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A Quality Improvement Collaborative Program for Neonatal Pain Management in Japan

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ABSTRACT

Background: Neonatal pain management guidelines have been released; however, there is insufficient systematic institutional support for the adoption of evidence-based pain management in Japan.

Purpose: To evaluate the impact of a collaborative quality improvement program on the implementation of pain management improvements in Japanese neonatal intensive care units (NICUs).

Methods: Seven Japanese level III NICUs participated in a neonatal pain management quality improvement program based on an Institute for Healthcare Improvement collaborative model. The NICUs developed evidence-based practice points for pain management and implemented these over a 12-month period. Changes were introduced through a series of Plan-Do-Study-Act cycles, and throughout the process, pain management quality indicators were tracked as performance measures. Jonckheere's trend test and the Cochran-Armitage test for trend were used to examine the changes in quality indicator implementations over time (baseline, 3 months, 6 months, and 12 months).

Findings: Baseline pain management data from the 7 sites revealed substantial opportunities for improvement of pain management, and testing changes in the NICU setting resulted in measurable improvements in pain management. During the intervention phase, all participating sites introduced new pain assessment tools, and all sites developed electronic medical record forms to capture pain score, interventions, and infant responses to interventions.

Implications for Practice: The use of collaborative quality improvement techniques played a key role in improving pain management in the NICUs.

Implications for Research: Collaborative improvement programs provide an attractive strategy for solving evidence-practice gaps in the NICU setting.

Key Words: collaborative quality improvement, evidence-based practice, neonatal intensive care unit, neonate, pain, pain management, quality improvement, quality indicators

BACKGROUND AND OBJECTIVE

In recent years, many governmental agencies, medical associations, universities, and other institutions have released evidence-based neonatal pain management guidelines[1-3] as initiatives to standardize pain management care. The Japanese Guideline for Pain Prevention and Management[4] was released in December 2014. This was expected to accelerate improvements in the care of pain in Japanese neonatal intensive care units (NICUs).

The release of a guideline does not ensure that it will be adopted into practice. A qualitative study of medical professionals in NICUs in Canada indicated that organizational factors, including hierarchical communication within the organization and restricted job-related discretionary authority, acted as obstacles to the adoption of evidence-based care.[5]

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A study conducted in the United States reported that the degree of cooperation between physicians and nurses was significantly correlated with the practice of evidence-based pain management.[6] In Japan, a 2012 survey[7] of neonatal pain management in NICUs throughout the country showed that practice of evidence-based pain management was limited by obstacles at organizational and at staff levels, including the lack of educational materials and training opportunities, and the lack of formalized cooperation between medical professionals and family members.

In recent years, quality indicators (QIs) have been introduced to reduce the "evidence-practice gap" between ideal care and actual care. The use of QIs to monitor the progress of improvement efforts has been shown to be an effective method for improving the quality of practice. Previous quality studies have reported the use of QIs for pain assessment and pain relief by both local[8,9] and collaborative groups.[10,11]

The Vermont Oxford Network, an international quality improvement collaborative dedicated to improving neonatal intensive care, introduced Plan-Do-Study-Act (PDSA) cycles to implement "potential better practices" that it had identified.[12] Twelve facilities participated in the Vermont Oxford Network project to improve the quality of pain management.[10,11] Among the reported interventions, a pain management form was added to the electronic medical record system to increase the frequency of pain assessment as the "fifth vital sign"; increased documentation of the use of opioids was also reported. A similar collaborative quality improvement project for the breastfeeding of extremely low birth-weight infants at 11 facilities reported increases in the breastfeeding rate and decreases in the prevalence of necrotizing enterocolitis.[13]

Thus, there is evidence that the use of collaborative quality improvement methods and PDSA cycles can accelerate the uptake of evidence-based pain management provided to newborns in NICUs. Therefore, in the present study, we conducted a trial pain management quality improvement collaborative program incorporating the use of PDSA cycles. The objective of this study was to evaluate the effect of the collaborative improvement program on the implementation of pain management improvements in NICUs in Japan.

METHODS

This study was a prospective pre-/postintervention study to improve neonatal pain management for invasive bedside procedures in Japan and was conducted from September 2014 to January 2016.

Participating Sites and Local Leaders

Seven sites were recruited for this project. In September 2014, an invitation to participate was sent to the neonatal physician chiefs and nursing managers at 100 level III perinatal medical centers with NICUs in addition to special care baby units throughout Japan. We selected the participating sites on the basis of the following criteria to cover various background hospitals: (1) organization of hospital management, (2) location, and (3) local ethics review committee approval before December 31, 2014. Each participating site selected a team of local leaders, including a designated site leader, 1 physician leader, 2 to 3 nurse leaders, and an administrative leader, to constitute the local pain management quality improvement team in the NICUs and special care baby units. The team leaders were provided with a written explanation of the study and were advised that participation as a local leader was voluntary.

This study was conducted with the approval of the respective ethics committees of our institution and of the participating sites.

Patients

The patients were neonates admitted to participating centers (both NICUs and special care baby units) between October 1, 2014, and January 27, 2016, following birth at the center or transfer from another facility. In this study, neonates older than 72 hours of life (excluding infants who were postoperative) were the specific targets of the pain management improvement efforts.

Because the object for interventions in this study was local leaders among participating sites, direct consent was not required from parents/guardians. Instead, a notice was posted at the entrances of the participating wards to introduce the study and to notify parents/guardians that patient medical records would be utilized in the study. The notice also advised that parents/guardians could refuse the use of their child's medical records for the study.

Interventions

The Institute for Healthcare Improvement Collaborative Quality Improvement Model was used to guide the program.[14] The key elements of the model include (1) the appointment of a local multidisciplinary team (within the participating site) that was trained to conduct small-scale tests of change and to help translate successful changes to standard practice; (2) provision of an education session (in this case, a 2-day session conducted in February 2015) on improvement methods and strategies, based on the Institute for Healthcare Improvement model[15]; (3) a supportive communication structure (in this case, ready access to a pain assessment expert for feedback during the test change period and to the participant contact list, which facilitated collaborative exchange between sites); (4) availability of best practice information; and (5) transparent data submission and reporting through the use of PDSA cycles (Figure 1).

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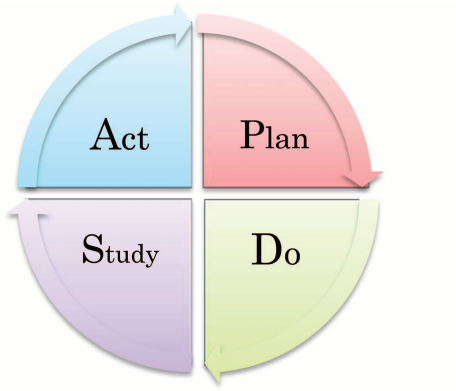
FIGURE 1



Aim of this improvement Overall goal you wish to achieve: Describe your first or next institutional change:	
Plan	List the tasks and plan needed to improve pain management:
	Predict which quality indicators will be implemented when the test is carried out:
Do	Describe what you actually did when you ran the test:
Study	Describe the measured results and how they compared with the predictions:
Act	Describe the required modifications to the plan that will be made for the next cycle: Yes (If yes, describe new plan) No

PDSA cycle and an explanation of what it is in this study. To describe the measured results and how they compared with the prediction, quality indicators monitoring at baseline and 3, 6, and 12 months in this study.

The authors developed comprehensive evidenced-based teaching material on pain management for invasive bedside procedures based on an extensive literature review. Previously, it was shown that local leaders improved the quality of neonatal pain management by acting as a catalyst for change, moving the process forward and maintaining orientation to the assigned tasks.[10,11] Therefore, we selected 3 primary "active collaboration" categories of leader interventions: (1) provision of education on basic neonatal pain management, including neonatal pain sensation, the effect of pain experiences in neonates, measurement of pain, and pain prevention and relief; (2) provision of advanced education on neonatal pain and on teaching methods and collaboration with other medical staff working in pain management; and (3) testing changes in the local work setting through the use of PDSA cycles.

To capture the baseline status of pain management at the participating sites, we reviewed the electronic medical records for the documentation of pain assessment scale scores and pain relief following interventions from October 2014 to January 2015. The data were recorded on a study survey form created by the researchers, which was then mailed to the first author (M.O.). These baseline data were later reviewed at the February session.

The intervention phase ran from February 2015 to February 2016, during which time the site teams made numerous process improvements. In total, pain management outcome data were reported at 4 points in time: just prior to the February education session (baseline) and at 3 months, 6 months, and 12 months after the start of the collaborative program. We required participating sites to provide full transparency in reporting, with open sharing of successes and of barriers. We compared the data from the 4 points in time and provided feedback to the sites in the form of reports showing outcome trends for all the sites.

Outcome Measurement

To investigate whether the PDSA cycles led to an improvement in pain management during invasive bedside procedures, we developed QIs as the primary outcome based on current Japanese standards of care for neonatal pain management.[16] The objective of these QIs was to quantify pain care and the effects of the pain management improvement activities at the study sites. The indicators were further elaborated using the Delphi method. A panel of 11 experts (including authors K.Y., R.F., and M.U.), consisting of physicians and nurses, evaluated the suitability of the initial indicators proposed by the first author (M.O.) following a review of the literature. This deliberation took place over 3 occasions and resulted in the selection of 4 structural indicators (QIs 8, 9, 11, and 12) and 8 process indicators (QIs 1-7 and 10) (Table 1). The 12 indicators allowed the results of pain management improvement initiatives to be quantified (Table 1) and were used to motivate improvement. During the February education session, we reviewed the baseline proportion of implementation of QIs at the participating sites with the team leaders from the respective sites; following the session, the team leaders discussed the findings with their staff members, set pain management aims for each site, and then selected the QIs for the upcoming year.

Statistical Analysis

In this study, the QIs were used to measure the quality of inpatient neonatal care at each of the study

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TABLE 1. QIs for Pain Management in the Participating Neonatal Intensive Care Units[a]

QI	Description	Calculation Method	
		Numerator	Denominator
1	Pain is monitored regularly by measuring vital signs	Number of patients who received regular pain monitoring during each shift by measuring vital signs	Number of hospitalized patients
2	Factors influencing the pain reaction are included in the pain assessment	Number of skin punctures with a pain assessment including factors influencing the pain reaction	Total number of skin punctures
3	A pain measurement has been performed	Number of skin punctures with a pain measurement	Total number of skin punctures
4	Nonpharmacological pain relief measures have been implemented	Number of skin punctures with nonpharmacological pain relief measures	Total number of skin punctures
5	The need for tracheal suctioning has been assessed	Number of patients who were assessed for the need for tracheal suctioning at each shift	Total number of patients
6	An explanation of the use of invasive procedures and pain relief measures has been provided to the parents/guardians	Number of patients whose parents/guardians received an explanation of invasive procedures and pain relief measures	Total number of patients
7	A pain care conference has been held with staff and related parties	Number of patients whose parent/guardians had a pain care conference with medical staff	Number of discharged patients
8	Medical staff have been provided with training on pain management	Number of nurses and physicians who have participated in annual hospital training for pain management	Total number of nurses and physicians
9	One person is in charge of coordinating training on pain management	Presence vs absence	
10	Individual pain management plans have been developed within 48 h of hospitalization	Number of patients for whom an individual pain management plan has been developed, including the content of invasive procedures after birth, pain response to the invasive procedures, which pain tool was used to measure pain, and evaluation of the effect of pain relief within 48 h of hospitalization	Number of hospitalized patients
11	An institutional protocol including pain assessment, pain prevention, and pain relief has been developed	Presence vs absence	
12	There is an organizational audit for pain management	Presence vs absence	

Abbreviation: QI, quality indicator.

[a]QIs 1-8, 10: QI implementation proportion (%) = numerator/denominator × 100. QIs 9, 11, and 12: QI implementation = presence or absence.

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sites. First, we calculated the proportion of implementation of QIs 1 to 8 and 10 from baseline to 12 months. Next, we used the Jonckheere's trend test to examine the changes in QI implementation among all sites over time (ie, at baseline, 3 months, 6 months, and 12 months). We also counted the presence/absence of QIs 9, 11, and 12 and then used the Cochran-Armitage test for trend to examine the changes in QI implementation over time. The data were analyzed using SPSS version 20.0 (IBM SPSS Japan, Tokyo).

RESULTS

Participating Sites and Participants

Nineteen facilities applied to the pain management quality improvement collaborative program, and 7 centers were selected to participate in the 12-month trial (Table 2). All 7 centers remained actively involved during the 12-month implementation phase. Twenty-five clinical team leaders, including 7 physicians and 18 nurses, participated in this study. There was a mean of 56.4 (range: 43-90) staff nurses and a mean of 8.5 (range: 6-15) neonatologists at each of the participating sites. The total number of nurses and physicians among the participating sites was 517 at baseline.

Pain Documentation

At baseline, 2 of the participating sites were already documenting pain with recommended pain assessment scales[4]—the Neonatal Infant Pain Scale (NIPS) and the Face Scale for Pain Assessment of Preterm Infants (FSPAPI)[17,18]; the remaining sites reported issues related to the selection of the best pain assessment scale, the lack of opportunities for training on the use of a pain assessment scale, and the difficulty of assessing pain during procedures, requiring the staff to be shielded. Three participating sites were using electronic forms for pain assessment and pain relief documentation.

All the participating sites without a recommended pain assessment tool[4] introduced these during the study period—1 site introduced the NIPS, 3 sites introduced the FSPAPI, and 1 site introduced both.

Quality Indicators

Table 3 shows the QIs that were implemented at each site during the 12-month period. Table 4 shows the number of admitted neonates who were older than 72 hours during the intervention phase and who were the targets for the QI implementation (this number was used in the calculation of the proportion of implementation at each site). Table 5 shows the outcome trends for each of the QIs over time (baseline, 3 months, 6 months, and 12 months). The total number of nurses and physicians among the participating sites who had undergone annual hospital education for pain management was 188 (36.3% of the total) at baseline, 330 (63.8%) at 3 months, 417 (80.6%) at 6 months, and 491 (94.9%) at 12 months.

DISCUSSION

The baseline data from the 7 sites revealed substantial opportunities for improvement in pain management. Testing change in the NICU setting through the use of PDSA cycles for selected QIs resulted in measurable improvements in pain management at all 7 participating sites. The precision of the statistical analysis was limited because the number of participating sites was small, but we confirmed a trend of increasing implementation rates of QI 1, 2, 3, 5,

TABLE 2. Participating Institutions

Hospital	Number of Beds	Total Number of Nurses and Physicians	Organization of Hospital Management
Hiroshima City Hiroshima Citizens Hospital	9-bed NICU 24-bed SCBU	68 (60 nurses and 8 physicians)	City
Hiroshima Prefectural Hospital	12-bed NICU 18-bed SCBU	54 (48 nurses and 6 physicians)	Prefecture
Japanese Red Cross Society Kyoto Daiichi Hospital	9-bed NICU 18-bed SCBU	58 (49 nurses and 9 physicians)	Japanese Red Cross Society
Nagoya University Hospital	12-bed NICU 24-bed SCBU	67 (60 nurses and 7 physicians)	National university
Saitama Medical Center	60-bed NICU 48-bed SCBU	161 (145 nurses and 16 physicians)	Private university
Tokyo Women's Medical University	15-bed NICU 24-bed SCBU	55 (47 nurses and 8 physicians)	Private university
Yamagata Prefectural Central Hospital	9-bed NICU 18-bed SCBU	54 (48 nurses and 6 physicians)	Prefecture

Abbreviations: NICU, neonatal intensive care unit; SCBU, special care baby unit.

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TABLE 3. Implemented Measures at Each of the Participating Sites[a]

QI	Blinded Site A	B	C	D	E	F	G	Total
1		○	○	○	○	○	○	6
2		○	○		○	○	○	5
3	○	○	○		○	○	○	6
4	○	○	○		○	○	○	6
5		○	○	○	○	○		5
6			○		○	○		3
7		○	○	○	○	○	○	6
8	○	○	○	○	○	○	○	7
9	○		○	○	○	○	○	6
10		○	○		○		○	4
11	○	○	○		○	○	○	6
12					○			1

Abbreviation: QI, quality indicator.

[a]*Circles (○) indicate implementation during the 12 months of testing improvements in the participating sites.*

6, 8, and 10. While other pain management quality improvement activities have been demonstrated in NICUs,[8-11] this report highlights possibilities for collaborative improvement in pain management across various types of organization of hospital management and various regions of hospitals in Japan. The key elements of this collaborative program, including (1) the presence of pain team leaders using PDSA cycles and leadership support for their activities from nurse managers and physician managers at each site, (2) a 2-day educational session with other participating sites, (3) a supportive communication structure involving experts and exchange of experiences among participating sites, and (4) availability of best practice information, might facilitate improvements in pain practice. The QIs in this study focused on pain assessment and relief of pain associated with invasive bedside procedures and did not evaluate postoperative pain management. It is difficult to develop QIs for postoperative pain management because of the lack of evidence for analgesia and sedation in neonates. Indeed, most guidelines for the prevention and management of pain in neonates have not included postoperative pain.[1,2,4]

TABLE 4. Number of Admitted Neonates Older Than 72 Hours During the Intervention Phase

Time	Total No. of Patients	GA Mean, wk	GA Range, wk
Baseline	90	36.2	24-66
3 mo	82	35.9	24-79
6 mo	75	37.3	24-78
12 mo	88	35.3	23-58

Abbreviation: GA, gestational age.

In this study, 8 of the QIs were not in evidence at any of the participating sites at baseline—the reasons may be that these practices had not been implemented or that lack of specific electronic forms made these difficult to measure. According to site reporting during the intervention phase, all the sites introduced electronic medical record forms to capture the selected QIs within 6 months of starting the trial. The development of standardized documentation that includes pain score, interventions, and infant responses to interventions has been shown to significantly facilitate pain management.[19,20] In the current study, the ability to record pain scores, interventions, and infant responses to interventions contributed to improved pain management because this information is needed for individualized planning (QIs 2, 3, 5, and 10). In addition, as was seen in a previous study,[13] the implementation of routine pain monitoring by measuring vital signs (QI 1) and the use of standardized pain assessment tools increased during this study. While the Japanese version of the Premature Infant Pain Profile[21,22] is also a recommended pain assessment tool,[4] none of the sites selected the tool. Four sites selected the FSPAPI, which has also been validated in the Japanese population and is easier to score than other tools.[17,18]

Notably, the relative implementation of QI 6 increased only at 12 months after the start of the intervention period (Table 5). Parental involvement in pain management in the NICU is a relatively new

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TABLE 5. Outcome Trends for All Participating Sites[a]

QI	Baseline	3 mo	6 mo	12 mo	P[b]
1 (n = 6)	0	0 (0-27.3)	0 (0-100)	85.7 (60-100)	.000
2 (n = 5)	0	0	0 (0-100)	0 (0-100)	.047
3 (n = 6)	0	0 (0-71.4)	40 (0-100)	68 (29-100)	.001
4 (n = 6)	0 (0-75)	65.5 (0-100)	66.5 (0-100)	48 (29-100)	.105
5 (n = 5)	18 (0-100)	0 (0-100)	100 (67-100)	100	.008
6 (n = 3)	0	0	0	80 (0-94)	.048
7 (n = 6)	0	0	0 (0-71)	0 (0-81)	.161
8 (n = 7)	40 (0-100)	50 (0-100)	100 (40-100)	100 (85.0-100)	.002
9 (n = 6)	83.3	100	100	100	.372
10 (n = 4)	0	0 (0-100)	75 (0-100)	69 (0-100)	.031
11 (n = 6)	0	33.3	50	66.6	.101
12 (n = 1)	0	0	0	0	...

Abbreviation: QI, quality indicator.

[a]QIs 1-8 and 10: Median (range) of implementation proportion among participating sites. QIs 9, 11, and 12: Percentage of implementation sites.

[b]P values were from Jonckheere's trend test for QIs 1-8 and 10 and from Cochran-Armitage test for trends for QIs 9 and 11. A number of sites were 4 at 6 months and 12 months for QI 5 because there were no patients with endotracheal intubation at 1 site.

area of research,[23] and previous study showed a low level of information sharing and parental participation in pain management in Japanese NICUs.[7] It is possible that the lack of practical examples of parental involvement in pain management made this a difficult improvement activity for the participating sites.

Quality improvement collaboratives were undertaken as a core activity of the Vermont Oxford Network Neonatal Intensive Care Quality Improvement Collaborative (NIC/Q) project in 1995.[24] Since then, the benefits of collaborative improvement work have been documented across settings and by different groups,[25] such as the California Perinatal Quality Care Collaborative, which showed the effectiveness of a multihospital collaborative quality improvement model compared with individual local projects.[26] In Japan, the nonprofit Neonatal Research Network of Japan was launched in 2004 to advance research in neonatal medicine and has 192 member

Summary of Recommendations

What we know:	• Many governmental agencies, professional associations, and other groups have released neonatal pain management guidelines. • The release of a guideline does not ensure that evidence-based care will be adopted in the neonatal intensive care unit setting. • The monitoring of quality indicators provides a measure for the adoption of standards of care and is an effective method for improving the quality of practice. • Projects employing a multihospital collaborative quality improvement model have shown greater effectiveness than single-site projects.
What needs to be studied:	• The development of a neonatal pain quality improvement collaborative program based on the current standards of care for pain management in neonatal intensive care units (NICUs) in Japan • The use of pain management quality indicators to evaluate NICU quality improvement collaborative programs • Determination of whether neonatal pain improvement collaborative programs enhance local quality improvement efforts in Japan
What we can do today:	• Introduce electronic medical record pain management forms based on practice standards to support standardized assessment and documentation as well as individualized care planning • Use pain management quality indicators to track the progress of quality improvement efforts and motivate staff • Provide education, structure, and feedback to support tests of change

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institutions to date; however, the Neonatal Research Network of Japan does not have a quality improvement collaborative program. In this study, the researchers planned and led this collaborative program without the support of a specific network; however, the fact that 19 institutions applied to participate suggests the need for a collaborative improvement program for pain management among Japanese NICUs. This is likely related to the absence of a systematic institutional approach to pain management and to insufficient collaboration between nurses and physicians in Japan.[7] In this study, the total number of nurses and physicians educated in pain management among the participating sites increased (QI 8), which might promote collaboration between nurses and physicians and make a difference through quality improvement efforts in each unit (QIs 1-3, 5, 6, and 10). In addition, our program was a driver for evidenced-based pain management improvement among the participating sites.

This study had 2 limitations. The outcomes in this study were selected by the participants themselves on the basis of their identification of deficiencies in pain management at their respective sites. Second, the data collection depended on the participants, and we did not actively participate or validate the data; as such, the findings in this study depend on the accuracy and transparency of the participants.

CONCLUSIONS

In this study, the 7 sites participating in the collaborative quality improvement program had improved pain management during the 12-month intervention period. This program played a key supportive role, providing knowledge, structure, and feedback. The pain team leaders learned, discussed, and worked together to improve pain management of their unit, and the ability to track their progress in the implementation of QIs increased their motivation. While the optimal method for continuous improvement is not known, collaborative improvement programs provide an attractive means of promoting evidence-based practice to reduce evidence-practice gaps in the NICU setting.

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