



**WINTER
2020**

Using Reports to Drive Critical Decisions

*by Michelle Robinson, Larry Cook, Christine Mahler,
Sally Jo Zuspan, and Melissa Metheney (DCC)*

PECARN

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“Using Reports to Drive Critical Decisions. Can We Make Them Better?””

by Michelle Robinson, Larry Cook, Christine Mahler, Sally Jo Zuspan, and Melissa Metheney (DCC)

Reports and study dashboards are a critical part of study management. For many years study progress has been displayed in the DCC’s SharePoint tool for research coordinators, investigators, and others to evaluate key aspects of PECARN studies. Metrics such as study screening numbers, consent rates, subject accrual, sample collection, and subject demographics are standard reports used by study teams. Sometimes the DCC staff work with investigators to develop custom reports for issues like protocol adherence and eligibility determination in addition to the standard reports. For example, bubble plots were used in the FLUID trial to assess fluid administration in order to help investigators determine whether the patients were getting more or less fluid than they were expected to receive.

Standardizing across studies improves efficiency at the DCC and increases familiarity for site-personnel working on multiple studies. The purpose of reporting should

be to: drive critical decisions in the study and to identify areas of risk to patient safety or data accuracy by displaying the data in a useful format. Rules, queries and site monitoring can identify data discrepancies or adherence issues on a patient level. Reports, on the other hand, identify important aspects of study progress on a site level or across the whole study. For example, a query or a monitoring visit might find a protocol compliance issue on a single patient (e.g., study drug administered late), but a report on drug accountability will identify trends and problems across the entire study. Reports should be carefully designed to identify potential problems early so that noncompliance, low enrollment, or other issues can be identified early in the enrollment period and can be continuously followed throughout the entire study. For example, if follow up rates at some sites are lower than expected, the DCC will work with the site investigators and coordinators to develop a plan to increase

patient follow up. If consent rates or enrollment rates differ substantially across sites, the DCC can help connect successful site staff with other sites to find solutions to improve performance. Reports can also be used to demonstrate protocol adherence so that study procedures are carried out successfully at all sites. Adverse events and protocol violations are also tracked at the DCC and may be provided, when appropriate, to assure patient safety. Determining which reports should be produced and helping sites interpret the values in a report is an important part of DCC study management. Sites, investigators, nodal administrators, and others must look at these reports regularly to notice trends and problems. The DCC can also produce site-specific reports if requested.

Most reports are descriptive and tend to display tables of numbers rather than tell a specific story. How can we create more



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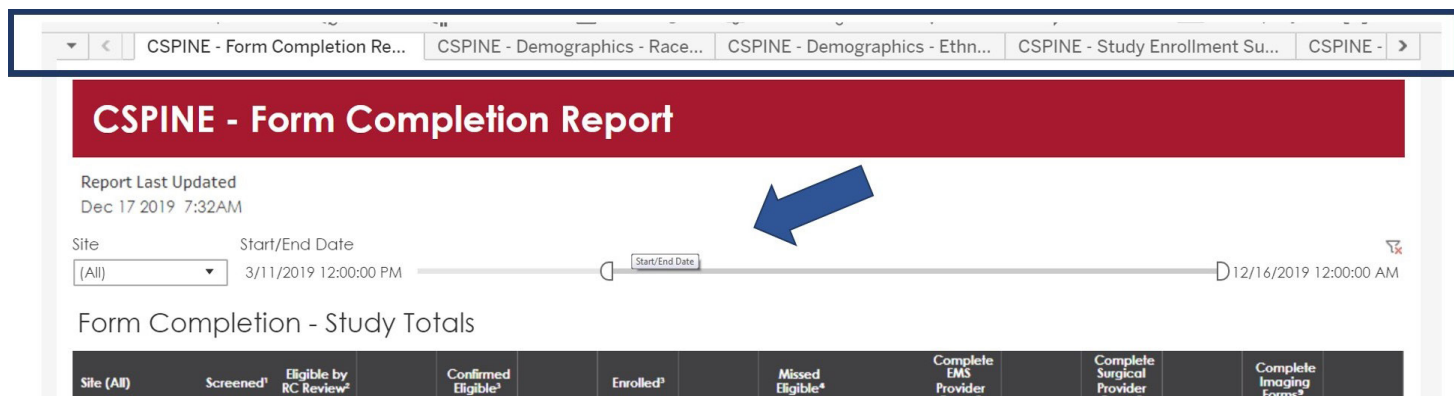


Figure 1: New C-Spine Reports

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effective dashboards/reports to help assure study success?

Displaying the information in a user friendly and informative way is a key factor. Reports should be easy to navigate, so that findings can be rapidly implemented into study decisions. The DCC is using some updated options to improve

user interface and make it easier for investigators, coordinators and funders to navigate to the most critical data.

Samples of the new C-Spine Reports can be seen in Figure 1.

There is a tabbed navigation feature available at the top that allows the user to easily jump from one

report to the next without reloading each page. There is also a new slide bar feature for assessing the dates or time frames of data you wish to display. This allows the report to be much more responsive, saving time and effort, eliminating the need to refresh the page each time you want to update the report. ■

Article graphic designed by pch.vector / Freepik.

Good Clinical Practice Tip

ALCOA-C: Are your source documents telling a "Complete" story?

by Zachary Mitchell, PECARN Project Manager, DCC

"[T]he investigator/institution should maintain adequate and accurate source documents...Source data should be attributable, legible, contemporaneous, original, accurate, and complete." - (ICH E6(R2), section 4.9.0)



The addition of "complete" to the list of key attributes for quality source documentation (now, ALCOA-C) raises the bar for source documents, requiring that study data be kept up-to-date, without omissions, and verifiable. A "complete" study record answers the 'who, what, when, where, why, and how' of study activities and events. All of the ALCOA-C elements apply to both paper and electronic source data. Maintaining complete records can be a challenge when there are multiple sources, large study teams, or long periods of time between research activities and documentation. However, complete records are critically important! Research must be reproducible and replica-

ble. The unavailability of data due to an incomplete source record diminishes confidence in the research and the generalizability of the findings. The source record is the ultimate authority on what actually happened in the study, helping to inform the interpretation of data and resolve discrepancies.

While there is no "one-size fits all" solution for maintaining a complete study record, being creative and flexible in your documentation is an important part of meeting the ALCOA-C requirements. Some methods for maintaining complete records include:

- knowing the true source for each data element in a study,
- documenting both new data

and data changes in real time,

- saving data electronically (when possible),
- maintaining clear delegation of duties and processes for data management and documentation (e.g., SOPs),
- downloading/printing EHR source data (or alternatively, maintaining a study note that references EHR source).

Implementing best-practices for data collection and documentation will do more than just fulfill the ICH GCP regulatory requirements, it will improve the already high-quality research conducted in PECARN and contribute to our goal of conducting meaningful and rigorous multi-institutional research. ■

PECARN Study Updates

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 spanning calendar years 2012 through 2019. 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 currently being used to directly populate pediatric emergency medicine quality-of-care performance measure report cards and has derived benchmarks for each of the measures. The Registry has data on over 4.3 M visits and 1.6 M unique patients. Data is also used for health services research, comparative effectiveness research, hypothesis generation, and grant planning for the network.

The Registry is utilized in four other funded PECARN grants.



ESETT

The Established Status Epilepticus Treatment Trial (ESETT) concluded enrollment in December 2018. This was a double blind, Bayesian-adaptive randomized trial of fosphenytoin, levetiracetam, and valproate for the treatment of convulsive status epilepticus refractory to benzodiazepines. The primary outcome was lack of clinically apparent seizures plus improving mental status at one hour without the use of other anticonvulsant medications (including medications used for intubation). The primary analysis of adult and pediatric patients was published in November 2019 in the *New England Journal*. The three study drugs were all effective in stopping benzodiazepine-refractory status in about 50% of patients. Safety profiles were similar. The age subgroup analysis with enriched pediatric enrollment has been completed and will be submitted to *Lancet* soon. Co-investigators are reminded to contact James Chamberlain at jchamber@cnmc.org if they are interested in authoring secondary analyses.

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* last year 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 are several secondary analyses ongoing and manuscripts being written. Several manuscripts are currently under review at medical journals including: 1) Predictors of successful patient enrollment into the FLUID trial; 2) Neurocognitive comparisons of DKA patients and non-DKA controls; 3) Frequency and predictors of acute kidney injury in DKA; 4) Hemodynamics in children with DKA. A supplemental chart review to support two other analysis and manuscripts was recently completed. Three abstracts have been submitted to the PAS/SAEM meeting for May 2020. Finally, the FLUID Public Use Dataset (PUD) is currently under development.

TIC-TOC (TXA)

TIC-TOC is a pilot and feasibility trial of tranexamic acid (TXA) for children with hemorrhagic injuries. TXA has the potential to safely reduce blood transfusions, morbidity, and mortality in injured children. The study has received FDA and sIRB approval to enroll children using the federal exception from informed consent (EFIC). UC Davis recently completed enrollment and NWCH is close. Enrollment at CHOP and PCMC are ongoing. In the meantime, we have completed a consensus process to determine the main trial outcome measure, and the manuscript is nearly complete. Several manuscripts have been published on this trial, with more on the way. We recently submitted two abstracts to the SAEM/PAS meeting for May 2020 (1. enrollment prior to and after EFIC, and 2. the consensus process to determine the main outcome measure). Grant writing for the main trial is ongoing.



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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 bacterial infections. This technology has the potential for rapid and accurate diagnosis of febrile infants. Biosignatures II is assessing the stability of the RNA signature via sequential sampling. We enrolled 2,612 infants, with 306 sequential samples (and 84 healthy controls)! We are focusing most of our efforts on the manuscripts for the Biosignature II studies. For Biosignatures I, we expect to submit the main manuscript on the accuracy of biosignatures to a major journal in the coming months. For Biosignatures II, our focus is to move forward with many analyses and manuscripts in addition to the sequential sample biosignature manuscript. We are currently drafting manuscripts pertaining to the validation of the prediction rule, and the association of an abnormal urinalysis and bacterial meningitis. Both have been submitted as abstracts to the SAEM/PAS meetings in May 2020. Several more manuscripts will follow! All of these studies will facilitate a more expeditious, accurate and safer evaluation of the febrile infant.

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 will capture 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 will automate the determination of organ dysfunction in children with sepsis directly from structured and narrative data in an expanded multicenter EHR patient registry. That data will be used to derive and validate a prediction model of pediatric sepsis that predicts 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 a prediction model of risk of sepsis.

STEC

Volume Expansion in Children with Shiga Toxin-Producing E. coli Infection to Prevent or Mitigate Hemolytic Uremic Syndrome: Planning a Multinational Randomized Clinical Trial (STEC) has been funded by the NIAID for one year with a R34 planning grant. The goal of this phase III, cluster-randomized, crossover trial is to compare early aggressive intravenous treatment with standard fluid management as treatment for STEC-infected children. This study has the potential to improve health outcomes in STEC-infected children. The investigators are currently working on finalizing the protocol and initiating the site-selection process.

SPEED

The aim of this study is to develop a electronic health record clinical decision support (EHR-CDS) tool for outpatient antibiotic prescribing of pediatric urinary tract infections and community acquired pneumonia. Currently we are in the early stages of prototype EHR-CDS development, with incorporation of adapted guidelines and specified triggering mechanisms. EHR-CDS development will serve as the centerpiece for implementation of ED-based antimicrobial stewardship programs.

Arginine

The STArT Trial was re-submitted as a UG3 grant to the NHLBI with an impact score of 19. It is scheduled to be reviewed by NHLBI council in February 2020. Just-in-Time documents were requested. The Arginine manuscript on Normal Saline bolus was published in Am Journal Hematology in June 2019. Two additional manuscripts on use of intranasal Fentanyl and ED adherence to the 2014 NHLBI guidelines are in development.

ED-STARS

To date, the ED Screen for Teens at Risk for Suicide (ED-STARS) has published four manuscripts and two are pending review. We are actively working on approximately ten additional manuscripts with five MARFs in preparation.

IMPROVE

This is a multi-center, longitudinal comparative effectiveness study combining Registry data with prospective outcomes data, which are collected via text messages. This study aims to provide evidence to inform optimal pain treatment for a long bone fracture. Enrollment has been open at all 6 sites since Summer 2019. As of the beginning of January, 589 subjects have been enrolled. Our target enrollment is 14,000 children over 4 years. Currently we are focusing on improving enrollment rates across all sites in order to reach this goal. A study amendment to include Spanish speaking participants is currently under review at the sIRB.

SCIENCE

The SCIENCE study, designed to prepare PECARN Registry sites for participation in a large implementation trial improving guideline adherent care for children with sickle cell disease presenting with pain, continues its excellent progress. Process maps for both opioid and hydroxyurea usage have been developed. We are now interviewing patient/family dyads and members of the care team to determine barriers and facilitators to delivering guideline adherent care.

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 decreasing healthcare costs. The STI study currently finished data collection for phase one (workflow analysis) and is working toward the goal of implementation of the pragmatic trial started in January 2020.

C-SPINE

To date, the Development and Testing of a Pediatric CSI Risk Assessment Tool (C-Spine study) has enrolled 7,487 patients for the prospective observational portion of the study and 134 of these patients had cervical spine injuries. Additionally, we have completed user-centered design (UCD) activities at 6 sites. We are happy to report that thanks to the hard work of the Round I sites we are ahead of schedule and expect to be done with Round I enrollments early. Lastly, we are excited to begin training the Round II sites for the validation phase of the study! Round II training will be conducted at the end of the February PECARN meeting in DC.



ED-SAMS

ED-SAMS enrolled their first subject September 9, 2019. We are recruiting subjects 6-12 years old who present to the ED with an acute asthma attack over a 90 day recruitment period and followed for 120 days. This preliminary study will be evaluating whether or not it is feasible to conduct, and if it will be acceptable to providers, schools and families to dispense medication in the ED and supervise its use in a school setting. The study has randomized 9 subjects and recruitment will end the first week of March with subjects being followed through the end of the school year.

Probiotics

The Probiotics investigators and the DCC have stayed busy as they continue to analyze data and write additional manuscripts. Most recently, the age/weight, adherence and IV hydration manuscripts are under review at journals, while the infectious agent abstract was submitted to PAS. Nine additional manuscripts are in various stages of completion, from preparation of results to editing. Stools are being analyzed at Dr. Tarr's lab at WashU in St. Louis for pathogen clearance and microbiome restoration analyses.

**“ CONDUCTING HIGH PRIORITY, HIGH-QUALITY RESEARCH
IN PEDIATRIC EMERGENCY CARE ”**

Federal Corner

National Highway Traffic Safety Administration (NHTSA), Office of EMS

Field Trauma Triage Guidelines – NHTSA, with EMSC funding support, has awarded a two-year cooperative agreement to the American College of Surgeons for revision of the prehospital field trauma triage guidelines. The field trauma triage guidelines are being updated to provide EMS clinicians across the country with evidence-based tools to use when deciding which patients will benefit from transport to a trauma center. The project will use the results of a systematic literature review supported by NHTSA and the Agency for Healthcare Research and Quality, published in 2017.

National Institute of Child Health and Human Development (NICHD)

The Pediatric Trauma and Critical Illness Branch (PTCIB) released an EMSC Notice of Special Interest (NOSI). This NOSI invites research applications that focus on three specific areas of research on emergency medical services for children:

- Clinical and translational research which includes building the evidence base for clinical aspects of emergencies and emergency care and assuring pediatric safety and quality in emergency care.
- Methodology which includes improving data collection, patient outcomes, and outcome measures in pediatric emergency care, and system organization, configuration, and operation to provide optimal care.
- Evaluation which includes costs and cost-effectiveness, diagnostic tests, procedures, and services provided by medical, nursing, social work, first responders, ancillary personnel and others involved in EMSC care, and the evaluation of systems of EMSC care.

The NOSI is available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-HD-19-022.html>

National EMS Education Standards – With support from NHTSA and the Health Resources and Services Administration (HRSA) EMSC program, the National Association of EMS Educators is leading a collaborative effort to update the National EMS Education Standards, which is designed to help ensure EMS clinicians receive education preparing them to perform their roles. The revision will align the standards with the new National EMS Scope of Practice Model and the latest evidence and current EMS practice. A second public comment period, which will include recommended changes to the 2009 Instructional Guidelines, will take place in February 2020. More info is available at: <https://www.ems.gov/projects/ems-education-standards.html>

Prehospital Pain Management

– After a systematic review of available research was published by the Agency for Healthcare Research and Quality and NHTSA in the fall of 2019, NHTSA is supporting the development of an evidence-based guideline (EBG) for the prehospital pharmacologic management of acute pain, as well as related education and implementation guidance for EMS services. The goal is to complete the EBG by mid-2021.

For more information on NHTSA activities, see the 2019 Annual Update from the NHTSA Office of EMS: <https://www.ems.gov/pdf/EMS-gov-Annual-Update-22019.pdf>



PEDIATRIC READINESS SPOTLIGHT

The PECARN program and the National Pediatric Readiness efforts share a common goal of ensuring children receive optimal emergency care no matter where they live or travel. Critical elements of this include developing the evidence for emergency clinical care and improved systems of care and adoption of these into pre-hospital and hospital settings to improve pediatric emergency care system readiness.

Starting in June, the second National Emergency Department (ED) Pediatric Readiness Assessment will be made available for EDs to complete and the portal will remain open through September. During the 2013-2014 National Assessment, 83% of EDs in the country completed the assessment and we are hoping to obtain a similar response rate in 2020.

The 2020 PedsReady Assessment is based on the updated 2018 joint guidelines: Pediatric Readiness in the Emergency Department published by the American Academy of Pediatrics (AAP), the American College of Emergency Physicians (ACEP) and the Emergency Nurses Association (ENA). Focus areas of the Assessment include:

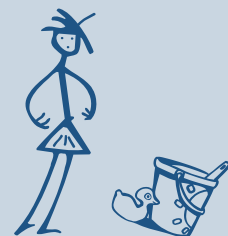
- Administration and Coordination for the Care of Children in the ED
- Physicians, Advanced Practice Providers (APPs), Nurses, and Other ED Healthcare Providers
- Guidelines for Quality Improvement in the ED

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- ED Policies, Procedures, and Protocols
- Interfacility Transfers
- Patient Safety
- Support Services
- Equipment, Supplies, and Medications



The Guidelines and Assessment will provide the basis for the National Pediatric Readiness Project (NPRP) ongoing quality improvement (QI) efforts from the EMSC program and national partners designed to promote optimal care of children in all state and territory EDs. A Pediatric Readiness Checklist with associated tools and resources will be made available to help EDs work to improve their readiness.

What can PECARN do? Ensure your institutions take the NPRP National Assessment. Encourage the ancillary hospitals you work with to take the Assessment. Work together with your State Partnership grantee and use the results to improve Pediatric Readiness of the EDs in your state.

More information on ED Pediatric Readiness is available here:

- 2020 National Assessment Page: <https://www.pedsready.org/>
- National Pediatric Readiness Project: <https://emscimprovement.center/domains/hospital-based-care/pediatric-readiness-project/>
- ENA Pediatric Readiness Infographic: https://www.ena.org/docs/default-source/resource-library/practice-resources/infographics/ed-readiness-for-children.pdf?sfvrsn=5d0e596e_6

A New Initiative: Pediatric Readiness in Emergency Medical Services Systems

In December 2019, a joint policy statement was released from the AAP, ACEP, ENA, National Association of Emergency Medical Services Physicians, and National Association of Emergency Medical Technicians on pediatric readiness in emergency medical services systems. Similar to ED Pediatric Readiness, Pediatric Readiness in EMS encompasses the presence of appropriate pediatric resources including equipment and medications, usage of pediatric-specific guidelines and policies, availability of education and training, incorporation of performance-improvement practices, and integration of EMS physician medical oversight to equip EMS systems to deliver optimal care to children.

An accompanying Technical Report was released by the AAP Committee on Pediatric Emergency Care, Section on Emergency Medicine and EMS subcommittee, Section on Surgery. The report provides more detail on key focus areas including provider competencies, EMS education, the Pediatric Emergency Care Coordinator (PECC), quality improvement, pediatric policies and protocols, and patient safety.

A pediatric EMS PedsReady Steering committee has formed, co-chaired by Dr. Kathy Brown, Dr. Kathleen Adelgais and Ms. Rachael Alter. This committee, which includes a PECARN representative as well as other PECARN investigators, will next meet in February 2020 and will develop an EMS-focused checklist for evaluating pediatric readiness as well as creating a prehospital readiness toolkit webpage. A long term goal is to create and disseminate a nationwide assessment for EMS pediatric readiness.

More information on EMS Pediatric Readiness is available here:

- Policy Statement: <https://pediatrics.aappublications.org/content/145/1/e20193307>
- Technical Report: <https://pediatrics.aappublications.org/content/early/2019/12/17/peds.2019-3308/tab-figures-data?versioned=true>
- AAP News Article: Medical groups issue '911 call' for pediatric readiness in all EMS agencies <https://www.aappublications.org/news/2019/12/19/ems121919> ■

SPARC Node

Welcome new Research Coordinators!!!



Shamiya Manoranjithan -
CHOA
October 2019 - RC



Reshika Mendis - CHOA
November 2019 - RC



Deborah Leake, FNP -
CHOA
January 2020 - RC/
Nurse Practitioner



Derek Hanley - UCSF
January 2020 - RC

DCC

Welcome new staff!!!



Chella Palmer
November 2019 -
Biostatistician II



Megan Varner
January 2020 -
Clinical Data Manager I



Sarah Neagle
December 2019 -
Clinical Data Manager I

NEW FACES & NODAL NEWS

PRIME Node

Welcome new Research Coordinators!!!



Jasman Kaur - UCDA
July 2019 - RC



Nickolas Okawa - UCDA
October 2019 - RC



Allison Huang - UCDA
October 2019 - RC



Priscila Monteiro - PCMC
July 2019 - RC

CHaMP Node

On January 10, 2020 CHaMP's **Dr. Manish Shah** gave a well received plenary talk on the prehospital care of pediatric seizures at the National Association of EMS Physicians Annual Meeting. This talk highlighted recent CHaMP publications on seizure as well as Dr. Shah's extensive seizure research portfolio and the need for the clinical trial that he is developing with PECARN.



Manish Shah, MD, MS

HOMERUN Node

Welcome to PECARN Dr. Thomas!!!



Danny Thomas, MD

Danny Thomas, MD, MPH will transition into the role of HEDA PI at the Medical College of Wisconsin starting March 1, 2020. This role is currently held by David Brousseau, MD, MS.

Baseline timeliness of opioid administration data from the SCIENCE study was invited for full manuscript submission at Annals of Emergency Medicine after competitive abstract review.

Congratulations to **Patricia Cobb, Co-Nodal Administrator**, on the birth of her daughter Audrey Cobb on October 28, 2019.



Audrey Cobb