**Complete Title:** Comparing Two Approaches to Care Coordination for High-Cost/High-Need Patients in Primary Care

**Short Title: M**innesota **Ca**re Coo**R**dination **E**ffectiveness **S**tudy (MNCARES)

**Study Sponsor:** Patient Centered Outcomes Research Institute (PCORI)
**PCORI Program Officer:** Tabassum Majid, PhD
**Study Contract Number:** IHS-2019C1-15625

**Principal Investigators:** Leif Solberg, MD and Steven Dehmer, PhD
**Institution:** HealthPartners Institute

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**Version 1.1**

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# List of Abbreviations

| | |
|---|---|
| AHRQ | Agency for Healthcare Research and Quality |
| BAA | Business Associate Agreement |
| BCBS | Blue Cross and Blue Shield of MN |
| CCQM-PC | Care Coordination Quality Measure for Primary Care |
| CESR | Center for Evaluation and Survey Research |
| CG-CAHPS | CAHPS Clinician & Group Survey |
| DAGs | Directed Acyclic Graph |
| DHS | Minnesota Department of Human Services |
| DUA | Data Use Agreement |
| EHR | Electronic Health Record |
| GLMMs | Generalized Linear Mixed Models |
| HCH | Health Care Home |
| HIPAA | Health Information Privacy and Accountability Act |
| HP | HealthPartners |
| HPI | HealthPartners Institute |
| ICSI | Institute for Clinical Systems Improvement |
| IRB | Institutional Review Board |
| MDH | Minnesota Department of Health |
| MN | Minnesota |
| MNCARES | Minnesota Care Coordination Effectiveness Study |
| MNCM | MN Community Measurement |
| PCORI | Patient Centered Outcomes Research Institute |
| PIs | Principal Investigators |
| SFTP | Secure File Transfer Protocol |
| STROBE | Strengthening the Reporting of Observational Studies in Epidemiology |

# Protocol Summary

| | |
|---|---|
| **Title:** | Comparing Two Approaches to Care Coordination for High-Cost/High-Need Patients in Primary Care |
| **Précis:** | This is an observational mixed method study of the outcomes from existing care coordination models among certified health care home primary care clinics in Minnesota. It combines existing quality and claims utilization data with a survey of patient needs and outcomes to compare models with and without a social worker among two cohorts of patients, one beginning coordination before and one after the disruptions caused by the COVID-19 pandemic. |
| **Study Aims and Outcome Measures** | **Aim 1:** To compare the healthcare quality, utilization, and patient-reported outcomes for adult patients who receive care coordination services from clinics that use a medical model versus a medical/social model<br><br>**Aim 2:** To identify the key components of the two models and quantify their association with the above outcomes.<br><br>**Aim 3:** To explore how organizational, community, care process, and patient factors help explain differences in the models and outcomes.<br><br>**Exploratory Aim:** To extend the comparative effectiveness analysis in the Historical Cohort by up to an additional 3 years and to investigate how the pandemic may have disrupted care, health, and wellbeing for these patients. |
| **Population** | **Historical Patient Cohort:** Patients starting care coordination in participating clinics between January 2018 and February 2019.<br><br>**Primary Patient Cohort:** Patients starting care coordination in participating clinics between January 2021 and December 2021. |
| **Number of Sites** | 397 potentially eligible clinics among 70 care systems |
| **Study Duration**<br>*Estimated time from start of subject enrollment to completion of data analysis* | 36 months |

## Key Roles and Contact Information

| | |
|---|---|
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| **Other Key Personnel:** | Leif Solberg, MD<br>Steven Dehmer, PhD |

# Study Protocol

# 1 Introduction: Background and Scientific Rationale

## 1.1 Background

People with multiple chronic conditions or multi-morbidity make up over 2/3 of those over age 65, but also 1/4 of those younger than 65 who receive health care.[1,2] Tinetti notes that such patients are also the "major users of health care services at all adult ages and account for more than 2/3 of health care spending."[2] Moreover, most chronic medical conditions are also associated with a higher frequency of depression, and Fortin et al. have shown that there is an inverse relationship between the number of medical conditions and patients' quality of life.[3,4] Sharma et al. found that among patients with the 14 most disabling chronic conditions, a majority were more likely to be seen by a primary care physician than a specialist; therefore, it is particularly important that primary care clinics be well-organized to coordinate such patients' care.[5] Finally, Penm et al. demonstrated that patients in the United States experience poor coordination twice as often as those in other high-income countries.[6] This situation has led many U.S. policy makers and care system leaders to emphasize the need for improved systems for care coordination, with a special focus on patients with complex needs and multi-morbidity.

## 1.2 Evidence Gaps in Care Coordination for High-cost/High-need Patients

An Agency for Healthcare Research and Quality (AHRQ)-sponsored review of 75 systematic reviews of care coordination concluded that coordination has resulted in health benefits for patients with heart failure, diabetes, severe mental illness, recent stroke, or depression.[7] However, it also found insufficient evidence to assess the impact of individual components of care coordination on effectiveness. Ovretveit's extensive systematic review found evidence that "most changes for better coordination improve quality and save resources," but that "it depends on which approach is used, how well it is implemented, and on features of the environment in which a provider is operating."[8] The AHRQ review found that there were over 40 distinct and extremely heterogeneous definitions of care coordination, so the authors combined the key elements of those definitions in a new one that has subsequently become widely used in its original formulation. They defined care coordination as "*the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of health care services. Organizing care involves the marshalling of personnel and other resources needed to carry out all required patient care activities, and is often managed by the exchange of information among participants responsible for different aspects of care*."

More recent systematic reviews and meta-analyses have not changed the conclusion that there is a large knowledge gap regarding not only how to best provide care coordination, but also the differential effect of various components of coordination and which other factors matter, including team roles and multiple levels (patient, care team, organization, and community).[9-17] This evidence gap regarding both the coordination models and the factors that contribute to coordination success makes it difficult for care systems, clinicians, and payors to know which components to implement and for patients to identify what type of services are most important. Teams participating in the Triple Aim Initiative of the Institute for Clinical Systems Improvement (ICSI) identified the need to match the needs of individuals to the coordinator skill sets of nurses versus social workers, but found that most people with multiple needs require both.[18]

## 1.3 How this study addresses evidence gaps

This study aims to learn which of two major approaches to care coordination currently being used by primary care clinics in Minnesota (MN)—i.e., with or without a social worker on the team—provides the best outcomes as well as what implemented components of those approaches and which contextual factors are most important for effectiveness. By addressing these critical evidence gaps, the findings will have a direct benefit to patients, because it will allow clinics and care systems to develop and implement care coordination strategies that improve patient care quality, reduce utilization burden, and improve patient-centered outcomes. This information will also enhance the interest of payors in reimbursing the costs of care coordination, as witnessed by their support of this proposal.

This study will also illuminate a related timely topic. Leaders of care systems, health plans, and government are increasingly realizing that health is often greatly affected by social needs (i.e., social determinants of health).[19] Katz et al. have shown that medical care is less effective for people who have large social needs, and the American College of Physicians has published a position paper on the need to better integrate them into the health care system.[20,21] As a secondary analysis of study aims, this project will assess whether addressing social needs through care coordination is effective and whether it reduces disparities.[22-25]

The COVID-19 pandemic has brought widespread and broadly documented disruptions to daily life in the United States and across the globe. The pandemic has also greatly disrupted health care, requiring us to modify the originally planned timing for identifying study subjects while providing an opportunity to study changes in the outcomes from these care models through separate cohorts drawn before and after the main impact period in 2020. It also provided an opportunity to learn how the care models and multi-morbidity complex patients have been affected by the pandemic.

## 1.4 Health Care Homes in Minnesota

In 2008, MN legislation established a mechanism to certify primary care clinics as patient-centered Health Care Homes (HCH) that includes an extensive application and inspection, both before certification and again every three years for recertification.[26,27] Five standards must be met for certification: access and communication, a searchable electronic registry, care planning, quality improvement, and care coordination, with specific requirements for each. HCH certification is administered and supported by the Minnesota Department of Health (MDH), a major partner in this study.

By 2021, 60% of the 653 primary care practices in the state (plus 20 clinics serving Minnesotans in bordering states) had been HCH certified, bringing the total certified clinics to 415 (397, excluding pediatric clinics). All have adopted one of two models for care coordination: one that uses medical/nursing personnel as care coordinators for primarily medical needs and another that adds a social worker to address social needs more completely. In both cases, these coordination services are focused primarily on high-cost/high-needs patients, usually with multiple morbidities, and there is an extra clinic payment available from the state for patients with high complexity and state-covered insurance. This situation provides an ideal natural experiment for comparing the structure, process, and outcome differences between these two different approaches to care coordination.

# 2 Study Aims and Outcomes

## 2.1 Study Aims

This protocol describes a comparative effectiveness observational study of two existing models of care coordination for high-cost/high-need patients among primary care clinics in MN. Due to the COVID-19 pandemic, there was substantial disruption in care during 2020 that required delaying the identification of a primary cohort for approximately one year. There is also substantial interest in understanding how approaches to care coordination compare before and after the emergence of the pandemic. Therefore, we plan to address the following specific aims separately for patient groups who experienced care coordination before (Historical cohort) and after (Primary Cohort) the worst of the disruptions:

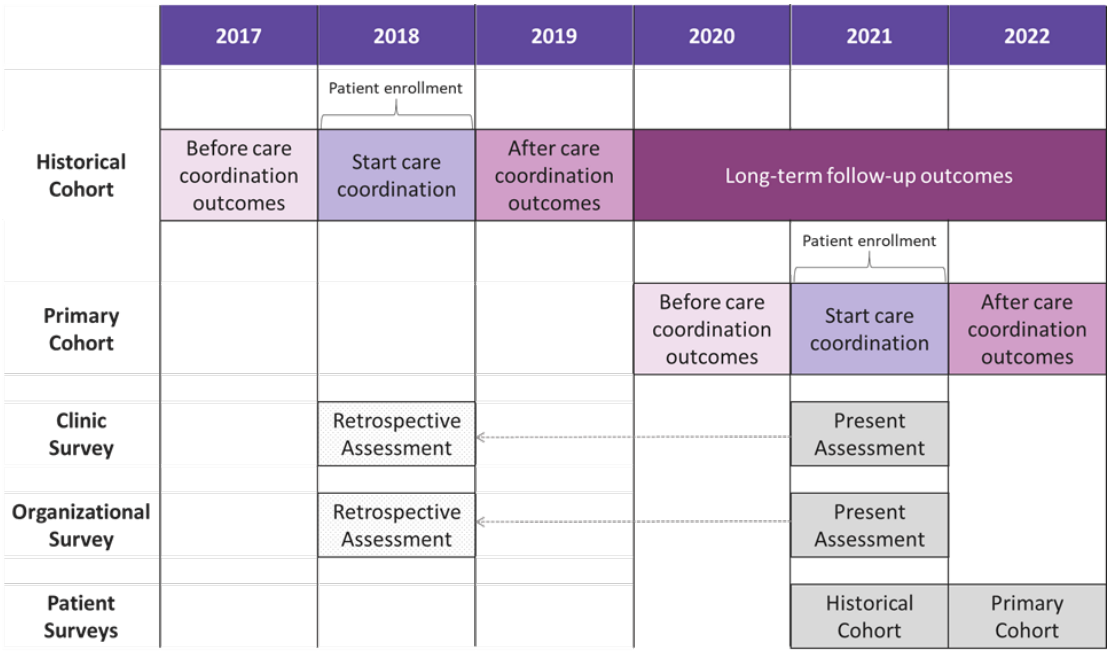
**Aim 1.** To compare the healthcare quality, utilization, and patient-centered outcomes for high-cost/high-need adult patients who receive care coordination services from clinics that use a "nursing/medical" model versus a "medical/social" model that includes a social worker on the care coordination team.

**Aim 2.** To identify the key components (e.g., personnel, content, dose, modality) of the two models and quantify their association with the above outcomes.

**Aim 3.** To explore how organizational, community, care process, and patient factors (including social determinants of health) help explain differences in the models and outcomes.

In addition to these overall specific aims, the study plans to address secondary objectives of the comparative effectiveness in the Historical Cohort over up to an additional 3 years and to investigate how the COVID-19 pandemic may have disrupted care, health, and wellbeing for those patients. **Figure 1** illustrates the timing of the two cohorts and associated survey data collection.

**Figure 1: Timing of Patient Cohort and Survey Data Collection Efforts**



## 2.2 Study Comparators (SC-1)

In its original certification process and its periodic recertification of clinics as Health Care Homes (HCH), MDH conducts both a written and a site visit-based evaluation to verify that every HCH clinic has implemented required standards or has obtained a variance if a particular subpart is not possible at that time. The relevant MDH standards (MN Administrative Rule #4764.0040) require that a HCH must address each of the following subparts related to care coordination:

- 1A Systematically screens patients to identify those who would benefit from care coordination
- 5A Collaboratively develops patient-centered goals, identifies resources to achieve goals, ensures consistency and continuity of care, including frequency of follow-up.
- 5B Designates one clinician for each patient and one care coordinator as the primary contact
- 5C Ensures that the clinician and care coordinator communicate with each other directly
- 5D Ensures the care coordinator has dedicated time to perform coordination responsibilities
- 6B Identifies and works with community-based organizations to facilitate the availability of appropriate resources for patients
- Establishes and implements policies and procedures that guide who would most benefit from a care plan and develops the plan for identified individuals in a way that engages patient and team, incorporates risk assessment, is updated, and is provided to the patient

It is from this information that we have developed definitions of the two care model comparators and have initially determined which model of care coordination is being used in each clinic and care system as well as estimating the extent to which there is change in models over time (Table 2). The two care models are:

| | |
|---|---|
| **Nursing/medical model** | Someone with medical/nursing training coordinates involvement of various medical resources and provides patients with education, self-management support, and referrals to community resources. |
| **Medical/social model** | In addition to the above services, a social worker by education has dedicated FTE as a member of the care team at the clinic, providing some direct services for care coordination patients and either spending some time on-site or in regular communication with its clinicians in addition to providing social work services. |

**Table 1** summarizes the core components that comprise each model of care coordination. MDH has descriptive data to support initial assignment of each adult HCH-certified clinic to one of the two comparator models for delivery of care coordination (total n=397, see **Table 2**). Adoption of these two approaches to care coordination is reasonably equal across types of care delivery environments and geographically throughout the state. Specific details about the coordination components at each clinic will be collected through patient and care coordinator interviews and surveys.

**Table 1: Core Components in each Care Coordination Model**

| Nursing/Medical Model | Medical/Social Model |
|---|---|
| No social worker on the clinic's care coordination team | Social worker is part of the clinic's care coordination team:<br>• Need not be licensed as a social worker<br>• Must have time dedicated to care coordination for a specific clinic or clinics<br>• Must interact with individual patients to provide them with services<br>• Must interact with individual clinicians about their individual patients in care coordination |
| Provide coordinated medical care for patients | Provide coordinated medical care for patients |
| Provide patient education | Provide patient education |
| Assist in developing care plan | Assist in developing care plan |
| Provide support for patient self-management | Provide support for patient self-management |
| Provide referrals for continuing care | Assist with referrals for continuing care |
| Refer patients to community resources | Provide assessment and plan to address social and resource needs including housing, transportation or financial needs; Assist patient in locating and obtaining needed community resources |
| Provide referral to mental health services if needed or requested | Assist with identifying and addressing psychological/emotional issues and referrals as needed |
| Provide referral to interventional counseling for behavioral health issues | Provide or refer to interventional counseling for behavioral health issues depending on licensure |

Note: Shaded components are common between care coordination models.

**Table 2: Prevalence of Comparators in MN Adult Clinics**

| Clinic type | Nursing/Medical | Medical/Social |
|---|---|---|
| Critical access hospital | 19 | 3 |
| Federally-qualified health center | 15 | 14 |
| Hospital-based | 6 | 2 |
| Independent medical group | 29 | 13 |
| Integrated delivery system | 137 | 141 |
| Other | 13 | 5 |
| **Grand Total** | **219** | **178** |

### 2.2.1 Measuring Fidelity and Model Components

In order to answer the main research question in Aim 1, it is crucial to have accurate knowledge about the type of care model present in each study clinic at the time the Primary Cohort began care coordination. It is also important to know how that model has changed since 2018 when the Historical Cohort was beginning to receive care coordination, during the pandemic in 2020, and whether any changes are planned during the post-coordination year for the Primary Cohort. Therefore, we will employ the three strategies in **Table 3** to ascertain and confirm both the overall model used, and the core functions/components of care coordination delivery at each clinic throughout this time. These data will allow us to characterize both fidelity to the overall model and the specific ways in which there is variation within and between both models at the level of individual clinics. Timing of the patient cohorts and data collection efforts is illustrated in **Figure 1**.

**Table 3: Strategies for Measuring and Accounting for Fidelity to Each Care Coordination Model**

| Strategy | Description | Sample Size | Expected Response Rate | Timeframe |
|---|---|---|---|---|
| 1 | Care Coordinator Survey | ~300-400 | 100% (required) | Q1 2022 |
| 2 | Organizational Survey | ~50-70 | 100% (required) | Q3 2021 |
| 3 | Primary Cohort Patient Survey | ~7,000 (~20/clinic) | 60% | Q3 2022 |

The primary strategy will involve requiring the lead care coordinator at each participating clinic to complete a survey that asks about each core component. This survey will be conducted in the fall of 2021, at a time when the clinics will have renormalized as COVID-19 pressures have declined. This timing will align with the Primary Cohort identification period (1/21-12/21), so it will provide a very specific verification of implementation models during the time the Primary cohort was being enrolled and receiving services. The response rate for this survey will be 100% because completing the survey is a requirement of participation in the study, which we have communicated to clinics throughout our recruitment process. We shall also ask the lead care coordinators whether any of these core components have changed in any significant way during the preceding 3 years (with a focus on 2018 to correspond with the Historical cohort) and whether they are expected to change in the next year. These surveys will be preceded by semi-structured interviews with about 20 care coordinators for the purpose of identifying every potentially important component of care coordination needed to be included in the survey. The study team will design the care coordination survey to measure these components, using existing and validated assessment tools wherever possible. We will draw upon measurement tools and definitions identified or endorsed by the Agency for Healthcare Research Quality (AHRQ) and National Quality Forum (NQF).[28-32] We will also rely on the expertise of our external consultants Kathryn McDonald (lead author of the 2014 update of the AHRQ Care Coordination Measures Atlas[28]) and Sarah Scholle (Vice President for Research & Analysis, National Committee for Quality Assurance) to translate existing measures and develop supplemental measures as needed.

The second strategy for measuring fidelity to each care coordination is to supplement our understanding of care coordination delivery at each clinic through surveys at the overall organizational level in the fall of 2021. Although the care coordinator survey will be the primary source of the specifics of care coordination, we will ask organizational leaders a broader set of questions to better understand the context, intent, resource support, and overarching design of care coordination within which each clinic system implements its modifications and refinements. A clear and detailed understanding of these

factors will be fundamental to our Aim 3 analysis, but where overlap in data collection exists, it will help to clarify aspects of our Aim 1 and Aim 2 analyses as well. These surveys will also provide insight into the effect of COVID on coordination policies and processes as well as any plans for changes in the coordination approach through the end of our study.

The third strategy is a survey of care coordination patients from our primary cohort. This will occur in the fall of 2022 and will be incorporated in our planned second patient survey. The primary goal of the patient surveys is to obtain patient-reported outcome measures for our comparative analyses. A secondary goal, applicable mainly to the primary cohort, will be to ask patients how they experienced the various components of care coordination, which we can then compare with the designated care coordination model. In cases where we see a pattern of divergence in accounting for fidelity, we will follow-up with clinic staff to further clarify these details. In this way, patient-level interactions will provide additional insight into care coordination model fidelity. Patient surveys will not be used this purpose for the Historical cohort due to the difficulty in patients recalling events or situations that occurred years ago. Instead, that survey will focus mainly on understanding COVID-19 impacts on these multi-morbidity patients' health and healthcare.

## 2.3 Study Outcomes

This study will evaluate comparative effectiveness measured across three outcome domains. The primary outcomes are identified by an asterisk:

| | |
|---|---|
| **Patient Care Quality** | Control of blood pressure, cardiovascular disease, diabetes, asthma, and depression and cancer screening (from standardized state-wide quality measures) as well as a composite measure* of overall quality comprised of the percentage of all care quality outcomes for which a patient qualifies and meets quality criteria |
| **Patient Healthcare Utilization** | Rates of urgent care, emergency department visits*, and hospitalizations*, as well as primary care and specialty visits, and substance use programs (from claims data) as primary care and specialty visits, and substance use programs (from claims data) |
| **Patient-Reported Outcomes** | Health status*, satisfaction with care*, clinician, access, and coordination, care integration, shared decision making, medication and care burden, change in insurance coverage, going without care due to cost or COVID-related problems, out-of-pocket medical costs, and changes in social needs (from patient surveys) |

Please see **Table 5** in Section 7 (Analysis Plan) for detailed outcome definitions.

# 3 Study Design

This is an observational mixed-methods comparative effectiveness study of a natural experiment in which clinics have chosen one of two models of care coordination for their own reasons in order to comply with requirements for state certification as a medical home. We will also address the related important questions raised by our stakeholder partners about what specific components of coordination and the local context are important and for which patients and needs coordination is most helpful. We will combine patient survey data (post only) with claims and quality measures (pre/post) and clinic coordination information to evaluate study outcomes. We will also use interviews of patients and health care professionals to develop study instruments and to increase understanding and validation of outcomes.

## 3.1 Conceptual Framework

This study is utilizing a Care Coordination Measurement Framework, developed by McDonald et al. in the 2014 update of the Care Coordination Measures Atlas for the AHRQ (Figure 2).[28] This framework was developed in order to have a way to organize measures of care coordination.[28,33] McDonald et al. also developed a validated patient survey (the Care Coordination Quality Measure for Primary Care or CCQM-PC) to measure domains used in this study (e.g., facilitate transitions, assess needs and goals, support self-management),[34] and have also linked the framework with a broad quality assessment approach created by Donabedian to categorize quality factors into Structure, Process, and Outcome,[28,35,36] as well as the Wagner Chronic Care Model.[7] We will utilize the Care Coordination Measurement Framework for organizing process characteristics of each clinic's coordination approach. As a consultant to this project, Dr. McDonald will be an invaluable help in applying it.

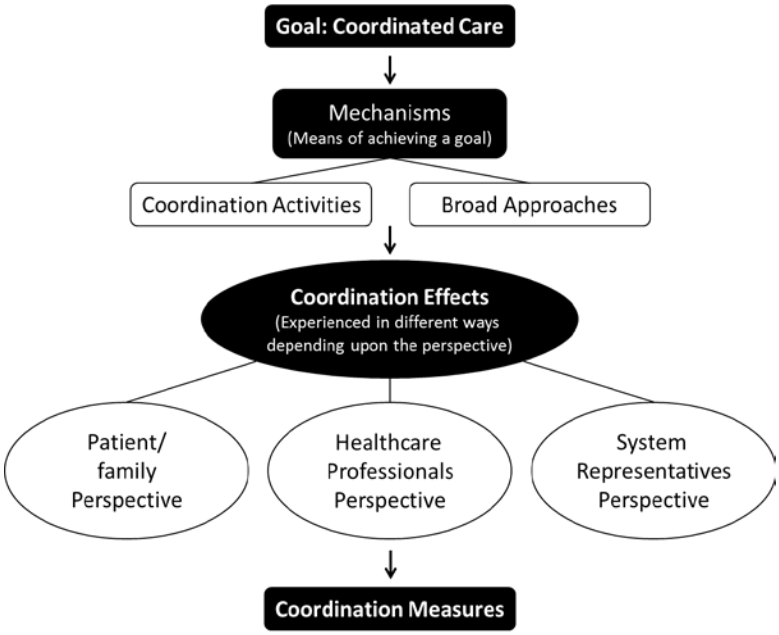



**Figure 2: Care Coordination Measurement Framework**

Construct definitions in the Care Coordination Measurement Framework[28]

| | |
|---|---|
| **Coordination Activities** | Actions that help achieve coordination, such as assessing needs and goals, facilitating transitions, or support self-management goals |
| **Broad Approaches** | Actions aimed at improving or facilitating coordination by building teamwork focused on coordination or health IT-enabled support for coordination |
| **Coordination Effects** | The effects of care coordination on outcomes, which will be perceived differently depending on who is asked and thus should be measured among the three represented groups |

### 3.2 How and why the study sites were selected

Because care coordination is a requirement for HCH certification and because the study is conducted on behalf of the MDH HCH program, we will include all HCH-certified clinics in MN meeting inclusion criteria in the study (see Section 4.2.1). Few uncertified clinics in MN have care coordination systems, and data from another study comparing certified and uncertified clinics in MN demonstrate similarity between the two groups.[37]

# 4 Study Population and Recruitment

## 4.1 Setting

The primary study population includes all adult patients who began receiving care coordination services during 2018 (Historical Cohort) or 2021 (Primary Cohort) and have not opted out of research from participating HCH-certified primary care clinics in MN and bordering areas of Wisconsin, Iowa, and the Dakotas that also submit data to MN Community Measurement (MNCM). Health care professionals from participating clinics, including clinicians, care coordinators, and clinical leaders, will also be included as study subjects for some data collection.

We do not expect that patients selected for care coordination will be representative of all patients at these clinics. They are receiving those services because they have complex multi-morbidities and are much more likely to have both high costs and high medical and social needs.

## 4.2 Inclusion Criteria

### 4.2.1 Clinics

- Adult primary care clinic, HCH-certified by MDH
- At least 10 adult patients/clinic currently in care coordination
- Agreement by clinic or medical group leader to participate and to complete the following study activities:
    - Attestation confirming agreement to participation requirements and compliance with HCH requirements in lieu of the next recertification
    - Signed modification of the data use agreement (DUA) with MNCM for data transmission and use
    - Completion of contact information for care system staff during the study
    - Completion of an initial organizational questionnaire describing the medical group and its primary care clinics and its approach to care coordination
    - Completion of a care coordination survey by the lead care coordinator or designated alternate for each participating clinic
    - Co-signature on a letter to their patients inviting them to complete a survey about their care coordination experience
    - Cooperation with arrangements for qualitative interviews with a small sample of care coordinators, clinicians, clinic leaders, and patients at two time points
    - Submission of specified data elements for all eligible adult (age 18+) patients receiving care coordination services at two time points

### 4.2.2 Patients

- Age 18 or older
- Historical Cohort: Receiving care coordination services in a participating clinic with a care coordination start date between January 2018 and February 2019
- Primary Cohort: Receiving care coordination services in a participating clinic with a care coordination start date between January 2021 and December 2021
- Currently insured by the MN Department of Human Services (DHS), Blue Cross Blue Shield MN (BCBS), UCare, or HealthPartners (HP) (for utilization outcomes only)
- Consents to participate in interview or responds to a survey (for those data collection events only)

### 4.2.3 HCH Clinic staff

- Primary care clinicians, clinic or system leader, and lead care coordinator in participating HCH clinics
- Consent to participate in interview and/or survey

## 4.3 Exclusion Criteria

### 4.3.1 Clinics

- Pediatric HCH clinics
- Clinics with fewer than 10 adult care coordination patients
- HCH-certified clinics with no active care coordination program (unless temporarily due to COVID-19)

### 4.3.2 Patients

- Cannot complete an interview in English (interviews only)
- Cannot complete a survey in English, Spanish, Somali, or Hmong (for interviews only, reflecting most prevalent languages in MN)
- On a known research exclusion list

## 4.4 Recruitment and Retention Strategies

### 4.4.1 Clinics

Clinic recruitment will be done at the level of the health care system to which each clinic belongs, with a goal of enrolling as many of the state's HCH clinics as possible and keeping them engaged over the course of the study. Dr. Leif Solberg will recruit large medical groups (with 10 or more clinics) and MDH HCH Program staff will recruit smaller groups (fewer than 10 clinics).

Clinic recruitment will follow these steps:

1. First, MNCM and the MDH HCH Program will distribute study information and publicity to the health care organizations and clinics they work with about the project and its benefits through their usual communication channels.

2. Then a letter will be emailed to a leader of each of the 70 potentially eligible independent health care organizations along with a study description that includes participation requirements and benefits and a promise of a follow-up phone call soon. The requirements are listed above in Section 4.2. Benefits include elimination of the need for the next recertification, possible coverage of some costs of data submission, opportunities for input about the study, and timely reports and feedback about study lessons and how their clinics compare with others. A copy of the e-mail will be sent to the contact for the HCH programs and to a lead administrator.

3. Follow-up calls will be made to the leader receiving the letter by either Dr. Solberg or by staff at the MDH HCH program (depending on system size) who are familiar with those organizations. At the follow-up call, the leader will have the opportunity to get questions answered and will either confirm a commitment to participate or will establish a date for that determination to be made. Health care organizational leaders in MN can commit all their owned clinics to such projects and we have found that their clinic leaders subsequently cooperate well.

4. Once the organizational leadership has agreed to participate, they will identify a liaison who will arrange for completion of an organizational survey, identify a contact for modification of the DUA they already have with MNCM for data submission, and sign an attestation to the HCH Program that they will comply with certification standards in exchange for not having to undergo the next recertification process. The liaison will serve as the main ongoing contact for subsequent study communications or data collection needs. The organizational leadership will also confirm the specific clinics that will participate in the study and estimate the total number of patients currently receiving care coordination services at those clinics.

A detailed database and tracking system will provide documentation of recruitment status and reminders for every eligible organization in order to provide recruitment reports to study personnel and PCORI.

### 4.4.2 Patients

Patients will be recruited individually for qualitative interviews, but their participation in surveys will depend on whether they fit the criteria for inclusion in the Historical or Primary Cohorts and then whether they choose to respond with a completed survey.

#### 4.4.2.1 Patient Interview Sampling and Recruitment (Phase 1 and 2)

Patient interviews will occur in three rounds over two phases: once each for the Historical Cohort and Primary Cohort (Phase 1), and a third round among Primary Cohort patient survey respondents who

have agreed to have an additional interview to discuss study findings (Phase 2). Each interview round is a separate one-time event that will involve approximately 20 patients. For the Phase 1 patient interviews, MDH staff will work with care coordinators from 6-10 randomly selected clinics based on the stratification criteria below to identify and invite patients to participate in interviews:

1. Clinic care coordination model (medical/social vs. nursing/medical)
2. Clinic geography (urban or rural based on US Census Bureau RUCA standards)
3. Health system size (<10 clinics or 10 or more)

Selection and recruitment of interview candidates will follow a convenience-sampling strategy in order increase the likelihood of participation and of obtaining diverse input. MDH staff will work with care coordinators in each selected clinic to identify and recruit their care coordination patients who they believe would provide diverse experiences and perspectives for study interviews. MDH will ask care coordinators in selected clinics to ask a few patients to contact the interview administrator with the Center for Evaluation and Survey Research (CESR) if they are willing to be interviewed. Care coordinators will be provided with an information sheet to share with selected patients with information about the interview, contact details, and frequently asked questions. When interested patients contact CESR, professional telephone interviewers will ask a few brief screening questions and conduct the interview at that time or schedule the interview appointment at a time that works better for the patient.

For the Phase 2 patient interviews, only Primary Cohort patients responding “yes” to a survey question indicating willingness to participate in a future interview will be invited. CESR will initiate outreach to a subset (depending on the number indicating interest) of these select individuals to conduct interviews.

Recruitment will continue until the study team reaches the desired N in each strata for each interview round.

#### 4.4.2.2 Patient Survey Sampling and Recruitment (Historical and Primary Cohorts)

Patient surveys will be conducted once for each of the Historical and Primary patient cohorts. A total of 3,000 patients in the Historical Cohort and 7,000 patients in the Primary cohort will be sent surveys, with an expected response rate of 60% (yielding approximately 1,800 and 4,200 responses respectively).

Survey recipients will be selected randomly. Clinics contributing small numbers of patients may be oversampled to ensure adequate representation. MNCM will provide CESR with the name, contact information, and home clinic of the sampled patient list through a secure data transfer for each cohort.

CESR will manage patient survey recruitment and data collection. CESR will mail the survey invitation to patients with a $2 non-contingent token incentive. A web survey link and personalized PIN will be sent with a cover letter co-signed by the patient’s home clinic as well as the study PIs. Initial non-responders will be called by CESR staff at various times of the day and days of the week to maximize the probability of successful contact and survey completion. Patients completing the survey will receive a $10 gift card as a thank you for their time. Recruitment will continue until the contact protocol specified in Section 5.4.4 has been exhausted.

### 4.4.3 Clinic Staff

Clinic staff (care coordinators, clinicians, and leaders) will be recruited individually for qualitative interview and survey data collection. Because of the pre-existing relationship between MDH and each clinic, MDH is a key partner in recruiting clinic staff for data collection.

#### 4.4.3.1 Care Coordinator Interview Sampling and Recruitment

Care coordinator interviews will occur in two phases, each as a separate one-time event. For Phase 1 interviews, MDH staff will identify and recruit approximately 20 lead care coordinators from selected clinics for qualitative interviews based on the same stratified clinic-based sampling criteria described in Section 4.4.2 above for patients. MDH staff will provide a brief description of the study and interview opportunity to care coordinators with instructions to contact CESR to schedule the interview. MDH will also provide coordinators' contact information to CESR as needed to complete the recruitment process (name, phone, email and clinic information). For Phase 2 interviews, the study team will first recruit from the pool of first round care coordinator interview respondents and follow the process above to identify additional care coordinators. Recruitment will continue until the study team reaches the desired N in each strata for each interview round.

#### 4.4.3.2 Care Coordinator Survey Recruitment

Care coordinator surveys will be collected at one time point with the lead care coordinator from each participating clinic. MDH will facilitate the care coordinator survey recruitment from the smaller organizations they recruited and HPI staff will work with the study liaisons in the large groups they recruited to complete this task. Once the appropriate care coordinators have been identified, MDH or HPI staff will e-mail the electronic survey link to each lead care coordinator to complete. Non-responders will receive follow-up by HPI or MDH staff via email or phone as needed until survey completion. Recruitment will continue until all surveys are complete.

#### 4.4.3.3 Clinician and Leader Interview Recruitment

Clinician and leader interviews will also occur in two phases, each as a separate one-time event. For Phase 1 interviews, MDH and HPI staff will use the same stratified sampling approach described in Section 4.4.2 for patient interview selection to identify organizations or clinics and then work with leaders to recruit clinicians or leaders from selected clinics for qualitative interviews. MDH staff will provide a brief description of the study and interview opportunity to organizational or clinic leaders who will then identify clinicians or leaders to be recruited for interviews. For Phase 2 interviews, the study team will first recruit from the pool of first round clinician or leader interview respondents and follow the process above to identify additional clinicians and leaders, only if needed. Recruitment will continue until the sample reaches the desired N in each strata for each interview round.

## 4.5 Clinic Participant Withdrawal

### 4.5.1 Reasons for Participant Withdrawal

A clinic will only be considered to be participating once its organizational leaders have agreed and contact information have been provided for the group and each clinic. After that, any inability to provide the items identified under Section 4.2.1 will be grounds for the study to assume clinic participant withdrawal, which can be done at any time for any reason. Patients and clinic staff may withdraw from survey and interview participation at any time.

### 4.5.2 Handling of Participant Withdrawals

Clinic withdrawals will be documented in a tracking database and reported to PCORI and study personnel in a timely way. However, if patient data has already been submitted to MNCM and we have other necessary contextual information, we may continue to include their data in subsequent analyses. Historically, only a few health care organizations per year have discontinued HCH certification, which is tracked by MDH, so that is unlikely to cause much loss of data. Patient and clinical personnel withdrawal from surveys or interviews will be tracked by CESR and individuals will not receive further contact for the purpose of data collection after withdrawal.

### 4.5.3 Premature Termination or Suspension of Study

Because this is an observational study without an intervention, there is no reason to anticipate termination or suspension related to safety or efficacy. The study may be terminated or suspended in the event of a serious data or privacy breach, or if the sponsor determines the study is not meeting contractual obligations.

# 5 Data Collection Procedures

## 5.1 Care Quality, Utilization, and Patient Reported Outcomes

As described in detail in Section 7.1, this study involves three categories of outcomes: care quality, healthcare utilization, and patient-centered/reported outcomes. **Figure 3** shows how the collection of these data will be managed through a multi-step process with MNCM acting as a data coordinator.

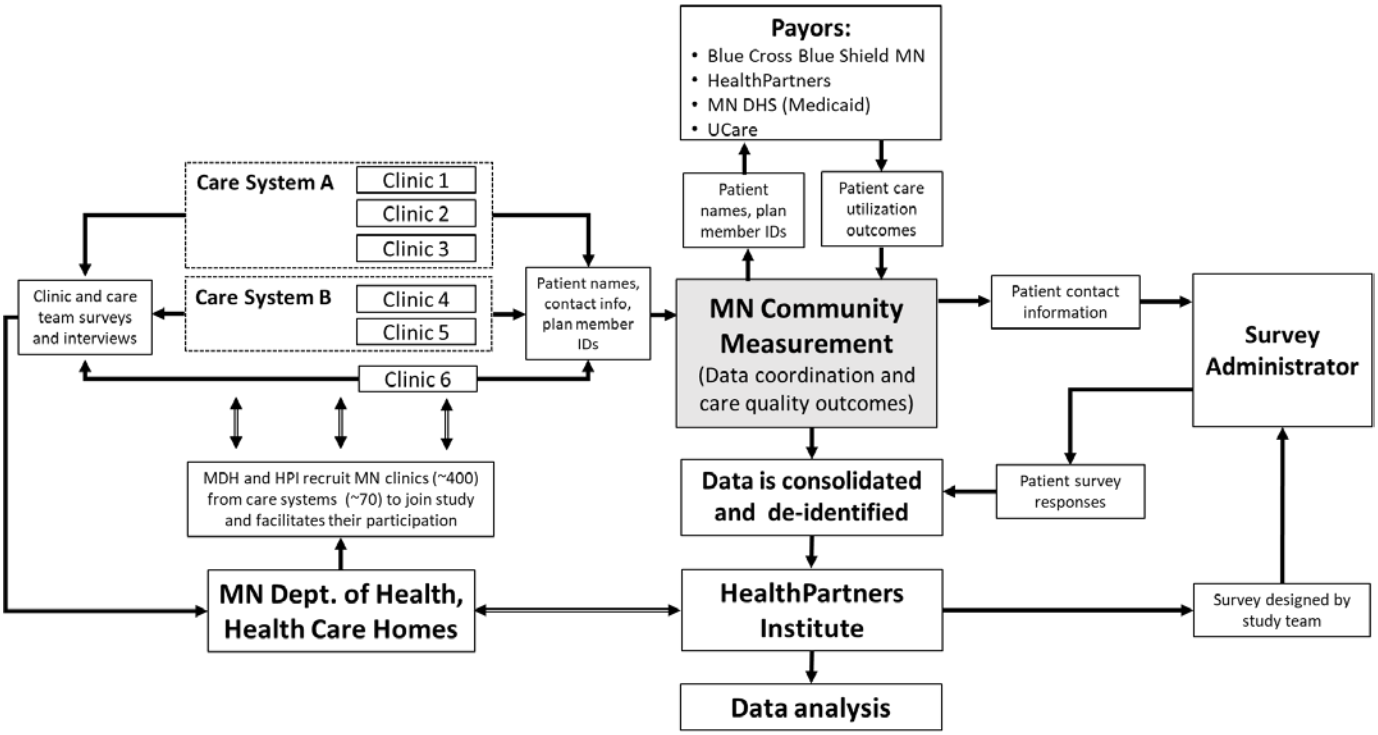



**Figure 3: Outcome Data Collection and Management**

### 5.1.1 Identification of Primary and Historical patient cohorts

Care quality, utilization, and patient-reported outcomes will be collected on both the Historical and Primary cohort patients identified by participating clinics in their submissions directly to MNCM. Clinics will identify their Historical and Primary cohorts of care coordination patients and submit their name, date of birth, demographics, date of starting coordination, contact information, and insurance information through a secure data submission portal directly to MNCM. See Appendix A for complete specifications of data to be submitted by clinics to MNCM.

Clinic data submission will occur in two rounds, one for the Historical Cohort (care coordination enrollment dates from January 2018-February 2019) and one for the Primary Cohort (care coordination enrollment dates January 2021-December 2021). MNCM will assign a unique study ID to each patient in these datasets, which will be used as a linkage to the quality, utilization, and patient-reported datasets described below while providing confidentiality.

### 5.1.2 Care Quality Outcomes data collection

Because MNCM routinely collects standardized data from participating clinics for calculating care quality measures and statewide public reporting, MNCM will have care quality data in their possession on patients in both cohorts who met criteria for inclusion in the clinical quality measures. MNCM will collate applicable person-level quality measures for 2017-2019 (Historical Cohort) and 2019-2021 (Primary Cohort). Measurement data and study ID will be provided to HPI by MNCM in a final de-identified dataset for each patient cohort. See Appendix B for a complete list of quality measures to be

included.

### 5.1.3 Utilization Outcomes data collection

For patients who are plan members of a participating payor, MNCM will provide the minimum necessary patient identifying information to each respective payor in order to facilitate collection of utilization outcomes data. First, payors will verify insurance coverage through a multi-step process with MNCM so that all patients are matched to either the correct commercial payor or to MN DHS if on a Medicaid or state-sponsored plan. Then, payors will collect specified utilization data from their claims databases and return data to MNCM after the necessary follow-up time has accrued. Utilization data and studyID will be provided to HPI by MNCM in a final de-identified dataset for each patient cohort. See Appendix C for complete specifications of data to be provided by payor partners to MNCM.

### 5.1.4 Patient Reported Outcomes data collection

MNCM will provide the study ID and minimum necessary patient identifying information to CESR in order to facilitate collection of patient reported outcomes in a sub-set of both cohorts as described in Section 4.4.2.2. Survey data and study ID will be provided to HPI by CESR in a final de-identified dataset for each patient cohort. See Section 5.4 for details on patient survey data collection.

## 5.2 Organizational Survey

The purpose of the organizational survey is to describe the organizations and clinics participating in this study, each organization's approach to care coordination, and any past or future changes in care coordination model or characteristics resulting from the impact of COVID and other disruptions. Each participating organization will submit one organizational survey and one clinic-level data form.

### 5.2.1 Organizational Survey content and design

The survey and accompanying clinic-level data form include questions designed to describe each organization and each of its certified clinics as well as their current general approach to care coordination and any changes during the COVID-19 crisis as well as changes since 2018 and any planned changes in the next year. This survey is the source of important contextual and independent variable information for all three specific aims. The content of the survey will be developed by a survey workgroup and is planned to include:

- Ownership and number of primary care sites in the care system/group
- Description of the number and type of clinicians and other staff at each clinic
- Care coordination goals and structure, current, previous, and planned
- Number of care coordinators across the organization
- Financial coverage and billing policies for coordination
- Impact of COVID-19 on care coordination and plans for future changes
- Patient characteristics (age, sex, race/ethnicity, language, insurance types) at each clinic
- Number of care coordination patients at each clinic
- Anticipated barriers to data submission
- Perceived barriers, facilitators, and benefits to providing care coordination

The survey and accompanying form will be piloted with select respondents from the sample pool or proxies with similar experience to ensure performance of the instrument.

### 5.2.2 Organizational Survey respondent sampling and recruitment

Each participating organization will be asked to complete a single survey and data collection form. In most cases, this will be completed by an administrative leader and staff at the care system level. During clinic recruitment, an organizational liaison is identified. This person will assist in identifying the appropriate responder for each the survey and form from each organization.

### 5.2.3 Organizational survey implementation

The organizational survey will be a web-based survey built in REDCap. The link to complete the survey will be sent via email to the designated respondent. Certain clinic-level questions soliciting data elements for each clinic will be structured in an accompanying data collection form such that the primary respondent can hand-off those to an analyst or someone else better positioned to complete that level of detail. Initial non-responders will be sent email reminders and/or telephone calls until an organizational survey and form are completed for each participating organization.

## 5.3 Semi-Structured Interviews

In order to fully understand care coordination practices and the experience and perspectives of patients, lead care coordinators, and clinicians/leaders, we will conduct semi-structured qualitative interviews with each of these groups. In Phase 1, these interviews will be used to be sure that we are not missing any important topics in the development of the care coordinator and patient surveys. In order to ensure that the patient interviews and surveys capture information important to patients, patient co-investigators will be involved in their development and analysis. In Phase 2 near the end of the project, interviews with patients, coordinators, clinicians, and leaders will instead seek to learn their reactions to our preliminary findings and recommendations and to help us identify the findings and messages of most interest for dissemination, as well as informing how the data will be used to strengthen study findings.

### 5.3.1 General semi-structured interview methods

For each interview time point (Phase 1 and 2) and for each population (Historical and Primary patient cohorts, lead care coordinators, clinicians, leaders) the following standardized approach will be used, except where specified in the more detailed sections below.

#### 5.3.1.1 Instrument design

Semi-structured interview guides will be developed based on prior research, literature, and experience. Interview guides will begin with rapport-building, transitioning to the primary areas of interest and focus, and ending with cool-down questions. Structured probes will be developed for correctness, clarity, and completeness of participant responses, avoiding bias and using neutral comments to

facilitate the interview process and encourage depth in participant responses. Interviews will be designed to take between 20 and 45 minutes.

#### 5.3.1.2 Pilot testing

All interview guides will be pilot-tested with 3-5 participant interviews sampled from the target population or proxies (i.e. patient co-investigators) with similar experiences. Interview guides will be refined before implementing with the study sample.

#### 5.3.1.3 Interview collection process

Trained, experienced qualitative interviewers will conduct the interviews via phone. Interviewees will be given a brief description of the study and purpose of the interviews, given the opportunity to ask questions about the interviews, and asked for verbal consent for the interview and audio-recording. Audio recordings will be sent to an external company for professional transcription. Consent, field notes, and interview completion status will be tracked for each round of interviews electronically, either in REDCap or another tracking system.

#### 5.3.1.4 Incentives for participation

After completion of the interviews, Historical and Primary cohort patient interview participants will be mailed a $35 gift card as a thank you for their time and effort involved in their participation. Care system personnel will not receive any incentive, because this is part of the participant organization expectation and will involve very few people at any single organization.

#### 5.3.1.5 Historical Cohort Patient Interviews (Phase 1)

In contrast to the Primary Cohort patient interviews described below, the Historical Cohort patient interviews will occur so long after they began care coordination (3-4 years) that they will not be able to reliably report on specific interactions and experiences from that time. Thus, these interviews will be designed to document instead how patients with multiple-chronic conditions were affected by the care and life disruptions caused by the COVID-19 pandemic, its impacts on their health, social needs, health care, and social services. This will provide an opportunity to identify any disparities in care or outcomes among those of minority race and ethnicity or those in various age, insurance type, socioeconomic factors, or medical condition subgroups.

Interviews will ask open-ended questions about topics such as:

- Impact of COVID on patients' lives – work, family, financial status, social connections, other social determinants
- Impact on their health (physical and mental) and health care (How have the experienced changes in life, care, etc. during COVID? How did they do with COVID?)
- Did the care coordination they received make them better able to cope with COVID stressors?
- If space, were they able to connect with pre-COVID services during COVID? What services from their clinic would they have liked during this time?
- What barriers they encountered in meeting their medical, mental, social, and physical needs
- What other services would have been important or helpful

#### 5.3.1.6 Primary Cohort Patient Interviews (Phase 1)

Phase 1 Interviews with primary cohort patients are intended to: (1) better understand patient perspectives about, and experiences with, care coordination, (2) identify the services respondents have received and might wish to receive, (3) learn whether the study's proposed patient reported outcomes are understandable and relevant, and (4) document respondent characteristics and needs.

Interviews will ask open-ended questions about topics such as:

- Their experience with care coordination
- What particular needs they had and how well were they are met
- Whether there are other services they would have liked to receive
- What barriers they encountered in trying to use coordination services
- Whether other family members or caregivers were involved or should have been
- What outcomes from care were most important to them

#### 5.3.1.7 Lead Care Coordinator Interviews (Phase 1)

Phase 1 Interviews with care coordinators are intended to: (1) identify factors important in specifying care coordination models, (2) identify changes that have happened in care coordination following disruptions from COVID-19, (3) identify clinic-specific factors affecting care coordination, including barriers and facilitators to use of care coordination, and (4) to obtain care coordinator perspectives on the most important components and processes of care coordination. This information will be used to develop the survey of lead care coordinators (see Section 5.5) that are key to addressing study aims.

Interviews will ask open-ended questions about topics such as:

- The personnel types and workflows involved in care coordination at their clinic
- What they think are the strategies and resources most important for successful care coordination
- The types of patients enrolled and how that process is conducted
- The information routinely collected about patients and services and how that is accessible
- The most common services provided and by whom they are provided
- The social services provided and how they are provided
- How patient follow-up is conducted and monitored
- The main barriers to their work
- What is needed to facilitate their work
- Retention and turnover issues for care coordinators at their clinic

#### 5.3.1.8 Clinician and Clinic Leader Interviews (Phase 1)

Phase 1 Clinician and leader interviews are intended to: (1) elicit opinions, perspectives, and experiences with care coordination that should be included in the care coordinator survey and (2) identify the most important barriers and facilitators of effective care coordination

Interviews will ask open-ended questions about topics such as:

- Their personal experience with referring patients to care coordination and their ongoing role with patients receiving care coordination.
- How they have been engaged and communicated with by the care coordinators

- How important care coordination has been for their patients and how satisfied they have been with the results and the way it is being done
- The most important features to a successful care coordination program
- The main barriers to successful care coordination
- How they would change the care coordination process if they could

#### 5.3.1.9 Patient Interviews (Phase 2)

Phase 2 interviews with patients are intended to: (1) obtain patient perceptions of the quantitative findings of the study, and (2) elicit suggestions and recommendations from patients regarding dissemination of study findings to patients more broadly, and (3) elicit their suggestions for improvements to the care coordination process.

The interviews will ask open-ended questions to understand opinions about:

- Their perception of the findings and whether there are any unexpected results
- Their recommendations to make care coordination more effective and responsive
- How to best disseminate findings to other patients more broadly

#### 5.3.1.10 Care Coordinator Interviews (Phase 2)

Phase 2 interviews with care coordinators are intended to (1) obtain their perspectives on the study's quantitative findings and recommendations, and, (2) elicit their suggestions for improvements and for dissemination and implementation of study findings.

Interviews will ask open-ended questions about topics such as:

- The findings and whether there are any unexpected results
- Whether recommendations are practical and can be implemented in practice
- The perceived validity and utility of the results
- How to best disseminate findings, both broadly and to care coordinators and care systems
- How the results may impact their practice

#### 5.3.1.11 Clinician and Clinic Leader Interviews (Phase 2)

Phase 2 interviews with clinicians and leaders are intended to: (1) obtain perspective on the study findings, (2) elicit recommendations for improvements in care coordination, and (3) elicit recommendations for dissemination and implementation of study findings.

Interviews will ask open-ended questions to understand perceptions regarding:

- Perspective on the study findings and whether there are any unexpected findings
- Whether recommendations are practical and can be implemented in practice
- How to best disseminate findings broadly and to other clinicians and clinic leaders
- How the results could impact their practice

## 5.4 Patient Surveys (Historical and Primary Cohorts)

Patient surveys will be conducted to provide both contextual patient information and outcome data central to the study goals. The patient survey of the Historical Cohort will be conducted to provide information related to patient experiences during the COVID-19 pandemic. Surveys will solicit patient characteristics not otherwise available through the electronic health record (EHR), patient experiences with care coordination, and patient-reported outcomes, in the case of the Primary Cohort.

### 5.4.1 Patient survey instrument design

Patient interviews will be used to inform closed-ended surveys. Both the Historical and Primary cohort surveys will include questions that provide validation of the coordination process at each clinic. The Primary Cohort will also provide the key patient-reported outcome measures as well as patient characteristics. The surveys will be designed using existing survey questions with known psychometric properties where they exist. When no existing questions match desired survey concepts, questions will be developed using known best-practices for question writing.[38] Patient partners will fully be engaged in the development of the concepts, questions, and overall survey process design.
The surveys will be designed using unified mode design to minimize measurement error due to mixed mode implementation. Prior to full implementation, the surveys will be piloted with a small population similar to our target population for face validity, asking participants for their feedback on survey acceptability, length, and understanding (see Section 5.4.3). Ambiguous or difficult items will be adjusted and retested.

### 5.4.2 Patient survey content

The constructs to be included in the patient surveys include:

- Demographic characteristics (age, sex, race/ethnicity, family, education, income, insurance)
- Caregiver availability
- Health status
- Social determinant needs and changes from care coordination
- Perceived care coordination model validation (Primary Cohort)
- Perceived care integration
- Satisfaction with care, access, coordination
- Medication and care burden
- Shared decision-making
- Out of pocket medical costs
- Going without care because of costs
- Other factors identified in interviews
- Personal goals and attainment
- How the pandemic affected their lives, health, and healthcare (Historical Cohort)
- What barriers they encountered and what services they most needed (Historical Cohort)

For measures related to assessing patient-reported outcomes, we will draw upon the expertise of our expert consultants to ensure we are using well-validated measures, such as Clinician and Group CAHPS Survey (CG-CAHPS) for patient satisfaction,[39,40] Elwyn's CollaboRATE and IntegRATE measures of shared decision-making and integration,[41,42] McDonald's CCQM-PC,[34] and the Patient Perceptions of Integrated Care (PPIC) survey for patient assessments of integration of care.[43]

### 5.4.3 Patient survey pilot testing

We will pilot test the survey with patients who participated in the interviews and indicated at that time a willingness to provide this additional service. As they complete the survey, there will be added opportunities to identify any questions that were difficult to understand or answer as well as a place to indicate suggestions. As a thank you incentive, we will provide them with another $20 gift card.

### 5.4.4 Patient survey collection process

The survey will be implemented using a sequential mixed-mode design including push-to-web and phone follow-up to maximize response rates and minimize potential for nonresponse bias. The initial survey invitation will be a mailed letter to patients with $2 as a non-contingent token incentive. The letter will include a URL and a unique PIN inviting the patient to complete the survey online. As possible, the letter will be printed on letterhead from the respective patient clinic organization and signed by appropriate leaders within the care group as well as the study PIs.

Surveys will be translated in Spanish, Hmong and Somali by professional translators using forward and back translation and subsequent reconciliation. Letters will be sent in English or Spanish for those whom these are the primary languages spoken. Individuals identified as Hmong or Somali speakers will be sent an English letter with a translated language block inviting them to call in to complete the survey with a bilingual telephone interviewer. Other languages will also be considered for the language blocked based on the prevalence in the sample population. Languages other than Spanish, Somali or Hmong that cannot be accommodated by CESR will be conducted using a synchronous third-party language line.

After approximately two weeks of sending the letter, initial survey non-responders will be called up to six times by CESR-trained telephone interviewers at various times of the day and days of the week to maximize the probability of successful contact and survey completion. Calls will be made Monday – Thursday between the hours of 9am and 8:30pm and Friday and Saturday between the hours of 9am and 5:30pm. Similar follow-up processes implemented by CESR in similar populations have yielded response rates in the range of 60% anticipated for this survey. We anticipate that having co-signatures from their source of care and the closeness of these patients with their care will help facilitate these response rates.

There will be a firewall between CESR and the rest of the project team to ensure that Protected Health Information (PHI) will never be available to anyone outside of CESR (see **Figure 3**).

### 5.4.5 Incentives for participation in patient surveys

All sampled patients can keep the $2 non-contingent token incentive. Patients that complete a survey either online or over the phone will be mailed a $10 gift card as a thank you for their time.

## 5.5 Care Coordinator Survey

In order to document details of the care coordination model at each clinic, including barriers and facilitators to implementation, a survey will be completed by a lead care coordinator from each clinic

site. The care coordinator survey will inform all three specific aims. The goal is to identify and systematically document the care model as well as all potentially important components, processes, and adaptations for coordination that are used there as well as any organizational, patient, or external environmental characteristics or resources that might be important in providing the most effective coordination services.

### 5.5.1 Care coordinator survey instrument design

The care coordinator survey will be designed using existing survey questions with known psychometric properties where they exist. When no existing questions match desired survey concepts, questions will be developed using known best-practices for question writing.[38] MDH research team members will fully be engaged in the development of the concepts, questions and overall survey process.

### 5.5.2 Care coordinator survey content

Survey constructs will be derived from a combination of coordinator interviews that precede it, from existing validated questionnaires like the CCQM-PC and pre-identified domains identified in the AHRQ Care Coordination Measures Atlas. The content will include topics such as:

- The current care model (see definition)
- Changes since 2017, during the 2020 pandemic, and any changes planned in the next two years
- Staffing, panel size, mode, follow-up approach
- Organizational and contextual factors considered important to outcomes
- Principal barriers and facilitators
- Wish list

### 5.5.3 Care coordinator survey pilot testing

Prior to full implementation, the surveys will be piloted with the care coordinators who participated in the earlier interviews and who indicated a willingness to do this as well. Besides completing the survey, these pilot respondents will be asked for general feedback on survey acceptability, length, and understanding as well as a way to highlight questions that are difficult to understand or answer. Ambiguous or difficult items will be revised and retested.

### 5.5.4 Care coordinator survey collection process

The care coordinator survey will be built as a web survey in REDCap by CESR. A unique URL will be emailed to each potential responder who has been identified by the organization as most knowledgeable about each clinic. Multiple reminders will be sent to initial non-responders. If needed phone calls will be made to encourage response until a survey is completed for each clinic. Individualized follow-up will be done by the HPI team for the large organizations that they recruited and by the MDH HCH staff for the smaller organizations that they recruited, building in both cases on the relationships established then.

### 5.5.5 Incentives for participation in care coordinator survey

No monetary incentives will be offered to care coordinators for completing the survey.

## 5.6 Independent Variables, Measured Potential Confounders

Contextual data needed for the analyses of all three specific aims will come from the survey of Historical and Primary Cohort patients, the organizational survey, the survey of a lead care coordinator at each clinic, and health record data shared by clinics. **Table 4** describes the independent variables that will be used in this study and their sources. These variables will allow us to both fully characterize the patients served and the care coordination model in actual use at each clinic. They will also be used to test both components of the models and other features of the setting that may impact our outcomes.

**Table 4: Independent Variables**

| **Patient characteristics**[a] | **Clinic characteristics**[b] | **Care coordination characteristics**[c] |
|---|---|---|
| Age | Location* | Number & FTE |
| Sex | Ownership* | Education & experience |
| Race/ethnicity | Size of organization (# of clinics)* | Types of services provided |
| Insurance coverage | Staffing | Location (in clinic or off-site) |
| Education | Services on site and in organization | Panel size/FTE |
| Employment status | Availability of specialists and resources | Modality (phone, in person, email) |
| Household income | Connection with inpatient and nursing home care | Proactivity/outreach |
| Major medical conditions | Characteristics of the overall clinic patient panel (age, race/ethnicity, insurance) | Tracking/monitoring |
| Reason for enrollment[a] | Visits/month | Measure outcomes |
| Number and mode of care coordination contacts[a] | Panel size | Payment/Charges |
| Social support/social isolation | Approach to care coordination | Satisfaction with resources/access |
| Problems with housing, food, safety, or transportation | Use of data and registries | Engagement of clinicians |
| Caregiver needs | % of practice income that is not fee-for-service | Others TBD based on coordinator interviews |

[a] Patient variables will be collected via patient survey
[b] Clinic characteristics collected using clinic survey
[c] Clinic characteristics collected using clinic survey

# 6 Data Management Plan

## 6.1 Data collection

Complete data collection methods are described in Section 5.

Multiple steps will be taken in order to ensure adequacy and completeness of data. Upon receiving patient lists from MNCM, payors will verify that each patient is a plan member and also de-duplicate if a patient is identified by more than one clinic. For care quality data, MNCM has standard processes and algorithms for matching patients and ensuring the quality of their data. For utilization data, payors will utilize their operational billing claims data systems which have existing systems in place to ensure accuracy for payment of billing claims. For patient, clinic, and coordinator surveys, each survey will be designed to minimize error and missing values. Answers will be reviewed for completeness and out-of-range responses. Care coordinator, clinician, and patient interviews will be recorded and professionally transcribed to ensure data accuracy.

## 6.2 Data organization

Patient data submitted by clinics to MNCM will be assembled in study-specific tables of an existing database server. Data transmitted between MNCM and participating payors or CESR will be exchanged in a standard file format (e.g., a delimited text or SAS file). Data transmitted between MNCM and HPI will be exchanged in a standard file format (e.g., a delimited text or SAS file) with the unique key based on an arbitrary (de-identified) identifier for each patient.
Patient, care coordinator, and organizational survey data will be assembled in survey-specific REDCap database tables. Survey data and label files will be exported into .csv format and/or SAS files as directed by the analysts for analyses.

Qualitative interview data collection will be tracked in interview-specific REDCap database tables. Interview data will be organized by participant type and date of data collection. Individual interviews will be saved as written transcripts in files which can be uploaded to a variety of qualitative analysis software. Each interview data collection event will have its own data folder indicating the time period and study population. Each data folder will contain a data file that describes the interview subjects and key attributes (for example demographics), individual files for each transcript, and audio files (e.g., .mp3 or .wav format).

## 6.3 Data handling

Management and version control of patient identifying information, care quality, and utilization datasets will be handled by MNCM. The people responsible for managing data at MNCM are the VP of Technology and Innovation, the Manager of Data Collection and Integrity, one Data Integration Engineer and one Data Quality Specialist. MNCM will provide secure, encrypted, and user role-based access for all data handling controls. Beginning with data encryption, all data will be encrypted using advanced encryption algorithms using no less than SHA-256. This will ensure that both data in transit and at rest will be fully secure and protected.

User access controls will govern who is able to submit, download, and review collected data. This will happen in three parts. First, clinics that will submit data to MNCM will utilize the MNCARES Data Collection Portal. Access to this portal will be governed by MNCM and only authorized users from each clinic will be able to submit and validate data within the portal. Clinic authorized users will only have access to their own data within the portal. Only MNCM authorized users will access to clinic portal data. All access to the system is logged by MNCM and reviewed on a periodic schedule.

Second, all other data transmission and collection will be facilitated through MNCM's secure file transfer protocol (SFTP) server. Similar to the clinic data portal, only authorized users from each participant or vendor will be provided role-based access to this system for submission and retrieval. All access to the system is logged by MNCM and reviewed on a periodic schedule.

Third and finally, as MNCM begins to compile data to be delivered per project goals, MNCM will utilize a secure encrypted drive to perform any analysis activity. Access to this drive will be limited to authorized MNCM staff who are assigned to the analysis and compilation work. All access to this drive is logged by MNCM and reviewed on a periodic schedule.

For the final research datasets, MNCM programmers will protect confidentiality by randomly assigning a project-specific studyID for each unique patient and complying with all requirements imposed by the Institutional Review Board (IRB) and applicable HIPAA requirements and Data Use Agreements (DUAs).

The person responsible for managing survey data is the Director of Survey and Evaluation Science at CESR. Version control is managed by using a single REDCap project across each data collection activity. As such when a web survey is completed, for example, the instrument will be marked complete and phone pursuit would be terminated. The singular survey response collected for each individual will be maintained in its original form in REDCap. If logical edits are made post-data collection to reflect skip patterns or other errors, they will be made outside of the REDCap environment or in a secondary variable so as never to overwrite source data The REDCap system is built with redundancy and is backed up in the HP data centers to ensure against data loss. Only those individuals who are cleared to work on this study will have access to the project specific REDCap environments.

The people responsible for managing qualitative data are the CESR evaluation associate and Director. Version control is managed by keeping raw transcripts in separate folders from clean, de-identified transcripts. Each interview should be represented by one final transcript, and any changes to the content (i.e., fixing typing errors) will be saved to over-ride any past version. The original raw transcript will always stay available for reference in order to locate changes if necessary. Audio recordings and raw transcripts will be saved as back-up to the final transcripts in the event of accidental loss of data. They will be saved in a separate folder so that identifiers will not be accessible to those accessing the final transcripts. The project drive the data are saved on is backed up on the HP network regularly. Folders containing identifiers will be labeled with "contains PHI" and study team members will be directed to access only final versions of transcript files.

The people responsible for handling the de-identified transferred datasets are the HPI informatics programmer and study biostatistician. Transferred datasets will be stored (as is) in a designated folder in the project directory for the duration of the study. Analytic datasets will be derived from these transferred

data sets and stored in a separate folder. Any residual identifying information found in the transferred sets will not be carried through analytic datasets.

Throughout the study, PHI will not be made available to study co-investigators, project managers, or statistician with the exception of staff at CESR who will have access to identifiable survey and interview data as described above. Patient confidentiality will be protected as specified in the protocol's protection of human research subjects (Section 13) and in compliance with HIPAA and other federal, state, and local patient privacy procedures.

## 6.4 Data documentation

Each data file will have an associated data dictionary that will be developed and vetted by the relevant study partners (i.e., the originator and users of each data file).

Data dictionaries to be developed will include the following data files: clinic data identifying care coordination patients, care quality data from MNCM, utilization data from each participating payor, interview/survey data for each administered interview/survey, and the final de-identified research analytic files. Where appropriate, metadata standards will also be collaboratively developed.

## 6.5 Data storage and preservation

HPI's networked workstation computers communicate with the larger HealthPartners (HP) corporate network. Data systems for storing and backing up data reside both at the HP corporate headquarters and in a secure offsite facility. Data are backed up daily, weekly and monthly. Computer and data needs are supported by the larger organization's Information Systems & Technology Department, which maintains all HP computer hardware, software and data, including electronic medical record, research, and administrative data.

Interview data is preserved for recovery by saving it in several forms: audio, raw transcripts, and clean transcript. Audio and raw transcript files are maintained with the transcription company, and can be re-downloaded at any time in the event of a file loss.

## 6.6 Data maintenance

Final de-identified study data, documentation, metadata, and analytic files will be maintained in a study-specific file folder using widely used file formats (e.g., text delimited files, PDFs, Microsoft Word documents, and SAS/R programs) that will require minimal maintenance during the course of the study or in the future. We do not have infrastructure to support a data repository for qualitative data at this time.

## 6.7 Data sharing

The project team outside of the data analysts will view data primarily as summaries, but will have full access to the clean and de-identified data sources. Other stakeholders will primarily interact with high level summaries of findings in manuscripts, presentations, and/or reports.

Individual consent to participate in the interviews assured participants that their information will not be shared on an identifiable individual level. We will not make identifiable individual level interview data or meeting notes available to stakeholders outside our study team, consultants named in the consent, and the outside transcription service. Regulatory bodies named in the interview consent forms will be able to access primary de-identified data for examination upon request.

To facilitate the conduct of future research, we will create de-identified data sets from the completed project in a manner consistent with human subject protection and HIPAA privacy regulations. These data sets will be kept at HPI along with data dictionaries, coding manuals, and other documentation relevant to data collection or measurement issues. These resources will be available to the funding agency or to other approved investigators according to requirements imposed by the governing IRB and legal requirements, including HIPAA and DUAs, and organizational and/or technical constraints.

## 6.8 Masking

When possible, clinic and comparator identities will be masked from the study team until the primary analyses are completed, but strict masking will not be possible due to the mixed methods used for data collection (i.e., the combination of qualitative and quantitative data) and due to data attributes that are known a priori (e.g., the number of clinics associated with a care system or a care coordination model)."

# 7 Statistical Analysis Plan

This observational study will use a mixed-method convergent design,[44] including exploratory and explanatory evaluation of the comparative effectiveness of two care coordination models implemented by up to 397 adult primary care clinics certified as HCH by MDH. For quantitative inferential analysis of each aim, standard multivariable generalized linear mixed effects regression models (GLMMs) will be constructed for each study outcome, using SAS (v9.4) and/or R (v3.4.3) analytic software. Causal inference will be informed by the PICOTS framework.[45] Descriptive analyses will include summaries (means, standard deviations, counts, proportions) of baseline characteristics of the study population along with tests of bivariate association (e.g., Fisher's exact test, Kruskal-Wallis, as appropriate) between patient, clinic, and contextual factors and the care coordination comparator, survey response, or study outcomes. Aims 2 and 3 will incorporate qualitative data obtained via patient surveys and clinic interviews. Qualitative findings will enhance understanding of the quantitative findings and our ability to address additional research questions raised by patients, partner organizations, and community stakeholder groups. We will follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines to help ensure sufficient information in reports to allow for assessments of the study's internal and external validity.[46]

## 7.1 Outcomes

Our outcomes fall into three categories: care quality (drawing on statewide quality measures reported by MNCM), utilization (drawing on insurance claims data collected by payor partners), and patient-centered/patient-reported outcomes (collected directly from care coordination patients who agree to complete a survey). Section 5 describes how data will be collected. **Table 5** summarizes study outcomes. Timing of outcome assessment will be anchored by the first date of receiving care coordination services,

thereby creating a consistency across comparators and mitigating potential sources of bias due timing.

**Table 5: Study Outcomes**

| Outcome measure | Definition | Source | Primary/ Secondary | Follow-up duration |
|---|---|---|---|---|
| **Care Quality from the healthcare professional perspective** | | | | |
| Overall care quality | Composite measure of overall quality comprised of the percentage of all care quality outcomes in which a patient qualifies and meets quality criteria for | MNCM | Primary | 12m |
| Asthma care at goal | Asthma pts. with controller meds, information, and <2 ED visits/hospital stays in a year | MNCM | Secondary | 12m |
| Breast Cancer Screening (up-to-date) | Women 50-74 yrs old who received a mammogram in the past two years | MNCM | Secondary | 12m |
| Colorectal Cancer Screening (up-to-date) | 50-75 yr old pts. up-to-date for an approved screening test | MNCM | Secondary | 12m |
| Cervical Cancer Screening (up-to-date) | Women 21-64 yrs old who received appropriate screening for cervical cancer | MNCM | Secondary | 12m |
| Chlamydia Screening (up-to-date) | Female patients 16-24 yrs old who had a screening test for chlamydia | MNCM | Secondary | 12m |
| Depression improvement | PHQ9 score improvement in patients with a major depression diagnosis | MNCM | Secondary | 12m |
| Diabetes care at goal (including component measures) | All-in-one measure of control A1c, blood pressure, lipids, & smoking + ASA use in patients with diabetes | MNCM | Secondary | 12m |
| Vascular care at goal (including component measures) | All-in-one measure of control of blood pressure, lipids, & smoking + ASA use in patients with vascular disease | MNCM | Secondary | 12m |
| **Utilization from the healthcare system perspective** | | | | |
| Emergency dept. visits | # of encounters with CPT-4 E&M codes (99281-99288) at emergency dept. site | Health plan claims | Primary | 12m |
| Hospitalizations | # of hospital inpatient admissions ≥ 1 days | Health plan claims | Primary | 12m |
| Hospital readmissions <30 days | # of hospital inpatient admissions ≥ 1 days following a prior hospitalization < days | Health plan claims | Secondary | 12m |

| | | | | |
|---|---|---|---|---|
| Primary care visits | # of encounters with CPT-4 E&M codes (99201-99215, 99381-99429) at primary care site | Health plan claims | Secondary | 12m |
| Specialty care visits | # of encounters with CPT-4 E&M codes (99201-99215, 99381-99429, 99241-99245, 92920-93895) at primary care site | Health plan claims | Secondary | 12m |
| Urgent care visits | # of encounters with CPT-4 E&M codes (99201-99215, 99381-99429) at urgent care site | Health plan claims | Secondary | 12m |
| Substance use treatment | Substance use treatment indicated by HCPCS codes (H0005-H0029, H0047, H2034-H2036) | Health plan claims | Secondary | 12m |
| # of chronic medications | # of distinct concurrent dispensed medications, combined across drug classes used for chronic conditions (e.g., hypertension, hyperlipidemia, diabetes, asthma, depression) | Health plan claims | Secondary | 12m |
| **Patient reports from the patient/family perspective** | | | | |
| General health status | NHIS | Patient survey | Primary | 6m-18m |
| Satisfaction with care | CG-CAHPS | Patient survey | Primary | 6m-18m |
| Satisfaction with access to care | CG-CAHPS | Patient survey | Secondary | 6m-18m |
| Satisfaction with care coordination | TBD but questions from the AHRQ CCQM-PC or the MHCCS-P[48] are likely | Patient survey | Secondary | 6m-18m |
| Shared decision making | 3 item CollaboRATE[41] | Patient survey | Secondary | 6m-18m |
| Perceived care integration | 4 item IntegRATE[42] | Patient survey | Secondary | 6m-18m |
| Going without care due to cost | National Health Interview Survey | Patient survey | Secondary | 6m-18m |
| Out-of-pocket medical costs | Medical Expenditure Panel Survey | Patient survey | Secondary | 6m-18m |
| Medication and care burden | 7-item Treatment Burden Questionnaire (TBQ)[49] | Patient survey | Secondary | 6m-18m |
| Changes in social needs | 10-item CMS HRSN Screening Tool[50] | Patient survey | Secondary | 6m-18m |
| Changes in insurance coverage | State Health Access Data Assistance Center (SHADAC) Coordinated State Coverage Survey | Patient survey | Secondary | 6m-18m |

Notes: MNCM = MN Community Measurement; m = months.

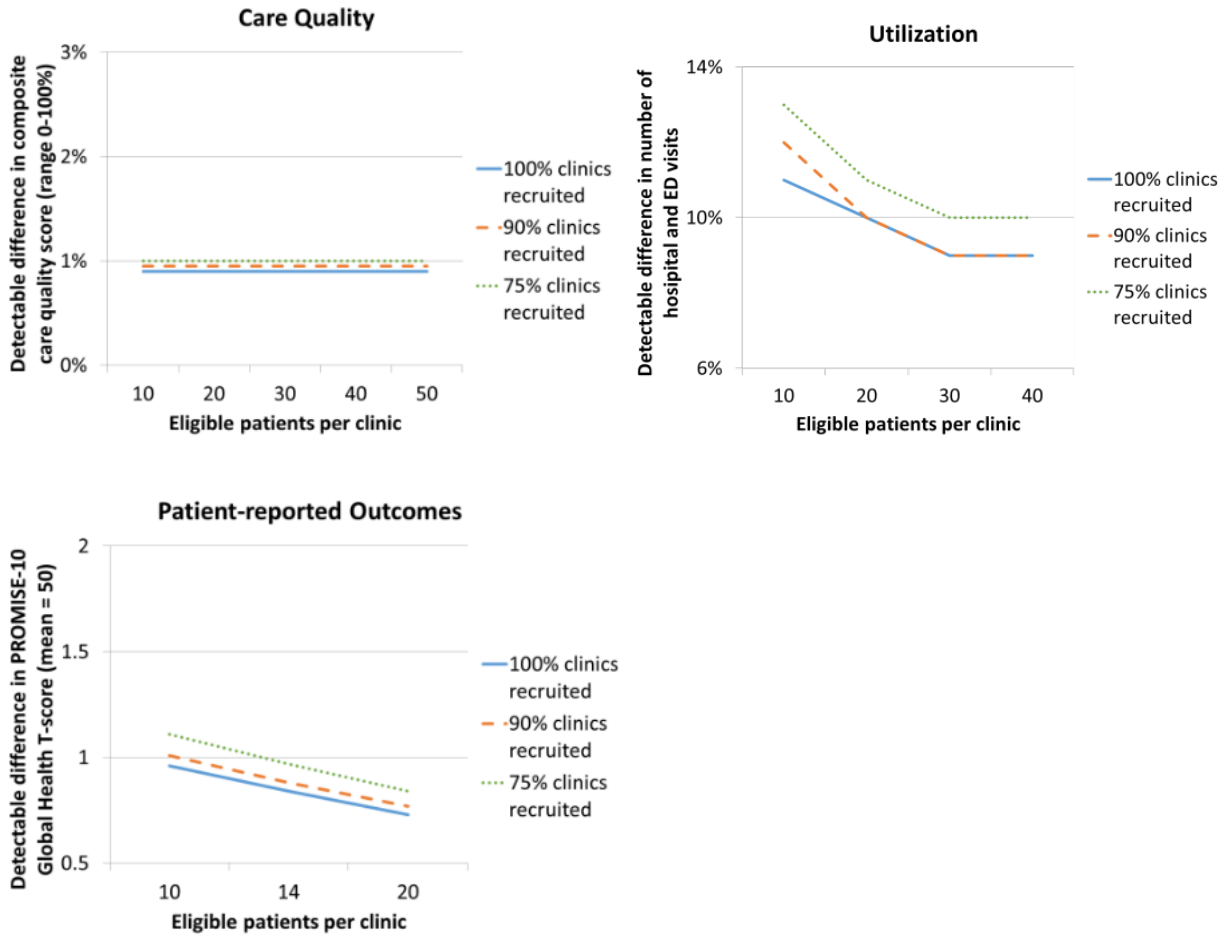
## 7.2 Sample Size and Power

### 7.2.1 Primary Cohort Sample Size and Power

As described in Section 4, we will recruit about 397 clinics—55% with a nursing/medical and 45% with medical/social care coordination model—to participate in this study. Although we recognize that we may not fully reach it, our goal is to recruit 100% of these clinics to participate in our study. All of these clinics will be eligible to contribute to our Primary Cohort analysis. Exact numbers of eligible patients from each clinic remains unknown, but we estimate that over a 12-month accrual period (01/01/2021 to 12/31/2021), each clinic will be able to contribute 57 patients on average. Among these patients, we estimate about 45%, or 26 patients per clinic, will be covered by one of our participating health insurance plans that will be contributing utilization outcomes. In addition, we have budgeted to survey 7,000 patients with an expected response rate of at least 60%, which would correspond with about 10 or 14 patients per clinic with 100% or 75% clinic recruitment, respectively.

**Figure 4** illustrates the differences in outcomes we will be powered to detect under a range of clinic participation rates (i.e., 75%, 90%, and 100%) and number of eligible patients per clinic (ranging from 10-50). Power and sample size analyses were conducted using PASS (v.19) software, assuming two-sided tests ($\alpha$=0.05) with 80% power and an intra-cluster correlation of 0.01. For the composite care quality score, all scenarios indicate sufficient power to detect a difference in the percentage of quality measures at goal (range 0-100%) of at least 1%. For the primary utilization outcome, most scenarios indicate power to detect at least a 10% difference in the number of hospitalizations and inpatient visits. For the primary patient-reported outcome, all scenarios indicate the ability to detect at least a 1 point difference in the PROMIS-10 Global Health score (mean=50, standard deviation=10). Thus, we feel confident in our plan with this adaptation to achieve sufficient power to discover meaningful differences between care coordination models across all of our primary outcome measures for the Primary Cohort.

**Figure 4: Power analysis for Primary Cohort**



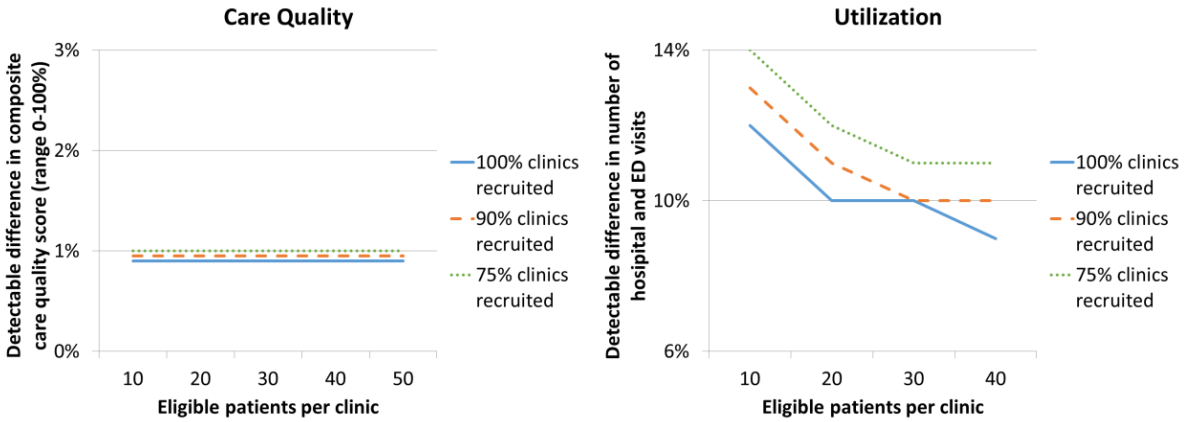

### 7.2.2 Historical Cohort Sample Size and Power

Among the 397 clinics we are recruiting for this study, 329 should be eligible to contribute patients to our Historical Cohort analysis. Exact numbers of eligible patients from clinic remains unknown, but we estimate that over a 14-month accrual period (01/01/2018 to 02/28/2019), each clinic will be able to contribute 66 patients on average. Among these patients, we estimate about 45%, or 30 patients per clinic, will be covered by one of our participating health insurance plans that will be contributing utilization outcomes.

**Figure 5** illustrates the differences in outcomes we will be powered to detect under various scenarios for the Historical Cohort. Power and sample size analyses were conducted using PASS (v.19) software, assuming two-sided tests (α=0.05) with 80% power and an intra-cluster correlation of 0.01. For the composite care quality score, all scenarios indicate sufficient power to detect a difference in the percentage of quality measures at goal (range 0-100%) of at least 1%. For the primary utilization outcome, most scenarios indicate power to detect at least a 10% difference in the number of hospitalizations and inpatient visits. Thus, we feel confident in our plan with this adaptation to achieve sufficient power to discover meaningful differences between care coordination models across all of our

primary outcome measures for the Historical Cohort.

**Figure 5: Power analysis for Historical Cohort**




## 7.3 Analysis Plan

### 7.3.1 Aim 1 Analysis

To evaluate the impact of coordination type (medical/social vs. nursing/medical) on study outcomes, we will specify a series of generalized linear mixed models (GLMMs). Individual patients (nested within clinic and organization) are the primary unit of analysis. To account for patient clustering, we will incorporate a random intercept for clinic into the model. Covariates will be specific to a given model (outcome) and will be selected based on a combination of substantive knowledge, empirical evidence, and model fit statistics (e.g., Bayesian Information Criterion). We will also use the least absolute shrinkage and selection operator (LASSO), to inform covariate inclusion. Random effects will be evaluated and retained in a given model based on model fit statistics and Wald tests for covariance parameters. Patient care quality outcomes for Aim 1 analyses will be modeled as binary dependent variables (e.g., meeting goal vs. not meeting goal), and corresponding GLMMs will have the general form:

$$(1)\ \eta_{ijk} = \gamma_{000} + u_{0j0} + \gamma_{100}X_{ijk} + \gamma_{010}CC_{jk} + \gamma_{020}W_{jk} + \gamma_{001}Z_k + \varepsilon_{ijk}$$

where $\eta$ represents the log-odds of a care quality outcome (e.g., BP control); $\gamma_{000}$ is the intercept (value for a 'typical' patient at a 'typical' clinic); $u_{0j0}$ is the random intercept at the clinic level; $X_{ijk}$ is a vector of covariates (including baseline BP control status, age, etc.) for patient *i* within clinic *j* and organization *k*; $CC_{jk}$ represents the exposure variable of interest, care coordination type, designated at the clinic level; $W_{jk}$ is a vector of clinic-level covariates; and $Z_k$ is a vector of organization-level covariates. Effect estimates will be calculated via γ coefficients (specifically $\gamma_{010}$ for the relative log-odds comparing the medical/social vs. nursing/medical care coordination model); $\varepsilon_{ijk}$ is an error term. In addition to analyses of individual care quality outcomes, we will also evaluate a composite outcome representing the proportion of applicable care quality outcomes that are met by a given patient. We intend to primarily evaluate this proportion as a continuous variable in a linear or tobit regression model that

follows the structure in equation (1) above. However, based on the empirical distribution, we may also evaluate transformations to binary or multilevel categorical versions of this outcome as warranted.

Utilization outcomes for Aim 1 analyses will be evaluated both as binomial (any occurrence vs. none) and as counts. GLMMs will follow the framework of equation (1) above, however, for the underlying distribution of count outcomes we will assume a Poisson (or negative binomial, as appropriate) distribution with a log (as opposed to logit) link function. We anticipate a similar modeling approach for quantitative analyses of the impact of care coordination type on patient-reported outcomes (again adapting assumptions of the underlying distribution and corresponding link function, specific to the nature of each outcome variable). The main exception will be that we will not have baseline values for patient-reported measures, given that they will only be collected at a single time point in follow-up.

Primary results for Aim 1 analyses will be reported as odds ratios, rate ratios, or (beta) differences (comparing the medical/social care coordination model to the nursing/medical model), with 95% confidence intervals, for each study outcome.

All Aim 1 analyses as described above will be replicated for both the Primary and Historical cohorts, and reported separately. To evaluate whether cohort-specific estimates statistically differ with respect to a given outcome, we will estimate pooled (Primary + Historical) models and evaluate the significance of the Wald test for the interaction term (*Cohort*CC Type*). Additionally, for the Historical cohort, care quality and utilization outcomes may potentially be available for up to 3 years from the onset of care coordination. Where data is available, we will estimate the impact of care coordination type on 1-year, 2-year, and 3-year outcomes respectively, using the framework described above, within the Historical cohort.

### 7.3.2 Aim 2 Analysis

To identify the key components of care coordination that associate with study outcomes, we will use the general approach described for Aim 1 analyses, with minor adaptations. For the designated care coordination characteristics (Section 2.2), we will first tabulate descriptive summaries as described above. We will then evaluate a series of GLMMs to evaluate care coordination components (part of the vector of clinic-level independent variables $W_{jk}$) for each study outcome: 1) using the full model specification in Equation 1; and 2) stratified models restricted to the populations within care coordination type. These analyses will be replicated in each of the Primary and Historical cohorts as described in Aim 1 above. Taken together, we anticipate these sets of results will provide comprehensive evidence of the impact of individual components of care coordination on study outcomes.

### 7.3.3 Aim 3 Analysis

Identification of significant organization, care process, and patient factors will be embedded in analyses for Aims 1 and 2, and will be represented as covariates in final selected models for study outcomes. Whereas Aim 1 analyses seek to quantify effect estimates for $\gamma_{010}CC_{jk}$ in equation 1 above, for Aim 3 we intend to quantify γ coefficients for patient-level factors *X*, clinic-level factors *W*, and organization-

level factors *Z*. As described above, we will iteratively optimize models using LASSO and model fit statistics. Summaries for unadjusted and adjusted comparisons for all variables under study will be tabulated and/or plotted accordingly. Again, Aim 3 analyses will be conducted separately for the Primary and Historical cohorts as described above.

### 7.3.4 Comparison between Patient Cohorts

In comparing the two cohorts with respect to Aim 1, we will test and measure whether the comparative effectiveness of the two care coordination models differs between the two cohorts (i.e., before and after COVID). For example, we might learn that the two care models were performing similarly prior to COVID, but since COVID, patients receiving attention from a social worker in the medical/social model have fared comparatively better in one or more ways. With respect to Aim 2, we will test and measure whether the core components in **Table 1**—and other factors including size of patient panels for coordination, resources available to the coordinators, duration and frequency of encounters, mode of encounter, etc.—have shifted over time or whether the individual effects of these components or factors on outcomes differ between cohorts. For example, we may learn that clinics primarily delivering care coordination in-person corresponded with better outcomes prior to COVID, but after COVID, we may learn that telemedicine is being used at greater prevalence and with similar effect as in-person care coordination services. Finally, with respect to Aim 3, we will test and measure whether organizational, community, care process, and patient factors differ between cohorts and whether any shifts in these contextual factors have had any differential effect on patient outcomes. For example, we might learn that patients are experiencing challenges with non-medical factors (i.e., "social determinants" such as housing, employment, transportation, or insurance) at greater rates now compared to before the pandemic and further that the medical/social model now has a more significant comparative effect on these patients' outcomes, potentially as a result. Importantly, Aims 2 and 3 will help us to understand what is driving any differences in the comparative effectiveness between the two care coordination models between the two population cohorts, should they be found to exist.

To help us understand if differences we see in the Historical vs. Primary cohorts are statistically significant, we will run the same statistical model we used to calculate the association between care coordination model and a given study outcome (e.g., care quality measure) in the separate cohorts on a combined data set (including patients from both the Historical and Primary cohorts), with the addition of an interaction parameter between the patient cohort and care coordination model. A statistical (Wald) test of this interaction term in the regression will help us determine if the relationship between choice of care coordination model and a given study outcome truly differs by cohort (timing relative to COVID).

Should we find no meaningful differences in the comparative effectiveness of the care coordination models between the two patient cohorts, our study analyses will still be enhanced by having the additional patient data added by the Historical cohort. Specifically, this will allow us to conduct further analyses using the combined data, which will provide additional statistical power to detect meaningful differences in subgroup analyses or in quantifying the contributions of specific core components or contextual factors related to care coordination, which could help deepen our understanding of our Aim 2 and Aim 3 findings, in particular.

### 7.3.5 Summary of outcomes by clinic or organization

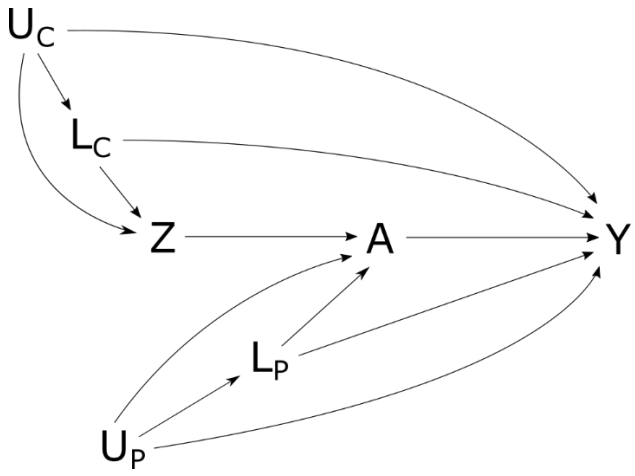
In addition to the comparative effectiveness analyses described in Sections 7.3.1-7.3.4, we will aggregate outcomes at the clinic or organizational levels using predicted margins from the appropriate analytic models described above in order to provide additional information and context to clinics or organizations to support implementation of study findings and comparisons to their peers.

### 7.3.6 Causal Inference

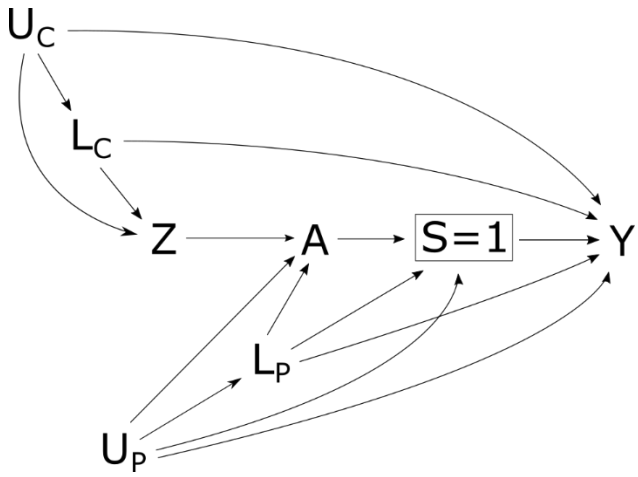
#### 7.3.6.1 Causal model underlying the research question

The primary causal research question(s) of interest in this study is, "What is the difference in risk/probability of outcome Y for care coordination patients under the medical/social model, versus the risk/probability of outcome Y for care coordination patients under the nursing/medical model," where Y refers to each of the designated study outcomes (quality measures, utilization, patient-reported measures). Analyses will align with the following representation of the PICOTS framework: (1) the study *population* will consist of care coordination patients in participating Minnesota primary care clinics meeting criteria for the Historical or Primary Cohorts (as described in Section 4.2.2); (2) the study *intervention* is delivery of care coordination services to high-cost/high-need patients in primary care; (3) primary *comparators* will be the medical/social model versus the nursing/medical model for delivering care coordination, which have been implemented at the clinic level; (4) several care quality measures (e.g., proportion of patients with diabetes under control), healthcare utilization measures (e.g., hospitalizations), and patient-reported measures (e.g., health status) will be independently evaluated as study *outcomes*; (5) *timing* of the source data for health care quality and utilization measures will be based on the 12 months preceding and 12 (up to 36 for Historical cohort) months following each patient's initiation of care coordination services (i.e., to account for the pre-to-post change in outcomes at the individual level upon exposure to the intervention) and patient-reported outcomes will be obtained by survey 6-18 months after initiation of care coordination services; and (6) the *setting* will be care coordination programs in Minnesota area clinics, with study data being drawn from electronic health records (as collected and combined from clinics statewide by MN Community Measurement), insurance claims, and patient surveys.

Directed acyclic graphs (DAGs) are the epidemiologist's primary tool for specifying an underlying causal model, its key assumptions, and potential sources of bias.[51-53] Briefly, DAGs are visual representations consisting of nodes (variables or vectors) and arrows (causal relationships, or more appropriately, lack of evidence that two variables are not causally related). They are 'directed' in that they depict unilateral temporal sequences (typically left to right), and 'acyclic' in that circular pathways cannot be included (variables cannot cause themselves). We envision that our proposed quality measure and utilization outcome models could be represented by the following DAG, where $\boldsymbol{A}$ is the care coordination model a patient receives (medical/social or nursing/medical), $\boldsymbol{Y}$ is a specific study outcome (quality measure or utilization measure), $\boldsymbol{Z}$ is the clinic-level decision to implement one care coordination model over the other, $\boldsymbol{L_c}$ and $\boldsymbol{L_p}$ are vectors of measured prognostic factors at the clinic and patient level, respectively, and $\boldsymbol{U_c}$ and $\boldsymbol{U_p}$ are vectors of unknown or unmeasured factors at the clinic patient levels, respectively.




We are interested in quantifying ***A*** → ***Y***. Estimates for this relationship can be biased when there are alternative 'backdoor' paths from ***A*** to ***Y***. In this case, we can identify multiple backdoor paths via $L_C$, $L_P$, $U_C$, or $U_P$. By conditioning on measured covariates (e.g., including them in multivariable models), we can block backdoor pathways through $L_C$ and $L_P$. Assuming the DAG is correct, we are then susceptible to bias only through unmeasured confounders $U_C$ or $U_P$ (to the extent they exist). To address this possibility, we will attempt to identify any relevant confounders that are undocumented in the data, and calculate e-values to determine if said confounder(s) could have plausibly accounted for the observed association.[54] For analyses of patient reported outcomes (via survey), we modified the previous DAG as follows:




We now have a selection step (***S=1***) between ***A*** and ***Y***, representing completion of the survey. All of the conditions of the previous DAG described above still apply – however, we now also have collider stratification (selection) bias, if survey responders differ from non-responders with respect to measured ($L_P$) or unmeasured ($U_P$) patient factors. To address this, we will use inverse probability (of survey response) weighting, which would effectively remove the arrow from $L_P$ into ***S=1***. We would still be potentially susceptible to bias if there is strong selection by factors in $U_P$; we will conduct additional

sensitivity/bias analyses to place reasonable bounds on our estimates under these conditions, and acknowledge any limitations that remain.

#### 7.3.6.2 Population used to generate effect estimates

As described in Section 4.2.2, patients will be eligible for analyses if they have been designated for care coordination at a participating clinic and have not opted out of research. For utilization outcomes, inclusion will additionally require health insurance coverage from a participating payor. For patient-reported outcomes, inclusion will additionally require completion of the study survey. As described above, patients will be followed for health care quality and utilization outcomes over the 12 months preceding and the 12-36 months following the first observed enrollment in care coordination, and patient-reported outcomes will be collected by survey in the 6-18 months following first enrollment in care coordination (Primary Cohort only). For a discussion of analytic implications of selection by survey response, please see Section 7.3.6.1 above. Differences in survey respondents vs. non-respondents will be assessed for potential selection bias and potential impact on validity of results.

#### 7.3.6.3 Timing of the outcome assessment relative to the initiation and duration of exposure

As described above, timing in the assessment of health care quality and utilization outcomes will account for outcomes in the 12 months preceding initiation of care coordination in comparison to outcomes in the 12 months following initiation of care coordination. Assessment of patient-reported outcomes will be collected in the 6-18 months following initiation of care coordination (Primary Cohort only). Patients' exposure time will be the observable duration of time spent in a care coordination program; they will be considered exposed for the entire follow-up period for each outcome. Exposure to the intervention (care coordination) will be determined at the patient level, whereas comparator status (choice of care coordination model) will be implemented by each clinic at the clinic level. Due to these conditions, sequential temporality will be ensured, and immortal time bias will not be applicable.

#### 7.3.6.4 Potential confounders

For primary analyses, covariates will be measured at or prior to baseline (entry into care coordination). Patient-specific follow-up duration (i.e., 6-18 months) for patient-reported outcomes collected by survey will be accounted for as a covariate. Section 7.3.6.1 also describes how potential confounders will be specified and addressed.

#### 7.3.6.5 Balance of covariates and use of propensity scores

We do not plan to calculate propensity scores for primary analyses, as the care model decision will not be made by providers based on individual patient indications. The care coordination model will be implemented at the clinic level, thus we anticipate patient factors will be relatively balanced between comparison groups. Remaining imbalances should reflect between-clinic differences in patient populations and will be addressed via covariate adjustment in statistical models.

### 7.3.7 Identification of participant subgroups and heterogeneity of treatment effects

The goal of analyses to assess the heterogeneity of treatment effects is to understand whether comparative effectiveness between the care coordination models varies by subgroup. There is sufficient evidence to hypothesize that the social/medical model may be more effective for patients with high social needs or low socioeconomic status.[55,56] We will also assess heterogeneity of treatment effects by age, sex, race/ethnicity, and disease status subgroups, but without an a priori hypothesis about the potential differences. Heterogeneity of treatment effects will be appropriately assessed using interaction terms in the statistical models described above.[57]

### 7.3.8 Bias Mitigation

To mitigate bias, we will: 1) rely on subject area experts on our project team and in the clinics to identify anticipated confounders for the relationship(s) between coordinated care model and study outcomes; 2) use directed acyclic graph methods to diagnose potential sources of confounding or selection bias, and identify analytic approaches to correct such biases[58]; 3) evaluate imbalances in empirical distributions of covariates with respect to care coordination model, and their associations with study outcomes (requisite criteria for presence of confounding); 4) employ appropriate analytic strategies (stratification, multivariable modeling, inverse probability weighting)[59]; 5) conduct sensitivity or quantitative bias analyses to calculate reasonable bounds for study estimates under varying assumptions[54]; and 6) acknowledge remaining limitations to be considered when interpreting our study results.

# 8 Qualitative Analysis Plan

Drs. Whitebird, JaKa, and Solberg in consultation with Dr. Crabtree will lead the qualitative data analysis of participant interviews. Qualitative data analysis will be approached from two perspectives: at baseline for survey development (Phase 1) and again in the final year (Phase 2) to understand meaning, implications, and recommendations regarding the study findings from the perspectives of patients, care coordinators, and clinicians/leaders.

In Phase 1 patient, clinician/leader, and care coordinator interviews, we will first conduct a rapid analysis of any content that needs to be incorporated in the subsequent surveys of being developed for patients or care coordinators, which will be followed by a more deliberative directed content analysis approach. Following interview completion, audio recordings will be transcribed using a professional transcription service. These transcripts will be discussed by the analysis team as they are completed in order to identify immediately actionable information regarding survey development. Then, interview data (transcripts and field notes) will be analyzed using an inductive, descriptive approach to assess, code, and categorize the data into *a priori* constructs and empirical constructs arising from the interview data. *A priori* constructs will be derived from prior work and the literature that is relevant to the survey development focus for each participant group. Constructs will be mapped onto developing measurement frameworks that will form the foundation of survey development for each study population. Coding differences will be discussed until consensus is reached on a final coding structure that will then be applied to all data. The survey development team will use the findings of the data analysis to guide survey development for patient and care coordinator surveys.

The data analysis for Phase 2 patient and care coordinator interviews will utilize a strategic and thematic approach to explore clinician/leader, care coordinator, and patient perceptions of study results and their implications.[60] A thematic analysis will be applied that that is flexible and accessible in interpretation and application.[61] Data will be systematically coded into categories, themes, and patterns emerging from and grounded in the data with an a priori focus on identifying the processes and elements of care coordination as experienced by clinicians and leaders, and the perception of study results and their applications from a variety of study participants. Open coding will be used to create the initial coding frame; data will then be coded into categories with similar characteristics.[62] Classification schemes and typologies will be used to identify and develop emerging themes, concepts, and patterns arising from and grounded in the data.

NVivo, a qualitative data-analysis software program, will be used for the data analysis. Issues of trustworthiness and rigor in the analysis defined as credibility, transferability, dependability, and confirmability of the data (a qualitative equivalent to validity and reliability) will be addressed through a number of strategies.[63-65] Confirmability and dependability will be addressed by maintaining a data codebook and audit trail mapping decision points in the analysis. Negative case analysis will be conducted on individual interviews that do not fit evolving patterns in the data. Credibility will be addressed by having the analysis team agree on final themes and patterns in the data. Issues of transferability will be addressed through triangulation with other data sources. This is particularly important in Phase 1 as the data will be used in triangulation with other sources to inform and guide survey development. In Phase 2 interview data will be compared and triangulated with other study data to clarify and enhance quantitative findings.

# 9 Data Quality Assurance

## 9.1 Missing Data

### 9.1.1 Methods to prevent and monitor missing data

The absence of documentation of a care process or vital sign in the care quality database should not be interpreted as a missing value, but rather as indicative of a care process or test not having been performed. Likewise, absence of utilization indicated by billing claims almost always indicates that the utilization (such as a hospitalization) did not occur. Truly missing observations (e.g., SBP measured, value not available) will be extremely rare, undetectable, and assumed to be missing at random (perhaps conditional on available measures). For surveys, CESR will employ state-of-the-art methods to minimize unit and item nonresponse for patient-reported outcomes. For item non-response, we expect <5% missing data on any single item.

### 9.1.2 Statistical methods to handle missing data and statistical uncertainty due to missing data

By definition, exposure status for Aim 1 analyses (care coordination type) will not be missing; this classification is determined at the level of participating clinics. Patients that are missing outcome measures will be excluded from analyses specific to that outcome. For primary analyses that include parameters derived by interview/survey, non-responders will be excluded. In sensitivity analyses, we will evaluate differences in available measures by survey response status, and construct weighted (by likelihood of response) models to reconstruct the full population and supplement results from complete case analyses. Where non-survey covariate values are substantially missing (e.g., >20%), these

covariates will not be included in primary models. Where non-survey covariate values are missing for <20% of a given analysis population, we will use a complete case approach for primary analyses. In sensitivity analyses, we will use multiple imputation (using the R package 'MICE') to fill in non-survey covariate values that are missing for <20% of a given analysis population, and reconstruct models of interest with partially imputed input data. Lastly, we will conduct bias analyses to quantify the potential impact of covariate missingness on outcome-specific model results as needed.[66,67]

### 9.1.3 Monitoring reasons for dropout and missing data

Utilization data may be incomplete if a patient switched insurance plans during the pre or post index period (note that switching among Medicaid or state-sponsored plans will generally not be lost to follow-up within the MN DHS data systems). The disposition of each contact attempt to complete a survey will be documented by the survey administrator(s). For mailings, this includes undeliverable addresses and active refusals. For telephone surveys, these dispositions include noncontact, refusal, ineligibility, and bad telephone number.

### 9.1.4 Sensitivity of inferences to missing data methods and assumptions

Given the primary and sensitivity analyses described above, we will accumulate empirical evidence on the potential impact of differential (informative) missingness on our results. We intend to maintain transparency and report all results accordingly. Interpretations based on our findings will be presented in the context of our assessments of missing data.

## 10 Key Study Milestones

The select dates below represent the expected data collection timeline and is subject to change. Legally contracted study milestones are included in the HPI contract with PCORI and are closely monitored by the PCORI Program Office.

| **Historical Cohort Data Collection** | **Expected completion date** |
|---|---|
| Historical Cohort data submission from clinics to MNCM | Sep 15, 2021 |
| Historical Cohort patient interviews | Aug 15, 2021 |
| Historical Cohort patientIDs verified with payors (multi-step process) | Nov 30, 2021 |
| Historical Cohort patient surveys | Dec 15, 2021 |
| Historical Cohort utilization data assembled and returned to MNCM | Dec 31, 2021 |
| Preliminary Historical Cohort dataset assessment | June 1, 2022 |
| Final Historical Cohort dataset available for analysis | July 1, 2022 |
| | |
| **Primary Cohort Data Collection** | |
| Primary Cohort data submission from clinics to MNCM | June 15, 2022 |
| Primary Cohort patient interviews | April 15, 2022 |
| Primary Cohort patientIDs verified with payors (multi-step process) | Aug 31, 2022 |
| Primary Cohort patient surveys | Nov 15, 2022 |
| Primary Cohort utilization data assembled and returned to MNCM | May 1, 2023* |

| | |
|---|---|
| Preliminary Primary Cohort dataset assessment | Aug 1, 2023 |
| Final Primary Cohort dataset available for analysis | Nov 1, 2023 |

**Time gap is for utilization data to accrue for approximately 12 months from date of CC enrollment*

| **Other data collection** | |
|---|---|
| Organizational survey and clinic descriptors table | Nov 1, 2021 |
| Care Coordinator and Clinician/Leader Interviews (Phase 1) | Oct 1, 2021 |
| Care Coordinator Survey | April 15, 2022 |
| Patient, Care Coordinator, and Clinician/Leader Interviews (Phase 2) | Dec 31, 2023 |

| **Analysis and Dissemination** | |
|---|---|
| All data analyses complete for all study aims | April 30, 2024 |
| Draft Final Research Report submitted to PCORI | June 30, 2024 |

# 11 Study Team Organization

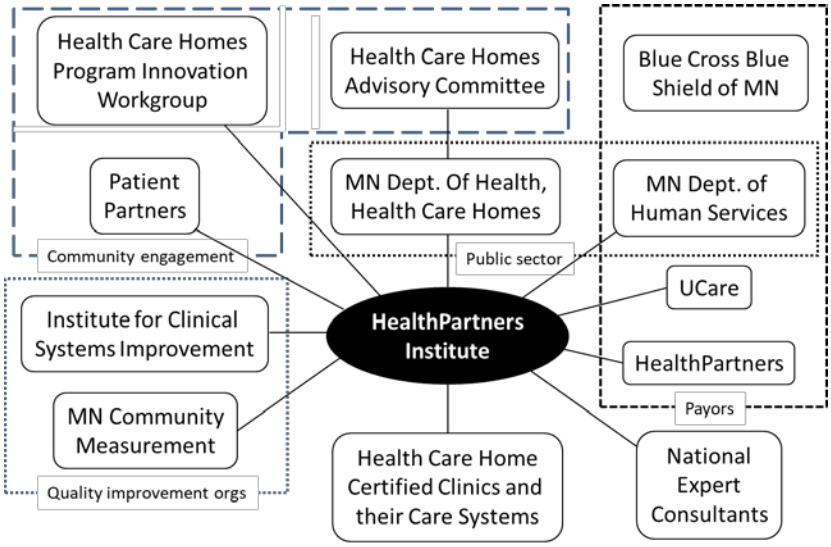
The study will be led by the co-Principal Investigators (Leif Solberg, MD and Steven Dehmer, PhD) with the assistance of a Principal Project Manager (Anna Bergdall, MPH). They will meet weekly along with additional project managers as a Core Team to plan every aspect of the study. Their plans and questions will be discussed in a biweekly Executive Team that includes leaders from the main partner organizations (MNCM and MDH) as well as a patient partner and a rotating member of the investigator team. Major concerns, progress, and decisions will also be reviewed at a quarterly meeting of the Steering Committee (which includes representatives of every collaborating organization, all patient partners, all consultants, and all co-investigators). Implementation of those plans will occur through standing and ad hoc work groups, including an operations committee for the three principal organizations, a survey/interview committee, an analysis committee, and a dissemination/publication committee. See Appendix G for a complete study team organizational chart.

# 12 Engagement Plan

This study is led by HealthPartners Institute in collaboration with MDH, Minnesota Community Measurement (MNCM), a statewide nonprofit for public reporting on standardized performance measures, the MN Department of Human Services (DHS), payor partners including HealthPartners, UCare, Blue Cross Blue Shield of MN (BCBS), and ICSI. This collaboration ensures wide dissemination of learnings throughout the state and that the findings, which will also be broadly applicable outside of MN, can be shared nationally by leveraging each partner's national networks.

From the beginning of the proposal planning, we have involved our major partners (MDH HCH program and MNCM) and patient investigators in all planning and will continue to do so through their participation in the Executive Committee and relevant subgroups. In order to foster awareness and engagement by them and all other collaborators in this large complex project, we have included everyone in **Figure 6** below in a Steering Committee that meets quarterly and are sending them monthly email updates of study progress, both with opportunities to provide input. Most are also participants in other subgroups and committees relevant to their roles and expertise. In order to assure broad stakeholder input, one PI is a member of the HCH Advisory Committee that includes patients, care system and payor leaders and other community representatives. We are particularly interested in having the clinics feel engaged, so we held a kickoff webinar for them and will distribute updates regularly through the newsletters of the HCH program and MNCM that reach every care system

**Figure 6: Study Partners**




participant. Finally, qualitative interviews with care system leaders are part of our data collection plan at two points in the study.

## 12.1 How patients and stakeholders have been involved in the selection of study outcomes

Patient co-investigators and organizational partners were involved in proposal development, including the study outcomes and in the several major revisions that have occurred since being awarded. Input has been obtained through meetings, individual outreach, and emailed edits to the materials. We also reviewed the outcome measures for this project with the multi-stakeholder Advisory Committee for the HCH program, which includes representatives of consumers, clinics, payers, employers, and others. We will continue to obtain ongoing input from patients and stakeholders on study outcomes.

## 12.2 Capabilities of the Research Team to Accomplish the Goals of the Proposed Research

The core team at HPI are supported by key research consultants, including Dr. Whitebird, a professor and mixed-methods research expert who worked as a care coordinator early in her career and has an in depth understanding of that role and responsibility. We also have Dr. Benjamin Crabtree, an

internationally renowned leader of qualitative and mixed methods studies at Rutgers Medical School, Dr. Glyn Elwyn, senior scientist at Dartmouth who is the world leader of shared decision-making and developer of both the CollaboRATE survey measure of shared decision-making and the IntegRATE survey measure of care coordination, both from the patient's perspective.[41,42,68] He works with Dr. Eugene Nelson, a leading authority on patient-reported outcomes and patient engagement and a long-term colleague. They are joined by a key new important consultant, Dr. Kathryn McDonald, an expert on coordination measures frameworks and leader in development of the AHRQ Care Coordination Measures Atlas as well as Dr. Sarah Hudson Scholle, director of research for the National Committee for Quality Assurance (NCQA).

Our investigator team is rounded out and greatly enhanced by our three patient and one family member co-investigators who bring diverse perspectives and experiences with the medical system. They have participated in the development of this proposal from the beginning and will be involved in every project committee or workgroup and every important decision.

# 13 Ethics and Human Subjects Protections

## 13.1 Institutional Review Board

Research activities at all study sites (HPI, MNCM, and MDH) is overseen by HealthPartners Institutional Review Board (IRB) FWA# 00000106, 8170 33rd Ave S, MS 23301A, Bloomington MN 55425.

## 13.2 Protected Health Information (PHI) and sources of data

All necessary data to determine patient-level study inclusion and evaluate care quality and utilization outcomes in the two patient cohorts are derived from EHR and claims data that will be reported by clinics and payors to MNCM. See **Appendices A and C** for detailed descriptions of the PHI provided by clinics and plans to MNCM for this purpose. All transfers of PHI to MNCM will be done under appropriate data agreements between MNCM and participating clinics and payors. MNCM will provide HPI with a final fully de-identified final dataset for research analysis; the HPI study team will not have access to the PHI used to construct the final research datasets.

Minimum necessary patient identifying information on a sampled sub-set of each patient cohort (n=3,000 Historical Cohort, n=7,000 Primary Cohort) will be provided by MNCM to CESR to conduct patient surveys to determine patient-reported outcomes. PHI for this purpose includes name, contact information, and clinic. All qualitative interviews with patients will be done on an opt-in basis with informed consent and will be used to help determine survey constructs and interpret study findings. CESR will provide HPI with a fully de-identified dataset for each survey collection to the HPI study team. Care coordinator surveys, care coordinator interviews, and clinician/leader interviews will not involve PHI. Instead, these data will provide professional information about organizations, workflows, responsibilities, and care models. However, all data collection with care coordinators, clinicians, and leaders will be collected with informed consent and only the minimum necessary study team staff will have access to the identifiable data. HPI study team members outside of CESR staff will not have any access to PHI used for any of the described purposes.

Detailed information about recruitment, sampling, and data collection for each of these data sources can be found in Sections 4 and 5.

## 13.3 Potential risks to subjects

This study does not involve any interventions. Potential risks to subjects relate primarily to loss of privacy and confidentiality. Privacy loss could occur during PHI transfers from clinics to MNCM, between MNCM and payor partners, or from MNCM to CESR. Privacy loss could also occur through survey and interview data collection. Measures to minimize these risks are discussed below.

## 13.4 Adequacy of protection against risks

### 13.4.1 Protection of Informed Consent

#### 13.4.1.1 EHR, care quality, and claims data collection

This study will plan to operate under a waiver of documentation of informed consent for patients for the use of EHR-derived and claims data for the following reasons:

1. Data exchanged for use in this study does not present more than minimal risk of harm to subjects and is exchanged between clinics, payors, and MNCM under legal data privacy agreements and under rigorous data security protocols;
2. The principal risk of data collection in this study is breach of confidentiality;
3. The inclusion of patients in the study dataset by clinics is based on participation in care coordination during specified time periods, and would be impractical to obtain written informed consent; and
4. The study will provide pertinent information for informed consent for the sub-set of patients receiving surveys and/or participating in interviews.

#### 13.4.1.2 Patient Surveys

Patient survey respondents will consent to the surveys through an affirmation demonstrated by survey completion. The patient survey will be mailed with a cover letter explaining elements of informed consent for completion of the survey, which will include pertinent information about the broader study. A completed survey indicates consent to use the survey data for research.

#### 13.4.1.3 Care Coordinator and Organizational Surveys

Care coordinator surveys will be distributed with a cover letter outlining all elements of consent, but they will not be asked to sign a formal consent statement or form. The care coordinator survey data will be used primarily as a means to collect factual information about how care coordination is implemented specifically in each clinic. However, these employees will be assured of their privacy.

Organizational surveys will not be distributed with elements of informed consent. The organizational survey data will be used primarily as a means to collect factual information about care models and organizational information across participating care systems.

For both surveys, the respondents are not research subjects, but instead are leaders participating in the survey as a means of partnership with the study team on behalf of their clinic or organization.

#### 13.4.1.4 Semi-Structured Interviews

A verbal consent process will be conducted for the collection of all patient, care coordinator, and clinician/leader interviews. Only respondents who verbally consent to participate will be interviewed and included in the dataset. All verbal consent will be outlined in interviewer scripts and documented by study staff in the appropriate method-specific tracking system.

### 13.4.2 HIPAA protections

HIPAA makes a special provision for a waiver of HIPAA authorization to use PHI for research under certain conditions (the HIPAA Privacy Rule), which this study meets.

Specifically in this study, PHI will only be disclosed to MNCM under existing business associate or DUAs, which outline privacy regulation between MNCM, clinics, and payors in compliance with HIPAA regulations. Entities exchanging data with MNCM for this study will be responsible for assuring privacy measures are properly followed. Additionally, PHI sent by MNCM to CESR for the purpose of facilitating survey data collection will be done under an appropriate DUA and will only be accessible to the recipient of that data and CESR staff.

The final research dataset provided by MNCM to HPI will be fully de-identified per Privacy Rule definitions and will therefore no longer require HIPAA protection. Still, an appropriate data use agreement will be made for receipt of the final de-identified dataset to safeguard protection of patient privacy.

### 13.4.3 Protection of confidentiality and data security

The study team has extensive experience in health services research and clinical research with human subjects, with procedures to safeguard privacy and personal information. All study records are protected by:

1. Use of untraceable studyID numbers instead of names wherever possible
2. Password protection as well as firewalls
3. Strong user login authentication on all electronic devices
4. Physical security for all electronic devices containing personal information
5. Locked storage for all paper records in a secure location

Data will be retained in secure storage following the completion of the study in accordance with Minnesota and federal law. We guard against the potential for breach of subject confidentiality through a multi-layered system of data protection policies, processes, staff training, software safeguards and

physical security measures for both paper and electronic data involved in research, at both MNCM, CESR, and HPI.

The following measures will be taken to protect subjects from the risk of breach of confidentiality at both MNCM, CESR, and HPI:

1. All data collected in the study will be identified by using an arbitrary and unique studyID number to each patient.
2. A file containing a link between the studyID and individually identifying information will be maintained at by a study team programmer at MNCM through the conclusion of the study.
3. A cross-walk table linking the studyID to a patient identity will be destroyed within 6 months after the linked databases needed to complete study analyses are completed.
4. All electronic study data will be maintained in a computerized database residing on a username- and password-protected file-server to which only the study team members will have access.
5. All study-related paper documents containing individually identifiable information will be maintained in locked file cabinets.

For protection of confidentiality of semi-structured interview participants, we will follow all of the above measures, which also apply to audio recordings and transcripts.

To protect the confidentiality of any clinic or organization employee participating in a survey, we will not allow anyone outside of the research team to know the identity of those respondents. All of the protection to electronic data sources, described above, also apply to survey collection.

## 13.5 Potential Benefits of the Proposed Research to Human Subjects and Others

Patients in the study will have no defined personal benefit from participating in this project. Compensation for the time to complete surveys and interviews will be minimal but appropriate according to effort involved with participation. All patients receiving a survey following enrollment will receive a small $2 non-contingent incentive with the survey to increase response rates. Patients completing a survey will receive another $10 gift card for their time. Interview participants will be offered compensation of a $35 gift card for their time.

## 13.6 Importance of knowledge to be gained

To date, no study has been able to compare models of care coordination in the systematic way described in this protocol. If the study reveals that one care coordination model results in better outcomes, then MDH and care systems can focus on promoting use of that care coordination model. If the study does not reveal better outcomes in one care coordination model over the other, then MDH and care systems can focus on optimal implementation of each care system's chosen model. Ultimately, the knowledge in this study will guide future implementation of care coordination and will serve as a resource to care systems in other settings as can use evidence about effectiveness to guide care coordination programs.

## 13.7 Inclusion and Accessibility

### 13.7.1 Inclusion of Women

All eligible patients utilizing care coordination services at a participating clinic will be included, so women should be included in the same proportion as they have those criteria and receive care in the study clinics. Preliminary data suggests that approximately 62% of patients receiving care coordination services are women. It is also likely that the great majority of care coordinators and other clinic personnel will also be women.

### 13.7.2 Inclusion of Ethnic and/or Racial Minorities

All eligible patients utilizing care coordination services at a participating clinic will be included, so ethnic and racial minorities should be included in the same proportion as they have those criteria and receive care in the study clinics. No one will be excluded based on language spoken. Surveys will be administered to Spanish, Hmong and Somali-speaking patients by CESR bilingual interviewers. Patients that speak languages other than English and the three non-English languages most common across the state will be facilitated using a third-party language line. Inclusion is important because one of the possible outcomes from our analysis of this study's data is an evaluation of any racial or ethnic disparity in participation or outcomes of care coordination.

### 13.7.3 Inclusion of Children

Children will not be included in this study, because the proportion of children with multiple chronic conditions or high complexity is too low to provide a sample large enough to analyze without selective recruiting that is incompatible with the way we have developed to obtain patient data.

### 13.7.4 Other Special Populations

The patient data will include all adults cared for in the study clinics who received care coordination services and have health insurance coverage from one of our participating payors, which includes the MN DHS that oversees coverage for all Medicaid patients in the state. Therefore, subjects will include all population groups in proportion to their representation in these clinics and with those conditions/needs. In particular, it will include persons with complex medical conditions, high social needs, the elderly, and minorities, because those are the types of patients most likely to be referred for care coordination services.

# 14 Data Safety and Monitoring Plan

The Principal Investigators (PIs) are responsible for monitoring the data and assuring protocol compliance.

Because this is an observational study (no intervention involved), risks to patients are minimal and involve the risk of violation of confidentiality of their identity (revealing that the patient utilized care coordination services) or of their care quality, utilization, or survey-provided information to

organizations who already maintain or exchange such information about the study patients. Risks to care coordinators and other clinic personnel who will be interviewed are similarly minimal, because they will not be asked about any personal information, only about the way that the care coordination process functions in their clinic and their recommendations about ways that it might be improved.

Several strategies will be employed to protect against risks to patients. First and foremost, we will employ the "minimum necessary" principal to only collect or use sensitive or personally identifiable information as necessary to conduct the study. Core identifying data will include the patient's name, date of birth, and plan member ID—which are data elements routinely shared among all the data partners for operational purposes. By design, the study analysis team will only receive de-identified data. In addition, data systems implemented for exchanging data will employ technical security measures of the partner with the most stringent security requirements. For clinic personnel, it is less feasible to completely de-identify their information, because it is important for the analysis that we retain a linkage between their information and their clinic and position in the clinic, but we can anonymize their identity and avoid asking any questions about their views or personal health information that could put them at risk.

Adverse events or other problems are not anticipated. In the unlikely event that such events occur, the PIs are responsible for reporting to the IRB and any appropriate funding and regulatory agencies any serious, unanticipated and related adverse events or unanticipated problems involving risks to subjects or others. The study's funder (PCORI) and the HealthPartners' IRB will be informed of adverse events within 10 working days of the event becoming known to the PIs. The PIs or the IRB have the authority to stop or suspend the study or require modifications.

# 15 Publication and Data Sharing Policy

## 15.1 Publication and Presentation Policy

The following policies and procedures are designed to facilitate more good publications and presentations, fewer presentations that don't lead to publications, and inclusion of as many project-associated personnel as co-authors as possible.

### 15.1.1 Publication and Presentation Policy Goals

1. To encourage publication of as many good papers in indexed journals as possible
2. To limit presentations to co-existing papers or to audiences that will use the information
3. To assure inclusion, fairness, and appropriate recognition and acknowledgements
4. To control project analytic resource use for addressing priority project aims
5. To prevent inappropriate, duplicate, or conflicting statements or use of data

### 15.1.2 Publication and Presentation Policy Process

1. The Executive Team will establish policies and procedures, suggest key needed articles, coordinate use of project resources, and resolve conflicts

2. Anyone wishing to take the lead on writing an article (or making a presentation) that uses study data or concepts should submit a very brief abstract (see below) to the PI for review
3. Any academic conference presentation should be viewed as a complement to a publication submission, either before or after the presentation
4. After review, proposed abstracts will be circulated to all interested parties, so anyone who might want to be included or to suggest changes can do so. Thereafter the lead author becomes the chair of that paper-writing group.
5. Both the original abstract and the final draft article must be approved by the Executive Team or a PI before submission
6. The first author is the one who prepares the initial draft, coordinates the input and contributions of co-authors, and has the last word in any differences of opinion. Co-authors are in approximate order relative to contribution as decided by the first author
7. The success of MNCARES depends on many people, so we should err on the side of including anyone who wants to be a co-author, subject to #8 below.
8. Requirements for being listed as a co-author are from the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" from the International Committee of Medical Journal Editors (ICMJE) and can be accessed at the following website: http://www.icmje.org/about-icmje/faqs/icmje-recommendations/
   All 4 of the following conditions must be met:
   1. Substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work;
   2. Drafting the work or revising it critically for important intellectual content;
   3. Final approval of the version to be published;
   4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

   Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is also not sufficient for authorship.
9. Any potential co-author who does not respond to requests for reactions to drafts or the final version of the paper in a timely way will be assumed to no longer wish to participate in authorship
10. PCORI (PO, PA, CA) must be notified promptly about any accepted papers and pre-print and final copies should be submitted through the Publications section of the PCORI Online Portal. All papers must acknowledge grant support and use the following notation:

    *"This work was supported through a Patient-Centered Outcomes Research Institute (PCORI) Project Program Award (IHS-2019C1-15625). All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the official views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee."*

11. Most papers should err on the side of over-acknowledging the clinics, organizations, and people who contributed to the paper's content

### 15.1.3 Publication and Presentation Policy Roles and Responsibilities

Roles and Responsibilities of Writing Team members include:

| | |
|---|---|
| **Lead Author** | • Submitting/revising the proposal abstract<br>• Identifying interested potential co-authors and making the final decision on which have satisfied the ICMJE requirements<br>• Identification of a realistic submission date goal<br>• Progress on meetings and paper drafts<br>• Developing the first draft of the paper<br>• Coordinating with appropriate staff to integrate data findings<br>• Scheduling and facilitating calls/meetings, as needed<br>• Distributing drafts to the writing team for input<br>• Making sure the final draft is copy-edited (Ann Harste to assist) |
| **Co-Author** | • Contributing ideas and references, not just copy-editing<br>• Responding to each draft distribution within the requested time |
| **Mentor** | When an investigator is the first author but has limited experience with publication, they should identify a mentor who can coach and/or support them in the development and completion of the manuscript in a timely way |
| **Co-PIs & Executive Team** | Responsible for approving proposal abstracts, prioritizing papers, identifying co-authors, and monitoring progress. |

### 15.1.4 Abstract for Proposed Publications and Presentations

Abstracts for proposed publications and presentations should describe the following elements:

1. Descriptive title and date
2. Main goal, question, or hypothesis to be addressed in the paper
3. Brief rationale and description of analyses
4. Data needed
5. Lead author and tentative co-authors
6. Audience and journal targeted
7. Target date for submission

## 15.2 Key Journal Publication milestones

1. Proposal submission to the PIs
2. Proposal approval
3. First draft to co-authors
4. Submission to a journal
5. Journal decision
6. Resubmissions
7. Acceptance
8. Publication

## 15.3 Making Research findings Publicly Available

### 15.3.1 Public Summary of Findings

Besides our primary outcomes paper, we will also produce a summary of research findings for patients and the general public in order to convey our findings in a "comprehensible and useful manner to patients and providers to use in making health care decisions." PCORI and our patient co-investigators and advisory group will help us to develop the summary and ensure that it is available in public-access format.

### 15.3.2 Public Access to Journal Articles

An electronic copy of the final peer-reviewed publication of our primary outcomes will be submitted to the National Library of Medicine's PubMed Central to be made available publicly. Costs for this are provided by PCORI.

### 15.3.3 Presentations and PCORI-initiated Events

We will attend PCORI meetings or other events to present research findings as requested by PCORI. Expenses for these trips will be covered by PCORI.

### 15.3.4 Other public and professional dissemination

Our imperative will be to provide any useful information to the care systems, insurers, and other organizations that want to improve the effectiveness, efficiency, and patient-centeredness of their own care coordination efforts. Most of these organizations in the MN area are active collaborators in the proposed study, so they are very interested in using the findings. Most importantly, the HCH Program will certainly put the lessons to use in their certification and recertification relationships with all certified HCH clinics and those applying for certification in the future. Besides individual contacts and visits, this program also has an annual learning day event that brings together representatives from all certified clinics and this topic will be a major focus for these events during and after the grant. ICSI (our regional quality improvement organization with most payors as sponsors and most large care systems as members) has many ways to communicate with most of the clinics in the region (bordering states as well as MN), and because they are also a founding member of the Network for Regional Healthcare Improvement (30 member organizations nationally), they will be able to disseminate the lessons widely.

Finally, we expect that our health system and state government collaborators will be eager to make use of the lessons that they have been part of producing. Hopefully, that will include modifications in the current rules for clinic certification as well as better payment for the most effective kinds of care coordination.

## 15.4 Making study results available to study participants after completing analyses

There are two kinds of study participants – patients and care system members. During the patient survey, we will ask if the respondent would like to receive a focused lay-language report of our findings

that are most relevant to patients and send them such by email. Our patient partners will assist in developing this and other ways to disseminate the information to patients and the community in a way that is meaningful for them. For example, one of our patient partners has his own radio program. We have promised participating care systems that we will provide them with their results in relation to the average so that they can see how their clinics compare. We will also provide citations or links to published papers and summaries of the most pertinent lessons, especially those that would help them in making decisions about improving care coordination. We also plan to make use of our many stakeholders and advisory groups to identify those lessons of most interest.

# 16 References


1. Glynn LG, Valderas JM, Healy P, et al. The prevalence of multimorbidity in primary care and its effect on health care utilization and cost. *Fam Pract.* 2011;28(5):516-523.
2. Tinetti ME, Fried TR, Boyd CM. Designing health care for the most common chronic condition--multimorbidity. *JAMA.* 2012;307(23):2493-2494.
3. Fortin M, Lapointe L, Hudon C, Vanasse A, Ntetu AL, Maltais D. Multimorbidity and quality of life in primary care: a systematic review. *Health Qual Life Outcomes.* 2004;2:51.
4. Read JR, Sharpe L, Modini M, Dear BF. Multimorbidity and depression: A systematic review and meta-analysis. *J Affect Disord.* 2017;221:36-46.
5. Sharma MA, Cheng N, Moore M, Coffman M, Bazemore AW. Patients with high-cost chronic conditions rely heavily on primary care physicians. *J Am Board Fam Med.* 2014;27(1):11-12.
6. Penm J, MacKinnon NJ, Strakowski SM, Ying J, Doty MM. Minding the Gap: Factors Associated With Primary Care Coordination of Adults in 11 Countries. *Ann Fam Med.* 2017;15(2):113-119.
7. McDonald KM, Sundaram V, Bravata DM, et al. *Care Coordination.* Rockville, MD: Stanford University-UCSF Evidence-based Practice Center;2007. 04(07)-0051-7.
8. Ovretveit J. *Does clinical coordination improve quality and save money?* London2011.
9. Backhouse A, Ukoumunne OC, Richards DA, McCabe R, Watkins R, Dickens C. The effectiveness of community-based coordinating interventions in dementia care: a meta-analysis and subgroup analysis of intervention components. *BMC Health Serv Res.* 2017;17(1):717.
10. Conway A, O'Donnell C, Yates P. The Effectiveness of the Nurse Care Coordinator Role on Patient-Reported and Health Service Outcomes: A Systematic Review. *Eval Health Prof.* 2017:163278717734610.
11. Dy SM, Apostol C, Martinez KA, Aslakson RA. Continuity, coordination, and transitions of care for patients with serious and advanced illness: a systematic review of interventions. *Journal of palliative medicine.* 2013;16(4):436-445.
12. Falconer E, Kho D, Docherty JP. Use of technology for care coordination initiatives for patients with mental health issues: a systematic literature review. *Neuropsychiatr Dis Treat.* 2018;14:2337-2349.
13. Gorin SS, Haggstrom D, Han PKJ, Fairfield KM, Krebs P, Clauser SB. Cancer Care Coordination: a Systematic Review and Meta-Analysis of Over 30 Years of Empirical Studies. *Ann Behav Med.* 2017;51(4):532-546.
14. Kroll-Desrosiers AR, Crawford SL, Moore Simas TA, Rosen AK, Mattocks KM. Improving Pregnancy Outcomes through Maternity Care Coordination: A Systematic Review. *Women's health issues : official publication of the Jacobs Institute of Women's Health.* 2016;26(1):87-99.
15. Snaterse M, Dobber J, Jepma P, et al. Effective components of nurse-coordinated care to prevent recurrent coronary events: a systematic review and meta-analysis. *Heart.* 2016;102(1):50-56.

16. Tricco AC, Antony J, Ivers NM, et al. Effectiveness of quality improvement strategies for coordination of care to reduce use of health care services: a systematic review and meta-analysis. *CMAJ.* 2014;186(15):E568-578.
17. Weaver SJ, Che XX, Petersen LA, Hysong SJ. Unpacking Care Coordination Through a Multiteam System Lens: A Conceptual Framework and Systematic Review. *Med Care.* 2018;56(3):247-259.
18. Craig C, Eby D, Whittington J. *Care coordination model: better care at lower cost for people with multiple health and social needs.* Cambridge MA: Institute for Healthcare improvement;2011.
19. Social determinants of health 101 for health care: five plus five. National Academy of Medicine; 2017.
20. Daniel H, Bornstein SS, Kane GC, Health, Public Policy Committee of the American College of P. Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An American College of Physicians Position Paper. *Ann Intern Med.* 2018;168(8):577-578.
21. Katz A, Chateau D, Enns JE, et al. Association of the Social Determinants of Health With Quality of Primary Care. *Ann Fam Med.* 2018;16(3):217-224.
22. Kaufman A. Theory vs Practice: Should Primary Care Practice Take on Social Determinants of Health Now? Yes. *Ann Fam Med.* 2016;14(2):100-101.
23. Solberg LI. Theory vs Practice: Should Primary Care Practice Take on Social Determinants of Health Now? No. *Ann Fam Med.* 2016;14(2):102-103.
24. Garg A, Boynton-Jarrett R, Dworkin PH. Avoiding the Unintended Consequences of Screening for Social Determinants of Health. *JAMA.* 2016;316(8):813-814.
25. Williams DR, Costa MV, Odunlami AO, Mohammed SA. Moving upstream: how interventions that address the social determinants of health can improve health and reduce disparities. *J Public Health Manag Pract.* 2008;14 Suppl:S8-17.
26. Soderberg K, Rajamani S, Wholey D, LaVenture M. Health Reform in Minnesota: An Analysis of Complementary Initiatives Implementing Electronic Health Record Technology and Care Coordination. *Online J Public Health Inform.* 2016;8(3):e204.
27. Shippee ND, Finch M, Wholey DR. Assessing medical home mechanisms: certification, asthma education, and outcomes. *Am J Manag Care.* 2018;24(3):e79-e85.
28. McDonald KM, Schultz E, Albin L, et al. *Care Coordination Measures Atlas Version 4.* Rockville, MD: AHRQ;2014.
29. McDonald KM, Sundaram V, Bravata DM, et al. In: *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 7: Care Coordination).* Rockville (MD)2007.
30. National Quality Forum. *Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for the Health Workforce* Washington, DC: National Quality Forum;2014.
31. National Quality Forum. *NQF-Endorsed Measures for Care Coordination: Phase 3, 2014 (Technical Report).* Washington, DC: National Quality Forum;2014.
32. National Quality Forum. *Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination.* Washington, DC: National Quality Forum;2010.
33. Schultz EM, Pineda N, Lonhart J, Davies SM, McDonald KM. A systematic review of the care coordination measurement landscape. *BMC Health Serv Res.* 2013;13:119.
34. AHRQ. *Care Coordination Measure for Primary Care Survey.* Rockville MD2016.
35. Donabedian A. The quality of care. How can it be assessed? *JAMA.* 1988;260(12):1743-1748.
36. McDonald KM, Schultz E, Chapman T, et al. *Prospects for care coordination measurement using electronic data sources.* Rockville, MD: Agency for Healthcare Research and Quality;2012. AHRQ Publication No. 12-0014-EF.
37. Solberg LI, Carlin CS, Peterson KA, Eder M. Certification as a medical home: does it make a difference in diabetes care. *Ann Fam Med.* 2019 (in review).

38. Fowler FJ, Jr. *Improving Survey Questions, Design, and Evaluation.* Thousand Oaks CA: Sage Publications; 1995.
39. Scholle SH, Vuong O, Ding L, et al. Development of and field test results for the CAHPS PCMH Survey. *Med Care.* 2012;50 Suppl:S2-10.
40. Stucky BD, Hays RD, Edelen MO, Gurvey J, Brown JA. Possibilities for Shortening the CAHPS Clinician and Group Survey. *Med Care.* 2016;54(1):32-37.
41. Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: a fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns.* 2013;93(1):102-107.
42. Elwyn G, Thompson R, John R, Grande SW. Developing IntegRATE: a fast and frugal patient-reported measure of integration in health care delivery. *International journal of integrated care.* 2015;15:e008.
43. Fryer AK, Friedberg MW, Thompson RW, Singer SJ. patient perceptions of integrated care and their relationship to utilization of emergency, inpatient and outpatient services. *Healthc (Amst).* 2017;5(4):183-193.
44. Wisdom J, Creswell JW. *Mixed Methods: Integrating Quantitative and Qualitative Data Collection and Analysis While Studying Patient-Centered Medical Home Models. AHRQ Publication No. 13-0028-EF.* Rockville, MD: Agency for Healthcare Research and Quality. February 2013.
45. Butler M, Epstein RA, Totten A, et al. AHRQ series on complex intervention systematic reviews-paper 3: adapting frameworks to develop protocols. *J Clin Epidemiol.* 2017;90:19-27.
46. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol.* 2008;61(4):344-349.
47. Gershon RC, Rothrock N, Hanrahan R, Bass M, Cella D. The use of PROMIS and assessment center to deliver patient-reported outcome measures in clinical research. *Journal of applied measurement.* 2010;11(3):304-314.
48. Zlateva I, Anderson D, Coman E, Khatri K, Tian T, Fifield J. Development and validation of the Medical Home Care Coordination Survey for assessing care coordination in the primary care setting from the patient and provider perspectives. *BMC Health Serv Res.* 2015;15:226.
49. Tran VT, Montori VM, Eton DT, Baruch D, Falissard B, Ravaud P. Development and description of measurement properties of an instrument to assess treatment burden among patients with multiple chronic conditions. *BMC medicine.* 2012;10:68.
50. Billioux A, Verlander K, Anthony S, Alley D. *Standardized screening for health-related social needs in clinical settings: the accountable health communities screening tool.* Washington, DC: National Academy of Medicine;2017.
51. Pearl J. Causal diagrams for empirical research. *Biometrika.* 1995(82):669-710.
52. Pearl J. *Causality: Models, Reasoning, and Inference, 2nd ed.* New York: Cambridge University Press; 2009.
53. Hernán M, Robins J. *Causal Inference.* Boca Raton: Chapman & Hall/CRC, forthcoming; 2019.
54. VanderWeele TJ, Ding P. Sensitivity Analysis in Observational Research: Introducing the E-Value. *Ann Intern Med.* 2017;167(4):268-274.
55. Rowe JM, Rizzo VM, Shier Kricke G, et al. The Ambulatory Integration of the Medical and Social (AIMS) model: A retrospective evaluation. *Soc Work Health Care.* 2016;55(5):347-361.
56. Steketee G, Ross AM, Wachman MK. Health Outcomes and Costs of Social Work Services: A Systematic Review. *Am J Public Health.* 2017;107(S3):S256-S266.
57. Duan N, Wang Y. Heterogeneity of treatment effects. *Shanghai Arch Psychiatry.* 2012;24(1):50-51.

58. Hernan MA, Hernandez-Diaz S, Robins JM. A structural approach to selection bias. *Epidemiology.* 2004;15(5):615-625.
59. Cole SR, Hernan MA. Constructing inverse probability weights for marginal structural models. *Am J Epidemiol.* 2008;168(6):656-664.
60. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology.* 2006;3(2):77-101.
61. Marshall C, Rossman GB. *Designing Qualitative Research, 5th edition.* 5th ed. Newbury Park: Sage Publications; 2011.
62. Saldana J. *The coding manual for qualitative researchers, 2nd edition.* 2 ed. Thousand Oaks, CA: Sage Publications; 2013.
63. Padgett DK. *Qualitative methods in social work research, 3rd edition.* 3 ed. Thousand Oaks, CA: Sage Publications Ltd.; 2017.
64. Lincoln YS, Guba EG. *Naturalistic Inquiry.* Newbury Park, CA: Sage; 1985.
65. Morse J, Barrett M, Mayan M, Olson K, Spiers J. Verification strategies for establishing reliability and validity in qualitative research. *International Journal of Qualitative methods.* 2002;1(2):13-22.
66. Rudolph KE, Stuart EA. Using Sensitivity Analyses for Unobserved Confounding to Address Covariate Measurement Error in Propensity Score Methods. *Am J Epidemiol.* 2018;187(3):604-613.
67. Vanderweele TJ, Arah OA. Bias formulas for sensitivity analysis of unmeasured confounding for general outcomes, treatments, and confounders. *Epidemiology.* 2011;22(1):42-52.
68. Elwyn G, Cochran N, Pignone M. Shared Decision Making-The Importance of Diagnosing Preferences. *JAMA internal medicine.* 2017.

# 17 Appendices

The below appendices represent currently developed study materials. Materials for future data collection events or any future changes to these instruments will be updated as amendments to the protocol once IRB approved.

## 17.1 Appendix A: Clinic Data Submission Specifications

*These data specifications are for identification of Care Coordination Cohorts as described in Section 5.1.1*
*Appendix A updated 6/10/21 with MNCM document Version 1.3*

### Clinical Data Preparations

Step 1: Identify those patients 18 years of age and older who had a care coordination start/enrollment date as follows:

- Historical Cohort: patients with start/enrollment date between 01/01/2018 to 02/28/2019
- Primary Cohort: patients with start/enrollment date between 01/01/2021 to 12/31/2021

Step 2: Pull the clinical data elements from your electronic systems and prepare two data files as specified in the tables below. Submit the data files during the following data submission periods by cohort:

- Historical Cohort data submission period: 06/14/2021 to 08/15/2021
- Primary Cohort data submission period: 3/15/2022 to 5/15/2022

➲Before you submit, remember to apply any appropriate research exclusion lists to exclude patients who have opted out of research in your organization.

### Data Elements & Field Specifications – Files 1 and 2

### File 1: Patient Demographic, Care Coordination Enrollment, Encounter Data

| Element Order | Field Name | Details | Required or Situational* | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| A | Patient ID | Enter the patient ID that is submitted for clinical quality data submission to MNCM. If your clinic has not submitted MRNs or a unique patient ID in past submissions, please contact support@mncm.org<br>• Unique patient identifier for clinic.<br>• DO NOT enter an SSN. | R | String; up to 50 characters | Blank fields |
| B | Patient First Name | Enter the first name of the patient. | R | Text | Blank fields |

| | | | | | |
|---|---|---|---|---|---|
| C | Patient Middle Name | Please enter the patient middle name or initial if it is recorded in the medical record. | S | Text | |
| D | Patient Last Name | Enter the last name of the patient. | R | Text | Blank fields |
| E | Patient Master Index (PMI) | This is a unique patient identification number that the Department of Human Services uses for previous and current Minnesota Health Care Program participants. | S | String; up to 50 characters | |
| F | Current Primary Insurance Member ID | Enter the most recent Member ID on file as of the date of the data pull.<br>• Unique patient identifier for health plan<br>• Do NOT enter an SSN; instead, enter "999" | R | String; up to 50 characters | Blank fields |
| G | Current Primary Insurance | Enter the most recent primary insurance on file as of the date of the data pull.<br>Please refer to a separate document entitled *Insurance Coverage Data Elements, Field Specifications &Codes* for field specifications. | R | Number; up to 2 digits | Blank fields<br>Values outside allowable range |
| H | Current Subscriber name | Enter the full name for the person that subscribes to the health plan. | S | Text | |
| I | Prior Primary Insurance Member ID | Enter the previous Member ID on file if obtainable.<br>• Unique patient identifier for health plan<br>• Do NOT enter an SSN; instead, enter "999". | S | String; up to 50 characters | |
| J | Prior Primary Insurance | Please refer to a separate document entitled *Insurance Coverage Data Elements, Field Specifications &Codes* for field specifications. | S | Number; up to 2 digits | Values outside allowable range |
| K | Prior Subscriber name | Enter the full name for the person that subscribed to the prior health plan. | S | Text | |
| L | Patient Date of Birth (DOB) | Must be age 18 years or older as of the start/enrollment date of care coordination (per AG below). | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| M | Patient Sex | F = Female<br>M = Male<br>U = Unknown/Undefined | R | Text; 1 character | Blank fields |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | Values outside allowable range |
| N | Patient Date of Death (DOD) | | S | mm/dd/yyyy or m/d/yyyy | |
| O | Patient Status | Enter the most recent patient status at the time of the data pull.<br>0 = Deceased<br>1 = Alive | S | Number; 1 digit | |
| P | Race1 | Enter the code that corresponds to the patient reported race. For patients who report more than one race, enter one code per field for each reported race, up to five. Do not submit the same code in multiple fields.<br>1 = American Indian or Alaska Native<br>2 = Asian<br>3 = Black or African American<br>5 = Native Hawaiian/Other Pacific Islander<br>6 = White<br>7 = Some other race/Patient does not identify with any of the race categories provided.<br>97 = Patient actively chose not to disclose/declined<br>98 = Patient reports that race is unknown.<br>If patient was not asked for their race or if race was left blank by patient, leave the fields blank. | S | Number; up to 2 digits | Values outside allowable range |
| Q | Race2 | | S | Number; up to 2 digits | |
| R | Race3 | | S | Number; up to 2 digits | |
| S | Race4 | | S | Number; up to 2 digits | |
| T | Race5 | | S | Number; up to 2 digits | |
| U | Ethnicity | Enter the code that corresponds to the patient-reported ethnicity<br>4 = Hispanic or Latino<br>8 = Not Hispanic or Latino<br>97 = Patient actively chose not to disclose/declined<br>98 = Patient reports that ethnicity is unknown<br>If patient was not asked for their ethnicity or if ethnicity was left blank by patient, leave the field blank. | S | Number; up to 2 digits | Values outside allowable range |

| | | | | | |
|---|---|---|---|---|---|
| V | Preferred Language | Enter the code that corresponds to the patient-reported preferred language. Please refer to a separate document entitled *RELC Data Elements, Field Specifications & Codes* for coding table. Additional options include:<br>97 = Patient actively chose not to disclose/declined<br>98 = Patient reports that preferred language is unknown.<br>99 = Patient reported preferred language does not match one of the available codes. Enter name of preferred language in *Preferred Language Other* field.<br>If patient was not asked for their preferred language or if preferred language was left blank by patient, leave the fields blank. | S | Number; up to 2 digits | Values outside allowable range |
| W | Preferred Language Other | If Element Position 12 = 99, submit preferred language. | S | String; up to 50 characters | |
| X | Country of Origin | Enter the code that corresponds to the patient-reported country of origin. Please refer to a separate document entitled *RELC Data Elements, Field Specifications & Codes* for coding table. Additional options include:<br>997 = Patient actively chose not to disclose/declined<br>998 = Patient reports that country of origin is unknown.<br>999 = Patient reported country of origin does not match one of the available codes. Enter name of country of origin in *Country of Origin Other* field.<br>If patient was not asked for their country of origin or if country of origin was left blank by patient, leave the fields blank. | S | Number; up to 3 digits | Values outside allowable range |
| Y | Country of Origin Other | If Element Position 14 = 999, submit country of origin. | S | String; up to 50 characters | |
| Z | Street Address | Patient's primary residence | R | String; up to 50 characters | Blank fields |

| | | | | | |
|---|---|---|---|---|---|
| AA | City | Patient's primary residence | R | String; up to 50 characters | Blank fields |
| AB | State | Standard two-character state abbreviation<br>Patient's primary residence | R | Text; 2 characters | Blank fields |
| AC | ZIP Code | Minimum of five digits<br>Patient's primary residence | R | Number | Blank fields<br>Values with less than five digits |
| AD | Primary Phone Number | Minimum of 10 digits | R | Number | |
| AE | Secondary Phone Number | Minimum of 10 digits | S | Number | |
| AF | Interpreter needed? | 0 = No<br>1 = Yes | S | Number | |
| AG | Start/enrollment date of care coordination | Enter the date that corresponds to the start of the patient's care coordination enrollment. | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| AH | Clinic ID from the start of care coordination enrollment | Enter the MNCM-assigned clinic ID associated with the start of the patient's care coordination enrollment. | R | Number; up to 4 digits | Blank fields |
| AI | Date of most recent care coordination encounter | Enter the date that corresponds with the patient's most recent care coordination encounter.<br>Type of encounter may be any of the following: office, phone, video, or home visit. | S | mm/dd/yyyy or m/d/yyyy | |
| AJ | Clinic ID from the most recent care coordination encounter | Enter the MNCM-assigned clinic ID associated with the patient's most recent care coordination encounter. | S | Number; up to 4 digits | |
| AK | Date of most recent encounter | Enter the most recent ambulatory encounter date, regardless of whether the visit was a care coordination visit. | S | mm/dd/yyyy or m/d/yyyy | |

| | | | | | |
|---|---|---|---|---|---|
| | | Type of encounter may be any of the following: office, phone, video, or home visit | | | |
| AL | Clinic ID from most recent encounter | Enter the MNCM-assigned clinic ID associated with the most recent ambulatory encounter. | S | Number; up to 4 digits | |
| AM | Count of care coordination encounters | Count of all care coordination encounters between the patient's start date (AG) and most recent care coordination encounter (AI)<br>Type of encounter may be any of the following: office, phone, video, or home visit. | S | Number; up to 3 digits | |

## File 2: Diagnosis Codes from Patient's Active Problem List

| Element Order | Field Name | Details | Required or Situational* | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| A | Patient ID | Enter the Patient ID that was submitted in File 1.<br>• Unique patient identifier for clinic.<br>• DO NOT enter an SSN. | R | String; up to 50 characters | Blank fields |
| B | Clinic ID from the start of care coordination enrollment | Enter the MNCM-assigned clinic ID associated with the start of the patient's care coordination enrollment. This is the same ID entered in the Demographic file, element order AH. | R | Number; up to 4 digits | Blank fields |
| C-AZ | Diagnosis Codes from Patient's Active Problem List | Enter all diagnosis codes (e.g., ICD-10) associated with the patient's active problem list. This includes diagnoses unrelated to the care coordination.<br>• All applicable characters, including decimals (e.g., E11.9)<br>• Up to 50 diagnoses may be submitted<br>• One code per field | R | String; up to 50 characters | Blank fields |

* Both Required (R) and Situational (S) data are relevant to and important for the study. Required data must be submitted and cannot be blank. Situational data is submitted if the clinic collects and can extract or obtain the information from their record system. Submit data for those patients when the information is available (e.g., secondary phone number). If the data was not collected or is not obtainable, the field can be left blank.

## 17.2 Appendix B: Clinical Quality Measures Collected by MNCM

*These measures define the Care Quality Outcomes as described in Section 5.1.2*

| Quality Measure category | Specific Measures |
|---|---|
| **Optimal Diabetes Care (Composite)** | HbA1c Control |
| | BP Control |
| | Tobacco-free |
| | Daily Aspirin/Antiplatelet Use |
| | Statin Use |
| **Optimal Vascular Care (Composite)** | BP Control |
| | Tobacco-free |
| | Daily Aspirin/Anti-platelets Use |
| | Statin Use |
| **Adult Depression Care Suite** | Six Month Remission |
| | Six Month Response |
| | Six Month Follow-up |
| | Twelve Month Remission |
| | Twelve Month Response |
| | Twelve Month Follow-up |
| | PHQ-9 Utilization |
| **Colorectal Cancer Screening** | |
| **Optimal Asthma Control - Adults (Composite)** | Well-controlled |
| | Low Risk of Exacerbation |

## 17.3 Appendix C: Payor Data Specifications

*These data specifications are for collection of Utilization Outcomes data as described in Section 5.1.3*

**General Rules for Administrative Claim files:**

- Date Range: One-year pre and post enrollment in Health Care Homes
- Time period is based on discharge date when applicable
- Payers should submit paid claims and final claims only (exclude denied claims)
- Partial facility claims are acceptable if the full claim is not available
- 
- *Notes: Medicare Cost Plan patients will not have hospital claims available*
- *Note: Pharmacy claims are not always available for commercial patients*
- *TBD: multiple payers for same patient*
- *Note: dollar amounts are for RVU study, not for a cost comparison*

# Enrollment Data File

Submit one record per patient per enrollment period. Patients may be listed in multiple rows if the enrollment was not continuous.

| Element Order | Who is responsible for supplying data? | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|---|
| A | MNCARES | Current Primary Insurance Member ID | • Unique patient identifier for health plan<br>• Do NOT use SSN. | R | String; up to 50 characters | Blank fields |
| B | MNCARES | Study ID | • Unique MNCARES assigned non-PHI study ID for patient. | R | String; up to 10 characters | Blank fields |
| C | MNCARES | Patient Master Index | • From Clinic Data File | S | | |
| D | MNCARES | Medical Record Number | • Unique patient identifier for clinic EMR<br>• Do NOT use SSN. | R | String; up to 50 characters | Blank fields |
| E | MNCARES | Patient First Name | Enter the first name of the patient. | R | String | Blank fields<br>Values outside allowable range |

| Element Order | Who is responsible for supplying data? | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|---|
| F | MNCARES | Patient Middle Name | Enter the middle name of the patient if available. | S | String | |
| G | MNCARES | Patient Last Name | Enter the last name of the patient. | R | String | Blank fields<br>Values outside allowable range |
| H | MNCARES | Patient Date of Birth (DOB) | | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| I | Health Plan | Product Type | • 1 = Commercial<br>• 5A = Medicare Advantage<br>• 5C = Medicare Cost<br>• 6 = MSHO<br>• 7A=Medicaid (MNCare)<br>• 7B=Medicaid (PMAP)<br>• 7C= Medicaid (Hennepin Health)<br>• 8= SNBC (Special Needs Basic Care) | R | String; 2 digits | Blank fields |
| J | Health Plan | Insurance Plan Enrollment Start Date | | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| K | Health Plan | Insurance Plan Enrollment End Date | | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| L | Health Plan | Pharmacy Data availability | 0=No<br>1=Yes<br>Is pharmacy data available in the plan data warehouse? | R | String; 1 digit | Blank fields |

## Professional Data File (HCFA 1500)

Standard claim form for physicians and other health care professionals.

Submit one line per patient per procedure claim. Patients may be listed in multiple rows for multiple procedure claims.

| Element Order | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| A | Study ID | • Unique MNCARES assigned non-PHI study ID for patient | R | String; up to 10 characters | Blank fields |
| B | Claim ID | | R | | Blank fields |
| C | Provider First Name | Enter the first name of the provider. | S | String | |
| D | Provider Middle Name | Enter the middle name of the provider if it is recorded in the medical record. | S | String | |
| E | Provider Last Name or Facility Name | Enter the last name of the provider. | R | String | Blank fields<br>Values outside allowable range |
| F | Provider Specialty Type | Enter the code that corresponds to the Provider's Specialty. Please refer to the *Standard Medicare Taxonomy Codes.* | R | String; up to 15 characters | Blank fields<br>Values outside allowable range |
| G | Clinic Site of Service | MNCM ID of clinic where encounter occurred | R | Number; up to 2 digits | Blank fields<br>Values outside allowable range |
| H | Start Date of service | | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| I | End Date of service | | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| J | Procedure Code | Enter the CPT/HCPCS code that corresponds to the procedure claim. Do not include modifiers. | R | String; 5 characters | Blank fields |
| K | Modifier(s) | | S | String; 8 characters | |
| L | Units | | R | | Blank fields |
| M | Billed Charges | To be used only for calculation of Relative Value | R | Number, 2 digits | |

## Facility Data File (UB04)

Hospital and Facility Header File, one line per admission or bundle of outpatient services.

| Element Order | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| A | Study ID | • Unique MNCARES assigned non-PHI study ID for patient | R | String; up to 10 characters | Blank fields |
| B | Claim ID | | R | | Blank fields |
| C | Facility Name | Facility Name | R | String | Blank fields<br>Values outside allowable range |
| D | Provider Specialty Type | Enter the code that corresponds to the Provider's Specialty. Please refer to the *Standard Medicare Taxonomy Codes.* | R | | |
| E | Bill Type | | R | String, 3 digits | |
| F | DRG | Inpatient only | S | String, 5 characters | |
| G | DRG Grouper | 1=MS DRG<br>2=APR DRG<br>3=All Other | R | String, 1 character | |
| H | Admission Date | | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| I | Discharge Date | | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| J | Billed Charges | To be used only for calculation of Relative Value | R | Number, 2 digits | |

## UB04 Detail File: Outpatient claims only

| Element Order | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| A | Study ID | Unique MNCARES assigned non-PHI study ID for patient | R | String; up to 10 characters | Blank fields |

| Element Order | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| B | Claim ID | | R | | Blank fields |
| C | Revenue Code | | R | String, 3 digits | Blank fields |
| D | Procedure Code | Enter the CPT/HCPCS code that corresponds to the procedure claim. | S | String, 5 digits | |
| E | Units | | R | Number, no digits | |
| F | Billed Charges | To be used only for calculation of Relative Value | R | Number, 2 digits | |

## Diagnosis Data File (HCFA and UB)

ICD10 diagnosis codes from both professional and facility claims. One line per diagnosis per claims. No limit to the number of diagnosis codes per claim.

| Element Order | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| A | Study ID | • Unique MNCARES assigned non-PHI study ID for patient | R | String; up to 10 characters | Blank fields |
| B | Claim ID | | R | | Blank fields |
| C | ICD-10 Diagnosis | All applicable characters, including decimals, MUST be included. One record per diagnosis code per claim. | R | String; up to 9 characters | Blank fields |

## ICD10 Procedure Data File (for UB04)

ICD10 procedure codes from inpatient UB04 claims. No limit to the number of procedures per claim.

| Element Order | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| A | Study ID | • Unique MNCARES assigned non-PHI study ID for patient | R | String; up to 10 characters | Blank fields |
| B | Claim ID | | R | | Blank fields |

| Element Order | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| C | ICD-10 Procedure Code | All applicable characters, including decimals, MUST be included. One record per procedure code per claim | S | String; up to 7 characters | Blank fields |

## Pharmacy Data File (take home Rx)

| Element Order | Field Name | Details | Required or Situational | Format/Field Length | Error Causes |
|---|---|---|---|---|---|
| A | Study ID | • Unique MNCARES assigned non-PHI study ID for patient | R | String; up to 10 characters | Blank fields |
| B | Claim ID | | R | | Blank fields |
| C | National Drug Code | | R | String; 11 digits | Blank fields |
| D | Drug Name | | R | | Blank fields |
| E | Fill Date | | R | mm/dd/yyyy or m/d/yyyy | Blank fields |
| F | Units | | R | String; up to 7 characters | Blank fields |
| G | Billed Amount | This will be used only for calculation of Relative Value | R | Number, 2 Digits passed decimal | |

## 17.4 Appendix D: Organizational Survey

*This survey will be collected via REDCap as described in Section 5.*

Thank you for taking the time to complete the following questions that will be used as part of the MNCARES research project. Together with clinic-level data, this information will be used to understand your approaches to care coordination for primary care patients and identifying other factors that might contribute to its effectiveness.
We realize that there may have been large changes recently due to COVID-19 or other factors, so please answer the questions as your medical group exists today. We have also included questions designed specifically to understand how the COVID-19 pandemic may have affected care coordination within your medical group, as well as future planned changes.
Please answer the questions as accurately as you can. If you are unsure of an answer, please provide an informed estimate. If you have any questions for us as you complete this, please contact [MNCARES Mailbox].

**Please select which medical group you are affiliated with [medical group] *required**

___ [drop down list with all medical group names]

**Which of the following best describes your role within your medical group? [role]**

___Clinician leader
___Care coordination leader
___Administrative leader (non-care coordinator)
___Other role, please specify: _____

**A: The following questions ask about your medical group's clinics and clinicians as of [date survey starts].**

**How many primary care clinics are there in your medical group? [cliniccount]**

_____

**How many clinics in your medical group are reported separately to MN Community Measurement? [clinicreport]**

_____

**How many clinics within your medical group are Health Care Home (HCH)-certified? [clinicHCH]**

_____

**How many hospitals are part of your medical group?**

_____

**Approximately how many adult primary care clinicians who provide patient care at least ½ time are there in your medical group? [adultPCP]**

_____

Of these, how many are MD/DOs? [adultPCP_MD] ____
How many are NP/PA advanced practice clinicians? [adultPCP_APC] ____

**Approximately how many <u>other clinicians</u> who provide non-primary care specialty services are there in your medical group? *For example, specialty physicians, dental professionals, NP or PA, etc.* [othercinician]**

_____

**<u>B: The following questions focus on how your medical group approaches care coordination for primary care patients at the current time.</u>**

**Across the primary care clinics in your medical group, approximately how many people are in the role of care coordinator [CCcount]?**

_____

**Approximately how many primary care patients in your medical group are <u>currently receiving</u> care coordination services? [Patientcount]**

_____

**On average, approximately how many patients in your medical group <u>begin receiving</u> care coordination services each month? (Please provide your best guess if a precise number is not known.) [Newpatients]**

_____

**What is the usual patient <u>case load</u> for a 1.0 FTE care coordinator? [caseload]**

_____

**Which of the following types of personnel are included on care coordination teams in your medical group? Please check all that apply.**

____ RNs
____ LPNs/CMAs
____ community health workers (CHW)
____ social workers
____ non-clinical staff
____ other, please specify: _____

**What percentage of patients receiving care coordination are "enrolled" for <u>ongoing care coordination services</u>? *As opposed to those who only have discrete or limited services (such as 1-2 calls/visits/reviews/etc.)* [percentenrolled]**

_____ %

**Does your medical group target any of the following <u>types of patients</u> for care coordination? (Please check all that are targeted).**

____ any patient that a clinician wants to have those services
____ patients transitioning between acute, post-acute and ambulatory care
____ patients that are particularly complex medically

____ patients with social or community resource needs
____ patients who might experience disparities by race, income, comorbidities, etc.
____ other (please explain) _____

**Do care coordinators in your medical group provide any of the following kinds of services? (Please check all that apply).**

____ facilitating medical/behavioral services by specialty providers
____ facilitating medical/behavioral services by primary care providers
____ transitional service needs (e.g. transitions in care or placement needs)
____ disease management services
____ patient education and health behavior counseling
____ financial needs assessment and referrals
____ mental health or emotional needs assessment and referrals
____ spiritual needs assessment and referrals
____ housing/transportation/food needs assessment and referrals
____referrals for other community resources
____ assistance finding culturally appropriate resources
____ other (please explain) _____

**Is any "tiering" or complexity tool used to assess the level of care coordination needed for individual patients? [tiering]**

____ yes, for all patients
____ yes, but only for some patients
____ no

**How many of the certified HCH clinics in your medical group currently have a social worker with dedicated time for care coordination activities at that clinic? *By social worker we mean someone with an educational degree in social work. This individual does not need to be a licensed social worker*. [clincSW] _____**

## C: Please answer the following questions about social workers with dedicated time for care coordination activities:

**[If more than one clinic in the organization clincSW >1], On average, how many clinics is each social worker assigned to? [SWcount] _____**

**[If one or more >=1 here and for rest of section], Does the social worker normally interact with individual patients to provide them with care coordination services? [SWpatient]**

____ yes
____ no

**Does the social worker normally interact with individual clinicians about their individual patients? [SWclinician]**

____ yes → If yes, are these interactions regularly scheduled or ad hoc?
____ no, social worker only provides general information about community resources or how to handle specific types of patient problems

**Does the social worker normally <u>work on site</u> at each assigned clinic at least 1 day/week? [SWonsite]**

____ yes, for all assigned clinics
____ for some, but not all assigned clinics
____ no

**Does your medical group bill any of the following <u>payment sources</u> for care coordination services? (Please check all that apply).**

____ Medicare
____ Medicaid/Medical Assistance/PMAP/MinnesotaCare
____ commercial insurance
____ specific ACO encounters/visits
____ patients (without insurance or out-of-pocket)
____ none
____ other (please explain) _____

**Does your medical group participate in any <u>Value Based/Risk Based contracts or Accountable Care Organization agreements</u> that include financial incentives for care coordination specifically? [ValueACO]**

____ Yes → If yes, (what % of your care coordination patients are in this category? [ValueACOper] _____%
____ No

**<u>D: Because we will be studying some patients who began receiving care coordination services in 2018, we want to know whether any aspect of the way your medical group currently provides care coordination was different in 2018. (*In case you have trouble recalling this time period, January 2018 was when Jan Malcom was appointed the commissioner of the Minnesota Department of Health).*</u>**

**Previously you told us that your medical group currently includes the following types of personnel on care coordination teams: [Pipe in response values from question above: Which of the following types of personnel are included on care coordination teams in your medical group?]. Was this different in 2018?**

**__Yes** → Which of the following types of personnel were included on care coordination teams in 2018? (check all that apply, use same response options as red question above]
**__No**

**<u>[If social worker in 2018],</u> In 2018, did the social worker normally <u>interact</u> with individual patients to provide them with care coordination services? [SWpatient]**

____ yes
____ no

**<u>[If social worker in 2018],</u> In 2018, did the social worker normally interact with clinicians about their individual patients? [SWclinician]**

____ yes → If yes, were these interactions regularly scheduled or ad hoc?

____ no, only provided general information about community resources or how to handle specific types of patient problems

**[If social worker in 2018], In 2018, did the social worker normally work on site at each assigned clinic at least 1 day/week? [SWonsite]**

____ yes, for all assigned clinics
____ for some, but not all assigned clinics
____ no

**Were there any other differences in the approach to care coordination in 2018 as compared to the current description in Sections B and C above? Please describe any other differences: *(e.g. how patients were enrolled, types of patients served, services provided, tools used to assess patient complexity, number of care coordinators, interactions with patients and/or care team, payment or anything else.)* [Approach2018]**

_____
_____

## We are interested in any major changes in approach to care coordination that may have occurred within your medical group since the onset of the COVID-19 pandemic in March 2020 or are planned for the future.

**Previously you told us that your medical group currently includes the following types of personnel on care coordination teams: [Pipe in values from red question above]. Has this changed since the onset of the COVID-19 Pandemic?**

__**Yes** → Which of the following types of personnel were included on care coordination teams prior to the onset of the COVID-19 Pandemic? (check all that apply, use same response options as red question above]
__**No**

**[If social worker included prior to COVID], Prior to the onset of the COVID-19 Pandemic, did the social worker normally interact with individual patients to provide care coordination services? [SWpatient]**

____ yes
____ no

**[If social worker included prior to COVID], Prior to the onset of the COVID-19 Pandemic, did the social worker normally interact with clinicians about individual patients? [SWclinician]**

____ yes → If yes, were these interactions regularly scheduled or ad hoc?
____ no, only provided general information about community resources or how to handle specific types of patient problems

**[If social worker included prior to COVID], Prior to the onset of the COVID-19 Pandemic, did the social worker normally work on site at each assigned clinic at least 1 day/week? [SWonsite]**

____ yes, for all assigned clinics
____ for some, but not all assigned clinics

____ no

**Are there any other <u>differences</u> in the approach to care coordination since the onset of the COVID-19 pandemic as compared to the current description in Sections B and C above? Please describe any other differences: *(e.g. how patients were enrolled, types of patients served, services provided, tools used to assess patient complexity, number of care coordinators, interactions with patients and/or care team, payment or anything else.)* [ApproachCOVID]**

_____
_____

**Has your medical group needed to reduce the budget for care coordination since the onset of the COVID-19 pandemic? [CCCovidbudget]**

___ yes, considerably
___ yes, somewhat
___ no

**Are any other major changes planned for the next year in how care coordination will be implemented in your medical group? If yes, please describe. [CCfuture]**

_____
_____

## <u>Now we have a few final questions about your thoughts on what makes care coordination work well.</u>

**How does your medical group measure whether your coordination program is a success? [measure]**

_____

**What do you think are the main barriers or challenges to the effectiveness of care coordination within your medical group? [barrierchallenge]**

_____
_____

**What factors or strategies help make care coordination in your medical group effective? [effective]**

_____
_____

What other factors or strategies not currently being used would make care coordination in your medical group more effective?

_____
_____

**From the <u>perspective of your medical group</u>, what are the main benefits of providing care coordination? [MGbenefit]**

_____
_____

**From the <u>patient perspective</u>, what does your medical group think the main benefits of receiving care coordination are for patients? [PatientBenefit]**

_____
_____

**Please tell us about any policies and/or plans related to care coordination that your medical group has to measure and/or address disparities in healthcare. [Disparities]**

_____
_____

**Do you anticipate any potential barriers (e.g., technical) for your medical group in contributing data to this study such as identifying patients who began use of care coordination services in 2018, or those who will begin doing so in 2021? (*These data will be securely transmitted to MN Community Measurement and subject to human subjects protection oversight by the HealthPartners Institutional Review Board).* [DataBarrier]**

Yes → If yes, what barriers do you anticipate?
No

_____
_____

Thank you for your responses. You may submit by clicking the button below. Please contact us at [MNCARES Mailbox] if you have any questions about this form or the additional clinic level data that you or a designee is providing about your medical group pursuant to earlier conversations with the MNCARES study team.

## 17.5 Appendix E: Clinic Descriptors Table

*This table will be sent as an excel file with the organizational survey as described in Section X.*

| **MNCARES Organizational Survey Clinic Descriptors: Organization [Name] V1.0**<br>We are interested in knowing more about <u>each clinic</u> in your medical group that is certified as a Health Care Home. Please have someone from your team complete the following table. | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Preferred definition | If preferred definition not possible, alternate definition used *(to be populated by person completing this table)* | HCH Site 1 | HCH Site 2 | HCH Site 3 | HCH Site 4 | HCH Site 5 | … | HCH Site N |
| 1. Which of the following best describes this clinic's ownership? (Place an X in all that apply) | | | | | | | | | |
| a. Clinician-owned | | | | | | | | | |
| b. Hospital/Health system owned | | | | | | | | | |
| c. Federally Qualified Health Center or Look-Alike | | | | | | | | | |
| d. Non-federal government clinic (state, county, city, public health clinic, etc.) | | | | | | | | | |
| e. Residency training clinic | | | | | | | | | |
| f. Federal (Military, Veterans Administration, Department of Defense) | | | | | | | | | |
| g. Rural Health Clinic | | | | | | | | | |
| h. Indian Health Service | | | | | | | | | |
| i. Other | | | | | | | | | |
| Describe the "other" ownership: | | | <describe with text here> | | | | | | |
| For the following role types, only include people who work at least one day a week at the clinic: | | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2a. Approximately how many **adult primary care clinicians (MD/DO)** are in this clinic? | Primary care includes family medicine, family practice, internal medicine | | | | | | | | |
| 2b. Approximately how many **adult primary care nurse practitioners** are in this clinic? | | | | | | | | | |
| 2c. Approximately how many **adult primary care physician assistants** are in this clinic? | | | | | | | | | |
| 2d. Approximately how many **behavioral health clinicians** are in this clinic? | | | | | | | | | |
| 2e. Approximately how many **medical specialist MDs** are in this clinic? | | | | | | | | | |
| 2f. Approximately how many **dental clinicians** are in this clinic? | | | | | | | | | |
| 2g. Approximately how many **other staff** are in this clinic? | | | | | | | | | |
| 3. Does this clinic have an on-site pharmacy? | | | | | | | | | |
| 4a. Approximately what percent of the patients seen in this clinic have **Commercial Insurance**? | A *patient* is defined as someone who has had one in-person, telephone or video encounter with primary care in the last year (2 years? Some studies have defined via 1 record of a BP reading) | | | | | | | | |
| 4b. Approximately what percent of the patients seen in this clinic have **Medicare** insurance? | | | | | | | | | |
| 4c. Approximately what percent of the patients seen in this clinic have **Medicaid** insurance? | | | | | | | | | |
| 4d. Approximately what percent of the patients seen in this clinic are **uninsured**? | | | | | | | | | |
| *Add up to a total of 100%* | | | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| 5a. Approximately what percent of patients seen in this clinic are **18-39 years old**? | | | | | | | | | |
| 5b. Approximately what percent of patients seen in this clinic are **40-64 years old**? | | | | | | | | | |
| 5c. Approximately what percent of patients seen in this clinic are **65 years or older**? | | | | | | | | | |
| *Add up to a total of 100%* | | | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 6a. Approximately what percent of patients seen in this clinic are **American Indian**? | | | | | | | | | |
| 6b. Approximately what percent of patients seen in this clinic are **Asian**? | | | | | | | | | |
| 6c. Approximately what percent of patients seen in this clinic are **Black/African American**? | | | | | | | | | |
| 6d. Approximately what percent of patients seen in this clinic are **Hawaiian/Pacific Islander**? | | | | | | | | | |
| 6e. Approximately what percent of patients seen in this clinic are **White**? | | | | | | | | | |
| 6f. Approximately what percent of patients seen in this clinic are **some other race**? | | | | | | | | | |
| 6g. Approximately what percent of patients seen in this clinic are **more than one race**? | | | | | | | | | |
| 6h. Approximately what percent of patients seen in this clinic **have an unknown race**? | | | | | | | | | |
| *Add up to a total of 100%* | | | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| 7a. Approximately what percent of patients seen in this clinic are **Hispanic or Latino**? | | | | | | | | | |
| 7b. Approximately what percent of patients seen in this clinic are **not Hispanic or Latino**? | | | | | | | | | |
| 7c. Approximately what percent of patients seen in this clinic **have an unknown ethnicity**? | | | | | | | | | |
| *Add up to a total of 100%* | | | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| 8a. Approximately what percent of patients seen in this clinic **speak English**? | | | | | | | | | |
| 8b. Approximately what percent of patients seen in this clinic **do not speak English**? | | | | | | | | | |
| 8c. Approximately what percent of patients seen in this clinic **need an interpreter?** | | | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |

Which of the following sources did you use to complete the table above?
a. Administrative records
b. Electronic data query
c. Estimate/guess
d. Some other source, describe:
Response: _____ (a, b, c, or d & describe)

## 17.7 Appendix F: Phase 1 Historical Cohort Patient Interview Guide

***Interview Content:***

*Primary:*

- Impact of COVID-19 on patients' lives – work, family, financial status, social connections, other social determinants, and on their physical and mental health and health care
- Impact of COVID-19 on care coordination, only for those still receiving services

*Secondary:*

- What healthcare services (care coordination or otherwise) would they have liked from their clinic during COVID?
- Did the care coordination they received make them better able to cope with COVID-19 stressors?

***Interview Length:*** 30 to 45 minutes

***Draft Phone Script and Interview Guide:***

Hello, is [first_name] [last_name] available?

1, Yes, continue to A

0, No → Is there a better time to call back? (Or call back in 10 minutes if they say "I don't know".)

If you have established that you are speaking to the correct participant, say:

A. Hello, my name is [interviewer first name], and I'm calling from HealthPartners Institute about the Care Coordination interview we have scheduled for today. Is now still a good time to do the interview?

1, Yes, continue to B

0, No → when is a better time to call back? [Reschedule interview and end call – or schedule a time to call back to reschedule if time does not permit rescheduling now.]

B. Thank you for agreeing to participate in this interview. Your thoughts and feedback will be very helpful to other patients in the future. The interview will last about 30 to 45 minutes and will be recorded and transcribed by an outside company. Your participation in the interview and your responses to interview questions will not be shared with your clinic, your insurance, or your health care providers. All information, including your name and responses, will be kept confidential. You will receive a $35 gift card for your participation in the interview today.

As a reminder, you were chosen for the interview because of the care coordination services you have received from your clinic. A care coordinator is a nurse or a social worker who helps patients manage their health or healthcare services. They can help with things like coordinating doctor's appointments or providing referrals for resources. This person might also be called a care manager or care navigator.

Also wanted to mention I will be taking notes to make sure I'm catching all the detail you provide in case you hear my keyboard in the background.

(*Note: Keep track of what language patients use to describe care, their clinic vs their doctor's office.)*

We are trying to understand how the COVID-19 pandemic has impacted people's lives and the health care they receive. A lot of things in life may have changed for many people, even if they have not been sick with COVID-19. We will use the information you give us today to design a statewide survey about COVID and healthcare coordination.

C. Do you have any questions before we begin?
1, Yes, record questions and answer using FAQ
0, No → Begin interview

I will begin the recording now.

<table>
<tr><th colspan="2">Introductory Question/s about Impact of COVID-19 (15 min)</th></tr>
<tr><td colspan="2">1. Tell me a little bit about how the COVID-19 pandemic has affected your life in general.<br>Note: Start with COVID-19 then use whatever terminology the participant uses.</td></tr>
<tr><td rowspan="5">Probes</td><td>Note: Probe for additional impacts, generally.<br>1. What other types of effects has COVID-19 had on your life?<br>Note: If not able to come up with additional impacts, use the topics below (depending on prior responses).</td></tr>
<tr><td>Topic: Impact on Social Connections<br>- The pandemic has impacted many people's relationships with friends and family. How has the pandemic affected your relationships?<br>- How did your day-to-day interactions or outings change with the pandemic?<br>Note: Be careful not to suggest impacts and stick closely to language provided here, without improvising (eg, don't ask if they feel 'lonely', let them use their own words), but probe further using the language the respondent offers.</td></tr>
<tr><td>Topic: Impact on Health Status<br>- How has the pandemic impacted your overall health?</td></tr>
<tr><td>Topic: Impact on Finances/Employment<br>2. Has the COVID-19 pandemic had any impact on your work or other responsibilities?<br>Note, only ask the below question for those who have mentioned above they are working.<br>3. How has the COVID-19 pandemic affected your ability get to work or do your work?<br>4. Has the COVID-19 pandemic affected your financial situation in any way?<br>5. Has the COVID-19 pandemic affected any government support you might receive?</td></tr>
<tr><td>Topic: Impact on Mental Health<br>- Do you think the pandemic has affected your mental health in any way?<br>- What stresses have you felt related to COVID-19?<br>  - Tell me about the stresess you have experienced and how this affected your health or mental health.<br>- Change and stress can affect mental health for many people. What types of changes have you experienced related to the COVID-19 pandemic?<br>- Has it affected how you interact with others? If yes, How so?<br>- Has it changed how you interact with family members or friends in any way? If yes, How so?<br>Note: Be very careful here to show no judgement on responses or current behaviors; if the participant has an extreme response, be neutral, de-escalate, re-frame the question.</td></tr>
</table>

| | |
|---|---|
| | *Note: If talking about impact on healthcare or care coordination, unprompted, go on to the next section and return after completed.* |
| 2. Is there anything specific that made the last year harder for you than it was for others? | |
| **Impact of COVID-19 on Healthcare (15 min)** | |
| 3. What difficulties have you had getting health care during the pandemic? | |
| *Probes* | - Are you able to access providers and services when you need to?<br>Note: Follow up with general probes to learn more details.<br>- Does anyone come into your home to help you? *If yes,* How has this been affected by the pandemic?<br>- Were you able to get in to the clinic when needed or reach providers you needed to see?<br>- Did talking with your care coordinator change in any way because of the COVID-19 pandemic? |
| 4. What types of things do you wish your clinic had done to help you during this time? Is there other support you wish you had during this time? | |
| **Impact on COVID-19 Care Coordination (5 min)** | |
| 5. I know you have met with a care coordinator, how did talking with this person help you manage your health and health care during this time of COVID? *Note: If they use the first name or other alias of their care coordinator, repeat this throughout.* | |
| *Probes* | - [If not still meeting with care coordinator] Did anything you and your care coordinator did before COVID help you manage changes in the last year? |
| *Note: Add branching so this question only appears if they've had CC during COVID-19 (collected in the screener)*<br>6. How has COVID-19 affected the coordination of care you receive/d from your clinic, specifically your experience with your care coordinator or social worker? | |
| *Probes* | - What's happening right now with your care coordinator? |
| 7. I want you to think back before COVID-19 started in March of 2020. Tell me a little bit about the care and care coordination you were receiving then. | |
| *Probes* | - Did your care coordinator help you deal with any of the challenges or stresses of COVID-19 that you mention earlier? How so?<br>- Did the care coordination services you received help you deal with these impacts or stresses? |
| 8. So now that we've talked about what's happening with your care coordinator currently and what happened before the COVID-19 pandemic, could you tell me a little bit about how has this changed for you? | |
| 9. Is there anyone else in your life helping you manage your health or healthcare services right now? | |
| *Probes* | *If yes,*<br>- Does anybody else live in your household?<br>- Tell me a bit about that person and how they are helping you.<br>- What things are they helping you with? |
| **Cool-down Question/s** | |
| 10. When you talk about care coordination with your family and friends, how do you describe it to them?<br>11. Is there anything else you'd like me to know about how COVID-19 has impacted your life, your health care or care coordination in general? | |

I have stopped the recording. Thank you so much for completing this interview.

Could you please provide your mailing address so that we can send you your gift card?

Address1 Address2
City, State Zip

We will send you your gift card soon. We appreciate you taking the time to participate in this important project/study.

## 17.8 Appendix G: Study Team Organizational Chart