Value Based Care Approach to GE Reflux in Infants

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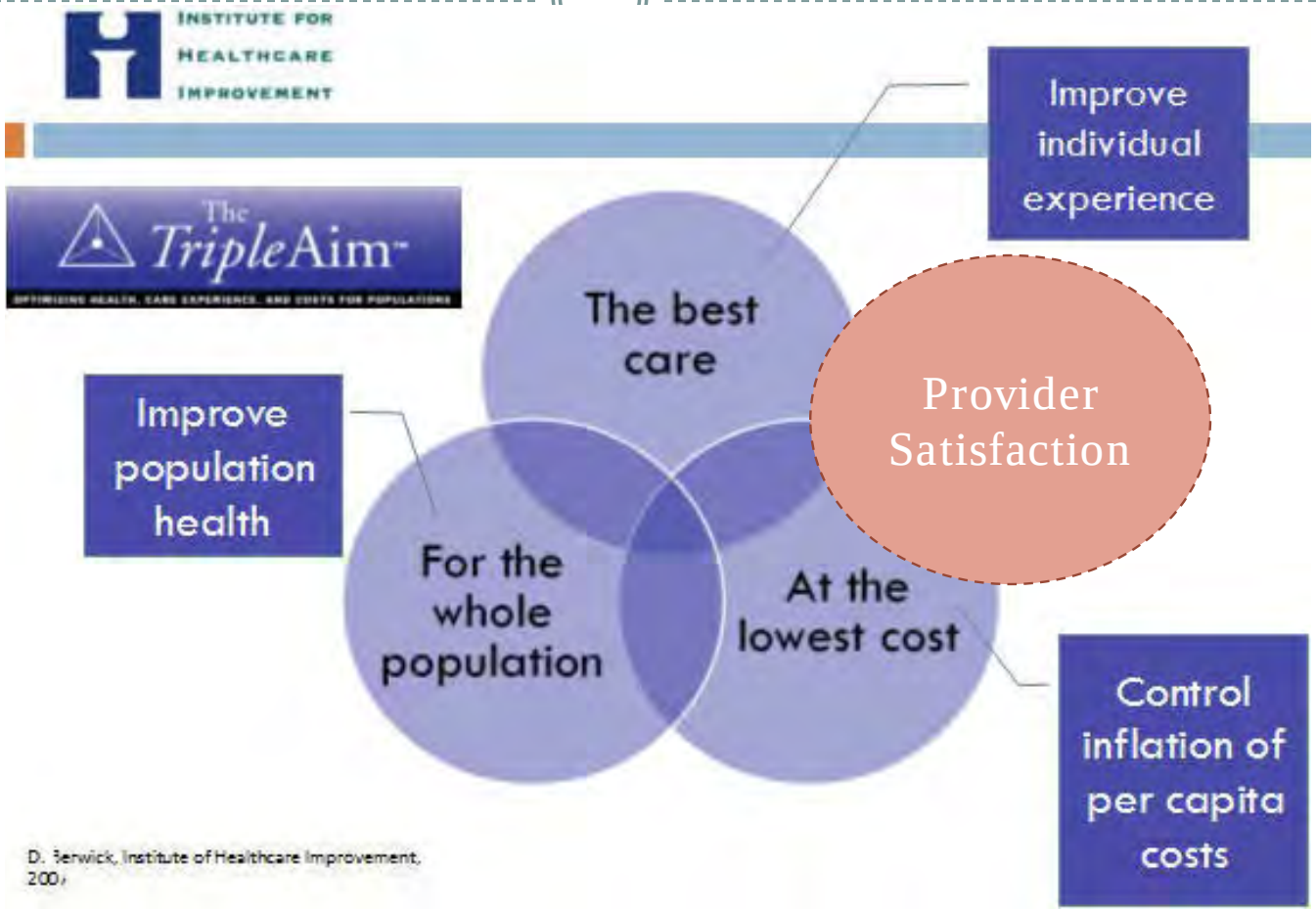
OBJECTIVES

- 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

Elizabeth (Betsy) Watts, MD	Ian Leibowitz, MD
• General Pediatrician in Northern VA, 1988 • Capital Area Pediatrics, Inc. merger 1998 • CEO / Medical Director • CNHN & Inova Pediatric Board Role	• Pediatric Gastroenterologist, Northern VA, 1989 • Chief, Pediatric Gastroenterology, Pediatric Specialists of Virginia • CMO, Pediatric Specialists of Virginia

Triple Aim


INSTITUTE FOR
HEALTHCARE
IMPROVEMENT
The TripleAim
Improve individual experience
The best care
Provider Satisfaction
Improve population health
For the whole population
At the lowest cost
Control inflation of per capita costs
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

Value

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 effective real 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

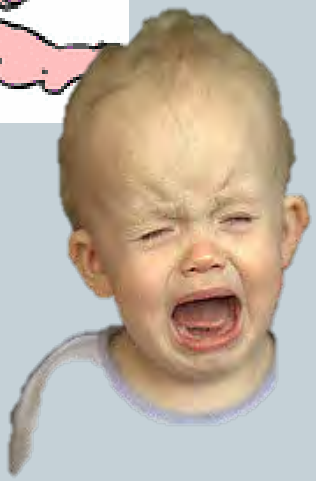
Why Infant GERD

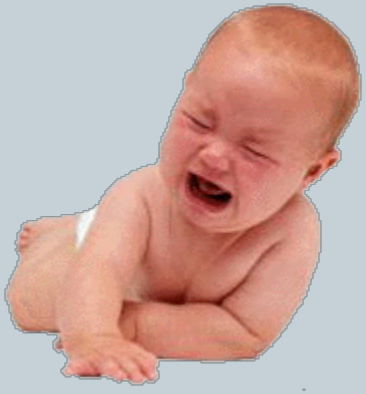
- Common Condition with fairly straightforward management guidelines and new data
- Current Variability in care (room for improvement)
- Guideline goal to reduce over treatment clinically
  - Improve parent communication (parent experience)
  - Potential reduced side effects (better care)
  - Potential reduced cost (at lower cost)
- Measurable

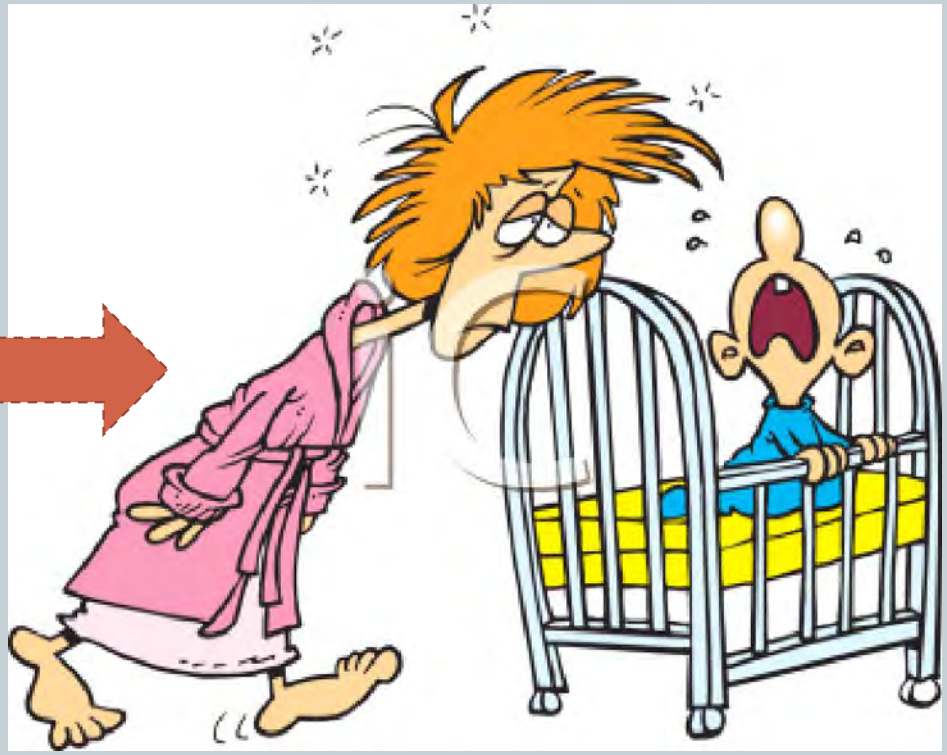
Infant GE Reflux: Current State

- 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; $P \leq .0017$). The number of patients with adverse events was similar between treatment groups.

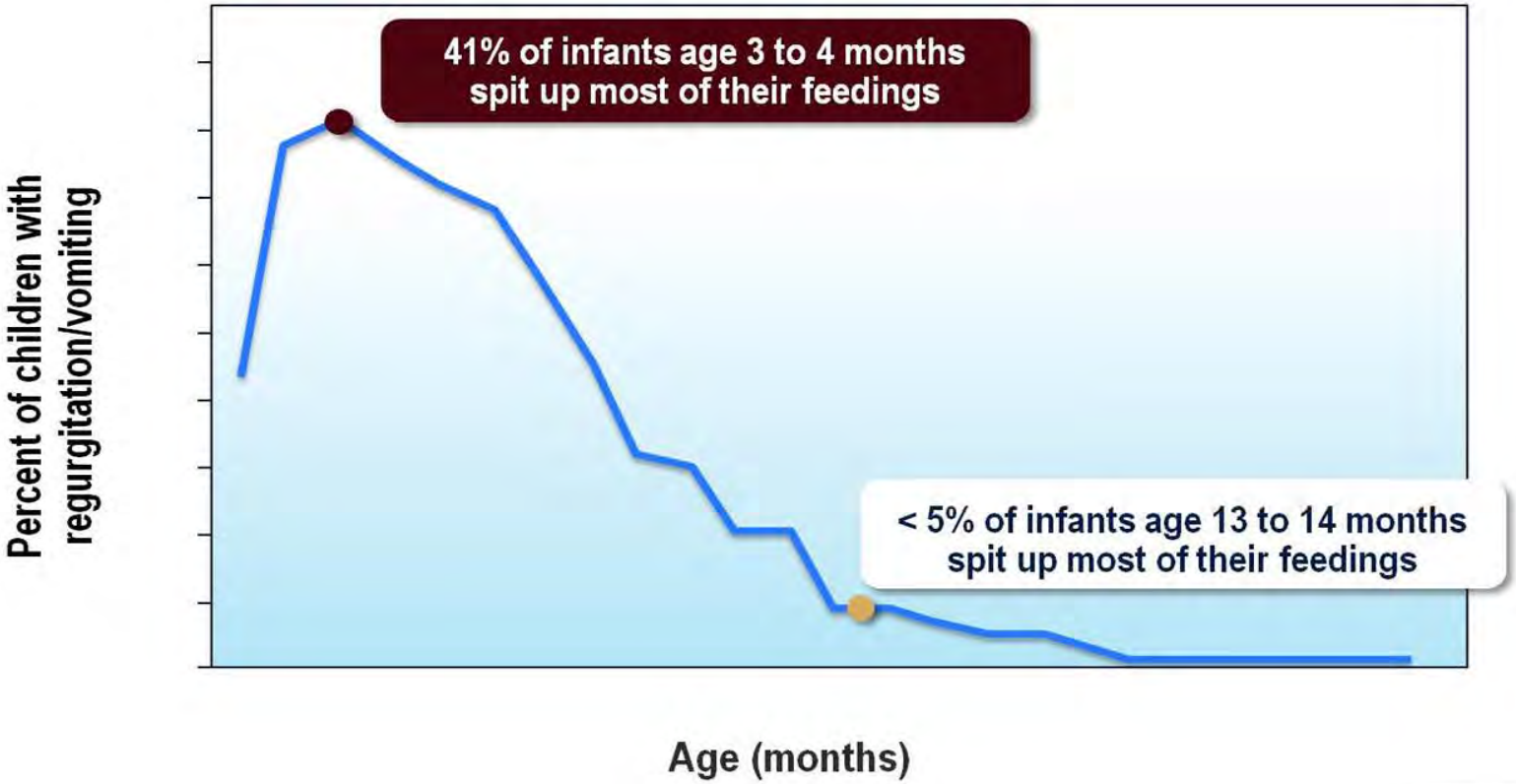
Davidson G et al. *J Pediatr* 2013;163:692-698.

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

Davidson G et al. *J Pediatr* 2013;163:692-698.

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



Martin AJ et al. *Pediatrics* 2002;109(6):1061-1067.

Infant Reflux: Natural History

Natural history study: 948 healthy infants

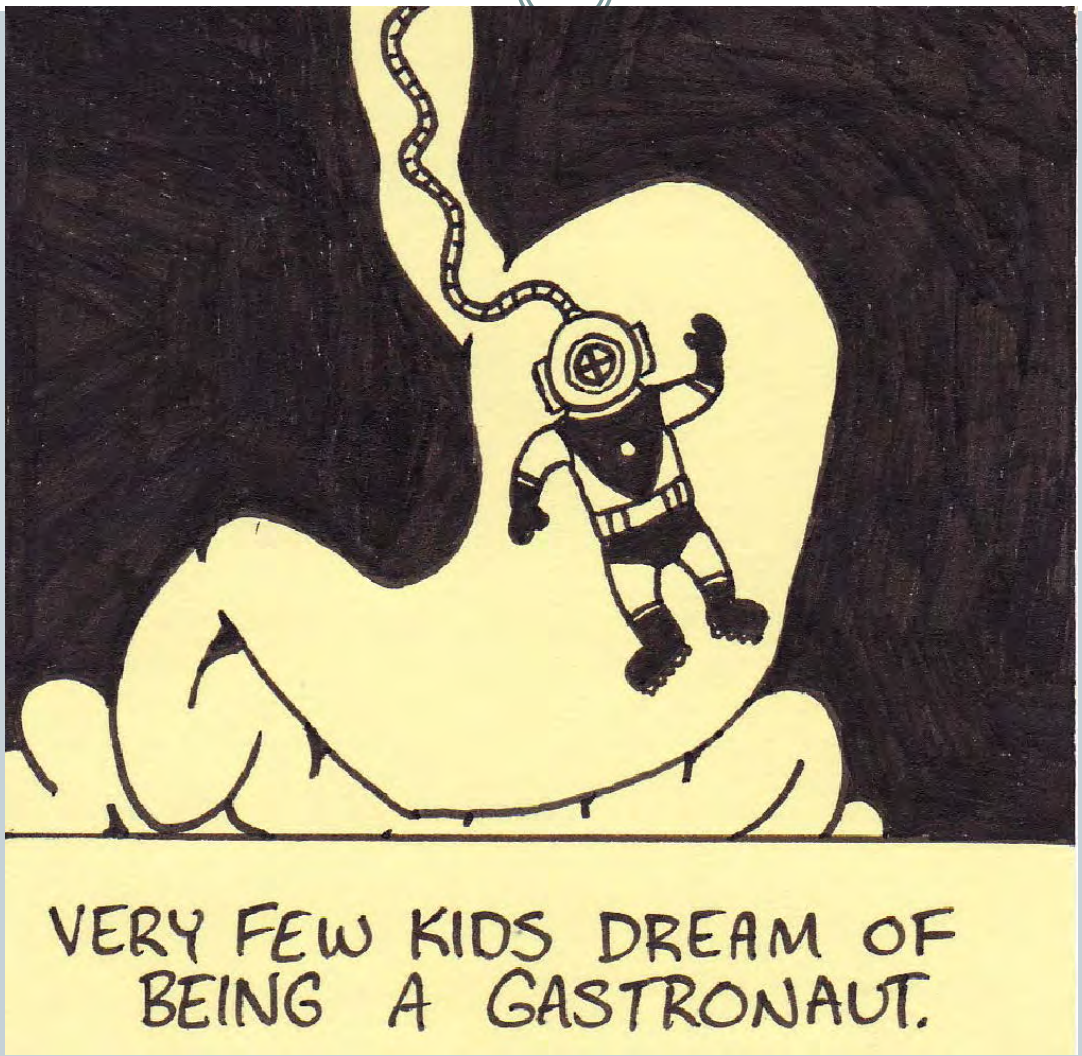
- Daily regurgitation occurs in:
  - 50% of 0-3 month old infants
  - 67% of 4-6 month old infants
  - 21% of 6-9 month old infants
  - 5% of 10-12 month old infants
- Excessive crying occurs in 40% of infants

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]

1. Ruigomez A et al. *Eur J Gastroenterol Hepatol* 2011;23:232-7.
2. Orenstein SR. *Curr Gastroenterol Rep* 2013;15:353.
3. Davidson G et al. *J Pediatr* 2013;163;692-8.
4. Van der Pol RJ et al. *Pediatr* 2011;127:925–35.
5. Gieruzczak-Bialek D et al. *J Pediatr* 2015;166:767-70.

Current Care



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

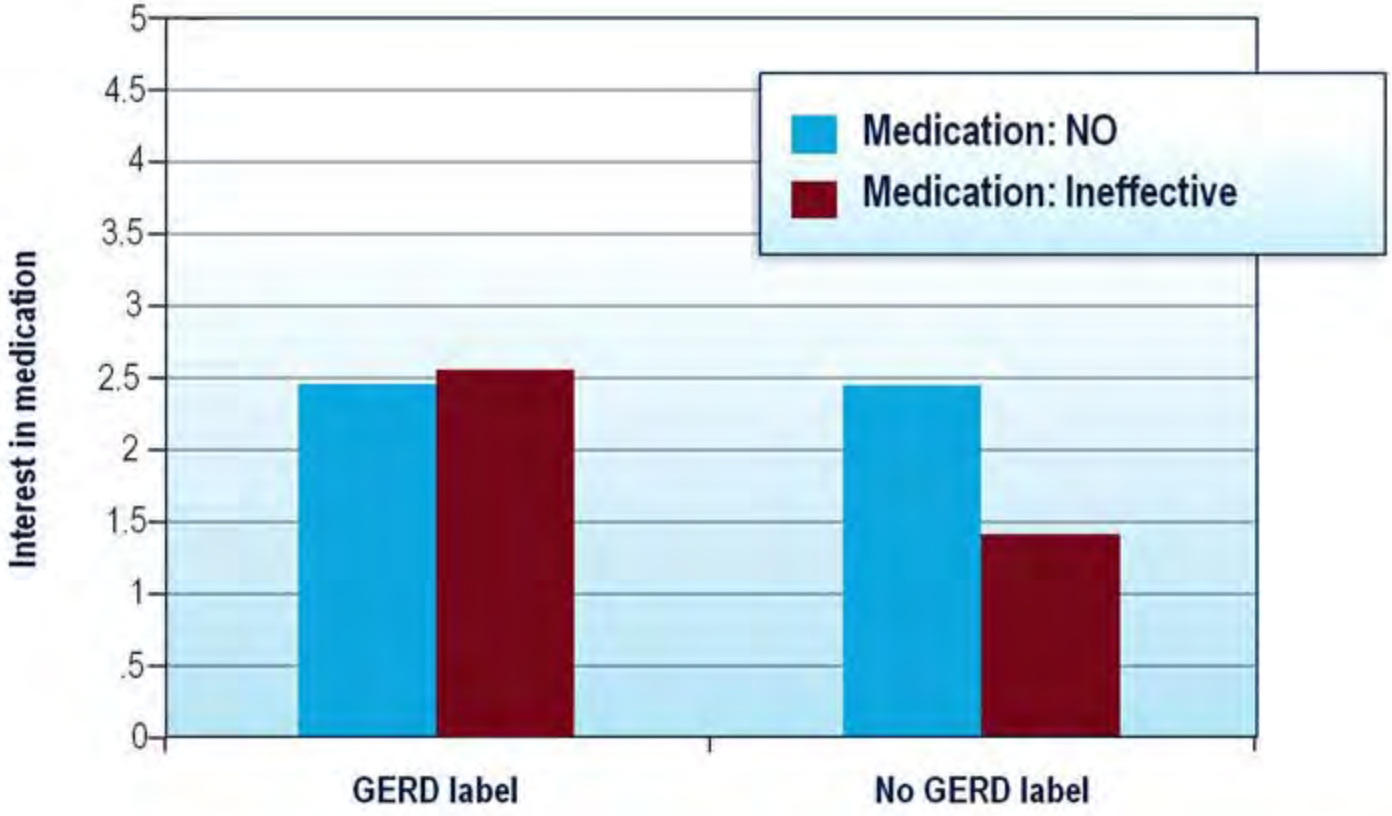
Studies

- 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



Scherer LD et al. *Pediatrics* 2013;131:839.

Current Care

Medication Cost per month

Dosage	Quantity	Price Without Insurance
CVS Pharmacy		
20mg	30 capsules	$289.00
40mg	30 capsules	$286.00
Kmart		
20mg	30 capsules	$270.00
40mg	30 capsules	$270.00
Kroger		
20mg	30 capsules	$293.00
40mg	30 capsules	$272.00
Publix		
20mg	30 capsules	$246.34
40mg	30 capsules	$295.00
Rite Aid		
20mg	30 capsules	$293.00
40mg	30 capsules	

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

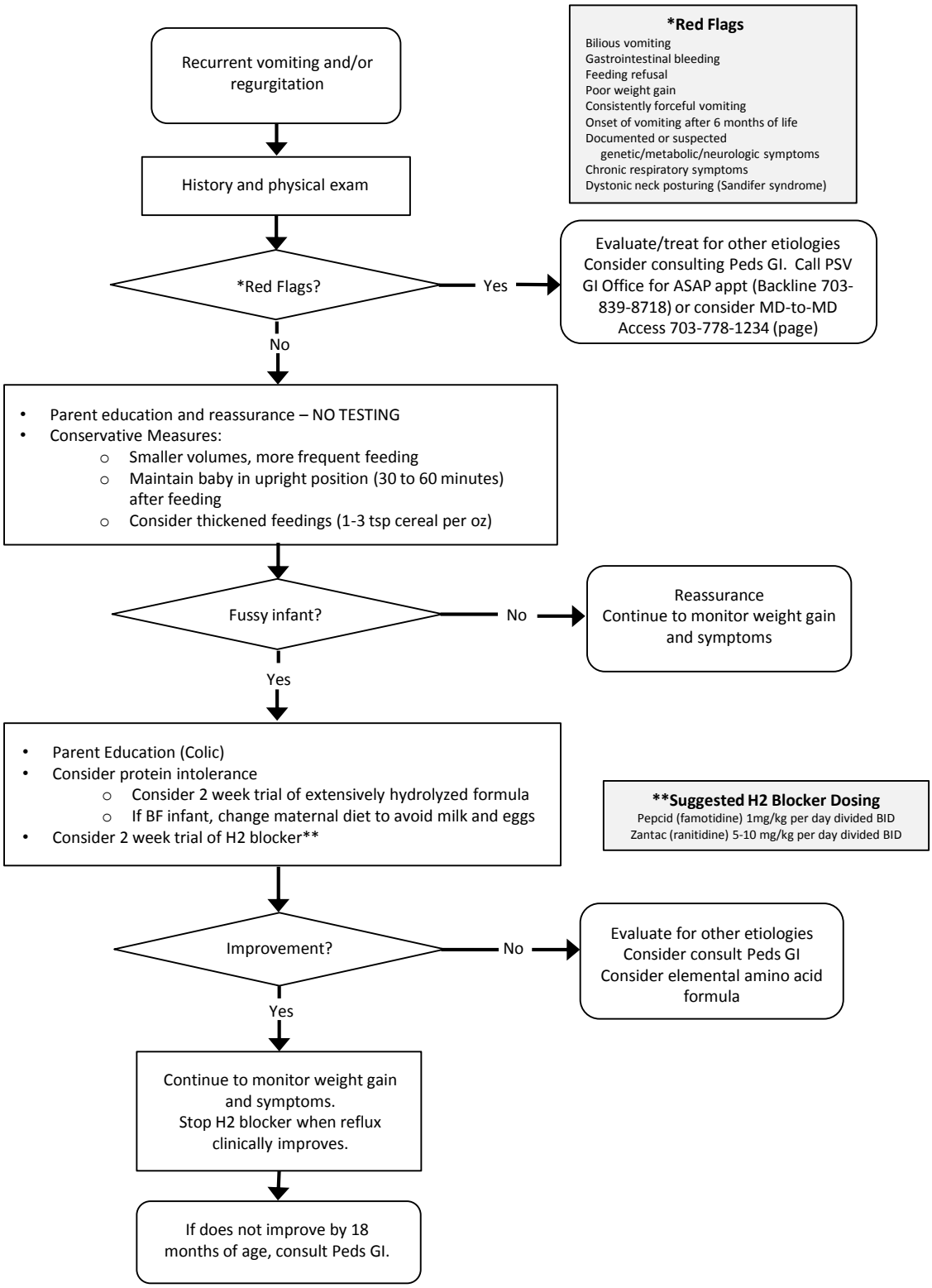
Barriers…to name a few

- 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



***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)

****Suggested H2 Blocker Dosing**

Pepcid (famotidine) 1mg/kg per day divided BID
Zantac (ranitidine) 5-10 mg/kg per day divided BID