
Care Coordination Models and Tools: A Systematic Review and Key Informant Interviews

June 2020

Prepared for:

Department of Veterans Affairs
Veterans Health Administration
Health Services Research & Development Service
Washington, DC 20420

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PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted health care topics of importance to clinicians, managers, and policymakers as they work to improve the health and health care of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program is comprised of 4 ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, and interface with stakeholders. To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers. The program solicits nominations for review topics several times a year via the [program website](#).

Comments on this evidence report are welcome and can be sent to Nicole Floyd, Deputy Director, ESP Coordinating Center at Nicole.Floyd@va.gov.

Recommended citation: Duan-Porter W, Ullman K, Majeski B, Miake-Lye I, Diem S, and Wilt TJ. Evidence review: care coordination models and tools. Washington, DC: Evidence Synthesis Program, Health Services Research and Development Service, Office of Research and Development, Department of Veterans Affairs. VA ESP Project #09-009; 2020. Available at: <https://www.hsrd.research.va.gov/publications/esp/reports.cfm>.

This report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the **Minneapolis VA Medical Center, Minneapolis, MN**, funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

ACKNOWLEDGMENTS

This topic was developed in response to a nomination from the Office of Nursing Services and the Office of Care Management and Social Work Services to support the Coordinated Care and Integrated Case Management (CC&ICM) Initiative. The scope was further developed with input from the topic nominators (*ie*, Operational Partners), the ESP Coordinating Center, the review team, and the technical expert panel (TEP).

In designing the study questions and methodology at the outset of this report, the ESP consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

The authors gratefully acknowledge the following individuals for their contributions to this project:

Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend Technical Expert Panel (TEP) participants; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for dissemination of the report to field and relevant groups.

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The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center and the ESP Center work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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EXECUTIVE SUMMARY

INTRODUCTION

Complexity of health care services and care fragmentation contribute to adverse health outcomes and poor patient experiences of care. Over the past 20 years, there has been substantial interest in care coordination interventions, particularly to reduce utilization of acute care services. Care coordination models usually involve systematic strategies that aim to improve continuity and bridge transitions of care. Often, this takes the form of care or case management, in which a designated person or team helps patients manage their medical care and navigate interactions with the health care system(s). It remains unclear whether care coordination interventions can sufficiently address gaps in care and improve patient outcomes.

The VA Care Coordination and Integrated Case Management (CC&ICM) initiative was launched in 2016, as a collaboration between the VA Offices of Care Management and Social Work, and Nursing Services. The main goals of this initiative are to standardize and integrate care coordination services across all VA facilities and points of care for Veterans. To assist the CC&ICM initiative, the VA ESP was asked to review evidence on implementation and outcomes of various care coordination models.

We summarize evidence from eligible systematic reviews (SR) on key characteristics and effectiveness of care coordination interventions for diverse adult populations at high risk for adverse outcomes. Additionally, we present results from primary research studies of effective interventions (*ie*, those able to reduce hospitalizations and/or emergency department [ED] visits) regarding tools and approaches to assess patient trust and care team integration, and to improve communication between patients and providers. To better understand which results may be most applicable to VA, we also provide information about the settings in which effective care coordination models were implemented. Finally, we present results from key informant interviews to address remaining gaps in the published literature, particularly with regard to tools and approaches used by various interventions.

METHODS

To guide scope refinement and protocol development, we selected the framework for Care Coordination in Chronic and Complex Disease Management. This framework focuses on characteristics, processes, and interactions within and between health care teams. We adapted this framework in 2 areas: 1) specification that team roles include who contacted patients (and in what manner); and 2) reorganization of outcomes by patients (*eg*, patient experience, quality of life, and survival), health care teams (*eg*, work satisfaction and burnout), and health systems (*eg*, acute care utilization and costs). While health care utilization and costs may be measured at the patient level (*eg*, number of admissions or ED visits per person), we considered such outcomes to be oriented towards the priorities of the health care system.

Applying this framework and in accordance with the priorities of our VA partners, we defined effective care coordination interventions as those that reduced hospitalizations and/or ED visits. We sought information about the key characteristics of effective interventions, such as multidisciplinary teams (vs primarily single case manager), and home visits (vs telephone contacts and/or outpatient visits). To support ongoing implementation and evaluation of care

coordination programs in the VA, we also searched for evidence on tools and approaches that addressed patient trust, team integration, and patient-provider communication. Finally, to support interpretation of the evidence with regard to applicability, we sought information on the characteristics of health care systems and communities where effective interventions had been implemented.

Key Questions

For community-dwelling adults with a variety of ambulatory care sensitive conditions and/or at higher risk of having repeat hospitalization or ED visits:

KQ1—What are the key characteristics of care coordination models (of varying types) that aim to reduce hospitalization or ED visits?

KQ2—What is the effect of implementing these care coordination models on hospitalizations, ED visits, and patient experience (*eg*, Consumer Assessment of Healthcare Providers and Systems)?

KQ3—What are the characteristics of settings in which effective models have been implemented?

KQ4—Among effective models, which approaches/tools have been used to:

- a) Measure patient trust or working alliance?
- b) Measure team integration?
- c) Improve communication between patients and providers?

To address these KQ, we first focused on identifying eligible SR on care coordination models. In order to address likely gaps in results from SR, particularly with regard to KQ 3 and 4, we also examined primary research studies of effective interventions and conducted key informant interviews with those who implemented interventions.

Search Strategy

We searched for English-language systematic reviews, from inception until September 2019, in MEDLINE, CINAHL, Embase, Cochrane Database of Systematic Reviews, Agency for Healthcare Research and Quality Evidence-based Practice Center reports, and VA ESP reports. We also identified relevant primary research studies included by reviews and conducted a search for randomized controlled trials (RCT) in MEDLINE and Embase, from 2018 until February 2020.

Study Selection

Using prespecified inclusion and exclusion criteria, SR search results were evaluated and excluded with the consensus of 2 reviewers. Eligible populations of interest included community-dwelling adults with a range of ambulatory care sensitive conditions (*eg*, heart failure and chronic lung disease) and/or at higher risk for acute care episodes. If a review focused exclusively on interventions for a single health condition, it was excluded. Eligible interventions covered different care coordination models, such as care or case management and home-based primary care. We required that eligible reviews reported inclusion of hospitalizations and/or ED

visits as outcomes of interest in objectives or results. At full-text review, 2 individuals separately determined inclusion and then resolved any conflicts through discussion. When consensus could not be reached, disagreements were discussed with a third reviewer.

From each eligible SR, we identified all included primary studies and 2 individuals evaluated them for potential relevance to KQ3 and 4. In addition to above criteria for SR, we also applied the following: conducted in US, and RCT or quasi-experimental observational studies (*eg*, comparative control cohort or interrupted time series). We also screened and reviewed results from an additional search of RCT published 2018 until February 2020. Two reviewers applied the same criteria used to evaluate SR, along with the additional requirement for RCT conducted in US.

Quality Rating & Data Abstraction

We assessed the quality of eligible SR using criteria adapted from AMSTAR 2 and rated overall quality as high, medium, or low. We abstracted data from reviews on: target population(s); dates of search queries; and number and characteristic of included primary studies (location, setting and study design). Additionally, from high- and medium-quality SR, we abstracted detailed results on: characteristics of care coordination model; pooled effects (or qualitative summaries) for hospitalizations, ED visits, and/or patient experience; characteristics of settings; and tools and approaches used to measure patient trust or working alliance, assess health care team integration, and/or improve communication between patients and providers.

From relevant primary research studies on care coordination models, we abstracted data on effectiveness for main outcomes; participant, intervention and setting characteristics; and relevant tools and approaches. Because the primary studies frequently referenced other studies for information on intervention characteristics, we also reviewed these associated studies for relevant data.

Data Synthesis for Systematic Reviews & Relevant Primary Studies

We conducted qualitative syntheses of results from eligible SR and relevant primary studies. We focused on eligible SR to address key characteristics and effectiveness of care coordination models, particularly with regard to reduction of hospitalizations and/or ED visits. We also included strength of evidence determinations by SR, if these were reported. We describe information from relevant primary studies regarding: setting characteristics; and tools and approaches used to measure patient trust or working alliance, assess health care team integration, and/or improve communication between patients and providers. To address remaining gaps, we also abstracted results from associated articles (*eg*, methods papers) for this set of primary studies.

Key Informant Interviews

We conducted semi-structured interviews with research investigators and members of teams who implemented care coordination models, as described in relevant primary studies. We included all relevant interventions, regardless of effectiveness in reducing hospitalizations and/or ED visits. We initially invited 22 individuals by email, and contacted another 3 individuals per recommendations of respondents. We completed interviews with 11 participants.

The main focus of these interviews was to address gaps in the published literature regarding tools and approaches. We also addressed intervention uptake and sustainability, as this information may be particularly useful to our VA stakeholders. Interview guides included questions in each of these areas and were individually adapted using published or online information about the interventions. Interviews lasted about 30 minutes and were audio-recorded. We reviewed contemporaneous notes and audio-recordings to first develop summaries for each care coordination intervention. We then examined summaries for all interviews to provide overall themes.

RESULTS

Overview of Eligible Systematic Reviews

Of 2,324 unique citations for SR, 72 underwent full-text review. We identified 16 eligible SR, 14 of which examined case management or transitional care interventions, and 2 evaluated intensive primary care models (eg, home-based primary care). All SR included a variety of care coordination models within these 2 broad categories. Four SR included only RCT, while the others allowed both RCT and observational studies. Three SR included only US studies, and the remaining SR included studies conducted in several different countries. Seven SR focused specifically on patients at higher risk for acute care utilization (*ie*, high-utilizers), and 1 SR examined interventions for individuals with frailty. Six reviews were high quality, 6 were medium quality, and 4 were low quality. We focused on the 12 medium- and high-quality SR for detailed results. We provide descriptions of results for each KQ in the following text.

KQ1: What Are the Key Characteristics of Care Coordination Models?

All SR provided general descriptions of different components included by interventions, with many providing some information on team composition and frequency of use of certain components (eg, multidisciplinary care plan). Outside of in-person contacts (whether in a clinical setting or at home), the other main form of communication with patients was via telephone. Four SR specifically addressed whether there are key characteristics for care coordination interventions. Among these, 1 used qualitative comparative analysis to examine intervention characteristics of effective case management models, reporting that careful case-finding was necessary but not sufficient; selection of patients needed to be combined with either a high-intensity model (defined by authors using caseload, frequency and types of contact with patients) or a multidisciplinary care plan. Another SR reported that interventions targeting specific risk factors were more likely to be effective. One SR conducted subgroup analyses by intervention duration and different approaches to address frailty, finding no significant differences in effect. The fourth SR examined home-based primary care and found no specific pattern of components that were associated with effective interventions. Additionally, 2 SR sought to determine the key components for care coordination models but were unable to draw conclusions; authors reported challenges due to lack of published information on components and fidelity of intervention implementation.

KQ2: What is the Effect of Implementing Care Coordination Models?

Of 10 SR examining case or care management and/or transitional care interventions, 2 conducted quantitative meta-analyses, while remaining SR used qualitative syntheses. Six SR evaluated effects on hospitalization, with 5 reporting mixed or unclear results and 1 finding lack of

effectiveness. One SR pooled results for transitional care interventions (most involved nurses who called patients and/or made home visits) for diverse patient populations. Using data from 11-35 RCT, this SR found no effect at 1 month (risk difference [RD] -0.03, 95% CI -0.05, 0) but some effects at 3-18 months (RD range -0.05 to -0.11). Another SR conducted meta-analyses to evaluate effects on hospitalization for a diverse set of case management interventions for frail community-dwelling older adults; pooled results from 5 RCT showed that case management did not reduce hospitalizations (odds ratio [OR] 1.13, 95% confidence interval [CI] 0.95, 1.35).

Seven SR examined effects of case or care management and/or transitional care interventions on ED visits. Two SR indicated that care coordination interventions reduced ED visits, and both provided descriptive information about included studies. One SR stated that 6 included studies reported reductions in ED visits, and the other found that the median rate ratio (of care coordination vs control) was 0.63, with interquartile range of 0.41-0.71. All 5 remaining SR reported unclear or mixed effects on ED visits, including 1 that conducted pooled meta-analyses over various timeframes (1-12 months).

Only 1 SR on case management evaluated effects on patient experience, and using qualitative synthesis found inconsistent results.

Two SR evaluated intensive primary care interventions, and both used qualitative synthesis. One SR focused on home-based primary care, reporting reduced hospitalizations. The other SR addressed several different models and described inconsistent results across studies. The SR on home-based primary care also found that there was improved patient and caregiver satisfaction (low strength of evidence).

KQ3: What Are the Characteristics of Settings in Which Effective Models Have Been Implemented?

Only 2 SR addressed characteristics of settings for interventions; 1 SR on case management stated that all but 1 of 16 included studies were single-site, usually in an urban setting.³³ The other SR sought to address organizational settings for home-based primary care but was unable to find published information.

To further address KQ 3 (and KQ 4), we identified 272 unique primary studies included by eligible SR, and found 18 RCT and 9 observational studies that were relevant. While 78% of relevant observational studies (n=7) reported reductions in hospitalizations and/or ED visits, only 22% of RCT (n=4) demonstrated effectiveness. Additionally, we searched for RCT that were published after the most recent eligible SR. This search resulted in 1048 unique citations, of which 21 underwent full-text review. We identified 2 relevant RCT; both studies reported that interventions were not effective for reducing hospitalizations and/or ED visits.

We categorized the primary studies on effective interventions into transitional care, outpatient care or case management (led by nurse or social worker), or other intensive primary care models. These interventions were implemented in a variety of settings, including rural community hospitals and health systems, academic medical centers (in urban settings), and public hospitals serving largely poor and uninsured populations. There was no clear connection between differences in settings, types of intervention, and various patient populations.

KQ4: What Are the Tools and Approaches Used by Effective Models?

No SR commented on tools and approaches used to measure patient trust or care team integration, or to improve communication between patients and providers. Primary research studies described several approaches to improve patient-provider communications, such as coaching patients on how to ask questions, making lists of key concerns, and role-playing visits with providers. In 2 studies, care coordinators supported communication by attending outpatient visits with patients and their providers. No primary research study described specific tools or measures to assess patient trust or care team integration. For 1 intervention, qualitative methods were used to evaluate patient experiences and relationship with care coordinators.

Key Informant Interviews

We conducted 11 interviews with investigators and other team members who implemented care models described by relevant primary research studies. Several interviewees described using approaches akin to health coaching (although not called that in the published studies) to improve patient communications with providers. None of the interviews provided additional information on specific tools or approaches used to assess patient trust, care team integration, or patient-provider communications. Review of additional intervention materials provided by some interviewees indicated that assessments of patient experience sometimes included factors conceptually related to patient trust (*eg*, perception that care coordinator was knowledgeable and understood patients' needs).

There was variation in the sustainability of care coordination interventions, with some stopping after completion of the research studies. Lack of financial viability was often a key factor in discontinuation. Others were substantially modified and adapted to meet changing health system priorities (*eg*, in targeted patient populations). Implementation teams had variable success in engaging stakeholders such as hospital leadership and front-line providers. Health care utilization and costs were high priority for those in leadership, and improved patient experiences were not usually sufficient for continuing interventions.

In terms of key issues for future care coordination interventions, some key informants questioned whether acute care utilization by high-risk populations was truly preventable. For example, 1 interviewee stated, *“Everything that could be possibly going wrong is going wrong...A lot of these people are going to get readmitted no matter what you do.”* There was concern with current readmission metrics and the ability to make substantial changes within a short timeframe: *“30 days doesn't give you sufficient time...especially in elderly patients with many issues.”* Some also suggested that care coordination interventions may work better in those with less severe conditions and/or modifiable factors; an important challenge with such an approach is that the intervention may need to serve a large number of patients before there are appreciable differences in acute care utilization. One individual described it thus: *“You can allocate a lot of resources to extremely high need patients...or you can allocate resources to a larger population and ... have a smaller impact on individual level, but on population level have greater impact...”*

DISCUSSION

Key Findings

To inform the VA CC&ICM initiative, we conducted a multi-stage review of evidence for care coordination models. We identified 16 eligible SR addressing care coordination interventions, and further examined 29 relevant primary research studies. We also conducted 11 key informant interviews with those who have implemented care coordination models. Key findings include:

- 2 SR reported that a key component of effective care coordination models was patient selection criteria focused on specific risk factors and/or needs.
- 1 SR reported that high-intensity models and/or multidisciplinary plans were required for effectiveness (in combination with selection criteria noted above).
- Most SR reported unclear or inconsistent effects of care coordination models in reducing hospitalizations or ED visits.
- Primary studies reporting effective interventions were conducted in a variety of settings, including rural community hospitals, academic medical centers in urban settings, and public hospitals serving largely poor and uninsured populations.
- Approaches to improve patient-provider communication included coaching patients, role-playing, and attending appointments with patients.
- SR, primary studies, and interviews provided little information on specific tools or approaches used to assess patient trust or health care team integration.
- Key informant interviews suggested variation in sustainability of care coordination interventions, with substantial adaptation occurring among many of those that have continued.

Care coordination models were complex and differed along multiple dimensions, thus presenting substantial challenges for SR authors in summarizing and comparing results across studies. Four SR drew conclusions with regard to key intervention characteristics, with 2 highlighting selection criteria, 1 indicating importance of high-intensity (defined by lower caseload and more patient contacts) and multidisciplinary plans, and 2 finding no key characteristics. Several SR seeking to examine key characteristics and/or organizational settings of care coordination models reported difficulty finding sufficient published evidence to address these questions.

Among 11 primary studies demonstrating effective care coordination models, none reported specific tools or approaches for measuring patient trust or health care team integration. Key informant interviews did not provide additional information on these areas. Interventions used a variety of approaches to improve communication between patients and providers, including coaching and role-playing. In some interventions, care coordinators also directly communicated with providers on patients' behalf, including participation at outpatient appointments.

Some interviewees described adaptation of the intervention over time to address evolving priorities for health care organizations. Some also highlighted the difficulty of modifying health

and social factors contributing to need for acute care utilization among many patients in the highest risk category. There were suggestions that there may be more benefit in focusing on patients at somewhat lower risk and improving health care processes for larger groups of patients.

Implications for Policy

It remains unclear whether care coordination interventions should be implemented in particular health care settings and how they may be adapted to improve effectiveness and sustainability. Two SR highlighted the importance of carefully selecting patients for care coordination interventions. The VA CC&ICM initiative has implemented several tools for evaluating Veteran needs and matching the level of care coordination services to those needs. It will be important for VA to evaluate the feasibility of applying these tools more widely, and the effects of implementing such tools on delivery of services and patient outcomes. Additionally, because VA medical centers and clinics are located in a variety of settings, it will be important to understand differences in utility of these tools across large and small sites, and those serving urban and more rural communities.

Understanding what type of services and programs are available at a particular facility may be challenging for Veterans, their caregivers, and VA clinical staff. A key goal of the CC&ICM initiative is to standardize care coordination across VA sites, and this may improve access and use of appropriate services for Veterans. However, the CC&ICM initiative acknowledges the importance of flexibility in adapting care coordination models to accommodate local circumstances. Our interview results also support the importance of local adaptations for uptake and sustainability of care coordination interventions. A potential avenue to achieving more consistency of services while allowing flexibility may be to align services and programs based on program goals and Veteran needs; this information could then be collected in a central hub that Veterans and/or VA staff can use to find appropriate services. Additionally, it may be valuable to provide educational materials as part of the CC&ICM initiative, to guide adaptations. Future evaluation of implementation should consider which adaptations were made and the rationale for these.

One SR indicated that a high-intensity (defined using case load and patient contacts) or multidisciplinary care coordination model was more likely to be successful. Our examination of effective primary research studies also found a high number and frequency of patient contacts, often involving home visits. Therefore, it may also be valuable to understand which VA programs or models are most similar to these high-intensity interventions, and consider whether it would be cost-effective to implement more broadly.

Finally, there may be specific patient groups that would benefit more from models that go beyond additional care coordination services (*eg*, by a nurse and/or social worker). For example, VA Primary Care Mental Health Integration is a collocated, collaborative model implemented to improve access to mental health services for Veterans. The VA has also been interested in potentially implementing different models of integrating oncology and palliative care for cancer patients.

Research Gaps/Future Research

Our examination of primary research studies suggested that those with observational quasi-experimental designs were more likely to report reductions in hospitalizations and/or ED visits. Observational studies may have residual confounding and are more likely to be affected by publication bias.

Studies of effective care coordination models did not report standardized tools used to assess patient trust or care team integration. It may be that these interventions relied on informal assessment by study staff or that there was an assumption that these domains would all improve. However, descriptions of these tools and strategies for assessment will support health systems in evaluating their existing services and implementing new care coordination models.

Finally, multiple SR raised concerns about lack of information on intervention implementation, including fidelity and frequency of various components. To improve evaluation and interpretation of the effectiveness of care coordination interventions, future studies should consider application of frameworks and designs with explicit consideration of implementation outcomes (eg, hybrid effectiveness-implementation designs, Consolidated Framework for Implementation Research [CFIR], and Reach, Effectiveness, Adoption, Implementation, and Maintenance [RE-AIM]). Studies using such frameworks should clearly define the “core” set of key components and describe the “adaptable periphery” of elements that can be adjusted to accommodate the local context.

Therefore, we recommend the following for future research:

- Evaluate future care coordination interventions using randomized designs.
- Consider application of standardized tools to assess patient trust or working alliance, health care team integration, and communication between patients and providers.
- Consider study designs that explicitly consider implementation outcomes in future studies of care coordination models.
- Define “core” intervention components and describe local adaptations, particularly in multi-site studies.

Limitations

To address the priorities of our VA partners, this work focused on care coordination models that were effective in reducing hospitalizations and/or ED visits; SR and studies that did not address these outcomes were excluded. While we acknowledge the importance of patient experience outcomes, our discussions with stakeholders and key informant interviews all supported the high priority of acute care utilization for health care system leadership, particularly with regard to sustainability of interventions. We prioritized high- and medium-quality reviews for abstracting detailed results. We relied on SR authors’ determination of overall effectiveness and strength of evidence for care coordination models. Because interventions in countries other than the US may be less relevant for the VA, we limited primary studies to those conducted in the US. It is possible that studies conducted in other countries may have been informative for VA policy, despite very substantial differences in health care financing and delivery. We were able to

complete interviews with less than half of those whom we invited to participate; it is possible that there was unpublished information on tools and approaches that we were unable to identify.

Conclusions

Existing evidence on care coordination models indicates that they have inconsistent effects on reducing hospitalizations and/or ED visits for high-risk community-dwelling adults. It remains unclear whether such interventions should be implemented and how they may be adapted to different health care settings. Implementation of new care coordination services should be carefully evaluated, preferably using randomized designs. Policymakers should also consider whether, for certain patient populations, a larger-scale redesign of care models may be necessary to improve continuity and collaboration.

ABBREVIATIONS TABLE

Abbreviation	Definition
AHRQ	Agency for Healthcare Research and Quality
CC&ICM	Coordinated Care & Integrated Care Management initiative
CFIR	Consolidated Framework for Implementation Research
CI	Confidence interval
ED	Emergency department
ESP	Evidence Synthesis Program
KQ	Key question
MeSH	Medical subject heading
OR	Odds ratio
RCT	Randomized controlled trial
RD	Risk difference
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance
SR	Systematic review(s)
TEP	Technical expert panel
US	United States of America
VA	Department of Veterans Affairs

EVIDENCE REPORT

INTRODUCTION

Complexity of health care services and care fragmentation contribute to adverse health outcomes and poor patient experiences of care.¹⁻⁴ Over the past 20 years, there has been substantial interest and investment in developing and implementing care coordination interventions, particularly for patients who have demonstrated high utilization of acute care services.^{5,6} Although there are multiple definitions for care coordination models, such interventions usually involve systematic strategies that aim to improve continuity and bridge transitions of care.^{5,7,8} Often, this takes the form of care or case management, in which a designated person or team helps patients manage their medical care and navigate interactions with the health care system(s). While there have been a variety of care coordination models evaluated across diverse settings, it remains unclear whether these interventions can sufficiently address gaps in care and improve patient outcomes.

The VA Care Coordination and Integrated Case Management (CC&ICM) initiative was launched in 2016, as a collaboration between the VA Offices of Care Management and Social Work, and Nursing Services.⁹ The main goals of this initiative are to standardize and integrate care coordination services across all VA facilities and points of care for Veterans. The CC&ICM initiative has developed several tools for identifying Veterans who may benefit from various levels of care coordination services; it is currently focused on evaluation of care coordination at pilot VA sites and implementation of additional tools to assist with team integration and communication with patients. To assist the CC&ICM initiative, the VA ESP was asked to review evidence on implementation and outcomes of various care coordination models.

In this report, we summarize results from eligible systematic reviews (SR) on key characteristics and effectiveness of care coordination interventions for diverse adult populations at high risk for adverse outcomes. Additionally, we present results from primary research studies of effective interventions (*ie*, those able to reduce hospitalizations and/or emergency department [ED] visits) regarding tools and approaches used to assess patient trust and care team integration, and to improve communication between patients and providers. To better understand which results may be most applicable to VA, we also provide information about the settings in which effective care coordination models were implemented. Finally, we present results from key informant interviews to address remaining gaps in the published literature, particularly with regard to tools and approaches used by various interventions.

METHODS

TOPIC DEVELOPMENT

Conceptual Framework of Care Coordination Models

To guide scope refinement and protocol development, we reviewed several existing resources on integrated care or care coordination, including the Agency for Healthcare Research and Quality (AHRQ) Care Coordination Atlas⁵ and a previous ESP report on care coordination frameworks.⁷ We examined specific frameworks, such as Care Coordination in Chronic and Complex Disease Management,⁸ the Integrated Team Effectiveness Model,¹⁰ Rainbow Model for Integrated Care,¹¹ and Coordination Networks.¹² In collaboration with VA stakeholders from the Office of Care Management and Social Work Services and the Office of Nursing Services, and our technical expert panel, we selected the framework for Care Coordination in Chronic and Complex Disease Management as the most applicable to the goals of this current review (Table 1). This framework focuses on characteristics, processes, and interactions within and between health care teams. We considered that evidence addressing these areas would be most relevant to support the goals of the VA CC&ICM initiative. We further adapted this framework in 2 areas: 1) specification that team roles include who contacted patients (and in what manner); and 2) reorganization of outcomes by patients (*eg*, patient experience, quality of life, and survival), health care teams (*eg*, work satisfaction and burnout), and health systems (*eg*, acute care utilization and costs). While health care utilization and costs may be measured at the patient level (*eg*, number of admissions or ED visits per person), we considered such outcomes to be oriented towards the priorities of the health care system (and payers).

Applying this framework and in accordance with the priorities of our VA partners, we defined effective care coordination interventions as those that reduced hospitalizations and/or ED visits. We sought information about the key characteristics of effective interventions, particularly with regard to elements depicted in the columns on Context & Setting and Coordinating Mechanisms (Table 1). For example, key characteristics may include multidisciplinary teams (vs primarily single case manager), and home visits (vs telephone contacts and/or outpatient visits). To support ongoing implementation and evaluation of care coordination programs in the VA, we also searched for evidence on tools and approaches that were used to assess Emergent Integrating Conditions (*eg*, trust within teams) and Coordinating Actions (*eg*, within team communication); such tools may assist programs in monitoring implementation progress before final outcomes are available. To these elements from the Care Coordination Framework, we additionally considered tools to assist with evaluating patient trust or working alliance with the care coordination team, and those to improve communication between patients and providers. Finally, to support interpretation of the evidence with regard to applicability to VA health care settings, we sought information on the characteristics of health care systems and communities where effective interventions have been implemented.

Table 1: Adapted Framework for Care Coordination in Chronic and Complex Disease Management*

	Context & Setting	Coordination Mechanisms	Emergent Integrating Conditions	Coordinating Actions	Outcomes
Within Teams	<ul style="list-style-type: none"> • Team composition • Experience & history • Power distribution • Resources 	<ul style="list-style-type: none"> • Plans, rules, & tools • Objects, representations, artifacts, & information systems • Roles (eg, who contacts patients & how) • Routines • Proximity 	<ul style="list-style-type: none"> • Accountability • Predictability • Common understanding • Trust 	<ul style="list-style-type: none"> • Situation monitoring • Communication • Back-up behavior 	<ul style="list-style-type: none"> • <u>Patients</u> • (eg, patient experience, quality of life, survival) • <u>Health care teams</u> (eg, job satisfaction)
Between Teams	<ul style="list-style-type: none"> • Multiteam system composition • Linkages between teams • Alignment of organizational cultures/ climates • Governance & payment structure 			<ul style="list-style-type: none"> • Boundary spanning • Information exchange • Collective problem-solving & decision-making • Negotiation • Mutual adjustment 	<ul style="list-style-type: none"> • <u>Health systems</u> (eg, acute care utilization, costs)

*Original framework by Weaver et al (2018)⁸

Key Questions (KQ)

For community-dwelling adults with a variety of ambulatory care sensitive conditions and/or at higher risk of having repeat hospitalization or ED visits:

KQ1—What are the key characteristics of care coordination models (of varying types) that aim to reduce hospitalization or ED visits?

KQ2—What is the effect of implementing these care coordination models on hospitalizations, ED visits, and patient experience (eg, Consumer Assessment of Healthcare Providers and Systems)?

KQ3—What are the characteristics of settings in which effective models have been implemented?

KQ4—Among effective models, which approaches/tools have been used to:

- a) Measure patient trust or working alliance?
- b) Measure team integration?
- c) Improve communication between patients and providers?

To address these KQ, we first focused on identifying eligible SR on care coordination models. We determined that a review of reviews would be appropriate given the broad scope and anticipated heterogeneity in types of care coordination models, as well as patient populations. In order to address likely gaps in SR results, particularly with regard to KQ 3 and 4, we also



examined primary research studies of effective interventions and conducted key informant interviews with those who implemented and evaluated interventions.

SEARCH STRATEGY

We searched for English-language SR in the following databases, from inception until September 2019: MEDLINE, CINAHL, Embase, Cochrane Database of Systematic Reviews, AHRQ Evidence-based Practice Center reports, and VA ESP reports. The search terms included MeSH and free text for care coordination interventions (*eg*, care or case management, interdisciplinary care, and intensive primary care), and systematic reviews (Appendix 1). We anticipated that eligible SR may not provide sufficient information, particularly with regard to KQ3 and 4. Therefore, we supplemented results from eligible SR with: 1) examination of primary research studies included by SR; 2) search of MEDLINE and Embase from the year of the most recent eligible SR (2018) until February 2020 for relevant randomized controlled trials (RCT) on care coordination models (Appendix 2); and 3) interviews with investigators and/or teams who implemented interventions described in research studies thus identified (see below).

STUDY SELECTION

Duplicates were removed from SR search results and uploaded into DistillerSR (Evidence Partners, Ottawa, Canada). Using prespecified inclusion and exclusion criteria (Appendix 3), titles and abstracts were screened for eligibility. Eligible populations of interest included community-dwelling adults with a range of ambulatory care sensitive conditions (*eg*, heart failure and chronic lung disease) and/or at higher risk for acute care episodes. If a review focused exclusively on interventions for a single health condition, it was excluded. Eligible interventions covered different care coordination models, such as care or case management and home-based primary care (Appendix 3). We required that eligible reviews reported inclusion of hospitalizations and/or ED visits as outcomes of interest in objectives or results. Articles underwent full-text review if at least 1 reviewer deemed it eligible during abstract screening. Exclusion of articles at screening required agreement of 2 reviewers. At full-text review, 2 individuals separately determined inclusion/exclusion and then resolved any conflicts through discussion. When consensus could not be reached, disagreements were discussed with a third reviewer.

From each eligible SR, we identified all included primary studies and 2 reviewers evaluated them for potential relevance to KQ3 and 4. In addition to the above criteria for SR, we applied the following: conducted in US, and RCT or quasi-experimental observational studies (*eg*, comparative control cohort or interrupted time series).¹³ To supplement this group of relevant primary studies, we also screened search results for RCT of care coordination models from 2018 until February 2020. Two reviewers applied the same criteria used to evaluate SR, along with the additional requirement for RCT conducted in US.

QUALITY RATING & DATA ABSTRACTION

We assessed the quality of eligible SR using criteria adapted from AMSTAR 2,¹⁴ and rated overall quality as high, medium, or low (Appendix 4). In general, a high-quality SR met all applicable criteria (*ie*, at least “partial Yes” for all questions). Two reviewers independently rated each SR, and consensus was reached through discussion.

We abstracted data from all eligible SR on: target population(s); dates of search queries; and number and characteristic of included primary studies (location, setting, and study design). Additionally, from medium- and high-quality SR, we abstracted detailed results on: description of care coordination model characteristics; pooled effects (or qualitative summaries) for hospitalizations, ED visits, and/or patient experience; characteristics of settings; and tools and approaches used to measure patient trust or working alliance, assess health care team integration, and/or improve communication between patients and providers.

From relevant primary studies on care coordination models, we abstracted data on effectiveness for main outcomes; participant, intervention and setting characteristics; and tools and approaches. Because the primary studies frequently referenced other studies for information on intervention characteristics, we also reviewed these associated studies for data relevant to KQ3 and 4.

For both SR and primary studies, data abstraction was done by 1 reviewer and results overread by a second reviewer.

DATA SYNTHESIS FOR SYSTEMATIC REVIEWS & RELEVANT PRIMARY STUDIES

We focused on results from SR to evaluate KQ 1 and 2, because this allowed us to address a broad scope including many types of care coordination interventions across diverse high-risk populations. Given this heterogeneity, we undertook a qualitative synthesis of these results. We summarized SR results on key characteristics of care coordination models, and effectiveness for hospitalizations, ED visits, and/or patient experience. We also included strength of evidence determinations by SR, if these were stated. Few SR provided information on KQ 3 and 4; we highlighted these results when provided.

For identified relevant primary studies, we focused on those reporting successful reductions in hospitalizations and ED visits, and summarized information from these studies that were relevant for KQ3 and 4. To address remaining gaps, we also included information from associated articles (eg, methods papers) and websites referenced by primary studies.

INTERVIEWS WITH KEY INFORMANTS WHO IMPLEMENTED CARE COORDINATION MODELS

We conducted semi-structured interviews with research investigators and members of teams who implemented care coordination models, as described in relevant primary studies (identified from both eligible SR and updated search for RCT). We included individuals from relevant primary studies, regardless of effectiveness in reducing hospitalizations and/or ED visits. We initially invited 22 individuals by email, and contacted another 3 individuals per recommendations of respondents. We completed interviews with 11 participants.

The main focus of these interviews was to address gaps in the published literature regarding tools and approaches. We also addressed intervention uptake and sustainability, as this information may be particularly useful to our VA stakeholders. Interview guides included questions in each of these areas and were individually adapted using published or online information about the

interventions. A general version of the interview guide is provided in Appendix 5. Interviews lasted about 30 minutes and were audio-recorded. We reviewed contemporaneous notes and audio-recordings to first develop summaries for each care coordination intervention. We then examined summaries for all interviews to provide overall themes.

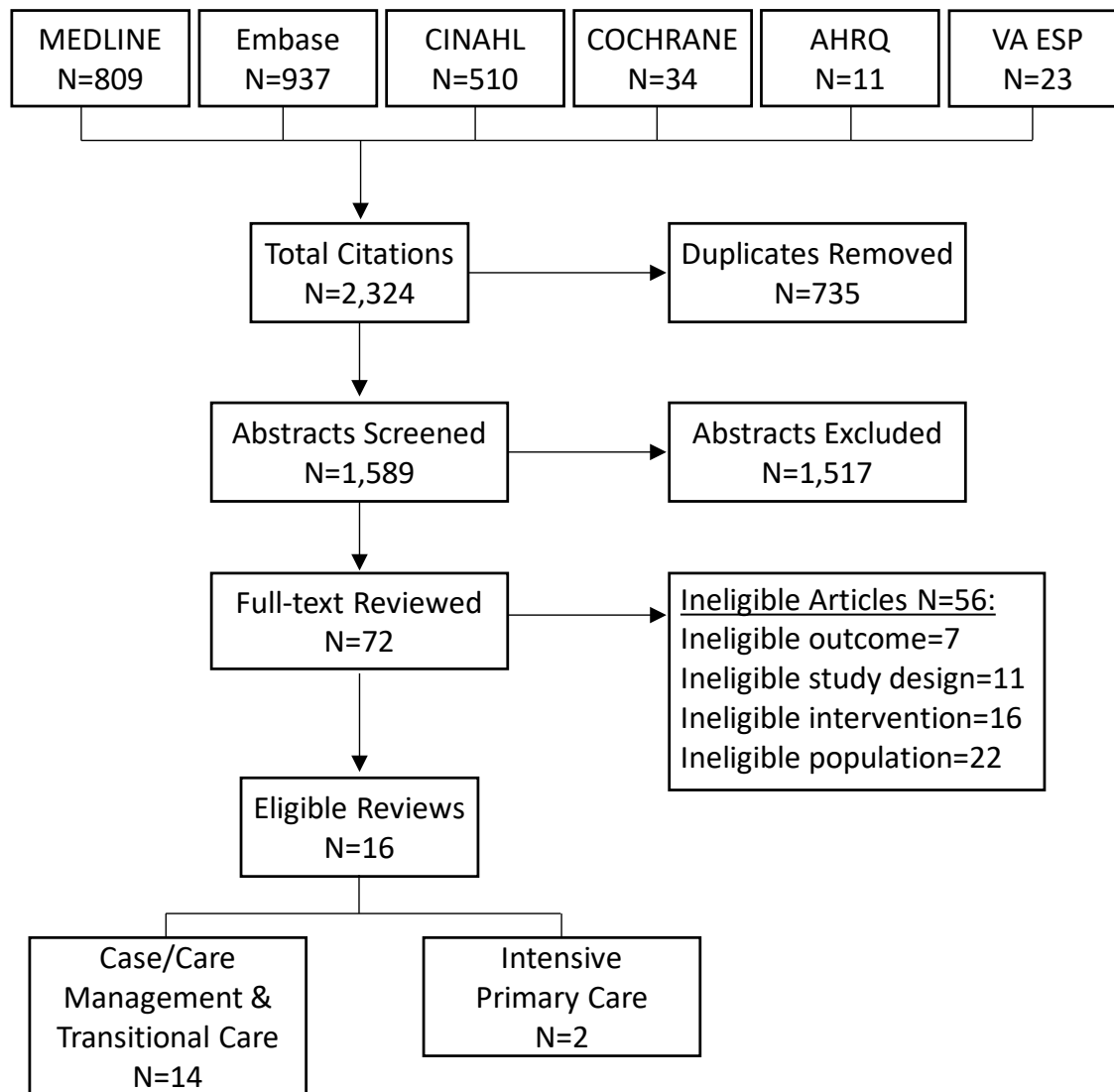
PEER REVIEW

A draft version of this report was reviewed by 6 technical experts, as well as VA operational partners. Their comments and our responses are presented in Appendix 6.

RESULTS

OVERVIEW OF ELIGIBLE SYSTEMATIC REVIEWS

Of 2324 unique citations, 72 underwent full-text review (Figure 1). We identified 16 eligible SR, 14 of which examined case management or transitional care interventions,¹⁵⁻²⁸ and 2 of which evaluated intensive primary care models (eg, home-based primary care).^{29,30} All SR included a wide range of interventions, using broad definitions for case coordination or intensive primary care models. Four SR included only RCT,^{15,21,22,27} while the others allowed both RCT and observational studies. Three SR included only US studies,^{16,20,24} and the remaining SR included studies conducted in several different countries. Seven SR focused specifically on patients at higher risk for acute care utilization (ie, high-utilizers),^{15,18-20,23,24,26} and 1 SR examined interventions for individuals with frailty.²⁷ Six SR were high quality,^{19,22,23,25,26,30} 6 were medium quality,^{15,18,20,21,27,29} and 4 were low quality.^{16,17,24,28} We focused on the 12 medium- and high-quality SR for detailed results addressing KQ. Key characteristics and summary of results from high- and medium-quality SR are shown in Table 2. We also provide descriptions of results for KQ1 and 2 in the following text and in Appendix 7 (along with detailed SR characteristics). SR reported very limited information regarding KQ 3 and 4.

Figure 1: Search & Selection of Eligible Systematic Reviews

KQ1—WHAT ARE THE KEY CHARACTERISTICS OF CARE COORDINATION MODELS?

All SR provided general descriptions of different components included by interventions, with many providing some information on team composition and frequency of use of certain components (eg, multidisciplinary care plan). Outside of in-person contacts (whether in a clinical setting or at home), the other main form of communication with patients was via telephone. Four SR^{19,25,27,30} specifically addressed whether there are key characteristics for care coordination interventions (Table 2). Hudon et al¹⁹ used qualitative comparative analysis to examine intervention characteristics of effective case management models, reporting “*case-finding...and complexity of health care needs are necessary to produce a positive outcome.*” Additionally, selection of cases needed to be combined with either a high-intensity model (defined by authors

using caseload and frequency and types of contact with patients) or a multidisciplinary care plan. Smith et al²⁵ reported that interventions “*targeted at specific risk factor management or focused areas...are more likely to be effective... [while] interventions that have a broader focus...seem less effective.*” Van der Elst et al²⁷ conducted subgroup analyses by intervention duration and different approaches to address frailty, finding no significant differences. Totten et al³⁰ examined home-based primary care and stated “*there is not an apparent pattern or cluster of services associated with differences in outcomes.*” Additionally, 2 SR^{15,29} sought to determine the key components for care coordination models but were unable to draw conclusions; authors reported challenges due to lack of published information on components and fidelity of intervention implementation.

KQ2—WHAT IS THE EFFECT OF IMPLEMENTING CARE COORDINATION MODELS?

Of 10 SR examining case or care management and/or transitional care interventions, 2 conducted quantitative meta-analyses,^{22,27} while the remaining SR used qualitative syntheses to describe results^{15,18-21,23,25,26} (Table 2). Six SR evaluated effects on hospitalization, with 5 reporting mixed or unclear results^{15,19,21,22,25} and 1 finding lack of effectiveness.²⁷ Among these, Le Berre et al²² pooled results for transitional care interventions (most involved nurses who called patients and/or made home visits) for diverse patient populations. Pooled results from 11-35 RCT found no effect at 1 month (risk difference [RD] -0.03, 95% CI -0.05, 0) and some effects at 3-18 months (RD range -0.05 to -0.11). Van der Elst et al²⁷ conducted meta-analyses to evaluate effects on hospitalization but examined a diverse set of case management interventions for frail community-dwelling older adults; pooled results from 5 RCT showed that case management did not reduce hospitalizations (odds ratio [OR] 1.13, 95% confidence interval [CI] 0.95, 1.35).

Seven SR examined effects of case or care management and/or transitional care interventions on ED visits (Table 2). Two SR^{21,23} indicated that care coordination interventions reduced ED visits, and both provided descriptive information about included studies. One SR stated that 6 included studies reported reductions in ED visits,²¹ and the other found that the median rate ratio (of care coordination vs control) was 0.63, with interquartile range of 0.41-0.71.²³ All 5 remaining SR^{18-20,22,26} reported unclear or mixed effects on ED visits, including 1 that conducted pooled meta-analyses over various timeframes (1-12 months).²²

Only 1 SR on case management evaluated effects on patient experience and, using qualitative synthesis, found inconsistent results.¹⁹

Two SR evaluated intensive primary care interventions, with the 1 focused on home-based primary care reporting reduced hospitalizations,³⁰ and the other describing inconsistent results across studies²⁹; both used qualitative syntheses (Table 2). The SR on home-based primary care also found that there was improved patient and caregiver satisfaction (low strength of evidence).³⁰

KQ3—WHAT ARE THE CHARACTERISTICS OF SETTINGS IN WHICH EFFECTIVE MODELS HAVE BEEN IMPLEMENTED?

Only 2 SR addressed characteristics of settings for interventions. 1 SR on case management stated that all but 1 of 16 included studies were single-site, usually in an urban setting.²⁶ The other SR sought to address organizational settings for home-based primary care models but was unable to find published information.³⁰

To further address KQ 3 (and KQ 4), we identified 272 unique primary studies included by eligible SR, and found 18 RCT³¹⁻⁴⁸ and 9 observational studies⁴⁹⁻⁵⁷ that were relevant. While 78% of relevant observational studies (n=7)^{49-53,55,56} reported reductions in hospitalizations and/or ED visits, only 22% of RCT (n=4)^{34,39,42,44} demonstrated effectiveness. Additionally, we searched for RCT that were published after the most recent eligible SR. This search resulted in 1048 unique citations, of which 21 underwent full-text review. We identified 2 relevant RCT^{47,48} but both studies reported that interventions were not effective for reducing hospitalizations and/or ED visits.

Characteristics of effective care coordination models described in these studies, their effects and the settings in which they were implemented are summarized in Table 3. We categorized the effective interventions into transitional care, outpatient care or case management (led by nurse or social worker), or other intensive primary care models. These interventions were implemented in a variety of settings, including rural community hospitals and health systems, academic medical centers (in urban settings), and public hospitals serving largely poor and uninsured populations. There was no clear connection between differences in settings, types of intervention and various patient populations.

KQ4—WHAT ARE THE TOOLS AND APPROACHES USED BY EFFECTIVE MODELS?

No SR commented on tools and approaches used to measure patient trust or care team integration, or to improve communication between patients and providers. Primary research studies described several approaches to improve patient-provider communications, such as coaching patients on how to ask questions, making lists of key concerns, and role-playing visits with providers.^{34,42,51,55,58} In 2 studies, care coordinators supported communication by attending outpatient visits with patients and their providers.^{42,55} No primary research study described specific tools or measures to assess patient working alliance with care coordination staff, care team integration, or patient-provider communications. For 1 intervention, qualitative methods were used to evaluate patient experiences and relationship with care coordinators.^{34,59}

KEY INFORMANT INTERVIEWS

We conducted 11 interviews with investigators and other team members who implemented care models described by relevant primary research studies. Several interviewees described using approaches akin to health coaching (although not called that in the published studies) to improve patient communications with providers. None of the interviews provided additional information on specific tools or approaches used to assess patient working alliance with care coordination staff, care team integration, or patient-provider communications. Review of additional

intervention materials provided by some interviewees indicated that assessments of patient experience sometimes included factors conceptually related to patient trust (eg, perception that care coordinator was knowledgeable and understood patients' needs).

Regarding the sustainability of care coordination interventions, we found great variation in long-term effects. In some cases, interventions were not continued after completion of the research studies. Lack of financial viability was often a key factor in discontinuation of these interventions. Others were substantially modified and adapted to meet changing health system priorities (eg, in targeted patient populations). There was variable success in engaging stakeholders such as hospital leadership and front-line providers. Health care utilization and costs were priorities for those in leadership, and improved patient experiences were not usually sufficient for continuing interventions. One interviewee indicated “*a tension between reducing costs/hospitalizations and adding value to the patient.*”

In terms of key issues to for future care coordination interventions, some key informants questioned whether acute care utilization by high-risk populations was truly preventable, as these patients often had multiple challenges and health needs that required hospitalization. For example, 1 interviewee stated, “*Everything that could be possibly going wrong is going wrong...A lot of these people are going to get readmitted no matter what you do.*” There was also concern with current readmission metrics and the ability to make substantial changes within a short timeframe: “*30 days doesn't give you sufficient time...especially in elderly patients with many issues.*” Some also suggested that care coordination interventions may work better in those with less severe conditions and/or modifiable factors; an important challenge with such an approach is that the intervention may need to serve a large number of patients before there are appreciable differences in acute care utilization. One individual described it thus: “*You can allocate a lot of resources to extremely high need patients...or you can allocate resources to a larger population and ... have a smaller impact on individual level, but on population level have greater impact...*”

Table 2: Summary of Results for Key Questions 1 and 2 from High- and Medium-Quality Systematic Reviews

Author, Year (Quality, Year of Search)	Included Populations; Study Designs; # Relevant Primary Studies	Synthesis Method	KQ1—What are the key characteristics of care coordination models?	KQ2—What is the effect of implementing care coordination models?		
				↓ Hospitalization? (Y/N)	↓ ED Visits? (Y/N)	↑ Patient Experience? (Y/N)
Case Management and Transitional Care Interventions						
Di Mauro, 2019 ¹⁸ (Medium, 2018)	High-utilizers; RCT, cohort; 3	Qualitative synthesis	NR	NR	Unclear (inconsistent across studies)	NR
Hudon, 2019 ¹⁹ (High, 2017)	High-utilizers with chronic conditions; RCT, cohort, cross-sectional; 4	Qualitative comparative analysis	Necessary characteristics: “ <i>case-finding</i> ” (high utilization and/or complexity of needs) AND High-intensity or multidisciplinary care plan	Unclear (inconsistent across studies)	Unclear (inconsistent across studies)	Unclear (inconsistent across studies)
Iovan, 2019 ²⁰ (Medium, 2017)	High-utilizers; RCT, cohort; 6	Qualitative synthesis	NR	NR	Unclear (inconsistent across studies)	NR
Van der Elst, 2018 ²⁷ (Medium, 2016)	Frail older adults; RCT; 0	Quantitative meta-analysis	No significant results in subgroup analyses by: intervention duration; recruitment method; “ <i>multi- versus unidimensional approach to frailty</i> ”	N	NR	NR
Joo, 2017 ²¹ (Medium, 2016)	Chronic conditions; RCT; 1	Qualitative synthesis	NR	Unclear (inconsistent across studies)	Y	NR
Baker, 2018 ¹⁵ (Medium, 2015)	Multimorbidity, high-utilizers; RCT; 4	Qualitative synthesis	“[C]ommon methodologic issues limited our ability to draw conclusions regarding the effectiveness of specific intervention components...”	Unclear (inconsistent across studies)	NR	NR
Le Berre, 2017 ²² (High, 2015)	Older adults with chronic conditions; RCT; 3	Quantitative meta-analysis	NR	Unclear (inconsistent across studies)	Unclear (inconsistent across studies)	NR



Author, Year (Quality, Year of Search)	Included Populations; Study Designs; # Relevant Primary Studies	Synthesis Method	KQ1—What are the key characteristics of care coordination models?	KQ2—What is the effect of implementing care coordination models?		
				↓ Hospitalization? (Y/N)	↓ ED Visits? (Y/N)	↑ Patient Experience? (Y/N)
Soril, 2015 ²⁶ (High, 2015)	High-utilizer; RCT, cohort; 3	Qualitative synthesis	NR	NR	Unclear (inconsistent across studies)	NR
Moe, 2017 ²³ (High, 2014)	High-utilizer; RCT, cohort; 3	Median, IQR for RR	NR	NR	Y	NR
Smith, 2016 ²⁵ (High, 2011)	Multimorbidity; RCT, cohort; 2	Qualitative synthesis	<i>"[I]nterventions that are targeted at specific risk factor management or focused areas where patients have difficulties, such as with functional ability or medicines management, are more likely to be effective... [while] interventions that have a broader focus...seem less effective."</i>	N	NR	NR
Intensive Primary Care Interventions						
Totten, 2016 ³⁰ (High, 2015)	Chronic conditions and/or disabilities; RCT, cohort; 1	Qualitative synthesis	<i>"There is wide variation in the services provided as part of [home-based primary care]. [T]here is not an apparent pattern or cluster of services associated with differences in outcomes..."</i>	Y	Y	Y
Edwards, 2017 ²⁹ (Medium, 2017)	High risk for hospitalization or death; RCT, cohort; 7	Qualitative synthesis	<i>"We had hoped to identify key program features... that may have contributed to the success or failure of these programs. Unfortunately, reporting of key intervention characteristics was inconsistent..."</i>	Unclear (inconsistent across studies)	N	NR

CI=confidence interval; ED=emergency department; IQR=interquartile range; NR=not reported; OR=odds ratio; RCT=randomized controlled trials; RD=risk difference; RR=risk (or rate) ratio

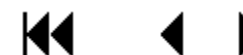


Table 3: Primary Studies—Characteristics and Results of Effective Care Coordination Models

Author, Year; Study Design*; N	Intervention Name; Eligibility Criteria	Description of Patient Contacts	Effects of care coordination interventions		KQ3—Characteristics of settings in which effective models have been implemented?
			Hospitalizations	ED Visits	
Transitional Care Interventions					
Capp, 2017 ⁴⁹ ; Cohort; I=406 C=3396	Bridges to Care; adults with ≥ 2 ED visits and/or hospitalizations in past 180 days	First home visit by community health worker within 24-72 hours, second visit by PCP within 1 week of ED or hospital discharge; 8 visits over 60 days (community health worker, nurse, primary care provider, and/or behavioral health provider) depending on patient needs.	Average # admissions per person, 180 days before enrollment: I=1.04, C=1.15 180 days after 60-day intervention: I=0.75, C=1.02 Difference of differences= -0.16, P<0.1	Average # visits per person, 180 days before enrollment: I=5.12, C=4.93 180 days after 60-day intervention: I=2.79, C=3.60, Difference of differences=-1.01, P=<0.01	Large urban academic medical center, Colorado
Hamar, 2016 ⁵² ; Cohort; I=560 C=3340	Care Transition Solution; adults admitted with ≥ 1 condition (COPD, heart failure, myocardial infarction, pneumonia)	Initial visit in hospital with nurse before discharge, then 4 calls over 4 weeks	Proportion with ≥ 1 readmission at 30 days: AOR=0.56 (0.41-0.77) At 6 months: AOR=0.47 (0.35-0.65)	NR	14 community hospitals in north Texas
Gardner, 2014 ⁵¹ ; Cohort; I=21 C=21	Care Transitions Intervention; adults participating in Medicare fee-for-service, admitted to hospital	Initial visit in hospital by nurse, home visit "shortly after discharge," 2-3 phone calls during 30-day post-discharge period	Propensity score matched # readmissions at 6 months: I=0.65, C=0.93 P=0.01	Propensity score matched # visits at 6 months: I=0.44, C=0.50 P=0.55	6 community hospitals, Rhode Island
Coleman, 2006 ³⁴ ; RCT; I=379 C=371	Care Transitions Intervention; older adults (≥65) admitted with ≥ 1 condition (stroke, heart failure, diabetes mellitus, etc)	Nurse met patients in hospital before discharge, home visit within 48-72 hours of discharge, then 3 more times during 28-day post-discharge period.	Proportion with ≥ 1 readmission at 30 days: I=0.08, C=0.12 AOR=0.59 (0.35, 1.00), P=0.048 At 90 days: I=0.17, C=0.23	NR	Community health system, Colorado



Author, Year; Study Design*; N	Intervention Name; Eligibility Criteria	Description of Patient Contacts	Effects of care coordination interventions		KQ3—Characteristics of settings in which effective models have been implemented?
			Hospitalizations	ED Visits	
			AOR=0.64 (0.42, 0.99), P=0.04 At 180 days: I=0.26, C=0.31 AOR=0.80 (0.54, 1.19), P=0.28		
Naylor, 1999 ³⁹ ; RCT; I=177 C=186	Transitional Care Model; older adults (≥65) admitted with ≥ 1 condition (heart failure, respiratory infection, orthopedic procedure, etc.)	Initial nurse visit within 48 hours of admission, visits at least every 48 hours during admission, home visits after discharge (first within 48 hours, second 7-10 days post-discharge, additional visits based on patients' needs), weekly nurse-initiated phone contact	Proportion with ≥ 1 readmission at 24 weeks: I=0.20, C=0.37 P=<0.01	NR	2 urban hospitals affiliated with University of Pennsylvania
Outpatient Care or Case Management					
Shah, 2011 ⁵⁵ ; Cohort; I=98 C=160	Care Management Program; adults aged 18-64, <200% federal poverty level, uninsured, " <i>met frequent user criteria</i> "	Care managers (social worker or medical office assistant) met with patients at least monthly in the home and/or clinic, for variable lengths of time (care manager decided when patient graduated program)	Adjusted ratio of # of admissions per year (I:C) was 0.81, P=0.38	Adjusted ratio of # of visits per year (I:C) was 0.67, P<0.001	Public safety-net hospital and clinics in Kern County, California
Peikes, 2009 ⁴² ; RCT; Mercy Medical Center (1 of 15 sites)—I=669, C=467	Medicare Coordinated Care Demonstration; adults participating in Medicare fee-for-service and with ≥ 1 condition (heart failure, COPD, etc.)	Nurse completed in-person evaluation within 2 weeks of enrollment, contacted patient at least monthly, 69% were in-person (either at home or during clinic visit)	Average # admissions per person per year: I= 1.15, C=0.98 P=0.02	NR	Mercy Medical Center—rural community hospital, Iowa
Shumway, 2008 ¹⁹ ; RCT; I=167, C=85	Comprehensive case management; adults with ≥ 5 ED visits in past 12 months and had " <i>psychosocial problems that could be addressed with case management</i> "	Social workers completed assessments, individual and group supportive therapy, assistance to a variety of community resources, and "assertive community outreach" (frequency and schedule of patient contacts NR)	Effect size NR, P=0.08 for treatment effect in adjusted model for visits over 2 years	Effect size NR, P<0.01 for treatment effect in adjusted model for visits over 2 years	Urban public hospital in San Francisco, California



Author, Year; Study Design*; N	Intervention Name; Eligibility Criteria	Description of Patient Contacts	Effects of care coordination interventions		KQ3—Characteristics of settings in which effective models have been implemented?
			Hospitalizations	ED Visits	
Sommers, 2000 ⁵⁶ ; Cohort I=280 C=263	Senior Care Connections; adults ≥65 with difficulty in ≥1 instrumental activity of daily living and 2 ≥ chronic conditions	Initial home visit with case manager (nurse or social worker), treatment plan drafted by care team (nurse, social worker, primary care provider), patients contacts via phone, home visits, small group sessions, or office/hospital visits at least once every 6 weeks	# of admissions per person per year at baseline: I=0.35, C=0.06 during year 1: I=0.38, C= 0.34 during year 2: I=0.36, C=0.52 P=0.03	Proportion with ≥1 visit at baseline: I=0.09, C=0.06 during year 1: I=0.20, C=0.17 during year 2: I=0.21, C=0.17 P=0.77	Primary care clinics in San Francisco Bay area, California
Other Intensive Primary Care Models					
Crane, 2012 ⁵⁰ ; Cohort; I=34 C=36	Drop-in group medical appointments; uninsured, family income ≤ 200% federal poverty level, ≥ 6 ED visits in past year	Twice-weekly groups sessions, short individual visit right after; direct phone access to nurse care manager; team included nurse, primary care and behavioral health providers	NR	Median # visits per month during 1 year before: I=0.58, C=0.58 during 1 year after: I=0.23, C=0.42 Difference in differences: 0.23, P=0.005	Rural community hospital, North Carolina
Meret-Hanke, 2011 ⁵³ ; Cohort; I=3889 C=3103	Program for All-Inclusive Care for the Elderly; adults >65, with functional limitations or dementia, income <300% Supplemental Security Income	Interdisciplinary care teams provided care management, clinical monitoring, and updated care plan in response to changes in enrollee's health and functional status	Propensity score matched any hospitalization at 6 months: AOR 0.35, P<0.01 At 2 years: AOR 0.16, P<0.01	NR	National US program

AOR=adjusted odds ratio; C=control group; COPD=chronic obstructive pulmonary disease; ED=emergency department; I=intervention group; RCT=randomized controlled trial

*Study designs were either RCT or observational cohorts with comparative controls



SUMMARY AND DISCUSSION

SUMMARY OF KEY FINDINGS

To inform the VA CC&ICM initiative, we conducted a multi-stage review of evidence for care coordination models. We identified 16 eligible SR addressing care coordination interventions, and further examined 29 relevant primary research studies. We also conducted 11 key informant interviews with those who have implemented care coordination models. Key findings include:

- One SR reported that high-intensity models and/or multidisciplinary plans were required for effectiveness (in combination with selection criteria noted above).
- Most SR reported unclear or inconsistent effects of care coordination models in reducing hospitalizations or ED visits.
- Primary studies reporting effective interventions were conducted in a variety of settings, including rural community hospitals, academic medical centers in urban settings, and public hospitals serving largely poor and uninsured populations.
- Approaches to improve patient-provider communication included coaching patients, role-playing, and attending appointments with patients.
- SR, primary studies, and interviews provided little information on specific tools or approaches used to assess patient trust or working alliance or health care team integration.
- Key informant interviews suggested variation in sustainability of care coordination interventions, with substantial adaptation occurring among many of those that have continued.

Care coordination models were complex and differed along multiple dimensions, thus presenting substantial challenges for SR authors in summarizing and comparing results across studies. Four SR drew conclusions with regard to key intervention characteristics, with 2 highlighting selection criteria, 1 indicating importance of high-intensity model (defined by lower caseload and more patient contacts) and multidisciplinary plans, and 2 finding no key characteristics. Several SR seeking to examine key characteristics and/or organizational settings of care coordination models reported difficulty finding sufficient published evidence to address these questions.

Among 11 primary studies demonstrating effective care coordination models, none reported specific tools or approaches for measuring patient trust or health care team integration. Key informant interviews did not provide additional information on these areas. Interventions used a variety of approaches to improve communication between patients and providers, including coaching and role-playing. In some interventions, care coordinators also directly communicated with providers on patients' behalf, including participation at outpatient appointments.

Some interviewees described adaptation of the intervention over time to address evolving priorities for health care organizations. Some also highlighted the difficulty of modifying health

and social factors contributing to need for acute care utilization among many patients in the highest risk category. There were suggestions that there may be more benefit in focusing on patients at somewhat lower risk and improving health care processes for larger groups of patients.

IMPLICATIONS FOR POLICY

It remains unclear whether care coordination interventions should be implemented in particular health care settings and how they may be adapted to improve effectiveness and sustainability. Two SR highlighted the importance of carefully selecting patients for care coordination interventions. The VA CC&ICM initiative has implemented several tools for evaluating Veteran needs and matching the level of care coordination services to those needs. The CC&ICM team has conducted site visits to assess the use of these tools and implementation of care coordination models at pilot VA facilities. It will be important for VA to evaluate the feasibility of applying these tools more widely, and the effects of implementing such tools on delivery of services and patient outcomes. Additionally, because VA medical centers and clinics are located in a variety of settings, it will be important to understand differences in utility of these tools across large and small sites, and those serving urban and more rural communities.

VA facilities differ in the number and types of care coordination services and programs that are offered. Understanding what is available at a particular facility may be challenging for Veterans, their caregivers, and VA clinical staff. A key goal of the CC&ICM initiative is to standardize care coordination across VA sites, and this may improve access and use of appropriate services for Veterans. However, the CC&ICM initiative also acknowledges the importance of flexibility to adapt care coordination models to accommodate local circumstances. Our interview results also support the importance of local adaptations for uptake and sustainability of care coordination interventions. A potential avenue to achieving more consistency of services while allowing flexibility may be to align services and programs based on program goals and Veteran needs; this information could then be collected in a central hub that Veterans and/or VA staff can use to find appropriate services. It may be also be valuable to provide educational materials as part of the CC&ICM initiative to guide adaptations (*eg*, highlighting the key program goals or outcomes, and distinguishing between core components and more flexible options). Additionally, evaluation of implementation should consider which adaptations were made and the rationale to support these.

One SR indicated that a high-intensity (defined using case load and patient contacts) or multidisciplinary care coordination model was more likely to be successful. Our examination of effective primary research studies also found a high number and frequency of patient contacts, often involving home visits. Therefore, it may also be valuable to understand which VA programs or models are most similar to these high-intensity interventions, and consider whether it would be cost-effective to implement more broadly. Currently, such high-intensity care coordination programs serve a limited number of Veterans with specific diagnoses (*eg*, VA Mental Health Intensive Case Management for those with bipolar disorder or schizophrenia).⁶⁰

Finally, there may be specific patient groups that would benefit more from models that go beyond additional care coordination services (*eg*, by a nurse and/or social worker). For example, VA Primary Care Mental Health Integration (PCMHI)⁶¹ is a colocated, collaborative model where mental health staff have frequent structured and informal communications with primary

care staff. The national implementation of VA PCMHI sought to improve access to mental health services for Veterans and improve integration of mental health concerns with other aspects of care. The VA has also been interested in potentially implementing different models of integrating oncology and palliative care for cancer patients.⁶²

EVIDENCE GAPS AND FUTURE RESEARCH NEEDS

Our examination of primary research studies suggested that those with observational quasi-experimental designs were more likely to report reductions in hospitalizations and/or ED visits. Observational studies may have residual confounding and are more likely to be affected by publication bias, as there are no requirements for a priori registration (with explicit description of primary outcomes and analysis strategy).

Studies of effective care coordination models did not report standardized tools used to assess patient trust or care team integration. It may be that these interventions relied on informal assessment by study staff or that there was an assumption that these domains would all improve. However, descriptions of these tools and strategies for assessment will support health systems in evaluating their existing services and implementing new care coordination models.

Finally, multiple SR raised concerns about lack of information on intervention implementation, including fidelity and frequency of various components. To improve evaluation and interpretation of the effectiveness of care coordination interventions, future studies should consider application of frameworks and designs with explicit consideration of implementation outcomes (eg, hybrid effectiveness-implementation designs, Consolidated Framework for Implementation Research [CFIR], and Reach, Effectiveness, Adoption, Implementation, and Maintenance [RE-AIM]).⁶³⁻⁶⁶ Studies using such frameworks should clearly define the “core” set of key components and describe the “adaptable periphery” of elements that can be adjusted to accommodate the local context.

Therefore, we recommend the following for future research:

- Evaluate future care coordination interventions using randomized designs.
- Consider application of standardized tools to assess patient trust or working alliance, health care team integration, and communication between patients and providers.
- Consider study designs that explicitly consider implementation outcomes in future studies of care coordination models.
- Define “core” intervention components and describe local adaptations, particularly in multi-site studies.

LIMITATIONS

To address the priorities of our VA partners, this work focused on care coordination models that were effective in reducing hospitalizations and/or ED visits; SR and studies that did not address these outcomes were excluded. While we acknowledge the importance of patient experience outcomes, our discussions with stakeholders and key informant interviews all supported the high priority of acute care utilization for health care system leadership, particularly with regard to

sustainability of interventions. We prioritized high- and medium-quality reviews for abstracting detailed results addressing KQ. However, we identified relevant primary studies from all eligible SR. We relied on SR authors' determination of overall effectiveness and strength of evidence for care coordination models. Because interventions in countries other than the US may be less relevant for the VA, we limited primary studies to those conducted in the US. It is possible that studies conducted in other countries may have been informative for VA policy, despite very substantial differences in health care financing and delivery. We were able to complete interviews with less than half of those whom we invited to participate; it is possible that there was unpublished information on tools and approaches that we were unable to identify.

CONCLUSIONS

Existing evidence on care coordination models indicate that they have inconsistent effects on reducing hospitalizations and/or ED visits for high-risk community-dwelling adults. It remains unclear whether such interventions should be implemented and how they may be adapted to different health care settings. Implementation of new care coordination services should be carefully evaluated, preferably using randomized designs. Policymakers should also consider whether for certain patient populations, a larger-scale redesign of care models may be necessary to improve continuity and collaboration.

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APPENDIX 1. SEARCH STRATEGIES FOR SYSTEMATIC REVIEWS

OID MEDLINE

1	(meta-analy\$ or metaanaly\$ or meta analy\$).tw. or exp Meta-Analysis/ or (systematic adj (review\$ or overview\$)).tw. or (systematic review or literature review or rapid review or umbrella review or meta synthesis or metasyntesis or meta-analysis or meta-synthesis or integrative review or data synthesis or comparative effectiveness review).mp.
2	(case report or case series or letter or comment or editorial).tw.
3	1 not 2
4	Exp Case Management/ or ((care or case) adj1 management).ti,ab.
5	Exp transitional care/
6	(home based primary care).ti,ab. or (home based primary care).kw. or (home based primary care).sh
7	(intensive primary care).ti,ab. or (intensive primary care).kw. or (intensive primary care).sh.
8	((integrat* or collaborat* or coordinat* or transition* or interdisciplin*) adj1 care).ti,ab.
9	or/4-8
10	3 and 9
11	Limit 9 to English
12	Limit 11 to yr="2015-current"

OID EMBASE

1	(meta-analy\$ or metaanaly\$ or meta analy\$).tw. or exp Meta-Analysis/ or (systematic adj (review\$ or overview\$)).tw. or (systematic review or literature review or rapid review or umbrella review or meta synthesis or metasyntesis or meta-analysis or meta-synthesis or integrative review or data synthesis or comparative effectiveness review).mp.
2	(case report or case series or letter or comment or editorial).tw.
3	1 not 2
4	Exp Case Management/ or ((care or case) adj1 management).ti,ab.
5	Exp transitional care/
6	(home based primary care).ti,ab. or (home based primary care).kw. or (home based primary care).sh
7	(intensive primary care).ti,ab. or (intensive primary care).kw. or (intensive primary care).sh.
8	((integrat* or collaborat* or coordinat* or transition* or interdisciplin*) adj1 care).ti,ab.
9	or/4-8
10	3 and 9
11	Limit 9 to English
12	Limit 11 to yr="2015-current"
13	Limit 12 to conference abstract status
14	12 not 13

CINAHL

1	(TI (systematic* n3 review*)) or (AB (systematic* n3 review*)) or (TI (systematic* n3 literature)) or (AB (systematic* n3 literature)) or (TI (integrative n3 review)) or (AB (integrative n3 review)) or (TI (information n2 synthesis)) or (TI (data n2 synthesis)) or (AB (information n2 synthesis)) or (AB (data n2 synthesis)) or (TI (meta-analy* or metaanaly*)) or (AB (meta-analy* or metaanaly*)) or (TI (umbrella* n2 review*)) or (AB (umbrella* n2 review*)) or (TI (rapid* review*)) or (AB (rapid* review*)) or (TI (compar* effect* review)) or (AB (compar* effect* review))
2	(TI (care or case) n2 management) or (AB (care or case) n2 management)
3	(TI (transitional care)) or (AB (transitional care))
4	(TI (home based primary care)) or (AB (home based primary care))
5	(TI (intens* primary care)) or (AB (intens* primary care))
6	(TI ((integrat* or collaborat* or coordinat* or transition* or interdisciplin*) n2 care)) or (AB ((integrat* or collaborat* or coordinat* or transition* or interdisciplin*) n2 care))
7	MH transitional care

8	MH case management
9	S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8
10	S1 AND S9 (Limiters: Research article, peer reviewed, published 2015 and later, human, English language)

COCHRANE REPORTS

1	("case management"):ti,ab,kw OR ("care management"):ti,ab,kw OR ("intensive primary care"):ti,ab,kw OR (transition* next care):ti,ab,kw OR ("home based primary care"):ti,ab,kw OR (integrat* next care):ti,ab,kw OR (collaborat* next care):ti,ab,kw OR (coordinat* next care):ti,ab,kw OR (transition* next care):ti,ab,kw OR (interdisciplin* next care):ti,ab,kw
2	with Cochrane Library publication date from Jan 2015 to Oct 2019, in Cochrane Reviews

AHRQ REPORTS

1	Keyword search for: Care coordination, case management, care management, collaborative care, integrative care, transitional care, home-based primary care, intensive primary care
2	Limited to 2015 and later

VA ESP REPORTS

1	Title search for: Care, case, coordin*, manage*, collab*, integrat*, transit*, home-based*, intens*, interd*
2	Limited to 2015 and later

APPENDIX 2. SEARCH STRATEGIES FOR PRIMARY STUDIES

OID MEDLINE AND EMBASE

1	Exp Case Management/ or ((care or case) adj1 management).ti,ab.
2	Exp transitional care/
3	(home based primary care).ti,ab. or (home based primary care).kw. or (home based primary care).sh
4	(intensive primary care).ti,ab. or (intensive primary care).kw. or (intensive primary care).sh.
5	((integrat* or collaborat* or coordinat* or transition* or interdisciplin*) adj1 care).ti,ab.
6	("delivery of health care, integrated" or "care continuity" or "continuum of care").ti,ab.
7	or/1-6
8	Randomized Controlled Trials as Topic/
9	randomized controlled trial.ti,ab,sh,kw,pt.
10	random allocation.ti,ab.
11	Double-Blind Method/
12	Single-Blind Method/
13	clinical trial/
14	clinical trial, phase i.pt.
15	clinical trial, phase ii.pt.
16	clinical trial, phase iii.pt.
17	clinical trial, phase iv.pt.
18	controlled clinical trial.pt.
19	clinical trial.pt.
20	exp Clinical trials as topic/
21	(clinical adj trial\$.tw.
22	((singl\$ or doubl\$ or treb\$ or tripl\$) adj (blind\$3 or mask\$3)).tw.
23	randomly allocated.tw.
24	(allocated adj2 random\$.tw.
25	or/8-24
26	7 and 25
27	Limit 26 to English
28	Limit 27 to yr="2018-current"
29	Remove duplicates from 28

CINAHL

1	TI "care management" or TI "case management" OR AB "care management" or AB "case management"
2	TI "transition* care" OR AB "transition* care"
3	TI "home based primary care" OR AB "home based primary care"
4	TI "intensive primary care" OR AB "intensive primary care"
5	TI "integrat* care" OR AB "integrat* care"
6	TI "care continuity" OR AB "care continuity"
7	TI "continuum of care" OR AB "continuum of care"
8	TI "collaborat* care" OR AB "collaborat* care"
9	TI "coordinat* care" OR AB "coordinat* care"
10	TI "care coordinat*" OR AB "care coordinat*"
11	TI "interdisciplin* care" OR AB "interdisciplin* care"
12	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11
13	TI (randomized controlled trial or randomised controlled trial) OR AB (randomized controlled trial or randomised controlled trial)
14	TI "random* allocat*" OR AB "random* allocat*"
15	S13 OR S14
16	S15 AND S12 (Limits applied: Peer reviewed; published 2018-current; English language; exclude MEDLINE records)

APPENDIX 3. STUDY SELECTION CRITERIA

	Inclusion Criteria	Exclusion Criteria
Population	Community-dwelling adults with a variety of ambulatory care sensitive conditions and/or at higher risk of having repeat hospitalization of emergency department [ED] visits	Restricted to single condition (eg, heart failure) or single combination (eg, diabetes and depression)
Intervention	Care coordination models: <ul style="list-style-type: none"> • Care or case management • Transitional care (if involving patient contact ≥ 1 month after discharge) • Home-based primary care • Intensive primary care • Integrated or interdisciplinary care • Collaborative care model 	Hospice and end-of-life care (if exclusive focus of intervention)
Comparator	Any (active or inactive)	
Outcomes	<ul style="list-style-type: none"> • Primary—Hospitalization, ED visits • Secondary—Patient experience; tools and approaches 	
Timing	Any duration	
Setting	Community-base, outpatient	
Study Design	<ul style="list-style-type: none"> • For KQ 1 & 2: Systematic review (SR) or Patient Level Meta-Analysis—must have search strategy, eligibility criteria, and analysis/synthesis plan; may include RCTs, observational studies, and/or qualitative studies • For KQ 3&4: RCTs or quasi-experimental studies (eg, cohorts with comparative controls) 	Expert or narrative reviews
Other	English Language	

APPENDIX 4. QUALITY ASSESSMENT

4.1 QUALITY ASSESSMENT CRITERIA FOR SYSTEMATIC REVIEWS (MODIFIED AMSTAR 2)¹⁴

6. Did the research questions and inclusion criteria for the review include the components of PICO?

Must have population, intervention, comparator group and outcome.

 Yes No

7. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify and signification deviations from the protocol?

Partial Yes=ALL of the following: review questions, search strategy, inclusion/exclusion criteria, risk of bias assessment

Yes=ALL of partial yes plus: protocol registered, a meta-analysis/synthesis plan (if appropriate) and a plan for investigating causes of heterogeneity, justification for any deviations from the protocol

 Yes Partial Yes No

8. Did the review authors explain their selection of the study designs for inclusion in the review?

Example: explanation for including RCTs only

 Yes No

9. Did the review authors use a comprehensive literature search strategy?

Partial Yes: must have searched at least 2 databases (relevant to research question), provided key word and/or search strategy, justified publication restrictions (eg, dates)

Yes=ALL of the above plus searched reference lists/bibliographies, searched trial/study registries, included/consulted content experts in the field, searched for grey literature where relevant, conducted search within 24 months of completion of the review

 Yes Partial Yes No

10. Did the review authors perform study selection in duplicate?

(at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include)

 Yes No

11. Did the review authors perform data extraction in duplicate?

(at least two reviewers achieved consensus on which data to extract)

12. Did the review authors use a satisfactory technique for assessing the quality of individual studies that were included in the review?

Partial Yes: must have described element of quality

Yes: must have also used standard quality or risk of bias tools

13. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?

(the authors justified combining the data in a meta-analysis and considered heterogeneity)

14. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

(performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias)

15. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

(the authors reported no competing interests OR they described their funding sources and how they managed potential conflicts of interest)

16. Taking into account your previous answers, please rate quality as:

4.2. QUALITY ASSESSMENT FOR ALL ELIGIBLE SYSTEMATIC REVIEWS

Author, Year	Research Questions include components of PICO?	Protocol established prior to conduct of review?	Explained selection of included study designs?	Comprehensive search strategy used?	Dual review for inclusion? Dual review for data extraction?	Assessed quality?	Meta analyses: Appropriate statistical methods and investigation of publication bias?	Reported any potential conflicts of interest?	Overall Quality
Baker, 2018 ¹⁵	Yes	Partial Yes	No	Partial Yes	Yes	Yes	NA	Yes	Medium
Bleich, 2015 ¹⁶	Yes	Partial Yes	Yes	No	Yes	No	NA	Yes	Low
De Pourcq, 2017 ¹⁷	No	No	Yes	Yes	Yes	Partial Yes	NA	Yes	Low
Di Mauro, 2018 ¹⁸	Yes	Partial Yes	No	Partial Yes	Yes	Yes	NA	Yes	Medium
Edwards, 2017 ²⁹	Yes	Partial Yes	No	Yes	Yes	Yes	NA	Yes	Medium
Hudon, 2019 ¹⁹	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	High
Iovan, 2019 ²⁰	Yes	Partial Yes	No	Yes	Yes No	No	NA	Yes	Medium
Joo, 2017 ²¹	Yes	Partial Yes	No	Partial Yes	Yes	Yes	NA	Yes	Medium
Le Berre, 2017 ²²	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	High
Moe, 2017 ²³	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	High
Raven, 2016 ²⁴	Yes	Yes	No	Yes	No	Partial Yes	NA	Yes	Low
Smith, 2016 ²⁵	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	High
Soril, 2015 ²⁶	Yes	Partial Yes	No	Yes	Yes	Yes	NA	Yes	High
Totten, 2016 ³⁰	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	High
Van der Elst, 2018 ²⁷	Yes	Yes	No	Partial Yes	No Yes	Yes	Yes	Yes	Medium
Weeks, 2018 ²⁸	Yes	No	Yes	Yes	No	Yes	No	Yes	Low

APPENDIX 5. KEY INFORMANT INTERVIEW GUIDE

A. INTERVENTION INFORMATION GAPS

1. Thank you. In this first part of the interview we'd like to get your perspective on and experience with *[name of intervention]*, as well as ask some specific questions about your project.
2. So to start, we have read your article in *[journal]*, **but could you please briefly tell us about your experience with this project?**
3. Now I have some specific questions on your study. As a quick reminder, your responses to these might be connected to your study in the report.
 - a. *If unclear in published studies*—Who was the team lead for care coordination? (eg, nurse, social worker, etc.)
 - b. Was there collaboration between clinical teams in primary care and specialty care? If so, please describe.
 - Were tools or surveys used to assess team integration?
 - c. Were there specific tools or approaches used to improve communication between patients and providers?
 - Were tools or surveys used to assess quality of communication between patients and providers?
 - d. Were tools or surveys used to assess patient trust or working alliance?
 - e. How were community groups involved?

PROBE:

- *Community service groups to assist older adults, community advocacy groups for uninsured*

B. UPTAKE AND SUSTAINABILITY

Now we'd like to ask some questions regarding the uptake and sustainability of your intervention. The responses on these questions will be kept private and reported only in summary (as in major themes).

1. Aside from team members, **who were some of the stakeholders that influenced the planning, uptake and sustainability of your intervention?**
 - a. What role did these stakeholders play?
 - b. How did you engage these stakeholders in discussions to determine which outcomes were important?

PROBE:

- *Local leadership, frontline staff, providers, patients, other important groups or individuals?*

2. Is this intervention still in place at your facility/institution?

If YES

- a. What has the long-term impact been?

PROBE:

- *Could you elaborate more on the long-term provider and patient satisfaction?*
- *Is there ongoing (or future) evaluation planned?*

If NO

- b. Why not?

C. OVERALL EXPERIENCE/REFLECTION ON INTERVENTION

1. To wrap up, we just have 2 final questions about your overall experience with this intervention.
2. First, what about your intervention seemed to work well?
3. Lastly, what about your intervention would you do differently next time?

D. IS THERE ANYTHING ELSE YOU'D LIKE TO ADD THAT I DIDN'T ASK ABOUT?



APPENDIX 6. PEER REVIEW COMMENTS/AUTHOR RESPONSES

Reviewer Comments	Response and Revisions
<i>Reviewer 1</i>	
<p>Are there any <u>published</u> or <u>unpublished</u> studies that we may have overlooked?</p> <p><i>Hynes, DM, Fischer, M, Fitzgibbon, M, Porter, AC, Berbaum, M, Schiffer, L, Chukwudozie, IB, Nguyen, H, Arruda, J. Integrating a Medical Home in an Outpatient Dialysis Setting: Effects on Health-Related Quality of Life. J Gen Int Med. 2019; 34(10): 2130-2140. doi: 10.1007/s11606-019-05154-9. PMID: 31342329.</i></p> <p><i>Hynes DM, Fischer MJ, Schiffer LA, Gallardo R, Chukwudozie IB, Porter A, Berbaum M, Earheart J, Fitzgibbon ML. Evaluating a novel health system intervention for chronic kidney disease care using the RE-AIM framework: Insights after 2 years. Contemp Clin Trials. 2016 Oct 18;52:20-26. DOI: 10.1016/j.cct.2016.10.003. [Epub ahead of print] PubMed PMID: 27769897.</i></p>	<p>Thank you for these suggestions. We reviewed these studies and have not included them because they are not systematic reviews. They also do not meet our criteria for relevant primary studies (eg, focused on a range of ambulatory care sensitive conditions).</p>
<p>[Page 1, line 53] Can you elaborate more on the scope—did your inquiry include PCMH, PACT, and variations of these models or was the definition of care coordination more narrow? One of our struggles in this space is definitions, so the more clear you are in explaining your inclusion and exclusion criteria, the more helpful this review will be</p> <p>[Page 2, line 25] Please define what is meant by "primary studies"</p> <p>[Page 4, lines 14-16] Did any mention any care management or communication tools used? software? processes? work flow? These process aspects are critical to care coordination and case management being successful</p> <p>[Page 6, line 28, line 39] which reviews? Please cite. Need to know which frameworks you are referring to...implementation or theoretical frameworks? And which ones within these categories?</p> <p>[Page 7, lines 10-19] I would suggest having the recommendation on implementation to be last. I suggest this because I think of the basic science needed first that needs to inform an implementation. The other 3</p>	<p>We agree with reviewer that describing and defining different care coordination models remains a challenge in interpreting results from these interventions. Our scope was very broad, and eligible systematic reviews included many types of care coordination interventions. We relied on review authors definitions and categorization of interventions, and provide this more detailed information for high and medium quality reviews in Appendix Table 7.</p> <p>Primary studies are research studies included by eligible reviews, or found through our updated search for RCTs. Primary studies are not reviews, whether systematic or narrative.</p> <p>We agree that these are important characteristics of care coordination interventions, and we abstracted information from eligible systematic reviews, when available. However, no systematic review provided this level of detailed information in distinguishing between effective and non-effective interventions (KQ 1).</p> <p>Citations are provided in the main body of the report, and are not included in the Executive Summary. There are a variety of implementation frameworks which may be applied, and we have added specific examples to the Discussion section.</p> <p>We appreciate reviewer’s suggestion. We believe that application of implementation frameworks helps in conceptualizing core vs peripheral components or characteristics.</p>

Reviewer Comments	Response and Revisions
<p>bullets are more foundation research needed prior to implementation studies, in my opinion.</p> <p>[Page 10, lines 50-51 and Page 13, lines 21-23] Did look for those at a patient level or at a system level. I would be very disappointed if this review excluded studies that examined patient level healthcare use... Please clarify if studies that focused on health care use at an individual level was included or limited to studies that reported only health system level healthcare use?</p> <p>[Page 17, lines 35-36] Why was review limited to these outcomes? Were any patient reported outcomes considered? These K2-K4 were to be focused on other outcomes</p> <p>[Table 3] I am getting confused about which KQ's are being addressed</p>	<p>Therefore, we have reordered the recommendation such that implementation frameworks are next to last.</p> <p>As indicated in Table 3, outcomes such as hospitalization and ED visits were assessed in a variety of ways, including the proportion of patients who had any hospitalization and the average number of admissions or ED visits per person over a set period of time. In classifying these outcomes as system-level in our adaptation of the Care Coordination Framework, we intended to indicate that utilization outcomes are more from the perspective of health systems (and payers), as compared with patient-centered outcomes, including patient experience. We have clarified this point in the Methods.</p> <p>As defined with our VA stakeholders and TEP, the main focus of this report was on care coordination models that had an impact on hospitalization and/or ED visits. When eligible systematic reviews (and primary research studies) provided information on patient experience, we also abstracted that information. However, few reviews or primary studies included results on patient experience. KQ 3 and 4 address settings and tools used by effective interventions, and do not define additional intervention outcomes.</p> <p>In Table 3, we provide detailed information from research studies reporting effective care coordination models. The main goal of identifying and examining primary research studies was to address KQ 3 and 4, but no studies provided information on KQ 4. Therefore, relevant information in Table 3 mainly addresses KQ 3. We also provide descriptive information on the intervention, and main outcomes reported in these studies (KQ 2), in order to put results for KQ3 in context. We have clarified the Results.</p>
<i>Reviewer 2</i>	
<p>Thank you for the opportunity to review this evidence synthesis on this important and timely topic. I think that the work presented has several strengths that, in the interest of brevity, I will not elaborate on. However, I am both confused and concerned that, somehow, an evidence synthesis entitled and aimed at synthesizing "Care Coordination Models" ended up being almost entirely about "Case Management Models." I appreciate that case management models were likely of most interest to the operational partner, which makes this work very useful to them, but what I can not discern is if this focus on case management models happened because of decisions made for the synthesis (i.e., there was an intentional decision to focus on case management models) or if the search strategy only yielded these case management models (and a couple on intensive</p>	<p>Our scope was very broad and we included a range of interventions. We relied on review authors categorization of different interventions, and as shown in Appendix Table 7, review authors often defined case or care management as collaborative and/or interdisciplinary. Thus, case or care management is itself a broad term that may include collaborative teams. Additionally, we also identified 2 reviews that were focused on different intensive primary care models. We did not exclude any systematic review based on our quality assessment, but notably, all low-quality eligible reviews also addressed case management and/or transitional care. The effective interventions described in primary research studies also varied, including case management led by a single nurse or social worker, variable involvement of primary care providers, and outpatient group visits. We have reorganized Table 3 and edited text in Results to highlight the variability in care coordination models included in this report.</p>



Reviewer Comments	Response and Revisions
<p>primary care). If this is a result of decisions made to meet the needs of the partner, then this needs to be more clearly explained, and consider changing the title to a synthesis of case management models. If the search strategy was designed to capture the breadth of care coordination models (which is what it seems is the case, both from the text and from Appendix 1, which included “collaborat” and “interdisciplin”), I am left wondering what happened to the reviews of other models (why did they not get included)? Did your search terms garner any reviews on other care coordination models (e.g., collaborative/ team-based care models)? If not, why not? If the search did garner reviews, at what point did they get dropped in the exclusion criteria (were they not high quality enough reviews)? I think explicit description of how such models did not get included is warranted, and then discussing the implications. For example, if they are not included because there are no high quality reviews of these models, what does that tell us about the state of the literature in this area?</p>	
<p><i>Reviewer 3</i></p>	
<p>Overall, amazing job making sense of a great deal of information! The ESP team, with support from the TEP members, designed and conducted a thorough and rigorous review of evidence on care coordination interventions to inform the VA CC&ICM initiative. My comments and suggestions are offered in the spirit of improvement and listed in order of appearance in the draft manuscript.</p> <p>Executive summary:</p> <p>1. My understanding of the CC&ICM initiative is that it is a multilevel intervention designed to deliver care coordination support at a level appropriate to the care needs of Veterans. Given that the innovation of this program is its stratification of Veterans and services by need, I expected this ESP evidence review to distinguish programs by level of service. Was there no element of this in the review?</p> <p>2. Was there any effort to speak with patients receiving these interventions? Before the VA takes up recommendations based on these programs, I think someone needs to hear directly from patients about their experience. If patient perspectives were not included in this review, you should say so in the limitations section.</p>	<p>Thank you.</p> <p>In abstracting results from eligible systematic reviews, we looked for any description of stratification and matching different levels of care coordination services. However, this was not reported in the reviews, most likely because the underlying primary research studies did not describe such a strategy. In the primary research studies that we examined, we also did not see a multi-level stratification and systematic matching of services. Instead, studies most often used risk factors as eligibility criteria, and implemented the intervention for patients who met these criteria.</p> <p>As this is an evidence synthesis report, we focused on existing published studies to address KQ. If reported in eligible systematic reviews and relevant primary studies, results on patient experiences of care were abstracted. Because we anticipated that information for KQ 3 and 4 may not be included in papers, we took the additional step of seeking interviews with investigators and other team members who implemented care coordination models. Collecting primary data from patients regarding their experiences of care would be beyond the scope of this report (and not expected for evidence synthesis projects).</p>

Reviewer Comments	Response and Revisions
<p>3. In defining effectiveness, I suggest you describe both sufficient and necessary conditions. Specifically, though not a sufficient condition, I think it's important that the reviews considered patient experience as part of its definition of effectiveness.</p> <p>4. The methods prioritize studies of interventions that demonstrate effectiveness. However, the most valuable learning from the review of prior interventions for the VA may come from the quality of descriptive information about how, why, and under what conditions an intervention was or was not effective. Did or could the review identify studies that were rich in information about mechanisms or theory of change? In producing this ESP evidence review, did the authors seek to summarize this type of information?</p> <p>5. On page 4 of the report, line 29, I am disappointed to see that only 1 study used qualitative methods. Could that be accurate? If so, I hope that 1 of the recommendations is that there is a qualitative assessment of the CC&ICM.</p> <p>6. The results don't seem to differentiate programs according to the level of health needs of the patient populations served. I think the CC&ICM would benefit from understanding results stratified by levels of need similar to the levels in the VA initiative.</p> <p>7. On page 6 of the report, line 18, the authors conclude that some local adaptations to the CC&ICM may be helpful for supporting uptake and</p>	<p>We agree with reviewer that patient experiences of care is an important consideration in evaluating care coordination models. However, in consultation with our VA stakeholders and TEP, hospitalizations and ED visits were selected as the primary outcomes of interest; they defined whether a care coordination intervention would be considered effective. Our interviews with investigators and staff who implemented care coordination models also substantiated these decisions, as the sustainability and spread of these interventions were affected by whether they were able to change acute care utilization. We have clarified these choices in Methods and added to limitations in Discussion</p> <p>We agree that understanding the exact situation or context when an intervention is effective (or not) is an important goal. As note in Results, multiple eligible reviews sought to answer such questions, but they were unable to draw conclusions. The heterogeneity of intervention components, along with variation in populations and settings, has continued to present challenges in summarizing and interpreting the evidence on care coordination models. In our examination of the relevant primary research studies, we similarly could not draw clear conclusions on whether variation in specific intervention components, population characteristics, and/or types of settings were key in determining the effectiveness.</p> <p>We agree that qualitative methods are important for the evaluation of these interventions, and they are often employed in implementation studies. We limited our search for additional information on assessment of patient relationships with the care team to those studies that were cited in the original articles identified from eligible reviews (and from the search for RCTs). We also examined any materials referred to us during interviews. However, if there were subsequent qualitative evaluations of interventions that were not cited in the original articles and we were unable to conduct an interview with the team, then we would have identified these.</p> <p>As noted above, eligible systematic reviews and relevant primary research studies did not provide results on systematic stratification of patients and matching of needs.</p> <p>Thank you. We have added to the Discussion the suggestion regarding the importance of evaluating adaptations and education on program goals.</p>

Reviewer Comments	Response and Revisions
<p>sustainability of CC&ICM. I couldn't agree more, particularly because the populations served are likely to vary. The VA should make an effort to document supportive adaptations and the circumstances in which they apply, because while they may not apply everywhere, they are likely to apply somewhere. Also, in addition to the concept of core versus adaptive periphery, I think the findings suggest that the CC&ICM should consider the conditions under which adaptation is appropriate. Further, the findings suggest that in rolling out the CC&ICM intervention, education must focus on communicating the intent of the intervention, in addition to the recommended approach, to increase the likelihood that adaptations will be supportive.</p> <p>8. On page 7 of the report, line 16, the authors conclude that future evaluations should use randomized designs. I respectfully disagree. Given the importance of implementation to the effectiveness of any intervention like CC&ICM, I don't believe that a study designed to tell you whether an intervention that is implemented across a wide variety of settings and participants works is particularly informative. More helpful will be studies that describe where, why, and how they work when they do succeed.</p> <p>Additional comments on the evidence report:</p> <p>9. Can you provide additional information about why the expert panel felt that the Care Coordination in Chronic and Complex Disease Management framework was the most applicable to the goals of this current review and how the group of existing resources were identified? Also, did you use this framework for anything other than to effective care coordination? To do that, I would think it most appropriate to look across coordination/integration frameworks to understand which outcomes are considered most relevant.</p> <p>10. KQ3 and KQ4 are potentially the most important. However, I don't see much written about the answers to these questions in the executive summary. (Note, I see later that the interviews are designed to get at these questions. I hope when the analysis of transcripts is complete, there will be more to say.) While Table 3 describes settings in which interventions were implemented, what would be most helpful is understanding which interventions were implemented in which settings and whether there were any systematic differences in intervention by setting.</p>	<p>We agree with reviewer that understanding where, why, and how are important aspects of future work. However, we do not believe that this precludes the use of randomized designs, especially when quantitative patient-level outcomes are featured. Additionally, the use of randomization can address important threats to the internal validity of research studies. For example, the recent RCT of healthcare hotspotting (Finkelstein et al. NEJM 2020; 382:152-162) showed that this intervention was not effective, in contrast to previous observational studies that suggested positive impacts. Mixed-methods designs that combine rigorous quantitative and qualitative techniques will likely be the most helpful in the future.</p> <p>In the Methods, we have clarified the rationale for selecting this framework, and how it informed the overall methodology of this report.</p> <p>We have included more information from the completed interviews in Results. In examining the primary research studies for characteristics of settings for effective (and non-effective) care coordination models, we found great variation and no discernable systematic differences.</p>

Reviewer Comments	Response and Revisions
<p>11. The most informative data may be in Table 3, the description of patient contacts, as this column describes the dose of the intervention. Could the team group the interventions targeting patients at different levels of need and then compare the intervention dosages applied. Most useful might be understanding the range of patient contacts attempted for a given level of need. Also, I presume these descriptions apply to the intervention as designed. If any information is available about fidelity to the intervention (I realize this is unlikely), this would make assessing the impact of these interventions more useful.</p>	<p>Aside from most studies including older adults, it was difficult to find commonalities that allowed us to clearly distinguish studies based on patient populations. We have reorganized Table 3 to indicate those interventions targeting those who were recently hospitalized (or discharged from ED). But there has been a range of patient contacts for this group of studies, as well as for those enrolling outpatients in general.</p>
<p><i>Reviewer 4</i></p>	
<p>This is a well-done report focused on meeting an operational partner's specific needs. As such, it does not answer all potentially relevant questions to care coordination in the VA, but rather those that the partner had an interest in. There are just a few minor items that came to my attention while reading the draft. All comments I make below apply equally to the executive summary and the main report, but I will use pages and line numbers from the main report.</p> <p>Page 10, lines 50-51. There is a disconnect between what is written here and the actual wording of KQ2 on the next page, which specifically mentions patient experience as if it had equal importance to hospitalizations/ED visits. Should patient experience be mentioned here, since it is in Table 1 as a patient outcome?</p> <p>Page 13, lines 21-23. Related to the comment above: it appears that the review was delimited to only those reviews covering at least hospitalizations and/or ED visits as outcomes of interest. From this, it seems that patient experience is not on the same footing of importance as hospitalizations and ED visits, but that contradicts the wording of KQ2, which places them on an even footing. This probably relates to partner prioritization as mentioned earlier in the report, but further clarification would be helpful. I suspect that there might be some systematic reviews in the literature that only focus on patient experience and not on hospitalizations/ED visits, and those would have been missed by delimiting the search to requiring mention of hospitalizations and/or ED visits as an outcome of interest.</p>	<p>Thank you.</p> <p>We appreciate reviewer suggestions, and as noted above, have clarified in Methods how we applied the care coordination framework (depicted in Table 1) to define scope and KQ.</p> <p>We have clarified the decisions in determining effective interventions in Methods and added the limitation regarding evidence on patient experience to the Discussion.</p>

Reviewer Comments	Response and Revisions
<p>Page 17, lines 44-47. I am not surprised that little was found on specific tools/measures in the published literature. Such things might show up in the grey literature or on the Web. Hopefully the rest of the key informant interviews will help, but it may be a limitation of the search strategy used that grey literature/websites were not searched (understandably given time constraints).</p> <p>Page 25, lines 38. "Goals and needs" are mentioned but I can't tell whose goals and needs are being referred to.</p> <p>Page 27, lines 18-20. Is there actual data to support this final sentence? How do we know that redesigning primary and specialty care teams to improve continuity and collaboration would be more effective than the approaches used by the studies reviewed? I'm concerned about extrapolating beyond the scope of the review.</p>	<p>We identified websites associated with primary research studies of care coordination models, if these were cited by the studies or linked with the investigators (via searches online). We examined information provided on these websites and have included relevant information in the Results section on interviews. We have clarified this additional source of information in Methods</p> <p>We have clarified this sentence in the Discussion.</p> <p>In the Discussion, we noted several examples of health care redesign that went beyond adding on of care coordination services. We agree that evidence on whether they are superior to care coordination is lacking. Therefore, we have edited this sentence to indicate such redesign efforts may be considered an option.</p>
<i>Reviewer 5</i>	
<p>No - Clarity of Objectives. It was difficult to find a paragraph or section where the study objectives were clearly and succinctly introduced. It appears objectives were stated on page 9, lines 35-45.</p> <p>The use of a header, along with clearer wording of objectives, would aid in clarification of objectives.</p> <p>Conceptual Framework. The conceptual framework (page 10, Table 1), while detailed, is not clearly linked to the key questions. Without these linkages, the scope of the synthesis is confusing. Some considerations for improving these linkages are as follows:</p> <ul style="list-style-type: none"> • When considering KQ1, "What are the key characteristics of care coordination models that aim to reduce hospitalizations and ED visits?": <ul style="list-style-type: none"> o Which, if any, of the categories shown in Table 1 represent key characteristics? o Page 16, lines 29-42 mentions an intervention component "multidisciplinary care plan" where would this fit in the conceptual framework? • When considering KQ3, "What are the characteristics of settings in which effective models have been implemented?": <ul style="list-style-type: none"> o Which, if any, of the categories shown in Table 1 represent "characteristics of settings"? 	<p>We clarified the goals presented in the Introduction. Additionally, KQ are described in Methods.</p> <p>We are unsure which headers were confusing for the reviewer. In the Methods, we used standard headers and sections for ESP reports. We also reviewed sections in the Results and separated out relevant results per KQ.</p> <p>As noted above, we have clarified in the Methods how we applied the Care Coordination Framework to the methodology for this report. We agree with reviewer that characteristics of interventions (and of settings) are broadly defined, and could come from multiple columns listed in Table 1. We relied on authors of eligible systematic reviews to define what they considered to be key characteristics. Similarly, we sought to abstract any review results on characteristics of where interventions were implemented. We have also clarified the application of the Framework to KQ. KQ4 addresses in part the column on Emergent Integrating Conditions, in seeking evidence on tools to assess team integration. The results shown in Table 3 are those reported by primary studies. To guide development of the methodology for this evidence review, the framework was selected before we had identified (or examined) all eligible reviews or relevant studies. It is best practice to define the protocol for the systematic review before seeing the results.</p>

Reviewer Comments	Response and Revisions
<p>o Why are the elements reported in Table 3 (and on page 17 lines 43-45) rural community hospitals, academic medical centers not accounted for in the model?</p> <ul style="list-style-type: none"> • Do the categories “Emergent Integrating Conditions” and “Coordinating Actions” relate to any of the key questions? If not, perhaps those columns of Table 1 could be shaded and a note indicating that the scope of this study does not include these elements. <p>In sum, mapping the key questions to the conceptual framework will clarify the scope of the synthesis. In addition, the text should provide a bit more detail for the reader as to how the key questions relate to the conceptual framework.</p> <p>Operational Definitions. The document could be strengthened by including operational definitions for the following terms: “key characteristics of care coordination models”; and “characteristics of settings”.</p>	<p>As noted above, we abstracted what eligible systematic reviews defined as key characteristics of interventions. For setting characteristics, we also abstracted a range of information about the health care system and the community. We have added some potential examples to the Methods.</p>
<p>Is there any indication of bias in our synthesis of the evidence? Yes - Care coordination interventions are inherently complex and this evidence synthesis was very ambitious. The methodologic decisions to study a range of ambulatory care sensitive conditions and to study different care coordination models, likely increased the heterogeneity and complexity of this synthesis to a level where the noise was stronger than the signal. Perhaps narrowing the selection criteria to arrive at a more homogeneous sample of papers was not an option. Nonetheless, I'd like to see the authors address this limitation and possible source of bias in the final paper. In addition, I'd like them to offer ideas for some alternative choices in the search strategy that could lead to more homogeneous samples in the future that may advance our understanding of care coordination interventions.</p>	<p>We determined the search strategy and inclusion/exclusion criteria to optimize identification of the most relevant evidence to address the priorities and needs of our VA stakeholders. As the CC&ICM initiative is meant to streamline care coordination programs throughout VA facilities nationally, we sought evidence on models that could be widely implemented (and locally adapted, whenever possible). We do not believe that these decisions introduced bias into identification or interpretation of the evidence. If the evidence review was meant to address a different goal for either a more limited patient population (eg, how to improve outcomes for heart failure patients with comorbidities), or a specific definition of care coordination (eg, nurse-led intervention), then the search strategy could be tailored to those needs.</p>
<p>The findings of this literature synthesis underscore that the science behind care coordination is in its infancy. In hindsight, this review may have benefitted from the inclusion of published QI studies. This particularly true with respect to KQ1 the key components of interventions which are generally more thoroughly described in the QI literature.</p>	<p>We did not exclude systematic reviews based on the types of studies they included. Additionally, there is not a specific study design that is shared by all QI studies. For relevant primary studies, we required that these be RCT or quasi-experimental (eg, observational study with comparative cohort). QI studies could employ these various designs, and there are current efforts to include randomization in QI work [Horwitz et al. NEJM 2019; 381:1175-1179].</p>
<p><i>Reviewer 6</i></p>	
<p>This is a rigorous evaluation of a complicated topic: care coordination models and tools. The challenge with a synthesis effort like this 1 is that the existing models are heterogeneous in the populations they focus on,</p>	<p>Thank you.</p>

Reviewer Comments	Response and Revisions
<p>structure, processes, goals, and outcomes. As such, most of the models develop their own care coordination tools and procedures, and there is likely variation in the degree to which their approaches are grounded in evidence vs reflective of home-grown practical clinical tools. The evidence synthesis reflects this challenge. Investigators found that existing evidence suggests that care coordination models have inconsistent effects on reducing hospitalizations and/or ED visits and unfortunately there have been few clear-cut lessons about how to move this field forward. Overall, the evidence synthesis appears rigorous and comprehensive, but the findings are a bit disappointing in that they do not reveal many practical strategies or lessons for the VA and others to adopt, and their literature review and interviews did not identify any specific tools.</p> <p>Specific suggestions:</p> <p>Pg 8/lines 50-52 (and Appendix 3): Add detail/clarification about inclusion criteria for patient populations. Did papers have to focus on patients with ACSCs in order to be eligible? What about papers focused on patients with mental health conditions or cancer (given the prevalence of these conditions among Veterans requiring care coordination)? Based on the final list of included papers, it looks like the review covers a wider range of patient populations/conditions than the inclusion criteria suggest.</p> <p>Pg 11/line 22 (and elsewhere): clarify the term “observational study”- it looks like these studies needed to have a control group in order to be included?</p> <p>Pg 11/line 34: I know interviews are still ongoing, but the purpose and value of these is unclear. The results don’t seem to address the main goal outlined on Pg 9 (addressing gaps regarding tools and approaches to assessing patient trust, team integration, and patient-provider communication). I am also surprised that these interviews did not reveal any tools, if you were able to contact individuals involved in the care coordination interventions/evaluations.</p> <p>Pg 12/line 14: what is a high-intensity model?</p>	<p>We have clarified in Methods the inclusion and exclusion criteria for eligible systematic reviews. Reviews needed to include a range of conditions and/or a more general definition of higher-risk patients. Reviews that included studies which addressed patients with mental health conditions or cancer would have been included, if the reviews did not exclusively focus on a single or narrow set of conditions.</p> <p>We have added some examples of what constituted quasi-experimental observational studies. The relevant primary studies included by reviews were either observational or RCT, and we required that observational studies used some form of quasi-experimental designs. Although there are a variety of potential designs, the selected studies all used comparative control cohorts.</p> <p>We have clarified the goals of the key informant interviews in Methods. We note that we were able to conduct interviews with ~50% of those whom we invited. It is possible that those who were not interviewed would have provided more information on tools and approaches. Among those we interviewed, and based on published studies, it appears that formal assessment of these areas was not often incorporated into the evaluation of care coordination interventions.</p> <p>In the Executive Summary and Discussion, we have added more information about how review authors defined this term.</p>

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<p>Pg 12/line 23-25: I am a little puzzled by the focus on tools/approaches that assess patient trust or working alliance and health care team integration. While these topics are important for care coordination, it seems like there are a lot of other practical tools for care coordination that would be valuable to review and share (e.g., assessing patient needs for care coordination, assessing patient goals and priorities, understanding social circumstances that are influence health and health care engagement, identifying modifiable risk factors for hospitalization/ED visits). It might not be possible to comment on these at this stage, but at the very least would justify the reason for focusing on the tools highlighted in the report.</p> <p>Pg 13/line 23-34: Here or elsewhere, consider mentioning some of the intensive outpatient programs in VA, including HBPC, MHICM, PIM. In addition to PC-MHI, the VA's PACT patient-centered medical home model provides an opportunity for case management of patients with higher levels of need, when implemented well.</p> <p>Pg 14/line 10-11: Here or elsewhere could refer to Hybrid effectiveness-implementation studies (Curran, Med Care, 2012- I see it listed in the references)</p> <p>Pg 14/line 18-19: As above (Pg 12 comments), I don't understand why these very specific domains are highlighted as necessary tools. Measuring "health care team integration" seems of interest from a research perspective, but not high on the list for a practical care coordination tool. Some of the specific examples pg 24/line 49-52 seem of higher value.</p> <p>Pg 24/line 31-33: To drive the point home, would add percentages for 7/9 and 3/18.</p> <p>Pg 24/lines 51-52: Is there any more work that could be done to identify tools/approaches? Given the number of papers reviewed, it seems hard to believe that none of the programs were able to share any effective tools. Even if the programs don't have outcomes data for hospitalizations, if the tools were found to be valuable to patients/staff that could still be important information. I know a lot of work has already gone into this review, but I am wondering if the investigators tried contacting the clinical leads of some of the interventions that they reviewed? I would think these</p>	<p>In the Methods, we have clarified the rationale for selecting these tools. These were topics that were particularly relevant to our VA stakeholders, whereas other tools (eg, for assessing patient needs) were not as salient given the current status of the CC&ICM initiative. For example, the initiative had already begun testing standardized assessments of patient needs and risk factors, and they were seeking evidence on how to evaluate (or further improve) various care coordination services.</p> <p>We appreciate reviewer's suggestions and have provided additional examples of VA programs that may be relevant for future care coordination efforts.</p> <p>We have added the names of specific implementation frameworks and categorization of studies that include implementation outcomes to the Discussion.</p> <p>As noted above, we have clarified in Methods the rationale for addressing these types of tools or assessments. They were selected as relevant to the initiative in evaluating current pilot efforts and future implementation results.</p> <p>We appreciate reviewer's suggestion and have made these additions.</p> <p>We agree that it is possible that tools or approaches used by interventions that did not assess hospitalizations or ED visits may still be valuable. However, that would have substantially expanded the scope of this review, and created additional challenges in interpreting the utility of these tools for the VA initiative. We invited lead authors of the identified relevant primary studies for interviews. We also sought referrals to other team members who may have greater knowledge about tools and approaches used to implement or evaluate these interventions. Our interviews suggested that formal assessments of these topics were often not conducted.</p>

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<p>individuals would be able to share the practical tools that they used for care coordination.</p>	
<p><i>Reviewer 7</i></p>	
<p>Are there any published or unpublished studies that we may have overlooked? Yes - I only selected yes to offer that for the qualitative interviews you might include the authors of this recently published protocol if it and they aren't included already: Miller, L.B., Sjoberg, H., Mayberry, A. et al. The advanced care coordination program: a protocol for improving transitions of care for dual-use veterans from community emergency departments back to the Veterans Health Administration (VA) primary care. BMC Health Serv Res 19, 734 (2019). https://doi.org/10.1186/s12913-019-4582-3 Full text link: https://rdcu.be/b4ao1</p>	<p>We appreciate this recommendation. We reviewed this study, and as it does not report results of the intervention, it would not meet the criteria for inclusion.</p>
<p>Thank you for the opportunity to review/contribute to this ESP. The draft is excellent.</p> <p>I have some thoughts/suggestions:</p> <p>1. re: the approaches to patient selection (as mentioned on p.16, line 34; 24, lines 19-23 and especially p. 25, lines 20-28 and especially interviewee comments, p. 18 lines 20-24). There is an interesting topic for future research (as the interviewee describes). Future research could also include inquiry into care coordination to different populations (less and more complex). The interviewee snippet on p. 18, lines 19-21 is so apt as our Veterans often have multiple conditions and may still need hospital or increased care.</p> <p>2. re: outcomes, medical hospitalization and ED visits were the primary outcomes, I could see Veterans benefiting from case management and care coordination in other ways (e.g. reduced stress and mental health symptoms). So perhaps expanding the focus in future research to other utilization or severity of other conditions. (Recognize this might be outside of the current ESP scope).</p> <p>3. While not part of the initial scope, I wonder about the technology used in the different reviews/studies analyzed (i.e. telephone and video). While this review was conceived, developed and started before COVID-19, given there has been a tremendous shift to non-face to face visits and increased use of telehealth, it might be informative to add that into the</p>	<p>Thank you.</p> <p>Thank you.</p> <p>We agree that there are potentially other benefits of improved care coordination. We selected hospitalizations and ED visits to address priorities of our stakeholders.</p> <p>We agree that use of technology is a potentially important characteristic of care coordination interventions. Eligible systematic reviews provided mainly descriptive information about incorporation of technology (generally of telephone calls) and did not draw conclusions on whether technology impacted the effectiveness of interventions. We have added this information to the Results. In the relevant primary studies,</p>

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<p>study details and then tie that topic, as appropriate, into future research and/or policy (e.g. How has COVID-19 affect care coordination and case management integration and implementation.)</p>	<p>telephone was also the main technology used (as described in Table 3). It would be interesting for future studies to address use of video-conferencing in various care models.</p>
<p><i>Reviewer 8</i></p>	
<p>Under Implications for Policy, lines 16-19, it is stated that the goal of the CC&ICM is standardization, which is a valid statement, however, this is currently balanced with the need for adaptability at the specific facility due to staffing, existing structure and practices. CC&ICM model recommendations are implemented with this flexibility and are reported to CC&ICM leadership for dissemination to the field as potential practices to implement or adapt as needed. As indicated further under Key Findings, lines 44-49, interviewees did indicate a lack of adaptability at the facility level in some circumstances. This was likely due to a variety of factors (facility leadership, resources, flexibility of staff, etc) but is not a result of "model" inflexibility. This slight misunderstanding leads to another issue in the same section, lines 28 - 34. This suggestion is in agreement/alignment with the CC&ICM model. The CC&ICM model is not for patient navigation (solely), but incorporates a wholistic, patient centered, collaborative approach which includes the components described in the Mental Health collaborative model. It would seem the authors are contrasting these similar VA models in this recommendation.</p> <p>There are several notations regarding ongoing interviews to compare tools and approaches used across models with only 6 of 22 conducted to date. However, under Key Informant Interview results (page 17 & 18, lines 15-29) results are curiously concluded.</p>	<p>We appreciate reviewer clarification of CC&ICM goals. We have adjusted the Discussion to better describe these goals. We have also clarified that the PCMH model is a co-located collaborative model between primary and specialty care (in this case, mental health). This is substantially different from care coordination services that are meant to be deployed to address a wide variety of potential risk factors and Veteran needs.</p> <p>We provided draft results and conclusions based on interviews that had been completed at that time. We have now updated the relevant sections in the Results and Discussion to include additional interviews completed after the draft report.</p>
<p><i>Reviewer 9</i></p>	
<p>Page 1 line 22 change VA Coordinated care to VA Care Coordination; Page 9 line 25 same as above</p>	<p>Updated to "VA Coordinated Care" as requested</p>

APPENDIX 7. DETAILED CHARACTERISTICS AND RESULTS FROM MEDIUM- AND HIGH-QUALITY SYSTEMATIC REVIEWS

Author, Year (Quality, Year of Search); # Relevant Primary Studies	Included Populations; Study Designs	Included Relevant Interventions	Main Objective(s) Results Summary
Case Management and Transitional Care Interventions			
Di Mauro, 2019 ¹⁸ (Medium, 2018); 3	“[frequent user] adult patients who visit the ED”; RCT, cohort	“Case Management...is a collaborative approach used to assess, plan, facilitate and coordinate healthcare related matters...It aims at meeting patients’ and their families’ health needs through communication and available resources, thus, improving individual and healthcare system outcomes...”	“to examine if and how the [case management] programs are implemented to reduce the number of [frequent user] visits to the ED.” “Ten papers showed...decrease in visits to the ED (from 14% to 58.5%) and in... 3 studies the results were insufficient to prove this utility.”
Hudon, 2019 ¹⁹ (High, 2017); 4	“adult frequent users...with physical chronic disease”; RCT, cohort, cross-sectional	“[Case management is] a collaborative approach to ensure, coordinate, and integrate care and services for patients, in which a case manager evaluates, plans, implements, coordinates, and prioritizes services on the basis of patients’ needs in close collaboration with other health care providers...”	“to identify characteristics of [case management] that yield positive outcomes among adult frequent users with chronic disease in primary care.” “analysis revealed that the case-finding characteristic (ie, high frequency of health care visits) and complexity of health care needs are necessary... [P]ositive outcomes were associated with the following 2 sufficient characteristics when each was combined with this necessary condition: high-intensity [case management] intervention and presence of a multidisciplinary/interorganizational care plan”
Iovan, 2019 ²⁰ (Medium, 2017); 6	“population studied...was classified as super-utilizer”; RCT, cohort	Case management: <ul style="list-style-type: none"> • “Holistic approach to care considering a patient’s complex medical and social needs...” • Connects patients with existing community resources • Creates a continuum of care that addresses medical, financial, psychosocial, and behavioral needs... <p>Care coordination:</p>	“systematic review of interventions aimed at reducing prehospital and emergency care use among super-utilizer populations in the United States.” “17 of 21 case management studies investigated intervention impact on ED use. Of those, 13 showed a reduction in utilization, yet only 5 of these 17 studies (29%) had a control group. Among the 5 studies with a control group, 3 showed some degree of positive impact of the intervention on ED utilization, including 2 of the 3 RCTs... [M]ethodological and study design weaknesses—especially regression to the mean—were widespread and call into question reported positive findings.”



		<i>"Thoughtful review of a patient's medical needs, resulting in more effective transitions between providers..."</i>	
Van der Elst, 2018 ²⁷ (Medium, 2016); 0	<i>"60 years or older, diagnosed as frail, and community-dwelling";</i> RCT	<i>"Case management – a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote quality, cost-effective outcomes."</i>	<i>"What effect do interventions have on frail community-dwelling older adults in terms of mortality, hospitalization... and institutionalization? [H]ow do age, study duration, and the multi- versus unidimensional approaches of frailty and recruitment influence the effect of an intervention?"</i> <i>"pooled OR for hospitalization when allocated in the experimental group was 1.13 [95% CI: 0.95, 1.35] for case management..."</i> <i>The influence of duration of intervention...multi- versus unidimensional approach to frailty, and recruitment [method] on the effect of an intervention was explored...[in] sub-analyses... but with no significant results."</i>
Joo, 2017 ²¹ (Medium, 2016); 1	<i>"[adult] populations who were diagnosed with chronic illnesses";</i> RCT	<i>"Case managers, who often work with multidisciplinary teams, are located within the space of transitional care, which means they are able to do continuous follow-up care, timely transitional care and patient-centred care as patients move from hospitals to their communities..."</i>	<i>"synthesizes recent evidence of the effectiveness of case management in reducing hospital use by individuals with chronic illnesses"</i> <i>"All [10] studies compared hospital readmission...in the intervention and control groups... Three of the studies reported statistically significant reductions in hospital readmissions... Three other studies...reported reduced readmissions but no statistically significant results... The remaining studies... reported no effect on readmission rates.</i> <i>Six studies reported the number of ED visits as an outcome.</i> <i>Five studies found a statistically significant reduction in the number of ED visits in pre- and post-[case management] intervention analysis...[T]he sixth study...found reductions...for the [case management] group over the control group, [but] the results were not significant."</i>
Baker, 2018 ¹⁵ (Medium, 2015); 4	Adults in 1 of 3 categories: "a) 2 or more chronic medical conditions, b) at least 1 chronic medical condition + depression, and c) high past or predicted utilization"; RCT	<i>"patient-focused, comprehensive care management intervention (areas of focus included some combination of self-management, healthcare system navigation, self-efficacy, symptom monitoring, symptom management, etc.) targeting the "whole" patient (e.g. including nurse- or case-manager led interventions, integrated care team strategies, group interventions)"</i>	<i>"What are the necessary components and appropriate intensity of effective care management interventions?"</i> <i>"Seven studies measured hospital admissions and readmissions in the post-intervention period; however, only 2 of these studies showed an improvement in [hospital readmission]..."</i> <i>[C]ommon methodologic issues limited our ability to draw conclusions regarding the effectiveness of specific intervention components...[I]nsufficient detail on implementation fidelity and participant adherence to the interventions limited any substantive observations on the relationships between intervention content and intensity and any patient benefits."</i>
Le Berre, 2017 ²² (High, 2015); 3	<i>"Patients 65 years old or older with at least 1 [chronic disease] who have been hospitalized and are being</i>	<i>"[Transitional care] interventions comprising all the following elements: (1) aimed at providing coordination and continuity of care; (2) pre-arranged structured post-discharge follow-up (e.g., home visits, phone calls); (3) at least 1</i>	<i>"to determine the effectiveness of interventions targeting transitions from hospital to the primary care setting for chronically ill older patients."</i> <i>"The risk of readmission in [transitional care] was lower than in [usual care] at 3 months post-discharge (RD: -0.08 [-0.14, -0.03]; NNT: 7), 6 months post-discharge (RD: -0.05 [-0.09, -0.00]; NNT: 20), at 12 months post-discharge (RD:</i>



	<i>discharged back to home</i> ; RCT	<i>follow-up starting within 30-days post-discharge.</i> "	<i>-0.11 [-0.17, -0.05]; NNT: 9), and at 18 months post-discharge (RD: -0.11 [-0.21, -0.01]; NNT: 9). No significant change was observed at 1 month... The risk of an ED visit... was lower... at 3 months post-discharge (RD: -0.08 [-0.15, -0.01]; NNT: 13). No significant change was observed at 1, 6, and 12 months..."</i>
Soril, 2015 ²⁶ (High, 2015); 3	<i>"general adult frequent ED user"</i> ; RCT, cohort	<i>"...case or care management is considered a comprehensive, interdisciplinary approach taken to assess, plan, personalize, and guide an individual's health services to promote improved patient and health system outcomes."</i>	<i>"to establish the effectiveness of interventions aimed at reducing the ED utilization, in comparison to usual care, for individuals who are frequent users of the ED" "Compared to the control groups, 1 RCT reported no change in the mean number of ED visits following [case management], whereas the second RCT reported a minor decrease in median ED visits among those in the intervention group. Of the 10 comparative cohort studies..., 9 studies reported outcomes related to the change in ED visits: 8 studies observed a decrease in the mean (between -0.66 and -37 ED visits) [or median number of ED visits (between -2.28 and -20 ED visits) compared to the controls or before [case management]; and 1 study reported an increase of 2.79 median ED visits post-intervention..."</i>
Moe, 2017 ²³ (High, 2014); 3	<i>"adult frequent ED users"</i> ; RCT, cohort	<i>"Case management involved multidisciplinary teams, including physicians, nurses, psychologists, social workers, and/or housing and community resource liaisons, who developed tailored care strategies for patients and linked them to necessary services."</i>	<i>"to summarize experimental studies evaluating the effectiveness of interventions targeting adult frequent ED users at reducing ED visit frequency and improving hospital admissions..." "Post- versus pre-intervention rate ratios were calculated for 25 studies and indicated a significant visit decrease in 21 (84%) of these studies. The median rate ratio was 0.63 (interquartile range = 0.41 to 0.71)."</i>
Smith, 2016 ²⁵ (High, 2011); 2	<i>"people... with multimorbidity"</i> ; RCT, cohort	<i>"...organizational changes delivered through practitioners or directly to patients. For example, any changes to care delivery such as case management or the addition of different healthcare workers such as a pharmacist..."</i>	<i>"To determine the effectiveness of health service or patient oriented interventions designed to improve outcomes in patients with multimorbidity in primary care and community settings" "Five studies reported outcomes on health service utilization...[One] reported significant improvements for intervention group...relating to hospital admissions, whereas [four studies] found no significant difference in outcomes... The results indicate that it is difficult to improve outcomes in this population but that interventions focusing on particular risk factors or functional difficulties in patients with co-morbid conditions or multimorbidity may be more effective."</i>
Intensive Primary Care Interventions			
Totten, 2016 ³⁰ (High, 2015); 1	<i>"Adults with chronic illnesses or disabilities"</i> ; RCT, cohort	Home-based Primary Care: <i>"1) Visits by a primary care provider... 2) Visits to a patients home... 3) Longitudinal management... 4) Comprehensive primary care..."</i>	<i>"To assess the available evidence about home-based primary care (HBPC) interventions for adults with serious or disabling chronic conditions." "The strongest evidence (moderate) was that HBPC reduces hospitalizations and hospital days. Reductions in emergency and specialty visits and in costs were supported by less strong evidence, while no or unclear effects were identified on hospital readmissions and nursing home days... HBPC had a positive impact on patient and caregiver experience, including satisfaction, quality of life, and caregiver needs, but the strength of evidence for these outcomes was low..."</i>



<p>Edwards, 2017²⁹ (Medium, 2017); 7</p>	<p><i>“Patients identified as high risk for hospital admission and/or death”;</i> RCT, cohort</p>	<p><i>“We classified programs as primary care replacement (home based), primary care replacement (clinic-based), or primary care augmentation, and assessed the impact of outcomes separately for each category...”</i></p>	<p><i>There is wide variation in the services provided as part of HBPC interventions. In the evidence presently available there is not an apparent pattern or cluster of services associated with differences in outcomes. Most included assessment and coordination...Four studies examined the incremental impact of additional services to HBPC.”</i></p> <p><i>“to classify interdisciplinary, multicomponent [intensive primary care] programs according to program characteristics, and to evaluate the effectiveness of these programs in reducing hospitalizations, emergency department...visits, and mortality among patients at high risk for hospitalization or death.”</i></p> <p><i>“Most studies showed no impact of intensive primary care on mortality or emergency department use, and the effectiveness in reducing hospitalizations varied...The programs varied in the way they identified and screened patients for enrollment, though most focused on older adults with functional limitations... All programs utilized multidisciplinary staff to meet a range of patient needs, and most commonly included physicians, nurses, social workers, physical therapists, mental health providers, and pharmacists... Given the negative results of many of these studies, it is possible that attempts to manage complex care using large multidisciplinary teams may be ineffective for some high-needs patients, as the burden of coordination may outweigh the benefits of the specialized skills of each team member... We had hoped to identify key program features, such as patient selection criteria, that may have contributed to the success or failure of these programs. Unfortunately, reporting of key intervention characteristics was inconsistent... In addition, the data collected on intervention fidelity, implementation process, and contextual factors at individual intervention sites varied among studies.”</i></p>
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CI=confidence interval; ED=emergency department; NNT=number needed to treat; OR=odds ratio; RCT=randomized controlled trials; RD=risk difference