

Evidence-based Practice Center Systematic Review Protocol

Project Title: Home-Based Primary Care Interventions Systematic Review

I. Background and Objectives for the Systematic Review

The aging of the population^{1,2} along with the increasing number of people with chronic illnesses³ and multimorbidity⁴ are changing health care. The motivation for many health care reform efforts is that chronically ill, frail, and disabled patients may not be best served by the current common model of care^{5,6} based on the combination of hospital care, specialist consultations, and office-based primary care.

High quality primary care is comprehensive and serves as the entry into the health care system, provides person-focused (rather than disease-oriented) care over time, addresses all but very uncommon or unusual conditions, and coordinates or integrates care across different types of providers and settings. Primary care is at the center of many health services delivery reform efforts, such as patient-centered medical home models, precisely because primary care provides a usual source of care, encourages relationships with a provider, is more likely to include preventive services, may increase patient satisfaction, and can decrease the use of emergency departments for conditions that are not urgent.⁷⁻⁹

Home-based primary care (HBPC) interventions have roots in the house call and community health outreach of the past. Today HBPC is a model that combines home-based care for medical needs with intense management, care coordination, as well as long-term services and supports (LTSS) when needed. HBPC interventions have been proposed as an alternative way of organizing and delivering care that may better address the needs, values, and preferences of chronically ill, frail, and disabled patients who have difficulty accessing traditional office-based care primary care or newer models of care that also require office visits.

The specific reasons a patient needs HBPC and the potential advantages vary. Functional impairments may make transportation to doctors' offices or clinics challenging, or caregivers may not be available to accompany patients during normal office or clinic hours. In some situations going to an office may be contraindicated. For example, patients with cognitive deficits may become confused or agitated in unfamiliar surroundings. Patients with complex needs may require frequent monitoring, intense management, or rapid follow-up that cannot be easily accommodated by an office-based provider or that is difficult when a patient cannot come to an office. Patients at high risk may avoid complications from hospital care (e.g., certain infections, delirium) if hospitalizations can be prevented, averted, or shortened. Potential benefits of HBPC include: 1) increased access to care for people who have difficulty traveling to outpatient medical offices or for whom going to a medical office is contraindicated; 2) better understanding of patients' environments, needs, and constraints that can improve care and ultimately outcomes; 3) decreased hospitalizations and urgent care use when acute incidents are prevented or addressed in the home; 4) potential for prevention or slowing

of functional and cognitive decline; 5) better support for and reduced burden on family caregivers; and 6) increased satisfaction of patients and providers. If all these benefits could be realized HBPC would offer, as one analyst stated, “a win-win for U.S. health care”.¹⁰

HBPC was developed as a pilot model in the U.S. Department of Veterans Affairs (VA) more than three decades ago.¹¹ While the details can vary across the many different VA medical centers, today’s VA HBPC program includes an interdisciplinary team that provides care in the home to veterans with complex needs for whom clinic-based care is difficult due to function or disease. The VA model has expanded over time to include more mental health services and to facilitate collaboration with other services. In other environments, HBPC has developed based on elements of programs designed for people who are eligible for both Medicaid and Medicare (frequently referred to as “dual-eligibles”), home and community-based LTSS programs, and physician house call programs.

Interest in HBPC is growing among the general public, health professionals in multiple disciplines and health care delivery organizations. This is reflected in current policy, practice and research. HBPC is currently the subject of a major Medicare demonstration project,¹² and even before this demonstration, an increasing number of public and private health systems and plans were beginning to offer HBPC.¹³ HBPC interventions have been the subject of articles in general publications,¹⁴ as well as a topic for policy analyses.¹⁵ Additionally, research studies on HBPC have been summarized in seven systematic reviews.¹⁶⁻²² This level of interest suggests that HBPC programs are likely to expand in the near future and continue to evolve to incorporate advances in communications, health information technology, and care management applications.

One of the challenges developing and promoting HBPC has been that there remain important questions about the impact of HBPC. While HBPC seems a logical solution to some current deficiencies in care for patients with chronic conditions and disabilities, uncertainties remain about potential harms, unintended consequences, costs, and sustainability of this model of care. In some cases, evaluations and research studies have contributed to, rather than resolved, this uncertainty.

Another challenge is that HBPC interventions are not standardized and often differ in terms of what care and services are offered, how frequently these services are available and used, and the resources required to deliver these services. Research articles often do not provide sufficient descriptions of the interventions to allow nuanced analyses of how these differences might impact effectiveness. The reviews completed to date have frequently highlighted this lack of detailed information about the intervention and potential harms as a weakness in the evidence base. Additionally, most studies provide little information about the comparison group, which is often simply described as “usual care”. Given that studies of HBPC have been conducted in several countries across a span of over 20 years, it is likely that “usual care” has meant different things, posing a challenge for synthesis across studies. Moreover, HBPC interventions have been used to provide services to populations with different health risks, ranging from generally well elderly to severely disabled patients, and have stated goals that span from preventing falls to providing palliative care. Given these differences, there remain questions about which outcomes best match the different goals of different versions of HBPC and which outcomes are most important to different patients.²³

In order to clarify the scope and purpose, HBPC interventions for this review are defined as requiring the four characteristics outlined in Table 1. These defining characteristics underscore how HBPC interventions differ significantly from other innovative models such as Hospital at Home, Program of All-inclusive Care for the Elderly (PACE), and Patient-Centered Medical Homes, each of which contain some, but not all of these characteristics.

Table 1. Defining Characteristics of Home-Based Primary Care Models for this Review

Required for this Review	Optional	Excluded
1. Visits by a primary care provider Visits by a physician, nurse practitioner, or physician assistant.	Additional visits Nurses, physical therapists, social workers, counselors, etc.	Other models not included in this report Telephone call care only, no physician visits, nurse (or other provider) only care.
2. Visits to a patient's home Home is defined as any non institutional setting where the patient resides. It can include adult homes or senior housing.	Following patient across care setting In hospital management and short term post-acute rehabilitation.	Patients in institutions Patients who live in nursing homes, prisons, or long-term care hospitals.
3. Longitudinal management The intention is to provide care for an indefinite period; until admission to an institution, change in status, or death.	Not applicable	Short-term One-time home visits or assessments; hospital at home models in which care is provided for an acute need and patient returns to previous primary care.
4. Comprehensive primary care Includes medical care for and the management of chronic conditions and disabilities, preventive care, and environmental assessments.	Inclusion of mental health services Assessment and management of serious mental illnesses including depression.	Single condition care or single topic risk assessments Fall risk assessments, programs that target a single condition such as congestive heart failure.

In addition to clarifying the definition of HBPC, challenges remain in conducting a systematic review about HBPC. The mechanism by which the HBPC interventions are expected to influence outcomes and what outcomes are appropriate is not always explicit in HBPC program designs or the evaluation of these programs. This is a difficult, but not unfamiliar, challenge in research on health service organizations and delivery. In order to address this challenge the review will attempt to document what is and is not reported about the intervention design and as well as the reported outcomes and draw on methods for researching and reviewing studies of complex interventions²⁴ to inform the presentation and synthesis of the review information.

One objective of this review is to determine what information the current research provides regarding the ability of these programs to optimize patient and caregiver goals while providing care that is more efficient. The review may also be able to identify trends in what services are included in HBPC and the relative contribution of some individual services or combinations. What evidence the review is and is not able to locate, what

questions this evidence can answer, and what questions remain unanswered can serve as the basis for future work in the development and evaluation of HBPC programs.

II. The Key Questions

A document containing the draft Key Questions (KQs) was developed during Topic Refinement and was available for public comment from August 15, 2014 to September 05, 2014. The comments did not lead to significant changes; however, they identified areas that required more explanation and reorganization in order to clarify our intentions for the systematic review.

In response to comments and our subsequent discussions we have: a) specified that visits may be made by other health care providers, but home visits by a primary care provider, who may be a physician, nurse practitioner or physician's assistant, are necessary for an intervention to be considered HBPC for this review; b) eliminated the confusing overlap of the intermediate outcomes with the health care and patient experience outcomes by incorporating what was previously labeled "intermediate outcomes" into three categories of outcomes for KQ1; c) expanded what is now KQ2b, "organizational characteristics" so that it includes characteristics that public comments suggested may be important; and d) deleting a sub question for KQ2 about HPBC intervention characteristics and incorporating this in to KQ3 in order to eliminate overlap.

Key Question 1: Among adults with chronic conditions that are serious or disabling, what are the effects (positive and negative) of home-based primary care interventions on:

- a. Health outcomes
- b. Patient and caregiver experience
- c. Utilization of services

Key Question 2: How do the effects of home-based primary care interventions differ across:

- a. Patient characteristics (including, but not limited to, reason for HBPC, type and number of diagnoses, level of physical and cognitive function, caregiver availability, and demographics)
- b. Organizational characteristics (including, but not limited: ownership organizational structure, payment structure, leadership, and staffing patterns of the practice or health system providing HBPC)

Key Question 3: Which characteristics of home-based primary care interventions are associated with effectiveness? (including but not limited to, use of teams, composition of teams, use of technology, frequency of visits, and types of visits/services)

PICOTS

Population(s):

- Adults (> 18 years old) with chronic conditions, at least one of which is serious or disabling, or who have other major impediments that limit access to care.

This may include:

- Patients for whom going outside their home for care places a significant burden on the patient and/or caregiver or is contraindicated.
 - Patients for whom home-based care is deemed medically necessary.
 - Patients targeted for HBPC because of one serious condition (e.g., amyotrophic lateral sclerosis, spinal cord injury, chronic obstructive pulmonary disease, chronic serious mental illness) as long as the care is comprehensive (see intervention definition) and not limited to care only for that condition.
 - Patients who have a high level of health service needs or patients with high levels of utilization or high total costs.
 - Patients with chronic conditions who have social or psychological barriers to access to care (e.g., homelessness, mental illness).
- For KQ2a patient characteristics that will be consider include: reason for HBPC, type and number of diagnoses, level of physical and cognitive function, caregiver availability, and demographics.

Interventions:

For this review, home-based primary care interventions must include all four of the following:

- Visits by a primary care provider (e.g., physician, nurse practitioner, or physician assistant).
- Visits to the patient's home.
 - Home can be any location as long as it is not an institutional setting such as a nursing home or prison. Programs that serve people who are homeless can be included as can programs that serve people in alternative housing arrangements such as assisted living or adult care homes as long as they are not receiving nursing home level of services.
- Longitudinal management.
 - Care must be intended for an indefinite period until admission to an institution, change in status that makes HBPC no longer appropriate, or death.
- Comprehensive primary care.
 - Including medical care and management of chronic conditions and disabilities, as well as preventive care and assessment of the home environment through any means (e.g. multidisciplinary teams and/or

referrals), with the goal of minimizing negative outcomes (e.g., acute care, decline in function) and maximizing positive outcomes (quality of life, avoiding institutional care).

Variations in how these four required components are operationalized as well as the additional, optional services included are considered characteristics of the HBPC interventions and are the focus of KQ3. These may include the nature and intensity of the services (e.g., who is part of the team, frequency of home visits, hours of availability) or services that could be provided separately, such as fall assessments, caregiver training, and transitional care after a hospitalization but are integrated into the comprehensive, coordinated care as part of HBPC.

Comparators:

- KQ1 comparators are any other model of primary care delivery such as:
 - Standard office-based outpatient management
 - Office-based medical home models
 - All inclusive care models such as PACE
 - Geriatric outpatient clinic
 - Adult day health care
 - Home-based care models that include home visits done exclusively by people other than a primary care provider (e.g., all visits are by social workers, community health workers, nurses, etc.)

For KQ2 and KQ3 comparisons will be made across studies as well as examining any subgroup analyses within studies. Sources of information are not limited to head to head comparisons within individual studies.

- KQ2 requires comparisons across HBPC programs. For this Key Question the comparisons are across:
 - Patient characteristics (including, but not limited to, type and number of diagnoses, level of physical and cognitive function, caregiver availability, and demographics)
 - Organizational characteristics (including, but not limited to, ownership organizational structure, payment structure, leadership, and staffing patterns)
- KQ3 comparisons are across HBPC intervention characteristics (including, but not limited to, use of teams, composition of teams, use of technology, frequency of visits, and types of visits/services).

Outcomes:

There are three categories of outcomes considered when assessing the positive and negative effects of HBPC for KQ1 and KQ3. Harms include negative effects of HBPC in any of the outcome categories. Categories of outcomes with examples are listed below.

For KQ1a, Health Outcomes:

- Function
 - Physical, psychological, and cognitive
- Mortality
- Morbidities
 - Examples: falls, incontinence, pressure ulcers, depression, delirium, dementia with behavioral problems, pain
- Patient Safety
 - Errors in diagnosis or treatment, including medication errors
 - Harms or unintended consequences of any procedures or treatments provided in the home

For KQ1b, Patient and Caregiver Experience

- Quality of life
 - Time patient remains in home and/or location of death/death at home if that is patient preference
 - Patient and caregiver burden and/or anxiety
- Patient and caregiver knowledge and engagement in health care
- Facilitation of patient and caregiver access to other services not included in the HBPC. This could including medical supplies and equipment, medications, or other services not part of the HBPC intervention
- Relationships with care providers
 - Maintenance of relationship with prior primary care provider (if desired)
 - Patient and caregiver trust in HBPC providers

For KQ1c, Utilization of Services:

- Hospitalizations: rate and length of stay
- Urgent care use (emergency departments and urgent care centers)
- Nursing home admission
- Use of specialty care (either in home or other location)
- Hospice care
- Other long-term services and supports (adult day health, respite, personal care, homemaker, home health)
- Informal care

For KQ3: The outcomes are the same as for KQ1 (Health outcomes, patient and caregiver experience, and utilization of services).

Timing:

The intention must be to provide primary care for an extended period as specified above in Interventions.

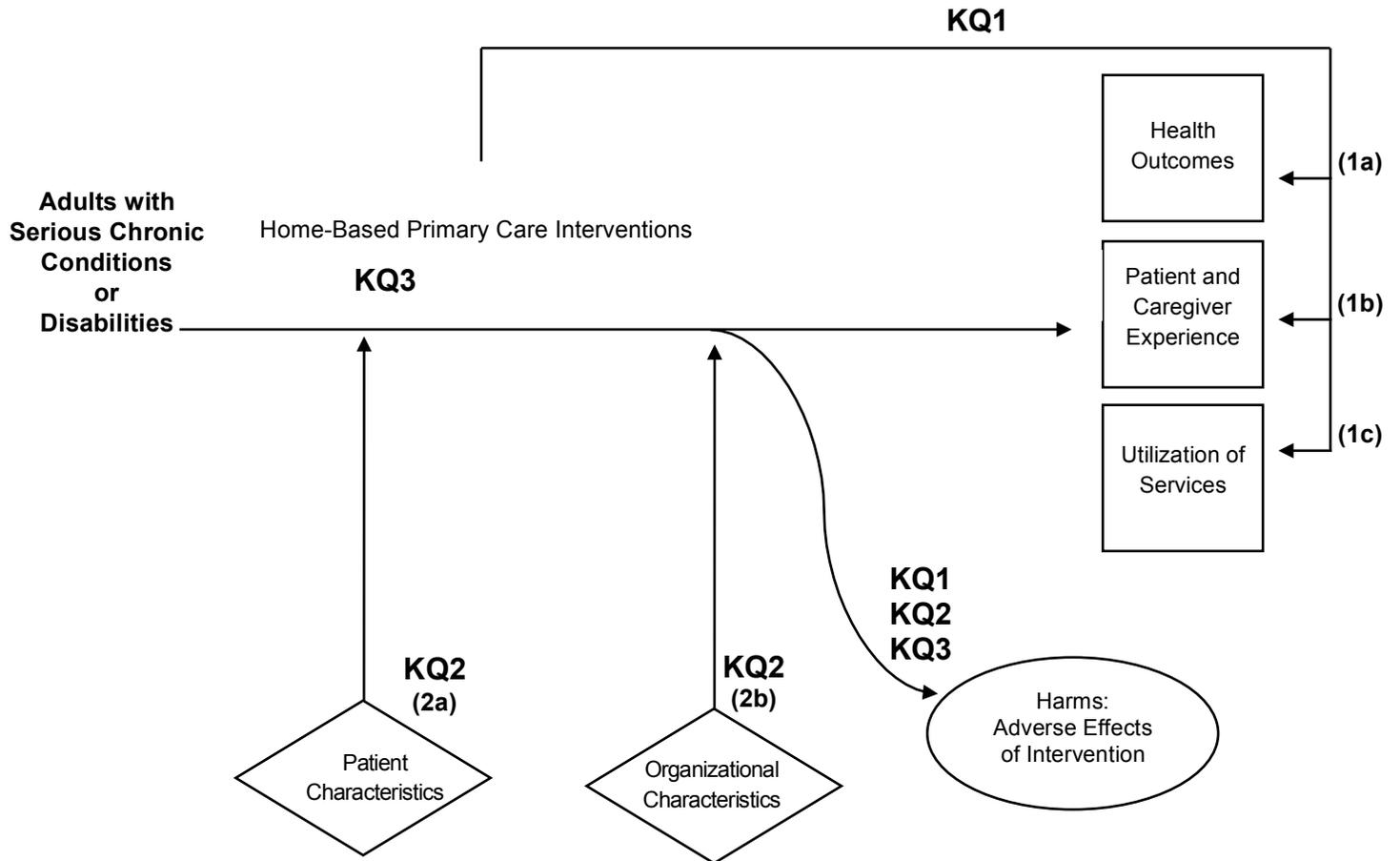
Settings:

Primary care must be provided in patients' homes as specified above in Interventions. Important organizational characteristics that will be considered include:

- Ownership organizational structure
- Payment structure
- Leadership
- Staffing patterns

III. Analytic Framework

Figure 1. Analytic framework for Home-Based Primary Care Interventions



IV. Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review

The criteria for inclusion and exclusion of studies are designed to identify studies that can answer the Key Questions and are based on the PICOTS described in the previous section.

Table 2: Inclusion and Exclusion Criteria

	Include	Exclude
Population	Adults with chronic illnesses or disabilities	Children with special needs Adults being assessed for a single risk factor or condition Well elderly
Intervention(s)	HBPC as defined above	Care models that do not include the four required characteristics. Examples of excluded care; preventive home visits, single visit home assessments, single purpose visits (fall risk assessments), care for a single condition, short-term home-based care such as Hospital at Home programs.
Comparator(s)	Any other model of primary care	Services that are not primary care
Outcomes	Health Care Outcomes Patient and Caregiver Experience Utilization of Services	None
Timing	Longitudinal care, expected to continue until change in status	Short-term, time-limited home-based care such as Hospital at Home programs.
Setting(s)	Patients' homes, broadly defined United States or other developed countries	Institutions such as nursing homes or prisons Countries with extremely different economies and/or health care systems
Study Design	<ul style="list-style-type: none"> • Randomized Controlled Trials • High quality observational studies including: comparative cohort studies and time series • Systematic reviews (for identification of studies only) • Pre/post studies with or without a comparison group 	<ul style="list-style-type: none"> • Descriptive studies • Case series or reports • Nonsystematic reviews
Publication Type	Peer reviewed journals Gray literature (if the study meets all other criteria)	Editorials or commentaries

Below are additional details on the scope of this project:

Study Designs: We will include studies that evaluate the effect of HBPC interventions, including randomized controlled trials (RCTs) and high quality observational studies such as comparative cohort studies and time series. We will include pre/post studies with or without a comparison group, though we will highlight

the relative higher risk of bias in studies without a comparison group and we may give more weight and attention to more rigorous study designs. We will exclude case series, and case reports as they are descriptive rather than assessments of effectiveness. We will not exclude studies based on any specific comparator or outcome; however, the comparators and approach to measuring the outcomes will be considered as part of the assessment of the quality of an individual study and of the quality of the body of evidence.

Systematic reviews will be used only to identify individual studies we may not have identified through our searches. This approach is based on our knowledge of the field and the results of Topic Refinement and preliminary searches, which suggest that there is not a large volume of literature and that the scope and purpose of reviews conducted to date, differ in key ways from those for this review.

Non-English Language Studies: We will restrict inclusion to English-language articles. We will review English language abstracts of non-English language articles in order to identify studies that would otherwise meet inclusion criteria and to assess the likelihood of language of publication bias.

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions

Publication Date Range: The primary searches will include articles published between 1995 and 2014. We confirmed through our literature scan and discussion with our technical expert panel (TEP) that the majority of programs began after 1997; therefore a search back to 1995 should capture these. We will also check reference lists of the included studies and systematic reviews to confirm that earlier studies were not missed.

Library searches will be designed and conducted by a medical librarian familiar with systematic reviews in consultation with the review team. Suggestions about search terms were requested and received from TEP members and these were evaluated and included when appropriate.

Literature Databases: Ovid MEDLINE, CINAHL, Clinical Trials.gov, and Cochrane Database of Systematic Reviews will be searched to capture published literature. Gray literature will be identified by searching the NYAM gray literature database and the websites of organizations that may fund or produce research evaluating HPBC.

Scientific Information Packets: Requests for unpublished evaluation data on HBPC interventions will be sent to professional organizations, organizations that fund or conduct research, and government agencies. Submissions are reviewed by the review team and assessed for relevance and quality.

Hand Searching: Reference lists of included articles will also be reviewed for includable literature.

Contacting Authors: If information regarding methods or results appears to be omitted from the published results of a study, or if we are aware of unpublished data, we will email the authors and request this information.

Process for Selecting Studies: We will establish criteria that will be used to determine eligibility for inclusion and exclusion of abstracts in accordance with the Key Questions and the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.²⁵ To ensure accuracy, all excluded abstracts will be dual reviewed. The full text will be retrieved for all citations deemed appropriate for inclusion by at least one of the reviewers. Each full-text article, including any articles suggested by peer reviewers or that may arise from the public posting process, will be independently reviewed for eligibility by two team members. Any disagreements will be resolved by consensus.

Updates: The searches will be updated while the draft report is posted for public comment and peer review to capture any new publications. Literature identified from the updated search will be assessed by following the same process of dual review as all other studies considered for inclusion in the report. If any pertinent new literature is identified for inclusion in the report, it will be incorporated before the final submission of the report.

C. Data Abstraction and Data Management

After studies are selected for inclusion, data will be abstracted into categories that include but are not limited to: study design, year, setting, geographic location, sample size, eligibility criteria, patient characteristics, HBPC intervention characteristics, organizational characteristics, and results relevant to each key question as outlined in the previous PICOTS section. Information that will be abstracted that is relevant for assessing applicability will include the characteristics of the population, intervention, and care settings.

Abstracted study data will be verified for accuracy and completeness by a second team member. A record of studies excluded at the full-text level with reasons for exclusion will be maintained and included in the report.

D. Assessment of Methodological Risk of Bias of Individual Studies

Predefined criteria will be used to assess the quality of individual controlled trials, systematic reviews, and observational studies by using clearly defined templates and criteria as appropriate. Randomized trials and observational studies will be evaluated according to criteria recommended in the AHRQ methods chapter, *Assessing the Risk of Bias of Individual Studies When Comparing Medical Interventions*.²⁵

Individual studies will be rated as “good,” “fair,” or “poor,” or as specified by the particular criteria.

Studies rated “good” will be considered to have low risk of bias, and their results will be considered valid. Good quality studies include clear descriptions of the population, setting, interventions, and comparison groups; a valid method for allocation of patients to treatment or identifying the treatment and control groups in observational studies; low dropout rates and clear reporting of dropouts; appropriate means of controlling for confounding; and appropriate measurement of outcomes.

Studies rated “fair” will be susceptible to some bias, though not enough to invalidate the results. These studies may not meet all the criteria for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems. The fair quality category is broad, and studies with this rating will vary in their strengths and weaknesses. The results of some fair quality studies are likely to be valid, while for others the validity may be uncertain.

Studies rated “poor” will have significant flaws that imply biases of various types that may invalidate the results. They will have a serious or “fatal” flaw in design, analysis, or reporting; large amounts of missing information; discrepancies in reporting; or serious problems in the delivery of the intervention. The results of these studies will be as likely to reflect flaws in the study design as the true difference between the compared interventions. We will not exclude studies rated as being poor in quality *a priori*, but poor quality studies will be considered to be less reliable than higher quality studies when synthesizing the evidence, particularly if discrepancies between studies of differing quality are present.

Each study evaluated will be dual-reviewed for quality by two team members. Any disagreements will be resolved by consensus.

E. Data Synthesis

We will construct evidence tables identifying the study characteristics (as described in section C. Data Abstraction and Data Management), outcomes, and quality ratings for all included studies.

We will review and highlight studies using a hierarchy-of-evidence approach. The best evidence available will be the focus of our synthesis for each key question. If high quality evidence is not available we will describe any lower quality evidence we were able to identify, but we will underscore the issues that make it lower quality. We assess and state whether the inclusion of lower quality studies would change any of our conclusions.

Meta-analyses will be considered and conducted to summarize data and obtain more precise estimates on outcomes for which studies are homogeneous enough to provide a meaningful combined estimate. The feasibility of a quantitative synthesis will depend on the number and completeness of reported outcomes and the amount of heterogeneity among the studies. To determine whether meta-analysis could be meaningfully performed, we will consider the quality of the studies and the

heterogeneity among studies in the design, patient population, interventions, and outcomes. The key questions are designed to assess the comparative effectiveness and harms by patient demographics, comorbidities, and treatment features. Meta-regression may be conducted to explore statistical heterogeneity using additional variables on methodological or other characteristics (e.g., quality, randomization or blinding, outcome definition and ascertainment) given a large enough number of studies.

Qualitative data about the studies will be summarized in tables, and descriptive analysis, and interpretation of the results will be provided. Based on the evidence tables, and these analyses and we will develop ways to summarize and present the data that may include summary tables, graphs, or matrixes as appropriate. For example, we may use a table to highlight results across studies of the impact of HBPC on caregiver burden, a graph to show the range of estimates of impact of HBPC on hospitalizations, or a matrix to show the characteristics of HBPC interventions that reduce nursing home admissions.

F. Grading the Strength of Evidence for Individual Comparisons and Outcomes

The strength of evidence for each key question will be initially assessed by one researcher for each outcome (see the PICOTS above), using the approach described in the AHRQ Methods Guide.²⁴ To ensure consistency and validity of the evaluation, the grades will be reviewed by the entire team of investigators for:

- Study limitations (low, medium, or high level of study limitations based on study design and the quality of the included studies)
- Consistency (consistent or inconsistent findings, or unknown/not applicable)
- Directness (direct or indirect evidence)
- Precision (precise or imprecise estimates of effect)
- Reporting bias (suspected or undetected)

The strength of evidence will be assigned an overall grade of high, moderate, low, or insufficient according to a four-level scale by evaluating and weighing the combined results of the above domains:

- High—We are very confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has few or no deficiencies. We believe that the findings are stable, i.e., another study would not change the conclusions.
- Moderate —We are moderately confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
- Low—We have limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.

- Insufficient—We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

G. Assessing Applicability

Applicability considers the extent to which results from a study or a body of evidence can be used to answer the questions of interest. Variability in the studies or studies with unique attributes may limit the ability to generalize the results to other populations, and settings. What may affect applicability can vary depending on the question of interest and currently the assessment of applicability is not standardized.

For this review we will consider if applicability is affected by the characteristics of the patient populations (e.g., demographic characteristics, reason for receiving home-based care, primary condition or disability, presence of co-morbidities) and the setting of the study (including geographic location and practice context). We will identify if individual studies have potential applicability issues during data abstraction and quality assessment, and then we will summarize our findings into an assessment of the applicability of the body of evidence available to answer each question.

V. References

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VI. Definition of Terms

Hospital at Home: A program that provides hospital-level care to adults in their own home. Rather than being admitted to the hospital the patient receives extended nursing care and is assessed and treated by a Hospital at Home physician for a specific condition but returns to their prior primary care provider when the acute episode is resolved.

Informal Care: Care given to a person who is sick or disabled by a family member or friend. The care provided is not paid, professional work.

Independence at Home Demonstration (IAH): This demonstration is testing a service delivery and payment incentive model that utilizes physician and nurse practitioner directed primary care teams to provide services to certain Medicare beneficiaries in their homes. The program is designed to improve health outcomes and reduce expenditure. IAH is funded by the Centers for Medicare & Medicaid Service and 17 practices and consortia are participating.

PACE (Program of All-inclusive Care for the Elderly): This is a Medicare and Medicaid program that provides care and services in the home, the community, and the PACE center, for people who might otherwise be in a nursing home or other care facility. Many PACE participants get most of their care from staff employed by the PACE organization in the PCE center.

Primary Care: Primary care provides entry into the health care system, provides person-focused (not disease-oriented) care over time, provides care for all but very uncommon or unusual conditions, and coordinates or integrates care, regardless of where the care is delivered and who provides it.

VA Home-Based Primary Care: The VA Home Based Primary Care program is for veterans who have complex health care needs for whom routine clinic-based care is not effective and who need skilled services, case management, and assistance with activities of daily living (e.g., bathing and getting dressed) or instrumental activities of daily living (e.g. fixing meals and taking medicines); are isolated or their caregiver is experiencing

burden. A VA physician supervises the health care team who provides services to veterans in their homes.

VII. Summary of Protocol Amendments

Not applicable

VIII. Review of Key Questions

AHRQ posted the key questions on the Effective Health Care Web site for public comment. The EPC refined and finalized the key questions after review of the public comments, and input from Key Informants and the Technical Expert Panel. This input is intended to ensure that the key questions are specific and relevant.

IX. Key Informants

Key Informants are the end users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform healthcare decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

X. Technical Experts

Technical Experts constitute a multi-disciplinary group of clinical, content, and methodological experts who provide input in defining populations, interventions, comparisons, or outcomes and identify particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicting opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design, and methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind nor do they contribute to the writing of the report. They have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Technical Experts must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. The EPC considers all peer review comments on the draft report in preparation of the final report. Peer reviewers do not participate in writing or editing of the final report or other products. The final report does not necessarily represent the views of individual reviewers. The EPC will complete a disposition of all peer review comments. The disposition of comments for systematic reviews and technical briefs will be published three months after the publication of the evidence report.

Potential peer reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Invited peer reviewers may not have any financial conflict of interest greater than \$10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

XII. EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than \$1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than \$1,000 will usually disqualify EPC core team investigators.

XIII. Role of the Funder

This project was funded under contract from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

APPENDIX

Search Strategy (Ovid MEDLINE)

1. exp Primary Health Care/
2. exp General Practice/
3. exp general practitioners/ or exp physicians, family/ or exp physicians, primary care/
4. exp Nurse Practitioners/
5. exp Physician Assistants/
6. exp Health Services for the Aged/
7. exp House Calls/
8. exp Home Care Services/9. exp Home Care Agencies/
10. exp Homebound Persons/
11. ((home or home-based) adj7 ((primary adj3 care) or (family adj3 (practic\$ or medic\$)) or (general adj3 practition\$)))mp.
12. ((home or homes or house) adj3 (visit\$ or base\$ or center\$) adj7 ((primary adj3 care) or (family adj3 (practic\$ or medic\$)) or (general adj3 practition\$)))mp
13. ((age or aging) adj2 place).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
14. 1 or 2 or 3 or 4 or 5 or 6
15. 7 or 8 or 9 or 10
16. 14 and 15
17. 11 and (14 or 15)
18. 13 and (14 or 15)
19. 12 or 16 or 17 or 18
20. limit 19 to yr="1995 -Current"