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Reducing Sugammadex Usage: Optimization of Use Criteria and Outcomes Evaluation

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Learning Objectives

- Describe how to create evidence-based use criteria to effectively manage high-cost medications.
- Explain how to leverage internal data collection and analysis to allow evaluation of patient outcomes associated with the formulary management process.

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Reducing Sugammadex Usage: Project Summary

Goal	• 90% utilization reduction
Pre-project 12 month spend (2019-2020)	• $3.8M
Post project 12 month spend (2020-2021)	• $526K
Realized reduction	• 86%

Overview: Sugammadex

- FDA approval December 16, 2015

Indications

- Sugammadex is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery

Dosage

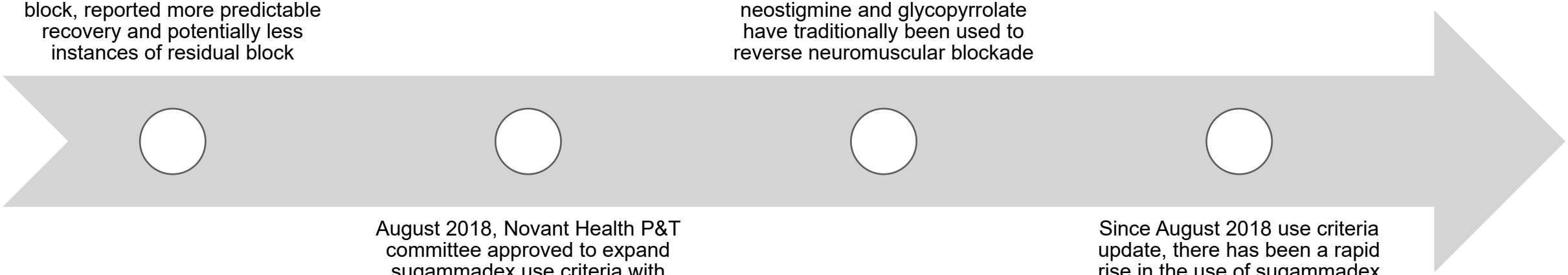
- 4 mg/kg is recommended if spontaneous recovery of the twitch response has reached 1 to 2 post-tetanic counts (PTC) and there are no twitch responses to train-of-four (TOF) stimulation.
- 2 mg/kg is recommended if spontaneous recovery has reached the reappearance of the second twitch in response to TOF stimulation.
- For rocuronium only: • 16 mg/kg is recommended if there is a clinical need to reverse neuromuscular blockade soon (approximately 3 minutes) after administration of a single dose of 1.2 mg/kg of rocuronium.

*Novant Health

- In 2018, Novant Health determined sugammadex as an acceptable reversal option for any surgery that utilized rocuronium/vecuronium

Background

Sugammadex offers a faster time to reversal of neuromuscular block, reported more predictable recovery and potentially less instances of residual block

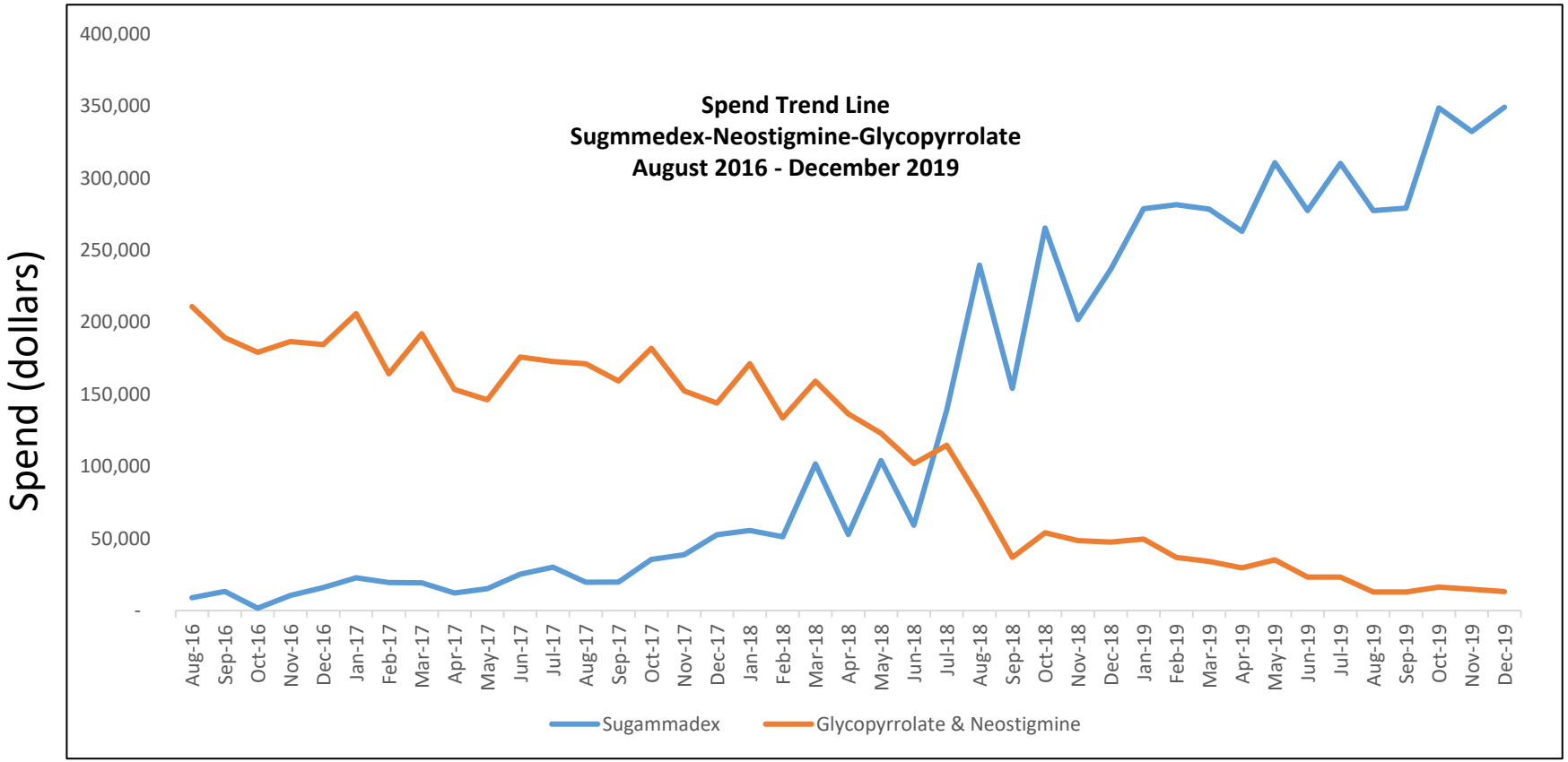


August 2018, Novant Health P&T committee approved to expand sugammadex use criteria with agreement that faster reversal would allow an increase in acute care surgical volumes

Prior to sugammadex availability, neostigmine and glycopyrrolate have traditionally been used to reverse neuromuscular blockade

Since August 2018 use criteria update, there has been a rapid rise in the use of sugammadex

Assessment
Pre-Project System Utilization Data



Assessment

- Sugammadex offers faster recovery time to reversal and less residual block. However, there has not been an increase in surgical volumes in the acute care space that has been associated with sugammadex use.
- There is lack of strong evidence supporting significant reductions in pulmonary complications, post-operative nausea and vomiting, or improvement in post-operative cognitive dysfunction and recovery when comparing sugammadex to neostigmine/glycopyrrolate. No benefits observed in length of stay.
- The increased utilization of sugammadex since August 2018 has led to an annual spend of approximately $3.8M
- The focus of this project is to prioritize sugammadex by developing appropriate use criteria

Recommendations

Propose New Use Criteria

- Evidence-based
- Utilization of internal data
- Consensus of expert clinicians
- Executive Leadership support

Construction of quality/outcomes-based dashboard

- Monitor progress of established goals
- Continuous evaluation of quality/outcomes measures for any opportunities

Sugammadex Current Use Criteria

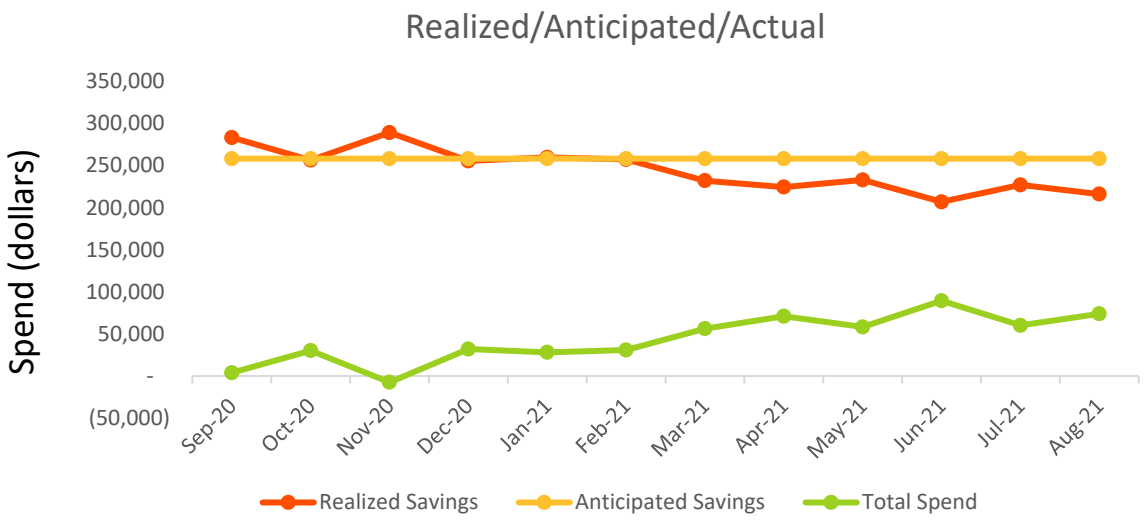
Novant Health Dosing Criteria

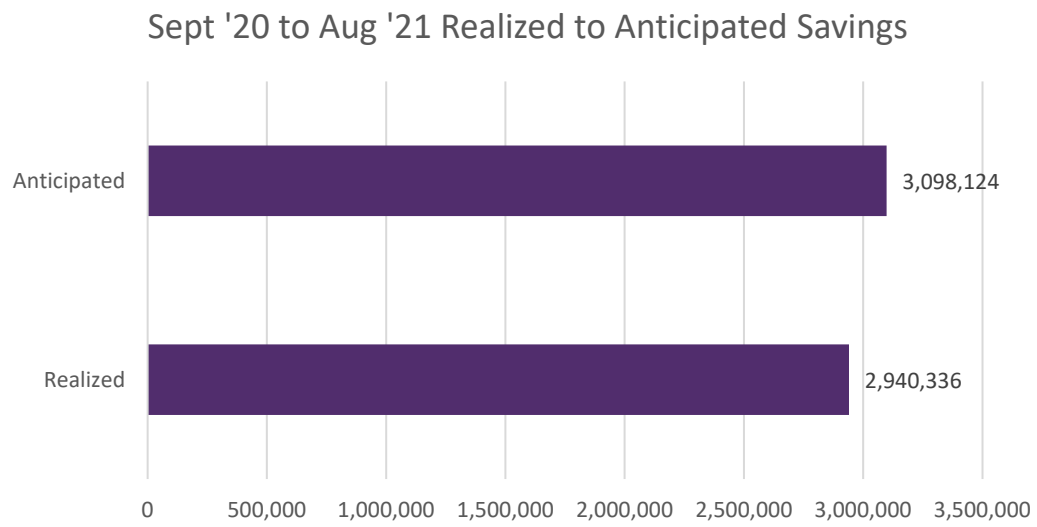
Novant Health Approved Use Criteria
• Need for immediate reversal of rocuronium 1.2 mg/kg blockade within 3 minutes (16mg/kg)
• Need for deep profound neuromuscular blockade in order to shorten anesthesia time for abandoned, cancelled, or prematurely terminated procedures
• Documented allergies to neostigmine and/or glycopyrrolate
• Rescue doses: ability to administer sugammadex ≥ 30 minutes after dose of neostigmine/glycopyrrolate given when incomplete reversal is present (0.5 mg/kg, consider repeat x1 in 3-5 minutes if necessary)

Sugammadex: Financial Summary

12 Month Trend: Sept 2020 – Aug 2021

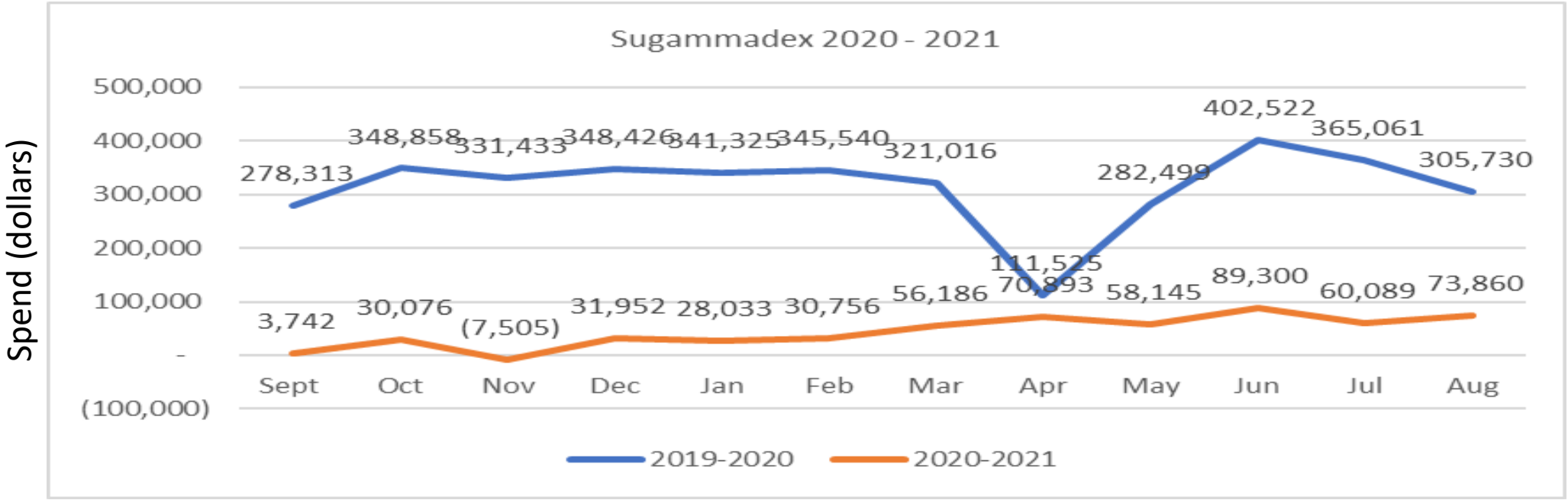
Goal: reduction in utilization of sugammadex by 90% over 12 months
Results: achieved an 86% reduction in utilization with the updated use criteria





Sugammadex Trending Updates

Spend: 2019-2020 pre-implementation versus 2020-2021 post implementation timeframe



Our Journey

Relationships

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Relationships

- **Within Pharmacy: TEAM effort**

  - ✓ Pharmacists, technicians, administrative support
  - ✓ Executive team, operations, clinical, automation, sourcing, procurement, business, medication safety, supply chain

- **External to pharmacy**

  - ✓ Executive Team
  - ✓ Institute leaders (including anesthesia and surgery)
  - ✓ Quality and Safety team
  - ✓ Informatics
  - ✓ Order set team
  - ✓ Facility leaders
  - ✓ Front line teams
  - ✓ Anesthesia Advisory Group

Our Journey

Formulary Management Process

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Timeline: Preparatory work

Jan 2020 – June 2020

- Literature Review/evaluation
- Internal data analysis
  - Clinical: use by specialty, location, dose (total, mg/kg)
  - Financial: total spend, spend by facility/specialty; comparative analysis versus neostigmine/glycopyrrolate
  - Modeling: construct conversion plan/analysis for sugammadex->neostigmine/glycopyrrolate
  - Goal setting
    - Use criteria: based on FDA approved indications, literature summary, anesthesia/surgery feedback
    - Percent reduction
- Quality/outcomes-based dashboard construction
  - Work with anesthesia, surgery, IT, OR/nursing teams, for data point consideration
  - Establish monthly refresh of dashboard data

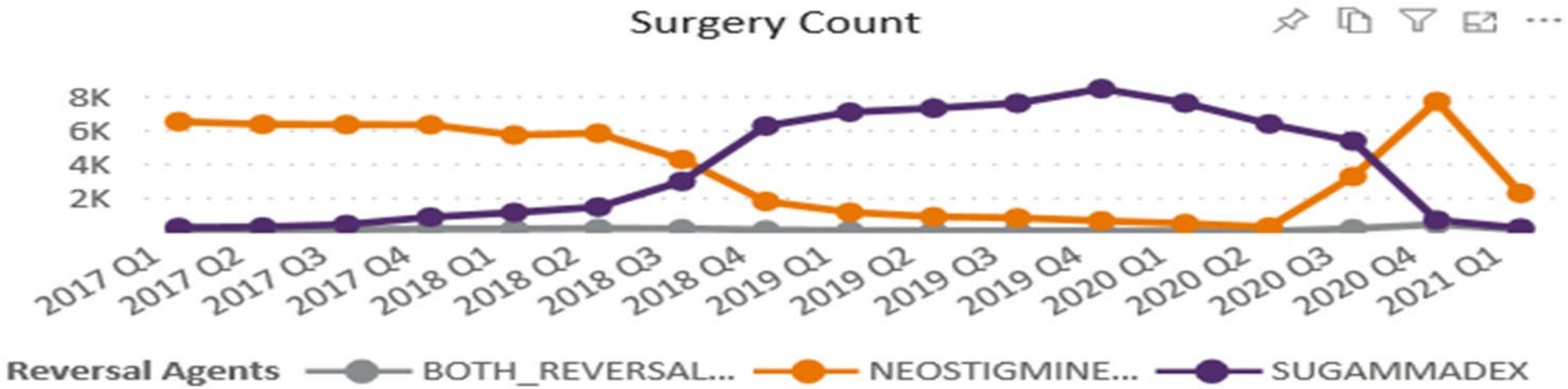
Timeline: Implementation

Aug 2020 P&T approval

- Presented last week of August and approved for adoption of new use criteria

Informatics

- 6 week build window dedicated for each month's P&T agenda items
- Surgery count is number of actual surgical cases



P&T Committee Overview

Scope:

Acute care facilities, ambulatory practices that dispense medications, infusion and specialty medication centers

Voting Members:

Medical staff (providers and pharmacists) representative of all service lines and markets

Non-Voting Members:

Chief Clinical Officers, Medical Directors, Physician Executives, Nurses, respiratory therapists, nutrition, radiology techs, educators, pharmacists, pharmacy residents

Stakeholders:

Physicians and other team members in service lines or areas that will be impacted by P&T decision-making on a given topic

P&T Committee Responsibilities

- Review and approve:
  - all proposed changes to the Novant Health system formulary
  - medication order sets, protocols, standing orders
  - all medication management policies
  - all pharmacy dosing and monitoring programs
- Enhance medication safety practices, quality assurance and improvement
- Review medication use evaluations and implement necessary changes
- Evaluate, oversee and recommend:
  - changes to automated dispensing machines
  - education regarding P&T actions

Novant Health Pharmacy & Therapeutics: 4 Pillars for Formulary Decision-Making

Clinical Gap

- Relative to existing formulary agents, does the medication fill a clinical need for the patient population served?

Safety

- What safety considerations exist relative to other comparable agents?

Efficacy

- What is the clinical efficacy profile relative to comparable agents?

Affordability

- Relative to comparable formulary agents, what are the affordability considerations? *(drug pricing, clinical outcomes cost, payer considerations, etc.*)

P&T Committee Meetings (Monthly)

Pre-P&T Meeting

- **Meeting Day and Time: 2nd Thursday at 12:00 PM** (except November and December when it moves up one week)
- **Attendees**:
  - representatives from pharmacy leadership at each facility
  - clinical pharmacy leaders
  - representatives from each of the P&T subcommittees
  - pharmacists presenting content at P&T
  - DPS Dimensions support
- **Purpose**: to review items to be presented at P&T for content, slide materials, and feasibility/concerns
- **Responsibilities of presenting pharmacists**:
  - present agenda item
  - take feedback
  - incorporate slide updates

P&T Committee Meetings (Monthly)

Post P&T Meeting

- **Meeting Day and Time: Friday after P&T at 11:00 AM**
- **Attendees**:
  - representatives from pharmacy leadership at each facility
  - clinical pharmacy leaders
  - representatives from each P&T subcommittees
  - pharmacists presenting content
  - other departments such as DPS, Order Sets, Clinical education
- **Purpose**:
  - to discuss follow up IT needs
  - builds within Epic or other systems
  - updates to formulary management solution
  - updates to order sets
- **Responsibilities of presenting pharmacists:**
  - present the decision made on agenda item and all work done to implement changes
  - get feedback on further needs
  - conduct all follow up to enter requests for implementation

Our Journey

Data

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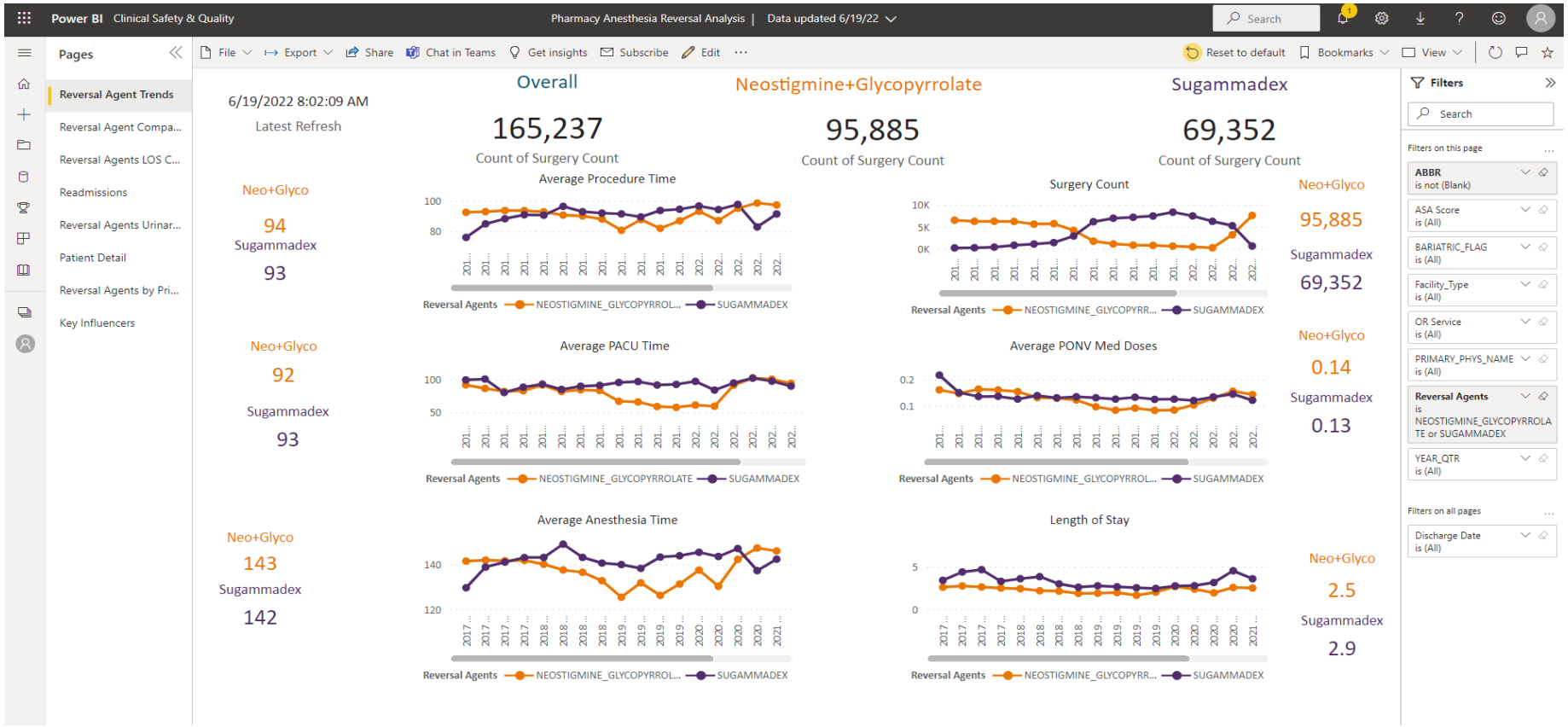
Sugammadex Data: Literature Summary

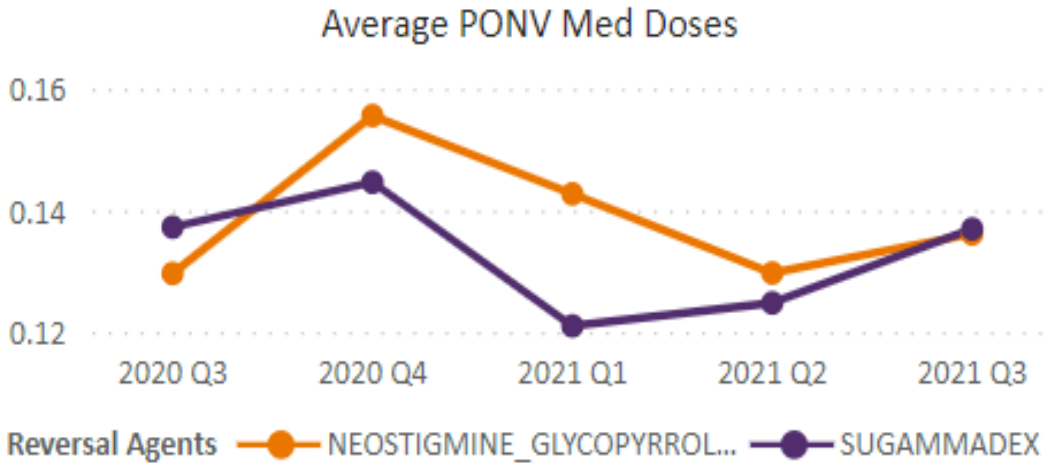
Author/Title	Design/Procedure	Comparator	Notable Outcomes	Conclusion
Deana C, Barbariol F, D'Incà S, Pompei L, Rocca GD. SUGAMMADEX versus neostigmine after ROCURONIUM **continuous infusion** in patients undergoing **liver transplantation.** BMC Anesthesiol. 2020;20(1):70.	Single-centered, non-blinded, randomized controlled trial to evaluate the *neuromuscular transmission* recovery time in hemodynamically stable patients only	sugammadex vs neostigmine (dose unknown)	Recovery from neuromuscular block was faster following sugammadex administration than neostigmine administration with mean times of 9.4 minutes and 34.6 minutes, respective ($p < 0.0001$).	Within this specific pt population, sugammadex provides an appreciable difference in recovery time. Of note, several variables to consider including: rocuronium is less than ideal in this population due to highly variable pharmacokinetic profile in cirrhosis, interaction with sugammadex/steroid administration and reported longer recovery times, need for urgent surgery within 24hrs of transplant and residual reversal activity may still be present. Additional recommendations are to consider administering sugammadex at least 15min prior to extubation

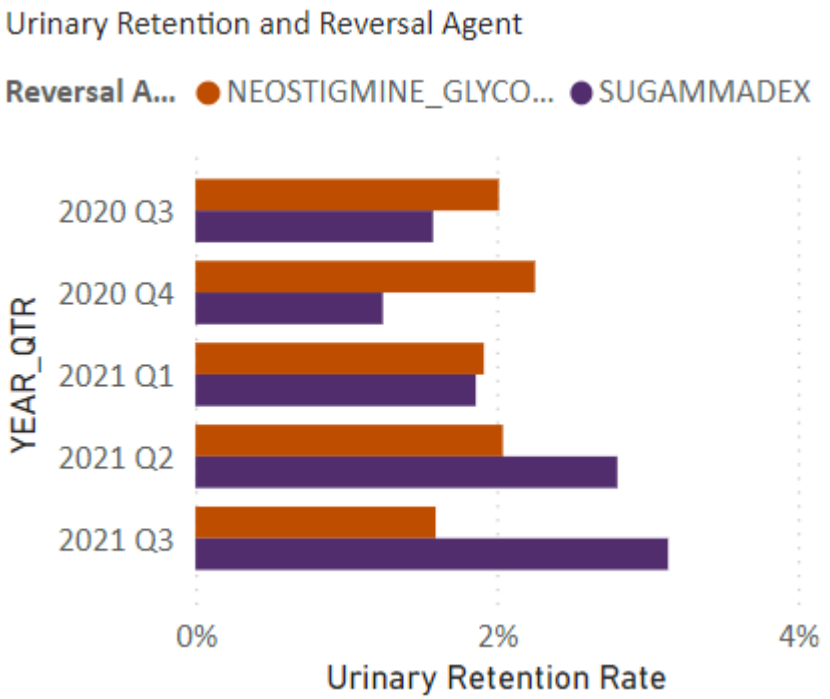
Utilization Data

Quality/Outcomes Dashboard
2017 - Present

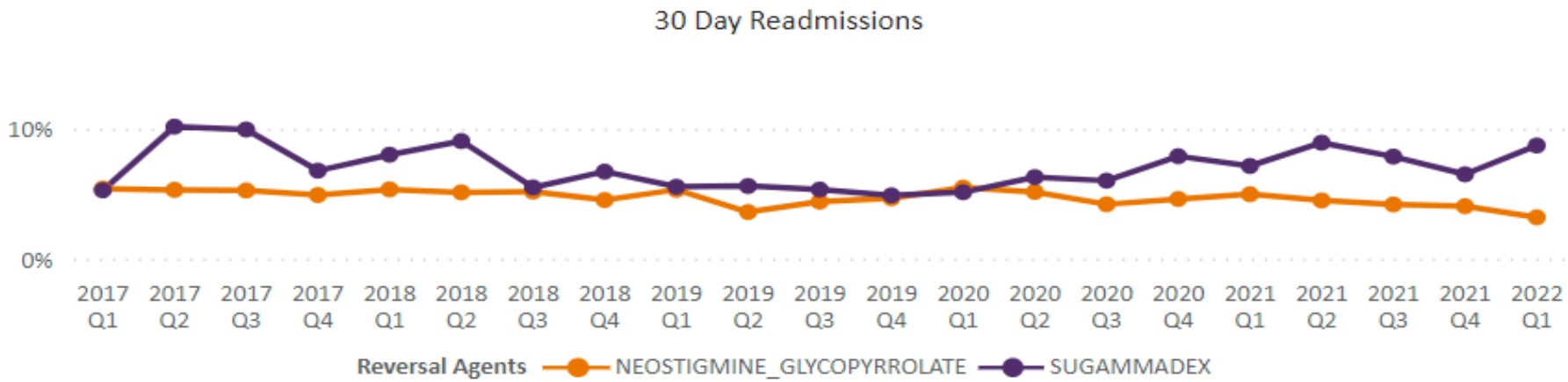


Quality/Outcomes Dashboard





Quality/Outcomes Dashboard

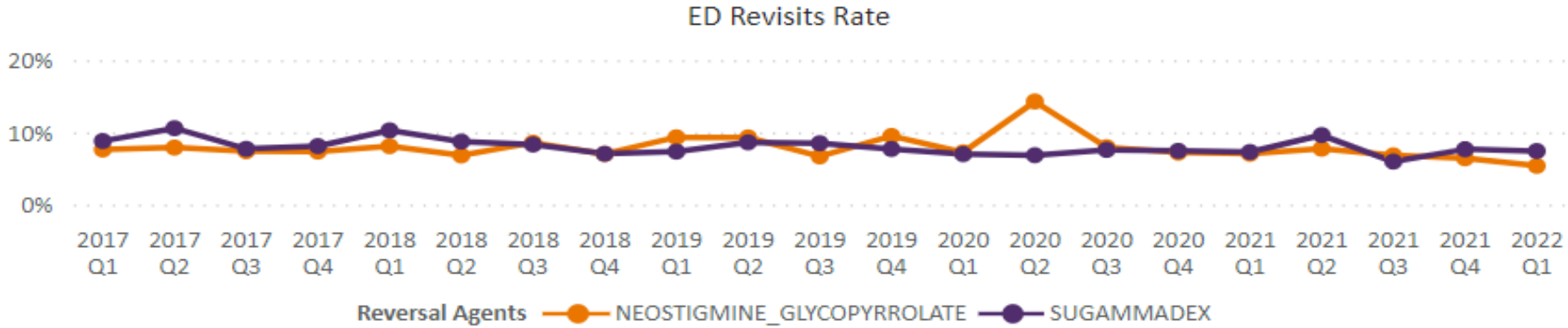


Neo+Glyco

4.7%

Sugammadex

6.0%



Neo+Glyco

7.3%

Sugammadex

7.7%

Our Journey

Opportunities

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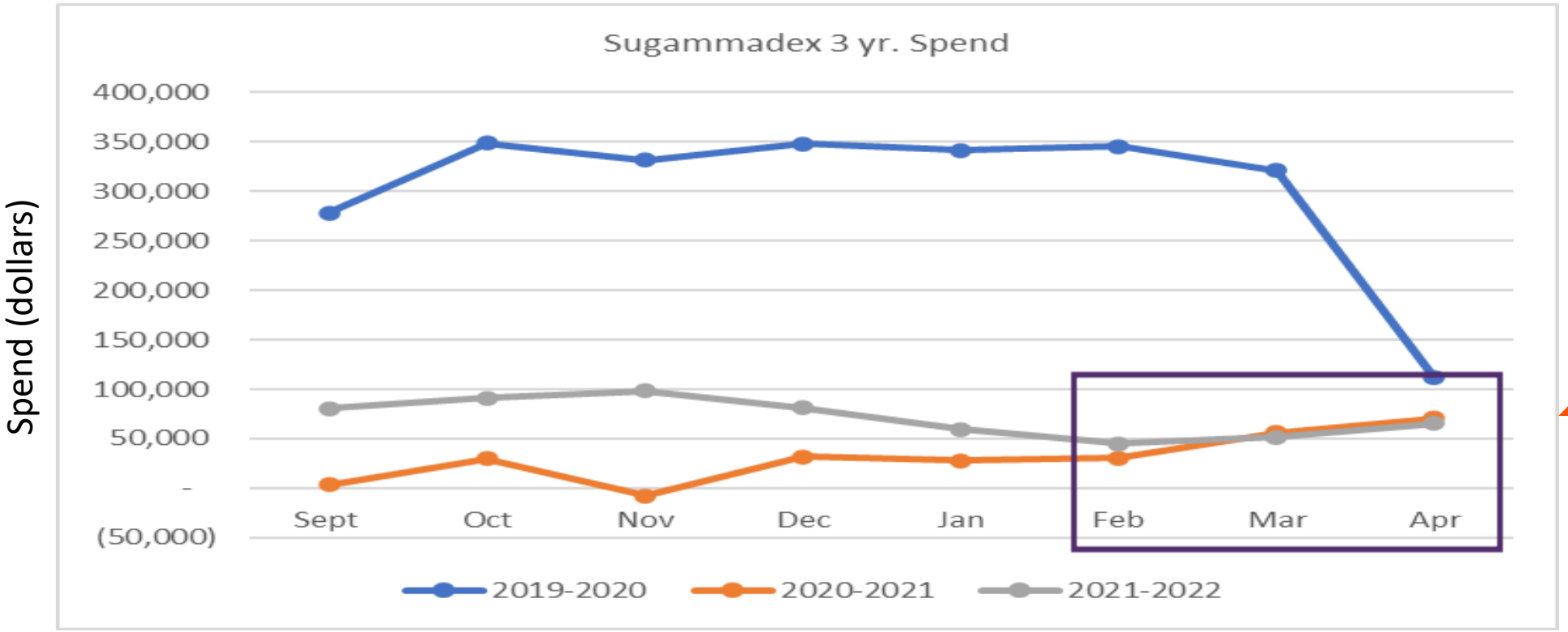
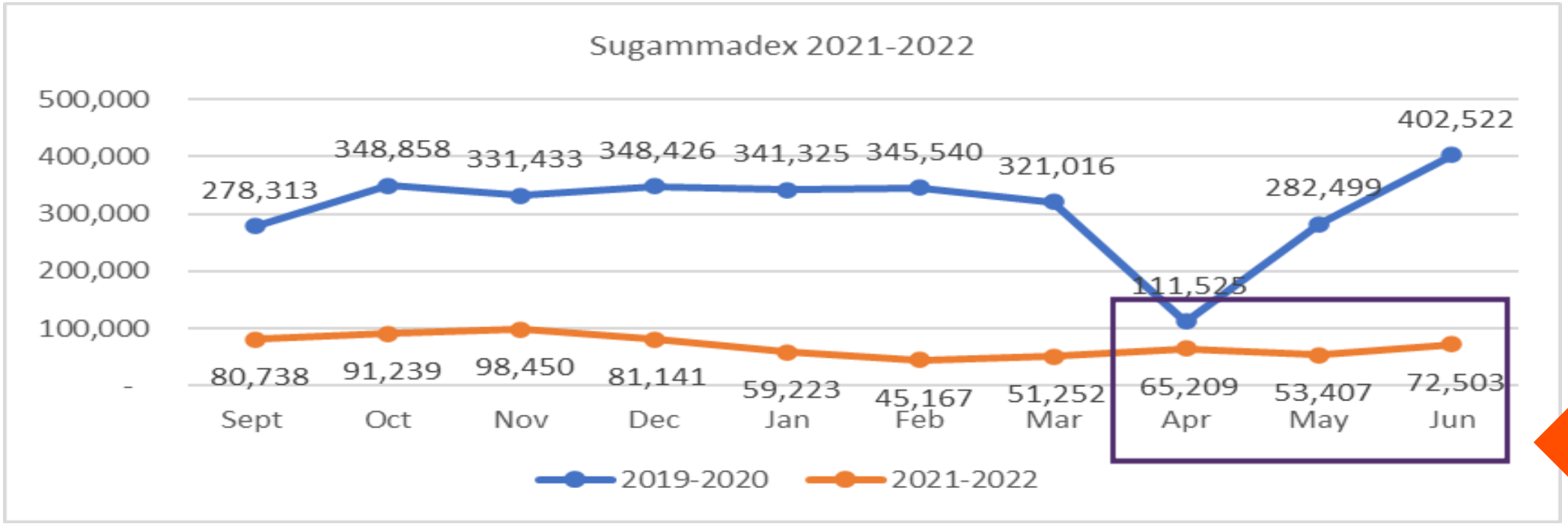
Sugammadex Trending Updates
Spend: 3-year Trend



Upward Trend

Sugammadex Trending Updates
Spend: 3-year Trend



Normalized Trend

Our Journey

In Summary

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Lessons Learned

1. Obtaining the data was challenging - we partnered with our analytics team (this dashboard took more than 6 months to achieve), but this also helped with the conversation since we would be proactively evaluating quality and outcomes in an ongoing fashion.

2. A strong subjective connection to the utilization of the medication was needed – we conducted an extensive literature evaluation, internal data evaluation, and sought executive sponsorship.

3. Creating appropriate use criteria was key - we utilized the data from point #2 above, and to be transparent, we frequently messaged the work and obtained feedback. Additionally, we set up small group discussions with key stakeholders often to allow more informal discussions (market-based conversations), we leveraged the system anesthesia meetings for updates on progress, and we modeled the updated use criteria impact for executive team.

4. We focused on quality and outcomes – as the project took shape, we created the dashboard which was a key component to the approval of reduced use. The dashboard allowed us to monitor outcomes, assess the impact, and quickly pivot if necessary; this review continues monthly by pharmacy and is reported out to the monthly system anesthesia meetings and the quarterly executive anesthesia/surgery meetings.

Key Takeaways

1. Build relationships across the enterprise (e.g., institute leaders, quarterly meetings)

2. Establish YOUR 4 pillars for formulary decision-making
   - ✓ Apply the pillars to ALL formulary work (internal to pharmacy, external to pharmacy, and industry)
   - ✓ Extend the process system-wide
   - ✓ Use clear messaging

3. Establish goals
   - ✓ Understand the “problem” – what are you trying to solve?
   - ✓ Know what you want to accomplish: frame the discussion; know your audience
   - ✓ Find your burning platform (change management - 8 steps)

4. DATA!
   - ✓ Gather baseline data to understand current state (related to the “problem”)
   - ✓ Identify metrics for success; continuous monitoring (if applicable): Quality/Outcomes

Questions?

Contact:

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