

# It Doesn't Have to be EviDense

## DON'T SHOOT THE MESSENGER

*Attending physicians do it. Residents do it. Hospitalists, emergency department doctors, general pediatricians...we all do it. In fact, in the United States, we do it >10 million times a year. We order the flu shot for our patients and often probably don't think too much of it (unless, of course, we have a patient with Kawasaki disease). But does the vaccine really work?*

### The study.

A 2012 Cochrane Review by Jefferson et al attempted to answer this question. This systematic review and meta-analysis included randomized controlled trials (RCTs), comparative trials, and cohort and case-controlled studies of healthy children in whom vaccination with influenza vaccine was compared with placebo or a control. The primary outcome measure was confirmed influenza illness along with an examination of several secondary outcomes.

### The key findings.

Seventy-five studies were included in the systematic review and 41 in the meta-analysis. Based on a compilation of 17 RCTs, 6 children aged 2 to 6 years and 28 children aged >6 years need to be vaccinated to prevent a case of influenza within the respective age groups. Based on a single RCT in children aged <2 years, the vaccine demonstrated effectiveness similar to placebo (relative risk [RR]: 0.55 [95% CI: 0.18–1.69]). Furthermore, compared with placebo, the vaccine showed little or no benefit for other outcomes such as prescriptions given (RR: 0.99 [95% CI: 0.87–1.12]), incidence of lower respiratory tract disease (RR: 0.20 [95% CI: 0.03–1.54]), socioeconomic impact (RR: 0.69 [95% CI: 0.46–1.03]), school absenteeism (RR: 0.49 [95% CI: 0.26–0.92]), and physician visits for pneumonia and influenza (RR: 0.76 [95% CI: 0.59–0.98]). The review did not find enough data to conduct an analysis of the safety of the flu vaccine.

### Why do we care?

Public health policy in much of the developed world recommends vaccinating healthy children aged >6 months, resulting in millions of doses given to children in the United States annually. Although the vaccine does seem to have some effectiveness in certain age groups, is reduction of a few cases of influenza, without a marked change in other outcomes such as doctor visits and socioeconomic factors, really worth an almost global vaccination policy? From these data, it could be argued that we are actually ahead of the available literature in recommending universal coverage, particularly when considering the fact that the review identified

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## KEY WORDS

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## ABBREVIATIONS

RCT: randomized controlled trial  
RR: relative risk

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“very little information” regarding vaccine safety. In children aged <2 years, the efficacy of inactivated vaccine (the only approved form in the age group) was similar to placebo.

This 219-page exhaustive review of >300 000 observations found an overall lack of evidence supporting use of the flu shot in children, as well as “widespread manipulation and spurious notoriety of the evidence.” In fact, publicly funded studies were significantly less likely than industry-sponsored studies to favor the vaccines. The authors contend that “large-scale studies assessing important outcomes... are urgently required.” As we continue to provide more and more doses of influenza vaccine each year in response to public policy initiatives, can you really blame them?

#### Why this article?

This study was chosen as the inaugural article for Journal Club because it symbolizes the importance of evidence-based medicine. What better way to commence this new section than with a meta-analysis which shows that something we do every day may not have the impact we think it does?

#### Straight from the author's mouth...

“I think the review shows how thin reliable evidence for the influenza vaccine in children is, as well as the chiasm existing between evidence and policy. Public health bodies are citing an increasing number of observational studies to back up their decisions. We debated long and hard on whether to include them, and the decision [to include] has meant that we have very little substance in the evidence base...as they say on TV, you may find the content disturbing.”

– Dr. Tom Jefferson,  
lead author

Citation: Jefferson T, Rivetti A, DiPietrantonj C, et al. Vaccines for preventing influenza in healthy children. *Cochrane Database Syst Rev.* 2012;(8):CD004879

#### BUT HE LOVES TO EAT!

*Does this sound familiar? You have a developmentally delayed, medically complex child on your inpatient service who is in need of better nutrition. His parents, however, are reluctant to agree to placement of a gastrostomy tube because they feel that “feeding time” is really the only chance they have to interact with their child. As a physician, you know that the child needs more calories than he can actually take orally. As a person, you know that the child and the parents need to feel connected, and you hesitate to remove the bond created during meals. So you ask yourself, does placement of a gastrostomy tube decrease parent-child interaction and communication?*

#### The study.

A 2013 Norwegian study by Åvitsland et al may help with this decision. This prospective cohort study examined child and parent satisfaction during meals before and after the placement of a gastrostomy tube. Parents and children (when able) were given questionnaires that included topics such as quantification of oral intake, meal duration, parental stress, parent and child satisfaction, and communication at 0 to 3 days before gastrostomy tube placement and then at 6 and 18 months' postoperatively. Newborns and those undergoing other procedures concomitantly were excluded.

#### The key findings.

Fifty-eight children were included, many of whom had used nasogastric tubes preoperatively. The median

age was 1.7 years, and roughly two-thirds had neurologic impairment. Parents reported increased oral intake in 34% by 6 months' postoperatively and 49% by 18 months' postoperatively. Frequency of vomiting was reduced in ~40% of all postoperative cases. Compared with preoperative responses, parents at 18 months' postoperatively reported reduced parental stress ( $P = .015$ ), increased satisfaction for parents ( $P < .001$ ) and child ( $P < .001$ ), and improved parent-child communication during meals ( $P = .001$ ).

#### Why do we care?

Feeding provides an important time for parent-child interaction, especially in children with complex medical issues. Although a child's inability to eat may create a stressful and frustrating situation, parents are often worried about losing this bonding experience through placement of a gastrostomy tube. In the hospital, we watch as parents spend hours with a bowl of applesauce or yogurt in their hand trying to spoon-feed their child. We admire their perseverance and see what feeding time means to the family. This interaction may even cause us to hesitate to intervene despite knowing that the child really is not receiving adequate nutrition and that the family's quality of life is suffering. This study suggests that parents and children are more satisfied after placement, stress levels drop, and children actually end up taking more orally, all indicators that quality of life for the family has improved.

#### Why this article?

This study helps us with the tough family discussions about gastrostomy

tube placement. Maybe the next time you have this difficult conversation with parents, the data from this article will provide some reassurance to you and to the family.

### **Straight from the author's mouth...**

"For children with major feeding problems, meals may be unpleasant for them and their parents. Our results show that children and parents are more satisfied during meals, and child-parent communication improves after placement of a gastrostomy tube. The main reason for this may be that the parents feel less pressure and inadequacy in feeding their child. Furthermore, half of parents report that their child has less vomiting and eats more by mouth. Thus, we think our study supports that placement of a gastrostomy tube is an important intervention for the children and their families."

– Dr. Ragnhild Emblem  
(senior author)

Citation: Åvitsland TL, Birketvedt K, Bjørnland K, Emblem R. Parent-reported effects of gastrostomy tube placement. *Nutr Clin Pract.* 2013;28(4):493–498

### **PRIMUM NON NOCERE**

*What would a pediatric hospital medicine Journal Club in Hospital Pediatrics be without discussing a study on bronchiolitis? Despite evidence-based guidelines and volumes of literature that have shown minimal, if any, treatment effect from therapies such as albuterol, steroids, and antiviral agents, there remains great variability in our*

*practice. This large European RCT examined the use of racemic epinephrine and nebulized normal saline in children with bronchiolitis.*

### **The study.**

A 2013 multicenter study published in the *New England Journal of Medicine* randomized 404 hospitalized infants with moderate to severe bronchiolitis to receive nebulized racemic epinephrine or normal saline either on a fixed schedule or on demand.

### **The key findings.**

Although length of stay, supplemental oxygen requirement, and respiratory support were found to be similar between the racemic epinephrine and normal saline groups, length of stay was significantly shorter for infants <3 months of age who received racemic epinephrine or normal saline on demand compared with a fixed schedule. Patients with scheduled therapy averaged 17.0 treatments during their stay compared with the 12.0 average treatments in the unscheduled group.

### **Why do we care?**

These data show that racemic epinephrine is no better than normal saline when it comes to treating bronchiolitis and that "as-needed" treatments are better than scheduled treatments. At a quick glance, this article may be read as an argument that racemic epinephrine and/or normal saline may be beneficial if ordered as needed. However, without an arm randomized to receive no nebulizer therapy, we really cannot

claim that either therapy is more beneficial than no therapy. Instead, what these data suggest is that limiting how often we disturb a child, particularly an infant, provides clinical benefit. This article reminds us of the vow we all took upon graduating medical school, which was "first, do no harm."

### **Why this study?**

It is bronchiolitis season, and we could not ignore a *New England Journal of Medicine* article suggesting that children with bronchiolitis do better when we do less.

### **Straight from the author's mouth...**

"The study should be another incentive to stop over-treating these children. We have a long tradition of giving them [various treatments] all without sufficient evidence. Everyone wants to help an infant in respiratory distress. The problem is we don't have anything that works. We have shown that children below three months actually do worse if they're treated on a fixed schedule, as opposed to a more dynamic approach, with an increased length of stay of more than 24 hours. These findings make us hypothesize that a 'minimal handling' approach, an accepted concept in the NICUs, may also be beneficial to the youngest infants with bronchiolitis."

– Dr. Håvard Ove Skjerven,  
lead author

Citation: Skjerven HO, Hunderi JO, Brugmann-Pieper SK, et al. Racemic adrenaline and inhalation strategies in acute bronchiolitis. *N Engl J Med.* 2013;368(2):2286–2293

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