

What is ACCORDS?

Adult and Child Center for Outcomes Research and Delivery Science

ACCORDS is a 'one-stop shop' for pragmatic research:

- A multi-disciplinary, collaborative research environment to catalyze innovative and impactful research
- Strong methodological cores and programs, led by national experts
- Consultations & team-building for grant proposals
- Mentorship, training & support for junior faculty
- Extensive educational offerings, both locally and nationally



ACCORDS Upcoming Events

April 26, 2023 Virtual	<u>ACCORDS/CCTSI Quarterly Community Engagement Forum</u> Forging and Funding a Community Partnership: An Example of In Tandem Partnering <i>Presented by: Karen Barret; Kimberley Penney</i>
May 3, 2023 Virtual	<u>Hot Topics in Mixed Methods and Qualitative Research</u> And Then A Miracle Happens: Getting Into The Complexity Of Mixed Methods Designs And Approaches <i>Presented by: Jodi Summers Holtrop, PhD</i>
May 15, 2023 Virtual	<u>Methods and Challenges in Conducting Health Equity Research</u> <i>Presented by: April Oh, PhD</i>
June 5-6, 2023 10:00 -3:30 PM MT	<u>COPRH Con 2023</u> – Registration open at COPRHCon.com Reassessing Evidence: What is Needed for Real World Research and Practice

*all times 12-1pm MT unless otherwise noted



Hot Topics in Mixed Methods and Qualitative Research

2023 Seminar Mini-Series

Using Longitudinal Qualitative Data and Cross-Sectional Quantitative Data to Understand Maternal Immunization Decision-Making



**Presented by:
Rupali Limaye, PhD**



Using longitudinal qualitative data and cross-sectional quantitative data to understand maternal immunization decision-making



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Overview of MIRI

Maternal Immunization Readiness Initiative (MIRI):

Conduct research to inform the future delivery of new maternal vaccines during pregnancy (COVID-19, RSV, GBS) in Kenya & Bangladesh

Immunization Readiness

Develop tools to assess readiness of MNH facilities for maternal immunization and quality of ANC before and after MI introduction

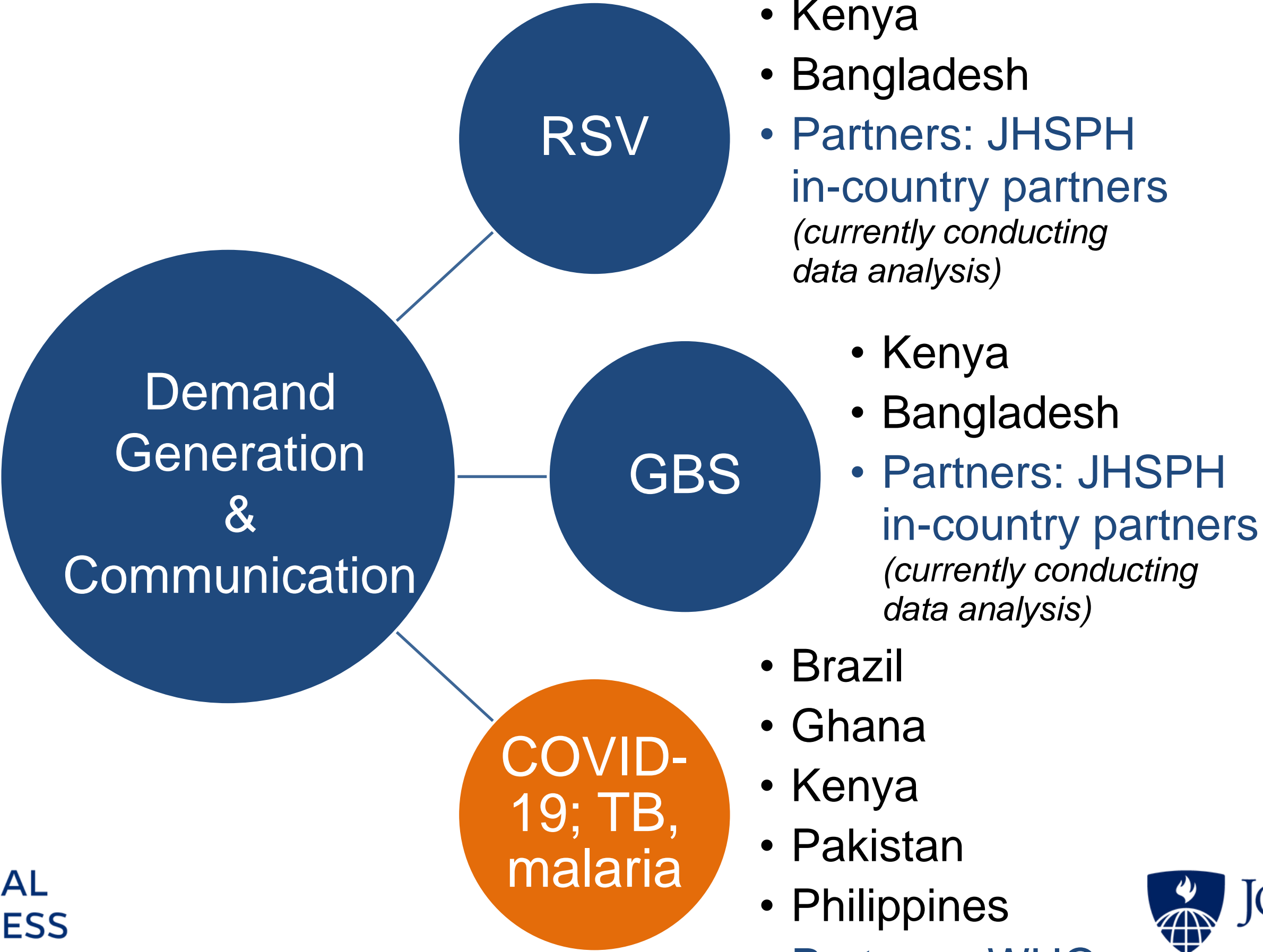
Maternal Immunization Policy

Assess the policy environment for MI
(COMIT: comitglobal.org)

Demand Generation & Communication

Gather insights on knowledge, attitudes, & behaviors relevant to maternal immunization and design communication strategies

Overview of Demand Work



Study Rationale

- Pregnant and lactating women (PLW) have been excluded from most SARS-CoV2 vaccine trials despite morbidity and mortality related to COVID-19
- Country recommendations vary on vaccinating pregnant women against COVID-19, creating considerable latitude in interpretation of vaccine recommendations
- Even in settings where COVID-19 vaccination during pregnancy has been strongly encouraged, vaccine uptake among pregnant women has been slow



Study Aim

To better understand how vaccine decision-making occurs among pregnant and postpartum women in 5 countries—**Brazil, Ghana, Kenya, Pakistan, and Philippines**



Understand risk perception of COVID-19 disease among pregnant and postpartum women



Document pregnant and postpartum women's knowledge of COVID vaccines and identify trusted sources of information



Identify and understand decision-making factors for getting the COVID vaccine among pregnant and postpartum women, including but not limited to social norms, knowledge, attitudes, and self-efficacy



Compare the decision-making process for the COVID vaccine across stages of pregnancy to understand how the process evolves from during pregnancy to postpartum

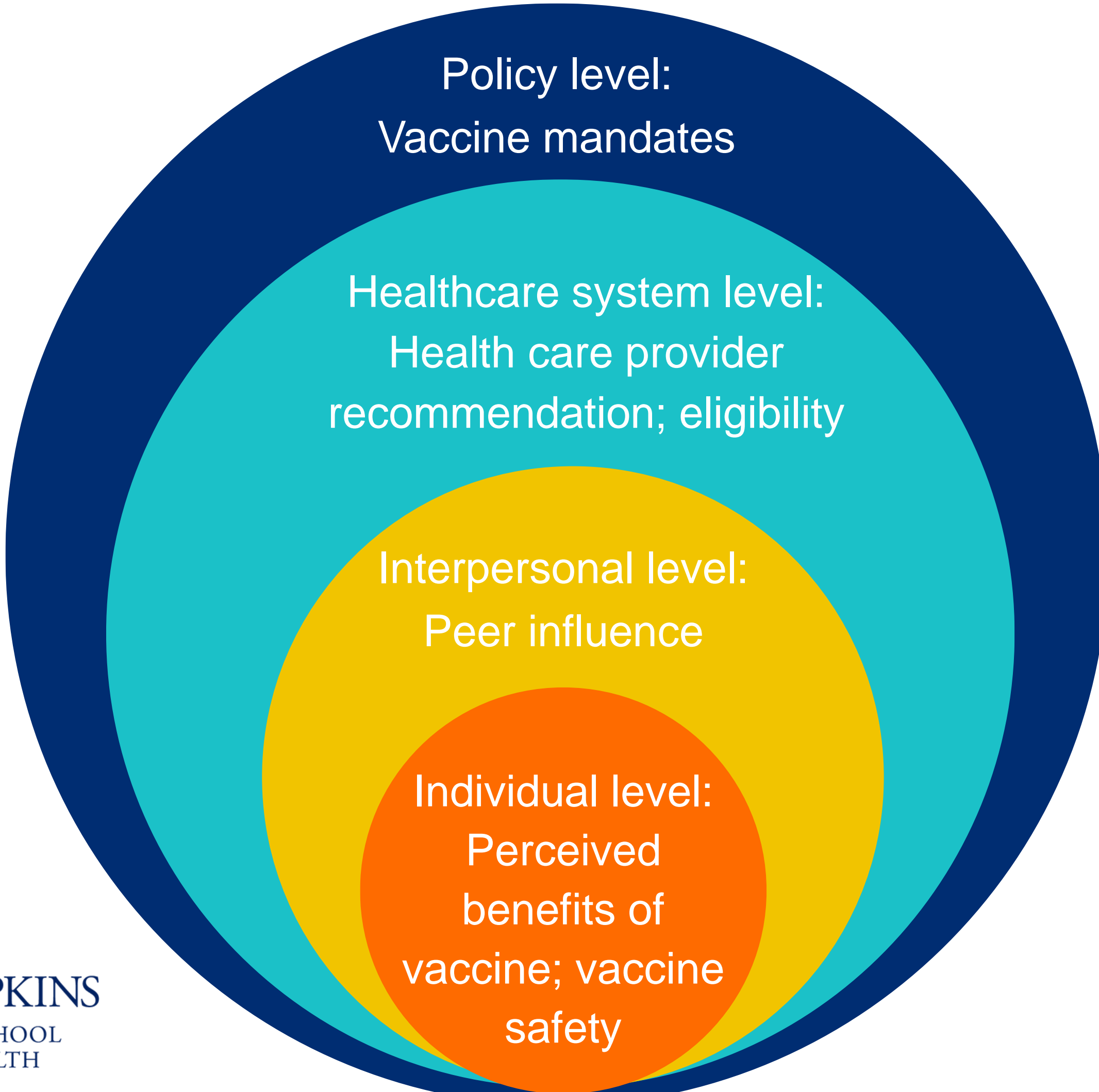


Assess COVID-19 vaccine uptake among pregnant and postpartum women



Explore vaccine intentions for other vaccines for pregnant and postpartum (TB, malaria)

Socio-ecological model of vaccine decision-making



Methods

Study linkages

WHO



**COVID-19 and Pregnancy
Longitudinal Cohort Study**

This study aims to determine if SARS-CoV-2 infection during pregnancy increases the risk of adverse pregnancy, perinatal, neonatal, or postpartum outcomes in 12 countries (Argentina, Brazil, Chile, Burkina Faso, Ghana, Kenya, Malawi, Pakistan, Iran, Tunisia, Georgia and the Philippines)

This study will be leveraged for its existing resources for coordination and data collection.

JHSPH



**Maternal Immunization
Readiness Initiative**

This study aims to better understand the vaccine decision-making process among PLW and their networks in Kenya and Bangladesh to provide information to their health systems to prepare them for the future delivery of new vaccines during pregnancy, specifically immunization readiness for COVID-19, respiratory syncytial virus (RSV), and group B Streptococcus (GBS) vaccines.

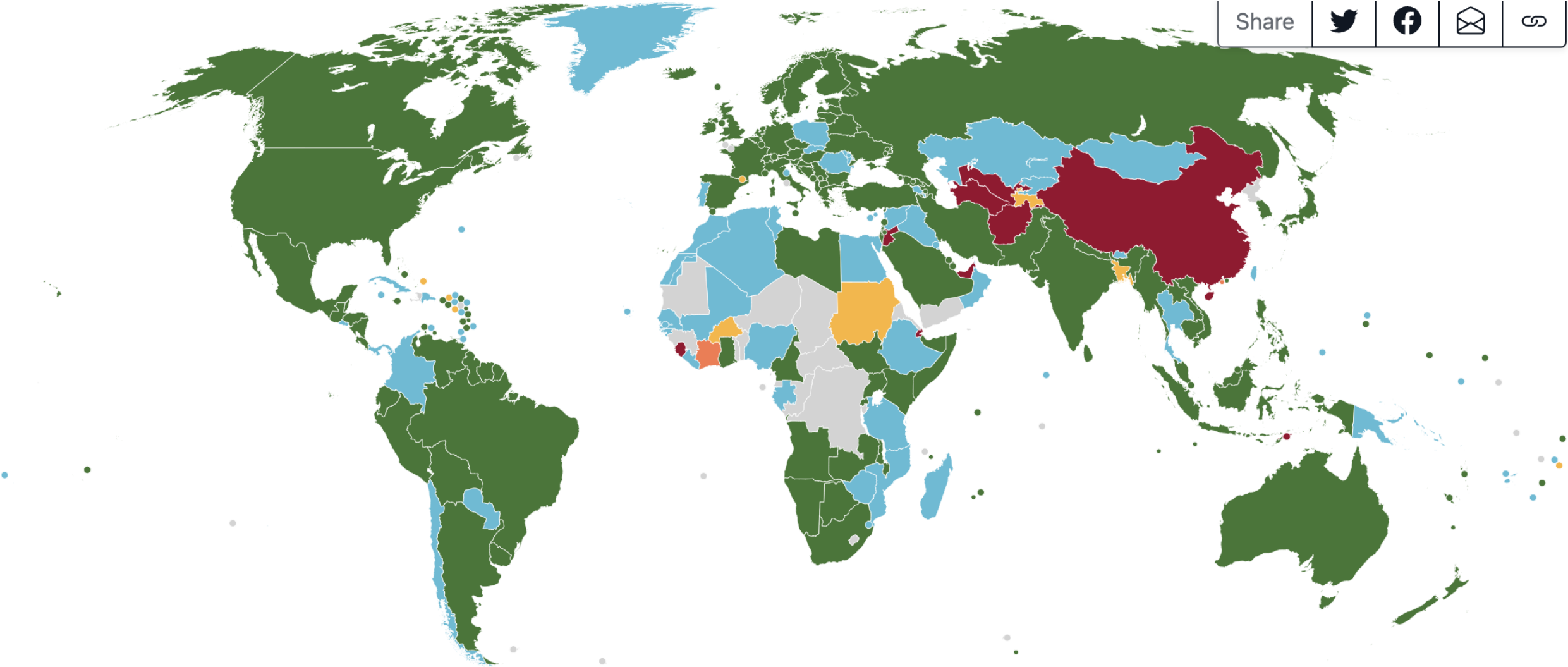
This study will be leveraged for study design, instrument design, and data analysis related to vaccine decision-making.

Country Selection

Country	# of deliveries/year (# study sites)	Pregnant women being vaccinated? (as of 2021)	Vaccine(s) used in pregnancy
Chile	~10,750 (3 sites)	Yes Permitted >16wks gestation	Sinovac (majority) Pfizer
Burkina Faso	? (10 sites)	No	
Ghana	>29,000 (5 sites)	No	
Kenya	~31,000 (2 sites)	No but unofficial uptake	AstraZeneca
Pakistan	101,653 (7 sites)	Yes Recommended in all trimesters	Sinopharm Sinovac AstraZeneca (only on request)
Philippines	25,342 (5 sites)	Yes Permitted without restriction	AstraZeneca Sinovac (?mRNA vaccines also)
Georgia	? (1 site)	No	
Tunisia	10,000 (1 site)	Yes Permitted >16wks	Pfizer

Country Selection

- Geographic diversity
- Gavi status
- Disease burden for COVID as well as other diseases affecting pregnant women and newborns
- Strong political will
- Influence in region



<https://www.comitglobal.org/explore/public-health-authorities/pregnancy>

Country Selection

Country	Region	Policy	Burden
Brazil	PAHO	Permitted	High
Ghana	AFRO	No rec	Low
Kenya	AFRO	No rec	Low
Pakistan	EMRO	Permitted	Low
Philippines	WPRO	Permitted	Low

Study Design

Activity A— in-depth interviews

A **qualitative** inquiry consisting of in-depth interviews (IDI) to understand how vaccine decision-making occurs among pregnant and postpartum women.

25 women from each of the 5 countries will be interviewed twice— once during pregnancy and once during postpartum



Activity B— quantitative survey

A **quantitative, cross-sectional** survey to identify attitudinal and behavioral correlates with vaccine status among pregnant women.

The survey will be conducted at a single point in time in each of the 5 countries and will only target pregnant women



Study Design: Why longitudinal qualitative?

- Two types of time: the characteristics and conditions that exist at each point in time (synchronic) and the change between these successive points in time (diachronic)
- Moves beyond linearity (look forwards and backwards at the same time)
- As participants' lives change, research questions can emerge which can have implications for data collection methods – in line with life course approach to immunization
- Ethical considerations

Participant Inclusion Criteria

Qualitative	Quantitative
<ul style="list-style-type: none"> • Able to provide consent 	<ul style="list-style-type: none"> • Able to provide consent
<ul style="list-style-type: none"> • Age: 18 years or older 	<ul style="list-style-type: none"> • Age: 18 years or older
<ul style="list-style-type: none"> • Trimester: Equal number of participants by trimester for visit 1; <6 weeks postpartum for visit 2 	<ul style="list-style-type: none"> • Trimester: Equal number of participants by trimester
-	<ul style="list-style-type: none"> • Vaccination status: approximately half vaccinated and half unvaccinated against COVID-19

Methods

Participants

Activity A— in-depth interviews

	Pregnancy (by Trimester)			Postpartum	Total # interviews
	1 st	2 nd	3 rd		
Brazil	8	9	8	25	50
Ghana	8	9	8	25	50
Kenya	8	9	8	25	50
Pakistan	8	9	8	25	50
Philippines	8	9	8	25	50
Total # interviews	40	45	40	125	250

Activity B— surveys

	Pregnancy (by Trimester)			Postpartum	Total # surveys
	1 st	2 nd	3 rd		
Brazil	80	80	80	160	400
Ghana	80	80	80	160	400
Kenya	80	80	80	160	400
Pakistan	80	80	80	160	400
Philippines	80	80	80	160	400
Total # surveys	400	400	400	800	2,000

Methods

Study Partners

JHSPH/IVAC

- Lead overall study
- Lead JHSPH ethics process
- Study design and coordination
- Oversee data management
- Lead data analysis
- Oversee dissemination

WHO HQ

- Lead RP2 and ERC ethics approval process
- Coordinate with in-country teams
- Contribute to data analysis and dissemination

WHO In-Country (with university local partner)

- Lead in-country IRB process
- Lead recruitment
- Lead data collection
- Transcribe/translate
- REDCap data entry
- Co-lead data analysis

Methods: Study Partners

Brazil

- Department of Obstetrics and Gynecology, University of Campinas, Campinas/SP

Ghana

- University of Ghana, Accra

Kenya

- Kenya Medical Research Institute, Nairobi

Pakistan

- Aga Khan University Hospital, Karachi

Philippines

- Santa Ana Hospital (SAH), Manila

Participant Recruitment

- All participant recruitment through health facilities
- Provincial/district health orientation meetings
- Health facility leadership meetings
- In each country, recruitment from facilities from at least 2 provinces/districts (with equal split between urban/rural)
- Recruitment by tier differs by country
- Specific days for recruitment
- Every nth individual is approached
- Quotas by trimester: once quota is reached for a trimester, will stop recruitment for that trimester
- Follow-up contact information collected from qualitative participants only

Instrument Constructs

Qualitative	Quantitative
<ul style="list-style-type: none"> COVID-19 awareness 	<ul style="list-style-type: none"> Socio-demographic questions
<ul style="list-style-type: none"> COVID-19 experience (self) COVID-19 experience (family) 	<ul style="list-style-type: none"> COVID-19 risk perception to self (severity and susceptibility) COVID-19 risk perception to unborn baby (severity and susceptibility)
<ul style="list-style-type: none"> Recommendation/policy related to COVID-19 vaccination for pregnant people 	<ul style="list-style-type: none"> COVID-19 vaccine self-efficacy
<ul style="list-style-type: none"> COVID-19 vaccine experience (including concerns) 	<ul style="list-style-type: none"> COVID-19 vaccine norms: descriptive COVID-19 vaccine norms: injunctive
<ul style="list-style-type: none"> Structural barriers and facilitators for COVID-19 vaccination 	<ul style="list-style-type: none"> COVID-19 vaccine information sources
<ul style="list-style-type: none"> Interpersonal barriers and facilitators for COVID-19 vaccination 	<ul style="list-style-type: none"> COVID-19 vaccine effectiveness for self COVID-19 vaccine effectiveness for unborn baby
<ul style="list-style-type: none"> Community barriers and facilitators for COVID-19 vaccination 	<ul style="list-style-type: none"> COVID-19 vaccine safety for self COVID-19 vaccine safety for unborn baby
<ul style="list-style-type: none"> Social media sources for COVID-19 vaccination 	<ul style="list-style-type: none"> COVID-19 vaccine hesitancy
<ul style="list-style-type: none"> Tetanus toxoid vaccination experience 	<ul style="list-style-type: none"> COVID-19 vaccine behavior
<ul style="list-style-type: none"> Risk perception related to other diseases (malaria, TB, RSV, GBS) 	<ul style="list-style-type: none"> Interest in future maternal vaccines (malaria, TB, RSV, GBS) <i>discrete choice</i>

Instrument Constructs

Future Vaccines

Vaccine introduction is complex, especially in LMIC

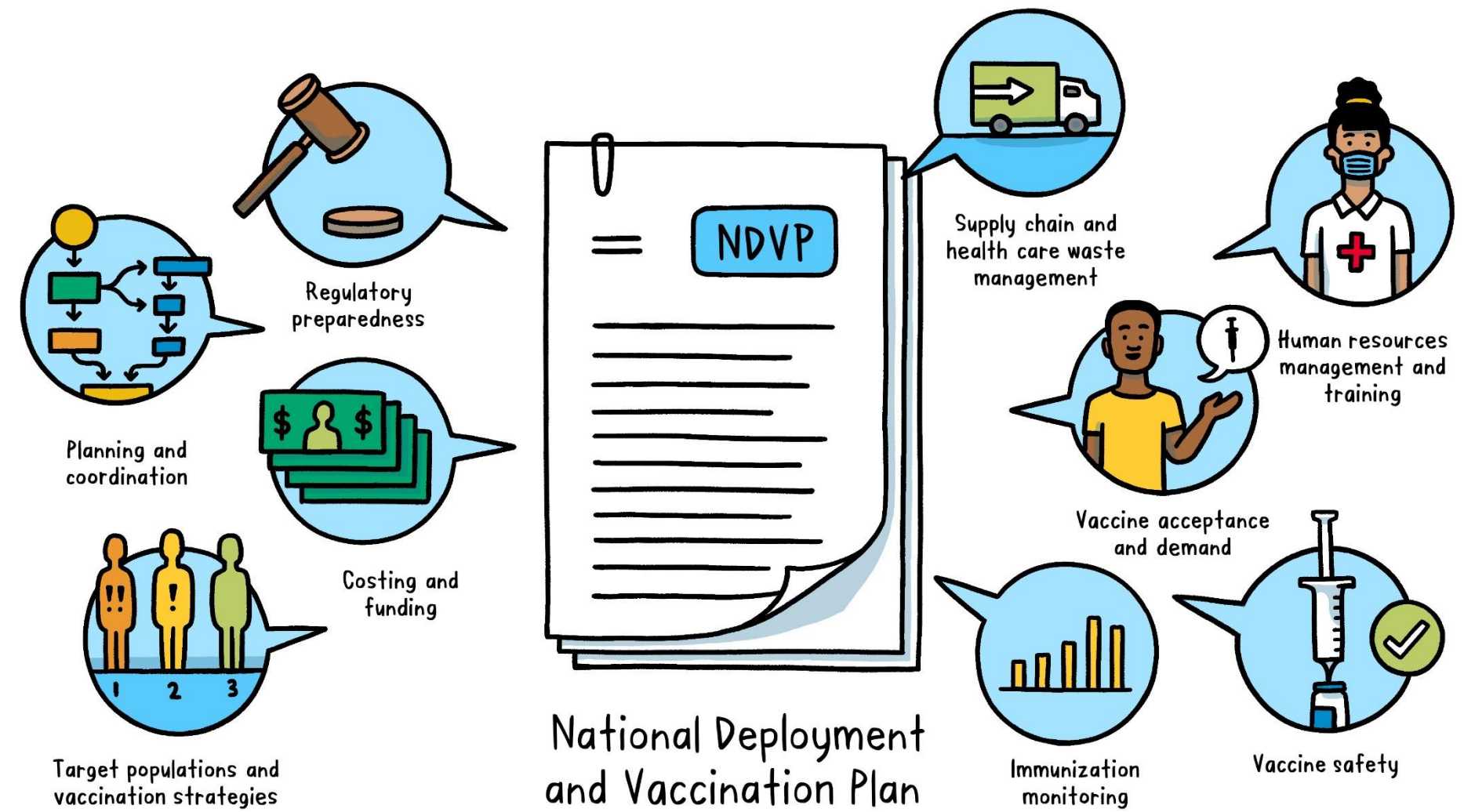
Critical to work in partnership with key stakeholders, including:

- Key beneficiaries including those affected by TB and their caregivers
- Vaccine manufacturers
- WHO, Gavi, UNICEF
- MOH, MOF
- RITAGs and NITAGs, and other immunization advisory boards
- Professional organizations for health care workers

Instrument Constructs

Future Vaccines

- Opportune moment: restore vaccine trust and confidence (many lessons learned from COVID-19 vaccine roll-out)
- Understand what populations and settings will most benefit from new MI vaccine introduction
- Identify factors that may drive acceptability, access, and uptake in highly vulnerable populations



Instrument Constructs: Future Vaccines

For each question, participants will select which factor is more important to them relative to the alternative. There are no wrong answers as these questions are about what features related to future vaccines that are most important to you. (malaria, TB, RSV, GBS)

Attribute	Description
Perceived risk associated with disease	How common (rare vs. common) and severe (mild vs. severe) the disease is that the vaccine protects against
Vaccine effectiveness	How well the vaccine protects against the disease (for example, 50% vs. 90%)
Number of doses required for full effectiveness	The number of vaccine doses required to be fully protected (1 dose only vs. 2 doses 1-2 months apart)
Requirement for booster	Whether or not a booster dose is needed to stay protected against the disease (for example: none, yearly, every 10 years)
Acute side effects	How likely (rare vs. common) and severe (mild vs. severe) short-term side effects of the vaccine are
Other side effects	How likely future problems from the vaccine are (none vs. very small risk of infertility or other disease)
Vaccine origin	The country/location where the vaccine was developed (USA/North America, UK/Europe, South Africa/Africa, India, China, Russia)
How long the vaccine has been available	How long the vaccine has been available (for example, 1 month, 6 months, >1 year)

Why Discrete Choice?

- Techniques for eliciting preferences emerged from a desire to understand demand for products where it is not possible to use revealed preference data on the actual choices made by individuals (i.e., a product that is not yet available = future vaccine)
- Theoretical foundation: random utility theory; assumes economic rationality and utility maximization

Instrument Development

- Literature search: maternal immunization vaccine decision-making in LMIC
- Iterative development process, including JHSPH investigators, WHO HQ investigators, and WHO in-country investigators
- Instruments are in at least two languages for each country + English
- Revised for accuracy in local language (terms)
- Pre-testing of instruments among pregnant and postpartum people in each country

Methods

Ethical Considerations

	Qualitative	Quantitative
<i>Eligibility</i>	<ul style="list-style-type: none"> Follow-up: miscarriage or stillbirth Follow-up: definition of postpartum (<6 weeks to <12 weeks) 	<ul style="list-style-type: none"> Vaccine status (Brazil: >90% of women vaccinated) Age of majority varies by country
<i>Partner Approval</i>	<ul style="list-style-type: none"> Male partner approval (Pakistan) 	<ul style="list-style-type: none"> Male partner approval (Pakistan)
<i>Terms</i>	<ul style="list-style-type: none"> Pregnant women vs pregnant people (Kenya, Pakistan) People who were recently pregnant vs nursing mothers (Ghana) 	<ul style="list-style-type: none"> Safety: concern about vaccine vs concern about ingredients (Pakistan)
<i>Socio-demographic questions</i>	-	<ul style="list-style-type: none"> Single as marital status (Pakistan) Ethnicity (Kenya)
<i>Knowledge of vaccination status</i>	-	<ul style="list-style-type: none"> Knowledge of COVID-19 vaccination status (Pakistan)

Ethics Reviews



“Pre-approval” by WHO’s RP2
(Research Project Review Panel)



Conditional ethical approval
by the BSPH IRB



Individual country approval by WHO
RP2



Approval by each country’s local IRB



Ethical approval by WHO ERC
(Ethics Review Committee)



Final ethical approval by the BSPH
IRB



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Ethics Reviews



Data Collection Training

- SOPs for each country
- 4-day in-country data collector training (didactic and experiential)
- Job aids for data collection for specific terms (i.e., visual representations for specific terms: RSV, immunity)
- JHSPH point in-country for 1st week of data collection
 - Daily debriefs
 - Daily download of data

“ In this section, I will read a statement. I am interested in understanding your level of agreement with the statement. You can either strongly agree with the statement, agree with the statement, disagree with the statement, or strongly disagree with the statement. ”

Strongly Disagree

Disagree

Agree

Strongly Agree

Don't know

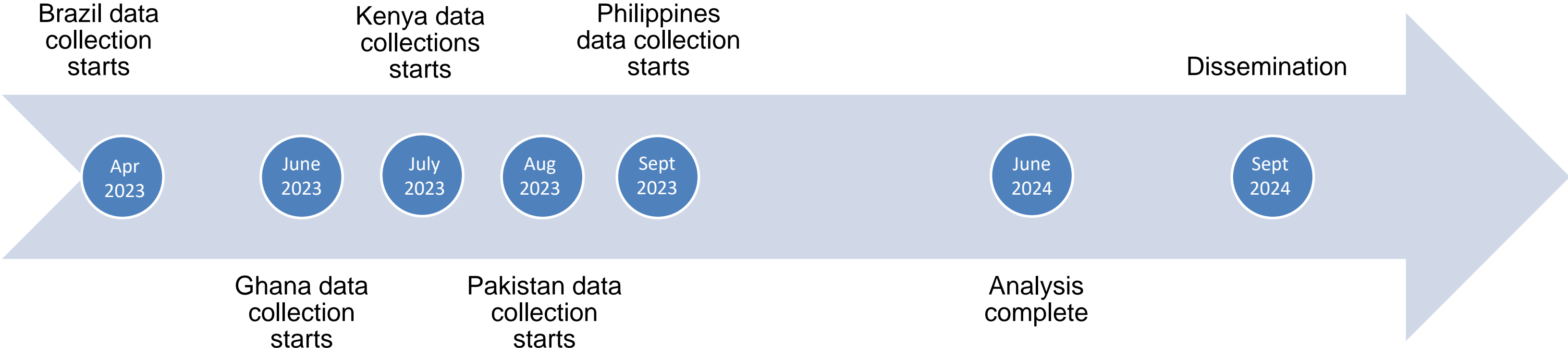
Only for knowledge-related questions

Data Collection Field + Storage

- All data collection teams using REDCap mobile except for Kenya and Philippines (paper)
- All data stored on REDCap (@JHSPH)
- For paper data collection, two-step data entry validation
- Paper data collection stored in locked cabinets at WHO in-country office

BEFORE DATA COLLECTION	
Maternal Immunization Readiness Initiative (MIRI): Demand and Communication	
Task	Complete?
Review the instrument(s)	
Review informed consent document(s)	
Test recorder/tablet	
<i>Have you made the following arrangements?</i>	
Private setting for data collection	
Transportation of staff to get to data collection site	
Transportation of participant(s) to get to data collection site	
Refreshments for participant(s)	
<i>Do you have the following equipment?</i>	
Audio recorder (for interviews)	
Batteries (for interviews)	
Notebook	
Pens	
Tablet (for surveys)	
Data collection instrument(s) (at least 3 copies)	
Consent forms (at least 3 extra)	
Survey ranking image sheet (for surveys)	
Participant reimbursement	
Reimbursement form	
PPE for staff	
PPE for participant(s)	
Envelope/box for all study materials	

Data Collection Timeline



Next Steps: Dissemination Ideas



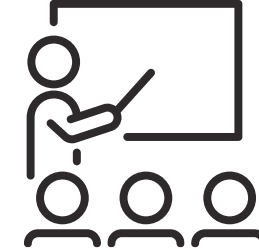
Communication Strategy

- Contains research results and tailored communication recommendations and techniques to promote uptake of maternal vaccines
- Help decision-makers create their own communication materials or programs



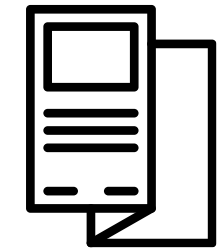
Policy Briefs

- Provide an overview of MI
- Inform about policy-related challenges identified by research results
- Provide recommendations for maternal vaccine-related policy and its dissemination



HCW Training Package

- Slide deck and facilitator guide with activities for a training on interpersonal communication about MI
- Includes materials for use by HCWs while providing ANC and PNC services, such as tracking charts, checklists, and SOPs for determining vaccine status and communicating about maternal vaccines



Health Facility IEC

- Posters that can be hung on walls of health facilities or pamphlets that can be distributed to ANC/PNC patients
- Inform about disease (burden, severity, risk factors, prevention, etc.) as well as maternal vaccines

JHSPH Team

Berhaun Fesshaye, MSPH, project officer: Ghana point

Emily Miller, MGH, project officer: Brazil point

Prachi Singh, project coordinator: Kenya point

Jessica Schue, PhD, MSPH, project manager: Pakistan point

Molly Sauer, MPH, doctoral student: Philippines point

Rupali Limaye, PhD, MPH, MA: PI



MIRI Publications

Lee, C., Holroyd, T. A., Gur-Arie, R., Sauer, M., Zavala, E., Paul, A. M., ... & Limaye, R. J. (2022). COVID-19 vaccine acceptance among Bangladeshi adults: understanding predictors of vaccine intention to inform vaccine policy. *PLoS One*, 17(1), e0261929.

Paul, A. M., Lee, C., Feshaye, B., Gur-Arie, R., Zavala, E., Singh, P., ... & Limaye, R. J. (2022). Conceptualizing the COVID-19 Pandemic: Perspectives of Pregnant and Lactating Women, Male Community Members, and Health Workers in Kenya. *International journal of environmental research and public health*, 19(17), 10784.

Limaye, R. J., Paul, A., Gur-Arie, R., Zavala, E., Lee, C., Feshaye, B., ... & Karron, R. (2022). A socio-ecological exploration to identify factors influencing the COVID-19 vaccine decision-making process among pregnant and lactating women: Findings from Kenya. *Vaccine*, 40(50), 7305-7311.

Zavala, E., Feshaye, B., Lee, C., Mutwiwa, S., Njagi, W., Munyao, P., ... & Limaye, R. J. (2022). Lack of clear national policy guidance on COVID-19 vaccines influences behaviors in pregnant and lactating women in Kenya. *Human Vaccines & Immunotherapeutics*, 18(6), 2127561.

Feshaye, B., Lee, C., Paul, A. M., Zavala, E., Singh, P., Karron, R. A., & Limaye, R. J. (2023). A qualitative inquiry in understanding trusted media sources to reduce vaccine hesitancy among Kenyans. *Frontiers in Communication*, 8, 995538.

Thank you!
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