FINAL REPORT

Title of Project:	Inpatient-Outpatient Transitions: Reducing the Rate of Readmissions
Principal Investigator:	J.B. Jones, PhD, MBA Mark J. Selna (original Principal Investigator)
Team Members:	Mark Selna, MD Dione Mercer, BS
Organization:	Geisinger Center for Health Research
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STRUCTURED ABSTRACT

Purpose: Patients are routinely transferred from an inpatient to an ambulatory care setting, and the available evidence suggests that a significant proportion of subsequent readmissions associated with these transitions may be preventable. The purpose of this project was to use Failure Mode Effects Analysis (FMEA) to identify modifiable risks associated with transition-related (inpatient-to-ambulatory) care processes.
Scope: We developed a conceptual framework that identifies four key factors that are critical to providing high-quality transitional care: 1) awareness of the receiving party that a transition is imminent, 2) transfer of relevant information between care teams, 3) transfer of responsibility for the care plan, and 4) comprehensive oversight of the care plan. This framework guided the creation of an ideal model of transitional care.
Methods: Working with a team of stakeholders, we conducted an FMEA of a process being piloted at Geisinger to reduce transition-related readmissions. The results of this FMEA were used to create an idealized model of transitional care. This model then underwent a second FMEA.
Results: The results of both FMEAs were used to develop a draft assessment tool that can be used to identify whether a healthcare entity has the procedures and/or tools necessary to provide high quality transitional care.

Key Words: Readmission, FMEA, Failure Mode Effects Analysis, Risk Assessment

PURPOSE

The overarching purpose of this study was to employ proactive risk assessment techniques in a healthcare setting in order to identify opportunities for improving the quality of care when patients transition between different healthcare settings (e.g., from inpatient to ambulatory care). More specifically, we employed failure mode effects analysis (FMEA) as a prospective risk assessment technique to identify risks associated with inpatient-to-ambulatory transitions; the FMEA, in turn, was used to identify opportunities for improving transitional care by identifying "capabilities" that are necessary for a healthcare entity (e.g., hospital, primary care practice) to possess in order to provide high-quality transitional care.

Our work consisted of three three specific aims, as follows:

> ***Aim 1:*** To develop a broadly applicable idealized operational model of inpatient-to-ambulatory transitions
>
> ***Aim 2a:*** To use Failure Mode and Effects Analysis to identify the key failure modes (and their causes) that contribute to preventable readmissions during inpatient-to-ambulatory transitions
>
> ***Aim 2b:*** To use to Failure Mode and Effects Analysis to refine the idealized operational model and to identify the key capabilities necessary to minimize preventable readmissions

Aim 3: To develop and pilot test a draft "transitional care capability assessment" tool that can be used to evaluate the ability of entities to collectively deliver highly reliable, high-quality transitional care

SCOPE

Background and Conceptual Framework

Care transitions are inherently complex and associated with errors; a single episode of care can span multiple care locations, involve multiple providers, and rely on data generated and stored in multiple locations. In other complex systems with multiple interactions (e.g. manufacturing, military), industrial and human factors engineers have developed and systematically applied risk analysis techniques as a means to identifying and reducing risks. A small but growing literature supports the application of these types of techniques to healthcare settings. Though this is a sensible approach to understanding how risks emerge, there are fundamental challenges in the widespread application of these methods. Specifically, the risk assessment techniques are complex and difficult to apply in practice, because they require specialized skills and a significant investment of human resources. When applied incorrectly or superficially, these techniques may actually do more harm than good – specifically, completion of a risk analysis may convey an impression that risks are well understood when, in fact, meaningful sources of risk have simply been obscured or overlooked. When done correctly, risk analysis allows organizations to improve the safety and quality of their processes; when published, the results provide useful "case studies" to guide risk analysis efforts in other organizations and/or industries. A traditional model for linking research to practice relies on the accumulation of a sufficient number of such risk analysis case studies to enable generalizable conclusions to be drawn and applied to a diversity of settings. In healthcare, however, because processes are idiosyncratic to a provider, generalizability from the available case studies can be difficult. As such, there exists significant potential value in being able to identify characteristics that are common to all transitions and which represent the dominant sources of risk.

There is a multitude of approaches that have been applied to the challenges of improving the management of care transitions. The approach we proposed complements the work of others and was used to both catalogue inpatient-to-ambulatory care risks and to understand commonalities of capabilities that mitigate such risk. We assumed that the risk profiling process itself could be simplified and standardized for more general use without substantial loss of information (i.e., knowledge of the factors that account for most of the risk).

We developed a conceptual framework for transitional care that guided the work we pursued in each of our three specific aims. The framework identifies four key factors that we believe are critical to providing high-quality transitional care. These four factors are:

1) **awareness** of the receiving (i.e., ambulatory) party that a transition is imminent,

2) **transfer of relevant information** from the inpatient to the ambulatory care team,

3) **transfer of responsibility** for each component of the care plan,

4) comprehensive **oversight of the care plan**.

We used this framework to deconstruct the transitional care process and to simplify the approach to identifying and understanding dominant sources of risk. We proposed three phases of work to link the risk analyses outcomes to a draft assessment tool intended for general use. We first developed an idealized operational model of an inpatient-to-ambulatory care transition and, second, applied traditional risk analysis techniques, specifically FMEA, to both develop and refine our model; in a third phase, we used these techniques to identify a generalized set of key capabilities necessary to provide high-quality transitional care. The idealized model itself was based on this conceptual model as well as findings gleaned from literature, experience, and stakeholder knowledge sharing. The conceptual model undergirds the draft assessment tool developed as part of Aim 3.

Setting

The Geisinger Health System (GHS) is an integrated delivery system offering healthcare services to residents of 31 of Pennsylvania's 67 counties, with a significant presence in central and northeastern Pennsylvania. The base population is stable. Census data indicate that, with the exception of two counties, the out-migration rate is less than 1% per year. GHS includes the Geisinger Clinic (GC) that provides ambulatory care, the Geisinger Health Plan (an insurance plan), Geisinger Medical Laboratory (a private lab that services all GHS facilities), a large tertiary care teaching hospital, and two other hospitals. GC, formed in 1981, is a Pennsylvania not-for-profit corporation operating a multispecialty group medical practice – one of the largest ambulatory practices in Pennsylvania. Currently, there are 780 GC physicians and physician's assistants; the practice is growing at more than 7% per year and treating patients at specialty care clinics, 40 outpatient community practice sites, and two ambulatory surgery centers (i.e., Wilkes-Barre, Danville). Our primary care physicians see approximately 350,000 patients annually. The age distribution of GC primary care patients is similar to that of the region it serves. The proportion of men at GC, however, is lower, with fewer young adult men represented in the GC population than in the population of the region as a whole. The patient base is predominantly White, like that of the region.

Participants

The primary study team consisted of the Principal Investigator, Mark Selna, MD, J.B. Jones, PhD, MBA, and Dione Mercer, BS. Dr. Jones replaced Dr. Selna as the Principal Investigator after Dr. Selna concluded his employment with the Geisinger Health System. Members of the FMEA team included members of Geisinger's Regulatory Performance Improvement department and nurses and clinicians from multiple departments involved in providing care on either side of the inpatient-outpatient transition.

METHODS (study design, data sources/collection, interventions, measures, limitations)

In this section, we summarize the methods we used to achieve the specific aims of our study. Table 1 summarizes the main tasks, inputs, and outputs associated with each aim. Briefly, our goal in Aim 1 was to develop an idealized model of transitional care. In Aim 2, we used failure mode effects analysis to identify risks associated with transitional care that lead to readmission. The results of Aims 1 and 2 were the basis for the primary deliverable associated with aim 3 (i.e., the creation of a draft "transitional care capability assessment" tool for assessing an entity's ability to provide high-quality transitional care).

Table 1: Overview of Methods

Study Aim	Task	Key Inputs & Required Resources	Output
Aim 1: Develop idealized care transition model	Stakeholder identification & engagement	Collaborate with Geisinger Transitions of Care committee	A committee of stakeholders with experience in transition-related care processes
	Literature review to identify determinants of successful transitional care	Search strategy	Literature-derived list of important determinants of high-quality transitions
	Develop idealized transition model	Preliminary FMEA, stakeholder input	Initial FMEA summary Process map describing the "ideal process"
Aim 2: Risk Analysis	Initial Failure Mode and Effects Analysis to develop ideal model	Aim 1 process map Stakeholder team	Prioritized assessment of risks inherent in ideal transition List of controls / necessary capabilities
	Second FMEA of "ideal" model	Initial FMEA and ideal model	FMEA summary, Draft "key capabilities"
	Gap analysis to assess validity of ideal model	Stakeholder team	Revised ideal model and process map
Aim 3: Draft & Test Assessment Instrument	Develop draft instrument for assessing an entity's transitional care capabilities	Synthesized Aim 2 results Multidisciplinary team	Draft assessment instrument
	Assess instrument validity	Draft instrument	Revised draft instrument based on non-GHS provider feedback

Aim 1: Develop a broadly applicable idealized operational model of inpatient-to-ambulatory transitions

Transitional Care Stakeholder Committee

Our initial plan was to develop an ideal model that reflected both the results of our literature review and our interactions with a committee of stakeholders. We planned to identify a diverse set of individuals representing each of the major steps and venues in the inpatient-ambulatory transition process. However, shortly after the grant was funded, Geisinger's system-level leadership initiated a system-wide "Transitions of Care" (TOC) initiative that was designed to reduce readmissions across the system by a meaningful percentage. As part of the TOC initiative, executive leadership at Geisinger created a committee to oversee all TOC-related activities and to provide a forum for communication among the teams that were charged with implementing various TOC-specific pilot projects to reduce readmissions. The original Principal Investigator on this project, Dr. Mark Selna, was also involved in the system-wide TOC initiative. Rather than create a separate committee to focus solely on the research project, the study team (Drs. Selna and Jones and Ms. Mercer) participated as members of the TOC committee. Dr, Selna led the effort to integrate the objectives of the grant in to the work being done by the TOC committee.

The association with the Geisinger TOC committee played an important role in the development of our ideal model.

Literature Review

We conducted a systematic review of the literature to confirm our conceptual framework and address the nature and extent of evidence to support the four key aspects (awareness, information, responsibility, oversight) of the transition of care model and, second, to examine the interventions that have been designed to assess the quality and safety of transitions of care We searched the National Library of Medicine's (NLM) PubMed database using the following search terms, both alone and using "AND" and "OR" operators: *continuity of care, accountability, transitions, handoffs, monitoring, supervision, reliability, liability.* In addition, we built structured search strategies using Medical Subject Heading (MeSH) terms that included:

> ("patient discharge"[MAJR] AND "patient readmission"[MAJR]) OR ("patient readmission"[MAJR] AND "continuity of care"[TIAB]) OR ("patient discharge"[MAJR] AND "continuity of care"[TIAB]) OR (care[All Fields] AND handoffs[All Fields]) AND English[lang]
> ("patient discharge"[MAJR] AND "patient readmission"[MAJR]) OR ("patient readmission"[MAJR] AND "continuity of care"[TIAB]) OR ("patient discharge"[MAJR] AND "continuity of care"[TIAB]) AND English[lang]

We searched the titles and abstracts of all articles retrieved using these search strategies to identify relevant articles. Our search strategy was intentionally broad. We included both empirical studies that evaluated a method to improve the quality of transitional care and studies that sought to identify causes and/or contributors of transitional care-related readmissions. We also included editorials and "thinkpieces" that addressed the challenges with causes of, or possible solutions to, the task of delivering high-quality transitional care. Last, we examined meta-analyses and systematic review articles of transitions of care, including specific articles related to Chronic Heart Failure as well as other diseases.

Ideal Model and FMEA #1

As noted above, after the grant was awarded, Geisinger instituted the system-wide TOC initiative to reduce readmissions across the system. The Transitions of Care initiative focused on a series of "pilot projects" to meet this system-level goal. Example pilot projects included TOC "bundle programs" rolled out on different units at both of the main Giesinger inpatient sites as well as pilots that included critiques of TOC methods for Skilled Nursing Facilities, Medical Home, and End-of-Life Care. The bundle programs focused on developing checklists and tools to reduce readmission rates. One of the pilots was focused on improving transitional care. This pilot was the basis for our initial ideal model as described below.

With approval from AHRQ, we modified slightly our approach to developing the ideal model. Rather than develop an ideal model and afterward conduct an FMEA, we opted to conduct two separate FMEAs. The rationale for this approach was twofold.

First, as part of the TOC initiative mentioned above, there was an effort to develop an improved approach to transitional care by piloting a new process for transitional care that was designed to reduce readmissions. We decided to base our development of the ideal model on this pilot process; to fully identify its strengths and weaknesses, we opted to do an initial FMEA that focused on several key areas of the overall process. We planned to revise the ideal model based on the results of the first FMEA, and the subsequent, fully vetted ideal model would undergo a second FMEA (Aim 2) as a means to develop the transitional care capability assessment tool (Aim 3).

The Geisinger Health System's Office of Regulatory Performance Improvement (RPI) has responsibility for providing system level assistance with risk assessment and risk analysis. RPI staff provide training to appropriate hospital personnel in risk analysis techniques (e.g., root cause analysis) and can provide staff to help lead/facilitate such meetings. We worked with the RPI office to train the key stakeholders that we invited to participate in the FMEA process. The initial FMEA that we conducted at Geisinger Medical Center consisted of six meetings, as summarized in Table 2.

Table 2. Summary of FMEA #1 Meetings

Meeting #	Purpose/Focus
1	Introduction to the grant, introduction to the FMEA process
2	Training in FMEA process, introduction to the process flow that will be the subject of the FMEA
3 & 4	FMEA – walk through process flow and ID failure modes/effects
5 & 6	Assigned frequency, detection, and severity scores and identified top 20% of most important process steps to consider in development of a new ideal model

As a prelude to FMEA, we worked with clinical experts and members of the TOC group to develop a detailed map of the proposed transitional care pilot process. This process map identified key sub-processes associated with transitional care; these sub-processes (Figure 1) became the focus for identifying failure modes during our FMEA activities.

Aim 2*a:* **To use Failure Mode and Effects Analysis to identify the key failure modes (and their causes) that contribute to preventable readmissions during inpatient-to-ambulatory transitions**

Aim 2b: **To use to Failure Mode and Effects Analysis to refine the idealized operational model and to identify the key capabilities necessary to minimize preventable readmissions**

Failure Mode Effects Analysis #2

Based on our experience and findings from the first set of FMEA meetings, we conducted a second FMEA to build an Ideal Model of transitions of care, which in turn guided the development of the draft assessment tool. We selected a smaller group of five of our key stakeholders who participated in the first round of meetings to take part in the second FMEA to critique and develop the Ideal Model. Table 3 provides an overview of the key activities associated with the second FMEA.

Table 3. Summary of FMEA #2 Meetings

Meeting #	Purpose/Focus
1	Introduction to the grant, introduce ideal model and its role
2	Developed Ideal Model process flow and critiqued and assigned risk scores to model steps, FMEA
3	Gained feedback from stakeholders on capabilities tool and discussed the final Ideal Model (see attached)

Aim 3: To develop and pilot test a draft "transitional care capability assessment" tool that can be used to evaluate the ability of entities to collectively deliver highly reliable, high-quality transitional care

The draft key capability assessment tool was developed as part of the second FMEA. In consultation with team members from the first FMEA, a draft version of the tool was developed prior to assembling the team for the second FMEA. The model was refined at and between each of the team meetings held as part of the second FMEA.

RESULTS (principal findings, outcomes, discussion, conclusion, significance, implications)

Aim 1: Literature Review

We focused our literature review on two research questions. In this section, we summarize our results for each question.

Research Question 1: What is the nature/extent of evidence supporting the conceptual framework of our grant?

The literature does support the four key objectives of an ideal transition as detailed in our conceptual framework. The majority of the evidence is implicit; no studies have expressly tested all four elements of the model, nor have any peer-reviewed think pieces conceptualized transitional care as including all four of these elements. Support for the four elements of the care plan is also found in the interventions summarized in the second question below, many of which have implicitly or explicitly included activities that address the elements in the conceptual framework.

This review has also identified at least one other objective – the elicitation and incorporation of patient and caregiver preferences – that we considered for inclusion in our conceptual framework as part of this literature review exercise. An extensive body of work by Coleman and colleagues (2003, 2004, 2007) points to the important role which patients and caregivers have in ensuring the success of transitional care. Coleman's work highlights the importance of including patient preferences in the post-discharge care plan and the importance of activating the patient and caregiver and preparing them for their roles in the next setting of care (Coleman, 2003).

Research Question 2: What interventions have been designed to address transitional care quality and/or safety and what were the results?

To address the second research question, we reviewed six systematic reviews and/or meta-analyses that considered discharge and transition-oriented interventions that were designed to reduce unplanned readmissions.

In addition, we summarized the results of a systematic "meta-review" that was conducted to synthesize the results of previously published systematic reviews. We also reviewed randomized controlled trials (RCTs) of discharge and transition-oriented interventions that have been published subsequent to the aforementioned systematic reviews to determine whether more recent studies alter the findings from the systematic reviews. Finally, we briefly cover the findings from several studies of non-randomized transition-related studies.

All six systematic reviews included in this analysis provide evidence that discharge and transition-related interventions can reduce readmissions, and these finding appear to be consistent for studies focused on CHF as well as for studies that are not specific to a given disease. The major gap that persists across all six reviews is that it is difficult to isolate which components of a discharge/transition-related intervention are responsible for the reduction in readmissions. Parker et al. (2002) found evidence for a hierarchy of effect across heterogeneous interventions; telephone-based interventions were least effective, followed by interventions delivered only in the home, whereas those provided in the hospital or in the hospital and the home were most effective. They conclude that "doing something is better than nothing" and that interventions that span the hospital-community (i.e., post-discharge) interface are more likely to favorably impact readmission. Though this conclusion provides little direction when trying to develop a de novo intervention, it does reflect the heterogeneity inherent in the evidence accumulated to date. Mistiaen et al. (2007) conducted a "meta-review" in an attempt to synthesize the diversity of evidence around different interventions and concluded that education interventions favorably impact readmission and that, similar to the conclusions of Parker et al. (2002), interventions with both pre-discharge and post-discharge components are more likely to have a positive impact.

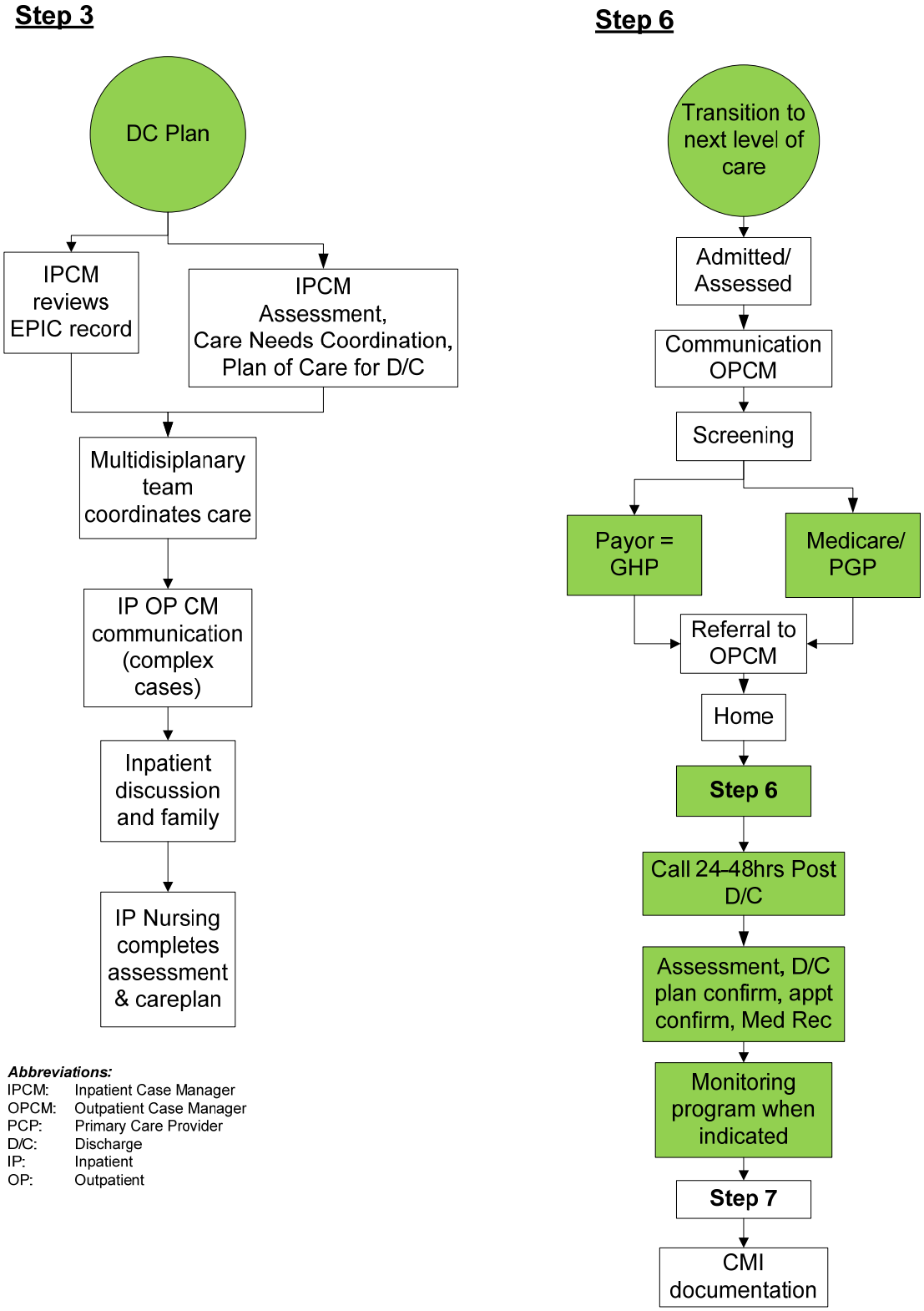
One implication of these findings from the systematic reviews is that there is no "gold-standard" intervention. Rather, providers and/or systems seeking to develop programs and interventions to reduce readmissions can look for solutions that leverage their existing resources. Overall, this review confirmed our FMEA results as well as informed our Ideal Model development.

Aim 1: FMEA Results

In the initial FMEA, we evaluated severity, detection, and frequency on a 1-10 scale. For severity, a "1" meant that the failure had "no effect" and did not impact the patient, whereas a "10" was defined as "catastrophic effect" that resulted in permanent harm to the patient. Similarly, for detection a score of "1" was defined as "certain" that failure can be detected and "10" as "impossible" to detect. For frequency, a "1" was defined as a failure that occurs "almost never" and a "10" as a failure that is "almost certain" to occur regularly. For each scale, the final score for each failure mode was determined through group discussion. In all cases, a consensus score was reached; in many cases, scoring frequency, detection, and severity was a relatively more time-consuming task as team members with different perspectives on the care process (e.g., a social worker versus a nurse) discussed their individual rationale for choosing a specific numeric score.

Figure 1 depicts two of the process steps that we evaluated during the first FMEA. We evaluated failure modes associated with each sub-step in the process flow.

Figure 1. Sample process flows for two steps in the transitional care pilot process



For the care processes that we analyzed in depth using FMEA, we identified more than 200 potential failure modes (Table 4). In order to prioritize failure modes, Risk Priority Numbers (RPNs) were calculated for each failure mode by multiplying the scores for Frequency, Detection, and Severity. Each was rated on a 1-10 scale, so the lowest possible RPN (low severity, easy to detect before the failure occurs, happens rarely) was "1" and the highest possible RPN (i.e., high severity, difficult to detect, and happens frequently) was "1000." After calculating a RPN for each failure mode, we sorted all failure modes by their RPN and analyzed the top 20% of all failure modes to identify those steps in the process that produced the greatest risk.

Among the 20% of failure modes with the highest risk, RPNs ranged from 200 to 420. The top failure modes were associated with five different process sub-steps that are part of the discharge planning and care transition processes outlined in Figure 1. Generally, the frequency scores associated with these failure modes ranged from 8 to, in many cases, 10 (i.e., happens "every day").

Among the top 20% of all failure modes, several common causes were identified. The "inpatient care manager assessment" step is important part of the care process, in part because it involves planning for discharge and identifying post-discharge needs. The highest RPN was associated with this step, and the primary cause was lack of appropriate documentation or that information might be poorly documented, potentially resulting, in both cases, in a missed diagnosis. Similarly, this process was resulted in high RPNs when it was required to be completed in a rushed timeframe (e.g., because beds were needed on a unit, physician decides to discharge without sufficient advance warning to care team, etc.).

One interesting finding had to do with the importance of the role of the patient's family and/or caregiver. Process step 6c (see "Assessment, DC plan confirm, appt confirm, med rec" step in Figure 1) was associated with several high-RPN failure modes, and one of the causes was lack of family/caregiver support.

Aim 1: Ideal Model

After reviewing the results of the first FMEA, we developed an initial draft of the ideal model. This ideal model was reviewed and revised in consultation with the second FMEA team. The composition of the second FMEA team differed from the first FMEA team, although both consisted of team members with deep clinical experience.

Our final ideal model is depicted in Figure 2. It consists of 12 steps that involve team members on both the inpatient and outpatient side of the care transition.

Aim 2: FMEA #2

In the second FMEA, we used the same methodology for assessing severity, detection, and frequency, and failure modes were again prioritized using RPNs.

Table 5 presents a sample of the failure modes and associated RPNs from FMEA #2.

Table 4. Sample FMEA results among the top 20% of RPNs

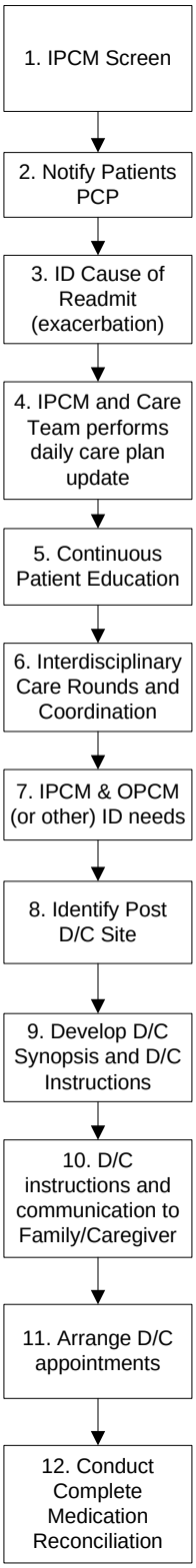
#	Failure mode	Potential causes of failure	Potential effects of failure	Severity	Detection	Frequency	RPN SCORE
68	**Process Step 3B: IPCM assessment, care needs coordinated, plan of care for D/C**	**No flow of documentation - different location**	missed DX	**6**	**7**	**10**	**420**
75	**Process Step 3B: IPCM assessment, care needs coordinated, plan of care for D/C**	**Changes not well documented or communicated**	missed DX	**6**	**7**	**10**	**420**
81	**Process Step 3B: IPCM assessment, care needs coordinated, plan of care for D/C**	**Increased needs in rushed timeframe**	med errors at D/C	**6**	**8**	**8**	**384**
207	**Process Step 3E: Inpatient discussion with family**	**Lack of preparation of questions**	risk of readmit	**7**	**6**	**9**	**378**
82	**Process Step 3B: IPCM assessment, care needs coordinated, plan of care for D/C**	**Increased needs in rushed timeframe**	lab errors not read or ordered for D/C	**6**	**7**	**8**	**336**
83	**Process Step 3B: IPCM assessment, care needs coordinated, plan of care for D/C**	**Increased needs in rushed timeframe**	Dx errors	**6**	**7**	**8**	**336**
122	**Process Step 3C: Multidisciplinary team coordinates care**	**Resources not available in the time needed (staff scheduling and man power)**	risk for readmission	**7**	**6**	**8**	**336**
305	**Process Step 6C: Assessment, DC plan confirm, appt confirm, med rec.**	**lack of family/caregiver support**	risk of readmit	**7**	**6**	**8**	**336**
281	**Process Step 6C: Assessment, DC plan confirm, appt confirm, med rec.**	**Patient non-compliant to treatment plan**	readmission	**7**	**5**	**9**	**315**

#	Failure mode	Potential causes of failure	Potential effects of failure	Severity	Detection	Frequency	RPN SCORE
285	Process Step 6C: Assessment, DC plan confirm, appt confirm, med rec.	orders not written meds/labs	readmission	7	5	9	315
286	Process Step 6C: Assessment, DC plan confirm, appt confirm, med rec.	orders not written meds/labs	pt safety, injury, harm	7	5	9	315
9	Process Step 3A: IP CM Reviews Epic Record	Lack of knowledge of Dx unknown	wrong plan	5	6	10	300
205	Process Step 3E: Inpatient discussion with family	Language barriers patient and physician	missed Dx	5	6	10	300
119	Process Step 3C: Multidisciplinary team coordinates care	Changes not well documented or communicated	risk for readmission	7	6	7	294
303	Process Step 6C: Assessment, DC plan confirm, appt confirm, med rec.	documentation incomplete epic/wisdom	readmission	7	5	8	280
316	Process Step 6D: Geisinger Monitoring Program when indicated	documentation incomplete epic/wisdom	non-compliance	4	7	10	280
137	Process Step 3C: Multidisciplinary team coordinates care	D/C plan lack of agreement with patient insurance plan on payment of care ie. RX equipment/meds o/p service	non-compliance with plan	6	5	9	270
208	Process Step 3E: Inpatient discussion with family	Lack of preparation of questions	edu not complete	5	6	9	270
319	Process Step 6D: Geisinger Monitoring Program when indicated	pt refusal	edu not complete	5	6	9	270
320	Process Step 6D: Geisinger Monitoring Program when indicated	pt refusal	non-compliance	5	6	9	270
12	Process Step 3A: IP CM Reviews Epic Record	Decreased Family communication	No compliance with plan	4	7	9	252
315	Process Step 6D: Geisinger Monitoring Program when indicated	documentation incomplete epic/wisdom	gaps in care	4	7	9	252

#	Failure mode	Potential causes of failure	Potential effects of failure	Severity	Detection	Frequency	RPN SCORE
149	**Process Step 3C: Multidisciplinary team coordinates care**	**Lack of disease specific educators**	non-compliance	**5**	**5**	**10**	**250**
185	**Process Step 3E: Inpatient discussion with family**	**No family**	non-compliance	**5**	**5**	**10**	**250**
202	**Process Step 3E: Inpatient discussion with family**	**Language barriers patient and physician**	non-compliance	**5**	**5**	**10**	**250**
224	**Process Step 6 : Referral to OP CM (GHP/Medicare/PGP**	**Missed/Incorrect Referral**	readmission	**7**	**5**	**7**	**245**
26	**Process Step 3A: IP CM Reviews Epic Record**	**Lack of Interdisciplinary collaboration**	incomplete plan of care	**4**	**6**	**10**	**240**
27	**Process Step 3A: IP CM Reviews Epic Record**	**Lack of Interdisciplinary collaboration**	barriers are not ID'd for D/C	**4**	**6**	**10**	**240**
29	**Process Step 3A: IP CM Reviews Epic Record**	**Lack of Interdisciplinary collaboration**	delays in services for pt	**4**	**6**	**10**	**240**
32	**Process Step 3A: IP CM Reviews Epic Record**	**Not knowing diagnosis communication of D/C**	delays in services for pt	**4**	**6**	**10**	**240**
126	**Process Step 3C: Multidisciplinary team coordinates care**	**Increased needs in rushed timeframe**	med errors	**4**	**6**	**10**	**240**

Figure 2. Ideal Model- CHF New Onset Admission

Abbreviations:
IPCM: Inpatient Case Manager
OPCM: Outpatient Case Manager
PCP: Primary Care Provider
D/C: Discharge



1. Screening will include risk stratification; IPCM should be considering D/C plan, patient needs (Post D/C site, environmental, diet ect.) This should be taking place continuously throughout the entire process

The highest-priority failure mode -- by far -- in FMEA #2 was associated with the medication reconciliation process. When this process fails, patients are highly susceptible to inadequate care or complications. Accordingly, medication reconciliation was included as a key step in our ideal model (Figure 2) and our draft assessment tool (Figure 3).

Table 5: Sample results from FMEA #2

Failure mode #	Potential causes of failure	Potential effects of failure	Severity	Detection	Frequency	RPN SCORE
Process Step 2: Notify PCP at Admission	**PCP not notified (no one available)**	No one to verify discharge plan inacted	**7**	**8**	**6**	**336**
Process Step 2: Notify PCP at Admission	**No PCP**	No follow-up	**7**	**8**	**6**	**336**
Process Step 2: Notify PCP at Admission	**PCP Notified-No Action Taken**	No follow-up	**7**	**8**	**6**	**336**
Process Step 4: Daily Care Plan Update	**No Daily Update**	Discharged w/wrong level of care	**9**	**7**	**6**	**378**
Process Step 4: Daily Care Plan Update	**Wrong plan**	Discharged w/wrong level of care/inadequate treatment	**9**	**7**	**6**	**378**
Process Step 4: Daily Care Plan Update	**No team plan communication**	Discharged w/wrong level of care/inadequate treatment	**9**	**7**	**6**	**378**
Process Step 4: Daily Care Plan Update	**Plan not communicated to patient/caregiver**	Patient would be following wrong level of care	**9**	**7**	**6**	**378**
Process Step 4: Daily Care Plan Update	**No care plan**	Discharged w/wrong level of care/inadequate treatment	**9**	**7**	**6**	**378**
Process Step 6: IDT Communication	**No IDT**	no plan/no communication of plan	**9**	**2**	**2**	**36**
Process Step 6: IDT Communication	**Poor/wrong updates**	wrong/poor plan inadequate care	**9** **9**	**9** **9**	**5** **5**	**405** **405**
Process Step 6: IDT Communication	**Not all team members present**	wrong/poor plan inadequate care	**9** **9**	**9** **9**	**5** **5**	**405** **405**
Process Step 9/10: D/C Synopsis and D/C Instructions	**None**	inadequate care wrong/poor plan no plan	**9** **9** **9**	**8** **8** **8**	**4** **4** **4**	**288** **288** **288**
Process Step 9/10: D/C Synopsis and D/C Instructions	**Completed-but not provided to doc or patient**	inadequate care wrong/poor plan no plan	**9** **9** **9**	**8** **8** **8**	**4** **4** **4**	**288** **288** **288**

Failure mode #	Potential causes of failure	Potential effects of failure	Severity	Detection	Frequency	RPN SCORE
Process Step 9/10: D/C Synopsis and D/C Instructions	**Error in instructions**	inadequate care wrong/poor plan no plan	**9** **9** **9**	**8** **8** **8**	**4** **4** **4**	**288** **288** **289**
Process Step 9/10: D/C Synopsis and D/C Instructions	**Caregiver unaware**	inadequate care wrong/poor plan no plan	**9** **9** **9**	**8** **8** **8**	**4** **4** **4**	**288** **288** **288**
Process Step 9/10: D/C Synopsis and D/C Instructions	**Communicate wrong plan**	inadequate care wrong/poor plan no plan	**9** **9** **9**	**8** **8** **8**	**4** **4** **4**	**288** **288** **288**
Process Step 12:Med Rec	**No med rec**	wrong meds inadequate care complications	**10** **10** **10**	**8** **8** **8**	**9** **9** **9**	**720** **720** **720**
Process Step 12:Med Rec	**Inaccurate med rec**	wrong meds inadequate care complications	**10** **10** **10**	**8** **8** **8**	**9** **9** **9**	**720** **720** **720**

Aim 3: Draft Assessment Tool

Based on the results of the second FMEA, we developed a draft assessment tool (Figure 3). This tool identifies a critical set of capabilities that are required to deliver high-quality transitional care. The draft tool is highly generalized and will need to be refined based on input from non-Geisinger stakeholders. Our initial goal was to have the instrument reviewed by non-Geisinger clinicians, but we had not completed this step (in part due to turnover in the Principal Investigator role making it more difficult to establish connections with external partners at non-Geisinger institutions) as of the completion of the grant period.

In designing the tool, we recognize that non-Geisinger entities may not have access to the same level of information technology infrastructure as Geisinger. Our experience conducting the FMEA, however, demonstrated that many if not all of these key process steps can be accomplished without sophisticated technology. In some cases, the technology may facilitate the process or make it more timely or make it possible to "hardwire" it in to a nurse's workflow (via the electronic health record), but these same processes can be accomplished in other ways.

The draft assessment tool also identifies whether processes are automatic or depend on a human to be accomplished. An automatic process is one for which the initiation or completion of the process step is not dependent on a manual process. For example, the draft assessment tool includes an item focused on notifying a patient's PCP that an admission has taken place (the "awareness" part of our conceptual framework). In an Electronic Health Record (EHR), it is possible to ensure that this step happens automatically by sending an autogenerated fax or email to the primary care provider listed in the patient's record.

Based on our FMEA results, the automatic vs. human-dependent distinction is important, because processes that depend on a human to complete are more prone to fail given the rushed timeframe that is so often associated with the care transition process.

Challenges

We encountered a significant delay during the first year of the study. Our initial goal was to have access to comprehensive EHR data on a cohort of patients who had undergone readmission for a cardiac-related condition. Our intent in gathering this data was to inform the FMEA process. For example, FMEA relies on the comprehensive identification of failure modes associated with a process or product. Once failure modes are identified, the possible effects associated with each failure mode are enumerated and each is assigned a numeric value that reflects the frequency with which the failure mode is observed and a numeric value that represents the severity of the effect itself. We expected that having comprehensive numeric data would allow us to estimate frequency and, to a lesser degree, severity with a high degree of accuracy, because we could assess the frequency of some failure modes identified during the FMEA by querying our EHR data.

The primary obstacle encountered in the course of this project was related to our efforts to assemble the EHR data set. In order to access the data, it was necessary to apply for study approval from our Institutional Review Board (IRB). The IRB process took approximately 6 months to complete, and this was the primary reason underlying our application for a no-cost extension.

Ultimately, we opted not to use the data for which we sought IRB approval. This decision was partly due to delays in obtaining the data; once the IRB approval was obtained, we still faced delays in the project due to the time that was required to extract the data and prepare it for analysis. More importantly, the decision to not use the data was influenced by an improved understanding of the FMEA process itself and the utility of actual data versus the accumulated judgment of a team of experts with experience in the clinical process that is subject to FMEA.

The FMEA process by its very nature deals with both potential and actual failure modes. As such, many of the assessments of frequency and severity rely as much on participant judgment as on “hard” data derived from retrospective analyses of similar events. As the FMEA process unfolded, it was felt that trying to bring EHR data to bear on the FMEA would unnecessarily slow the process while only marginally (if at all) improving the accuracy of the estimates of frequency and severity that could be provided by experienced team members engaged in a consensus-seeking debate.

Conclusions and Significance

By systematically identifying where, how, why, and how frequently failures in the transitional care process can lead to readmission, we developed a rigorous understanding of the capabilities required to reduce and/or eliminate the risk of transition-related readmissions. We defined “capabilities” as the processes, information systems, expertise, staff, and facilities necessary to ensure high-quality care. Although organizations may vary widely in how they develop and operationalize such a capability, we believe that our initial efforts to use FMEA to characterize these essential capabilities may have widespread value for organizations seeking to improve the quality of transitional care they provide.

To extend the value of our research, we developed a draft assessment instrument that incorporates our findings related to key capabilities and that, with further development and refinement, may be used by payors, providers, and even patients as a means to assess the potential for any healthcare entity or system to provide high-quality transitional care.

Publications

To date, there are no publications associated with this project. A manuscript based on the systematic literature review is currently in draft form, and we are planning a manuscript to summarize our experience with and results from the FMEA process.

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Figure 3. Draft Transitional Care Capability Tool

Draft Transitional Care Capabilities Tool						
Do you have a process and/or tool for:			*Indicate Whether This Process Is:*			
Y	N		Paper-based	Electronic	Automatic	Human-Dependent
☐	☐	Screening patients upon admission to identify readmission risk?	☐	☐	☐	☐
☐	☐	Reconciling medications upon admission	☐	☐	☐	☐
☐	☐	[inpatient facility] Notifying the PCP that their patient has been admitted	☐	☐	☐	☐
☐	☐	[outpatient provider] Identifying patients that have been admitted	☐	☐	☐	☐
☐	☐	Identifying causes of readmission	☐	☐	☐	☐
☐	☐	Documenting the care plan	☐	☐	☐	☐
☐	☐	Updating the care plan on daily basis	☐	☐	☐	☐
☐	☐	Educating patients	☐	☐	☐	☐
☐	☐	Documenting the post-discharge care plan	☐	☐	☐	☐
☐	☐	Identifying the post-discharge provider	☐	☐	☐	☐
☐	☐	Notifying the post-discharge provider of a patient's pending discharge	☐	☐	☐	☐
☐	☐	Transmitting the discharge note/care plan to post-discharge provider	☐	☐	☐	☐
☐	☐	Accepting/acknowledging receipt of information from inpatient institution	☐	☐	☐	☐
☐	☐	Scheduling post-discharge appointments	☐	☐	☐	☐
☐	☐	Identifying missed post-discharge appointments	☐	☐	☐	☐