What is ACCORDS?

Adult and Child Center for Outcomes Research and Delivery Science

ACCORDS is a 'one-stop shop' for pragmatic research:

- A multi-disciplinary, collaborative research environment to catalyze innovative and impactful research
- Strong methodological cores and programs, led by national experts
- Consultations & team-building for grant proposals
- Mentorship, training & support for junior faculty
- Extensive educational offerings, both locally and nationally





ACCORDS Upcoming Events – mark your calendars!

October	 October 20 – ACCORDS Grand Rounds, Laura Scherer, PhD: Open Science October 22 – ACCORDS/CCTSI Community Engagement Forum 	
November	November 4 & 6 – Introduction to Qualitative Research Workshop	
December	December 8 – ACCORDS Highlights	
January	 January 12 – ACCORDS Grand Rounds, Bethany Rose-Daubman, MD January 15 – D&I Science Graduate Certificate application launch January 28 – ACCORDS/CCTSI Community Engagement Forum 	
May 20-21, 2026	Colorado Pragmatic Research in Health Conference Pragmatic Outcomes Research: Methods, Tools, and Technology for Rapidly Changing Contexts	

Full list of events and dates are available on ACCORDS Education website





Advances in Vaccine Communication & Delivery



David Higgins, MD, MPH
Assistant Professor, University of
Colorado School of Medicine,
General Academic Pediatrics



Sean O'Leary, MD
Associate Professor, University of
Colorado School of Medicine,
Pediatrics









Before the Clinician Knocks: Pre-visit Vaccine Communication in Primary Care

David Higgins, MD, MPH, FAAP

Assistant Professor of Pediatrics
University of Colorado School of Medicine
Children's Hospital Colorado







Disclosures

• I have no financial disclosures







Objectives

• **Describe** the current roles and untapped opportunities for nurses, medical assistants, and other non-clinician frontline staff in supporting effective vaccine communication in primary care.

• **Identify** practical strategies and interventions that empower frontline health professionals to communicate confidently about vaccines and improve uptake in primary care.

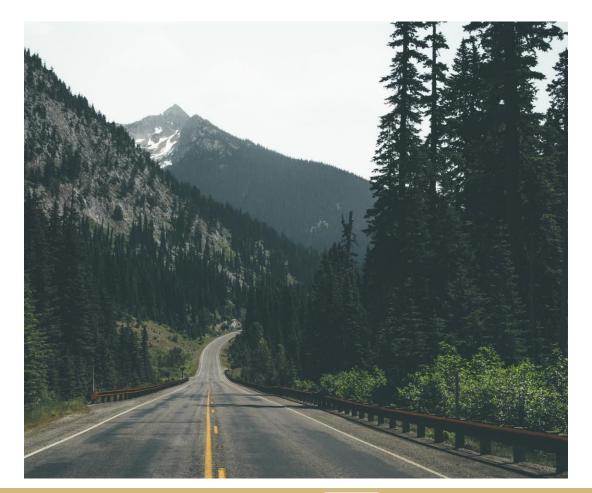






Roadmap

- 1) The Problem
- 2) Potential Approaches
- 3) Describing the Role of Clinical Staff
- 4) Next Steps and Opportunities









The Importance of Engaging All Team Members

"Front desk staff, medical assistants, nurses, and other staff often play a major role in vaccination processes, so engaging all team members in the office setting or inpatient unit who communicate with parents about vaccines on the rationale and technique for initiating the vaccine discussion...could maximize its effect."

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care



nroving Vaccine

Strategies for Improving Vaccine Communication and Uptake

Sean T. O'Leary, MD, MPH, FAAP, Douglas J. Opel, MD, MPH, Jessica R. Cataldi, MD, FAAP, Jesse M. Hackell, MD, FAAP, COMMITTEE ON INFECTIOUS DISEASES: COMMITTEE ON PRACTICE AND AMBULATORY MEDICINE: COMMITTEE ON BIOETHICS







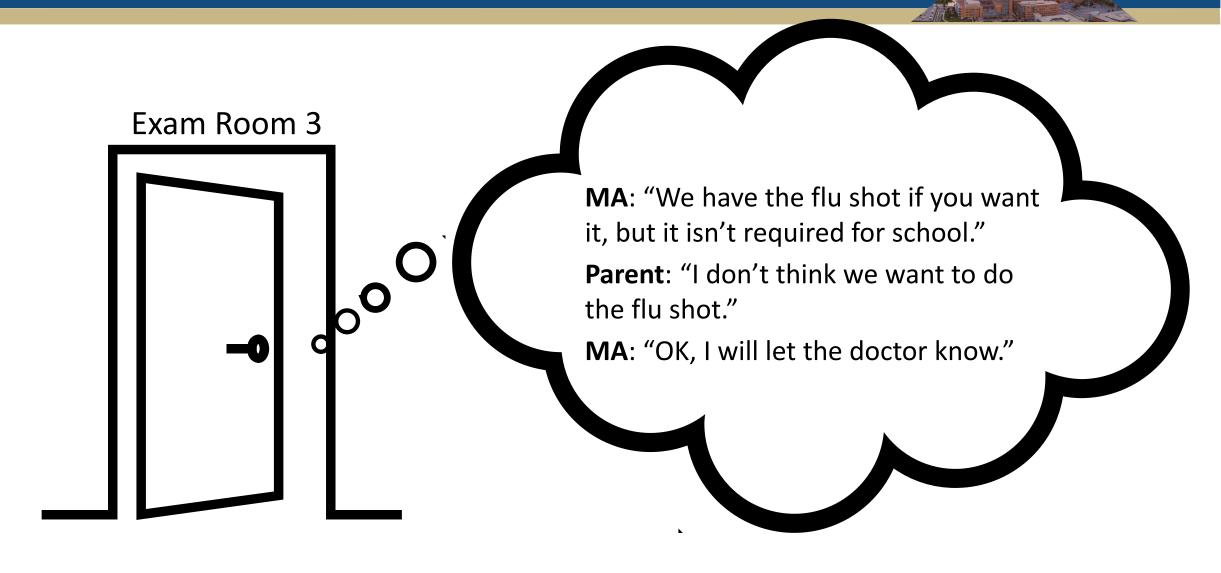
The Importance of Engaging All Team Members

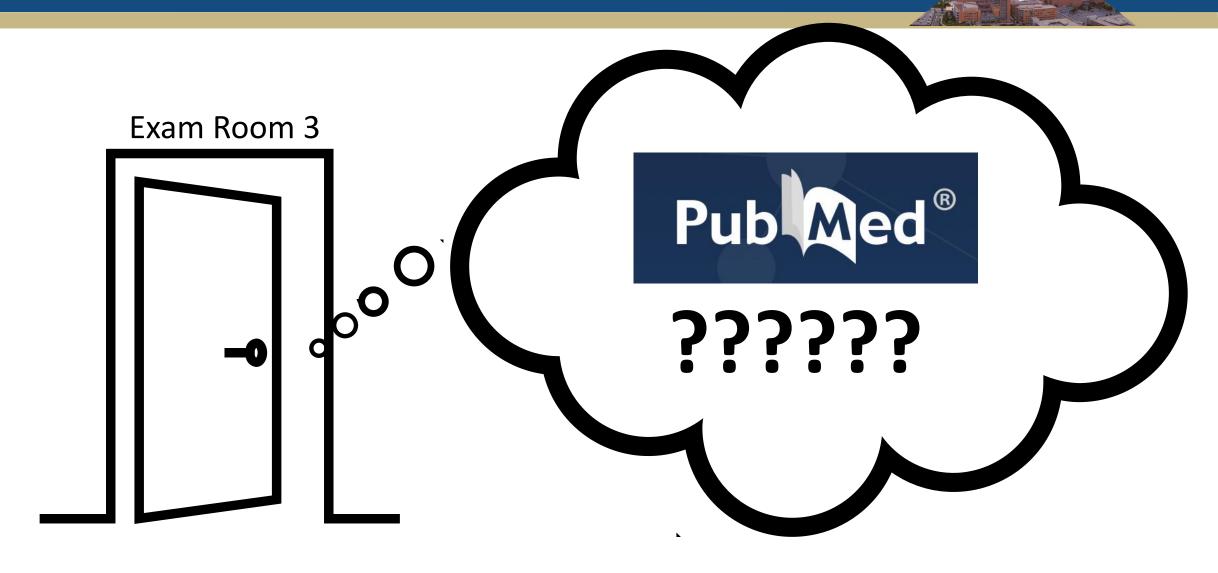
- These team members are already central to vaccine delivery and have frequent contact with families.
- A team-based approach improves quality of care and preventive health outcomes.
- They may offer greater sociocultural concordance with parents than clinicians do.
- As community members, they can also reinforce vaccine messaging beyond the clinic walls.















The Questions

- Do staff communicate before the clinician-parent conversation? If so, what?
- What **opportunities exist** for staff to communicate more effectively about vaccines?
- How does staff communication shape the clinician-parent conversation?
- What interventions could enhance effective vaccine communication from staff?











Adapt and **implement** a physician-based HPV vaccine communication training **(PCOM)** for **the entire care team** in two rural CO practices to <u>improve</u> adolescent HPV vaccine uptake.

PCOM



Entire Primary Care Team















Step 1: Adapt PCOM for rural clinics and the entire care team context

Advisory group

Direct observations/ Process Mapping Nominal group technique

iPRISM



Step 2: Create adapted PCOM training, media, and implementation plan

Graphic design support

Iterative feedback

Partner with organization leadership



Step 3: Implement training, disseminate media, and evaluate outcomes

Deliver trainings

Disseminate media

Pre/post surveys

Implementation tracking

Vaccination rates









Practice 1:

- FQHC on eastern plains
- 2 clinic locations
- 9 clinicians (1 ped), 4 nurses, 10 MAs, 4 front desk staff and 1 supervisor
- 95% VFC eligible

Practice 2:

- Health organization on the western slope
- 2 clinic locations
- 17 clinicians (3 ped), 4 nurses, 14 MAs, 5 front desk staff, 2 supervisors
- 60% VFC eligible



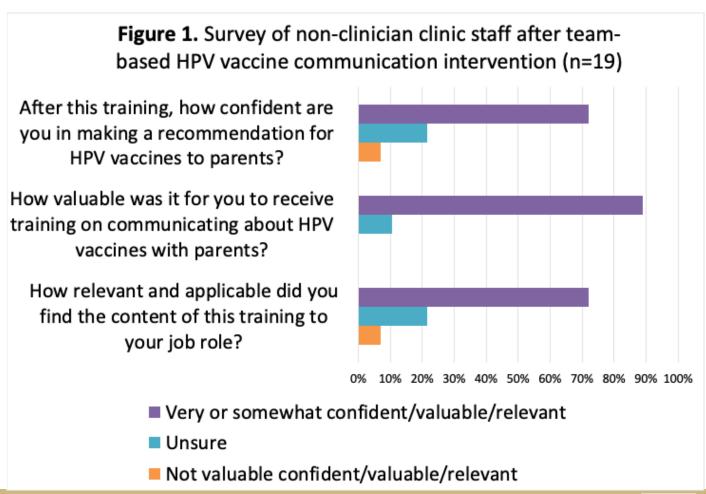


















Takeaways on MA/Nurse Communication

<u>Practice 1:</u> Medical assistants and nurses should have a basic foundation in vaccine communication. Providing them with preferred scripts, rather than full motivational interviewing training, is more important. MAs and nurses are especially valuable for developing patient- and parent-facing materials.

<u>Practice 2:</u> Because MAs and nurses often administer vaccines under standing orders and engage in **full conversations before the clinician enters**, they also need a more **advanced level of vaccine communication training** to navigate these discussions confidently.











Practice Management



Home / Practice Management / Project ECHO









Scenario: MA or RN talking with family about vaccinations at the beginning of the visit



Damian's due for 3 shots today. I am going to get those ready.

Damian's due 3 vaccines. I'll get those ready while you're seeing Dr. Roberts. We just got our flu shots in and we're recommending those for all our patients.





Practice Management









Scenario: Another team member has told you family is hesitant about flu vaccine



Standard 1

"Jamie is due for his flu shot today. Sam mentioned you had some concerns."

Standard 2

"I heard you have some vaccine concerns, and I'd like to get Jamie caught up today. He's due for his flu shot."





Practice Management











But is this the right approach?











ACCORDS

Adult & Child Center for Outcomes Research & Delivery Science

Ergen Family Chair In Pediatric Outcomes Research Pilot Program

Title: Team-Based Vaccine Communication in Pediatric Primary Care

Objective: Describe the roles, barriers, and facilitators for all pediatric primary care team members in delivering high-quality vaccine communication to inform future interventions that engage the entire care team.







<u>Methods</u>

Two community-based pediatric practices in Denver, CO

- Practice 1: Private, serving mostly privately insured patients
- Practice 2: Nonprofit, serving mostly Medicaid patients

Methods

- 1) Conducted 174 direct observations of medical assistants (MAs) and front office staff during the patient rooming process.
- 2) 24 semi-structured interviews of MAs and clinicians



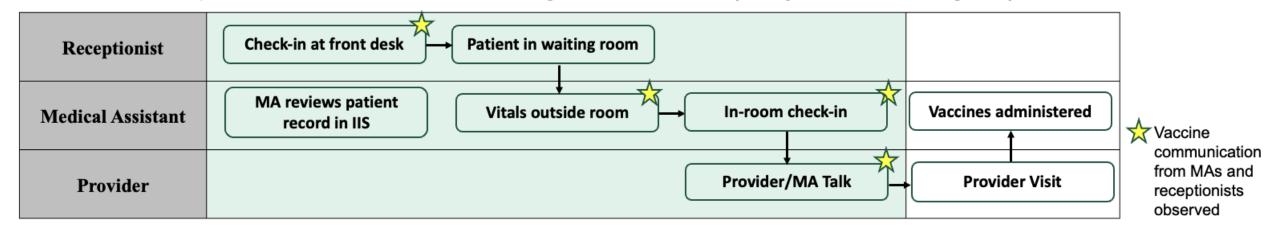




Direct Observations

Trained observers followed staff during patient check-in until the clinician entered the room. 174 encounters were observed across two practices (92 at site 1 and 82 at site 2), including 127 medical assistant-parent interactions and 47 receptionist-parent interactions.

Process Map of Vaccine Communication During Patient Check-in (Study observation in green)









Direct Observations

	Total Encounters	No Influenza Season	Influenza Season	p-
Characteristic	n (%)	n (%)	n (%)	valuea
Total encounters	127	84	43	N/A
Child age (years)				
≤3	45 (35%)	30 (36%)	15 (35%)	
4-6	32 (19%)	19 (23%)	13 (30%)	N/A
7-8	14 (8%)	6 (7%)	8 (19%)	N/A
9-12	21 (12%)	15 (18%)	6 (14%)	
>13	15 (9%)	14 (16%)	1 (2%)	
Any vaccine				
communication				<0.001
Yes	65 (51%)	33 (39%)	32 (74%)	0.001
No	62 (49%)	51 (61%)	11 (26%)	
Vaccines recommended				
Yes	54 (43%)	25 (30%)	29 (67%)	<0.001
No	73 (57%)	59 (70%)	14 (33%)	
Presumptive format usedb				
Yes, for all vaccines	25 (46%)	19 (76%)	6 (21%)	0.004
Yes, for some vaccines	6 (11%)	1 (4%)	5 (17%)	0.004
No	23 (43%)	5 (20%)	18 (62%)	







Direct Observations

Key Observation	Examples	
Variable use of presumptive approach to initiate vaccine communication.	Strong Presumptive: "She is going to get her 2nd hepatitis A vaccine today" Weak Presumptive: "He is due for HPV vaccine today. do you want to do it?" Participatory: "What do you think about the flu shot today?"	
Differences in communication styles for non-influenza and influenza vaccines.	Non-influenza: "She is due for 1 vaccine today - HepA" Influenza: "We have the flu shot if you want."	
MA communication about vaccines was limited to offering vaccines.	Medical assistant: "We are giving out the flu shot if you want it". Parent: "Not today". Medical assistant: "OK."	
MA communication with clinicians about parental vaccine preferences was limited to parental requests only.	Medical assistant to clinician: "Family is not sure about MMR vaccine." or "They don't want a flu shot today."	







Interviews

Finding	Supporting quote
MAs had reported following set	I think we all approach the family the same way. We all offer it, at least
protocol at their clinic	that's—the MAs that trained me when I started, they all offer it at the
	check-ins, so I don't think it's any different – ECP300
While bringing up vaccines is	The process of mentioning that they're due for vaccines is standard in
standard, the language used up to	my training. The exact verbiage is just definitely depends on who it is.
MA	We're not told to say anything in particular. – ECP200
Language used typically learned on	The way she [senior MA] trained me is the way I caught on. APA1
the job	







Interviews

Finding	Supporting quote
Additional training on	Maybe just knowing the correct way to answer questions, I guess I would
communication would improve	say, or the correct way to address their concerns. Sometimes I'll be like—
how MAs do their job	like if I don't know something, I would say, "Oh, I'm not sure of that
	information. You can ask your provider, and they'll know better." I feel like
	maybe a better way of saying that. – ECP4
Variations of presumptive	"Oh, you're due." I'm all done with vitals at this point and I'm just telling
approach was used on "standard"	them, "Your kids are due for the vaccines. You'll still get to go over it with
vaccines	the providers, but if you're interested, we could always do this today." –
	ECP300













Clara Wheeler Trust FBO Cancer Research/ Milheim Foundation Pilot

Title: TeamVax HPV

Objective: Describe the knowledge, attitudes, and practices of pediatric primary care nurses and medical assistants regarding HPV vaccine communication and recommendations.





Approach: A cross-sectional survey of all nurses and medical assistants at the 22 clinics in Kansas and Missouri currently participating in CCOM, assessing knowledge, attitudes, and practices regarding HPV vaccine communication.

Results: Survey closed last week. Response rate of 79% (n= 227/287). Analyzing data.



Clara Wheeler Trust FBO Cancer Research/ Milheim Foundation Pilot







Questions Still to Answer

How does staff communication shape the clinician—parent conversation?

What **interventions** could enhance effective vaccine communication from staff?







Funding Challenges











Opportunities

- Collaboration across health professional fields: community health workers, patient navigators, dental assistants, pharmacists, social workers.
- Training, QI, & capacity-building: equip MAs, nurses, and front-desk staff with concise, evidence-based vaccine communication tools.
- Workflow integration: embed pre-visit messaging into scheduling, reminders, and intake processes, guided by the entire team.
- Culturally tailored approaches: leverage staff who share language, culture, or community ties with families.







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- Steve Waddell (CTE Learning)

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Delwyn Catley

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Ergen Grant: Ergen Family Chair In Pediatric Outcomes Research Pilot Program at the University of Colorado School of Medicine, Department of Pediatrics.

The practices and staff who participated in these projects.





UNIVERSITY OF COLORADO
CHILDREN'S HOSPITAL COLORADO



ACCORDS HIGHLIGHTS: RECENT WORK IN VACCINE COMMUNICATION

SEAN O'LEARY, MD, MPH, FAAP

PROFESSOR OF PEDIATRICS

DIRECTOR, COLORADO CHILDREN'S OUTCOMES NETWORK (COCONET)

DISCLOSURES • I have no financial disclosures

OBJECTIVES: AT THE END OF THIS PRESENTATION, PARTICIPANTS CAN EXPECT TO:

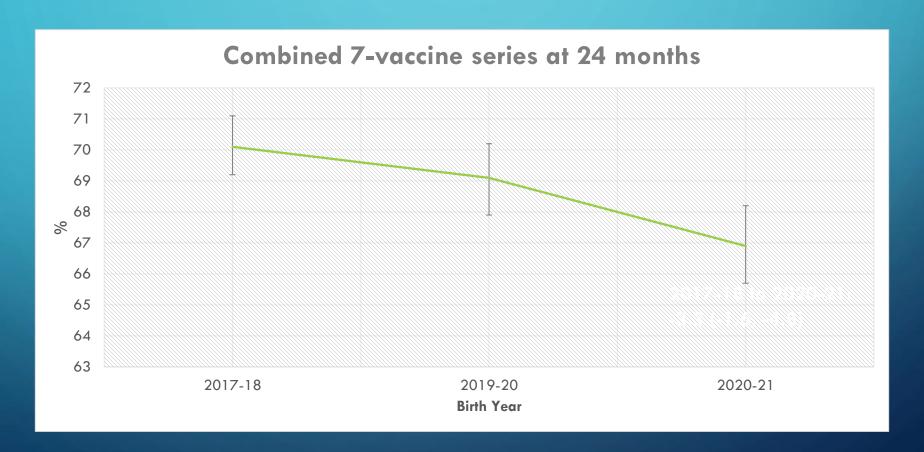
- Be able to describe the current state of research in clinician-parent vaccine communication in primary care settings;
- Be able to explain evidence-based communication strategies clinicians can use in vaccine conversations.

OUTLINE

- Background
- Current, Recent, and Future Clinician Communication Interventions
- Translating the Research into the Community

The Problem

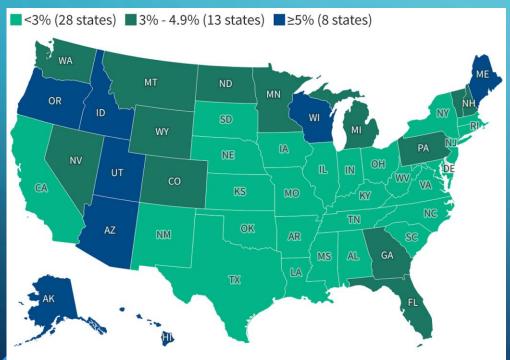
Childhood vaccine coverage levels have declined



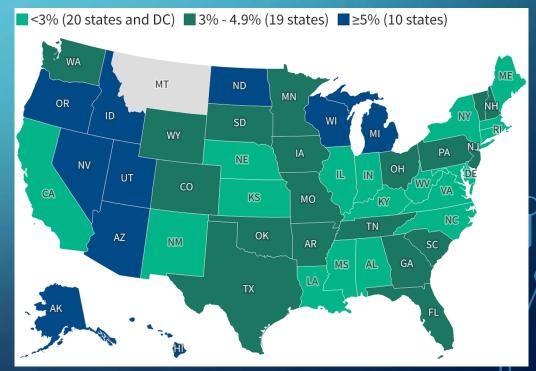
The Problem

The proportion of parents claiming an exemption from required kindergarten vaccines in 2023-24 is at highest level ever (3.3%)

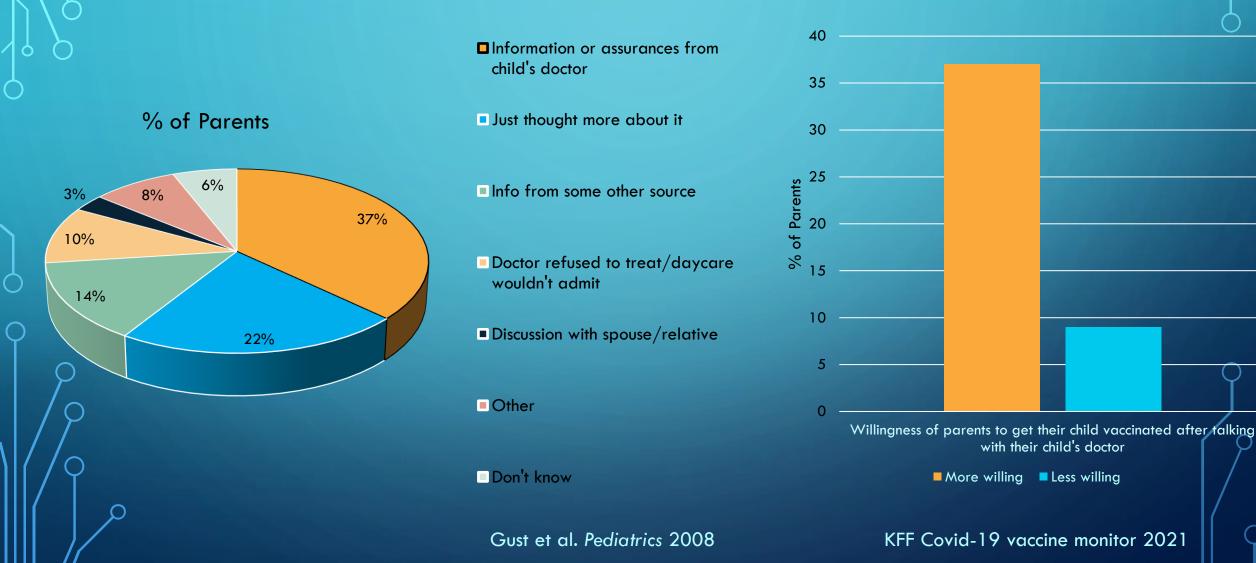
Pre-Pandemic (2019-2020)



Post-Pandemic (2022-2023)



One Potential Solution: Clinician Communication



RECENT VACCINE COMMUNICATION INTERVENTIONS

"THE PHYSICIAN COMMUNICATION STUDY" (PCOM)

JAMA Pediatrics | Original Investigation

Effect of a Health Care Professional Communication Training Intervention on Adolescent Human Papillomavirus Vaccination A Cluster Randomized Clinical Trial

Amanda F. Dempsey, MD, PhD, MPH; Jennifer Pyrznawoski, MSPH; Steven Lockhart, MPH; Juliana Barnard, MA; Elizabeth J. Campagna, MS; Kathleen Garrett, MA; Allison Fisher, MPH; L. Miriam Dickinson, PhD; Sean T. O'Leary, MD, MPH

STRENGTHENING PROVIDER COMMUNICATION FOR INCREASING UPTAKE OF HPV VACCINE

- CDC funded U01
- Cluster RCT Among 16 public and private practices in Colorado
- Multi-component intervention which included training in a presumptive vaccine recommendation and Motivational Interviewing

Presumptive format

- Format that clinicians use to initiate vaccine recommendations that linguistically presuppose that parents will vaccinate
 - "So she's due for several vaccines today." or "Sara is going to get 3 shots today."
 - As opposed to: "How do you feel about vaccines today?" (participatory format)

Motivational Interviewing

- Parent: "I know shots are important and all, but I'm just too worried about side effects."
- Clinician: "You want to be sure these vaccines are safe. I get that. I
 also hear that you appreciate that vaccines are important. Tell me
 more about why you think shots are important."

- Self-efficacy for changing parents' minds about HPV vaccine improved among clinicians
- Time spent in HPV vaccine discussions was the same or decreased from baseline at 4 months after the training in intervention clinics
- 9.5% increase in HPV initiation in intervention versus control practices

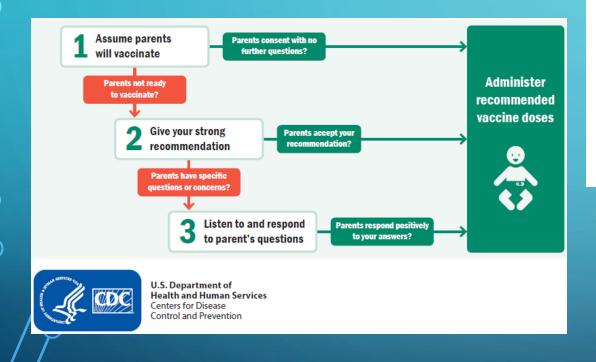
JAMA Pediatrics | Original Investigation

Effect of a Health Care Professional
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PROVIDED EVIDENCE THAT USE OF MI INCREASES VACCINE UPTAKE

Presumptive format and MI for vaccine conversations now recommended by many entities



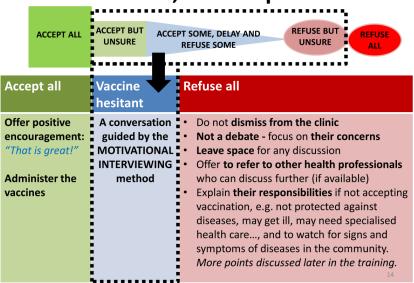
Conversations to build trust in vaccination

A training module for health workers

May 2017



If hesitant, how to proceed?



THE PCOM STUDY LED TO SEVERAL OTHER PROJECTS

- MI4MI: Motivational Interviewing for Maternal Immunization
 - R21AI141822 (NIAID)
- PIVOT with MI: Presumptively Initiating Vaccination and Optimizing Talk with Motivational Interviewing
 - R01HD093628-01A1, with multi-PI Doug Opel (U.Washington) (NICHD)
- PCOM2 The Physician Communication Intervention, Version 2.0
 - R01CA254931-01A1 (NCI)

MI4MI: MOTIVATIONAL INTERVIEWING FOR MATERNAL IMMUNIZATIONS Motivational interviewing for mater development.

Motivational interviewing for maternal Immunizations: Intervention development



Jessica R. Cataldi ^{a,b,*}, Mary E. Fisher ^{a,c}, Sarah E. Brewer ^{a,c}, Christine I. Spina ^a, Russell E. Glasgow ^{a,c}, Cathryn Perreira ^a, Fiona Cochran ^a, Sean T. O'Leary ^{a,b}

- Adult and Child Center for Outcomes Research and Delivery Science, University of Colorado Anschutz Medical Campus and Children's Hospital Colorado, Aurora, CO, United States Department of Pediatrics, University of Colorado Anschutz Medical Campus, Aurora, CO, United States
- Department of Family Medicine, University of Colorado Anschutz Medical Campus, Aurora, CO, United States

• 5 obstetric clinics in Colorado

Vaccine 40 (2022) 7604-7612

- Trained clinicians in vaccine communication, including use of a presumptive format and brief MI skills
- HCPs reported better experiences talking about vaccines and reported they would keep using the skills in the future
 - Mixed methods evaluation using PRISM/RE-AIM

Vaccine communication training using the Brief Motivational Interviewing for Maternal Immunization intervention: A PRISM implementation evaluation

Jessica R. Cataldi^{1,2,4}, Sarah E. Brewer^{1,3}, Cathryn Perreira¹, Mary E. Fisher^{1,3}, Christine I. Spina¹, Fiona Cochran¹, Russell E. Glasgow^{1,3} and Sean T. O'Leary^{1,2}

Translational Behavioral Medicine, 2024, **14**, 285–297 https://doi.org/10.1093/tbm/ibae012 Advance access publication 16 March 2024

Original Research

BMJ Open Motivational Interviewing for Maternal Immunisation (MI4MI) study: a protocol for an implementation study of a clinician vaccine communication intervention for prenatal care settings

Sarah E. Brewer ^{1,2} Jessica R. Cataldi, ³ Mary Fisher, ^{1,2} Russell E. Glasgow, ^{1,2} Kathleen Garrett, ⁴ Sean T. O'Leary^{2,3}

Brewer SE, et al. BMJ Open 2020;10:e040226. doi:10.1136/bmjopen-2020-040226

PCOM2 - THE PHYSICIAN COMMUNICATION INTERVENTION, VERSION 2.0

- Non-inferiority cluster-randomized trial comparing the original PCOM intervention of in-person vaccine communication training to a virtual version of the same training
 - Primary outcomes: initiation and completion of HPV vaccine series by age 13
- 22 pediatric and family medicine practices in Kansas
- "SMART" trial design, with randomization of virtual practices if they don't demonstrate mastery to either further training or not
- PRISM/REAIM eval
- All practices have completed trainings, study outcomes next year

PIVOT WITH MI: PRESUMPTIVELY INITIATING VACCINATION AND OPTIMIZING TALK WITH MOTIVATIONAL INTERVIEWING

- Cluster RCT among 24 practices in Colorado and Washington
- Intervention clinic clinicians were trained in:
 - Use of presumptive format with all parents
 - Pivot to MI for those parents who continue to refuse or express concerns
- Tested the impact of this tiered clinician vaccine communication strategy on childhood vaccine uptake by age 19 months

Tiered clinician communication strategy

Start the vaccine conversation with parents by presuming that shots will be given at the visit

Example: "Today we're going to do 2 shots."

Parent refuses vaccines or expresses concerns

Example: "I'm not sure.
I'm thinking I want to wait
on vaccines today."

Parent agrees to vaccines
(with or without
subsequent questions)

Example: "OK."

Use MI

Vaccinate

Motivational Interviewing skills

MI Skill	Rationale					
Open Ended Questions	helps explore and understand a parent's stance on vaccination					
Affirmation	improves parent engagement in an open discussion by helping them feel supported, appreciated, and understood					
Reflection	encourages partnerships, deepens rapport, and allows a parent to understand themselves and their motivations on a deeper level					
Autonomy Support	enhances a parent's sense of control and makes them feel more at ease with the conversation					
Ask Permission to Share	puts parents in a less defensive posture and makes them more receptive to the information you'd like to share					

Primary population

- Parents of infants <2 months with negative vaccine attitudes (defined as score of ≥2 on validated screening survey: short form of the Parent Attitudes about Childhood Vaccines, or PACV)
- 4 questions: 2 or more hesitant responses is threshold for inclusion

No.	Item	Hesitant Response
1	Have you ever delayed having your child get a shot	Yes
	for reasons other than illness or allergy?	
2	How concerned are you that a shot might not	Very concerned, somewhat concerned, or
	prevent the disease?	not sure
3	Overall, how hesitant about childhood shots would	Very hesitant, somewhat hesitant, or not
	you consider yourself to be?	sure
4	I trust the information I receive about shots.	Strongly disagree, disagree, or not sure
	2	 Have you ever delayed having your child get a shot for reasons other than illness or allergy? How concerned are you that a shot might not prevent the disease? Overall, how hesitant about childhood shots would you consider yourself to be?

Primary outcome

Receipt of 8 routine childhood vaccines (Hep B, Rota, DTaP, Hib, Pneumococcal, IPV, MMR, and Varicella) by 19 months

Days under-immunized

- Captures both vaccine receipt and whether received on time
- Calculated by comparing the date a dose was received to when it should have been received using child's DOB and vaccine schedule
 - Range: 0 to 2830 days late

Percent days under-immunized

Sum the days late for each dose and divide this by the maximum number of days a child could be late if they had received no doses (2380), then convert to 0-100 scale

Zero days under-immunized

Proportion of children who receive all doses of the 8 vaccines within the accepted age range for each dose, accounting for the minimum acceptable age and interval for each dose

Participation rates in PIVOT with MI curriculum among intervention clinicians

Table 2
Clinician Participation in the PIVOT with MI Training by Practice and Overall (n = 134).

Clinic	Number of Clinicians	Viewed Video Module		Attended or Viewed Baseline		Attended or Viewed 1st Refresher		Attended or Viewed 2nd refresher	
		n	%	n	%	n	%	n	%
WA01	25	22	88 %	25	100 %	21	84 %	19	76 %
WA02	10	10	100 %	10	100 %	10	100 %	10	100 %
WA03	3	3	100 %	3	100 %	3	100 %	3	100 %
WA04	8	8	100 %	7	88 %	6	75 %	6	75 %
WA05	14	13	93 %	13	93 %	12	86 %	10	71 %
WA06	13	11	85 %	12	92 %	12	92 %	10	77 %
CO01	7	7	100 %	7	100 %	7	100 %	6	86 %
CO02	12	10	83 %	10	83 %	6	50 %	5	42 %
CO03	15	13	87 %	14	93 %	11	73 %	12	80 %
CO04	11	11	100 %	11	100 %	11	100 %	11	100 %
CO05	2	2	100 %	2	100 %	2	100 %	2	100 %
CO06	14	13	93 %	11	79 %	9	64 %	9	64 %
Total	134	123	92 %	125	93 %	110	82 %	103	77 %

Abbreviations: PIVOT with MI, Presumptively Initiating Vaccination and Optimizing Talk with Motivational Interviewing; WA, denotes practice based in Washington; CO, denotes practice based in Colorado.

Overall results

Intervention vs. Control

Percent Days Under-Immunized

1.06 (0.69, 1.63)

Adjusted Incidence Rate Ratio (95% CI)

Zero Days Under-Immunized Adjusted Odds Ratio (95% CI)

1.45 (0.69, 3.04)

Variation by state: multivariable results

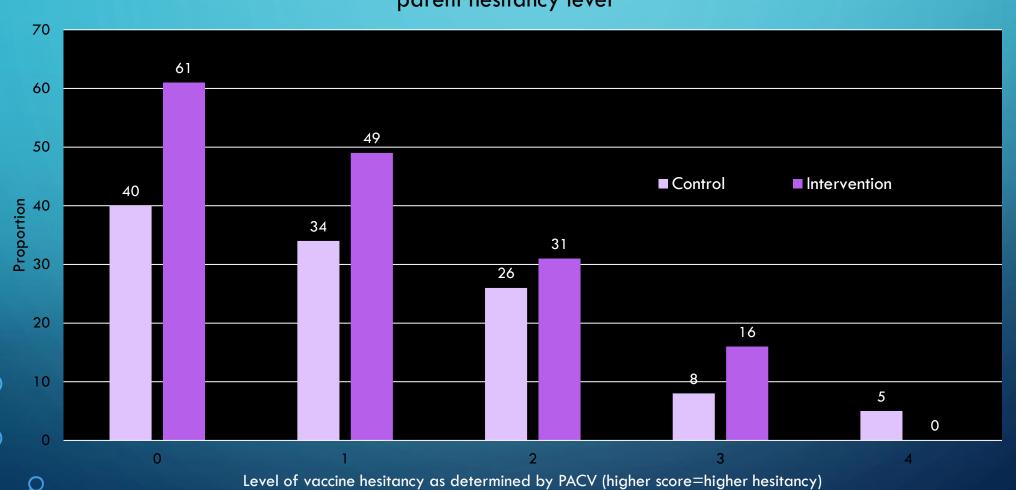
Odds of a child of parents with negative vaccine attitudes in intervention (vs. control) arm having zero days under-immunized after controlling for within-clinic correlation and parent demographic confounders



1.45 (95% Cl: 0.69, 3.04) 2.47 (95% Cl: 1.09, 5.59) 0.79 (95% Cl: 0.24, 2.57)

Variation across parent hesitancy levels

Proportion of children in each study arm with zero days under-immunized by parent hesitancy level



PIVOT with MI study summary

- No effect of intervention among parents with negative vaccine attitudes
 - Intraclass correlation among practices was much higher (0.09) than power calculation and prior studies (0.02)
- The effect of the intervention appeared to vary by state and parent hesitancy level
 - Significantly improved odds of a child having zero days under-immunized in Washington State if they received the intervention

PIVOT WITH MI: PUBLICATIONS SO FAR

"It's Like 1998 Again": Why Parents Still Refuse and Delay Vaccines

Global Pediatric Health
Volume 8: 1–7
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sagepub.com/journals-permissions
DOI: 10.1177/2333794X211042331
journals.sagepub.com/home/gph

Jiana L. Ugale¹, Heather Spielvogle, PhD¹, Christine Spina, MSPH², Cathryn Perreira, MA², Ben Katz¹, Barbara Pahud, MD, MPH³, Amanda F. Dempsey, MD, PhD^{2,4}, Jeffrey D. Robinson, PhD⁵, Kathleen Garrett, MA², Sean T. O'Leary, MD, MPH^{2,4}, and Douglas J. Opel, MD, MPH^{1,6}

Parent Attitudes Towards Childhood Vaccines After the Onset of SARS-CoV-2 in the United States

Douglas J. Opel, MD, MPH; Anna Furniss, MS; Chuan Zhou, PhD; John D. Rice, PhD; Heather Spielvogle, PhD; Christine Spina, MSPH; Cathryn Perreira, MA; Jessica Giang, BS; Nicolas Dundas, MPH; Amanda Dempsey, MD, PhD[#]; Barbara Pahud, MD^{\$}; Jeffrey Robinson, PhD; Sean O'Leary, MD, MPH

Acad Pediatr. 2022 Jul 1;22(8):1407-1413.

BMJ Open 'Presumptively Initiating Vaccines and Optimizing Talk with Motivational Interviewing' (PIVOT with MI) trial: a protocol for a cluster randomised controlled trial of a clinician vaccine communication intervention

Douglas J Opel o 1.2 Jeffrey D Robinson, Heather Spielvogle, Christine Spina, Kathleen Garrett, Amanda F Dempsey, 5.6 Cathryn Perreira, 5.5 Miriam Dickinson, 5.5 Chuan Zhou, 2.2 Barbara Pahud, James A Taylor, Sean T O'Leary, 5.6 Chuan Zhou, 1.2 Barbara Pahud, James A Taylor, Sean T O'Leary, 5.6 Chuan Zhou, 5.7 Chuan Zhou, 5.7 Chuan Zhou, 5.7 Chuan Zhou, 5.8 Chuan

Opel DJ, et al. BMJ Open 2020;10:e039299. doi:10.1136/bmjopen-2020-039299

Development of PIVOT with MI: A motivational Interviewing-Based vaccine communication training for pediatric clinicians



Sean T. O'Leary ^{a,b,*}, Christine I. Spina ^b, Heather Spielvogle ^e, Jeffrey D. Robinson ^c, Kathleen Garrett ^b, Cathryn Perreira ^b, Barbara Pahud ^f, Amanda F. Dempsey ^{a,b}, Douglas J. Opel ^{d,e}

Vaccine 41 (2023) 1760-1767

Original Investigation | Pediatrics

Tiered Clinician Vaccine Communication Strategy to Improve Childhood Vaccine Uptake A Cluster Randomized Clinical Trial

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NEXT STEPS: The Problem and Opportunity

- PROBLEM: Unclear implications for clinical practice from the PIVOT with MI study
 - Difficult to separate out the effect of the presumptive strategy alone
 - Do these strategies work differently in particular populations?

OPPORTUNITY:

- Clinicians need evidence-based strategies for improving childhood vaccine uptake
- Understand the effect of presumptive format alone on childhood vaccine uptake and determine the incremental value of adding MI
- National scope to better account for state-level variation

PIVOT +/- MI

PIVOT +/- MI Trial: Planned and accepted by PROS (AAP's PBRN)

Parents with negative vaccine attitudes enrolled at PROS practices

Presumptive only

Presumptive + MI

Usual care

Childhood vaccine uptake at 2 years

- 3-arm cluster RCT to assess effectiveness of presumptive and MI components
- Would be first study to assess effectiveness of presumptive format alone in childhood vaccine context

Training curriculum

- 5 interactive training modules:
 - Introductory (10 min)
 - Baseline 1 and 2 (15 min each)
 - Refresher 1 (15 min)
 - Refresher 2 (15 min)
- Year 1
 - Add presumptive only curricula; revise existing PIVOT with MI curricula
 - Pilot with clinicians and parents to assess acceptability, understandability
- MOC Part IV credit upon completion for physicians; CME/CNE for other clinicians

Prior to start of parent enrollment

6 months after start of parent enrollment

12 months after start of parent enrollment

Methods

- Design: 3-arm cluster RCT
 - Presumptive-only arm: <u>clinicians use presumptive</u> format to initiate vaccine conversation with all parents, <u>then usual care if parents have concerns</u>
 - Presumptive + MI arm: <u>clinicians use presumptive format</u> to initiate vaccine conversation with all parents, <u>then MI if parents have concerns</u>
 - Usual care arm: clinicians practice usual care
- Sample size: 60 total practices (20 practices per arm)
 - 10% effect size in % zero days under-immunized with 80% power assuming ICC of 0.05 and 50 participants per practice (3000 total participants)
 - Exclusion criteria: participated in PIVOT with MI, PROS vaccine or MI study in last 2 years, or <50% of clinicians in a practice agree to participate

Primary study population

- Inclusion criteria:
 - English and Spanish-speaking parents
 - Have an infant ≤ 2 months old receiving health supervision
 - Have negative vaccine attitudes (score ≥2 on the validated Parent Attitudes about Childhood Vaccines (PACV) survey)
 - PACV incorporated into check-in paperwork handed out by clinic staff to all parents at 2-month visit (or earlier); includes PACV and demographic Qs; intro to survey has elements of consent and clear statement that this is research
 - PIVOT with MI: about 1 in 10 parents screened had PACV score ≥2

Primary outcome

- Receipt of routine childhood vaccines (Hep B, Rota, DTaP, Hib, Pneumococcal, IPV, MMR, and Varicella) by 19 months (using EMR)
 - Secondary outcomes: receipt of influenza, COVID-19

Days under-immunized

- Captures <u>both receipt of vaccine dose</u>
 <u>and whether dose received on time</u>
- Calculated by comparing date a dose was received to when it should have been received using child's DOB and ACIP schedule
- Range: 0 to 2830 days late

Up-to-date

- Captures <u>receipt of vaccine dose</u>
- Calculated by summing how many of the 23 doses of 8 childhood vaccines the child received by 19 months

PIVOT +/- MI: NEXT STEPS

• LOI to PCORI in September

TRANSLATING THE RESEARCH INTO QI IN THE COMMUNITY

KITE (KINDERGARTEN TRAINING AND ENGAGEMENT) PROJECT

- Falling kindergarten vaccination rates in Colorado
- CDPHE funded, July 2024-June 2025
- 2 arms
 - A series of online vaccine communication trainings
 - Rapid Boot Camp Translation
- Online trainings: 33 enrolled practices with 155 participating clinicians
- Rapid BCTs: 3 separate BCTs (Western Slope, Steamboat, Denver metro), 7
 practices, 2 school districts and 4 counties

AAP ECHO SERIES

- Funded by AAP
- Series of 90 minute ECHO trainings on vaccine communication with pediatricians across the US
- July, August, September (this Wednesday)

AAP CLINICAL REPORT

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care





DEDICATED TO THE HEALTH OF ALL CHILDREN®

Strategies for Improving Vaccine Communication and Uptake

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TABLE ON VACCINE SAFETY SURVEILLANCE SYSTEMS

NA, not applicable.

TABLE 3 Examples of Major Vaccine Safety Surveillance Systems in the United States						
Surveillance System	Data Source	Population Under Surveillance	Management	Characteristics	Strengths	Limitations
Vaccine Adverse Event Reporting System (VAERS)	Online reporting system; Health care providers and vaccine manufacturers are required by law to report certain events after vaccination	Entire United States	FDA, CDC	"Nation's early warning system"; Passive, spontaneous reporting; Hypothesis-generating; 85% to 90% of reports are nonserious; Serious reports are followed up	Accepts reports from anyone; All data are publicly available	Generally cannot assess causality; Prone to both overreporting and underreporting
Vaccine Safety Datalink (VSD)	Electronic health record data from 13 large health care organizations across the United States	12.5 million	CDC, in collaboration with integrated health care organizations	Active surveillance system; Hypothesis-testing; Can conduct medical record review to verify outcomes; Multiple methods developed to conduct valid, accurate vaccine safety studies	Can estimate potential causal associations; Capable of real-time monitoring; High-quality data	Limited ability to assess adverse events with delayed or insidious onset; May not be able to control for all confounders; Represents an insured population
Biologics Effectiveness and Safety System (BEST)	Large-scale claims data, electronic health records (EHRs), and linked claims-EHR databases	100 million	FDA	Enables rapid queries to detect or evaluate adverse events as well as studies to answer specific safety questions for vaccines	Very large population; Possible to study the safety of vaccines in subpopulations with preexisting conditions or in pregnant persons	Limited evaluation of pediatric vaccines to date; Statistical signals must be further evaluated through rigorous epidemiologic study
Clinical Immunization Safety Assessment (CISA)	Generally medical records from clinicians	NA	CDC, in collaboration with medical research centers	In-depth clinical, pathophysiological, and vaccinology expertise to assess causal relationships between vaccines and adverse events	US health care providers with a complex vaccine safety question about a specific patient may contact CISA to request a consult	Limited in scope

TABLE: MYTHS/MISCONCEPTIONS

CLAIMS FACTS

"Natural" methods of enhancing immunity, such as contracting the disease and breastfeeding, are better than vaccinations.

Vaccinations are the safest way to achieve immunity; having immunity the "natural way" means being sick with a potentially very serious infectious disease. Immunity from a preventive vaccine provides protection against disease when a person is exposed to it in the future. That immunity is usually similar to what is acquired from natural infection, although several doses of a vaccine may have to be administered for a child to develop an adequate immune response. While breastfeeding has many benefits, including immunologic, it does not provide anywhere near the same level of protection from vaccine-preventable diseases as vaccines.

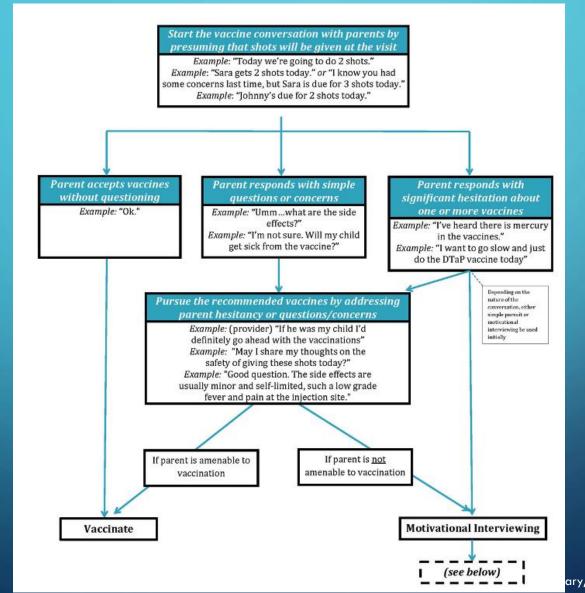
Giving multiple vaccines at the same time causes an "overload" of the Vaccination does not overburden a child's immune system; the immune system.

Vaccination does not overburden a child's immune system; the recommended vaccines use only a small portion of the immune system's "memory." Although the number of unique vaccines administered has risen over recent decades, the number of antigens administered has decreased because of advances in science and manufacturing. The National Academy of Medicine (NAM) has concluded that there is no evidence that the immunization schedule is unsafe.

Vaccines are ineffective.

Vaccines have spared millions of people the effects of devastating diseases.

FIGURE ON VACCINE COMMUNICATION



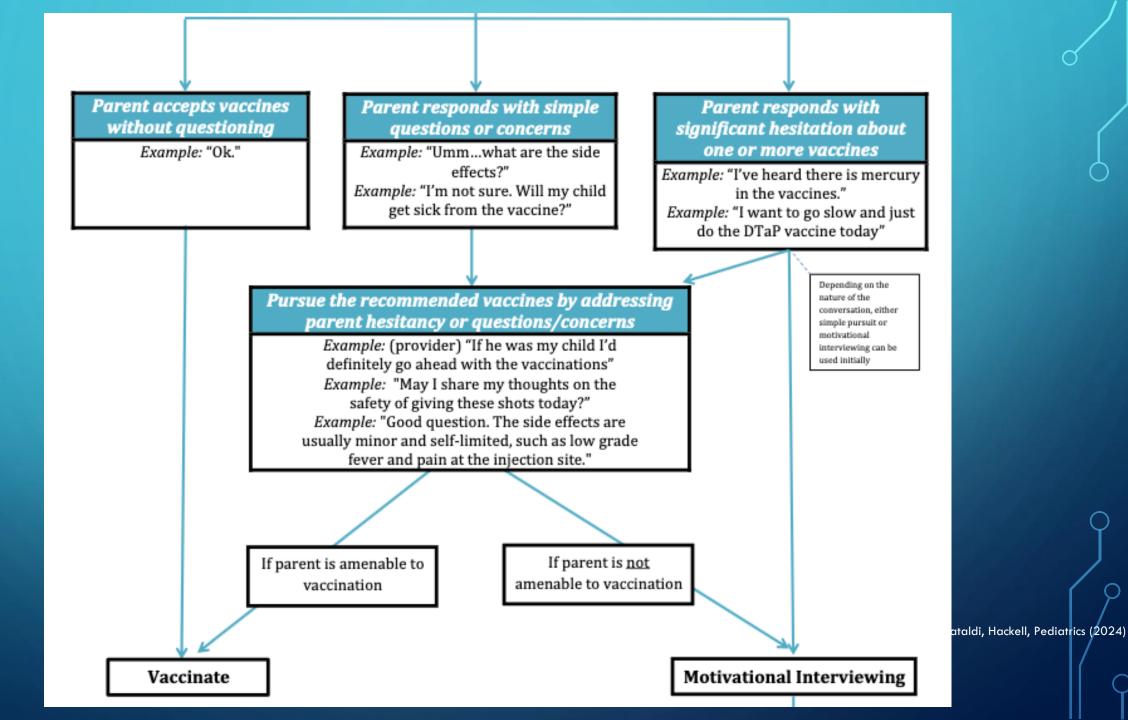
Start the vaccine conversation with parents by presuming that shots will be given at the visit

Example: "Today we're going to do 2 shots."

Example: "Sara gets 2 shots today." or "I know you had

some concerns last time, but Sara is due for 3 shots today."

Example: "Johnny's due for 2 shots today."



Presumptive Pearls

Tone and body language matter. Don't make the presumptive format sound like a question. When delivering the presumptive format, make eye contact, square shoulders, and don't be distracted. Know what the child is due for before walking in the room.

You can use a presumptive format at a visit even though a parent has voiced resistance at a previous visit. (example: "I know we talked about vaccines last time, but I'd like to get her caught up today. She's due for 3 shots.")

Medical assistants and other staff who communicate with parents about vaccines should use the presumptive format too. (Example: "Sara is due for 3 shots today. I'll go ahead and get those ready.")

You can still use a presumptive format after a medical assistant (or other staff) tells you the parent is hesitant.

Don't undermine the presumptive format by reverting quickly to a participatory format. After using the presumptive format, allow parents time to respond. Our natural inclination is to fill the silence. Try to resist this. (Avoid: "So, we're going to do 3 shots today, or... is that what you want to do?")

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