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Setting Standards at the Forefront of Delivery System Reform: Aligning Care Coordination Quality Measures for Multiple Chronic Conditions

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Abstract

The primary study objective is to assess how three major health reform care coordination initiatives (Accountable Care Organizations, Independence at Home, and Community-based Care Transitions) measure concepts critical to care coordination for people with multiple chronic conditions. We find that there are major differences in quality measurement across these three large and politically important programs. Quality measures currently used or proposed for these new health reform-related programs addressing care coordination primarily capture continuity of care. Other key areas of care coordination, such as care transitions, patient-centeredness, and cross-cutting care across multiple conditions are infrequently addressed. The lack of a comprehensive and consistent measure set for care coordination will pose challenges for health care providers and policymakers who seek, respectively, to provide and reward well-coordinated care. In addition, this heterogeneity in measuring care coordination quality will generate new information, but will inhibit comparisons between these care coordination programs.

Keywords

Care coordination; quality measurement; chronic disease

INTRODUCTION

The Patient Protection and Affordable Care Act of 2010 (ACA) authorized several demonstration programs and new permanent programs with care coordination as a key objective. Three of the law's highest-profile initiatives targeting care coordination are Accountable Care Organizations (ACOs), the Independence at Home (IAH) demonstration program and the Community-based Care Transitions Program (CCTP). While IAH and CCTP specifically target people with multiple chronic conditions (MCCs), the success of all

three programs depends on how well they manage care for these frequent and costly users of health care.

These initiatives, and in turn the ACA, will be judged by their ability to lower costs and meet specified quality of care measures. Quality of care measures, or performance measures, are quantitative measures that typically assess what proportion of patients have received care consistent with a particular standard of care. The Medicare program and other payers have adopted quality measures to not only assess the quality of care provided to beneficiaries, but also to provide economic incentives to encourage providers to perform well or show improved performance on certain measures (VanLare & Conway, 2012). Previous studies of pay for performance programs found that financial incentives result in improvements on some quality measures (Chang, Lin, & Aron, 2012; Lindenauer et al., 2007; Mehrotra, Damberg, Sorbero, & Teleki, 2009). However, in some cases these programs have found that these pay for performance efforts can also have deleterious results in other areas and create perverse incentives to avoid noncompliant and complex patients (Campbell, Reeves, Kontopantelis, Sibbald, & Roland, 2009; Chang et al., 2012; Doran, Fullwood, Reeves, Gravelle, & Roland, 2008).

Despite the importance of quality measures to these high-profile ACA programs, there is little research on how these programs measure quality—especially care coordination—and how these programs will shape future medical practice. Ideally, quality measures in these ACA programs would reward and promote care coordination, particularly for people with MCCs, and have the same core measurement set to allow for comparisons between programs, and utilize measures endorsed by a national standard-setting organization, such as the National Quality Forum (NQF).

The NQF's Multiple Chronic Conditions Steering Committee suggests that in order to evaluate care for people with MCCs, quality measurement should be comprehensive ("Multiple Chronic Conditions Measurement Framework," 2012). Within care coordination, quality measurement sets that do not account for the full range of care coordination activities or include important elements of care for people with MCCs may have unintended consequences such as focusing providers' attention on relatively insignificant aspects of care or patients with one or no chronic conditions.

We recognize that care coordination programs may have unique study objectives, which necessitate the use of particular quality measures. We do not suppose that any one measure, set of measures, or component of care coordination quality may be more important than another. The goal of this paper is to identify what care coordination processes are being measured (and not measured) by three major ACA care coordination programs and to assess the alignment of these three high-profile care coordination programs with each other and expert recommendations as represented by the NQF Care Coordination measure set.

METHODS

Conceptual Framework

Quality measures typically assess to what extent care is consistent with clinical practice guidelines (Schuster, McGlynn, & Brook, 1998). Care coordination processes are challenging to measure in this regard because there are few guidelines on what are the appropriate care coordination processes. For example, in a review of care coordination program features associated with success in the Medicare Care Coordination program, Brown and colleagues found that certain features were common in successful programs, such as having care coordinators manage care transitions or having information about a patient's medications, but were also found in unsuccessful programs (Brown, Peikes, Peterson, Schore, & Razafindrakoto, 2012). There is also not yet a consensus in the literature to suggest that any one process, such as providing patients with a discharge summary upon leaving the hospital, is more important than another, such as following up with a physician after discharge, or that any particular combination of activities will achieve good care coordination and better subsequent health outcomes.

It is also important to consider that the context for implementing care coordination is a constantly shifting landscape of care providers, sites of care, and caregivers. Sites of care can include primary and specialist community-based offices, hospitals, post-acute facilities, and pharmacies. The number and type of providers may also be changing. A patient with 5 or 6 chronic conditions sees a median of two different primary care physicians and four different specialists across four different practices (Pham, Schrag, O'Malley, Wu, & Bach, 2007).

We use the Care Coordination Measurement Framework and Mapping Table (McDonald et al., 2010) to assess what aspects of care coordination the ACO program, Independence at Home, Community-based Care Transitions, and the NQF Care Coordination Measurement Set capture. This framework was originally created by McDonald and colleagues to help the researchers catalogue care coordination measures, identify gaps in the measurement landscape, and help researchers select appropriate measures based on their study goal. The Framework identifies 11 activities, listed in column 2 of Table 1, considered to be important for care coordination. These activities include defined tasks such as "create a proactive care plan" and "assess needs and goals", as well as continuous activities such as "interpersonal communication".

Given the prevalence of people with MCCs to these three ACA care coordination programs, we also assess measures against one of the principles of the NQF MCC Measurement Framework: whether a measure applies to a multiple conditions or to a single condition that affects multiple organ systems (cross-cutting) ("Multiple Chronic Conditions Measurement Framework," 2012). Many clinical practice guidelines, which serve as the basis for quality measures, do not adequately account for how clinical care may change depending on a person's comorbidities (Boyd et al., 2005). It is important that care coordination programs assess care processes and outcomes that apply to people with multiple conditions.

For purposes of presentation, we group the 11 activities and the NQF cross-cutting principle into five categories (Table 1). **Communication** includes interpersonal communication and information transfer. **Continuity of care** includes the capacity to monitor and respond to change, support self-management goals, and link to community resources. **Patient centered** includes creating a proactive plan of care, assessing needs and goals, and aligning needs and resources. **Care transitions** includes facilitation transitions as coordination needs change and facilitate transitions across settings. Finally, **Cross-Cutting** assesses whether the measure applies to multiple conditions.

Study Design

We first identified all quality measures currently proposed for use in three ACA programs, Accountable Care Organization (ACO) program, Independence at Home (IAH) program, and Community based Care Transitions Program (CCTP), as well as the National Quality Forum's recommended care coordination quality measure set (NQF, 2010). We used the solicitation notice for the IAH and CCTP available on the Medicare web site (CMS, 2012; CMS, 2011) and the Final Rule published in the *Federal Register* for the ACO program (CMS, 2011). We used the National Quality Forum (NQF) Quality Positioning System website to collect the specifications on all available measures (NQF).

We included all measures classified as assessing care coordination and those linked to financial incentives. Where quality measurement domains were not listed, as in IAH and CCTP, we only applied the second criterion: a link to financial incentives. We then categorized these measures as follows: one of two reviewers reviewed each measure and determined if the measure captured each care coordination activity or cross-cutting (1 point) or did not (0 points). Measures could be eligible for a maximum of 12 points. A second reviewer then independently categorized all measures using same approach. The two reviewers discussed and reconciled any disagreements. Scores are summed for each of five categories according to the crosswalk described in Table 1.

RESULTS

Across three major ACA care coordination programs, Accountable Care Organization program, Independence at Home, and Community-based Care Transitions, we identified a total of 24 eligible quality measures, of which there are 21 unique measures. The National Quality Forum care coordination measure set included 10 quality measures of which two were also included by the ACA care coordination programs

Center for Medicare Services (CMS) Programs

Accountable Care Organization (ACO) Program—The ACO program is one of the highest-profile programs created by the Patient Protection and Affordable Care Act. According to CMS, ACOs are "groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to their Medicare patients" (CMS, 2011). At the time of its passage, the Congressional Budget Office estimated that the Medicare Shared Savings Program would save \$5.4 billion over 10 years.

CMS specified 33 measures for public reporting and incentive payment in its final rule. (CMS, 2011) Within this larger measure set, we included the six measures, excluding 27, that were classified as assessing "care coordination/patient safety" (Table 2). All six measures are tied to financial incentives. Five of the six ACO measures are endorsed by NQF. Of these six measures, four are not disease specific. Two measures assessing hospitalizations for ambulatory care sensitive condition are specific to patients with COPD and CHF.

The ACO program does not include quality measures relevant to patient centered care. Of the two measures assessing communication, only medication reconciliation after discharge from an inpatient facility captures both interpersonal communication as well as information transfer. Fall risk captures interpersonal communication, but does not capture information transfer. Only one measure, medication reconciliation, captures care transitions, which may miss other important components of the transition (Table 3). Across all quality measures, two measures do not capture any of the 11 care coordination activities: ambulatory care sensitive condition hospitalizations for COPD and CHF.

None of the quality measures assess whether providers create a proactive plan of care, links to community resources, and align resources with patient and population needs.

Independence at Home (IAH) Demonstration Program—The IAH provides home-based primary care to people with MCCs who are high users of health care services and need help with at least two activities of daily living. Participating practices must report on 14 measures, six of which are tied to incentive payments. The solitication notice does not categorize measures as capturing care coordination versus other domains of care. For this analysis, we excluded the eight measures not tied to financial incentives, leaving six measures that are tied to incentive payments (Table 2).

All of the six IAH quality measures apply to multiple conditions. Four measures capture components of continuity of care. Two measures assess care transitions (readmissions within 30 days and contact with the beneficiary following discharge). Only one measure assesses communication between providers: contact with beneficiary within 48 hours of discharge. Two measures capture communication between providers and patients: patient preferences documented and medication reconciliation in the home. Two of the six measures assess patient centered care. Two measures did not capture any care coordination activities: number of inpatient ambulatory care sensitive condition hospitalizations and emergency department visits.

None of the measures assessed whether resources were aligned resources with patient and population needs.

Community Based Care Transitions Program (CCTP)—CCTP is a \$500 million program focused on improving hospital discharge processes to other settings of care. As part of the Partnership for Patients, a patient safety initiative, the goal of the program is to reduce hospital readmissions rates for high-risk beneficiaries as well as improve their quality of care. The solicitation notes that grantees are expected to target care transitions programs on

beneficiaries with multiple chronic conditions, depression, cognitive impairments, or a history of multiple admissions.

In the CCTP solicitation, 11 quality measures were classified as either outcome, process, or survey measures and are tied to financial incentives. We review all 11 quality measures (Table 2). The measures include disease specific and non-disease specific readmission rates, primary care follow-up after discharge, hospital transitions, and the Patient Activation measure. The CCTP program includes four patient survey measures.

Of the 11 measures, eight are not disease specific. All measures capture components of continuity of care. Communication is assessed by four measures using both patient survey measures and administrative records. Care Transitions are measured by four measures. Two measures, primary care provider follow up after discharge within 7 and 30 days, assess aspects of patient centered care.

National Quality Forum's Care Coordination Measures—As part of the National Quality Forum's National Priorities Partnership, NQF endorsed 11 performance measures for care coordination in 2010 (NQF, 2010). Like other NQF performance measures, the care coordination measures were endorsed through NQF's formal Consensus Development Project. We include all 11 NQF measures in this analysis.

The Care Transitions Measure three-item survey is an NQF endorsed care coordination measure that was also included in CCTP. Medication reconciliation following discharge was also used in the ACO and IAH programs. Three measures which require medical record abstraction (receipt of a transition record by the patient, receipt of a hospital discharge record by another site of care, and an emergency room transition record received by the patient) were not included in any of the Medicare care coordination initiatives. All of the NQF measures capture the continuity of care. Nine measures capture coordination; five measures capture patient centered care and seven assess care transitions.

None of the NQF measures specifically assess facilitating transitions as coordination needs change, links to community resources or aligning resources with patient and population needs.

Summary—Overall, we found that these ACA care coordination quality measures most frequently capture aspects of continuity of care. Patient-centered care was not captured by the ACO measures, but was assessed in IAH and CCTP. None of the ACA programs measured aligning resources with patient and population needs. Care coordination activities assessing how well the health care team responds to changes in health needs, care transitions, and monitoring and follow-up were infrequently captured.

DISCUSSION

We found that quality measures currently used or proposed for three major new programs aiming to improve care coordination primarily address only one of five key areas: continuity of care. Other key categories of care coordination (communication, care transitions, patient-centered care and inclusion of measures that can apply to multiple conditions) were not as

frequently captured by these ACA initiatives. Furthermore, we found little overlap in the quality measures used by these programs and the NQF care coordination measurement set.

The NQF recommended measures set for care coordination measures reflected similar gaps in its ability to measure the full range of care coordination activities. A number of measures captured communication and continuity and fewer assessed patient centered care, care transitions, and non-disease specific measures. Only two measures recommended by NQF were included in any of the ACA initiatives. While limited, the NQF measures may provide a resource for programs interested in adopting additional measures that have been vetted and endorsed by a consensus development process.

Similar to previous research on the impact of major ACA initiatives on adults who need long-term care services and supports, we found that the quality measures in these programs focus on coordination between outpatient and hospital care (Naylor et al., 2012). The measures do not explicitly promote shared accountability across different providers (i.e., outpatient and long-term services and supports, primary care and specialists, or hospital and post-acute care), which is particularly important for people with MCCs.

We found key differences in quality measurement in these domains between three large and politically important programs aiming to improve care coordination. Similarities in measures were in the areas of readmission and medication reconciliation. While this heterogeneity may reflect the characteristics and needs of different target populations, these differences will inhibit comparison between these programs.

All three programs include quality measures designed to capture specific care processes as well as outcome measures. For example, all three programs assess hospital utilization (i.e., admissions and readmissions). These programs present a unique opportunity to hold assigned providers accountable for overall health outcomes. Under a traditional care model, attributing responsibility to one or even a set of providers for a patient's health outcomes is challenging. Under these three programs, providers have proactively taken responsibility for particular patients, allowing policymakers and researchers to better assess the relationship between the provider's performance on process measures and the subsequent outcome measures.

While these programs allow more careful study of the link between care coordination processes to health outcomes, these program results should be carefully considered before attributing a direct causal relationship between providers and outcomes. In some cases good coordination of care can and should result in hospital admission or readmission. Some hospitalization measures, such as those for ambulatory care sensitive conditions, (see Appendix Table 1) do not directly assess whether care is coordinated. Lower rates of hospital utilization may result from unmeasured processes that have little to do with how well the health care system coordinates care and may reflect efforts of patients and family members to coordinate care. While hospital utilization measures may capture the consequences of poor care coordination (or its success), they may also capture higher use among individuals with poor health status (Anderson, 2010). The focus on hospital outcomes across these three programs may set perverse incentives for providers to shed

patients with MCCs and worse health status from their practice. It is important to emphasize that the results of this evaluation do not suggest that hospitalization measures are inappropriate in this population and for this purpose. Rather, we find that these measures alone do not capture the full range of care coordination domains.

An interesting difference in the measurement approach in these programs was differences in the use of survey data. Only one program, CCTP, collects patient survey data to assess care coordination. Patient survey data is challenging and costly to collect, but it is the only way to capture the patient's perspective on their care. The ACO and IAH programs may be missing important information on how these programs affect patient satisfaction and the patient's and family's experience of care. In a 2010 review, McDonald and colleagues assessed a number of care coordination surveys that could also be employed by care coordination programs (McDonald et al., 2010).

Overall, we find that there are serious gaps in Medicare's ability to fully assess the impact of the care coordination activities being employed in the Accountable Care Organization program, Independence at Home, and Community-based Care Transitions Program. The NQF measure set offers few measures that are appropriate for people with MCCs. A particular area of concern for people with MCCs is the lack of measures assessing care across settings of care.

While these ACA initiatives are already underway, different approaches to addressing this gap could be adpoted by Medicare in the short term. One option is for the Medicare program to align the quality measures to the extent possible across these three programs. While this approach might elicit protests from providers who have already invested resources in measuring and improving on certain quality measures, it is likely feasible. A second option would be to phase in a core set of quality measures in all programs emphasizing care coordination. The core measures could be used first as a tracking mechanism and be tied to financial incentives in the future.

Over the long term the Medicare program should consider investing in new research and development of quality measurement that better meet the needs of the people with MCCs. One potential framework is the concept of an episode of care, defined as "a series of temporally contiguous healthcare services related to the treatment of a given spell of illness" (Hornbrook, Hurtado, & Johnson, 1985). One application of this concept is the bundled payment, where care during a hospitalization is linked with post-acute care, including readmissions (Birkmeyer et al., 2010; Brennan, Lee, Wilk, Lyttle, & Weiss, 2010). Another example could be a composite measure that links a set of quality measures reflecting chronic disease care over a one-year period. The concept of an episode can therefore link care across settings (and among providers) or reflect care of a chronic disease over time. However, defining episodes of care may be challenging in people with MCCs because of the number of providers and types of care involved.

Developing appropriate care coordination measures for people with MCCs poses a number of challenges, including patient attribution to a provider or set of providers, data collection (electronic medical records, patient surveys, billing records), flexible timeframes to capture

the start of an episode, and determining the accountable entity. The Care Coordination Framework used in this paper provides one way for policymakers to systematically assess whether a program's quality measure set captures a broad range of care coordination activities.

This evaluation has a number of important limitations. We only reviewed a limited set of measures tied to incentive payments and categorized as measuring care coordination. We excluded measures such as caregiver stress, symptom management, and beneficiary needs and goals assessment in the IAH program because they were not tied to payment and are therefore may provide less incentive for providers to demonstrate improvement. We also excluded the Consumer Assessment of Healthcare Providers and Systems survey measures in the ACO program because they were classified as measures of the patient experience, not care coordination. In addition, this analysis was based on the assessment of only two reviewers. Our results reflect the focus of the Care Coordination Measurement Framework and a different conceptual model may have identified different results. Lastly, while we sought to obtain complete information about each of the proposed measures, some measures were not yet publicly available.

Conclusion

In summary, measures in the major ACA care coordination initiatives relevant to people with MCCs mainly addressed continuity of care, followed by communication, care transitions, and cross-cutting care. Few measures included in these initiatives addressed patient-centered care in ways relevant to people with MCCs who are the most in need of care coordination. As policymakers and providers evaluate these programs, these gaps in quality measurement will pose challenges in understanding what these programs did well and areas for improvement. In addition, the heterogeneity in measurement selection will provide new information for evaluators, but will make it challenging to compare across these programs. Quality measures are needed to evaluate the full spectrum of care for people with MCCs that can be compared across providers, regardless of the complexity of these conditions. In order to appropriately guide federal and state investments in care coordination, we need to invest in further measure development and testing.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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DuGoff et al.

Page 12

Table 1

Crosswalk between Care Coordination Measurement Criteria and Categories

	Care Coordination Measurement Framework Activities	National Quality Forum Multiple Chronic Conditions Measurement Framework
Communication	Interpersonal Communication	
	• Information Transfer	
Continuity of Care	Establish accountability or negotiate responsibility	
	Monitor, follow-up and respond to change	
	Support self-management	
	Link to community resources	
Patient Centered	Create a proactive plan of care	
	Assessing needs and goals	
	Aligning resources with patient and population nee	ds
Care Transitions	Facilitate transitions across settings	
	Facilitate transitions as coordination needs change	
Cross-Cutting		Assessing if quality measures apply to multiple conditions

DuGoff et al.

 Table 2

 Description of Selected Care Coordination Measures by Program

Measure	Measure Objective	NQF
Accountable Care Organizations		:
Risk-Standardized, All Condition Readmission	To measure hospital level unplanned all-cause readmissions	NQF #1789
Ambulatory Care Sensitive Conditions Admissions (ACSC): Chronic Obstructive Pulmonary Disease (COPD)	Assess admissions for COPD	NQF #0275
ACSC Admissions: Congestive Heart Failure (CHF)	Assess admissions for CHF	NQF #0277
Medication Reconciliation after Discharge from an Inpatient Facility	Reconciliation within 60 days by a physician	NQF #0097
Electronic Health Record Use	Percent of Primary Care Physicians who successfully qualify for an EHR incentive payment	No
Screening for Future Falls Risk	Measures the proportion of patients over 65 who have been screened for future fall risk within the past 12 months	NQF#0101
Independence at Home		
Number of inpatient admissions for ambulatory care sensitive conditions (ACSC) per 100 patient enrollment months	Not Available	No
Number of readmissions within 30 days per 100 inpatient discharges	days per 100 inpatient Assess the number of acute inpatient stays during the measurement year that were followed by an acute readmission for any diagnosis within 30 days	
Number of emergency department (ED) visits for ACSC per 100 patient enrollment months	Not Available	No
Contact with beneficiaries within 48 hours upon admission to the hospital and discharge from the hospital and/or ED	Not Available	No
Medication reconciliation in the home	Not Available	Similar to NQF # 0554
Patient preferences documented	Not Available	No
Community-based Care Transitions Program		
30-Day Risk Adjusted All Cause Readmissions	Measures all hospital level unplanned readmissions among patients 65 and older	NQF #1789
30-Day Unadjusted All Cause Readmission Rate		No
30-Day Risk Adjusted Acute Myocardial Infarction (AMI) Readmission Rates	Measures hospital readmissions within 30 days of discharge when diagnosed with an AMI	NQF #0505
30-Day Risk Adjusted Heart Failure (HF) Readmission Rates	Measures any readmission within 30 days of discharge when diagnosed for HF	NQF #0330
30-Day Risk Adjusted Pneumonia Readmission Rates	Measures any readmission within 30 days of discharge when diagnosed for pneumonia	NQF #0506
Primary Care Provider follow-up within 7 days of discharge	Not Available	No
Primary Care Provider follow-up within 30 days of discharge	Not Available	No
Hospital Consumer Assessment of Healthcare Providers and System (HCAHPS): Information about medicines	To assess the how often medical staff communicated well about hospital discharge	NQF #0166
HCAHPS: Information at hospital discharge	To assess the how often medical staff communicated well about new medications.	NQF #0166
Care Transitions Measure	Evaluates information transfer, patient and caregiver preparation, and self-management support from a patient-centered perspective for care transitions	NQF #0228

DuGoff et al.

Measure Objective NQF Measure The Patient Activation Measure 13-item version Assesses patient knowledge, skill, and confidence for selfmanagement. **NQF** Care Coordination Measures Cardiac Rehabilitation Patient Referral from an Inpatient NOF #0642 Assess percentage of patients with acute myocardial infarction or chronic stage angina who underwent an inpatient Setting heart surgery who are referred to an early outpatient cardiac rehabilitation program Cardiac Rehabilitation Patient Referral from an Assess percentage of patients with acute myocardial NQF #0643 Outpatient Setting infarction or chronic stage angina who underwent an inpatient heart surgery who are referred to an outpatient cardiac rehabilitation program who did not participate in an early outpatient cardiac rehabilitation program NQF #0644 Patients with a Transient Ischemic Event ER Visit That Percentage of emergency department patients who had a Had a Follow Up Office Visit cerebral ischemic event who had a follow up physician visit within 14 days Assesses when a biopsy was performed whether that NQF #0645 Biopsy Follow Up information was entered into a tracking log, reviewed and community to the patient or caregiver and other responsible Reconciled medication list received by discharged Assess if patients/caregivers received a reconciled list of NQF #0646 medications at hospital discharge which included new medications, ongoing medications, and any changes in dosage and directions Transition record received by discharged patients Assess if patients/caregivers received a transition record at NQF #0647 hospital discharge that included specific elements about what happened during the hospital stay and follow-up care. Timely transmission of inpatient transition record to any Assess if a transition record was sent to either the facility or NOF #0648 other site of care primary care physician following a hospital discharge Emergency Department Transition Record with Specified Assess if a transition record was sent to community-based NQF #0649 Elements Received by Discharged Patients care profession or caregiver following discharge from the emergency department Melanoma Continuity of Care-Recall System Assess if physicians entered information on patients with NQF #0650 melanoma into a recall system that tracks next physical skin exam and an appoint follow up process Care Transitions Measure Description under Community-based Care Transitions NQF #0228 Program

Page 14

DuGoff et al.

Page 15

Table 3

Number of Care Coordination Activities Addressed by Quality Measures By Care Coordination Category

	Communication	Continuity of Care	Patient Centered	Care Transitions	Cross- Cutting
Accountable Care Organizations	3	6	0	2	4
Independence at Home	5	11	2	4	6
Community Based Care Transitions	7	18	2	7	8
NQF Measures	11	15	5	7	6

Note: Each quality measure may apply to multiple care coordination activities in a given category. The number in each box represents the total number of care coordination activities assessed by each program and National Quality Forum Care Coordination Measures. We present the results by care coordination category listed in Table 1.