Evaluation and Development of Potentially Better Practices to Improve Pain Management of Neonates


The authors have indicated they have no financial relationships relevant to this article to disclose.

ABSTRACT

OBJECTIVE. Despite increased knowledge, improved options, and regulatory mandates, pain management of neonates remains inadequate, promoted by the ineffective translation of research data into clinical practice. The Neonatal Intensive Care Quality Improvement Collaborative 2002 was created to provide participating NICUs the tools necessary to translate research, related to prevention and treatment of neonatal pain, into practice. The objective for this study was to use proven quality improvement methods to develop a process to improve neonatal pain management collaboratively.

METHODS. Twelve members of the Neonatal Intensive Care Quality Improvement Collaborative 2002 formed an exploratory group to improve neonatal pain management. The exploratory group established group and site-specific goals and outcome measures for this project. Group members crafted a list of potentially better practices on the basis of the available literature, encouraged implementation of the potentially better practices at individual sites, developed a database for sharing information, and measured baseline outcomes.

RESULTS. The goal “improve the assessment and management of infants experiencing pain in the NICU” was established. In addition, each site within the group identified local goals for improvement in neonatal pain management. Data from 7 categories of neonates (N = 277) were collected within 48 hours of NICU admission to establish baseline data for clinical practices. Ten potentially better practices were developed for prioritized pain conditions, and 61 potentially better practices were newly implemented at the 12 participating sites. Various methods were used for pain assessment at the participating centers. At baseline, heel sticks were used more frequently than peripheral intravenous insertions or venipunctures, with substantial variability in the number of avoidable procedures between centers. Pain was assessed in only 17% of procedures, and analgesic interventions were performed in 19% of the procedures at baseline.
CONCLUSIONS. Collaborative use of quality improvement methods resulted in the creation of self-directed, efficient, and effective processes to improve neonatal pain management. Group establishment of potentially better practices, collective and site-specific goals, and extensive baseline data resulted in accelerated implementation of clinical practices that would not likely occur outside a collaborative setting.

NEONATES IN THE NICU routinely experience pain from both acute invasive procedures and surgical procedures.1–3 Evidence suggests that pain, when unrelied, severe, or prolonged, may hamper resolution of underlying disease processes, delay surgical recovery, and result in higher health care costs.4 The physiologic responses to pain include alterations in gastrointestinal and pulmonary function as well as impairment of the immune response.5 The neonate exhibits a greater hormonal, metabolic, and cardiovascular response to surgical operations when compared with older children. Preterm and term neonates experience pain and its consequences much differently than older children and adults and therefore require study and interventions that are tailored to their specific needs.6,7

Despite the knowledge that infants undergo frequent painful procedures, evidence suggests that pain is undertreated in this population.8 Several reasons for this undertreatment exist, including a lack of appropriate pain assessment tools, limited therapeutic options, and a lack of knowledge among health care professionals regarding neonatal pain perception and management.9,10 Management of pain in the newborn also is hampered by a lack of awareness that the neonate is capable of experiencing pain and exaggerated concerns about the adverse effects of analgesic use.7–11

In addition, our internal collaborative survey of clinical practices suggests that many evidence-based interventions have not yet been applied effectively in NICUs. A recent report from the Institute of Medicine12 noted a large chasm in many areas of medicine between what we know and what we do. This seems to be true of efforts to improve neonatal pain management as well.

Recent evidence-based guidelines and professional practice standards have described approaches to the prevention and management of pain in the newborn.5,11 The “I Feel Good” (IFG) exploratory group, consisting of 12 sites, convened to work collaboratively to improve neonatal pain management. This exploratory group was a subset of the Neonatal Intensive Care Quality Collaborative 2002 (NIC/Q 2002), a 3-year quality improvement collaborative that was overseen by the Vermont Oxford Network (VON).

With the goal of collaboratively improving the quality of pain management in each site’s NICU, IFG participants evaluated, edited, and implemented previously identified evidence-based potentially better practices (PBPs) related to neonatal pain management. This strategy differed from the NIC/Q 2000 collaborative, which required the exploratory groups to create their own list of PBPs on the basis of extensive literature review.14 This article reviews the strategies that were undertaken by the 12 institutions (Table 1) to improve neonatal pain management, using previously defined PBPs with the guidance of clinical experts.

METHODS
Structure of the Neonatal Pain Management Group
At the first meeting of the neonatal pain management exploratory group (IFG group), an experienced facilitator and a content expert were assigned by the VON, and a group leader was chosen. The facilitator advised the group on data-collection tools, measurement strategies, data analysis, and group processes. The content expert provided a list of evidence-based practices, advised the group on the strength of published evidence, and provided real-time expertise for issues related to neonatal pain management. The group leader facilitated discussions on the group goals, delegated individual site responsibilities, established time lines and accountability for assigned tasks, led conference call discussions, and corresponded with the leaders of the NIC/Q 2002 project. Each site in the group selected a representative to coordinate individual site efforts.

Establishment of Goals and Outcome Measures
The initial task of the IFG group was to establish primary and secondary goals for the group. Outcome measures were selected to assess the effectiveness of interventions. The primary goal identified was to “improve pain assessment and management of infants experiencing pain in the NICU.” Five secondary goals were established (Table 2), with 8 outcome measures and 2 process measures selected (Table 3).

Creation of PBP List
A content expert joined the IFG group and provided a list of evidence-based practices for group review.7 Group
members reviewed these PBPs (Table 4), critically evaluated the supporting evidence, and determined the relevance of each PBP to the defined IFG goals.

Once the final PBP list was created, each PBP was assigned to a subgroup for extensive review and refinement. On completion of this process, a PBP tool kit (including a description of the PBP, evidence supporting the PBP, and suggestions for implementation strategies) was created to facilitate implementation. Each participating site then was asked to implement as many of the PBPs as possible, subject to site characteristics and needs.

Database Creation
To determine each site’s pain management practices at baseline, multiple data-collection tools were created ( Appendices 1 and 2). Specific data were collected on the following: (1) pain measurement tools used and (2) pain management policies defined. In addition, each site was required to collect data on 5 patients in each of the following categories:

1. <29.0 weeks’ gestational age and on ventilatory support
2. <29.0 weeks’ gestational age and not on ventilatory support

3. From 29.0 to 36.6 weeks’ gestational age and on ventilatory support
4. From 29.0 to 36.6 weeks’ gestational age and not on ventilatory support
5. Term (≥37.0 weeks’ gestational age) and on ventilatory support
6. Term (≥37.0 weeks’ gestational age) and not on ventilatory support
7. All gestational ages in the postoperative period

These data were collected at each site via retrospective chart review for patients who were admitted to the NICU between January 1 and April 15, 2002.

RESULTS

PBPs
Ten PBPs to improve pain management for infants in the NICU were identified and approved. Following the terminology of the NIC/Q collaboratives, these were labeled as “potentially” better practices because they represented clinical research that may or may not translate into better outcomes if implemented at an individual site. All 10 PBPs (Table 4) were based on published evidence that was available at that time (January 2002). A total of 62 PBPs were implemented by members of the IFG group before (1 PBP) or during (61 PBPs) the NIC/Q 2002 collaborative (Table 5).
Resource Kit
A resource kit (“tool kit”) was developed by the IFG group and included the 10 PBPs and 20 descriptions of implementation efforts, including common barriers to implementation and strategies to overcome these barriers. Four appendices (Suggested Dosing and Administration of Analgesics; Pharmacokinetic and Pharmacodynamic Considerations When Determining Optimal Opiate Dosing for the Neonatal Population; Potential Adverse Effects of Opiates; and A Sample Flowchart for the Administration of Analgesics in Mechanically Ventilated Infants) and implementation aids such as audit tools, slide presentations, literature references, and site-specific data related to implementation efforts also were included in the IFG tool kit. This resource kit also was distributed to NIC/Q 2002 sites that were not involved in the IFG group to facilitate the implementation of PBPs that were appropriate for non-IFG sites.

Database Creation
Members of the IFG group created a preintervention database to document clinical practices at baseline, which consisted of (1) pain assessment scales that were used and procedure specific guidelines/policies that were available for 11 of the IFG sites (1 site joined after baseline data collection) and (2) invasive procedures that were performed and pain assessment scores on 277 neonatal patients from the 11 initial IFG group members.

The participating sites used various assessment scales (Neonatal Infant Pain Scale; CRIES; Premature Infant Pain Profile; Face, Legs, Arms, Cry, Consolability Pain Scale; and Distress Scale for Ventilated Newborn Infant) to document neonatal pain and distress in the NICU. Invasive procedures were documented during the first 48 hours after NICU admission. From the invasive (skin-breaking) procedures documented, heel sticks for capillary blood sampling were used more frequently (on average 2.5–5.3 times per patient among the 7 patient categories studied) than peripheral intravenous (PIV) insertion (on average 0.7–1.9 times per patient among the 7 patient categories) or venipuncture (average 0.3–1.9 times per patient among the 7 patient categories). The highest frequencies for all 3 invasive procedures occurred among nonventilated infants who were >29 weeks’ gestation (on average, 5.3 heel sticks, 1.9 PIV insertions, and 1.9 venipunctures per patient) and non-ventilated term infants (on average, 4.7 heel sticks, 1.5 PIV insertions, and 1.1 venipunctures per patient) during the first 48 hours after NICU admission. Greater proportions of the patients in these groups were subjected to heel sticks (96% of nonventilated infants who were >29 weeks, 91% of nonventilated term neonates), PIV insertion (83% and 86%, respectively), or venipuncture (48% and 56%, respectively) as compared with the other patient categories (heel sticks: 37%–70%; PIV insertion: 42%–68%; venipuncture: 16%–24%). Endotracheal tube (ETT) suctioning was performed on 77% to 100% of ventilated infants on average 8.5 to 9.3 times per patient during the first 48 hours after NICU admission.

Participating sites identified a marked degree of variability in the number of avoidable invasive procedures between centers during the first 48 hours of life (1.0–9.5 total heel sticks per patient, 0.25–1.9 PIV insertions per patient, 0.14–1.57 venipunctures per patient, 3.9–12.4 ETT suctionings per ventilated patient). Relatively few patients received pharmacologic or nonpharmacologic interventions for pain management during these procedures (heel sticks: 16%; PIV insertions: 16%; venipunctures: 6%; nasogastric tube insertions: 25%; ETT placements: 18%). Pain was assessed in 17% of these procedures (133 of 774), and analgesic interventions were provided for 19% of these procedures (148 of 774). Demographic data for the 277 patients are shown in Table 6.

DISCUSSION
The IFG group moved from the creation of a group structure, to the establishment of goals and measures, and finally to the identification of 10 PBPs with implementation of several of these PBPs at each site. The IFG

### TABLE 5 PBPs Implemented at Each Participating IFG Site

<table>
<thead>
<tr>
<th>PBP</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. Reduce the frequency of avoidable painful procedures: ETT suctioning</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
<td>X</td>
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<td>X</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>1b. Reduce the frequency of avoidable painful procedures: heel sticks</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>2. Develop and use standardized recommendations for sucrose analgesia</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>3. Assess pain frequency</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>O</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>4. Implement strategies to manage pain during heel sticks</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<td>5. Implement strategies to manage pain during peripheral vascular procedures</td>
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<tr>
<td>6. Implement strategies to manage pain during circumcision</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>7. Implement strategies to manage pain during nonemergent intubation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>8. Implement strategies to manage pain during mechanical ventilation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
</tr>
<tr>
<td>9. Implement strategies to manage pain during the postoperative time frame</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>10. Implement strategies to wean neonates effectively and safely from opiates</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

X indicates implemented during inclusion in the IFG exploratory group; O, implemented before IFG exploratory group.
group simultaneously developed a database to describe the status of pain assessment and management at baseline to identify and prioritize clinical practice areas that were particularly appropriate for improvement efforts. A secondary purpose was to provide the foundation for subsequent evaluation of clinical outcomes after implementation of the PBPs. Group members acknowledged that these sequential accomplishments could not have occurred by the quality improvement efforts at individual sites alone; rather, they occurred as a direct result of collaboration. Published data also suggest a relatively lower effectiveness of changes in neonatal pain management at individual institutions.

There are several advantages to collaboration when working to improve quality of patient care. First, the work can be divided among the group members, maximizing the use of available resources while minimizing duplication of efforts. Second, the collective enthusiasm that is generated by collaborative work often is difficult to generate and maintain when working at only 1 site. Third, a culture of mutual accountability accelerates the completion of assigned tasks. Fourth, the group provides a rich environment for learning. Site-specific strengths inevitably are discovered and discussed. Topics of mutual interest promote discussion during conference calls and meetings. Finally, data can be shared, creating larger databases for comparisons and combined analyses with larger numbers of patients and the ability to stratify and identify significant trends.

Our experience revealed several essential ingredients for creating an effective collaborative group. Clear, evidence-based, and measurable goals are critical to establishing and maintaining an effective exploratory group. An experienced and dedicated leader also is critical, acting as a catalyst to move the process forward and maintain orientation to the assigned tasks. Each participating site must be willing to dedicate time and resources to the project and be willing to forego concerns of confidentiality to provide data and candidly discuss care practices. It is important to have frequent contact within the group, using such strategies as conference calls, listservs, and face-to-face meetings. Logical and aggressive timelines must be established with deadlines for each component of the process, and a sense of accountability must be instilled into each site to maintain equitable distribution of work. This accountability stems from the need for a significant return on investment, the peer pressure that is instilled from frequent contact among members, clearly defined expectations, and an established timeline.

Changing practices in large institutions requires energy, flexibility, and risk and rarely occurs without credible support from the literature. Thus, the initial literature review, completed by our content expert and reviewed internally by specific PBP-assigned subgroups, was critical to this process. This literature review and endorsement strategy allowed a comprehensive review of the published data related to neonatal pain management.

Another advantage of the exploratory group format was that each subgroup chose a single area of expertise, thereby increasing the group’s knowledge base while minimizing the duplication of efforts. This strategy added to the efficiency of the process because clinical practices that lacked supportive data were not pursued. The subgroups’ expertise allowed each recommended PBP to be discussed relative to the strength of the study design and validity of the data. An example of the value of this strategy is reflected in our selection of sucrose use as a PBP for pain prevention in the NICU population. The presence of a single yet influential study suggesting that sucrose use in infants who are <31 weeks’ gestation may “put infants at risk for poorer neurobehavioral and physiologic outcomes” was evaluated extensively by the Sucrose subgroup. Intensive review of the sucrose literature, as well as detailed discussion with the lead author of the above mentioned study (C. Celeste Johnson, DEd, RN) regarding her data and her study design, reassured the Sucrose subgroup that the benefits outweighed the risks regarding this recommendation. Finally, the IFG group endorsement of evidence-based PBPs provided the necessary “buy-in” to recommend implementation of these PBPs at their own sites as well as non-IFG sites.

The final component of the IFG group’s project was the patient database. This database eventually will prove to be the most compelling argument for aggressive implementation of PBPs. Change concepts can be suggested on the basis of the literature and anecdotal evidence; however, positive results must be achieved, maintained,

<table>
<thead>
<tr>
<th>Group</th>
<th>Group Description</th>
<th>No. of Patients</th>
<th>GA, mean, wk</th>
<th>SD</th>
<th>Range, wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Ventilated ≤29.0 wk</td>
<td>53</td>
<td>25.6</td>
<td>1.6</td>
<td>23–28</td>
</tr>
<tr>
<td>B</td>
<td>Ventilated 29.1–36.6 wk</td>
<td>51</td>
<td>31.6</td>
<td>2.5</td>
<td>29–37</td>
</tr>
<tr>
<td>C</td>
<td>Nonventilated ≤29.0 wk</td>
<td>27</td>
<td>26.6</td>
<td>1.3</td>
<td>24–28</td>
</tr>
<tr>
<td>D</td>
<td>Nonventilated 29.1–36.6 wk</td>
<td>56</td>
<td>32.9</td>
<td>1.9</td>
<td>29–36</td>
</tr>
<tr>
<td>E</td>
<td>Ventilated ≥37 wk</td>
<td>47</td>
<td>38.7</td>
<td>1.5</td>
<td>34–42</td>
</tr>
<tr>
<td>F</td>
<td>Nonventilated term ≥37 wk</td>
<td>54</td>
<td>39.2</td>
<td>1.4</td>
<td>36–43</td>
</tr>
<tr>
<td>G</td>
<td>Postoperative</td>
<td>54</td>
<td>34.0</td>
<td>5.9</td>
<td>23–45</td>
</tr>
</tbody>
</table>

GA indicates gestational age.
and demonstrated for changes in practice to become ingrained and sustained. Without the ability to demonstrate measurable improvement, clinical improvement efforts eventually would be abandoned. Another advantage of the database is the ability to monitor and stratify outcomes on the basis of known risk factors such as birth weight, gender, ethnicity, or site of care.

CONCLUSIONS
Collaborative use of quality improvement methods resulted in the creation of logical, efficient, and effective processes to improve neonatal pain management. Group identification and endorsement of PBPs and collaborative efforts to implement these PBPs resulted in accelerated implementation that would be unlikely to occur outside a collaborative setting. Data analysis is under way to determine the effect of this accelerated PBP implementation on the primary and secondary outcomes defined.

ACKNOWLEDGMENTS
We thank Jim Handyside, the focus group facilitator, for excellent leadership skills. We also thank the staff at each of the 12 sites for dedication to this study and to the quality of care that is provided at their respective institutions.

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**APPENDIX 1: DATA-COLLECTION TOOLS FOR DESCRIBING PAIN MANAGEMENT PRACTICES USED BY SITES IN THE IFG GROUP**

I. Pain Scale Assessment
   Which scale(s) do you use?
   Why did you choose this scale?
   Since using this scale what advantages have you observed?
   Since using this scale what disadvantages have you observed?

II. Guidelines for Pain Scale Use: Indicate in the columns below your center’s protocol for pain scale assessment in the different patient scenarios

<table>
<thead>
<tr>
<th>Scenarios</th>
<th>Center Has a Guideline or Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Pt Group</strong></td>
<td></td>
</tr>
<tr>
<td>Ventilated infant &lt;29 wk</td>
<td></td>
</tr>
<tr>
<td>Ventilated infant: 29.1–36.6 wk</td>
<td></td>
</tr>
<tr>
<td>Nonventilated infant &lt;29 wk</td>
<td></td>
</tr>
<tr>
<td>Nonventilated infant: 29.1–36.6 wk</td>
<td></td>
</tr>
<tr>
<td>Ventilated term infant: ≥37 wk</td>
<td></td>
</tr>
<tr>
<td>Nonventilated term infant: ≥37 wk</td>
<td></td>
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<tr>
<td>Post-op patient</td>
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</tr>
<tr>
<td><strong>Procedures</strong></td>
<td></td>
</tr>
<tr>
<td>Heelstick</td>
<td></td>
</tr>
<tr>
<td>Peripheral IV</td>
<td></td>
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<tr>
<td>Venipuncture</td>
<td></td>
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<tr>
<td>Peripheral, arterial line</td>
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<tr>
<td>Percutaneous inserted central catheter</td>
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<tr>
<td>Umbilical vessel catheterization</td>
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<tr>
<td>Lumbar puncture</td>
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<tr>
<td>Endotracheal intubation</td>
<td></td>
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<tr>
<td>ETT suctioning</td>
<td></td>
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<tr>
<td>Nasogastric tube insertion</td>
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<tr>
<td>Chest tube insertion</td>
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<tr>
<td>Circumcision</td>
<td></td>
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</tbody>
</table>

III. Expected Interventions: Indicate the type of intervention that is expected according to your center’s pain protocols/guidelines
APPENDIX 2: DATA-COLLECTION TOOLS OF THE IFG GROUP

Patient Group A: Ventilated Infant <29.0 Weeks’ Gestation

Center Name:

Instructions: Review at least 5 (1–5) patients during their first 48 h in your NICU. Indicate the total number of pain assessments and the different number of listed procedures the patient experienced during the 48-h period. Use this data sheet for all patients in this category.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Center Guideline or Protocol</th>
<th>No Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pharmacological (Analgesics/Sucrose)</td>
<td>Nonpharmacological (eg, Positioning, Nonnutr. Sucking Without Sucrose)</td>
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<tr>
<td>Heelstick</td>
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<tr>
<td>Peripheral intravenous catheter</td>
<td></td>
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<tr>
<td>Venipuncture</td>
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<td></td>
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<tr>
<td>Peripheral artery catheterization</td>
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<tr>
<td>PICC line insertion</td>
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<td>Umbilical vessel catheterization</td>
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<tr>
<td>Lumbar Puncture</td>
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<tr>
<td>Endotracheal intubation</td>
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<tr>
<td>Endotracheal tube suctioning</td>
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<tr>
<td>Nasogastric tube insertion</td>
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<td>Chest tube insertion</td>
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<tr>
<td>Circumcision</td>
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</table>

<table>
<thead>
<tr>
<th>Pt Group/ #</th>
<th>Gest. Age (wk)</th>
<th>Diagnosis</th>
<th># Pain Scale Assessments</th>
<th># Heel sticks</th>
<th># PIVs</th>
<th># Venipunctures</th>
<th># ETT intubations</th>
<th># SQ/IM injections</th>
<th># NG insertions</th>
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SQ indicates subcutaneous; IM, intramuscular; NG, nasogastric tube.

Individual Patient Data Sheet for Procedural Interventions

Center: Pain Scale Used:

Patient Group: _ Patient # _ Gest. Age: _

Diagnosis:

Note: One patient may be reviewed for multiple different procedures, but don’t review the same procedure more than once for each patient.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Chronological Age at time of procedure</th>
<th>Pharm. Intervention (drugs/sucrose)</th>
<th>Non-pharm Intervention (eg. Non-nutr. sucking w/o sucrose, positioning, etc)</th>
<th>Highest Pain Score During Procedure</th>
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