Clinical Safety & Effectiveness
Cohort #16

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

CENTER FOR PATIENT SAFETY & HEALTH POLICY

UT Health Science Center™
SAN ANTONIO
The Team

• Division
  – Ashlie Stowers, M.D.  CS&E Participant
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    Anesthesiology Resident, CA-2/PGY-3
  – Jeanette Jackson, CRNA  Team Member
    Certified Registered Nurse Anesthetist
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    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
- Data Analysis: Did we reach our aim statement goal?  In progress
- 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 control\(^1\)
  – 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 hours\(^4\)
  – Further evidence suggests, that various modes of premedication, including oral, does not increase gastric volumes or acidity\(^5\)
  – 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:

Patient presents to OPS/Holding for surgery

Pre-operative patient evaluation

History of hepatic failure/allergy?

- **YES**
  - Patient should NOT receive IV Tylenol

- **NO**
  - Should patient receive IV Tylenol?

Discretion of the anesthesia provider

???????
**Decision making process is not well defined!**
**Decision making process is not well defined! ...stay tuned**
Process Analysis:

Providers

- Lack of education
  - On cost
  - On pharmacokinetics
  - On evidence to the contrary

- Resistance to change

OR Environment

- Pressured by PACU nurses

- Unrestricted access to anesthesia providers

Process (of pain control)

- Emphasis on multi-modal approach to pain control

System

- Easily obtainable via PYXIS
- Ability to charge for 1 bottle but take out multiple doses

Intra-operative Over-utilization of IV Tylenol

Limited use of alternate routes (rectal, po) when appropriate

Given to pedi pts < 5yo → partial dose → waste!

"Tradition" (ie, lack of conscious decision making)
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:

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

1. Patient presents to OR/holding for surgery
   - Pre-operative patient evaluation
     - History of hepatic failure/allergy?
       - YES
         - Patient should not receive acetaminophen
       - NO
         - Pedi <5 yo?
           - YES
             - Consider rectal acetaminophen if not contraindicated
           - NO
             - Consider giving IV acetaminophen
       - NO
         - Pedi <5 yo?
           - YES
             - Consider giving IV acetaminophen
           - NO
             - Consider pre-operative oral acetaminophen

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

Suspect epidural/block working intraop?
- YES
  - Consider giving IV acetaminophen
- NO
  - Consider giving IV acetaminophen
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:

<table>
<thead>
<tr>
<th>MONTH</th>
<th># Pre-op Epidurals Placed</th>
<th># Pts with Epidurals who received Intra-op IV Ofirmev</th>
<th>%</th>
</tr>
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<tr>
<td>July</td>
<td>32</td>
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<td>27</td>
<td>10</td>
<td>37.0</td>
</tr>
<tr>
<td>February</td>
<td>34</td>
<td>15</td>
<td>44.1</td>
</tr>
<tr>
<td>March</td>
<td>23</td>
<td>3</td>
<td>13.0</td>
</tr>
<tr>
<td>April</td>
<td>19</td>
<td>2</td>
<td>10.5</td>
</tr>
</tbody>
</table>
UH Surgical Patients with Epidurals Receiving IV Ofirmev

Intervention #1

Interventions #2 & #3

Month


# pre-operative epidurals placed

# patients with epidurals that received intra-operative Ofirmev

%
UHS Surgical Inpatients with an Epidural Receiving IV Tylenol

- Pre and Post Intervention
- CL: 0.520
- UCL: 0.778
- 0.263
- 0.342
- 0.119
# Post-intervention Data:

<table>
<thead>
<tr>
<th>MONTH (2014 - 2015)</th>
<th># Ofirmev Bottles Distributed by OR Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>July</td>
<td>762</td>
</tr>
<tr>
<td>August</td>
<td>786</td>
</tr>
<tr>
<td>September</td>
<td>753</td>
</tr>
<tr>
<td>October</td>
<td>854</td>
</tr>
<tr>
<td>November</td>
<td>722</td>
</tr>
<tr>
<td>December</td>
<td>814</td>
</tr>
<tr>
<td>January</td>
<td>822</td>
</tr>
<tr>
<td>February</td>
<td>616</td>
</tr>
<tr>
<td>March</td>
<td>384</td>
</tr>
<tr>
<td>April</td>
<td>319</td>
</tr>
</tbody>
</table>
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 1014 - 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)

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References


Thank you!