Working with RAPID PACE (GPC engagement) to enhance grant applications – a personal story

Presentation to GPC Learning Engagement Conference

Albert L. Hsu
Division of Reproductive Endocrinology and Infertility
University of Cincinnati, Dept of Ob/Gyn
27 August 2024

UC CINCINNATI

Disclosures

- No financial conflicts of interest to disclose.

Grant support

- **1R21MD019175-01A1** (PD/PI: Hsu) 9/22/2023-9/21/2025 1.2 calendar
- **NIH/NIMHD** $209,121

- Title: *DRIVERs: Data systems Research to Identify driVers of Ethnic & Racial Inequities in Maternal Mortality*

- This R21 application will improve understanding of hospital and patient-level causes that lead to maternal morbidity and mortality. Better understanding of hospital- and patient-level factors is critical to inform and guide interventions to address racial disparities in maternal mortality, especially in Black, Indigenous, People of Color (BIPOC) populations. These studies will help establish drivers of maternal mortality and SMM, to facilitate targeting of resources and interventions for this multi-faceted national crisis.

Learning Objectives

- Upon successful completion of this educational program, the participant should be able:
  - (1) to appreciate the timeline associated with successful NIH grant applications
  - (2) to understand the benefit of engaging with patient advocates, for NIH grant applications
  - (3) to discuss the process for engaging with Rapid PACE team with GPC.

- Caveat: this talk is about *process*, not the actual substance of our research grant

Who am I?

Training

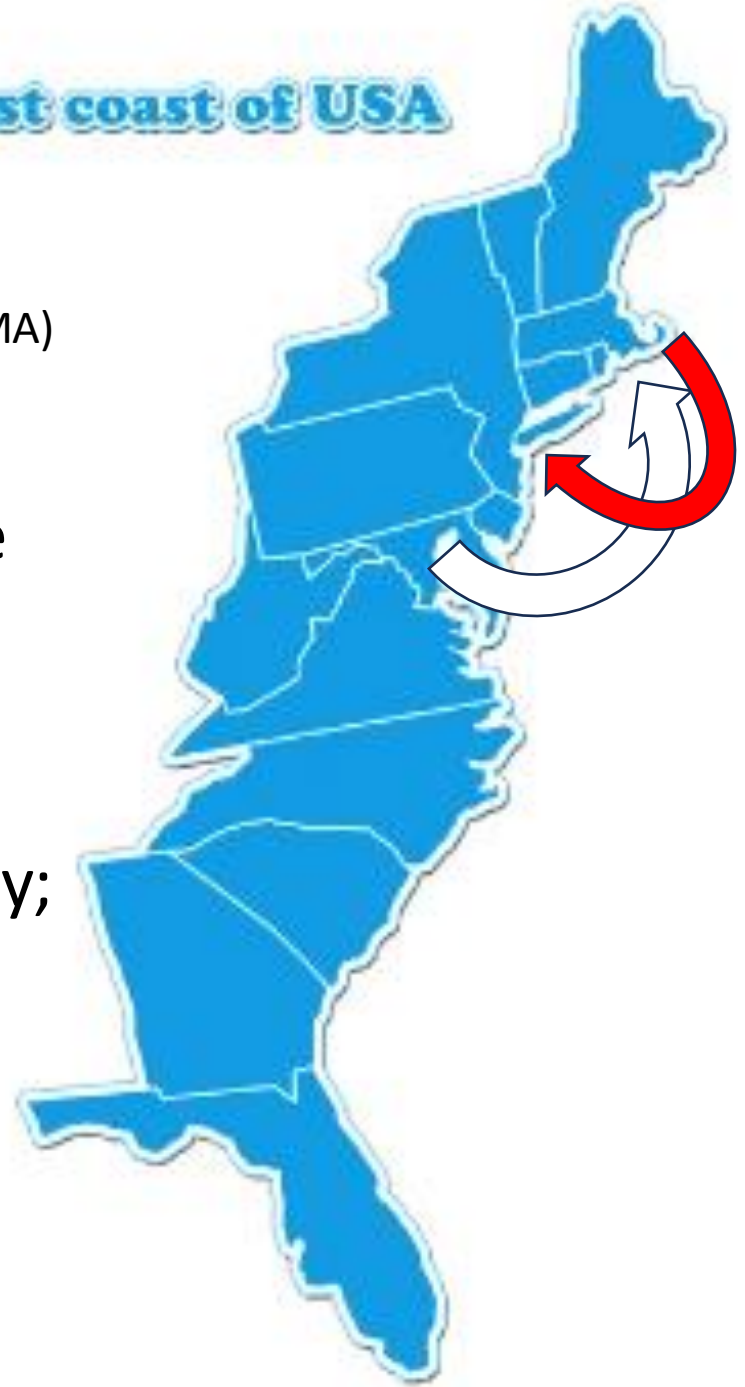
- BS, Materials Science and Engineering, MIT (Cambridge, MA)
- MD/MS; Albert Einstein College of Medicine (Bronx, NY)
- Residency, Obstetrics and Gynecology; Tufts-Baystate Medical Center (Springfield, MA)
- Research fellowship; National Institutes of Health (Bethesda, MD)
- Fellowship, Reproductive Endocrinology and Infertility; Jones Institute for Reproductive Medicine (Norfolk, VA)

Training

- BS, Materials Science and Engineering, MIT (Cambridge, MA)
- MD/MS; Albert Einstein College of Medicine (Bronx, NY)
- Residency, Obstetrics and Gynecology; Tufts-Baystate Medical Center (Springfield, MA)
- Research fellowship; National Institutes of Health (Bethesda, MD)
- Fellowship, Reproductive Endocrinology and Infertility; Jones Institute for Reproductive Medicine (Norfolk, VA)

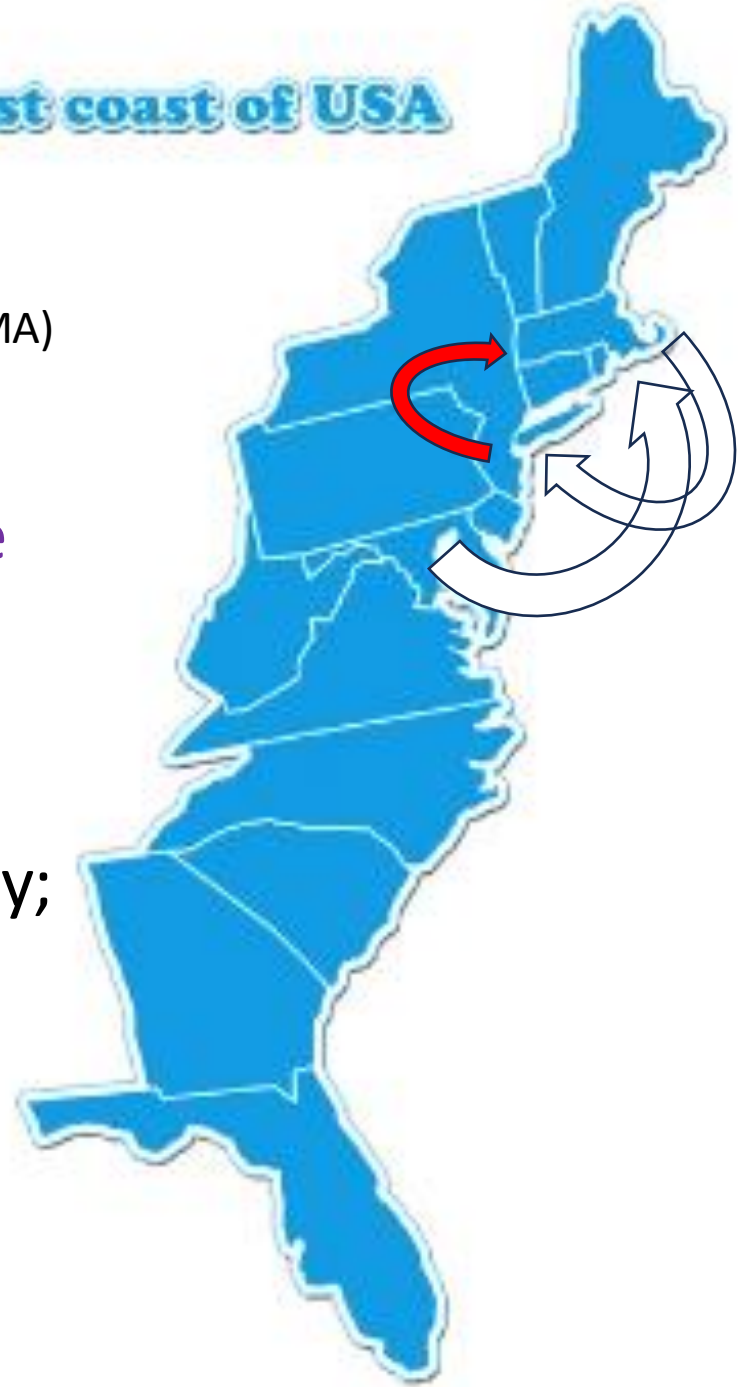
Training

- BS, Materials Science and Engineering, MIT (Cambridge, MA)
- MD/MS; Albert Einstein College of Medicine (Bronx, NY)
- Residency, Obstetrics and Gynecology; Tufts-Baystate Medical Center (Springfield, MA)
- Research fellowship; National Institutes of Health (Bethesda, MD)
- Fellowship, Reproductive Endocrinology and Infertility; Jones Institute for Reproductive Medicine (Norfolk, VA)



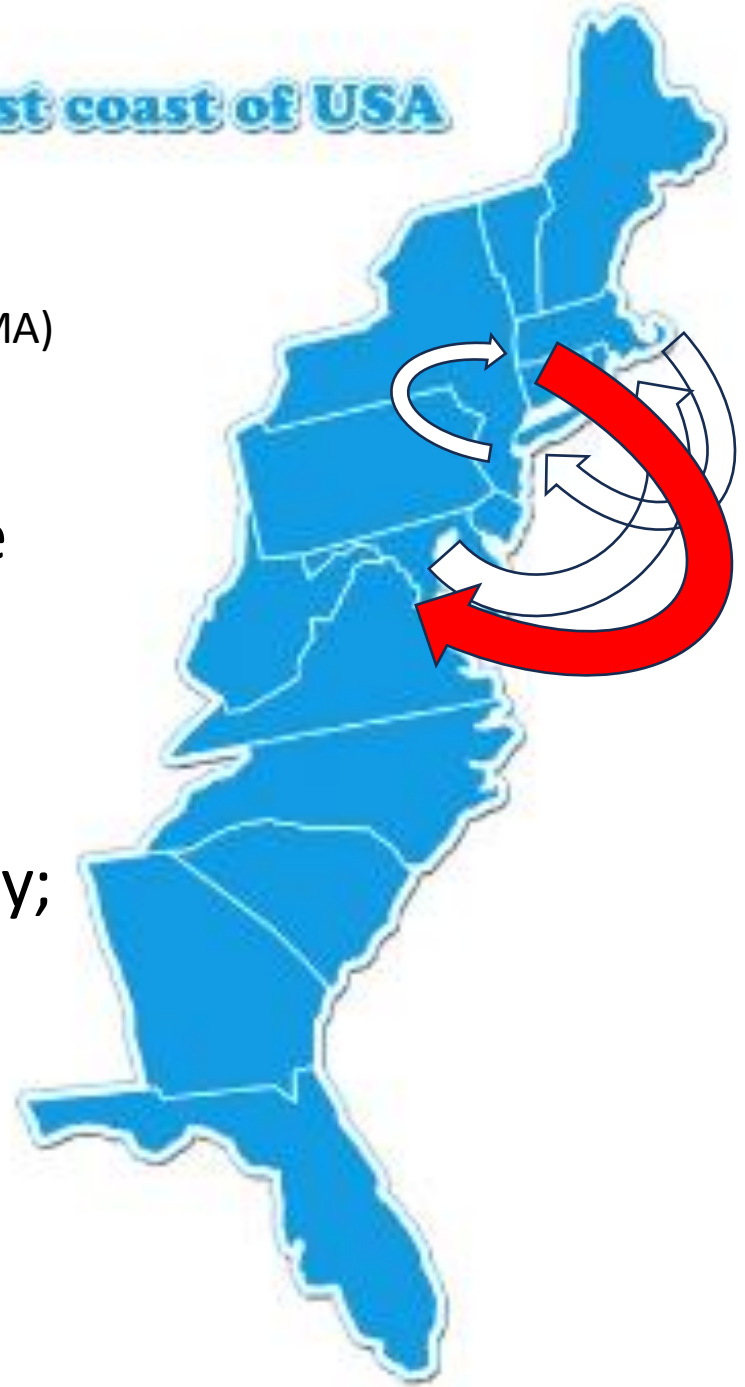
Training

- BS, Materials Science and Engineering, MIT (Cambridge, MA)
- MD/MS; Albert Einstein College of Medicine (Bronx, NY)
- Residency, Obstetrics and Gynecology; Tufts-Baystate Medical Center (Springfield, MA)
- Research fellowship; National Institutes of Health (Bethesda, MD)
- Fellowship, Reproductive Endocrinology and Infertility; Jones Institute for Reproductive Medicine (Norfolk, VA)



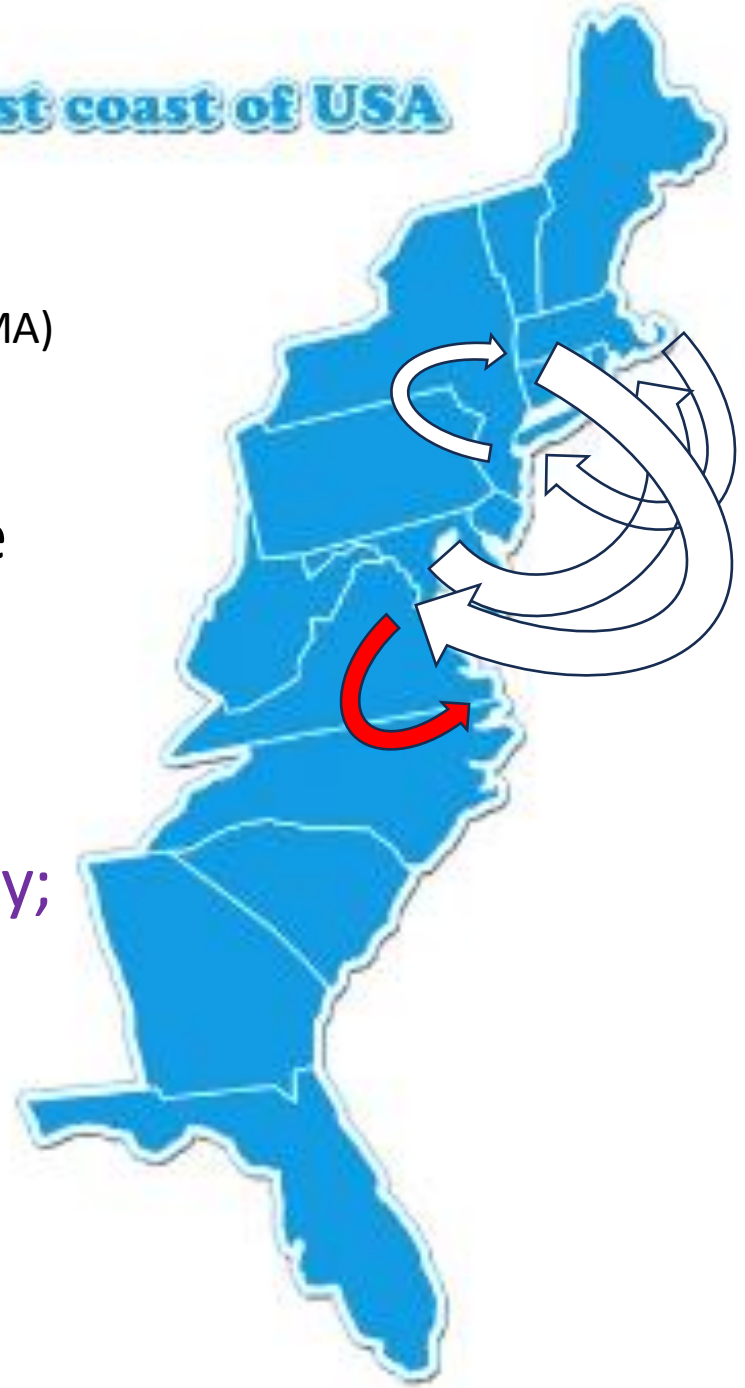
Training

- BS, Materials Science and Engineering, MIT (Cambridge, MA)
- MD/MS; Albert Einstein College of Medicine (Bronx, NY)
- Residency, Obstetrics and Gynecology; Tufts-Baystate Medical Center (Springfield, MA)
- Research fellowship; National Institutes of Health (Bethesda, MD)
- Fellowship, Reproductive Endocrinology and Infertility; Jones Institute for Reproductive Medicine (Norfolk, VA)



Training

- BS, Materials Science and Engineering, MIT (Cambridge, MA)
- MD/MS; Albert Einstein College of Medicine (Bronx, NY)
- Residency, Obstetrics and Gynecology; Tufts-Baystate Medical Center (Springfield, MA)
- Research fellowship; National Institutes of Health (Bethesda, MD)
- Fellowship, Reproductive Endocrinology and Infertility; Jones Institute for Reproductive Medicine (Norfolk, VA)



Practice

- Dartmouth-Hitchcock Medical Center (Lebanon, NH)

Dartmouth-Hitchcock

- University of Missouri – Columbia (Columbia, MO)

- University of Cincinnati (Cincinnati, OH)

CINCINNATI

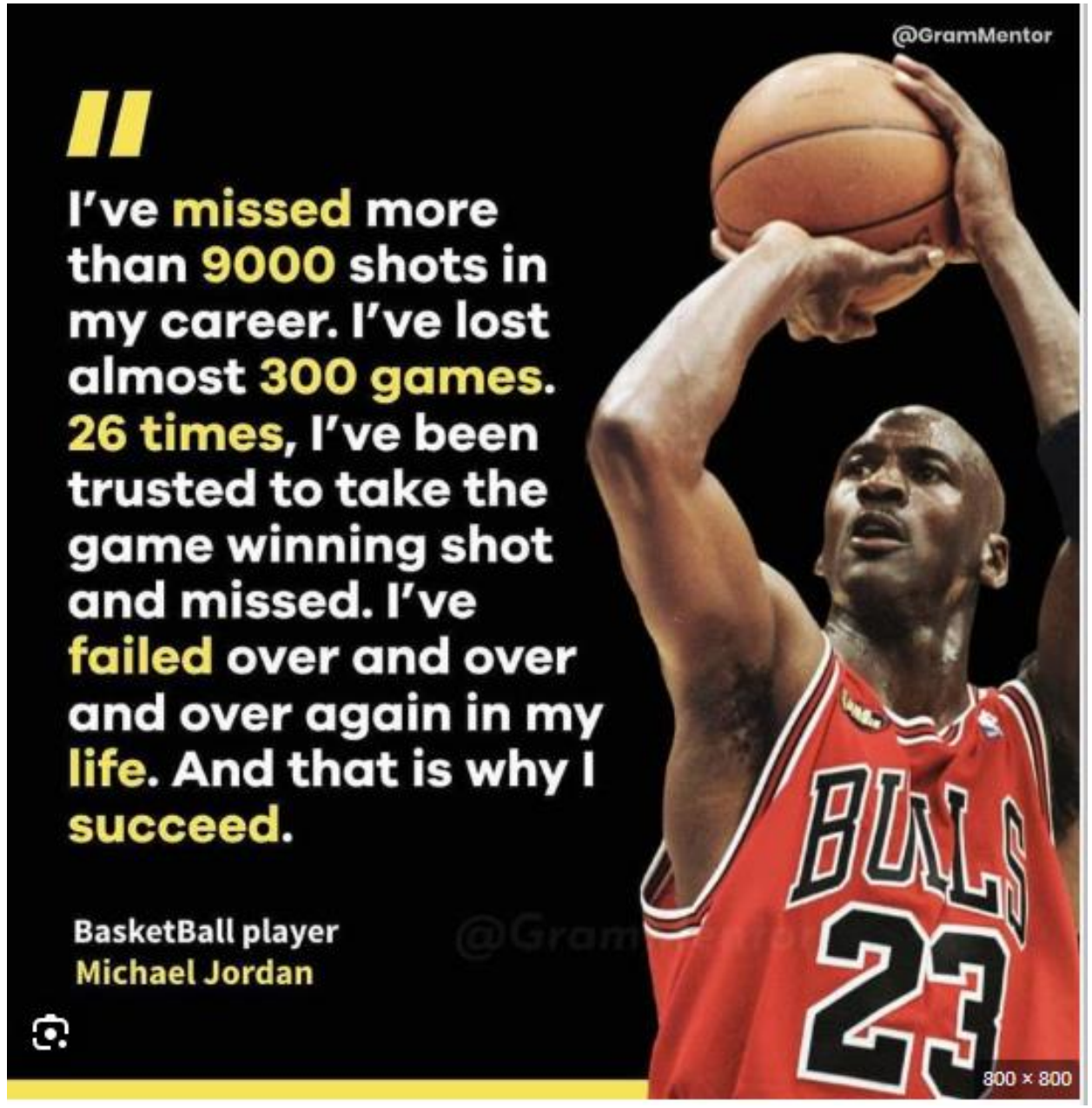
Grant timeline

Timeline of grant application

- (2021) Prior related work – “Big Data” research on COVID-in-pregnancy
- Fall 2021 - Preliminary grant application on this topic (not awarded)

- **1/26/22 - Greater Plains Collaborative Rapid PACE session 1**
- February 2022 – submission of original NIH application
- Summer 2022 – “triage” (rejection), feedback from NIH/NIMHD

- **1/23/23 - Greater Plains Collaborative Rapid PACE session 2**
- March 2023 – resubmission of NIH application
- Summer 2023 – “request for more information”
- Sept 2023 – notice of award
- Nov 2023 – funding actually awarded


@GramMentor
"
I've missed more than 9000 shots in my career. I've lost almost 300 games. 26 times, I've been trusted to take the game winning shot and missed. I've failed over and over and over again in my life. And that is why I succeed.
BasketBall player
Michael Jordan
BULLS
23
800 × 800

Persistence

- By my count, I've submitted approximately 20 grant applications (including 8-9 NIH grant applications) since 2011
  - First successful grant application of any kind = 2016 ASRM Research Grant on "Mitochondrial Dysfunction in women with Endometriosis" (#15-ish)
  - First successful NIH Loan Repayment Program (LRP) Grant application = 2018 (3rd try for NIH LRP funding)
  - First successful NIH Grant = 2024 NIH R21

Background

Prior work

Clin Infect Dis. 2022 Feb 11;74(3):467-471. doi: 10.1093/cid/ciab441.

Coronavirus Disease 2019 (COVID-19) Disease Severity: Pregnant vs Nonpregnant Women at 82 Facilities

Albert L Hsu [1], Adrienne M Ohler [2], Andrea Goldstein [3], Sarah Truong [1], Cynthia Y Tang [3 4 5 6 7], Xiu-Feng Wan [4 5 6 7 8], Jane A McElroy [9]

Affiliations + expand

PMID: 35148386 DOI: 10.1093/cid/ciab441

Abstract

Background: Pregnancy has been reported to be a risk factor for severe COVID-19. We evaluated the impact of pregnancy on severe COVID-19 and mortality in an electronic medical record (EMR) database that enabled exclusion of labor and delivery (L&D) encounters.

Methods: In this retrospective cohort study, EMRs from 82 healthcare facilities in the Cerner COVID-19 Datamart were analyzed. The study comprised 38 106 individuals aged 18-45 years old with COVID-19 who had emergency department, urgent care, or inpatient encounters from December 2019 to September 2020. Subgroups were balanced through propensity score weights for age, race, smoking status, and number of comorbidities. The primary outcome was COVID-19-related mortality; secondary outcomes were markers of severe COVID-19: intubations, mechanical ventilation, use of vasopressors, diagnosis of sepsis, and diagnosis of acute respiratory distress syndrome.

Results: In comparing pregnant and nonpregnant women, no statistical differences were found for markers of severe COVID-19, after adjusting for age, smoking, race, and comorbidities. The adjusted odds of an inpatient encounter were higher for pregnant vs nonpregnant women (adjusted odds ratio [aOR], 13.2; 95% confidence interval [CI], 11.6-15.3; P < .001), but notably lower after excluding L&D encounters (aOR, 2.3; 95% CI, 1.89-2.88; P < .001). In comparison to women without L&D encounters, hospitalization was significantly more likely for men.

Conclusions: We did not find an increased risk of severe COVID-19 or mortality in pregnancy. Hospitalization does not necessarily indicate severe COVID-19 in pregnancy, as half of pregnant patients with COVID-19 were admitted for L&D encounters in this study.

UC CINCINNATI

Prior work

Mo Med. 2022 Sep-Oct;119(5):474-478.

A Summary of Maternal Mortality in Missouri: A Historical Perspective (1999–2018)

Brittany N Carson [1], Andrea Schaeffer [1], Megan Burnam [2], Alisea Brooks [3], Kristin McCowan [4], Traci Johnson [5], Michelle Debbink [6], Jean Goodman [2], Albert L Hsu [7]

Affiliations + expand

PMID: 36338005 PMCID: PMC9616463

Abstract

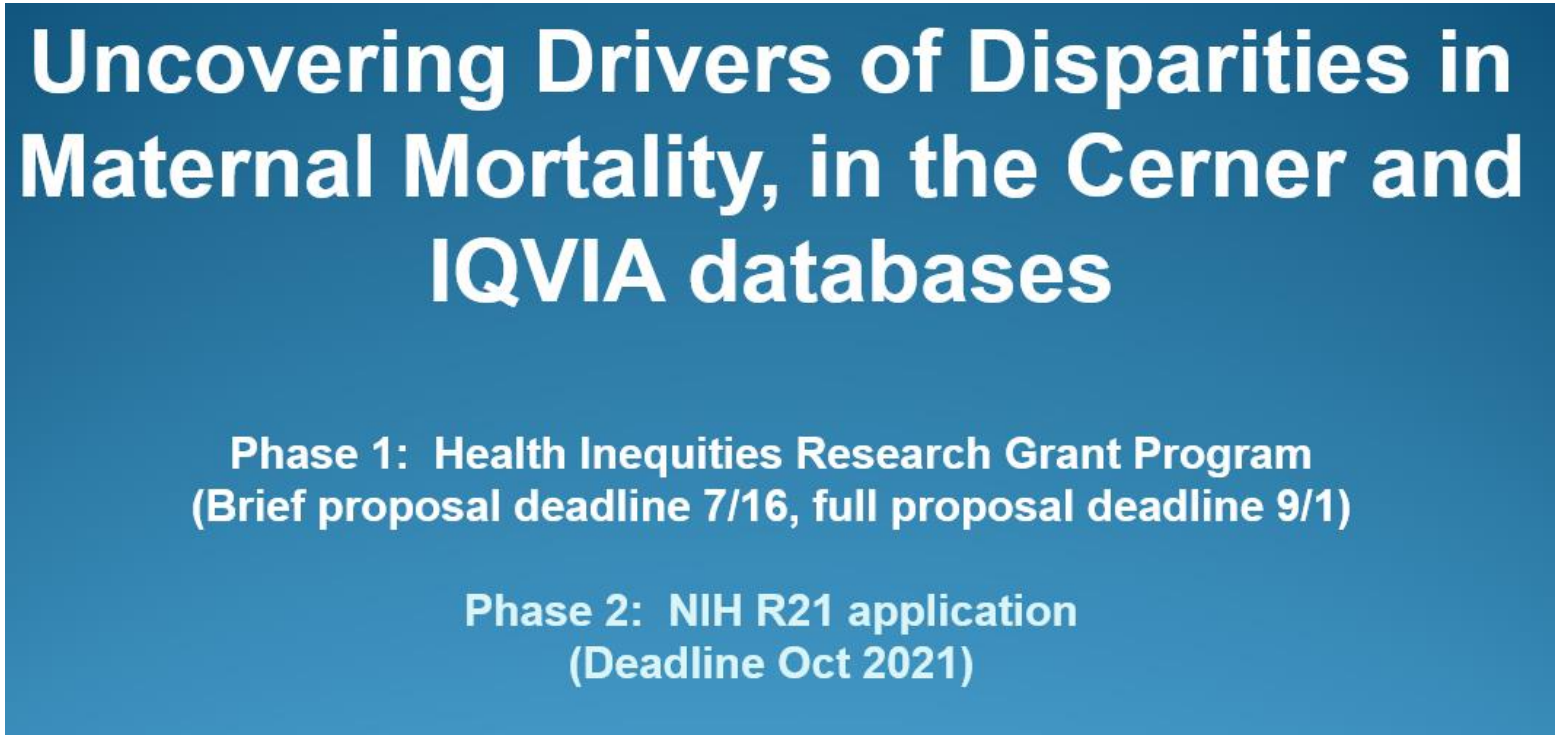
The rate of maternal mortality in the United States (U.S.) is higher than any other industrialized nation, at 23.8 per 100,000 deliveries from 2000-2014. Although maternal mortality ratios decreased by 44% globally from 1990 to 2015, emerging evidence suggests that maternal mortality in the U.S. has been increasing.2-4 One study quotes 700 maternal deaths every year, with 50,000 "near misses."1 By one metric, Missouri ranks as the 44th-worst state for maternal mortality in the U.S.5.

Prior grant application: Summer-Fall 2021

- Submission to “Prepared and Treatment Equity Coalition” (PTEC) grants: “Uncovering Drivers of Disparities in Maternal Mortality, in a Database of the Greater Plains Collaborative”
  - Brief proposal submitted in June/July 2021
  - Invited to submit full proposal (Aug 2021)
  - Submission 9/1/21
  - Notice (not funded): Fall 2021

Initial meeting with GPC staff

- 9/30/21
  - Deandra Cassone, Xiaofan Niu, Ali Lund
  - “Research Opportunity Assessment Form” to connect with potential GPC collaborators, and also meet with the Rapid PACE team….



What is Rapid PACE?

Greater Plains Collaborative Rapid Community and Patient Engagement (GPC Rapid PACE) Resource

Purpose and Background:

The GPC Rapid Community and Engagement (Rapid PACE) Resource consists of trained *patient research advocates* from diverse communities across all participating GPC sites (visit http://www.gpcnetwork.org/?q=AboutUs for a list of participating organizations and institutions). The term *"patient research advocate"* means these individuals have experience as patients, caregivers and community leaders. They bring their patient experiences and insights into the research process. They are familiar with research approaches and methods and value research that advances evidence-based medicine to improve people's health. They understand research advocacy is not about patient care *today* – it's about supporting research to improve care for patients in the future. Their lived experience and network with other patients and caregivers provide unique perspectives and insights to better inform research and collaborate with researchers. These individuals are members of GPC's Patient Advisory Council (PAC).

What is Rapid PACE?

- prior to disseminating study findings.
  For example, the Rapid PACE team can review lay abstracts, or react to a draft poster or oral presentation to improve accessibility and understanding for diverse audiences.

To access the GPC Rapid PACE resource, the researcher/research team must schedule a time to present their study using a prescribed, formatted set of PowerPoint slides. The Rapid PACE session is conducted online using video conferencing (with cameras activated). This improves communication by allowing everyone to be connected visually, as well as by voice. Rapid PACE patient research advocates may participate by telephone only if they do not have computer access. Video conferencing is always preferred.

The GPC Rapid PACE process can help provide the following:

- prioritize research topics
- recommend and/or assist in selecting patient-reported outcomes
- inform research strategy to increase acceptability of methods and requirements needed to engage stakeholders
- increase the relevance of the study to patients and their communities
- strengthen recruitment and retention efforts
- provide input to enhance dissemination materials' relevance and interest to patients and communities, thereby increasing dissemination and acceptance of study results

Rapid PACE 1

1/26/22 - Greater Plains Collaborative Rapid PACE session 1

UC CINCINNATI

1/26/22 - Greater Plains Collaborative Rapid PACE session 1

- Presented 5-6 slides
  - (but I also had another 15-20 slides after my main presentation, in case people had questions, and for further background)

Rates of Mortality Vary by Race and Age

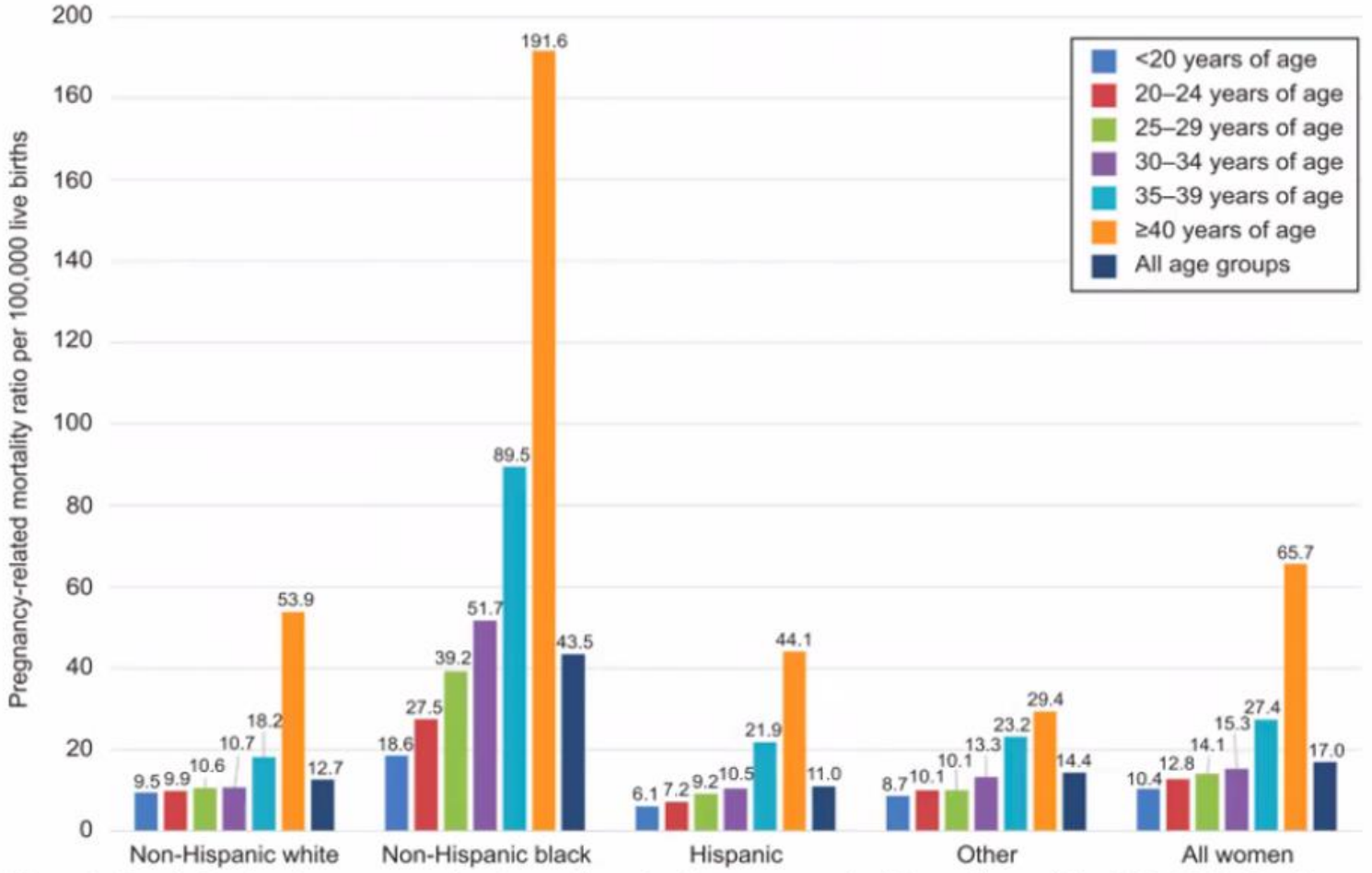


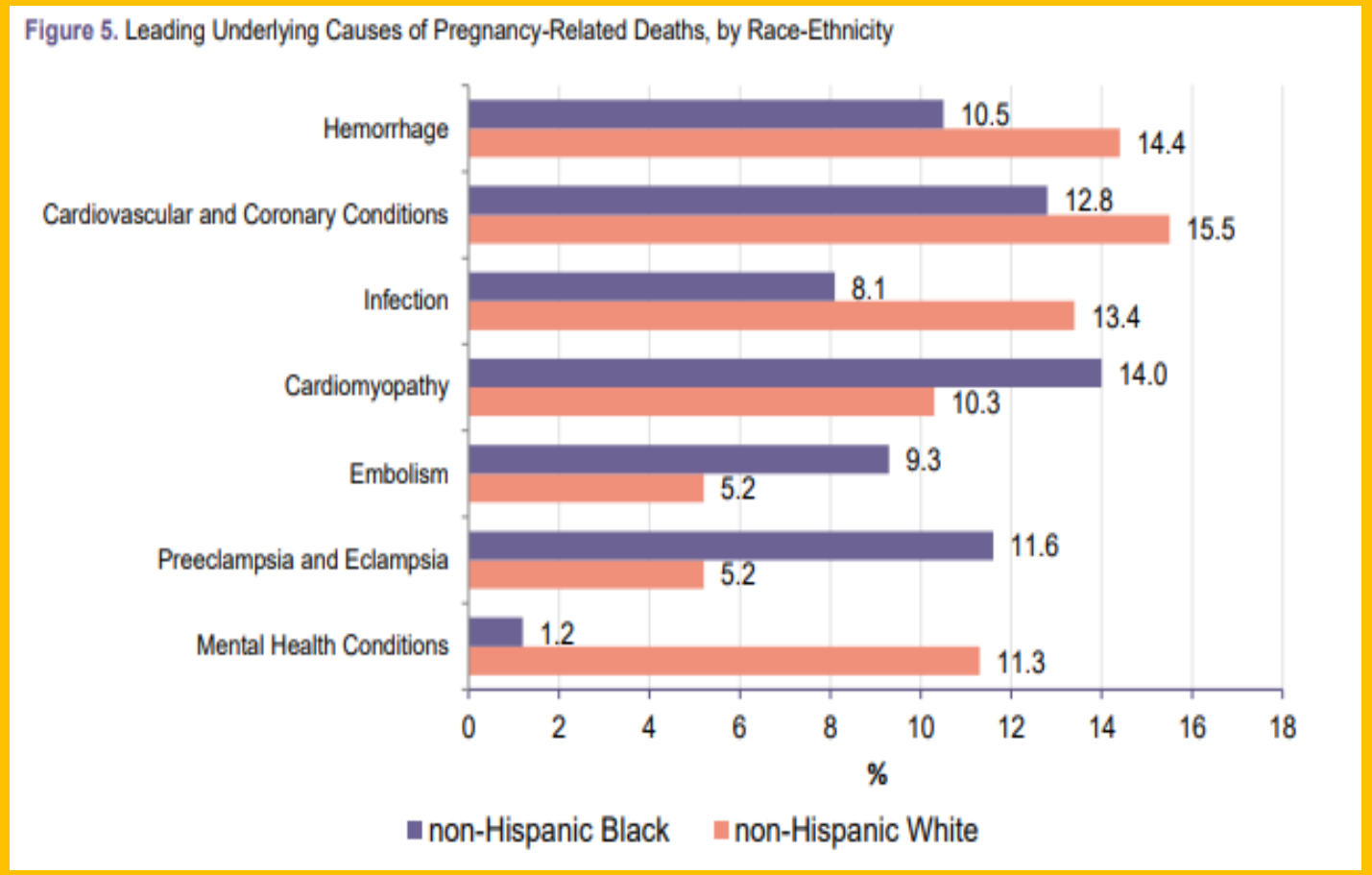
Figure 1. Population-level pregnancy-related mortality ratios by age, race–ethnicity, and overall for 2011–2013. Results are population-level and can be compared as absolute values.

Creanga. Pregnancy-Related Mortality in the United States. Obstet Gynecol 2017.

QUESTION: How have the **cause(s)** of maternal mortality and severe maternal morbidity (SMM) **changed over time**, in different racial groups in the U.S.?

UC CINCINNATI

Causes of Mortality Vary by Race



- Our **hypothesis** is that cardiac causes (cardiomyopathy, cardiovascular conditions) of maternal mortality in Black women have increased, while other causes (such as hemorrhage) have decreased from 1990-2020

UC CINCINNATI

Disparities in maternal mortality

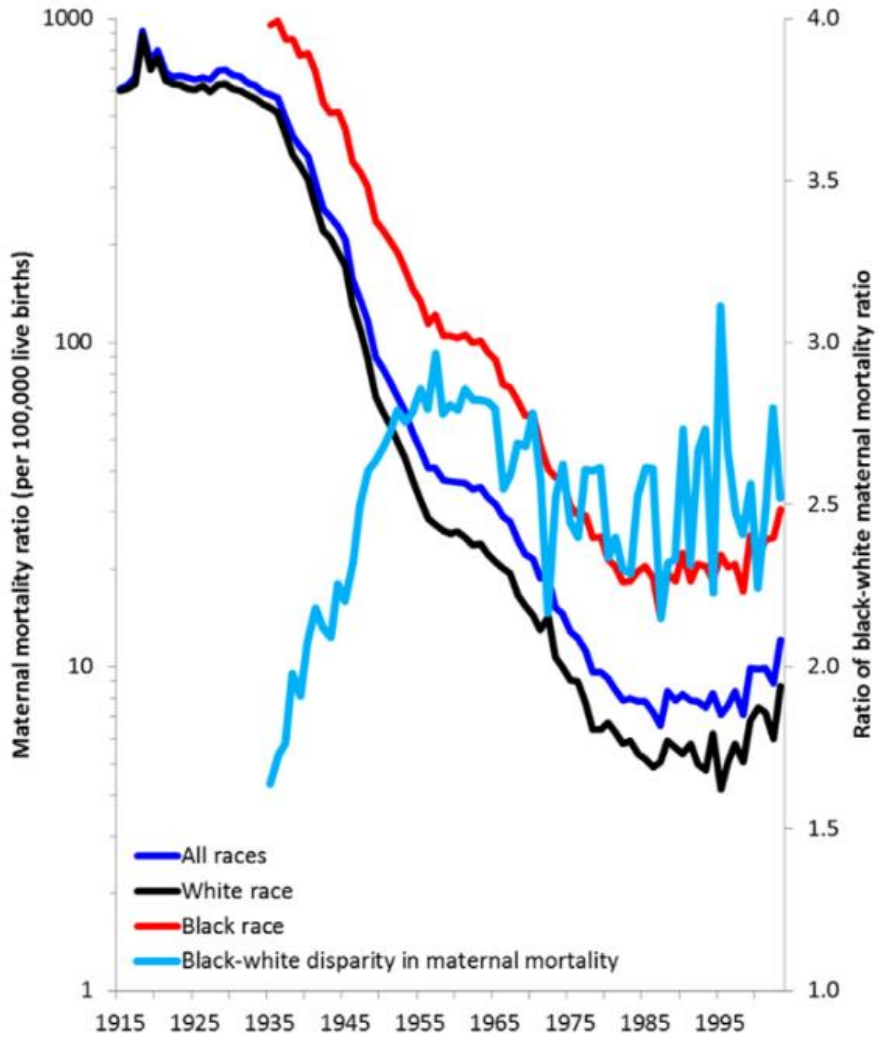


Fig – Maternal mortality ratio (per 100,000 live births) based on race: United States, 1915–2003.

Research Proposal - Impact

- **Impact**:
  Results will help us understand and address **drivers** of racial and socioeconomic disparities in maternal mortality and severe maternal morbidity (SMM)

- **Goal**:
  Develop interventions to **decrease the rate** of maternal mortality and severe maternal morbidity in the United States.

Request/focus for session

- We are interested in your ideas about measurement and collecting information. This may include
  - Co-morbidities (other illnesses)
  - Health metrics
  - Social Determinants of Health
  - (Future) Use of questionnaires

Other input

1. How should we continue patient/family engagement?
   - How should we set up an advisory board of patients and community members that are interested in this work?
   - How often do you recommend the advisory board meet?
   - Should we send E-mail invitation and explain we want them to meet to discuss study design, analysis, publications, etc.?
2. Letter of support?

   A letter of support for our upcoming grant application

Take-home points from Rapid PACE #1

From: Kimminau, Kim <kkimminau@health.missouri.edu>
Sent: Thursday, January 27, 2022 10:52 AM
To: Janine Parham <j9parham@gmail.com>; Jeff Ordway <ordwayj63@live.com>; Curt Anderson <curt.anderson@comcast.net>; Laurel Hoeth <lhoeth@charter.net>; Bill Stephens <stephens@ktis.net>; June Eilers <juneeilers402@msn.com>; Sandi Stanford <sandisues@sbcglobal.net>
Cc: Kirk Knowlton <Kirk.Knowlton@imail.org>; Hase, Judith L <hase.judith@MARSHFIELDRESEARCH.ORG>; Thomas, Traci <tmtqpk@health.missouri.edu>; Hsu, Albert <hsual@health.missouri.edu>; Michelle Debbink <Michelle.Debbink@hsc.utah.edu>; Song, Xing <xsm7f@health.missouri.edu>; Cassone, Deandra <cassoned@health.missouri.edu>; Niu, Xiaofan <niux@health.missouri.edu>; buyuk@umn.edu; Tuhlei, Breanna (MU-Student) <bt3mh@health.missouri.edu>; Hamai, Callie (MU-Student) <cjhhd4@health.missouri.edu>; Brooks, Alisea <adb24c@health.missouri.edu>; Williams, Savannah <williamssav@health.missouri.edu>; Carson, Brittany <bnc449@health.missouri.edu>
Subject: Summary from Hsu Rapid PACE session 1/26/2022

GPC PAC Team,
Here is the list of issues/ideas you raised during our session last night :

1. Include distance to the hospital or primary care medical home if possible
2. Include obesity/normal/underweight as a comorbid predictor (and does it need to be revised to account for population differences?)
3. Include pregnancy order and if other prior pregnancies or miscarriages resulted in SMM (and perhaps if previous pregnancies resulted in any infant-related events, too)
4. Geography (characterizing zip code sociodemographic factors like poverty or food desert, etc.)
5. Are there ways to measure trust in doctors/health care? (vaccine status, "late" access to prenatal care)
6. Age of mother
7. Historical factors given vast difference in care during these mothers' early life to when they become mothers (especially for the older age groups)
8. Recognize that the categorization of race is influenced by who is collecting or entering that data
9. Is there a way to know if a home birth or doula-assisted birth results in high(er) SMM?
10. Duration of time between pregnancies (interpregnancy interval)
11. Time between the birth and mother's death
12. Is there a way to categorize/identify preventable SMM?
13. Insurance status
14. Was the mother someone using safety net services leading up to the (hospital) birth

Take-home points from Rapid PACE #1

- Other issues:
  - "Why is your hypothesis focused on cardiovascular causes of mortality?"
  - How is race categorized (self-identified, or labelled by someone else)?
  - What about "near-miss" events, that don't result in mortality?
  - How can you/will you account for prior pregnancies?
- Other issues (not addressed in application version 1.0):
  - What about delays in accessing prenatal care? Cultural distrust of the healthcare system, revealed by missed appointments, prior pregnancy events, etc?
  - Is BMI more important, or BMI trends? What about fluctuations in weight during pregnancy?
  - Can you stratify by age and risk factor together, rather than separately?
  - Does the race of the doctor matter? There was a Jan 2021 Washington Post article on how "Black women and babies do better with black doctors"

Rapid PACE
Letter of support #1

GPC
Greater Plains Collaborative

26 January 2022

Albert L. Hsu, MD
Division of Reproductive Endocrinology
Department of Obstetrics, Gynecology and Women's Health
University of Missouri – Columbia
PO Box 10043
Columbia, Missouri 65205

Dear Dr. Hsu:

As members of the Greater Plains Collaborative Patient Advisory Council, we are pleased to offer this letter of support for your National Institute on Minority Health and Health Disparities R21 grant application in response to PAR-20-150, on "Uncovering Drivers of Disparities in Maternal Mortality, in a Database of the Greater Plains Collaborative."

We are pleased that you engaged with us to review your study aims and design using the GPC's Rapid Patient and Community Engagement (Rapid PACE). This innovative platform is open to all GPC investigators and their teams. The objective of Rapid PACE is to offer a streamlined way for research teams to learn from patient and community member insights. As trained research advocates, we work to illuminate features of a study from our lived experience and community perspective. We appreciate that you recognized the unique contributions GPC Rapid PACE offered to your team.

We are very supportive of our institutions working together, so a project that includes both you at the University of Missouri and Dr. Debbink at the University of Utah is ideal. The engagement teams at both institutions along with the overall GPC engagement team resource stand ready to support your project. We will be available to discuss your project periodically, as you continue to generate data to test this interesting hypothesis.

With best wishes for success in your project.

Sincerely,

Jeff Ordway
Greater Plains Collaborative Engagement Team co-Leader on behalf of Rapid PACE participants:

Curt Anderson (Allina Health)
June Eilers (University of Nebraska)
Laurel Hoeth (Marshfield Clinic)
Sandi Sanford (University of Texas Health Science Center – San Antonio)
William Stephens (University of Missouri)

UC CINCINNATI

As members of the Greater Plains Collaborative Patient Advisory Council, we are pleased to offer this letter of support for your National Institute on Minority Health and Health Disparities R21 grant application in response to PAR-20-150, on "Uncovering Drivers of Disparities in Maternal Mortality, in a Database of the Greater Plains Collaborative."

We are pleased that you engaged with us to review your study aims and design using the GPC's Rapid Patient and Community Engagement (Rapid PACE). This innovative platform is open to all GPC investigators and their teams. The objective of Rapid PACE is to offer a streamlined way for research teams to learn from patient and community member insights. As trained research advocates, we work to illuminate features of a study from our lived experience and community perspective. We appreciate that you recognized the unique contributions GPC Rapid PACE offered to your team.

We are very supportive of our institutions working together, so a project that includes both you at the University of Missouri and Dr. Debbink at the University of Utah is ideal. The engagement teams at both institutions along with the overall GPC engagement team resource stand ready to support your project. We will be available to discuss your project periodically, as you continue to generate data to test this interesting hypothesis.

Waiting for NIH study section….

- Initial NIH grant submission in Feb 2022
- May-Jun 2022: notice that it was assigned a number, and due to be reviewed

First NIH grant application rejected ("triaged")

- One (interesting) critique was that the study "does not include perspectives from impacted communities, and that the **involvement of a community advisory board could strengthen the proposal**."
  - *Actually, we *did* include an appropriate letter of support, but easy to miss.*
  - *In retrospect, it would have been better to emphasize our engagement with Rapid PACE throughout our application.*

- Time for a grant re-application!

Rapid PACE 2

1/23/23 - Greater Plains Collaborative Rapid PACE session 2

UC CINCINNATI

1/23/23 - Greater Plains Collaborative Rapid PACE session 2

- Key points:
  - Briefly reviewed: research team, hypothesis, specific aims
  - Presented **feedback** from NIH study section, with our proposals for improvement
  - Most importantly, discussed what elements should go into our “Conceptual Framework” for Racial Disparities in Maternal Mortality

Research team

- Research team @ MU:
  - Co-investigator: Xing Song, PhD (HMI)
  - Research team: Deandra Cassone, Xiaofan Niu, Ali Lund
  - With support from Katie Wilkinson, Abu Mosa, Russ Waitman

- Utah site investigator: Michelle Debbink, MD/PhD

Grant application - hypothesis

- **Overall objective** of this proposal is to better-understand factors associated with maternal mortality and severe maternal morbidity in the United States.
- **Critical knowledge gap** is a comprehensive understanding of causes of maternal morbidity and mortality in different patient populations, with an emphasis on preventable factors that may vary with racial or socioeconomic disparities.
- **Our central hypothesis** is that the **root causes of maternal mortality have been changing over time**; we propose to test this hypothesis using electronic medical record data in these two specific aims:

Grant application – specific aims

- **Our central hypothesis** is that cardiac causes of maternal mortality in Black women have increased over time
  - Aim 1: To interrogate de-identified healthcare records from **patient care encounters in the Cerner Corporation's multi-institutional *Real-World Data*™ database**
    - for correlations between baseline characteristics, health conditions, urban/rural status, and regions of the country with maternal mortality and severe maternal morbidity (SMM),
    - to determine factors associated with racial and socioeconomic disparities in maternal mortality and SMM,
    - and with a focus on whether cardiac causes of maternal mortality and SMM have been increasing in Black women; and

Grant application – specific aims

- **Our central hypothesis** is that cardiac causes of maternal mortality in Black women have increased over time
  - Aim 2: **to use de-identified linked data from the Greater Plains Collaborative™, PCORnet, social security death files, obituary files, and geocoding (to help identify relevant social determinants of health)**
    - to determine factors associated with racial disparities in maternal mortality and SMM at the University of Missouri and the University of Utah, and
    - with a focus on whether cardiac causes of maternal mortality have been increasing in Black women.
    - Such linked data is more robust than hospital-based databases, as data linked to death files can capture pregnancy-associated deaths up to one year after delivery.

Grant application - innovation

- 1) will build knowledge about drivers of racial disparities in maternal mortality, including the effects of disparities in cardiovascular and metabolic disease on pregnancy;
- 2) will further establish trends in maternal morbidity and severe maternal mortality, because of the longitudinal nature of the available data;
- 3) will link data to determine drivers of racial and socioeconomic disparities in maternal mortality;
- 4) quasi-experimental approach to better-account for the observational nature of this data, to more appropriate compare controls and treatment groups through propensity-weighting, and to account for bias caused by rare events.

Committee feedback 1

1) (1) Novelty was seen in the potential to explore the role of social determinants of health on maternal mortality and SMM, but that "since leading causes of maternal death by race are known to differ by race, it is unclear what significance elucidating trends would have."

- In response to these comments, Aim 2 is now rewritten with a more innovative approach to **quantitate** the relative impact of each factor (age, BMI, race, tobacco use, comorbidities, medical history, social determinants of health) on maternal mortality and SMM. We anticipate **developing a "point score"** to quantitate factors that have the greatest impacts on maternal mortality in different races and age groups. To our knowledge, such quantitation has not been systematically developed for maternal mortality **before** (e.g. "factors increasing maternal mortality include tobacco use [1.5-fold increase]; BMI < 20 [2.8x increase], BMI > 60 [5x increase], BMI > 40 [3x increase]; age < 18 and > 39 [both 2x increase], Black race [3-5x increase], COVID illness"). We anticipate that impacts of age and BMI will both show a bimodal distribution, as age and BMI extremes are associated with pregnancy complications.

- **"Quantitation has not been developed before" => Too provocative?**

Committee feedback 2

1) <u>(2) It was noted that the two aims seem duplicative</u>.

While it is acknowledged and appreciated that the aims may seem overlapping at first glance, vast differences in these datasets will result in dramatically-different findings. Cerner's "Real World" database will provide a high volume of patients, while the Greater Plains Collaborative (GPC) at the Universities of Missouri and Utah will give depth; we are not aware of any database that can provide **both volume and depth**.

- Cerner is a large multi-institutional database that enable an analysis of contributors to in-hospital deaths and severe maternal morbidity (SMM).
- GPC will link geocoding with state death files and hospital records, providing valuable information about deaths up to 1 year after delivery, which is not available in Cerner. The latest Missouri data show most maternal mortality deaths happen after delivery.

Committee feedback 3

1) (3) It was noted that the concept of race is underdeveloped and the team "missed an opportunity to examine race and ethnicity beyond Blacks and non-Hispanic Whites."

- In our initial analysis, it will be important to **first confirm** that our analysis will continue to show significant and known disparities between Blacks and non-Hispanic Whites.
- Once this finding is confirmed in both datasets, we will investigate maternal mortality and SMM disparities **between Native Americans and non-Hispanic Whites**.
- In future directions, we also plan to **compare Hispanic vs non-Hispanic Whites and Hispanic vs non-Hispanic Blacks as well**.

Committee feedback 4

1) (4) A missed opportunity was identified, in that our aims did not explicitly quantify the impact of exposure to structural racism and discrimination, although the panel further notes that "a conceptual model would be helpful" since structural racism is not part of the proposed datasets.

- Indeed, many elements of our study are associated with structural racism, including social drivers of health (including SES status, poverty, crime, education, life expectancy), comorbidities, access to care, measures of dental health, and measures of allostatic load.
- Linking measures of vaccine hesitancy with geocoding will also help elucidate those minority communities with higher skepticism of Western medicine and health institutions, which may also reflect neglect and structural racism. While structural racism is indeed not part of our proposed datasets, we have rewritten Aim 2 to reflect that we will analyze a plethora of factors that may comprise critical components of structural racism and discrimination.
- A novel strength of our study is that we will also potentially be able to quantitate the relative weight and even provide a "point score" to these subcomponents of structural racism, with regard to their contributions to SMM and maternal mortality.
    - Is this an "over-promise?"
- *While geocoding may help uncover the impact of residential segregation and environmental injustice locally, on SMM and maternal mortality, we note that our research does not address the direct impact of biased policing and voter suppression on maternal mortality.*
    - can be developed further; we should state "race is a social construct" early in the application…"

Committee feedback 5

1) (5) Resources related to disparities, health equity, or racism are not described at the University of Missouri.

- The resources section of this grant application has been updated accordingly.
- I should also probably ask for a letter of support!

Take-home points from Rapid PACE #2

- Reviewed concerns from NIH study section feedback, agreed with our plan
- Helped develop “conceptual framework” for organizing and defining factors that may contribute to maternal mortality and morbidity

Rapid PACE
Letter of support #2

GPC
Greater Plains Collaborative

March 1, 2023

Albert L. Hsu, MD
Division of Reproductive Endocrinology
Department of Obstetrics, Gynecology and Women's Health
University of Missouri – Columbia
PO Box 10043
Columbia Missouri

Dear Dr. Hsu:

Last January, members of the Greater Plains Collaborative Patient Advisory Council (PAC) offered a letter of support for your National Institute on Minority Health and Health Disparities R21 grant application in response to PAR-20-150, titled "Uncovering Drivers of Disparities in Maternal Mortality, in a Database of the Greater Plains Collaborative." The PAC recognizes that proposals often receive feedback that encourage resubmission, and the engagement team was very pleased that you chose to engage them again for input for the study now titled "DRIVERs: Data Systems Research to Identify Drivers of Ethnic and Racial Inequities in Maternal Mortality".

We asked all members of the PAC to participate in a second GPC's Rapid Patient and Community Engagement (Rapid PACE) session. The members of the PAC are trained research advocates, and they can respond to a myriad of features to provide highly relevant input on the research question, methods, materials, recruitment and retention challenges, social determinants that may influence the study question, data-dependent determinants that may influence the study question as well as recommend effective ways to share and disseminate findings once a study is completed. Four members who participated in the first session and who signed a support letter in January 2021 were joined by three additional members for the second session held January 23, 2023.

For your study, the group made several recommendations to strengthen your proposal. For example, in response to a reviewer's critique that the study "does not include perspectives from impacted communities and that the involvement of a community advisory board could strengthen the proposal", the PAC argues that they are evidence of your engagement to bring patient-centered perspectives to your proposal. While the PAC was not convened specifically from a roster of "near miss" cases related to maternal mortality, during the session we learned that several members either themselves or a family member had relevant lived experience that informed their interest in the study topic. The GPC PAC stands ready to consult with you throughout your study to assist and bring their questions and concerns to the research study team.

UC CINCINNATI

Last January, members of the Greater Plains Collaborative Patient Advisory Council (PAC) offered a letter of support for your National Institute on Minority Health and Health Disparities R21 grant application in response to PAR-20-150, titled "Uncovering Drivers of Disparities in Maternal Mortality, in a Database of the Greater Plains Collaborative." The PAC recognizes that proposals often receive feedback that encourage resubmission, and the engagement team was very pleased that you chose to engage them again for input for the study now titled "DRIVERs: Data Systems Research to Identify Drivers of Ethnic and Racial Inequities in Maternal Mortality".

We asked all members of the PAC to participate in a second GPC's Rapid Patient and Community Engagement (Rapid PACE) session. The members of the PAC are trained research advocates, and they can respond to a myriad of features to provide highly relevant input on the research question, methods, materials, recruitment and retention challenges, social determinants that may influence the study question, data-dependent determinants that may influence the study question as well as recommend effective ways to share and disseminate findings once a study is completed. Four members who participated in the first session and who signed a support letter in January 2021 were joined by three additional members for the second session held January 23, 2023.

Last January, members of the Greater Plains Collaborative Patient Advisory Council (PAC) offered a letter of support for your National Institute on Minority Health and Health Disparities R21 grant application in response to PAR-20-150, titled "Uncovering Drivers of Disparities in Maternal Mortality, in a Database of the Greater Plains Collaborative." The PAC recognizes that proposals often receive feedback that encourage resubmission, and the engagement team was very pleased that you chose to engage them again for input for the study now titled "DRIVERs: Data Systems Research to Identify Drivers of Ethnic and Racial Inequities in Maternal Mortality".

We asked all members of the PAC to participate in a second GPC's Rapid Patient and Community Engagement (Rapid PACE) session. The members of the PAC are trained research advocates, and they can respond to a myriad of features to provide highly relevant input on the research question, methods, materials, recruitment and retention challenges, social determinants that may influence the study question, data-dependent determinants that may influence the study question as well as recommend effective ways to share and disseminate findings once a study is completed. Four members who participated in the first session and who signed a support letter in January 2021 were joined by three additional members for the second session held January 23, 2023.

For your study, the group made several recommendations to strengthen your proposal. For example, in response to a reviewer's critique that the study "does not include perspectives from impacted communities and that the involvement of a community advisory board could strengthen the proposal", the PAC argues that they are evidence of your engagement to bring patient-centered perspectives to your proposal. While the PAC was not convened specifically from a roster of "near miss" cases related to maternal mortality, during the session we learned that several members either themselves or a family member had relevant lived experience that informed their interest in the study topic. The GPC PAC stands ready to consult with you throughout your study to assist and bring their questions and concerns to the research study team.

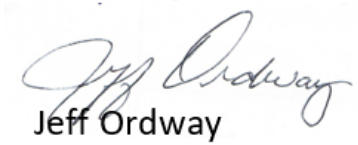
For your study, the group made several recommendations to strengthen your proposal. For example, in response to a reviewer's critique that the study "does not include perspectives from impacted communities and that the involvement of a community advisory board could strengthen the proposal", the PAC argues that they are evidence of your engagement to bring patient-centered perspectives to your proposal. While the PAC was not convened specifically from a roster of "near miss" cases related to maternal mortality, during the session we learned that several members either themselves or a family member had relevant lived experience that informed their interest in the study topic. The GPC PAC stands ready to consult with you throughout your study to assist and bring their questions and concerns to the research study team.

A central focus of our Rapid PACE session was to talk about variables that might inform the racial and ethnic differences in maternal mortality embedded in the GPC's common data model as well as how other data sets might be queried to better describe unequal access and unequal outcomes. For example, use of patient ZIP code can be used to describe neighborhood features such as walkability, food desert status and density of liquor stores. Urban/rural differences with respect to minority populations also was discussed. For example, very few African Americans live in rural communities in the Midwest, so rural/urban differences should be viewed in this context. PAC members raised their concerns about predisposing events or conditions that might contribute to differential mortality including when a women initiated prenatal care and whether any data regarding trauma, adverse childhood experiences, and the earlier-than-expected presence of a comorbidity (such as Type II diabetes in a young adult) could contribute to higher risk. The members were concerned about stress, abuse, and poor housing (i.e., living in a home that might expose individuals to poor water or air quality or exposure to lead based paint). Prior pregnancies, home birth experience and pregnancy termination were also mentioned as variables that may influence the risk of maternal mortality.

We will be available to discuss your project periodically, as you continue to generate data to test this concerning maternal health issue. The topic is of substantial interest and each time the group comes together to discuss the project, I know you agree that we have a rich, informative exchange.

With best wishes for success in your project.

Sincerely,



Jeff Ordway

Greater Plains Collaborative Engagement Team co-Leader on behalf of Rapid PACE participants:

A central focus of our Rapid PACE session was to talk about variables that might inform the racial and ethnic differences in maternal mortality embedded in the GPC's common data model as well as how other data sets might be queried to better describe unequal access and unequal outcomes. For example, use of patient ZIP code can be used to describe neighborhood features such as walkability, food desert status and density of liquor stores. Urban/rural differences with respect to minority populations also was discussed. For example, very few African Americans live in rural communities in the Midwest, so rural/urban differences should be viewed in this context. PAC members raised their concerns about predisposing events or conditions that might contribute to differential mortality including when a women initiated prenatal care and whether any data regarding trauma, adverse childhood experiences, and the earlier-than-expected presence of a comorbidity (such as Type II diabetes in a young adult) could contribute to higher risk. The members were concerned about stress, abuse, and poor housing (i.e., living in a home that might expose individuals to poor water or air quality or exposure to lead based paint). Prior pregnancies, home birth experience and pregnancy termination were also mentioned as variables that may influence the risk of maternal mortality.

We will be available to discuss your project periodically, as you continue to generate data to test this concerning maternal health issue. The topic is of substantial interest and each time the group comes together to discuss the project, I know you agree that we have a rich, informative

A central focus of our Rapid PACE session was to talk about variables that might inform the racial and ethnic differences in maternal mortality embedded in the GPC's common data model as well as how other data sets might be queried to better describe unequal access and unequal outcomes. For example, use of patient ZIP code can be used to describe neighborhood features such as walkability, food desert status and density of liquor stores. Urban/rural differences with respect to minority populations also was discussed. For example, very few African Americans live in rural communities in the Midwest, so rural/urban differences should be viewed in this context. PAC members raised their concerns about predisposing events or conditions that might contribute to differential mortality including when a women initiated prenatal care and whether any data regarding trauma, adverse childhood experiences, and the earlier-than-expected presence of a comorbidity (such as Type II diabetes in a young adult) could contribute to higher risk. The members were concerned about stress, abuse, and poor housing (i.e., living in a home that might expose individuals to poor water or air quality or exposure to lead based paint). Prior pregnancies, home birth experience and pregnancy termination were also mentioned as variables that may influence the risk of maternal mortality.

We will be available to discuss your project periodically, as you continue to generate data to test this concerning maternal health issue. The topic is of substantial interest and each time the group comes together to discuss the project, I know you agree that we have a rich, informative

A central focus of our Rapid PACE session was to talk about variables that might inform the racial and ethnic differences in maternal mortality embedded in the GPC's common data model as well as how other data sets might be queried to better describe unequal access and unequal outcomes. For example, use of patient ZIP code can be used to describe neighborhood features such as walkability, food desert status and density of liquor stores. Urban/rural differences with respect to minority populations also was discussed. For example, very few African Americans live in rural communities in the Midwest, so rural/urban differences should be viewed in this context. PAC members raised their concerns about predisposing events or conditions that might contribute to differential mortality including when a women initiated prenatal care and whether any data regarding trauma, adverse childhood experiences, and the earlier-than-expected presence of a comorbidity (such as Type II diabetes in a young adult) could contribute to higher risk. The members were concerned about stress, abuse, and poor housing (i.e., living in a home that might expose individuals to poor water or air quality or exposure to lead based paint). Prior pregnancies, home birth experience and pregnancy termination were also mentioned as variables that may influence the risk of maternal mortality.

We will be available to discuss your project periodically, as you continue to generate data to test this concerning maternal health issue. The topic is of substantial interest and each time the group comes together to discuss the project, I know you agree that we have a rich, informative

A central focus of our Rapid PACE session was to talk about variables that might inform the racial and ethnic differences in maternal mortality embedded in the GPC's common data model as well as how other data sets might be queried to better describe unequal access and unequal outcomes. For example, use of patient ZIP code can be used to describe neighborhood features such as walkability, food desert status and density of liquor stores. Urban/rural differences with respect to minority populations also was discussed. For example, very few African Americans live in rural communities in the Midwest, so rural/urban differences should be viewed in this context. PAC members raised their concerns about predisposing events or conditions that might contribute to differential mortality including when a women initiated prenatal care and whether any data regarding trauma, adverse childhood experiences, and the earlier-than-expected presence of a comorbidity (such as Type II diabetes in a young adult) could contribute to higher risk. The members were concerned about stress, abuse, and poor housing (i.e., living in a home that might expose individuals to poor water or air quality or exposure to lead based paint). Prior pregnancies, home birth experience and pregnancy termination were also mentioned as variables that may influence the risk of maternal mortality.

We will be available to discuss your project periodically, as you continue to generate data to test this concerning maternal health issue. The topic is of substantial interest and each time the group comes together to discuss the project, I know you agree that we have a rich, informative exchange.

A central focus of our Rapid PACE session was to talk about variables that might inform the racial and ethnic differences in maternal mortality embedded in the GPC's common data model as well as how other data sets might be queried to better describe unequal access and unequal outcomes. For example, use of patient ZIP code can be used to describe neighborhood features such as walkability, food desert status and density of liquor stores. Urban/rural differences with respect to minority populations also was discussed. For example, very few African Americans live in rural communities in the Midwest, so rural/urban differences should be viewed in this context. PAC members raised their concerns about predisposing events or conditions that might contribute to differential mortality including when a women initiated prenatal care and whether any data regarding trauma, adverse childhood experiences, and the earlier-than-expected presence of a comorbidity (such as Type II diabetes in a young adult) could contribute to higher risk. The members were concerned about stress, abuse, and poor housing (i.e., living in a home that might expose individuals to poor water or air quality or exposure to lead based paint). Prior pregnancies, home birth experience and pregnancy termination were also mentioned as variables that may influence the risk of maternal mortality.

We will be available to discuss your project periodically, as you continue to generate data to test this concerning maternal health issue. The topic is of substantial interest and each time the group comes together to discuss the project, I know you agree that we have a rich, informative exchange.

Conceptual Framework for "Racial Disparities in Maternal Mortality"

Proposed 1/3/23 by Albert Hsu and team

(FINALIZED in March 2023…)

UC CINCINNATI

Fig4. Conceptual Framework for "Racial Disparities in Maternal Mortality"

Patient factors

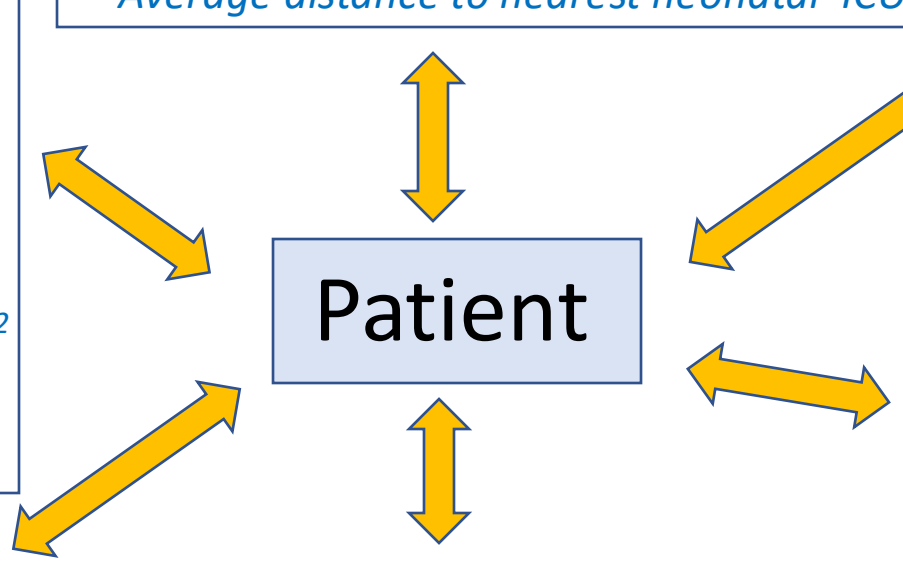
- Demographics: Age,[1,2] BMI[1,2]
- Comorbidities [1,2]
- SDOH (education level, [2] marital status,[1,2] occupation,[2] income,[2] urban/rural status,[2] local life expectancy) [2]
- Prenatal care (number and timing of visits [1,2]) "encounter table"
- Substance use [1,2]
- Pregnancy history (prior miscarriages, near-misses, etc)[1,2]
- ER visits/touchpoints [1,2]
- Mental health (medications/admissions)[1,2]
- Medication refill rates (number and consistency) [1,2]

Access issues

- Insurance status [1,2]
- Average distance to nearest hospital [2]
- Average distance to (and # of) nearest obstetrician, MFMs [2]
- *Telehealth/broadband access* [2]
- *Average distance to nearest neonatal ICU* [2]

Hospital-level factors

- Regions of the country (ie maternal care deserts; Medicaid expansion states) [1]
- Urban/rural status [1,2]
- Obstetric Levels of Care [1]



*Provider issues

- *Prenatal care provider (obstetrician, midwife, home birth, etc), markers of unconscious bias, circumstances of transport to higher level of Ob care*
- likely unavailable in Cerner and PCORnet
- may be accessible in future prospective studies

Neighborhood factors

- Environmental pollution, water quality [2]
- Societal norms (ie *vaccine confidence [2])

*Family factors

- *Family history, family support, community resources*
- likely unavailable in Cerner and PCORnet
- may be accessible in future prospective studies

[1]Accessible in Cerner Database

[2]Accessible in "PCORnet Common Data Model" (including geocoding, consumer-based information)

Ongoing work, and next steps

- Hoping to schedule another RAPID PACE meeting this fall, to
  - Discuss findings from our current work, as well as
  - Seek feedback on proposed follow-up R01 NIH grant application for Feb 2025.

What should I know about setting up a Rapid PACE session?

GPC Rapid PACE Researcher's Presentation and Format:

- Each Rapid PACE session will not exceed **one hour.** If the team needs more time for discussion, an additional Rapid PACE session will be scheduled.

- The GPC Rapid PACE session will be **facilitated** by one or more members of the KUMC GPC engagement team to ensure the allocated time for each session is adhered to and all participants have a chance to respond and provide input. The KUMC GPC engagement team:
    - will provide guidance to the research team and review their slides prior to a scheduled GPC Rapid PACE session and
    - will moderate sessions and take notes that will be shared with all participants and presenting research team.

GPC Rapid PACE Researcher's Presentation and Format:

- The researcher/research team will give a brief oral presentation (no more than 10 minutes) about their project augmented by PowerPoint slides.
- This will outline the specific request they have for the GPC Rapid PACE participants.
- The researcher will use plain language, avoiding acronyms and research jargon. After the presentation, the researcher will hear the advocates' reactions, answer questions and discuss the project, as needed.

TITLE:

This slide should include the title of study (with a lay title, if needed), researcher name, researcher/department/institution, and date.

RESEARCH PROPOSAL:

- A brief statement describing the research study. Specifically state why the research is needed and how it could impact patients. For instance, how may it increase understanding and advance care for those with a specific condition or disease, etc.

The Request or Focus for the Session:

- Discuss what the researcher/research team is specifically requesting from GPC Rapid PACE session. If the request concerns a new project/proposal, include a statement about what are you trying to study and why it is important. If the request concerns some aspect of a current project, describe the feedback you seek (i.e., feedback on a newsletter format or survey questions). Use plain language and define terms likely to be unfamiliar with the audience of stakeholders participating in the Rapid PACE session.

- Be specific about your "ask" for this session…what input you desire; and when or if you need any additional input following the session. For example, if the request concerns a new project/proposal, what aspect of the project are you seeking input on? For example, do you want clarification about the relevance of the research question? Do you want input into the various methods that could be used to answer the question? Do you want feedback on the protocol or design aspects of the study? If there is some current project phase or item you want the group to respond to, be sure to provide relevant documents separately or clearly describe the issue on this slide.

What I Need Going Forward from GPC Related to Engagement:

- Anticipate what your engagement needs from the project might be. For example:
- • Will there be an additional request related to engagement at the local level or across the GPC?
- • Do you need a letter of support from the Raid PACE team?
- • Are you asking for ongoing input from an individual patient(s) as a collaborator on your project?
- • Include any other requests you would like the group to consider.

Discussion (optional slide):

- If you need decisions or other information from the participants, discuss them on this slide. For example, if there are additional opportunities for the GPC Patient Advisory Council members to engage with the research team, include those here. Include a timeline reflecting those opportunities and any other requests you may have (for example, if you require a letter of support, who it should be sent to and a due date).

Take-home messages

Take home messages – NIH grant applications

- NIH grant reviewers are (generally) not “out to get you,” but are rather giving you input on how to improve your applications
  - but sometimes the feedback hurts!
- Redundancy is a virtue in NIH grant applications
  - they probably didn’t see our first RAPID PACE letter, when they gave us feedback on initial submission

Take home messages

- Be organized when you meet with Rapid PACE
  - Small # of slides
  - Have specific questions in mind

- Patient engagement is a process, which can be really fun!

- The next time you engage a Rapid PACE group, ask everyone to pose for a picture before the end…!

Acknowledgments

- Xiaofan Niu, PhD; Kim Kimminau, PhD; Jeff Ordway (GPC engagement team)
- Xing Song, PhD; Christie Spinka, PhD
- Deandra Cassone, PhD; past GPC Admin Director (MU)
- Ali Lund; Breanna Tuhlei, MD; Callie Hamai, MD
- Jane McElroy, PhD; Adrienne Ohler, PhD
- MFMs: Michelle Debbink (Utah) and Karen Florio (Missouri)
- Utah team: Jacob Kean, Haddy Bah, Jackson Barlocker, Megan Douros
- All members of the Rapid PACE teams that worked with us!

Questions?