Title: Caregiver innovations to reduce harm in Neonatal Intensive Care (P30HS024459); 9/30/18-9/29/21

Agency for Healthcare Research and Quality

The University of Texas Health Science Center at Houston

PI: Dr. Eric Thomas

Administrative Core Abstract

Purpose: The purposes of the Admin Core were to 1) provide an annual budget plan and cost analysis to the leadership committee of the UT Patient Safety Learning Lab in the first month of each grant year; 2) establish internal controls to monitor grant expenditures across all cores and receipt of in-kind contributions; and 3) supply cores and projects with the resources needed, including personnel, for timely completion of goals and objectives.
Scope: The scope of the Admin Core included all activities of the Learning Lab.
Methods: NA
Results: The Admin Core successfully helped all projects and cores of the learning lab to create and monitor budgets and subcontracts; hire personnel, schedule meetings, keep projects on track, submit and oversee human subjects approval; and facilitate communication and innovation among all components of the learning lab.
Key Words: Budget, project management, innovation, reporting

Administrative Core Final Report

Purpose: The purposes of the Admin Core were to 1) provide an annual budget plan and cost analysis to the leadership committee of the UT PSLL in the first month of each grant year; 2) establish internal controls to monitor grant expenditures across all cores and receipt of in-kind contributions; and 3) supply cores and projects with the resources needed, including personnel, for timely completion of goals and objectives.
Scope: The scope of the Admin Core included all activities of the Learning Lab.
Methods: This section does not clearly apply to the Admin Core. It provided support for the projects and did not conduct research with methods to report.
Results: The Admin Core successfully supported the Learning Lab by accomplishing its three aims. It provided an annual budget plan and cost analysis to the leadership committee of the University of Texas Patient Safety Learning Laboratory (UT PSLL) in the first month of each grant year. Each core and project had a budget created in conjunction with the Admin Core. The Admin Core team worked with UT Houston to set up accounts for each core, project, and subcontract. The Admin Core team (Thomas, Ottosen, Danielson) met weekly to review every budget and monitor grant expenditures. This effort was quite time intensive because of the large number of budgets and subcontract budgets. The Admin Core also led the effort to submit all progress reports and no-cost extensions. Because of the reliable process for monitoring budgets, each core and project encountered no significant budgetary issues other than delays at times in setting up subcontracts. The Admin Core also facilitated hiring of Research Assistants (posted jobs, scheduled interviews, and led selection process) and supplied cores and projects with the resources needed, including personnel, for timely completion of goals and objectives. Other activities were to schedule meetings, create file sharing space, encourage innovation, ensure that cores and projects were meeting goals, create project dashboards, communicate with internal and external advisors, facilitate communication and teamwork, and lead human subjects research compliance efforts. Meetings included biweekly Patient Safety Leadership Calls, biweekly NICU Quality Council Patient Safety Meetings, Annual Meetings, Monthly Parent Advisory Council Meetings, and biweekly measurement core calls with the Admin Core.

The Admin Core encouraged Innovation in the Learning Lab primarily by facilitating engagement with stakeholders, such as parents and frontline clinicians. We worked with parents and frontline caregivers in almost all aspects of the cores and projects. Meetings with frontline caregivers occurred twice a month during the NICU quality council. We also created three subcommittees to develop triggers; they were led by and composed of frontline multidisciplinary clinicians and parents. We also solicited advice from external experts (Jack Toellner from ExxonMobile and Brian Wong from University of Toronto).

List of Publications and Products (Bibliography of Published Works and Electronic Resources from Study —Use AHRQ Citation Style for Reference Lists).
No publications directly related to the Admin Core, but this core provided support for publications by the other components.

Measurement Core Final Progress Report

Component Project Lead Information: Etchegaray, Jason

Core Project Team: Tomoaia-Cotisel, Andrada (RAND), Allen, Samuel (consultant), Rod MacDonald (consultant)

Abstract

Purpose: The measurement core supported the methodological and analytic needs for all project cores. The measurement core was responsible for leading data collection efforts that addressed five research questions the grant team developed.
Scope: We focused on understanding individual-, team-, and unit/organizational-level factors/processes that impact the ability of QI teams to complete their projects.
Methods: We utilized QI team meeting observations, interviews of subject matter experts, surveys of stakeholders, and system dynamics approaches, including causal loop diagramming and simulation modeling to collect/analyze data.
Results: We identified various individual-, team-, and unit/organizational-level factors that are associated with harms and other QI-related outcomes and showed how policies designed to affect those factors result in changes to outcomes.
Key Words: team meetings, stakeholder perceptions, system dynamics, causal loop diagram, simulation

Measurement Core Final Report

Purpose: We had two initial aims for our measurement core as it pertained to working with the other cores on the project:

Aim 1: To work with the cores and project leadership to determine the most important individual and unit-level constructs to measure for each NICU project, the operational definitions for the constructs, and the measurement approaches for each construct.

Aim 2: To measure the most important individual- and unit-level constructs for the NICU projects. We will engage with all cores and project leadership to address the first aim, which will give us confidence that we have identified the key aspects for project success. We will identify/develop ways to measure these constructs and then measure them, allowing us to achieve the second aim.

As we met with the other cores, we identified key constructs that led to different data collection efforts during the course of the grant. Additionally, we developed specific research questions to examine that were based on these key constructs and data collection efforts. These included the following:

Research question 1: Which behaviors exhibited by QI team members during QI project team meetings were most associated with QI project success? (herein: team behavior research question). *Research question 2:* What did SMEs (Subject Matter Experts; i.e., NICU staff, NICU leaders, and hospital/healthcare system leaders) perceive as key factors that impacted the ability of QI projects to reduce all-cause harm? (herein: themes research question) *Research question 3:* How are the various factors that SMEs viewed as related to each other also related to key outcomes? (herein: causal loop diagram research question) *Research question 4*: What policies are most important for a NICU to implement when simulating the impact of various factors on outcomes? (herein: simulation research question). *Research question 5*: What is an approach for QI teams to use to understand stakeholder perceptions of a QI intervention? (herein: stakeholder survey research question)

Scope: Our project focused on quality improvement activities at Memorial Hermann Hospital that were part of the Learning Lab.

Methods: (We describe the methods used for to answer each of the five research questions below)

Team behavior research question (RQ1).

We documented 91 team meetings (each meeting averaged 50 minutes in length) held by three QI teams working on different projects over the course of 1 year. All three teams were trained at the same time by Joint Commission in RPI® techniques, received mentoring from a RPI® leader from the Joint Commission Center for Transforming Healthcare for the majority of their project, and worked in the same unit (i.e., NICU) of the same hospital. The three teams had different goals, with Team A focused on improving prescribed nutrition, Team B focused on reducing unplanned extubations, and Team C focused on reducing and preventing IV infiltrates and burns. All teams had similar staffing composition, with all being co-led by a physician and a non-physician staff member, and all included a parent representative from the Parent Advisory Council (PAC). Team member roles and responsibilities were assigned by the leaders prior to initiation of team meetings. Other disciplines were included on the team depending on the expertise needed (e.g., pharmacists, nutritionists, and respiratory therapists).

To accomplish our first objective, our research team developed a QI Team Meeting Checklist (QITMC) to assess meeting-specific processes/tools/behaviors (herein processes) used during QI team meetings. We developed QITMC at the same time as the QI teams were being trained in RPI® techniques by The Joint Commission. Our research team reviewed several sources to determine the range of content to include in QITMC including RPI® training curricula focused on Lean, Six Sigma, and formal change management, an RPI® project deliverable checklist used by the hospital system, and team science and patient safety resources.[14-15] Pilot testing was done with the three QI teams affiliated with our grant in 19 early team meetings before they were paired with mentors from The Joint Commission (i.e., n=9 for Team A, 4 for Team B, and 6 for Team C).

An observer from our research team who led data collection efforts was responsible for attending QI meetings for the three teams and documenting their use of processes via a paper version of QITMC.

Themes research question (RQ2)

Stakeholders eligible for interviews were those who had knowledge of a) the NICU where QI projects were to be conducted as part of our grant *and/or* b) QI efforts within the healthcare system in which the NICU resides. We included the latter because there are multiple organizational levels potentially impacting QI projects implemented in the NICU: 1) the NICU, 2) the children's hospital in which the NICU resides, and 3) the multi-hospital system with which the children's hospital is affiliated.

Most of the interviews were conducted before the unit-based QI projects began. For interviews conducted after initial implementation of the unit-based approach, the interview protocol asked respondents to focus on the period before these projects began. In all cases, the purpose was to collect a contextual baseline of QI implementation in the NICU – what contextual elements were impactful and how were they impactful in the previous (top-down) approach QI improvement. We conducted 20 semi-structured interviews (1 hour in length, in person or by telephone) during the summer of 2016 that reflected a sampling of key positions with knowledge of the NICU and/or QI efforts.

Causal loop diagram research question (RQ3)

This study used a case study framework consisting of four phases, in which the first and second phases took place at the beginning of implementing a unit-based approach (UBA) to improvement; the third phase took place close to the ending of external funding for UBA implementation; and the fourth phase took place thereafter. We used a convergent mixed-methods design for which qualitative and quantitative data were collected over a similar timeframe. Research followed an interactive approach: initial diagramming and simulation modeling results informed subsequent qualitative data collection, and those qualitative data informed further collection of operations data. We recurrently integrated qualitative data collection and quantitative data collection (embedding) by (1) building from the Causal Loop Diagram (CLD) to the simulation and then back again and (2) merging the structure found in the CLD and that found in the simulation model to develop the conceptual model that visualizes a comprehensive understanding of what we learned. Results presented in this paper are drawn from that conceptual model.

Simulation research question (RQ4).

The CLD (RQ3) and the simulation model were repeatedly tested using informal discussions in the vein of disconfirmatory interviews during the study with system dynamics experts, NICU staff and leaders, and other key stakeholders. Information on the Average Motivation to Change, Staff UBA Capabilities, and Quality Improvement Effort were all normalized to 1 for the simulations. The normalization of these variables serves two purposes. First, it allows us to develop the model in equilibrium so that all variables are in steady state. These steady-state conditions generate values that are similar to the data collected for key variables found in the model. Second, the normalization also captures variables that are difficult to numerically measure but are important. For example, when introducing a new program, staff motivation is critical. If motivation increases, this indicates an improved situation; if motivation falls, this indicates that a situation that is less desirable. The model is capturing normalized values for Average Motivation to Change, Staff UBA Capabilities, and Quality Improvement Effort and is examining how they change over time, given a new policy.

***Stakeholder survey research question (RQ5)* – survey development and administration**

We invited three QI teams by purposely sampling from a large pool of QI projects being conducted at the center. Our goal was to survey QI stakeholders from different clinical settings and different size QI teams who experienced different types of QI interventions. Several authors (EF, EJT, MJO, JE, ES, ATC) drafted initial survey items based on Normalization Process Theory (NPT) components applicable to stakeholders of QI projects of the type routinely conducted in hospitals.

Results: (We describe the methods used for to answer each of the five research questions below.)

Team behavior research question (RQ1).

We found a significant difference ($\chi^2 = 10.08$, $p < .05$) in the extent to which team members prepared for meetings in advance. Across all of the processes, five of the 26 tools were significantly different across the teams, with two of these in the hypothesized direction of Teams A and B outperforming Team C, pointing to minimal support of our post hoc hypothesis. As an exploratory analysis, we examined the extent to which the teams used different RPI® processes for each of the DMAIC phases. Team A and Team B used more processes than Team C did, with Teams A and B using ~1.5 processes on average per phase and Team C using less than one process on average across all phases.

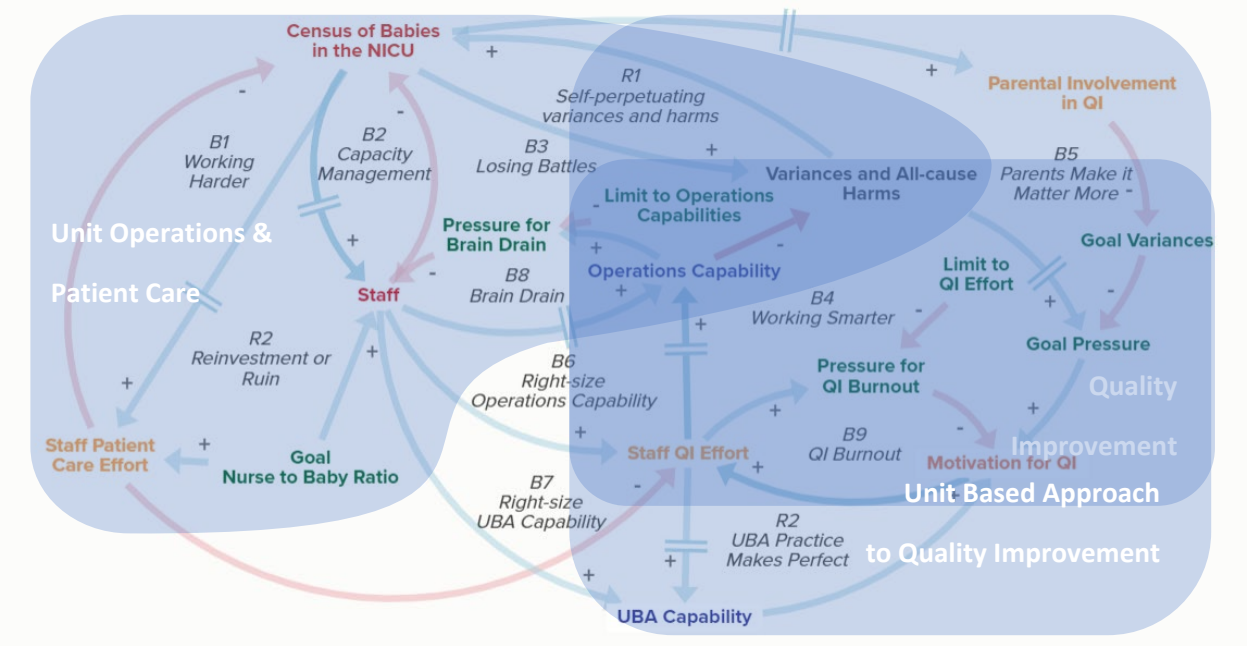
Themes research question (RQ2)

Emerging themes coalesced around the presence of drivers of QI efforts both internal and external to the NICU. Internal Drivers involved team member motivation for and availability to engage with QI. External Drivers involved resources that impacted the capability and availability of NICU staff to participate in QI and to sustain QI gains. We can share a table and additional details about these drivers to anyone interested.

Causal loop diagram research question (RQ3)

The key findings are best shown via the causal loop diagram model that we developed in Figure 1.

Figure 1: Core Dynamics – UBA & Its Context Through a Feedback Lens



This helped us identify different policies that can be implemented to impact various outcomes.

Simulation research question (RQ4).

Our results highlight several key findings that we learned by running scenarios that examined various policies. First, we learned that a policy increasing parental involvement in QI efforts as well as a policy focused on increasing the external motivation of NICU staff to work on QI projects took longer in terms of time to reduce harms than the more global policy focused on improving UBA goals. Interestingly, though, these two policies ultimately reduced harms by greater than the more quick-acting focus of the UBA goal improvement policy. In addition to the direct effect of UBA QI effort of reducing harms, ripple effects were observed for staffing and the census. Intentionally developing responses to these ripple effects will lessen their impacts as *unintended* consequences. For example, the census is projected to decline under all policies considered due to the decreased length of stay when harms are reduced. Thus, under all policies simulated, those implementing UBA should consider their existing admissions policies and what could be done to increase admissions when capacity increases or when they face disruptions to their operations because of a demand shortage. Furthermore, staff turnover is projected to increase under all policies considered – as staff become more capable through the UBA QI projects, they also become more attractive on the job market.

Stakeholder survey research question (RQ5).

After surveying stakeholders of three QI teams, we found that the Stakeholder Quality Improvement Perspectives Survey (SQuIPS) was feasible for QI teams to use, resulted in good response rates, and was sensitive to differences among QI projects. Also, we found that leaders used the results to alter their QI interventions. See published paper for details.

List of Publications and Products

Publications – accepted and in process

Etchegaray, J, Sedlock, E, Tomoaia-Cotisel, A, Ottosen, M, T, Thomas, EJ. Development of the Meeting Observation Tool for Quality Improvement Projects (MOTQIP): Understanding facilitation tools/processes. Under review at Journal for Healthcare Quality.

Fris, EA, Sedlock, E, Etchegaray, J, Ottosen, M, Pucio, R, Mistry, A, Saunders, T, Tomoaia-Cotisel, A, Thomas, EJ. (2021, in press). Development and Testing of the Stakeholder Quality Improvement Perspectives Survey (SQuIPS). BMJ Open Quality.

Tomoaia-Cotisel et al., Sustaining Quality in a High Reliability Organization: Feedback Dynamics in Implementing a NICU Unit-based Approach. Social Science & Medicine. Working Paper.

Tomoaia-Cotisel et al., Curbing Long Term Oscillation in NICU All Cause Harm: An Integrative Simulation-based Policy Analysis. Social Science & Medicine. Working Paper.

Tomoaia-Cotisel, A, Etchegaray, JM, Sedlock, E, Ottosen, M, Sittig, DF, Allen, SD, Thomas, EJ. Motivation, Time in the Day & External Resources Strengthen NICU Quality Improvement: A Case Study. Engineering Management Review. Working Paper.

Presentations

Tomoaia-Cotisel, A., MacDonald, R., Etchegaray, J.M., Thomas, E.J. Applying strategy modeling to a NICU quality improvement program. Presented at 2019 Annual Research Meeting of Academy Health, June 2019, Washington, DC.

Tomoaia-Cotisel, A., MacDonald, R., Etchegaray, J.M., Thomas, E.J. NICU quality improvement and its context: A causal map involving feedback & time delays. Presented at 2019 Annual Research Meeting of Academy Health, June 2019, Washington, DC.

Sedlock EW, Etchegaray JM, Tomoaia-Cotisel A, Strauss SG, Jaiswal N, Thomas EJ. Assessing Quality Improvement Team Processes – A Meeting Observation Tool. Oral presentation at the Science of Team Science Conference, May 22, 2018, Galveston, TX.

Robust Process Improvement Core

Abstract

Purpose and Scope: To Implement a robust process improvement program in the NICU to reduce harm.
Method*s*: Leaders, staff, and parents were trained in Robust Process Improvement® (RPI®) concepts and tools. Multidisciplinary teams, including parent members, applied the training and received regular mentorship for their improvement initiatives.
Results: Participants (N=67) completed pre-training and post-training surveys. Training scores (0-10 scale) improved from an average of 4.45 to 7.60 ($p<0.001$) for confidence in leading process improvement work, 2.36 to 7.49 ($p<0.001$) for RPI® knowledge, and 2.19 to 7.30 ($p<0.001$) for confidence in using RPI® tools; relative improvements were 71%, 217%, and 233%, respectively. Participants applied their RPI® training on improvement initiatives that resulted in improvements of central line bloodstream infections, very low birth weight infant nutrition, and unplanned extubations.

Conclusions: Implementing a robust process improvement program in the NICU to reduce harm resulted in significant and sustainable improvements on their improvement initiatives.
Keywords: Lean, Six Sigma, Patient Safety, Robust Process Improvement, Neonatal Intensive Care Unit

RPI Core Final Report

Purpose and Scope

A full third of quality improvement projects are not sustained after a year, and almost 70% are not sustained over time. Our understanding about what leads to sustainability is not yet well developed, but change management is likely a key factor. Managing the change for sustainability is specifically addressed by Robust Process Improvement® (RPI®) through its blended approach of Lean, Six Sigma, and formal change management. We sought to implement a robust process improvement program within a Patient Safety Learning Laboratory focused on reducing harm in the NICU.

Methods

Project Setting: This project was conducted in the neonatal intensive care unit (NICU) at the children's hospital. The children's hospital is one of 13 hospitals in the health system. One of the country's largest pediatric hospitals, the children's hospital is a 310-bed quaternary care women and children's hospital.

Project Planning and Implementation: The RPI® Yellow Belt training provides education so that process improvement concepts and tools are used in the daily work of staff and PAC members. Online content is complemented by face-to-face classes on change management and regular mentoring sessions led by our institution's process improvement experts. See published paper for details. Parent Advisory Council members also received training on patient and family-centered care, their role as members, and information about current improvement initiatives. See parent core and publication for details. Mentoring with our institution staff on the RPI® tools and improvement initiatives occurred every 2 weeks as the trained RPI® leaders guided their teams through the different discovery and problem solving phases. The mentoring calls lasted for about 60 minutes and included a status update on work to date, any challenges, and barriers the team was facing, next steps the team was planning (including concepts and tools being used), strategy for next steps, and a work plan outlining the next steps---called a WWW (What, Who, When) plan.

Results

Statistical Analysis of the RPI® Yellow Belt Training: To evaluate the RPI® Yellow Belt Training, paired sample t-tests were performed to test for significant improvement. The t-tests were conducted on the pre- and post-training survey results for training participants who completed the RPI® Yellow Belt training. Two-sample proportions tests were conducted on the improvement initiative outcomes. All statistical tests were conducted at the 0.05 level of significance. The data were analyzed using Minitab software, version 19.

RPI® Yellow Belt Training Results: Sixty-seven of 88 participants (76%) completed the training. The participants included NICU leadership and staff (frontline staff, medical staff, unit educators, and unit leadership), university medical school research staff who worked or conducted improvement initiatives in the NICU, and members of the PAC.

Training scores (0-10 scale) improved from an average of 4.45 to 7.60 for confidence in leading process improvement work, 2.36 to 7.49 for RPI® knowledge, and 2.19 to 7.30 for confidence in using RPI® tools; relative improvements were 71%, 217%, and 233%, respectively. All three indicators showed a statistically significant ($p<0.001$) improvement and less variability in post-training scores. We also analyzed the data of staff and PAC members separately and found similar results.

Improvement Initiative Results: The heart of implementing a robust process improvement program was the application of process improvement concepts and tools learned by participants during training to reduce harm in the NICU. See publication and descriptions of projects 1 and 2 below for results.

Limitations

A limitation of this study is that we cannot be certain which solutions (training, leadership support, mentoring, or parent engagement) had the greatest impact on the improvement initiatives.

Discussion

We found that implementing a robust process improvement program not only addressed gaps by providing the training to increase confidence and knowledge for improvement work but also led to sustainable improvements. See additional discussion in our publication.

Conclusions

The RPI® Yellow Belt training, including leadership support, mentoring, and parent engagement in improvement initiatives, not only led to improvements in confidence and knowledge for process improvement but also resulted in significant and sustainable improvements in the initiatives that were completed as part of the training.

Implications

The implementation of a robust process improvement program helps create a culture of continuous improvement as the children's hospital progresses on its journey toward high reliability and zero harm.

*References available directly from authors upon request.

List of Publications

1. Nether, Klaus G.; Thomas, Eric J.; Khan, Amir; Ottosen, Madelene J.; Yager, Lauren. Implementing a Robust Process Improvement Program in the Neonatal Intensive Care Unit to Reduce Harm. Journal for Healthcare Quality: May 21, 2021. doi: 10.1097/JHQ.0000000000000310

Parent Engagement Core

Component Project Lead Information: Madelene J. Ottosen, PhD, RN

Abstract

Purpose: To create an interprofessional, family-centered approach to reducing all-cause preventable harm in the NICU, a Patient Safety Learning Laboratory (PSLL) was instituted. One of the core components was the engagement of parent advisors as partners with frontline clinicians in reporting on and improving healthcare delivery.
Scope: Through the implementation of patient and family engagement in the NICU, two specific aims were accomplished: 1) to evaluate the engagement by parents of hospitalized neonates to reporting harms or concerns related to the care of their infant/s and 2) to describe the impact of parent engagement for quality improvement activities in the NICU.
Methods: Using an observational, mixed methods design of field observations, interviews, and surveys with parent advisors, clinicians, leaders involved with the NICU, we obtained data to detect preventable harms in the NICU and about the impact of parent engagement on quality improvement initiatives.
Results: Parents of hospitalized infants in the NICU observe and can report problems/harms if asked and if they believe those asking will act on their input. Parent advisors of infant graduates from the NICU can provide important insights about infants' healthcare delivery in the NICU and objective feedback toward quality improvement initiatives. Through this work, a stepwise approach to implementing a quality improvement-based PAC is described that could be applicable to any hospital or ambulatory unit.
Key Words: Quality improvement, Parent engagement, Patient safety, Parent Advisory Council

Parent Engagement Core Final Report

Purpose: Through the implementation of patient and family engagement in the NICU, we focused on two specific goals or aims: 1) evaluate the engagement by parents of hospitalized neonates in reporting harms or concerns related to the care of their infant/s and 2) describe the impact of parent engagement in NICU quality improvement activities as evidenced through the participation of NICU parent/family advisory councils and/or parents who have hospitalized infants in the NICU**.**

Scope: Through the PSLL, we sought to enable the frontline caregivers, including parents and parent advisors, to identify errors and adverse events and their respective causes and to design and implement the changes needed to improve care and reduce all preventable harm.

Methods: The PSLL used an observational, mixed methods design of chart reviews, field observations, interviews, and surveys across all cores over the 4-year duration of the project. Primary outcomes for the parent engagement core were parent-reported harms or areas of concern by parents of infants hospitalized in the NICU. Secondary outcomes were described impacts of parent engagement to quality improvement initiatives in the NICU. A combination of observational techniques, including interviews, field notes, and surveys, were used to obtain data on detect preventable harms in the NICU and parent engagement impact. Interviews/focus groups: We conducted interviews with caregivers, parent advisors, and quality project team members to understand the impact and satisfaction with RPI training and parent engagement, identify organizational issues affecting project completion/success, and determine teamwork processes used. Surveys: Surveys were conducted with various participants associated with the NICU and Parent Advisory Council (PAC) to examine perceptions, attitudes, beliefs, or knowledge related to parent engagement. Field notes: Notes of PAC, quality council, and project meetings were obtained by members of the PSLL to document outcomes of parent engagement processes, outcomes, and lessons learned. Analysis: Content analysis was conducted on qualitative interview transcripts, field notes, and open-ended survey questions led by M. Ottosen in collaboration with PSLL research members and PAC members. Frequencies of survey responses were collated and presented as mean scores for each question and/or cumulative scores.

Results

Parent advisor group interviews. During the first PAC meeting and at subsequent PAC meetings, parent advisors shared concerns and potential harms their infants experienced in the NICU. These initial insights were just the beginning of many stories with issues that surfaced and influenced a change in NICU practice. After 6 months, nurse managers initiated a new NICU nurse scheduling program called "Communities of Caring" aimed at increasing continuity of care. Also, after 8 months, parents were no longer asked to leave during shift change.

Use of parent-centered reporting tool. Efforts to initiate a self-reporting tool for parents of infants in the NICU were not successful. Parents expressed being hesitant to report concerns with their infants in the NICU and/or to complain about care. More clinician and parent engagement will be required for planning and implementation of future projects.

Use of parent-centered safety culture tool (PCSCT) assessment. A parent-centered safety culture assessment was conducted with parents in the NICU from August to September 2018. The PCSCT was created from previous work completed by our group in the NICU. We obtained a 38% response rate of parents with infants currently in the NICU. The tool was reliable, with a Cronbach's alpha of 0.86. The overall response rate was highly positive and correlated to parents' responses to safety grade questions in the NICU. Open-ended comments within the tool revealed that parents had concerns related to ability to be present and staff interactions with their infants. A manuscript of this pilot is pending final revisions.

Parent advisor Rounds. Parent advisors embarked on developing their own project, entitled parent-to-parent (P2P) support, to be able to support with other parents in the NICU one on one and learn about problems they were experiencing. To prepare themselves to have these conversations, they received sensitivity training from a licensed counselor and discussed processes for reaching parents most in need. Unfortunately, lead advisors critical to the project had to leave the council due to family issues. Just as new parents were being identified, the COVID-19 epidemic put a stop to all activities.

Nevertheless, parent advisors made notable contributions in each phase of the quality improvement process for PSLL quality improvement projects; see Table 1.

Table1: Parent Advisor Involvement in NICU Quality Improvement Phases

	Define	Measure	Analyze	Improve	Control
NICU Projects					
Unplanned extubations (UPE)	Parent views of UPE practices	Reviewed measures of problem	Reviewed ideas/results of change	Reviewed/participated in training video for clinicians; Reviewed change outcomes	Recommended complimentary parent video

IV Burns	Parent views of long-term infant effect of IV burns	Reviewed measures of problem	Reviewed initial results and discussed practice changes	Not completed	
CLABSI/ Handwashing	Parent views of handwashing practices	Reviewed measures of problem	Reviewed results of change	Assisted development/ production video training tool for clinicians; Reviewed outcome data	Reviewed outcome reports; Recommended parent viewing of video
Parent2Parent	Project charter completed	Developed parent input form	Advisors attended parent rounds with managers	Advisors attended sensitivity training with licensed counselor	

Discussion

As we evaluated our work over these past few years, we recognized several lessons. Of primary interest to others doing this work are the steps taken to integrate this council into quality improvement work on a unit. We evaluated the meeting documents, surveys, and interviews done by and through this council to describe a three-step process for integration of patient/family advisor into unit-based quality improvement. A manuscript is ready for submission, and it includes co-authorship by a parent advisor. It describes three key steps to integrating parent advisors into quality programs: 1) purposeful development of parent advisory council; 2) preparing advisors for quality improvement work; and 3) integrating parents into improvement work.

Conclusion

Parents of NICU graduates can be integral partners as parent advisors in quality improvement work.

Significance

Parent advisors played a key role in humanizing the impact of problems in care to those responsible for conducting improvement work. Finding and sharing successes of parent advisor integration built confidence among clinical teams, which encouraged team members to involve them in projects.

Implications

The success of this council was shared in hospital leadership meetings and thus created the impetus for two other units, Pediatric ICU and Pediatric Surgical Services, to develop parent and family councils based on our defined three-step process.

Dissemination activities:

1. Ottosen, MJ and Duffy, C (parent advisor). Engaging Parents as Partners in Unit-based Quality Improvement, podium presentation to Academy of Neonatal Nurses, Annual conference on September 6, 2018, New Orleans.
2. Andrew, Meghan (parent advisor) A Parent Advisor Story, Annual Quality Congress, Vermont Oxford Network, October 2018, Chicago, Illinois.
3. Andrew, Meghan (parent advisor) and Alyssa Meyer (parent advisor) Issues of quality in health care: Being a parent and parent advisor in the NICU, invited presenter to Obstetrics and Women's Health, Baccalaureate Nursing program, Cizik School of Nursing, October 2018, March 2019, October 2019.
4. Ottosen, MJ, Parent/family engagement in research: an investigator's perspective, invited speaker to "Implementation Science for APRNs" conference at Prairie View A&M College of Nursing, Houston, Texas, October 2021.
5. Manuscript ready for submission to Journal of Healthcare Quality: Ottosen, MJ, Yager, L., Sedlock, E., Nether, K., Swanson, M., Meyer, A. (parent) & Thomas, EJ. Steps to engaging parents as partners in neonatal intensive care quality improvement.

Project Title: Electronic Health Record Core

Component Project Lead Information: SITTIG, DEAN F.

Abstract

Purpose: Develop tools and techniques to help ensure that EHRs are working as designed, developed, and implemented and are functioning safely, reliably, and effectively; develop methods and assess whether the EHR was being used correctly and completely by the clinicians as they cared for their patients; and explore the potential for the EHR to be used to monitor and improve the efficiency, safety, and reliability of the care of patients.
Scope: "EHR-enabled care" delivered in the NICU, a high-risk, high-reward care setting.
Methods: We used the ONC-sponsored SAFER guides to assess the safety and effectiveness of the EHR in use in the local NICU as well as across the other 13 hospitals in their health system. We collected data on DDI alerts and override reasons from 10 clinical sites across the United States. We developed e-triggers to identify specific types of EHR errors.
Results: Key results from the SAFER guide assessments for the two foundational guides included a high degree of variation. Key results from our work to identify a set of valid DDI override reasons included identification of 12 categories of override reasons. We identified and developed the Safer Dx Trigger Tools Framework that enables health systems to develop and implement e-trigger tools. We identified nine challenges to help healthcare organizations, health information technology developers, researchers, policymakers, and funders focus their efforts on health information technology–related patient safety. **Implications**: CMS now requires eligible hospitals to attest to having completed an annual self-assessment of their electronic health record (EHR) using SAFER Guides.

Key Words: Electronic Health Record; Patient Safety

EHR Core Final Report

Purpose: The objectives of the EHR core were to 1) ensure that the EHR was working as designed, developed, and implemented and was functioning safely, reliably, and effectively; 2) develop methods and assess whether the EHR was being used correctly and completely by the clinicians as they cared for their patients; and 3) explore the potential for the EHR infrastructure to be used to monitor and improve the efficiency, safety, and reliability of the care of patients.

Scope: Effective use of EHRs can fundamentally improve the safety of healthcare. To complement the other cores, we focused on the "EHR-enabled care" delivered in the NICU, a high-risk, high-reward care setting. EHRs can play a pivotal role in targeting common safety problems in the NICU, such as patient or specimen misidentification, age- and weight-based dosing errors, and communication breakdowns between providers. Despite the promise of EHRs, for a variety of reasons, these benefits have yet to be fully realized. Moreover, EHR use can introduce its own unique set of risks.

Methods: To address whether the EHR was functioning safely, reliably, and effectively, we used the ONC-sponsored SAFER guides that we developed in a previous research project to assess the safety and effectiveness of the EHR in use in the Memorial Hermann NICU as well as across the other 13 hospitals in their health system. In addition, to gain some perspective on the findings from the Memorial Hermann NICU, we also used the SAFER guides to assess EHR implementations at seven other healthcare systems in the USA and Australia. This involved convening groups of clinicians and IT professionals to assess various aspects of the EHR as implemented. To address issues involving collection of inaccurate drug-drug interaction (DDI) alerts, we collected data on DDI alerts and override reasons from 10 clinical sites across the United States. These sites used a variety of EHRs. This helped us determine availability and use of structured override reasons for drug-drug interaction (DDI) alerts in electronic health records (EHRs). To create the e-triggers, we used the following seven iterative development steps. See "Overview of the process used to create e-Triggers." BMJ Qual Saf. 2019 Feb;28(2):151-159. doi: 10.1136/bmjqs-2018-008086.

Results: Key results from the SAFER guide assessments included demonstration of considerable heterogeneity in implementation of SAFER recommendations across the sites. For example, implementation of CPOE/CDS guide's 29 recommendations ranged from 25-100% in the organizations we surveyed. Key results from our work to identify a set of valid DDI override reasons included the identification of 177 unique override reasons across the 10 sites. The number of coded override reasons at each site ranged from three to 100. Many sites offered override reasons not relevant to DDIs. Based on our e-trigger work, we identified and developed a knowledge discovery framework, the Safer Dx Trigger Tools Framework, that enables health systems to develop and implement e-trigger tools to identify and measure diagnostic errors using comprehensive electronic health record (EHR) data. Briefly, the Safer Dx e-trigger tools can be used to detect potential diagnostic events, allowing health systems to monitor event rates, study contributory factors, and identify targets for improving diagnostic safety. Based on all our safety assessment work, we identified nine key, short-term challenges to help healthcare organizations, health information technology developers, researchers, policymakers, and funders focus their efforts on health information technology–related patient safety. We also wrote an article, discussing how key stakeholders in the EHR-enabled healthcare system have complementary roles in improving EHR safety and must share responsibility to improve the current state of EHR use.

Implications: Based on this research, we encouraged all EHR-enabled healthcare organizations to use the SAFER guides to assess their current adherence to these recommendations and work to come into adherence with those that they are not currently following. In addition, we encouraged EHR-enabled healthcare organizations to recognize these challenges, because they represent key "to-do's" that must be completed before we can expect to have safe, reliable, and efficient health information technology–based systems that are necessary to care for patients.

On August 13, 2021, the Center for Medicare & Medicaid Services (CMS) published new rules regarding the Medicare Promoting Interoperability Program and its Protect Patient Health Information Objective. Specifically, CMS added an unscored, attestation-only measure that requires eligible hospitals to attest to having completed an annual self-assessment of their electronic health record (EHR) using the Office of the National Coordinator for Health Information Technology (ONC)-sponsored SAFER (Safety Assurance Factors for EHR Resilience) Guides beginning in 2022. This is a major development in health information technology (IT) and patient safety policy.

PUBLICATIONS

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Project 1: Reducing Unplanned Extubations

Abstract

Purpose: 1) Measure all-cause preventable harm related to respiratory care. 2) Assemble several teams of frontline caregivers who have been trained by the RPI core to design, develop, implement, and evaluate multiple interventions to reduce respiratory care preventable harms by 50%.
Scope: After baseline date collection and review of preventable harms, we decided to reduce unplanned extubations (UPEs). These were defined as any intubated neonate with endotracheal tube removed at any time, or fashion, not specifically intended or ordered by a physician. UPEs are preventable harms of invasive mechanical ventilation that most institutions strive to avoid because of their potential as a life-threatening event, detrimental complication, and/or worsened patient outcomes. Such events have also been shown to have a financial impact on hospital costs and to increase hospital and ICU LOS. **Methods:** We used Robust Process Improvement tools to measure baseline UPEs, determine causes of UPEs, prioritize interventions, and carry out three PDSA cycles: #1 involved developing the UPE triggers and measurement system and providing feedback on rate of UPEs; #2 was teaching RTs proper taping technique; and #3 was additional intensive training for RNs and RTs that included proper ETT assessment and positioning and how to move infants with ETTs.

This information was delivered via a video we made and included competency testing. The training and testing were mandatory.
Results: The NICU UPE rate centerline shifted down from 1.007 to 0.534 after the interventions. The unit has stayed below the benchmark rate for Solutions for Patient Safety.
Key Words: Unplanned extubations, robust process improvement

Project 1 Final Report

Purpose: 1) Measure all-cause preventable harm related to respiratory care; and 2) assemble several teams of frontline caregivers who have been trained by the RPI core to design, develop, implement, and evaluate multiple interventions to reduce respiratory care preventable harms by 50%.
Scope: In August 2016, as part of the AHRQ Patient Safety Learning Lab, we applied the robust process improvement (RPI) methodology, provided Yellow-Belt training for RNs, RTs, physicians, and parents, and set a goal to decrease the UPE to zero by November 2018. This also involved close to a year of work to refine our UPE triggers and the system for measuring UPEs.
Methods: We redeveloped our UPE debriefing tool so that caregivers could more easily complete and designated the RT to ensure that it gets completed. This tool and our trigger report have allowed us to capture 100% of our UPEs, and we feel confident that we are capturing a vast majority of the events. The unit culture improved as well to include verbal report of UPEs in different forums. UPEs were reported to RT team leads and in RN and medical team huddles, in RT documentation in Cerner, and in Variance reporting, all of which served as safety nets in capturing instances of missed documentation. From the UPE debriefing forms, we were able to compile the data to track trends for possible causes for these events. Causes of UPEs included ETT positioning, kangaroo care, ETT securement, retaping, repositioning, agitated or active infant, and suctioning.
Next, we performed random audits on specific elements, including assessments, documentation, taping, securement, and communication, and we sent out questionnaires to gauge knowledge. We found that staff did not know how to assess depth of ETT; did assess integrity of ETT regularly; and had inadequate documentation.
Our interventions included three PDSA cycles: #1 involved developing the UPE triggers and measurement system and providing feedback on rate of UPEs; #2 was teaching RTs proper taping technique; and #3 was additional intensive training for RNs and RTs that included proper ETT assessment and positioning and how to move infants with ETTs. This information was delivered via a video that we made and included competency testing. The training and testing were mandatory.
Results: SPC charts (not shown due to space) revealed decreases in UPE rates and increases in days between UPEs. Our NICU UPE rate compared to the Solutions for Patient Safety (SPS)Network was below the SPS centerline (1.09), and we have been below the network rate for nine of the past 10 months, with a great continued downward trend overall (at time of project completion).
Conclusion: Our unit-based approach that involved tracking and prioritizing harms, training caregivers (including parents) to participate in QI efforts, and using support from the learning lab cores resulted in reductions in unplanned extubations. These results indicate that future improvement efforts should also focus on training clinicians and engaging parents, two relatively underutilized improvement activities.

List of Publications and Products:
No publications. Training videos, figures/charts, and other materials can be shared upon request.

Project 2: Reducing Nutritional Related Harms

Abstract

Purpose and scope*:* In this quality improvement initiative in a level IV academic neonatal intensive care unit (NICU), we aimed to reduce the energy and protein deficits that accumulate over the first month of life in very-low-birthweight (VLBW) newborns.

Methods*:* We prospectively followed all inborn infants and those transferred in <24 hours, <33 gestational age (GA), and <1500 g birth weight (BW) from September 2016-July 2018 (n=318), excluding infants with major congenital anomalies and deaths before 28 days. Practice changes included publishing tables of energy and protein goals by day of age, updating feeding protocols, and improving documentation within daily progress notes. Additionally, feedback reports showing compliance were disseminated. Nutrition prescriptions were compared by phase and adjusted for differences in GA and BW.

Results*:* The average GA and BW were 27.8 ± 2.9 wks and 1.02 ± 0.3 kg and were similar through all phases. The adjusted increase from over three phases was 10.1 cal/kg/d, (95% CI 4.7 – 15.5, $p<0.001$). For prescribed protein, the adjusted increase from baseline versus phase 3 was 0.3 g/kg/d, (95% CI 0.13 – 0.45, $p<0.001$). Detailed nutritional documentation by the primary provider was positively associated with improved nutritional orders ($p<0.05$). After adjusting for GA, BW, and antenatal steroids, higher average calorie administration over the first month of life was associated with less severe bronchopulmonary dysplasia ($p<0.05$).

Conclusion*:* A series of practice changes resulted in significantly improved prescribing and energy and protein. Implementing these practices could improve nutrition for VLBW newborns.

Key Words: preterm infants, nutrition

Project 2 Final Report

Purpose: 1) Measure all-cause preventable harm related to nutritional care. 2) Assemble several teams of frontline caregivers who have been trained by the RPI core to design, develop, implement, and evaluate multiple interventions to reduce nutritional care preventable harms by 50%.

Scope: Nutritional deficits are common in very-low-birthweight infants (VLBW) infants (1). Adequate growth of VLBW infants is associated with reduced risk of bronchopulmonary dysplasia (BPD), lower rates of retinopathy of prematurity (ROP), better growth, and improved neurodevelopmental outcomes (2-4). Studies have shown neonatal intensive care practices vary widely within and between centers (5, 6). We hypothesized that focusing on both individual-level and protocol-driven changes will enhance the quality of nutritional administration, yielding more appropriate quantities of nutrition given to our infants.

Methods: This was a prospective quality improvement project approved by the IRB of McGovern Medical School at the University of Texas in Houston and was not deemed human subject research. A quality improvement interest group met weekly and included three neonatal dietitians, a neonatologist, a neonatal fellow, a clinical neonatal pharmacist, and a neonatal nurse practitioner. We included bimonthly phone calls from an “Black Belt-Level” expert from The Joint Commission who is trained in Quality Improvement Yellow Belt Program© techniques specifically for hospital quality improvement.

Cohort Selection: All VLBW infants born from September 2016-October 2018 and admitted to Children’s Memorial Hermann Neonatal Intensive Care Unit (NICU) or born in Memorial Hermann Hospital or transferred in within 24 hours of birth were identified. Patients were eligible if they were younger than 33 weeks gestational age (GA) and less than 1500 (g) birth weight (BW). Babies were excluded if they had major life-threatening congenital anomalies (e.g., cyanotic heart disease, meningomyelocele, gastroschisis, etc.) or had known chromosomal anomalies diagnosed in the first 28 days of life.

Data Collection: Calorie and protein prescribed from both enteral and parenteral sources were carefully abstracted from the hospital electronic medical record to the nearest tenth of calorie or gram by neonatal dietitians on days of life 7, 14, 21, 28 for each qualifying infant.
Growth Data: Fenton Z-scores for weight, length, and fronto-occiptal circumference by gestational age were calculated based on Fenton published tables, which were collected at birth and discharge. Z-scores for weights at 28 days were also obtained.
Definitions and Morbidity: After discharge, demographic data and comorbidities were collected. *Robust Process Improvement (RPI):* Robust process improvement training via modules for the Six Sigma Yellow Belt Program© was completed by the project team.
Phase Interventions: Process improvements lasted 3 years and were defined by four main epochs (baseline and intervention phases 1-3) that were dated by when the prospective interventions began. Baseline period was defined as September 22, 2016, to September 7, 2017. The first phase of interventions included educational lectures and a survey of practice habits. We created and disseminated day-of-life nutrition goals for VLBW nutrition. The second phase began November 28, 2017, with an update of the feeding protocol. Beginning in phase 2, we introduced a new rounding style called "nutrition-focused rounding," in which direct patient care providers (NNPs, fellows, and residents) received a script and would state both the calories and protein the infant received daily (reporting the totals from both enteral and parenteral nutrition) up to 28 days of life. Rounding scripts also included whether nutritional goals were met for the day and, if not, if increases in the kcal or protein were medically possible. Full documentation in the progress notes was defined as the totals of protein and calories and the goals for the current day. The scripted rounding style and documentation lasted until the infant reached 28 days of life or full feeds (as defined as 160 mL/kg/d of fortified expressed breast milk (EBM) to 24 kcal/kg or appropriate 24 kcal/oz formula). We trained individual providers by selecting specific infants throughout this phase 2 and generated a resistance survey to elucidate the reasons for any lack of compliance. Phase 3 began June 4, 2018, and ran to October 31, 2018; rounding and documentation became required for all infants meeting eligibility criteria.
Statistical Analysis
Univariate analyses of covariance were used to find adjusted outcomes for gestational age and birth weight. General linear models were used to find significant factors affecting outcomes such as BPD, length of stay, and growth. Fisher's exact tests were used for categorical variables, and t-tests were used for scalar outcomes when appropriate.

Results

Calorie and protein orders significantly increased between baseline and phases 1-3 (see figures; $p<0.001$). There were no significant changes in BW or GA between baseline and phases. Documentation increased significantly between phase 2 and 3 when the new nutrition-based rounding style was piloted and fully implemented. Patients who did not require documentation (full fortified feeds) were not included in these totals. Using GLM, correcting for BW, GA, antenatal steroids, female gender, and IUGR or placental insufficiency, positive calorie intake was still associated with decreased severity of BPD, ($p=0.02$). Protein was not significant in this model.

Conclusion, discussion, and implications

A multidisciplinary quality improvement group was trained in RPI and met weekly with the aim to improve nutrition in the NICU by using the latest evidenced-based literature. Design Failure Mode and Effects Analysis (DFMEA) was key to predicting and preparing for barriers before they presented themselves. Resistance analysis increased communication with all staff members (NNPs, nurses, pharmacists, fellows, residents) to address problems such as missing education on our interventions and increasing buy-in to change.

Techniques, including identifying a physician champion (supportive faculty and director of unit), were key to unit compliance.

A series of interventions, including nutrition education, an updated feeding protocol, nutrition-focused rounding, and audits, led to significant increases in calorie and protein prescriptions. Our new feeding protocol shortened days to full feeds by 3 days in the lowest birthweight group, and by 1 day in larger-GA and BW groups. The new protocol included fortifying donor or mothers' milk at 80 mL/kg/day instead of 120 mL/kg/d enteral volumes. We designed goals for calories and protein for VLBW infants per day of life based on calorie and protein quantities that were practical to achieve based on recommended feeding volumes and enteral advancement schedules. Over a series of days, these practical goals merged with established optimal nutritional goals, as published in Nutrition by the Preterm Infant by Tsang et al, and nutritional recommendations by ESPHAN for VLBW infants.

Quantitative amounts of calorie/kg and protein/kg significantly increased over the three phases, even after adjusting for BW and GA. Scripted documentation was associated with higher protein and calorie orders. When adding phase change to the regression model (which would account for protocol changes), documentation was still highly associated with calorie administration ($p<0.001$) but not with protein administration ($p=0.18$).

Length of stay was not significantly associated by phase changes, though we did see a decrease in length of stay from baseline to phase 3. This may be attributable to the wide variation in LOS, which is highly associated with late-onset diseases processes like BPD, NEC ,and IVH in this cohort. We did see a reduction in parenteral nutrition days by approximately 5 days (data not shown). With these data, increased severity of BPD was positively associated with lower GA and BW, male gender, incomplete or missing course of antenatal steroids, and low caloric intake. The association between BPD and early calorie intake was reported by Klevebro et al in 2018. In their study, for VLBW infants between days 7 and 27, every 10 kcal/kg/d increase in energy intake was associated with a 9% reduced risk of BPD (95% CI 1–16; $p=0.029$) (4). Severity of BPD was not associated with early protein intake in our model. Step-wise, well-executed, multidisciplinary interventions using RPI framework with Black Belt mentoring resulted in positive nutrition in our VLBW NICU.

Figure 1. Percentage of Days Meeting Calorie Goals by Phase

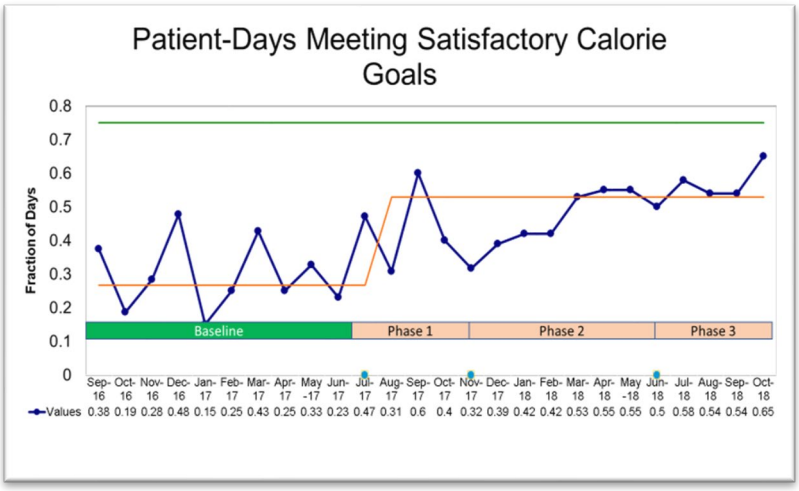
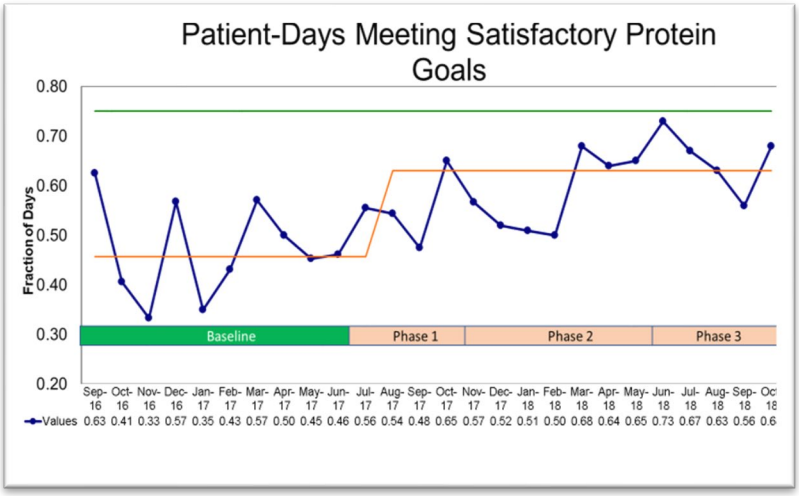


Figure 2. Percentage of Days Meeting Protein Goals by Phase



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List of Publications and Products (Bibliography of Published Works and Electronic Resources from Study—Use AHRQ Citation Style for Reference Lists).

None