as well as during the following period of ESRD due to increased prevalence of complications and increased risk of infection from catheters compared with access provided by fistulas. KTBH expanded its clinical focus during Phase II to include care management services for ESRD patients. During the extension period, the KTBH program expanded from six partner nephrology groups to 17, and planned to continue increasing the number of nephrology partners.

1.2.2 Market Characteristics

VillageHealth selected Suffolk, Nassau, and Queens, New York, as its target region for the CMHCB program. This section provides a summary of the main factors that motivated VillageHealth to choose this region for its launch of the KTBH program. VillageHealth selected Suffolk and Nassau counties because they have a dense population of Medicare beneficiaries. Queens, New York, was added to the target area during initial negotiations with CMS and collaboration with ARC to ensure that there were a sufficient number of beneficiaries eligible for the program and to populate an intervention and comparison group for the CMHCB Demonstration. For Phase II, the counties selected were Nassau, Suffolk, Queens, Kings, Westchester, Richmond, Rockland, and Bronx. VillageHealth's review of census data during Phase I indicated an increase in the ESRD population. As mentioned earlier, the KTBH program

added ESRD as a clinical focus of the program and began outreach to ESRD beneficiaries during Phase II.

1.2.3 Phase II KTBH Intervention and Comparison Populations

VillageHealth worked with its CMS project officer and analysts from Actuarial Research Corporation (ARC) to develop a methodology for selecting the starting population for the Phase II KTBH CMHCB Demonstration. Beneficiaries had to meet the following four inclusion criteria for eligibility in the Phase II KTBH CMHCB Demonstration:

- Medicare fee-for-service beneficiaries, who had a primary residence in Nassau, Suffolk, Queens, Kings, Westchester for the ESRD population with the addition of Richmond, Rockland, or Bronx counties for the CKD population.
- High costs based on Medicare claims from July 1, 2007 through June 30, 2008 (i.e., $5,000 or more for CKD beneficiaries and $12,000 or more for ESRD beneficiaries); and
- Diagnosis of chronic kidney disease (CKD) as evidenced by at least one claim with a diagnosis code indicative of CKD of stage 3 or higher
- Beneficiaries with an ESRD flag on the EDB.

Beneficiaries were excluded if they had one of the following exclusion criteria for eligibility in the Phase II KTBH CMHCB Demonstration:

- Met the specific VillageHealth diagnostic criteria for exclusion, generally identifying patients with cancer;
- any transplant was an exclusion for ESRD beneficiaries, however if a CKD beneficiary had a CKD claim after their transplant claim, they were still eligible,
- reside in a nursing home (custodial care),
- institutionalized in a mental health facility,
- elected the Medicare hospice benefit, enrolled in a commercial Medicare Advantage plan, did not have both Part A and Part B Medicare coverage, had Medicare as a secondary payer, or did not have a phone number from a search of the Social Security Administration's contact information database.

The remaining beneficiaries were randomly assigned to the intervention and comparison groups at a ratio of 1 to 1. The final Phase II original population was composed of 2,945 intervention beneficiaries and 2,944 comparison beneficiaries, of which 1,500 were ESRD beneficiaries in both populations. Because these beneficiaries are assigned prior to the start of the Phase II Demonstration, another check for eligibility is done on the start date and ineligible beneficiaries are dropped at that time.

The Phase II CMHCB Demonstration was designed using an intent-to-treat model, which means that the CMOs are held accountable for outcomes across the full intervention population, not just those who agree to participate. This model provides CMOs with flexibility in their operations and strong incentives to keep evolving toward outreach and intervention strategies that are most effective in improving population outcomes. Once individuals were assigned to either the intervention or comparison group, they remained in their assigned group for all days in which they were eligible. Eligibility for the KTBH program and hence membership in either the intervention or comparison group was lost for any period(s) during which the beneficiary:

- enrolled in an MA plan,
- lost eligibility for Medicare Part A or B,
- got a new primary payer (i.e., Medicare becomes the secondary payer),
- moved out of the KTBH program service area,
- elected the hospice benefit, or
- died.

Phase II refresh population— VillageHealth worked with its CMS project officer and analysts from ARC to develop a methodology identifying the Phase II refresh populations for the intervention and comparison groups. A Phase II refresh population of 2,234 intervention beneficiaries and 2,233 comparison group beneficiaries was received by the KTBH program in April 2010. The basic criteria for selection of the intervention and comparison Phase II refresh populations were similar to the criteria used to select the initial populations with one noted exception. Westchester County was no longer needed to reach the target ESRD population.

1.2.4 KTBH Operations

VillageHealth's fee strategy was based on a literal interpretation of participation, i.e., only patients who agreed to actively participate by receiving care support services via telephone and/or home visits from nursing staff were defined as program participants. Lower risk individuals who agreed to receive periodic educational mailings are classified as non-participants in terms of program fees collected. For the refresh cohorts (Phase I refresh and Phase II original and refresh), a fee was paid for the refresh beneficiaries only if they became participants.

Participation continued until a beneficiary became ineligible for the Demonstration or opted out of services provided by the KTBH program. Participants could drop out of the program at any time and begin participation again at any time, as long as they were eligible. Beneficiaries who declined participation could be re-contacted by the KTBH program after a sentinel event, such as a hospitalization or an emergency room visit.

For Phase II, fees were reduced from $225 per member per month (PMPM) to $180 PMPM. In addition to the reduction in fees for Phase II, the reduction in the savings threshold from 5% to 2.5% for the Phase I refresh beneficiaries also applied to both Phase II populations.

Participating nephrology partners in Phase II received a nominal fee of $15 PMPM (down from $25 PMPM during Phase I) in exchange for primarily providing the KTBH program with laboratory and other relevant beneficiary medical information and corresponding with the KTBH care managers.

1.2.5 Overview of the Phase II KTBH CMHCB Demonstration Program

1.2.5.1 KTBH Program Changes Implemented During Phase II

VillageHealth introduced a number of changes and enhancements to its KTBH program and operations between the January 2008 (Phase I) and October 2009 (Phase II) site visits. The most notable changes to the program content and delivery process include:

- changes in corporate and program leadership;
- addition of new program staff;
- collection of beneficiary survey data;
- change in fees;
- expansion of nephrology partners;
- expansion of relationships with local hospitals, other care agencies, and community organizations;
- termination of service provider contracts and a return to in-house provision of services;
- availability of classes for beneficiaries;
- provision of additional training for care managers;
- availability of new technology for care managers; and
- expanded clinical focus that includes ESRD.

Changes in VillageHealth and KTBH Program Leadership

KTBH was a department of VillageHealth (formerly RMS Disease Management) that maintained its own budget, although VillageHealth funded periodic staff training out of its clinical operations budget. VillageHealth and KTBH program leadership staff changed between RTI's 2008 and 2009 site visits. Jess Parks served as the new President/General Manager of VillageHealth and oversaw the interim Project Director for the KTBH program, Tami Deeb. Ms. Deeb assumed full operational responsibility for the KTBH program and also served as VillageHealth's Director of Strategy and Government Relations. KTBH also added a new Vice President of Clinical Operations who maintained oversight of the KTBH Regional Operations Manager and Nursing Team Leader. KTBH eliminated the position of Regional Operations Director.

Addition of New Program Staff

The program hired seven new nurse care managers for the Phase II extended KTBH program to serve the ESRD population. Most of the nurses had case management experience, but very little renal experience. Site visit participants reported that KTBH program leadership devoted significant time and attention to educating the nurse care managers on renal issues during orientation and during the time that care managers spend with their preceptors. However, given that the nursing team provided care management rather than dialysis treatment, KTBH program leadership believed that it was more critical for the nurses to have care management skills and the ability to coach participants, rather than to have renal experience.

In addition to adding care managers, KTBH program leadership added a local social worker to conduct home visits and address the social needs of participants. The program included six telephonic nurses, 10 field nurses, a registered dietician, a pharmacist (the dietician and pharmacist served programs across VillageHealth and were not solely dedicated to the KTBH program); and two social workers (one social worker was field-based; the other was located in New Jersey and provided telephonic support). All of the nurses were registered nurses; several had advanced nurse practitioner certification. All of the nurses provided the same care management services regardless of whether they were field- or telephonic- based. However, the telephonic nurses primarily worked with CKD beneficiaries whereas the field nurses typically worked with ESRD beneficiaries in the dialysis facilities or conducted home visits to CKD or ESRD beneficiaries.

In addition to hiring a social worker and care managers, KTBH program leadership also hired a Provider Relations Representative to improve the program's relationship with physicians in the community.

Collection of Beneficiary Survey Data

During Phase II, VillageHealth began administering the SF-12 Health Survey to participants in an effort to evaluate their quality of life. The survey was administered as part of the baseline assessment and was re-administered again at six months after assessment, one year after assessment, and annually thereafter. VillageHealth also administered member satisfaction surveys six months after assessment, one year after assessment, and annually thereafter. The surveys were mailed from the VillageHealth Quality Department along with a postage-paid return envelope. Responses were entered into VillageHealth's member database system. VillageHealth planned on compiling a report of the responses at the end of 2009.

Expansion of Physician Group Partners

As previously noted, the KTBH program expanded from 6 partner nephrology groups to 17 during the extension period. The program provider strategy also included providing more information to physicians through a quarterly newsletter and the KTBH program website. KTBH program staff reported that the care managers worked closely with the partner nephrologists on both outreach and beneficiary management. With the assistance of the KTBH program physician leader and nephrologist, Dr. Steven Fishbane, at the time of the site visit, the KTBH program was in the process of creating a community Medical Advisory Board to further engage nephrologists in the clinical elements of the program. Dr. Fishbane noted that the KTBH

program worked very hard in Phase I to build a nephrologist network. Although the nephrologists were very engaged initially, the program had less of a renal focus than anticipated given that the beneficiary population did not have the extent of CKD that was originally projected. As a result, the program did not maintain as high visibility among physicians during Phase I as the KTBH program leadership would have liked. Dr. Fishbane underscored the importance of establishing effective partnerships with the partner nephrologists during Phase II and was optimistic about the efforts to secure physician champions, garner enthusiasm and support, and improve physician engagement at the first Medical Advisory Board meeting. The KTBH program leadership believed that the physicians perceived the PMPM fees as very nominal; consequently, the fees were not the driving force for physicians to participate in the program.

Expansion of Relationships with Local Hospitals, Other Care Agencies, and Community Organizations

KTBH staff reported the care managers worked hard during Phase II to expand their relationships with hospitals, skilled nursing facilities, and rehabilitation facilities. In particular, they emphasized introducing the KTBH program to skilled nursing facilities and rehabilitation facilities in Kings County (where they had no beneficiaries in Phase I). They also worked on developing relationships with community not-for-profit agencies such as The Jewish Guild for the Blind, Parker Jewish Institute for Health Care & Rehabilitation, and Visiting Nurse Services, and reported progress in working with hospitals such as St. Frances to better coordinate discharge planning.

Termination of Service Provider Contracts and a Return to In-House Provision of Services

During Phase I, RMS contracted with Intellicare to conduct telephonic outreach to the intervention beneficiaries but KTBH staff decided to discontinue the contract in Phase II and bring outreach efforts in-house to allow the nurse care managers to make the calls and speak more directly about the potential benefits of the Phase II KTBH Demonstration. During Phase II, the nurse care manager recruitment calls were taped, reviewed, and rated. The care managers were matched with a nurse mentor and were also provided with a customized plan to help them to become more proficient at coaching beneficiaries. In addition, the nurses received scripted talking points to allow them to feel more comfortable calling beneficiaries and move beyond the perception that they were selling something to the beneficiaries versus involving them in a demonstration project.

VillageHealth also terminated its subcontract with Enclara, a firm that specializes in end-of-life planning and preparation for hospice referral. In Phase I, once a KTBH program care manager made a referral, Enclara provided telephonic or in-person support and reported the outcome of the intervention back to the KTBH program team. During Phase II, KTBH contracted with an external vendor, LifeMasters, to train their nurse care managers on speaking directly with beneficiaries about end-of-life issues.

In Phase I, the KTBH program provided a Cardiocom telemonitoring scale to selected participants with heart failure, or who had been hospitalized, or who were at risk for hospitalization based on disease progression. Cardiocom's telescale is a product that electronically transmits beneficiary weight and responses to questions related to health status and

self-management back to the KTBH program. In November 2007, the program switched to using Cardiocom nurses to perform the monitoring because KTBH staff felt that Cardiocom staff had greater expertise in the use of the software. In the past, Cardiocom nurses alerted the KTBH nurses in the event that there were concerns about a beneficiary's weight gain. The KTBH nurse then followed up with the beneficiary or made a home visit to address the situation and possibly prevent a hospitalization. During the extension period, however, VillageHealth scaled back their relationship with Cardiocom. Although the KTBH program continued to use Cardiocom scales in Phase II to capture the weight of their participants at-risk for fluid-related hospital admissions, KTBH program leadership brought the monitoring of the weights and alerts in-house to provide care managers with the ability to address potential issues in a timelier manner, particularly on weekends and holidays.

More Frequent Contact with Beneficiaries

In Phase I, beneficiaries were contacted every one, two, or three months depending on how they rated according to thirteen different factors/service intensity guidelines. In Phase II, contact with all participants was initiated by the care managers at least once every 30 days. This effort was based on the idea that more frequent, shorter contact will facilitate greater beneficiary activation. The monthly contacts allowed care managers to better monitor participants—especially with respect to recent hospitalizations whereby an opportunity may exist to potentially prevent costly readmissions. Care managers contacted beneficiaries more often if they believed it was necessary.

Availability of Classes for Beneficiaries

The KTBH program began offering in-person educational classes to participants with CKD and also created a website that provides participants with access to additional educational materials. In addition, they began inviting KTBH participants to DaVita's EMPOWER educational program session on CKD. The KTBH staff held two sessions that lasted approximately 1 ½ hours and also planned to hold subsequent regular sessions throughout their geographic area.

Provision of Additional Training for Care Managers

Site visit participants reported that VillageHealth invested heavily in additional motivational interviewing (MI) training, a client-centered, semi-directive technique used to engage participants' own intrinsic motivation to facilitate behavior change. Prevention and protection of kidney function are greatly influenced by self-care, compliance, and following physician orders. Based on the belief that beneficiary empowerment is a critical part of the KTBH's overall disease management approach, the former Chief Medical Officer and Medical Directors felt that it was necessary to include MI in their approach to improve beneficiary outcomes. KTBH staff received initial MI training in the fall of 2007 from the Motivational Interviewing Network of Trainers (MINT) at Oregon Health and Sciences University, and additional training in September 2009. Anecdotally, KTBH staff reported experiencing some clear MI successes. However, in an effort to test the effectiveness of MI in a more systematic way, KTBH care managers were collecting patient activation measures (PAM) to establish a baseline and planned to re-survey beneficiaries to determine the effectiveness of the care managers in increasing beneficiary activation.

By integrating MI techniques into KTBH processes, care managers were able to obtain an early assessment of a participant's activation level on a scale of zero to four. If, for example, a patient persisted at a low activation level of zero or one, KTBH program managers used this information to help guide their resources toward those for whom the program may make the most difference (i.e., those demonstrating progression in activation levels). At the time of the site visit, care managers had just begun scoring each patient's activation level at baseline. KTBH program leadership planned to correlate activation levels with clinical outcomes to determine the impact that patient activation levels may have on clinical outcomes.

KTBH contracted with LifeMasters to conduct a two-day training session on end-of-life care issues with a subset of the care management team. Upon completion of the LifeMasters session, KTBH staff held 12 follow-up advanced care planning meetings. The entire care management team participated in on-line courses as part of the Gunderson Lutheran Medical Foundation's Respecting Choices advanced care planning series. Staff also received VillageHealth-funded training on new tools and processes introduced during Phase II pertaining to vascular access planning, hospitalization admission review, medication therapy management, and fluid treatment metrics.

Availability of New Technology for Care Managers

During Phase I, the KTBH care managers used an internally developed clinical care management tool known as the Medical Information System Technology (MIST) to operate its disease management program. The application included beneficiary evaluation and encounter forms that allowed care managers to document information about a beneficiary's condition and care needs primarily using drop-down menus. Although MIST served as a good repository of information, staff found it difficult to navigate and indicated that it was challenging to visualize information across all of their assigned beneficiaries unless a particular report was pulled. This was the impetus for creating the Nurse Panel, a tool developed to provide a quick and easy way to access information stored in MIST. The Nurse Panel permitted the care managers to view their entire panel of beneficiaries and provided access to key clinical outcomes, recent contacts, and provider information. The Nurse Panel also provided a current and on-going summary of measures that the nurse care manager or the team was achieving, thereby providing an aggregate view of performance on key clinical indicators. For example, the Nurse Panel sorted beneficiaries by recent contact, type of vascular access, or by those who need an influenza vaccine, as well as numerous other data elements. The care managers reported that they were very fond of the new Nurse Panel since it provided easy access to all of the information that they needed.

The Nurse Panel was part of the KTBH program's updated model for care management, Capella, which was introduced at the beginning of Phase II. Capella included new processes, tools, technology, and training for ESRD and CKD beneficiaries. It tied together clinical, operational, and technical components with the intent of enabling care managers to focus on the correct interventions with beneficiaries, standardize and simplify clinical processes, and facilitate the use of integrated technology to provide decision-making support to care managers. It focused on elements of the basic nursing model and includes:

- coaching for beneficiary activation (motivational interviewing);

- medication therapy management;
- depression screening and intervention;
- advanced care planning;
- basic care management;
- geriatric care; and
- managing cultural and health literacy in a diverse environment

VillageHealth also added a number of other tools during Phase II:

Vascular Access Plan: A tool used by nurses to track and document a step-by-step approach for patients with a central venous catheter (CVC) to move them to a permanent vascular access (i.e., arteriovenous fistula or arteriovenous graft). It is a seven-step process that includes beneficiary acceptance, vessel mapping, surgical evaluation, surgical procedure, evaluation for maturation, first cannulation, and CVC out. This information was tracked at a beneficiary level in the tool, with the ability to view time between steps.

Hospital Admission Review: A hospitalization tracking tool that guided the care manager through key steps in discharge planning and follow-up contacts. It also provided a view of where, why, and when hospitalizations occur.

Medication Therapy Management: A tool that enabled the medications entered to be "seen" by a software pharmacy system that conducted daily reviews of the entire list for medication-related problems. Alerts were created for any potential medication-related problems and were addressed by a pharmacist.

Fluid Treatment Metrics Window: A system that alerted the care manager for DaVita dialysis center patients when the beneficiary leaves a treatment > 1 kg over their estimated dry weight (EDW) for 3 consecutive treatments, or was > 2 kg over EDW at the beginning of the long interval.

Expanded Clinical Focus that Includes End-Stage Renal Disease (ESRD)

Phase I targeted outreach and participation of late stage CKD beneficiaries. In Phase II, engagement of CKD beneficiaries remained telephonic. The outreach to ESRD beneficiaries, however, was entirely new in Phase II since ESRD was not part of the clinical focus in Phase I. KTBH program leadership found that when a nurse had an in-person contact with an ESRD beneficiary, the beneficiary was more than twice as likely to enroll in the program. As a result, KTBH program leadership decided to send a nurse to every dialysis facility with more than two eligible beneficiaries. Prior to the visit, the care manager sent a packet to the facility's administrator, placed a call to the administrator, and tried to make an appointment to conduct an informational breakfast or lunch session with the entire staff to introduce the KTBH program and assuage any concerns about the program. The goal of the informational sessions was to explain to staff that the care managers hoped to accomplish things with the beneficiary that would enable the intervention participants to better manage their condition. They tried to convey to staff that

the care managers were not there to make their lives more difficult or to take the place of the existing staff that provided services to beneficiaries. KTBH staff reported receiving the biggest pushback from facility social workers. KTBH staff believed that there was a direct correlation between having the support of social workers and beneficiary participation in that when they received the support of the social workers, prospective participants were more likely to join the KTBH program.

At the time of the site visit, KTBH staff had visited 50 dialysis facilities. Out of the total number of eligible ESRD beneficiaries, KTBH staff recruited approximately one-third of them to participate in the program. They felt that most facilities were receptive to learning more about the KTBH program and anticipated that the number of participants would continue to increase over time. Some facilities, however, were not quite as welcoming of the KTBH care managers and suggested that there would be duplication of purposes, stating that they already provide the services that the KTBH care managers are offering (a claim the KTBH staff characterized as inaccurate). Some of the KTBH care managers were told that they were not allowed to enter some of the facilities to talk with and recruit beneficiaries to the program. The care managers felt that the inability to conduct in-person visits to some dialysis facilities made it far more difficult to interact with ESRD beneficiaries, which then had to be conducted telephonically. The KTBH staff hypothesized that the defensive posture of some facilities may have been due in part to concerns that DaVita could acquire their patients, despite the care managers' attempts to explain that the purpose of their visits and provision of services was to act as "the extra set of hands that you don't have right now." Given that a beneficiary's stay at the dialysis facility is short, KTBH care managers could provide continuity by following the beneficiaries and providing on-going accounts of the beneficiaries' medical history—a new service rather than duplication of services already provided.

Some KTBH staff members observed a change in the perception of some facilities' staff in which the care managers were viewed as "more of partner rather than a usurper," which KTBH staff considered to be a big step forward. As one care manager noted, "I say to them, 'We won't do anything without discussing it with you first. We don't want to do this in a vacuum and tell you what to do. We won't try to go over you or step around you. We want to discuss first so that we have a good plan.' We also offered to sit in during care meetings for the beneficiaries so that we can have better communication about what is going on. We're just starting to get that into place."

1.2.5.2 Other Aspects of the Extended KTBH Program

In addition to a series of changes and enhancements to its operations, we discussed other aspects of the extended KTBH program pertaining to:

- comparison of clinical characteristics of the Phase II population and Phase I original and Phase II refresh populations,
- changes in outreach,
- corporate support for the extended KTBH program, and
- relationship with CMS.

Each of these is discussed in detail in this section.

Comparison of Clinical Characteristics of the Phase II Population and Phase I Legacy Population

At the time of the October 2009 site visit, 42% of the Phase II original population was participating in the Phase II KTBH Demonstration. In Phase I, VillageHealth's expectations were that the population would have chronic kidney disease. However, over the course of the program, they discovered that many of the beneficiaries were elderly with congestive heart failure and vascular disease, but did not have kidney disease. As a result, VillageHealth felt that their interventions were not ideally matched to the population. They managed a population of beneficiaries in which their major interventions were diluted down to a small proportion of their intervention population. In Phase II, they changed the population selection criteria specifying that eligibility required a diagnosis code for stage 4 or 5 CKD or ESRD, with the hope of obtaining a population comprised of those with true late stage kidney disease, who are on dialysis or who are projected to be on dialysis in the near future. Given that their clinical interventions were specifically designed for these populations, they felt that the KTBH program would be more effective with this change. Those that we interviewed noted that beneficiaries with late stage kidney disease were frequently hospitalized and experience a tremendous crash period as they start dialysis, with resource use steadily increasing in the months prior to the start of dialysis and skyrocketing during the first six months of dialysis. They felt that there were numerous downstream interventions that could take place to delay or arrest the progression of CKD and ESRD that could effectively reduce costs, hospitalizations, and improve the lives of the beneficiaries and their families.

KTBH program leadership initially encountered many challenges when trying to locate the late stage kidney disease population from Medicare claims data when they began the search for Phase I beneficiaries in 2005. At that time, ICD-9 diagnosis codes identifying CKD stage (585.x codes) were unavailable. Consequently, the CKD identification codes/algorithm fared poorly in identifying the targeted late stage CKD population. For Phase II, the algorithm was changed to using the stage-specific ICD-9 diagnosis codes of 585.4, 585.5 (stage 4 and 5 chronic renal failure), and the dialysis flag in the EBD file (ESRD). The scope of diagnosis codes was also expanded to include secondary diagnoses of CKD and ESRD. VillageHealth and KTBH program leadership felt that this more focused approach by diagnosis code would facilitate better identification of the relevant population compared to the Phase I population. However, they were cognizant of the possibility that some providers, particularly primary care physicians, were underutilizing the correct CKD diagnoses codes and were instead, using the more generic 585 code as opposed to the more accurate stage-specific codes based on a glomular filtration rate (GFR).

Changes in Outreach

As noted earlier, VillageHealth discontinued their contract with Intellicare to conduct beneficiary recruitment for the KTBH program and instead, opted to provide training to care management staff to allow the internal ability to conduct beneficiary outreach. Beneficiaries were stratified by stage (stage 5 beneficiaries were prioritized most highly) and whether they were under the care of a nephrologist. The nurses utilized an algorithm developed by a third

party to assess beneficiary activation and tie this into their motivational interviewing techniques. The algorithm enabled them to obtain an early assessment of a patient's activation level.

The patient activation measure (PAM) is comprised of four levels:

- **Level 1: Starting to take a role**

  Beneficiaries act as passive recipients of care and do not yet understand that they must play an active role in their own health.

- **Level 2: Building knowledge and confidence**

  Beneficiaries lack the basic health-related facts or have not placed the facts within the context of the larger understanding of their health or health regimen.

- **Level 3: Taking action**

  Beneficiaries have the key facts and start to take action, but may lack the confidence and skill to support their behaviors.

- **Level 4: Maintaining behaviors**

  Beneficiaries have adopted new behaviors but may not be able to maintain them in light of stress or health crises.

A beneficiary that persistently scored a 0 or 1 may not be well-suited for the KTBH program since so much was needed for them to change certain behaviors. If, for example, a beneficiary was depressed, it was believed that the care managers may not be able to impact the beneficiary's ability to care for themselves until the beneficiary received help for their depression. Hence, the patient activation level functioned as an index to help guide the allocation of resources and to identify those beneficiaries for whom the KTBH program may be most beneficial. The goal was to increase beneficiaries' activation levels so that they became more involved in their care.

One of the primary goals of the KTBH program was to reduce the use of catheters for dialysis. A less activated/engaged beneficiary would want to use a catheter to avoid needle sticks, whereas an educated beneficiary would want to have a fistula in place of the catheter to lower infection risk and have better blood flow. Another goal that KTBH care managers aimed to achieve was a reduction in hospital admissions due to fluid overload. Dialysis patients are often admitted for volume overload despite clear ways to reduce their intake. They are aware of what they eat and drink and should be aware of early symptoms. Balance is needed to ensure that proper diets are maintained. Thus, beneficiary activation where beneficiaries feel that they have control, knowledge, and/or the ability to positively affect their well-being is critical in reducing hospitalizations and health care costs. The KTBH care managers had just begun to score each patient's activation level at baseline and planned to analyze beneficiaries' activation levels over time and correlate them with specific clinical outcomes to determine the impact of using the index to allocate resources over time.

Corporate Support for the Extended KTBH Program

At the time of the site visit, staff noted that corporate support for the KTBH program was very high, both within VillageHealth and their parent company, DaVita. Site visit participants reported that the KTBH program was one of VillageHealth's top priorities for the next three years. Their progress was reviewed regularly with DaVita's CEO and Senior Vice Presidents. Similarly, DaVita had consistently supported the investment made by VillageHealth.

Relationship with CMS

KTBH program leadership noted that their relationship with CMS had become closer since RTI's previous visit. During the initial months of the renewal, they spoke with the CMS team on a weekly basis to ensure transparency. They transitioned to bi-weekly calls in the spring of 2009. They sent intervention reports and weekly updates to CMS regarding progress with outreach. As issues or questions arose, they reported that VillageHealth and KTBH program leadership and CMS were able to resolve the issues in a timely manner. VillageHealth and KTBH program leadership felt that the more frequent, consistent contact with CMS had strengthened their partnership.

1.2.5.3 KTBH Program Closeout

In January 2011, VillageHealth submitted a memo to CMS electing to terminate KTBH program operations early on April 22, 2011. Staff from RTI International, KTBH and VillageHealth leadership participated in a telephone conference call on April 14, 2011 to discuss program changes made since the October 2009 RTI site visit, factors leading to the termination of the KTBH program, and lessons learned. Participants from KTBH and VillageHealth included the KTBH Program Director, Director of Medical Cost Analysis, and Director of Finance.

Key KTBH Program Changes Implemented Between October 2009 and Program Termination

Efforts to obtain patient clinical data. KTBH staff reported that care managers continued to face challenges in obtaining good clinical data that allowed them to be more proactive in clinically managing the patients and noted, "Our system is only as good as the data that goes in it." They developed an automatic feed with their DaVita dialysis centers enabling all labs and vital signs from the dialysis treatment for end-stage renal disease (ESRD) patients in a DaVita center to flow into the VillageHealth system. In addition, if a patient missed a treatment, an alert was triggered notifying care managers that the patient was not in dialysis and may be hospitalized. Labs, missed treatment, and dialysis session information were entered into the system, but only for DaVita patients.

For non-DaVita patients, the system alerted care managers if a patient was due for a medication review, which staff felt was very helpful from a clinical perspective; however, it did not solve the larger overall issue. In addition to the treatment alerts, staff also took the following actions:

- Provided bracelets to patients who were frequently hospitalized that contained the message "please call my VillageHealth nurse."

- Asked nephrologist partners for notification of hospitalized patients who participated in the KTBH program.

- Approached hospitals to inquire about the possibility of interfacing with their system to flag patients who were KTBH participants.

Despite these attempts, none were met with the level of success they desired. At the time of the program closeout call, VillageHealth was exploring broader data interfaces and data exchange. Program staff acknowledged that although these options were very expensive from a commercial standpoint, they were critical in resolving the greatest missed opportunity – knowing when patients are in the hospital. They reported that the improvements they wanted to achieve regarding hospital readmissions were made more difficult because they were missing this key piece of information.

Management of "frequent flyers." KTBH continued to refine its approach to managing "frequent flyers," defined as patients who were hospitalized four or more times per year. Staff reviewed the medical history of these participants on a bi-weekly basis. In addition, an interdisciplinary team reviewed the medical histories to determine other services that should be offered to these patients (e.g., psychiatric care).

Distribution of Cardiocom scales. KTBH continued to struggle with distribution of Cardiocom scales to the appropriate patients. Cardiocom scales were intended to capture the weight of beneficiaries at-risk for fluid-related hospital admissions. Program staff reported that patients who received the scale (i.e., those with heart failure (HF) or fluid overload) were less likely to have an admission. However, there were also many patients who did not want the scales, or who had the scales in their possession but never weighed themselves. As a result, program staff began delivering the scales in person, setting them up, demonstrating how they should be used, and ensuring that patients weighed themselves before they left the patient's home. Although this effort resulted in an increase in the number of patients who received the scales and weighed themselves, staff acknowledged that it was resource-intensive.

Distribution of nutritional supplements. KTBH began offering nutritional supplements, free of charge, to patients considered malnourished and who had low albumen. Program staff acknowledged that this effort was not in place long enough to determine its effectiveness since patients must generally take the supplements for a minimum of six months in order to see true improvements in reducing morbidity and mortality.

Facts Leading To Program Termination

Divergence in costs between the intervention and comparison groups. In reviewing the first few Phase II monitoring reports, VillageHealth staff observed that the Phase II intervention group became more expensive than its Phase II comparison group after randomization but before enrollment began. Upon seeing a persistent trend, they asked CMS if ARC could perform some analyses on the 9-month period between the time of claims used for randomization and the time they actually started the program (July 08 to April 2009). Program staff was very concerned that if the intervention group was 4% more expensive (or greater) the groups were diverging in some material way that they did not understand because the comparison group was randomized. VillageHealth staff felt unclear about which direction to

take since they did not know anything about the comparison group and did not have access to their claims.

Upon reviewing the results, program staff discovered that the nature of the patients in the interim period had changed, meaning that a number of patients in their intervention group had switched over from the lower cost chronic kidney disease (CKD) to ESRD during that period. By the time they were able to recruit this population, overall ESRD costs were considerably higher because these patients had already begun dialysis at that point. Program staff also discovered that from the beginning to the intervention time when they actually started the demonstration, the trajectory of the comparison group's cost was fairly flat month-to-month relative to the intervention population, which started out low but had an upward cost trajectory. The CKD population's cost increased 50% in the interim year and the ESRD population's cost increased 25%. Staff was very surprised by the abnormally large increase seen in the less than one-year period for this population and found it difficult to explain.

Lack of comparison group data. One area that VillageHealth had been trying to work on with their commercial clients involved conducting a better match using propensity score matching or methodology in which cohorts are matched at a member level, rather than at a group level. Had comparison group data been available, program staff indicated that they would have wanted to see if they could isolate sub-segments within both the comparison and intervention groups that had similar utilization information. This would have enabled them to a) feel more comfortable in knowing that they were actually making comparisons that were appropriate between the two groups, and b) provide a better understanding of whether or not they were improving utilization.

For example, the program had protocols for diabetic foot exams and staff would have liked to explore whether there were differences in admission rates between diabetics in their intervention versus comparison groups. They would have used the comparison group data as flags to try to match groups together to see if there were differences for specific interventions. Moreover, they felt that comparison group data would help them benchmark their populations at a risk-stratified level as opposed to just a general "they're all on dialysis so they're all the same risk level."

"I understand CMS' reason. I'm sure they don't want a bunch of contractors running around data mining on thousands of beneficiaries—I get that. So we're not questioning their reasoning at all, but we come at it wanting to be able to do some of that internally or at least have a third party do it, and we'd be willing to pay for it."

Limited access to some dialysis facilities and providers. Program staff thought it would be fairly easy to access ESRD patients since they knew the patients could be found at the dialysis facilities. They did not anticipate encountering difficulty accessing patients in non-DaVita dialysis facilities and resistance from those providers. Program staff felt it was unfortunate, especially given that they were willing to sign a non-solicitation agreement and other reassurances indicating that the program's intention was not to steal patients away from their existing providers and dialysis facilities.

"It's one thing to not let us in the door, but it's really disheartening the ones that wouldn't let us talk to the nurse or the dietician to see what was going on with the patient. That's what really ties our hands. It makes sense that they're nervous, especially the smaller independent ones thinking we're going to come in and take all of their patients, but given that wasn't the intent, it was really frustrating."

Difficulty recruiting CKD patients. The program faced even greater challenges recruiting CKD patients than ESRD patients because the CKD program was based on purely telephonic support. Program staff estimated the bad phone number rate was greater than 30% and reported that they were unable to reach approximately 35-40% of the CKD population. In addition, many people are moving away from landlines to cell phones, which complicated the search for contact information.

Financial modeling of the expected participation rate. Program staff acknowledged the benefit of being able to understand what worked and what did not work with Phase I while they were in the process of planning Phase II. The program aimed for 60% enrollment. Regarding the financial aspects of reaching this target, when CMS approved a 2.5% savings requirement, VillageHealth leadership felt it was a reasonable target because of the addition of ESRD patients. With ESRD, they had a much longer track record with their commercial clients and because they felt the ESRD costs were more predictable, they had a savings target in mind that was more in line with their experience with ESRD. They felt that having a target of 2.5% was achievable and that the fees were manageable on the assumption that they could enroll 50% of the population, and that at least half were considered ESRD.

The uncertainty of the model revolved around CKD because there was no reliable way to identify these patients with certainty without any lab information. As a result, VillageHealth leadership felt they needed to incorporate more variability in the saving, which posed some difficulty in forecasting with their model.

"In terms of modeling this out, let's say this becomes a policy item for CMS—I think we would advocate having a separate target for ESRD vs. CKD until someone out there can find a better way to identify CKD patients. The level of certainty between the two populations is actually quite different. There's a specific ICD-9 code for CKD and our experience is that if you look for that code once vs. twice over a 12-month period, it cuts that population in half. We don't know what that means if people are billing it erroneously or don't know how to use that ICD-9 code, but it cuts it in half if you try to look for two hits on that particular ICD-9 code."

Program staff felt that coding accuracy improved in Phase II, particularly with ICD-9 codes 585.4 and 585.5, but added that providers still needed education on coding CKD correctly.

Demonstration design limitations. Program staff attributed much of the rationale leading to program termination to a combination of design limitations and financial constraints.

"Certainly we wanted to exceed the 2.5% hurdle and keep our fees and all of that. That's tremendously important but at the end of the day what we're really trying to do is prove this is possible for this population. So even if we had started out more expensive for whatever reason, but we could really demonstrate that we reduced the cost, but hadn't yet met the financial

structure we wanted to, we'd probably still be in the demonstration to be honest. We were just very concerned that if these two groups aren't comparable then what can we possibly show. Our concern was absolutely a financial one in terms of the health of the program, but it was really also from an evaluation and a proof standpoint. We wanted to show we had the right design and the right groups and we had the right evaluation to be able to show that. I think that was one of our biggest concerns, and not having the control group data contributed to that...We probably have a 50 analysis wish list and you could probably only do 15 of those things and we'd love to be able to do the rest, but if we don't have the control group we can't. So it was the finances, but it was also that we wanted to learn and to understand at the end of this program but we knew with the way this was set up that we weren't going to be able to."

Knowledge Gained/Lessons Learned

Lessons learned – outreach. KTBH program staff felt they did everything they could to increase their participation rate, short of going door-to-door. They acknowledged that better alignment with providers and a smaller number of providers likely would have increased their participation rate. Their enrollment rate with DaVita patients was approximately 80%, which they expected, since they had support of the providers and care managers were able to enter the dialysis facility and personally speak with patients.

Although most physicians were supportive of the outreach efforts, they generally only had one or two patients participating in the program. The program had greatest success with offices that had approximately 30 patients participating in the program. These offices developed an endorsement letter and allowed KTBH staff to speak with their patients at appointments. To the extent that patients were concentrated with providers, program staff felt that the physicians were better allies and facilitated the clinical interventions.

"A couple things we've gotten a little bit smarter about—one is the alignment to the provider. . . One of the things I would definitely do differently is for ESRD patients, I would do DaVita only and see what kind of change we could drive there. Then if we had a great solution, we could think about how we could scale it. That was probably 70% of the operational hassle that didn't actually do anything for patients but took a lot of time and energy. The same is true on the CKD side with the nephrologists."

Enlist an experienced biostatistician to project how the population selection algorithm should work and to develop alternative plans if randomization is unsuccessful. "We just really didn't have a plan if the randomization failed, which is something we hadn't really thought about because we didn't have that expertise. We have a little more of that expertise now, but I wouldn't go into this again unless I had a really thoughtful biostatistician to really help scope this out and determine exactly what we wanted it to be."

Six-month pilot that would allow participants to make design changes prior to launching the full-scale intervention. "When I think about the assumptions we made that turned out to be wrong... It was an iterative process—we didn't realize going into eight counties meant our patients were hospitalized in about 250 different hospitals. For that kind of thing, a pilot phase would have helped us figure out what it looked like so we could think about what we could have done differently. From our own perspective here as a renal disease management

company, if we could design a demo project for ESRD patients that could just include DaVita patients so all issues involved in contacting, seeing, and enrolling patients would go away and all those administrative costs would go away, then we could just concentrate on people that are coming into our centers three times a week. That would take a lot of noise out of the data and give us a better perspective to do an evaluation of the intervention."

Program Successes. Program staff examined clinical measures on a daily basis and felt that their successes could be measured by their clinical outcomes:

- Reduced their catheter rate down to 12% compared to the greater than 20% network average for the area. This is the leading cause of hospitalization for their patients.
- Immunization rates for their patients were much higher than the fee-for-service average, although they did not provide any rates.
- Consistent decrease in hospitalizations in the intervention group over the course of the demonstration, although rates were not provided.

"Do we know if that's meaningful or not given what was going on with the control group? No, because we didn't have the same level of data. But from our perspective, admissions going down is a good thing and not something you usually see in this population."

Ways in Which CMS May Have Been Able To Help Address Challenges Earlier

- Program staff felt that it would have been helpful to obtain more upfront guidance from CMS on what approaches make sense to pursue from a design perspective.
- Greater communication from CMS to patients indicating support for the program may have increased credibility and impacted patients' willingness to participate.

"(…) in some cases when we tried to work with facilities or physicians or patients, they said, 'If this program is so good, why aren't I hearing about it from CMS? Why isn't CMS telling me to participate?' I know they're reluctant to say CMS is requiring patients to do anything—they did give us a letter; but patients said if CMS wanted me to do this they'd be telling me. There were several instances…with patients calling 1-800-Medicare to make sure we weren't a scam and being told that we were because there are thousands of operators and they didn't all know about this teeny tiny program. Even stuff like that was tough even though it was a relatively minor incident and uncommon, but it did occur."

1.3 Organization of Report

In ***Chapter 2***, we provide an overview of our evaluation design and a description of the data and methods used to conduct our analyses of the Phase II original and Phase II refresh populations. ***Chapter 3*** provides the results of our analyses of participation levels in the Phase II KTBH Demonstration and level of intervention with participating beneficiaries (i.e., the number of in-person visits and/or telephonic contacts). In ***Chapters 4 and 5***, we provide the results of our analyses of changes in clinical quality of care and health outcomes, respectively. ***Chapter 6*** presents our analyses of financial outcomes. We conclude with an overall summary of key findings and a discussion of the policy implications of these findings for future Medicare care

management initiatives. The supplement to ***Chapter 2*** is available from the CMS Project Officer upon request.

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CHAPTER 2
EVALUATION DESIGN AND DATA

2.1 Overview of Evaluation Design

2.1.1 Gaps in Quality of Care for Chronically Ill

Medicare beneficiaries with multiple progressive chronic diseases are a large and costly subgroup of the Medicare population. The Congressional Budget Office (CBO) estimated that in 2001 high-cost beneficiaries (i.e., those in the top 25% of spending) accounted for 85% of annual Medicare expenditures (CBO, 2005). Three categories of high-cost users—beneficiaries who had multiple chronic conditions, were hospitalized, or had high total costs—were identified by CBO for study of persistence of Medicare expenditures over time. Beneficiaries that were selected based upon hospitalization or being in the high total cost groups had baseline expenditures that were four times as high as expenditures for a reference group. Beneficiaries selected based upon presence of multiple comorbid conditions had baseline expenditures that were roughly twice as high as expenditures for a reference group. Subsequent years of costs remained higher for all three cohorts than the reference group; however, total expenditures declined the most for those beneficiaries who were identified as high cost due to a hospitalization followed by beneficiaries who had had high total costs in the base year. Subsequent costs were virtually unchanged for beneficiaries with multiple chronic conditions.

Further, these beneficiaries currently must navigate a health care system that has been structured and financed to manage their acute, rather than chronic, health problems. When older patients seek medical care, their problems are typically treated in discrete settings rather than managed in a holistic fashion (Anderson, 2002; Todd and Nash, 2001). Because Medicare beneficiaries have multiple conditions, see a variety of providers, and often receive conflicting advice from them, there is concern that there is a significant gap between what is appropriate care for these patients and the care that they actually receive (Jencks, Huff, and Cuerdon, 2003; McGlynn et al., 2003). The CMHCB demonstration has been designed to address current failings of the health care system for chronically ill Medicare fee-for-service (FFS) beneficiaries.

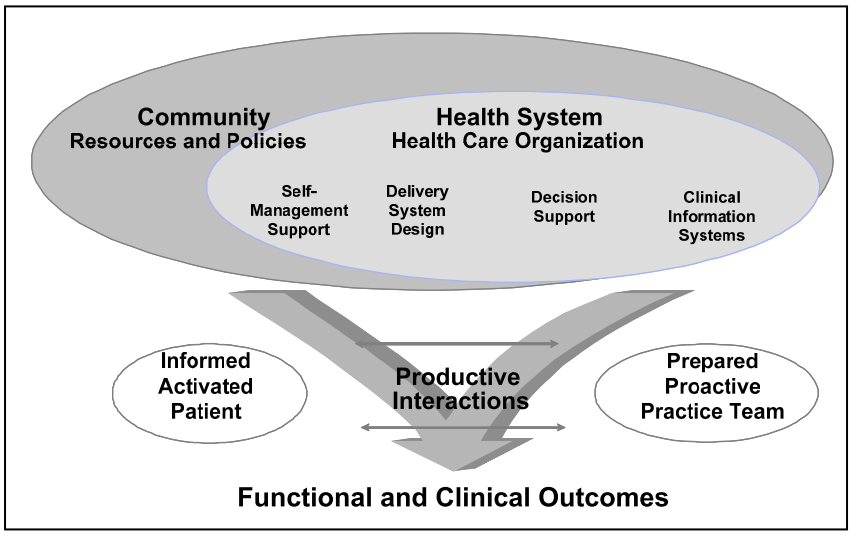
2.1.2 Emerging Approaches to Chronic Care

The Chronic Care Model—The concept of chronic care management as a patient-centered and cost-effective approach to managing chronic illness has been evolving for years. The Chronic Care Model (CCM), developed by Wagner (1998), has become a familiar approach to chronic illness care (***Figure 2-1***). This model is designed to address systematic deficiencies and offers a conceptual foundation for improving chronic illness care. The model identifies six elements of a delivery system that lead to improved care for individuals with chronic conditions (Glasgow et al., 2001; Wagner, 2002; Wagner et al., 2001):

- the community,
- the health system,
- self-management support,

- delivery system design,
- decision support, and
- clinical information systems.

Figure 2-1
Chronic Care Model



SOURCE: Wagner (1998). Reprinted with permission.

According to the model, patients are better able to actively take part in their own care and interact productively with providers when these components are developed, leading to improved functional and clinical outcomes.

Disease management and case management—The two most common approaches to coordinating care for people with chronic conditions are disease management and intensive case management programs (Medicare Payment Advisory Commission [MedPAC], 2004). Disease management programs teach patients to manage their chronic conditions and are often provided on a broader scale than case management programs. Services provided under a disease management program may include health promotion activities, patient education, use of clinical practice guidelines, telephone monitoring, use of home monitoring equipment, registries for providers, and access to drugs and treatments. Most disease management programs target persons with specific medical conditions but then take the responsibility for managing all of their additional chronic conditions. Case management programs typically involve fewer people than disease management programs (Vladek, 2001). Case management programs also tend to be more intensive and individualized, requiring the coordination of both medical and social support services for high-risk individuals. Typically, disease management programs are used with intensive case management for high-risk individuals who have multiple chronic conditions and complex medical management situations.

The empirical research on the effectiveness of disease management and case management approaches is mixed. Some studies have shown support for the clinical improvements and cost-

effectiveness of disease management programs (Lorig, 1999; Norris et al., 2002; Plocher and Wilson, 2002; Centers for Disease Control and Prevention [CDC], 2002). Other programs, such as the CMS case management demonstration programs in the early 1990s, which required physician consent for patient participation, resulted in increased beneficiary satisfaction but failed to achieve any improvement in health outcomes, patient self-care management, or cost savings (Schore, Brown, and Cheh, 1999). In 2002, CMS selected 15 demonstration programs of varying sizes and intervention strategies as part of the Medicare Coordinated Care Demonstration (MCCD). None of the 15 programs produced any statistical savings in Medicare outlays on services relative to the comparison group, and two had higher costs (Peikes et al., 2009).[2] There were a few, scattered quality of care improvement effects. Two programs did show some promise in reducing hospitalizations and costs, suggesting that care coordination might at least be cost neutral. A major reason given for the lack of success in both Medicare savings and better health outcomes is attributed to the absence of a true transitional care model in which patients were enrolled during their hospitalizations. Studies have shown that approach to significantly reduce admissions within 30/60 days post-discharge, when patients are at high risk of being readmitted (Coleman et al., 2006; Naylor et al., 1999; Rich et al., 1995).

2.1.3 Conceptual Framework and CMHCB Demonstration Approaches

The care management organizations (CMOs) awarded contracts under this CMS initiative offered approaches that blend features of the chronic care management, disease management, and case management models. Their approaches relied, albeit to varying degrees, on engaging both physicians and beneficiaries and supporting the care processes with additional systems and staff. They proposed to improve chronic illness care by providing the resources and support directly to beneficiaries through their relationships with insurers, physicians, and communities in their efforts. The CMOs also planned to use all available information about beneficiaries to tailor their interventions across the spectrum of diseases that the participants exhibited.

Although each of the CMOs has unique program characteristics, all have some common features. These features include educating beneficiaries and their families on improving self-management skills, teaching beneficiaries how to respond to adverse symptoms and problems, providing care plans and goals, ongoing monitoring of beneficiary health status and progress, and providing a range of resources and support for self-management. Features of the CMHCB programs include:

- *Individualized assessment*. Several CMOs use proprietary algorithms to calculate a risk score or risk scores, while others depend on judgment of clinical staff. The scores are used to customize interventions to the participants' needs.

- *Education and skills*. A key step in improving self-management is educating beneficiaries and their families about their illnesses, how to react to symptoms, and what lifestyle changes to make. All of the CMOs provide a range of educational resources.

[2] These findings were based on regressions controlling for age, gender, race, disabled/aged entitlement, Medicaid coverage, and whether beneficiaries used skilled nursing facility (SNF) or hospital services prior to the demonstration.

- *Medication management and support.* All of the CMO programs include efforts to optimize the medication regimens of participating beneficiaries. Some monitor compliance, some facilitate access to low-cost pharmaceuticals, and others offer face-to-face meetings with pharmacists.

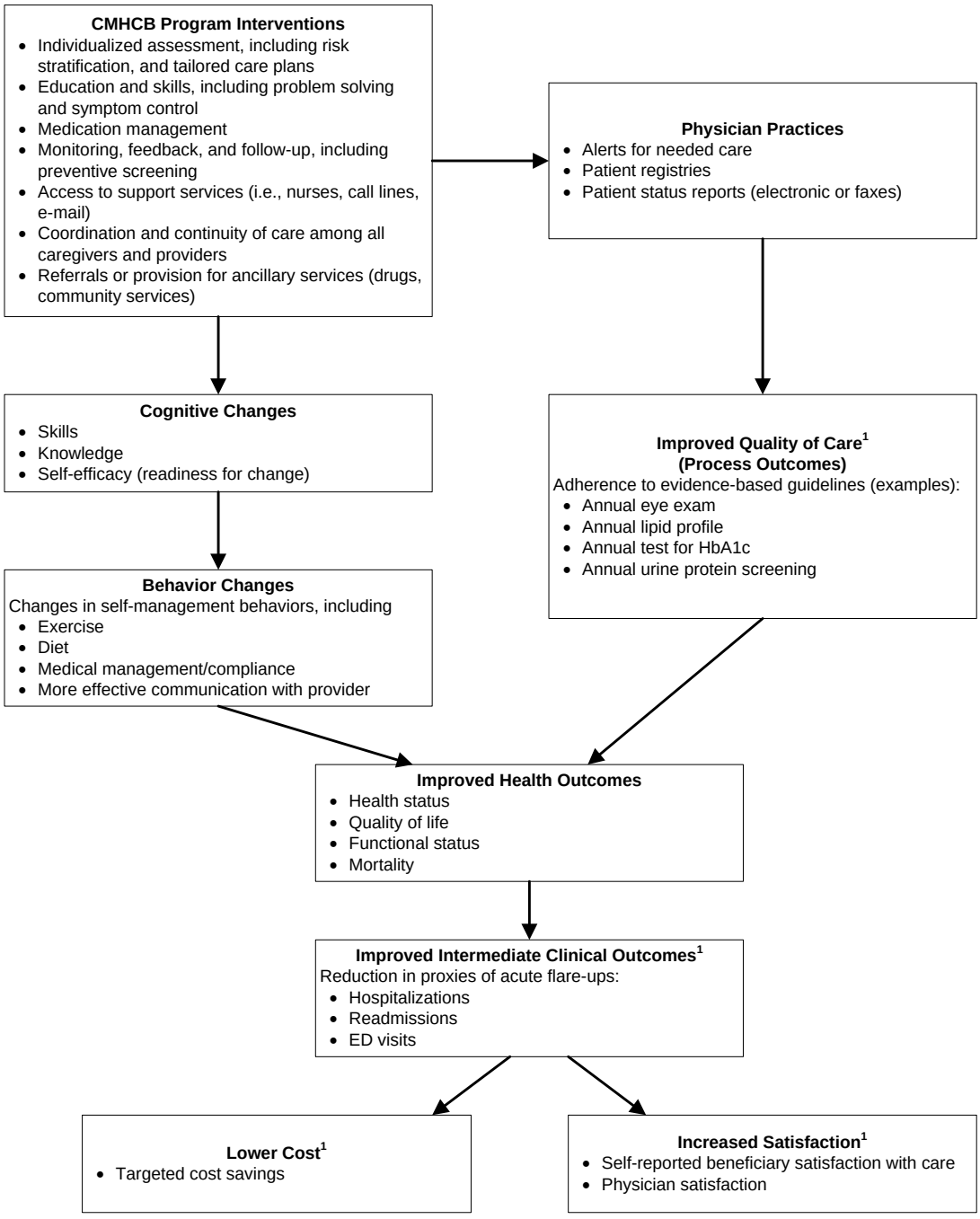
- *Monitoring, feedback, and follow-up*. Activities in this domain include ongoing biomonitoring of beneficiaries by placing scales or other equipment in their homes or by having the beneficiaries self-report their weights, blood sugars, or other measures. When data on preventive services, screenings, or recommended tests are available, the programs remind beneficiaries and/or their doctors to have them done. Flu shots are just one example.

- *Coordination and continuity of care.* One hallmark of the care management model is that it uses data from all available sources to disseminate information to providers and caregivers involved with a beneficiary's care. A limited number of the CMOs have care managers directly embedded in the physician practices, allowing for day-to-day and face-to-face interactions. Several CMOs also have direct communication with physicians via a shared electronic medical record. However, the majority of CMOs must engage physicians or physician practices more indirectly through telephone and fax communication.

- *Referrals or provision for community-based ancillary services.* Not all of a participant's needs are provided directly by the CMOs. All CMOs have recognized the need for transportation, low-cost prescriptions, or other services typically provided by community service organizations (e.g., social workers, dieticians). The CMOs developed relationships with other service providers and programs and helped selected beneficiaries receive these services through their participation in the CMHCB program.

Figure 2-2 presents RTI's conceptual framework for the overall CMHCB demonstration evaluation. It synthesizes the common features of the CMHCB demonstration implemented interventions and the broad areas of assessment within our evaluation design. The CMHCB demonstration programs employ strategies to improve quality of care while reducing costs by empowering Medicare beneficiaries to better manage their care. The programs do so in three ways: (1) by enhancing beneficiaries' knowledge of their chronic condition through educational and coaching interventions, (2) by improving beneficiaries' communication with their care providers, and (3) by improving beneficiaries' self-management skills. Successful interventions should alter beneficiaries' use of medications, eating habits, and exercise and should allow beneficiaries to interact more effectively with their primary health care providers. All of the CMHCB demonstration programs hypothesized that lifestyle changes and better communication with providers as well as improved adherence to evidence-based quality of care should improve health and functional status, which will mitigate acute flare-ups in chronic conditions, thereby reducing hospital admissions and readmissions and the use of other costly health services such as emergency rooms and visits to specialists. Experiencing better health and less acute care

Figure 2-2
Conceptual framework for the CMHCB programs



NOTE: CMHCB = Care Management for High Cost Beneficiaries; CMO = Care Management Organization; ED = emergency department.

SOURCE: RTI conceptual framework for the Medicare Care Management for High Cost Beneficiaries evaluation. Portions of this model are adapted from other sources, including the Chronic Care Model and the disease management model described in CBO (2004).

utilization, beneficiaries should also be more satisfied that their health care providers are effectively helping them cope with their chronic medical conditions, and providers should be more satisfied with the outcomes of care for their chronically ill Medicare FFS beneficiaries.

In this report, we present our findings with respect to the degree to which the Phase II KTBH Demonstration was able to engage its randomized intervention population and achieve four outcomes. ***Table 2-1*** presents a summary of research questions and data sources, organized by three evaluation domains: Reach, Implementation, and Effectiveness. The Phase II KTBH Demonstration implementation experience is reported in Chapter 1.

Table 2-1
Evaluation research questions and data sources

Research questions	Site visits	CMO data	Claims	Survey
IMPLEMENTATION: To what extent was VillageHealth able to implement its Phase II KTBH Demonstration?				
1. To what extent were specific program features implemented as planned? What changes were made to make implementation more effective? How was implementation related to organizational characteristics of the Phase II KTBH Demonstration?	Yes	Yes	No	No
2. What were the roles of physicians, the community, the family, and other clinical caregivers? What was learned about how to provide this support effectively?	Yes	No	No	No
3. To what extent did the Phase II KTBH Demonstration engage physicians and physician practices in their programs?	Yes	No	No	No
REACH: How well did the Phase II KTBH Demonstration engage its intended audiences?				
1. Were there systematic baseline differences in demographic characteristics and disease burden between the intervention and comparison group beneficiaries at the start of the demonstration?	No	No	Yes	No
2. How many individuals did the Phase II KTBH Demonstration engage, and what were the characteristics of the participants versus nonparticipants (in terms of baseline clinical measures, demographics, and health status)?	No	Yes	Yes	No
3. What beneficiary characteristics predict participation in the Phase II KTBH Demonstration?	No	Yes	Yes	No
4. To what extent were the intended audiences exposed to the Phase II KTBH programmatic interventions? To what extent did participants engage in the various features of the program?	No	Yes	No	Yes
5. What beneficiary characteristics predict a high level of Phase II KTBH Demonstration intervention versus a low level of intervention?	No	Yes	Yes	No

(continued)

Table 2-1 (continued)
Evaluation research questions and data sources

Research questions	Site visits	CMO data	Claims	Survey
Quality of care and health outcomes				
1. Did the Phase II KTBH Demonstration improve quality of care, as measured by improvement in the rates of beneficiaries receiving guideline concordant care?	No	No	Yes	No
2. Did the Phase II KTBH Demonstration improve intermediate health outcomes by reducing acute hospitalizations, readmissions, and ER utilization?	No	No	Yes	No
3. Did the Phase II KTBH Demonstration improve health outcomes by decreasing mortality?	No	No	Yes	No
Financial and utilization outcomes				
1. What were the Medicare costs per beneficiary per month (PBPM) in the base year versus the 21 months of Phase II original or 11 months of Phase II Refresh demonstration for the intervention and the comparison groups?	No	No	Yes	No
2. What were the levels and trends in PBPM costs for intervention group participants and nonparticipants? Did nonparticipation, alone, materially reduce the intervention's overall cost savings?	No	No	Yes	No
3. How variable were PBPM costs in this high cost, high risk, population? What was the minimal detectable savings rate given the variability in beneficiary PBPM costs?	No	No	Yes	No
4. How did Medicare savings for the 21- or 11-month period compare with the fees that were paid out? How close was the Phase II KTBH Demonstration in meeting budget neutrality?	No	No	Yes	No
5. How balanced were the intervention and comparison group samples prior to the demonstration's start date? How important were any differences to the estimate of savings?	No	No	Yes	No
6. Did the intervention have a differential effect on high cost and high risk beneficiaries?	No	No	Yes	No
7. What evidence exists for regression-to-the-mean in Medicare costs for beneficiaries in the intervention and comparison groups?	No	No	Yes	No

NOTE: CMHCB = Care Management for High Cost Beneficiaries; CMO = care management organization; CMS = Centers for Medicare & Medicaid Services; ER = emergency room; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month.

2.1.4 General Analytic Approach

The CMHCB initiative is what is commonly called a "community intervention trial" (Piantadosi, 1997). It is a "community" in the sense of being population based for a prespecified geographic area. It is "experimental" because it tests different CMHCB program interventions in different areas. It is a "trial" that employs randomization (or selection of a comparison population) following an "intent-to-treat" (ITT) model. The initiative is unusual because it employs a "pre-randomized" scheme, wherein CMS assigns eligible beneficiaries to an intervention or comparison stratum before gaining their consent to participate. In fact, comparison beneficiaries are not contacted at all. Further, beneficiaries opting out of the intervention are assigned to the intervention group, even though they will receive no CMO services. These refusals are included in the same stratum as those receiving care coordination services on an ITT basis.

Beneficiaries who become ineligible during the Phase II Demonstration program are removed from the intervention and comparison groups for the remainder of the demonstration for purposes of assessing cost savings and quality, outcomes, and satisfaction improvement. Our evaluation includes only months in which a beneficiary is eligible for the initiative, up until they become ineligible for any reason. We accounted for differential periods of eligibility in the analysis.

Further, the CMOs differentially engaged and interacted more with beneficiaries for whom they believe their programs will result in the greatest benefit, either in terms of health outcomes or cost savings. Thus, not all intervention beneficiaries participated nor did all beneficiaries receive the same level of intervention. In fact, some participants received very few services.

The CMHCB programs reflect a dynamic process of system change leading to behavioral change leading to improved clinical outcomes, and the type of experimental design within this demonstration calls for a pre/post, intervention/comparison analytic approach—sometimes referred to as a difference-in-differences approach—to provide maximum analytic flexibility. The strategy will be used to construct estimates of all performance outcomes of each demonstration program.

Our proposed model specification to explain any particular outcome variable, Y_{t+1}, measured during the intervention program follow-up period:

$$Y_{t+1} = \alpha + \beta_1 I + \beta_2 Y_t + \beta_3 I \bullet Y_t + \beta_4 X + \varepsilon \tag{2.1}$$

where

α = the intercept term, or reference group;

I = 0,1 intervention indicator;

Y_t = the outcome measured during a base or predemonstration period;

X = a vector of beneficiary covariates; and

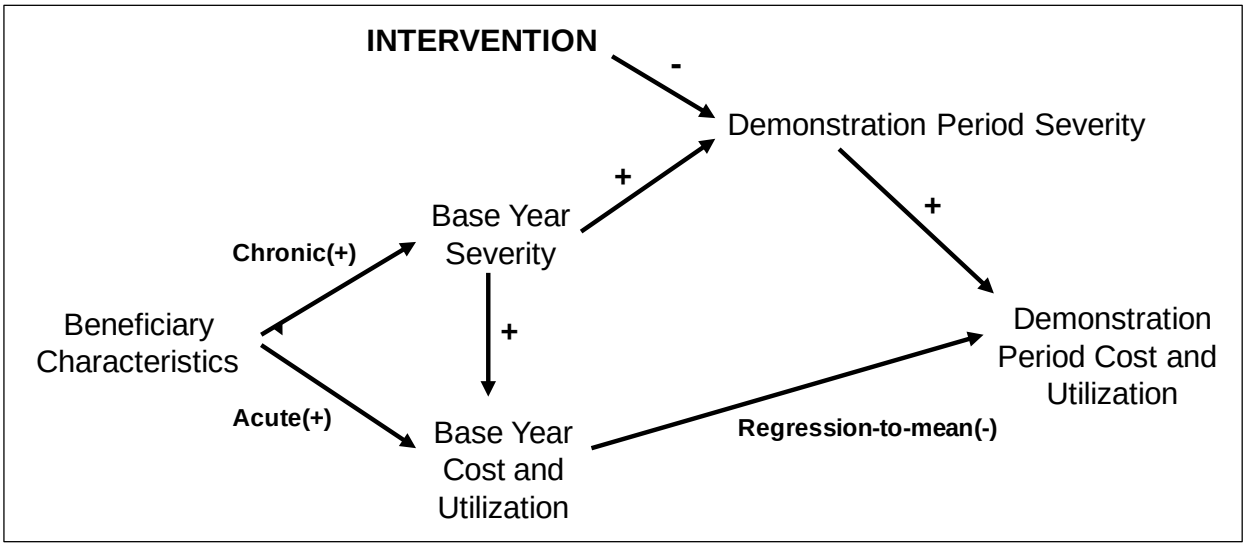
ε = a regression error term.

This model uses three sets of variables in analysis of covariance (ANCOVA) format to capture differences between intervention and comparison beneficiaries. The β_1 coefficient provides a test of the difference between the intervention group and comparison group in the base period for a particular outcome variable. (The reference comparison group mean value is in the α intercept.) If preprogram random assignment is successful, β_1 will be approximately zero before controlling for beneficiary-specific (X) factors. The β_2 coefficient tests for temporal changes between pre- and post-demonstration outcomes, while the β_3 interaction coefficient tests whether the intervention group's performance profile differs over time from the comparison group's performance. The vector of β_4 coefficients controls for beneficiary-specific covariates influencing individual differences in the dependent variable of interest. Including covariates should set the estimated β_1 equal to 0, if selection of a comparable comparison population is contravened in some way. Program effects during the demonstration are reflected in the interaction coefficients. The null hypothesis is that the coefficient for β_3 is zero, implying no CMHCB program impact. Estimates that are significant at the 95% confidence level imply distinct program effects. The model may also be expanded to conduct analyses across beneficiary subpopulations and CMHCB intervention characteristics.

Because we will be analyzing change over time, it is important to consider the likely trajectory in our outcome measures as a function of beneficiary characteristics at baseline. ***Figure 2-3*** displays an alternative conceptualization of how the CMHCB intervention could alter the expected demonstration period outcomes of interest. At baseline, beneficiaries were selected for the demonstration because of higher baseline risk scores as well as high baseline expenditures as a proxy for clinical severity. These beneficiaries also have a multiplicity of other health care issues—chronic and acute—leading to high baseline costs and acute care utilization. The bottom half of ***Figure 2-3*** displays the statistical phenomenon observed in cohort studies of regression-to-the-mean. Beneficiaries with high costs and utilization are likely to regress toward average levels in a subsequent period and vice versa. Because we start with beneficiaries with high costs and utilization, our expectation is that there would be significant negative regression to the mean; thus, we would observe lower costs and utilization in the demonstration period absent an intervention effect.

Prior research has shown that physical health status declines rather substantially over time for elderly populations, and in particular, for chronically ill elderly populations (Ware 1996). The top half of ***Figure 2-3*** displays the expected positive relationship between base year

Figure 2-3
Conceptualization of influence of beneficiary baseline health status and cost and utilization patterns on Phase II CMHCB Demonstration acute care utilization and costs



and demonstration period severity and the positive relationship between increasing severity of illness and medical costs and utilization during the demonstration period absent an intervention effect. The Phase II CMHCB Demonstration is aimed at improving or preventing further deterioration in health and functional status. Thus, our expectation is that the Phase II CMHCB Demonstration intervention would have a negative or moderating influence on growing patient severity during the demonstration period, thereby reducing the expected positive relationship between demonstration period severity and costs and utilization.

2.2 Participation, Clinical Quality and Health Outcomes, and Financial Outcomes Data and Analytic Variables

This section provides a description of the data used to evaluate participation in and the effectiveness of the Phase II KTBH CMHCB Demonstration.

2.2.1 Data

We used six types of data for our evaluation analyses related to participation, clinical quality and health outcomes, and financial outcomes. Specifically, we used the following data sources:

- *Participant status files*. We received participant status files from ARC. The participant status information originates from the Phase II KTBH Demonstration and was submitted to ARC. This file was updated quarterly and logged status changes among the intervention groups by the Phase II KTBH Demonstration. Participation status was able to be determined on a monthly basis using three monthly indicators on a given quarterly file, and we used these indicators to determine the participation decision of the original and refresh intervention beneficiaries during each month of the demonstration.

- *Finder file*. RTI used this file, produced by ARC, to identify the group into which each Phase II KTBH Demonstration beneficiary was randomized—intervention or comparison—for both the Phase II original and Phase II refresh populations.

- *Enrollment Data Base (EDB) daily eligibility files*.

  — ARC provided RTI with an EDB file for the Phase II KTBH Demonstration comprised of all randomized Phase II original and refresh beneficiaries. RTI used this file to determine daily eligibility based on the Phase II KTBH Demonstration eligibility criteria (***Table 2-2***). The EDB file, in conjunction with the eligibility criteria, allowed us to identify beneficiaries as eligible or ineligible for each day of the intervention period and retrospectively for each day one-year prior to the Phase II KTBH Demonstration launch date. We used the files to identify days of eligibility during the 12-month baseline period for the Phase II original population and 11–month baseline for the Phase II refresh population and the intervention periods of the demonstration and to select claims data during periods of eligibility in both the baseline and intervention periods. *Only beneficiaries who had at least 1 day of eligibility in the baseline and the demonstration periods are included in our evaluation.* This file also contains an indicator of disease (CKD or ESRD) at the time of randomization

  — RTI conducted an EDB extract to obtain demographic characteristics at the time of randomization (March 2, 2009) for KTBH's Phase II original population.

  — RTI conducted an EDB extract to obtain demographic characteristics at the time of randomization (April 16, 2010) for KTBH's Phase II refresh population.

- *Medicare claims data produced by ARC*. In keeping with the financial reconciliation, CMS requested that RTI use the ARC claims files for all analyses. Monthly, ARC receives claims data from a CMS prospective claims tap, and on a quarterly basis creates netted claims files. As of each quarter's processing, ARC updates prior quarterly netted claims files with claims data processed after the prior cutoff dates. These files contain the claims experience for Phase II original and refresh intervention and comparison beneficiaries during the 12 months prior[3] to the Phase II KTBH Demonstration start date and claims with processing dates that span the full intervention period and 9 months thereafter (or claims run out).

- *CMO beneficiary intervention data files*. Quarterly, the Phase II KTBH Demonstration sent RTI beneficiary-level intervention files that contained summary counts of intervention activities, such as the total number of contacts to specific entities (i.e., participants, nephrologists, health plans, facilities) detailed by who the contact was from (i.e., providers, social workers, health service coordinators). These files also contain detailed information on the type of contact (in-person, telephonic)

[3] ARC provided 12 months of baseline data for the Phase II refresh population and RTI subset these claims to an 11-month period mirroring the 11 months of intervention period experience.

and who was contacted (patient/caregiver, physician, facility). More detailed information on the contents of these files is in ***Chapter 3***.

- *FU Long Term Indicator (LTI) file*. Information in this file is obtained from the Minimum Data Set (MDS) of nursing home assessments and contains data on which Medicare beneficiaries are residents of nursing homes. We use this file to determine institutionalization status during the Phase II original and refresh intervention periods for the participation analysis.

Table 2-2
Criteria used for determining daily eligibility during the Phase II KTBH CMHCB Demonstration

Ineligibility reasons	Description
Death	Ineligible beginning on day following date of death.
Hospice	Ineligible on hospice coverage start date. Eligible on day following hospice coverage end date.
MA plan	Ineligible on day of MA plan enrollment when GHO contract number does not equal the contract number for the Phase II KTBH Demonstration. Eligible on day following MA plan disenrollment.
Medicare secondary payer	Ineligible on day Medicare becomes secondary payer for working-aged beneficiary with an employer group health plan (primary payer code A) or for working disabled beneficiary (primary payer code G). Eligible on day following Medicare secondary payer end date.
Residence	Ineligible on residence change date indicating that a beneficiary has moved out of the service area determined by state code or state and county codes. Eligible on subsequent residence change date indicating that a beneficiary has moved into the service area determined by state code or state and county codes.
Part A/Part B enrollment	Eligible on day Part A/Part B coverage begins/resumes. Ineligible on day after Part A/Part B coverage ends.

NOTES: CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; GHO = Group Health Organization; KTBH = VillageHealth's Key to Better Health; MA = Medicare Advantage.

Table 2-3 contains the Phase II KTBH Demonstration's evaluation start and end dates, both baseline and intervention periods, for the Phase II original and Phase II refresh populations.

Table 2-3
Analysis periods used in the Phase II KTBH CMHCB Demonstration analysis of performance

Intervention period start date	Intervention period final end date	Intervention period months of intervention data	Baseline period start date	Baseline period end date
Phase II original population				
8/1/09	4/30/11	21	8/1/08	7/31/09
Phase II refresh population				
6/1/10	4/30/11	11	6/1/09	4/30/10

NOTES: CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health.

2.2.2 Analytic Variables

To conduct our participation, clinical quality and health outcomes, and financial analyses, we constructed nine sets of analytic variables from the aforementioned files.

1) ***Demographic Characteristics and Eligibility***. Age, gender, race, Medicare status (aged-in versus disabled), and urban residence were obtained from the EDB and determined as of the date of randomization, March 2, 2009, for the Phase II original population and, April 16, 2010, for the Phase II refresh population randomization date. Medicaid enrollment was determined at any time during the baseline period and was also determined using the EDB.

   Daily eligibility variables were used to create analytic variables representing the fraction of the Phase II baseline and demonstration periods that the intervention and comparison beneficiaries were CMHCB program eligible. These eligibility fractions were created based on the time period of the analysis. For example, the baseline eligibility fraction is constructed using the number of eligible days divided by 365 for the Phase II original population and 334 for the Phase II refresh population. For the full intervention period, the denominator is adjusted based on the number of days that the Phase II KTBH Demonstration was active in the demonstration. The numerator is the number of days the beneficiary is eligible during that time period. The Phase II KTBH Demonstration participated in the demonstration for 21 months, so the number of days in the denominator for each Phase II original population beneficiary in the Phase II KTBH Demonstration is 638 (KTBH end date minus KTBH start date + 1). If a beneficiary died 420 days into the intervention period, the eligibility fraction for the participation analysis would be 420 divided by 638, or 0.658.

2) ***Institutionalized Status.*** Four binary indicators of institutionalization were created for both the original and Phase II refresh populations:

- Whether a beneficiary was in a nursing home for any one or more months of the initial 6 months of the demonstration period using the FU LTI file. This measure of institutionalization is used in all but the financial analyses.

- Whether a beneficiary had any baseline long-term-care (LTC) hospital costs in the baseline year. LTC hospitals are identified if the last four digits of the provider ID ranged from 2000 to 2299.

- Whether a beneficiary had any baseline skilled nursing facility (SNF) costs.

3) ***Hierarchical Condition Category (HCC) Risk Scores.*** One HCC score was used in this evaluation:

- A *prospective HCC score* calculated by RTI for a 12-month period prior to the *start* of the demonstration program using the 2006 CMS-HCC risk-adjustment payment model for both the Phase II original and Phase II refresh populations.

4) ***Health Status***. We constructed three sets of analytic variables to reflect health status prior to and during the demonstration:

- *Charlson index.* We constructed the Charlson comorbidity index using claims data from the inpatient, outpatient, physician, and home health claims files. We created an index for the year prior to the start of the Phase II KTBH Demonstration. ***Supplement 2A*** contains the SAS code used to create this index.

- *Comorbid conditions.* RTI created indicators of frequently occurring comorbid conditions: heart failure; coronary artery disease; other respiratory disease; diabetes without complications; diabetes with complications; essential hypertension; valve disorders; cardiomyopathy; acute and chronic renal disease; renal failure; peripheral vascular disease; lipid metabolism disorders; cardiac dysrhythmias and conduction disorders; dementias; strokes; chest pain; urinary tract infection; anemia; malaise and fatigue (including chronic fatigue syndrome); dizziness, syncope, and convulsions; disorders of joint; and hypothyroidism. This list is also inclusive of the top 11 groups of comorbidities that were provided to RTI by the Phase II KTBH Demonstration. Beneficiaries were identified as having a comorbid condition if they had one inpatient claim with the clinical condition as the principal diagnosis or had two or more physician or outpatient department (OPD) claims for an E&M service (CPT codes 99201-99429) with an appropriate principal or secondary diagnosis. The physician and/or OPD claims had to have occurred on different days. The diagnosis codes used to identify these clinical conditions are in ***Supplement 2A***.

- *Ambulatory Care Sensitive Conditions (ACSCs).* We constructed variables to indicate the presence of an ACSC in the year prior to the demonstration and during the demonstration, using the primary diagnosis on a claim. ACSCs include

heart failure, diabetes, asthma, cellulitis, chronic obstructive pulmonary disease (COPD) and chronic bronchitis, dehydration, bacterial pneumonia, septicemia, ischemic stroke, and urinary tract infection (UTI). The diagnosis codes used to identify these conditions are found in ***Supplement 2A***.

5) ***Utilization***. We constructed three sets of utilization variables for this evaluation as proxies for intermediate clinical outcomes. These sets of variables were also constructed for the following principal diagnoses: all-cause and the 10 ACSCs, using the primary diagnosis (from the header portion of the claim) for claim types inpatient and outpatient:

- the number of acute hospitalizations,
- 90-day readmissions, and
- emergency room visits, including observation bed stays.

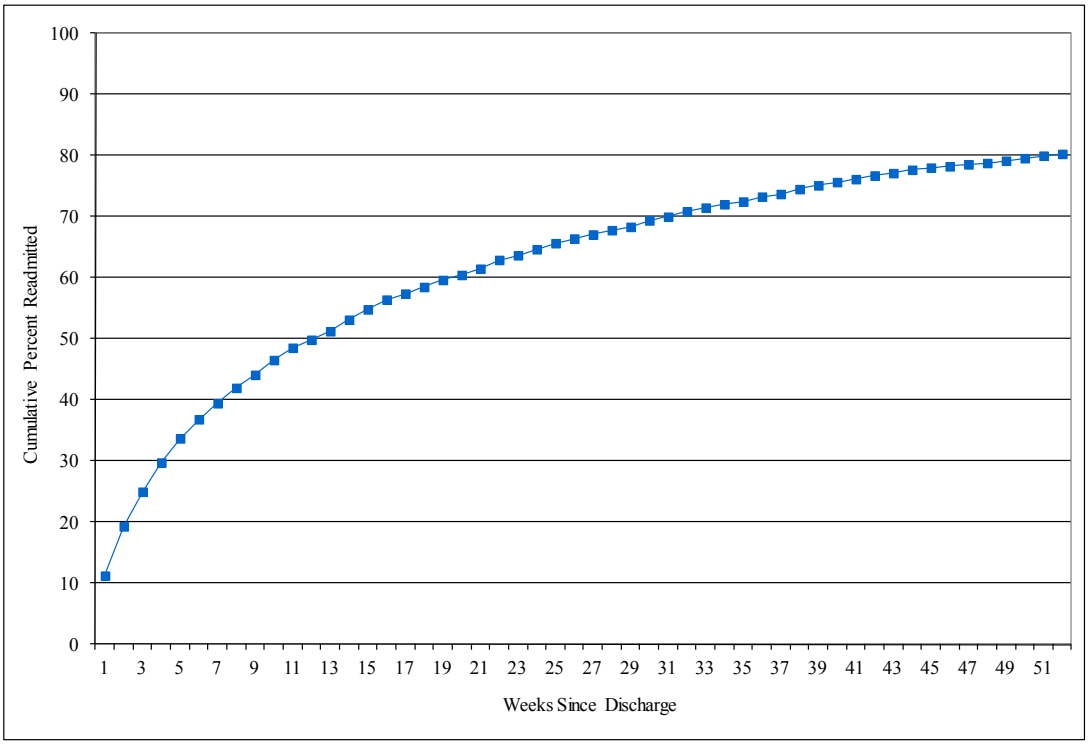
Only claims that occurred during periods of eligibility were included in the utilization measures. For both the demonstration and baseline periods, claims were included if services were started during days that the beneficiary met the Phase II KTBH CMHCB Demonstration eligibility criteria, as determined from the ARC daily eligibility file. We flagged claims for services that occurred during a period of eligibility by comparing the eligibility period with a specific date on the claim, following the decision rules that were applied for the financial reconciliation. The exact date fields used are based on the claim type, as follows:

- inpatient and skilled nursing facility claims: *admission date;*
- all other types of services: *from date.*

Prior to conducting our final set of analyses, we critically examined the timing of readmissions using data from the year prior to the start of the demonstration. ***Figure 2-4*** displays a graphic representation of time from discharge to next admission for Phase II original population comparison beneficiaries who had a subsequent admission. In this figure, we display all-cause readmission; thus, beneficiaries were not required to have the same reason for both the initial and subsequent admission for the hospitalization to be considered a readmission. The graphic shows that there is a steep trajectory of readmissions during the first 90-day period following discharge, with a gradual tapering off of number of readmissions thereafter. Thus, we constructed 90-day readmission rates to capture close to 50% of subsequent admissions in our analyses[4].

[4] We evaluated time to readmission based upon days post sentinel hospitalization discharge; however, the graph displays time to readmission in increments of weeks for visual presentation purpose.

Figure 2-4
Percent with readmission for any diagnosis during the Phase II KTBH CMHCB Demonstration: Phase II original baseline comparison population



We examined readmissions following admissions that occurred during one 12-month period for the Phase II original population. No readmission analyses were conducted for the Phase II refresh population because there was less than one year of demonstration experience. In order to capture readmissions following admissions that occurred late in the baseline and demonstration periods, we used a total of 15 months of data for each period to identify readmissions. For the baseline period, we identified admissions during the 12 months preceding the start of the Phase II KTBH Demonstration and also included readmissions through the first 3 months of the intervention period for those admissions that occurred within 3 months of the start of the demonstration. The intervention period for the Phase II original population examined admissions during the periods of months 7 through 18 and included readmissions through month 21. A readmission was defined as an admission up to 90 days after an index hospitalization discharge date. We constructed all-cause readmission rates for all hospitalizations and same-cause readmission rates for the 10 ACSCs.

6) Expenditures. RTI constructed a set of Medicare payment variables to reflect payments during periods of baseline and demonstration eligibility using the claims selection decision rules discussed previously. Total Medicare payments—exclusive of beneficiary deductibles, coinsurance payments, and third-party payments—were summarized for the annual period prior to the start date of the Phase II KTBH Demonstration and also for the full intervention period and placed on a per

beneficiary per month (PBPM) basis by dividing total payments by the total number of eligible days divided by 30.42. We defined a month as 30.42 days (365 days in a year divided by 12 months, rounded to two decimal places). This standardizes the definition of a month. For the Phase II KTBH Demonstration period, total Medicare payments were summarized for the 21-month Phase II original intervention period and the 11-month Phase II refresh intervention period.

7) Guideline Concordant Care. We define quality of care as adherence to evidence-based guideline-concordant care and have selected measures from the National Quality Forum (NQF)-endorsed National Voluntary Consensus Standards for Physician-Focused Ambulatory Care (February 2008). The selected measures are also used by other CMS pay-for-performance initiatives, such as the PQRI, or in evaluations of other pay-for-performance demonstrations (physician group practice demonstration) or pilot programs (Medicare Health Support). Thus, these measures have been extensively tested and are widely accepted as clinically important measures and appropriate for use in pay-for-performance initiatives. Further, we restrict the selection of measures to those that do not require the use of CPT II codes.

First, we selected several measures that are specific to beneficiaries with diabetes and ischemic vascular disease (IVD) as these populations are prevalent in the Phase II KTBH Demonstration population. We subset the study populations to the appropriate clinical cohorts when constructing these measures. Special consideration was given to identifying measures appropriate for KTBH's population of chronic kidney disease (CKD) beneficiaries.

The selected measures and relevant disease population are as follows:

<u>Diabetes beneficiaries</u>:

- Rate of annual HbA1c testing – diabetes
- Rate of low-density lipoprotein cholesterol (LDL-C) screening – diabetes
- Rate of annual retinal eye exam
- Rate of medical attention for nephropathy
- Rate at which beneficiaries received all four of these measures
- Rate at which beneficiaries received none of these measures

<u>IVD beneficiaries</u>:

- Rate of complete lipid profile

<u>CKD beneficiaries who initiated dialysis during the Phase II KTBH Demonstration period:</u>

- Rate of progression to ESRD
- Rate of fistula/graft placement prior to initiation of dialysis among beneficiaries with ESRD

With respect to the Phase II KTBH Demonstration special population of CKD, the HbA1c testing measure focuses on the importance of careful control of blood glucose in diabetics to slow progression of CKD toward ESRD. Because diabetes is the leading cause of CKD, we expect that there will be large numbers of beneficiaries with diabetes in both the intervention and comparison groups of the Phase II KTBH Demonstration. A key goal of the Phase II KTBH Demonstration is to have a permanent arteriovenous (A-V) fistula in place prior to the initiation of hemodialysis.

The methodology used to create these measures can be found in ***Supplement 2A***. CMS requested that we use existing, widely adopted specifications for evidence-based measures of care. Based on that request, RTI selected the National Quality Forum (NQF)–endorsed National Voluntary Consensus Standards for Physician-Focused Ambulatory Care. While the NQF-endorsed specifications restrict the diabetes quality-of-care measures to beneficiaries ages 18 to 75, we did not use this age restriction because no such restriction is used by the Phase II KTBH Demonstration. The specifications used for the final set of analyses are from NQF-Endorsed™ National Voluntary Consensus Standards for Physician-Focused Ambulatory Care—National Committee for Quality Assurance (NCQA) Measure Technical Specifications, 2011.

Claims for these process-of-care measures were included regardless of Phase II KTBH CMHCB Demonstration eligibility in order to ensure that we fully captured the behavior of intervention and comparison populations that was not subject to Medicare eligibility or payment rules and to provide credit to the Phase II KTBH Demonstration in case the services occurred after exposure to the CMHCB demonstration intervention and during the intervention period. One could envision that the Phase II KTBH Demonstration encouraged the receipt of the process-of-care measures; however, the actual service was provided during a brief period of ineligibility (e.g., nonpayment of the Part B premium for a month). To the extent that the service was included in the Medicare claims files during a period of ineligibility as a denied claim, it reflects actual receipt of the service and was therefore included in our analyses.

8) Mortality. Date of death during the demonstration period was obtained from the Medicare EDB and was used to create a binary mortality variable.

9) Measures of CMHCB Program Intervention. Using the encounter data submitted by the Phase II KTBH Demonstration, we constructed counts of the number of contacts with the participants—either telephonically or in-person—as well as total contacts (both).

CHAPTER 3
PARTICIPATION RATES IN THE PHASE II KTBH CMHCB DEMONSTRATION AND LEVEL OF INTERVENTION

3.1 Introduction

Our participation analysis is designed to critically evaluate the level of engagement by the Phase II KTBH Demonstration in this population-based demonstration program and to identify any characteristics that systematically predict participation versus nonparticipation. Furthermore, we seek to evaluate the degree to which beneficiaries who consented to participate were exposed to the KTBH programmatic interventions. The analyses are designed to answer a broad policy question about the depth and breadth of the reach into the community: how well did the Phase II KTBH Demonstration engage their intended audiences? Specific research questions include the following:

- Were there systematic baseline differences in demographic characteristics and disease burden between the intervention and comparison group beneficiaries at the start of the demonstration?

- How many individuals did the Phase II KTBH Demonstration engage, and what were the characteristics of the participants versus nonparticipants (in terms of baseline clinical measures, demographics, and health status)?

- What beneficiary characteristics predict participation in the Phase II KTBH Demonstration?

- To what extent were the intended audiences exposed to the Phase II KTBH programmatic interventions? To what extent did participants engage in the various features of the program?

- What beneficiary characteristics predict a high level of Phase II KTBH Demonstration intervention versus a low level of intervention?

The overall design of the CMHCB Demonstration follows an intent-to-treat (ITT) model, and all CMOs are held at risk for their monthly management fees based on the performance of the full population of eligible beneficiaries randomized to the intervention group and compared with all eligible beneficiaries in the comparison group. The CMHCB Demonstration has been designed to provide strong incentives to gain participation by all eligible beneficiaries in the intervention group. In our November 2009 site visit, KTBH staff reported that they hoped to engage 60% of CKD beneficiaries and 70% of ESRD beneficiaries, since CKD beneficiaries have historically been a harder population to recruit into the KTBH program (Lenfestey and McCall, 2010). VillageHealth terminated its contract with Intellicare to conduct the initial outreach and engagement with the intervention population. Program staff thought it would be fairly easy to access ESRD patients since they knew the patients could be found at the dialysis facilities. However, they had difficulty accessing patients in non-DaVita dialysis facilities and experienced resistance from those providers. The program faced even greater challenges recruiting CKD patients than ESRD patients because the CKD program was based on purely telephonic support. Program staff estimated the bad phone number rate was greater than 30%

and reported that they were unable to reach approximately 35-40% of the CKD population. In addition, the shift from landlines to cell phones further complicates the search for contact information. In this report, we examine the level of participation for the full intervention period for both the Phase II original and Phase II refresh populations and the beneficiary characteristics that predict participation.

We also examine the level of intervention between the Phase II KTBH Demonstration and its randomized beneficiaries. The KTBH intervention had a variety of telephonic and in-person elements (e.g., facilitated patient relationships with physicians, helped patients to comply with physician care plans, hospital discharge planning support, support patient adherence to medication regimens, and provided education related to self-management activities to decrease risk for acute exacerbations of chronic diseases). Therefore, we examine the number of telephonic and in-person contacts between KTBH staff and their participants. For each participating beneficiary, the KTBH program provided RTI with a count of the number of contacts by type: telephonic, in-person visits, and written communications (e.g., mail, fax, and e-mail). The KTBH program also provided information on who was contacted (e.g., caregiver, patient, provider, and nephrologist). Because of the low number of beneficiaries that received any contact in the Phase II refresh population (20 beneficiaries), we only conduct the intervention analyses on the Phase II original population.

3.2 Methods

3.2.1 Participation Analysis Methods

We determined participation status during the demonstration period using a monthly indicator provided to us by ARC in the Participant Status file to align with dates of eligibility for the Phase II KTBH Demonstration. We report the percentage of intervention beneficiaries who consented to participate for at least 1 month during the intervention period as well as those who never consented to participate and the reason for nonparticipation (refused or never contacted/unable to be reached). We also report the percentage of beneficiaries who, after initial consent, were continuous participants (while eligible for the Phase II KTBH Demonstration) and the percentage of beneficiaries participating for more than 75% of their eligible months.[5] These latter two sets of numbers provide an estimate of the number of beneficiaries with whom the Phase II KTBH Demonstration had the greatest opportunity to intervene. Because beneficiaries lose eligibility for various reasons over time (e.g., loss of Part A or Part B benefits, or due to death), we report counts of full-time equivalents (FTEs) or numbers of intervention and comparison beneficiaries weighted by the fraction of the demonstration period each beneficiary was eligible. Only beneficiaries who had at least 1 day of eligibility in both the baseline and demonstration periods are included in these analyses.

We also conducted a multivariate logistic regression analysis to determine the predictors of participation versus nonparticipation among those in the intervention group. The logistic model used in this study to identify differences in the likelihood of a beneficiary being in the

[5] A beneficiary becomes ineligible to participate if he/she enrolls in a Medicare Advantage (MA) plan, loses eligibility for Part A or B of Medicare, moves out of the demonstration area, gets a new primary payer (i.e., Medicare becomes secondary payer), receives hospice care, or dies.

participant group versus the nonparticipant group as a function of baseline and intervention period clinical factors, baseline cost, and baseline demographic factors is specified as

$$\text{Log e } (p_i / [1 - p_i]) = \beta X_i + \text{error}, \qquad (3.1)$$

where P_i = the probability that the ith individual will consent to participate, βX_i = an index value for the ith individual based on the person's specific set of characteristics (represented by the vector), and e = the base of natural logarithms. The probability of a beneficiary being in the participant group is thus explained by the variables.

Logistic regression produces an odds ratio for every predictor variable in the model; that is, an estimate of that variable's effect on the dependent variable, after adjusting for the other variables in the model. The odds ratio is greater than 1.0 when the presence (or higher value) of the variable is associated with an increased likelihood of being in the participant group versus the nonparticipant group; odds ratios less than 1.0 mean that the variable is inversely associated with being in the participant group.

The participation regression model investigates whether group membership is influenced by beneficiary demographic attributes, clinical characteristics, and utilization and cost factors previously defined in Chapter 2. The demographic variables included in the model are defined as follows from the Medicare enrollment database (EDB) and determined as of the date of randomization for the Phase II original population (March 2, 2009) and the Phase II refresh population (April 16, 2010):

- male, a dichotomous variable, set at 1 for males;
- African American/other/unknown, a dichotomous variable, set at 1 for beneficiaries whose race code is African American, other, or unknown;
- aged-in, a dichotomous variable, set at 1 for beneficiaries whose entitlement to Medicare benefits is based on age rather than disability;
- age, three dichotomous variables set at 1 for age less than 65 years, age 75-84, and age greater than or equal to 85 years; age 65-74 is the reference group; and
- Medicaid, a dichotomous variable, set at 1 for beneficiaries enrolled in Medicaid. Medicaid enrollment is based on a beneficiary being enrolled in Medicaid at any point 1 year prior to the go-live date.

Baseline clinical and financial characteristics included in the model are defined as follows:

- ESRD indicator is set at 1, if the beneficiary had ESRD at the time of randomization based on the historical EDB data provided by ARC;
- baseline Charlson score medium and high, two dichotomous variables set at 1 if the Charlson index score was 3 or 4 (medium) and 5 or greater (high); Charlson score of 2 or less is the reference group.

- baseline costs PBPM medium and high, two dichotomous variables set at 1 if the PBPM cost calculated by RTI for a 12-month period prior to the *start* of the Phase II KTBH original demonstration program was greater than or equal to $2,575 and less than $6,022 (medium) and $6,023 or greater (high); PBPM cost less than $2,575 is the reference group for the Phase II original population. For the Phase II refresh population, baseline PBPM costs greater than or equal to $2,424 and less than $5,706 were assigned to the medium group and $5,706 or greater to the high category; PBPM cost less than $2,424 is the reference group. These ranges were determined using the tertile values for each population.

Intervention period beneficiary characteristics included in the model are defined as follows:

- died, a dichotomous variable, set at 1 for beneficiaries who died during the intervention period;

- institutionalized, a dichotomous variable, set at 1 for beneficiaries who were resident in a long-term care setting for any 1 or more months of the initial 6 months of the intervention period.

3.2.2 Level of Intervention Analysis Methods

The KTBH program provided RTI with the number and nature of contacts with participating beneficiaries at the beneficiary level from August 1, 2009 through the end of Phase II of the CMHCB Demonstration (April 30, 2011). We used these data to develop estimates of the level of intervention provided to Phase II KTBH participants. In Phase II, KTBH reported that contact with all beneficiaries is initiated by the care managers at least once every 30 days to focus on areas that need to be addressed. The outreach to ESRD beneficiaries was new in Phase II since ESRD beneficiaries were not included in the scope of Phase I. The KTBH program hired seven new nurse care managers for the Phase II extended KTBH program to serve the ESRD population. In addition to adding care managers, KTBH program leadership added a local social worker to conduct home visits and address the social needs of participants. At the time of the November 2009 site visit, the program included six telephonic nurses, 10 field nurses, a registered dietician (based out of Texas), a pharmacist (the dietician and pharmacist now serve programs across VillageHealth and are not solely dedicated to the KTBH program); and two social workers (one social worker is field-based; the other is located in New Jersey and provides telephonic support). All of the nurses provide the same care management services regardless of whether they are field- or telephonic-based. However, the telephonic nurses primarily work with CKD beneficiaries and the field nurses typically work with ESRD beneficiaries in the dialysis facilities or conduct home visits to CKD or ESRD beneficiaries.

Using the encounter data submitted by the KTBH program, we constructed counts of the number of contacts with participants (both inbound and outbound), in total, by who was contacted or doing the contacting: patient/caregiver, provider, or facility, and by method of contact: telephonic, in-person, or other (mail, fax, e-mail). We also reported the mean and median number of total contacts and the distribution of beneficiaries across six categories of contacts (0, 1, 2-4, 5-9, 10-19, and 20 or more). Further, we estimated a multivariate logistic regression model of the likelihood of being in the high total contact category relative to the low

total contact category. A dichotomous dependent variable was created and set at 1 for beneficiaries who had a high level of contact with the Phase II KTBH Demonstration and 0 for beneficiaries who had a low level of contact. Beneficiaries who had a medium level of contact with the Phase II KTBH Demonstration were the reference group in the regression analysis. Independent variables in the contact regression model included those that we have described for the participation regression model and two additional demonstration period utilization measures:

- one intervention period hospitalization set at 1 if the beneficiary had one hospitalization in months 10-21 for the Phase II original population and months 1-11 for the Phase II refresh population; and

- multiple intervention period hospitalizations set at 1 if the beneficiary had more than one hospitalization during these same time periods.

We included these two additional demonstration period intervention variables because KTBH staff attempted to identify beneficiaries at risk of a hospitalization and to intervene to prevent the hospitalization from occurring or to identify beneficiaries at the time of hospitalization or shortly thereafter to intervene to prevent readmission. Thus, we would expect these two variables to be positively associated with being in the high contact group.

We reported levels of intervention with the Phase II original intervention period during the last 15 months of the demonstration (February 1, 2010 through April 30, 2011) and for the last 5 months of the demonstration for the Phase II refresh population (December 1, 2010 through April 30, 2011). Because beneficiaries could have intermittent periods of eligibility and participation, we restricted inclusion in this analysis to beneficiaries who were eligible for and participating in the Phase II KTBH Demonstration for each month during these time periods. This is the subset of beneficiaries with whom the KTBH program would have had the maximum opportunity to intervene. Beneficiaries who died during this period but were fully eligible and participating up to their deaths were also included. The number of intervention beneficiaries that met these criteria was 1,057 for the Phase II original population and 710 for the Phase II refresh population. Of these eligible beneficiaries, only 483 had any contact in the Phase II original cohort and 16 in the Phase II refresh cohort. Thus, after showing the distribution of interactions for these beneficiaries, no further evaluation of the Phase II refresh population was conducted.

3.3 Findings

3.3.1 Participation Rates for the Phase II KTBH Demonstration Population

Analyses presented in this section include only beneficiaries who had at least 1 day of eligibility in the year prior to the start of the intervention period and at least 1 day of eligibility in the demonstration. The results are based on the full demonstration period for both the Phase II original and Phase II refresh populations. The number of months for the full demonstration period for the Phase II KTBH Demonstration is 21 months for the Phase II original population and 11 months for the refresh.

Table 3-1 displays the number of beneficiaries included in our participation analyses for the Phase II original and Phase II refresh populations and illustrates the impact of loss of eligibility by reporting the full time equivalents (FTEs). We report

1. Number of beneficiaries. The number of beneficiaries is equal to all beneficiaries who had at least 1 day of eligibility in the 1-year baseline period and had at least 1 day of eligibility in the period tabulated.

2. Full-time equivalents. FTEs defined here are the total number of beneficiaries weighted by the number of days eligible in the intervention period divided by the total number of days in the intervention period. For example, a beneficiary in the Phase II KTBH Demonstration had a total of 21 months (or 638 days) of possible enrollment. If they died after 90 days, their FTE value would be 90/638 0.141 FTEs. If someone were eligible for all 21 months, then his or her value is 1. The sum of this value across all beneficiaries gives the total FTE value reported in the tables below.

3. Number fully eligible. The number fully eligible is the number of beneficiaries that had no gap in the Phase II KTBH Demonstration eligibility during the demonstration period.

The ratio of FTEs to the total number of eligible beneficiaries in the Phase II original intervention population is 0.86 for the entire intervention period (months 1-21). The FTE illustrates the effect of attrition over time of the original beneficiaries due primarily to death. Beneficiaries also became ineligible for participation in the Phase II KTBH Demonstration if they joined a Medicare Advantage (MA) plan, lost Medicare Part A or B eligibility, Medicare became a secondary payer, elected the hospice benefit, or they moved out of the service area.

Twenty-six percent of the Phase II original intervention and comparison beneficiaries had a spell of ineligibility. This can be estimated as the difference in the number of eligible beneficiaries and the number of fully eligible beneficiaries. Within the intervention group, eligibility was higher for participants and lower for nonparticipants. KTBH's nonparticipant group was eligible only 77% of all possible days—much lower than the 89% of days for participants. Also, the participant group had a higher rate of beneficiaries being fully eligible for the entire intervention period (77%) compared with 74% for the nonparticipant group. There is no difference by disease (CKD versus ESRD).

Table 3-1 also displays eligibility data for the Phase II refresh population. The ratio of total number of beneficiaries to FTEs was about 0.92 intervention and comparison populations. However, the percent of beneficiaries that were fully eligible for the full refresh time period is higher among participants (89%) than nonparticipants (91%) or the comparison group (85%) Once again, there is no noted difference by disease status.

Table 3-1
Number of Medicare FFS beneficiaries eligible for and participating in the Phase II KTBH CMHCB Demonstration: Phase II original and Phase II refresh populations

Characteristics	Original Months 1–21	Refresh Months 1–11
Intervention group		
Number eligible[1]	2,701	2,155
Full time equivalent[2]	2,330	1,992
Number fully eligible	1,986	1,819
Participants		
Number eligible	2,037	899
Full time equivalent	1,817	859
Number fully eligible	1,566	800
Participants > 75%		
Number eligible	1,048	452
Full time equivalent	992	438
Number fully eligible	895	415
Non-participants		
Number eligible	664	1,256
Full time equivalent	513	1,133
Number fully eligible	420	1,019
Comparison group		
Number eligible	2,763	2,159
Full time equivalent	2,394	2,001
Number fully eligible	2,031	1,841

NOTES: CMHCB = Care Management for High Cost Beneficiaries ; FFS = fee-for-service; KTBH = VillageHealth's Key to Better Health.

[1] Numbers reported for the intervention periods include only persons who have some baseline eligibility.

[2] Counts of beneficiaries are adjusted for CMHCB program eligibility during the entire period the Care Management Organization (CMO) was active in the program.

SOURCES: Medicare claims data, Medicare enrollment database.

Program: tableKTBH-1; tableKTBH-1a

Table 3-2 presents participation rates for the KTBH Phase II original and Phase II refresh populations and displays the participation status of the beneficiary after verbal consent to participate was given (continuous participation, became a continuous nonparticipant after initial participation period, or intermittent participation). We also display the reasons for nonparticipation and the percent of beneficiaries who participated more than 75% of eligible months. Numbers of participants by selected months are also reported. Continuous versus intermittent participation is important because it effects the ability of the KTBH program to contact beneficiaries and, ultimately, to have any impact on utilization and costs.

Participation rates for the KTBH Phase II original population. Of all KTBH Phase II original intervention group beneficiaries, 75% verbally consented to participate in its demonstration at some point during the intervention period, much higher than the 47% participation rate during Phase I (McCall, Cromwell, and Urato 2010). Only 25% of beneficiaries were continuous participants (Table 3-2), which equates to one-third of participants. Among the Phase II original KTBH beneficiaries, 22% refused to participate. The percent not contacted or unable to be located was 2%.

Participation rates were heavily influenced by length of eligibility during the intervention period. An alternative measure of participation is the percentage of beneficiaries who participated more than 75% of months they were eligible for the Phase II CMHCB Demonstration. Of KTBH's Phase II intervention beneficiaries, 39% participated for more than 75% of their eligible months, which is higher than the continuous participant percentage. Table 3-2 also reports the number of participants over time (for months 6, 12, 21, the last month of the demonstration). The number of participants declined over time as would be expected given the attrition due to loss of eligibility primarily due to death.

Participation rates for the Phase II KTBH Phase II refresh population. The participation rate for the Phase II refresh population is much lower than that of the Phase II original population. Overall, 42% of the Phase II refresh intervention beneficiaries consented to participate at some point during the 11-month period (Table 3-2). Of those, 34% were continuous participants, which equates to 81% of participants. The percent that refused to participate was more than double (57%), and the percent that were not contacted or were unable to be contacted was 1%.

Table 3-2
Participation in the Phase II KTBH CMHCB Demonstration:
Phase II original and Phase II refresh populations

Characteristics	Original	Refresh
Number of intervention months	21	11
Participation rate (entire demonstration period)	75%	42%
Length of participation		
Continuous participation after engagement	25%	34%
After initial participation, became a continuous non-participant	24%	7%
Intermittent participation	26%	0%
Nonparticipation (never agreed)	25%	58%
Refused to participate when contacted	22%	57%
Not contacted/unable to be contacted	2%	1%
Beneficiaries participating more than 75% of eligible months	39%	21%
Number of participants in selected months[1]		
Month 6	1,182	760
Month 12	1,168	n/a
Last month[2]	1,026	677

NOTES: CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health.

[1] Numbers reported for the intervention periods include only persons who have some baseline eligibility.

[2] The last month represents month 21 for the Phase II original population and month 11 for the Phase II refresh population.

Data Sources: Medicare claims data, Medicare enrollment database.

Program: tableKTBH-2.sas

3.3.2 Characteristics of the Phase II KTBH Intervention and Comparison Populations

In addition to evaluating the level of initial engagement by KTBH, our participation analysis is designed to confirm that the selection procedures produced similar demographic, disease, and economic burden profiles between the intervention and comparison groups for both the Phase II original and refresh populations. Identifying any systematic baseline differences in demographic characteristics, health status, or baseline chronic condition patterns between the intervention and comparison group beneficiaries is important because the contractual and financial benchmarks established as part of the CMHCB Demonstration are based on an ITT framework and an assumption that the intervention and comparison groups are equivalent or essentially equivalent at the start of the demonstration.

We used the go-live date as our reference point and examined claims for 1 year prior to the go-live date. Only beneficiaries that had some eligibility in both the baseline and intervention periods were selected for this analysis. We explore the sufficiency of the randomization procedures for producing similar populations based on the selection strata and other variables. We also examine whether there are any systematic baseline differences in the disease burden between the intervention and comparison group beneficiaries assessed at the start of the demonstration.

Characteristics of the KTBH Phase II original population (not shown)— Beneficiaries for both the Phase II intervention and comparison groups were eligible based on having annual Medicare costs of $5,000 or higher (CKD) or greater than or equal to $12,000 (ESRD) from July 1, 2007 through June 30, 2008 and meeting specific diagnostic criteria. We observe both cost and HCC score equivalency between the intervention and comparison groups. The mean HCC score for both the intervention and comparison groups was 2.65, meaning that beneficiaries selected for the demonstration were, on average, predicted to be 165% more expensive than the average fee-for-service (FFS) beneficiary.

Based on beneficiary characteristics, there were no statistically significant differences between the intervention and comparison populations at baseline. The intervention group had similar beneficiary characteristics and similar baseline rates of chronic conditions. Out of a large number of comparisons, one would expect to find a small number of the comparisons statistically significant by chance, but none were found.

Characteristics of the KTBH Phase II refresh population (not shown)—Beneficiaries for both the original and Phase II refresh populations were eligible for the same reasons as above. We observed a few statistically significant differences in the beneficiary characteristics – the intervention population had a higher rate of beneficiaries in the medium PBPM group and a smaller percentage in the low PBPM group than the comparison population. The intervention population had a 2.6 percentage point higher rate of cardiac dysrhythmias and conduction disorders at baseline than the comparison group. They also had slightly lower rates of Medicaid beneficiaries and beneficiaries ages 65-69. All five statistically significant differences were less than 4 percentage points.

3.3.3 Characteristics of Participants in the KTBH Original and Phase II Refresh Populations

In order to better understand the characteristics that most strongly predicted participation in the demonstration, we estimated a logistic regression model for both the Phase II original and refresh populations:

- Beneficiaries who participated at least 75% of eligible months compared with all other beneficiaries (nonparticipants and minimal participants).

This model reflects characteristics of the beneficiaries who demonstrated the greatest willingness or ability to participate in the Phase II KTBH Demonstration. We estimated two equations; an equation with just demographic characteristics and a full model equation that includes baseline and demonstration utilization and health status variables. Because there is correlation between beneficiary characteristics and the other variables, such as health status and baseline characteristics, we were most interested in examining which beneficiary characteristics had the greatest effect on willingness to participate before controlling for these other factors.

Tables 3-3 and ***3-4*** present the results of the logistic regression analyses that predict participation based on various beneficiary characteristics for the Phase II original and refresh populations. Model A (columns 1 and 2) contains the odds ratio and associated statistical level of significance for the equation with just beneficiary characteristics. Model B (columns 3 and 4) contains the odds ratio and associated statistical level of significance for the equation with additional utilization and health status variables. An odds ratio less than 1 means that beneficiaries with a particular characteristic were less likely to participate; an odds ratio greater than 1 means that beneficiaries with the particular characteristic were more likely to participate. In general, the reference group comprises characteristics associated with younger and healthier beneficiaries. The explanatory power of the studied beneficiary characteristics was extremely low. Thus, the set of variables that we used were not strong predictors of likelihood of participation. Pseudo R-squares for all of the models were 0.06 or less, with the full model exhibiting pseudo R-squares of 0.03 for the Phase II original population and 0.06 for the Phase II refresh population.

Table 3-3
Logistic regression modeling results comparing beneficiaries that participated at least 75% of eligible months during the Phase II KTBH CMHCB Demonstration intervention period to all other intervention beneficiaries: Phase II original population[1,2] Model A = beneficiary characteristics only; Model B = full model adding in baseline characteristics and demonstration period health status

Characteristics[3]	Model A OR	*P*[4]	Model B OR	*P*[4]
Intercept	0.84	N/S	0.67	**
Beneficiary characteristics				
Male	0.90	N/S	0.89	N/S
African American/other/unknown	1.00	N/S	0.89	N/S
Age < 65 years	1.13	N/S	0.97	N/S
Age 75-84	0.90	N/S	0.99	N/S
Age 85 + years	0.64	*	0.88	N/S
Medicaid	0.85	N/S	0.84	N/S
Baseline characteristics				
ESRD	N/I	N/I	1.55	**
Medium baseline PBPM	N/I	N/I	1.21	N/S
High baseline PBPM	N/I	N/I	1.23	N/S
Baseline Charlson score medium	N/I	N/I	1.14	N/S
Baseline Charlson score high	N/I	N/I	0.97	N/S
Demonstration period health status				
Died	N/I	N/I	0.53	**
Institutionalized	N/I	N/I	0.39	**
Number of cases	2,701	N/A	2,701	N/A
Chi-square (p<)	15.79	*	80.62	**
Pseudo R-square	0.01	N/A	0.03	N/A

NOTES: CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health; OR = odds ratio; PBPM = per beneficiary per month.

[1] Numbers reported for the intervention periods include only persons who have some baseline eligibility.

[2] The regressions are adjusted for CMHCB program eligibility during the entire period the Care Management Organization (CMO) was active in the demonstration.

[3] The age reference group is 65-74 years. The disease reference group is the CKD population. The PBPM reference group is LT $2,575. The baseline Charlson score reference group is 2 or less.

[4] * denotes statistical significance at the 5% level;** denotes statistical significance at the 1% level.

N/I means not included; N/A means not applicable; N/S means not statistically significant.

Data Sources: RTI analysis of 2008-2011 Medicare enrollment, eligibility, claims and encounter data.

Program: bene02, partab4b, partab5b

Table 3-4
Logistic regression modeling results comparing beneficiaries that participated at least 75% of eligible months during the Phase II KTBH CMHCB Demonstration intervention period to all other intervention beneficiaries: Phase II refresh population[1,2] Model A = beneficiary characteristics only; Model B = full model adding in baseline characteristics and demonstration period health status

Characteristics[3]	Model A OR	P[4]	Model B OR	P[4]
Intercept	0.31	**	0.21	**
Beneficiary characteristics				
Male	0.89	N/S	0.88	N/S
African American/other/unknown	1.19	N/S	1.01	N/S
Age < 65 years	1.60	**	1.22	N/S
Age 75-84	0.83	N/S	0.96	N/S
Age 85 + years	0.66	N/S	0.84	N/S
Medicaid	0.54	**	0.54	**
Baseline characteristics				
ESRD	N/I	N/I	2.28	**
Medium baseline PBPM	N/I	N/I	1.09	N/S
High baseline PBPM	N/I	N/I	1.41	*
Baseline Charlson score medium	N/I	N/I	1.30	N/S
Baseline Charlson score high	N/I	N/I	0.96	N/S
Demonstration period health status				
Died	N/I	N/I	0.49	*
Institutionalized	N/I	N/I	0.21	**
Number of cases	2,155	N/A	2,155	N/A
Chi-square (p<)	60.33	**	139.71	**
Pseudo R-square	0.03	N/A	0.06	N/A

NOTES: CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health; OR = odds ratio; PBPM = per beneficiary per month.

[1] Numbers reported for the intervention periods include only persons who have some baseline eligibility.

[2] The regressions are adjusted for CMHCB program eligibility during the entire period the Care Management Organization (CMO) was active in the demonstration.

[3] The age reference group is 65-74 years. The disease reference group is the CKD population. The PBPM reference group is LT $2,424. The baseline Charlson score reference group is 2 or less.

[4] * denotes statistical significance at the 5% level;** denotes statistical significance at the 1% level.

N/I means not included; N/A means not applicable; N/S means not statistically significant.

Data Sources: RTI analysis of 2009-2011 Medicare enrollment, eligibility, claims and encounter data.

Program: bene02, partab4b, partab5b

Model A for the Phase II original population shows that beneficiaries who were 85 years of age and older were less likely to be participants, a proxy for poorer health status (Table 3-3). Examining Model B for the Phase II original population (Table 3-3), we do not observe the same pattern of influence of beneficiary characteristics on the likelihood of participation – no baseline beneficiary characteristics are significant indicators of participation. Demonstration period health status was a strong predictor of participation. Beneficiaries who died were less likely to have been demonstration participants and beneficiaries who were institutionalized during the first 6-month period of the demonstration were about 60% less likely to participate than those not institutionalized, holding other factors constant. During Phase I, KTBH staff had reported challenges engaging both the disabled and the institutionalized populations and worked with CMS to exclude institutionalized beneficiaries from their Phase I refresh population. For this analysis, there were only 75 beneficiaries that were institutionalized, of which 12 were participants more than 75% of the eligible months. Most baseline health status characteristics (PBPM costs and comorbidity indices) had no impact on the likelihood of participation when controlling for baseline demographics and demonstration period health status. However, having ESRD at baseline was a very strong indicator of participation. This is surprising given the KTBH staff reported that they felt this group was most difficult to engage for a variety of reasons noted in Chapter 1.

There are a few noted differences in the results for the Phase II refresh population (Table 3-4), such as being age 85 and older had no impact on the likelihood of participation. For the Phase II refresh population, Medicaid enrollees are less likely to participate and high baseline PBPM was a positive predictor of participation (Model B). ESRD continued to be associated with a higher likelihood of participation, indicating more success in engaging sicker or more costly beneficiaries into their program. In the Phase II refresh population, there were only 72 institutionalized beneficiaries, of which 4 participated more than 75% of eligible months. It is important to note that because the Phase II refresh was only operational for 11 months, beneficiaries had to participate more than 8 months, leaving very little time for enrolling beneficiaries into the program. Thus, only 21 percent of the Phase II refresh population met this criterion.

During Phase I, KTBH leadership recommended that future renal management programs target a younger age group so that they could make a difference in the trajectory of beneficiaries' quality of life at an earlier stage. In the Phase II original cohort, 41% of beneficiaries were less than 65 years of age and only 9 percent were 85 years or older. The Phase II refresh population had a lower percentage of younger beneficiaries (34 percent were less than 65 years of age) and a slightly higher percentage of beneficiaries age 85 and older (13%).

3.3.4 Level of Intervention

In this section, we report the frequency of interaction between KTBH staff and intervention beneficiaries for a subset of original intervention population beneficiaries who were fully eligible and participating for the last 15 months of the Phase II original population's demonstration experience and the last 5 months for the Phase II refresh population.[6] This allows

[6] No further analyses on the Phase II refresh population are conducted after the Table 3-6.

for a 6-months enrollment period. Therefore, this analysis focuses on the time period during which the KTBH program would have the most effect. We also examine whether there is evidence of selective targeting of beneficiaries for intervention contacts based upon level of perceived need as determined by beneficiary demographic, health status, baseline costliness, and acute care utilization during the demonstration period. The KTBH program target population had a high prevalence of comorbid conditions, such as diabetes and heart failure (HF). During Phase I, KTBH staff reported that they had expanded the clinical focus of the program to also include identifying and treating the comorbid conditions of CKD—HF, hypertension, cardiovascular disease, and diabetes mellitus – in order to slow the progression of CKD. The KTBH program continued to target members with Stage 4 and 5 CKD in Phase II and added beneficiaries with ESRD. Thus, we expect to see a pattern of higher levels of intervention contacts for beneficiaries in poorer health status or higher users of hospitalization services.

Descriptive statistics were performed using beneficiaries participating in the Phase II KTBH Demonstration to determine the breadth and depth of contacts related to care management. The data represent beneficiaries who were fully eligible and participating (unless they died) for the last 15 months of the Phase II original population's demonstration experience and the last 5 months for the Phase II refresh population. ***Tables 3-5 and 3-6*** provide a detailed description of the type of contact and number of contacts during this time period for the subset of eligible beneficiaries. Data in ***Table 3-5*** gives a broad sense of the primary person with whom the KTBH care managers were contacting. The majority of contacts were made to or from the patient/caregiver (about 80 percent) followed by providers at nearly 8 percent. This confirms that the contacts are really focused on coaching intervention and not on care coordination with providers. ***Table 3-6*** displays the method of contact. Telephonic contact was the dominant form of contact (about 70 percent), with about 13% of contacts being in-person for the Phase II original population and 10% for the Phase II refresh population.

Table 3-5
Frequency distribution of Phase II KTBH CMHCB Demonstration Care Manager interactions: Total contacts[1,2]

Contacted	Phase II Original Frequency	Percent	Phase II Refresh Frequency	Percent
Patient/caregiver	20,023	78.1	327	80.0
Patient	17,793	69.4	300	73.3
Caregiver	2,230	8.7	27	6.6
Total provider	1,930	7.5	31	7.6
Nephrologist	646	2.5	17	4.2
Healthcare Professional (non Nephrologist)	511	2.0	1	0.2
Community Resource	465	1.8	2	0.5
Health Plan	94	0.4	n/a	n/a
Other[3]	214	0.8	11	2.7
Facility/other	3,691	14.4	51	12.5
Dialysis center	1,365	5.3	31	7.6
Facility-non dialysis center	2,142	8.4	16	3.9
Hospital	161	0.6	3	0.7
Pharmacy	23	0.1	1	0.2
Total contacts	25,644	100.0	409	100.0

NOTES: CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health.

[1] Phase II original beneficiaries had to be fully eligible and full participants in the last 15 months of the Phase II KTBH Demonstration and refresh beneficiaries had to meet these criteria for the last 5 months of demonstration.

[2] Includes any inbound and outbound contact as well as fax, e-mail, and mailings.

[3] Includes Dietician, Social Worker, Primary Care Provider, Home Health Agency, Nurse Practitioner, and Medical Director.

Data Sources: RTI analysis of 2010-2011 Medicare enrollment, eligibility, and KTBH encounter data.

Program: encount2

Table 3-6
Frequency distribution of Phase II KTBH CMHCB Demonstration's method of interaction: Total contacts[1]

Method	Phase II Original Frequency	Percent	Phase II Refresh Frequency	Percent
Total telephonic	18,051	70.4	279	68.2
Telephonic outbound	16,784	65.5	263	64.3
Telephonic inbound	1,257	4.9	16	3.9
Telephonic not specified	10	0.0	n/a	n/a
In-Person[2]	3,225	12.6	41	10.0
Other[3]	4,368	17.0	89	21.8
Total contacts	25,644	100.0	409	100.0

NOTES: CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health.

[1] Phase II original beneficiaries had to be fully eligible and full participants in the last 15 months of the Phase II KTBH Demonstration and refresh beneficiaries had to meet these criteria for the last 5 months of demonstration.

[2] Any in-person contact: outbound, inbound, and not specified.

[3] E-mail, fax, and mail outbound, inbound, and not specified.

Data Sources: RTI analysis of 2008-2011 Medicare enrollment, eligibility, and KTBH encounter data.

Program: encount2

Table 3-7 displays the overall distribution of care management-related contacts for the Phase II original population. A total of 1,057 unique Phase II original population beneficiaries met the selection criteria - fully eligible and participating (unless they died) for the last 15 months of the Phase II Demonstration. Observations were weighted by the fraction of eligible days, accounting for fewer contacts due to attrition because of death, which resulted in 957 full-time equivalent beneficiaries. The mean number of contacts for each beneficiary was 18 and the median was 0. Over fifty percent of beneficiaries had no contacts and approximately one-third of beneficiaries had 26 or more contacts over the 15 month period.

Table 3-7
Distribution of number of contacts[1] with participants[2] in the Phase II KTBH CMHCB Demonstration: Phase II original intervention population

Statistic	Number	Percent
Number of beneficiaries[3]	1,057	—
FTE beneficiaries[4]	957	—
Mean number of contacts	18	—
Median number of contacts	0	—
Mean number of months of contact	9	—
Median number of months of contact	1	—
Distribution low to high contact variables	FTE beneficiaries	Percent
0 contacts	512	53.5
1–25 contacts	105	11.0
26+ contacts	339	35.5
Total	957	100.0

NOTES: CMHCB = Care Management for High Cost Beneficiaries; FTE = full-time equivalent; KTBH = VillageHealth's Key to Better Health.

[1] Contacts are restricted to in-person and telephonic inbound and outbound.

[2] Participants are defined as patients and caregivers in this analysis.

[3] Beneficiaries had to be fully eligible and full participants in the last 18 months of the Phase II KTBH Demonstration.

[4] Beneficiary counts weighted by fraction of eligible days = full-time equivalents.

Data Sources: RTI analysis of 2008-2011 Medicare enrollment, eligibility, and KTBH encounter data.

Program: enctab2, encount5

Table 3-8 displays the percent of participants with care manager interactions – in-person visits, telephone contacts inbound and outbound, and total contacts (telephonic and in-person) by frequency of contact over the last 15 months of the Phase II Demonstration for the Phase II original population. This table also provides information by baseline disease status (CKD and ESRD). Contact mode was not mutually exclusive in that a beneficiary could have a combination of telephone and visit contacts any time during the last 15 months of the Phase II KTBH Demonstration.

Table 3-8
Percent distribution of participants[1] with Phase II KTBH CMHCB Demonstration care manager interactions[2]: Phase II original intervention population

Type and frequency of contact	All N = 957 Frequency[3,4]	%	CKD N = 272 Frequency[3,4]	%	ESRD N = 359 Frequency[3,4]	%
In-person						
0	658	68.7	353	88.7	305	54.5
1	34	3.6	18	4.5	17	3.0
2–4	51	5.4	11	2.8	40	7.1
5–9	78	8.1	10	2.4	68	12.2
10–19	119	12.4	6	1.5	113	20.2
20+	17	1.8	0	0.0	17	3.0
Telephonic inbound						
0	730	76.3	328	82.5	402	71.9
1	82	8.6	25	6.2	57	10.3
2–4	81	8.4	31	7.8	50	8.9
5–9	41	4.3	11	2.7	30	5.4
10–19	19	2.0	1	0.3	18	3.2
20+	4	0.4	2	0.5	2	0.3
Telephonic outbound						
0	513	53.6	249	62.7	263	47.2
1	0	0.0	0	0.0	0	0.0
2–4	2	0.2	0.	0.0	2	0.4
5–9	29	3.1	1	0.3	28	5.1
10–19	104	10.9	12	3.1	92	16.5
20+	308	32.2	135	33.9	173	31.0
Total telephonic and in-person						
0	512	53.5	249	62.7	262	47.0
1	0	0.0	0	0.0	0	0.0
2–4	0	0.0	0	0.0	0	0.0
5–9	0	0.0	0	0.0	0	0.1
10–19	32	3.4	8	2.1	24	4.3
20+	412	43.0	140	35.2	272	48.6

NOTES: CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; FTE = full time equivalent; KTBH = VillageHealth's Key to Better Health.

[1] Participants are defined as patients and caregivers in this analysis.

[2] Contacts are restricted to in-person and telephonic inbound and outbound.

[3] Beneficiaries had to be fully eligible and full participants in the last 15 months of the Phase II KTBH Demonstration.

[4] Beneficiary counts weighted by fraction of eligible days = full-time equivalents.

Data Sources: RTI analysis of 2008-2011 Medicare enrollment, eligibility, and KTBH encounter data.

Program: enctab1, enctab1a

In-person visits— Nearly 70% of beneficiaries had no in-person visits. About 4% of beneficiaries had one in-person visit and another 14% of beneficiaries had 10 or more in-person visits during the 15-month period. These distributions vary by disease. Eleven percent of CKD participants received an in-person visit compared to 45% of ESRD participants. Twenty-three percent of ESRD participants had 10 or more in-person visits. During the November 2009 site visit, KTBH staff stated that contact with CKD beneficiaries was primarily telephonic and there was an emphasis on in-person visits for the ESRD population. These findings suggest that KTBH made a focused effort to visit their higher acuity beneficiaries.

Telephone contacts—About one-half of participants received phone calls during the Phase II KTBH program, with a higher percentage of ESRD receiving calls that CKD beneficiaries. Forty-three percent of participants received 10 or more calls. Also of note is the number of inbound calls made to the care managers – about 25% of participants contacted the care manager. Combining telephone and visit contacts, we observe that about one-half of fully eligible and participating beneficiaries had no contact for the 15-month period, yet at the same time, we observe 43% of beneficiaries had 20 or more contacts with the majority being telephone contacts.

There is also a difference in the percent of beneficiaries that received one or more contacts when all modes of contact are combined – a higher percentage of ESRD participants (53%) had any contact compared to the CKD participants (37%), all of whom received 10 or more contacts.

Table 3-9 provides a snapshot of the contact information for the Phase II original population. Beneficiary participation was 75% during the Phase II KTBH Demonstration. For beneficiaries who were fully eligible and fully participating the last 15 months of the demonstration, the mean number of contacts during the Phase II KTBH Demonstration was about 0.57 per month. An alternative way of looking at rate of contact is number of months between contacts. On average, Phase II original population participants were contacted about every 1.8 months with 54 days between contacts. Over a 15-month month intervention period, every 1.8 months converts into 9 contacts. These statistics are also provided by disease category. ESRD participants were contacted more frequently than CKD participants - over the 15-month month intervention period, contact every 1.3 months for ESRD beneficiaries converts into 12 contacts compared to CKD beneficiaries with contact approximately every two months converting to about 7 contacts over the same time period.

Table 3-9
Phase II KTBH CMHCB Demonstration beneficiary contact rates among fully eligible and fully participating beneficiaries[1]

Population	Overall participation rate (%)[2]	Mean contacts per active month[3]	Mean number of months between contacts[4]	Mean number of days between contacts[5]
Phase II Original	75	0.57	1.76	53.55
CKD	73	0.46	2.19	66.59
ESRD	78	0.78	1.28	38.87

NOTES: CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health.

[1] Contacts include telephonic and in-person.

[2] Overall participation rate for all beneficiaries for the full demonstration period.

[3] Mean contacts per active month: Ratio of mean number of contacts per month to active intervention months.

[4] Number of months between contacts: Inverse of mean contacts per active month, which is defined as ratio of mean contact months to active intervention months.

[5] Number of days between contacts: Number of months between contacts multiplied by 30.42.

Data Sources: RTI analysis of 2008-2011 Medicare enrollment, eligibility, and KTBH encounter data.

Program: encount4; encount5, encount5a

To more directly examine the targeting strategy of the Phase II KTBH Demonstration, a multivariate logistic regression model was estimated with the number of total contacts as the dependent variable. The model estimates the likelihood of a participant receiving a high number of contacts. The medium contact group was omitted, thus comparing the high contact group to the low contact group. ***Table 3-10*** displays the odds ratios for discrete categories of demographic characteristics, baseline health status, baseline Medicare payments, and demonstration health status for the Phase II original population. Beneficiaries were weighted by their period of eligibility during the last 15 months of the demonstration, and their number of contacts categorized either as low (0) or high (26+). Odds ratios are partial in the sense that all other variables are held constant. For example, the odds of a beneficiary 85 years or older experiencing a high contact rate are 1.2 times greater than those for beneficiaries less than 85 years of age, adjusting for any baseline differences in disease and characteristics.

Table 3-10
Logistic regression modeling results comparing the likelihood of being in the Phase II KTBH CMHCB Demonstration high contact category relative to the no contact category: Phase II original intervention population[1,2]

Characteristics[3]	Odds ratio	*P*[4]
Intercept	0.55	*
Beneficiary characteristics		
Male	0.95	N/S
African American/other/unknown	0.73	N/S
Age <65	1.08	N/S
Age 75–84	0.94	N/S
Age 85+ years	1.17	N/S
Medicaid	0.76	N/S
Baseline characteristics		
ESRD	2.35	**
Medium base PBPM	1.00	N/S
High base PBPM	0.79	N/S
Baseline Charlson score medium	0.95	N/S
Baseline Charlson score high	1.26	N/S
Demonstration period health status		
Died	0.48	**
Institutionalized	0.33	N/S
One hospitalization	0.95	N/S
Multiple hospitalizations	1.28	N/S
Number of cases	926	N/A
Chi-square (p<)	41.42	**
Pseudo R^2	0.04	N/A

NOTES: CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month.

[1] Beneficiaries had to be fully eligible and full participants in the last 18 months of the demonstration.

[2] Beneficiary counts weighted by fraction of eligible days = full-time equivalents

[3] The age reference group is 65-74 years. The disease reference group is the CKD population. The PBPM reference group is LT $2,575. The baseline Charlson score reference group is 2 or less.

[4] * denotes statistical significance at the 5% level;** denotes statistical significance at the 1% level.

N/A means not applicable; N/S means not statistically significant.

Data Sources: RTI analysis of 2008-2011 Medicare enrollment, eligibility, claims and encounter data.

Program: enctab4a

For the Phase II original population, no beneficiary characteristics were found to be statistically significant indicators of the likelihood of being in the high contact category (Table 3-10). Of the five baseline characteristic variables, having ESRD at the time of randomization was a positive and statistically significant indicator of being in the high contact category. Demonstration period acute care utilization was not a strong predictor of a high level of contact and likely reflects the challenges that the KTBH staff expressed in knowing when one of their participants had been to an emergency room or hospitalized. Beneficiaries who died during the demonstration were less likely to be in the high contact category. The explanatory power of the studied beneficiary characteristics was extremely low, suggesting that there is not a strong set of variables that predict likelihood of a beneficiary being in the high contact group. The pseudo R-square for the model was 0.04.

3.4 Summary

For the Phase II KTBH Demonstration, we find that participants for more than 75% of the eligible months from the Phase II original population tended to be younger than beneficiaries who never participated (44% were less than 65 years of age compared to 39% for the nonparticipants). In the multivariate regression analysis, institutionalized beneficiaries and those that died were less likely to be participants, while ESRD beneficiaries were more likely to participate. This suggests that the KTBH program was able to engage the sicker Medicare beneficiaries (beneficiaries with ESRD). For the Phase II refresh population, in addition to institutionalized beneficiaries and those that died being less likely to be participants, Medicaid enrollees were also less likely to participate. Beneficiaries with high baseline per beneficiary per month (PBPM) costs were a positive predictor of participation and ESRD continued to be associated with a higher likelihood of participation. These findings suggest that the Phase II KTBH Demonstration continued to be successful at gaining participation from the sicker and more costly beneficiaries in their program as it matured.

A cornerstone of the KTBH's program was health coaching interactions with care manager nurses. However, over one-half of participating Phase II original beneficiaries received no call or in-person visit from a care manager in the last 15 months of the demonstration. A majority of those that did have contact had ten or more total contacts. Telephone contact was the most dominant form of contact. That being said, among the ESRD beneficiaries, nearly one-half received an in-person visit during the demonstration period. In our multivariate regression modeling of likelihood of being in a high contact versus low contact group for the Phase II original population, we found that beneficiary characteristics were not indicators of being in the high contact category. Among the baseline characteristics and demonstration period health status indicators, only having ESRD increased the likelihood of being in the high contact group while dying during the demonstration decreased that likelihood. Demonstration period acute care utilization was not a strong predictor of a high level of contact and likely reflects the challenges that the KTBH staff expressed in knowing when one of their participants had been to an emergency room or hospitalized. No other variables were found to be statistically significant.

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CHAPTER 4
CLINICAL QUALITY PERFORMANCE

4.1 Introduction

RTI's analysis of quality of care focuses on measuring effectiveness of the Key to Better Health (KTBH) Demonstration by answering the following evaluation question:

- *Clinical Quality of Care:* Did the Phase II Key to Better Health Demonstration improve quality of care, as measured by improvement in the rates of beneficiaries receiving guideline concordant care?

In this chapter, we present analyses related to clinical quality performance during the Phase II KTBH Demonstration by examining changes in the rate of receipt of nine evidence-based process-of-care measures during the demonstration, relative to a 12-month baseline period in both the intervention and comparison populations for the Phase II original population, and relative to an 11 month baseline period in both the intervention and comparison populations for the Phase II refresh population. Six of these measures pertain to beneficiaries with diabetes: rate of annual HbA1c testing, low-density lipoprotein cholesterol (LDL-C) screening, receipt of a retinal eye exam, medical attention for nephropathy, as well as the rate at which beneficiaries received all four of those measures, or none of those measures. Completion of a complete lipid profile will be used for beneficiaries with ischemic vascular disease (IVD). We also created two ESRD-related measures applicable to the solely to the demonstration period: rate of progression to ESRD during the demonstration period, and rate of fistula/graft placement prior to initiation of dialysis among beneficiaries who initiated dialysis during the demonstration period.

Given the use of an intent-to-treat (ITT) model and our difference-in-differences evaluation approach, seven of our measures require information for the pre-demonstration and demonstration periods for both the intervention and comparison populations. Therefore, we selected measures that could be reliably calculated using Medicare administrative data. These data are available for both the intervention and comparison populations and do not require medical record abstraction or beneficiary self-report. Medical record data are not available to us for either the intervention or comparison populations, and beneficiary self-report data would only be available for the intervention beneficiaries who participated during the demonstration. Further, beneficiary self-report is subject to recall error and the willingness of beneficiaries to provide the information.

4.2 Methodology

Seven of the nine process-of-care measures were assessed for the12-month period immediately prior to the beginning of the Phase II demonstration period for the Phase II original population, and the 11 month period immediately preceding the beginning of the Phase II demonstration period for the Phase II refresh population. All nine measures were assessed for the demonstration period; months 10–21 were used for the Phase II original population and months 1–11 for the Phase II refresh population. This is equivalent to the last 12 months of the demonstration period for the Phase II original population, and the entire 11 month demonstration period for the Phase II refresh population.

Rates of progression to ESRD and fistula/graft placement prior to initiation of hemodialysis were calculated for the full demonstration period for both the Phase II original and refresh populations with chronic kidney disease (CKD). Baseline rates were not calculated for these measures because beneficiaries who had progressed to ESRD, or started hemodialysis, prior to the selection of either the Phase II original or the Phase II refresh populations were considered ineligible. Only beneficiaries who had at least 1 day of eligibility in both baseline and intervention periods were included in the analysis of all nine measures. ***Table 4-1*** provides the number of beneficiaries who were included in the analyses of the quality of care measures, in total, and by three disease cohorts: diabetes, CKD, and IVD.

Table 4-1
Number of beneficiaries included in analyses of guideline concordant care and acute care utilization for the Phase II KTBH CMHCB Demonstration: Phase II original and Phase II refresh populations

Statistics	All	Diabetes	CKD	Ischemic vascular disease
Phase II original beneficiaries				
Months 10-21				
Intervention				
Total number of beneficiaries	2,389	1,125	1,591	1,007
Full time equivalents[1]	2,383	1,121	1,376	1,005
Comparison				
Total number of beneficiaries	2,444	1,159	1,568	1,023
Full time equivalents[1]	2,439	1,156	1,345	1,022
Phase II refresh beneficiaries				
Months 1-11				
Intervention				
Total number of beneficiaries	2,155	1,083	833	1,032
Full time equivalents[1]	2,110	1,055	775	1,012
Comparison				
Total number of beneficiaries	2,159	1,119	830	1,029
Full time equivalents[1]	2,122	1,096	771	1,010

NOTES: CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health.

[1] Full time equivalent for the intervention group during the baseline period is the total number of beneficiaries weighted by their period of eligibility for the demonstration.

SOURCE: RTI analysis of 2008-2011 Medicare enrollment, eligibility, claims and encounter data; Computer runs: gcc01, gcc02, gcctab, gcc_rob, gcctabx, gcctab1, acsctab1

Medicare claims for the baseline and intervention periods were included regardless of beneficiary eligibility for the Phase II KTBH Demonstration (e.g., claims were included even if beneficiaries did not pay the Part B premium for 1 or 2 months). This allowed the Phase II KTBH Demonstration to receive credit for services received after exposure to their intervention, which potentially resulted from the intervention. Services rendered during a period of ineligibility for the Phase II KTBH Demonstration but still included in the Medicare claims files, such as a denied claim due to Part B disenrollment, reflect actual receipt of the service and were therefore included in our analysis. Rates per 100 beneficiaries are reported for the intervention and comparison groups for the 12-month and 11-month baseline periods and for the demonstration periods, weighted by beneficiary eligibility in each time period. For each measure, the reported difference-in-differences (D-in-D) rate reflects the growth (or decline) in the intervention group's mean rate of receipt of care relative to the growth (or decline) in the comparison group's mean rate. A positive intervention effect for the guideline-concordant care measures occurred if the intervention group's mean rate either increased more, or declined less, than the comparison group's mean rate during the demonstration period. A negative intervention effect occurred if the intervention group's mean rate increased less, or declined more, than the comparison group's mean rate during the demonstration period. For each of the two CKD measures, the difference in the rates was calculated by subtracting the comparison group rate from the intervention group rate.

Statistically testing the difference-in-differences rate of receipt of the measures was performed at the individual beneficiary level. The standard method for modeling a binary outcome, such as receiving an HbA1c test, is logistic regression. An eligibility fraction ranging from 0 to 1 was assigned to the pre- and post- time periods for each sample member. STATA SVY was used to fit the model with robust variance estimation. Operationally, the five strata and a beneficiary identifier were included in the SVYSET statement to reflect the stratified sampling design. The eligibility fraction was included as the weight to reflect the period of time during which the beneficiary met the Phase II KTBH Demonstration eligibility criteria in both the baseline and demonstration periods.

Logistic regression produces an odds ratio for every predictor variable in the model; that is, an estimate of that variable's effect on the dependent variable after adjusting for the other variables (randomization factors) in the model. The odds ratio is greater than 1.0 when the presence of the variable is associated with an increased likelihood of receiving the service; an odds ratio less than 1.0 means that the variable is inversely associated with receiving the service. The statistical test determines whether the odds ratio is 1.0. For seven of the measures, we report the odds ratio associated with the D-in-D interaction term, or the test of the difference-in-differences of the rate, in addition to the odds ratio's associated *p* value and 95% confidence level. For the two CKD measures, we report the odds ratio associated with the likelihood of receipt during the demonstration period, in addition to the odds ratio's associated *p* value and 95% confidence level.

4.3 Findings

Process-of-care rates per 100 KTBH Phase II original population beneficiaries and Phase II refresh population beneficiaries are reported in ***Table 4-2*** and ***Table 4-3***, respectively. We report the baseline and intervention period rates for the intervention and comparison groups as

well as the difference-in-differences rates (baseline period intervention versus comparison rate difference minus intervention period intervention versus comparison rate difference). Positive difference-in-differences rates per 100 beneficiaries indicate that the intervention group's mean rate improved more than the comparison group's mean rate or the intervention group's mean rate declined at a lower rate than the comparison group's mean rate. Negative difference-in-differences rates per 100 beneficiaries indicate that comparison group exhibited higher rates of growth or less of a decline, than the intervention group. For progression to ESRD and graft/fistula placement prior to initiation of hemodialysis, we report the odds ratio of the statistical test of differences in likelihood of ESRD progression or receipt of graft/ fistula placement during the demonstration period between the intervention and comparison groups.

Table 4-2
Comparison of rates of guideline concordant care for the last 12 months of the Phase II KTBH CMHCB Demonstration with rates for a 1-year period prior to the start of the Phase II KTBH CMHCB Demonstration: Phase II original population

Process of care measures	Rate per 100 Baseline I[1]	Rate per 100 Baseline C[1]	Rate per 100 Demo period I[1]	Rate per 100 Demo period C[1]	D-in-D Rate per 100	D-in-D OR	D-in-D p	D-in-D CI Low	D-in-D CI High
Phase II original population Months 10-21									
Beneficiaries with CKD									
Progression to ESRD[2,3]	N/A	N/A	59	56	2.92	2.18	0.03	0.30	5.54
Graft or fistula prior to hemodislaysis[2,3]	N/A	N/A	20	23	-3.09	-2.13	0.03	-5.93	-0.24
Beneficiaries with diabetes									
HbA1c test	94	95	94	93	1.10	1.22	0.44	0.73	2.03
LDL-C test	91	92	89	91	0.13	1.05	0.82	0.70	1.58
Eye Exam	72	72	68	67	1.20	1.05	0.69	0.81	1.37
Nephropathy	62	61	61	62	-1.88	0.92	0.52	0.72	1.18
All 4 measures	42	42	41	41	0.31	1.01	0.92	0.80	1.29
None of the 4 measures	0.4	0.4	1.0	0.7	0.40	1.74	0.50	0.35	8.70
Beneficiaries with IVD[4]									
Lipid Panel	64	65	63	62	2.31	1.10	0.46	0.85	1.44

NOTES: CI = confidence interval; CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease ; IVD = ischemic vascular disease KTBH = VillageHealth's Key to Better Health; LDL-C = low-density lipoprotein cholesterol; I = intervention population; C = comparison population; D-in-D = difference-in-differences; OR = odds ratio.

[1] All rates are per 100 beneficiaries and are adjusted for periods of demonstration eligibility during the one-year period prior to the start of the demonstration and each set of months the Phase II KTBH Demonstration was active. Only beneficiaries who had at least one day of eligibility in both the baseline and demonstration periods are included in this analysis.

[2] The calculated difference for CKD beneficiaries is intervention rate minus comparison rate.

[3] The rates are calculated for only the intervention time period.

[4] Ischemic Vascular Disease is defined using the National Qualify Forum definition.

SOURCE: RTI analysis of 2008-2011 Medicare enrollment, eligibility, claims and encounter data; Computer runs: gcc01, gcc02, gcc_rob, gcctabx, gcctab1, gcctab

Table 4-3
Comparison of rates of guideline concordant care for the 11 months of the Phase II KTBH CMHCB Demonstration with rates for a comparable 11 month period prior to the start of the Phase II KTBH CMHCB Demonstration: Phase II refresh population

Process of care measures	Rate per 100 Baseline I[1]	Rate per 100 Baseline C[1]	Rate per 100 Demo period I[1]	Rate per 100 Demo period C[1]	D-in-D Rate per 100	D-in-D OR	D-in-D p	D-in-D CI Low	D-in-D CI High
Phase II refresh population Months 1-11									
Beneficiaries with CKD									
Progression to ESRD[2,3]	N/A	N/A	39	39	0.37	0.25	0.80	-2.53	3.28
Graft or fistula prior to hemodislaysis[2,3]	N/A	N/A	28	30	-2.05	-0.92	0.36	-6.39	2.30
Beneficiaries with diabetes									
HbA1c test	95	94	90	91	-2.07	0.76	0.26	0.47	1.23
LDL-C test	88	87	89	86	1.57	1.15	0.45	0.80	1.67
Eye Exam	78	79	73	69	4.39	1.25	0.12	0.94	1.66
Nephropathy	60	61	64	58	6.24	1.30	0.04	1.01	1.67
All 4 measures	47	45	44	38	4.04	1.18	0.18	0.93	1.52
None of the 4 measures	1	0	2	2	-0.13	0.60	0.47	0.16	2.33
Beneficiaries with IVD[4]									
Lipid Panel	74	74	71	68	4.15	1.22	0.17	0.92	1.61

NOTES: CI = confidence interval; CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; IVD = ischemic vascular disease; KTBH = VillageHealth's Key to Better Health; LDL-C = low-density lipoprotein cholesterol; I = intervention population; C = comparison population; D-in-D = difference-in-differences; OR = odds ratio.

[1] All rates are per 100 beneficiaries and are adjusted for periods of demonstration eligibility during the 11 months the Phase II KTBH Demonstration refresh population was active and an 11-month period prior to the start of the demonstration mirroring the 11 months of intervention period experience. Only beneficiaries who had at least one day of eligibility in both the baseline and demonstration periods are included in this analysis.

[2] The calculated difference for CKD beneficiaries is intervention rate minus comparison rate.

[3] The rates are calculated for only the intervention time period.

[4] Ischemic Vascular Disease is defined using the National Qualify Forum definition.

SOURCE: RTI analysis of 2009-2011 Medicare enrollment, eligibility, claims and encounter data; Computer runs: gcc01, gcc02, gcc_rob, gcctabx, gcctab1, gcctab

Rates of progression to ESRD within the Phase II original population's intervention and comparison and groups were 59% and 56%, respectively (p=0.03). Among beneficiaries with chronic kidney disease who started hemodialysis during the demonstration period, 20% of the intervention group and 23% of the comparison population had a graft or fistula inserted prior to initiating dialysis. This difference is also statistically significant. Thus, beneficiaries in the Phase II original intervention group were more likely to progress to ESRD during the demonstration period but were less likely to have a graft or fistula inserted prior to initiation of hemodialysis.

At baseline, the Phase II original population's intervention group had individual measures of diabetes care with rates ranging from 62% for nephropathy screening to 94% for HbA1c

testing. Forty-two percent of beneficiaries in this group received all 4 diabetes measures, with more than 99% receiving at least one of the four. The rates were similar for the Phase II original population's comparison group at baseline. Over the course of the demonstration period, the rates did not change by more than 5 percentage points. Rates in the comparison group declined over the course of the demonstration period across all measures with one exception: nephropathy screening increased by 1 percentage point during the demonstration period. For the intervention group, all measures declined during the demonstration period excepting HbA1c, which remained at 94%. Not surprisingly, we observe only modest separation in the difference-in-differences rates with none having statistical significance.

For beneficiaries with ischemic vascular disease, the rate of lipid panel testing was similar between the intervention and comparison groups at baseline, around 65%. Both groups' rates declined during the intervention period.

Rates of progression to ESRD within the Phase II refresh population's intervention and comparison groups were both 39%. Among beneficiaries with chronic kidney disease who started hemodialysis during the demonstration period, 28% of the intervention group and 30% of the comparison population had a graft or fistula inserted prior to initiating hemodialysis. Neither measure was statistically significant.

At baseline, the Phase II refresh population's intervention group had individual measures of diabetes care with rates ranging from 60% for nephropathy screening to 95% for HbA1c testing. Forty-seven percent of beneficiaries in this group received all 4 diabetes measures, with 99% receiving at least one of the four. The rates were similar for the Phase II refresh population's comparison group at baseline.

Over the course of the demonstration period, the rates varied from baseline from one to ten percentage points. Rates in the comparison group declined over the course of the demonstration period across all measures. For the intervention groups, all measures declined during the demonstration period except LDL-C testing and nephropathy screening, which increased by one and four percentage points, respectively. Again, we observe only modest separation in the difference-in-differences rates. We observe a positive intervention effect for nephropathy screening, a D-in-D rate of 6 per 100 ($p=0.04$), reflecting a higher rate of screening during the demonstration period among the Phase II refresh intervention beneficiaries.

For ischemic vascular disease, the rate of lipid panel testing was the same for the intervention and comparison groups at baseline, 74%. Both groups' rates declined during the intervention period.

4.4 Summary of Findings and Conclusion

In this chapter, we reported on RTI's assessment of the effect of the Phase II KTBH Demonstration on quality of care. Specifically, we reported findings for the key research question: did the Phase II KTBH Demonstration improve quality of care, as measured by improvement in the rates of beneficiaries receiving guideline concordant care? We find no evidence of systematic improvement in quality of care in the Phase II KTBH CMHCB Demonstration. Out of nine measures, few exhibited statistically significant differences in the rate of receipt of evidence-based care between the intervention and comparison groups, and none of the significance differences were seen consistently across the Phase II original and refresh populations. Beneficiaries in the Phase II original intervention group were more likely to progress to ESRD during the demonstration period but were less likely to have a graft or fistula inserted prior to initiation of hemodialysis. Among the Phase II refresh intervention beneficiaries, we observe a positive intervention effect for nephropathy screening, reflecting a higher rate of screening during the demonstration period.

Over the course of the demonstration, the Phase II KTBH Demonstration had expected to increase rates of adherence to evidence-based care. However, during the last year of its demonstration, we observe lower or very similar rates of adherence to the selected measures among its intervention beneficiaries relative to the comparison group beneficiaries for all measures. These findings suggest that improving or sustaining adherence to guideline concordant care in a cohort of ill Medicare FFS beneficiaries was more challenging than originally envisioned.

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CHAPTER 5
HEALTH OUTCOMES

5.1 Introduction

RTI's analysis of health outcomes focuses on answering the following two evaluation questions:

- Did the Phase II KTBH Demonstration improve intermediate health outcomes by reducing acute hospitalizations, readmissions, or emergency room (ER) utilization?
- Did the Phase II KTBH Demonstration improve health outcomes by decreasing mortality?

In this chapter, we present analyses related to intermediate clinical health outcomes by examining changes in the rate of hospitalizations, ER visits, and readmissions for Phase II of the KTBH CMHCB Demonstration during the last 12 months of the demonstration period for the Phase II original population and during the entire 11 months of the demonstration period for the Phase II refresh population relative to a 12-month baseline period for the Phase II original population and a comparable 11 month baseline period for the Phase II refresh population. We also examine differences in the rate of mortality between the intervention and comparison Phase II original and refresh beneficiaries during the entire Phase II demonstration period. For all analyses, we present the results for all beneficiaries within the Phase II original or Phase II refresh population and stratified by renal disease status at the time of randomization, either CKD or ESRD.

5.2 Methodology

5.2.1 Rates of Hospitalizations and Emergency Room Visits

For Phase II, rates of hospitalization and ER visits were constructed for the 12-month period immediately prior to the launch demonstration program date and for months 10-21 of the demonstration for the Phase II original population. For the Phase II refresh population, these rates were constructed for the full 11 months of demonstration period and for the comparable 11 months immediately prior to the start of the Phase II refresh demonstration period. We constructed rates of all-cause hospitalizations and all-cause ER visits. We also created a utilization measure that includes 10 ambulatory care sensitive conditions (ACSC) as reasons for hospitalization—heart failure, diabetes, asthma, cellulitis, chronic obstructive pulmonary disease (COPD)/ chronic bronchitis, dehydration, bacterial pneumonia, septicemia, ischemic stroke, and urinary tract infection— identified using the primary diagnosis on the claim, and generated an hospitalization rate and an ER visit rate based on these 10 ACSCs. Only claims that occurred during periods of eligibility were included in the utilization measures, and only beneficiaries who had at least 1 day of eligibility in both baseline and the demonstration periods are included in these analyses. Table 4-1 in ***Chapter 4*** displays the number of beneficiaries who were included in these utilization analyses. All-cause and 10 ACSC rates of hospitalization and ER visits per 1,000 beneficiaries are reported for the intervention and comparison groups for the baseline period and for intervention period, weighted by beneficiary eligibility in each time period. For

each measure, the difference-in-differences (D-in-D) rate is reported and reflects the decline (or growth) in the intervention group's mean rate of utilization relative to the decline (or growth) in the comparison group's mean rate. A positive intervention effect for the acute care utilization measures occurs if the intervention group's mean rate decreased more, or increased less, than the comparison group's mean rate during the demonstration period. A negative intervention effect occurs if the intervention group's mean rate declined less, or grew more, than the comparison group's mean rate during the demonstration period.

We performed statistical testing of the change in the utilization rates at the individual beneficiary level. The distributional properties of the data led us to select a negative binomial generalized linear model, which accounts for the presence of beneficiaries with no hospitalizations or ER visits in either time period, as well as heterogeneity in rates of acute care service use. As with the process-of-care measures, STATA SVY was used to fit the model with robust variance estimation. An eligibility fraction ranging from 0 to 1 was assigned to the pre- and post- time periods for each beneficiary. It was included as the weight to reflect the period of time the beneficiary met the Phase II KTBH CMHCB Demonstration eligibility criteria in both the baseline and demonstration periods.

Negative binomial regression models produce an incidence rate ratio (IRR), which is an estimate of that intervention's effect on the outcome. An IRR greater than 1.0 is associated with an increased likelihood of acute care utilization, and an IRR less than 1.0 is associated with a decreased likelihood of acute care utilization. We report the IRR associated with the D-in-D rates of hospitalizations and ER visits in addition to the IRR's associated *p* value and 95% confidence interval.

5.2.2 Rates of 90-Day Readmissions

We estimated the percent of beneficiaries with at least one readmission within 90 days of discharge and the readmission rate per 1,000 beneficiaries with an index hospitalization. For the Phase II original population, readmissions are identified for index hospitalizations that occurred during 12-month spans in both the baseline and demonstration periods. For the baseline period, we included index hospitalizations in the 12-month period immediately prior to the go-live date of the Phase II original population demonstration period. Therefore, readmissions for baseline period hospitalizations were counted through the first 3 months of the demonstration period. The intervention period for the Phase II original population examined admissions during the periods of months 7 through 18 and included readmissions through months 21. No readmission analysis was done for the Phase II refresh population because there was less than one-year of demonstration experience.

For all hospitalizations, we calculated readmissions for any diagnosis (all-cause readmissions). For the 10 ACSC conditions, a subset of the hospitalizations, we calculated readmissions with a primary diagnosis in the same ACSC category (same cause readmissions). Because readmissions can only occur if there is an initial hospitalization, hospitalization rates can influence readmission rates. To provide context for readmission rate estimates, we estimated the percent of beneficiaries with a hospitalization for any diagnosis and the percent with a hospitalization for one of the 10 ACSC conditions.

Readmission estimates were weighted by the fraction of days eligible until a readmission occurred or up to 90 days following an index hospitalization discharge, if there were no readmission within 90 days. For beneficiaries with more than one index hospitalization, the fraction was calculated by summing eligible days following each hospitalization. To equalize the impact of differences in days of eligibility on readmission rates per 1,000 beneficiaries, counts of hospitalizations were inflated by the fraction of days eligible following index hospitalizations.

The percent of beneficiaries with hospitalization, the percent with a readmission, and the readmission rate per 1,000 beneficiaries with an index hospitalization are presented for the intervention and comparison groups during both the baseline and demonstration periods. For each measure, we compare the change between the baseline and demonstration periods for the intervention group relative to the comparison group, and test for the significance of the D-in-D between the groups. If the Phase II KTBH Demonstration reduced hospitalizations and readmissions, we expect to observe a negative D-in-D, reflecting greater reductions (or smaller increases) in the intervention group relative to the comparison group.

Logistic regression was used to estimate the likelihood of having a hospitalization, and a negative binomial generalized linear model was used for readmission rate estimates. STATA SVY was used to fit the model with robust variance estimation. Regression models were weighted by the eligibility fractions described above. We report the odds ratio (OR) from the logistic regressions and the IRR from the negative binomial regressions of the D-in-D test, along with the associated *p* value and 95% confidence interval. ORs and IRRs less than 1.0 are associated with a negative D-in-D, indicating that the Phase II KTBH Demonstration reduced hospitalizations or readmissions for the intervention group relative to the comparison or slowed the growth in rates.

5.2.3 Mortality

Another outcome metric in this evaluation is mortality. We constructed mortality rates per 100 beneficiaries and compared differences in mortality rates between the Phase II original and refresh intervention and comparison groups between the Phase II go-live dates and the end of the Phase II demonstration period. Date of death was obtained from the Medicare enrollment data base (EDB). Statistical comparison of the mortality rates was made using a *t*-test of differences in mean rates between the intervention and comparison groups.

5.3 Findings

5.3.1 Rates of Hospitalizations and Emergency Room Visits

Hospitalization and ER visit rates per 1,000 Phase II original population beneficiaries for the year prior to go-live and the KTBH Phase II Demonstration period are presented in ***Table 5-1***. Rates of hospitalization and ER visits are presented for all causes and for the 10 ACSCs. Next to the utilization rate columns are the D-in-D rates of change observed between the baseline period and the demonstration period for the intervention and comparison groups. Negative D-in-D rates indicate that the intervention group's mean rate of hospitalization or ER visits declined more, or grew more slowly, than the comparison group's mean hospitalization or ER visit rates.

Table 5-1
Comparison of rates of utilization for the last 12 months of the Phase II KTBH CMHCB Demonstration with rates of utilization for a 1-year period prior to the start of the Phase II KTBH CMHCB Demonstration: Phase II original population

Utilization	Baseline rate per 1,000 I [1,2,3]	Baseline rate per 1,000 C[1,2,3]	Demo period rate per 1,000 I[1,2,3]	Demo period rate per 1,000 C[1,2,3]	D-in-D	IRR[4]	*p*-value	Low CI	High CI
All									
Hospitalizations									
All cause	1,136	1,210	1,519	1,522	71	1.06	0.31	0.95	1.19
10 ACSCs[5]	301	336	436	460	10	1.05	0.59	0.87	1.28
ER/Obs visits									
All cause	1,385	1,401	1,854	1,823	47	1.03	0.67	0.90	1.17
10 ACSCs[5]	284	314	439	444	25	1.09	0.38	0.90	1.33
CKD									
Hospitalizations									
All cause	898	918	1,259	1,253	26	1.03	0.78	0.86	1.23
10 ACSCs[5]	283	302	427	433	12	1.05	0.74	0.79	1.40
ER/Obs visits									
All cause	1,048	1,094	1,510	1,471	84	1.07	0.54	0.86	1.33
10 ACSCs[5]	267	296	419	420	29	1.11	0.50	0.82	1.50
ESRD									
Hospitalizations									
All cause	1,363	1,499	1,769	1,791	114	1.09	0.28	0.94	1.26
10 ACSCs[5]	319	369	444	487	7	1.06	0.68	0.82	1.36
ER/Obs visits									
All cause	1,706	1,704	2,182	2,173	8	1.00	0.97	0.86	1.18
10 ACSCs[5]	300	331	458	469	21	1.08	0.57	0.83	1.40

NOTES: ACSC = ambulatory care sensitive condition; CI = confidence interval; CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ER/Obs = emergency room visits, including observation bed stays; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health; I= intervention population; C = comparison population; D-in-D = difference-in-differences; IRR = incidence rate ratio.

[1] The baseline period is the one-year period prior to the go-live date of the Phase II KTBH Demonstration.

[2] Rates are per 1,000 beneficiaries adjusted for periods of Phase II KTBH CMHCB Demonstration eligibility for the 1-year period prior to the start of the demonstration and for Phase II KTBH CMHCB Demonstration eligibility during the intervention period.

[3] Only beneficiaries who at least 1 day of eligibility in the baseline and demonstration period are included in this analysis.

[4] Statistical testing of the difference-in-differences is conducted in STATA using negative binomial regression for rates/1,000 beneficiaries with robust variance estimation. The IRR is reported for negative binomial regressions. The p-value and confidence interval is reported for the IRRs.

[5] The 10 ambulatory care sensitive conditions are as follows: Heart failure, Diabetes, Asthma, Cellulitis, COPD and Chronic Bronchitis, Dehydration, Bacterial Pneumonia, Septicemia, Ischemic Stroke, and UTI.

SOURCE: RTI analysis of 2008-2011 Medicare enrollment, eligibility, claims and encounter data; Computer runs: acsc01 acsc02 acsctab acsc acsctab1, acsctab1a

Positive D-in-D rates indicate that the comparison group exhibited either lower rates of growth, or a greater rate of decline, for hospitalization or ER visits than the intervention group. The last four columns contain the IRR, its respective statistical level of significance (*p*-value) as well as the high and low 95% confidence interval thresholds for the IRR.

Not unexpectedly, the baseline rates of hospitalization and ER visits were very high in the Phase II original intervention and comparison populations. The baseline rate of all-cause hospitalization was 1,136 per 1,000 Phase II original intervention group beneficiaries. The baseline rate of all-cause ER visits was 1,385 per 1,000 Phase II original intervention beneficiaries. The 10 ACSC reasons for hospitalization combined accounted for roughly one-fourth of all-cause hospitalizations and one-fifth of all-cause ER visits. Thus, Medicare fee-for-service (FFS) beneficiaries in the program were being treated in acute care settings for reasons other than prevalent chronic medical conditions such as heart failure, diabetes, and COPD or prevalent acute medical conditions such as pneumonia.

The rates of all-cause and ACSC hospitalization and ER visits increased between the baseline and demonstration periods for both the Phase II original intervention and comparison beneficiaries. The D-in-D is positive for all the hospitalization rates and all ER visit rates, indicating that the rate for the comparison group grew more slowly than the intervention group. None of the differences are statistically significant.

While we observed different levels of acute care utilization between beneficiaries with CKD versus ESRD with ESRD beneficiaries having almost twice the rate of acute care utilization, the pattern of slower rates of growth within the comparison group versus the intervention group is the same. None of the differences are statistically significant.

For the Phase II refresh beneficiaries, hospitalization and ER visits rates per 1,000 Phase II refresh beneficiaries during the 11 months of the demonstration period and for a comparable 11 months prior to demonstration period are presented in ***Table 5-2***. In contrast to growth patterns observed within the Phase II original population, we observe a slower rate of growth rates of hospitalizations and ER visits within the intervention group compared with the comparison group. The majority of D-in-D rates are negative; however, none are statistically significant. The pattern is the same for beneficiaries with CKD or ESRD; however, we do observe higher growth rates of both hospitalizations and ER visits during the demonstration period among beneficiaries with ERSD as compared to beneficiaries with CKD.

Table 5-2
Comparison of rates of utilization for the 11 months of the Phase II KTBH CMHCB Demonstration with rates of utilization for a comparable 11 month period prior to the start of the Phase II KTBH CMHCB Demonstration: Phase II refresh population

Utilization	Baseline rate per 1,000 I[1,2,3]	Baseline rate per 1,000 C[1,2,3]	Demo period rate per 1,000 I[1,2,3]	Demo period rate per 1,000 C[1,2,3]	D-in-D	IRR[4]	*p*-value	Low CI	High CI
All									
Hospitalizations									
All cause	1,430	1,462	1,329	1,389	-28	0.98	0.74	0.86	1.11
10 ACSCs[5]	454	481	416	450	-6	0.98	0.85	0.80	1.20
ER/Obs visits									
All cause	1,622	1,673	1,535	1,632	-47	0.97	0.64	0.85	1.10
10 ACSCs[5]	419	465	389	435	1	1.00	0.96	0.81	1.23
CKD									
Hospitalizations									
All cause	1,459	1,432	1,240	1,224	-11	0.99	0.94	0.85	1.16
10 ACSCs[5]	511	516	422	433	-6	0.98	0.90	0.77	1.25
ER/Obs visits									
All cause	1,588	1,594	1,448	1,436	17	1.01	0.88	0.87	1.18
10 ACSCs[5]	478	492	403	421	-4	0.99	0.91	0.77	1.26
ESRD									
Hospitalizations									
All cause	1,378	1,516	1,483	1,683	-62	0.97	0.79	0.77	1.21
10 ACSCs[5]	351	418	405	480	-7	1.01	0.97	0.69	1.48
ER/Obs visits									
All cause	1,683	1,815	1,686	1,983	-164	0.92	0.45	0.73	1.15
10 ACSCs[5]	314	417	366	459	9	1.06	0.78	0.71	1.57

NOTES: ACSC = ambulatory care sensitive condition; CI = confidence interval; CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ER/Obs = emergency room visits, including observation bed stays; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health; I = intervention population; C = comparison population; D-in-D = difference-in-differences; IRR = incidence rate ratio.

[1] The baseline period is a comparable 11 months during the one-year period prior to the go-live date for the Phase II KTBH CMHCB Phase II refresh population.

[2] Rates are per 1,000 beneficiaries adjusted for periods of Phase II KTBH CMHCB Demonstration eligibility for 11 month period prior to the start of the demonstration and for Phase II KTBH CMHCB Demonstration eligibility during the 11 months the CMO was active in the program.

[3] Only beneficiaries who at least one day of eligibility in the baseline and demonstration period are included in this analysis.

[4] Statistical testing of the difference-in-differences is conducted in STATA using negative binomial regression for rates/1,000 beneficiaries with robust variance estimation. The incidence rate ratio (IRR) is reported for negative binomial regressions. The p-value and confidence interval is reported for the IRRs.

[5] The 10 ambulatory care sensitive conditions are as follows: Heart failure, Diabetes, Asthma, Cellulitis, COPD and Chronic Bronchitis, Dehydration, Bacterial Pneumonia, Septicemia, Ischemic Stroke, and UTI.

SOURCE: RTI analysis of 2009-2011 Medicare enrollment, eligibility, claims and encounter data; Computer runs: acsc01 acsc02 acsctab acsc acsctab1, acsctab1a

5.3.2 Rates of 90-Day Readmissions

Table 5-3 displays the total number of Phase II original and refresh beneficiaries included in the readmission analyses. ***Table 5-4*** displays the percent of Phase II original population beneficiaries with a hospitalization, the percent of beneficiaries with readmission within 90 days, and the rate of 90-day readmission per 1,000 beneficiaries with an index hospitalization. Data are displayed for all-cause hospitalizations and readmissions, and ACSC hospitalizations and readmissions, in total, and stratified by renal disease status at the time of randomization.

In general, we observe a pattern of stable or modestly changing percentages of beneficiaries hospitalized or readmitted. However, we observe considerable growth in the rate of readmission for all causes and for ambulatory care sensitive conditions during the demonstration period. This indicates that the rate of readmission among the beneficiaries readmitted is growing during the demonstration period likely signaling deterioration in health status. When comparing differences in the rates of growth between the intervention and comparison groups, there is generally a pattern of higher rates of growth within the intervention group. The noted exception is for ACSC same-cause readmissions. The rate declined during the demonstration period for the comparison group while it increased for the intervention group yielding a 7 readmission per 1,000 beneficiaries with and index hospitalization higher growth rate (p=0.02). The trend is observed among beneficiaries with CKD or ESRD; however, the difference in rates of growth is statistically significant only among beneficiaries with CKD (p=0.04).

5.3.3 Mortality

Mortality rates for intervention and comparison groups for both the Phase II original and Phase II refresh populations of the Phase II KTBH Demonstration are displayed in ***Table 5-5.*** Over the demonstration period approximately one-fifth of the Phase II original beneficiaries died in both the intervention and comparison groups. Approximately one-tenth of Phase II refresh beneficiaries died in each of the intervention and comparison groups during the demonstration period. No statistically significant differences in mortality rates for either population or by disease status were observed. The percentage point difference in mortality rates between the Phase II original and Phase II refresh populations is due to a longer demonstration period for the Phase II original population. As noted in ***Chapter 3***, the original and comparison groups had very similar baseline characteristics, thus we would expect similar mortality rates without any intervention.

Table 5-3
Number of beneficiaries included in analysis of readmissions for the Phase II KTBH CMHCB: Phase II original population

Counts of beneficiaries	Intervention	Comparison
All		
Total number of beneficiaries	2,481	2,544
Full time equivalents[1]	2,474	2,539
CKD		
Total number of beneficiaries	1,213	1,265
Full time equivalents[1]	1,209	1,262
ESRD		
Total number of beneficiaries	1,268	1,279
Full time equivalents[1]	1,266	1,277

NOTES: CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health.

[1] Full Time Equivalent for the intervention group during the baseline period is the total number of beneficiaries weighted by their period of eligibility for the demonstration.

SOURCE: RTI analysis of 2008-2011 Medicare enrollment, eligibility, claims and encounter data; Computer runs: readm01 readmtab readm readmtab1, readmtab1a

Table 5-4
Change in 90-day readmission[1] rates between the year prior to the Phase II KTBH CMHCB Demonstration and months 10-21 of the demonstration: Phase II original population

Utilization	Baseline rate per 1,000 [1,2,3] I	Baseline rate per 1,000 [1,2,3] C	Demo period rate per 1,000 [1,2,3] I	Demo period rate per 1,000 [1,2,3] C	D-in-D	OR/IRR[4]	*p*	Low CI	High CI
All									
Hospitalizations									
Percent with hospitalization	51	51	54	53	1	1.03	0.75	0.87	1.20
Percent with ACSC[5] hospitalization	20	21	23	24	-0	0.98	0.86	0.81	1.19
All-cause 90-day readmission									
Percent with readmission	46	49	53	54	2	1.08	0.51	0.86	1.34
Readmission rate / 1,000	1,077	1,242	1,523	1,561	127	1.12	0.17	0.95	1.33
ACSC[5] same-cause 90-day readmission									
Percent with readmission	13	17	16	13	7	1.80	0.02	1.12	2.89
Readmission rate / 1,000	182	250	217	212	72	1.40	0.19	0.84	2.33
CKD									
Hospitalizations									
Percent with hospitalization	45	43	48	47	-1	0.95	0.63	0.75	1.19
Percent with ACSC[5] hospitalization	19	19	22	23	-0	0.99	0.93	0.74	1.31
All-cause 90-day readmission									
Percent with readmission	42	45	50	48	6	1.26	0.19	0.90	1.76
Readmission rate / 1,000	863	1,047	1,321	1,350	154	1.19	0.22	0.90	1.56
ACSC[5] same-cause 90-day readmission									
Percent with readmission	15	19	17	12	9	2.05	0.04	1.03	4.09
Readmission rate / 1,000	219	275	240	226	70	1.33	0.45	0.64	2.79
ESRD									
Hospitalizations									
Percent with hospitalization	57	59	59	59	3	1.11	0.35	0.89	1.40
Percent with ACSC[5] hospitalization	22	24	24	25	-0	0.98	0.87	0.75	1.27
All-cause 90-day readmission									
Percent with readmission	49	52	55	59	-1	0.94	0.69	0.70	1.26
Readmission rate / 1,000	1,239	1,384	1,678	1,730	93	1.08	0.46	0.87	1.34
ACSC[5] same-cause 90-day readmission									
Percent with readmission	12	16	16	14	6	1.61	0.15	0.84	3.09
Readmission rate / 1,000	153	229	198	200	74	1.48	0.26	0.74	2.94

(continued)

Table 5-4 (continued)
Change in 90-day readmission[1] rates between the year prior to the Phase II KTBH CMHCB Demonstration and months 10-21 of the demonstration: Phase II original population

NOTES: ACSC = ambulatory care sensitive condition; CI = confidence interval; CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health; I= intervention population; C = comparison population; D-in-D = difference-in-differences; OR = odds ratio; IRR = incidence rate ratio.

[1] Readmissions are defined as hospitalizations that occur within 90 days after the discharge date of an index hospitalization.

[2] Rates are per 1,000 beneficiaries adjusted for periods of CMHCB program eligibility for the one-year period prior to the start of the demonstration and for CMHCB program eligibility during the demonstration period.

[3] Only beneficiaries who at least one day of eligibility in the baseline and demonstration period are included in this analysis.

[4] Statistical testing of the difference-in-differences is conducted in STATA using logistic regression for percentages and negative binomial regression for rates/1,000 beneficiaries. Robust variance estimation is used for both logistic and negative binomial regressions. The OR is reported for logistic regressions; the IRR is reported for negative binomial regressions. The *p*-value and confidence interval is reported for odds ratios and IRRs.

[5] The 10 ambulatory care sensitive conditions are as follows: Heart failure, Diabetes, Asthma, Cellulitis, COPD and Chronic Bronchitis, Dehydration, Bacterial Pneumonia, Septicemia, Ischemic Stroke, and UTI.

SOURCE: RTI analysis of Medicare enrollment, eligibility, claims and intervention data; Computer runs: readm01 readm02 readmtab1, readmtab1a

Table 5-5
Mortality rates during the Phase II KTBH CMHCB Demonstration: Phase II original and Phase II refresh populations

Description	Intervention number of deaths	Percent	Comparison number of deaths	Percent	Difference	p value
Phase II original population (21 months)						
All	590	21.8	588	21.3	0.6	0.61
CKD	270	20.5	251	18.4	2.1	0.18
ESRD	320	23.2	337	24.1	-0.9	0.56
Phase II refresh population (11 months)						
All	254	11.8	248	11.5	0.3	0.76
CKD	169	12.3	162	11.7	0.6	0.62
ESRD	85	10.9	86	11.1	-0.2	0.88

NOTES: CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health.

SOURCE: RTI analysis of Medicare enrollment, eligibility, claims and intervention data; Computer runs: mortality.sas, mortalitya.sas

5.4 Conclusions

RTI's analysis of quality of care focuses on measuring effectiveness of the Phase II KTBH CMHCB Demonstration intervention by answering the following evaluation questions:

- Did the Phase II KTBH Demonstration improve intermediate health outcomes by reducing acute hospitalizations, readmissions, or ER utilization?
- Did the Phase II KTBH Demonstration improve health outcomes by decreasing mortality?

During the course of the Phase II KTBH Demonstration, we generally observed increasing rates of all-cause and ACSC hospitalizations, ER visits, and 90-day readmissions in both the intervention and comparison groups and for both the Phase II original and refresh populations. We observed no statistically significant differential rates of hospitalizations or ER visits during the demonstration period relative to the baseline period for either population. Of all

the 33 outcome measures reported for the Phase II original population[7], only two were found to be statistically significant: percent of beneficiaries with ACSC same-cause readmissions for all Phase II original beneficiaries and for the CKD group within that population. However, that measure showed a decline during the demonstration period for the comparison group, while the measure increased for the intervention group during the same period. While the trend for this measure was the same for beneficiaries with ESRD, it was not statistically significant for those beneficiaries. Further, we found no differential rate of mortality between the Phase II intervention and comparison groups in either the Phase II original or Phase II refresh populations, nor by disease.

[7] Note that none of the 15 outcome measures for the Phase II refresh population were statistically significant.

CHAPTER 6
FINANCIAL OUTCOMES

6.1 Introduction

In this section, we present *final* evaluation findings on levels and trends in Medicare costs for the year prior to the Phase II go-live date and through 21 or 11 months for the original and refresh groups, respectively. The evaluation cost questions we address are:

- What were the Medicare costs per beneficiary per month (PBPM) in the Phase II base year versus the next 21 or 11 months of the demonstration for the intervention and the comparison groups?

- What were the levels and trends in PBPM costs for intervention group participants and nonparticipants? Did nonparticipation, alone, materially reduce the intervention's overall cost savings?

- How variable are PBPM costs in this high cost, high risk, population? What was the minimally detectable savings rate given the variability in beneficiary PBPM costs?

- How did Medicare savings compare with the fees that were paid out? How successful was the Phase II KTBH Demonstration in meeting budget neutrality?

- How balanced were the intervention and comparison group samples prior to the demonstration's start date? How important were any imbalances to the estimate of savings?

- Did the intervention have a differential effect by CKD or ESRD group?

- What evidence exists for regression-to-the-mean (RtoM) in Medicare costs for beneficiaries in the intervention and comparison groups?

The cost analyses presented in this section differ from those conducted for financial reconciliation by ARC under contract to CMS. ARC determined savings based on the demonstration's terms and conditions negotiated between CMS and KTBH. RTI's estimation of savings, detailed subsequently, differs from ARC's in that

- differences in savings rates between intervention and comparison groups are first determined at the beneficiary level and are then tested using statistical confidence intervals,

- beneficiary PBPM costs are not trimmed using a 1% outlier dollar threshold, and

- both base year and demonstration period PBPM costs are weighted by each beneficiary's fraction of eligible days during the demonstration period.

A more detailed explanation and justification for these differences is provided in ***Section 6.3***.

The rest of this chapter has five sections. The next two sections describe our data sources, variable construction, and analytic methods. ***Section 6.4*** presents our primary findings on trends in PBPM costs between base and demonstration periods. ***Section 6.5*** shows PBPM savings in relation to average monthly fees and whether the Phase II KTBH Demonstration achieved budget neutrality using RTI's costing methods. ***Section 6.6*** stratifies PBPM costs and savings by disease group and other beneficiary characteristics to test for possible imbalances in the intervention and comparison groups. ***Section 6.7*** uses multivariate regression to control for any imbalances between intervention and comparison samples that might affect t-tests of mean differences in PBPM growth rates. The chapter concludes in ***Section 6.8*** with a summary of key findings.

6.2 Data and Key Variables

6.2.1 Sample Frame and Data

RTI's analyses of PBPM costs were based on Medicare Parts A and B claims for all eligible beneficiaries in the Phase II KTBH Demonstration intervention and comparison groups. Two cohorts were analyzed:

1. The Phase II original cohort that started Phase II on August 1, 2009.
2. The Phase II refresh cohort that started on June 1, 2010.

Performance in both was evaluated through April 30, 2011.

We restrict all analyses to beneficiaries who were alive at the start date of the Phase II demonstration. Claims costs are accumulated until a beneficiary dies or otherwise becomes ineligible (e.g., joins a managed care plan). Claims represent utilization anywhere in the United States, not just the target area of the demonstration. Medicare costs are based on eligible claims submitted during the full demonstration period plus 12 months prior to the start date for each cohort participating in Phase II. A 9-month "run-out" period after the demonstration ended assures a complete set of costs.

6.2.2 Constructing PBPM costs

All financial analyses were conducted on a PBPM basis using the ratio of eligible Medicare costs to eligible months. The baseline period is defined as 365 days (or 1 year) prior to the Phase II KTBH Demonstration's start date. The 21-month demonstration period for the Phase II original population includes 639 days (21 months × 30.42 days/month) after the start date. The Phase II refresh population covers 11 months, or 335 days.

Medicare program costs in the numerator of PBPM costs include

- only Medicare program Part A and B payments; patient obligations and Part C (managed care) and D (drugs) are excluded;

- only claims for utilization of beneficiaries when they are eligible for the demonstration[8]; and

- only claims for eligible services.

To statistically test hypotheses regarding *trends* in beneficiary costs, average PBPM costs first must be calculated at the beneficiary level. Constructing individual PBPM costs required dividing a beneficiary's total cost during eligible periods by his or her own fraction of eligible months during the base year and the demonstration period. Most beneficiaries had 12 months of base year eligibility and 21 or 11 months of demonstration period eligibility. However, some beneficiaries had fewer than the maximum number of eligible months (or days), usually due to death. At the extreme, a beneficiary could have a 10-day hospital admission at the beginning of the intervention period with a combined Part A and B payment of $30,000 before dying. This $30,000 outlay is divided by approximately 1/3 (10 days / 30.42 days), resulting in an adjusted PBPM outlay of $90,000. Consequently, (unweighted) PBPM costs exhibit substantial variation that, in turn, reduces the likelihood of finding statistical differences. Weighting by the fraction of eligible days corrects for having to "blow up" costs to the PBPM level.

Variation can be reduced by trimming high PBPM outliers at the 99th percentile, as done by CMS for financial reconciliation. While the 1% trim reduces the Phase II KTBH Demonstration's financial risk, we wanted to avoid biasing comparisons against interventions that constrained spending among the most expensive beneficiaries. Instead of trimming or deleting outliers, RTI weighted PBPM mean costs and standard errors by each beneficiary's eligible fraction of days, or exposure to the intervention. In the previous example, the beneficiary's adjusted $90,000 PBPM cost is weighted by 10/639 = 0.016 in the Phase II original population, or roughly 64-times less than beneficiaries with full eligibility through the entire demonstration period. This weighting method is equivalent to simply adding the beneficiary's $30,000 and 10 eligible days to total costs and days of fully eligible beneficiaries and then calculating the combined PBPM cost.

Table 6-1 shows unweighted mean intervention group PBPM costs in KTBH's Phase II original population (2,701 with eligible days in both the base and intervention period) stratified by beneficiaries' percentage of eligible days in the demonstration period (639 maximum). Those with one-third or fewer eligible days had overall PBPM costs averaging $21,351. Beneficiaries eligible for the entire Phase II had average PBPM costs of $4,842. Beneficiaries with truncated eligibility averaged monthly costs 4.4 times greater than those with much longer eligibility. Although beneficiaries with less than 33% of eligibility were only 9.4% of the entire intervention group, their PBPM costs add disproportionately both to the mean and variation in PBPM costs. (See ***Section 6.3.2*** for statistics on PBPM variation.) Maximum intervention period PBPM costs were $351,827.

[8] For example, if a beneficiary joined a managed care plan for a few months then returned to fee for service (FFS) Medicare, any claims for plan services were excluded.

Table 6-1
Mean PBPM costs by percent of eligible days for the Phase II KTBH CMHCB Demonstration: Phase II original population

Eligible days[1]	N (%)	PBPM	Range
< = 33%	255 (9.4%)	$21,351	$0–351,827
34-66%	227 (8.4)	11,989	0–53,199
67–99%	229 (8.5)	9,091	0–35,864
100%	1,990 (73.7)	4,842	1,016–57,950
Overall	2,701 (100.0)	7,361	0–351,827

NOTES: Observations unweighted. CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month; N (%) = number of beneficiaries (percent of all eligibles).

[1] Percent of days beneficiary eligible for intervention.

SOURCE: Medicare 2008-2011 Part A & B claims; COSTRUN2 (9/7/12).

Table 6-2 shows the unweighted cost effects of 2,155 eligible beneficiaries in the Phase II refresh population. Again, beneficiaries with less than 33% eligibility were 4.3 times more costly per month as those with complete eligibility. Maximum PBPM costs were $96,817.

Table 6-2
Mean PBPM costs by percent of eligible days for the Phase II KTBH CMHCB Demonstration: Phase II refresh population

Eligible days[1]	N (%)	PBPM	Range
< = 33%	101 (4.7%)	$17,852	$0–96,817
34–66%	117 (5.4)	10,520	0–49,177
67–99%	114 (5.3)	9,484	34–42,021
100%	1,823 (84.6)	4,159	0–37,979
Overall	2,155 (100.0)	5,428	0–96,817

NOTES: Observations unweighted. CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month; N (%) = number of beneficiaries (percent of all eligibles).

[1] Percent of days beneficiary eligible for intervention.

SOURCE: Medicare 2009-2011 Part A & B claims; COSTRUN2 (9/7/12).

6.2.3 Monthly Fees

Demonstration Care Management Organizations (CMOs) proposed monthly fees when submitting their applications for the demonstration program to the CMS Office of Demonstrations. CMS then negotiated final fees as part of each CMO's agreed-upon contract terms and conditions. RTI benchmarked savings against each CMO's initially negotiated fee. For the Phase II KTBH Demonstration, its negotiated management fee was $180 for both the Phase II original and Phase II refresh populations (ARC's Financial Reconciliation for VillageHealth Phase II, May 11, 2012, Table 3).

6.3 Analytic Methods

RTI's analytic approach is based on a *comparison of growth rates in PBPM costs at the individual beneficiary level*. This approach has two principal strengths:

- First, it controls in a more precise, beneficiary-specific manner for any differences in PBPM costs between the base year and the demonstration period that are not accounted for through the selection process.

- Second, by calculating changes in PBPM costs at the beneficiary level (i.e., "paired" base-demonstration period PBPM costs), we can conduct statistical *t*-tests of the differences in spending growth rates between intervention and comparison groups.

In addition to answering the question of whether any or all of the CMHCB demonstration programs achieved budget neutrality (or any savings), we also are interested in *generalizing* results to future care management activities by answering the question, "What savings are likely to be realized if the demonstration is expanded?" This question necessarily requires testing the hypothesis that any savings in a sample of beneficiaries during a particular time period could have been caused by chance with no long-run implications. RTI conducted a range of analyses to answer the key financial questions.

6.3.1 Tests of Gross Savings

Gross savings to Medicare is defined as the difference between the claims costs of the intervention and comparison groups. There are two ways to calculate these differences. Assuming that the selection process balanced the intervention and comparison populations, PBPM cost differences between the two groups can be based solely on the demonstration period. That is, the Phase II KTBH Demonstration was neither advantaged nor disadvantaged by the costliness of their sample relative to their comparison group. However, more than one year passed between the time the beneficiaries were assigned to the intervention and comparison groups and when the Phase II KTBH Demonstration began recruiting beneficiaries to the intervention. Also, because we wanted to conduct statistical tests of intervention effects, it was necessary to construct PBPM cost estimates at the beneficiary level and then use variation in the observations to produce confidence intervals around the estimates.

Recognizing that base year costs may be different between intervention and comparison populations, we used a mixed paired sample approach. First, we used each beneficiary's own mean PBPM costs in the base year just prior to the Phase II KTBH Demonstration's start date

and the intervention period to construct a change in costs. This was done for all beneficiaries in both the intervention and comparison groups, thereby producing a paired comparison within group. Next, we determined the mean difference in the differences in PBPM cost growth rates for each group, treating the mean differences as independent samples.[9] The strength of first calculating the change in PBPM costs at the beneficiary level is that it completely controls for any unique clinical and socioeconomic characteristics that might differ between the intervention and comparison groups. Any imbalances in beneficiary characteristics that might produce inter-temporal differences in medical utilization or costs are factored out using first-differencing. Our gross savings rate, in equation form, is

$$Gross\ Savings = Diff[I] - Diff[C] = [I_t * - I_b *] - [C_t * - C_b *] = \Delta I * - \Delta C * \quad (6.1a)$$

$$Gross\ Savings = [I_t * - C_t *] - [I_b * - C_b *], \quad (6.1b)$$

where * = the mean difference in PBPM costs within all intervention (I) or comparison (C) beneficiaries, t and b = demonstration and base periods, and Δ = the change in PBPM costs between the base and demonstration periods. Savings, as the difference-in-(paired) differences, is equivalent to adjusting the difference in intervention and comparison means during the demonstration by the mean difference that existed in the base year (eq. 6.1b).

In calculating mean changes in PBPM costs across beneficiaries, each beneficiary's *change* needs to be weighted to produce an unbiased estimate of the overall mean change. We used the beneficiary's fraction of eligible days during the demonstration period as weights. This effectively weights each beneficiary's base period PBPM costs by their proportion of days during the demonstration period. Consequently, early demonstration dropouts (usually due to death) will have their base period PBPM costs underweighted relative to their actual contribution when displaying base period mean costs for intervention or comparison groups. As early demonstration dropouts tend to be more costly in the base period, our mean base year costs will appear lower than actuarial means based on their proportion of days during the base period. It did not seem reasonable to give beneficiaries with only a few days involvement in the actual demonstration full credit in calculating mean base year costs even if they had 12 months of base year Medicare eligibility.

6.3.2 Detectable Savings

In all of the analyses in this chapter, we test the hypothesis of whether gross savings is statistically different from zero, or no savings. Gross savings must be sufficiently greater than zero to assure the government that the measured savings rate was not due to chance.[10] A critical evaluation question is the power we had to detect relatively small savings rates. By "detectable" we mean the rate of savings that would force us to reject the null hypothesis of no savings at all.

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[9] For a more detailed description of this approach, see Rosner (2006, chapter 8).

[10] Chance savings can occur primarily because of random fluctuations in the utilization of health services required in the intervention and comparison groups. It is possible that random declines in health in the intervention group unrelated to the intervention could explain lower savings rates.

Having completed the demonstration, we now have the information on both the level and variation in savings rates that allows us to calculate the detectable savings threshold for the Phase II KTBH Demonstration.

The fundamental test statistic is the Z-ratio of gross savings (see eq. 6.1a) to its standard error (SE)

$$Z = [\Delta I - \Delta C] / SE_{[\Delta I - \Delta C]} \tag{6.2}$$

$$SE_{[\Delta I - \Delta C]} = [SE_{\Delta I}{}^2 + SE_{\Delta C}{}^2]^{0.5} \tag{6.3}$$

A two-sided test[11] of intervention savings uses the following confidence interval:

$$-1.96 SE_{[\Delta I - \Delta C]} <= Savings <= 1.96\, SE_{[\Delta I - \Delta C]}, \tag{6.4}$$

and the detectable threshold is

$$Detectable\, Threshold\ (DT) = -1.96\, SE_{[\Delta I - \Delta C]} \tag{6.5}$$

Intervention savings must equal or exceed -1.96 times the standard error of the difference in the growth in intervention and comparison PBPM costs. (Savings are expressed in negative terms if intervention PBPM cost growth is less than the comparison group cost growth.) The detectable threshold (DT) is approximately double the standard error of the difference in mean growth rates, which in turn varies with the square root of the intervention and comparison group sample sizes. It is also convenient for some analyses to express the DT as a percent of the comparison group's demonstration mean PBPM cost, or $DT/PBPM_c$.

Tables 6-3 and ***6-4*** show the variation that exists in the (unweighted) PBPM costs in the base year and demonstration period for the Phase II KTBH Demonstration's intervention and comparison samples. Mean Phase II original PBPM costs in the base period ranged from a low of $0 to a high of $42,428 in the comparison group. The coefficient of variation (CV), or the standard deviation of beneficiary-level PBPM costs divided by the mean, is approximately 1.0 in the base year. CVs in the original and refresh samples increased in both the comparison and intervention groups during the demonstration period. Extraordinary maximum PBPMs occurred in the demonstration period partly because of very short eligibility spells. Some of the variation is reduced later in this chapter after weighting observations by the eligibility fraction when determining intervention savings.

[11] A reasonable argument can be made that the detectable threshold should be based on a one-sided *t*-test if one assumes that any chronic care management intervention would not be expected to *increase* Medicare outlays. If an intervention is likely only to reduce costs, a one-sided test effectively puts all 5% of the possible error on the negative side, resulting in a detectable threshold only -1.68 times the standard error.

Table 6-3
PBPM cost distribution thresholds, original comparison and intervention groups, base and demonstration periods for the Phase II KTBH CMHCB Demonstration program

Quantiles[1]	Base year comparison	Base year intervention	Demonstration period comparison	Demonstration period intervention
(N)	(2763)	(2701)	(2763)	(2701)
Minimum	$0	$0	$0	$0
<10%	421	408	587	585
<25%	1,276	1,400	1,915	2,150
Median	4,345	4,367	4,381	4,537
>25%	7,467	7,330	8,561	8,559
>10%	12,021	11,724	14,814	15,747
Maximum	42,428	54,547	221,238	351,827
Mean	5,390	5,418	6,837	7,361
CV	0.96	0.97	1.36	1.63

NOTES: Observations unweighted. CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month; N = number of beneficiaries; CV = coefficient of variation.

[1] <10%, <25%, >25%, >10%: Percent of PBPMs below or above percentage.

SOURCE: Medicare 2008-2011 Part A & B claims; COSTRUN2 (9/7/12).

The difference between median and mean PBPM costs indicates how skewed costs are. Mean costs are over 50% greater than median costs in the refresh group during the intervention period, indicating a strong right tail of very high costs (Table 6-4). Note that 25% of refresh beneficiaries had demonstration year costs less than $930-944. Maximum values show how high intervention PBPM costs can be before weighting, $96,817-$233,948 per month. As shown earlier in Table 6-1, these costs are often incurred by beneficiaries with very short eligibility who died early in the demonstration period. Weighting these short-eligible, very high cost beneficiaries reduces overall variance and produces lower detectable thresholds.

Because of the relatively large variances in the base year PBPM costs, coupled with adjustments for the repeated nature of the experimental design, the power afforded by the sample sizes was modest, i.e., about 40% at best.[12]

[12] Power for a comparison of two mean changes in PBPMs is given by $\Phi[-1.96 + (vn\Delta/(\sigma_d v2)]$ (Rosner, 2006, p. 336). $\sigma_d = [\sigma_1^2 + \sigma_2^2 - 2\rho\sigma_1\sigma_2]^{0.5}$, where subscripts 1 and 2 pertain to variances in study and control PBPMs, and ρ = correlation between observations between the base and intervention periods. The study and control standard deviations in the base period were 4,714 and 4,883, respectively. Assuming a .33 intra-patient period correlation, $\sigma_d = 5{,}556$. If there were no increase in the comparison group's PBPM over time, then Δ = .05($5,066) = $253. The treatment n = 2,701. Thus, power = $\Phi[-1.96 + (\$253 \bullet 52/\$5556 \bullet 1.41 = 1.67) = -.29] = 1 - \Phi[.29] = 0.39$. With the KTBH intervention sample, we had 39% likelihood of accepting a significant difference if the true mean change in the intervention PBPM was $253 less than the change in the comparison PBPM.

Table 6-4
PBPM cost distribution thresholds, refresh comparison and intervention groups, base and demonstration periods for the Phase II KTBH CMHCB Demonstration program

Quantiles[1]	Base year comparison	Base year intervention	Demonstration period comparison	Demonstration period intervention
(N)	(2159)	(2155)	(2159)	(2155)
Minimum	$0	$0	$0	$0
<10%	654	727	311	331
<25%	1,416	1,575	930	944
Median	3,804	3,954	3,142	3,165
>25%	7,390	7,165	7,071	6,728
>10%	13,474	12,541	13,699	12,417
Maximum	65,915	71,293	233,948	96,817
Mean	5,721	5,550	5,919	5,428
CV	1.14	1.06	1.78	1.41

NOTES: Observations unweighted. CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month; N = number of beneficiaries; CV = coefficient of variation.

[1] <10%, <25%, >25%, >10%: Percent of PBPMs below or above percentage.

SOURCE: Medicare 2008-2011 Part A & B claims; COSTRUN2 (9/7/12).

6.3.3 Budget Neutrality

Each CMO is obligated to produce net savings for the Medicare program. The net savings requirement for Phase II original and refresh cohorts was 2.5%. Thus, to avoid paying back any fees with a 2.5% net savings requirement,

$$PBPM_I <= 0.975PBPM_C - MF \quad (6.6a)$$

or as a fraction of the comparison PBPM cost,

$$PBPM_I/PBPM_C < = 0.975- (MF/PBPM_C, \quad (6.6b)$$

where $PBPM_I$, $PBPM_C$ = average monthly costs in the intervention and comparison groups, MF = the average monthly fee.

For example, if a KTBH's monthly fee were 5% of the comparison groups' PBPM cost, then intervention PBPM costs could be only 92.5% or less of monthly comparison costs to avoid

paying back fees. KTBH's payback obligation per intervention beneficiary month is the positive difference:

$$\text{Payback} = PBPM_I - [0.975PBPM_c + MF]. \quad (6.6c)$$

RTI's conclusion regarding budget neutrality will differ from that reported by the CMS financial reconciliator given the way we adjust for unequal base period costs, how fees are calculated, the lack of an outlier trim, and a few other minor differences. Because we use statistical confidence intervals to judge the extent of gross savings, we test whether a KTBH achieved any savings at all: the Z-test against zero savings.

In addition to Z-tests of mean cost differences between the entire intervention group and the comparison group, we also tested for differences in PBPM cost growth rates between intervention beneficiary participants and nonparticipants relative to the comparison group. If the intervention had more success with those beneficiaries it actually engaged, then savings should be greater for participants than nonparticipants.

6.3.4 Adjusting for Unbalanced Intervention and Comparison Groups

Two approaches were used to test the effects of imbalances between the intervention and comparison groups in base year characteristics. First, we produced frequency distributions of key beneficiary characteristics between the two groups. Second, we used multivariate regressions to quantify the effects of any imbalances on trends in PBPM costs. We pooled base and demonstration period observations and regressed each beneficiary's own demonstration period PBPM cost on group status (I = intervention; C = comparison); each beneficiary's own base period $PBPM_{pb}$ cost; the beneficiary's disease group (CKD or ESRD) in the base year, and a vector of base period beneficiary characteristics (Char):

$$PBPM_{pt} = \alpha + \beta Status_p + \gamma PBPM_{pb} + \Sigma_r \rho_r Dis_{pr} + \Sigma_k \delta_k Char_{pk} + \varepsilon_{pt} \quad (6.7)$$

The intercept, α, is the comparison group's average PBPM cost in the base year, while γ = the average dollar increase in PBPM costs over 16.5 months (i.e., between the sixth month of the base year to the 10.5 mid-period month of the demonstration). γ provides a test of regression to the mean (RtoM) effects. The smaller the γ, the greater the RtoM. The *t*-value for β tests the differences in intervention and comparison demonstration cost growth, while ρ_r tests for the difference in the growth rates for the two disease groups. By including each beneficiary's age, gender, race, urban/rural residence, disabled status, Medicaid eligibility, and institutional status at the start of the demonstration, we purge the intervention effect and other coefficients of any systematic differences between the intervention and comparison groups that remained at the start of the demonstration. Inclusion of these variables also narrows the confidence intervals around the other coefficients, thereby reducing detectable thresholds that result in more precise estimates of mean intervention effects (Greene, 2003, chapter 6).

6.4 PBPM Cost Levels and Trends

6.4.1 Original Sample

Table 6-5 displays PBPM cost levels and rates of growth in average PBPM costs between the base year and the demonstration period for the original Phase II sample. Results are shown for the entire intervention group and for participating and nonparticipating beneficiaries, separately. PBPM costs in both periods have been weighted by the fraction of days beneficiaries were eligible in the demonstration period so as not to overweight beneficiaries who were exposed to the intervention for shorter periods. Only beneficiaries with at least 1 day of demonstration eligibility in both periods were included.

Table 6-5
PBPM cost growth rates between base year and demonstration period, intervention and comparison groups for the KTBH Phase II CMHCB Demonstration: Phase II original population

Study group	Beneficiaries	Base year PBPM mean[1]	Base year PBPM standard error	Demonstration PBPM mean[1]	Demonstration PBPM standard error	Differences in means	Standard error
Intervention	2,701	$5,066	90.7	$5,725	114.5	$659**	110.7
Participants	664	5,197	104.4	5894	127.4	697**	122.7
Nonparticipants	2,037	4,604	182.8	5126	256.0	522*	250.3
Comparison	2,763	5,062	92.9	5515	108.8	453**	104.6
Differences							
I – C	—	4.1	129.9	210	157.9	206	152.2
Participants – C	—	134.7	140.2	379*	167.1	244	166.7
Nonparticipants – C	—	-458.9	217.5	-389	263.8	69	254.4
Participants – Nonparticipants	—	593.2**	218.8	768**	276.1	175	267.1

NOTE: CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month; I = intervention; C = comparison.

[1] Means weighted by beneficiary fraction of eligible days in demonstration period.

*$p < .05$; **$p < .01$.

SOURCE: Medicare 2008-2011 Part A&B claims; run costrun1 (10/8/12).

Overall. The weighted base year average PBPM cost was $4.10 more ($p$ = insig) in the intervention group versus the comparison group ($5,066 versus $5,062), or 0.08%. The intervention-comparison difference in PBPM Medicare costs increased to $210 ($p$ = insig) in the demonstration period ($5,725 versus $5,515). Between the base year and the end of the demonstration period, the average comparison group PBPM cost increased significantly by $453 ($p < .01$), while the intervention group's PBPM average Medicare costs rose even faster by $659 ($p < .01$). Consequently, the intervention group's PBPM cost rose $206 faster ($p$ = insig) than the comparison group's PBPM cost. Intervention beneficiaries, who were essentially equally costly on a weighted basis at baseline, became 3.7% more costly, on average, than the comparison group during the demonstration period.

Participation Status. The participation rate, based on beneficiaries used in the cost analysis, was 25% (664/2,701). Participants in the KTBH intervention were $135 more costly than the comparison group in the base period. Non-participants were $459 less costly (p = insig). Participants became $379 more costly (p = insig) than comparison beneficiaries during the demonstration period. Non-participants became $389 less costly (p<.05) during the demonstration period.

6.4.2 Refresh Sample

Table 6-6 displays PBPM cost levels and rates of growth in average PBPM costs between the 12-month base year and the end of the 11-month demonstration period for the refresh sample. The weighted base year average PBPM cost was $166 less ($p$ = insig) in the intervention versus comparison group ($5,332 versus $5,497), or 3%. The intervention-comparison gap in PBPM Medicare costs reversed in the demonstration period ($4,698 versus $4,963). The average comparison group PBPM decreased $535 (p<.01) while the intervention group's PBPM average Medicare costs decreased $633 (p<.01). As a result, the intervention group's PBPM cost grew $99 slower ($p$ = insig) compared with the comparison group's PBPM cost. Intervention beneficiaries, who were 3% more costly at baseline, were 6% less costly than the comparison group, on average, after 11 months.

Table 6-6
PBPM cost growth rates between base year and demonstration period, intervention and comparison groups for the Phase II KTBH CMHCB Demonstration: Phase II refresh population

Study group	Beneficiaries	Base year PBPM mean[1]	Base year PBPM standard error	Demonstration PBPM mean[1]	Demonstration PBPM standard error	Differences in means	Standard error
Intervention	2,155	$5,332	120.9	$4,698	124	-$633**	131.8
Participants	899	5,739	186.1	4,958	185	-781**	202.5
Nonparticipants	1,256	5,023	158.6	4,502	167	-522**	173.6
Comparison	2,159	5,497	133.6	4,963	148	-535**	159.1
Differences							
I – C	—	-166	180.2	265	192.8	-99	206.6
Participants – C	—	241	237.7	5	256.1	-246	277.0
Nonparticipants – C	—	-474*	213.8	-461*	232.6	13	248.2
Participants – Nonparticipants	—	716**	243.8	456	250	-259	266.1

NOTE: CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month; I = intervention; C = comparison.

[1] Means weighted by beneficiary fraction of eligible days in demonstration period.

*p < .05; **p < .01.

SOURCE: Medicare 2009-2011 Part A&B claims; run costrun1 (10/8/12).

The participation rate, based on beneficiaries used in the refresh cost analysis, was 42% (899/2,155). Participants in the base period in the KTBH intervention group were $241 more costly (p<.01) than comparison group beneficiaries and nonparticipants were $474 less costly (p<.05). Participants and comparison beneficiaries were essentially equally costly (p < .01) in

the demonstration period. Consequently, the participant group's PBPM cost fell $246 faster (p=insig) than the comparison group's costs.

6.5 Savings and Budget Neutrality

6.5.1 Phase II Original Sample

Table 6-7 presents summary statistics on savings from the KTBH's original intervention sample. It also includes the minimum level of savings necessary to achieve statistical significance, expressed in negative terms, and as a percentage of the comparison group's PBPM cost. The Phase II KTBH Demonstration's monthly fee is reported also as a percentage of the comparison group's PBPM cost.

Table 6-7
Average PBPM gross savings, fees, and budget neutrality status for the Phase II KTBH CMHCB Demonstration: Phase II original population

Description	PBPM cost change
Intervention group	$659
Comparison group	$453
Difference	$206
Gross (dis)saving %[1]	3.7%
Minimal Detectable Savings[2]	
Absolute	-$298
% of comparison PBPM[3]	-5.4%
Monthly Fee	
Absolute[4]	$180
% of comparison PBPM[3]	3.3%
Net Fee	
Absolute[5]	$386
% of comparison PBPM[3]	7.0%
Return on Investment (RoI)[6]	-1.14

NOTES: CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month.

[1] Gross (Dis)Savings % = Difference in PBPM outlay changes as % of comparison PBPM (= $5,515). Negative values imply true savings.

[2] Minimum Detectable Savings = 1.96*standard error of difference in mean PBPM changes.

[3] % Comparison PBPM = Absolute variable as % of comparison PBPM ($5,515) in demonstration period.

[4] Absolute Monthly Fee = $180 for 21 months.

[5] Absolute Net Fee = Monthly fee + Difference in PBPM outlay change.

[6] RoI = gross savings difference/Absolute Monthly Fee.

SOURCE: Medicare 2009-2011 Part A&B claims; PBPM cost changes and detectable savings: Table 6-5; monthly fees: ARC, Final Reconciliation for VillageHealth Phase II, May 11, 2012, Table 3.

Over the course of the 21-month intervention, average monthly costs increased $659 in the intervention group and $453 in the comparison group. The result was a $206 higher average PBPM cost growth in the intervention group. This positive difference implies *dis-savings* at a rate of 3.7% of the comparison group's demonstration period PBPM cost. The rate of dis-savings was statistically insignificant.

With over 2,700 beneficiaries each in the intervention and comparison groups, the minimal detectable savings threshold was -$298 at the two-sided 95% confidence level. This rate was 5.4% of the comparison group's PBPM cost. The intervention would have had to achieve this level of savings to be considered statistically reliable in repeated patient samples.

The Phase II KTBH Demonstration's average monthly fee was $180, which amounted to 3.3% of the comparison group's PBPM during the demonstration period. Thus, the KTBH Phase II Demonstration would have had to achieve 5.8% (3.3% + 2.5%) savings in order to retain all of its fees—at least according to RTI's calculations, which are not official under financial reconciliation. Because of negative gross savings, the demonstration's effective monthly fee was $386 ($180 + $206). The Phase II original intervention group had a negative return on investment.

6.5.2 Phase II Refresh Sample

Table 6-8 presents summary statistics on savings from the KTBH Phase II intervention refresh sample. Over the course of the 11-month intervention, average monthly costs fell $633 in the intervention group and $535 in the comparison group. The result was a $99 greater relative decline in PBPM cost growth in the intervention group. This negative difference implies *savings* at a rate of 2.0% of the comparison group's PBPM cost.

With roughly 2,160 beneficiaries in each study group, the minimal detectable savings threshold was -$405 at the 95% confidence level. This rate was 8.2% of the comparison group's PBPM cost, implying that the intervention would have had to achieve this level of savings to be considered statistically reliable in repeated patient samples. Ignoring the fact that the $99 in intervention savings was not statistically different from zero, the net fee to Medicare was reduced from $180 per beneficiary per month to $81, resulting in a net cost of 1.6% of the comparison group's average monthly outlay on claims. Based on actuarial methods, Medicare's return on investment was 0.55, implying that Medicare saved $0.55 in the Phase II refresh sample for every $1in fees it invested. However, the refresh RoI could also be zero in a future intervention.

6.6 Imbalances Between Intervention and Comparison Samples

Initial random sampling should have balanced the intervention and comparison groups on factors affecting cost growth. Yet, it is still possible that small, but possibly important, imbalances remained simply by chance. It is possible that CKD and ESRD patients, with very different annual costs, were not equally distributed across the two groups.

For differences in beneficiary characteristics to have any effect on intervention savings, two things must happen. First, one or more characteristics must have a statistically important effect on PBPM cost growth rates. Second, the same important characteristics must significantly differ, numerically, between the intervention and comparison groups. Because most characteristics are simple binary (0, 1) indicators, there must be substantial numbers of "costly" beneficiaries involved and not just large differences in relative frequencies. If Medicaid coverage were 2% in the intervention group and only 1% in the comparison group, this 100% difference in relative frequencies will not materially affect overall growth rates.

Table 6-8
Average PBPM gross savings, fees, and budget neutrality status for the Phase II KTBH CMHCB Demonstration: Phase II refresh population

Description	PBPM cost change
Intervention group	-$633
Comparison group	-$535
Difference	-$99
Gross (dis)saving %[1]	2.0%
Minimal Detectable Savings[2]	
Absolute	-$405
% of comparison PBPM[3]	-8.2%
Monthly Fee	
Absolute[4]	$180
% of comparison PBPM[3]	3.6%
Net Fee	
Absolute[5]	$81
% of comparison PBPM[3]	1.6%
Return on Investment (RoI)[6]	0.55

NOTES: CMHCB = Care Management for High Cost Beneficiaries; KTBH = VillageHealth's Key to Better Health; PBPM = per beneficiary per month.

[1] Gross (Dis)Savings % = Difference in PBPM outlay changes as % of comparison PBPM (= $4,963). Negative values imply true savings.

[2] Minimum Detectable Savings = 1.96*standard error of difference in mean PBPM changes.

[3] % Comparison PBPM = Absolute variable as % of comparison PBPM ($4,963) in demonstration period.

[4] Absolute Monthly Fee = $180 for 11 months.

[5] Absolute Net Fee = Monthly fee + Difference in PBPM outlay change.

[6] RoI = gross savings difference/Absolute Monthly Fee.

SOURCE: Medicare 2009-2011 Part A&B claims; PBPM cost changes and detectable savings: Table 6-5; monthly fees: ARC, Final Reconciliation for VillageHealth Phase II, May 11, 2012, Table 3.

6.6.1 Frequencies of Beneficiary Characteristics

Tables 6-9 and ***6-10*** show that the intervention and comparison groups were nearly identically distributed by disease category during the randomization period. No material differences are found in patient characteristics between the two groups. These similarities indicate that the lack of intervention savings cannot be explained by intervention-comparison group differences based on disease status.

Table 6-9
Frequency distribution of beneficiary characteristics, intervention and comparison groups, base year for the Phase II KTBH CMHCB Demonstration: Phase II original population

Characteristics	Intervention (%)	Comparison (%)
Disease Group		
CKD	48.7%	49.5%
ESRD	51.3	50.5
Age Group		
<65	42.2	42.4
65-69	12.7	13.5
70-74	14.3	13.8
75-79	12.9	12.2
80-84	10.3	10.0
85+	7.6	8.2
Gender		
Female	46.3	46.0
Male	53.7	54.0
Race		
Minority	55.4	55.7
White	44.6	44.4
Medicaid Eligible		
No	59.2	57.7
Yes	40.8	42.3
Disabled		
No	67.1	67.4
Yes	32.9	32.7
Urban residence		
No	0.0	0.0
Yes	100.0	100.0
Long-term care		
No	100.0	99.9
Yes	0.0	0.1
SNF		
No	92.6	92.2
Yes	7.4	7.8

NOTE: Beneficiaries weighted by fraction of eligible days in demonstration period. CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = Key to Better Health; SNF = skilled nursing facility.
SOURCE: Medicare 2009-2011 Part A & B claims; Cost4b1 (10/9/12).

Table 6-10
Frequency distribution of beneficiary characteristics, intervention and comparison groups, base year for the Phase II KTBH CMHCB Demonstration: Phase II refresh population

Characteristics	Intervention (%)	Comparison (%)
Disease Group		
CKD	63.7%	64.%
ESRD	36.3	36.0
Age Group		
<65	34.5	32.5
65-69	13.1	16.2
70-74	12.6	13.1
75-79	14.8	13.1
80-84	12.9	12.2
85+	12.2	12.9
Gender		
Female	43.5	43.6
Male	56.5	56.4
Race		
Minority	48.8	50.2
White	51.2	49.8
Medicaid Eligible		
No	62.2	59.0
Yes	37.8	41.0
Disabled		
No	72.0	73.6
Yes	28.0	26.4
Urban residence		
No	0.0	0.0
Yes	100.0	100.0
Long-term care		
No	99.8	99.9
Yes	0.2	0.1
SNF		
No	89.2	89.3
Yes	10.8	10.7

NOTE: Beneficiaries weighted by fraction of eligible days in demonstration period. CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = VillageHealth's Key to Better Health; SNF = skilled nursing facility.

SOURCE: Medicare 2008-2011 Part A & B claims; Cost4b1 (10/9/12).

6.6.2 PBPM Cost Levels and Trends by Disease and Risk Group

6.6.2.1 Phase II Original Sample

Table 6-11 displays PBPM costs stratified by disease group for the Phase II original samples. Extreme cost differences are found between the CKD and ESRD groups in the base year. CKD intervention beneficiaries averaged PBPM costs of $2,564 in the base year compared with $7,461 for ESRD beneficiaries (nearly 3 times greater). Intervention CKD costs rose $1,241 compared with only $83 for ESRD beneficiaries. Comparison CKD beneficiaries had a similar increase, but ESRD beneficiaries had a $235 decrease in costs.

Based on the difference in trends at the bottom of Table 6-11, we find no statistically significant differences between the original intervention and comparison group growth rates in the two disease groups.

Table 6-11
PBPM costs by disease risk group, intervention and comparison groups, base and demonstration periods for the Phase II KTBH CMHCB Demonstration: Phase II original population

Description	CKD PBPM	CKD SE	t-value	ESRD PBPM	ESRD SE	t-value
Intervention (N)	(1,298; 49%)	—	—	(1,367; 51%)	—	—
Base Year	$2,564	94.1	—	$7,461	123.3	—
Demonstration	3,804	133.6	—	7,544	167.7	—
Difference	1,241	134.9	9.19	83	170.3	0.49
% Change[1]	48%	—	—	1%	—	—
Comparison (N)	(1,349; 49%)	—	—	(1,377; 51%)	—	—
Base Year	2,424	93.0	—	7,679	127.0	—
Demonstration	3,561	131.0	—	7,444	156.9	—
Difference	1,137	131.4	8.68	-235	160.2	1.47
% Change[1]	47%	—	—	-3%	—	—
Difference-in-Differences	104	188.3	0.55	317	233.8	1.36

NOTE: Beneficiary PBPM weighted by fraction of eligible days in demonstration period.
CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = Key to Better Health; N = number of beneficiaries; PBPM = per beneficiary per month; SE = standard error.

[1] % Change: Cost Difference/Base Year.

SOURCE: Medicare 2008-2011 Part A & B claims; Cost4b2 (10/9/12).

6.6.2.2 Phase II Refresh Sample

Table 6-12 presents similar results on PBPM cost trends by the two disease groups for the Phase II refresh samples. None of the difference-in-differences in growth rates are statistically significant across the four groups. CKD costs per beneficiary-month fell by $400-$500 in both the intervention and comparison groups. PBPM costs among intervention ESRD beneficiaries fell $961, but costs also fell $555 in the comparison group. Even though PBPM costs fell $406 more in the ESRD intervention group, this difference was statistically insignificant. Much larger sample sizes would be required to accept the $406 as unlikely to happen by chance.

Table 6-12
PBPM costs by disease group, intervention and comparison groups, base and demonstration periods for the Phase II KTBH CMHCB Demonstration: Phase II refresh population

Description	CKD PBPM	CKD SE	t-value	ESRD PBPM	ESRD SE	t-value
Intervention (N)	(1,366; 64%)	—	—	(777; 36%)	—	—
Base Year	$4,056	130.9	—	$7,549	220.9	—
Demonstration	3,610	147.5	—	6,588	206.7	—
Difference	-446	157.4	2.84	-961	236.4	4.07
% Change	-11%	—	—	-13%	—	—
Comparison (N)	(1,375; 64%)	—	—	(773; 36%)	—	—
Base Year	4,299	150.9	—	7,644	239.5	—
Demonstration	3,772	174.8	—	7,089	249.2	—
Difference	-527	199.6	—	-555	262.7	2.11
% Change[1]	-12%	—	2.64	-7%	—	—
Difference-in-Differences						
Difference-in-Differences	81	254.6	0.32	-406	353.2	1.15

NOTE: Beneficiary PBPM weighted by fraction of eligible days in demonstration period.
CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; KTBH = Key to Better Health; N = number of beneficiaries; PBPM = per beneficiary per month; SE = standard error.

[1] % Change: Cost Difference/Base Year.

SOURCE: Medicare 2009-2011 Part A & B claims; Cost4b2 (10/9/12).

6.7 Multivariate Regression Tests of Intervention Savings

6.7.1 Phase II Original Sample

Three sets of regression coefficients in ***Table 6-13*** test the Phase II original intervention effect by controlling for the beneficiary's base year PBPM cost (PBPM_base). Coefficients can be interpreted as differences between each beneficiary's demonstration and base year PBPM costs after adjusting for the average change from the baseline level. In the first column of results controlling only for each beneficiary's base period PBPM cost, the intervention coefficient of $203 implies higher cost increases in the intervention sample, albeit statistically insignificant. This intervention effect is almost identical to the $206 faster growth shown in Table 6-5.

The base period PBPM cost coefficient (0.552; $p < .01$), when combined with the intercept coefficient, implies substantial RtoM effects on costs (= 0.552 - 1 = -0.448, the RtoM effect). Imagine two comparison group beneficiaries, one with a relative low ($1,000) and another with a relatively high ($6,000) PBPM cost in the base period. The predicted PBPM cost of the initially "low cost" comparison beneficiary would increase 250% on average during the intervention period while the "high cost" beneficiary's PBPM cost would increase by only 4%.[13] Whereas cost differences were 6:1 in the base period, they would now be compressed to 1.8:1.

The second regression model controls for which disease group the beneficiary was in during the base period. ESRD beneficiaries are in the reference (intercept) group. The key intervention coefficient is relatively unaffected and still insignificant. Adjusting for the average RtoM and intervention effects, the -$1,398 CKD coefficient indicates lower cost growth compared with ESRD beneficiaries. This appears inconsistent with cost trends in Table 6-11. However, Table 6-11 does not control for base year differences between CKD and ESRD groups.

In the third model controlling for beneficiary characteristics, the intervention coefficient remains positive and insignificant ($190; $t = 1.4$). After controlling for the beneficiary's base year PBPM cost, disease group, and many other sociodemographic and utilization characteristics, we still find no statistically reliable cost-saving intervention effect on the trend in Medicare PBPM costs.

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[13] The calculation is as follows based on Table 7-15, column 1:

PBPM[base]	PBPM[demo]	PBPM Change	%Change
$1,000	$3,468	$2,468	+247%
$6,000	$6,228	-$228	4%

Table 6-13
Regression results: Intervention gross savings controlling for base period PBPM and beneficiary characteristics for the Phase II KTBH CMHCB Demonstration: Phase II original population. Model 1 = unadjusted baseline level; Model 2 controls for beneficiary disease group; Model 3 controls for beneficiary characteristics

Independent variable	Model 1. PBPM_demo[1] coefficient	t-value	Model 2. PBPM_demo[1] coefficient	t-value	Model 3. PBPM_demo[1] coefficient	t-value
Intercept	2,916	23.5	3,990	22.7	7,238	1.5
Intervention	203	1.5	190	1.4	190	1.4
PBPM_Base[2]	0.552	37.9	0.475	27.9	0.487	25.7
CKD	N/I	N/I	-1,398	-8.5	-1,516	-8.3
Male	N/I	N/I	N/I	N/I	65	0.5
Minority	N/I	N/I	N/I	N/I	-197	-1.2
Age 65-69	N/I	N/I	N/I	N/I	897	3.4
70-74	N/I	N/I	N/I	N/I	740	2.6
75-79	N/I	N/I	N/I	N/I	660	2.3
80-84	N/I	N/I	N/I	N/I	707	2.3
85+	N/I	N/I	N/I	N/I	743	2.2
Medicaid	N/I	N/I	N/I	N/I	254	1.7
Disabled	N/I	N/I	N/I	N/I	490	2.2
Urban	N/I	N/I	N/I	N/I	-3840	-0.8
LTCB[3]	N/I	N/I	N/I	N/I	-3255	-1.3
SNFB[3]	N/I	N/I	N/I	N/I	-404	-1.4
R^2	0.211	N/A	0.222	N/A	0.225	N/A
N	5,391	N/A	5,391	N/A	5,391	N/A

NOTES: Dependent Variable: Beneficiary's demonstration period PBPM cost. CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; KTBH = Key to Better Health; LTCB = long-term care beneficiaries; N = number of beneficiaries; N/I = not included; PBPM = per beneficiary per month; SNFB = skilled nursing facility beneficiaries.

Observations weighted by beneficiary's fraction of eligible days during demonstration.

[1] PBPM_Demo: Dependent variable: Beneficiary's average PBPM during demonstration.

[2] PBPM_Base: Beneficiary's average PBPM in base period just prior to start date.

[3] LTCB, SNFB = 1 if beneficiary had long-term care hospital or SNF payments in base year.

SOURCE: Medicare 2008-2011 Part A & B claims; Cost4b2 (10/9/12).

6.7.2 Phase II Refresh Sample

Based on the first column of ***Table 6-14*** that controls only for each beneficiary's base period PBPM cost, the intervention coefficient of -$194 indicates savings, but the estimate is statistically insignificant. The base period PBPM cost coefficient (0.415; $p < .01$), when combined with the intercept coefficient, again implies substantial RtoM effects in the refresh sample (= 0.415 - 1 = -0.585, the RtoM effect).

Table 6-14
Regression results: Intervention gross savings controlling for base period PBPM and beneficiary characteristics for the Phase II KTBH CMHCB Demonstration: Phase II refresh population. Model 1 = unadjusted baseline level; Model 2 controls for beneficiary disease group; Model 3 controls for beneficiary characteristics

Independent variable	Model 1. PBPM_demo[1] coefficient	t-value	Model 2. PBPM_demo[1] coefficient	t-value	Model 3. PBPM_demo[1] coefficient	t-value
Intercept	2,486	16.7	3,900	18.9	2,990	7.8
Intervention	-194	-1.1	-214	-1.2	-183	-1.0
PBPM_Base[2]	0.415	0.0	0.373	24.1	0.385	22.9
CKD	N/I	N/I	-1,874	-9.8	-1978	-9.2
Male	N/I	N/I	N/I	N/I	139	0.8
Minority	N/I	N/I	N/I	N/I	-32	-0.2
Age 65-69	N/I	N/I	N/I	N/I	860	2.4
70-74	N/I	N/I	N/I	N/I	947	2.4
75-79	N/I	N/I	N/I	N/I	811	2.1
80-84	N/I	N/I	N/I	N/I	929	2.3
85+	N/I	N/I	N/I	N/I	848	2.1
Medicaid	N/I	N/I	N/I	N/I	579	3.1
Disabled	N/I	N/I	N/I	N/I	479	1.5
Urban	N/I	N/I	N/I	N/I	0	0.0
LTCB[3]	N/I	N/I	N/I	N/I	-1420	-0.7
SNFB[3]	N/I	N/I	N/I	N/I	-701	-2.3
R^2	0.152	N/A	0.170	N/A	0.174	N/A
N	4,291	N/A	4,291	N/A	4,291	N/A

NOTES: Dependent Variable: Beneficiary's demonstration period PBPM cost. CKD = chronic kidney disease; CMHCB = Care Management for High Cost Beneficiaries; KTBH = Key to Better Health; LTCB = long-term care beneficiaries; N = number of beneficiaries; N/I = not included; PBPM = per beneficiary per month; SNFB = skilled nursing facility beneficiaries.

Observations weighted by beneficiary's fraction of eligible days during demonstration.

[1] PBPM_Demo: Dependent variable: Beneficiary's average PBPM during demonstration.

[2] PBPM_Base: Beneficiary's average PBPM in base period just prior to start date.

[3] LTCB, SNFB = 1 if beneficiary had long-term care hospital or SNF payments in base year

SOURCE: Medicare 2009-2011 Part A & B claims; Cost4b1 (1/19/10).

The second regression model controls for which disease group the beneficiary was in during the base period. The key intervention coefficient remains insignificant. In the third model, controlling for beneficiary characteristics, the intervention coefficient remains highly insignificant (-$183; t = 1.0).

6.8 Conclusion

PBPM costs showed considerable variability because of the nature of the population selected for the demonstration, including a few very high cost beneficiaries with short spells of eligibility. The roughly 5,400 beneficiaries combined in the Phase II original group allowed us to detect an intervention savings rate as low as 5.4% compared with 8.2% in the smaller (4,300 beneficiaries) refresh group.

No statistically significant savings, however, were found for the intervention in either the original or refresh samples. Costs rose $206 faster, not slower in the original intervention group (3.7% of comparison costs). The Phase II KTBH Demonstration may have performed slightly better with its refresh sample because intervention costs increased $99 slower than in the comparison group. Still, this difference was insignificant because savings needed to be $405 to be considered statistically significant.

Because the Phase II KTBH Demonstration's intervention and comparison groups were randomly determined, no material imbalances were found across disease, severity, and other patient characteristics in the base period. Consequently, any slight differences that did exist in the subsequent base year had no material effects on our final conclusion of no significant savings.

RTI conducted analyses of savings, separately, for CKD and ESRD groups. Neither group showed statistically significant savings due to the intervention in either the original or refresh group.

Responding to KTBH's request, CMS staff selected a very costly, complex set of Medicare beneficiaries for their intervention and comparison groups. As a result, the comparison group exhibited substantial regression-to-the-mean (RtoM) effects. While the randomized experimental design should cancel out RtoM effects and isolate a pure intervention effect, the large churning of beneficiaries from lower (higher) to higher (lower) cost groups over time adds considerable statistical noise to the test of savings. Even still, we would have considered the Phase II original intervention to be a success if it had saved as little as 5.4% of costs. Large increases in demonstration period costs in less costly beneficiaries in the base period make it very difficult for intervention staff to target those at highest financial risk. It is much easier to target beneficiaries during the intervention period who actually incur major flare-ups and hospitalizations. Unfortunately, these beneficiaries have already incurred major expenditures by the time they receive intensive disease management services.

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CHAPTER 7
KEY FINDINGS FROM PHASE II OF VILLAGEHEALTH'S KEY TO BETTER HEALTH MEDICARE CARE MANAGEMENT FOR HIGH COST BENEFICIARIES DEMONSTRATION EVALUATION

The purpose of this report is to present the findings from RTI International's evaluation of the Phase II Key to Better Health (KTBH) Extended Medicare Care Management for High Cost Beneficiaries (CMHCB) Demonstration. Our evaluation focuses upon three broad domains of inquiry:

- **Implementation.** To what extent was the Phase II KTBH Demonstration able to implement its Phase II program?
- **Reach.** How well did the Phase II KTBH Demonstration engage its intended audience?
- **Effectiveness.** To what degree was the Phase II KTBH Demonstration able to improve clinical quality and health outcomes and achieve targeted cost savings?

Organizing the evaluation into these areas focuses our work on the policy needs of the Centers for Medicare & Medicaid Services (CMS) as it considers the future of population-based care management programs or other interventions in Medicare structured as pay-for-performance initiatives. We use both qualitative and quantitative research methods to address a comprehensive set of research questions within these three broad domains of inquiry.

7.1 Key Findings

In this section, we present key findings based upon the 21 months of Phase II KTBH Demonstration operations with the Phase II original population and 11 months with its Phase II refresh population. Our findings are based on the experience of approximately 2,700 ill Medicare beneficiaries with CKD and 2,200 beneficiaries with ESRD assigned to an intervention or a comparison group. Five key findings on participation, intensity of engagement in the KTBH program, clinical quality, health outcomes, and financial outcomes have important policy implications for CMS and future disease management or care coordination efforts among Medicare FFS beneficiaries.

Key Finding #1: During the Phase II KTBH Demonstration, VillageHealth was able to engage a variety of beneficiaries across the spectrum of health status.

Of all KTBH Phase II original intervention group beneficiaries, 75% verbally consented to participate in its demonstration at some point during the intervention period. For the Phase II KTBH Demonstration, we find that participants for more than 75% of the eligible months from the Phase II original population tended to be younger than beneficiaries who never participated (44% were less than 65 years of age compared to 39% for the nonparticipants). These are beneficiaries entitled to Medicare due to a disability. In the multivariate regression analysis, however, beneficiaries that died or were institutionalized during the demonstration were less likely to be participants, yet ESRD beneficiaries were more likely to participate.

For the Phase II refresh population, in addition to beneficiaries that died or were institutionalized during the demonstration being less likely to participate, Medicaid enrollees were also less likely to participate. Beneficiaries with high baseline PBPM costs were a positive predictor of participation and ESRD continued to be associated with a higher likelihood of participation. These findings suggest that the Phase II KTBH Demonstration staff were able to engage beneficiaries across the spectrum of health status.

Key Finding #2: The Phase II KTBH Demonstration was not successful at targeting intervention beneficiaries at high risk of hospitalization or who had been hospitalized.

A cornerstone of the KTBH's program was health coaching interactions with care manager nurses. However, over one-half of participating Phase II original beneficiaries received no call or in-person visit from a care manager in the last 15 months of the demonstration. Everyone that did have contact had ten or more total contacts. Telephone contact was the most dominant form of contact. That being said, among the ESRD beneficiaries, nearly one-half received an in-person visit during the demonstration period. In our multivariate regression modeling of likelihood of being in a high contact versus low contact group for the Phase II original population, we found that beneficiary characteristics were not indicators of being in the high contact category. Among the baseline characteristics and demonstration period health status indicators, only having ESRD increased the likelihood of being in the high contact group while dying during the demonstration decreased that likelihood. Demonstration period acute care utilization was not a strong predictor of a high level of contact and likely reflects the challenges that the KTBH staff expressed in knowing when one of their participants had been to an emergency room or hospitalized. No other variables were found to be statistically significant.

Key Finding #3: The Phase II KTBH Demonstration had difficulty improving adherence to quality of care process measures.

We defined quality improvement for this evaluation as an increase in the rate of receipt of nine claims-derived, evidence-based process-of-care measures. Six of these measures pertain to beneficiaries with diabetes: rate of annual HbA1c testing, low-density lipoprotein cholesterol (LDL-C) screening, receipt of a retinal eye exam, medical attention for nephropathy, as well as the rate at which beneficiaries received all four of those measures, or none of those measures. Completion of a complete lipid profile was used for beneficiaries with ischemic vascular disease (IVD). We also created two ESRD-related measures applicable to the solely to the demonstration period: rate of progression to ESRD during the demonstration period, and rate of fistula/graft placement prior to initiation of dialysis among beneficiaries who initiated dialysis during the demonstration period for beneficiaries with CKD at the time of randomization. Out of nine measures, few exhibited statistically significant differences in the rate of receipt of evidence-based care between the intervention and comparison groups, and none of the significant differences were seen consistently across the original and Phase II refresh populations. Beneficiaries in the Phase II original intervention group were more likely to progress to ESRD during the demonstration period but were less likely to have a graft or fistula inserted prior to initiation of hemodialysis. Among the Phase II refresh intervention beneficiaries, we observed a positive intervention effect for nephropathy screening, reflecting a higher rate of screening during the demonstration period.

Over the course of the demonstration, the Phase II KTBH Demonstration had expected to increase rates of adherence to evidence-based care. However, during the last year of its demonstration, we observe lower or very similar rates of adherence to the selected measures among its intervention beneficiaries relative to the comparison group beneficiaries for all measures. These findings suggest that improving or sustaining adherence to guideline concordant care in a cohort of ill Medicare FFS beneficiaries was more challenging than originally envisioned.

Key Finding #4: The Phase II KTBH Demonstration did not reduce acute care utilization as measured by rate of hospitalization, ER visits, or 90-day readmissions nor did they have any success reducing mortality.

During the course of the Phase II KTBH Demonstration, we generally observed increasing rates of all-cause and ambulatory care sensitive condition (ACSC) hospitalizations, ER visits, and 90-day readmissions in both the intervention and comparison groups and for both the Phase II original and refresh populations. We observed no statistically significant differential rates of hospitalizations or ER visits during the demonstration period relative to the baseline period for either population. Of all the 33 outcome measures reported for the Phase II original population, only two were found to be statistically significant: percent of beneficiaries with ACSC same-cause readmissions for all Phase II original beneficiaries and for the CKD group within that population. While the trend for this measure was the same for beneficiaries with ESRD, it was not statistically significant for those beneficiaries. Further, we found no differential rate of mortality between the Phase II intervention and comparison groups in either the Phase II original or Phase II refresh populations, nor by disease.

Key Finding #5: Medicare cost growth in the intervention group was not different from the rate of growth in the comparison group.

No statistically significant savings were found for the intervention in either the original or refresh samples. Costs rose $206 faster, not slower in the original intervention group (3.7% of comparison costs). The Phase II KTBH Demonstration may have performed slightly better with its refresh sample because intervention costs increased $99 slower than in the comparison group. Still, this difference was insignificant because savings needed to be $405 to be considered statistically significant.

Phase II KTBH Demonstration's intervention and comparison groups were randomly determined. We found no material imbalances across disease, severity, and other patient characteristics in the base period. Consequently, any slight differences that did exist in the subsequent base year had no material effects on our final conclusion of no significant savings.

RTI conducted analyses of savings separately for the CKD and ESRD groups. Neither disease group showed statistically significant savings due to the intervention in either the Phase II original or Phase II refresh populations.

7.2 Conclusions

Based on extensive quantitative analysis of performance, we find that the Phase II KTBH Demonstration had no success improving key processes of care, reducing acute care utilization or reducing mortality. PBPM costs rose faster in the Phase II original intervention group relative to the comparison group. Although PBPM costs rose slower in the Phase II refresh intervention group relative to the comparison group, statistically significant savings were not achieved. The lack of program savings to offset monthly management fees and lack of any impact on other outcomes cannot justify the Phase II KTBH Demonstration model for chronically ill Medicare fee-for-service beneficiaries with CKD or ESRD on cost-effectiveness grounds.

What might explain the lack of success in the Phase II KTBH Demonstration? One explanation may be the targeting of beneficiaries at greatest risk of intensive, costly, service use (as distinct from the need for general care management). Responding to KTBH's request, CMS staff selected a very costly, complex set of Medicare beneficiaries for their intervention and comparison groups. As a result, the comparison group exhibited substantial regression-to-the-mean (RtoM) effects. While the randomized experimental design should cancel out RtoM effects and isolate a pure intervention effect, the large churning of beneficiaries from lower (higher) to higher (lower) cost groups over time adds considerable statistical noise to the test of savings. Even still, we would have considered the Phase II original intervention to be a success if it had saved 5.4% of costs. Large increases in demonstration period costs in less costly beneficiaries in the base period make it very difficult for intervention staff to target those at highest financial risk. It is much easier to target beneficiaries during the intervention period who actually incur major flare-ups and hospitalizations. Unfortunately, these beneficiaries have already incurred major expenditures by the time they receive intensive disease management services.

A second explanation may be their recruitment strategy. Given the KTBH program's high monthly management fee ($180 per month) and the population-based financial risk feature of this demonstration, engagement of 75% of the Phase II original population and less than 50% of the Phase II refresh intervention population required the Phase II KTBH Demonstration to have been extremely successful in reducing costs associated with the participating beneficiaries. The Phase II KTBH Demonstration was not successful in reducing hospitalizations during the demonstration period for the Phase II original or Phase II refresh populations. The lack of substantive improvements in acute care utilization broadly across their intervention population translated into limited financial savings. And, their targeting strategy was costly. Each contact cost was roughly $150 ($5 million in total fees divided by 33,594 contacts), higher than the national average payment amount for a face-to-face office visit with an established patient with the ***highest level of complexity*** under the Medicare Fee Schedule[14].

Lastly, a third explanation may be the model of intervention itself. Prior evaluations of Medicare care management programs that were primarily telephonic have not demonstrated savings sufficient to cover fees one-half the size of the Phase II KTBH Demonstration's fee. A cornerstone of the Phase II KTBH Demonstration was health coaching interactions with care

[14] National non-facility price of $ 135.80 for HCPCS code 99215 for 2011.

manager nurses. However, nearly one-half of participating beneficiaries during the last 15 months of the program received no calls or in-person visits from a care manager. KTBH staff reported greater challenges recruiting CKD patients than ESRD patients because the CKD program was based on purely telephonic support. KTBH program staff estimated the bad phone number rate was greater than 30% and reported that they were unable to reach approximately 35-40% of the CKD population. Additionally, KTBH care managers felt that the inability to conduct in-person visits to some dialysis facilities made it far more difficult to interact with ESRD beneficiaries, which then had to be conducted telephonically.

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SUPPLEMENT APPENDIX

SUPPLEMENT 2A
DETAILED SPECIFICATIONS FOR THE CONSTRUCTION OF CLINICAL ANALYTIC VARIABLES

4. Health Status Variables

1. Charlson Comorbidity Index SAS Code

Array all the diagnoses from the dataset and search for each of the codes in the Charlson categories. If any are found, the category has a value of 1, else 0. Add weighted categories to create Charlson score.

```
AMI=0;              Acute Myocardial Infarction;
CHF=0;              Congestive Heart Failure;
PVD=0;              Peripheral Vascular Disease;
CVD=0;              Cerebrovascular Disease;
dementia=0;         Dementia;
COPD=0;             Chronic Pulmonary disease;
conn_tissuedz=0;    Connective Tissue disease;
ulcer=0;            Ulcer disease;
liverdz_mild=0;     Mild liver disease;
diabetes=0;         Diabetes without complications;
hemiplegia=0;       Hemiplegia;
CRF=0;              Moderate or severe renal disease;
DMwcc=0;            Diabetes with complications;
neoplasia=0;        Neoplasia;
leukemia=0;         Leukemia;
lymphoma=0;         Lymphoma;
liverdz_modsev=0;   Moderate or severe liver disease;
cancer_mets=0;      Metastatic solid tumor;
HIV=0;              HIV/AIDS

%MACRO CHECKDX(DX);
 DG3 = SUBSTR(&DX,1,3);
 DG4 = SUBSTR(&DX,1,4);
 SELECT;
 WHEN (DG3 in ('410','412')) AMI=1;
 WHEN (DG3='428') CHF=1;
 WHEN (DG3='441' OR DG4 IN ('4439','7854','V434')) PVD=1;
 WHEN (DG3 IN ('430','431','432','433','434','435','436','437','438'))
  CVD=1;
 WHEN (DG3='290') DEMENTIA=1;
 WHEN (DG3 IN ('490','491','492','493','494','495','496','500','501',
  '502','503','504','505') OR DG4='5064') COPD=1;
 WHEN (DG3 IN ('710','714','725')) CONN_TISSUEDZ=1;
 WHEN (DG3 IN ('531','532','533','534')) ULCER=1;
 WHEN (DG3 IN ('571')) LIVERDZ_MILD=1;
 WHEN (DX4 IN ('2504','2505','2506','2507','2508','2509')) DMWCC=1;
 WHEN (DX3 = '249' or DX4 in ('7915','9623','250 ','2500','2501',
  '2502','2503') or &DX in ('V5867','99657')) DIABETES=1;
 WHEN (DG3='342' OR DG4='3441') HEMIPLEGIA=1;
```

```
    WHEN (DG3 IN ('582','583','585','586','588')) CRF=1;
    WHEN (DG3 IN ('200','201','202','203','204')) LYMPHOMA=1;
    WHEN (DG3 IN ('205','206','207','208')) LEUKEMIA=1;
    WHEN (DG3 IN ('140','141','142','143','144','145','146','147',
     '148','149','150','151','152','153','154','155','156','157','158',
     '159','160','161','162','163','164','165','170','171','172','174',
     '175','176','179','180','181','182','183','184','185','186','187',
     '188','189','190','191','192','193','194','195')) NEOPLASIA=1;
    WHEN (DG4 IN ('5722','5723','5724','5728','4560','4561','4562'))
     LIVERDZ_MODSEV=1;
    WHEN (DG3 IN ('196','197','198','199')) CANCER_METS=1;
    WHEN (DG3 IN ('042','043','044')) HIV=1;
    OTHERWISE;
   END;
   %MEND;

%LET NEWVARS=%STR(AMIx CHFx PVDx CVDx DEMENTIAx COPDx
   CONNx_TISSUEDZx ULCERx   LIVERDZ_MILDx DIABETESx HEMIPLEGIAx
   CRFx DMWCCx NEOPLASIAx LEUKEMIAx      LYMPHOMAx
   LIVERDZ_MODSEVx CANCER_METSx HIVx);

CHARL=SUM(OF &newvars)+(HEMIPLEGIAx+CRFx+DMWCCx+NEOPLASIAx+
   LEUKEMIAx+LYMPHOMAx)+2*(LIVERDZ_MODSEVx)+5*(CANCER_METSx+HI
   Vx);
    output;
   END;
```

2. Chronic Conditions SAS code

```
     DX4=SUBSTR(&DX,1,4);
     DX3=SUBSTR(&DX,1,3);
     DXL=SUBSTR(&DX,5,1);
     IF DX4='4280' THEN CHF_CC=1;
     IF (('41400'<=&DX<='41407') OR
       ('41000'<=&DX<='41092') OR DX4 in ('4142','4143','4148','4149') OR
       ('4110 '<=&DX<='41189') OR
       ('4130'<=DX4<='4139') OR DX3='412') THEN CAD_CC=1;
     IF (DX3 IN ('496','492','493','494') OR DX4='4912') THEN
       RESP_CC=1;
     IF DX4='2500' or DX4='2490' THEN DIABWO_CC=1;
     IF ('2501'<=DX4<='2509' or '2491'<=DX4<='2499' or
       DX4 in ('7915','9623') or &dx in ('V5867','99657')) THEN DIABC_CC=1;
     IF (DX3='401') THEN HYPER_CC=1;
     IF (DX3='424') THEN VALV_CC=1;
     IF (DX3='425') THEN CARD_CC=1;
     IF (DX3 IN ('584','586')) THEN RENFAIL_CC=1;
```

```
 IF (DX4='4439') THEN PVD_CC=1;
 IF (DX3='272') THEN LIPID_CC=1;
 IF (DX3 IN ('427','426')) THEN DYS_CC=1;
 IF (DX3='290') THEN DEM_CC=1;
 IF ((DX3 IN ('434','433') & DXL='1') OR DX3='431' OR
   &DX='V1259') THEN STROKE_CC=1;
 IF (DX4 IN ('2504','4039','5811','5818','5819','5829','5939','5996','7100',
  '7531','7910') OR DX3 IN ('582','585') OR &DX='58381') THEN ACREN_CC=1;
 IF DX4='7865' then CHPAIN_CC=1;
 IF DX4 in ('5990','5999') THEN UTI_CC=1;
 IF DX3='285' THEN ANEMIA_CC=1;
 IF DX4='7807' THEN MALAISE_CC=1;
 IF (&DX IN ('78002','78009','78093','78097','78039') OR DX4 IN ('7802','7804'))
  THEN DIZZ_CC=1;
 IF DX3='719' THEN JOINT_CC=1;
 IF DX3='244' THEN THYROID_CC=1;
%MEND;

%LET CCDXLIST=%STR(CHF_CC CAD_CC RESP_CC DIABWO_CC DIABC_CC
    HYPER_CC   VALV_CC CARD_CC ACREN_CC RENFAIL_CC PVD_CC
    LIPID_CC DYS_CC DEM_CC   STROKE_CC CHPAIN_CC UTI_CC
    ANEMIA_CC MALAISE_CC DIZZ_CC JOINT_CC THYROID_CC);
```

3. Ambulatory Care Sensitive Conditions (ACSCs).

```
%LET ACSCLIST = %STR(ALL DIAB CELL ASTHMA COPD CHF DHYD PNEU
    SEPT STROKE UTI);

 %macro chkdx(diag);
  dx3=substr(&diag,1,3);
  dx4=substr(&diag,1,4);

  all=1;
  if dx3='250' or dx4='7915' then diab=1;
  if dx3 in ('681','682') then cell=1;
  if dx3 in ('493') then asthma=1;
  if dx3 in ('491','492','494','496') then copd=1;
  if dx3='428' or &diag in ('40201','40211','40291','40401','40411','40491',
  '39891','40403','40413','40493','78550','78551') then chf=1;
  if dx4='2765' then dhyd=1;
  if dx3 in ('481','482','483','485','486') then pneu=1;
  if dx3='038' then sept=1;
  if dx3 in ('434','436') then stroke=1;
  if dx4 in ('5990','5999') then uti=1;
 %mend;
```

5. Hospitalization, Emergency Room and Readmission Analytic Variables

To report descriptive statistics on the rates of ACSCs by location of service using claims files to create of rates of ACSCs by location of service: 1) inpatient; 2) hospital outpatient department or physician's office; and) ER/observation bed stays. For example, we will be examining the number of inpatient cellulitis admissions per 1,000 beneficiaries, the number of physician office/OPD visits per 1,000 beneficiaries, and the number of ER visits per 1,000 beneficiaries in the baseline, and the last 12 months of the intervention period.

A. Hospitalizations: Step 1 Combine transfer records as follows:

1. If the admission date (ADMSN_DT) or discharge date (DSCHRGDT) is missing on the claim, or equal to "0," set them equal to "from" (FROM_DT) and "through" (THRU_DT) dates, respectively.

2. Combine multiple claims that represent pieces of stays or transfers between hospitals, or separately administered units of a single hospital, into a single record representing a hospitalization. Some records in the Inpatient claims file that look like new admissions are actually transfers between or within facilities. This process uses all claims; do not exclude claims for periods if ineligibility until after the transfers have been processed.

    1. Create a claim type variable as CLMB_TYP = FAC_TYPE || TYPESRVC

    2. Sort the data by HICNO FROM_DT THRU_DT

    3. Designate the first record for each HICNO in the reference period as a new hospitalization..

    4. If the length between reference record discharge date and next admission date is more than one day, the next admission record is considered a new hospitalization.

    5. If the discharge status code of the reference record is not equal to 30, 02, 05, 61, or 62 and the status code of the record previous to the reference record is not equal to 30, 02, 05, 61, or 62, then the reference record is considered a new hospitalization. The definition of the discharge status codes are:
    30: Still a patient
    02: Discharged/transferred to other short term general hospital for inpatient care
    05: Discharged/transferred to skilled nursing facility (SNF)
    61: Discharged/transferred within this institution to a hospital-based Medicare-approved swing bed (1/1/02)
    62: Discharged to another IRF or IRF unit (1/1/02)

    6. If the discharge status code of the record previous to the reference record is equal to 30, 02, 05, 61, or 62 and the difference between the reference record's admission date and the record previous to the reference record's admission date is less than or equal to 1 day, then the reference record is considered a transfer.

7. If the discharge status code of the reference record is equal to 30, 02, 05, 61, or 62 and the discharge status code of the record previous to the reference record is not equal to 30, 02, 05, 61, or 62, then the reference record is considered a new hospitalization.

8. The length of stay is calculated, as described for the row 2 measure below. If the length of stay is negative, the record is removed.

9. The system counts each unique hospitalization falling within the reference period.

10. Note that admission dates that fall within the reference period are counted even if the discharge date falls outside of the reference period. Also note that, in some cases, the system will be missing the later pieces of a stay that commences within the period, especially when hospitals "split-bill" at calendar year-end, but the hospitalization will still be counted in the reference period.

B. Step 2: Create Causes of Hospitalization Analytic Variables: All cause and 10 ACSCs

1. All cause hospitalizations:
   Select if PDGNS_CD = any diagnosis code

2. Heart failure hospitalization:
   Select if PDGNS_CD = 428
   40201
   40211
   40291
   40401
   40411
   40491
   39891
   40403
   40413
   40493
   78550
   78551

3. Diabetes hospitalization:
   Select if PDGNS_CD = 250
   7915

4. Cellulitis:
   Select if PDGNS_CD = 681
   682

5. Asthma hospitalization:
   Select if PDGNS_CD = 493

6. COPD and Chronic Bronchitis
   Select if PDGNS_CD = 491
   492
   494
   496

7. Dehydration
   Select if PDGNS_CD = 2765

8. Bacterial Pneumonia
   Select if PDGNS_CD = 481
   482
   483
   485
   486

9. Septicemia
   Select if PDGNS_CD = 038

10. Ischemic Stroke
    Select if PDGNS_CD = 434
    436

11. UTI
    Select if PDGNS_CD = 5990
    5999

C. Emergency Room Visits, including observation stays

Calculate the number of beneficiary visits to a hospital's outpatient emergency room (ER) **or** for an observation stay during the reference period. Restrict the measure to ER and observation visits identified on the Outpatient (OPD) claims file. Keep records with a revenue center line item (REV_CNTR) equal to 045X or 0981 (emergency room care) unless the HCPCS for the line item equals 70000 through 79999 or 80000 through 89999 (thus excluding claims where only radiological or pathology/laboratory services were provided) for revenue code dates (REV_DT) that fall within the reference period. Keep records with a revenue center line item (REV_CNTR) equal to 0762 (treatment of observation room-observation room) for revenue code dates (REV_DT) that fall within the reference period. This will capture ER claims for beneficiaries that were not subsequently admitted to the hospital.

To capture ER visits that led to a hospitalization, claims are identified in the MedPAR (inpatient) file. Keep records with revenue center code values of 0450-0459, 0981, and 0762. The diagnostic emergency room details are on the inpatient claim.

Count each of the 10 types of ACSC visits for a unique beneficiary on a unique date. If a beneficiary has more than one visit on the same day, count them insofar as they are of

different types. That is, no one can have more than one "all cause" visits on a given day; no one can have more than one CHF visit on a given day. A person can have a CHF visit and a CAD visit on the same day, however. Visit type is the same as for hospitalizations.

D. 30-day Hospital Readmissions

Each hospitalization within the reference period is eligible to be a readmission; that is, a single beneficiary can be counted more than once if she/he had more than one hospitalization during the period. Calculate all measures after handling transfers, as described in the hospitalization specifications. After identifying unique hospitalizations in the reference period, calculate the number of days between the admission date and the most immediate previous discharge date, if any, from a short-stay acute-care inpatient hospital department, for any reason, as identified in the Inpatient claims file. Flag as a 90-day readmit, if admission date is less than or equal to 90 days from date of discharge. The intervention period examined hospitalizations during the period from months 10-21 and included readmissions through the end of the demonstration period (month 24) for the Phase II original population. We constructed: all cause readmission rates for all hospitalizations and same cause readmission rates for the ten ambulatory care sensitive conditions.

a. All cause readmissions after all cause hospitalizations

b. Same cause readmissions for the 10 ACSCs.

6. Guideline Concordant Care

A. Quality of Care Variables

1) Diabetes beneficiaries

i. ***Denominator***: All beneficiaries with diabetes identified in the baseline period and at least one day of eligibility in both baseline and the demo period.

a. Rate of annual HbA1c testing – beneficiaries with diabetes in baseline (Alliance, NQF endorsed measure – exclusive of CPT II or LOINC codes for identification of test being performed).

ii. ***Numerator:*** Beneficiaries who have a claim for a test as defined by CPT codes in the physician and OPD file: 83036, 83037.

b. Rate of annual eye exam (retinal) as evidenced by an eye exam (codes below) by an eye care an optometrist (specialty code 41) or an ophthalmologist (specialty code 18). However code S0625 does not need to be limited to an optometrist or an ophthalmologist – performance by an eye care professional in inherent to the code.

iii. ***Numerator:*** Beneficiaries who have a claim for a retinal or dilated eye exam by an eye care professional (optometrist (specialty = 41) or

ophthalmologist (specialty = 18)). Refer to Table CDC-H for codes to identify eye exams.

Table CDC-H: Codes to Identify Eye Exams*

CPT	HCPCS	ICD-9-CM Procedure
67028, 67030, 67031, 67036, 67039-67043, 67101, 67105, 67107, 67108, 67110, 67112, 67113, 67121, 67141, 67145, 67208, 67210, 67218, 67220, 67221, 67227, 67228, 92002, 92004, 92012, 92014, 92018, 92019, 92134, 92225-92228, 92230, 92235, 92240, 92250, 92260, 99203-99205, 99213-99215, 99242-99245	S0620, S0621, S0625**, S3000	14.1-14.5, 14.9, 95.02-95.04, 95.11, 95.12, 95.16

***** Eye exams provided by eye care professionals are a proxy for dilated eye examinations because there is no electronic way to determine that a dilated exam was performed.

****** The organization does not need to limit HCPCS S0625 to an optometrist or an ophthalmologist. These codes indicate an eye exam was performed by an eye care professional.

c. Rate of annual low-density lipoprotein cholesterol (LDL-C) testing – beneficiaries with diabetes or ischemic vascular disease (Alliance, NQF endorsed for diabetes and NCQA, NQF endorsed for ischemic vascular disease – exclusive of CPT II or LOINC codes for identification of test being performed).

iv. ***Numerator:*** Beneficiaries who have a claim for a test as defined by CPT codes in the physician and OPD file: 80061, 83700, 83701, 83704, 83721.

d. Rate of annual medical attention for nephropathy - a nephropathy screening test or evidence of nephropathy

v. Numerator:

- Beneficiaries with a nephropathy screening test (Table CDC-J);
- Beneficiaries with a claim with a code to indicate evidence of nephropathy (Table CDC-K); or
- A nephrologist (specialty = 39) visit

Table CDC-J: Codes to Identify Nephropathy Screening Tests

Description	CPT
Nephropathy screening test	82042, 82043, 82044, 84156

Table CDC-K: Codes to Identify Evidence of Nephropathy

Description	CPT	HCPCS	ICD-9-CM Diagnosis	ICD-9-CM Procedure
Evidence of treatment for nephropathy	36145, 36147, 36800, 36810, 36815, 36818, 36819-36821, 36831-36833, 50300, 50320, 50340, 50360, 50365, 50370, 50380, 90935, 90937, 90940, 90945, 90947, 90957-90962, 90965, 90966, 90969, 90970, 90989, 90993, 90997, 90999, 99512	G0257, G0392, G0393, S9339	250.4, 403, 404, 405.01, 405.11, 405.91, 580-588, 753.0, 753.1, 791.0, V42.0, V45.1	38.95, 39.27, 39.42, 39.43, 39.53, 39.93-39.95, 54.98, 55. 4-55.6

Description	UB Revenue	UB Type of Bill
Evidence of treatment for nephropathy	0367, 080x, 082x-085x, 088x	72X (ESRD Claims)

e. Annual rate of all four diabetes interventions

f. Annual rate of none of the four diabetes interventions

2) Rate of annual lipid panel testing for IVD beneficiaries

vi. ***Denominator***: All beneficiaries with IVD identified in the baseline period and at least one day of eligibility in both baseline and the demo period.

vii. ***Numerator:*** Beneficiaries with a complete lipid panel (Table IVD-D)

Table IVD-D: Codes to Identify a Complete Lipid Profile

Description	CPT
Lipid panel	80061

OR

Description	CPT
Total cholesterol	82465
AND High density lipoprotein (HDL)	83701
AND Triglycerides	84478

3) Rate of Progression to ESRD

viii. ***Denominator***: All beneficiaries with CKD at the time of randomization and at least one day of eligibility in both baseline and the demo period.

ix. ***Numerator:*** Beneficiaries who have ESRD during the demonstration period. Use EDB to identify ESRD status

4) Rate of fistula/graft placement prior to initiation of dialysis

x. ***Denominator***: All beneficiaries with CKD at the time of randomization with initiation of hemodialysis in the demo period.

xi. ***Numerator:*** Numerator: Beneficiaries who have a claim for a graft or fistula prior to the initiation of hemodialysis.

a. Graft or fistula CPT codes (physician):
36830, 36818, 36819, 36820, 36821, 36825.
Retain first date if multiple claims are present.

b. Select only claims for evaluation that have one of the listed primary diagnosis codes provided by KTBH.

```
if dx3 in ('160','580','581','582','583','584','585','586','587','588',
    '591','954') or dx4 in ('1890','1899','2230','2504','2714','2741','4401',
    '4421','4473','5724','5800','5804','5808','5809','5810','5811','5812','5813',
    '5818','5819','5820','5821','5822','5824','5828','5829','5830','5831','5832',
    '5834','5836','5837','5838','5839','5845','5846','5847','5848','5849','5851',
    '5852','5853','5854','5855','5856','5859','5880','5881','5888','5889','6421',
    '6462','7532','7944') or &diag in ('23691','25040','25041','25042','25043',
    '28311','40301','40311','40391','40402','40403','40412','40413','40492',
    '40493','58081','58089','58181','58189','58281','58289','58381','58389',
    '58881','58889','75312','75313','75314','75315','75316','75317','75319')
    then gftdx=1;
```

c. Initiation of hemodialysis rev codes (IP or OP claims):
0801, 0820, 0821, 0825, 0829.
Identify first date