

Using Perioperative Surgical Home Goals to Facilitate a Novel Therapy: Spinraza™ (nusinersen) Intrathecal Treatment for Children with Spinal Muscular Atrophy

Maura Berkelhamer, MD¹, Carlyann Miller, DO¹, Jessica Goldstein, MD², Nancy Bass, MD²,

Rainbow Babies and Children's Hospital, University Hospitals Cleveland, Department of Anesthesiology and Perioperative Medicine, Cleveland, OH¹.
Rainbow Babies and Children's Hospital, University Hospitals Cleveland, Department of Pediatric Neurology, Cleveland, OH².

The Perioperative Surgical Home (PSH)

GOAL: To improve quality by coordinating care **before, during, and after** surgical procedures

- Improving the patient experience of care (quality and satisfaction metrics)
- Improving the health of populations & health outcomes for individuals (evidence based protocols and systems)
- Reducing the per capita cost of health care
- Provide Evidence Based and Standardized Care

PSH is an Entry Point for new treatments and new patient populations as they emerge

Example: Spinraza™ (nusinersen) for treatment for Spinal Muscular Atrophy (SMA)

- Identify the patient early → Optimize the medically complex patients!
- Streamline the process of care coordination & scheduling
 - Decrease cost, improve communication, best timeline

Anesthesiologists: The Best Fit

Anesthesiologists are the ideal leaders and architects of the PSH concept

- Anesthesiologist Training
 - Involves pre, intra- and post-operative care
 - Uniquely qualified and experienced with care of all types of patients
- Anesthesiologists are Gate-Keepers to the OR
 - PMD: "Cleared for Surgery" is useless and becomes obsolete
 - Optimization in consultation with patient's care team
- Consistency
 - The Anesthesia Care Team is always primarily involved
- Communication Hub
 - Regularly communicates with surgeon, consultants, pre and post-operative care teams

Rainbow's PSH Process

1. Pediatric Neurologist identifies SMA patient eligible for Spinraza™
2. Neurologist emails Anesthesiology PSH Coordinator
3. Anesthesiologist reviews Patient's Medical/Anesthetic history
No need to see the patient in "Pre-op Clinic": **keep parents at work and patients have fewer school/therapy absences**
4. Anesthesiologist contacts & consults with patient's specialist physicians to create a Perioperative Plan
 - Determine/Optimize patient's baseline
 - Need for stepped up care/intervention prior to OR?
 - Assure prompt follow up if needed
 - Determine Additional OR & OOR resources necessary
5. Anesthesiologist communicates
 - Plan of care to all necessary physicians and healthcare professionals
 - Coordinates Anesthetizing & Procedure Location/Radiology/Respiratory
6. Procedure scheduled into reserved OR "Block Time"

*Currently, of 15 referrals, 7 patients (ASA 3) have been enrolled and treated with no anesthetic related complications.

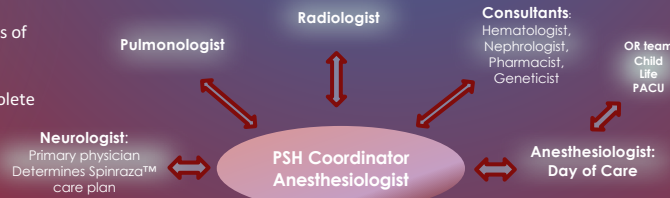


Figure 2: The PSH: Coordination of multiple healthcare professionals

Key Points for Spinraza™ PSH

- Spinraza™ Treatment is life long
 - Intrathecal injection requiring General Anesthesia & Monitoring
 - Pediatric Neurologists need OR block time
 - Tight treatment schedule does not allow for cancellations/ delays
- These patients are almost all typically ASA 3 or greater: Complicated and compromised respiratory dynamics expected
 - Requires experience Anesthesiologist
 - Cannot wait for patients to improve
 - Benefit from thorough pre-operative care plan, procedure familiarity
- Complex medical history and care = complex, supportive multidisciplinary care team
- Intrathecal injection can be difficult/complicated
 - May require radiology
 - Anesthesia/sedation & positioning changes over time
- Procedure must be done as an outpatient
 - Cannot have unexpected admissions/unprepared PACU

Spinraza™ Dosing Schedule	Calendar	Dose
Week 1	January 2 nd , 2017	Loading Dose
Week 3	January 16 th , 2017	Loading Dose
Week 5	January 30 th , 2017	Loading Dose
Week 9	February 27 th , 2017	Loading Dose
Week 25	June 19 th , 2017	Maintenance Dose (approx. q4mo for life)
Week 41	October 9 th , 2017	Maintenance Dose
Week 57 (5)	January 29 th , 2018	Maintenance Dose

*Treatment pathway continues life long

Figure 3: example of Spinraza™ dosing schedule

References

1. ASA: Perioperative Surgical Home. <http://asaah.orh/psb>. 2018. accessed 01/25/2018.