PECARN

Pediatric Emergency Care Applied Research Network

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FEATURE ARTICLE:

PECARN Future Investigator Meetings Developing the Next Generation of Pediatric Emergency Medicine Researchers

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PECARN Future Investigator Meetings

Developing the Next Generation of Pediatric Emergency Medicine Researchers

Authors: Sherry Goldfarb, Julie Leonard, Krista Wheeler & Rachel Stanley - GLACiER

Origin

As the work of PECARN began to impact pediatric emergency practice, network leadership recognized the importance of developing the next generation of PEM researchers. In 2012, Dr. Stanley (PI, GLACiER) founded the PECARN Future Investigator meeting and a decade later, continues to lead this successful program.

Meeting Structure

The half-day meeting is held annually in conjunction with a PECARN meeting and is composed of a series of small group sessions designed to provide research career mentorship to participants. Nodes sponsor future investigators from Hospital Emergency Department Affiliate Sites, EMSA nodal sites, and non-PECARN sites. Participants get an opportunity to present their research concepts to experienced investigators for feedback. They also attend panel discussions covering topics such as how to attain funding, tips on partnering in multi-centered research, and achieving work-life balance. The agenda includes networking opportunities by kicking off with meet and greet and closing with a group dinner.

Mentors

Mentors include senior PECARN investigators, outside investigators and experts and federal partners, including HRSA/Maternal and Child Health Bureau (MCHB), NHLBI, National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Child Health and Human Development (NICHD), National Institute of General Medical Sciences (NIGMS) and the Office of Emergency Research at the NIH. Mentors have experience in research design, managing large multi-center studies, grant writing, data analytics, funding sources and work-life balance. We also invite mentors with experience in specific research topics that are of interest to the mentees.

Mentees

Each year, three or more future investigators are selected to attend the meeting by each of the PECARN nodes. The investigators are drawn from a range of specialties, educational background, and research interests. We have hosted MDs, DOs, MBBCH and PhDs in academic positions from resident to professor. Secondary degrees include MPH, MS, MSc, MED, CTrop, RDMS, PhD, NREM P-T, and JD. Attendees have included 96 women and 69 men. In addition to pediatric emergency medicine, their specialties include ultrasound, injury prevention, hematology/oncology, critical care, molecular diagnostics, psychiatry, and pediatric neurology.

"The meetings have resulted in the identification of many future investigators that are actively mentored in their career development by PECARN investigators..."

...Continued from pg 2

Outcomes and Post-Meeting Mentoring

Sepsis, pain management, health disparities, pneumonia, traumatic brain injury, and ultrasound were among the topics addressed at the inaugural PECARN future investigator meeting in 2012. Two current PECARN trials are led by attendees of the inaugural meeting, Fran Balamuth, Prompt-Bolus, PRIME and Daniel Tze, HEADACHE, PEM-NEWS. While we cannot take credit for their success, we hope that the mentor/mentee relationships the program facilitated have contributed to their research. A total of 164 early investigators from 30 different sites have participated with 36 investigators attending two or more meetings.

Examples of other participants who have active PECARN studies include Jordee Wells, C-Spine Diversity Supplement, GLACiER; Manish Shaw, PediDOSE, CHaMP, Todd Florin, PRAPP and PedCAPS, HOMERUN/PRIME. This list is not exhaustive and there are many others who have received funding or whose grants are in the pipeline.

The meetings have resulted in the identification of many future investigators that are actively mentored in their career development by PECARN investigators with the aim of developing independent research projects. The meetings also provided a forum for collaboration between future investigators who exchanged ideas and ultimately supported each other's work as colleagues.

Investigator areas of research have been as varied as the investigators and include the following topics.

Adolescent Health	Decision Tools	Injury Prevention	Screening
Airway Managment	Dissemination	Lyme Disease	Sickle Cell Disease
Analgesia	Drug Trials	Mental Health	Traumatic Brain Injury
Asthma	Drug Risk Assessment	Migraine	Technology
Biomarkers	Education	Pain Management	Toxicology
Bronchiolitis	Global Health	Patient Centered Outcomes	Translational Res.
Cardiac Arrest	Firearm Injuries	Patient Safety/QI	Trauma
Child Abuse	Head Injury	Pre-Hospital Education	Ultrasound
Clinical Informatics	Health Services Research	Quality Improvement	Value Based Care
Comparative Effectiveness	Imagiing	Respiratory Disease	Video Laryngoscopy
Concussion	Infectious Disease	Sedation	Violence

"Conducting high priority, high quality research in pediatric emergency care."

PediDOSE

Sites have collectively completed 2,312 surveys and 209 interviews as part of the year 1 community consultation activities for this exception from informed consent (EFIC) study. Enrollment at several sites has begun, with all 20 sites for Pediatric Dose Optimization for Seizures in Emergency Medical Services (PediDOSE) starting by October 2022. PediDOSE aims to measure the effectiveness and safety of a standardized pediatric seizure protocol with age-based midazolam dosing. If the intervention is safer and more effective than current practice (calculation-based dosing), the potential impact is a paradigm shift in EMS pediatric seizure treatment that can be implemented across the country.

HIKO STEC

Hyperhydration to Improve Kidney Outcomes in Children with Shiga Toxin-Producing E. coli Infection (HIKO STEC): A Multinational Cluster Randomized Crossover Trial is in the final stages of pre-enrollment activities. HIKO STEC is a 26-site phase III, embedded, cluster-randomized, crossover trial comparing hyperhydration (e.g. early aggressive intravenous treatment) with conservative fluid management as treatment for STEC-infected children. This study aims to discover which treatment method most effectively mitigates the renal and extrarenal complications of the hemolytic uremic syndrome (HUS) and improves health outcomes in STEC-infected children. All sites are anticipated to begin enrollment in September 2022.

HEADACHE

The Headache Assessment in Children for Emergent Intracranial Abnormalities (HEADACHE) study aims to create the first decision-making algorithm that will allow physicians to determine the precise risk of emergent intracranial abnormalities in children with headaches, and accurately identify those who require emergent neuroimaging and those who do not. We have enrolled over 5,200 children and completed over 360 interrater assessments over the past 17 months. Emergent intracranial abnormalities have been identified in approximately 0.9% of children. Approximately 32% of children received ED neuroimaging, with over 60% of them undergoing CT scans.

Study Updates

ED-STARS

The ED Screen for Teens at Risk for Suicide (ED-STARS) study is in the final manuscript writing phase with 1 manuscript submitted to JAMA Open, 3 manuscripts at or heading to GAPS and 5 in progress. We anticipate initial drafts of all manuscripts this fall.

PED SCREEN

PED SCREEN addresses the critical need to improve pediatric sepsis outcomes by developing methods to accurately identify at-risk children presenting for emergency care. The project captures electronic health record (EHR) data to create a multi-center registry with the ultimate goal of improving the detection and treatment of pediatric sepsis in the emergency department (ED) setting. To accomplish this, we are automating the determination of organ dysfunction in children with sepsis directly from structured and narrative data in an expanded multicenter EHR patient registry. That data are being used to derive and validate prediction models of pediatric sepsis that predict subsequent organ dysfunction within 48 hours using ED EHR data from the first 4 hours of care. Innovative deliverables from this project include the existence of a broad and rich EHR registry, an automated process of outcome determination, and prediction models of risk of sepsis.

SCIENCE II

The investigators on the SCIENCE interventional trial are progressing towards study implementation. We had our first DSMB meeting in early January and the central IRB is reviewing our amended protocol. We are excited to continue our work improving the emergency department care of the children with sickle cell disease.

BIOSIGNATURES I & II

The Biosignature I/II studies are evaluating the ability of the “RNA Biosignature” to distinguish febrile infants ≤ 60 days-old with viral versus serious bacterial infections (UTIs, bacterial meningitis and bacteremia). This technology has the potential for rapid and accurate diagnosis of febrile infants. Biosignatures II is assessing the stability of the RNA biosignature via sequential sampling. We enrolled 2,612 infants, with 306 sequential samples. We have published a dozen manuscripts on Biosigs I and II, have several manuscripts under review, are working on others, and have one that is in press including a video abstract (Urinalyses and Meningitis). Finally, we are submitting a PECARN-endorsed grant to PCORI regarding Implementation of the PECARN febrile infant prediction rule which will involve computerized decision support and shared decision-making. All of these studies will help facilitate a more expeditious, accurate and safer evaluation of the febrile infant.

PRAPP

Procalcitonin to Reduce Antibiotic Use in Pediatric Pneumonia (P-RAPP) is a pilot study evaluating the feasibility of a future large-scale clinical trial evaluating use of amoxicillin vs no antibiotics (i.e., placebo) in children with mild clinical presentation and low procalcitonin values. We have 2 manuscripts under review and a third in preparation from our work during year 1 of the grant. Enrollment in the pilot trial concluded the end of May 2022. A manuscript is in development, and we are turning our focus to planning the larger trial.

STArT

The STArT study investigates the benefits and safety of arginine for the treatment of patients with Sickle Cell Disease and pain. There are 10 sites enrolling and to date our sites have screened more than 1,000 patients. We have exceeded our November enrollment milestone with 87 enrolled participants! In-person monitoring visits are continuing with 5 sites completed, and 3 scheduled through the end of the year. Our project period runs through the end of August 2026 and we aim to enroll 360 subjects.

FLUID

The FLUID study enrolled ~1,800 children with diabetes: ~1400 with DKA and 400 without DKA. The main analysis was published in the NEJM and demonstrated no significant differences between fast and slower fluid rates on neurological outcomes. This liberates clinicians to use their clinical judgment when hydrating children with DKA. There have been many secondary analyses and manuscripts written from the study, and we are near completion. Most recently, we had 4 important publications, including "Cerebral Injury at DKA Presentation" in Journal of Pediatrics. There are just a few manuscripts left, the FLUID Public Use Dataset (PUD) is currently under review, and we are planning for an NIH grant submission exploring inflammation and perfusion in a new DKA cerebral injury discovery grant.

BEEPER

BEdside Exclusion of Pulmonary Embolism in children without Radiation (BEEPER) is a large multi-center, observational study. This project will prospectively test if Pulmonary Embolism Rule out Criteria (PERC-Peds), or PERC rule, can safely exclude PE in approximately 4,030 children ages 4 to 17 years old who raise a suspicion of PE in the emergency department setting. Enrollment began on November 30, 2020 and to date has enrolled 2,041 participants between 21 sites (Wayne State joined in May 2022). The rate of venous thromboembolism in the study population continues to be on target at ~4.3%.

PECARN Registry

The PECARN Registry is an emergency care visit registry with automated transmission from the electronic health record data for pediatric patients at participating sites. The Registry currently contains data from all ED visits from nine sites with data spanning calendar years 2012 through 2022. Each site transmits data to the DCC monthly. Comprehensive data quality assurance rules have been automated to assess data quality and validation of the transmitted data. The Registry is about to undergo an upgrade to the data collection system and is currently onboarding five new sites. The Registry has data on over 5 M visits and 2 M unique patients. Data are also used for health services research, comparative effectiveness research, hypothesis generation and grant planning for the network. The Registry is utilized in at least four funded PECARN grants.

STI

Sexually transmitted infections (STIs) are highly prevalent among adolescents. Despite established principles for STI control, clinical practices related to screening, diagnosis, treatment and prevention of STIs among adolescents are suboptimal. This study aims to determine the most clinically efficient and cost-effective ED STI screening method among adolescents who would otherwise not receive preventive healthcare. This study has the potential to improve diagnosis of asymptomatic STIs and decrease the time interval to treatment, consequently decreasing reinfection rates as well as healthcare costs for children. The STI study team completed data collection for phase one (workflow analysis) and is currently implementing the pragmatic trial at all sites through September 2022. Two manuscripts have been published: one, in JAMA Pediatrics, comparing the cost-effectiveness of these two screening strategies based on literature estimates, and a second manuscript describing the results of the workflow analysis. We also presented an abstract at Pediatric Academic Societies 2021 describing the impact of the COVID pandemic on ED-based STI testing and detection.

C-SPINE

Enrollment and data cleaning are complete for the prospective observational study aimed at the Development and Testing of a Pediatric Cervical Spine Injury Risk Assessment Tool (C-Spine study). Abstracts presenting the derived and validated clinical decision rule for neck imaging after blunt trauma have been accepted for oral presentations at the annual meetings of the American Academy of Pediatrics and the Pediatric Trauma Society. Next steps for the clinical decision rule will be validation using the observations from EMS providers. Additionally, we have begun coding the transcripts from the first 70 user-centered design interviews and are preparing manuscripts that will inform implementation of the clinical decision rule. Lastly, the diversity supplement, which was awarded to support Dr. Jordee Wells, has been completed. Parental surveys which will be used to investigate disparities in injury risk and health care delivery for children with cervical spine injuries.

AZ-SWED

The AZithromycin Therapy in Preschoolers with a Severe Wheezing Episode Diagnosed at the Emergency Department (AZ-SWED) Trial will test two primary hypotheses: Azithromycin given for 5 days to preschool children with severe acute wheezing and harboring pathogenic bacteria in their nasopharynx will decrease the severity of the acute episode; and Azithromycin given on an identical schedule and dose will decrease the severity of wheezing episodes in children who do not harbor pathogenic bacteria in their nasopharynx. Total expected enrollment: 1476. Sub-group of 370 will be tested for antibiotic resistance. Study Enrollment: First participant randomized on 9/22/2021, currently 145 randomized (8/25/2022) 36% female; 52% Black/African American; 16% Hispanic/Latino.

PROBIOTICS

The Probiotics trial showed that LGG, a commonly used probiotic, was not better than placebo in improving outcomes in children 3-48 months of age with acute gastroenteritis. This landmark study, published in the NEJM, reverses previously held beliefs regarding the effectiveness of probiotics products, an industry worth 32 billion dollars per year globally. This work has had a major role in reversing the American Gastroenterology Society's guidelines and the latest Cochrane review, which no longer recommend the use of probiotics in children with acute gastroenteritis. To date the team has published 13 manuscripts including NEJM & Annals of EM. The two final manuscripts are under review at journals. The data set is now public.

IMPROVE

IMPROVE is a multi-center, longitudinal comparative effectiveness study combining Registry data with prospective outcomes data collected via text messages. IMPROVE aims to provide evidence to inform optimal pain treatment for children discharged home with a long bone fracture. Enrollment of English and Spanish speaking participants is ongoing at 7 sites. 5,426 subjects have been enrolled as of August 19, 2022. We continue to focus on enrollments across all sites with an evaluation of whether we can enroll for more than 4 years. A Supplement was submitted to analyze COVID impacts on opioid use. Manuscript writing and manuscript analyses plans are in progress.

FEDERAL CORNER

The U.S. Department of Health & Human Services (HHS) News:

HHS Secretary Becerra Announces More Than $20 Million in Funding to End HIV Epidemic
Funding will expand HIV prevention, testing, and treatment services at health centers nationwide. During the National Ryan White Conference on HIV Care and Treatment, HHS Secretary Xavier Becerra announced more than $20 million in funding to expand HIV prevention, testing, and treatment services at health centers nationwide. Funding will be awarded by the Health Resources and Services Administration (HRSA) to 64 health centers as part of HHS' Ending the HIV Epidemic in the U.S. initiative, which aims to reduce the number of new HIV infections in the U.S. by 90 percent by 2030.

COVID-19 Vaccine Parent Messaging

The HHS COVID-19 public education campaign is a national initiative to increase public confidence in and uptake of COVID-19 vaccines while reinforcing basic prevention measures such as mask wearing and social distancing. Through a nationwide network of trusted messengers and consistent, fact-based public health messaging, the campaign helps the public make informed decisions about their health and COVID-19, including steps to protect themselves and their communities. Researchers with the campaign released results from a survey research study conducted from March 11 to March 23, 2022 as part of the HHS COVID-19 Public Education Campaign. The research evaluated, validated, and prioritized 31 messages to identify the most effective messages that increase the likelihood of parents getting a COVID-19 vaccine shot for their child. For results and other resources, please visit: **https://wecandothis.hhs.gov/**

HHS/DoD National Emergency Tele-Critical Care Network.

A joint program between HHS and the U.S. Department of Defense is available at no cost to hospitals caring for COVID-19 patients. Teams of critical care clinicians - critical care physicians, nurses, respiratory therapists, and other specialized clinical experts – are available to deliver virtual care through telemedicine platforms, such as an app on a mobile device. To learn more, please visit: https://www.tatrc.org/netccn/#.

HHS Announces Proposed Rule to Strengthen Nondiscrimination in Health Care

Comments Requested: Proposed Rule on Nondiscrimination in Health Programs and Activities – September 26, 2023. The proposed rule affirms protections consistent with President Biden's executive orders on nondiscrimination based on sexual orientation and gender identity, and on protecting access to reproductive health care. For more information, please visit https://www.hhs.gov/.

Health Resources and Services Administration (HRSA) News:

HRSA Awards Nearly $90 Million to Community Health Centers to Advance Health Equity through Better Data

During National Health Center Week, HHS, through HRSA, awarded nearly $90 million in American Rescue Plan funding to nearly 1,400 community health centers across the country to advance health equity through better data collection and reporting. On Friday, August 5, President Biden issued a proclamation on National Health Center Week to recognize the vital role health centers play in safeguarding the well-being of Americans and honor the heroic staff who keep these facilities running.

New Analysis of Unmet Needs for HIV Care Services Published in Journal AIDS

HRSA's HIV/AIDS Bureau, in partnership with CDC and the Kaiser Family Foundation, published a new analysis of unmet needs for HIV ancillary care services among people with HIV in the journal AIDS. In this analysis, people with HIV had substantial unmet needs for ancillary care services, particularly for subsistence services, such as transportation, food, and shelter services. These gaps can make engaging in HIV care and treatment and reaching viral suppression more challenging. HRSA's Ryan White HIV/AIDS Program (RWHAP) helped reduce unmet needs for some ancillary care services, particularly among those who were uninsured. Expanded access to ancillary care services – especially subsistence services – through RWHAP or other care systems may improve HIV outcomes and supports national efforts to end HIV in the U.S.

Solicitation of Nominations for Membership to Serve on the National Advisory Council on Migrant Health

HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the National Advisory Council on Migrant Health (NACMH or advisory committee). The NACMH advises, consults with, and makes recommendations to the HHS Secretary concerning the organization, operation, selection, and funding of Migrant Health Centers (MHCs) and other entities under grants and contracts under the Public Health Service (PHS) Act. HRSA is seeking nominations to fill seven positions on the NACMH. HRSA will receive written nominations for NACMH membership on a continuous basis. For more information, please visit: https://www.federalregister.gov/.

Emergency Medical Services Children (EMSC) News:

Emergency Medical Services for Children State Partnership Grant Funding HRSA-23-063

This notice announces the opportunity to apply for funding under the EMSC State Partnership Program. The purpose of this program is to support demonstration projects for the expansion and improvement of emergency medical services for children who need treatment for trauma or critical care. For more information please visit: https://www.hrsa.gov/grants/find-funding/hrsa-23-063. Applications are due November 7, 2022.

Good Clinical Practice Tip
Overview of Essential Documents for the Conduct of a Clinical Trial

Michelle Robinson (DCC)

During a site monitoring visit, the monitor will review the participating site's Essential Documents. The ICH E6(R2): Good Clinical Practice (GCP) Guideline states "Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced." It is important for a site to have Essential Documents readily available during an audit. The monitor will need to verify that the trial is following the protocol, everyone involved is properly trained, and collected data is valid. A helpful tip is to place study documents in an Essential Document Binder (EDB), in a timely manner to avoid scrambling to find documents that might be needed for review during a monitoring visit. In PECARN we have Florence eBinder as a tool to use for a site's EDB.

The ICH E6(R2): Good Clinical Practice (GCP) Guideline has a minimum list of essential documents for each stage of a clinical trial:

1. Before the clinical phase of the trial commences
2. During the clinical conduct of the trial, and
3. After completion or termination of the trial

Below is an example of a list of documents participating sites should be maintaining During the Clinical Conduct of the Trial.

- Investigator's brochure updates
- Any revision to the protocol, CRF, study specific documents
- Dated, documented IRB approvals
- Curriculum vitae for new investigator(s) and/or sub-investigator(s)
- Updates to normal value(s) / range(s) for medical / laboratory / technical procedure(s) / test(s) included in the protocol
- Updates of medical/laboratory/ technical procedures/tests
- Documentation of investigational product(s) and trial-related materials shipment
- Certificate(s) of analysis for new batches of investigational products
- Monitoring visit reports
- Relevant communications other than site visits
- Signed informed consent forms
- Source documents
- Signed, dated and completed case report forms and any corrections
- Notification of serious adverse events, safety information and related reports
- Interim or annual reports to IRB
- Subject screening and enrollment log
- Subject identification code list
- Investigational products accountability at the site
- Signature sheet
- Record of retained body fluids/ tissue samples (if any)

For more detailed information or to learn the purpose of each document, and where they should be located, visit www.ich.org. Download the Guideline for Good Clinical Practice and begin on page 51.

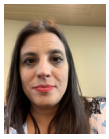
All images in this publication are resources of freepik.com and pexels.com

NODAL NEWS & NEW FACES

DCC

The DCC welcomes four new PM's, Spencer Freeman, Amanda Slater, Jessica Becker & Sara McCormick, two new stats, Allison Schuette & Rachel Crady, two new CDM's, Brenda Northrup & Nancy Hergert and 1 new PMP Michael Nolan. (pictured in order left to right)



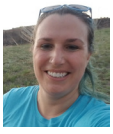



GLACiER

Annie Truelove is now the manager of our Research Coordinator/Assistant team and a Co-NA. Several Research Assistants at NWCH have been promoted to Research Coordinator! Kameron Clinton and Tim Hagemeister are our HEDA RCs. Fikir Abayneh has also been promoted. Steffanie Rodgers joined as the EMSA RC (pictured left). We are also welcoming new Research Assistants: Abbas Doctor, Daijah Singleton, and Breanna Vance (not pictured). Dustin Nelson at NWCH moved to Knoxville, Tennessee and is starting medical school at Lincoln-Memorial University – DeBusk College of Osteopathic Medicine! University of Michigan's newest RC is Sydney Schembri (pictured right).


PEM-NEWS

PEM-NEWS welcomes four new Research Services Professionals, Jenna Jordan, Brianna Simmons, Kylie Futral, Hannah Reyes, two new Research Coordinators, Jaylia Jackson and Michael Vasquez and an EMSA Research Coordinator Nicolena Mitchell. (pictured in order left to right)






WPEMR

Neil Uspal, MD will be the HEDA PI for Seattle Children's beginning September, taking over the role from Nodal PI Eileen Klein, MD, MPH. Seattle Children's has 2 new RA's working PECARN studies: Catherine Nguyen and Zac Irelan.
CHLA has one new RA, Samantha Lozano. (pictured left to right)




SPARC

Bridget Wynn, CHOA/Emory University
SPARC Nodal Administrator
We are sorry to see Erin Ryan go and wish her all the best in her new position.

Mark Griffiths MD
CHOA/Emory University
HEDA Co-investigator

Shabir Din
UCSF PEM
Clinical Research
Coordinator

Colleen Kellison
UCSF, EMSA Sr.
Clinical Research
Coordinator

Nicole Hinz
Hasbro PEM
Clinical Research
Coordinator

HOMERUN

HOMERUN is proud to announce a new nodal study, PRECISE ED, led by junior faculty, Tim Dribin MD and mentored by David Schnadower, which seeks to determine optimal anaphylaxis observation periods based on initial reaction severity and to determine whether candidate anaphylaxis biomarkers (tryptase, plasma and urine histamine) are associated with reaction severity and clinical courses. Validation of these findings may result in reduced ED observation periods and hospitalizations and will provide compelling pilot data to support future studies to determine how biomarkers might be incorporated into routine clinical care.

With mixed emotions, we announce the retirement of Duke Wagner. Duke has played an integral part of PECARN since its inception and a key player in the creation of the RCAC Group. Thank you Duke for your years of service with PECARN. You will be missed!

Please welcome Jordan Baker, BS as Cincinnati's new HEDA RC! Jordan has been the Cincinnati Lead CRC for HEADACHE and Registry the last two years. Welcome, Jordan!

CHaMP

CHaMP is excited to welcome Jennifer Hernandez-Meier (left) as the new Academic Advisor for Milwaukee and to congratulate Christyn Magill (right) for taking on the role as the Academic Advisor for Charlotte.

PRIME

Sophia Graham - RC,
UC Davis, May 2022

Natalie Williams - RC,
CHOP, July 2022

Ananya Vohra - RC,
CHOP, August 2022

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