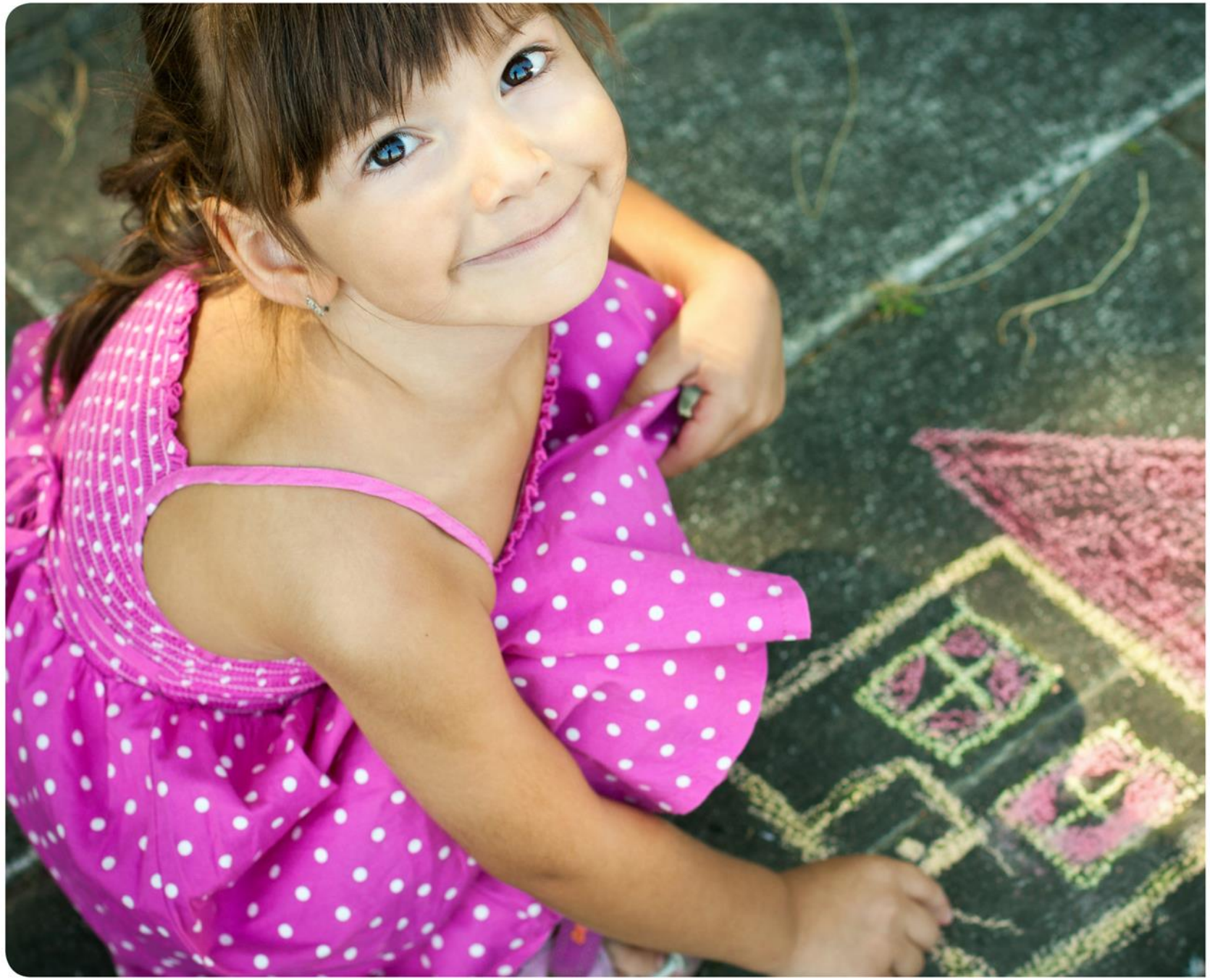

Denied, Again

Helpful Hints to Ensure our Complex Patients Receive Palivizumab

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Objectives

- Compare the American Academy of Pediatrics and the National Perinatal Association Guidelines for RSV immunoprophylaxis
- Identify reasons that patients are denied for RSV prophylaxis and strategies for optimizing approval
- Summarize Akron Children's Heart Center's Quality Improvement goals for the 2019/2020 RSV season

Background

- The recommendations vary from different professional organizations on who should receive RSV prophylaxis, and insurance authorization can be cumbersome

- The drug is expensive
  - ~$7500 per patient per season
    - A 2011 study out of Austria looked at CHD patients and found that the the costs/Quality-Adjusted-Life-Years (an international cost-effectiveness metric) was about $10,000

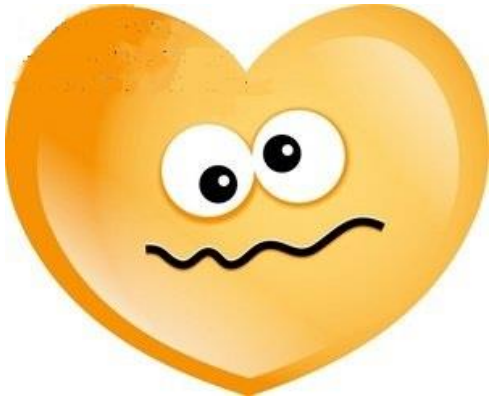
      (Medicare and Medicare set their "value threshold" at anything < $50,000)
    - Mac, et al, 2018, Pediatrics
      - Looked at data from 2000-2018 from Organization for Economic Cooperation and Development countries using the Joanna Briggs Institute checklist.
      - From a payer perspective, palivizumab was found to be relatively cost-effective in infants with BPD or CLD, **infants with CHD**, term infants from specific remote communities, and preterm infants with and without lung complications

Variation in Recommendations

FDA Approval	2014 AAP Guidance	2018 NPA Guidelines	International Expert Review 2018*
Hemodynamically significant congenital heart disease ≤24 months (chronological age) at the start of RSV season	Hemodynamically significant congenital heart disease < 12 months of age at the start of RSV season	Hemodynamically significant congenital heart disease <24 months of age at the start of RSV season, unless cardiology waiver obtained	Infants ≤12 months with Haemodynamically significant cyanotic or acyanotic disease ≤12 months of age at the start of RSV season 12–24 months, cyanotic or acyanotic, who remain haemodynamically unstable

*RSV experts from Europe, Canada and Israel, including representatives from European Neonatal, Perinatal and Paediatric Scientific Societies

Hemodynamically Significant



- What is significant?
  - Congenital heart disease that requires surgical intervention in the first year of life
  - Cyanotic heart disease that has been palliated, but remains high risk
    - Heart failure that requires medical management
    - Pulmonary hypertension
    - Growth failure
- Hemodynamically **in**significant
    - Secundum ASD, small VSD, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and PDA

Do they need Synagis after surgery?

- Bypass effect
  - Mean concentration decreases by 50%
- Palliation vs. Repair
  - Hemodynamic instability
  - Pulmonary Hypertension

Akron Children's Quality Improvement Data

- Taking into account the various recommendations, consensus within the Heart Center is that any child with CHD who requires surgery in the first year of life, and those under age 2 with cyanotic CHD who are palliated and remain at risk should receive Palivizumab
- For the last 3 Palivizumab seasons (16/17, 17/18, 18/19), 103 Heart Center patients were identified as qualifying for Palivizumab because of their cardiac disease on retrospective chart review
- 24 patients did not receive Palivizumab
  - 6/24 of these patients +RSV
    - 1 refusal, 1 inpatient
  - 5/79 received Palivizumab +RSV
- 25 patients were delayed in receiving their first dose of Palivizumab
  - 2 most common delays were lack of identification and insurance issues
- Overall, 49/103 patients did not receive Palivizumab or were delayed in receiving their first dose

Better Identification is key

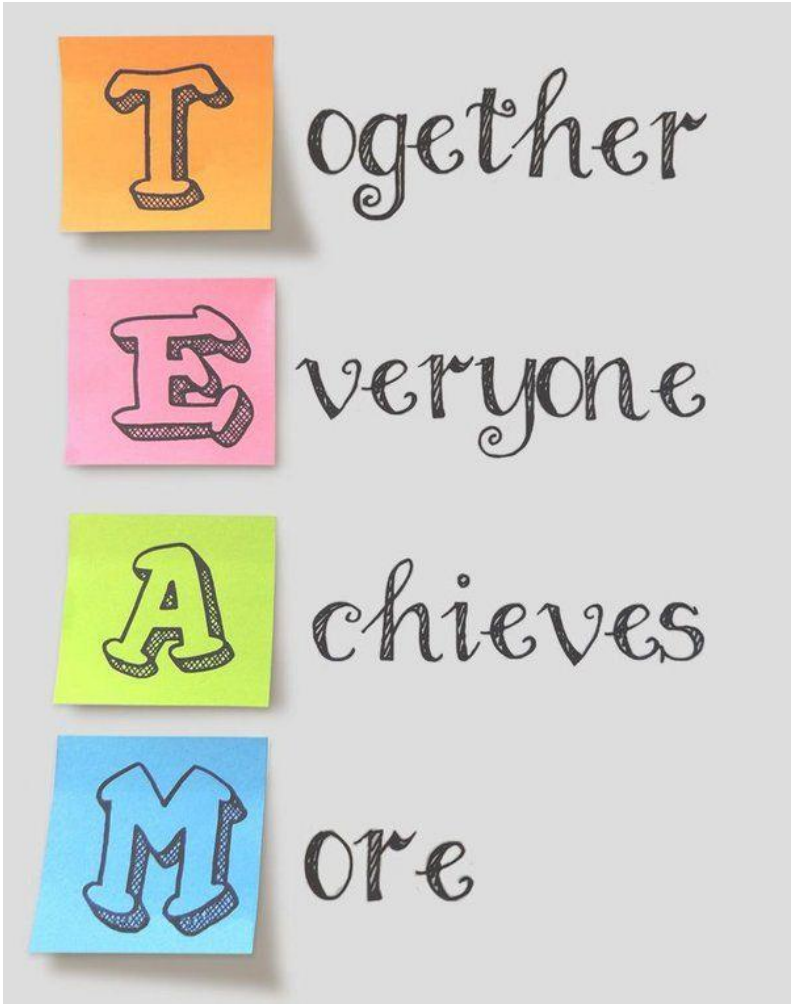
- 2018/2019 Season
  - 5/12 of patients who did not receive Palivizumab were not identified by the cardiologist as candidates
  - 5/11 patients who were delayed in receiving their first dose of Palivizumab were not identified by the cardiologist as candidates

  - **Overall, 10/23 (43%) patients were either delayed in receiving their first dose, or did not receive Palivizumab at all because they were not identified as candidates**

Quality Improvement work

- Consistent recommendations
- Better Identification
- Be proactive and collaborative with primary care providers
  - Submit supporting documentation with initial application
  - Enlist the help of cardiology

I am working on this Palivizumab referral…Can you review this chart and let me know if you think this patient's cardiac condition is acyanotic or cyanotic. I have reviewed all notes and even did some research, but I am still not sure? Thanks.



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