



# Background

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- Neonatal pain is poorly recognized and managed
- Presence of pain in neonates has been well established → behavioral, physiological, metabolic and hormonal responses to nociceptive stimuli
- Subsequent short and long term adverse events
- American Academy of Pediatrics - Implementation of the fifth vital sign

Batton et al. Paediatrics. 2006

Anand et al. Pain 2013

AAP guidelines. Pediatrics. 2006

Hall et al. Clinics in perinatology

# Special challenges in neonates

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- Neonates are unable to express their discomfort → need behavioral and physiological assessment
- Limiting factors: Inter-reliability and subjectivity of human assessments
- Drug safety concerns → lack of pharmacokinetic and pharmacodynamics data
- Data is subjective and not quantitative → analgesic therapy is variable and inconsistent.



# Too little or too much?

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## Failure to treat pain can cause

- altered pain processing
- attention deficit disorder
- impaired visual-perceptual ability or visual-motor integration and poor executive functions



## Overuse of analgesia and sedatives

- prolongs need for mechanical ventilation
- delays feeding
- impaired brain growth, poor socialization skills
- impaired performance in short-term memory tasks

# Why the Neonatal ICU?

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- Vulnerable population
- Neonates experience 10-15 painful procedures per day
- Enhanced survival of ELBW neonates - greater exposure to pain and stress



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Pre-intervention

# Pre-interventional analysis

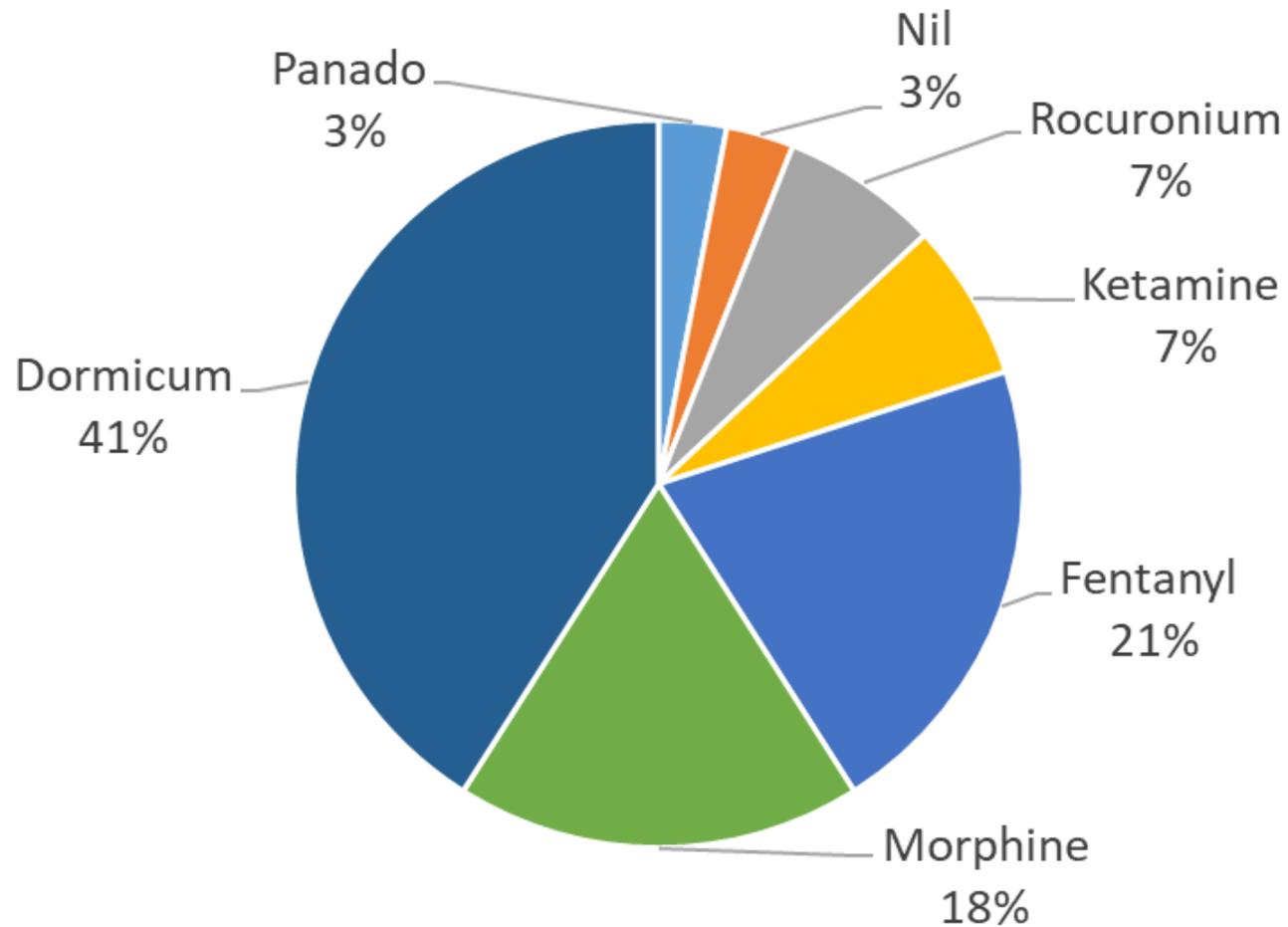
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## Patient profile in CHBAH NICU (n=14), mean (range)

Average age (days)	64 (3-297)
Average duration of stay in NICU (days)	16 (0-85)
Gestational Age (n)	
27-31 weeks	5
31-37 weeks	8
> 37 weeks	1

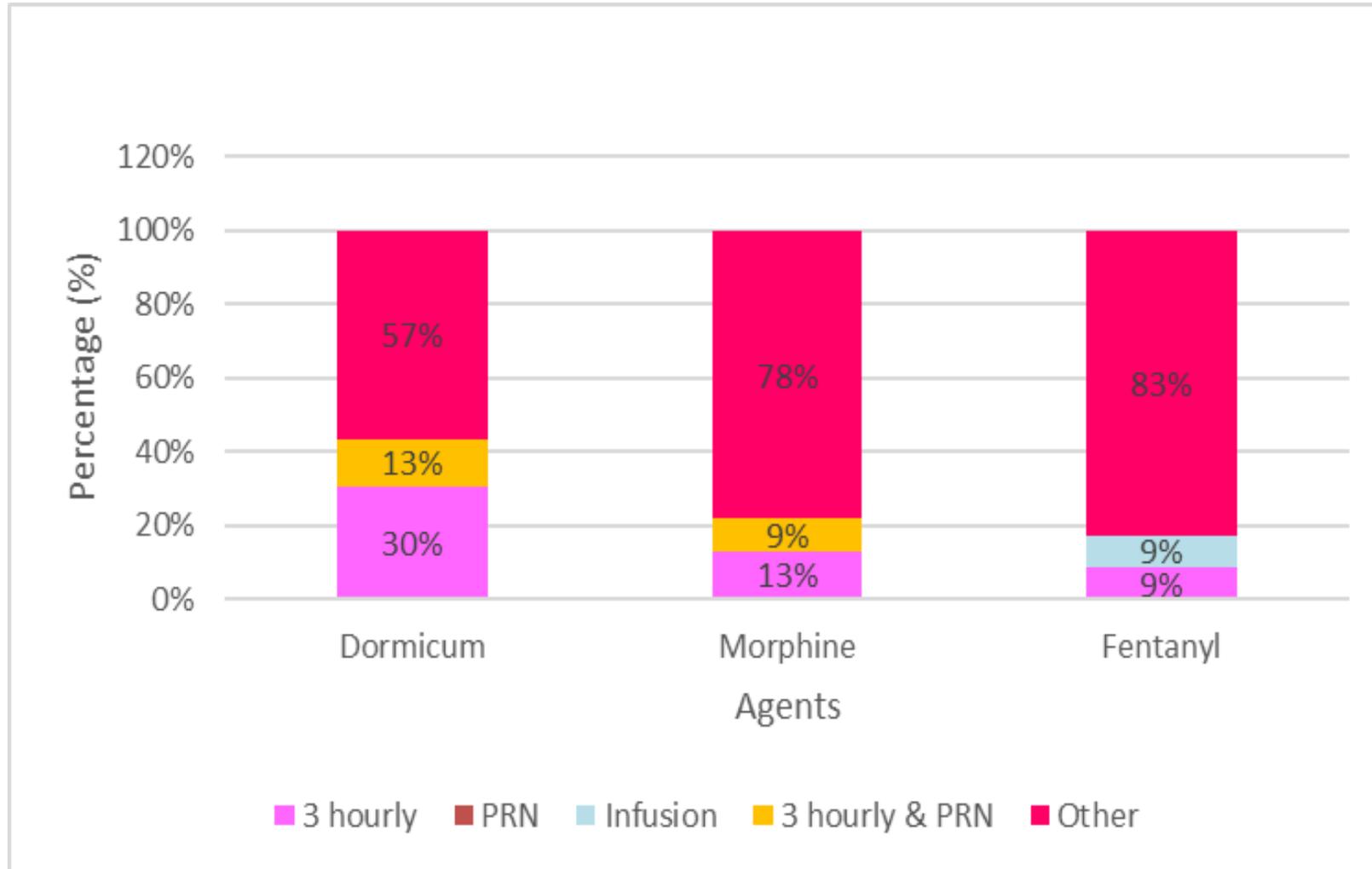
# Drugs used for pain and sedation

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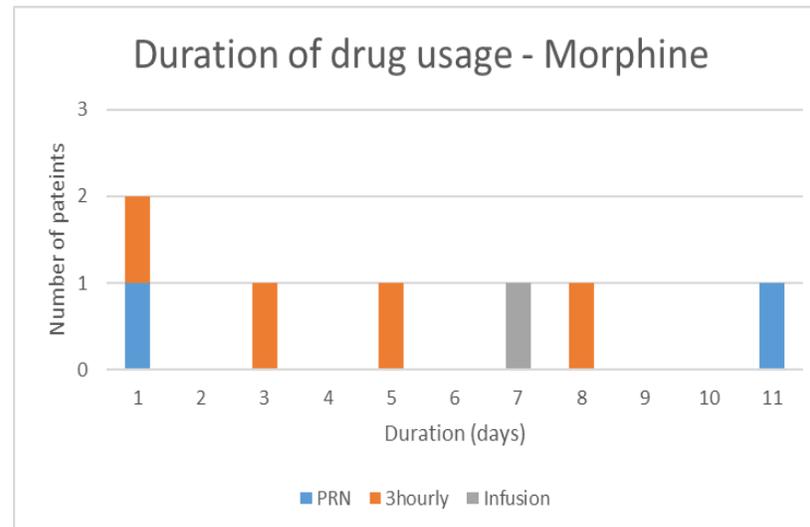
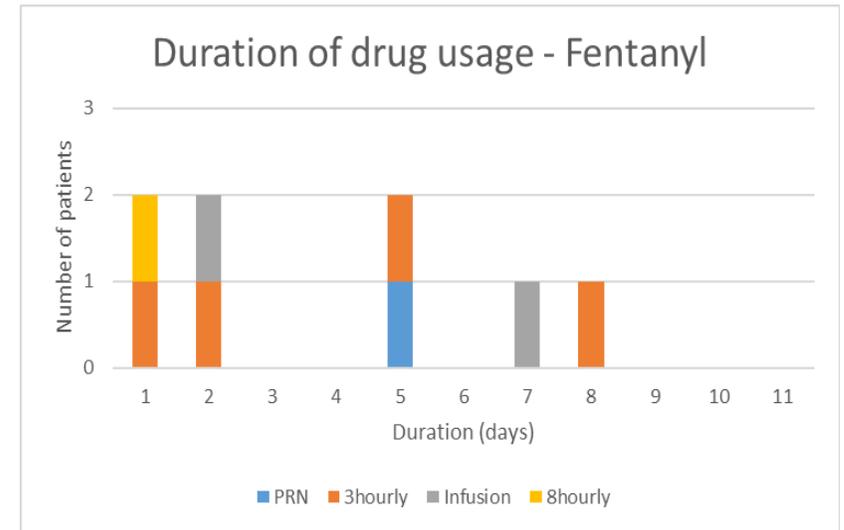
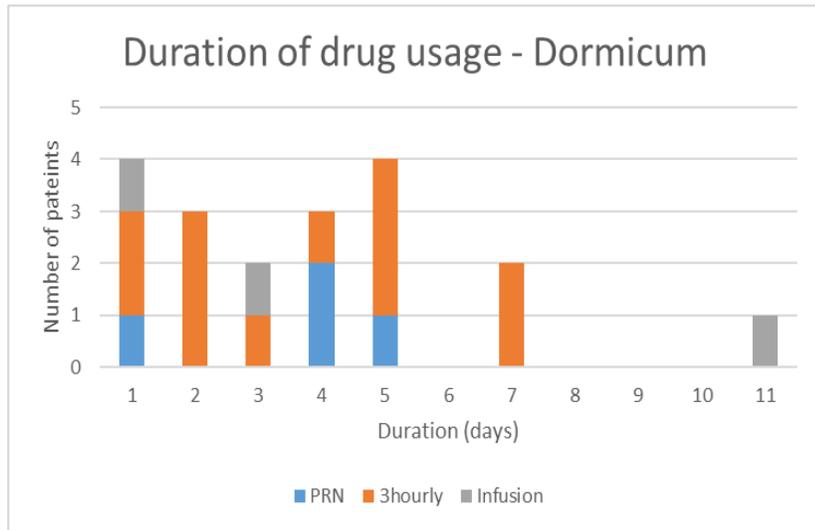


# Frequency of prescription

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# Duration of drug usage



# Summary of findings (pre-intervention)

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- No standardized pain and sedation assessment tool
- No specified protocol followed for management of neonatal pain and sedation
- Idiosyncratic use of analgesics and sedatives
- Stat doses given and no documentation of indication
- Midazolam most widely used drug despite increasing evidence of its risks in preterm infants
- Acute and procedural pain inadequately managed
- Overuse of sedative

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# The Intervention

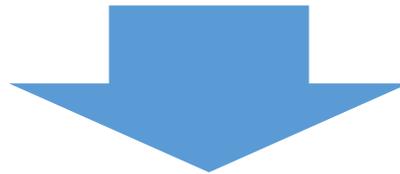
# The need for a protocol

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- Pain management is an integral part of standard effective management in the NICU and practically every NICU should have a protocol.
- Responsibility of every health care worker caring for the newborn.

# Selection of a validated pain and assessment tool

- Development of criteria for selection of appropriate tool to our setting
- Reviewing various assessment tools
- Algorithm to facilitate utilization



**Neonatal Pain, Agitation and  
Sedation Scale (N-PASS)**

# N-PASS

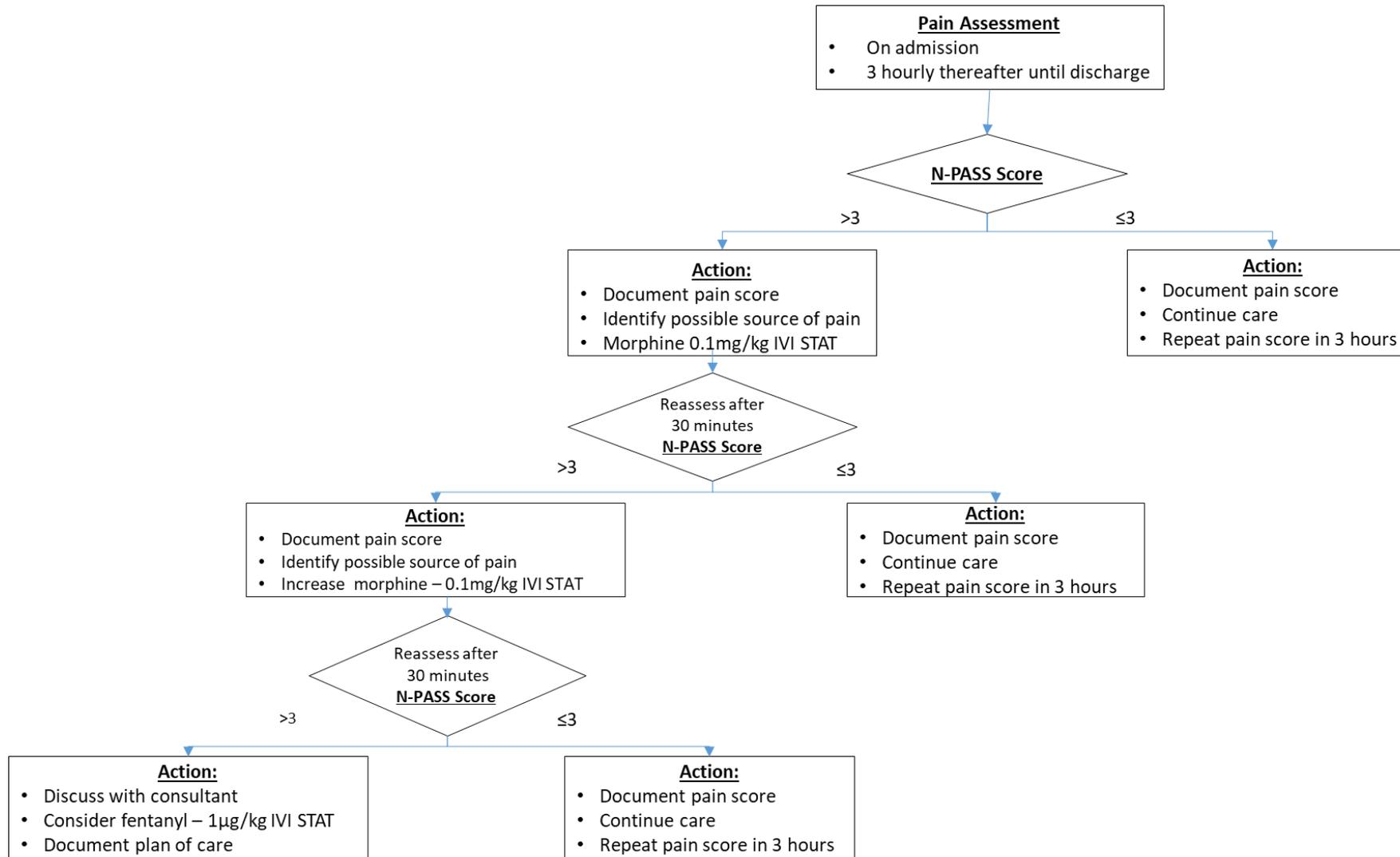
Assessment Criteria	Sedation		Normal	Pain / Agitation	
	-2	-1	0	1	2
<b>Crying Irritability</b>	No cry with painful stimuli	Moans or cries minimally with painful stimuli	Appropriate crying Not irritable	Irritable or crying at intervals Consolable	High-pitched or continuous cry Inconsolable silent-
<b>Behavior State</b>	No arousal to any stimuli No spontaneous movement	Arouses minimally to stimuli Little spontaneous movement	Appropriate for gestational age	Restless, squirming Awakens frequently	Arching, kicking Constantly awake or Arouses minimally / no movement (not sedated)
<b>Facial Expression</b>	Mouth is lax No expression	Minimal expression with stimuli	Relaxed Appropriate	Any pain expression intermittent	Any pain expression continual
<b>Extremities Tone</b>	No grasp reflex Flaccid tone	Weak grasp reflex ↓ muscle tone	Relaxed hands and feet Normal tone	Intermittent clenched toes, fists or finger splay Body is not tense	Continual clenched toes, fists, or finger splay Body is tense
<b>Vital Signs HR, RR, BP, SaO<sub>2</sub></b>	No variability with stimuli Hypoventilation or apnea	< 10% variability from baseline with stimuli	Within baseline or normal for gestational age	↑ 10-20% from baseline SaO <sub>2</sub> 76-85% with stimulation - quick ↑	↑ > 20% from baseline SaO <sub>2</sub> ≤ 75% with stimulation - slow ↑ Out of sync with vent

# N-PASS - Assessment of sedation

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- Sedation is scored in addition to pain for each behavioral and physiological criteria to assess the infant's response to stimuli
- Sedation does not need to be assessed/scored with every pain assessment/score
- Sedation is scored from 0 → -2 for each behavioral and physiological criteria, then summed and noted as a negative score (0 → -10)
  - A score of 0 is given if the infant's response to stimuli is normal for their gestational age
- Desired levels of sedation vary according to the situation
  - "Deep sedation" → score of -10 to -5 as goal
  - "Light sedation" → score of -5 to -2 as goal
- Deep sedation is not recommended unless an infant is receiving ventilatory support, related to the high potential for apnea and hypoventilation
- A negative score without the administration of opioids/sedatives may indicate:
  - The premature infant's response to prolonged or persistent pain/stress
  - Neurologic depression, sepsis, or other pathology

# Algorithm for pain and sedation assessment using N-PASS Tool





# Implementation

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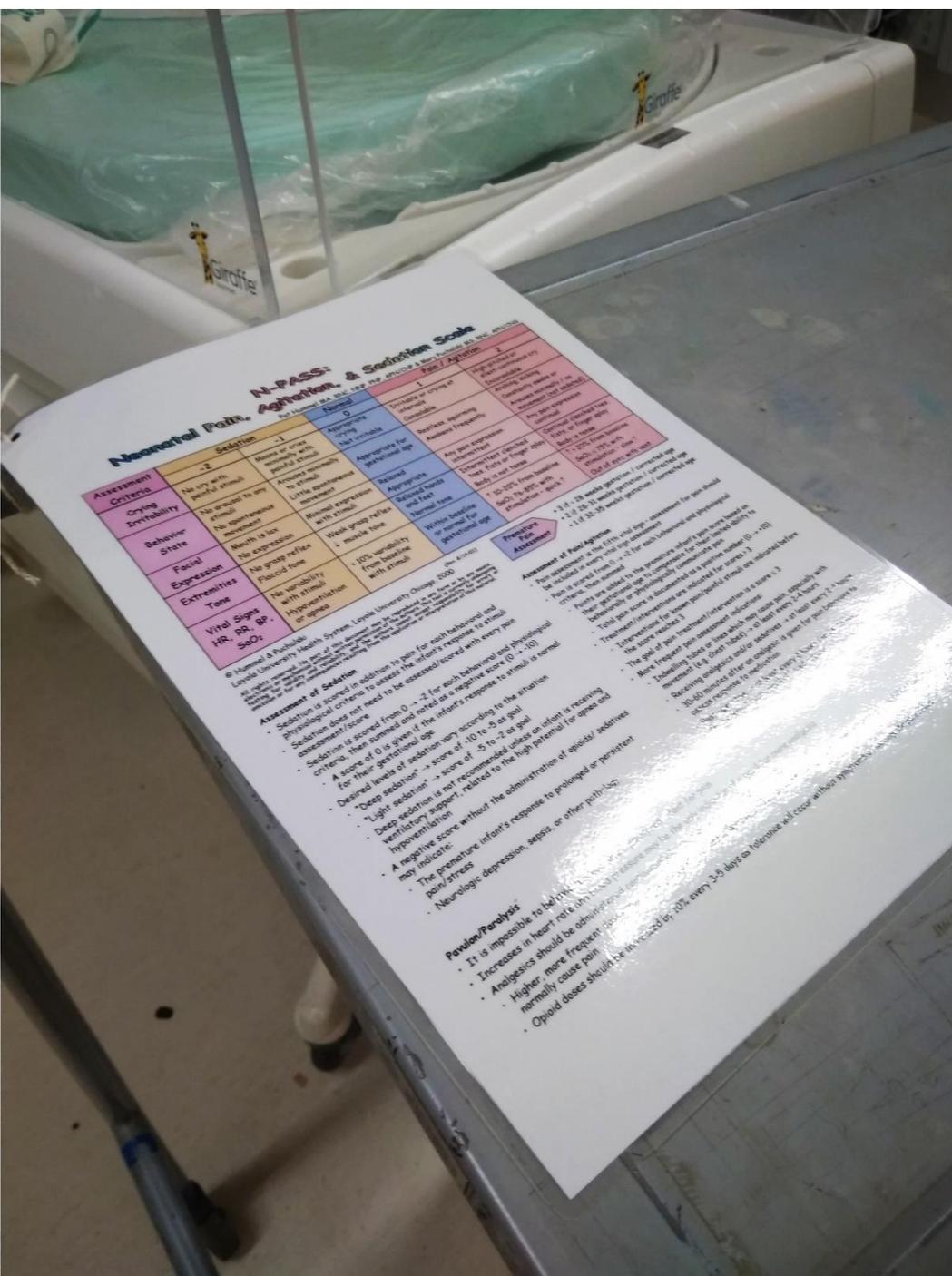
Placement of laminated copies at each bedside



Group presentations and individual teaching sessions



Continued reinforcement & recommendations



# Neonatal Pain, Agitation, & Sedation Scale

Assessment Criteria	Sedation	Pain / Agitation
<b>Crying / Irritability</b>	-2 - No cry with painful stimuli	0 - No response to painful stimuli, e.g. needle sticks, ETT or nares
<b>Behavior / State</b>	-1 - Mouth is lax, no expression	0 - Relaxed hands and feet - normal palmar or sole grasp elicited - appropriate tone for gestational age
<b>Facial Expression</b>	-1 - No grimace	0 - Relaxed hands and feet - normal palmar or sole grasp elicited - appropriate tone for gestational age
<b>Extremities / Tone</b>	-1 - No variability with stimuli	0 - Relaxed hands and feet - normal palmar or sole grasp elicited - appropriate tone for gestational age
<b>Vital Signs (HR, BP, SpO<sub>2</sub>)</b>	-1 - No variability with stimuli	0 - Relaxed hands and feet - normal palmar or sole grasp elicited - appropriate tone for gestational age

**Assessment of Sedation**

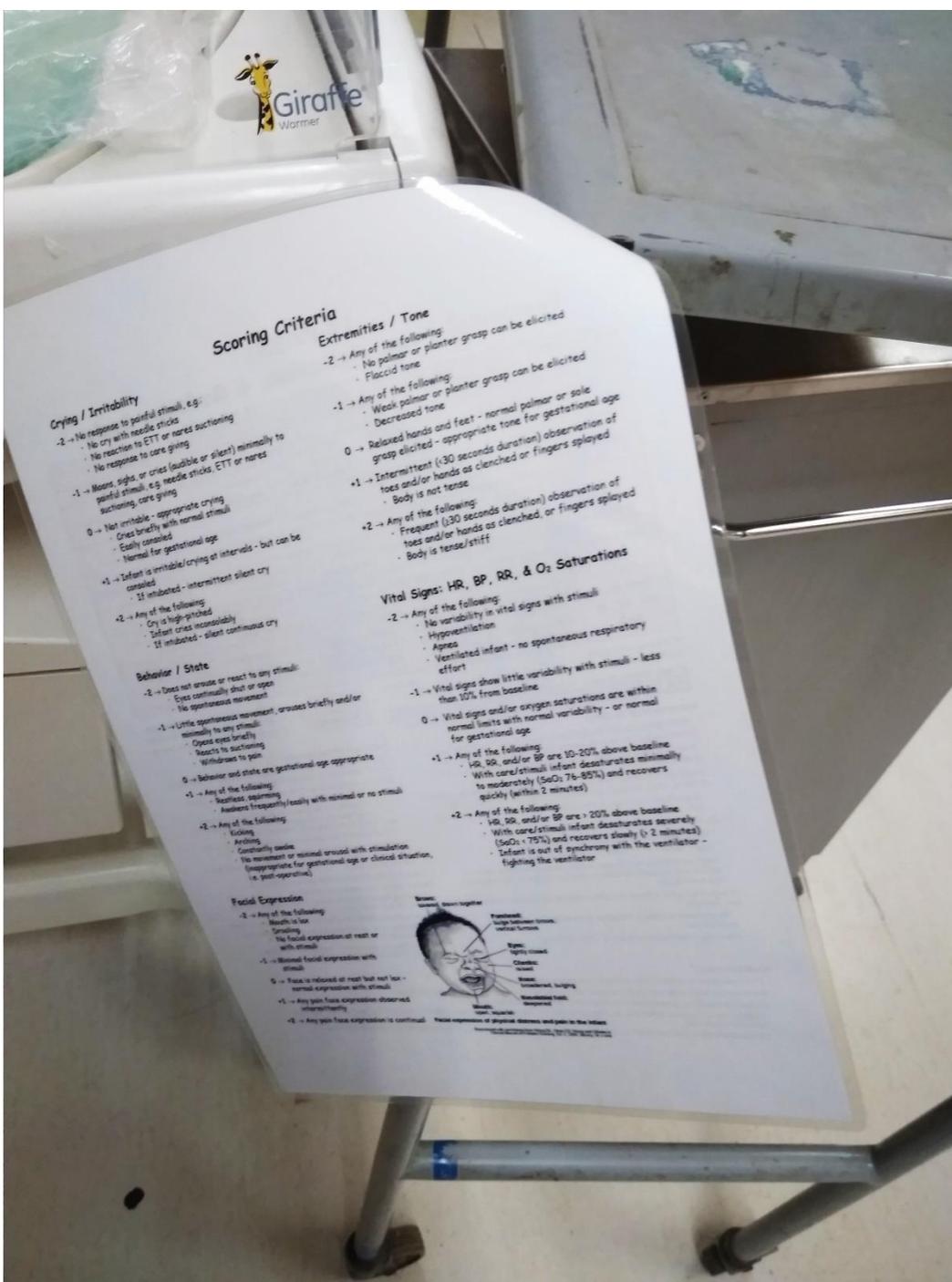
- Sedation is scored in addition to pain for each behavioral and physiological criteria to assess the infant's response to stimuli
- Sedation does not need to be assessed/recorded with every pain assessment
- A score of 0 is given if the infant's response to stimuli is normal
- "Deep sedation" - score of -10 to -5 as goal
- "Light sedation" - score of -5 to -3 as goal
- Deep sedation is not recommended unless an infant is receiving ventilatory support
- A negative score without the administration of opioid/sedatives may indicate:
  - The premature infant's response to prolonged or persistent hyperventilation
  - Neurologic depression, sepsis, or other pathology

**Assessment of Pain/Agitation**

- Pain assessment is the first vital sign assessment for each behavioral and physiological criteria to assess the infant's response to stimuli
- Pain is scored from 0 to 2 (for each behavioral and physiological criteria, then summed)
- Points are added to the sum of behavioral and physiological criteria for each behavioral or physiological criterion at a score number (0 to 10)
- Total pain score is calculated as the sum of behavioral and physiological criteria
- Treatment response for lower pain score is a score of 1
- The goal of pain treatment (sedation) is a score of 1
- Indications for pain relief include:
  - Behavioral and/or physiological criteria at a score of 1 or higher
  - Respiratory depression or apnea
  - Abnormal vital signs

**Pain/Paralysis**

- It is impossible to tell if an infant is in pain if they are paralyzed
- Increases in heart rate, blood pressure, and oxygen saturation may be the only signs of pain
- Analgesics should be administered
- Higher, more frequent doses
- Opioid doses should be increased by 10% every 3-5 days as tolerance will occur when appropriate



# Scoring Criteria

**Crying / Irritability**

- 2 - No response to painful stimuli, e.g. needle sticks
- 1 - No reaction to ETT or nares suctioning
- 0 - No response to care giving
- 1 - Moans, sighs, or cries (audible or silent) minimally to painful stimuli, e.g. needle sticks, ETT or nares
- 0 - Not irritable - appropriate crying
- 1 - Infant is irritable - appropriate crying
- 2 - Infant is irritable - crying at intervals - but can be consoled

**Extremities / Tone**

- 2 - Any of the following:
  - No palmar or plantar grasp can be elicited
  - Flaccid tone
- 1 - Any of the following:
  - Weak palmar or plantar grasp can be elicited
  - Decreased tone
- 0 - Relaxed hands and feet - normal palmar or sole grasp elicited - appropriate tone for gestational age
- +1 - Intermittent (30 seconds duration) observation of toes and/or hands as clenched or fingers splayed
- +2 - Any of the following:
  - Frequent (30 seconds duration) observation of toes and/or hands as clenched, or fingers splayed
  - Body is tense/stiff

**Vital Signs: HR, BP, RR, & O<sub>2</sub> Saturations**

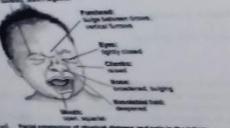
- 2 - Any of the following:
  - No variability in vital signs with stimuli
  - Hypoventilation
  - Apnea
  - Ventilated infant - no spontaneous respiratory effort
- 1 - Vital signs show little variability with stimuli - less than 10% from baseline
- 0 - Vital signs with normal variability - or normal normal limits with normal variability - or normal for gestational age
- +1 - Any of the following:
  - HR, BP, and/or SpO<sub>2</sub> are 10-20% above baseline
  - With care/stimuli infant desaturates minimally to moderately (SpO<sub>2</sub> 74-85%) and recovers quickly (within 2 minutes)
- +2 - Any of the following:
  - HR, BP, and/or SpO<sub>2</sub> are > 20% above baseline
  - With care/stimuli infant desaturates severely (SpO<sub>2</sub> < 75%) and recovers slowly (> 2 minutes)
  - Infant is out of synchrony with the ventilator - fighting the ventilator

**Behavior / State**

- 2 - Does not arouse or react to any stimuli
- 1 - Little spontaneous movement, arouses briefly and/or normally to any stimuli
- 0 - Behavior and state are gestational age appropriate
- +1 - Any of the following:
  - Restless, squirming
  - Awakens frequently/easily with minimal or no stimuli
- +2 - Any of the following:
  - Awakened
  - Awakened easily
  - No movement or minimal arousal with stimulation (appropriate for gestational age or clinical situation, & post-operative)

**Facial Expression**

- 2 - Any of the following:
  - Mouth is lax
  - Spindling
  - No facial expression at rest or with stimuli
- 1 - Minimal facial expression with stimuli
- 0 - Face is relaxed at rest but not lax - normal expression with stimuli
- +1 - Any pain face expression observed intermittently
- +2 - Any pain face expression is continual



# Revision of the current pain and sedation protocol

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- Based on AAP guidelines
- Best evidence practices
- Safety profiles of drugs
- Institution-specific drugs and management practices



**Pain and sedation protocol → Neonatal  
protocol book**

# Drug safety profile

Drug Name	Advantages	Disadvantages
<b>Morphine</b>	<ul style="list-style-type: none"> <li>• Potent pain relief</li> <li>• Better ventilator synchrony</li> <li>• Sedation</li> <li>• Hypnosis</li> <li>• Muscle relaxation</li> <li>• Inexpensive</li> </ul>	<ul style="list-style-type: none"> <li>• Respiratory depression</li> <li>• Arterial hypotension</li> <li>• Constipation, nausea</li> <li>• Urinary retention</li> <li>• Central nervous system depression</li> <li>• Tolerance and dependence</li> <li>• Long-term outcomes not studied</li> <li>• Prolonged ventilator use</li> </ul>
<b>Midazolam</b>	<ul style="list-style-type: none"> <li>• Most studied benzodiazepine</li> <li>• Quickly metabolized</li> </ul>	<ul style="list-style-type: none"> <li>• Short acting</li> <li>• No safety established in premature neonates.</li> <li>• Concerns about neurotoxicity</li> <li>• New-born animal models – induces brain cell apoptosis</li> </ul>
<b>Fentanyl</b>	<ul style="list-style-type: none"> <li>• Fast acting</li> <li>• Less hypotension</li> </ul>	<ul style="list-style-type: none"> <li>• Respiratory depression</li> <li>• Short half-life</li> <li>• Quick tolerance and dependence</li> <li>• Chest wall rigidity</li> <li>• Inadequately studied</li> </ul>
<b>Paracetamol</b>	<ul style="list-style-type: none"> <li>• For mild and moderate procedural pain</li> <li>• Opioid sparing effect</li> <li>• Renal and hepatic toxicity rare in neonates</li> </ul>	<ul style="list-style-type: none"> <li>• Not for acute pain</li> </ul>

# Step-wise pain management

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	Agents/Measures used (examples)
Step 3 - Analgesia & Sedatives	<ul style="list-style-type: none"><li>• Morphine</li><li>• Fentanyl</li><li>• Paracetamol</li><li>• Ketamine</li><li>• Midazolam</li></ul>
Step 2 - Local Anaesthetic	<ul style="list-style-type: none"><li>• Lignocaine</li></ul>
Step 1 - Non-pharmacological interventions	<ul style="list-style-type: none"><li>• Breastmilk</li><li>• 25 - 50% glucose</li><li>• Swaddling (in a sheet)</li><li>• Facilitated tucking (limbs flexed)</li></ul>
Baseline - Avoid painful procedures, physical handling	<ul style="list-style-type: none"><li>• None</li></ul>

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Post-intervention

# What was different?

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- Routine 3 hourly pain assessments
- Documentation of pain scores in chart
- No routine analgesia or sedation prescribed
- No PRN or infusions routinely (Infusions can be considered postoperatively)
- No role for dormicum (Midazolam) as a sedative in preterm and rarely in term neonates



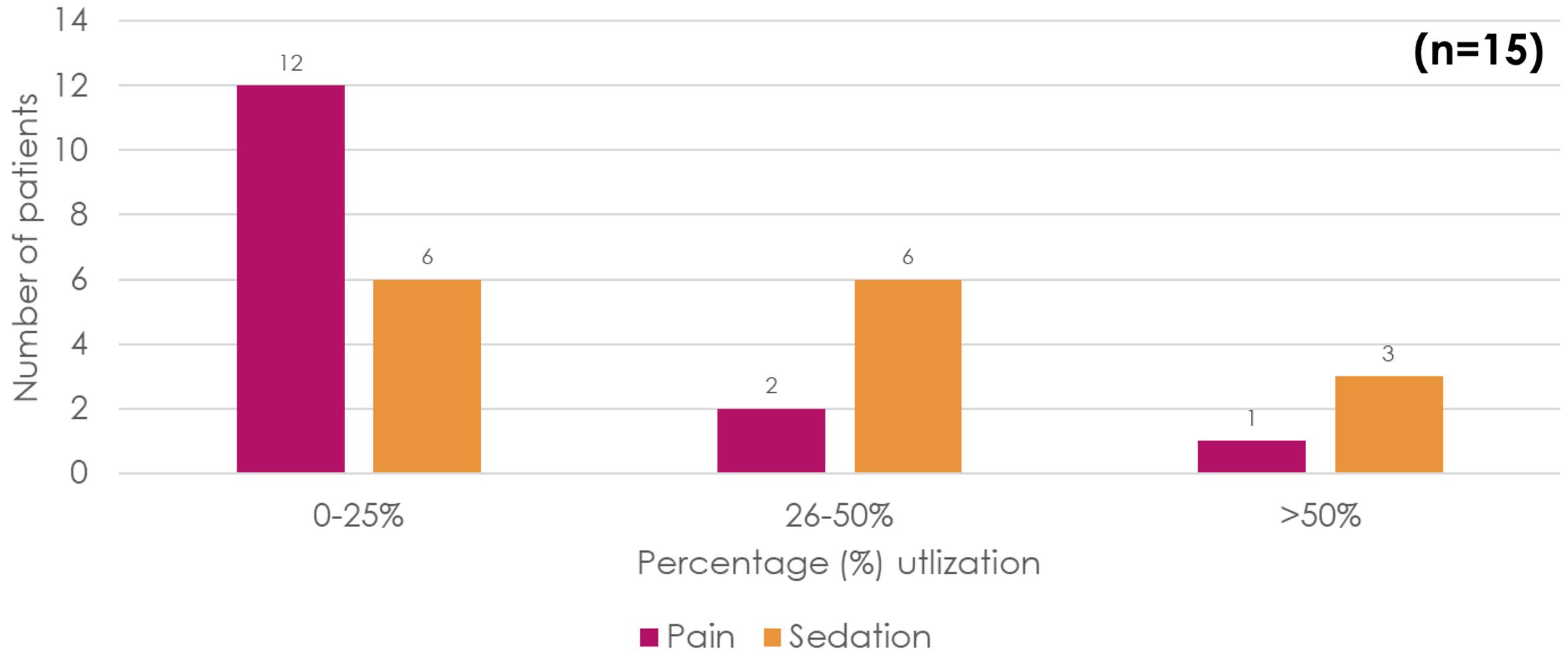
# Post Interventional Analysis

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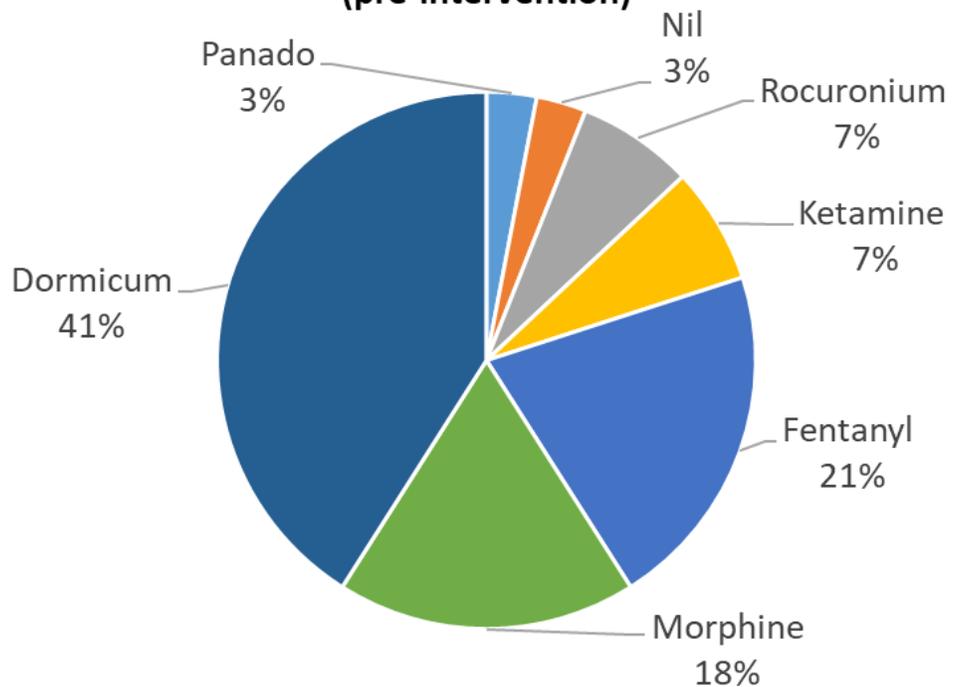
## Patient profile in CHBAH NICU (n=15)

Average age (days)	42 (3-298)
Average duration of stay in NICU (days)	10 (0-32)
Gestational Age (n)	
27-31 weeks	6
31-37 weeks	6
> 37 weeks	3

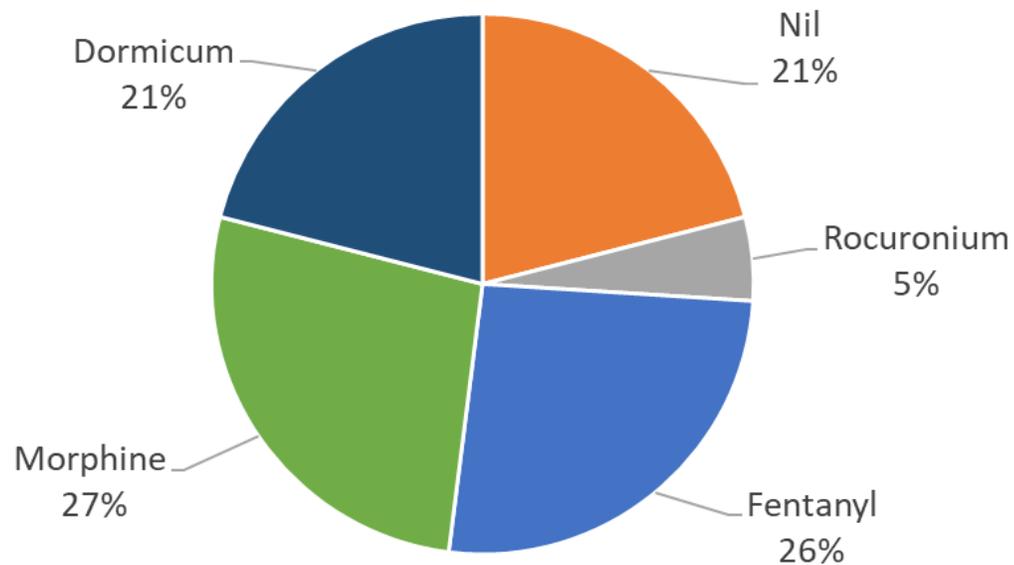
# Utilization of pain assessment and sedation assessment tool over 72 hours



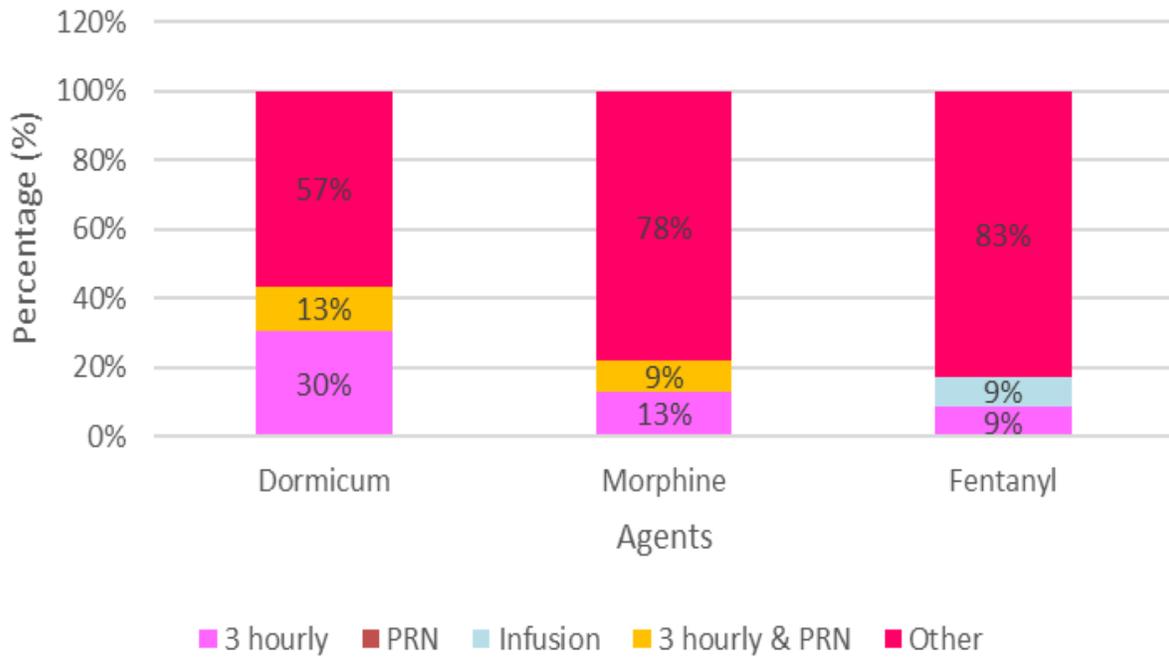
**Proportions of drugs used for pain and sedation  
(pre-intervention)**



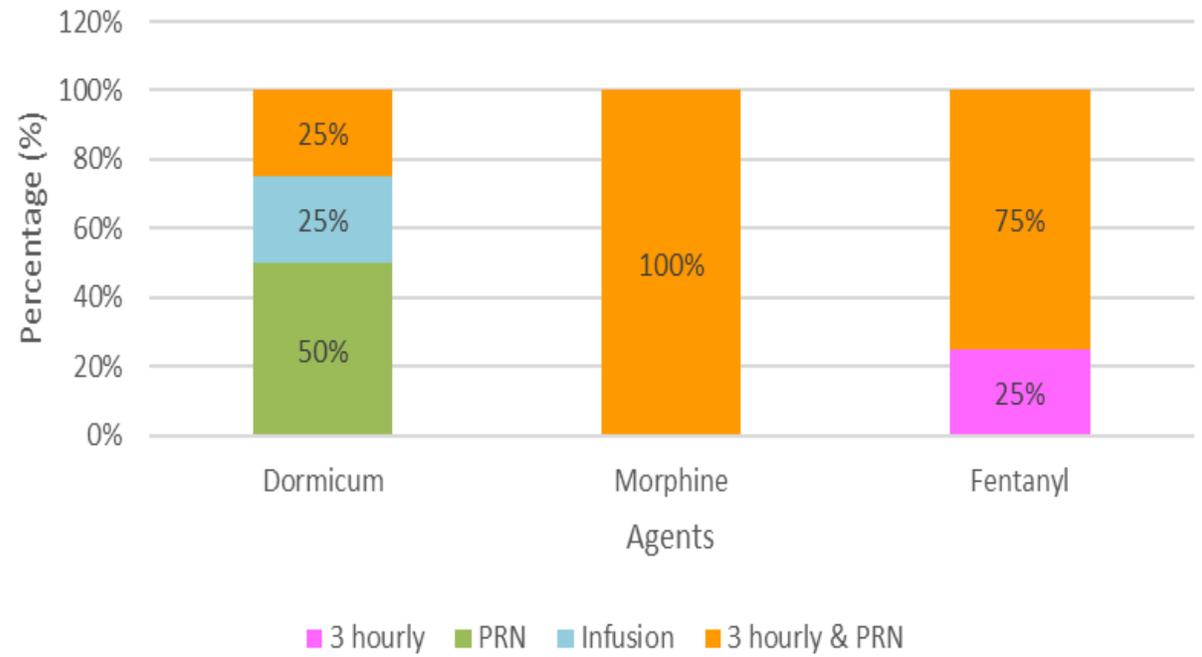
**Proportion of drugs used for pain and sedation  
(post-intervention)**



### Frequency of prescription (pre-intervention)



### Frequency of prescription (post-intervention)



# Successes

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- Implementation of a pain assessment and response strategy in the NICU
- Ease of use and availability of assessment tool at each bedside facilitated compliance
- Individual mentoring sessions → greater impact
- When utilized correctly → guided increased appropriate analgesic use and decrease in inappropriate use
- Increased knowledge of safety profiles → reduced use of midazolam
- Patient care → less routine prescription
- Personal and professional growth

# Feedback

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“I was quite happy to see that there’s an awakening to the presence of pain in children. The sedation has been an eye opener for me. I am thrilled to be using the charts to make informed decisions when managing our patients. I hope this lasts far beyond the reaches of this QIP.”

**Paediatric registrar**

- Many were unaware of midazolam safety profile in pre-term neonates
- Easy to use
- Nurses: Unwilling to do assessments 3 hourly – “short staffed”

# Limitations and Failures

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- Short time period for implementation
- Post interventional analysis done over period of new shift of nursing staff
- Disengaged health care professionals → “short-staffed”, optional, “time consuming”, unaware of the protocol, “too busy”
- High staff turnover
- Poor documentation in bed-letters, no re-assessment
- Management practices unlinked to pain scores → knowledge gaps and algorithm not used

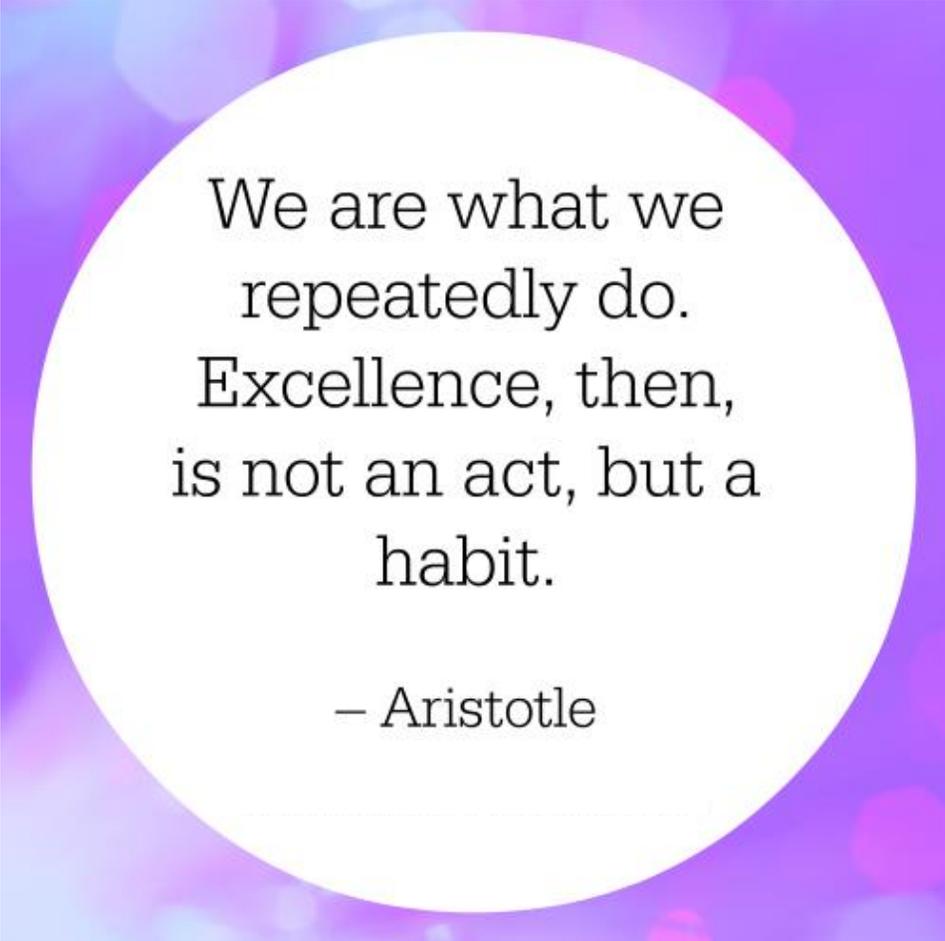
# Future Considerations

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- Extending the use of the assessment tool to other areas in the neonatal unit .
- An ongoing “pain programme” (at least bimonthly) to allow for sustained practices of effective pain and sedation management and to orient new staff members – led by neonatal consultants
- Impact of non-pharmacological methods to reduce pain in the NICU. Includes minimizing painful procedures
- Ongoing revision of management strategies as new evidence becomes available or additional agents become available at the pharmacy.
- Prospective study to determine short and long term outcomes associated with improved pain management.

# Lets make a change

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We are what we  
repeatedly do.  
Excellence, then,  
is not an act, but a  
habit.

– Aristotle



THANK  
YOU

