Hut, Hut, Hike! Breaking Even During Price Hikes in the Intensive Care Unit

William R. Vincent III, PharmD, BCCCP
Larren U. Suh, PharmD, MS

Disclosure Statement

- The presenters have no conflicts of interest to disclose
Objectives

- Describe the current prescription medication price hike epidemic
- Discuss use of improvement science to break even during the intravenous acetaminophen and sodium nitroprusside price hikes
- Identify lessons learned and proactive approaches to overcome future drug pricing challenges

Game Plan

- Briefly describe what we are seeing
  - Why?
  - Literature reported strategies

- Case examples using improvement science

- Lessons learned and developed tools
Drug Cost Drivers

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Clinics</th>
<th></th>
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<th></th>
<th>Nonfederal Hospitals</th>
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<td>New Products</td>
<td>Price</td>
<td>Volume and Mix</td>
<td>Percent Growth</td>
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# Selected Percent Increases

<table>
<thead>
<tr>
<th>Drug</th>
<th>Percent Increase</th>
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<tbody>
<tr>
<td>Acetaminophen</td>
<td>136%</td>
</tr>
<tr>
<td>Nitropussite</td>
<td>480%</td>
</tr>
<tr>
<td>Ioprofenol</td>
<td>480%</td>
</tr>
<tr>
<td>Nicodimine</td>
<td>316%</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>316%</td>
</tr>
<tr>
<td>Glycopyrrolate</td>
<td>212%</td>
</tr>
<tr>
<td>Pegaspargate</td>
<td>129%</td>
</tr>
<tr>
<td>Vasopressin</td>
<td>81%</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>293%</td>
</tr>
<tr>
<td>Glucagon</td>
<td>52%</td>
</tr>
<tr>
<td>Phynotadone</td>
<td>355%</td>
</tr>
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</table>

Why the Concern?

- Unprecedented healthcare spend
  - Drug spend continues to significantly outpace inflation

- Limited resources, high focus cost center

- Disproportionally increased spend
  - Specialty Drugs
  - Branded small molecule drugs
  - Drugs with recent significant percent increases

FDA and Unapproved Drugs

Federal Food, Drug, and Cosmetic Act (1938)

Kefauver-Harris Amendment (1962)

Unapproved Drugs Initiative (UDI) of 2006

Drug Efficacy Safety Initiative (DESI)


Unapproved Drug Initiative Intent

- Modernize safety/efficacy, Good Manufacturing Practices (GMP)
- ~5000 drugs affected
- Once approved, market exclusivity granted
Unapproved Drug Initiative Intent

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- Once approved, market exclusivity granted

Unapproved Drugs Initiative Effect

- FDA does not consider cost when approving or granting exclusivity
  - Up to seven years exclusivity under the Orphan Drug Act
  - Prices rose exponentially
  - Drug Shortages
UDI Ex: Colchicine

- Ancient drug
- No prior review under amendments
- Labeling vague, little oversight
- Narrow therapeutic index, high patient variability
- Reported: 117 deaths

UDI Ex: Colchicine

- Granted 3 years exclusivity for Gout
- Granted 7 years exclusivity for Familial Mediterranean Fever

- Price per tab: $0.09 → $4.85
- Medicare/Medicaid Cost: $1M → $50M
Generic Manufacturers

- Under Hatch-Waxman Act:
  - Generic manufacturers faced reduced regulatory constraint
  - Medications reduced cost in the overall market

- By 2009 the market was saturated
  - Competitive environment
  - Difficult to make a dollar
Re-branded Medications

Company decides to pursue approval

Submit to FDA

Recoup investment cost through price increases

Manufacturer Consolidation and Rights

- Nitroprusside and isoproterenol
  - Originally Hospira products
  - Sold to Marathon (price increase #1)
  - Sold to Valeant (price increase #2)
Drug Shortages

Supply and Demand

- Supply
  - Fragmented
  - Inconsistent and unpredictable

- Generally stays consistent barring
  - Guideline/practice changes
  - Seasonality
Association Between Shortages and Price Hikes

<table>
<thead>
<tr>
<th>Medication</th>
<th>Drug Shortage Period</th>
<th>% AWP Increase During Shortage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ephedrine</td>
<td>Mar 2014-Oct 2015</td>
<td>690</td>
</tr>
<tr>
<td>Furosemide inj.</td>
<td>May 2010-May 2016</td>
<td>56-128</td>
</tr>
<tr>
<td>Hydralazine inj.</td>
<td>Sep 2014-May 2016</td>
<td>921</td>
</tr>
<tr>
<td>Ketorolac</td>
<td>Nov 2009-May 2016</td>
<td>251</td>
</tr>
<tr>
<td>Magnesium sulfate</td>
<td>Mar 2011-Nov 2015</td>
<td>49-120</td>
</tr>
<tr>
<td>Sodium phosphate</td>
<td>Dec 2012-Aug 2015</td>
<td>2220</td>
</tr>
</tbody>
</table>

Pharmacotherapy 2017;37(1):36-42

Strategies

- Manage dispensing through systems
- Centralize stock and look at operational efficiencies
- Med Use Evaluations: Evaluate the literature against practice
- Evaluate contract opportunities
- Compounding oral solutions
Assessment Question #1

- Which of the following best represents the root cause for increased drug cost during the last three budget cycles?
  A. Truly generic oral tablets
  B. Re-branded injectable drugs
  C. Truly generic oral capsules
  D. Truly injectable drugs

Half-Time Break

- Changes in FDA regulations and initiatives have increased cost to manufacturers
- In a capitalistic economy, profit drives private companies
- The results have created increased costs in drug with little to no added benefit nor knowledge to the medical community
Add Improvement Science to Your Price Hike Playbook

- Right tools for the job
  - Align projects with department and institutional goals
- New ASHP residency standards embrace QI
  - PGY1 – Goal R2.2: Demonstrate ability to evaluate and investigate practice, review data, and assimilate scientific evidence to improve patient care and/or the medication-use system.
  - PGY2 CC – Goal R2.2: Demonstrate ability to conduct a quality improvement or research project.
- Develop new knowledge and skills
  - Lean, six sigma for operations
  - Institute for Healthcare Improvement for clinical initiatives


IHI Model for Improvement

http://www.ihi.org/education/IHIOpenSchool/Courses/Pages/PracticumForms.aspx
Add Improvement Science to Your Price Hike Playbook

- Set an aim
  - How good? For whom? By when?
- Build a team
- Describe the problem
  - Focus on local problem
  - Develop cause-and-effect and driver diagram
- Identify and implement interventions through small tests of change on your ICU patients
  - Learn from and share your experience
- Identify outcome, process, and balancing metrics
  - (Generally) no IRB \(\rightarrow\) collect your own data, plot over time

Local Context for Surgery ICU Price Hikes

- About BMC
  - Largest safety net hospital, busiest trauma, ED services in New England
  - Services include trauma and acute care, bariatric, colorectal, otolaryngology, cardiac, thoracic, vascular, orthopedic, neuro, urology, and plastics
- Medicine, ICU-focused pharmacy services
  - Trauma ICU (2004-present), surgical ICU (2012-present) including kidney transplant
  - Acute care, OR/PACU pharmacists (2017)
- Challenges with surgery
  - No clear training path for surgery pharmacists
  - Multiple teams with low census, resident/APP only rounds
  - Strong personalities, disagreements escalated to director
  - Perceive pharmacy as barrier to care, cost first
Should You Add IV Acetaminophen to Formulary?

- Shift away from opioids as first-line towards adjuncts
  - Fast-track, enhanced recovery protocols emphasize reductions in opioids
  - 5.9-6.5% of patients newly prescribed opioids chronically after surgery
  - Advance directives can exclude opioids
- Limited IV options
  - Pain reduction by 50% over 4 hours
    - IV x1 = 36%, placebo = 16% (NNT 5)
  - Inconsistent impact on opioid use and opioid-related side effects, outcomes
    - Patients and providers tell a different story

**IV Acetaminophen Timeline at BMC**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun 2012</td>
<td>2nd request for addition to formulary → accepted with stringent prescribing restrictions: 1) NPO/NPR and 2) limited to PONV, neurologic injuries, or ileus. Anesthesia approval needed for &gt;24h duration.</td>
</tr>
<tr>
<td>Nov 2013</td>
<td>MUE showed 90% adherence to criteria, projected $14K annual expenditure</td>
</tr>
</tbody>
</table>
| Feb-Mar 2014 | Mallinckrodt Pharmaceuticals acquires IV acetaminophen
  Revised prescribing restrictions to be less stringent: change to 48h initial default duration, added to IV-to-PO pharmacist conversion policy, pharmacist approval for therapy >48h |
| May 2014   | Transition to new EHR, added to all post-op order sets                 |
| Sep 2014   | Approximately $55K spend in August 2014 and projected $540K spend in fiscal year 2015 → QI team  |
Driver Diagrams Can Help Develop a Game Plan

Aim

Primary Drivers

Secondary Drivers

Change Concepts

Increased cost

Acquisition by Mallinckrodt

Market factors

National shift away from IV acetaminophen across institutions

Congress investigations into price hikes

Investors/public response to price hikes

Limited use of other routes, alternatives

Limited use of other routes, alternatives

Early diet, early PODPR analgesia, promote NSAIDs, gabapentin via ERAS initiative

Lack of standard analgesia protocol around surgery

Anecdotally experience more influential than evidence

PGY1 resident outcomes-based research project

Raise awareness about limited evidence, increased cost

Challenges with formulary restrictions

Limited CPOE support

No surgery patient restrictions

Streamline prescribing to a new order set with clear restrictions

Antagonistic surgery-pharmacy relationship

Require attending surgeon approval beyond one postoperative dose

Nonadherence to prescribing restrictions

Collaborate with surgery to improve restrictions

Short-cycle QI, clinical pharmacy focus to improve pharmacel adherence


IV Acetaminophen Playbook

Interventions

- PGY1 resident outcome-based, IRB-approved research project (Jul 2014)
  - Less opioids but no impact on outcomes
- Short-cycle pharmacy initiative to improve adherence to prescribing restrictions (Dec 2014-Feb 2015)
- Revised prescribing restrictions via order set only, ERAS protocol implementation (Fall 2015)
  - 1 dose only, service limits, attending approval for >1 dose.

Tools

- Asana™ for project and task management
  - Track timeline, feedback
- Access to real-time use and dispensing data
  - IV room doses prepared
  - Automated dispensing cabinet doses dispensed
  - Doses administered
  - Interventions
  - Cost from wholesaler
- QI macro for MS Excel™
  - Create run and statistical process control charts
Assistant Coach

Team MVPs

Information Systems Tactics
How did we do?

**Rule 1: Shift**

**Rule 2: Trend**

**Rule 3: Number of Runs**

**Rule 4: Astronomical Data Point**

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*Bmj Qual Saf* 2011;20:46-51

Massachusetts Society of Health-System Pharmacists
2017 Annual Meeting

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How did we do?

**Type of Data**

- **Count**
  - Discrete events: count of items, occurrences, or events.
  - Continuous data: measurements.

- **Count or Classification**
  - Discrete events: count of items, occurrences, or events.
  - Continuous data: measurements.

- **Continuous**
  - Continuous data: measurements.

**Subgroup Size**

- **Subgroup Size > 1**
  - Continuous data: measurements.
  - Discrete events: count of items, occurrences, or events.

**Other Chart Types**

- **Run Chart**
  - Continuous data: measurements.

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QI-Charts, Scoville Associates. 2009

*Clin Perinatol* 2010;37(1):101-22

Massachusetts Society of Health-System Pharmacists
2017 Annual Meeting
**Outcome Metric – Rate of IV Acetaminophen Use (U Chart)**

Rate of IV Acetaminophen Use in Surgery Inpatients
June 2014 to September 2016

- Jan 2014 – Sep 2014: 46th default duration
- Postop use common for most surgery services
- via order sets
- Limited adherence to restrictions (NPO only)
- Jan 2015 – Oct 2015: 23% reduction in use
- Change to 24th default duration
- Pharmacy focus to improve adherence to restrictions
- Hospital-wide communication about restrictions due to cost
- PGY-1 outcomes evaluation
- Nov 2015 – Sep 2016: 43% reduction in use
- Restricted to trauma, general, and CT surgery
- Only 1 post-op dose, attending approval for >1 dose
- CPGE order and order set optimization

**Process/Balancing Metric – Rate of Non-Opioid Adjunct Use (U Chart)**


- Jun 2014 – Nov 2015: no change in adjunct use
- Increased IV acetaminophen use promoted use of all adjuncts
- Dec 2015 – Sep 2016: 17% increased use due to ERAS
  - Pre-op acetaminophen, gabapentin in order sets
  - Intra-op acetaminophen, ketorolac in protocol
  - Decreased IV acetaminophen use
Sustain Success (for 3 More Years)

- Revisit eligible services/patients
  - Omits neurocritical care, septic shock
- Revisit approval process
  - Stop calling attending surgeons for approval for > 1 dose
  - Strict NPR
  - OR/PACU only

End of the Third Quarter

- Reduce IV acetaminophen annual spend to < $100,000 in FY16
  - Short-cycle, incentivized pharmacy focus on prescribing restrictions
  - PGY1 outcomes evaluation
  - Enhanced recovery after surgery
  - Service-based, duration restrictions
- Reported data over time
  - Doses per 100 patient days, cost, interventions, all adjunct doses per 100 patient days
- Lessons learned
  - Better relationships with surgery and possibly better care
  - IHI model for improvement = tools to tackle future initiatives
  - Need to continue monitoring monthly, revisit restrictions and approval process
Assessment Question #2

- Which of the following statements about improvement science is true?
  A. All PGY1 residents must complete research projects according to the 2015 competency areas and goals
  B. All institutions require Investigational Review Board review of quality improvement projects
  C. Pre vs. post/before vs. after analysis is one way to demonstrate improvement
  D. Driver and cause-and-effect diagrams can be used to describe your change theory

Sodium Nitroprusside Re-Branding

- Spring 2015
  - Purchaser: “Hey Will, we need to start talking about Nipride. It’s like $800 per dose”
  - Me: “…” (inaudible muttering)
The ICU Blood Pressure Players

<table>
<thead>
<tr>
<th>Category</th>
<th>Nitroprusside</th>
<th>Nicardipine</th>
<th>Clevidipine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemodynamic Effects</td>
<td>Reduces afterload and preload → may increase ICP</td>
<td>Decreases afterload, minimal effect on preload → improved CPP, CO</td>
<td>Decreases afterload, minimal effect on preload → improved CPP, CO</td>
</tr>
<tr>
<td>Onset for hypertension</td>
<td>30-60 secs, peak 2 mins</td>
<td>60 secs, peak 2 mins (w/bolus), t½α = 3-15 min</td>
<td>2-4 min, peak 3 min</td>
</tr>
<tr>
<td>Distribution &amp; Elimination</td>
<td>Vd = ECF, MetHgb buffer 500 mcg/kg SNP, CN radicals converted to TCN</td>
<td>Vd=7-8 L/kg, 95% highly protein bound. Hepatic metabolism → feces 40%, urine 60%</td>
<td>Poor water solubility → 20% soy-based lipid emulsion 99% protein bound, Vd 0.17 L/kg. Rapid hydrolysis by esterases</td>
</tr>
<tr>
<td>Half-life</td>
<td>2-4 minutes (parent); 3 days (thiocyanate)</td>
<td>t½β = 45 min, t½γ = 14.4 hrs</td>
<td>t½β = 1 min (predominant), t½γ = 15 min</td>
</tr>
<tr>
<td>Titration</td>
<td>Every 5 minutes</td>
<td>Every 5-15 min; decrease dose by 2.5-5 mg/hr once target BP achieved</td>
<td>Double dose every 90 secs; as BP approaches goal, increase dose by less than double every 5-10 mins</td>
</tr>
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Clevidipine as an Alternative to Nitroprusside

- Superiority doubts
  - Limited belief clevidipine or nitroprusside (SNP) > nicardipine
- Safety concerns
  - Potential for propofol look-alike errors?
  - Propofol-clevidipine co-administration?
- Easy to say yes, hard to say no
SNP vs. NIC in Cardiac Surgery

<table>
<thead>
<tr>
<th>Reference</th>
<th>Patients &amp; Study Design</th>
<th>Intervention &amp; Comparator</th>
<th>Outcomes</th>
<th>Conclusions/Comment</th>
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<tr>
<td>J Cardiothorac Vasc Anesth 1991;5(4):3 57-61</td>
<td>Open, randomized, multicenter trial N=74 CABG pts with post-op HTN</td>
<td>NIC 2.5-12.5 mg bolus followed by 2-4 mg/hr infusion, vs. SNP 0.5-6.0 mcg/kg/min</td>
<td>NIC&gt;SNP: goal MAP &lt; 90 mmHg achieved more quickly. ▼ SVR, 2x fewer dose adjustments/24hr SNP&gt;NIC: ▲ HR, 400 mL more blood transfused</td>
<td>Bolus helped NIC achieve BP target faster NIC is an alternative to SNP</td>
</tr>
<tr>
<td>J Cardiothorac Anesth 1989;3(6):700-6</td>
<td>Prospective cohort N=45 CABG pts</td>
<td>NIC 3 mcg/kg/min (           12.5 mg/hr) vs. SNP 1 mcg/kg/min started before surgery</td>
<td>Comparable MAP control ▼ PAP with SNP prior to sternotomy Myocardial ischemia: NIC (9%) vs. SNP (24%) (from induction to start of CPB)</td>
<td>High initial NIC infusion NIC may be a suitable alternative after coronary artery surgery</td>
</tr>
<tr>
<td>Am J Cardiol 1989;64(15):22-7H</td>
<td>Prospective RCT N=120 CABG pts</td>
<td>1:1:1 = NIC 3 mcg/kg/min vs. SNP 1 mcg/kg/min vs. no vasodilator</td>
<td>Comparable MAP control Myocardial ischemia: NIC (10%) vs. SNP (25%) vs. 28% (control)</td>
<td>High NIC infusion rate</td>
</tr>
</tbody>
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Nicardipine Bolus Pharmacodynamics

SBP Reductions with Bolus

Am Heart J 1990;119:438-42
BMC’s Response to SNP Price Hike

- Consider alternatives – revisit clevidipine
- Pharmacy operations modifications
  - Add NIC to ADCs, on override to ICUs
  - Decrease SNP inventory
  - ADC alerts for preparation instructions for nursing, do not give NIC bolus IVP
- Systems improvements
  - Do not automatically dispense SNP from post-op order sets
  - Add NIC bolus from bag, update administration instructions, decrease lower rate limit to 2.5 mg/hr
  - Update smartpumps for ORs and ICUs
- Education about the SNP million dollar sweepstakes

Outcome Metric – SNP Doses Dispensed (C Chart)
Lessons Learned – Two Minute Warning

- Unit experience has been informative
  - Uncomfortable experiences waiting for nicardipine to come up from pharmacy, titrating at the bedside
  - We persisted!
  - “A new scientific truth does not triumph by convincing its opponents and making them see the light, but rather because its opponents eventually die.” – Physicist Max Planck (Originals, Adam Grant)
- Hourly nurse-filed BPs in the flowsheet vs. monitor-EHR interface BPs → missed opportunity for real-time efficacy data
- Significant pressures applied to manufacturer → cost decreased, new “generic” manufacturer in market

Lessons Learned- Improvement
Science as a Tool

1. Identify an issue
2. Collect baseline data
3. Driver diagram
4. Define metrics
5. Track metrics as data over time
## Who Will Be Ready for the Next Price Hike?

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<th>Clinical Pharmacists</th>
<th>Pharmacy Managers</th>
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<tbody>
<tr>
<td>- Relationship with prescribers</td>
<td>- Administrative and political connections</td>
</tr>
<tr>
<td>- Patient, product, process knowledge, and empathy</td>
<td>- Negotiating skills/experience</td>
</tr>
<tr>
<td>- Build leadership experience</td>
<td>- Purchasing data and trends and experience</td>
</tr>
<tr>
<td>- Track real-time data (frontline feeling, feedback, observations &amp; patient encounters/med use)</td>
<td>- Ability to negotiate with distributors</td>
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<td>- Demonstrate your value to your team</td>
<td>- Important scope and perspective (forest, not just trees)</td>
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## How We Broke Even

- Budget
- Strategies
- Outcomes
- Relationships
Assessment Question #3

Which of the following statements best describe why clinical pharmacists should lead initiatives to combat price hikes?

A. Knowledge of product, process, and patient
B. Ability to negotiate with distributors
C. Administrative and political connections
D. Expertise in analyzing purchasing data

Huddle Up

Price hikes and shortages in the ICU are common, relevant, and largely driven by the unapproved drugs initiative

- Hospital budgets cannot keep up with this inflationary rate

Improvement science can help demonstrate and sustain success with IV acetaminophen, sodium nitroprusside, and other cost-focused initiatives

Critical care pharmacists should lead team efforts to mitigate patient and financial harm due to price hikes and shortages
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