Value Based Care Approach to GE Reflux in Infants

IAN LEIBOWITZ, MD & BETSY WATTS, MD
6.20.17
OBJECTIVES

● Review newer data on GE reflux in infants
● Explain the evolution of shared baseline of care
● Review our efforts at extending the primary care – specialist relationship.
# Relationship

<table>
<thead>
<tr>
<th>Elizabeth (Betsy) Watts, MD</th>
<th>Ian Leibowitz, MD</th>
</tr>
</thead>
<tbody>
<tr>
<td>● General Pediatrician in Northern VA, 1988</td>
<td>● Pediatric Gastroenterologist, Northern VA, 1989</td>
</tr>
<tr>
<td>● Capital Area Pediatrics, Inc. merger 1998</td>
<td>● Chief, Pediatric Gastroenterology, Pediatric Specialists of Virginia</td>
</tr>
<tr>
<td>● CEO / Medical Director</td>
<td>● CMO, Pediatric Specialists of Virginia</td>
</tr>
<tr>
<td>● CNHN &amp; Inova Pediatric Board Role</td>
<td></td>
</tr>
</tbody>
</table>
Triple Aim

- Improve individual experience
- Improve population health
- The best care
  - For the whole population
  - At the lowest cost
- Control inflation of per capita costs
- Provider Satisfaction

D. Berwick, Institute of Healthcare Improvement, 2007
Two key efficiency (cost) drivers

- **CareFirst BCBS**
  - They provide us with the “cost” of the specialists based on episodes of care. Their desire is to drive doctors to use specialists that are lower cost.

- **CareFirst, Anthem, Medicaid, ALL payers etc...**
  - Are providing a great deal of pressure for avoidable ER visits
MICHAEL PORTER DEFINED VALUE IN HEALTHCARE AS:
HEALTH OUTCOMES ACHIEVED/DOLLAR SPENT OR OUTCOME/COST
VALUE IS NOT A CODE WORD FOR COST REDUCTION
OUTCOMES, THE NUMERATOR IS CONDITION SPECIFIC COST, THE DENOMINATOR, REFERS TO THE TOTAL COST OF THE CONDITION, NOT AN EVENT OF CARE
Quality Efforts

- Why are we talking about this?
- How do we change current practice systems?
- How do we measure progress?
- Who are our partners?
Change—WHY?

- Only systems of care can effectively change.
- Power is in aligned clinical systems.
- Engaging physician and patient perspectives can create transformation.
- We are the front line.
- In our small way, this is our effort.
Change-How?

- Establish a shared vision
- Define priorities
- Form teams
- Create a joint product
- Review, revisit, revise
Why Infant GERD

- Common Condition with fairly straightforward management guidelines and new data
- Current Variability in care (room for improvement)
- Guideline goal to reduce over treatment clinically
  - Improve parent communication (parent experience)
  - Potential reduced side effects (better care)
  - Potential reduced cost (at lower cost)
- Measurable
Baby GS, born at term, no complications, breast feeding at discharge

Seen at 7 days, below BW but feeding well, extremely fussy and constant spitting

Mother goes dairy free

14 days, no improvement, but weight improved, crying, excessive vomiting and spitting

Started on Ranitidine

21 days, no better, mother now dairy and soy free, started on Lansoprazole
Current Care
Efficacy/Safety of Once-Daily Esomeprazole for Treatment of GERD in Neonatal Patients

**Objective** To evaluate the efficacy and safety of proton pump inhibitors in infants aged <1 year with gastroesophageal reflux disease (GERD).

**Study design** In this randomized, double-blind, placebo-controlled multicenter study, neonates (premature to 1 month corrected age; n = 52) with signs and symptoms of GERD received esomeprazole 0.5 mg/kg or placebo once daily for up to 14 days. Change from baseline in the total number of GERD symptoms (from video monitoring) and GERD-related signs (from cardiorespiratory monitoring) was assessed with simultaneous esophageal pH, impedance, cardiorespiratory, and 8-hour video monitoring.

**Results** There were no significant differences between the esomeprazole and placebo groups in the percentage change from baseline in the total number of GERD-related signs and symptoms (−14.7% vs −14.1%, respectively). Mean change from baseline in total number of reflux episodes was not significantly different between esomeprazole and placebo (−7.43 vs −0.2, respectively); however, the percentage of time pH was <4.0 and the number of acidic reflux episodes >5 minutes in duration was significantly decreased with esomeprazole vs placebo (−10.7 vs 2.2 and −5.5 vs 1.0, respectively; P ≤ .0017). The number of patients with adverse events was similar between treatment groups.

Efficacy/Safety of Once-Daily Esomeprazole for Treatment of GERD in Neonatal Patients

- Signs and symptoms of GERD traditionally attributed to acid reflux in neonates were not significantly altered by esomeprazole treatment.
- Esomeprazole was well tolerated and reduced esophageal acid exposure and the number of acid reflux events in neonates.

Natural History of GER in Children Up to Two Years of Age

- 41% of infants age 3 to 4 months spit up most of their feedings
- < 5% of infants age 13 to 14 months spit up most of their feedings

Infant Reflux: Natural History

Natural history study: 948 healthy infants

- Daily regurgitation occurs in:
  - 50% of 0-3 month old infants
  - 67% of 4-6 month old infants
  - 21% of 6-9 month old infants
  - 5% of 10-12 month old infants

- Excessive crying occurs in 40% of infants
Introduction

• There has been a tremendous rise in use of proton pump inhibitors (PPIs) in children over past 15 years\(^1\)
  – Particularly an issue in infants <12 months of age \(^2\)
• Preponderance of evidence that PPIs do not
  – reduce GER symptoms in infants \(^3,4\) or
  – decrease infant crying and irritability \(^5\)

Very few kids dream of being a gastronaut.
Treatment

- 1999-2004: 7x increase in PPI use in infants
- 50% of infants diagnosed with GER were tried on PPIs by 4 months
- 2011: Systematic review of data
- 5 studies on different PPI’s concluded PPI were not effective in reducing crying or irritability
Studies

- Davidson-2013
- 64 infants-double blind, placebo control trial with omeprazole.
- PH probe data improved but no change in crying or irritability in medication versus placebo
- Over 4 week trial, both groups improved
Hospital study

- 2016-NICU study in midwest
- 122,000 infants in 43 NICU’s
- 19% treated with H2RA’s and 11% with PPI’s
- Almost all on these medication at discharge
Influence of "GERD" Label on Parents' Decision to Medicate Infants

Current Care
### Medication Cost per month

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Quantity</th>
<th>Price Without Insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CVS Pharmacy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20mg</td>
<td>30 capsules</td>
<td>$289.00</td>
</tr>
<tr>
<td>40mg</td>
<td>30 capsules</td>
<td>$286.00</td>
</tr>
<tr>
<td><strong>Kmart</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20mg</td>
<td>30 capsules</td>
<td>$270.00</td>
</tr>
<tr>
<td>40mg</td>
<td>30 capsules</td>
<td>$270.00</td>
</tr>
<tr>
<td><strong>Kroger</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20mg</td>
<td>30 capsules</td>
<td>$293.00</td>
</tr>
<tr>
<td>40mg</td>
<td>30 capsules</td>
<td>$272.00</td>
</tr>
<tr>
<td><strong>Publix</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20mg</td>
<td>30 capsules</td>
<td>$246.34</td>
</tr>
<tr>
<td>40mg</td>
<td>30 capsules</td>
<td>$295.00</td>
</tr>
<tr>
<td><strong>Rite Aid</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20mg</td>
<td>30 capsules</td>
<td>$293.00</td>
</tr>
<tr>
<td>40mg</td>
<td>30 capsules</td>
<td></td>
</tr>
</tbody>
</table>
Costs of Care

- Repeated Primary care visits
- Potential ER visits
- Studies such as UGI
- Specialist visits
- Medication Cost
- Loss of work
Change-How?

- Create referral systems to provide data
- Use teams to create baselines or pathways
- Monitor use of the pathways (difficult)—few standard measures exist in these areas
- Be willing to change
- Be patient
The Process

- Clinical algorithm on the chosen topic to serve as a shared baseline among primary care pediatricians and specialists in our community
- Include evidence-based peer reviewed references for the algorithm
- Feedback from primary care and specialist communities during creation process
- Provide parent education handout templates and provider education materials if appropriate
- Determine objective measures to determine effectiveness
Barriers...to name a few

- There is not alignment in the payment models yet.
  - FFS vs. P4P – we’re stuck in the middle
- Secure communication platforms
  - How do we share what we are working on to all PEDS in community?
Change-WHO?

- Currently: Primary care physicians and specialists
- Future: Payers-changing payment systems will require alignment with outcome efforts
- Future: Parents-aligning parents and patients as value is defined around the patient
- Future: Other components of the health care system
**Gastroesophageal Reflux Management < 1 year of age**

- **Recurrent vomiting and/or regurgitation**
  - History and physical exam
    - **Red Flags?**
      - Yes: Evaluate/treat for other etiologies. Consider consulting Peds GI. Call PSV GI Office for ASAP appt (Backline 703-839-8718) or consider MD-to-MD Access 703-778-1234 (page)
      - No: Evaluate/treat for other etiologies. Consider consulting Peds GI.

- **Red Flags**
  - Bilious vomiting
  - Gastrointestinal bleeding
  - Feeding refusal
  - Poor weight gain
  - Consistently forceful vomiting
  - Onset of vomiting after 6 months of life
  - Documented or suspected genetic/metabolic/neurologic symptoms
  - Chronic respiratory symptoms
  - Dystonic neck posturing (Sandifer syndrome)

- • Parent education and reassurance – NO TESTING
  • Conservative Measures:
    - Smaller volumes, more frequent feeding
    - Maintain baby in upright position (30 to 60 minutes) after feeding
    - Consider thickened feedings (1-3 tsp cereal per oz)

- **Fussy infant?**
  - Yes: Reassurance. Continue to monitor weight gain and symptoms.
  - No: Continue to monitor weight gain and symptoms.

- **Parent Education (Colic)**
  - Consider protein intolerance:
    - Consider 2 week trial of extensively hydrolyzed formula
    - If BF infant, change maternal diet to avoid milk and eggs
  - Consider 2 week trial of H2 blocker**

- **Improvement?**
  - Yes: Continue to monitor weight gain and symptoms. Stop H2 blocker when reflux clinically improves.
  - No: Evaluate for other etiologies. Consider consult Peds GI. Consider elemental amino acid formula.

- **If does not improve by 18 months of age, consult Peds GI.**

**Suggested H2 Blocker Dosing**
- Pepcid (famotidine) 1mg/kg per day divided BID
- Zantac (ranitidine) 5-10 mg/kg per day divided BID