



Clinical Safety & Effectiveness Cohort #16

Reducing Potential Intra-operative Over-utilization of Ofirmev (IV Tylenol)



The Team

- Division

- Ashlie Stowers, M.D. CS&E Participant

- Associate Program Director, Dept. of Anesthesiology

- Blanche Hensgens, M.D. Team Member

- Anesthesiology Resident, CA-2/PGY-3

- Jeanette Jackson, CRNA Team Member

- Certified Registered Nurse Anesthetist

- Stephen Rupp, RPh, BCPS Team Member

- Pharmacist for Operating Room

- Hope Nora, PhD Facilitator

- Sponsor Department:

- Travis Wilson, M.D. Program Director, Dept. of Anesthesiology

Project Milestones:

- Create team: anesthesia providers + pharmacy representative Completed 2/1/2015
- AIM statement created Completed 2/6/2015
- Map the process (flowsheet) Completed 2/7/2015
- Process analysis (cause & effect diagram, aka “fishbone” diagram) Completed 2/7/2015
- Identify potential interventions Completed 2/9/2015
- Collect pre-intervention data:
 - # patients w/ epidurals for post-op pain control (7/1/14 – 2/28/15) Completed 2/2/2015
 - What percentage of these patients received intra-op IV Tylenol? Completed 2/15/2015
 - Acquisition cost to UHS per bottle, OR pharmacy expenditure, cost to patient, etc. Completed 2/6/2015
 - IV Tylenol information: efficacy studies, pharmacokinetics, contraindications, etc. Completed 2/26/2015
- Implement Intervention #1 Completed 2/28/2015
- Implement Intervention #2 Completed 4/1/2015
- Implement Intervention #3 Completed 4/1/2015
- Collect post-intervention data In progress
- Data Analysis: Did we reach our aim statement goal?
- CS&E presentation May 2015

Background



- History of the problem:
 - Overall lack of discretion as to which patients receive intra-operative Ofirmev leads to poor allocation of an expensive resource
 - Lack of knowledge on Ofirmev pharmacokinetics
 - Peak effect within 1 hour and lasts only 4-6 hours
 - Patients with alternate means of pain control (ie, epidurals, long-acting nerve blocks) are less likely to benefit from its analgesic effects
 - High cost could potentially lead to removal from UH formulary making it unavailable to patients who would benefit from an opioid-sparing technique the most

Background



- Rationale: Why is this important to address?
 - Total annual expenditure by UH from Oct 2013 – October 2014 on Ofirmev = **\$348,334**
 - Prior to July 2014, acquisition cost = \$12.55/bottle
 - Cost per bottle has since risen to **\$30.67**
 - Projected annual expenditure based on current prescribing practices ~ **\$490,000**
 - Current cost charged to patient = \$247.50/dose
 - Acquisition cost of alternate routes:
 - 325mg oral tablet = \$0.02
 - 650mg rectal suppository = \$0.42

Background



- What does the literature say about this issue?
 - American Society of Anesthesiology guidelines stress the use of multimodal pain management, listing acetaminophen as an important adjunct to pain control¹
 - Ofirmev generally improved post-surgical pain relief and demonstrated opioid-sparing effects compared with placebo...it did not consistently reduce the frequency of opioid-related adverse events (e.g., postop nausea/vomiting)²
 - Overall lack of research specifically looking at the efficacy of intra-operative Ofirmev in patients with epidurals for post-operative pain control

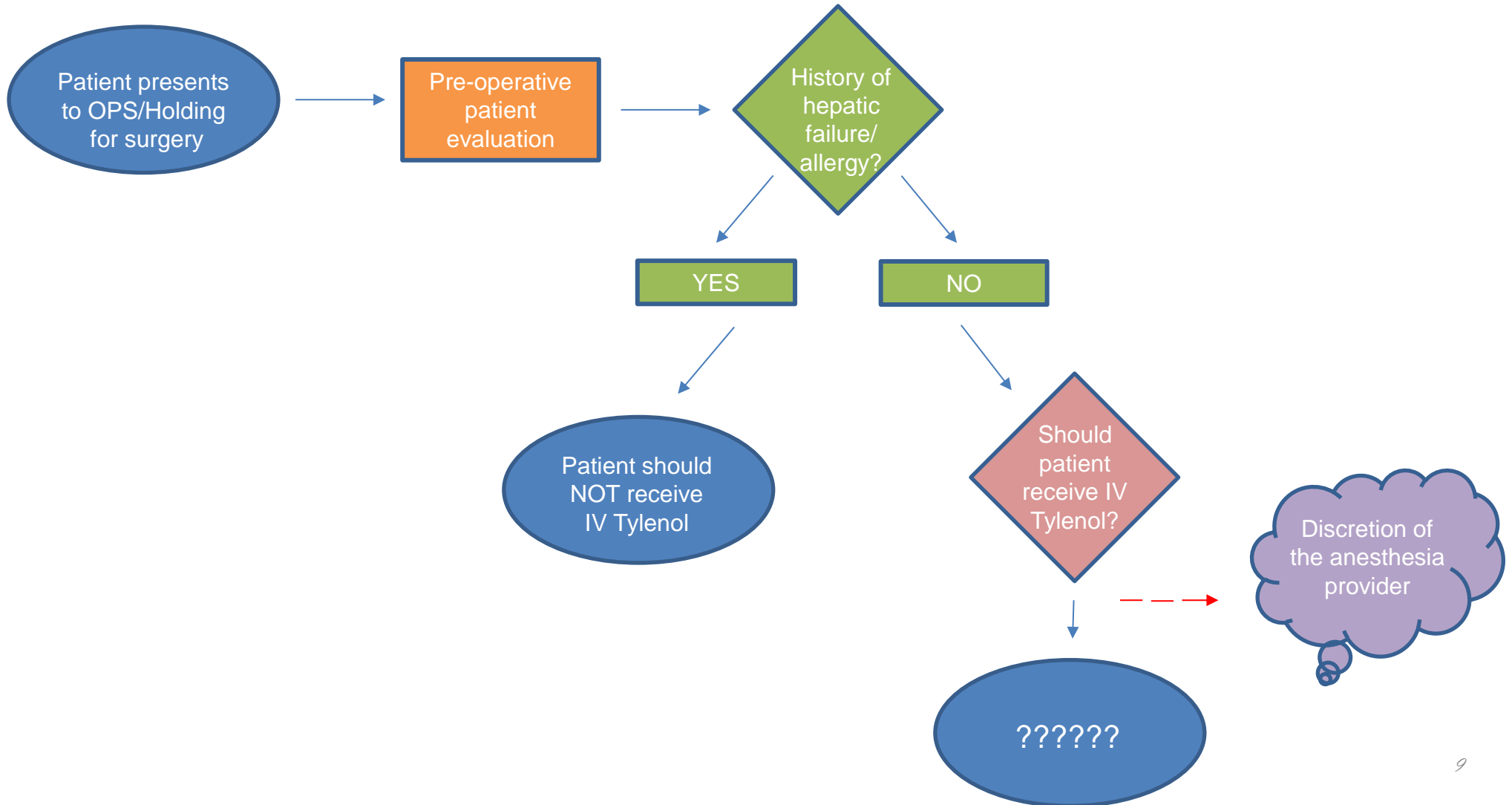
Background



- What about keeping the patient NPO for 8 hours prior to surgery?
 - Practice Guidelines for Preoperative Fasting by the ASA discusses a meta-analysis of multiple randomized controlled trials that report smaller gastric volumes and higher gastric pH values in healthy adult patients given clear liquids (100ml to unrestricted amounts) from 2-4 hours preop compared to more than 4 hours⁴
 - Further evidence suggests, that various modes of premedication, including oral, does not increase gastric volumes or acidity⁵
 - Other studies support the practice of administering oral premedication with up to 150ml of water 1-2 hours before surgery^{6, 7}

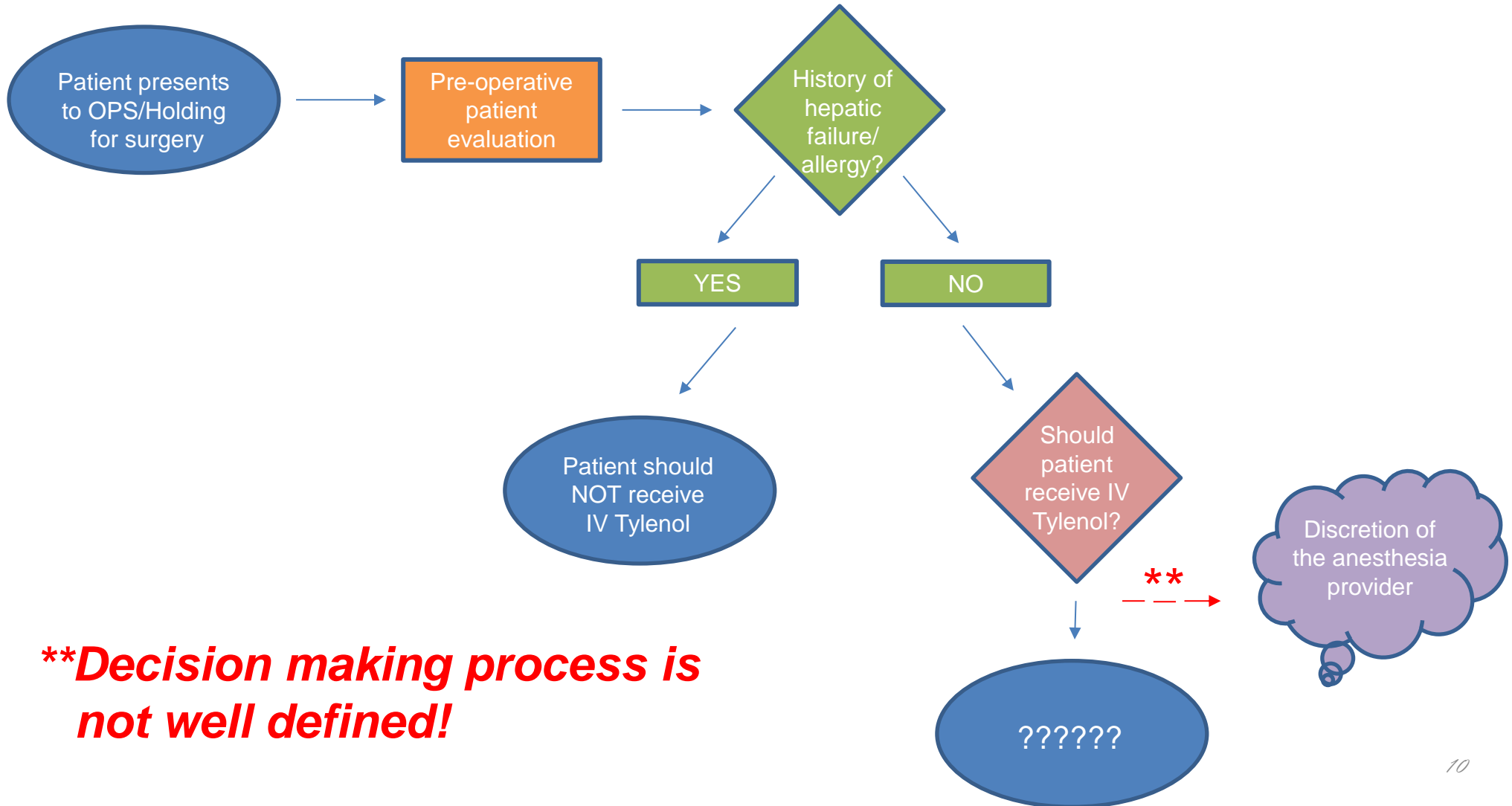
Project Mapping

Current state:



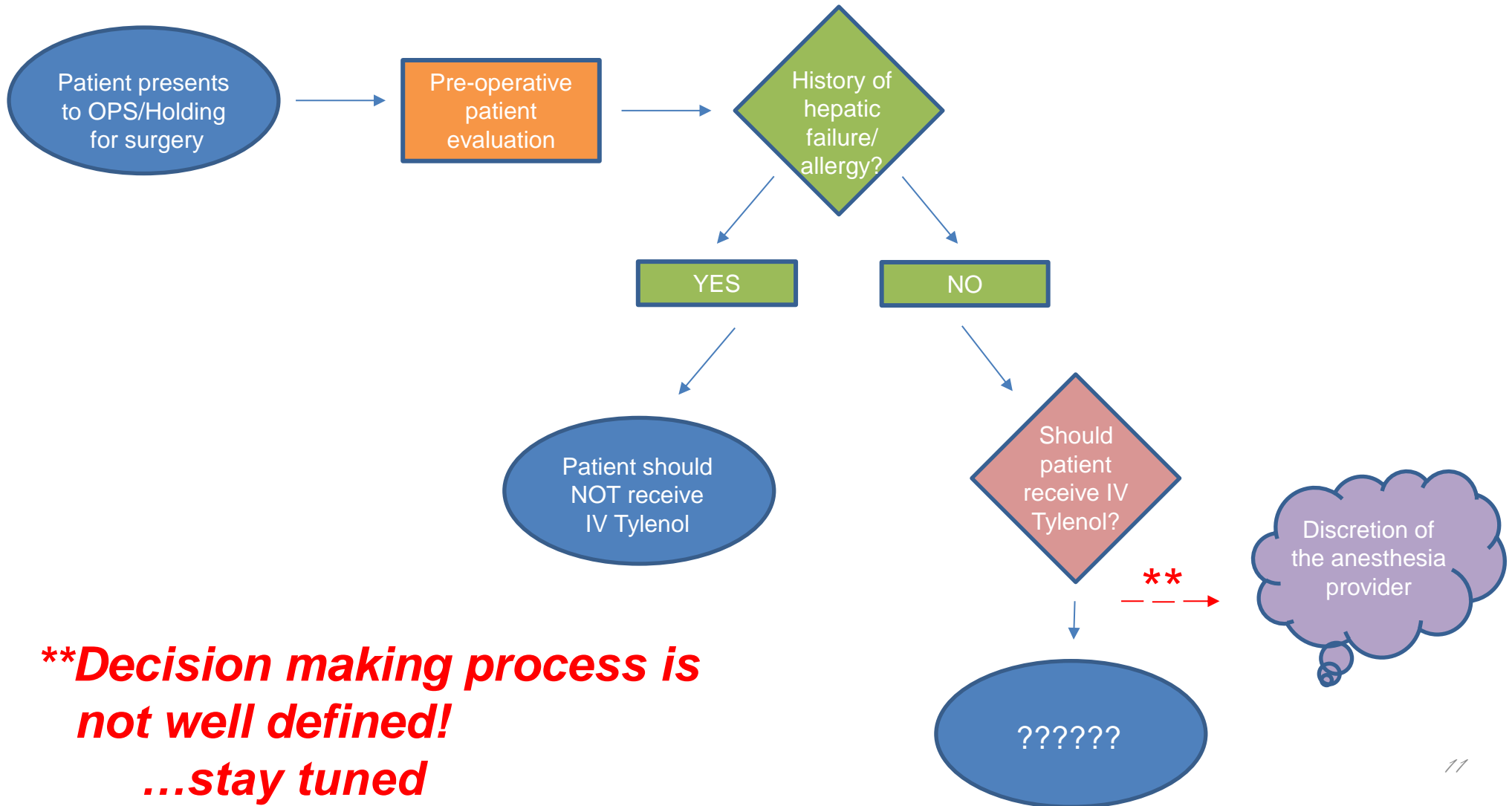
Project Mapping

Current state:



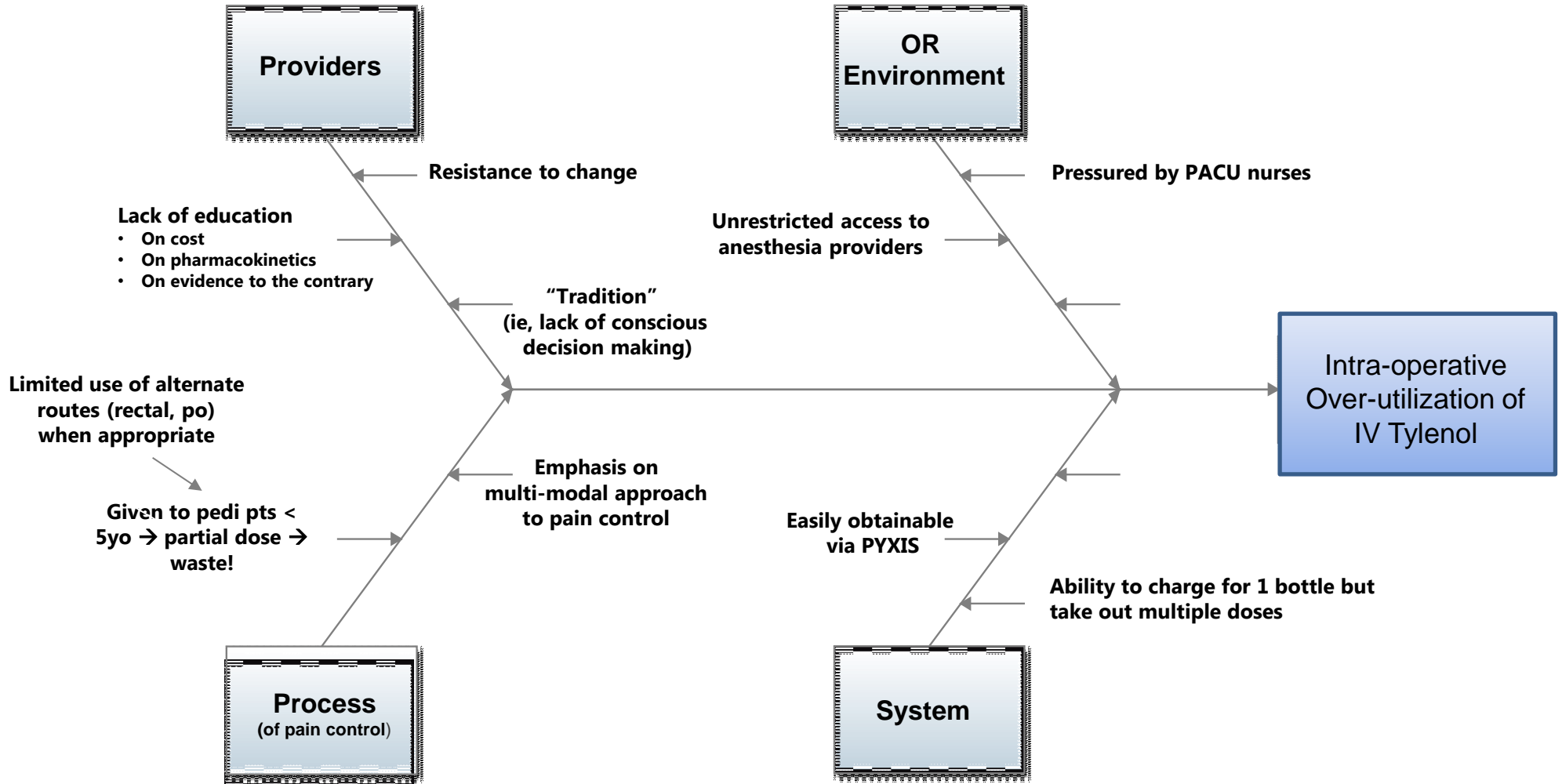
Project Mapping

Current state:



****Decision making process is not well defined!
...stay tuned**

Process Analysis:



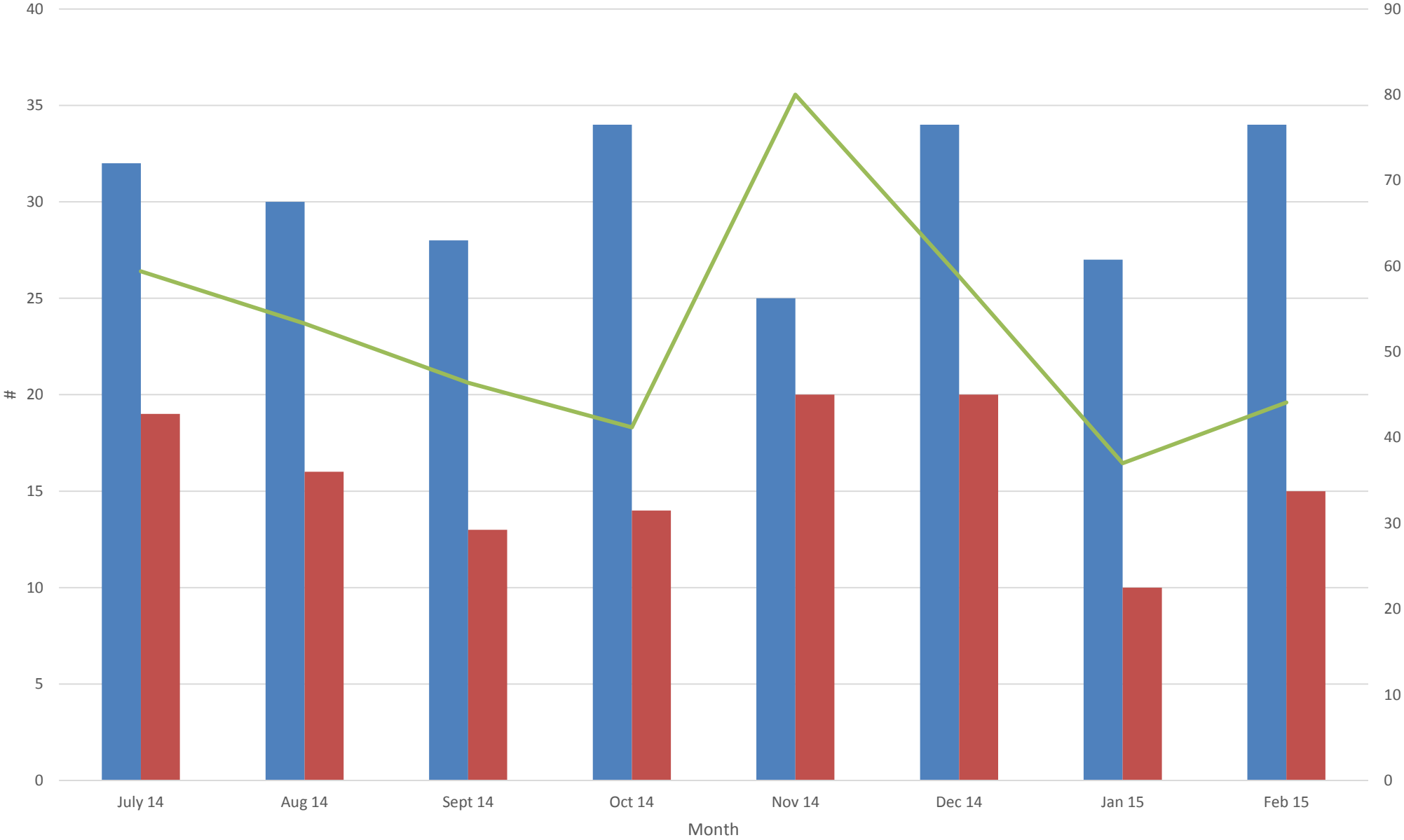
Pre-intervention Data:

- Gathering the data:
 - Review of Acute Pain Service patient list to identify patients with pre-operative placement of epidurals for post-operative pain control
 - Review of PICIS (electronic anesthesia record) to identify which of those patients with epidurals also received intra-operative IV acetaminophen (Ofirmev)
 - Data recorded on an excel spreadsheet

Pre-intervention Data:

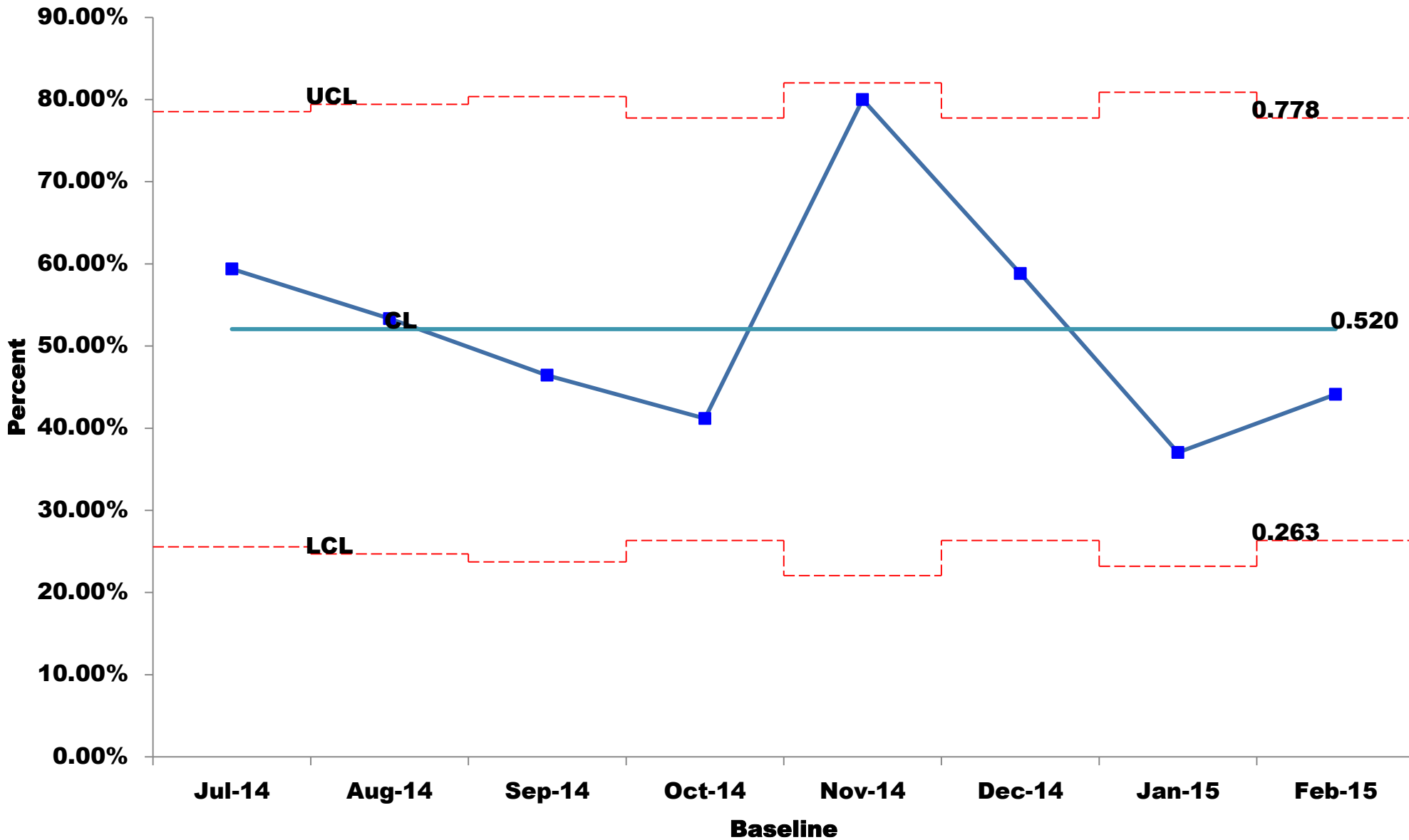
MONTH (2014 - 2015)	# Pre-op Epidurals Placed	# Pts with Epidurals who received Intra-op IV Ofirmev	%
July	32	19	59.4
August	30	16	53.3
September	28	13	46.4
October	34	14	41.2
November	25	20	80.0
December	34	20	58.8
January	27	10	37.0
February	34	15	44.1
Overall:	244	127	52.0%

UH Surgical Patients with an Epidural Receiving IV Ofirmev



■ # pre-operative epidurals placed
 ■ # patients with epidurals that received intra-operative Ofirmev
 — %

UH Surgical Inpatients with an Epidural Receiving IV Ofirmev

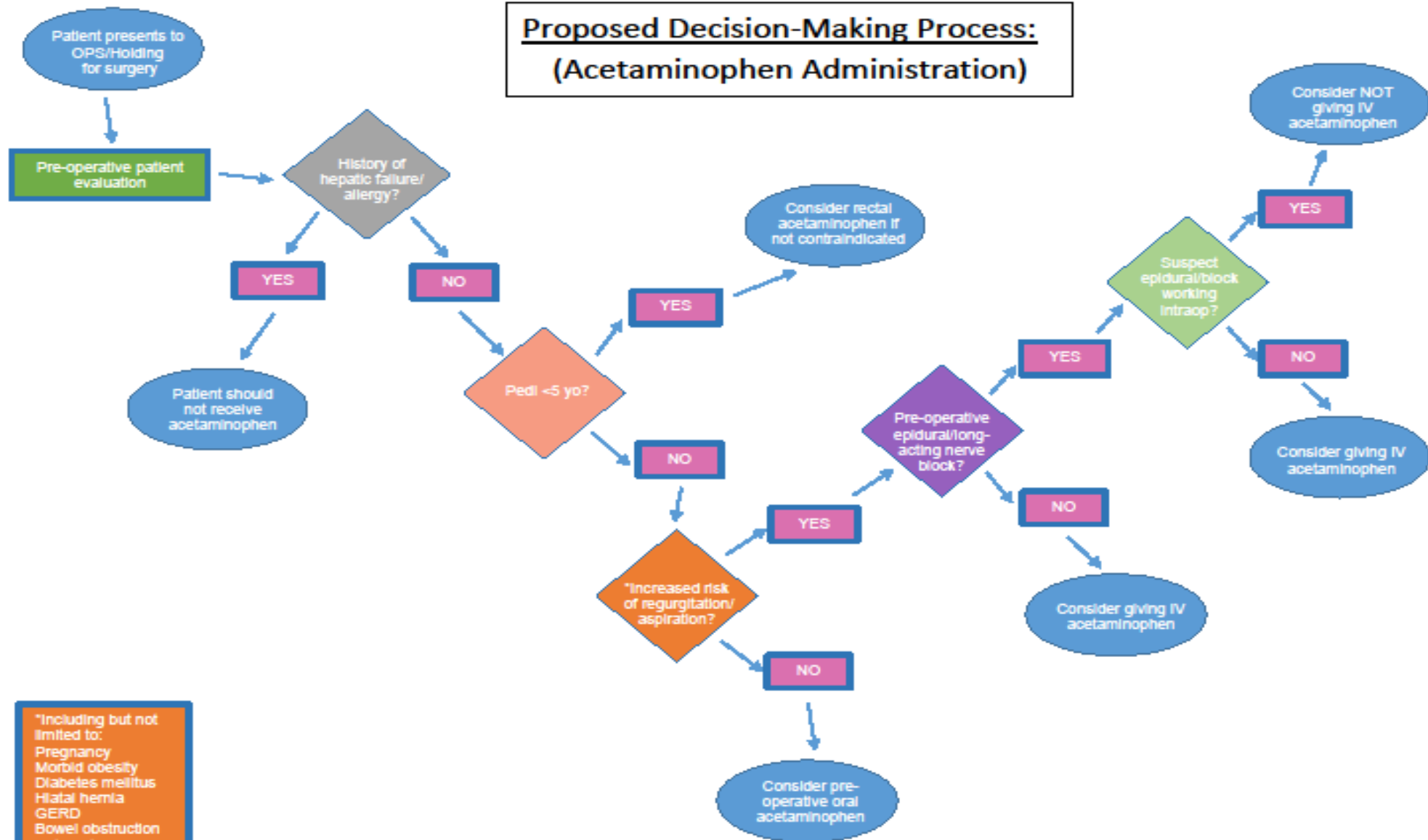


Intervention #1:

(Completed 2/28/2015)

- Education of anesthesia providers → to “break the tradition” of reflexive administration
- Accomplished via an educational email discussing:
 - IV acetaminophen acquisition cost, price comparison of alternate routes of administration, cost charged to the patient
 - Potential future unavailability of Ofirmev due to high cost
 - Pharmacokinetics of acetaminophen
 - Current studies to promote evidence-based practice
 - Proposed decision-making flowchart

**Proposed Decision-Making Process:
(Acetaminophen Administration)**



*Including but not limited to:
 Pregnancy
 Morbid obesity
 Diabetes mellitus
 Hiatal hernia
 GERD
 Bowel obstruction
 Enteral tube feeds
 Difficult Airway
 Undergoing airway procedure

Intervention #2:

(Completed 4/1/2015)

- Initiation of PYXIS prompts →
 - Does this patient have hepatic failure?
 - Does this patient have an epidural or post-op pain nerve block?
 - Is rectal administration an appropriate alternative (pediatrics)?
- Laminated flow-chart posters in anesthesia workrooms
- Purpose?
 - To serve as reminders of our initiative
 - To encourage more discretion before administering IV Ofirmev

Intervention #3:

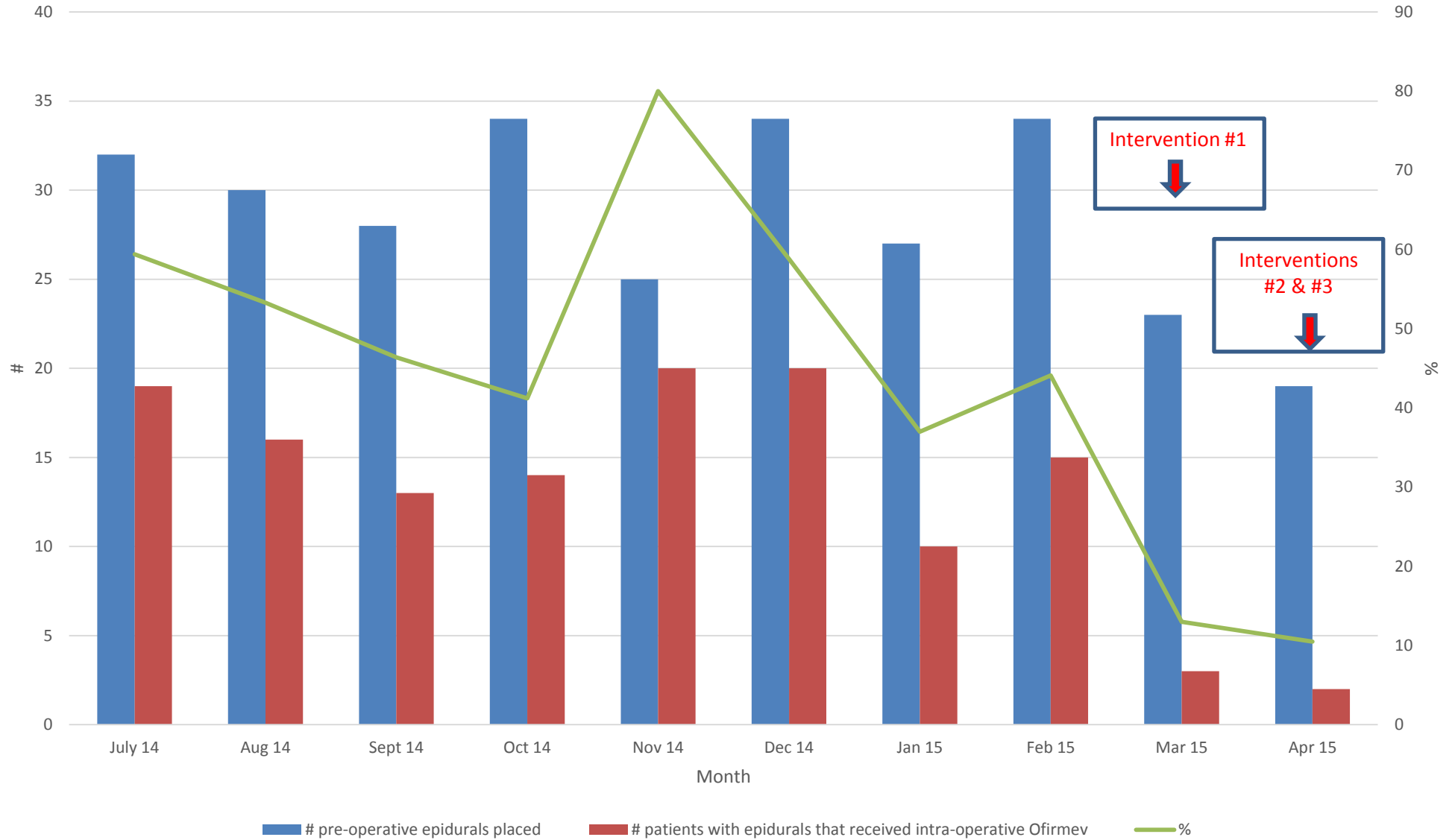
(Completed 4/1/2015)

- Providing feedback to anesthesia providers on current results
- Purpose?
 - To show that progress is being made in hopes that it will reinforce the encouraged behavior of using more discretion before administering IV Ofirmev

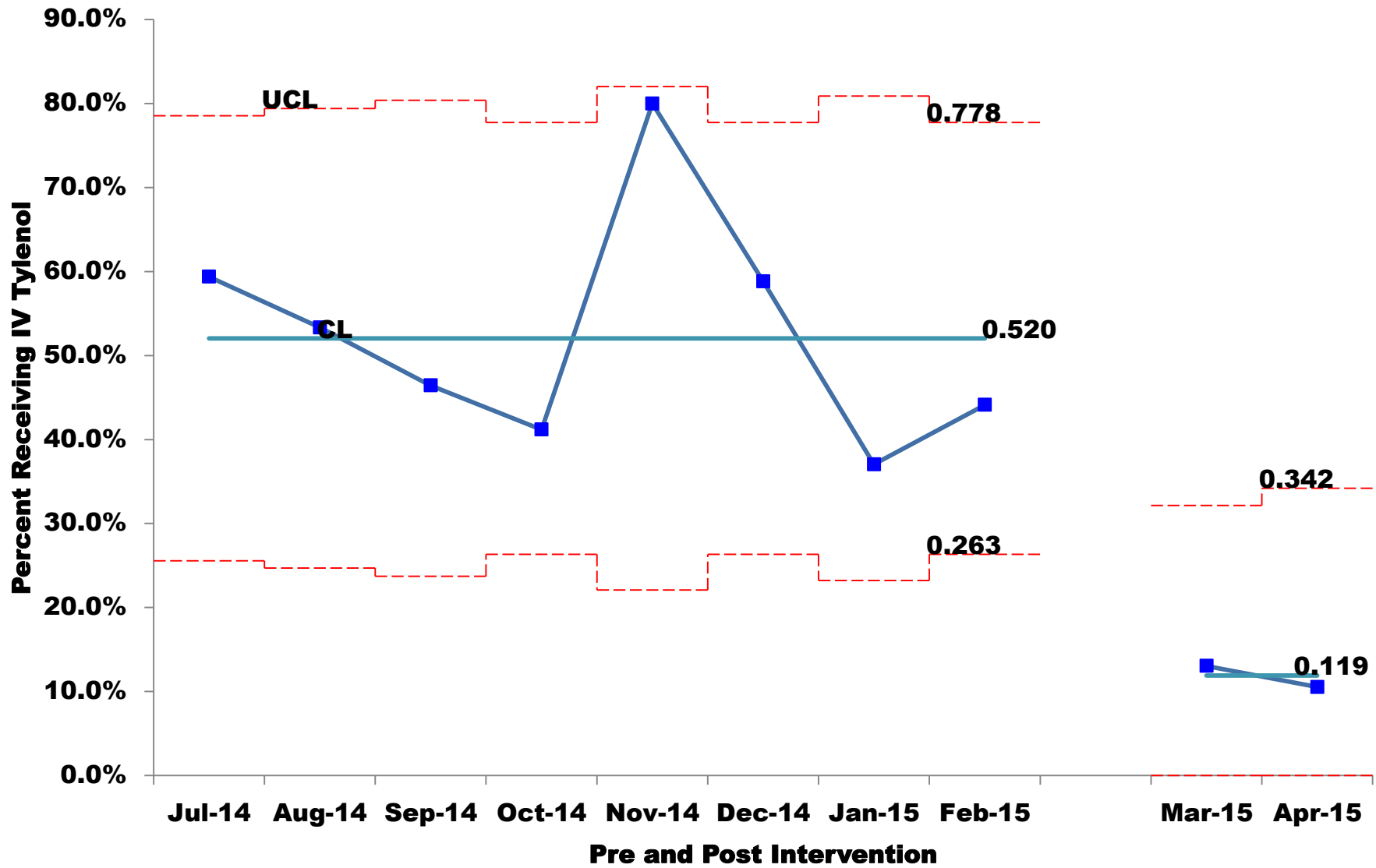
Post-intervention Data:

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December	34	20	58.8
January	27	10	37.0
February	34	15	44.1
March	23	3	13.0
April	19	2	10.5

UH Surgical Patients with Epidurals Receiving IV Ofirmev



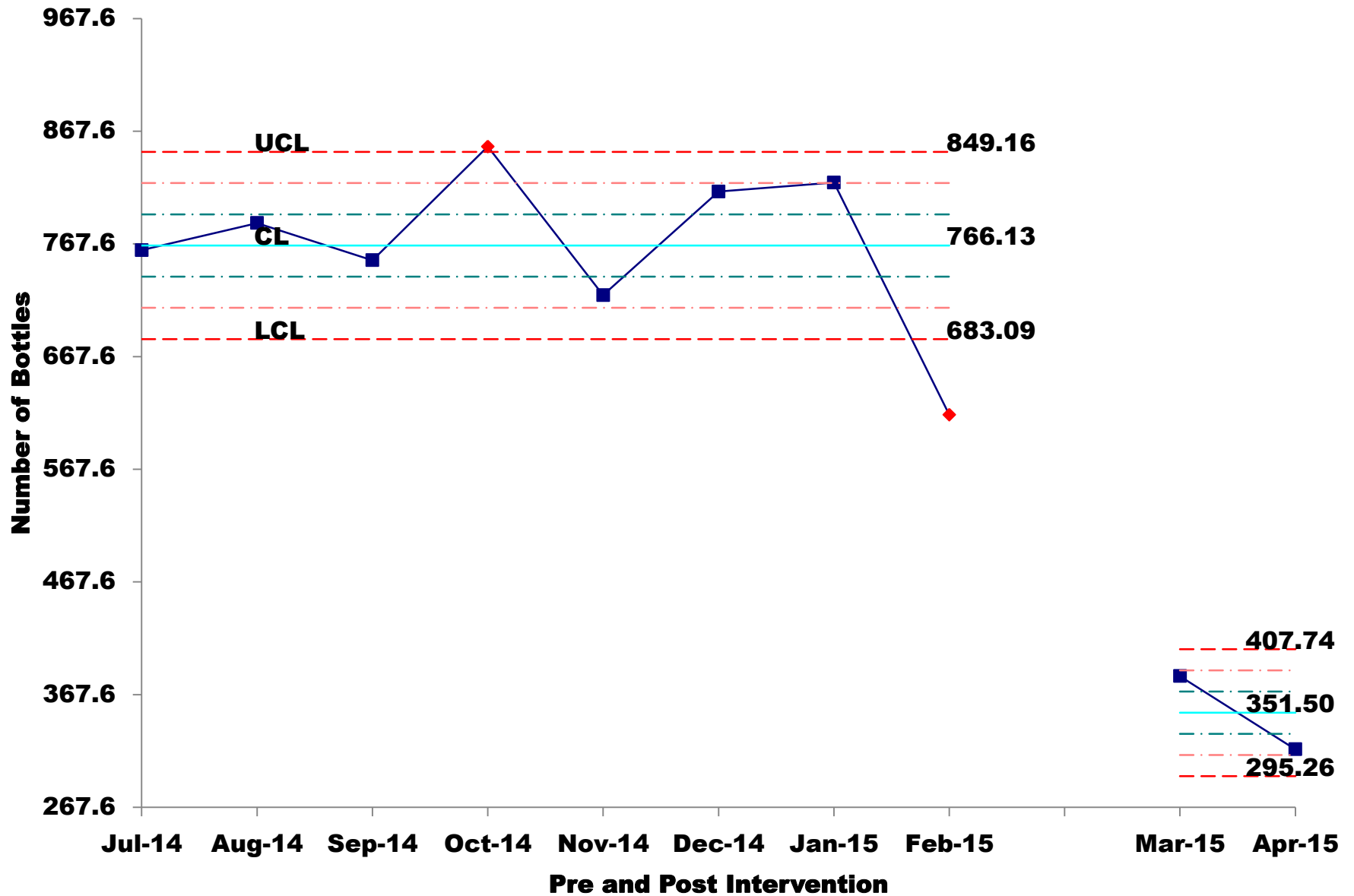
UHS Surgical Inpatients with an Epidural Receiving IV Tylenol



Post-intervention Data:

MONTH (2014 - 2015)	# Ofirmev Bottles Distributed by OR Pharmacy
July	762
August	786
September	753
October	854
November	722
December	814
January	822
February	616
March	384
April	319

Number of Ofirmev Bottles Dispensed by Pharmacy



ROI: Net Return

(cost savings)

- preliminary results (March only) show a decrease from avg 52% to **11.9%** of patients with epidurals receiving IV Ofirmev (goal <10%)
- the overall number of bottles of Ofirmev dispensed from the OR pharmacy decreased from an average of 766 per month (from July 2014 - Feb 2015) to 351 averaged for the month of March and April
- based on the hospital's acquisition cost at \$30.67/bottle, this correlates to an average savings of **\$12,728.05** for OR use per month

ROI: Investment Costs

Outreach & communication: emails	→	\$0
laminated flow-chart posters	→	\$1
Information Systems: EMRs already in place	→	\$0
Equipment: Pyxis medication dispensers		
already in place	→	\$0
Time (minimal loss from clinical duties)	→	??

ROI: Net Return/Investment costs

~12,700.0/1.0

ACT: Sustaining the Results

1. Making the proposed decision-making flow chart for acetaminophen administration readily available for review
 - posted in both resident and CRNA lounges
2. Intervention #2 → PYXIS (electronic medication dispenser) prompts
 - questions that providers must answer before accessing IV Ofirmev
3. Continuing education of incoming residents and newly-hired CRNAs

Conclusion/Knowledge gained

- Considering the project a success as we approach the goal of <10%
- May be difficult to actually reach <10%...Ofirmev still given to patients with epidurals when there is concern that the epidural may not be effective/properly placed
- Anesthesia staff very responsive and receptive to project goals when made more aware of evidence-based practices
- Providing continued updates on progress is an important part of maintaining the success of this project and preventing reversion back to reflexive administration

What's Next?

For consideration (possible research project?):

- Have post-op pain scores been affected?
- Have post-op nausea/vomiting rates increased/decreased?
- Any associated changes in length of PACU stay?

...if this change in IV Tylenol administration correlates with increased PACU time due to increased pain or N/V then the ROI calculation would be negatively affected due to a decreased return and increased costs...a very plausible reason to reassess the continuation of the project

Team Picture(s)



Ashlie Stowers, MD
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Stephen Rupp, RPh
Clinical Pharmacist
UH OR Pharmacy

References

1. American Society of Anesthesiologists Task Force on Acute Pain Management. Practice guidelines for acute pain management in the perioperative setting: an updated report by the American Society of Anesthesiologists Task Force on Acute Pain Management. *Anesthesiology*. 2012; 116(2): 248-73.
2. Yeh YC, Reddy P. Clinical and economic evidence for intravenous acetaminophen. *Pharmacotherapy*. 2012; 32: 559-579.
3. Acetaminophen Injection (Ofirmev®) Package Insert. Cadence Pharmaceuticals Inc., 2013.
4. Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures. *Anesthesiology* 2011; 114:495–511.
5. Manchikanti, L. Assessment of effect of various modes of premedication on acid aspiration risk factors in outpatient surgery. *Anesthesia & Analgesia*. Jan 1987. 66 (1): 81-4.
6. Søreide, E., et al. Effects of giving water 20-450ml with oral diazepam premedication 1-2 hours before operation. *Br Journal of Anaesthesiology*. 1993. 71 (4): 503-506.
7. Søreide, E., et al. "Pre-operative fasting guidelines: an update." *Acta Anaesthesiologica Scandinavica* 49.8 (2005): 1041-1047.

Thank you!

