MATERNAL OUTCOMES (MOMS) PROGRAM: TESTING INTEGRATED MATERNAL CARE MODEL APPROACHES TO REDUCE DISPARITIES IN SEVERE MATERNAL MORBIDITY

NINR R01NR021134

NIH Pragmatic Trials Collaboratory
Onboarding Meeting
November 1, 2023

Feinstein Institutes for Medical Research
Northwell Health®

BACKGROUND

- Severe maternal morbidity (SMM) – "unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a birthing person's health." (CDC)

- SMM increases the risk for re-hospitalization post-delivery, disability, and maternal mortality. [Black et al. *J Womens Health*. 2021;30(12); Admon et al. *Obstet Gynecol*. 2018;132(5)]
  - BUT, most cases are avoidable if timely, appropriate care is provided.

- Black birthing people have the highest rate of SMM throughout the birthing continuum; [Liese et al. *J Racial Ethn Health Disparities*. 2019;6(4); Brown et al. *Obstet Gynecol*. 2020;136(5)]
  - 2 times more likely to experience SMM than non-Hispanic White birthing people, even with similar economic backgrounds and medical coverage [Howell et al. *Obstet Gynecol*. 2020;135(2); Howland et al. *Matern Child Health J*. 2019;23(3)]

BACKGROUND – NORTHWELL HEALTH'S MOMS PROGRAM

- Maternal OutcoMes (MOMs) Program launched in 2020 at Northwell Health, the largest healthcare provider in New York state

- Program consist of:
  - Identification of high-risk birthing people using clinical diagnoses documented in the EHR
  - Close clinical and behavioral health monitoring via a chatbot and weekly phone check-ins during the first month postpartum
  - Access to a 24/7 nurse-led call center
  - Navigation to obstetric and specialty care, and emergency services as needed
  - Home visits with a nurse practitioner to monitor and support birthing person's and baby's health (if needed)
  - Connection to social services and community-based resources to address unmet social needs

- Program delivered by team of care management coordinators, RNs, and nurse practitioner

BACKGROUND – NORTHWELL HEALTH'S MOMS PROGRAM


Original Research ajog.org

OBSTETRICS

Postpartum navigation decreases severe maternal morbidity most among Black women

Zenobia Brown, MD, MPH; Choukri Messaoudi, MBA; Emily Silvia, MHA; Hallie Bleau, RN, MS; Ashley Meskill, MS, FNP; Anne Flynn, MD, MSW; Amparo C. Abel-Bey, MPH; Trever J. Ball, PhD, MPH

- From 2020 – 2021, 2,590 racially and ethnically diverse birthing people enrolled in MOMs
  - 615 Black Birthing people

- Overall, there was 56% reduction in 30-day hospital readmissions (post-delivery) related to SMM
  - **Among Black birthing people, 77% reduction in SMM-related rehospitalizations**

- Quotes from focus groups with MOMs participants:
  - "…you feel more human, you don't feel like a number or a quota. I felt like the people that I was interacting with were all moms in a sense because they got it. They understood it."
  - "And if it wasn't for her [MOMs Program staff], I probably would've never even thought I had an infection or bacteria or anything. She was like, I need you to go in [doctor's office] and get it checked out."
  - "So, it wasn't just questions about her [the baby], they also asked me how I'm doing, how I'm feeling. So, it's like reminding me I have to take care of myself as well."

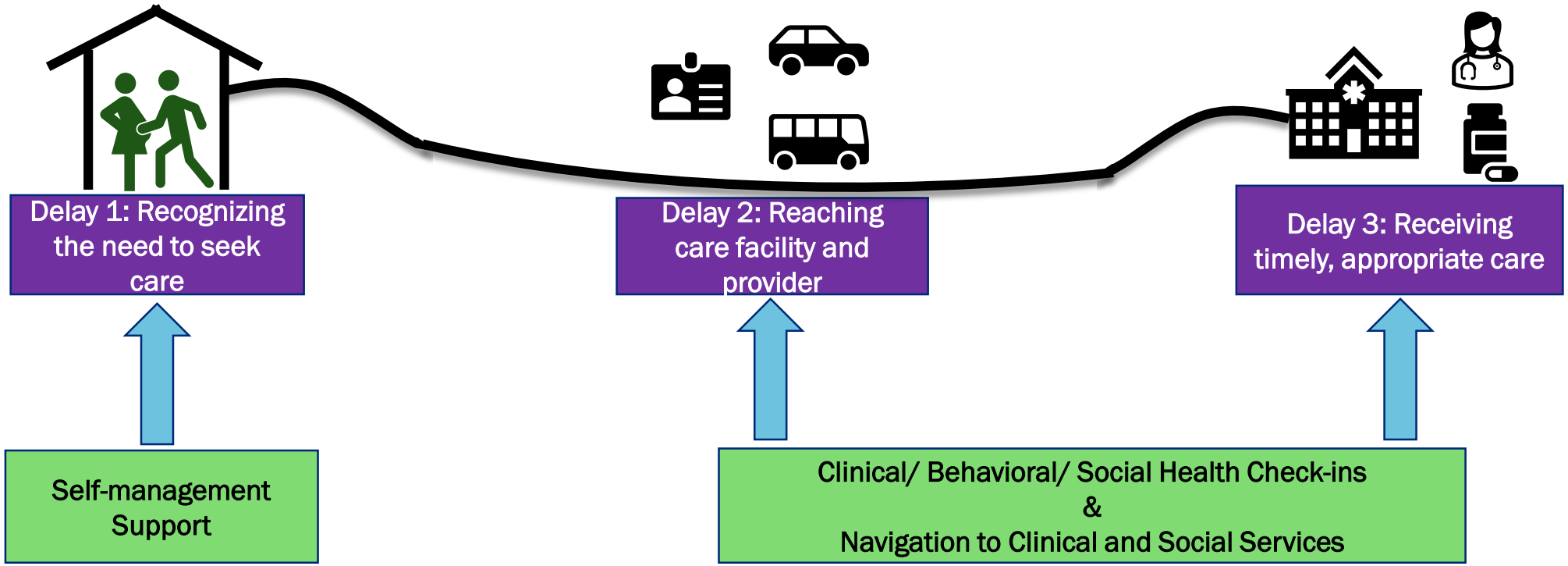
BACKGROUND – CONCEPTUAL MODEL

Reproductive Health Matters
An international journal on sexual and reproductive health and rights

ISSN: 0968-8080 (Print) 1460-9576 (Online) Journal homepage: https://www.tandfonline.com/loi/zrhm20

The role of delays in severe maternal morbidity and mortality: expanding the conceptual framework

Rodolfo Carvalho Pacagnella, Jose Guilherme Cecatti, Maria Jose Osis & João Paulo Souza

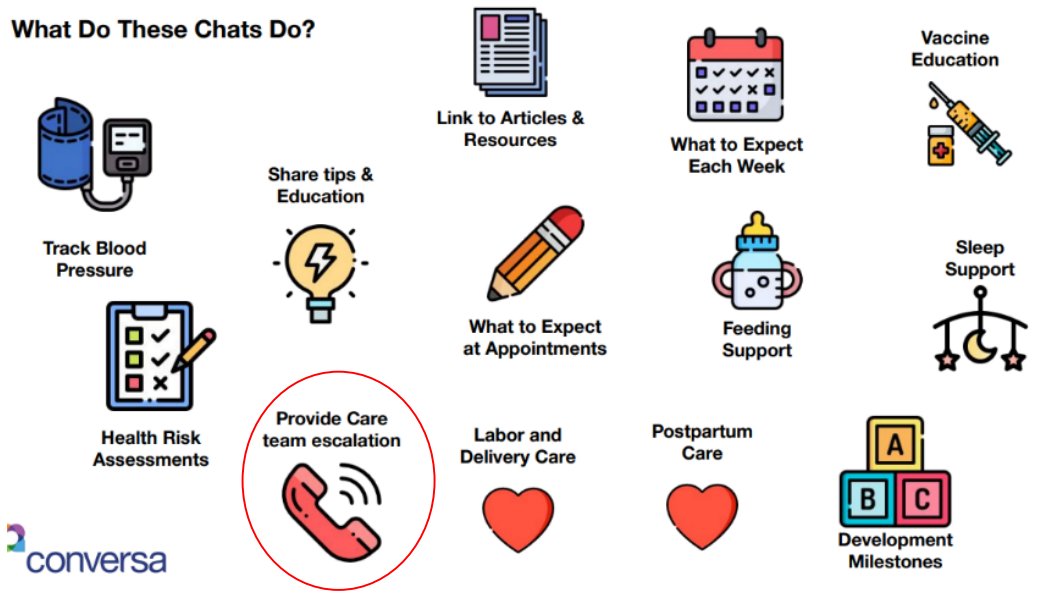


Three Delays Model with MOMs Program Intervention Components

2-ARM PRAGMATIC RANDOMIZED CLINICAL TRIAL DESIGN

MOMs Low-Touch (MOMs-LT), n = 337

- Northwell OB Chats (Prenatal to 1-year Postpartum)
- 4-weekly postpartum clinical check-ins (original MOMs program)
- Fitbit (Prenatal to 1-year Postpartum)



MOMs High-Touch (MOMs-HT), n = 337

- Northwell OB Chats (Prenatal to 1-year Postpartum)
- 12 bi-weekly self-management support telehealth visits (Prenatal)
- 4-weekly postpartum clinical check-ins (original MOMs program)
- Fitbit (Prenatal to 1-year Postpartum)

+

- Home Blood Pressure Monitoring Training

SPECIFIC AIMS/STUDY OUTCOMES

1. Compare MOMs-HT to MOMs-LT on the incidence of SMM at the time of labor and delivery.

   1a. Compare study arms on the incident rate of SMM-related hospital admissions at 1-month and 1-year postpartum.

2. Compare the two study arms on time to documented preeclampsia diagnosis and initiation of treatment.

3. Examine the effect of the two study arms on perceived social support domains (informational, emotional, and tangible) from enrollment to 1-month and 1-year postpartum.

4. Explore the effect of each study arm on patterns of engagement in physical activity from study enrollment to 1-year postpartum and subsequent association with maternal health outcomes.

5. Examine implementation determinants and outcomes using a mixed methods approach.

INCLUSION CRITERIA (N = 674)

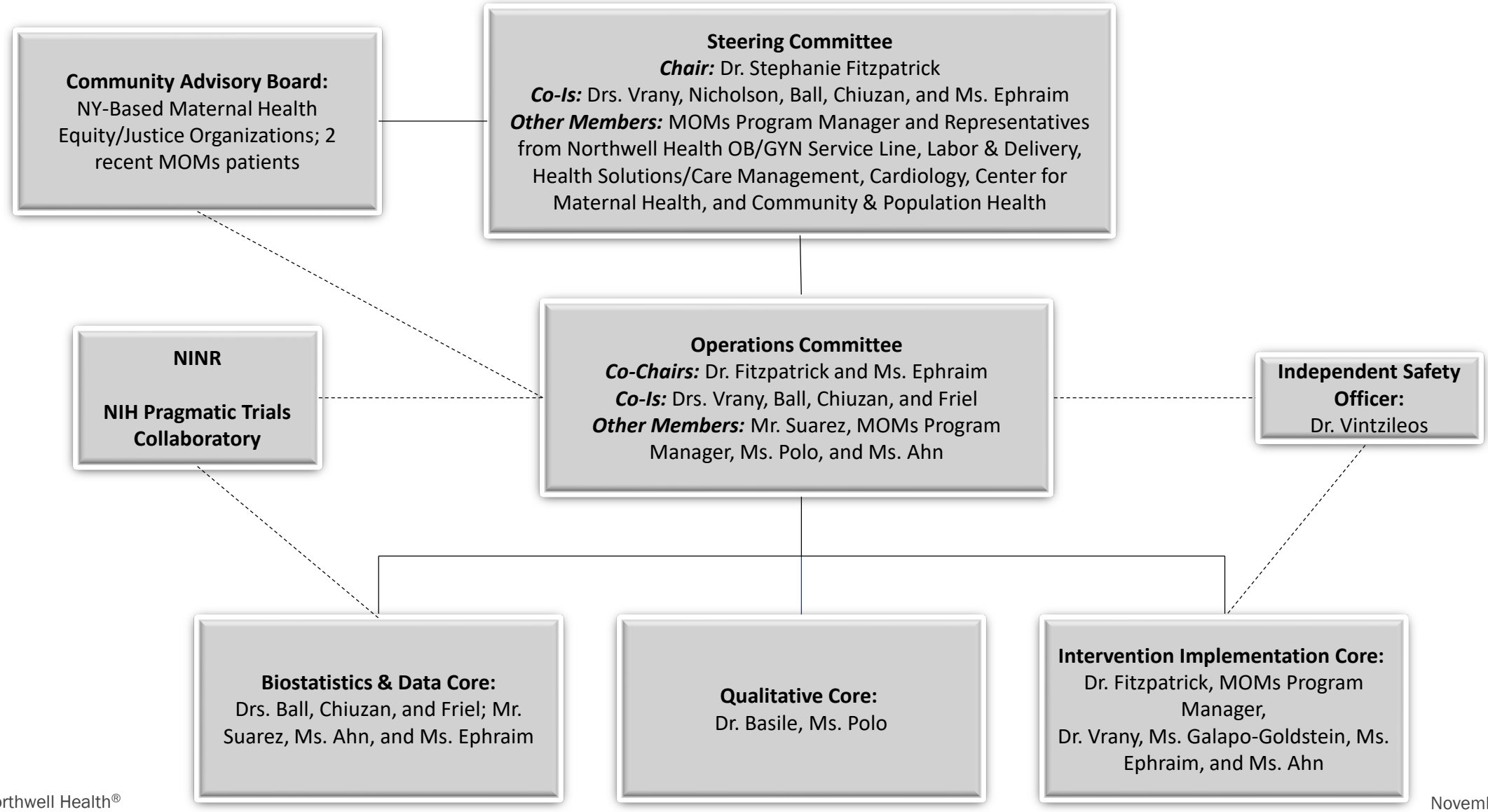
- Age 18 or older
- Self-identify as Black/African American
- Pregnant with gestational age no higher than 12 weeks
- OB-CMI risk score ≥ 3 and/or history of preeclampsia
- Primary language is English or Spanish
- Receive OB care at a NHPP practice site

RECRUITMENT PLAN

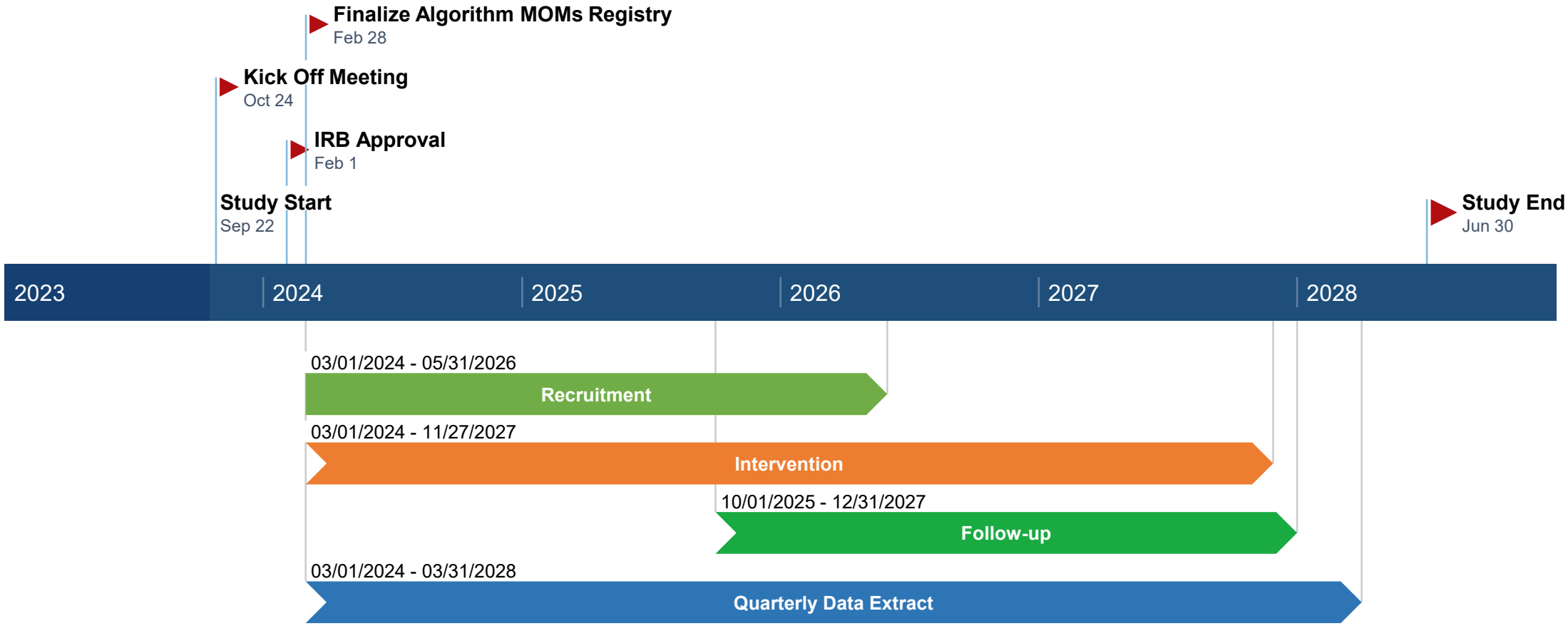
1. Will leverage Northwell Health Perinatal Data Center (registry of prenatal, birth, and postpartum EHR data) to develop and refine algorithm for recruitment list
2. Research coordinators will mail and email recruitment letters to potentially eligible patients; follow-up with recruitment phone calls

- ❑ Recruitment over 27 months; aim to recruit and enroll ~25 participants per month
- ❑ Randomization at 1:1 ratio

STUDY TEAM


Community Advisory Board:
NY-Based Maternal Health Equity/Justice Organizations; 2 recent MOMs patients
Steering Committee
Chair: Dr. Stephanie Fitzpatrick
Co-Is: Drs. Vrany, Nicholson, Ball, Chiuzan, and Ms. Ephraim
Other Members: MOMs Program Manager and Representatives from Northwell Health OB/GYN Service Line, Labor & Delivery, Health Solutions/Care Management, Cardiology, Center for Maternal Health, and Community & Population Health
NINR
NIH Pragmatic Trials Collaboratory
Operations Committee
Co-Chairs: Dr. Fitzpatrick and Ms. Ephraim
Co-Is: Drs. Vrany, Ball, Chiuzan, and Friel
Other Members: Mr. Suarez, MOMs Program Manager, Ms. Polo, and Ms. Ahn
Independent Safety Officer:
Dr. Vintzileos
Biostatistics & Data Core:
Drs. Ball, Chiuzan, and Friel; Mr. Suarez, Ms. Ahn, and Ms. Ephraim
Qualitative Core:
Dr. Basile, Ms. Polo
Intervention Implementation Core:
Dr. Fitzpatrick, MOMs Program Manager,
Dr. Vrany, Ms. Galapo-Goldstein, Ms. Ephraim, and Ms. Ahn

MOMS CLINICAL TRIAL TIMELINE



MOMs R01: Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects	X				
Engagement of clinicians and health systems	X				
Data collection and merging datasets		X			
Regulatory issues (IRBs and consent)		X			
Stability of control intervention			X		
Implementing/delivering intervention across healthcare organizations	X				

*Your best guess!
1 = little difficulty
5 = extreme difficulty

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Data Sharing – Planning Phase

- *What is your current data sharing plan and do you foresee any obstacles?*
  - *We plan to share de-identified, individual-level clinical, questionnaire, and summary of Fitbit data. We do not foresee any obstacles to this.*

- *What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent, if applicable?*
  - *IRB submission is in process*

- *What data are you planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?*
  - *Individual-level clinical (e.g., SMM-related conditions, preeclampsia diagnosis), questionnaire (i.e., social support, type of physical activity, barriers to physical activity), and Fitbit (e.g., minutes of physical activity)*

QUESTIONS?