

Preventing Cancer Shot by Shot! Clinic Interventions to Improve **HPV** Vaccination Rates

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Disclosures

- Potential conflicts
 - Safety Review Committee
 - Gardasil or 4-valent human papillomavirus vaccine in males (Merck)
 - Gardasil®9 or 9-valent human papillomavirus vaccine (Merck)
 - Data and Safety Monitoring Board
 - Adult and infant 15-valent pneumococcal conjugate vaccine (Merck)
- No off-label use discussion

Learning Objectives

- Upon completion, you will be able to
 - Demonstrate the **announcement** (presumptive language) approach to recommending the HPV vaccine as opposed to the discussion (shared decision making) approach
 - Describe the **C.A.S.E.** approach to parental and teen hesitancy
 - List and describe a number of **proven initiatives** a practice should adopt clinic wide to boost HPV vaccination rates

HPV Infections

- Human papillomavirus infections
- Spread by direct contact
- 14 million new genital infections a year in US
- ½ are with a high-risk HPV type
- Most persist 1 to 2 years
- Silent, contagious, undiagnosed
- Some persist for years, progress to cancer

HPV and the Cancers They Cause

- **30,700** new cancers a year in the US caused by HPV
 - **19,200** among women
 - **11,600** among men
- 30,700 new cancers a year in the US caused by HPV
 - **10,700** cervical
 - **11,000** oropharynx

Cervical Ca Treatable?

- **300,000** invasive tests and treatment a year
 - Costly and anxiety-provoking
 - Long-lasting effects
 - Infertility
 - Second trimester pregnancy loss
 - Premature rupture of membranes
 - Preterm delivery

HPV Vaccine Efficacy

- Large clinical trials
 - Per protocol cervical intraepithelial neoplasia (CIN)
 - 4vHPV
 - 2 double-blind, placebo-controlled trials
 - Types 16 and 18
 - Among HPV naïve, **97-100%** for CIN2 or more severe
 - 9vHPV
 - Single international trial with 4vHPV as control
 - Types 31, 33, 45, 52, 58
 - Among HPV naïve, **97%** for CIN2 or more severe

Specifics of Current Recs

- Routinely recommended **11-12** years of age
- Permission to start at 9-10 years of age
- Catch-up for initiation with 1st dose
 - Through 26 years of age for females
 - Through 21 years of age for males
 - For males 22 through 26 years
 - If desiring immunity (option)
 - If at increased **risk** (recommended)



High Risk Males

- HIV
- Immune compromise
- Males who have sex with males



Dosing

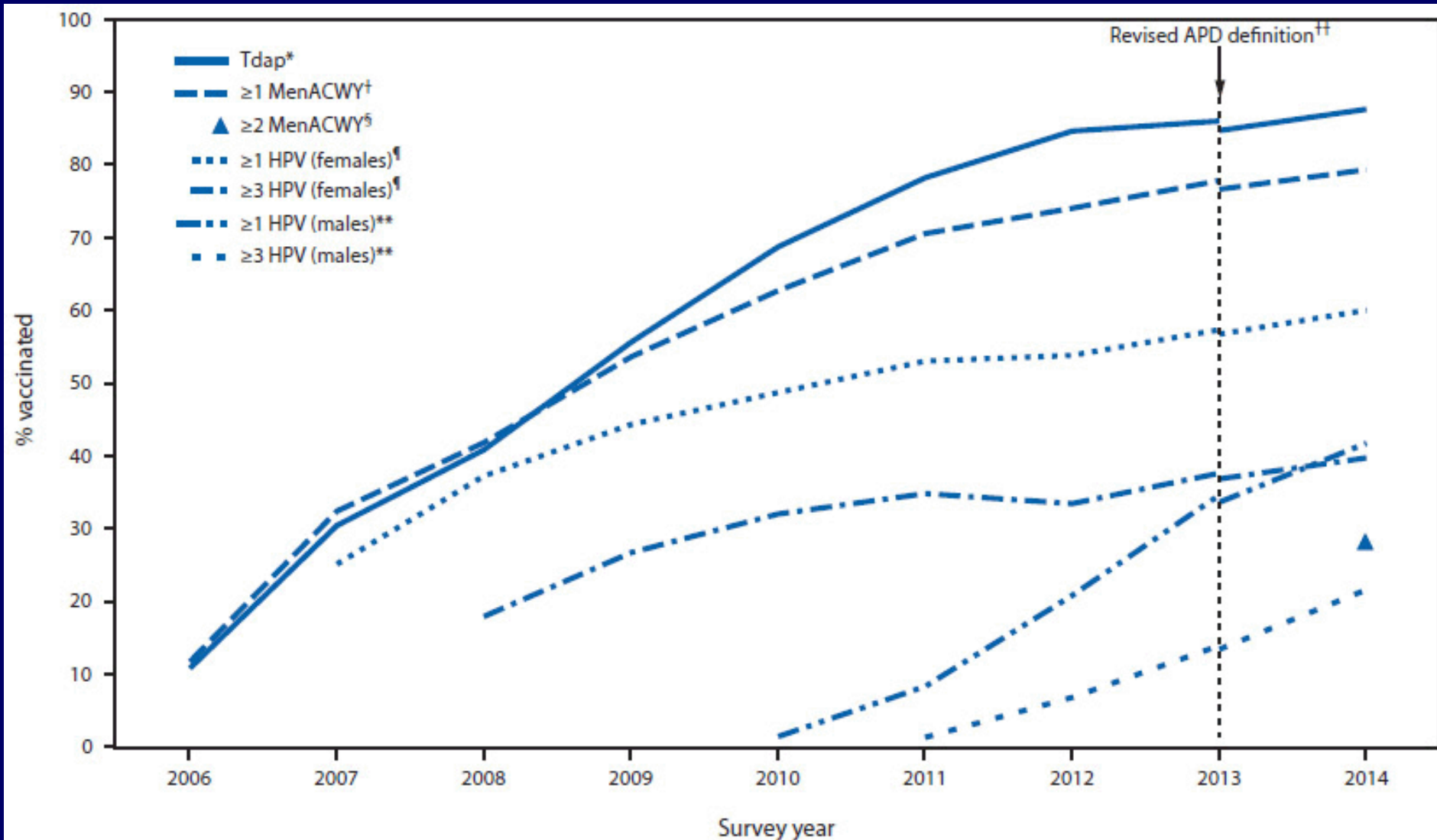
- Three doses
 - 0, 1-2 months, 6 months
 - Minimum intervals
 - 4 weeks between 1st and 2nd doses
 - 12 weeks between 2nd and 3rd doses
 - 24 weeks between 1st and 3rd doses
- **Two doses**
 - 0 and 6 months
 - Immunocompetent males and females
 - First dose < 15 years of age
 - Minimum interval **5 months**
 - May start as early as 9 or 10 years of age

HPV Vaccine

- Uptake surprising poor
 - Introduced 2 years after Tdap and 1 year after MCV4
 - HPV diseases prevented far more common
 - More effective than either
 - Just as safe or safer
 - Tdap 88%, 1st dose MCV4 79%, 3-doses HPV 22-40%



Uptake in US 13-17 Years Old



How To Present the Vaccines

- Present them as **strong** recommendations
- Discuss them as
 - Matter-of-fact
 - Routine steps in care
 - What you clearly recommend
 - Due today to be given today
 - **Presume** acceptance the way you do with other steps of care

Recs Perceived as Strong Are Better

- Rosenthal et al in 2011
- 19 to 26 year old females re HPV vaccine
- 1375 who had received 1 dose in 4 months
- Compared to 1375 who did not
- Rated recommendation 1 thru 5 in strength
 - 1 “did not strongly recommend the vaccine”
 - 5 “strongly recommended the vaccine”
- Strong rec **4 times more likely** to get vaccine

Why Presumptive Language?

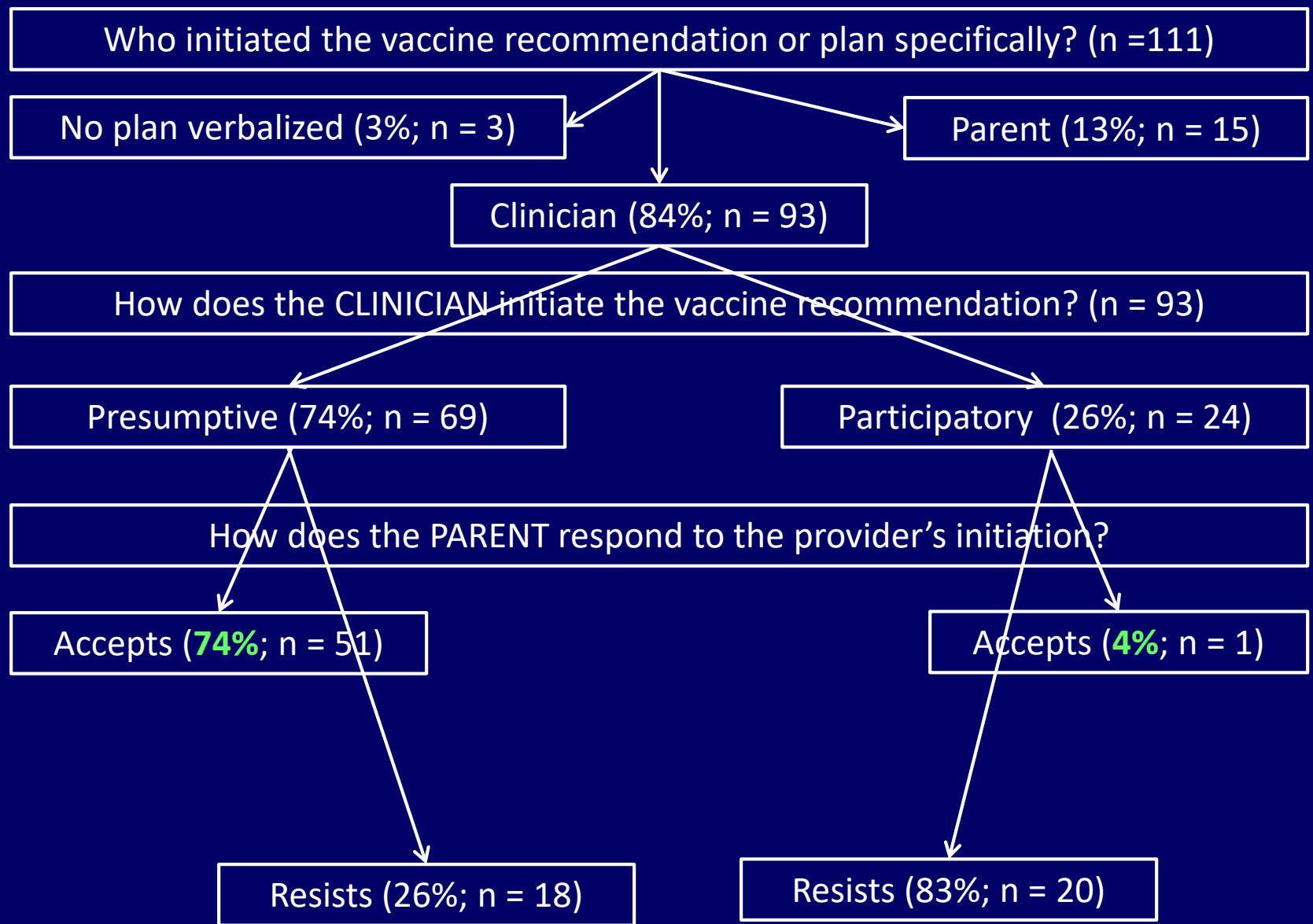
- For Tdap and influenza vaccination in pregnancy
 - These are **not choices** in the sense of choosing comfort care in labor where there are tradeoffs in benefits and risk
 - These are **not options** where expert opinion is divided such as circumcision for male newborns

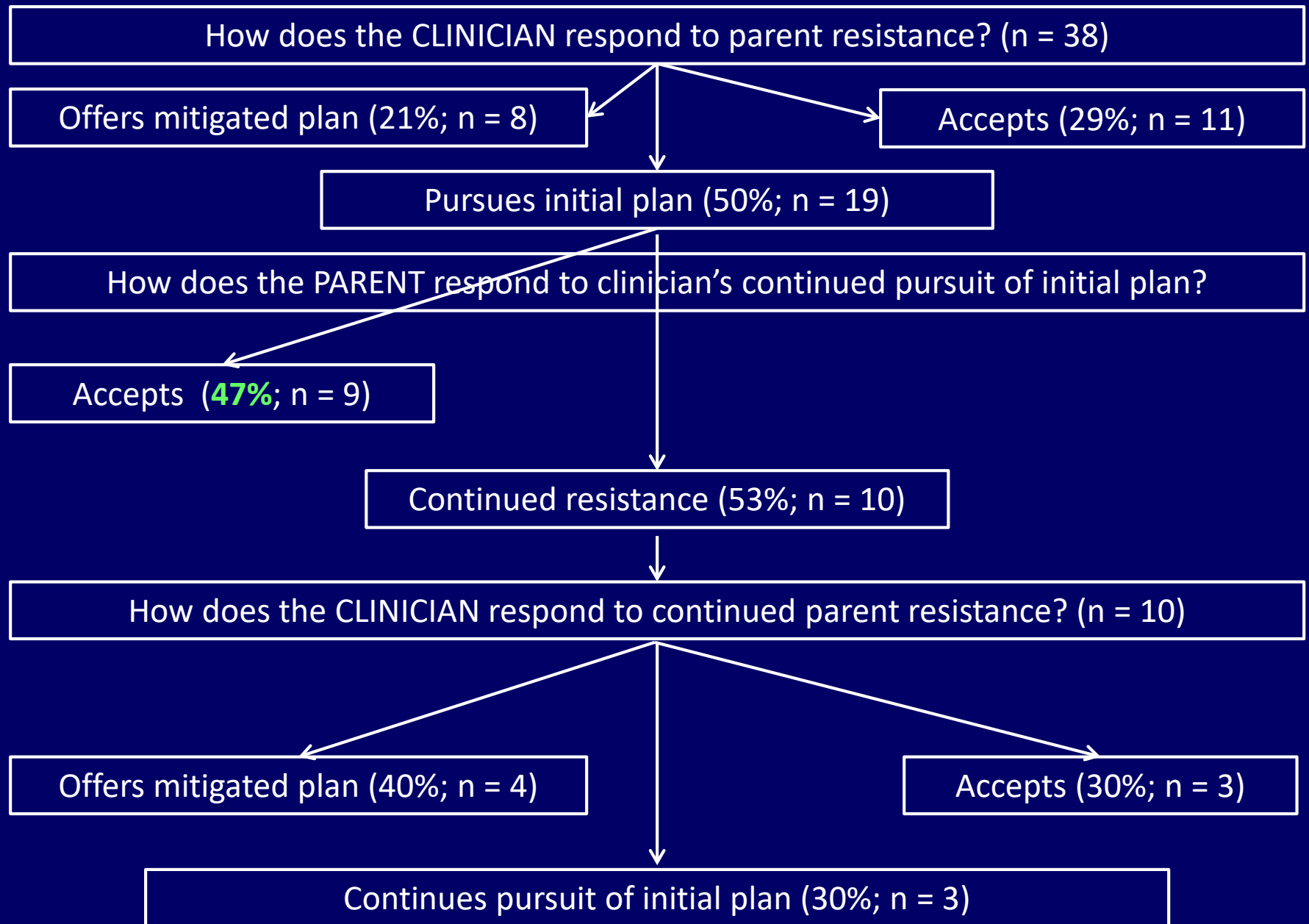
More on Presumptive Language

- Presumptive language better communicates your **strong** recommendation
- **Data** from recorded conversations with primary care clinicians, parents and patients support presumptive language

Landmark Study

- Opel et al in 2013
- 111 parents of children aged 1 to 19 years of age
- Oversampled vaccine hesitant parents
- Videotaped health-maintenance visits
- 74% providers presumptive (eg, “Well, we have to do some shots”) rather than participatory (eg, “What do you want to do about shots?”)
- Odds of parents accepting if presumptive **17.5** times more than participatory!



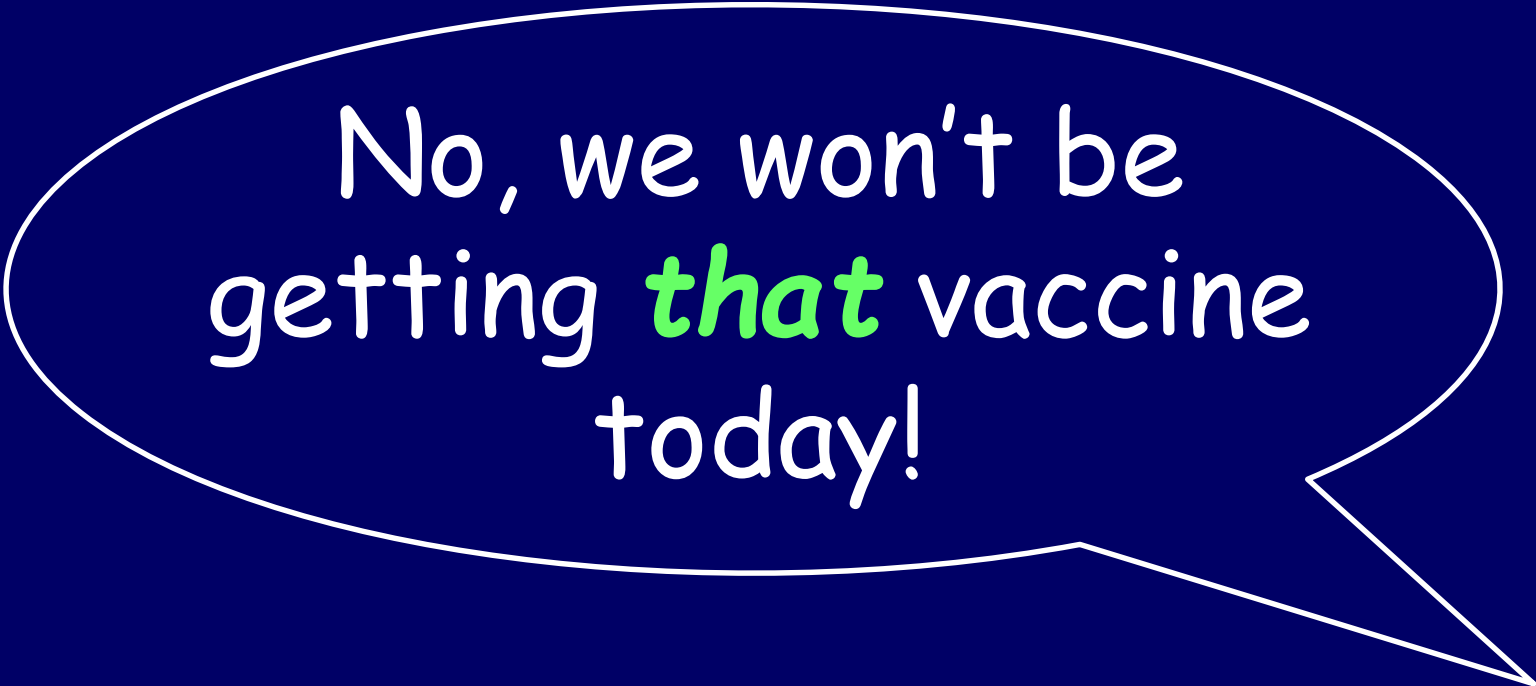


Repeated with HPV Vaccine

- Brewer et al in 2017
- Randomized 30 pediatric and family med clinics
- No training (control), announcement (presumptive) training, or conversation (participatory) training
- 17,173 adolescents 11 or 12 years of age
- Six month increases in HPV vaccination larger for patients in clinics with **announcement training**

How to Address Vaccine Hesitancy

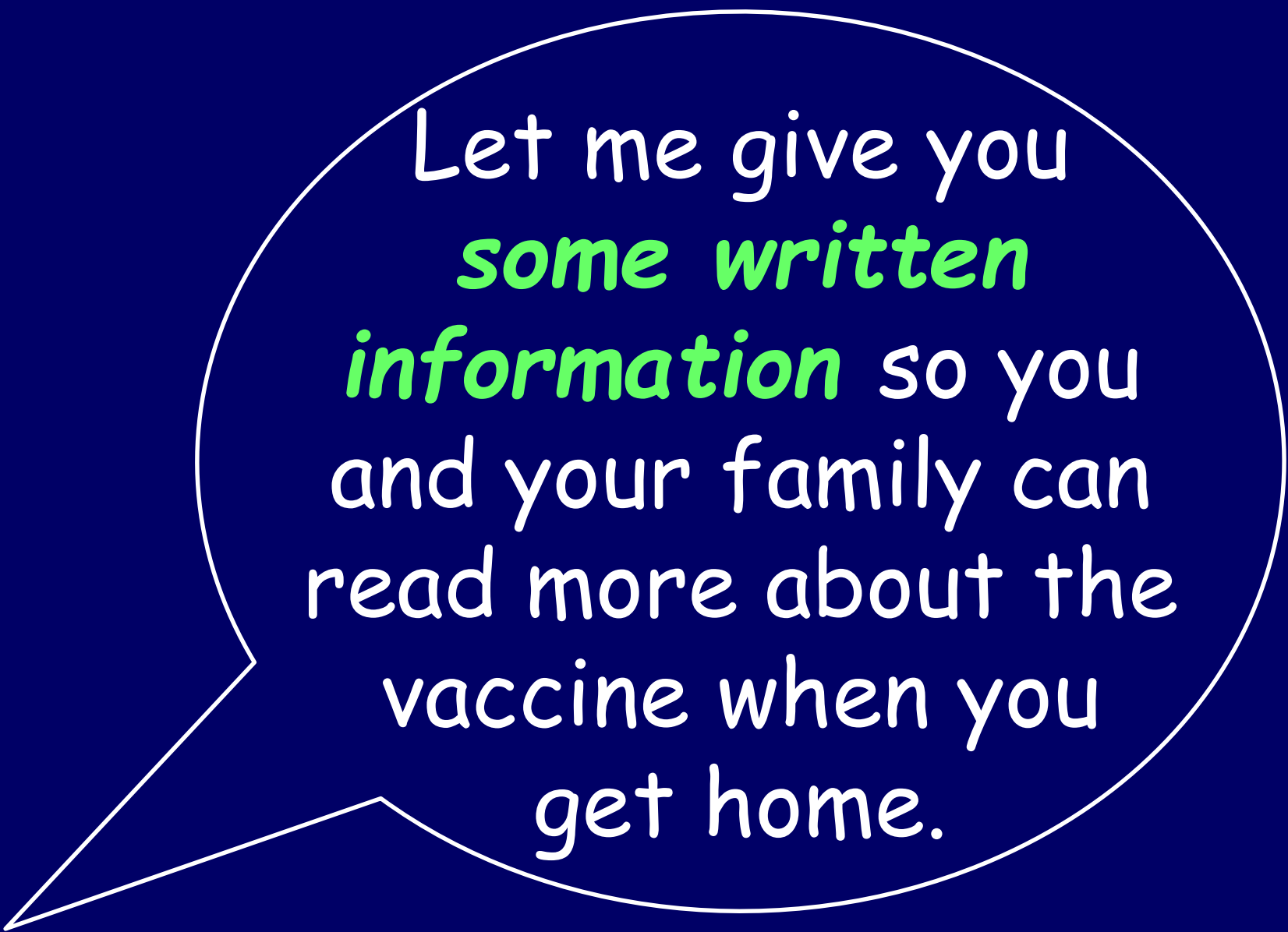
- Your strong recommendation matters
- Your addressing it early and often matters
- Your management of **hesitancy** matters too
 - Don't give up or give in
 - Use the **C.A.S.E.** approach
 - **Stop** using the common approaches of the past



No, we won't be
getting *that* vaccine
today!



I agree that
there's a lot to
consider. Let's talk
about it further at
our *next visit!*



Let me give you
*some written
information* so you
and your family can
read more about the
vaccine when you
get home.

The C.A.S.E. Approach

- Model for talking to vaccine-hesitant patients
- **Organized, rapid, and useful** response
- Created by Alison Tepper Singer
 - Former NBC and CNBC television producer
 - Mother of an autistic child
 - Quit Autism Speaks over its anti-vaccine stance
 - Founding CEO of Autism Science Foundation
 - Strong advocate of science, vaccination

The Case for C.A.S.E.

- Provides more than just information
- Has historical roots in Aristotelian rhetoric
- Lacks published studies of its efficacy
- Nonetheless has face validity
- Lacks competing alternatives
- Preserves the relationship

The C.A.S.E. Approach

- **Corroborate:**
 - Identify and acknowledge the person's concern
 - Find some point on which you can agree
 - Set the tone for a respectful, successful talk
- **About Me:**
 - Describe what you have done to build your knowledge base
 - Appeal to the reason why the person is talking to you
- **Science:**
 - Relate what the science says, briefly
 - Recognize that this is only a part of the response
- **Explain/Advise:**
 - Explain your advice to patient, based on the science
 - Do make your recommendation clear

C.A.S.E. and Aristotle

- Corroborate--*pathos*
- About Me--*ethos*
- Science--*logos*
- Explain/Advise--*telos*

No, we won't be
getting **that** vaccine
today.

I do recommend it. Let
me give you some material
to read about it.



No, we won't be
doing **that** vaccine
today!

Why not? Why don't
you want to do **that**
vaccine?

He's just
too young! He just
turned eleven.

Ah. Lots of parents
have that reaction
at first!

I thought *the same thing*
ten years ago when the
vaccine first came out.

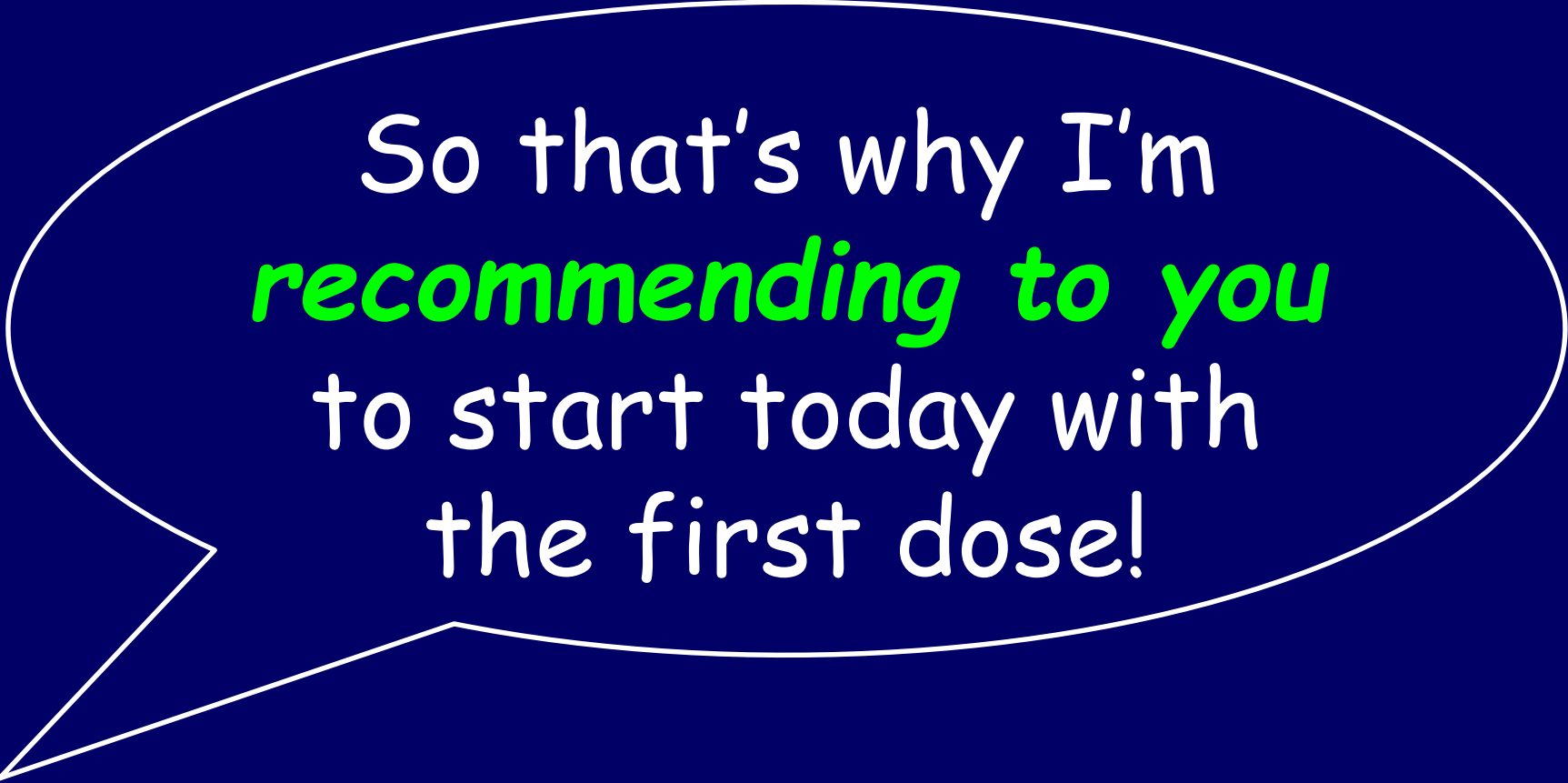
But *I read* the studies,
listened to the experts,
and learned otherwise!

With HPV vaccine, the
younger you are the *better*
you respond to the vaccine!

Eleven-year-olds
respond much better
than sixteen-year-olds.

And the immune response
lasts and lasts so you can't
give it too early.

Starting young also helps
us get in all three doses.
Older teens have much
busier schedules and just
don't get in!



So that's why I'm
recommending to you
to start today with
the first dose!

The C.A.S.E. Approach

- **Corroborate:**
 - Why not? What is your specific concern?
 - Lots of parents have that reaction at first
- **About Me:**
 - I felt the same way at first as well
 - I read the studies, listened to the experts, learned otherwise
- **Science:**
 - The younger you are the better the response
 - The response lasts and lasts; can't give it too soon
 - Starting young helps us get in all three doses
- **Explain/Advise:**
 - So that's why I'm recommending you start today

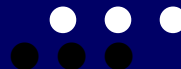
Briss's 2000 Systematic Review

- **What didn't work**
 - Community-wide education only
 - Clinic-based education only
 - Provider education only
 - Family incentives
 - Family-held vaccine records
 - Expanding access alone



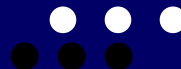
What Clearly Worked

- **Strong** scientific evidence
 - Reminder/recall/point-of-care prompts
 - Assessment and feedback of coverage
 - Standing orders
 - Reduction of out-of-pocket costs



Also Appeared to Work

- **Sufficient** scientific evidence
 - School requirements
 - Daycare requirements
 - College requirements
 - Interventions in WIC settings
 - Home-visiting interventions



In Brief

- Socrates was wrong
- Knowledge $\neq$ action
- Successful strategies
 - Rely on engineering human behavior
 - Measure and report
 - Hold persons & organizations accountable



Newest Systematic Reviews

- Focus on vaccine uptake
- Adolescent vaccine specific
- HPV vaccine specific



Linda Y Fu et al, 2014

- Educational Interventions to Increase HPV Vaccination Acceptance: A Systematic Review
- 33 studies
- Minority of studies measured HPV vaccine uptake
- Very few studies adequately powered to detect uptake rate changes
- Generally **no effectiveness** of tested interventions



Jai K Das et al, 2016

- Systematic Review and Meta-Analysis of Interventions to Improve Access and Coverage of Adolescent Immunizations
- 23 studies
- Minority of studies measured HPV vaccine uptake
- Included low, middle and high income countries
- Used Cochrane tool to rate quality
 - High, moderate, low and very low



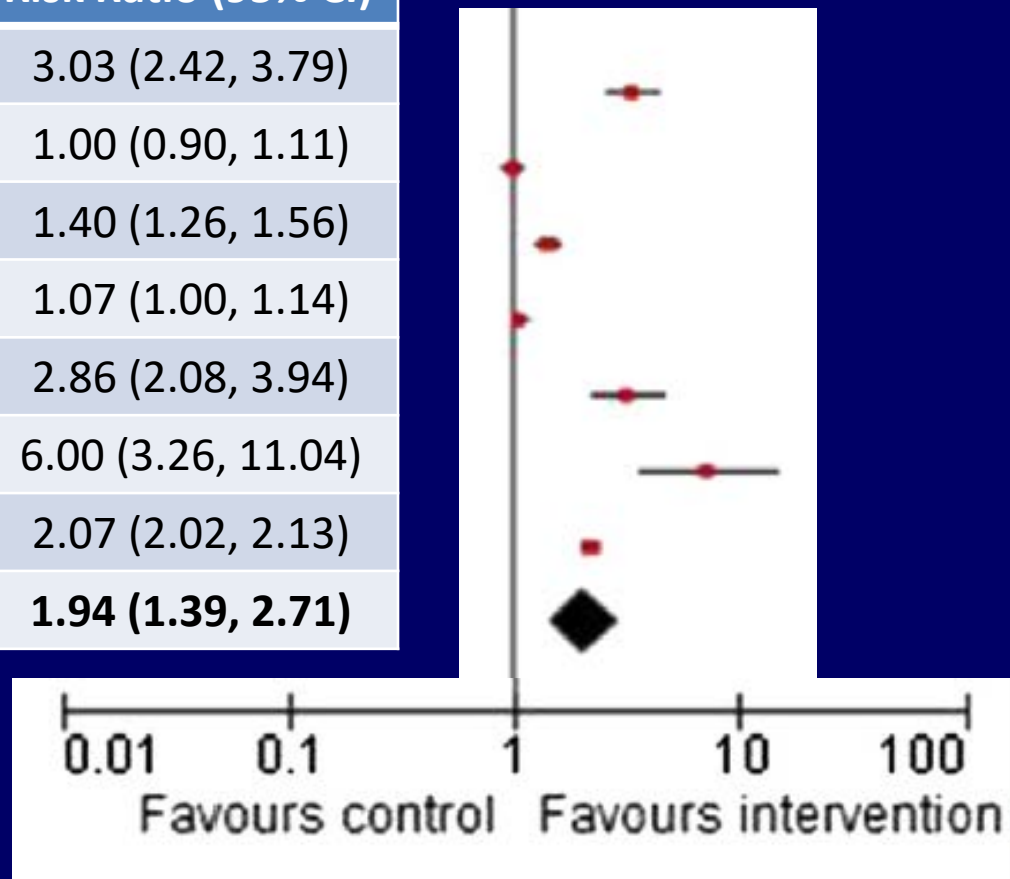
Results

- 13 studies of **moderate quality**
 - All in high-income countries
 - RCT, quasi, and observational studies
 - Targeted adolescents 11-19 years
 - 5,092 received intervention
 - 4,303 were controls
 - Relative Risk 1.78 (1.41-2.23)



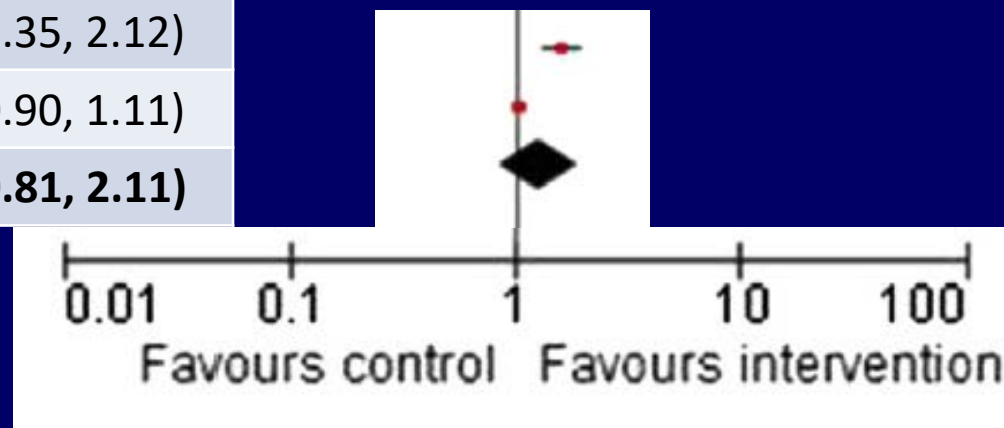
Vaccine Required for School

Study	Weight	Risk Ratio (95% CI)
Averhoff 2004	14.6%	3.03 (2.42, 3.79)
Bugenske 2012	15.3%	1.00 (0.90, 1.11)
Carlson 1985	15.3%	1.40 (1.26, 1.56)
Fogarty 2004	15.5%	1.07 (1.00, 1.14)
Kharbanda 2010A	13.6%	2.86 (2.08, 3.94)
Kharbanda 2010B	9.90%	6.00 (3.26, 11.04)
Musto 2013	15.7%	2.07 (2.02, 2.13)
Total	100%	1.94 (1.39, 2.71)



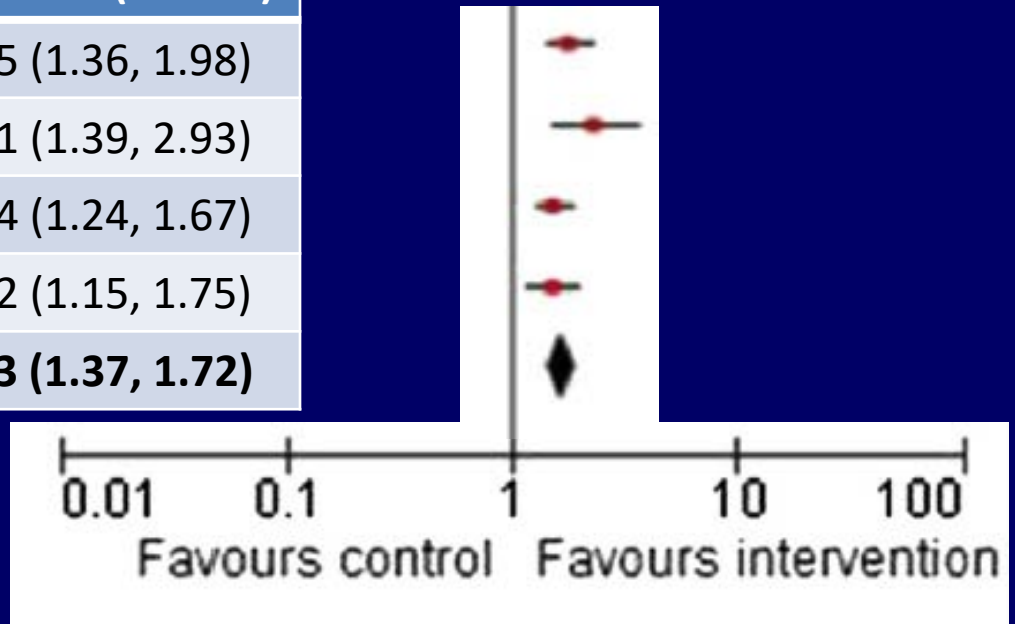
Clinical Staff Training

Study	Weight	Risk Ratio (95% CI)
Harper 1994	48.4%	1.69 (1.35, 2.12)
Moss 2012	51.6%	1.00 (0.90, 1.11)
Total	100%	1.31 (0.81, 2.11)



Reminders

Study	Weight	Risk Ratio (95% CI)
Kempe 2012	25.9%	1.65 (1.36, 1.98)
Stockwell 2012	22.2%	2.01 (1.39, 2.93)
Suh 2012	26.3%	1.44 (1.24, 1.67)
Szilagyi 2013	25.6%	1.42 (1.15, 1.75)
Total	100%	1.53 (1.37, 1.72)



Jai K Das et al, 2016 Results

- Mod. quality evidence: some interventions work
 - Vaccination requirement in school
 - ~~Clinical staff training~~
 - Patient/parent reminder-recalls

What We've Done at Mayo Clinic

- In place
 - **Every visit** status reviewed
 - Clinicians **prompted** with electronic prompts
 - Patients start **at 9-10 years** old rather than 11-12
 - **Express Care** sites
- Incoming
 - **Reminder-recall** notices
 - Clinician dashboards for **assessment/feedback**



9-10 versus 11-12?

- Routinely recommending at 9 yrs since 2006
- Pop 9.5 to 27 yrs residing in Olmsted County
- Index date 31 December 2012
- Compared ages at **vaccine-initiation**
- Examined those complete by 13.5 years and by 15 years
- Only examined those eventually completing series



Results

- 11,536 (31.8 %) got 1 dose
- 6,989 (19.3 %) had received all 3 doses
- Completion associated with younger age
 - 9-10 years at initiation versus 11-12 years at initiation
 - 97.5 % complete by 13.5 years rather than 78.0% (P value <0.0001)
 - 99.6% percent complete by 15 years rather than 94.0%
 - Both differences P value **<0.0001**



Summary

- Upon completion, you will be able to
 - Demonstrate the **announcement** (presumptive language) approach to recommending the HPV vaccine as opposed to the discussion (shared decision making) approach
 - Describe the **C.A.S.E.** approach to parental and teen hesitancy
 - List and describe a number of **proven initiatives** a practice should adopt clinic wide to boost HPV vaccination rates