The Care Transitions Innovation (C-TraIn) for Socioeconomically Disadvantaged Adults: Results of a Cluster Randomized Controlled Trial

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BACKGROUND: Despite growing emphasis on transitional care to reduce costs and improve quality, few studies have examined transitional care improvements in socioeconomically disadvantaged adults. It is important to consider these patients separately as many are high-utilizers, have different needs, and may have different responses to interventions.

OBJECTIVE: To evaluate the impact of a multicomponent transitional care improvement program on 30-day readmissions, emergency department (ED) use, transitional care quality, and mortality.

DESIGN: Clustered randomized controlled trial conducted at a single urban academic medical center in Portland, Oregon.

PARTICIPANTS: Three hundred eighty-two hospitalized low-income adults admitted to general medicine or cardiology who were uninsured or had public insurance.

INTERVENTION: Multicomponent intervention including (1) transitional nurse coaching and education, including home visits for highest risk patients; (2) pharmacy care, including provision of 30 days of medications after discharge for those without prescription drug coverage; (3) post-hospital primary care linkages; (4) systems integration and continuous quality improvement.

MEASUREMENTS: Primary outcomes included 30-day inpatient readmission and ED use. Readmission data were obtained using state-wide administrative data for all participants (insured and uninsured). Secondary outcomes included quality (3-item Care Transitions Measure) and mortality. Research staff administering questionnaires and assessing outcomes were blinded.

RESULTS: There was no significant difference in 30-day readmission between C-TraIn (30/209, 14.4 %) and

control patients (27/173, 16.1 %), $p=0.644$, or in ED visits between C-TraIn (51/209, 24.4 %) and control (33/173, 19.6 %), $p=0.271$. C-TraIn was associated with improved transitional care quality; 47.3 % (71/150) of C-TraIn patients reported a high quality transition compared to 30.3 % (36/119) control patients, odds ratio 2.17 (95 % CI 1.30–3.64). Zero C-TraIn patients died in the 30-day post-discharge period compared with five in the control group (unadjusted $p=0.02$).

CONCLUSIONS: C-TraIn did not reduce 30-day inpatient readmissions or ED use; however, it improved transitional care quality.

KEY WORDS: care transitions; patient readmission; underserved populations; health care reform.

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INTRODUCTION

Poorly executed care transitions from hospital to home may contribute to a higher risk of hospital readmission and emergency department use¹, threaten patient safety², and detract from patient-centered care³. During the post-discharge period, patients report confusion about their medications and when to seek additional care, difficulty accessing their providers, and concern that information is not being communicated across sites^{3–5}. These challenges are compounded in socioeconomically disadvantaged patients who have a higher prevalence of mental health and substance abuse disorders, limited social support, as well as difficulty accessing medications and timely outpatient care.^{3,5–7}

Reducing 30-day readmissions, which represent a significant burden on the health care system, has become an important focus of recent health policy initiatives designed to spur transitional care quality improvement and save on costs associated with potentially preventable readmissions.^{8,9} While some transitional care interventions

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have not reduced readmission rates,^{2,10} a number of interventions have.^{11–13} Most of these programs have been conducted in settings where patients have access to outpatient care, and many have included older patients enrolled in HMOs. Few studies have assessed interventions designed specifically for socioeconomically disadvantaged individuals who may have different needs and different responses to interventions.

We developed a multicomponent transitional care intervention, called the Care Transitions Innovation (C-TraIn), for uninsured and low-income publicly insured adults. In this article, we report the results of a clustered randomized controlled trial examining the effects of C-TraIn on hospital readmission, emergency department (ED) use, and transitional care quality.

METHODS

Study Design. We conducted a single-center cluster randomized trial to evaluate the impact of C-TraIn. Earlier publications describe C-TraIn's development and design.^{4,14}

Intervention

Description of Usual Care. Usual care consisted of (1) routine inpatient nurse intake that includes screening about housing, substance abuse, and functional status; and (2) medication reconciliation performed by treating physicians. Given resource constraints, at the time of our study, routine medication reconciliation did not include corroborating medication histories with outpatient pharmacies, routine use of pill cards or pill boxes, or review of Medicaid formularies. Uninsured patients were financially responsible for post-discharge medications. (3) Discharge patient education was performed by inpatient nurses and treating physicians. For patients with heart failure, many received additional patient education and occasionally a home visit from a heart failure nurse practitioner. (4) There were no well-developed partnerships between hospital and clinics for uninsured or Medicaid patients and no systematic approach to securing post-discharge follow-up care. Any care coordination of post-discharge services was performed by inpatient care managers, social workers, and treating physician teams. (5) Patients without a usual source of care were often given a list of 14 area safety-net clinics, which have limited capacity for uncompensated care. Our prior work showed that uninsured—and to a lesser degree Medicaid—patients had difficulty establishing primary care and frequently could not access appointments or navigate the complex system.^{4,14}

Description of Intervention. C-TraIn was delivered in addition to usual care. The intervention began early upon hospitalization and continued through 30 days post-discharge.

C-TraIn consists of four main components including (1) transitional nurse coaching and education, including post-discharge phone calls and home visits for highest risk patients; (2) pharmacy care that includes patient education, medication reconciliation, guidance to inpatient providers to encourage low-cost medications, and provision of 30 days of medications at discharge for those without prescription drug coverage; (3) post-hospital primary care linkages; (4) and explicit efforts at system integration through monthly quality improvement meetings.⁴ After the intervention period, patients maintained access to primary care. Though they were no longer given free medications, patients without prescription coverage could access prescription medications through clinic dispensaries and \$4 formularies. The C-TraIn nurse could access a needs assessment that was administered by blinded researchers upon study enrollment. She used a framework to guide intervention dosing (Appendix A¹⁵) based on medical complexity, psychosocial need, and prior utilization. This was not a formal risk scoring system. Rather, it was a guide, and follow-up amount ultimately fell to the nurse's discretion.

Sample Size. We based target enrollment of 200 intervention and 200 control patients on the anticipated transitional care nurse capacity for 1 year. Assuming a 25 % baseline rate of readmission (based on patient self-reported rates and OHSU administrative data¹⁵), our study would have 82 % power to detect an absolute reduction in readmission rate of 12 % assuming an alpha of 0.05 and a between-cluster standard deviation of 0.15.

Blinding. Researchers performing surveys/consent and outcome assessors remained blinded to intervention status throughout the enrollment period. Upon consent, participants were told they had a 50-50 chance of being enrolled in a program designed to improve transitional care quality; however, intervention status was not disclosed, and the components distinguishing intervention and usual care were not described to participants.

SETTING AND PARTICIPANTS

C-TraIn was conducted at a single, urban, academic medical center in Portland, Oregon, prior to development of regional Coordinated Care Organizations (CCOs). Among patients admitted to general medicine and cardiology wards in the year prior to C-TraIn implementation, 15 % were uninsured and 19 % had Medicaid.⁴

Medical inpatients at OHSU are randomly assigned to one of six general medicine teams or, for those with primary cardiac problems, a cardiology team. Eligible patients were hospitalized on one of these seven study teams and had to: (1) be uninsured or low-income publicly insured (Medicaid,

Medicare/Medicaid, or Medicare without supplemental insurance and ≤ 200 % poverty level), (2) reside in one of three metro-area counties (Multnomah, Washington, Clackamas), (3) be community dwelling (i.e., not from a long-term care facility), (4) have access to a working telephone (participants could list a friend or shelter phone), (5) speak English, (6) be HIV negative (HIV+ patients were eligible for overlapping transitional care resources), (7) have no disabling mental illness (as characterized by active psychosis or active suicidal ideation) or severe cognitive deficits, and (8) have no plans to enter hospice.

MEASUREMENTS

Outcomes and Follow-up

All outcomes were pre-specified. Hypothesis and outcome measures pertain to the individual with analysis that accounts for clustering. Primary outcomes included rates of 30-day readmission and emergency department use. We assessed 30-day readmissions using the Oregon Hospital Discharge Dataset (HDD), which includes information from all Oregon hospitals and two Southwest Washington hospitals and has been used in other studies with similar populations.^{16,17} The dataset matches individuals by name and demographics and includes uninsured and insured individuals. It includes inpatient admission and discharges and excludes encounters coded with observation codes. We assessed 30-day ED use using a research data warehouse that includes all OHSU utilization.¹⁸ There were no changes to study outcomes after the trial commenced.

Mortality in both groups was assessed through chart review and state death records. For participants who did not respond to 30-day surveys, research staff queried the electronic health record and state death records.¹⁹ We measured transitional care quality using the 3-item Care Transitions Measure.¹

Blinded researchers abstracted chart data on patient demographics and diagnoses at the time of initial recruitment. Baseline survey data consisted of demographics; outpatient and inpatient access and utilization; medication barriers; patient activation; social support; depression screening (PHQ2); self-rated health (EQ5D); health literacy; functional status; and drug, tobacco, and alcohol usage. The Charlson-Deyo comorbidity index was derived from the electronic record.

DATA COLLECTION

Randomization and Recruitment

We enrolled consecutive eligible hospitalized patients. Though physician teams were not given special trainings,

we anticipated the possibility of contamination effects if a given team cared for intervention and control patients. To minimize this, we used a clustered study design according to hospital team. Using coin flip, four teams were randomly assigned to intervention (usual care plus C-TraIn) and three were assigned to control (usual care alone). Teams crossed over at 3-month intervals (total of 4 crossovers) (see [Appendix B¹⁵](#) for detailed visual of cluster design). Each cluster was unique: residents/ interns change monthly, and attendings change every 2 weeks. General medicine patients were assigned to one of six teams based on an on-call rotation that was pre-determined and independent from team randomization. Cardiology patients were assigned based on admission diagnosis. One medical team was added after the first 3-month interval to meet recruitment goals. Otherwise, there were no important changes in eligibility criteria or methods.

Researchers identified participants upon hospitalization using daily automated lists in the electronic health record. They obtained written consent to perform surveys and obtain demographic and utilization data. They enrolled participants Monday through Friday. A blinded researcher contacted all participants by telephone 30 days after discharge. Participants received a \$5 Subway® gift card for completing the baseline survey, and the card was reloaded with \$10 after participants completed the 30-day survey.

Analyses

Bivariate comparisons to compare responders and non-responders and to assess randomization used chi-square tests for independence and *t*-tests for comparison of means. To compare the intervention and control groups on the primary outcomes of hospital readmission and emergency department visits and the secondary outcome of care transitions measure, we used generalized linear mixed models for binomial outcomes with each outcome as the dependent variable. All models included a fixed effect for the intervention group and a random effect to account for patient-level clustering by study team. Patient-level covariates were examined, but these did not affect the magnitude or direction of the intervention effects so covariates were excluded from the final models. Covariates examined included age, gender, and the Enhanced Charlson comorbidity index. Odds ratios and 95 % confidence intervals were calculated from the model estimates.

RESULTS

Between November 2010 and January 2012, we screened 2,290 patients, of whom 382 were enrolled (209 to

intervention team, 173 to control; Figure 1). Of those enrolled, 293 (76.7 %) completed a follow-up phone survey 30 days after index discharge, with a similar proportion of patients responding in the intervention and control groups (78.5 vs. 74.6 %, $p=0.37$). Survey non-responders were more likely to be uninsured (50 % vs. 38 %, $p=0.04$), have marginal housing (39.1 % vs. 26.9 %, $p=0.03$), drink alcohol or use illicit substances (69.7 % vs. 54.9 %, $p=0.01$), and have limited access to outpatient care (64 % vs. 51.2 %, $p=0.03$) (Appendix C¹⁵). Intervention and control groups were well matched, and there were no significant differences in any variables between the groups (Table 1). The majority of participants were men, over half were uninsured, over three-fourths lacked a usual source of primary care, over 40 % had a history of illegal drug use, and over one-quarter had marginal housing.

Among intervention patients, 49.7 % (104/209) received a home visit and 92.8 % (194/209) received an inpatient pharmacy consultation. New primary care linkages were established in 42.1 % of patients (88/209), including 68.7 % (68/100) uninsured and 16.8 % (20/119) publicly uninsured patients. Table 2 provides examples of C-TraIn care, highlighting examples of how intervention components worked in this population.

Table 3 shows the main study results. Among the 382 participants, 57 (15.1 %) had an inpatient readmission within 30 days of discharge. The proportion of patients with one or more readmissions within 30 days of index hospital discharge was similar in intervention and control groups (14.4 vs. 16.1 %; unadjusted OR 0.88, 95 % CI 0.50–1.54). A similar proportion of intervention and control patients visited the OHSU ED within 30 days (24.4 vs. 19.6 %; unadjusted OR 1.38; 95 % CI 0.83–2.31). Multivariate regression models adjusting for baseline differences in covariates yielded similar results.

C-TraIn was associated with improved transitional care quality, as assessed by the 3-item Care Transitions Measure.¹ Finally, C-TraIn was associated with lower mortality. Zero C-TraIn patients died in the 30 days post discharge compared with five controls (unadjusted $p=0.02$).

Basic intervention costs, including nurse and pharmacist salary, totaled \$129,539; additional costs for uninsured patients totaled \$110,876 and included payments for medical homes (\$104,960) and medication costs (\$5,916). Average cost per publicly insured patient approximated \$620 and \$1,552 per uninsured patient. A detailed cost description is included in Appendix D.¹⁵

Figure 1. Participant flow diagram.

Table 1. Baseline Demographics

	C-TraIn (n=209)		Control (n=173)		p-value
Uninsured (n)	56.9 %	(119)	62.0 %	(106)	0.373
No usual source of care (n)	78.8 %	(164)	73.4 %	(127)	0.262
Female (n)	40.7 %	(83)	40.8 %	(69)	1.000
Non-white (n)	31.6 %	(66)	23.8 %	(41)	0.119
Some HS or less (n)	19.7 %	(41)	16.2 %	(28)	0.449
Marginal housing (n)	27.2 %	(56)	32.7 %	(56)	0.287
Current smoker (n)	31.7 %	(66)	29.7 %	(51)	0.745
Alcohol use (n)	30.9 %	(63)	32.5 %	(55)	0.817
Illegal drug use (n)	44.7 %	(93)	42.4 %	(73)	0.734
Prescription drug misuse (n)	10.1 %	(21)	9.9 %	(17)	1.000
Limited outpatient access (n)	53.6 %	(112)	54.9 %	(95)	0.876
Mean Charlson Comorbidity Index score (SD)	2.3	(3.0)	2.2	(3.2)	0.940
Mean score rating: How good or bad is your health today? (0–100) (SD)	52.9	(24.5)	48.3	(25.7)	0.080

Charlson comorbidity score^{20,21} was calculated as described in references

DISCUSSION

We found that a multicomponent transitional care intervention for socioeconomically disadvantaged adults did not reduce 30-day readmissions or ED visits; however, it improved transitional care quality and was associated with reduced mortality.

There are several possible reasons why our intervention did not reduce readmissions. It is possible that a different or more intensive intervention could reduce readmissions. We are, in fact, testing this as C-TraIn teams are partnering with community outreach workers who focus entirely on social determinants of health in the context of regional health

Table 2. C-TraIn Program Description, Including Patient Examples that Highlight Intervention Activities

C-TraIn component	Activity	Patient example
Transitional care nurse (TCN)	Admission needs assessment facilitates anticipatory planning	Young woman with unrecognized opiate abuse and no PCP. TCN arranged follow-up with a PCP expert in pain management and substance abuse treatment
	Health coaching	Newly diagnosed diabetic had intermittent hypoglycemia after discharge. At home visit, TCN identified errors in insulin dosing, color-coded insulin vials, and reinforced diabetic teaching
	Navigate health and social service system	Elderly woman with heart failure and close PCP relationship admitted with recurrent falls and nonhealing leg wound. TCN home visit found home in disarray. TCN alerted PCP who arranged for home health to assist with wound care and Adult Protective Services to assist in home clean up
	Point of contact and triage across settings	Chronically homelessness man with no usual source of care admitted with pneumonia. Patient developed increased dyspnea after discharge and contacted TCN who arranged same-day clinic appointment and additional outreach from community case worker
Pharmacy consultation	Create and manage value-based formulary	Uninsured man hospitalized for a myocardial infarction and emergent drug-eluting stent. He was started on six new medications including clopidogrel. Pharmacists tailored medications to low-cost options available through the C-TraIn formulary, provided 30 days of post-discharge medications, and initiated process for outpatient medication assistance
	Assessment of medication adherence barriers with patient-centered teaching	Middle-aged man with heart failure admitted with volume overload after stopping lasix. C-TraIn team identified cognitive deficits, polypharmacy, and use of multiple pharmacies as contributors to medication nonadherence. Pharmacist filled pillbox and used pictorial pill card to educate patient and wife. C-TraIn nurse reinforced teaching at home visit
Primary care medical home linkage	Warm handoff with transitional care nurse and clinic nurse	Man with developmental delay, marginal housing, surgical panhypopituitarism, and no PCP admitted to ICU with adrenal crisis after missing outpatient medications. TCN handoff to clinic nurse facilitated cross-site communication with new primary care team, including close pharmacy follow-up and prompt disability and housing screening
Monthly improvement meetings	Case reviews ground quality improvement	Uninsured woman with new diabetes was taught to use three different glucometers over course of her hospitalization and 30-day post-discharge. In- and outpatient pharmacists coordinated to use a common glucometer and test strip sets among (1) the hospital-based diabetic educator, (2) the C-TraIn formulary, and (3) FQHC dispensary

Table 3. Main Study Results

Outcome	C-TraIn	Usual care	OR (95 % CI)	Adjusted [‡] OR (95 % CI)
Readmission within 30 days (n)	14.4 % (30/209)	16.1 % (27/168)	OR 0.88 (0.50–1.54)	OR 0.88 (0.49–1.59)
ED visit* within 30 days (n)	24.4 % (51/209)	19.6 % (33/168)	OR 1.32 (0.81–2.17)	OR 1.38 (0.83–2.31)
CTM-3 above median [†] (n)	47.3 % (71/150)	30.3 % (36/119)	OR 2.17 (1.30–3.64)	OR 2.38 (1.38–4.10)
• Patient-centered care plan (strongly agree)	37.3 % (56/150)	18.5 % (22/119)	OR 2.75 (1.54–4.91)	OR 3.06 (1.66–5.63)
• Self-management understanding (strongly agree)	36.0 % (54/150)	24.4 % (29/119)	OR 1.76 (1.03–3.02)	OR 1.87 (1.06–3.32)
• Understanding of medications (strongly agree)	36.7 % (55/150)	27.7 % (33/119)	OR 1.55 (0.91–2.62)	OR 1.60 (0.92–2.78)
Number of deaths	0.0 % (0/209)	2.9 % (5/173)	NA [§] ; <i>p</i> =0.019	NA

*ED utilization includes OHSU administrative data only

[†]Not all participants completed the entire survey; 150/164 C-TraIn and 119/129 control 30-day survey respondents completed the CTM-3. CTM-3 comprises three items (cite) ranking (1) presence of a patient-centered care plan (The hospital staff took my preferences and those of my family or caregiver into account in deciding what my healthcare needs would be when I left the hospital), (2) self-management understanding (When I left the hospital, I had a good understanding of the things I was responsible for in managing my health), and (3) understanding of medications (When I left the hospital, I clearly understood the purpose of taking each of my medications)

[‡]Adjusted for age, gender, Charlson comorbidity index, and patient-level clustering

[§]Model estimation did not converge because of zero deaths in the control group; *p*-value from Fisher's exact test=0.019

reform.²² However, C-TraIn was an intensive intervention that improved transitional care quality and was informed by both local needs⁴ and other interventions that reduced readmissions in different populations,^{11,12,23} suggesting that the nature of the intervention may not entirely explain our findings. Another important difference may be that other transitional care interventions selected patients based on specific disease categories,^{10–13} whereas ours were broadly selected. It is possible that targeting specific chronic illnesses might yield different results. Additionally, few studies have targeted socioeconomically vulnerable patients, many of whom are at even higher risk for adverse outcomes at times of transitions.⁶ Our findings are similar to a recently published study in a similar population that also found improvements in processes of care and patient experience, but no consistent effect on readmission²⁴.

It is also possible that many readmissions are not preventable.^{25,26} Though several interventions in different populations have lowered readmissions,^{11–13,23} many have failed.^{10,2} Estimates of the proportion of readmissions that are preventable have ranged widely²⁶, in part because the definitions and methods used to characterize preventability have varied broadly, supporting that true rates are unknown. This may be particularly true in socioeconomically disadvantaged patients, for whom intensive self-management and other transitions activities may be of lesser priority or less feasible⁵. For example, a patient with food insecurity and homelessness—even if supported—may not be able to effectively manage diabetes enough to prevent readmission.

The finding that C-TraIn, despite not lowering readmission rates, was associated with lower mortality is interesting, but warrants further study and confirmation in larger trials. The relationship between readmission and mortality outcomes has been disputed.^{27,28} It is plausible that, with closer follow-up and enhanced access to outpatient care, our intervention recognized ill people earlier and linked them to needed care, thus improving

mortality without reducing hospitalizations. Indeed, prior studies have shown that more intensive outpatient care may result in more, not fewer, hospitalizations for chronic conditions in severely ill adults³² and that expanded insurance to low-income uninsured adults may increase hospitalizations.^{29–31}

Our study adds to the transitional care literature in two main ways. First, few interventions have been designed specifically for socioeconomically disadvantaged populations in which lack of access to medications, outpatient care, and a sense of abandonment after discharge are important issues.²⁴ The C-TraIn intervention was designed to minimize the impact of these challenges while promoting transitional care quality improvements. Many components of C-TraIn are similar to prior interventions (i.e., development of a personal health record,¹¹ post-hospital home visits,^{11,13} detailed medication reconciliation,^{12,32} and post-hospital phone calls^{7,33}), though the way these components add value may be different in our socioeconomically vulnerable population in a non-integrated system, as highlighted in Table 2.

Second, we are one of the first studies to look at community-level systems integration through hospital and community clinic partnerships. Initially, our team found the diverse needs of this population overwhelming and that the intervention needed to use the C-TraIn experience as a platform for broader system change. By bringing together multidisciplinary providers from across the care continuum and grounding monthly discussions in patient cases, we identified, prioritized, and fixed system gaps to improve information flow, care coordination across sites, and understanding of services available at different sites. Furthermore, C-TraIn's structured integration of inpatient and outpatient clinical sites may have additional value given current Accountable Care Organization models, which emphasize shared accountability. Indeed, this is one reason that OHSU has continued to fund C-TraIn despite unchanged readmission rates.

There are several notable limitations. This was a single-center study at an academic medical center, which may limit generalizability to other settings. It is possible that the transitional care nurse and pharmacist absorbed work typically done by hospital-based care managers and social workers, allowing them more time to coordinate resources for non-C-TraIn patients and thus changing the quality of 'usual care.' We do not know the proportion of patients (usual care or C-TraIn) who received additional home services such as a home visit, and this may have differed across groups; however, given the lack of such resources for the uninsured in our community, this is unlikely. Survey non-responders were different from responders. This may have affected results of the care transitions measure; however, this imbalance would not have affected utilization or mortality because we had administrative data on all patients. Our study was limited to English speakers. While this excluded only a small number of participants, it may limit relevance to other safety-net settings, and our future work includes non-English speakers. Finally, our study may have been underpowered to detect smaller—yet still clinically relevant—reductions in readmission rates. Readmission rates were lower than anticipated, in part because statewide records do not include observation readmissions, and this may have further diminished power. However, given that the observed point estimate and confidence interval were not close to showing a significant difference between groups, a moderate increase in precision would likely not have altered our conclusions. Furthermore, an analysis using OHSU-only data that included inpatient and observation readmissions (and therefore higher baseline event rates) also showed similar readmission rates in the intervention and control groups (26.8 % vs. 24.3 %, $p = 0.51$). Also, our findings are consistent with many other studies showing that transitional care interventions have not always successfully reduced readmission rates.^{10,34,24}

We are currently exploring partnerships with C-TraIn teams and community-based outreach workers who focus entirely on social determinants to learn whether these linkages might improve utilization and care quality among hospitalized adults with complex medical and social transitional care needs. Other future studies might consider combining a highly intensive intervention such as ours with post-hospital phone-based interventions^{33,34} to identify those needing home visits and close-term follow-up. Additionally, our mortality findings are hypothesis generating, and the association of readmissions and mortality warrants future study. While we used 30-day readmission as a proxy for cost, future studies may warrant more cost-effectiveness analysis.

In conclusion, a multicomponent transitional care intervention for socioeconomically vulnerable adults did not reduce inpatient readmissions or repeat ED use. Implementing C-TraIn did, however, improve patient-perceived care quality and strengthened hospital-communi-

ty linkages and collaboration across disciplines. These improvements may be especially relevant as we move toward models of shared risk across health systems and settings and as patient-centered care metrics become part of the payment reward structure.

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