Addressing Vaccine Hesitancy in the Prenatal Population

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I have no known conflict of interest to disclose.

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Abstract

False accusations concerning the development of autism and other hazardous side effects have triggered parental vaccine hesitancy, leading to outbreaks of vaccine-preventable diseases. This opposition to vaccination risks the health of both individuals and entire communities. The purpose of this project was to determine the effectiveness of prenatal education on maternal vaccine hesitancy and infant immunization rates. In a pretest posttest design, pregnant mothers greater than or equal to 30 weeks gestation were recruited by The Arizona Partnership for Immunization (TAPI) and virtually educated about infant immunization. A voice-over PowerPoint presentation was delivered to the participants virtually and focused on vaccine knowledge, intention to vaccinate, and vaccine hesitancy. These outcomes were evaluated virtually pre- and post-intervention with the Parent Attitudes about Childhood Vaccines (PACV) survey ($\alpha = 0.84$), and the infants' vaccination records were compared against the recommended immunization schedule at two months of age. Using the Wilcoxon Signed-Ranks test, data analysis revealed vaccine hesitancy was significantly reduced between pre- and post-intervention (Z = 27.70, p = .000), and 100% of the 2-month-old infants were fully immunized with the recommended vaccines. The effect size (d = 12.807) also indicated a strong relationship between pre- and post-intervention vaccine hesitancy. Vaccine hesitancy remains a threat to public health. With prenatal education, pregnant mothers will likely become more knowledgeable of vaccine benefits and better prepared to make informed decisions. Confident vaccination will decrease vaccine hesitancy and improve immunization rates, while promoting individual and societal health.

Keywords: Vaccine hesitancy, pregnant mothers, vaccine education, infant immunization

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Vaccination of children continues to be a widely debated topic in parenting culture. Uncorroborated claims of dangerous side effects and links to autism have led to *vaccine hesitancy*. As vaccine apprehension grows, it threatens children's wellbeing and the societal benefit of *herd immunity*. Although concern of a potential link between autism and vaccines has generated hesitancy, education can expose the falsity of these claims. When educated parents confidently vaccinate their children, both individual and societal health will be achieved.

Background/Significance

With the controversial nature of vaccination in today's parenting culture, a hesitancy to vaccinate children has been observed. Salmon et al. (2015) define *vaccine hesitancy* as the reluctance or refusal to vaccinate based on the understanding of alleged risks versus benefits. Because vaccines have successfully prevented infectious diseases for several decades, young parents are often unfamiliar with once-common childhood illnesses. Vaccine hesitancy not only endangers individual health, but societal health as well by affecting *herd immunity*. Herd immunity refers to a high proportion of vaccinated individuals, enabling protection for both vaccinated and unvaccinated individuals (Logan et al., 2018). Additionally, outbreaks of vaccine-preventable diseases warrant an increased need for healthcare and its subsequent costs. Thus, patients, providers, communities, and entire healthcare systems are negatively impacted.

With vaccination rates decreasing and outbreaks of vaccine-preventable diseases increasing, it is crucial that parental hesitancy be addressed to achieve vaccine benefits. Recent literary sources have demonstrated the relevance of vaccine hesitancy, and the need for vaccine education (Opel et al., 2016). With prenatal education, pregnant mothers become knowledgeable of vaccine benefits and are consequently able to make informed decisions. Confident vaccination will decrease vaccine hesitancy and occurrence of vaccine-preventable diseases, while increasing individual and societal health. This paper will serve to establish significance of vaccine education in the prenatal period, synthesize current evidence, describe theoretical and implementation frameworks, and describe methods and results.

In review of recent literature, parental vaccine hesitancy remains prevalent and problematic for worldwide health. Unfortunately, vaccines have become victims of their own success, as many parents are unfamiliar with vaccine-preventable diseases. As a national health initiative, the Centers for Disease Control and Prevention (CDC) (2019) have declared the fight against vaccine preventable diseases as a *winnable battle*. To increase vaccination coverage, several studies have examined the etiology of vaccine hesitancy and its contributing factors; however, substandard immunization rates and outbreaks of vaccine-preventable diseases persist (Logan et al., 2018; Opel et al., 2016; Salmon et al., 2015).

Education remains a popular and consistent response to vaccine hesitancy. However, recent studies revealed that pregnant women are often seeking vaccine information late in the gestational period and/or 0-2 weeks following the child's birth. This is problematic as the standard of care typically involves childhood immunization education provided by the pediatrician at well-child visits (Corben & Leask, 2018; Danchin et al., 2018; O'Leary et al., 2018). Consequently, recent literature examined the effect of prenatal vaccine education on decreasing vaccine hesitancy and improving infant immunization.

An immunization-focused nonprofit organization in the southwest noticed the local increase in outbreaks of vaccine-preventable diseases correlating with decreasing childhood immunization rates and increasing nonmedical vaccine exemptions. Objective data reveals that 80-84% of North Scottsdale Arizona Kindergarten students are immunized against the measles;

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ninety-five to 100% is the target rate to establish herd immunity. Furthermore, Arizona experienced 7,129 confirmed cases of vaccine-preventable diseases in 2019 (Arizona Department of Health Services, 2020). Nationally, 70.4% of children ages 19-35 months are receiving the seven recommended vaccination series (CDC, 2017).

Concerned for individual and public safety, the organization contemplated an educational intervention that had not yet been attempted. With the belief that pregnant women form their position on infant immunization by late gestation, the organization focused on pregnant women as a target population. A preliminary interest of this topic has led to the clinically relevant PICOT question: In pregnant women (P), how does prenatal vaccine education (I) compared to standard of care (C) influence vaccine hesitancy or predict infant immunization rates (O)?

Evidence Synthesis

To best answer the PICOT question, an exhaustive search and review of current literature was performed. Three literature databases were thoroughly searched—PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL), and Cochrane Library. These three databases were selected for medical credibility, peer review, and quantity and relevance of information available related to pregnant women, vaccine hesitancy, and infant immunization. Additionally, grey literature from the ASU DNP Final Projects Collection was reviewed. Within the digital repository, there are four projects related to vaccination and vaccine hesitancy but none target pregnant women. Consequently, none of these studies were included for evaluation.

Database search keywords included: *pregnant*, *vaccine education*, *vaccine hesitancy*, and *infant immunization*. Inclusion criteria included primary research published in English, peerreviewed articles or systematic reviews, and publication date within the past five years. Additionally, MeSH and Boolean terms were utilized to expand the search results. Exclusion criteria included secondary research and the focus of pregnant women to vaccine themselves, opposed to infant vaccination.

An initial PubMed search yielded 17 results. Thus, MeSH terms were utilized to broaden the search and the following search yielded 11,801 results. Additional terms to specify keywords, such as *infant immunization*, were added to the narrow search. However, utilizing the term *vaccine hesitancy* severely limited results, so *vaccine education* OR *vaccine compliance* were used as alternatives. First or second authors of high-quality articles were also searched for other relevant studies. Studies from various countries were also considered. The final search yielded 142 results. Utilizing rapid critical appraisal (RCA), seven studies were included in the final work.

Similar to the PubMed search, the initial CINAHL search with Boolean phrases included *pregnant women* OR *expectant mothers*, *vaccine education*, and *vaccine hesitancy* within the past five years, which yielded one result. Adding Boolean phrases, such as *infant vaccination* yielded 478 results. Including the term *vaccine education* severely limited search results, so only *education* was searched instead. The final search yielded 13 results, and through RCA, two new studies were included.

The Cochrane Library was the final database searched. First, trials were searched and the initial search included keywords, such as: *pregnant, education, vaccine hesitancy,* and *immunization,* which resulted in 6,340 trials. In this database, utilizing the term *vaccine education* rather than *education* limited the final yield to 18 results. Nine studies were appropriate for inclusion but had been previously discovered through PubMed and CINAHL. The Cochrane systematic reviews (SR) were also searched with the same key terms and yielded one result, which was included. In summary, 10 total studies were included for final review and

evaluation, which included: four RCTs, one SR, two correlational studies, two cross-sectional surveys, and one observational cohort study.

After an exhaustive literature search, 10 studies were selected for rapid critical appraisal. Half of the studies are high-level, including four RCTs and one SR. The remaining five studies consist of nonexperimental cross-sectional surveys or correlational studies. The literature review included international sampling, with only one study conducted in the U.S. All studies are recent (2017-2019), and the majority utilized the Health Belief Model (HBM) as theoretical framework. Eight out of 10 studies disclosed funding sources and limited bias was evident throughout. Significant homogeneity was apparent in demographics, with all participants consisting of pregnant women. The average age amongst studies was approximately 30 years. Only one study also included expectant fathers (Otsuka-Ono et al., 2019). Slightly more than half of the participants were multiparous, and the majority were educated (high school or college graduates). Heterogeneity existed in number of participants amongst studies, ranging from 175 to 6182 (see Appendix A, Table 1).

The majority of experimental studies utilized face-to-face vaccine education (FTFVE) as an intervention with commonalities among variables of interest, including: intention to vaccinate (ITV), infant immunization rates, vaccine knowledge and decision making, and vaccine hesitancy. Heterogeneity existed among study setting, with approximately half of the studies conducted in a hospital setting and half in an obstetrician office clinic, with three studies performed in both settings (see Appendix A, Table 2). Only one study conducted virtual FTFVE (Veerasingam et al., 2017). Significant heterogeneity was also observed among measurement tools, with several studies comparing immunization rates to the national immunization requirements and/or utilizing Likert scales (self-developed by authors; validity and reliability not discussed). This finding suggests a gap in current literature. Measuring parental vaccine hesitancy and efficacy of FTFVE is not yet well-researched or supported, and a valid, reliable tool would greatly benefit current and future practice. Homogeneity was observed among primary outcomes, with the majority of studies focusing on identification of vaccine hesitancy, increased maternal vaccine knowledge, and increased infant immunization rates and intention to vaccinate. Lastly, common themes were also evident among studies, including: prevalence of vaccine hesitancy among pregnant women, FTFVE and decreased vaccine hesitancy, and FTFVE and increased ITV and infant immunization rates. All study results were communicated in confidence intervals, odds ratios, means, standard deviations, and/or level of evidence (see Appendix A, Table 1).

Current literature confirms the significance of vaccine hesitancy in pregnant women and suggests FTFVE delivered in the antenatal period can significantly improve maternal vaccine knowledge, ITV and decision making, and infant immunization rates (see Appendix A, Table 2). Additionally, primiparous mothers are significantly more vaccine hesitant than multiparous mothers. The literature review also demonstrates the indirect relationship between vaccine hesitancy and trust in healthcare providers. Lastly, pregnant mothers willing to receive influenza or pertussis vaccinations during pregnancy for themselves were significantly less vaccine hesitant toward infant immunization. Establishing a trusting provider-patient relationship during pregnancy, especially with first-time mothers, and providing FTFVE during the antenatal period can positively impact infant health and societal wellbeing by supporting herd immunization status can significantly decrease the occurrence of VPD, thus decreasing disease-related treatment costs and positively impacting medical providers and entire healthcare systems.

Theoretical Framework and Implementation Framework

Theory is essential in development of evidence-based practice, as it provides an organized view of complex phenomena. In short, theory helps to explain what is known and inspires what is yet to be learned (Moran et al. 2020). For this project, the Health Belief Model (HBM) was chosen for the theoretical framework due to its prevalence in relevant studies and its ease of application. Originally developed in the 1950s by Dr. Hochman and social scientist colleagues, HBM was utilized to explain health-related behaviors (as cited in Larsen, 2019). HBM was updated in the 1980s and currently consists of four foundational components: 1) perceived benefits versus perceived barriers, 2) perceived threat (based on perceived seriousness and susceptibility), 3) self-efficacy, and 4) cues to action (see Appendix B, Figure 1). These components determine the likelihood of engagement in the health behavior. HBM continues to be utilized today and is particularly helpful in exploration of attitudes and beliefs related to adherence behaviors (Larsen, 2019).

When applied to pregnant mothers and vaccine hesitancy related to infants, HBM suggests that pregnant mothers will not decide to vaccinate unless they believe the infant is at risk and understand how severe that risk may be. Benefits and barriers to infant immunization must also be assessed. Lastly, HBM suggests that pregnant mothers may want to make a change but are unable to follow through. Thus, self-efficacy and cues to action are imperative. Cues to action may include external or internal events that motivate an individual to change. In this particular project, it may include positive infant vaccination marketing (i.e. health fair, billboard, social media) and/or personal or relative experience with vaccine-preventable illnesses. Lastly, empowering pregnant mothers to confidently vaccinate their children will contribute to self-efficacy. This may be most successful when applied to the foundation of a trusting patient-

provider relationship. Improving patients' self-efficacy may include setting attainable goals, reframing perceived obstacles, and visualizing the long-term, "big picture" benefits.

In addition to HBM, Rosswurm and Larabee's (1999) model for evidence-based practice was selected to guide the implementation process. This framework was chosen not only for its applicable stepwise process, but also for the incorporation of planned change during the implementation phase. Utilizing data from a variety of sources is also an advantageous component of this framework. Rosswurm and Larabee's (1999) model includes six necessary steps to generate evidence-based change: 1) assess need for change in practice, 2) link problem intervention and outcomes, 3) synthesize best evidence, 4) design practice change, 5) implement and evaluate change in practice, and 6) integrate and maintain change in practice (see Appendix B, Figure 2). Additionally, utilizing HBM as theoretical underpinning fits well within the Rosswurm and Larabee model.

Specifically, Rosswurm and Larrabee's model is appropriate for use in this project, evident by the feasible completion of the models' initial steps. A need for change was identified with the increasing occurrence of VPDs, decreasing infant/childhood immunization rates, and increasing prevalence of parental vaccine hesitancy. Comparing the internal and external data lead to the identification of a problem. Using standardized classification systems, potential interventions, such as education, and desired outcomes, such as increased infant immunization rates and decreased occurrence of VPDs, were identified. Through RCA, high-quality evidence was synthesized for common themes (i.e. effectiveness of prenatal FTFVE) and assessed for feasibility (see Appendix A, Tables 1 and 2). The next step involves designing a practice change, including the proposed change of educating pregnant women on infant immunization as the standard of care. Necessary resources, such as access to/willingness of pregnant women and agreeable setting accommodations, would be identified. Measurement outcomes would also be defined. The following steps include implementation of the design, evaluation, integration into standard of care, and maintenance with continuous monitoring for process improvement.

Methods

Arizona State University's Institutional Review Board (IRB) approved the study September 22nd, 2020. Participants were recruited by Women, Infant, and Children (WIC) Maricopa Clinics and The Arizona Partnership for Immunization (TAPI). Inclusion criteria included: pregnant women greater than or equal to 30 weeks of gestation, at least 18 years of age, proficient in English, and planning to parent the infant after birth. Due to the pandemic and social distancing recommendations, vaccine education was delivered virtually via PowerPoint presentation. The educational presentation is approximately ten minutes in length with voice recording and was emailed directly to the consenting participants. Ethical considerations were contemplated, participants' confidentiality was maintained throughout, and consent was obtained from all participants.

The project's online educational intervention focused on vaccine knowledge, intention to vaccinate, and vaccine hesitancy. Through prenatal vaccine education, a decrease in vaccine hesitancy and an increase in infant immunization was anticipated. If accomplished, prenatal vaccine education has the potential to create a multi-tier impact: improvement in individual health, fulfillment of herd immunity, and lessened costs and demands on healthcare providers and healthcare organizations. The eligibility survey, which included the consent and inclusion criteria, was distributed to potential participants in November and December 2020. Once participants were identified through the eligibility survey, they were immediately sent the pretest. Once the pretest survey was completed, the voice-over PowerPoint educational tool was

distributed to project participants. When the participants finished viewing the PowerPoint, they were directed to complete the post-intervention survey immediately afterward. The majority of participants completed the viewing of the PowerPoint and post-intervention survey in December 2020, with a few participants completing the education and survey in January 2021. Lastly, the participants completed a final, 2-month post-intervention survey and sent a picture of their infant's immunization record following the 2-month well-child visit. Two-month surveys and infant immunization records were collected in March and April 2021.

To evaluate the outcomes of the vaccine education provided to pregnant mothers, two different measurements were utilized. First, the Parent Attitudes about Childhood Vaccines (PACV) survey was repeated pre-, immediate post-, and 2-months post-intervention to assess changes in vaccine knowledge, intention to vaccinate, and vaccine hesitancy. The PACV's three subsections (safety and efficacy, general attitudes, and behavior) indicate good reliability with Cronbach's α of 0.74, 0.84, and 0.74, respectively (Opel et al., 2011). Lastly, the PACV is an appropriate measurement tool for the project due to its strong alignment with the evaluation questions. Secondly, infant immunization status (including adherence and timeliness) was assessed when the infant reached two months of age. The immunization status of the following vaccines was evaluated: Hib, PCV13, polio, DTaP, rotavirus, and completion of the hepatitis B series. This information was accessed from the infant's mother (project participant), who sent a picture of the infant's state immunization record booklet.

All data was collected and stored within the REDCap application. This application was also utilized for survey creation and distribution. Data analysis included description statistics (mean, standard deviation, percentages) to describe all variables. The Wilcoxon Signed-Ranks test was conducted to compare the difference between pre-and post-intervention surveys. Finally, the effect size was calculated to estimate clinical significance and establish the presence of relationship(s). Lastly, there was no outside funding available for this project, and the only cost was the monetary reward disbursed to participants for completing all required surveys (see Appendix B, Figure 3). This cost was covered by the survey's author.

Results

Results were analyzed using the SPSS statistic software. Demographic results indicated the mean age range of project participants was 25-34 years, the mean gestational age was 38-40 weeks, the majority were multiparous and had completed timely vaccination for their previous children. All participants were Caucasian and married, and the majority had completed a bachelor's degree and were currently employed. The Wilcoxon Signed-Ranks test revealed a mean PACV score of 34.2 (SD = 1.398) for pre-intervention and 6.5 (SD = 1.780) for postintervention and indicated that vaccine hesitancy was significantly reduced between the pre- and post-intervention (Z = 27.70, p = .000). The effect size (d = 12.807) exceeded Cohen's convention for a large effect (d = .80), which indicates a strong relationship between pre- and post-intervention vaccine hesitancy. Lastly, 100 percent of the infants were fully immunized based on the CDC recommended 2-month vaccines.

The results indicate a statistically significant reduction in vaccine hesitancy after the educational intervention and demonstrate a strong relationship between vaccine hesitancy and vaccine education. The impact of this project allows for promotion of individual health through routine vaccination and reduction in outbreaks of VPDs and promotion of community health through herd immunity. Consequently, healthcare providers and systems are positively impacted by reduction in time and costs associated with treatment of vaccine-preventable diseases. Based on the results of this project, policymakers should strongly consider legislation that requires

prenatal vaccine education as standard of care. Lastly, the project has a high likelihood of sustainability due to the ease of application with various healthcare providers and low cost of implementation.

Discussion

Virtual vaccine education was delivered to pregnant women to assess the influence of education on infant immunization rates and maternal vaccine hesitancy. As evidenced by preand post-intervention surveys and assessment of 2-month infant immunization status, prenatal vaccine education significantly reduced maternal vaccine hesitancy and increased infant immunization rates. Thus, prenatal vaccine education has the potential to reduce outbreaks of VPDs and decrease VPD-associated treatment and cost, which will positively impact entire healthcare systems. Due to the pandemic, the project's intervention was conducted virtually and may have been more effective if the education had been delivered in person. The project is limited by its single setting and small sample size (N = 10). Additionally, the maternal self-report of infant immunization status may reveal potential bias. Overall, the project's findings are consistent with the literature supporting FTFVE as an effective way to reduce vaccine hesitancy and increase immunization rates (Hu et al., 2017; Kaufman et al., 2018; Otsuka-Ono et al., 2019; Saitoh et al., 2017). Future recommendations include conduction of a similar project or study with a larger sample size, diverse demographics, and various settings.

References

- American Academy of Pediatrics. (2019). *Immunizations: Vaccine hesitant parents*. <u>https://www.aap.org/en-us/advocacy-and-policy/aap-health-</u> initiatives/immunizations/pages/vaccine-hesitant-parents.aspx
- Arizona Department of Health Services. (2020). Summary of selected reportable diseases Jan-December, 2019. <u>https://azdhs.gov/documents/preparedness/epidemiology-disease-</u> <u>control/disease-data-statistics-reports/data-statistics-archive/2019/2019-ytd-</u> <u>communicable-disease-summary.pdf</u>
- Bechini, A., Moscadelli, A., Pieralli, F., Sartor, G., Seravalli, V., Panatto, D., Amicizia, D.,
 Bonanni, P., & Boccalini, S. (2019). Impact assessment of an education course on
 vaccinations in a population of pregnant women: A pilot study. *Journal of Preventive Medicine and Hygiene*, 60(1), E5–E11. <u>https://doi.org/10.15167/2421-</u>
 4248/jpmh2019.60.1.1093
- Centers for Disease Control and Prevention. (2019). *Winnable battles: Vaccine preventable disease*. <u>https://www.cdc.gov/winnablebattles/vaccination/index.html</u>
- Centers for Disease Control and Prevention. (2017). *National center for health statistics: Immunization*. <u>https://www.cdc.gov/nchs/data/hus/2018/031.pdf</u>
- Corben, P., & Leask, J. (2018). Vaccination hesitancy in the antenatal period: A cross-sectional survey. *BMC Public Health*, *18*(566), 1-13. <u>https://doi.org/10.1186/s12889-018-5389-6</u>
- Cunningham, R. M., Minard, C. G., Guffey, D., Swaim, L. S., Opel, D. J., & Boom, J. A. (2018). Prevalence of vaccine hesitancy among expectant mothers in Houston, Texas. *Academic Pediatrics*, 18(2), 154–160. <u>https://doi.org/10.1016/j.acap.2017.08.003</u>

- Danchin, M., Costa-Pinto, J., Attwell, K., Willaby, H., Wiley, K., Hoq, M., Leask, J., Perrett, K.
 P., O'Keefe, J., Giles, M. L., & Marshall, H. (2018). Vaccine decision-making begins in pregnancy: Correlation between vaccine concerns, intentions and maternal vaccination with subsequent childhood vaccine uptake. *Vaccine*, *36*(44), 6473–6479. https://doi.org/10.1016/j.vaccine.2017.08.003
- Hu, Y., Chen, Y., Wang, Y., Song, Q., & Li, Q. (2017). Prenatal vaccination education intervention improves both the mothers' knowledge and children's vaccination coverage: Evidence from randomized controlled trial from eastern China. *Human Vaccines & Immunotherapeutics*, *13*(6), 1–8. <u>https://doi.org/10.1080/21645515.2017.1285476</u>
- Hu, Y., Li, Q., & Chen, Y. (2018). Evaluation of two health education interventions to improve the varicella vaccination: A randomized controlled trial from a province in the east China. *BMC Public Health*, 18, 1-7. <u>https://doi.org/10.1186/s12889-018-5070-0</u>
- Kaufman, J., Ryan, R., Walsh, L., Horey, D., Leask, J., Robinson, P., & Hill, S. (2018). Face-to-face interventions for informing or educating parents about early childhood vaccination.
 Cochrane Database of Systematic Reviews, 5, 1-105. <u>https://doi-</u>

org.ezproxy1.lib.asu.edu/10.1002/14651858.CD010038.pub3

Larsen, P. (2019). Lubkin's chronic illness: Impact and intervention (10th ed.). Jones & Bartlett.

- Logan, J., Nederhoff, D., Koch, B., Griffith, B., Wolfson, J., Awan, F. A., & Basta, N. E. (2018).
 'What have you HEARD about the HERD?' Does education about local influenza vaccination coverage and herd immunity affect willingness to vaccinate? *Vaccine*, 36(28), 4118-4125. https://doi.org/10.1016/j.vaccine.2018.05.037
- Moran, K., Burson, R., & Conrad, D. (2020). *The doctor of nursing practice project: A framework for success* (3rd ed.). Jones & Bartlett.

- O'Leary, S., Brewer, S., Pyrzanowski, J., Barnard, J., Sevick, C., Furniss, A., & Dempsey, A. (2018). Timing of information-seeking about infant vaccines. *Journal of Pediatrics*, 203, 125–125. <u>https://doi.org/10.1016/j.jpeds.2018.07.046</u>
- Opel, D. J., Kronman, M. P., Diekema, D. S., Marcuse, E. K., Duchin, J. S., & Kodish, E. (2016). Childhood vaccine exemption policy: The case for a less restrictive alternative. *Pediatrics*, 137(4), 1-4. <u>https://doi.org/10.1542/peds.2015-4230</u>
- Otsuka-Ono, H., Hori, N., Ohta, H., Uemura, Y., & Kamibeppu, K. (2019). A childhood immunization education program for parents delivered during late pregnancy and one-month postpartum: A randomized controlled trial. *BMC Health Services Research*, 19(5), 1–10. https://doi.org/10.1186/s12913-019-4622-z

Rosswurm, M. A., & Larrabee, J. H. (1999). A model for change to evidence-based practice. Image--the Journal of Nursing Scholarship, 31(4), 317–322.

https://doi.org/10.1111/j.1547-5069.1999.tb00510.x

- Saitoh, A., Saitoh, A., Sato, I., Shinozaki, T., Kamiya, H., & Nagata, S. (2017). Effect of stepwise perinatal immunization education: A cluster-randomized controlled trial. *Vaccine*, 35(12), 1645–1651. https://doi.org/10.1016/j.vaccine.2017.01.069
- Salmon, Dudley, Glanz, & Omer. (2015). Vaccine hesitancy: Causes, consequences, and a call to action. American Journal of Preventive Medicine, 49(6), S391-S398. https://doi.org/10.1016/j.amepre.2015.06.009
- Stahl, J., Cohen, R., Denis, F., Gaudelus, J., Martinot, A., Lery, T., & Lepetit, H. (2016). The impact of the web and social networks on vaccination. New challenges and opportunities offered to fight against vaccine hesitancy. *Médecine Et Maladies Infectieuses, 46*(3), 117-122. <u>https://doi.org/10.1016/j.medmal.2016.02.002</u>

Veerasingam, P., Grant, C., Chelimo, C., Philipson, K., Gilchrist, C., Berry, S., Atatoa Carr, P., Camargo Jr, C., & Morton, S. (2017). Vaccine education during pregnancy and timeliness of infant immunization. *Pediatrics*, 140(3), 1–10. <u>https://doi.org/10.1542/peds.2016-3727</u>

Appendix A

Evaluation and Synthesis Tables

Table A1

Evaluation Table Quantitative Studies

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Bechini et al., (2019). Impact assessment of an education course on vaccinations in a population of pregnant women: A pilot study. Funding: None explicitly disclosed; no grants received	HBM - inferred	Design: Correlation al pilot study Purpose: Evaluate PG women's VK and attitudes towards vaccination , ITV, and impact of educational interventio	N: 201 Demographics: Gender (%): 100% PG females Race (%): 94% Italian Age (mean): 34 yr Education (%): 45% graduates Setting: OB Department of University of Florence, Italy Inclusion	IV: FTFVE DV1: ITV DV2: VK, ATV Definition: ITV in this study included both intent to vaccine themselves during pregnancy and their infants	3-point Likert scale (self- developed by authors; validity and reliability not discussed)	Stata 12, paired- sample t- Test	DV1 : 42.57 95%CI: 41.31- 43.82 t = 7.36 p < 0.00 DV2 : 22.47 95%CI: 21.63- 23.32 t = 10.61 p < 0.001	LOE: IIIa Strengths: Small attrition, significant results, feasible and cost-efficient intervention Weaknesses: Small N, no funding disclosed, low hierarchy of evidence, Likert scales lacked reliability and validity due to authors' self- development Conclusions: FTFVE significantly increased ITV, VK, and ATV. FTFVE also increased ITV for both mother
listed			criteria: 1) PG women					and infant—imperative to

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Country : Italy		n on vaccination	 2) Referred to OB Department at University of Florence Exclusion criteria: None explicitly listed Attrition: 4% (lost to follow- up/incompletion of post survey) 					 deliver FTFVE in antenatal period. Applicability: Likely applicable, but may not be generalizable—immunization policies and practices differ between countries. Utility to PICO: Applies to PICO—consistent with all elements. Recommended for use in practice due to the effectiveness of interventions.
Corben, & Leask, (2018). Vaccination hesitancy in the antenatal period: A cross-sectional survey Funding : University of Sydney and Mid North	HBM - inferred	Design: Cross- sectional survey Purpose: Assess ITV, DM, social influences, and concerns toward vaccines	N: 221 Demographics: Gender (%): 100% PG female Age (%): 33% 30- 34yr # PG (%): 64.9% multipara Trimester (%): 61% 3 rd trimester Education (highest year of	IV1: PMP women IV2: PG women support for infant vaccination IV3: PG women trust in HCP IV4: PG women vaccinating themselves	42- question survey, based on Decisional Conflict Scale, $(\alpha=0.87)$ and PACV $(\alpha=0.84)$	Fisher's exact test, Chi- squared, Wilcoxo n rank- sum	DV1: IV1: more likely to be VH OR = 3.40 95%CI: 1.34 - 8.60 IV2: less likely to be VH p < 0.005 IV3: Decreased trust = increased VH p < 0.0001	LOE: IIIb Strengths: Significant results r/t vaccine DM, adequate N for survey, measurement tools thoroughly discussed and based on valid/reliable scales Weaknesses: Lower level of evidence, large attrition (r/t lack of consent to access immunization records), possible selection bias (pro- vaccination mothers may have

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Health District Bias: Possible selection bias Country: Australia		immunizati on rates among pregnant mothers	 Setting: Antenatal clinics across six hospitals on the NSW north coast Inclusion criteria: 1) PG 2) At least 18 yr Exclusion criteria: None explicitly listed Attrition: 56% (did not consent to access infant immunization records) 0% for post survey completion 	DV2: Perceived vaccine risks DV3: Decision- making DV4: Infant immunization* *Based on accordance with Australian Immunization Register (AIR) at 8 mo	on to the AIR		IV1: Less sure of balance of vaccine risks OR = 4.84 95%CI: 1.44 - 16.29 DV3 : IV1: less likely to have decided about vaccination by end of 2^{nd} tri p = 0.0015 and higher decisional conflict p = 0.0033 DV4 : IV1: p = 0.242 IV4: OR = 1.78 95%CI: 0.63 - 4.99	 complete survey) Conclusions: PMP women = more VH and undecided about infant immunization. Results indicate a strong justification to screen for hesitancy in the antenatal period and offer assistance in this decision- making. Applicability: FTFVE may benefit mothers in the antenatal period, but mothers' attitudes/beliefs may also differ between countries/cultures. Utility to PICO: Applies to PICO—consistent with all elements. Recommend antenatal screening for vaccine hesitancy—ideal timing in antenatal period remains unknown.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Cunningham et al., (2018). Prevalence of vaccine hesitancy among expectant mothers in Houston, Texas. Funding: None disclosed Bias: None disclosed Country: U.S. (Houston, TX)	HBM - inferred	Design: Cross- sectional survey Purpose: Assess the prevalence of vaccine hesitancy among pregnant mothers in Houston, TX	N: 648 Demographics : Gender (%): 100% PG female # PG (%): 51% FTM Maternal age (%): 66% > 30yr Marital status (%): 89% married Education (%): 43% more than 4- yr college degree Household income (%): 75% >\$50K/yr # of children in household (%): 46% 0 children Race (%): 54% White High-risk PG (%): 78% not high-risk Setting : Baylor College of Medicine	IV1: PG women IV2: PG women receipt of annual influenza vaccine IV3: PG women education level DV: VH	PACV (α=0.84)	Fisher's exact, multivari able logistic regressio n, Bland- Altman plots	DV : IV1: 8.2% VH 95%CI: 6.1- 10.7 IV2: Decreased VH p < 0.001 Maternal decline of annual influenza vaccine = 7.4x more likely VH 95%CI: 3.9- 14.0 IV3: Higher education = decreased VH p = 0.003	LOE: 1116 Strengths: Large N, very small attrition, detailed description of data collection and analysis, valid/reliable measurement Weaknesses: Lower level of evidence, no funding disclosed, single variable measured, single setting, majority participants = Caucasian, high income, higher level education Conclusions: VH is prevalent among PG mothers, especially those with lower education. Screening for VH in PG is feasible and may be beneficial in improving parental vaccine education and infant immunizations. Applicability: Identify VH prior to infant birth. Educating

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Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			OBGYN practice at Texas Children's Pavilion for Women, Houston, TX					PG mothers may positively influence vaccine DM. Utility to PICO: Applies to PICO—consistent with all elements.
			Inclusion criteria: 1) English- speaking 2) At least 18 yr 3) PG, 12-31 wks gestation (fathers could also be included) 4) No prior participation in previous vaccine study at study institution Exclusion criteria: None explicitly listed					

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			Attrition: 1.5% (unable to link father to PG mother)					
Danchin et al., (2018). Vaccine decision- making begins in pregnancy: Correlation between vaccine concerns, intentions and maternal vaccination with subsequent childhood vaccine uptake Funding : Grants from Murdoch Childrens Research Institute and	HBM	Design: Correlation al study Purpose: To determine correlation between 1) intentions and concerns regarding childhood vaccination , 2) concerns about pregnancy vaccination , 3) SES, and 4) update of influenza	N: 975 Demographics: Gender (%): 100% PG female Gest. (mean): 31wk Education (%): 60% University degree Birth country (%): 62% Australia # children (%): 49% 0 (first child) Setting: 4 public hospitals across Australia Inclusion criteria: 1) PG female 2) English proficiency	IV1: PMP mothers DV1: Vaccine DM DV2: VH r/t vaccine safety IV2: PMP + MP PG women DV3: Vaccine information sources DV4: VK provided in PG DV5: Vaccine receipt in PG DV6: HCP recommendatio n for vaccines during PG IV3: VH PG women	Paternal Immunisat ion Needs and Attitudes- Antenatal survey (validity/r eliability not discussed) Maternal self-report ACIR records compared to survey	Chi- square tests, binary regressio n, logistic regressio n	DV1 : More undecided than MP; 15% difference in proportion 95%CI: 10-21% p < 0.001 DV2 : More VH than MP mothers p = 0.002 DV3 : 56% discussed vaccines during PG; Midwives (66%) and GP (58%) = most popular sources DV4 : 66% felt they received adequate VK during PG 95% CI: 60-72;	LOE: IIIb Strengths: Large N, solid theoretical framework, significant results Weaknesses: Very high attrition, lower level of evidence, non-English proficient women were excluded from study, funding by grant from a vaccine organization (possible bias), validity/reliability of measurement scale not discussed Conclusions: Maternal DM r/t infant/childhood immunization begins in prenatal period. PMP are significantly more hesitant than MP. All PG mothers should be provided VK by HCP and advised to receive

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Wesfarmers Centre of Vaccines and Infectious Diseases, Telethon Kids Institute Bias : None disclosed Country : Australia		and pertussis vaccines during pregnancy and routine childhood vaccines	Exclusion criteria: None explicitly listed Attrition: 58% (lost to follow-up survey)	DV7: Timely infant immunization IV4: Perceived vaccine safety DV8: Vaccine uptake			DV5 : 46% received influenza vaccine; 82% received pertussis vaccine DV6 : HCP recommendatio n = more likely to receive Pertussis: OR 3.5 95%CI: 1.9-5.0 p = 0.002 Influenza: OR 3.1 95%CI: 1.9-5.0 p = 0.000 DV7 : VH mothers = less likely to have their infants up- to-date on vaccines 95% CI: 1-41% p = 0.035	 pertussis and influenza vaccines during PG. Applicability: Although Australia's NIP differs from the U.S., the results are likely still applicable. Providing vaccine education in the prenatal period is also feasible. Utility to PICO: Applies to PICO—consistent with all elements, especially that the antenatal period is crucial to address vaccine hesitancy. This article also contained extra information about the correlation between maternal vaccine uptake and its effect on infant immunization.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
		2	N. 1969		2		DV8 : Increased acceptance of vaccine safety = increased vaccine uptake 95% CI: 14-79 p = 0.005	
Hu et al., (2017). Prenatal vaccination education intervention improves both the mothers' knowledge and children's vaccination coverage: Evidence from randomized controlled trial from eastern China Funding : Funded by the general medical	HBM - inferred	Design: RCT Purpose: Examine and verify effectivene ss of PVE, specifically on the improveme nts of mother's vaccine knowledge and improveme nt of completene ss and	N: 1252 n: 626 (IG) n: 626 (CG) Demographics: Gender: 100% PG female Age (range): 20- 30 yr Gest. wk (range): 29-36 wks Educational level (mean): college or above Occupation (mean): farmer, worker, or businessman SES: similarly divided among high, middle, and	IV: FTFVE DV1: VK DV2: Vaccination coverage* DV3: Completeness and timeliness of vaccine doses* Definition: FTFVE included one- on-one 15- minute interactive FTFVE sessions	Pre- and post-test (self- developed by authors; validity and reliability not discussed) Comparis on with China's NIP requireme nts and China's public immunizat	Chi- square analysis, Wilcoxo n rank- sum test, logistic regressio n, MANOV A	DV1 : Knowledge of required vaccines: IG: 16.7% p < 0.001 Knowledge of vaccination policy: IG: 84.2% p < 0.001 OR: 5.2 95%CI: 2.6-8.8 DV2 : IG: 90.0% p < 0.01 OR: 3.4 95%CI: 2.1-4.8 DV3 : IG: 51.9% p < 0.01	LOE: II Strengths: RCT design, large N, significant results, SES diverse participants, homogeneity between IG and CG, no apparent author bias Weaknesses: Large attrition, validity and reliability not measured, no exclusion criteria specifically listed, 3- mo interval between intervention may allow participants to receive vaccine information from other sources (TV, Internet) Conclusions: Prenatal FTFVE can significantly improve VK and timely and complete

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
research program of Zhejiang province Bias : None recognized or reported Country : China		timeliness of infant immunizati on based on the China NIP guidelines	low for both IG and CG. Setting: 6 districts within the Zhejiang province (Yinzhou, Dinghai, Dongyang, Changxing, Liandu, and Kecheng); 4 obstetric hospitals with >500 deliveries annually were chosen from each district = 24 hospitals total. Intervention took place in educational classrooms. Inclusion criteria: Female, PG, residing	*Vaccination coverage and timeliness was based on China's NIP schedule for a child at 12 mo, including: BCG, HBV ₃ , OPV ₃ , DTP ₃ , MR, and JEV. "Fully immunized" indicates 1 dose of BCG, 3 doses of HBV, 3 doses of OPV, 3 doses of DTP, 1 dose of MR, and 1 dose of JEV.	ion records.		OR: 2.3 95%CI: 1.6-3.5	 vaccination. HCPs involved in prenatal care should develop partnership with NIPs. Applicability: China's NIP differs from US immunization requirements. Unsure whether results will be applicable in a country or region with differing immunization requirementsquestionable generalizability. Utility to PICO: Greatly beneficial—consistent with all PICO elements.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			within Zhejiang province Exclusion criteria: None explicitly listed Attrition: 32% (lost to drop out)					
Hu et al., (2018). Evaluation of two health education interventions to improve the varicella vaccination: A randomized controlled trial from a province in the east China. Funding :	ELM	Design: RCT Purpose: Evaluate the effect of two health education interventio ns on VarV coverage and timeliness and	N: 204 n: 68 (IV1) n: 68 (IV1) n: 68 (CG) Demographics: Gender (%): 100% PG female Age (mean): 25.8 Education (%): 59% vocational or college graduated Job status (%): 75.5% employed Immigration status (%): 61.5%	IV1: Video VarV education IV2: Booklet VarV education DV1: VarV coverage* DV2: VarV timeliness* DV3: VarV ITV Definition: Coverage measured at 24 mo of age,	Comparis on to Zhejiang provincial immunizat ion informatio n system 5-point Likert scale (self- developed by	Chi- squared tests, u- tests, STATA	DV1 : IV1: 86.4% <i>RR</i> : 4.8 95%CI: 2.1- 11.3 IV2: 76.1% <i>RR</i> : 2.4 95%CI: 1.2-5.1 DV2 : IV1: 70.1% IV2: 61.2% DV3 : IV1: 93.9% IV2: 82.1% p < 0.05	LOE: II Strengths: High-quality RCT design, small attrition, good theoretical framework Weaknesses: Small N, no blinding, limited to East China province (possibly not generalizable), validity and reliability not measured, control group could have intentionally read/watched VarV educational material Conclusions: Vaccine
General medical		knowledge and attitude	resident	timeliness measured based	authors; validity			education through video or booklet methods may improve

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Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
research program of Zhejiang province Bias : None disclosed Country : China		toward VarV vaccination	 # children (mean): 0 Gest. wk at enrollment (mean): 16.8wk Setting: 4 OB hospitals within the Zhejiang Province Inclusion criteria: 1) PG women 2) At least 12wk gest. 3) Living within Zhejiang Province Exclusion criteria: Not explicitly discussed Attrition: 1.9% (lost to follow-up) 	on Zhejiang recommendatio ns	and reliability not discussed)			infant vaccination. Video education > booklet education. Applicability: Recommended for use in practice due to the significance of the interventions. However, may not be generalizable due to its homogenous population in the study. Utility to PICO: Valuable— only one vaccine examined but consistent with all PICO elements.

Citation Theor Concept Framew	/ Design/ al Method ork	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Kaufman et al., (2018).HBM, TI al., (2018).Face-to-face interventions for informing or educating parents about early childhood vaccinationTTM, an Social Cognitive TheoryFunding: La Trobe University grant, NHMRC, Sydney's Children Hospital NetworkTheoryBias: None reported Country: 10 RCTs conducted in various countries: AuxtraliaHBM, TI all, TPB, IBN Total, and Social Cognitive Theory	A, Design : SR of RCTs and cluster- RCTs Purpose : To assess the effects of face-to- face interventio ns for educating parents about early childhood vaccination on vaccination status and parental knowledge, attitudes, and ITV	N: 10 n: 4527 DS: Cochrane Library, Medline, Embase Ovid, CINAHL, PsycINFO Inclusion criteria: 1) RCT or cluster- RCT 2) FTFVE intervention 3) Intervention targeted toward parents and relevant to childhood immunization Exclusion criteria: 1) Intervention was based on maternal outreach or support	IV: FTFVE DV1: Vaccination status (at final time point) DV2: VK DV3: ATV DV4: ITV DV5: Adverse effects (anxiety r/t intervention) Definition: Final time point varied between studies (3mo- 15mo)	RoR and/or parental survey Pre- and post-tests Likert scale (based on HBM, IBM) and questionn aire based on Beliefs about Flu Vaccinati on Questionn aire $(\alpha=0.82)$ 1-wk post- and 3-mo post surveys	PRISMA , GRADE	DV1: Low QoE Z = 2.53 p = 0.01 RR = 1.2 95%CI: 1.04- 1.37 DV2: Moderate QoE Z = 1.99 p = 0.05 SMD = 0.19 95%CI: 0-0.38 DV3: Low QoE Z = 0.28 p = 0.78 SMD = 0.03 95%CI: -0.2- 0.27 DV4: Low QoE Z = 3.5 p = 0 SMD = 0.55 95%CI: 0.24- 0.85 DV5: Low QoE Z = 0.71 p = 0.48 SMD = -1.93	LOE: I Strengths: High-quality RCTs, use of standardized GRADE tool for evaluation, reputable theoretical frameworks discussed Weaknesses: Small sample size with 10 articles, majority (8/10) of articles > 5 yr old, high levels of statistical heterogeneity leading to downgraded certainty of evidence Conclusions: FTFVE may improve vaccination status, VK, ATV, and slightly increase ITV. Some populations may be more receptive to FTFVE than others—important to address specific barriers. Applicability: Recommended for use in practice, although results are not moderate to

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Canada, China, England, Japan, Nepal, Pakistan			intervention— immunization content not specified 2) FTFVE could not be isolated (i.e. mass media campaign)				95%CI: -7.27- 3.41	 high. Several countries evaluated in the SR—may not be generalizable. Address populations for specific barriers and modify FTFVE appropriately. Utility to PICO: Valuable— consistent with all PICO elements.
Otsuka-Ono et al., (2019). A childhood immunization education program for parents delivered during late pregnancy and one-month postpartum: A randomized controlled trial.	HBM, IBM	Design: RCT Purpose: To assess the effect of individual education sessions including both mother and father in late	N: 175 n: 88 (IG) n: 87 (CG) Demographics: Age, mother (mean): IG: 32.8, CG: 33.0 Age, father (mean): IG: 34.8, CG: 35.1 Race (mother): 100% Japanese (both IG & CG) # of prog (%):	IV: FTFVE DV1: Immunization status* DV2: ITV DV3: Vaccine DM Definition: FTFVE involved mothers and fathers delivered in late PG and early	Parental self- reports 5-point Likert scale (based on HBM, IBM) (α=0.80)	Fisher's exact test, Mann- Whitney U test, Spearma n's rank correlatio n coefficie nt	DV1: HBV: 76% p < 0.001 RV: 84% p = 0.019 Hib: 95% p > 0.999 PCV13: 97% p = 0.491 Number of completed vaccinations (0- 4): 3.5 (0.9%) p < 0.001 Completed all four	LOE: II Strengths: High-quality RCT design, small attrition, homogeneity between IG and CG, detailed discussion of intervention development and contents utilized Weaknesses: Small N, Pfizer funding, intervention setting had previously tried to improve immunization rates, educator and researcher had the same role—possible conflict of interest
Funding : Pfizer Health		pregnancy and PP on	# of preg (%): IG: 53% FTM	PP			vaccinations: 72%	

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Research Foundation Bias : Possible self-reporting bias; no bias disclosed from authors Country : Japan		immunizati on rates, ITV, and vaccine DM	CG: 55% FTM Marital status (%): 99% married (both IG & CG) Education level (%): IG: 40% university CG: 36% university Mothers' job status (%): IG: 44% unemployed CG: 46% unemployed Fathers' job status (%): IG: 97% FT employment CG: 96% FT employment Annual income (thousands of yen): IG: 42% 4000- 5999 CG: 37% 4000- 5999	*Immunization status based on HBV, RV, Hib, and PCV13 vaccines, recommended by Japan's PVL			p < 0.001 DV2 : Intention to receive most vaccines: 77% p = 0.001 DV3 : DM regarding vaccinations: Father and mother: 68%, mother only: 32% p = 0.043	Conclusions: Prenatal and PP FTFVE = significant increase in infant immunization rates and parental ITV. Involving fathers in the FTFVE sessions may have contributed to the findings. Applicability: May be applicable, but cost- effectiveness was not evaluated. May not be generalizable—immunization policies and practices differ between countries. Utility to PICO: Valuable— consistent with all PICO elements.

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Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			Setting: Private Tokyo hospital Inclusion criteria: 1) PG, gestational wk: 29-33 2) At least 18 yr Exclusion criteria: None explicitly listed Attrition: 2% (lost to follow-up)					
Saitoh et al., (2017). Effect of stepwise perinatal immunization education: A cluster- randomized controlled trial.	НВМ	Design: Cluster- RCT Purpose: To evaluate the impact of stepwise FTFVE interventio	N: 188 n: 100 (IG) n: 88 (CG) Demographics: Mean age (IG): 31.9 Mean age (CG): 31.5	IV: FTFVE in three separate occasionsDV1: Completion of recommended vaccines*	Parental self- reports 5-point Likert scale (self- developed by	Fisher's exact test, Mann- Whitney U test	DV1* : All 5 vaccines- 43.0% 95% CI: 0.5-1.6 p = 0.77 Hib- 85.0% 95% CI: 0.7-3.3 p = 0.26 PCV13-	LOE: II Strengths: RCT design, explicit details of stepwise education intervention, small attrition, homogeneity between IG and CG Weaknesses: Small N, lack of confirmation of accuracy on

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Funding: St. Luke's Life Science Institute Bias: None reported Country: Japan		in on mant immunizati on status and maternal knowledge	Junior college # PG (%): FTM (48%, 40%) Job status (%): Unemployed (73%, 60%). Household income (%): 3000-4999 (thousands of yen) (38%, 32%) Setting: Five hospitals and four private OB clinics Inclusion criteria: 1) PG, gestational wk: 24-30 2) At least 18 yr 3) Able to communicate in Japanese Exclusion criteria:	DV2 : vaccine schedule adherence* DV3 : VK Definition : FTFVE provided in prenatal period (34-36 wk), postnatal period (3-6 days post- delivery), and 1-mo PP at well baby check-up *Completion and adherence based on the 5 vaccine doses required at 6mo (Hib, PCV13, DTaP-IPV, HBV, and RV)	validity and reliability not discussed)		83.0% 95% CI: 0.7-3.5 p = 0.19 DTaP-IPV- 85.0% 95% CI: 1.0-4.3 p = 0.04 HBV- 54.0% 95% CI: 0.5-1.8 p = 1.00 RV- 66.0% 95% CI: 0.1-2.3 p = 0.45 DV2: Hib ₃ - Mean+/-SD: 129.3+/-14.8 p = 0.003 PCV13 ₃ - Mean+/-SD: 129.5+/-15.9 p = 0.006 DTaP-IPV ₃ - Mean+/-SD: 160.1+/-14.9 p = 0.03 HBV ₂ -	 parental sen-reporting, Likert scale utilized lacked reliability and validity, potential for exposure to other sources for vaccine information (TV, Internet) Conclusions: FTFVE = improvement in immunization rates and maternal VK. Repeating study in different country and/or with larger N may yield significant results. Overall, may help with development of standardized prenatal FTFVE programs. Applicability: May not be generalizable—immunization policies and practices differ between countries. Applicability is also uncertain—cost-effectiveness was not evaluated.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			None explicitly listed Attrition : 9.6% (lost to follow-up)				Mean+/-SD: 112.2+/-35.2 p = 0.60 RV ₃ - Mean+/-SD: 130.9+/-15.9 p = 0.34 DV3** : Mean+/-SD: 10.7+/-1.6 p = 0.70 *Based on ITT analysis **Knowledge at 6-mo follow- up	Utility to PICO: Consistent with all PICO elements—may be a valuable reference
Veerasingam et al., (2017). Vaccine education during pregnancy and timeliness of infant immunization.	HBM - inferred	Design: Observatio nal cohort study Purpose: Describe the source of encouragin	N: 6182 Demographics: Gender (%): 100% PG female Ethnicity (%): 54% European Age group (%): 52% 30-39yr	IV1: PG women DV1: Characteristics of VK DV2: Sources of VK	Survey (self- developed by authors; validity and reliability not discussed)	Multivari able logistic regressio n	DV1 : IV1: 30%-only encouraging 10%-both encouraging and discouraging 4%-only discouraging	LOE: IIIb Strengths: large N, nationally generalizable, no bias, very low attrition rate Weaknesses: Lower level of evidence, no details on the type of media used for VK, self-developed survey

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Funding: New Zealand Ministries of Social Development, Health, Education, Justice, and Pacific Island Affairs and other various government departments and ministries Bias : None disclosed Country : New Zealand		g and discouragin g immunizati on information received by PG women and its association with timeliness of infant immunizati on	Parity (%): 58% subsequent child Planned PG (%): 60% planned Education (%): 69% tertiary Setting: Computer-assisted face-to-face interview, no additional details provided Inclusion criteria: 1) PG women 2) EDD between 4/25/2009- 3/25/2010 3) Residents of defined region of NZ (chosen for its population diversity) Exclusion criteria: None	IV2: Characteristics of VK DV3: Infant vaccination timeliness Definition: Timeliness based on NZ's NIR and the NZ Immunization Schedule	Comparis on to NIR		56%-no information DV2 : 14%-from family/friends 35%-from HCP 14%-from media DV3 : IV2: Discouraging info only, taking all immunizations: OR = 0.49 95%CI: 0.38- 0.64 Timeliness: OR = 2.61 95%CI: 1.87- 3.59 Both encouraging and discouraging, taking all immunizations: OR: 0.51	Conclusions: PG women who received discouraging VK = increased VH, regardless of receipt of encouraging VK. Large amount of PG women did not receive any VK during PG—it is imperative that HCP discuss vaccines in antenatal period. Applicability: Providing truthful, encouraging VK to PG mothers is recommended in practice due to potential benefits. May not be generalizable due to differing immunization policies and practices between countries. Utility to PICO: Consistent with all PICO elements— valuable to also know the sources of VK

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Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurem ent/ Instrumen tation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			Attrition: 1% (lost to incompletion of interview)				95%CI: 0.42 - 0.63 Timeliness: OR: 2.70 95%CI: 2.08- 3.50 No information, taking all immunizations: OR = 1.00 Timeliness: OR = 1.00	

Table A2

Synthesis Table

Author	Bechini et al.	Corben & Leask	Cunningham et al.	Danchin et al.	Hu et al.	Hu et al.	Kaufman et al.	Otsuka-Ono et al.	Saitoh et al.	Veerasingam et al.
Year	2019	2018	2018	2018	2017	2018	2018	2019	2017	2017
Study Design (LOE)	CRS (IIIa)	CSS (IIIb)	CSS (IIIb)	CRS (IIIb)	RCT (II)	RCT (II)	SR (I)	RCT (II)	RCT (II)	OCS (IIIb)
Theoretical Framework	HBM (inferred)	HBM (inferred)	HBM (inferred)	HBM	HBM (inferred)	ELM	HBM	HBM, IBM	HBM	HBM (inferred)
Demographie	cs									
Age (% or mean)	34yr	33% 30-34yr	66% > 30yr	NR	20-30yr	25.8		32.8yr (M) 34.8yr (F)	31.9yr	52% 30-39yr
%Females	100%	100%	100%	100%	100%	100%	100%	100% (expectant fathers also included)	100%	100%
ED level (% or mean)	45% college graduates	73.1% high school graduates	43% more than 4-yr college degree	60% university degree	College or above	59% vocational or college graduation		40% university graduates	Junior college	69% tertiary
% # PG	NR	64.9% multiparous	46% primiparous	49% primiparous	NR	NR		53% primiparous	48% primiparous	58% multiparous
Setting										
Hospital		Х		X	X	X	X	Х	X	
OB clinic	Х	Х	Х				X		Х	
Virtual										Х

Key: CRS-correlational study; CSS-cross-sectional survey; DM-decision making; ED-education; ELM-Elaboration Likelihood Model; FTFVE-face-to-face vaccine education; HBM-Health Belief Model; IBM-Integrated Behavioral Model; II-infant immunization; LOE-level of evidence; NR-not reported; OB-obstetrician; OCS-observational cohort study; PG-pregnant/pregnancy; SR-systematic review; RCT-randomized control trial; VH-vaccine hesitancy; VK-vaccine knowledge; U.S.-United States; yr-years; # -number of; *-statistically significant with p < 0.05; ~ - low/moderate evidence in SR; + - strong evidence in SR; - increase

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Independent	Variables									
FTFVE	Х				Х		Х	Х	Х	
Video education						X				
Booklet education						Х				
PG women		X	Х	Х						Х
Dependent V	ariables									
VH		Х	Х	Х						
II & Timeliness		Х		Х	Х	Х		Х	Х	Х
ITV	X					Х	Х	Х		
VK/DM	X	X		Х	Х		Х	Х	Х	Х
Themes		·								
FTFVE & ITV or II	↑ *				*		↑ ~	*	*	
FTFVE & VK	*				*		↑ +	*	*	
PG women & VH prevalence		*	*	*						

Key: CRS-correlational study; CSS-cross-sectional survey; DM-decision making; ED-education; ELM-Elaboration Likelihood Model; FTFVE-face-to-face vaccine education; HBM-Health Belief Model; IBM-Integrated Behavioral Model; II-infant immunization; LOE-level of evidence; NR-not reported; OB-obstetrician; OCS-observational cohort study; PG-pregnant/pregnancy; SR-systematic review; RCT-randomized control trial; VH-vaccine hesitancy; VK-vaccine knowledge; U.S.-United States; yr-years; # -number of; *-statistically significant with p < 0.05; ~ - low/moderate evidence in SR; + - strong evidence in SR; - increase

Appendix B

Models and Frameworks

Figure 1

Health Belief Model



as cited in Larsen (2019).

Figure 2



Rosswurm & Larrabee Evidence-Based Practice Model

Rosswurm & Larrabee (1999).

Figure 3

Phase	Activities	Cost	Subtotal	Total					
	Direct	Costs							
Preparation	Design PowerPoint presentation to be used during virtual implementation	\$0							
	Design of pre- and post- survey in virtual format (via REDCap) and emailed to participants	\$0	\$0						
Delivery	Voice-over PowerPoint	\$0	\$0						
Evaluation	Email remainders to complete post-survey and inform of infant's immunization status	\$0	\$0 \$0						
Indirect Costs									
Delivery	Computer and Internet access for virtual delivery	\$0	\$0						
Evaluation	Small monetary participant gift (\$10/participant x 20)	\$200	\$200	\$200					
	Fund	ing	<u> </u>	<u> </u>					
	None			\$0					
	Cost Sa	vings							
Providing vaccine e	ducation to pregnant mothers may	y significantl	y decrease vaccin	e hesitancy and					
increase vaccine kn	owledge and infant immunization	rates. Imple	mentation of vacc	ine education in the					
prenatal period can	provide parents with confidence t	o vaccinate t	heir infants, whicl	h proactively					
improves both the i	nfant's health and societal health	by contributi	ng to <i>herd immun</i>	<i>ity</i> (Logan et al.,					
2018; Salmon et al.	, 2015). Decreased vaccine hesita	ncy and incre	eased infant immu	nization rates will					
also lessen the outb	reaks of vaccine-preventable dise	ases (VPDs).	Although the pro	ject does not					
provide direct rever	nue to TAPI or the WIC clinics, th	e cost saving	s have monument	tal potential. With					
less treatment of VI	PDs, healthcare-related costs (time	e off work for	r patients/family,	hospital stays,					

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medication prescribed, healthcare providers time/pay, etc.) and demands are lessened and entire

healthcare systems are positively impacted (Opel et al., 2016).