



# Implementing a Robust Process Improvement Program in the Neonatal Intensive Care Unit to Reduce Harm

Klaus G. Nether • Eric J. Thomas • Amir Khan • Madelene J. Ottosen • Lauren Yager

## ABSTRACT

**Introduction:** Preventable harm continues to occur with critically ill neonates despite efforts by hospital neonatal intensive care units (NICUs) to improve processes and reduce harm. Attaining significant and sustainable improvements will require training including leadership support, mentoring, and patient family engagement to improve care processes. This paper describes the implementation of a robust process improvement (RPI) program in the NICU to reduce harm.

**Methods:** Leaders, staff, and parents were trained in 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 pretraining and post-training surveys. Training scores (0–10 scale) improved from an average of 4.45–7.60 ( $p < .001$ ) for confidence in leading process improvement work, 2.36 to 7.49 ( $p < .001$ ) for RPI knowledge, and 2.19 to 7.30 ( $p < .001$ ) for confidence in using RPI tools; relative improvement of 71%, 217%, and 233% respectively. Participants applied their RPI training on improvement initiatives that resulted in improvements of central line blood stream infections, very low birth weight infant nutrition, and unplanned extubations.

**Conclusions:** Implementing an RPI 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

## Introduction

Two decades after the publication of the Institute of Medicine report “To Err Is Human,” errors in health care delivery continue to lead to patient harm and death.<sup>1–4</sup> Although some improvements have been made industry-wide, significant and sustainable breakthroughs in reducing patient harm remain elusive.<sup>5</sup> Despite efforts to improve processes and reduce harm, critically ill neonates continue to be harmed in the

neonatal intensive care unit (NICU) because of such events as central line blood stream infections, very low birth weight infant nutrition issues, or unplanned extubations.<sup>6–13</sup> Neonatal Intensive Care Units are complex and relatively free-standing with staff and processes that are largely independent from the rest of the health system.<sup>13</sup> The NICU delivers care to the most fragile of patients (infants) who are easily harmed.<sup>13</sup> The infants in the NICU are often hospitalized for months, increasing their risk for harm events.<sup>13</sup>

In 2013, in their review of high reliability industries such as commercial airlines and nuclear power that have achieved high reliability despite complex operations and the potential for catastrophe, Chassin and Loeb proposed a framework for the transformation of health care to high reliability and zero harm.<sup>5</sup> The High-Reliability Health Care Maturity Model presents three major and interrelated domains of change for health care organizations to pursue so that they can progress on their journey toward high reliability.<sup>5</sup> These are: leadership commitment to zero harm, a culture of safety and robust process improvement (RPI).<sup>5</sup> Robust process improvement refers to widespread use of process improvement tools within health care organizations, so

*Journal for Healthcare Quality, Vol. 44, No. 1, pp. 23–30*

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The authors declare no conflicts of interest.

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This work was funded by grant #5P30HS024459-03 from the Agency for Healthcare Research and Quality. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.

DOI: 10.1097/JHQ.0000000000000310

that staff have the skills to identify and pursue sustainable improvements. Health care organizations also continue to have challenges sustaining improvements; this has had a detrimental effect on their ability to pursue high reliability.<sup>14,15</sup> A full third of quality improvement projects are not sustained after a year and almost 70% are not sustained over time.<sup>16,17</sup> Our understanding about what leads to sustainability is not yet well developed, but change management is likely a key factor.<sup>15,18</sup> Managing the change for sustainability is specifically addressed by RPI through its blended approach of Lean, Six Sigma, and formal change management.<sup>5</sup>

In addition to building confidence and knowledge with RPI concepts and tools, other components such as leadership support, mentoring, and patient/family engagement in improvement initiatives are necessary to implement a RPI program.<sup>5,13,19</sup> This goes beyond having patients and families provide input through committees or gathering feedback, but rather having them in the redesign of the processes that need improvement.<sup>5</sup>

Through funding from a grant, our institution partnered with colleagues at the university medical school and the children's hospital to implement an RPI program within a Patient Safety Learning Laboratory focused on reducing harm in the NICU. This paper describes how an NICU within a large health care system implemented an RPI program ("RPI Yellow Belt training") including the provision of leadership support, the methods for training and mentoring of staff and parents, and the sustained outcomes to date for the improvement initiatives completed as part of the training.

## Methods

### Project Overview

This project was part of a grant to reduce harm in the NICU. It was designed to improve the confidence and knowledge in improvement concepts and tools of NICU staff and parents of the Parent Advisory Council (PAC) from the children's hospital by implementing an RPI program.<sup>13</sup> Our institution's staff collected data from December 2016 through August 2019 on the RPI Yellow Belt training through surveys that were administered before and after training, assessing participants' confidence and knowledge in improvement concepts and tools. The staff also collected data on the outcomes including sustainability of the improvement initiatives that were completed as part of the training. Given that our

focus was on implementing an RPI program, we do not report the details of each improvement initiative. This study was approved by our university's Committee for the Protection of Human Subjects as Non-Human Subjects Research (IRB#HSC-MS-16-0542).

### Project Setting

This project was conducted in the NICU at the children's hospital.<sup>13</sup> The children's hospital is one of 13 hospitals in the health system.<sup>20</sup> One of the country's largest pediatric hospitals, the children's hospital is a 310-bed quaternary care women and children's hospital.<sup>13</sup> Neonatal intensive care unit leadership and staff (frontline staff, medical staff, unit educators and unit leadership), university medical school research staff that worked or conducted improvement initiatives in the NICU, and members of the PAC participated in the RPI Yellow Belt training and improvement initiatives.<sup>13</sup>

### 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. The RPI Yellow Belt training is an online and interactive course consisting of seven modules that lead a training participant through the different phases of Six Sigma called DMAIC (Define, Measure, Analyze, Improve, and Control) by answering the questions that need to be asked for each phase.<sup>21</sup> The online training is four hours and can be stopped and started at any time, so that participants could receive training at their own pace. Integrated into the online training was a pretraining and post-training survey (0–10 scale) that participants had to take to be given credit for completing the training. Training participants then joined improvement initiative teams and used their RPI skills to address safety problems in the NICU.

Building an RPI program for the NICU required two phases of engagement: program building and training. Program building was the first step and began with training of NICU leaders since a transformation to continuous improvement requires leadership support. Training of NICU leaders started with formal change management (*Facilitating Change Model*).<sup>22</sup> The training provided NICU leaders with change management concepts and tools to support improvement initiatives such as a stakeholder

analysis, communication plan, priority payoff matrix, and helping/hindering to sustain the gains (See Table 1 for Complete List of Concepts and Tools for Formal Change Management).<sup>22</sup> In addition, NICU senior leaders built the infrastructure for a successful and sustainable program by examining roles and responsibilities, developing selection criteria for trainees, and selecting improvement initiatives and focus areas that aligned with the NICU's strategic initiative of reducing harm.

The second phase, which was the RPI Yellow Belt training phase, started almost 5 months later and included NICU leadership and staff who were selected to lead improvement initiatives. Participants completed RPI Yellow Belt training (See Table 2 for List of Concepts and Tools for RPI Yellow Belt training).<sup>21</sup>

One of the goals of the grant was to integrate and engage parents in improvement initiatives. The PAC was created as a component of the Patient Safety Learning Laboratory to engage former NICU parents as partners in the improvement process. Parent Advisory Council members were parents of NICU infants discharged from the hospital within the past one and a half to 5 years and who had experienced varied complications throughout their NICU stay. They were nominated by NICU clinicians, interviewed by a PAC steering committee, and selected based on their ability and motivation to serve on improvement initiatives in the unit. The 11-member council included 7 parents, 3 NICU nurse clinicians (manager, nurse practitioner and staff nurse), and a nurse researcher who facilitated implementation and evaluation of the council activities.

Parent Advisory Council members received training on patient and family-centered care, their role as members, and information about current improvement initiatives. In preparation to work on improvement initiatives, each member also received RPI Yellow Belt training.

Robust process improvement Yellow Belt training included a requirement for participants to apply the concepts and tools they learned in their training to an actual improvement initiative. For example, every team worked together to create a project charter to define the improvement initiative including the problem, business case, primary customer, scope, goals, timeline, and team. The team then got signoff from a project sponsor and champion that was identified for leadership support to move forward with the initiative. Some other tools that were used by multiple teams during their improvement initiative included the stakeholder analysis to gain support, process maps, communication plans, Pareto charts, cause and effect diagrams, control charts, design failure modes and effects analysis, standard work, and control plans. Neonatal intensive care unit leaders identified three improvement initiatives by focusing on the greatest opportunities to reduce harm in the NICU. These included reducing central line blood stream infections, improving very low birth weight (VLBW) infant nutrition, and reducing unplanned extubations.<sup>13</sup>

Process improvement teams formed to address each of the three improvement initiatives. Each multidisciplinary team including one PAC member was led by a physician and clinician such as a nurse or respiratory therapist, depending on the improvement initiative.<sup>13</sup> Parent Advisory Council members were asked to participate on teams that they had personal experience with based on their infant's NICU journey. For example, parents of infants who had been intubated for several months participated on the unplanned extubation team. In addition, each of the teams had mentors from our institution who were experts in RPI.<sup>13</sup> 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

**Table 1. The Formal Change Management Curriculum (Facilitating Change Model): Face-To-Face Training With NICU Leaders<sup>22</sup>**

Plan your project	Inspire people	Launch the initiative	Support the change
Assess the culture Define the change Assemble a strategy Engage the right people Brainstorm barriers to success Build the need for change Paint a picture of the future state	Solicit support and involvement Make it personal Look for resistance Lead change	Align operations and infrastructure Get the word out	Permeate the culture Monitor progress Sustain the gains

**Table 2. The Online RPI Yellow Belt Training Curriculum: Interactive Online Training Consisting of 7 Modules Including Examples and Activities to Complement the Concepts and Tools<sup>21</sup>**

Module 1—Welcome to yellow belt Problems occur, why? What is robust process improvement? Lean reduces waste Six sigma eliminate defects Change management involves people in creating and sustaining solutions				
Module 2—What needs to be improved? Tool list 15 Words Threats versus opportunities Elevator speech Includes/excludes Process map (current state) SIPOC Project charter	Module 3—How do you know? Tool list Voice of customer Pareto chart Statistics 5 Whys Cause and effect diagram Spaghetti diagram	Module 4—How do you get others involved? Tool list Cultural landscape map Stakeholder analysis Resistance analysis More of/Less of GRPI Communication plan Meeting facilitation	Module 5—How will you solve it? Tool list Brainstorming Priority payoff matrix DFMEA 6S Process map (future state)	Module 6—How will you make it last? Tool list Control plan Helping/hindering Standard work Data display Celebrate
Module 7—Training review and next steps: Tools Taking action Challenging yourself Use robust process improvement everyday Next steps				

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 Robust Process Improvement Yellow Belt Training**

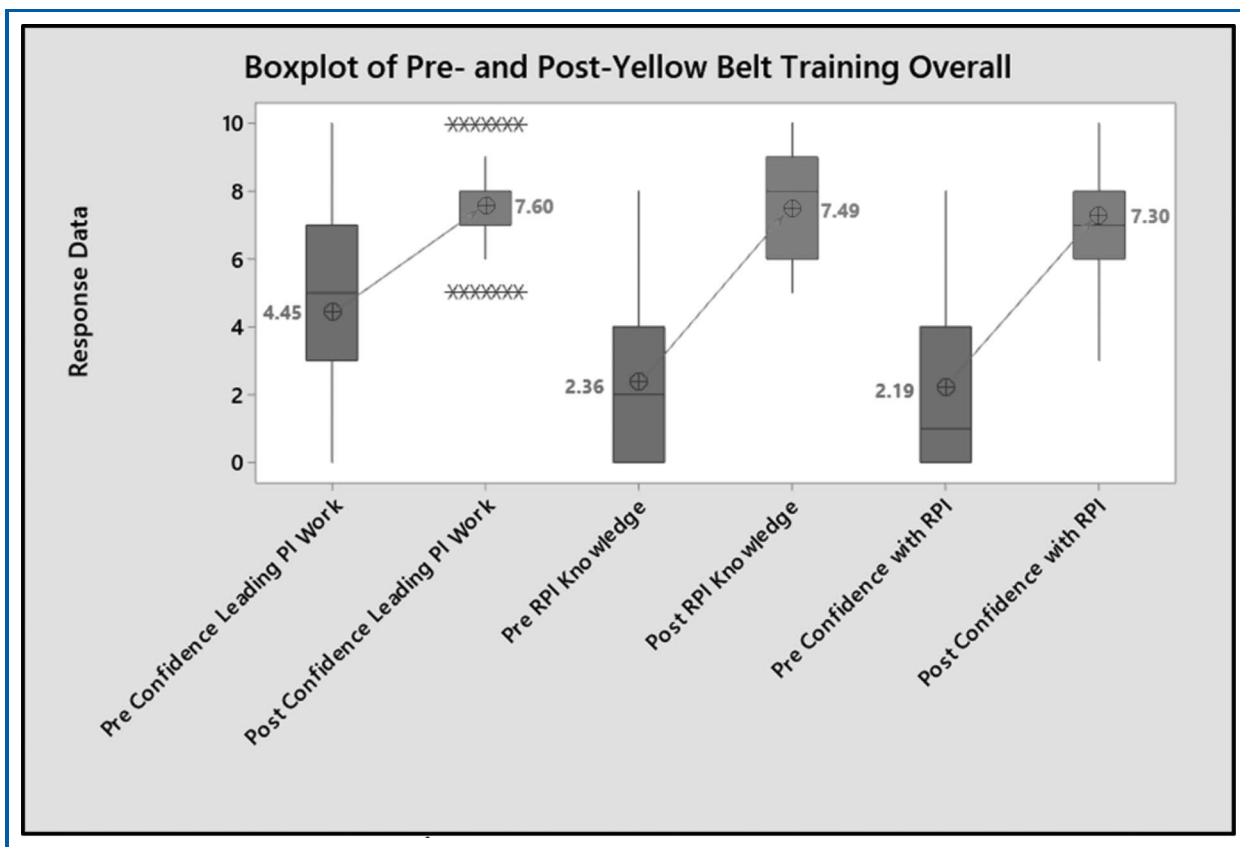
To evaluate the RPI Yellow Belt Training, paired sample T-tests were performed to test for significant improvement. The paired sample T-Tests were conducted on the pretraining and post-training survey results for training participants who completed the RPI Yellow Belt training. Two-sample proportions 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.

### **Robust Process Improvement 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 that worked or conducted improvement initiatives in the NICU and members of the PAC. Training scores (0–10 scale) improved from an average of 4.45–7.60 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 improvement of 71%, 217%, and 233% respectively (Figure 1). All three indicators showed a statistically significant ( $p < .001$ ) improvement and less variability in post-training scores. We also analyzed the data of staff and PAC members separately and found similar results (Figures 2 and 3).

### **Improvement Initiative Results**

The heart of implementing an RPI program was the application of process improvement concepts and tools learned by participants during training to reduce harm in the NICU. The teams were formed



**Figure 1.** Box plot on the pre- and post-robust process improvement (RPI) Yellow Belt Training Survey Results (zero-10 scale) overall (N = 67) on Confidence in Leading Process Improvement Projects, RPI (Lean, Six Sigma and formal change management) Knowledge and Confidence in using RPI tools (all three indicators had a  $p < .001$ ).

from staff and PAC members that completed the RPI Yellow Belt training. The improvement initiatives started once RPI Yellow Belt training was completed and focused on reducing central line blood stream infections, improving nutrition of VLBW infants, and reducing unplanned extubations.

The results from these initiatives showed significant and sustainable improvements. The central line blood stream infections rates showed a relative reduction of 67.1% from baseline to the improve phase that has been furthered reduced and sustained for 17 months with a relative reduction of 77.9% from baseline to the control phase ( $p = .001$ ). The unplanned extubations rate showed a relative reduction of 22.7% from baseline to the improve phase that has also been furthered reduced and sustained for 20 months with a relative reduction of 54.3% from baseline to the control phase ( $p = .001$ ). Nutrition of VLBW infants improved. Calories and protein orders that met daily goals showed a relative improvement of 63% and 35%, respectively

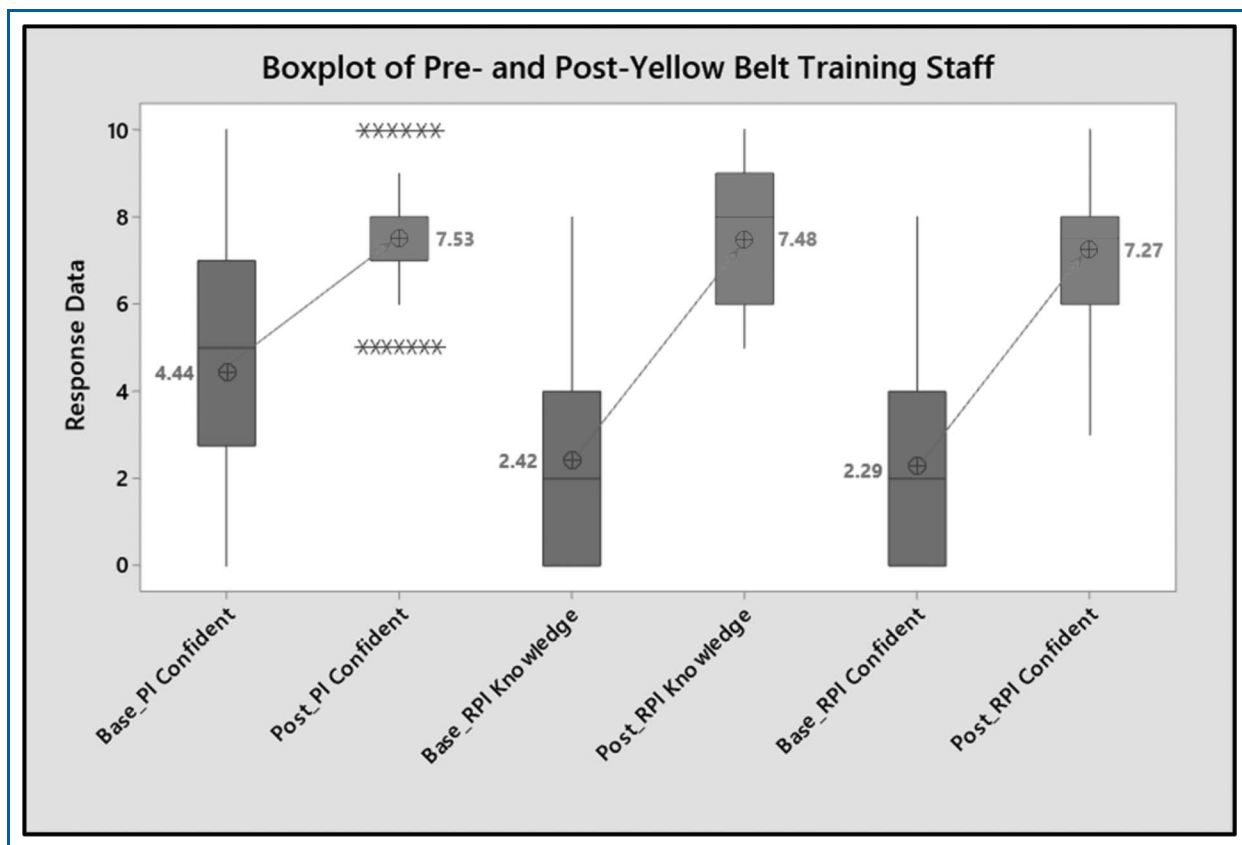
from the baseline to the improve phase ( $p < .001$ ). Two of the three projects showed sustainability beyond 1 year as we continue to monitor the outcomes. One of the projects was entering the phase for sustainability so at this time we cannot validate the sustainability of those improvements made. The children's hospital's definition for sustainability is that improvements are sustained forever unless the improvement is no longer relevant, or the process is eliminated.

### Limitations

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

### Discussion

It is well known that frontline staff, and patients/families have highly variable levels of knowledge

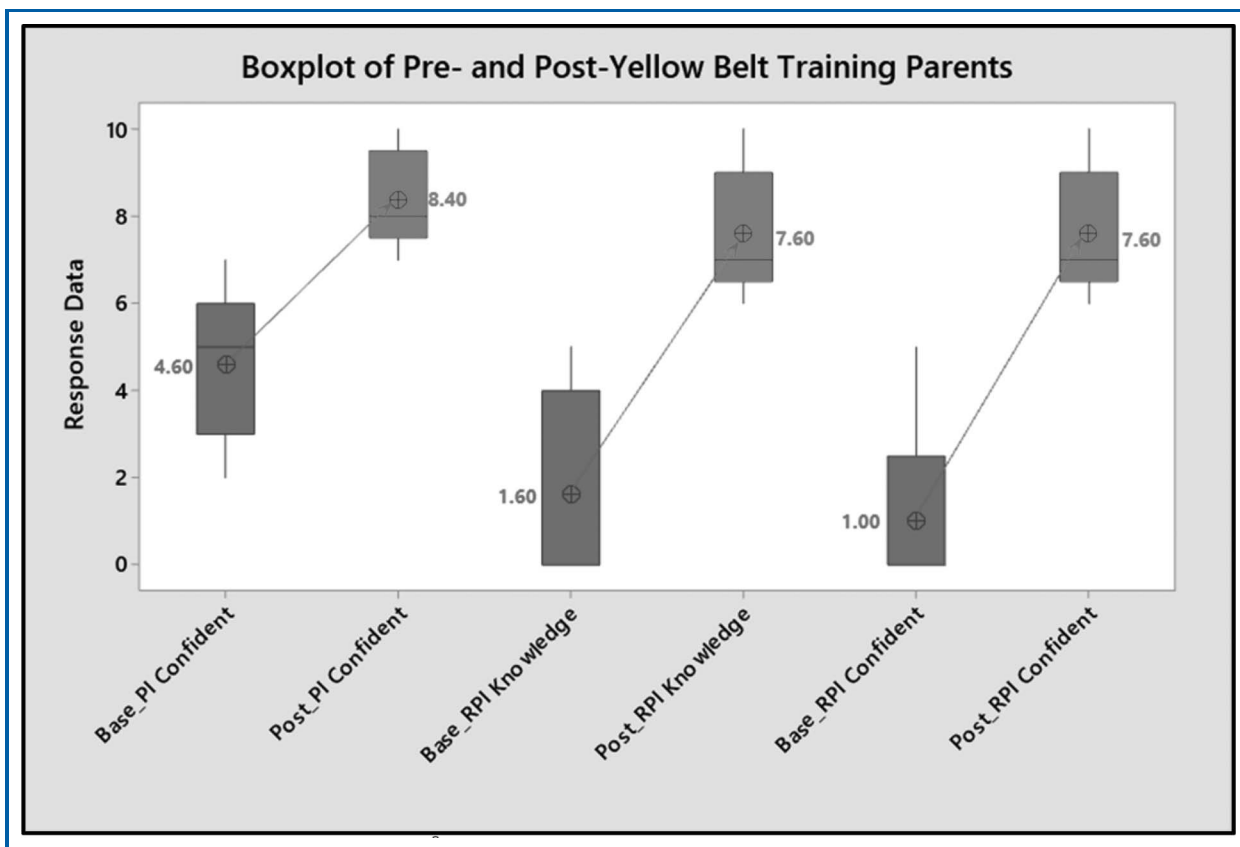


**Figure 2.** Box plot on the pre- and post- robust process improvement (RPI) Yellow Belt Training Survey Results for Staff (zero-10 scale) staff (N = 62) on Confidence in Leading Process Improvement Projects, RPI (Lean, Six Sigma and formal change management) Knowledge and Confidence in using RPI tools (all three indicators had a  $p < .001$ ).

about and experience with process improvement concepts and tools. In addition, health care organizations continue to struggle with sustaining improvement gained through project work.<sup>14-18</sup> We found that implementing an RPI program not only addressed these gaps by providing the training to increase confidence and knowledge for improvement work but led to sustainable improvements.

Our experience also suggests that several additional factors were associated with the success and sustainability of the improvement initiatives. These factors were validated through the continuous monitoring of the improvement initiative outcomes. They are also equally important to the success and sustainability of an RPI program. It starts with the leadership support necessary to implement a program. Neonatal intensive care unit leaders provided dedicated time for staff to attend training, conduct process improvement initiatives during work time and provide the support needed for the improvement teams to be successful. The leadership

support for the RPI program created a common language for improvement work for NICU staff and PAC members including an approach for that work. Common language allowed exchange of ideas, clarity of timelines, and more confidence. The common language empowered members from the PAC to be more involved in improvement initiatives. The PAC members were part of the team providing feedback on what the team identified as root causes and participated in the identification of solutions addressing those root causes. Even PAC members felt confident to lead an improvement initiative in the future. Having access to and participating in the same type of improvement training leveled the field, making everyone feel like they had an equal stake in the improvement initiatives especially the PAC members. This was achieved through training and validated by the pre- and post-training surveys. Sustainability was also designed into the RPI program. Leaders of the NICU were trained in RPI tools and coached in developing and leading a program resulting in a culture for improvement because NICU



**Figure 3.** Box plot on the pre- and post- robust process improvement (robust process improvement) Yellow Belt Training Survey Results for PAC members (zero-10 scale) parents (N = 5) on Confidence in Leading Process Improvement Projects, RPI (Lean, Six Sigma and formal change management) Knowledge and Confidence in Using RPI Tools (the three indicators had a  $p = .030$ ,  $p = .008$  and  $p = .004$  respectively).

staff and PAC members are actively seeking out opportunities for improvement, engaging in improvement initiatives and sustaining improvements that were made. Increased capability and capacity for process improvement was achieved through the RPI training which created a common language and skillset that became embedded into daily work.

The second factor that was key to the success and sustainability of the improvement initiatives was the mentoring provided from our institution experts in improvement work. This is critical to the application of the concepts and tools learned by the staff and PAC members during the training. Mentoring was essential to help team members remember to use tools, focus on the right problem and to maintain accountability of milestones or outcomes.

The final factor was the involvement of the PAC members in the actual improvement initiatives. Because training of members from the PAC was delivered through this project, parents became active

participants in improvement initiatives. Parent Advisory Council member participation added a patient-centered dimension. One member was part of each team working on an improvement initiative. Parent Advisory Council members were assigned to each team based on the completion of the RPI training and on the experiences of their own infant in the NICU. Members were able to share stories of their infant's NICU journey, which shed light on important quality and safety aspects of care delivery. Their input to the improvement initiatives were invaluable and assisted in the implementation of solutions that were not only successful but also sustainable.

## Conclusions

Patients continue to experience death and harm during the course of receiving care despite the best efforts of health care organizations to improve processes and reduce harm. Attaining significant

and sustainable improvements will require training of all staff and patients/families to improve care processes. However, improvement training programs designed to meet these goals are uncommon. This project focused on implementing an RPI program by building confidence and knowledge in RPI concepts and tools. 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

Although improvements have been made in health care, the magnitude of those improvements have not significantly moved the needle when it comes to sustainment and high reliability. Having an effective RPI program addresses the issues with improvement initiatives which is essential for achieving significant and sustainable improvements. The implementation of an RPI program helps to create a culture of continuous improvement as the children's hospital progresses on its journey towards high reliability and zero harm.

### Author's Biographies

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