PAS 2019 Meeting Press Kit

Welcome to the Pediatric Academic Societies (PAS) 2019 Meeting. The PAS 2019 Meeting brings together more than 8,000 pediatricians, research scientists, health care providers, and policy makers from around the world united by a common mission: to improve the health and well-being of children worldwide.

This document contains information about the following:

- Press room
- Social media & program guide
- Press releases

If you have any questions, please contact the PAS press room at (832) 371-6239 or PAS2019@piercom.com.

Press Room

Location

Conference room # 304

Onsite Contacts

Hunter Dodson (512) 914-6745 PAS2019@piercom.com

Amber Fraley (832) 371-6239 Amber.Fraley@pasmeeting.com

WiFi

pasm2019 (WiFi name & password)

Hours

- Saturday, April 27: 7:30 a.m. 5 p.m.
- Sunday, April 28: 8 a.m. 5 p.m.
- Monday, April 29: 8 a.m. 5 p.m.
- Tuesday, April 30: 8 a.m. 2:45 p.m.

Press Badges

You will receive a QR code to scan and print your press badge onsite. A photo ID is required. While at the meeting, journalists must:

- Wear or display their official PAS 2019 Meeting press badge at all times while on site
- Not exchange, loan, or borrow PAS 2019 Meeting press badges; individuals who do so will be required to leave the meeting
- Follow the same camera/recording policy as regular PAS 2019 Meeting attendees; attendees
 may not use cameras, including mobile phone and tablet cameras, or any other audio and/or
 video recording devices in meeting session rooms, on the Exhibit Hall floor, or in poster/oral
 presentations

About the Pediatric Academic Societies Meeting

The Pediatric Academic Societies (PAS) Meeting brings together thousands of pediatricians and other health care providers united by a common mission: to improve the health and well-being of children worldwide. This international gathering includes pediatric researchers, leaders in pediatric academics, clinical care providers and community practitioners. Presentations cover issues of interest to generalists as well as topics critical to a wide array of specialty and sub-specialty areas. The PAS Meeting will be the premier North American scholarly child health meeting. The PAS Meeting is produced through a partnership of four pediatric organizations that are leaders in the advancement of pediatric research and child advocacy: American Pediatric Society, Society for Pediatric Research, Academic Pediatric Association and American Academy of Pediatrics.

Website

www.pas-meeting.org

Social Media

- Hashtag: #PAS2019
- Twitter @PASMeeting
- Facebook PASMeeting
- Instagram <u>PASMeeting</u>

Logo



Pediatric Academic Societies Meeting

April 24 – May 1, 2019 | Baltimore, MD

April 24-26 • Pre-conference Events | April 27-30 • PAS 2019 Meeting | May 1 • Post-conference Events

Online Program Guide

- Presenters
- General Information
- Baltimore Convention Center Map

Press Releases



PAS Media Contact:

PAS2019@piercom.com

Pediatric Academic Societies 2019 Meeting Features the Latest Advancements in Pediatric Research

Thousands of pediatric researchers and health care providers will convene in Baltimore on April 27-30.

Dr. Mona Hanna-Attisha, the pediatrician and public health advocate who exposed the Flint water crisis, will deliver the keynote address.

BALTIMORE, April 16, 2019 – The Pediatric Academic Societies (PAS) 2019 Meeting, the largest and most prestigious pediatric research meeting in the world, will feature the latest advancements in child health research that address today's most pressing issues in pediatrics. This international gathering, taking place on April 24 – May 1 in Baltimore, brings together thousands of pediatric researchers, leaders in pediatric academics, clinical care providers and community practitioners. The meeting will feature over 4,000 scientific presentations.

Mona Hanna-Attisha, MD, MPH, founder and director of the Michigan State University and Hurley Children's Hospital Pediatric Public Health Initiative, will deliver the keynote address during the Opening General Session on Saturday, April 27. Joshua Sharfstein, MD, vice dean for Public Health Practice and Community Engagement at Johns Hopkins Bloomberg School of Public Health, will interview Dr. Hanna-Attisha as part of the opening session.

Dr. Hanna-Attisha exposed the Flint, Mich. water crisis and wrote about her experiences in the fight for justice in the book, *What the Eyes Don't See*. Her research revealed how children in Flint were exposed to lead. Dr. Hanna-Attisha courageously publicized the water crisis in Flint despite facing a brutal backlash.

"We are excited to welcome esteemed researchers and physicians from around the world to Baltimore to share the latest discoveries in pediatric research," said Thomas P. Shanley, MD, the 2019 PAS Program Chair. "The meeting features an expansive conglomeration of scientific minds, whose contributions broaden attendants' perspectives with respect to pediatric medicine."

F. Bruder Stapleton, MD, senior vice president of Scientific Affairs at Seattle Children's Research Institute and professor at the University of Washington, will receive the Joseph W. St. Geme, Jr. Leadership Award, which recognizes a pediatrician who is a role model for others to emulate as a clinician, an educator and/or an investigator.

The PAS is grateful for the continued support of its sponsors, including its Platinum Sponsor, <u>Mead Johnson</u>, and Gold Sponsors, <u>Sobi</u> and <u>Mallinckrodt</u>.

The PAS 2019 Meeting will be held at the Baltimore Convention Center (1 W Pratt St). The event features new scientific session formats designated as "PAS Labs," which include a basic-clinical-translational roundtable, debate pro-con discussion and a panel discussion. Pre-conference events will begin on April 24 and run through April 26, with post-conference events held on May 1.

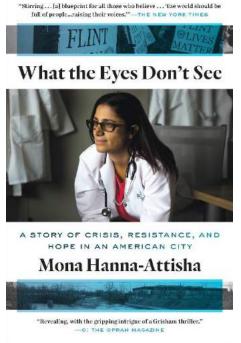
Attendees can track sessions, speakers, abstracts, topic areas and more through the online <u>program</u> <u>guide</u> and PAS Meeting <u>mobile app</u>. For more information about the PAS 2019 Meeting and to register, please visit <u>www.pas-meeting.org</u>.

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About the Pediatric Academic Societies Meeting

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Research Press Releases

- The 2020 Census: Why It Is Important for Children's Health, and the Challenge of the Young Child Undercount
- <u>Electronic Vapor Product Usage and Alcohol- & Drug-Related Risk Behaviors in U.S. Adolescents:</u>
 Data from the 2017 National Youth Risk Behavior Survey
- <u>Electronic Vapor Product Usage and Sexual Risk Behavior in U.S. Adolescents: Data from the 2017 National Youth Risk Behavior Survey</u>
- <u>US Pediatric Residents' Experience Treating Gun Injuries & Views on Approaches to Reduce Gun</u> Injury
- Evolution of the Firearm Epidemic in the United States, 1990 2016
- Firearm Child Access Prevention Laws and Firearm Death Rates among Children, 1991-2016
- Gun Access and Adolescent Health: Safety in Numbers?
- Changes in Opioid Prescriptions for Medicaid-enrolled Children, 2012-2016
- Geographic Variation in Pediatric Deaths from Prescription and Illicit Opioid Poisonings, 1999-2016
- Impact of Prescription Drug Monitoring Programs on Pediatric Opioid Exposures
- Rapid Decrease in Length of Stay and Postnatal Use of Opiate Medication Using "Eat, Sleep and Console" in a Single Center NICU
- Improving Outcomes for Pregnancies Impacted by Opioid Use Disorder: The Massachusetts Experience
- Current Primary Care Practices and Experiences with the Delivery of HPV Vaccine
- <u>Pediatric Practitioners Report Using Strategies to Improve HPV Vaccination, yet Barriers Persist:</u>
 Results from the National AAP Pediatric Research in Office Settings (PROS) Network
- <u>Trends in Human Papillomavirus Vaccination Uptake in Girls and Boys in the United States: Real-</u> World Evidence From 2003 To 2016
- Impact of Text Message Reminders on HPV Vaccine Series Completion
- The State of Vaccine Safety Science: Systematic Reviews of the Evidence
- Vaccine Hesitancy and Influenza Beliefs Among Parents of Children Requiring a 2nd Dose of Influenza Vaccine in a Season: An AAP Pediatric Research in Office Settings (PROS) Study
- Barriers to Vaccination in Immunocompromised Children
- The Resurgence of the Wet Nurse
- Clinical Utility of rWGS in the Evaluation of Neonatal Seizures
- Monoclonal Antibodies from Children with Kawasaki Disease (KD) Recognize Hepacivirus
 Peptides
- Clonal expansion within circulating plasmblast populations lends support for an infectious disease etiology of Kawasaki disease
- Validation of the Pediatric Sequential Organ Failure Assessment Score and Evaluation of Sepsis-3
 Definitions in the Pediatric Emergency Department

PAS2019@piercom.com

PAS Press Office (April 24 – May 1, 2019): (832) 371-6239

Plenary to Address the Importance of the 2020 US Census and the Challenge of the Young Child Undercount

Participants will understand why it matters that 5 percent of children under the age of five were missed in the 2010 Census.

The Census not only determines how over \$675 billion in federal funds are allocated, but it is used to draw district lines and to give voice to those who live in the U.S.

BALTIMORE, April 27, 2019 – An estimated 5 percent of all children under the age of five were missed in the 2010 U.S. Census. A plenary during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u> in Baltimore will address the impact this significant undercount had, how the Census relates to health care resources and the role pediatricians, clinics, hospitals and communities can play to help make sure all children are counted in the 2020 Census.

"Young children under the age of five are among the groups who are most likely to be undercounted by the Census which can greatly impact the resources that are available to educate, feed, house and care for them," said Judy Aschner, MD, Chairperson of the Federation of Pediatric Organizations (FOPO); Professor and the Marvin I. Gottlieb, M.D., Ph.D. Chair, Department of Pediatrics Hackensack Meridian Health; Physician-in-Chief, Joseph M. Sanzari Children's Hospital.

Dr. Aschner continued, "This plenary is not only to educate the pediatric community about the impact that the Census has on our children, but a launch pad for actionable steps and initiatives pediatricians can take to inform our communities."

The Decennial Census not only determines how over \$675 billion in federal funds are allocated, but it is used to draw district lines and to give voice to those who live in the U.S. If individuals are not counted, they, their families and their communities have a lot to lose. The plenary will educate the audience on the importance of the Census and why it is critical to count everyone, in particular, young children. It will set the stage for an in-depth discussion on the topic and action items for the pediatric health care community.

There are numerous programs that determine specifically where the \$675 billion of funding is distributed, including Medicaid and the Children's Health Insurance Program (CHIP), Supplemental

Nutrition Assistance Program (SNAP), the foster care system, school lunch programs and Title I funding to schools in low income communities and IDEA special education funding for children with disabilities.

Additionally, the data and findings derived from the decennial Census has more than just monetary implications. The Census data is used by businesses, governments and civic organizations to inform decision-making as well as by investigators for epidemiologic, health services, environmental, and population-based research.

Dr. Aschner concluded, "As trusted voices in the communities we serve, the Census Bureau needs the help of all pediatricians to help educate parents on the importance of completing the census survey and including all family members, including young children."

The plenary will be introduced and moderated by Dr. Aschner. The session will feature presentations by Dr. Ron Jarmin of the U.S. Census Bureau, Lisa Hamilton of the Annie E. Casey Foundation and Arturo Vargas of the NALEO Educational Fund.

Session affiliations include: American Academy of Pediatrics (AAP), AAP Section of Neonatal Perinatal Pediatrics, American Pediatric Society (APS), APS Day, Federation of Pediatric Organizations and Society for Pediatric Research.

The plenary entitled "The 2020 Census: Why It Is Important for Children's Health, and the Challenge of the Young Child Undercount" will be held on Sunday, April 28 at 8 a.m. EDT in the Baltimore Convention Center Ballroom II. Reporters interested in an interview with Dr. Aschner should contact PAS2019@piercom.com.

The <u>PAS 2019 Meeting</u> brings together thousands of pediatricians and other health care providers to improve the health and well-being of children worldwide. For more information about the PAS 2019 Meeting, please visit <u>www.pas-meeting.org</u>.

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New Studies Examine Teen Vaping Association with Sexual Risk Behavior and Drug Usage

BALTIMORE, April 27, 2019 – Electronic vapor product (EVP) usage among U.S. high school students is associated with a higher likelihood of engagement in nine out of 10 sexual risk behaviors, according to a new study which analyzed data from the 2017 National Youth Risk Behavior Survey. A related study found that adolescent EVP use is associated with a higher likelihood of engagement in several substance-use behaviors. Findings from the studies will be presented during the Pediatric Academic Societies (PAS) 2019 Meeting, taking place on April 24 – May 1 in Baltimore.

According to the Centers for Disease Control, EVPs remain the most popular tobacco product among U.S. high school students, and current EVP usage in this population increased nonlinearly since 2016.

"Vaping has reached epidemic proportions among U.S. youth," said Andrew Adesman, MD, senior investigator of the study. "Our study not only expanded upon previous studies examining teen vaping and drug use, but we also investigated novel associations between vaping and various sexual risk behaviors. In this analysis of a nationally representative sample of U.S. teens, we found that vaping was associated with engagement in sexual risk behaviors such as early sexual debut and alcohol use before sex."

In 2017, 6.5% of U.S. high school students used only EVPs in the past 30 days, 2.8% used only cigarettes, and 6.5% used both products. EVP use only and dual use were associated with a greater likelihood of engagement in nine of 10 sexual risk behaviors compared to non-users. Prevalence proportions did not significantly differ between EVP-only users and dual-users for seven of 10 behaviors. Past 30-day EVP use at any frequency was also associated with a higher likelihood of engaging for nearly all risk behaviors examined. Occasional EVP users were similarly likely as frequent and daily users to engage in all 10 risk behaviors.

Past research has shown that high school EVP users are more likely to engage in certain risk behaviors. However, the association of current EVP usage and EVP usage frequency with specific alcohol and drug-related risk behaviors has not been studied using a recent national sample.

The study found that cigarette, EVP and dual use were associated with greater likelihood of engaging in 12 of 13 substance-use behaviors compared to non-users. Dual-users were more likely than EVP-only users to engage in 12 of 13 behaviors. Past 30-day EVP use at any frequency was also associated with

higher likelihood of engaging in nearly all risk behaviors examined. Occasional EVP users were similarly likely as frequent and daily users to engage in 11 of 13 behaviors.

"We found that vaping was associated with a wide variety of substance-use risk behaviors, ranging from prescription pain medicine misuse to binge drinking," said Devyn Rigsby, principal investigator of the study. "Somewhat surprisingly, for the majority of substance-use risk behaviors examined, we found no difference in the likelihood of engagement in these behaviors when comparing teens who vaped occasionally, frequently or daily."

Dr. Adesman added, "Although vaping was strongly associated with many substance-use and sexual risk behaviors, we were surprised that, in general, teens who vape only occasionally were no less likely to engage in these risk behaviors than teens who vape frequently. Initiatives to reduce youth substance use and youth engagement in risky sexual behaviors should include efforts to reduce teen vaping at all frequency levels."

Rigsby will present findings from "Electronic Vapor Product Usage and Sexual Risk Behavior in U.S. Adolescents: Data from the 2017 National Youth Risk Behavior Survey" on Saturday, April 27 at 1:15 p.m. EDT. Findings from "Electronic Vapor Product Usage and Alcohol- & Drug-Related Risk Behaviors in U.S. Adolescents: Data from the 2017 National Youth Risk Behavior Survey" will be presented on Saturday, April 27 at 5:45 p.m. EDT. Reporters interested in an interview with Dr. Adesman or Ms. Rigsby should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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Abstract: Electronic Vapor Product Usage and Sexual Risk Behavior in U.S. Adolescents: Data from the 2017 National Youth Risk Behavior Survey

Background: According to the 2017 National Youth Tobacco Survey, electronic vapor products (EVPs) remain the most popular tobacco product among U.S. high school (HS) students, and current EVP usage in this population increased nonlinearly since 2016. Prior studies have linked adolescent EVP usage with greater likelihood of engagement in other risk behaviors. However, there is a lack of current research regarding the association of EVP usage and EVP usage frequency with specific sexual risk behaviors.

Objective: To examine, in a nationally representative sample of U.S. HS students, how current cigarette, EVP, and dual usage as well as EVP usage frequency are related to specific sexual risk behaviors in U.S. adolescents.

Design/Methods: Respondents (N=12,667) of the 2017 National Youth Risk Behavior Survey (YRBS) were categorized by previous 30-day EVP and cigarette usage into one of four groups: nonuse, cigarette only, EVP only, or dual use. Separately, respondents were categorized by 30-day EVP usage frequency: 0, 1-9, 10-29, or 30 days. Ten sexual risk behaviors were identified as dependent variables. Adjusted prevalence ratios (aPRs) were calculated using multivariable modified Poisson regression to determine associations between sexual risk behaviors and both current EVP/cigarette usage and current EVP usage frequency among U.S. adolescents (Tables 1 & 2). Linear contrasts were conducted to compare aPRs across usage categories.

Results: In 2017, 6.5% of U.S. HS students used only EVPs in the past 30 days, 2.8% used only cigarettes, and 6.5% used both products. EVP use only and dual use were associated with greater likelihood of engagement in 9 of 10 sexual risk behaviors compared to non-users. Prevalence proportions did not significantly differ between EVP-only users and dual-users for 7 of 10 behaviors. Past 30-day EVP use at any frequency was also associated with higher likelihood of engaging for nearly all risk behaviors examined. Occasional EVP users were similarly likely as frequent and daily users to engage in all 10 risk behaviors.

Conclusions: EVP usage among U.S. HS students, with or without concurrent cigarette use, is associated with a higher likelihood of engagement in 9 of 10 sexual risk behaviors. Prevalence of most risk behaviors does not differ between either EVP-only users and dual-users or between occasional EVP users and frequent or daily EVP users.

Authors: Devyn Rigsby, Sarah Keim, Ruth Milanaik, Andrew Adesman

Tables:

Table 1: Prevalence of Sexual Risk Behaviors by Cigarette and Electronic Vapor Product Use among High School Students in the United States, 2017 National YRBS (N=12,667)

	Cigarette and EVP Usage in Past 30 Days								
	N	lonuse	Cigare	ette Use Only	EVP	Use Only	Dual Use		
Sexual Risk Behavior	(n =	= 10,716)	(1	n = 337)	(n	1 = 867)	(1	n = 747)	
Scaudi Risk Beliavioi	%	aPR† (95% CI)	%	aPR† (95% CI)	%	aPR† (95% CI)	%	aPR† (95% CI)	
Ever Engaged in Sexual Intercourse	29.2	Ref	80.5	2.22 (2.00 – 2.46)	71.7	2.15 (1.97 – 2.34)	83.0	2.36 (2.15 – 2.59)	
Engaged in Sexual Intercourse In Last 3 Months	20.6	Ref	55.9	2.07 (1.76 – 2.44)	53.4	2.20 (1.98 – 2.44)	66.9 ^b	2.59 (2.31 – 2.90)	
Sexual Debut at Age <13	2.0	Ref	6.2	2.68 (1.46 – 4.89)	6.6	3.01 (2.03 – 4.46)	11.8	3.76 (2.26 – 6.25)	
Sexual Debut at Age <16	17.7	Ref	58.1	2.95 (2.50 – 3.49)	47.2	2.48 (2.18 – 2.82)	63.2	3.09 (2.71 – 3.53)	
≥4 Lifetime Sexual Partners	5.2	Ref	32.4	4.64 (3.55 – 6.05)	19.0 a	2.93 (2.20 – 3.91)	37.8 °	5.31 (4.07 – 6.93)	
Did Not Use Condom During Last Sexual Intercourse	43.6	Ref	64.3	1.44 (1.25 – 1.66)	41.0 a	.96 (.81 – 1.14)	58.3 °	1.30 (1.12 – 1.51)	
Drank Alcohol or Used Drugs Before Most Recent Sexual Intercourse	9.1	Ref	31.0	3.03 (2.11 – 4.36)	25.6	2.64 (2.07 – 3.35)	41.2 °	3.62 (2.75 – 4.77)	
Ever Physically Forced into Sexual Intercourse	5.0	Ref	19.6	2.72 (2.05 – 3.61)	9.8	1.92 (1.44 – 2.56)	20.6	2.75 (2.09 – 3.60)	
Experienced Sexual Violence in Last 12 Months	7.1	Ref	18.0	1.92 (1.44 – 2.57)	13.8	2.08 (1.66 – 2.60)	23.7	2.52 (1.94 – 3.28)	
Experienced Sexual Dating Violence in Last 12 Months	5.2	Ref	8.3	1.14 (.72 – 1.80)	8.9	1.69 (1.11 – 2.56)	14.3	1.79 (1.20 – 2.67)	

[†] Adjusted for grade, sex, sexual orientation, current smokeless tobacco use, current cigar use, race and ethnicity a Linear contrast significant (P < .05) for EVP Use Only vs. Cigarette Use Only b Linear contrast significant (P < .05) for Dual Use vs. Cigarette Use Only

^c Linear contrast significant (P < .05) for Dual Use vs. EVP Use Only

Table 2: Prevalence of Sexual Risk Behaviors by Current Electronic Vapor Product Use Frequency among High School Students in the United States, 2017 National YRBS (N=12,667)

		Current EVP Use Frequency									
		se of EVPs in ast 30 Days Occasional Use of EVP (1-9 days in last 30 days)		EVP (10	ent Use of 0-29 days in 30 days)	Daily Use of EVP (30 days in last 30 days)					
Sexual Risk Behavior	(n =	= 11,178)	(n :	= 1,104)	(n	= 289)	(n = 273)				
Sendar High Benavior	%	aPR† (95% CI)	%	aPR† (95% CI)	%	aPR† (95% CI)	%	aPR† (95% CI)			
Ever Engaged in Sexual Intercourse	31.1	Ref	73.9	1.86 (1.71 – 2.04)	80.9	2.04 (1.78 – 2.34)	82.6 °	1.63 (1.44 – 1.84)			
Engaged in Sexual Intercourse In Last 3 Months	22.0	Ref	55.4	1.94 (1.77 – 2.12)	66.0	2.35 (1.95 – 2.82)	67.8	1.90 (1.55 – 2.33)			
Sexual Debut at Age <13	2.2	Ref	8.1	2.79 (1.97 – 3.95)	5.8	1.65 (.89 – 3.06)	17.7	2.67 (1.33 – 5.38)			
Sexual Debut at Age <16	19.2	Ref	51.9	2.09 (1.88 – 2.33)	56.6	2.22 (1.81 – 2.72)	62.8	1.86 (1.53 – 2.25)			
≥4 Lifetime Sexual Partners	6.3	Ref	23.5	2.28 (1.87 – 2.79)	27.7	2.68 (2.08 – 3.45)	45.0	2.63 (2.07 – 3.36)			
Did Not Use Condom During Last Sexual Intercourse	45.2	Ref	50.5	1.00 (.89 – 1.13)	44.0	.89 (.71 – 1.11)	57.0	1.05 (.85 – 1.31)			
Drank Alcohol or Used Drugs Before Most Recent Sexual Intercourse	11.9	Ref	29.3	2.09 (1.64 – 2.66)	39.0	2.51 (1.95 – 3.24)	43.2	1.89 (1.40 – 2.56)			
Ever Physically Forced into Sexual Intercourse	5.6	Ref	15.2	1.75 (1.37 – 2.23)	12.7	1.39 (.89 – 2.18)	20.7	1.62 (.99 – 2.67)			
Experienced Sexual Violence in Last 12 Months	7.6	Ref	18.6	2.04 (1.60 – 2.60)	16.3	1.88 (1.47 – 2.41)	23.8	2.40 (1.60 – 3.60)			
Experienced Sexual Dating Violence in Last 12 Months	5.4	Ref	11.6	1.78 (1.24 – 2.54)	9.4	1.33 (.71 – 2.50)	17.0	2.23 (1.14 – 4.35)			

[†] Adjusted for grade, sex, sexual orientation, current smokeless tobacco use, current cigar use, current cigarette use, race and ethnicity

^a Linear contrast significant (P < .05) for Frequent EVP Use vs. Occasional EVP Use

^b Linear contrast significant (P < .05) for Daily EVP Use vs. Occasional EVP Use

^c Linear contrast significant (P < .05) for Daily EVP Use vs. Frequent EVP Use

Abstract: Electronic Vapor Product Usage and Alcohol- & Drug-Related Risk Behaviors in U.S. Adolescents: Data from the 2017 National Youth Risk Behavior Survey

Background: According to the Centers for Disease Control, electronic vapor products (EVPs) remained the most utilized tobacco product among U.S. high school (HS) students in 2017, and EVP usage in this population increased from 2016. Past research has shown that HS EVP users are more likely to engage in certain risk behaviors. However, association of current EVP usage and EVP usage frequency with specific alcohol- & drug-related risk behaviors has not been studied using a recent national sample.

Objective: To assess how current EVP, cigarette, and dual-product usage as well as EVP usage frequency are related to alcohol- & drug-related risk behaviors in a nationally representative sample of U.S. HS students.

Design/Methods: Respondents (N=12,667) of the 2017 National Youth Risk Behavior Survey (YRBS) were categorized by previous 30-day EVP and cigarette usage into one of four groups: nonuse, cigarette only, EVP only, or dual use. Separately, respondents were categorized by 30-day EVP usage frequency: 0, 1-9, 10-29, or 30 days. Thirteen substance-use behaviors were selected as dependent variables. Adjusted prevalence ratios (aPRs) were calculated using multivariable modified Poisson regression to determine associations between outcome behaviors and both current EVP/cigarette usage and EVP usage frequency (Tables 1 & 2). Linear contrasts were conducted to compare aPRs across usage categories.

Results: In 2017, 6.5% of U.S. HS students used only EVPs in the past 30 days, 2.8% used only cigarettes, and 6.5% used both products. Cigarette, EVP, and dual use were associated with greater likelihood of engaging in 12 of 13 substance-use behaviors compared to non-users. Dual-users were more likely than EVP-only users to engage in 12 of 13 behaviors. Past 30-day EVP use at any frequency was also associated with higher likelihood of engaging in nearly all risk behaviors examined. Occasional EVP users were similarly likely as frequent and daily users to engage in 11 of 13 behaviors.

Conclusions: Adolescent EVP use, with or without concurrent cigarette smoking, is associated with a higher likelihood of engagement in several substance-use behaviors. Prevalence of risk behaviors is generally greater for dual users than EVP-only users, but prevalence proportions do not significantly differ among occasional, frequent, or daily EVP users for most behaviors.

Authors: Dev	yn Rigsby, S	Sarah Kei	im, And	lrew Ad	desman
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Tables:

Table 1: Prevalence of Drug and Alcohol Risk Behaviors by Cigarette and Electronic Vapor Product Use among High School Students in the United States, 2017 National YRBS (N=12,667)

		Cigarette and EVP Usage in Past 30 Days									
	N	Nonuse Cigarette Use Only			EVP	Use Only	Dual Use				
Substance Use Risk	(n =	= 10,716)	(1	n = 337)	(n	= 867)	(1	n = 747)			
Behavior	%	aPR† (95% CI)	%	aPR† (95% CI)	%	aPR† (95% CI)	%	aPR† (95% CI)			
Marijuana Use in Past 30 Days	9.5	Ref	58.7	5.49 (4.52 – 6.68)	49.6	4.97 (4.31 – 5.73)	70.7 b, c	6.74 (5.88 – 7.73)			
Lifetime Marijuana Use	22.8	Ref	86.8	3.45 (3.03 – 3.92)	74.2	3.14 (2.84 – 3.48)	88.7 °	3.68 (3.24 – 4.18)			
Lifetime Synthetic Marijuana Use	2.3	Ref	24.9	8.96 (5.87 – 13.69)	13.3 a	5.31 (4.31 – 6.53)	37.5 °	11.93 (8.76 – 16.25)			
Lifetime Prescription Pain Medicine Use	8.1	Ref	38.7	4.13 (3.25 – 5.23)	23.7 a	2.84 (2.32 – 3.49)	55.6 b, c	5.66 (4.74 – 6.76)			
Lifetime Cocaine Use	1.2	Ref	19.6	11.96 (8.06 – 17.74)	9.1 ^a	6.24 (4.56 – 8.53)	31.4 °	16.60 (11.94 – 23.07)			
Lifetime Methamphetamine Use	.7	Ref	6.0	6.45 (3.20 – 12.99)	1.7	1.77 (.82 – 3.81)	17.7 b, c	13.73 (7.90 – 23.87)			
Lifetime Ecstasy (MDMA) Use	1.0	Ref	16.8	11.59 (6.76 – 19.88)	7.6 ^a	5.61 (3.87 – 8.12)	24.7 °	14.72 (9.52 – 22.78)			
Lifetime Hallucinogen Use	1.9	Ref	28.7	10.80 (6.92 – 16.87)	14.5 a	6.42 (4.70 – 8.77)	38.2 b, c	13.53 (9.12 – 20.06)			
Lifetime Alcohol Consumption	49.8	Ref	97.0	1.74 (1.61 – 1.87)	93.4	1.79 (1.70 – 1.89)	98.0	1.77 (1.66 – 1.90)			
First Consumed Alcohol at Age <13	10.9	Ref	38.6	3.27 (2.64 – 4.07)	24.8 a	2.13 (1.78 – 2.56)	38.1 °	2.77 (2.23 – 3.45)			
Consumed Alcohol in Past 30 Days	17.1	Ref	69.4	3.25 (2.87 – 3.68)	70.8	3.76 (3.36 – 4.21)	91.7 b, c	4.33 (3.86 – 4.85)			
Engaged in Binge Drinking in Past 30 Days	5.5	Ref	41.5	5.15 (4.05 – 6.54)	39.3	6.06 (5.05 – 7.28)	68.8 b, c	8.27 (6.64 – 10.31)			
Drove a Car While Drunk in Past 30 Days	1.7	Ref	13.9	5.34 (2.70 – 10.57)	10.1	4.65 (3.15 – 6.86)	28.2 °	8.98 (6.06 – 13.31)			

[†] Adjusted for grade, sex, current smokeless tobacco use, current cigar use, race and ethnicity

^a Linear contrast significant (P < .05) for EVP Use Only vs. Cigarette Use Only

^b Linear contrast significant (P < .05) for Dual Use vs. Cigarette Use Only

^c Linear contrast significant (P < .05) for Dual Use vs. EVP Use Only

Table 2: Prevalence of Drug and Alcohol Risk Behaviors by Current Electronic Vapor Product Use Frequency among High School Students in the United States, 2017 National YRBS (N=12,667)

		Current EVP Use Frequency									
		No Use of EVPs in Last 30 Days Occasional Use of EVP (1-9 days in last 30 days)		1-9 days in	EVP (1	ent Use of 0-29 days in 30 days)	Daily Use of EVP (30 days in last 30 days)				
Substance Use Risk	(n =	= 11,178)	(n :	= 1,104)	(n	= 289)	(n	= 273)			
Behavior	%	aPR† (95% CI)	%	aPR† (95% CI)	%	aPR† (95% CI)	%	aPR† (95% CI)			
Marijuana Use in Past 30 Days	11.4	Ref	55.1	3.78 (3.28 – 4.35)	68.3	4.59 (3.72 – 5.66)	67.5 °	3.42 (2.70 – 4.33)			
Lifetime Marijuana Use	25.2	Ref	77.5	2.55 (2.29 – 2.84)	87.2 ª	2.94 (2.59 – 3.33)	89.2 °	2.40 (2.06 – 2.81)			
Lifetime Synthetic Marijuana Use	3.1	Ref	21.6	3.99 (3.21 – 4.96)	25.9	4.41 (3.05 – 6.39)	41.5	4.00 (2.80 – 5.70)			
Lifetime Prescription Pain Medicine Use	9.2	Ref	34.9	2.60 (2.24 – 3.01)	39.4	3.00 (2.42 – 3.72)	58.6	3.08 (2.45 – 3.88)			
Lifetime Cocaine Use	1.9	Ref	15.7	4.33 (3.28 – 5.72)	21.3	5.58 (3.53 – 8.81)	39.8	5.50 (3.29 – 9.20)			
Lifetime Methamphetamine Use	.9	Ref	7.2	3.15 (1.96 – 5.08)	5.4	1.68 (.76 – 3.70)	27.6	4.54 (2.22 – 9.29)			
Lifetime Ecstasy (MDMA) Use	1.6	Ref	12.4	3.57 (2.50 – 5.10)	15.6	4.10 (2.78 – 6.04)	34.4	4.19 (2.60 – 6.74)			
Lifetime Hallucinogen Use	2.8	Ref	21.8	4.04 (3.06 – 5.34)	25.9	4.52 (3.18 – 6.43)	46.6	4.85 (3.63 – 6.48)			
Lifetime Alcohol Consumption	51.5	Ref	95.7	1.64 (1.55 – 1.74)	94.3	1.63 (1.51 – 1.77)	97.9 ^ь	1.51 (1.40 – 1.62)			
First Consumed Alcohol At Age <13	12.0	Ref	29.0	1.86 (1.52 – 2.29)	29.9	1.84 (1.40 – 2.43)	42.5	1.70 (1.25 – 2.30)			
Consumed Alcohol in Past 30 Days	19.0	Ref	79.7	3.25 (2.84 – 3.73)	82.1	3.37 (2.95 – 3.85)	87.2 °	2.82 (2.33 – 3.42)			
Engaged in Binge Drinking in Past 30 Days	6.7	Ref	48.1	4.96 (4.06 – 6.06)	58.7	5.63 (4.50 – 7.04)	65.1	4.18 (2.80 – 6.23)			
Drove a Car While Drunk in Past 30 Days	2.3	Ref	14.5	3.73 (2.81 – 4.95)	21.2	4.98 (3.09 – 8.05)	32.9	3.32 (2.17 – 5.08)			

[†] Adjusted for grade, sex, current smokeless tobacco use, current cigar use, current cigarette use, race and ethnicity

^a Linear contrast significant (P < .05) for Frequent EVP Use vs. Occasional EVP Use

^b Linear contrast significant (P < .05) for Daily EVP Use vs. Occasional EVP Use

^c Linear contrast significant (P < .05) for Daily EVP Use vs. Frequent EVP Use

PAS2019@piercom.com

PAS Press Office (April 24 – May 1, 2019): (832) 371-6239

New AAP Research Examines US Pediatric Residents' Experience Treating Gun Injuries and Views on Approaches to Reduce Gun Injury

Recent tragic instances of suicide, urban violence and mass shootings have generated renewed concern among pediatricians regarding firearm violence.

In attitudes toward public policy, high portions agree with policies such as universal background checks (95%) or banning assault weapons (90%), while few, (14%), support allowing teachers to carry guns in K-

BALTIMORE, April 27, 2019 – A new American Academy of Pediatrics (AAP) study examines U.S. pediatric residents' experience during training in caring for children injured by guns, and their attitudes toward counseling families and public policies to address gun injury. Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

"Recent, tragic increases in deaths of children, teens and young adults from suicide, urban violence and mass shootings have generated renewed concern among pediatricians regarding firearm violence," said Lynn Olson, PhD, one of the authors of the study. "What we found in this study, is that clinicians' experience treating gun injuries begins very early in their training."

The study found that by completion of residency, seven of 10 pediatricians have direct experience with gun injuries. While personal background and geographic region shape attitudes on best approaches to reduce gun violence, large majorities believe pediatricians have a role in counseling families and support policies aimed at reducing gun injury for children.

The results indicated 69% of residents report caring for gun injuries during training (median injuries=3). In their own background, 30% grew up in a home with a gun. In attitudes toward counseling, 90% agree (strongly agree or somewhat agree combined) pediatricians should ask about the presence of guns in the home, 96% agree pediatricians should ask parents to unload/lock guns; and 44% agree pediatricians should ask parents to remove guns from the home. In attitudes toward public policy, high portions agree with policies such as universal background checks (95%) or banning assault weapons (90%), while few, (14%), support allowing teachers to carry guns in K-12.

Data was drawn from the 2018 AAP Annual Survey of Graduating Residents, a random sample across all U.S. programs (response=49%; analytic sample=480). Respondents were asked if they cared for children injured by guns during training. Using a 5-point scale (strongly agree to strongly disagree), respondents also expressed their attitudes toward counseling by pediatricians (three items) and public policies that may reduce firearm injuries (six items). Chi-Square examined variations in attitudes by: experience treating gun injury, gender, region of residency training, and whether guns in their home growing up.

No attitude variations were found by whether the resident had treated gun injury. Few variations were found by gender. Support of public policies varied most by region of the country where trained and firearms in home growing up. For example, 98% in the Northeast, 93% in the West, 88% in the Midwest versus 80% in the South support banning assault weapons (p<.001); 93% of those who grew up without a gun in the home versus 81% of those who did, support banning assault weapons (p<.001).

Dr. Olson will present findings from "U.S. Pediatric Residents' Experience Treating Gun Injuries and Views on Approaches to Reduce Gun Injury" on Monday, April 29 at 4 p.m. EDT. Reporters interested in an interview with Dr. Olson should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

The <u>PAS 2019 Meeting</u> brings together thousands of pediatricians and other health care providers to improve the health and well-being of children worldwide. For more information about the PAS 2019 Meeting, please visit <u>www.pas-meeting.org</u>.

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About the Pediatric Academic Societies Meeting

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Abstract: U.S. Pediatric Residents' Experience Treating Gun Injuries and Views on Approaches to Reduce Gun Injury

Background: Recent tragic instances of mass shootings and urban violence have generated renewed concern among pediatricians regarding firearm violence. Experience as a clinician with gun injuries begins in training.

Objective: Examine pediatric residents' experience during training in caring for children injured by guns, and attitudes toward 1) counseling families and 2) public policies to address gun injury.

Design/Methods: Data drawn from the 2018 AAP Annual Survey of Graduating Residents, a random sample across all U.S. programs (response=49%; analytic sample=480). Respondents were asked if they cared for children injured by guns during training. Using a 5-point scale (strongly agree to strongly disagree), respondents also expressed their attitudes toward counseling by pediatricians (three items) and public policies that may reduce firearm injuries (six items). Chi-Square examined variations in attitudes by: experience treating gun injury, gender, region of residency training, and whether guns in their home growing up.

Results: 69% of residents report caring for gun injuries during training (median injuries=3). In their own background 30% grew up in a home with a gun. In attitudes toward counseling (Figure 1): 90% agree (strongly agree or somewhat agree combined) pediatricians should ask about the presence of guns in the home, 96% agree pediatricians should ask parents to unload/lock guns; and 44% agree pediatricians should ask parents to remove guns from the home. In attitudes toward public policy (Figure 2) high portions agree with policies such as universal background checks (95%) or banning assault weapons (90%), while few, (14%), support allowing teachers to carry guns in K-12. No attitude variations were found by whether the resident had treated gun injury. Few variations were found by gender. Support of public policies varied most by region of the country where trained and firearms in home growing up. For example, 98% in the Northeast, 93% in the West, 88% in the Midwest versus 80% in the South support banning assault weapons (p<.001); 93% of those who grew up without a gun in the home versus 81% of those who did, support banning assault weapons (p<.001).

Conclusions: By completion of residency, seven of 10 pediatricians have direct experience with gun injuries. While personal background and geographic region shape attitudes on best approaches to reduce gun violence, large majorities believe pediatricians have a role in counseling families and support policies aimed at reducing gun injury for children.

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Tables/Figures:

Figure 1: Attitudes Toward Counseling on Gun Safety

FIGURE 1: ATTITUDES TOWARD PEDIATRICIANS' COUNSELING FAMILIES ON GUN SAFETY: % AGREEING AMONG PEDIATRIC RESIDENTS 2018, N=480

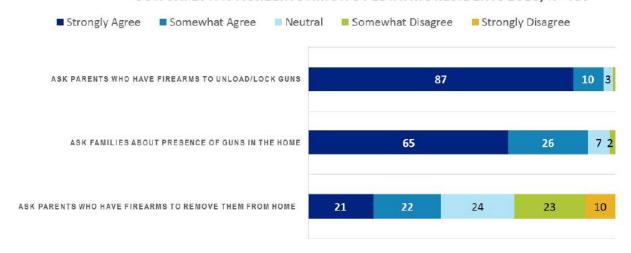
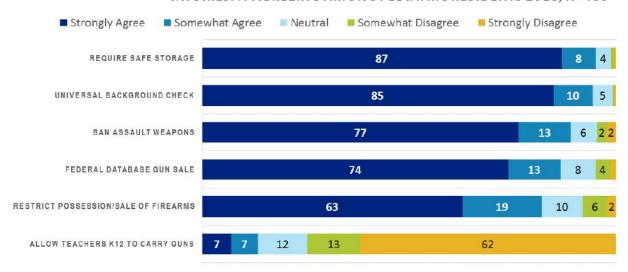


Figure 2: Attitudes Toward Public Policies to Address Gun Violence

FIGURE 2: ATTITUDES TOWARD POLICIES THAT MAY REDUCE FIREARM INJURIES: % AGREEING AMONG PEDIATRIC RESIDENTS 2018, N=480



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New Research Examines the Evolution of the Firearm Epidemic in the US

Public health approaches to firearm violence need to consider underlying demographic trends and differences by intent.

A related study evaluating child access prevention firearm laws and pediatric firearm fatalities found the passage of negligence laws across all states has the potential to reduce firearm fatalities in children up to age 17.

BALTIMORE, April 27, 2019 – High rates of firearm fatalities in the U.S. are principally due to elevated rates of homicide among black, non-Hispanic and Hispanic males age 20-40 years and suicide among white, non-Hispanic males age 70-85+, according to a new study. Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

Each day, over 100 firearm deaths occur in the U.S. In 2016, there were over 3,000 pediatric deaths (0-19 years). Over the past decade, total fatalities from firearms increased by 25% and are now the leading cause of death in young adults (15-24 years). Few studies have explored the interaction of urbanicity, sex and race/ethnicity in firearm fatalities across the spectrum of age.

Researchers analyzed firearm fatalities over a 26-year period as reported in the Centers for Disease Control's Web-based Injury Statistics Query and Reporting System. There were 897,026 firearm fatalities in the U.S., including 97,366 pediatric deaths, that occurred during the study period.

Though all-intent total firearm fatality rates peaked in the early 1990s, over the past decade, maximum and average rates have trended upward especially via suicide among females and in non-metropolitan areas. Marked disparities in rates of firearm fatalities exist by sex and race. Suicide rates were highest among white, non-Hispanic males age 70-85+, and rates of homicide were highest among black, non-Hispanic males and Hispanic males age 20-40. Unintentional deaths peaked among black and Hispanic males age 20-40 and 70-85+ in the 1990s, but then decreased over time. Males have higher rates of suicide, homicide and unintentional deaths compared to females. Black males had maximum and average homicide rates an order of magnitude higher compared to all females. Non-metropolitan areas had high rates of suicide and unintentional deaths, while metropolitan areas had high rates of homicide. The study concluded that public health approaches to firearm violence need to consider underlying demographic trends and differences by intent.

A related study found that child access prevention (CAP) laws could save lives and the passage of negligence laws across all states has the potential to reduce firearm fatalities in children up to age 17. Over 50,000 pediatric firearm fatalities have occurred since 1990. Researchers examined the association between state CAP firearm laws and total and intent-specific firearm death rates in children 0-17 years old from 1991 to 2007. Since 1989, nine states have passed recklessness laws and 16 states have passed negligence laws.

The study found that recklessness laws were not associated with significantly lower firearm death rates for any intent in any age group and were associated with an increase in unintentional fatalities among 14 to 17-year-olds. Negligence laws were associated with significantly lower firearm death rates overall, by homicide, and by unintentional intent, but not by suicide across age groups. The broadest negligence laws reduced unintentional deaths by up to 69% in children 10 to 13 years of age and firearm homicide deaths up to 36%.

Eric Fleegler, MD, MPH, one of the authors of the studies, will present findings from "Evolution of the firearm epidemic in the United States, 1990 – 2016" on Monday, April 29 at 3:30 p.m. Dr. Fleegler will present "Firearm Child Access Prevention Laws and Firearm Death Rates among Children, 1991-2016" on Sunday, April 28 at 1 p.m. EDT. Reporters interested in an interview with Dr. Fleegler should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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Abstract: Evolution of the firearm epidemic in the United States, 1990 – 2016

Background: Each day over 100 firearm deaths occur in the United States (U.S.). In 2016, there were over 3,000 pediatric deaths (0-19 years). Over the past decade, total fatalities from firearms increased by 25% and are now the leading cause of death in young adults (15-24 years). Few studies have explored the interaction of urbanicity, sex and race/ethnicity in firearm fatalities across the spectrum of age.

Objective: To describe rates of firearm fatalities stratified by intent and demographics in the U.S. from 1990 to 2016.

Design/Methods: We analyzed firearm fatalities over a 26-year period as reported in the Centers for Disease Control's Web-based Injury Statistics Query and Reporting System. We created heat maps and maximum fatality rate line graphs (the highest rate for any of the age-groups for a given year) and average age-adjusted fatality rate line graphs to examine trends over time by the demographic factors of age, urbanicity, sex, and race/ethnicity. We evaluated intent of injury (i.e. suicide, homicide, or unintentional) to understand variations in firearm fatalities across different demographic groups.

Results: 897,026 firearm fatalities in the U.S., including 97,366 pediatric deaths, occurred during the study period. Though all-intent total firearm fatality rates peaked in the early 90s (figures 1a & 1b), over the past decade maximum and average rates have trended upward especially via suicide among females and in non-metropolitan areas (figures 2a & 2b). Marked disparities in rates of firearm fatalities exist by sex and race. Suicide rates were highest among white, non-Hispanic males age 70-85+, and rates of homicide were highest among black, non-Hispanic males and Hispanic males age 20-40. Unintentional deaths peaked among black and Hispanic males age 20-40 and 70-85+ in the 1990s, but then decreased over time. Males have higher rates of suicide, homicide and unintentional deaths compared to females. Black males had maximum and average homicide rates an order of magnitude higher compared to all females. Non-metropolitan areas had high rates of suicide and unintentional deaths, while metropolitan areas had high rates of homicide.

Conclusion(s): High rates of firearm fatalities in the U.S. are principally due to elevated rates of homicide among black, non-Hispanic and Hispanic males age 20-40 years and suicide among white, non-Hispanic males age 70-85+. Public health approaches to firearm violence need to consider underlying demographic trends and differences by intent.

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Figures:

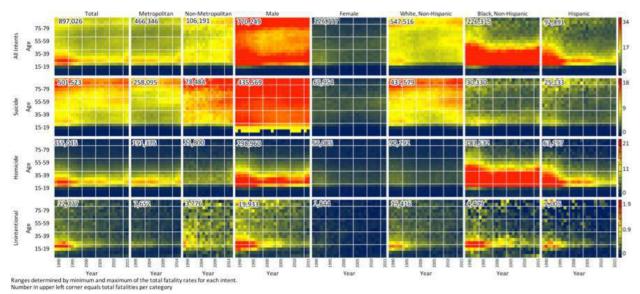


Figure 1a. Heatmaps showing the subepidemics by urbanicity and demography

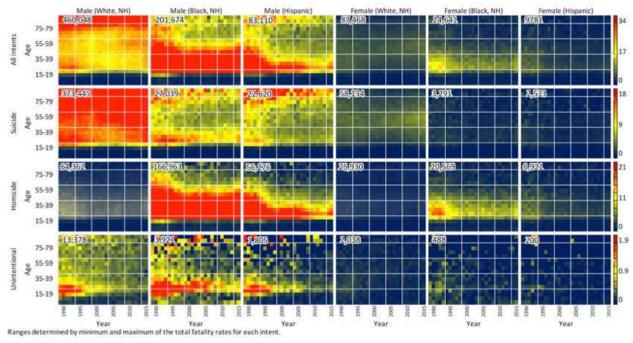


Figure 1b. Heatmaps showing the subepidemics by urbanicity and demography

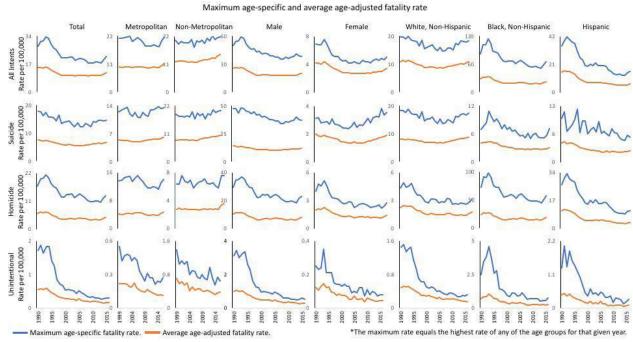


Figure 2a. Maximum age-specific and average age-adjusted fatality rate

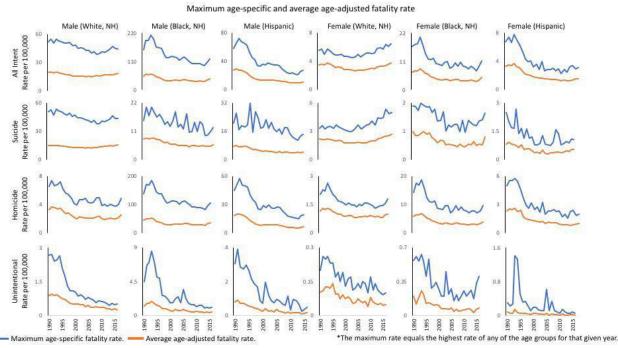


Figure 2b. Maximum age-specific and average age-adjusted fatality rate

Abstract: Firearm Child Access Prevention Laws and Firearm Death Rates among Children, 1991-2016

Background: Since 1990, over 50,000 pediatric firearm fatalities have occurred. To reduce fatalities, some states have passed child access prevention (CAP) laws.

Objective: To evaluate the association between state CAP firearm laws and pediatric firearm fatalities.

Design/Methods: We examined the association between state CAP firearm laws and total and intent-specific firearm death rates in children 0-17 years old from 1991 to 2007. Predictor laws were categorized into 4 groups: recklessness laws (Group A), negligence laws requiring firearm use by the child (Group B), negligence laws requiring possible firearm access by the child (Group C), and negligence laws imposing liability regardless of child firearm use (Group D). Firearm deaths were tabulated using the Center for Disease Control's Web-based Injury Statistics Query and Reporting Systems (WISQARS). We estimated a negative binomial model within the generalized estimating equation framework, with robust standard errors and a first-order, autoregressive, within-state correlation structure. We modeled fatalities by intent and age group as the dependent variable, and laws (binary indicator, lagged by one year) as the primary independent variable. We used a backward selection procedure with a p-value criterion of 0.10 to select potential state-level confounders, retaining percent Black, percent Hispanic, and violent crime rate. We a priori retained year- and region-fixed effects, a firearm ownership proxy, and binary indicators for laws requiring firearm permits, minimum waiting periods, and background checks universally or with handgun purchase.

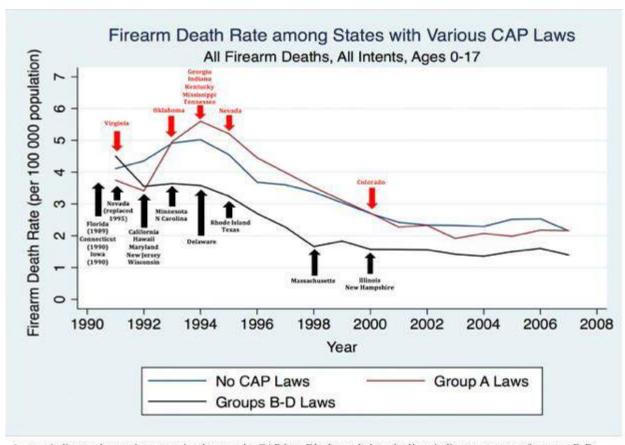
Results: Since 1989, 9 states have passed recklessness laws (Group A) and 16 states have passed negligence laws (Groups B-D) (Figure). Recklessness laws (Group A) were not associated with significantly lower firearm death rates for any intent in any age group, and were associated with an increase in unintentional fatalities among 14-17-year olds. Negligence laws (Groups B-D) were associated with significantly lower firearm death rates overall, by homicide, and by unintentional intent, but not by suicide across age groups (Table). The broadest negligence laws (Group D) reduced unintentional deaths by up to 69% in children 10-13 years of age and firearm homicide deaths up to 36%.

Conclusion(s): CAP laws could save lives. The passage of negligence laws across all states has the potential to reduce firearm fatalities in children up to age 17.

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Figures/Tables:



Arrows indicate when a given state implemented a CAP law. Black text below the lines indicates passage of a group B-D law. Red text above the lines indicates passage of a group A law.

Figure: Change in firearm death rate among all children 17 and younger by type of law

Age Groups	≤ 17	0-9	10-13	14-17
All Intents	Incidence rate ratio (95% CI)	Incidence rate ratio (95% CI)	Incidence rate ratio (95% CI)	Incidence rate ratio
States with Group A Law***	1.019 (0.911 to 1.140)	1.003 (0.847 to 1.188)	1.082 (0.918 to 1.276)	1.065 (0.948 to 1.197)
States with Group B Law	0.893 (0.793 to 1.007)	0.925 (0.760 to 1.126)	0.792 (0.703 to 0.891)^	0.900 (0.788 to 1.029)
States with Group C Law	0.840 (0.701 to 1.008)	0.685 (0.533 to 0.881)^	0.852 (0.713 to 1.018)	0.867 (0.706 to 1.066)
States with Group D Law	1.003 (0.800 to 1.257)	0.625 (0.505 to 0.774)^	0.787 (0.668 to 0.927)^	1.061 (0.821 to 1.372)
Homicide		W		
States with Group A Law	1.069 (0.877 to 1.304)	0.979 (0.812 to 1.180)	1.149 (0.920 to 1.434)	1.126 (0.907 to 1.398)
States with Group B Law	0.785 (0.622 to 0.992)^	0.893 (0.706 to 1.130)	0.705 (0.572 to 0.869)^	0.766 (0.591 to 0.994)
States with Group C Law	0.716 (0.571 to 0.898)^	0.697 (0.514 to 0.945)^	0.761 (0.594 to 0.975)^	0.717 (0.564 to 0.911)
States with Group D Law	0.886 (0.695 to 1.129)	0.637 (0.507 to 0.799)^	0.679 (0.554 to 0.833)^	0.921 (0.721 to 1.176)
iuicide				
States with Group A Law	0.979 (0.865 to 1.108)	NA*	1.068 (0.849 to 1.343)	1.009 (0.891 to 1.144)
States with Group B Law	0.984 (0.845 to 1.145)	NA*	0.868 (0.717 to 1.051)	0.993 (0.848 to 1.163)
States with Group C Law	0.902 (0.752 to 1.082)	NA*	1.029 (0.817 to 1.297)	0.906 (0.747 to 1.099)
States with Group D Law	0.957 (0.741 to 1.234)	NA*	1.092 (0.850 to 1.402)	0.944 (0.726 to 1.228)
Jnintentional			ti e e e e e e e e e e e e e e e e e e e	
States with Group A Law	1.080 (0.901 to 1.295)	1.075 (0.826 to 1.400)	1.100 (0.808 to 1.496)	1.176 (1.001 to 1.380)
States with Group B Law	0.835 (0.689 to 1.012)	0.843 (0.631 to 1.125)	0.788 (0.598 to 1.038)	0.827 (0.675 to 1.015)
States with Group C Law	0.676 (0.485 to 0.941)^	0.533 (0.351 to 0.810)^	0.700 (0.393 to 1.248)	0.730 (0.543 to 0.982)
States with Group D Law	0.445 (0.311 to 0.637)^	0.401 (0.273 to 0.590)^	0.315 (0.156 to 0.638) [^]	0.509 (0.336 to 0.772)

[∧] Statistically significant with a p-value criterion of 0.05.

Table: Intent-specific death rates by age-group and type of law

^{*} Estimates diverged due to sample size.

^{***} The Group A laws were regressed against states that never had a CAP law. The Groups B-D laws were regressed against all other states (including both those having less stringent laws and those never having a CAP law).

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New Research Examines Association Between Gun Access and Adolescent Health

BALTIMORE, April 27, 2019 – A new study found that personal gun access was associated with depression, suicidal ideation and perceiving school as unsafe, while attending a school where gun access was common was associated with lower odds of perceiving school as unsafe. Findings from the study will be presented during the Pediatric Academic Societies (PAS) 2019 Meeting, taking place on April 24 – May 1 in Baltimore.

Recent high-profile shootings have raised awareness of the health effects of both access and exposure to firearms and firearm violence among youth and adolescents. Access to guns and perceived unsafe school environments have been associated with gun-related injury, depression and suicidality among adolescents. Whether widespread acceptance of guns among peers alters these associations, however, is unknown.

The study found that when interaction terms were included in the models, the association between individual gun access and suicidal ideation was weaker when attending a school where gun access was more common. Additionally, as access to guns within a school was more common, the odds of poor general health decreased for students with personal gun access but increased for students with no personal gun access.

"For better or for worse, guns are an important part of American culture," said Samantha Chung, one of the authors of the study. "Some studies have shown that having a gun in the home is associated with poor mental health among adolescents. We wanted to study how overall gun access in adolescents' communities might also impact their mental health. We found that it probably does, but the effects are complex and may go in both directions."

The study concluded that gun access is a complex social phenomenon. In an otherwise low-access environment, personal gun access may signify a high-risk physical and mental state. In schools where access to guns is common, however, personal gun access may signify social belonging that might reduce potential negative health effects of guns. Although overall evidence that widespread gun access is harmful remains clear, our findings suggest that nuance based on local cultural norms may be significant.

Chung will present findings from "Gun Access and Adolescent Health: Safety in Numbers?" on Monday, April 29 at 2:15 p.m. EDT. Reporters interested in an interview with Chung should contact

<u>PAS2019@piercom.com</u>. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

The <u>PAS 2019 Meeting</u> brings together thousands of pediatricians and other health care providers to improve the health and well-being of children worldwide. For more information about the PAS 2019 Meeting, please visit <u>www.pas-meeting.org</u>.

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About the Pediatric Academic Societies Meeting

The Pediatric Academic Societies (PAS) Meeting brings together thousands of pediatricians and other health care providers united by a common mission: to improve the health and well-being of children worldwide. This international gathering includes pediatric researchers, leaders in pediatric academics, clinical care providers and community practitioners. Presentations cover issues of interest to generalists as well as topics critical to a wide array of specialty and sub-specialty areas. The PAS Meeting will be the premier North American scholarly child health meeting. The PAS Meeting is produced through a partnership of four pediatric organizations that are leaders in the advancement of pediatric research and child advocacy: American Pediatric Society, Society for Pediatric Research, Academic Pediatric Association and American Academy of Pediatrics. For more information, please visit www.pas-meeting.org. Follow us on Twitter @PASMeeting and #PAS2019, and like us on Facebook.

Abstract: Gun Access and Adolescent Health: Safety in Numbers?

Background: Recent high-profile shootings have raised awareness of the health effects of both access and exposure to firearms and firearm violence among youth and adolescents. Access to guns and perceived unsafe school environments have been associated with gun-related injury, depression, and suicidality among adolescents. Whether widespread acceptance of guns among peers alters these associations, however, is unknown.

Objective: To examine in a nationally representative sample of adolescents whether peer acceptance of guns (measured by the percent of students in one's school with personal gun access) moderates associations between one's own gun access and general health, depression, suicidality, and perceived school safety.

Design/Methods: We used the National Longitudinal Study of Adolescent to Adult Health (Add Health) Wave I youth surveys to assess both individual-level (e.g., personal gun access) and school-level (e.g., proportion of students at school with access to a gun) variables. We used weighted multilevel analyses with interactions to determine the associations among personal gun access, school-level proportion of gun access, and adolescent depression, suicidal ideation, self-rated health, and perceived school safety, controlling for demographics and school characteristics.

Results: We found that personal gun access was associated with depression (OR 1.21 p=0.03, suicidal ideation (OR 1.74, p<0.001) and perceiving school as unsafe (OR 1.60, p<0.001) while, contrary to our hypothesis, attending a school where gun access was common was associated with a lower odds of perceiving school as unsafe (OR 0.83, p=0.003). When interaction terms were included in the models, the association between individual gun access and suicidal ideation was weaker when attending a school where gun access was more common. Additionally, as access to guns within a school was more common, the odds of poor general health decreased for students with personal gun access but increased for students with no personal gun access.

Conclusion(s): Gun access is a complex social phenomenon. In an otherwise low-access environment, personal gun access may signify a high-risk physical and mental state. In schools where access to guns is common, however, personal gun access may signify social belonging that might reduce potential negative health effects of guns. Although overall evidence that widespread gun access is harmful remains clear, our findings suggest that nuance based on local cultural norms may be significant.

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Figures/Tables:

Table 1. Weighted Descriptive Individual Characteristics

	N/Mean	Weighted %/Std. Dev
Easy access to a gun	4138	24.3
Male	9162	50.7
Race/Ethnicity		
White	9919	67.2
African American	3998	15.9
Latino	2944	11.2
Other	1783	5.8
Family structure		
Two biological parents	9595	53.5
One biological/one step-parent	3419	17.3
Single parent	4597	23.4
Other	1098	5.8
Household income		
<\$24,000	4135	22.7
\$25,000-\$49,000	4605	25.8
\$50,000-\$74,000	3158	17.8
2\$75,000	1980	10.7
Missing	4831	23.0
Parental level of education		
Less than high school	1922	10.1
High school/GED	5366	32.1
Some college	3847	21.6
College graduate	4580	24.4
More than college	2424	11.9
Mean age in years	15.5	1.8
Depression	3816	18.8
Suicidal ideation	2477	13.2
Low self-rated health	1327	7.0
Perceives school unsafe	2562	12.8

Table 2. Weighted Descriptive School Characteristics

	N/Mean	Weighted %/Std. Dev
Mean % of students with easy gun access	24.4	14.7
School size		
Large (1001-4000)	9160	37.8
Medium (401-1000)	6806	44.7
Small (1-400)	2743	17.5
School type		
Public	17342	93.2
Private	1367	6.8
Urbanicity		
Urban	5499	26.2
Suburban	10111	58.4
Rural	3099	15.5
Region		
West	4591	16.5
Midwest	4464	31.3
South	6920	38.5
Northeast	2734	13.7
Average daily attendance		
95% or more	5934	37.8
90-94%	8117	45.8
75-89%	4438	16.5
Parental involvement		
30-100%	4875	26.4
15-29%	3369	20.5
0-14%	8615	39.7
Missing	1850	13.4
Mean teacher retention	66.7	21.0
Mean student promotion rate	93.1	7.3

Table 3. Associations Among Individual and School-Level Gun Access and Adolescent Health											
		Self-Rated Health	Depression		Suicidal Ideation		Feeling School Unsafe				
	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI			
Individual gun access	IOI	0.80 - 1.28	1.21	1.02 - 1.43	1.74	1.50 - 2.01	1.6	1.31 - 1.95			
School level gun access	107	0.97 - 118	0.96	0.90 - 102	0.95	0.89 - IOI	0.83	0.74 - 0.94			

Models control for gender, race/ethnicity, age, family structure, parental level of education, household income, school size, school type, urbanicity, region, school average daily attendance, school-level parental involvement, school teacher retention, and school promotion rate.

Table 4. Associations Amon Individual and School-Level Gun Access and Adolescent Health										
	Low Self-Rated Health		Depression		Suicidal Ideation		Feeling School Unsafe			
	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI		
Individual gun access	1.73	1.15-2.59	140	0.97 -203	2.35	1.77 - 3.12	2.07	1.33 - 3.22		
Proportion of students at school with gun access	1.12	1.01 - 1.23	0.98	0.91 - 105	0.99	092-106	0.86	0.78 - 0.95		
Individual access * School-level proportion with access	0.85	0.76 - 0.95	0.95	0.86 - 106	0.91	0.45-0.63	092	0.79 - 107		

Models control for gender, race/ ethnicity, age, family structure, parental level of education, household income, school size, school type, urbanicity, region, school average daily attendance, school-level parental involvement, school teacher retention, and school promotion rate.

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New Study Aims to Understand Opioid Fill Patterns in Children

Prescription opioid misuse results in numerous poor health consequences among children in the U.S.; however, knowledge of recent opioid prescribing trends in Medicaid-enrolled children are conflicting and limited to certain subpopulations.

Improved understanding of current opioid prescription trends in children is needed to inform development of future pediatric pain management guidelines.

BALTIMORE, April 27, 2019 – A new study describes trends in filled opioid prescriptions by patient and clinical characteristics for Medicaid-enrolled children. Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

"In this retrospective cohort study of Medicaid-enrolled children and young adults (1 to 21 years old) we found that filled opioid prescriptions are relatively rare (1% of all visits) and adjusted rates decreased from 2012 to 2016," said Abbey Masonbrink, MD, MPH, a pediatric hospitalist at Children's Mercy Kansas City and one of the authors of the study. "Providers frequently prescribed opioids combined with non-opioid analgesics and opioids with a black box or safety warning. Future efforts should support development of pediatric pain management guidelines based in a multimodal approach to minimize use of opioids and target reduction of opioids with pediatric safety warnings."

This study involved a retrospective cohort study of children 1 to 21 years old enrolled in Medicaid from 2012-2016 using the IBM Watson Medicaid Marketscan claims database. It defined clinical visits as an "opioid visit" if there was a new opioid prescription filled in a retail pharmacy within seven days of the visit. The opioid visit was then assigned to the clinical provider most likely to have prescribed an opioid. Only visits to providers submitting claims in every year from 2012-2016 were included. Changes in patient and clinical characteristics over time were assessed using descriptive statistics and chi-square tests and logistic regression was used to estimate the change in adjusted probability of an opioid visit over time. Due to the large volume of visits analyzed, p<0.001 was considered statistically significant.

From 2012 to 2016, there were 113,068,027 visits among Medicaid-enrolled children and 1% (n=1,130,006) of these were considered an opioid visit. After adjusting for patient demographics, the researchers found that the adjusted probability for an opioid prescription decreased from 1.2% to 0.8% from 2012 to 2016. The clinical settings with the highest adjusted rates of opioid prescriptions were dental surgery (29%), surgery (21%), and inpatient (upon-discharge) (10%). Furthermore, the adjusted rates of an opioid visit significantly decreased (p<0.001) from 2012-2016 in all settings, except dental

surgery and surgery. The most frequently prescribed opioids were hydrocodone (48%), codeine (22%), and oxycodone (14%); most of these prescriptions were in combination with acetaminophen or ibuprofen.

Opioid prescriptions filled in Medicaid-enrolled children are relatively rare (1% of all visits), however adjusted rates of opioid visits decreased from 2012 to 2016. Understanding changes in prescriptions over time can inform opioid stewardship efforts to develop clinical guidelines for appropriate pain management in children.

Dr. Masonbrink will present findings from "Changes in Opioid Prescriptions for Medicaid-enrolled Children, 2012-2016" on Sunday, April 28 at 8 a.m. EDT. Reporters interested in an interview with Dr. Masonbrink should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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Abstract: Changes in Opioid Prescriptions for Medicaid-enrolled Children, 2012-2016

Background: Prescription opioid misuse results in numerous poor health consequences among children in the United States; however, literature describing opioid prescriptions in Medicaid-enrolled children is lacking or demonstrates conflicting findings. Understanding the epidemiology of opioid fill patterns is essential to address the current opioid crisis.

Objective: To describe trends in filled opioid prescriptions by patient and clinical characteristics for Medicaid-enrolled children.

Design/Methods: We performed a retrospective cohort study of children aged 0-21 years old enrolled in Medicaid from 2012-2016 using the IBM Watson Medicaid Marketscan claims database. We defined clinical visits as an "opioid visit" if there was a new opioid prescription filled in a retail pharmacy within 7 days of the visit. The opioid visit was then assigned to the clinical provider most likely to have prescribed an opioid. Only visits to providers submitting claims in every year from 2012-2016 were included. We assessed changes in patient and clinical characteristics over time using descriptive statistics and chisquare tests. We used logistic regression to estimate the change in adjusted probability of an opioid visit over time. Due to the large volume of visits analyzed, p<0.001 was considered statistically significant.

Results: From 2012 to 2016, there were 113,068,051 visits among Medicaid-enrolled children and 0.9% (n=1,049,851) of these were considered an opioid visit. Patient characteristics are described in Table 1. Clinical settings most likely to result in an opioid prescription were dental surgery (36%), followed by outpatient surgery (26%), and ED (4%). After adjusting for patient demographics, we found that the adjusted probability for an opioid prescription decreased from 2012-2016 (aOR 0.88 95% CI [0.88, 0.89], p<0.001). Furthermore, the adjusted odds of an opioid visit significantly decreased (p<0.001) from 2012-2016 in all settings, except dental surgery (aOR [95% CI]: 1.02 [1.01,1.03], p<0.001)The most frequently prescribed opioids were hydrocodone (52%), codeine (25%), and oxycodone (15%) (Figure 1); most of these prescriptions were in combination with acetaminophen or ibuprofen.

Conclusion(s): Opioid prescriptions filled in Medicaid-enrolled children are relatively rare (0.9% of all visits), however adjusted rates of opioid visits still decreased from 2012 to 2016. Understanding changes in prescriptions over time can help opioid stewardship programs develop clinical guidelines for appropriate pain management in children.

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New Study Examines Geographic Differences in Fatal Pediatric Opioid Poisonings

In the U.S., prescription and illicit opioids are implicated in the deaths of approximately 500 children and adolescents per year.

BALTIMORE, April 27, 2019 – A new study shines light on pediatric opioid deaths by U.S. region, the first time a study of this nature has been conducted. Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

"Although we know that nearly 10,000 children and adolescents died from opioid poisonings over the past two decades in the United States, we have little understanding of how kids in particular regions of the country have been affected by the opioid crisis," said Julie Gaither, PhD, MPH, RN, the lead author of the study. "In this study, we found that while there was a four-fold increase in pediatric deaths from opioids in the Midwest, while there was only a two-fold increase in the West. Moreover, unlike with every other region of the country, there has not been a recent upsurge in deaths from heroin and illicit fentanyl in the western states."

The study analyzed CDC mortality data—stratified by the four U.S. census regions—for children and adolescents less than 20 years of age who died from opioid poisonings between 1999 and 2016. Generalized smoothing spline Poisson regression was used to estimate mortality rates per 100,000.

Nationally, 8,986 children and adolescents died from opioid poisonings between 1999 and 2016; the pediatric mortality rate increased 268.2%, from 0.22 to 0.81 per 100,000. Mortality rates were highest in the Northeast in both 1999 and 2016 at 0.33 and 1.05, respectively, but the largest increase over time occurred in the Midwest, where rates rose by 429.4%, from 0.17 to 0.90. The smallest increase was in the West, where rates increased by 200.0%, from 0.19 to 0.57. In all regions but the West, there was a marked upswing in mortality rates between 2013 and 2016. This increase can be attributed to a recent surge in deaths from heroin and synthetic opioids (primarily illicit fentanyl) among 15 to 19-year-olds. In this group, heroin was implicated in 32.1% of all opioid deaths in the Northeast (highest proportion), compared to 18.3% in the South (lowest proportion). Similarly, synthetic opioids were implicated in 17.5% of opioid deaths in the Northeast, compared to 8.9% in the South.

In the U.S., pediatric mortality rates for opioid poisonings increased nearly 3-fold over 18 years; however, substantial variation exists in the degree to which children and adolescents in particular regions of the country were affected. Mortality rates in the Midwest increased more than 4-fold, compared to a 2-fold increase in the West. A better understanding of how fatal pediatric opioid

poisonings vary geographically has the potential to aid in the development of targeted interventions to mitigate what is a growing public health problem for the young in the U.S.

Dr. Gaither added, "We are interested in finding out what is at the root of this variation, and whether there are public health policies in place in the West that are serving as safeguards for kids; and if so, how do we begin to implement them across the rest of the country?"

Dr. Gaither will present findings from "Geographic Variation in Pediatric Deaths from Prescription and Illicit Opioid Poisonings, 1999-2016" on Saturday, April 27 at 5:30 p.m. EDT. Reporters interested in an interview with Dr. Gaither should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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Abstract: Geographic Variation in Pediatric Deaths from Prescription and Illicit Opioid Poisonings, 1999-2016

Background: In the U.S., prescription and illicit opioids are implicated in the deaths of approximately 500 children and adolescents per year. No study has yet examined geographic differences in fatal pediatric opioid poisonings.

Objective: To examine pediatric opioid deaths by U.S. region.

Design/Methods: We analyzed CDC mortality data—stratified by the 4 U.S. census regions—for children and adolescents < 20 years of age who died from opioid poisonings between 1999 and 2016. Generalized smoothing spline Poisson regression was used to estimate mortality rates per 100,000.

Results: Nationally, 8,986 children and adolescents died from opioid poisonings between 1999 and 2016; the pediatric mortality rate increased 268.2% (P trend < .001), from 0.22 (95% CI, 0.19-0.25) to 0.81 (95% CI, 0.76-0.88) per 100,000. The Table shows demographic and clinical characteristics by U.S. region. Mortality rates were highest in the Northeast in both 1999 and 2016 at 0.33 (95% CI, 0.27-0.40) and 1.05 (95% CI, 0.92-1.20), respectively, but the largest increase over time occurred in the Midwest, where rates rose by 429.4% (P trend < .001), from 0.17 (95% CI, 0.14-0.21) to 0.90 (95% CI, 0.79-1.02). The smallest increase was in the West, where rates increased by 200.0% (P trend < .001), from 0.19 (95% CI, 0.15-0.24) to 0.57 (95% CI, 0.49-0.67). As Figure 1 shows, in all regions but the West, there was a marked upswing in mortality rates between 2013 and 2016. This increase can be attributed to a recent surge in deaths from heroin and synthetic opioids (primarily illicit fentanyl) among 15- to 19-year-olds (Figure 2). In this group, heroin was implicated in 32.1% of all opioid deaths in the Northeast (highest proportion), compared to 18.3% in the South (lowest proportion) (P < .001). Similarly, synthetic opioids were implicated in 17.5% of opioid deaths in the Northeast, compared to 8.9% in the South (P < .001).

Conclusion(s): In the U.S., pediatric mortality rates for opioid poisonings increased nearly 3-fold over 18 years; however, substantial variation exists in the degree to which children and adolescents in particular regions of the country were affected. Mortality rates in the Midwest increased more than 4-fold, compared to a 2-fold increase in the West. A better understanding of how fatal pediatric opioid poisonings vary geographically has the potential to aid in the development of targeted interventions to mitigate what is a growing public health problem for the young in the U.S.

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Tables/Figures:

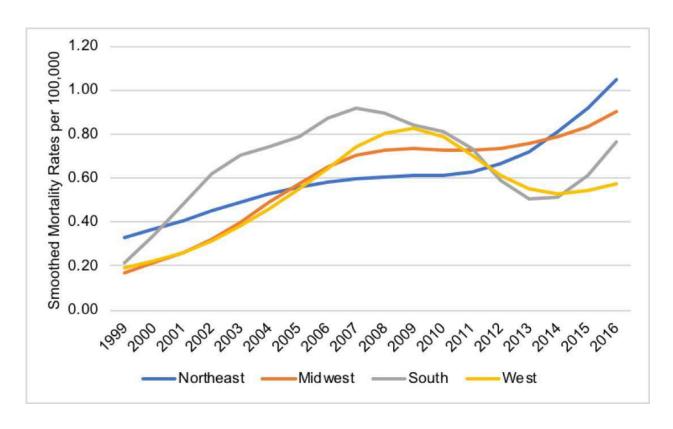
Figure 1. Pediatric Mortality Rates for Opioid Poisonings in Children and Adolescents Ages 0 to 19 Years by U.S. Region

Table. Pediatric Deaths from Prescription and Illicit Opioids by U.S. Region, 1999-2016

	Northeast	Midwest	South	West	
Characteristics	n=1524	n=1928	n=3624	n=1910	p
Age category. y. n (%)					< .001
0-4	61 (4.0)	139 (7.2)	286 (7.9)	119 (6.2)	
5-9	14 (0.9)	24 (1.2)	40(1.1)	18 (0.9)	
10-14	40 (2.6)	68 (3.5)	152 (4.2)	104 (54)	
15-19	1409 (92.5)	1697 (88.0)	3146 (86.8)	1669 (874)	
Male sex, n (%)	1081 (70.9)	1404 (72.8)	2671 (73.7)	1411 (73.9)	.17
Non-Hispanic white race, n (%)	1307 (85.8)	1634 (84.8)	2885 (79.6)	1357 (710)	< .001
Died at home, n (%)	582 (38.2)	773 (40.1)	1261 (34.8)	803 (42.0)	< .001
Accidental intent, n (%)	501 (32.9)	639 (33.1)	1068 (29.5%)	617 (32.3)	.01
Suicidal intent, n (%)'	28 (2.0)	36 (2.1)	67 (2.1)	56 (34)	.03
Implicated opioid, n (%) ъ					< .001
Prescriptionc	861 (61.1)	1081 (63.7)	2384 (75.8)	1309 (784)	
Heroin	452 (32.1)	503 (29.6)	576 (18.3)	341 (204)	
Synthetic at	246 (17.5)	265 (15.6)	363 (8.9)	149 (8.9)	

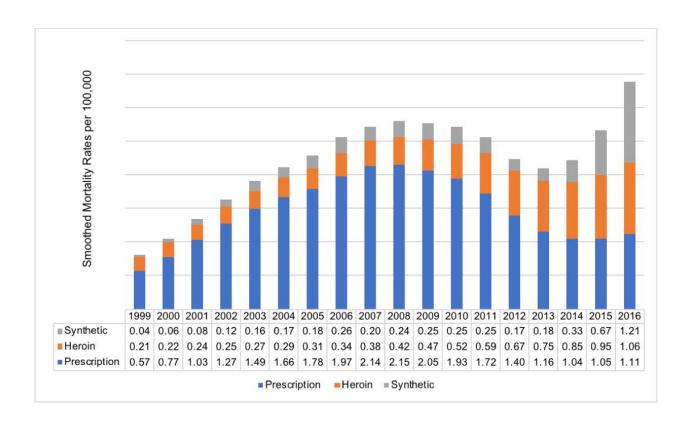
^{&#}x27;Among adolescents 15-19 years, n=7,921.

<1]ncludes pharmaceutical and illicitly manufactured fentanyl but excludes methadone.</p>



b Categories are not mutually exclusive; percentage totals exceed 100%.

c Includes methadone but excludes other synthetics.



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New Study Measures the Impact of Prescription Drug Monitoring Programs on Pediatric Opioid Exposures

Opioids represent a significant source of morbidity and mortality for children who have experienced higher intentional and unintentional exposures as the availability of opioids has increased.

BALTIMORE, April 27, 2019 – A new study measures the impact state-run, prescription drug monitoring programs (PDMPs), pain clinic legislation and opioid prescribing guidelines have on opioid exposures among children. Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS)</u> 2019 Meeting, taking place on April 24 – May 1 in Baltimore.

"The U.S. remains in the throes of an opioid epidemic born out of the overzealous prescribing of opioids over the past two decades and with national guidelines and monitoring programs primarily focused on adult populations, there is limited information on the effects of opioid policies on opioid exposures and poisonings in children," said Michael Toce, MD, one of the authors of the study. "We investigated the effects of state-level PDMPs, pain clinic legislation and mandatory opioid prescribing limits on pediatric opioid exposures reported to U.S. Poison Control Centers. Our results indicate that these policies—though designed primarily for adults—are associated with significant reductions in opioid exposures among children."

The study analyzed opioid exposures reported to the National Poison Data System (NPDS) for children less than 20 years of age between 2005 and 2017. The NPDS database is maintained by the American Association of Poison Control and collects data on exposures reported to 55 poison control centers across the U.S. Then, the authors conducted a state-level interrupted time series analysis to examine the impact of PDMPs, pain clinic legislation and opioid prescribing guidelines have on the rate of opioid exposures in children per month. The primary outcome was the change in rate of pediatric opioid exposures, before and after implementation of each opioid reduction policy at the state level. Models included covariates to account for socioeconomic and demographic factors that are associated with opioid exposure.

There were 332,745 opioid exposures in children reported to the NPDS during the study period. The majority of exposures in children at or less than 4 years were unintentional (99.2%) while the majority among those 15 to 19 years were intentional (88.8%). The total number of exposures peaked in 2009. The rate of exposures per 100,000 children was highest for children less than or equal to 4 years of age, followed by children 15 to 19 years of age. The implementation of a PDMP was associated with an

overall decrease of 0.27 fewer opioid exposures per 100,000 children per month. Implementation of an opioid prescribing guideline was associated with an immediate 20% reduction in the rate of opioid exposures, but the overall effect was not statistically significant. Conversely, implementation of pain clinic legislation was associated with an immediate 22% reduction in exposures, and overall was associated with a decrease of 0.84 fewer opioid exposures per 100,000 per month.

The findings indicate that state opioid reduction policies are associated with a significant decrease in opioid exposures among children.

Dr. Toce added, "Building on this work, additional analyses will be conducted to identify policy features most protective to children so that future initiatives can further promote the public health benefits of opioid policies for pediatric populations."

Dr. Toce will present findings from "Impact of Prescription Drug Monitoring Programs on Pediatric Opioid Exposures" on Monday, April 29 at 1 p.m. EDT. Reporters interested in an interview with Dr. Toce should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Impact of Prescription Drug Monitoring Programs on Pediatric Opioid Exposures

Background: Opioids represent a significant source of morbidity and mortality for children, who have experienced higher intentional and unintentional exposures as the availability of opioids has increased. Prescription Drug Monitoring Programs (PDMPs) are state run databases that make controlled substance dispensing information accessible to prescribers, with the aim of promoting judicious use of these drugs. PDMPs have been associated with reductions in opioid-related overdoses among adults. However, it is unknown whether they have also had an indirect effect on opioid exposures among children.

Design/Methods: We analyzed opioid exposures reported to the National Poison Data System (NPDS) for children <20 years of age between 2005 and 2017. The NPDS database is maintained by the American Association of Poison Control and collects data on exposures reported to 55 poison control centers across the US. We conducted a state-level interrupted time series analysis using negative binomial regression models to examine the impact of PDMPs on the rate of opioid exposures in children per month. The primary outcome was the change in rate of pediatric opioid exposures, before and after implementation of a PDMP at the state level. Models included covariates to account for socio-economic and demographic factors. Incident rate ratios (IRR) were calculated and represent the monthly change in the rate of opioid exposures after PDMP implementation.

Results: There were 338,476 single substance opioid exposures in children reported to the NPDS during our study period. The majority of exposures in children \leq 4 years were unintentional (99.2%) while the majority among those 15- 19 years were intentional (88.8%) (Table 1). The total number of exposures peaked in 2009 (Figure 1). The rate of exposures per 100,000 children was highest for children \leq 4 years of age, followed by children 15-19 years of age (Figure 1). The implementation of PDMPs was associated with a monthly decrease in pediatric opioid exposures of 0.4% (p<0.001), equivalent to a yearly decrease of 4.8% (Table 2). The benefits of PDMPs was greatest for children \leq 4 years of age, where the yearly reduction in opioid exposures was 6%.

Conclusion(s): Our findings indicate that PDMPs are associated with a significant decrease in opioid exposures among children, with the greatest benefit among children \leq 4 years of age. Future work defining the specific features of PDMPs leading to these reductions will inform additional initiatives aiming to protect children from opioid exposures.

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Tables/Figures:

Figure 1. Number of pediatric opioid exposures reported to NPDS by age group, 2005-2017.

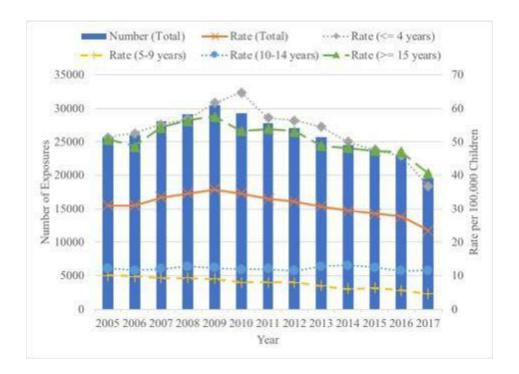


Table 2. Impact of PDMPs on pediatric opioid exposures.

Table 2. Impact of PDMPs on pediatric opioid exposures.					
	IRR (95% CI)	Monthly Reduction			
Overall	0.996 (0.994-0.997)	0.4%			
Age Category	-				
≤ 4 Years	0.995 (0.993-0.996)	0.5%			
5-9 Years	0.996 (0.994-0.998)	0.4%			
10-14 Years	0.999 (0.997-1.000)	0.1%			
15-19 Years	0.997 (0.995-0.999)	0.3%			

Table 1. Characteristics of Opioid Exposures Among Children < 20 Years of Age, 2005–2017							
-	Age Category, Frequency (%)						
Reason	≤ 4 Years	5-9 Years	10-14 Years	15-19 Years			
Intentional	270 (0.2)	946 (4.7)	22,845 (71.1)	124,150 (88.8)			
Unintentional	139,590 (99.2)	18,661 (92.5)	8,497 (26.5)	13,385 (9.6)			
Other/Unknown	845 (0.6)	558 (2.8)	771 (2.4)	2,227 (1.6)			
Total	140,705	20,165	32,113	139, 762			

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Eat, Sleep and Console Tool Decreases Length of Stay and Post Natal Use of Opiates

As numbers of opioid exposed newborns have increased throughout the U.S., many approaches have been used to improve care of these infants.

BALTIMORE, April 27, 2019 – A new quality improvement tool called Eat, Sleep and Console (ESC) shows consistent signs of improved care of opioid-exposed newborns in neonatal intensive care units (NICUs). Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

"The opioid epidemic has had an enormous impact on newborn care and our goal in this project was to improve the care of opioid-exposed newborns at our hospital using quality improvement methods to adapt previously demonstrated successful approaches that focused on three things; simplified assessment of newborns experiencing opioid withdrawal, engaging and educating families in best practices to support their babies through drug withdrawal symptoms, and minimizing exposures of babies to medications," said Susan Townsend, MD, one of the authors of the study. "Our philosophy is to 'use hugs, not drugs' in treating newborn opioid withdrawal symptoms. This approach was effective in rapidly reducing hospital stay for this large group of patients."

To conduct this study, a quality improvement (QI) process was initiated using an ESC tool in a NICU. It included all opioid exposed newborns admitted to this NICU. A multidisciplinary team met monthly to direct process change using plan-do-study-act (PDSA) cycles, change from Finnegan Score (FS) to ESC, emphasize non-pharmacologic care, increase family involvement, and use morphine on an as-needed basis instead of tapered methadone for medication treatment when needed. Clinical practice change was supported with education and charting tools, "just in time" teaching moments on bedside rounds and during morning unit huddles. As part of a statewide perinatal QI collaborative, it used a REDCap deidentified patient database to track length of birth hospitalization (LOS) and use of medication.

During the pre-intervention period in 2017, 635 infants were admitted to the NICU. Among these admissions, 71 infants (11.2%) had fetal opioid exposure, and 46 of these 71 infants (64.7%) were treated with methadone for neonatal abstinence (NAS) with an average LOS of 22.7 days. Between January 1 and October 31, 2018, there were 50 NICU admissions with fetal opioid exposure. Of these, 43 were ≥34 weeks gestation and discharged home from the NICU. LOS decreased from a median 21 days in the first quarter (Q1) (n=12), to 5.5 days in the third quarter (Q3) (n=18). Use of medication to treat NAS decreased from 75% in Q1 to 27.8% in Q3, with median length of exposure to medication decreasing from 16 to two days.

Implementing a care path for newborns with fetal opioid exposure that relies on non-pharmacologic interventions and uses the ESC evaluation tool can substantially shorten hospital stays and decrease exposure to pharmacologic treatment for symptoms of NAS.

Dr. Townsend will present findings from "Rapid Decrease in Length of Stay and Postnatal Use of Opiate Medication Using 'Eat, Sleep and Console' in a Single Center" on Monday, April 29 at 1 p.m. EDT. Reporters interested in an interview with Dr. Townsend should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

Dr. Townsend added, "We are hopeful that this will provide long term benefits to families and babies exposed to opioids; however, it remains to be seen whether there are other unintended consequences of this approach."

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About the Pediatric Academic Societies Meeting

Abstract: Rapid Decrease in Length of Stay and Postnatal Use of Opiate Medication Using "Eat, Sleep and Console" in a Single Center

Background: As numbers of opioid exposed newborns have increased throughout the US, many approaches have been used to improve care of these infants. The "Eat, Sleep, and Console" method (ESC) was proposed in 2017 as an alternative to traditional Finnegan scoring (FS) and medication-based strategies.

Objective: To decrease length of birth hospitalization (LOS) and use of postnatal opiates among opioid exposed newborns born ≥ 34 weeks GA by 50% in a high-volume community-based NICU by December 2018.

Design/Methods: In 2018 we initiated a quality improvement (QI) process using the ESC tool in our NICU. We included all opioid exposed newborns admitted to our NICU. A multidisciplinary team met monthly to direct process change using plan-do-study-act (PDSA) cycles, change from FS to ESC, emphasize non-pharmacologic care, increase family involvement, and use morphine on an as needed basis instead of tapered methadone for medication treatment when needed. Clinical practice change was supported with education & charting tools, "just in time" teaching moments on bedside rounds and during morning unit huddles. As part of a statewide perinatal QI collaborative, we used a REDCap deidentified patient database to track LOS and use of medication.

Results: During the pre-intervention period in 2017, 635 infants were admitted to the NICU. Among these admissions, 71 infants (11.2%) had fetal opioid exposure, and 46 of these 71 infants (64.7%) were treated with methadone for neonatal abstinence (NAS) with an average LOS of 22.7 days. Between January 1 and October 31, 2018 there were 50 NICU admissions with fetal opioid exposure. Of these, 43 were ≥34 wks gestation and discharged home from our NICU. LOS decreased from a median 21 days in the first quarter (Q1) (n=12), to 5.5 days in the third quarter (Q3) (n=18) (Figure 1). Use of medication to treat NAS decreased from 75% in Q1 to 27.8% in Q3 (Figure 2), with median length of exposure to medication decreasing from 16 to 2 days.

Conclusion(s): Implementing a care path for newborns with fetal opioid exposure that relies on non-pharmacologic interventions and uses the "Eat, Sleep, and Console" evaluation tool can substantially shorten hospital stays and decrease exposure to pharmacologic treatment for symptoms of NAS.

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Tables/Figures:

Figure 1: Run Chart

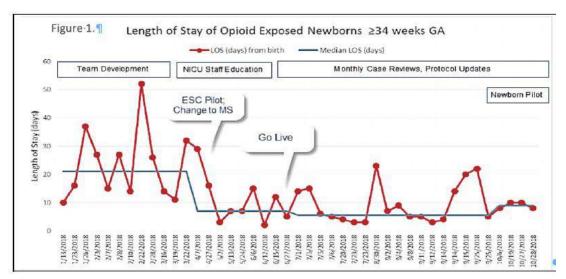
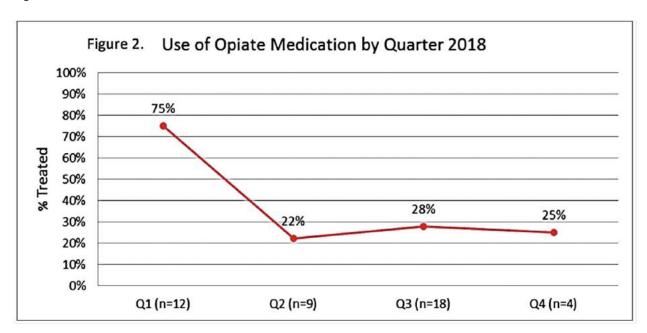


Figure 2: Use of Medication



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New Study Aims to Improve Outcomes for Pregnancies Impacted by Opioid Use Disorder

Since 2012, birthing hospitals in Massachusetts started to identify and share best practices for pregnancies impacted by Opioid Use Disorder under the umbrella of Neonatal Quality Improvement Collaborative, to improve maternal-infant outcomes.

BALTIMORE, April 27, 2019 – A new study aims to actively involve birthing hospitals to improve health and social outcomes for the maternal infant dyads impacted by Opioid Use Disorder (OUD). Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

"Since 2016, the Perinatal-Neonatal Quality Improvement Network of Massachusetts along with other state level stakeholders, launched an initiative to actively involve birthing hospitals in the state to improve overall health and social outcomes for the maternal infant dyads impacted by OUD," said Dr. Rachana Singh, MD, one of the authors of the study. "This process included sharing best practices; a shared database to collect de-identified data; educational materials; serial webinars; biannual quality summits; sharing of statewide and comparative individual hospital reports; and hospital site visits."

All voluntarily participating hospitals were invited to identify, share and adopt best care practices as was feasible within the resources available. Commonly shared materials included: a shared database storing de-identified data; educational materials (antenatal screening tools; NAS toolkit; Eat, Sleep, Console scoring); webinars to share hospital-based successes; biannual quality summits; sharing of statewide and individual hospital reports; and hospital site visits. With these efforts, of the 47 birthing hospitals caring for mothers or newborns, over 30 are participating in this initiative, including 26 sharing data to the database since 2017.

Between January 2017 to November 2018, data for 1,434 maternal-infant dyads was reported in the central database. Of these, \sim 80% mothers with OUD were receiving medication assisted treatment (MAT) with <40% using illicit drugs during pregnancy, 69% opioid exposed newborns (OENs) received skin-to-skin care in the first 24 hours of life, 70% roomed-in for at least one night prior to maternal discharge and 80% of eligible OENs received any mother's milk during hospitalization. \leq 50% of OENs needed pharmacotherapy. The average hospital length of stay (LOS) for all OENs born \geq 37 weeks was \sim 14 days and while for those not requiring pharmacotherapy was \sim 6 days. Eighty percent of OENs were referred to early intervention prior to discharge and 72% of OENs were discharged home to a biologic

parent. Significant increases in skin-to-skin contact (median 64.7% to 72.3%) and significant decreases in pharmacologic therapy (median 52.5 % to 45.8%) were seen by run chart rules.

This statewide multidisciplinary collaborative effort was able to engage a majority of birthing hospitals in improving care provision for OUD impacted pregnancies resulting in a trend toward less need for pharmacologic treatment through greater focus on non-pharmacologic methods.

Dr. Singh concluded, "Through these efforts we have been able to engage a majority of birthing hospitals in improving care provision for OUD impacted pregnancies resulting in a trend toward less need for pharmacologic treatment through greater focus on non-pharmacologic methods."

Dr. Singh will present findings from "Improving Outcomes for Pregnancies Impacted by Opioid Use Disorder: The Massachusetts Experience" on Monday, April 29 at 1 p.m. EDT. Reporters interested in an interview with Dr. Singh should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Improving Outcomes for Pregnancies Impacted by Opioid Use Disorder: The Massachusetts Experience

Background: Since 2012, birthing hospitals in Massachusetts started to identify and share best practices for pregnancies impacted by Opioid Use Disorder (OUD) under the umbrella of Neonatal Quality Improvement Collaborative (neoQIC), to improve maternal-infant outcomes. In 2016, the Maternal Perinatal Quality Collaborative (MPQC), with state level stakeholders, joined the initiative to create the Perinatal-Neonatal Quality Improvement Network of Massachusetts (PNQIN).

Objective: The overarching aim was to actively involve birthing hospitals to improve health and social outcomes for the maternal infant dyads impacted by OUD.

Design/Methods: All voluntarily participating hospitals were invited to identify, share and adopt best care practices as was feasible within the resources available. Commonly shared materials included - a shared database storing de-identified data; educational materials (antenatal screening tools; NAS toolkit; Eat, Sleep, Console scoring); webinars to share hospital based successes; biannual quality summits; sharing of statewide and individual hospital reports; and hospital site visits. With these efforts, of the 47 birthing hospitals caring for mothers or newborns, over 30 are participating in this initiative, including 26 sharing data to the database since 2017.

Results: Between 1/17 to 11/18 data for 1434 maternal-infant dyads was reported in the central database. Of these, \sim 80% mothers with OUD were receiving medication assisted treatment (MAT) with <40% using illicit drugs during pregnancy, 69% Opioid Exposed Newborns (OENs) received skin-to-skin care in the first 24 hours of life, 70% roomed-in for at least 1 night prior to maternal discharge and 80% of eligible OENs received any mother's milk during hospitalization [Fig 1]. ≤ 50% of OENs needed pharmacotherapy [Fig 2]. The average hospital length of stay (LOS) for all OENs born ≥ 37 weeks was \sim 14 days and while for those not requiring pharmacotherapy was \sim 6 days. 80% of OENs were referred to Early Intervention prior to discharge and 72% of OENs were discharged home to a biologic parent. Significant increases in skin-to-skin contact (median 64.7% to 72.3%) and significant decreases in pharmacologic therapy (median 52.5 % to 45.8%) were seen by run chart rules.

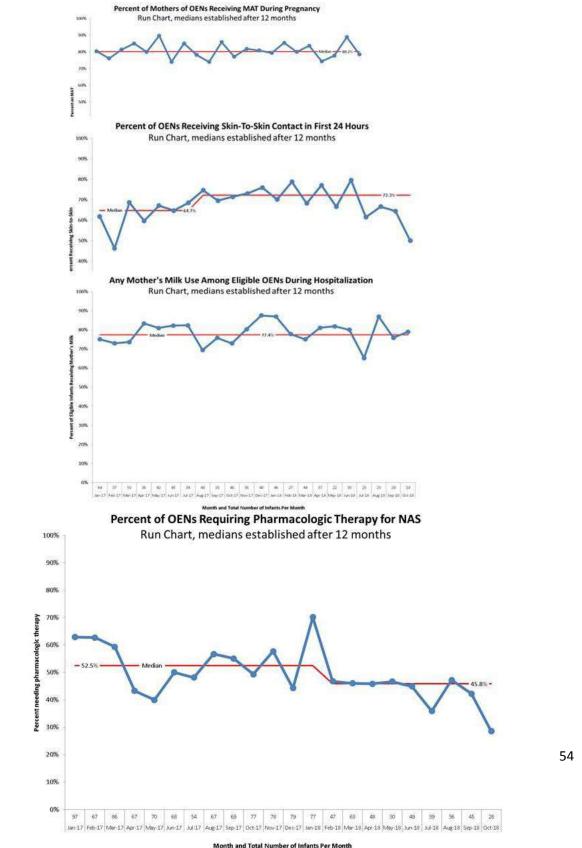
Conclusion(s): Our statewide multidisciplinary collaborative effort was able to engage a majority of birthing hospitals in improving care provision for OUD impacted pregnancies resulting in a trend toward less need for pharmacologic treatment through greater focus on non-pharmacologic methods.

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Tables/Figures:

Run Charts demonstrating trends of maternal MAT enrollment during pregnancy, skin to skin contact in first 24hours and any maternal breast milk feeding rates for opioid exposed newborns. Run Charts demonstrating trends of need for pharmacologic therapy for opioid exposed newborns.



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National Survey of Pediatricians and Family Physicians Assesses HPV Vaccine Delivery Practices

Despite a recommendation for routine HPV vaccination of adolescents over 10 years, vaccination series completion rates remain less than 50% in the U.S.

BALTIMORE, April 27, 2019 – A new national survey of pediatricians and family physicians examines and compares how providers are recommending and communicating about human papillomavirus (HPV) vaccine, their current delivery practices, reported refusal/deferral rates and associated factors, and perceived barriers to vaccination. Findings from the survey will be presented during the Pediatric Pediatric Pediatric

"This was a national survey of pediatricians and family physicians assessing their practices regarding HPV vaccine delivery and their perceptions of the effect of changes from a three to a two-dose recommendation for adolescents younger than 15 years of age," said Allison Kempe, MD, one of the authors of the study. "Our data are very encouraging in showing substantial progress over the past five years in the percent who report strongly recommending to 11 to 12-year-olds. Our findings also point out important areas for improvement in vaccine delivery, especially in how physicians introduce discussions about the vaccine and in the use of standing orders or alerts in the medical record."

Despite a recommendation for routine HPV vaccination of adolescents for over 10 years, vaccination series completion rates remain less than 50% in the U.S. A variety of approaches to increase coverage have been proposed, focused at the practice or provider level, but approaches currently being used in primary care are not well described.

Although the majority of physicians strongly recommend HPV vaccine at 11 to 12 years old, data suggest areas for improvement in strength and style of recommendation and in practice-based delivery methods. The findings suggest that physicians reporting high refusal rates may be anticipating and accommodating refusals by altering recommendation strength and style.

Dr. Kempe added, "The findings also suggest that, from the physicians' perspective, the two-dose schedule could result in meaningful increases in HPV vaccination initiation and completion among adolescents, leading to greater protection against HPV-associated cancers in the U.S."

Dr. Kempe will present findings from "Current Primary Care Practices and Experiences with the Delivery of HPV Vaccine" on Monday, April 29 at 10:30 a.m. EDT. Reporters interested in an interview with Dr. Kempe should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Current Primary Care Practices and Experiences with the Delivery of HPV Vaccine

Background: Despite a recommendation for routine HPV vaccination of adolescents for >10 years , vaccination series completion rates remain <50% in the United States. A variety of approaches to increase coverage have been proposed, focused at the practice or provider level, but approaches currently being used in primary care are not well described.

Objective: To examine and compare among nationally representative panels of pediatricians (Peds) and family physicians (FPs): 1) how providers are recommending and communicating about HPV vaccine; 2) current delivery practices; 3) reported refusal/deferral rates and associated factors; and 4) perceived barriers to vaccination.

Design/Methods: We surveyed nationally representative networks of Peds and FPs by internet or mail from 7/2018-9/2018. Multivariable regression (MV) analyses were conducted assessing factors associated with reported refusal/deferral of ≥50% for 11-12 y.o.

Results: The response rate was 65% (588/908); after excluding 5% of Peds and 16% of FPs not administering HPV vaccine, analyses included 302 Peds and 228 FPs. Peds strongly recommending HPV vaccine ranged from 98% for ≥15 y.o. to 83% for 11-12 y.o.; FPs ranged from 83% for ≥15 y.o. to 66% for 11-12 y.o. (p<.0001). Providers most frequently discussed prevention of cancers and genital warts (Figure 1). 65% of Peds and 42% of FPs reported always/almost always using a presumptive style when discussing HPV vaccine (p<.0001). Overall, 40% used standing orders, 66% had a system for identifying those needing vaccination and 42% had a flagging system. Both specialties reported high rates of refusal/deferral for 11-12 y.o.; FPs reported high rates for all age groups (Figure 2). MV analyses demonstrated that ≥50% refusal/deferral at 11-12 y.o. was associated with not "strongly recommending" in this age group [Risk Ratio 1.88 (95% Confidence Interval 1.40-2.52)], not using a presumptive style "always/almost always" [1.70 (1.22-2.37)] and perceiving less resistance introducing at 13 rather than 11-12 y.o. [1.62 (1.27-2.07)]. Frequently reported barriers to vaccination included misinformation parents receive from social media and concerns about HPV vaccine safety (Figure 3).

Conclusion(s): Although the majority of physicians strongly recommend HPV vaccine at 11-12 y.o., our data suggest areas for improvement in strength and style of recommendation and in practice-based delivery methods. Our data suggest that physicians reporting high refusal rates may be anticipating and accommodating refusals by altering recommendation strength and style.

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Pediatricians and Nurse Practitioners Report Using Strategies to Improve HPV Vaccination, yet Barriers Persist

BALTIMORE, April 27, 2019 – Pediatricians and nurse practitioners report using several strategies to improve human papillomavirus (HPV) vaccination, yet also perceive barriers, according to a national American Academy of Pediatrics (AAP) Pediatric Research in Office Settings (PROS) network study. Findings from the study will be presented during the Pediatric Academic Societies (PAS) 2019 Meeting, taking place on April 24 – May 1 in Baltimore.

A safe and effective vaccine that prevents HPV-attributable cancers has been available since 2006. Despite demonstrated safety and effectiveness, coverage rates for the HPV vaccine remain suboptimal, and considerably lower than coverage for other adolescent vaccinations.

The study examined barriers to HPV vaccination and strategies used to improve HPV vaccination rates in a sample of pediatricians and nurse practitioners from 19 states who participate in the AAP's primary care practice-based research network. As part of the NIH-funded STOP HPV trial, the lead respondent from 47 practices recruited from the PROS research network completed an online, confidential survey in 2018. The survey measured office characteristics, standard office procedures for and communication about HPV vaccination, and use of evidence-based strategies such as performance feedback, prompts, reminder-recall, and standing orders. Proportions and medians were calculated for categorical and continuous variables, respectively.

All respondents reported more than one barrier to HPV vaccination. The most commonly reported major barrier was parent refusal or delay (over 80%). Respondents reported approximately 30% (range 5%-75%) of parents of their 11 to 12-yr-old patients due for an HPV vaccine refused and 15% (range 5%-60%) hesitated without refusing. Other major barriers reported by respondents included the time required to discuss HPV vaccination with families (17% of practitioners), low proportion of adolescents coming in for well visits (13%), lack of training in providing a strong recommendation (11%), respondents sense that others may view that HPV vaccination can wait (9%), and challenges associated with administering HPV vaccine at acute or chronic care visits (7%).

The most commonly reported strategy to improve HPV vaccination rates was use of prompts when HPV vaccination is needed (89%). Respondents also reported that their practices commonly use tools to improve communication about HPV vaccination with parents and adolescents (87%) and receive

performance feedback about HPV vaccination rates (83%). Only 17% of respondents cited that their practice uses reminder-recall messages specific to the HPV vaccine.

The study concluded that respondent-perceived barriers to HPV vaccination remain. Practices are already using a wide variety of strategies to improve delivery of this vaccine, yet room for improvement remains. Alexander Fiks, MD, FAAP, MSCE, the senior author on the abstract, primary care pediatrician at Children's Hospital of Philadelphia, PROS Director and associate director of the Center for Pediatric Clinical Effectiveness and researcher at PolicyLab, added: "The ongoing STOP HPV trial will test the effectiveness of distinct strategies, alone or in combination, to overcome barriers to vaccination and, if effective, may ultimately minimize the burden of HPV-related disease."

Margaret Wright, PhD, one of the authors of the study, will present findings from "Pediatric Practitioners Report Using Strategies to Improve HPV Vaccination, yet Barriers Persist: Results from the National AAP Pediatric Research in Office Settings (PROS) Network" on Monday, April 29 at 10:30 a.m. EDT. Reporters interested in an interview with Dr. Fiks should contact PAS2019@piercom.com.

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About the Pediatric Academic Societies Meeting

Abstract: Pediatric Practitioners Report Using Strategies to Improve HPV Vaccination, yet Barriers Persist: Results from the National AAP Pediatric Research in Office Settings (PROS) Network

Background: A safe and effective vaccine that prevents HPV-attributable cancers has been available since 2006. Despite demonstrated safety and effectiveness, coverage rates for the HPV vaccine remain suboptimal, and considerably lower than coverage for other adolescent vaccinations.

Objective: Examine a) barriers to HPV vaccination and b) strategies used to improve HPV vaccination rates in a sample of pediatric primary care practitioners from 19 states.

Design/Methods: As part of the NIH-funded STOP HPV trial, the lead practitioner from 47 practices recruited from the PROS research network completed an online, confidential survey in 2018. The survey measured office characteristics, standard office practices for and communication about HPV vaccination, and use of evidence-based strategies such as performance feedback, practitioner prompts, reminder-recall, and standing orders. Proportions and medians were calculated for categorical and continuous variables, respectively.

Results: Barriers: All practitioners reported >1 barrier to HPV vaccination. The most commonly reported major barrier was parent refusal or delay (>80%, Table 1). Practitioners reported approximately 30% (range 5%-75%) of parents of their 11-12-yr-old patients due for a HPV vaccine refused and 15% (range 5%-60%) hesitated without refusing. Other major barriers reported by practitioners included the time required to discuss HPV vaccination with families (17% of practitioners), low proportion of adolescents coming in for well visits (13%), lack of training in providing a strong practitioner recommendation (11%), practitioners' view that HPV vaccination can wait (9%), and challenges associated with administering HPV vaccine at acute or chronic care visits (7%). Strategies: The most commonly reported strategy to improve HPV vaccination rates was use of prompts when HPV vaccination is needed (89%, Table 2). Practitioners also reported that their practices commonly use tools to improve communication about HPV vaccination with parents and adolescents (87%) and receive performance feedback about HPV vaccination rates (83%). Only 17% of practitioners cited that their practice uses reminder-recall messages specific to the HPV vaccine. Table 2 provides details about each specific strategy.

Conclusion(s): Practitioner-perceived barriers to HPV vaccination persist. Practices are already using a wide variety of strategies to improve delivery of this vaccine, yet room for improvement remains.

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Despite Increasing Trends in Uptake, HPV Vaccine Coverage is Far Behind Other Infant Vaccines in Many US States

BALTIMORE, April 27, 2019 – Despite the increasing trends in uptake, the human papillomavirus (HPV) vaccine coverage is far behind other infant vaccines in many states, according to a new study, which describes the trends in HPV vaccine uptake in children in the U.S. Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

"In this cohort study containing more than 7.5 million children in the U.S., the HPV vaccine coverage among girls and boys by age 15 increased from 38% and 5% in 2011 to 54% and 45% in 2016," said Szu-Ta Chen, MD, one of the authors of the study. "Despite the increase in uptake, the HPV vaccine coverage varied substantially between states and remained behind the Healthy People 2020 goal of 80%."

Researchers identified a cohort of children within the Truven MarketScan healthcare database between January 2003 and December 2016. Children were followed from the year they turned 9 until the first dose of HPV vaccination, death, end of insurance coverage, or the end of the year when they turned 17, whichever came first. The first dose of HPV vaccination was ascertained by current procedure terminology (CPT) codes. The monthly vaccination rate was calculated as the number of children that received the HPV vaccination in that month divided by the sum of person-months contributed by the eligible children that month. The cumulative incidence of HPV vaccination was estimated based on the monthly rate of vaccination using survival analysis. The study population was stratified by birth year and gender. The cumulative incidence of HPV vaccination at age 15 was mapped across 50 States.

The study included 7,500,397 children (49% females) and 18.8 million person-years. In 2011, the proportion of 15-year-old children that had been vaccinated with at least one dose of HPV was 37.8% for girls and 4.8% for boys (1996-birth cohort); by 2016 this proportion had increased to 53.6% for girls and 45.1% for boys (2001- birth cohort). The HPV vaccine uptake varied substantially across states and, by 2016, it was above 60% for 15-year-old girls and boys only in 13 and three states, respectively.

The Advisory Committee on Immunization Practices recommends HPV vaccination at age 11 and 12 to prevent HPV infection and subsequent occurrence of various cancers. There is a lack of large-scale longitudinal data on the trends of vaccine uptake in the U.S.

Dr. Chen will present findings from "Trends in human papillomavirus vaccination uptake in girls and boys in the United States: real-world evidence from 2003 to 2016" on Monday, April 29 at 11:15 a.m. EDT. Reporters interested in an interview with Dr. Chen should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

The <u>PAS 2019 Meeting</u> brings together thousands of pediatricians and other health care providers to improve the health and well-being of children worldwide. For more information about the PAS 2019 Meeting, please visit <u>www.pas-meeting.org</u>.

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About the Pediatric Academic Societies Meeting

Abstract: Trends in human papillomavirus vaccination uptake in girls and boys in the United States: real-world evidence from 2003 to 2016

Background: Background: The Advisory Committee on Immunization Practices recommends human papillomavirus (HPV) vaccination at age 11 and 12 to prevent HPV infection and subsequent occurrence of various cancers. There is a lack of large-scale longitudinal data on the trends of vaccine uptake in the United States.

Objective: To describe the trends in HPV vaccine uptake in children in the US.

Design/Methods: We identified a cohort of children within the Truven MarketScan healthcare database between January 2003 and December 2016. Children were followed from the year they turned 9 until the first dose of HPV vaccination, death, end of insurance coverage, or the end of the year when they turned 17, whichever came first. The first dose of HPV vaccination was ascertained by current procedure terminology (CPT) codes. The monthly vaccination rate was calculated as the number of children that received the HPV vaccination in that month divided by the sum of person-months contributed by the eligible children that month. The cumulative incidence of HPV vaccination was estimated based on the monthly rate of vaccination using survival analysis. The study population was stratified by birth year and gender. The cumulative incidence of HPV vaccination at age 15 was mapped across 50 States.

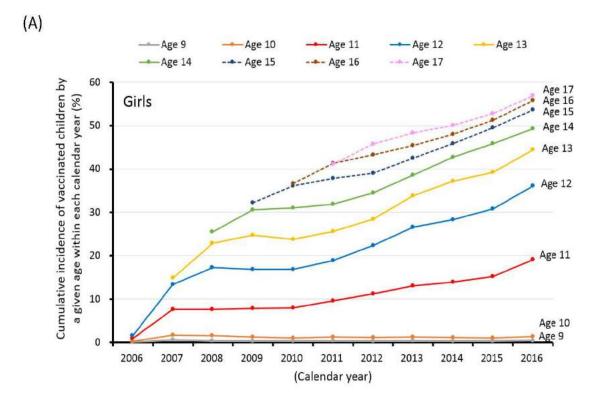
Results: The study included 7,500,397 children (49% females) and 18.8 million person-years. In 2011, the proportion of 15 years old children that had been vaccinated with at least one dose of HPV was 37.8% for girls and 4.8% for boys (1996-birth cohort); by 2016 this proportion had increased to 53.6% for girls and 45.1% for boys (2001- birth cohort). The HPV vaccine uptake varied substantially across states and, by 2016, it was above 60% for 15-year- old girls and boys only in 13 and 3 states, respectively.

Conclusion: Despite the increasing trends in uptake, the HPV vaccine coverage is far behind other infant vaccines in many states.

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Tables/Figures:



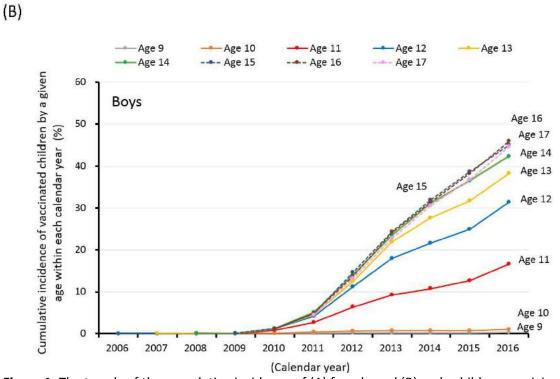
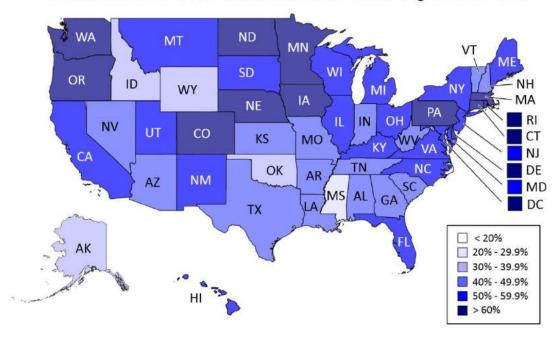


Figure 1. The trends of the cumulative incidence of (A) female and (B) male children receiving human papillomavirus (HPV) vaccination by a given age within each calendar year.

(A)

Cumulative incidence of HPV vaccination in female children at age 15 in 2015-2016



(B)

Cumulative incidence of HPV vaccination in male children at age 15 in 2015-2016

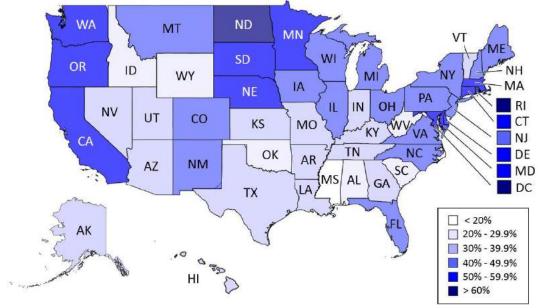


Figure 2. The geographic distribution of the cumulative incidence of human papillomavirus (HPV) vaccination at age 15 among (A) female and (B) male children between 2015-2016 in the United States.

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New Study Measures the Impact of Text Message Reminders on HPV Vaccine Series Completion

HPV vaccine is a critical cancer-protecting vaccine; yet only half of adolescents have received their needed doses.

Text message vaccine reminders are effective, but less is known about the effects across a population.

BALTIMORE, April 27, 2019 – Text message reminders led to timely HPV vaccine series completion across a low-income, urban, minority population, according to a new study. Findings from the study will be presented during the Pediatric Academic Societies (PAS) 2019 Meeting, taking place on April 24 – May 1 in Baltimore.

"HPV vaccine is a critical cancer-protecting vaccine; yet, only half of adolescents have received their needed doses," said Melissa Stockwell, MD, MPH, FAAP, Associate Professor of Pediatrics and Population and Family Health at Columbia University Irving Medical Center, the lead author of the study. "Even among those who start the series, only three-quarters get all the doses needed for protection. In this study, we found that text message vaccine reminders are a powerful, rapid and scalable way to help encourage families to have adolescents complete their vaccine series."

In this AHRQ-funded study, eligible 9 to 17-year-olds receiving their first HPV vaccine at four affiliated community clinics in Northern Manhattan from December 2014 through December 2016 were randomized 1:1 to receive one of two types of text message vaccine reminders. Conventional messages included next dose due date and site-specific walk-in hours. Enhanced educational reminders included educational information targeted to the parent's stage of vaccine decision-making based on the transtheoretical model. The primary outcome was timely HPV vaccine series completion within 12 months (receipt of two or three doses, based on age and enrollment date, accounting for the 2016 change in CDC guidelines).

Chi-square analyses compared the intervention arms to concurrent non-enrollees who received their first vaccine dose during the study period, but who were not enrolled because they were ineligible, not able to be contacted or refused. Participants were also compared to historical controls (first dose administered 2011-2013); for this analysis adolescents from the intervention arms who only needed two doses to complete the series were removed in order to be more directly comparable. In addition,

population coverage for those who received their first dose within the three years prior (2011-2013) and three years (2014-2016) during the intervention were calculated.

Overall, 956 parents of 1,264 eligible families enrolled. Adolescents were half female, and primarily Latino (89%), ≤14 years (92%), and publicly insured (94%). Two-thirds of parents were primarily Spanish speaking; 60.0% had not finished high school. Both text message arms had similarly high timely series completion rates within 12 months: educational (72.4%) versus conventional (75.7%). Those who were in any text message arm had significantly higher completion rates than non-enrollees (n= 1503)(74.1% vs 45.2%; P<0.0001). In addition, even after removing those who only needed two doses to complete the series, they had higher rates than the historical controls (n= 2823)(71.1% vs. 34.8%; p<0.0001). Finally, a population-wide effect was seen during the years of the study 2014-16, above historical trends.

Dr. Stockwell will present findings from "Impact of Text Message Reminders on HPV Vaccine Series Completion" on Monday, April 29 at 10:30 a.m. EDT. Reporters interested in an interview with Dr. Stockwell should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Impact of Text Message Reminders on HPV Vaccine Series Completion

Background: Text message vaccine reminders are effective, but less is known about effects across a population.

Objective: To assess the effect on timely HPV vaccine series completion of text message vaccine reminders vs. historical and concurrent comparison groups.

Design/Methods: In this AHRQ-funded study, eligible 9-17-year-olds receiving their 1st HPV vaccine at 4 affiliated community clinics in Northern Manhattan from December 2014- December 2016 were randomized 1:1 to receive one of two types of text message vaccine reminders. Conventional messages included next dose due date and site- specific walk-in hours. Enhanced educational reminders included educational information targeted to the parent's stage of vaccine decision-making based on the transtheoretical model. The primary outcome was timely HPV vaccine series completion within 12 months (receipt of 2 or 3 doses, based on age and enrollment date, accounting for the 2016 change in CDC guidelines). Chi-square analyses compared the intervention arms to concurrent non-enrollees who received their first vaccine dose during the study period, but who were not enrolled because they were ineligible, not able to be contacted or refused. Participants were also compared to historical controls (1st dose administered 2011-2013); for this analysis adolescents from the intervention arms who only needed 2 doses to complete the series were removed in order to be more directly comparable. In addition, population coverage for those who received their first dose within the three years prior (2011-2013) and three years (2014-2016) during the intervention were calculated.

Results: Overall, 956 parents of 1,264 eligible families enrolled. The adolescents were half female, and primarily Latino (89%), ≤14 years (92%), and publicly insured (94%). Two-thirds of parents were primarily Spanish speaking; 60.0% had not finished high school. Both text message arms had similarly high timely series completion rates within 12 months: educational (72.4%) vs. conventional (75.7%). Those who were in any text message arm had significantly higher completion rates than non-enrollees (n= 1503)(74.1% vs 45.2%; P<0.0001). In addition, even after removing those who only needed 2 doses to complete the series, they had higher rates than the historical controls (n= 2823)(71.1% vs. 34.8%; p<0.0001). Finally, a population-wide effect was seen during the years of the study 2014-16, above historical trends.

Conclusion: Text message reminders led to timely series completion across a low-income, urban, minority population.

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New Research Reviews the State of Vaccine Safety Science

BALTIMORE, April 27, 2019 – A new systematic review provides a succinct summary of the scientific evidence for and/or against causal associations for 47 adverse events following immunization (AEFI). Findings from the study will be presented during the Pediatric Academic Societies (PAS) 2019 Meeting, taking place on April 24 – May 1 in Baltimore.

"Health care providers desire objective and clear information on a broad range of vaccine safety issues to assist them in answering patient questions," said Matthew Dudley, PhD, MSPH, one of the authors of the study. "There have been no recent comprehensive reviews on AEFI, and previous reviews were not written for providers or the public. This systematic review provides an update to the scientific evidence assessing possible causal associations of AEFI compiled in the 2012 report from the Institute of Medicine (IOM) and the 2014 report from the Agency for Healthcare Research and Quality (AHRQ), along with clear causality conclusions intended for health care providers."

The review found that for 12 of the 47 AEFI studied, a causal relationship has been established with at least one vaccine currently routinely recommended to the general population in the U.S. These 12 confirmed adverse reactions are: anaphylaxis, arthralgia/arthritis (mild, acute and transient, not chronic), deltoid bursitis (when vaccine is administered improperly), disseminated varicella infection (in immune deficient individuals for whom the varicella vaccine is contraindicated), encephalitis, febrile seizures, Guillain-Barré Syndrome, hepatitis (in immune deficient individuals for whom the varicella vaccine is contraindicated), herpes zoster, immune thrombocytopenic purpura, meningitis and syncope. Most of these adverse reactions are rare.

For the other 35 AEFIs, the evidence does not support a causal relationship with vaccines recommended for routine use in the U.S. In particular, the evidence shows a clear lack of association between certain vaccines and AEFIs: influenza vaccines do not cause asthma, childhood vaccines do not cause autism, vaccines do not cause diabetes, vaccines given to immunocompetent persons do not cause hepatitis, influenza vaccines do not cause MS in adults, and DTP and hepatitis B vaccines do not cause Sudden Infant Death Syndrome (SIDS).

Dr. Dudley added, "Although vaccines currently recommended for the general population in the U.S. do cause some adverse reactions, vaccines have an excellent safety profile overall and provide protection against infectious diseases to individuals and the general population."

Dr. Dudley will present findings from "The State of Vaccine Safety Science: Systematic Reviews of the Evidence" on Monday, April 29 at 10:30 a.m. EDT. Reporters interested in an interview with Dr. Dudley should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: The State of Vaccine Safety Science: Systematic Reviews of the Evidence

Objective: This systematic review provides a succinct summary of the scientific evidence for and/or against causal associations for 47 AEFI.

Design/Methods: We reviewed 44 AEFI studied in the 2012 report from the Institute of Medicine (IOM) and the 2014 report from the Agency for Healthcare Research and Quality (AHRQ). We also reviewed 3 other AEFI and 2 special topics which have been raised as concerns among the media. We updated the evidence base from the IOM and AHRQ reports using systematic English-language PubMed literature reviews. We provide causality conclusions for each of these AEFIs, and the attributable risk (when possible) for AEFIs caused by vaccines.

Results: For 12 of the 47 AEFI studied, a causal relationship has been established with at least one vaccine currently routinely recommended to the general population in the United States. These 12 confirmed adverse reactions are: anaphylaxis, arthralgia/arthritis (mild, acute and transient, not chronic), deltoid bursitis (when vaccine is administered improperly), disseminated varicella infection (in immune deficient individuals for whom the varicella vaccine is contraindicated), encephalitis, febrile seizures, Guillain-Barré Syndrome, hepatitis (in immune deficient individuals for whom the varicella vaccine is contraindicated), herpes zoster, immune thrombocytopenic purpura, meningitis, and syncope. Most of these adverse reactions are rare. For the other 35 AEFIs, the evidence does not support a causal relationship with vaccines recommended for routine use in the U.S. In particular, the evidence shows a clear lack of association between certain vaccines and AEFIs: influenza vaccines do not cause asthma, childhood vaccines do not cause autism, vaccines do not cause diabetes, vaccines given to immunocompetent persons do not cause hepatitis, influenza vaccines do not cause MS in adults, and DTP and hepatitis B vaccines do not cause Sudden Infant Death Syndrome (SIDS).

Conclusion(s): Although vaccines currently recommended for the general population in the U.S. do cause some adverse reactions, vaccines have an excellent safety profile overall and provide protection against infectious diseases to individuals and the general population.

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Figures/Tables:

Figure 1. Literature Review Diagram

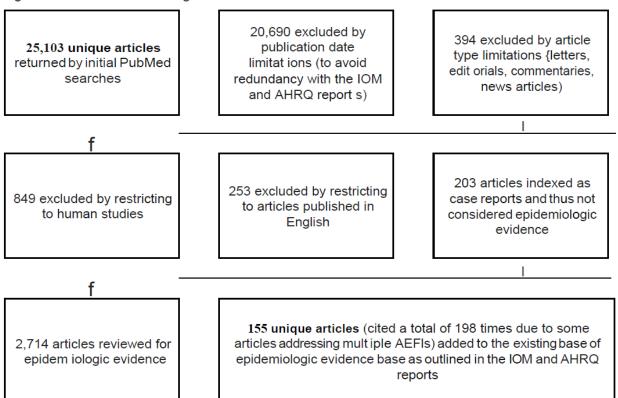


Table 1. Categori es of Causalit y Conclusions

Categories	Definitions
Vaccines can cause the event.	The evidence shows a clear association between the event and at least one vaccine routinely recommended in the U.S.
Vaccines did cause the event.	The evidence showed a clear association between the event and at least one previously recommended vaccine. However, these vaccine(s) are no longer used in the U.S., if they ever were.
Vaccines have not been shown to cause the event.	The evidence of an association between the event and vaccines currently routinely recommended to the general population in the United States is insufficient or non-existent.
Vaccines do not cause the event.	The evidence shows clear lack of association between the event and vaccines currently routinely recommended to the general population in the United States.

Table 2. Standard Categories of Fre qu ency for Adverse Drug Reactions (pro vided by "Guidelines for Preparing Core Clinical-Safety Information on Drugs" - Report of CIOMS Working Group 111, 1995)

Categories	Definitions
Very common	1/10 (10%)
Common	1/100 and< 1/10 (-1%-10%)
Uncommon	1/1,000 and < 1/100 (-0.1-1%)
Rare	1/10,000 and< 1/1,000(-0.01-0.%)
Very rare	< 1/10,000 (< 0.01%)

Table 3. Causal Relationship Establ ished WithvaccinesCurrently Routinely Recommen ded for the General Popu lation in the UnitedStates-

Adverse event following Immun 1 zation (AEFI	Conclusion	Attributable Risk(doses	
Anaphy1as	Vaccine components can very rarely cause anaphylaxis	1/100,000-1,000,000	
Arthralgia/Arthritis (mild, acute, transient- not chronic)	Rubellacontaining vaccines can cause mild, acute, transient arthralgia or arthrit,is verycommonly in adult women but rarely in children. Other U.S. vaccines have not been shown to cause arthralgia or arthritis. Vaccines have not been shown to cause chronic arthralgia/arthritis, as staled in the table below	10-25/100 rubella-containing vaccinedoses (adult females)	
Deltoid Bursitis	Incorrect administration of vaccines can cause deltoid bursitis.	o/a	
Disseminaled Varicella Infection	Varicella vaccinecan rarely cause disseminated varicella infection in immune deficientindividuals for whom the vaccine is contraindicated	ola	
Encephaliits	Measles vaccine can very rarely cause encephalitis. Mumps vaccine used in other countries did cause encephalitis (but not the vaccine licensedin the U.S.)	IOM found one case with strong mechanistic evidence	
Febrile Seizures	Vaccines that induce fever in infants andyoung children, such asMMRV, influenza, and PCV vaccines, can rarely cause febrile seizures	3.92/100,000 (all vaccines given ages 3-5 months)	
Guitlain-Barre Syndrome(GBS)	Influenza vaccinecan cause GBS very rarely in adults. An old formulation of rabies vaccine did cause GBS (but is no longer available). Other vaccines, including current rabies vaccine, have not been shown to cause GBS	1-311,000,000	
Hepatitis	Varicella vaccine can rarely cause hepatitis if administered to persons with certainimmune deficiencies. Vaccines given to immunocompetent persons do not cause hepatitis	o/a	
Herpes Zoster	Varicella vaccine can rarely cause herpes zoster due to vaccine-strain viral reactivation.	IOM found several cases with strong mechanistic evidence	
Immune ThrombocytopenicPurpura (ITP)	MMR vaccine can very rarely cause tTP in children.	1-3/100,000	
Meningtiis	Reactivation of varicella vaccine can very rarely cause meningitis. Mumps vaccine used in other countries did cause meningitis (but not the vaccine licensed in the U.S.).	IOM found severalcases with strong mechanistic evidence	
Syncope	Vaccines (andother injections) can rarely cause syncope.	4.4-14.11100,000	

These conclusions do not necessarily consider vaccmes recommended only for special populations m the UnitedStates such as Yellow Fever vaccme (mternat, on a I travelers) or Smallpox vaccme (military personnel).

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New AAP PROS Study Assesses Influenza Vaccine Hesitancy Among Caregivers of Children

Results from the study underscore the importance for the clinical team to broadly address inaccurate perceptions and promote vaccination even after caregivers agree to the first dose.

BALTIMORE, April 27, 2019 – Even caregivers whose children receive the first dose of influenza vaccine may be vaccine hesitant and have inaccurate beliefs regarding influenza vaccine and disease, according to a new American Academy of Pediatrics (AAP) Pediatric Research in Office Settings (PROS) study that was a collaboration between investigators at Children's Hospital of Philadelphia (CHOP), Columbia University Irving Medical Center, and the AAP. Findings from the study will be presented during the Pediatric Academic Societies (PAS) 2019 Meeting, taking place on April 24 – May 1 in Baltimore.

The study assessed vaccine hesitancy and influenza disease and vaccine beliefs among caregivers of children who received the first of the two required influenza vaccine doses. To receive adequate protection against influenza, many children six months to eight years old need two doses of influenza vaccine in a season. Only half of those receiving a first dose receive a second.

"In our study, over 90% of caregivers, whose children required two doses of influenza vaccine that season, believed that their child would be 'protected with only one flu shot', and 12% had moderate/high vaccine hesitancy," said Ekaterina Nekrasova, MPH, a research assistant at PolicyLab and the Center for Pediatric Clinical Effectiveness at CHOP, and one of the authors of the study. "Caregivers held other inaccurate beliefs about influenza and vaccination even after their child received the first of the two required influenza vaccine doses. Our findings emphasize the importance of promoting the second dose influenza vaccination and educating caregivers about influenza disease and vaccination before and after they agree to the first dose."

As part of the NIH-funded Flu2Text national study conducted during the 2017-2018 season, a telephone survey collected demographic information of caregivers (age, English proficiency, education, relationship to a child) and the participating child (age, gender, race, ethnicity, insurance type, health status). Each child received the first dose of influenza vaccine, needed a second dose that season, and was enrolled in a study of text message influenza vaccine reminders. Caregivers completed a validated measure of vaccine hesitancy (PACV-5) and a series of questions to evaluate their knowledge about influenza infection and vaccine.

Researchers assessed the association of caregiver and child demographic characteristics with vaccine hesitancy and influenza beliefs. The standardized (adjusted) proportion of caregivers endorsing each outcome was calculated using logistic regression.

Analyses included responses from 256 participants from 36 AAP PROS primary care network practices across 24 states. The study found that 11.7% of caregivers had moderate or high vaccine hesitancy. A high proportion of caregivers held the following inaccurate beliefs: "flu is just a bad cold" (40.2%); child will be protected with "only one flu shot" (93.8%); "flu shot causes the flu" (57%); children cannot "die from the flu" (68%).

The results from the study underscore the importance for the clinical team to broadly address inaccurate perceptions and promote vaccination even after caregivers agree to the first dose.

Nekrasova will present findings from "Vaccine Hesitancy and Influenza Beliefs Among Parents of Children Requiring a Second Dose of Influenza Vaccine in a Season: An AAP PROS Study" on Monday, April 29 at 10:30 a.m. EDT. Reporters interested in an interview with Nekrasova should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Vaccine Hesitancy and Influenza Beliefs Among Parents of Children Requiring a 2nd Dose of Influenza Vaccine in a Season: An AAP Pediatric Research in Office Settings (PROS) Study

Background: To receive adequate protection against influenza, many children six months - eight years old need two doses of influenza vaccine in a season. Only half of those receiving a first dose receive a second.

Objective: To assess vaccine hesitancy and influenza disease and vaccine beliefs among caregivers of children who received the first of the two required influenza vaccine doses.

Design/Methods: As part of the NIH-funded Flu2Text national study conducted during the 2017-2018 season, a telephone survey collected demographic information of caregivers (age, English proficiency, education, relationship to a child) and the participating child (age, gender, race, ethnicity, insurance type, health status) [Table 1]. Each child received the first dose of influenza vaccine, needed a second dose that season, and was enrolled in a study of text message influenza vaccine reminders. Caregivers completed a validated measure of vaccine hesitancy (PACV-5) [Table 2] and a series of questions to evaluate their knowledge about influenza infection and vaccine. We assessed the association of caregiver and child demographic characteristics with vaccine hesitancy and influenza beliefs. The standardized (adjusted) proportion of caregivers endorsing each outcome was calculated using logistic regression.

Results: Analyses included responses from 256 participants from 36 AAP PROS primary care network practices across 24 states [Table 1]. 11.7% of caregivers had moderate or high vaccine hesitancy. A high proportion of caregivers held the following inaccurate beliefs: "flu is just a bad cold" (40.2%); child will be protected with "only one flu shot" (93.8%); "flu shot causes the flu" (57%); children cannot "die from the flu" (68%) [Table 2]. In a multivariable model including the demographic characteristics above, only lower English ability was a significant predictor of vaccine hesitancy (p=.01) [Table 3]. No one variable consistently predicted inaccurate influenza disease and vaccine beliefs across all outcomes.

Conclusions: Even caregivers whose children receive the first dose of influenza vaccine may be vaccine hesitant and have inaccurate beliefs regarding influenza vaccine and disease. These results underscore the importance for the clinical team to broadly address inaccurate perceptions and promote vaccination even after caregivers agree to the first dose.

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PAS Press Office (April 24 – May 1, 2019): (832) 371-6239

New Research Examines Barriers to Vaccination in Immunocompromised Children

BALTIMORE, April 27, 2019 – A new study examines the barriers to vaccination of immunocompromised children (ICC). Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS)</u> <u>2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

"Immunosuppressive medications have dramatically improved the outcomes of autoimmune diseases such as lupus and inflammatory bowel disease (IBD)," said Vidya Sivaraman, MD, one of the authors of the study. "While the long-term outcomes of these patients have improved, their care has become more complex and fragmented between the specialist and primary care physician (PCP). We realized that vaccination in these patients has been suboptimal, leaving these patients susceptible to many vaccine-preventable diseases. In this study, our primary aim was to assess vaccine knowledge, comfort, and vaccination practices among parents and PCPs of children with childhood onset systemic lupus and IBD and determine measures to reduce these gaps in preventive care."

Researchers surveyed 31 systemic lupus erythematosus (c-SLE) and 26 IBD patients. The survey found that most patients received their vaccines from their PCP or health department and 16% received vaccines from their subspecialist. The survey indicated that 96% felt that their PCP was well informed about vaccines and 91% reported that their subspecialist discussed vaccines in the past year, most commonly influenza, human papilloma virus, pneumococcal and Hepatitis B. Only two parents expressed concerns for vaccine adverse effects and triggering a disease flare.

Of the 30 PCP responses, 70% had over 20 years' experience and 50% preferred to provide all vaccines to ICC. Yet, there were major barriers to completing vaccines: 14 of 16 (85%) stated they did not stock the 23-valent pneumococcal vaccine. PCPs felt "very confident" about providing vaccines in their ICC only 40% of the time. Practitioners felt poorly informed about their patients' immunosuppressive medications and concern for exacerbating the underlying illness as the main reason for their lack of confidence.

The study concluded that there was discordance between patients feeling confident in their PCP being aware of vaccine recommendations and PCP comfort in vaccinating their ICC patients due to lack of knowledge and concern for triggering a disease flare. Despite that most ICC received vaccines at their PCP's office, most offices did not carry the 23-valent pneumococcal vaccine and did not routinely recommend vaccination of household members. Providing recommended vaccines and lack of education about appropriate vaccination in ICC remain significant barriers and areas for improvement.

Audrey Lloyd, MD, one of the authors of the study, will present findings from "Barriers to vaccination in immunocompromised children" on Sunday, April 28 at 10:30 a.m. EDT. Reporters interested in an interview with Dr. Sivaraman and/or Dr. Lloyd should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Barriers to vaccination in immunocompromised children

Background: The vaccination of immunocompromised children (ICC) remains suboptimal.

Objective: Our primary aim was to assess vaccine knowledge, comfort, and practices among parents of and primary care physicians (PCP) caring for children with systemic lupus erythematosus (c-SLE) and inflammatory bowel disease (IBD).

Design/Methods: Surveys were obtained from patients ≥18y and parents of younger children during routine clinic visits to the Rheumatology and Gastroenterology clinics at Nationwide Children's Hospital (NCH) between Jan - Aug 2018 as a random convenience sample. PCPs affiliated with NCH were surveyed at their monthly meeting followed by an online survey. Responses were recorded in a Redcap database for statistical analysis. Chart review was performed for demographic information, medication exposure, and confirmation of diagnosis. This study was exempt from IRB approval.

Results: We surveyed 31c-SLE and 26 IBD patients. Patient characteristics are detailed in Table 1. Patient data: Most patients received their vaccines from their PCP or Health Department, 16% received vaccines from their subspecialist. 96% felt that their PCP was well informed about vaccines. 91% reported that their subspecialist discussed vaccines in the past year, most commonly Influenza, Human Papilloma Virus, pneumococcal and Hepatitis B. Only 2 parents expressed concerns for vaccine adverse effects and triggering a disease flare. PCP data: 30 responses. 70% had over 20 years' experience and 50% preferred to provide all vaccines to ICC. Yet, there were major barriers to completing vaccines: 14 of 16 (85%) stated they did not stock the 23-valent pneumococcal vaccine. PCP felt "very confident" about providing vaccines in their ICC only 40% of the time. Practitioners felt poorly informed about their patient's immunosuppressive medications and concern for exacerbating the underlying illness as the main reason for their lack of confidence.

Conclusion(s): In our survey of patients and PCPs, there was discordance between patients' feeling confident in their PCP being aware of vaccine recommendations and PCP comfort in vaccinating their ICC patients due to lack of knowledge and concern for triggering a disease flare. Despite that most ICC received vaccines at their PCP's office, most offices did not carry the 23-valent pneumococcal vaccine and did not routinely recommend vaccination of household members. Providing recommended vaccines and lack of education about appropriate vaccination in ICC remain significant barriers and areas for improvement.

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PAS Press Office (April 24 – May 1, 2019): (832) 371-6239

New Study Examines the Resurgence of Milk Sharing

Physicians must understand the history of milk sharing—the important role it once played and its previous status as a well-regulated profession—in order to best advocate to patients and to policymakers for safer sharing practices and regulations.

BALTIMORE, April 27, 2019 – A new study examines the history and resurgence of milk sharing. Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

Wet nursing was considered the safest and most popular alternative form of nutrition until further options were invented, leading to the eventual decline in the profession. Now, society is seeing a resurgence in milk sharing practices through women with an oversupply who are storing extra breast milk and selling it. Unlike wet nursing, however, these interactions often take place away from the regulations and medical examinations that once kept this practice relatively safe.

"While the practice of milk sharing has been around for centuries (as highlighted in this abstract), unregulated milk sharing via the internet presents safety concerns and is therefore discouraged," said Ruth Milanaik, DO, one of the authors of the study. "Physicians should be aware of the resurgence of this practice and encourage participation in regulated milk sharing via milk banks."

Practices of milk sharing can be traced to 2000 B.C., when wet nurses would breastfeed a child that was not biologically their own. At this time, wet nurses played a vital, lifesaving role in feeding infants who had no alternative form of nutrition if their mother could not provide enough breastmilk herself. Wet nursing evolved into a well-regulated profession, with laws and contracts that governed its practice, including a requirement for completion of a medical examination before being registered.

Though commonplace, wet nursing did also face widespread criticism from those concerned about its effect on the mother-infant bond as well as the risk of disease transmission (exacerbated by the low socioeconomic status of many wet nurses). Despite these objections, the lack of hygienic bottles, suitable infant formula, and proper food sterilization techniques (to allow for storage of breastmilk) left feeding via wet nurse as the only safe alternative to a mother's own breastmilk for centuries. It was not until these inventions in the 18th and 19th century—combined with society's historical distrust of wet nurses—that wet nursing fell out of popularity.

Physicians must understand the history of milk sharing—the important role it once played and its previous status as a well-regulated profession—in order to best advocate to patients and to policymakers for safer sharing practices and regulations.

"This project was actually borne out of another study we were conducting looking into the milk sharing practices of parents of newborns," said Nikita Sood, one of the authors of the study. "We thought it was important to examine the history of this practice so that we could better understand the culture around milk sharing and advocate for safe sharing of human milk."

Sood will present findings from "The Resurgence of the Wet Nurse" on Saturday, April 27 at 8 a.m. EDT. Reporters interested in an interview with Sood should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

The <u>PAS 2019 Meeting</u> brings together thousands of pediatricians and other health care providers to improve the health and well-being of children worldwide. For more information about the PAS 2019 Meeting, please visit <u>www.pas-meeting.org</u>.

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About the Pediatric Academic Societies Meeting

Abstract: The Resurgence of the Wet Nurse

Background: The last few years have seen a rise in informal milk sharing among breastfeeding mothers who are able to connect online to buy and sell their breast milk. Though this practice is discouraged by the medical community due to safety concerns, milk sharing is not a new phenomenon. In order to understand the motivations for milk sharing and encourage safe practices, we must first examine the origins and historical significance of milk sharing.

Objective: To understand the history of milk sharing.

Design/Methods: Scholarly literature regarding the history of infant feeding, wet nursing, and milk sharing were reviewed.

Results: Practices of milk sharing can be traced to 2000 B.C., when wet nurses would breastfeed a child that was not biologically their own. At this time, wet nurses played a vital, lifesaving role in feeding infants who had no alternative form of nutrition if their mother could not provide enough breastmilk herself. Wet nursing evolved into a well-regulated profession, with laws and contracts that governed its practice, including a requirement for completion of a medical examination before being registered. Though commonplace, wet nursing did also face widespread criticism from those concerned about its effect on the mother-infant bond as well as the risk of disease transmission (exacerbated by the low socioeconomic status of many wet nurses). Despite these objections, the lack of hygienic bottles, suitable infant formula, and proper food sterilization techniques (to allow for storage of breastmilk) left feeding via wet nurse as the only safe alternative to a mother's own breastmilk for centuries. It was not until these inventions in the 18th and 19th century—combined with society's historical distrust of wet nurses—that wet nursing fell out of popularity.

Conclusion(s): Milk sharing is a practice that has been around for centuries. Wet nursing was considered the safest and most popular alternative form of nutrition until further options were invented, leading to the eventual decline in the profession. Now, society is seeing a resurgence in milk sharing practices through women with an oversupply who are storing extra breast milk and selling it. Unlike wet nursing, however, these interactions often take place away from the regulations and medical examinations that once kept this practice relatively safe. Physicians must understand the history of milk sharing—the important role it once played and its previous status as a well-regulated profession—in order to best advocate to patients and to policymakers for safer sharing practices and regulations.

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PAS2019@piercom.com

PAS Press Office (April 24 – May 1, 2019): (832) 371-6239

New Study Evaluates Clinical Utility of Rapid Whole Genome Sequencing in Neonates with Seizures

BALTIMORE, April 27, 2019 – A new study aims to determine the underlying etiology of seizures and help to target therapy, improve control of seizures, and potentially reduce morbidities in children. Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

"As a neonatologist working with the team at the Genomics Institute, I've seen first-hand that rapid whole genome sequencing (rWGS) can be effective in identifying etiology of unexplained seizures in neonates and subsequently optimizing their care," said Jeanne Carroll, MD, one of the authors of the study. "Early rWGS can give answers to distressed families, help physicians provide a prognosis, and most importantly may help guide therapy with the potential to impact outcomes. A retrospective analysis of 19 patients who were admitted to the neonatal intensive care unit (NICU), with unclear etiology of seizures received WGS resulting in a molecular diagnosis for six infants. Of those six patients, four received a change in medical management as a result of the genetic diagnosis."

This study retrospectively identified a cohort of patients admitted in the first 30 days of life with presenting symptom of seizures who also underwent rapid whole genome sequencing during the admission. These cases were reviewed to assess for etiology of seizure, results of rWGS, and changes in management based on rWGS results.

Nineteen patients were identified with average age at admission of four days and average hospital day at which sequencing was sent of 3.3. There were six diagnoses made by rWGS (31.6%). Four patients were later found on neuroimaging to have a stroke and three had changes of hypoxic ischemic encephalopathy (HIE) on MRI. Four of the six diagnoses led to a change in management including three with targeted seizure medications, and one with a referral to neurometabolic specialist and addition of dietary supplements. Two patients were found to have KCNQ2 mutations, both had significant side effects from antiepileptic medications. In each case, the medication regimen was optimized based on genetic findings leading to control of seizures and reduction in side effects from non-targeted therapies. In this cohort there was also a pyridoxine dependent epilepsy, two syndromic causes of seizures and one metabolic condition identified.

The study concluded that rWGS can identify etiology and direct therapy in the neonate with unexplained seizures.

Dr. Carroll will present findings from "Clinical Utility of rWGS in the Evaluation of Neonatal Seizures" on Saturday, April 27 at 9:15 a.m. EDT. Reporters interested in an interview with Dr. Carroll should contact PROSE019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Clinical Utility of rWGS in the Evaluation of Neonatal Seizures

Background: Seizures are a common reason for admission to the neonatal intensive care unit. Rapidly determining the underlying etiology can help to target therapy, improve control of seizures, and potentially reduce morbidities. The most common causes of neonatal seizures are hypoxic ischemic encephalopathy (HIE), stroke, and intracranial hemorrhage. There are additionally many genetic etiologies for seizures including syndromic causes, primary epilepsies, and metabolic conditions. In some cases, there is a high index of suspicion for a single gene disorder and testing can be narrowly focused. However, more often than not the etiology is elusive. Sequential panel tests and metabolic work up can take weeks to months to complete leading to a missed opportunity to intervene with targeted therapies in the ICU setting.

Objective: Our objective was to evaluate the clinical utility of early rapid whole genome sequencing (rWGS) in neonates with seizures of unclear etiology including diagnostic rate and changes in management based on results.

Design/Methods: We retrospectively identified a cohort of patients admitted in the first 30 days of life with presenting symptom of seizures who also underwent rapid whole genome sequencing during the admission. These cases were reviewed to assess for etiology of seizure, results of rWGS, and changes in management based on rWGS results.

Results: Nineteen patients were identified with average age at admission of 4 days and average hospital day at which sequencing was sent of 3.3. There were 6 diagnoses made by rWGS (31.6%). Four patients were later found on neuroimaging to have a stroke and 3 had changes of HIE on MRI. Four of the 6 diagnoses led to a change in management including 3 with targeted seizure medications, and one with a referral to neurometabolic specialist and addition of dietary supplements. Two patients were found to have KCNQ2 mutations, both had significant side effects from antiepileptic medications. In each case the medication regimen was optimized based on genetic findings leading to control of seizures and reduction in side effects from non-targeted therapies. In this cohort there was also a pyridoxine dependent epilepsy, two syndromic causes of seizures and one metabolic condition identified.

Conclusion(s): Rapid whole genome sequencing can identify etiology and direct therapy in the neonate with unexplained seizures.

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PAS Press Office (April 24 – May 1, 2019): (832) 371-6239

New Study Demonstrates Viral Family Targeted by the Immune Response to Kawasaki Disease

By preparing antibodies from clonally expanded peripheral blood plasmablasts from Kawasaki Disease children, antigens of a previously unidentified virus targeted by the antibody response to the disease have been identified.

BALTIMORE, April 27, 2019 – A new study identifies antigens targeted by the antibody response of children with Kawasaki Disease (KD). Findings will be presented during the <u>Pediatric Academic Societies</u> (<u>PAS</u>) 2019 Meeting, taking place on April 24 – May 1 in Baltimore.

"To identify antigens targeted by the antibody response of children with KD, we identified plasmablasts that were clonally expanded in the peripheral blood of 11 children with KD and made monoclonal antibodies from these plasmablasts," said Anne Rowley, MD, one of the authors of the study. "Monoclonal antibodies from nine of the 11 patients identified intracytoplasmic inclusion bodies in ciliated bronchial epithelium of fatal KD cases. A subset of these antibodies recognizes peptides from a hepacivirus non-structural protein, and an optimized peptide blocked binding of these antibodies to the inclusion bodies, demonstrating the presence of a hepacivirus-like protein in the inclusion bodies. These results strongly suggest that a new human virus, closely related to the hepaciviruses and with a respiratory portal of entry, is etiologically related to KD."

The study isolated peripheral blood (PB) from KD children 1-3 weeks after fever onset, and characterized the response using single cell RT-PCR. It identified oligoclonal PB sets and highly mutated IgA PB, and generated monoclonal antibodies from these PB. It used the monoclonal antibodies to evaluate reactivity to KD tissues and to a peptide array comprising 29,939 peptides derived from 13,123 B cell epitopes of animal viruses reported in the Immune Epitope Database and Analysis Resource.

The study sequenced 1,156 PB from 11 KD patients, and identified 44 sets of oligoclonal PB in these patients. It prepared 61 monoclonal antibodies (Mab) from oligoclonal PB and from IgA PB that showed high levels of somatic mutation. Ten of these antibodies strongly bind to KD ICI, and 23 weakly bind. Animal virus peptide array revealed that Mab KD4-2H4 (from patient KD4), which strongly binds ICI, recognized multiple similar peptides from a nonstructural protein of hepacivirus C with an identified motif that was highly significant at e-118. Patient KD4 had negative hepatitis C serology. Peptide substitution analysis was performed to identify optimal amino acids for binding of KD4-2H4 at each position. ELISA using an optimized peptide revealed that four other KD Mab from two additional KD

patients also recognized this peptide; all three patients had coronary aneurysms. The strong ICI binding of KD Mabs KD4- 2H4 and KD6-2B2 was completely blocked by pre-incubation with the optimized peptide.

Children with KD make antibodies to hepacivirus peptides, and KD ICI contain protein with a hepaciviruslike epitope. These results strongly suggest that a new human virus, closely related to the hepaciviruses and with a respiratory portal of entry, is etiologically related to KD. Identification of the specific etiology of KD could revolutionize KD diagnosis and treatment in the future.

Dr. Rowley will present findings from "Monoclonal Antibodies from Children with Kawasaki Disease (KD) Recognize Hepacivirus Peptides" on Monday, April 29 at 2 p.m. EDT. Reporters interested in an interview with Dr. Rowley should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Monoclonal Antibodies from Children with Kawasaki Disease (KD) Recognize Hepacivirus Peptides

Background: We previously reported an oligoclonal IgA plasma cell response in KD arteries, and made antibodies using oligoclonal immunoglobulin alpha heavy chains with random light chains. These antibodies identified intracytoplasmic inclusion bodies (ICI) in KD ciliated bronchial epithelium by immunohistochemistry, but could not identify specific antigen, likely because they did not have correct in vivo cognate heavy and light chain partners. Analysis of peripheral blood plasmablasts (PB) has emerged as a powerful tool for the study of antibody responses to infectious diseases, and single cell approaches allow for identification of cognate heavy and light chains in each PB.

Objective: To identify antigens targeted by the antibody response of children with KD.

Design/Methods: We isolated PB from KD children 1-3 weeks after fever onset, and characterized the response using single cell RT-PCR. We identified oligoclonal PB sets and highly mutated IgA PB, and generated monoclonal antibodies from these PB. We used the monoclonal antibodies to evaluate reactivity to KD tissues and to a peptide array comprising 29,939 peptides derived from 13,123 B cell epitopes of animal viruses reported in the Immune Epitope Database and Analysis Resource (www.iedb.org).

Results: We sequenced 1156 PB from 11 KD patients, and identified 44 sets of oligoclonal PB in these patients. We prepared 61 monoclonal antibodies (Mab) from oligoclonal PB and from IgA PB that showed high levels of somatic mutation. Ten of these antibodies strongly bind to KD ICI, and 23 weakly bind. Animal virus peptide array revealed that Mab KD4-2H4 (from patient KD4), which strongly binds ICI, recognized multiple similar peptides from a nonstructural protein of hepacivirus C with an identified motif that was highly significant at e-118. Patient KD4 had negative hepatitis C serology. Peptide substitution analysis was performed to identify optimal amino acids for binding of KD4-2H4 at each position. ELISA using an optimized peptide revealed that 4 other KD Mab from two additional KD patients also recognized this peptide; all 3 patients had coronary aneurysms. The strong ICI binding of KD Mabs KD4- 2H4 and KD6-2B2 was completely blocked by pre-incubation with the optimized peptide.

Conclusion(s): Children with KD make antibodies to hepacivirus peptides, and KD ICI contain protein with a hepacivirus-like epitope. These results strongly suggest that a new human virus, closely related to the hepaciviruses and with a respiratory portal of entry, is etiologically related to KD.

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PAS Press Office (April 24 – May 1, 2019): (832) 371-6239

New Study Results Aim to Better Understand Kawasaki Disease

Kawasaki Disease is a childhood vasculitis, marked by prolonged fevers and coronary artery inflammation/aneurysms in near one quarter of those untreated.

BALTIMORE, April 27, 2019 – A new study looks to define the antibody characteristics, including clonality, of plasmablasts during Kawasaki Disease (KD). Findings from the study will be presented during the <u>Pediatric Academic Societies (PAS) 2019 Meeting</u>, taking place on April 24 – May 1 in Baltimore.

"We still don't know the cause of KD, the leading cause of childhood acquired heart disease in developed nations," said Mark Hicar, MD, PhD, one of the authors of the study. "During a normal infectious immune response, special B cells called plasmablasts that are specific to the infection are found in the peripheral blood. We are characterizing these responses in a number of children with KD, have created antibodies from these plasmablasts, and are using these to identify the cause of KD."

Researchers used antibody repertoire next-generation sequencing to characterize memory and PB populations. Additionally, pairing of heavy and light chains was performed with Chromium Single Cell Gene Expression (10x Genomics, Pleasanton, CA) using the Human B cell Single Cell V(D)J Enrichment Kit.

From plasmablasts from subject 24, antibody sequences using VH4-34 and a 19 amino acid length complementarity determining region 3 showed a massive expansion between day four and six of fever. Chromium single cell sequencing produced over 946 heavy and light chain paired sequences. Sequence comparison showed 40% of sequences demonstrated markers of clonal expansion, which represented 100 clonal groups. One clonal group (24-01) reflected the massive clonal expansion (VH4-34, CDR3 19) previously shown within the next-generation sequencing data.

This clonal expansion within plasmablast populations supports that KD is caused by an infection. Antigen targeting of monoclonal antibodies from these clones is currently being explored.

Dr. Hicar will present findings from "Clonal expansion within circulating plasmblast populations lends support for an infectious disease etiology of Kawasaki disease" on Monday, April 29 at 10:30 a.m. EDT. Reporters interested in an interview with Dr. Hicar should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Clonal expansion within circulating plasmblast populations lends support for an infectious disease etiology of Kawasaki disease

Background: Kawasaki Disease (KD) is a childhood vasculitis, marked by prolonged fevers and coronary artery inflammation/aneurysms in near one quarter of those untreated. The cause remains unknown; however, epidemiologic and demographic data support a single preceding infectious agent may lead to KD. Plasmablasts (PBs) are a stage of transitional B-cells that lead to plasma cells, the long-lived antibody producing cells of the bone marrow. After initial infection, peripherally circulating PB populations are enriched for cells with antibodies against the preceding infection.

Objective: We have recently published data showing children with KD have similar PB responses to children with infections. We sought to define the antibody characteristics, including clonality, of these PBs during KD.

Design/Methods: We used antibody repertoire next-generation sequencing to characterize memory and PB populations. Additionally, pairing of heavy and light chains was performed with Chromium Single Cell Gene Expression (10x Genomics, Pleasanton, CA) using the Human B cell Single Cell V(D)J Enrichment Kit.

Results: From subject 24, antibody sequences using VH4-34 and a 19 amino acid length complementarity determining region 3 showed a massive expansion between day 4 and 6 of fever. Chromium single cell sequencing produced over 946 heavy and light chain paired sequences. Sequence comparison showed 40% of sequences demonstrated markers of clonal expansion, which represented 100 clonal groups. One clonal group (24-01) reflected the massive clonal expansion (VH4-34, CDR3 19) previously shown.

Conclusion(s): This clonal expansion within plasmablast populations supports that Kawasaki disease is caused by an infection. Antigen targeting of these monoclonal antibodies is currently being explored.

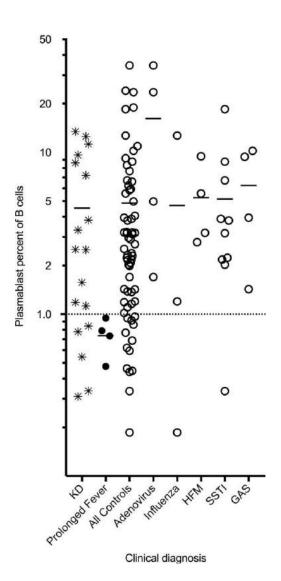
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Tables/Figures:

Figure 1: PBs in KD are similar to infectious diseases

Plasmablast levels, as a per- centage of overall B cell number, were compared between children with KD (star), prolonged fever (closed circle), and febrile control groups as marked (open circles). Abbreviations: Hand-foot-and- mouth (HFM), Skin and Soft tissue infections (SSTI), and Group A streptococcal pharyngitis (GAS). (figure 2 in Martin et al, 2018.)



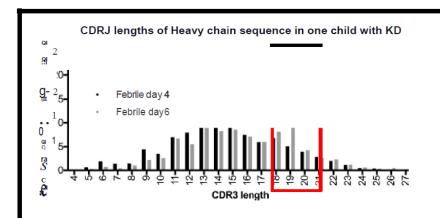


Figure 2: CDR3 analysis shows massive clonal expansion in subject 24's repertoire from day 4 to 6. RNA was extracted from total PBMCs and heavy chain primers were used on the Illumina MiSeq platformper the methods section. The IMGT HighV-QUEST Database matches sequences to the closest V-, D-, and J-gene families and allele and provided output of 265000 day 4 (black) and 190024 day 6 (gray) analyzed sequences. Sequences analyzed by CDR3 length are shown as percentage of total. Strikingly, there is a massive expansion of B cell sequences with CDR3 length of 19 on day 6 of fever (red box). This child's ciirculat ing PBs as a percentage of 8 cells for day 4

and '6 were 13.5% and 7.0% respectively.

Clones	Clonal membe,r-s	Sequeive with exact matches ()	VH ie "g th	VI le1gth
2,4 - 01 *	10	01(s1	19	1,1
14.02	6	02(5)]L 9	9
24-25	6	25(2.)]L 1	9
24-29	6	29(2.)]L]L	8
24-39	5	3:9(2.)]L5	11
24-49	3	49(2.)	2. 0	13
24-161	5]LB	9
24-311	4]L4 ,	9
24-439	2]L]L	11
24-441/659	15		JL JL	9
24-595	5]L5	9
2 4 - '81 5	8]L.5	Hl
24-893	4]L2.	HJ
24-908	5		2. 0	9
* H:la.ted to	s equences	not e l	i n miseq	da.taLbase

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PAS Press Office (April 24 – May 1, 2019): (832) 371-6239

New Study Aims to Validate Pediatric Version of Sequential Organ Failure Assessment

BALTIMORE, April 27, 2019 – A new study aims to validate the pediatric version of Sequential Organ Failure Assessment score in the emergency department (ED) setting as a predictor of mortality in all patients and patients with suspected infection. Findings from the study will be presented during the Pediatric Academic Societies (PAS) 2019 Meeting, taking place on April 24 – May 1 in Baltimore.

In adult Sepsis-3, sepsis is defined as a Sequential Organ Failure Assessment (SOFA) score ≥2 plus suspected infection. A pediatric version (pSOFA) was derived among pediatric intensive care unit (PICU) patients.

"Our study is the first evaluation of pSOFA and Sepsis-3 outside of the PICU setting in a broad, multi-centered cohort of children seeking emergency care," said Frances Balamuth, MD, PhD, MSCE, one of the authors of the study. "We found that hospital mortality is a very rare outcome in this setting due to the diverse population that seek care in the ED and differentiating it from prior areas of pSOFA study. We found that pSOFA in the ED has face validity in that we observed increasing mortality with increasing pSOFA scores in both the ED population overall, and in those with sepsis according to Sepsis-3 definitions. Interestingly, we found that an ED pSOFA score of ≥2 had poor sensitivity for predicting in hospital death, and not surprisingly had better test characteristics in those with suspected infection compared to the ED population overall."

This study involved a retrospective observational study in seven U.S. children's hospitals using the Pediatric Emergency Care Applied Research Network (PECARN) Registry from January 1, 2012 through - March 31, 2018. It included all ED visits for patients less than 18 years.

There were 3,087,746 ED visits during the study period. The pSOFA scores ranged from 0 to 14, with median (IQR) of 0 (0, 0). There were 88,916 (2.9%) visits with pSOFA \geq 2. Visits with pSOFA \geq 2 had increased risk of death (RR 31.8 (95% CI 28.5, 35.7) and longer median length of stay (LOS) (116 [41, 358] versus 41 [20, 85] hours, p<0.001) compared to those with pSOFA <2. Increasing pSOFA scores were associated with increased hospital mortality. The pSOFA had fair discrimination for hospital mortality with AUROC 0.79 (95% CI 0.77, 0.81). There were 490,314 patients with suspected infection, of which 30,339 (6.2%) had sepsis, and 154 (0.03%) had septic shock. In these categories, hospital mortality was 0%, 0.8%, and 5.8% respectively; and median hospital LOS was 45, 83 and 164 hours, respectively. The pSOFA had increased discrimination for hospital mortality among patients with suspected infection (AUROC 0.86 [95% CI 0.84, 0.88]).

The study evaluated the pSOFA score in a large, multicenter sample of pediatric ED visits. The pSOFA ≥2 was uncommon but associated with increased mortality. The pSOFA had fair discrimination for inhospital mortality among all ED visits; and improved discrimination among patients with suspected infection.

Dr. Balamuth continued, "Because the pSOFA score incorporates laboratory values as components of the score, and many children in the ED setting appropriately do not undergo laboratory testing, the pSOFA score likely has limited utility in improving initial clinician sensitivity for mortality risk in children with possible infections. Additional risk stratification tools are needed that are specifically designed for improving sensitivity for the 'needle in the haystack' problem of finding pediatric severe sepsis in the emergency setting."

Dr. Balamuth will present findings from "Validation of the Pediatric Sequential Organ Failure Assessment Score and Evaluation of Sepsis-3 Definitions in the Pediatric Emergency Department" on Sunday, April 28 at 3:30 p.m. EDT. Reporters interested in an interview with Dr. Balamuth should contact PAS2019@piercom.com. Please note that only the abstracts are being presented at the meeting. In some cases, the researchers may have additional data to share with media.

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About the Pediatric Academic Societies Meeting

Abstract: Validation of the Pediatric Sequential Organ Failure Assessment Score and Evaluation of Sepsis-3 Definitions in the Pediatric Emergency Department

Background: In adult Sepsis-3, sepsis is defined as a Sequential Organ Failure Assessment (SOFA) score ≥2 plus suspected infection. A pediatric version (pSOFA) was derived among PICU patients.

Objective: Our aims were to validate the pSOFA score in the emergency department (ED) setting as a predictor of mortality in 1) all patients; and 2) patients with suspected infection.

Design/Methods: Retrospective observational study in 7 US children's hospitals using the Pediatric Emergency Care Applied Research Network (PECARN) Registry from 1/1/12-3/31/18. We included all ED visits for patients <18 years. Using only ED data, pSOFA components (cardiovascular, respiratory, hematologic, hepatic, renal, neurologic) were assigned a score from 0 to 4. We compared hospital length of stay (LOS) and mortality for visits with ED pSOFA ≥ 2 and <2 and calculated discrimination for mortality using area under the ROC curve (AUROC). Within the subset with suspected infection, defined by any infectious testing during the ED visit, we determined the LOS and mortality for sepsis (suspected infection + pSOFA ≥ 2) and septic shock (suspected infection + vasoactive infusion + serum lactate >2 mg/dL).

Results: There were 3,076,500 ED visits during the study period. pSOFA scores ranged 0 to 14, with median (IQR) of 0 (0, 0). There were 88,986 (2.9%) visits with pSOFA ≥2. Visits with pSOFA ≥2 had increased risk of death (RR 31.8 (95% CI 28.5, 35.7) and longer median LOS (54 [IQR] vs 39 [IQR] hours, p<0.001) compared to those with pSOFA <2. Increasing pSOFA scores were associated with increased hospital mortality (Figure 1). pSOFA had fair discrimination for hospital mortality with AUROC 0.77 (95% CI 0.75, 0.78); test characteristics in Table 1. There were 490,388 patients with suspected infection, of which 30,366 (6.2%) had sepsis, and 154 (0.03%) had septic shock. In these categories, hospital mortality was 0%, 0.9%, and 5.8% respectively; and median hospital LOS was 45, 83, and 164 hours, respectively (Table 2). pSOFA had increased discrimination for hospital mortality among patients with suspected infection (AUROC 0.86 [95% CI 0.84, 0.88]).

Conclusion(s): We evaluated the pSOFA score in a large, multicenter sample of pediatric ED visits. pSOFA ≥2 was uncommon but associated with increased mortality. pSOFA had fair discrimination for in-hospital mortality among all ED visits; and improved discrimination among patients with suspected infection.

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Tables/Figures:

oSOFA 2:2 as oredictor of hosoital mortality	% 195% CII	
ensitivitv	48.6145.8, 51.4)	
peci fi city	97.1(97.1, 97.2)	
Positive Predictive Value	0.0110.01, 0.01)	
Negative Predictive Value	1 .0 11.0. 1.0)	
Positive Likelihood Ratio	1697.011628.0,1769.0)	
Negative Likelihood Ratio	52.9150.1. 55.9)	
li\rea Under ROC Cur ve	77.0 (75.0, 78.0)	

	Suspected Infection (infectio us test ing sent in ED) (n=459,868)	Sepsi s (suspected infection + pSOFA 2) (n =30,366)	Septic Shock (sepsis + vasoactive + lactate;,:2.0) (n=154)	p-value
Age (median years, IQR)	5.6 (2.0, 10.3)	3.8 (0.9,9.7)	10.0 (5.2, 14.7)	<0.001
Female (n, %)	263,798 (57.4)	13,827 (45.5)	75 (48.7)	<0.001
Comolex Chronic Cond iti on In, %)	54,0 26 111.9)	17,804 (59.9)	121 180.7)	<0.001
Mechanical ventil ation (n, %)	2423 (0.5%)	2722 (9.0)	44 (28.6)	< 0.001
Vasoactive in fusio n (n, %)	1 (0 .0)	342 (1 .1)	154 (1 00)	<0.001
In- h osoi tal dea th In, %)	132 {0	273 10.9)	9 (5.8)	<0.001
Hosoital LOS(med ian hour s. IQR)	45.0 (25.5, 86.1)	132.8 (44.7. 164.5	163.5 (97.6. 280.4)	< 0.001

In Hospital Mortality by Maximum pSOFA Score in ED

