Increasing men’s engagement in preventive healthcare through an enhanced cocoon vaccination strategy

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1. Objectives

The goal of this project is to understand whether the combination of vaccination access and connection to services tailored for men improves vaccination rates among men and engagement in healthcare. Additionally, this project aims to understand variations in effectiveness between low-touch and high-touch approaches. To achieve these goals, the project has two specific aims:

Aim 1: Assess the effectiveness of cocoon vaccination interventions on a continuum of minimum to high-touch in terms of vaccination completion and healthcare engagement. The initiative will roll out in three randomly timed clusters, the control group that includes current standard of care (SOC) where there is the offer of bedside vaccinations to support persons of birthing parents, another that includes the SOC offer of bedside vaccinations in addition to a low-touch information sheet that provides information about the importance of vaccines and preventive care, and a third that includes the SOC offer of bedside vaccinations and high-touch connection to the UH Cutler Center for Men through the Joe Team. Aggregate results from the department of pharmacy regarding the number of male patients receiving the vaccine during the time periods of each of the three arms will be assessed. Aggregate results from the UH Cutler Center for Men of the number of people enrolling in the center during the time periods of each of the three arms will be assessed. Male-identifying individuals will be recruited and enrolled to complete a survey to assess facilitators and barriers to vaccination completion and healthcare engagement.

Aim 2: Examine the factors that impact uptake of vaccination and healthcare engagement after a cocoon vaccination intervention. Factors that impact intervention uptake will be assessed through the survey and semi-structured interviews with a subsample of survey participants. Additionally, contextual factors related to the implementation of the intervention, such as hours of operation for high touch connections/vaccine distribution will be assessed. By understanding the factors that impact intervention uptake, we will assess the barriers and facilitators of this strategy.

Hypothesis. This pilot study will examine whether implementing a cocoon vaccination strategy that provides access to vaccinations and overall health education for men leads to increased uptake of vaccines and engagement in overall healthcare of male identifying support persons. Additionally, it will assess the factors that impact intervention uptake. We anticipate that vaccination rates and engagement with healthcare will be highest among male visitors at the Ahuja Medical Center who receive the SOC vaccination offer at bedside and the high-touch healthcare navigation information provided by a patient navigator present in the birthing center relative to those who are only offered information on health care or those who are offered bedside vaccines and information.

2. Background

Adult men are less likely to engage in preventive healthcare including vaccinations. A recent review to examine men's engagement with primary health care, found that barriers for engagement include personal thoughts around care seeking, perceptions of primary care as being for acute needs as opposed to preventive, perception of being unwelcome and not the focus of primary care, and access issues. **This project addresses barriers to men's engagement in preventive care by improving access, changing perceptions about the purpose of primary care, and providing a welcoming targeted connection to primary care.**

Cocoon vaccination is a strategy that aims to protect infants through vaccination of the household and caregiving network. Research on this strategy has shown it to be effective for increasing vaccination rates of non-birthing partners and other support persons. Specific efforts for this approach have used education and offering vaccination clinics in birthing centers in a hospital.6,7 **This work has only focused on the vaccinations of support persons near the time of birth and not on the potential of this strategy for increasing regular engagement in preventive healthcare.**

The Potash Women and Newborn Center located at Ahuja Medical Center has implemented a standard protocol to offer bedside vaccinations to support persons of birthing parents. This standard of care (SOC) protocol has been occurring since 12/1/2023. Currently, the SOC is that when a pregnant person is admitted for labor, the nursing teams asks them a series of questions for admission. One of the questions asked is if the patient has received the TDAP vaccine (which is verified through the patient's electronic records. If the patient has not received the TDAP, they are provided education about the vaccine and the vaccine is offered to them. Next, the patient is asked if there is any caregiver (for the baby) that will be with them during their labor/postpartum visit that may be interested in the vaccine. IF there is a caregiver interested, the nursing team sends a secure message to the Pharmacy 'Meds to Beds' team to inform them of the interest. After the patient delivers and goes to the postpartum unit, the pharmacy team comes to the unit, consents the interested caregiver for the vaccine, and administers the vaccine to the interested caregiver. When the influenza vaccine is available for the next season, this same protocol will be followed.

University Hospitals Cutler Center for Men provides men with access to men's health experts, programming, services, and other resources that help facilitate a lifetime of good physical, mental and emotional health. As part of their services, the UH Cutler Center for Men offers the support of a responsive team of knowledgeable men's health care guides. UH Cutler Center navigators make the process of managing appointments and other health care-related tasks as easy as possible. UH Cutler Center for Men aims to build personal, tailored, wow moments for their members through technology and a "personal" navigator, Joe. Additionally, the UH Cutler Center for Men has a focus on health equity with an initiative dedicated to Minority Men's Health, which includes tailored community events and community outreach. The UH Cutler Center for Men has partnered with Rainbow Babies and Children, Potash Women & Newborn Center, Ventures, and Pharmacies to implement and test a pilot program at Ahuja Medical

Center to develop and provide education about preventive care, including vaccinations, and connection to support services at UH Cutler Center for Men.

The first three months of the project (as detailed in the NHR protocol, STUDY20240628) will involve engagement with community partners, Centering Pregnancy. In coordination with Dr. Randy Vince, Minority Men's Health at Cutler Center, and the UH Cutler Center for Men Community Outreach Coordinators, we will engage this partner to reach male-identifying individuals as well as the birthing parents to participate in meetings to inform and refine the recruitment procedures and materials, as well as the study tools, including survey items and the interview guide. A goal of this community outreach will be to engage individuals who are from minoritized populations to ensure that materials and procedures reflect the needs of these communities.

3. Inclusion and Exclusion Criteria

All male-identifying individuals visiting the birthing center during the implementation of any of the clusters will be recruited and invited to participate in the research study that includes a survey and an optional interview. While recruitment methods will be refined during the community engagement in the first three months of the project, there will be flyers that include the inclusion criteria and a unique QR code/link so that we can identify the cluster the person was in. The QR code will take the interested individual to the consent form in REDCap.

	Inclusion Criteria
1.	*Male adult 18 years old or older*
2.	Visited the Birthing Center at Ahuja Medical Center
3.	
4.	

	Exclusion Criteria
1.	
2.	
3.	
4.	

4. Study Design

This project uses a Cluster Randomized Trial design. The clusters will be 2-3 week blocks of time (Figure 1). There will be three arms (Figure 2) randomized to each cluster:
1. Control Offer of Bedside Vaccinations only (Ahuja Medical Center QI initiative) - all male visitors in the birthing center at Ahuja Medical Center will be offered a flu and Tdap vaccination at bedside that is part of the Ahuja Medical Center QI initiative
2. Offer of Bedside Vaccines+Information – In addition to the QI initiative of the offer of vaccinations at bedside, all male visitors in the birthing center at Ahuja Medical Center will receive the informational flyer about the importance of preventive healthcare including vaccinations and the UH Cutler Center for Men

3. Offer of Bedside Vaccines+Personal connection - all male visitors in the birthing center at Ahuja Medical Center will be offered bedside vaccinations, receive the informational flyer, as well as have the ability to connect in person with healthcare navigation supports through the Joe Team from the UH Cutler Center for Men.

Each intervention will only be randomly selected to be implemented in a cluster so that each intervention is implemented for a total of 2-3 weeks.

Figure 1: Timeline of the clusters.

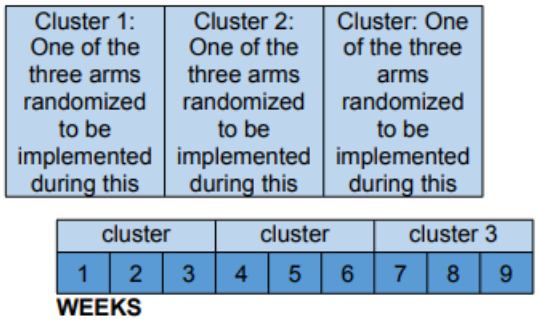
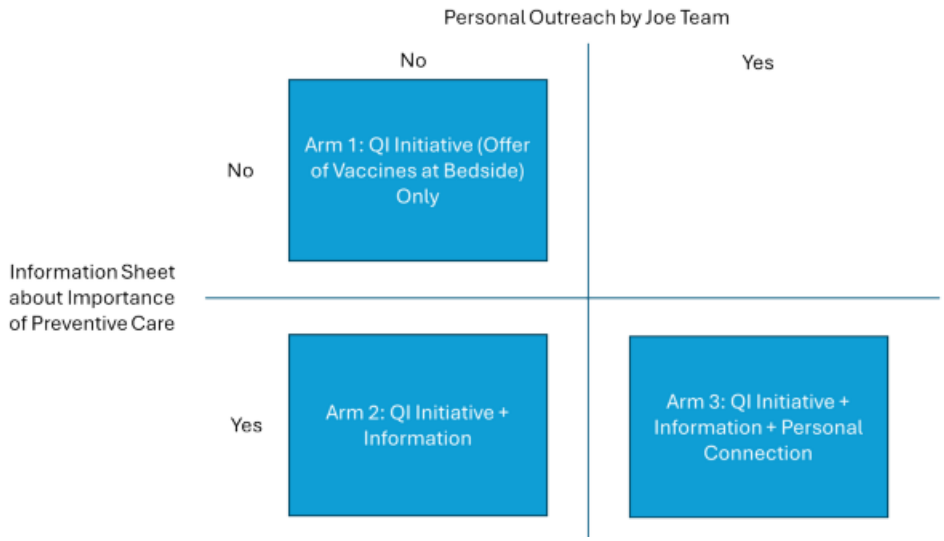


Figure 2: Image of the three arms



Pharmacy department at Ahuja Medical Center will share with the Research Team the total number of vaccinations per week during the research period. The Potash Women and Newborn Birthing Center will share the total number of birthing patients seen at each week of the research period.

The UH Cutler Center for Men will share the total number of enrollees per week during the research period.

All male-identifying individuals visiting the birthing center during the implementation of any of the clusters will be recruited and invited to participate in the survey and an optional interview

to better understand the context of the outcomes, engagement in healthcare in the past and future intentions for engagement in preventive care.

5. Study Procedures

While recruitment methods will be refined during the community engagement in the first three months of the project, there will be flyers that include a unique QR code/link so that we can identify the cluster the person was in. Upon admission to the birthing center, all birthing parents receive an admission folder that they retain as they are moved to the postpartum unit. The admission folder will contain 3 copies of the flyer that will be indicated as for all visitors to the unit. The postpartum unit staff will have extra copies of the flyer on hand in case a birthing parent needs additional copies for additional visitors. These flyers will inform all visitors about the three-arm research that is occurring. The QR code will take the interested individual to the information sheet in REDCap for the survey.

After reading the Information Sheet, potential participants can decide if they want to join the study and follow the link to access and complete the survey. The survey will ask items to assess the participant's demographics, history with vaccinations, including the most recent flu vaccine and Tdap vaccination, current healthcare utilization, and intention to engage in preventive healthcare, including future vaccinations. This survey will include a question to ask if the particpants would be willing to participate in a short 20-minute semi-structured virtual interview. If the survey participant selects yes to this item, they will be asked for the email they would like to be contacted at for invitation to the interview. Using a phenomenological approach, interviews will be completed with 12 survey participants from each cluster to examine factors impacting the uptake of the vaccines and engagement in healthcare. Those who say yes to interest in participating in the interview will be contacted by email to invite them to schedule the consent process and interview over Zoom for a date/time of their preference at least one week after the contact to ensure they have received the consent form prior to the scheduled date/time. The individual will receive the consent form for the interview by email or physical mail depending on the preference of the individual. At the time of the scheduled meeting, the researcher will ask the participant if they had received the consent form in the mail/email. If they haven't, the researcher will reschedule for a later date/time.

If they have received the consent form, the researcher on Zoom with the individual, will verify their identity. The study team member will explain the need to verify identity just as if the interaction was in person. The potential participant will be asked their full name and DOB, and will be asked to display their driver's license or if not available, any state or government-issued picture identification card. If the bandwidth or connection does not permit a virtual visit with audiovisual capabilities, the potential participant can take a picture of their face (also known as a "selfie") and a picture of their photo ID and email, both of these photographs to the study team's University Hospitals e-mail address to verify identify. Once identity verification is completed, the full informed consent process will occur in real-time. The researcher will review the consent form with the individual and answer any questions. If the potential participant decides to enroll, an electronic signature will be obtained during the virtual visit. The study

team member will witness the signature. REDCap will be utilized for this electronic capture. If the potential participant is unable to utilize the electronic format for signature, the prospective participant can sign a paper copy during the virtual visit , take a picture of the signature page, and email that photograph to the study team's University Hospital's email address at the end of the consent process.

Only upon consent will the researcher turn on the recording feature in Zoom to record the interview.

In addition, the project team members involved in the clinical implementation of the intervention will provide contextual information regarding the hours of operation for the vaccination at bedside and for the Joe Team engagement at the birthing center.

6. Study Timeline

	Consent to surveys	Electronic Baseline Survey	Consent for Optional Interview	Optional Interview survey
Estimated time requirement of visit	2 minutes	5 minutes	10 minutes	20 minutes

7. Data to be Collected for your study (AFTER consent and HIPAA Authorization have been obtained)

Pharmacy department at Ahuja Medical Center will share with the Research Team the total number of vaccinations per week during the research period. The Potash Women and Newborn Birthing Center will share the total number of birthing patients seen at each week of the research period.

The UH Cutler Center for Men will share with the Research Team the total number of enrollees in the center per week during the research period.

The following data will be collected from participants in the survey if they choose to provide it for future contact: name and email. The first survey will ask items to assess the participant's demographics, history with vaccinations, including the most recent flu vaccine and Tdap vaccination, current healthcare utilization, and intention for future healthcare engagement including vaccinations.

For individuals participating in the interviews, voice and video will be recorded through UH Zoom cloud feature. Interviews will examine factors impacting the uptake of the vaccines and engagement in healthcare, which may include patient self-report of dates of healthcare utilization and/or vaccines.

8. Data Analysis Plan

The primary outcome that will be assessed is influenza vaccination rate as calculated from the aggregate data. We will compare vaccine uptake between all three arms using generalized estimating equations allowing for correlation within the blocks. Assuming 42.6% of men will be vaccinated for the flu prior to the study, a 52% increase in vaccine uptake between the SOC arm and the bedside vaccination + high-touch connection, and an intercluster coefficient of 0.005, we calculate that we will need 104 people per arm for 80% power for two-sided hypothesis test with an alpha-level of 0.05. With an average of 100 deliveries per month, assuming an average of 1 male caregiver per delivery, we expect the offer of bedside vaccinations will be made to 150 potential trial enrollees per arm which will more than sufficiently power our study.

We will use generalized estimating equations to compare Tdap vaccination rates and enrollment in the UH Cutler Center for Men rates between trial arms. For Flu vaccination, Tdap vaccination, and UH Cutler Center for Men enrollment, we will incorporate other variables such as demographics and medical history into the models as independent variables and as interaction terms with the treatment arm to better understand the impact on healthcare engagement and the impact on the treatment effect.

Audio recordings of the interview data will be transcribed verbatim and de-identified. The deidentified transcripts will be coded using a codebook developed from inductive and deductive methods. A thematic analysis will be conducted to examine themes related to barriers and facilitators to vaccination and preventive healthcare engagement.

9. Risks to Research Participants

Participants in this study may feel uncomfortable answering some of the questions in the survey or interview. They will be free to skip any questions they don't want to answer or stop participation at any time. There is also a risk of breach of confidentiality. We take measures to protect participant information, including storing everything electronically in a secure password protected electronic file.

10. Provisions to Protect the Privacy Interests of Research Participants

Surveys will be completed on REDCap which will only be accessible by the research study team. Participants will complete the survey at a time/location of their preference so that it is a comfortable setting for them.

Interviews will be scheduled for a day and time of the preference of the participant so they are in a comfortable location and place of their choosing. Interviews will be recorded using UH Zoom and stored in REDCap. The de-identified transcript will be stored on the S:Drive.

11. Potential Benefit to Research Participants

Participants will not receive any direct benefits from participating in the surveys or interviews, but their responses will help the understanding of the effectiveness of including tailored and specific information for men about preventive care for increasing healthcare engagement, including vaccination, among male-identifying individuals.

12. Withdrawal of Research Participants

There are no circumstances when a participant would be withdrawn without their consent. If the participant wishes to withdraw from the study, already collected data will be maintained with research records.

13. Alternatives to Participation

The alternative to participation is not participating.

14. Drugs or Devices
N/A

15. Additional Information

The offer of vaccinations at bedside for caregivers is a SOC at the Potash Women and Newborn Center. The development of the informational flyer is an initiative that has been developed from a collaboration between UH Cutler Center for Men, Ahuja Medical Center, Potash Women & Newborn Center, Ventures, and Pharmacies.

16.Community-Based Participatory Research

The first three months of the project will involve engagement with community partners, Centering Pregnancy as described in the NHR protocol STUDY20240628. In coordination with Dr. Randy Vince, Minority Men's Health at Cutler Center, and the UH Cutler Center for Men Community Outreach Coordinators, we will engage this partner to reach male-identifying individuals as well as the birthing parents to participate in meetings to inform the recruitment procedures and materials, as well as the study tools, including survey items and the interview guide. A goal of this community outreach will be to engage individuals who are from minoritized populations to ensure that materials and procedures reflect the needs of these communities. All refined materials, including the recruitment materials, survey instruments, and interview guide, that will be used for this study will be submitted to the IRB after completion of the community engagement component during the first three months of the project.

17. International information
N/A

18. References

1. Applewhite A, Stancampiano FF, Harris DM, et al. A retrospective analysis of gender-based difference in adherence to influenza vaccination during the 2018-2019 season. Journal of Primary Care & Community Health. 2020;11. doi:10.1177/2150132720958532
2. La EM, Trantham L, Kurosky SK, Odom D, Aris E, Hogea C. An analysis of factors associated with influenza, pneumococcal, Tdap, and herpes zoster vaccine uptake in the US adult population and corresponding inter-state variability. Hum Vaccin Immunother. 2018;14:430-441
3. Lu PJ, O'Halloran A, Ding H, Liang JL, Williams WW. National and State-Specific Td and Tdap Vaccination of Adult Populations. Am J Prev Med. 2016 May;50(5):616-626. doi: 10.1016/j.amepre.2015.09.033.
4. Vaidya V, Partha G, Karmakar M. Gender differences in utilization of preventive care services in the United States. J Womens Health (Larchmt). 2012 Feb;21(2):140-5. doi: 10.1089/jwh.2011.2876.
5. Mursa R, Patterson C, Halcomb E. Men's help-seeking and engagement with general practice: An integrative review. J Adv Nurs. 2022;78:1938-1953. doi://10.1111/jan.15240
6. Dylag AM, Shah SI. Administration of tetanus, diphtheria, and acellular pertussis vaccine to parents of high-risk infants in the neonatal intensive care unit. Pediatrics. 2008;122(3):e550-e555. doi:10.1542/peds.2008-0813
7. Rowe SL, Cunningham HM, Franklin LJ, Lester RA. Uptake of a government-funded pertussis-containing booster vaccination program for parents of new babies in Victoria, Australia. 2015;15(8):1791-1796. doi://10.1016/j.vaccine.2015.02.051