

# BMJ Open Motivational Interviewing for Maternal Immunisation (MI4MI) study: a protocol for an implementation study of a clinician vaccine communication intervention for prenatal care settings

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## ABSTRACT

**Introduction** Vaccination against influenza and pertussis in pregnancy offers a ‘two-for-one’ opportunity to protect mother and child. Pregnant patients have increased risk of severe disease from influenza and newborns have increased risk of severe disease from both influenza and pertussis. Obstetricians need communication tools to support their self-efficacy and effectiveness in communicating the importance of immunisation during pregnancy and ultimately improving maternal vaccination rates.

**Methods and analysis** We describe the protocol for a pragmatic study testing the feasibility and potential impact of a clinician communication strategy on maternal vaccination uptake. This study will be conducted in five prenatal care settings in Colorado, USA. The Motivational Interviewing for Maternal Immunisation strategy involves training prenatal care providers to use motivational interviewing in the vaccine conversation with pregnant patients. Our primary outcomes will be the adoption and implementation of the intervention measured using the Enhanced RE-AIM/Practical Robust Implementation and Sustainability Model for dissemination and implementation. Secondary outcomes will include provider time spent, fidelity to Motivational Interviewing and self-efficacy measured through audio recorded visits and provider surveys, patients’ visit experience based on audio recorded visits and follow-up interviews, and maternal vaccine uptake as measured through chart reviews.

**Ethics and dissemination** This study is approved by the following institutional review boards: Colorado Multiple Institutional Review Board. Results will be disseminated through peer-reviewed manuscripts and conference presentations.

**Trial registration number** NCT04302675.

## INTRODUCTION

Vaccination against influenza and pertussis in pregnancy offers a ‘two-for-one’ opportunity to protect mother and child. Pregnant patients have increased risk of severe disease from influenza<sup>1–4</sup> and newborns

## Strengths and limitations of this study

- This study uses a robust dissemination and implementation science framework to assess primary outcomes of the adoption and implementation of a communication strategy for prenatal care providers.
- In measuring vaccination uptake, we will provide preliminary data on the effectiveness of the intervention to improve (1) provider skill and perceived competence and (2) maternal vaccine uptake.
- Qualitative audioelicitation interviews will provide in-depth knowledge about the patient acceptability and necessary adaptations.
- This study will not randomise providers or practices and given the limited sample size cannot provide definitive conclusions regarding effectiveness.

have increased risk of severe disease from both influenza<sup>5–7</sup> and pertussis.<sup>8,9</sup> The Advisory Committee on Immunisation Practices (ACIP) and American College of Obstetricians and Gynecologists (ACOG) recommend women receive influenza and Tdap vaccine during each pregnancy.<sup>10,11</sup> Despite the benefits of these vaccines and evidence of their effectiveness<sup>12–19</sup> and safety<sup>20–26</sup> in pregnancy, uptake of influenza and Tdap vaccination in pregnancy remains low.<sup>27–32</sup> Influenza vaccination coverage among pregnant women was 54% for the 2018–2019 season and Tdap coverage was 55%,<sup>33</sup> well below the Healthy People 2020 goal of 80%.<sup>34</sup>

Several barriers must be addressed to improve maternal immunisation rates, including patient concerns about the need for and safety of vaccination during pregnancy.<sup>35,36</sup> Obstetrics and gynaecology (ob-gyn) providers report patient concerns including desire for a ‘natural pregnancy’ and lack of concern about getting influenza.<sup>37</sup>

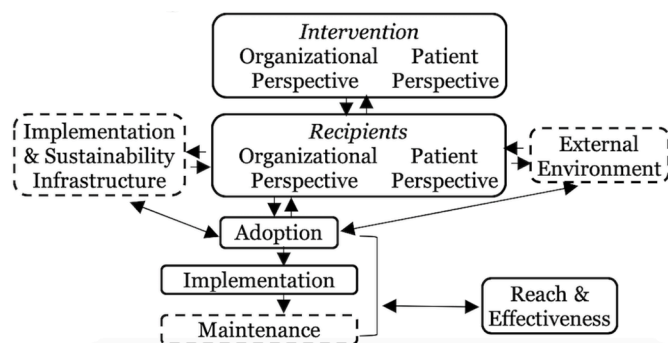
Provider recommendation is associated with receipt of Tdap and influenza vaccines during pregnancy,<sup>38</sup> and lack of a recommendation is a known barrier.<sup>35</sup> During the 2018–2019 influenza season, 73% of pregnant women received a provider recommendation and offer for vaccine<sup>33</sup> of whom 66% received the influenza vaccine, showing that a recommendation and offer for vaccination are insufficient to achieve optimal vaccine uptake.

A key issue that this study addresses is the lack of evidence to guide providers in communicating about vaccination during pregnancy. One study of educational text messages showed no impact on maternal influenza vaccination.<sup>39</sup> Another text messaging study showed a modest impact on influenza vaccine uptake (49% vs 47%).<sup>40</sup> A multi-modal intervention that provided educational materials and evidence-based practice training for clinicians failed to improve maternal immunisation rates.<sup>41</sup> None of these interventions focused on provider communication about maternal immunisations during clinical encounters. A recent qualitative study of ob-gyn providers revealed a need for provider training in communication techniques to enhance uptake of maternal immunisations.<sup>42</sup>

Little is known about how to address vaccine concerns and communicate about vaccinations with pregnant patients. For childhood vaccines, communication techniques impact vaccine acceptance.<sup>43–47</sup> For example, presumptive recommendation such as ‘Your child needs the measles mumps and rubella (MMR) vaccine today’ yields substantially higher acceptance of all vaccines over a participatory recommendation like, ‘What do you think about getting the MMR vaccine today?’<sup>43 45</sup> These studies imply that provider education should address vaccine recommendations and how to communicate these recommendations.

Motivational interviewing (MI) is a communication framework that has been shown effective for communicating with vaccine hesitant parents about childhood vaccines. MI is an established, evidence-based collaborative conversational style for strengthening a person’s own motivation to change an established, evidence-based, patient-centred framework for behavioural change<sup>48–65</sup> that is effective even when delivered in a single session.<sup>51 59</sup> MI’s core elements—having a person-centred conversation and leveraging inherent motivation for behaviours—make it well suited for use with vaccine hesitant parents given their communication preferences regarding vaccines.<sup>66 67</sup> In a large randomised control trial, we found that, paired with a presumptive recommendation,<sup>45</sup> provider use of MI with parents resulted in increased human papillomavirus vaccine acceptance and improved provider self-efficacy for influencing parental vaccine decisions.<sup>68</sup> Contrary to some providers initial concerns, providers found MI to be time-efficient, which is crucial as many ob-gyn providers report lacking adequate time to discuss risks and benefits of vaccines with patients.<sup>69</sup>

This manuscript describes the protocol for a pilot implementation study to evaluate the use of MI communication strategies—the Motivational Interviewing for Maternal Immunisation (MI4MI) intervention—on (1) adoption and implementation including audio recorded



**Figure 1** Enhanced Reach Effectiveness Adoption Implementation Maintenance (RE-AIM)/practical robust implementation and sustainability model (PRISM) for evaluation of the MI4MI intervention. MI4MI, Motivational Interviewing for Maternal Immunisation.

clinical encounters; (2) parent and provider experience including self-efficacy and patient autonomy and (3) maternal vaccination status.

### Conceptual model

The application of MI for vaccination in prenatal care settings is based in self-determination theory.<sup>70–73</sup> This theory holds that motivation to make a positive change (accept a vaccine) is both external and internal, and internal motivation is often related to connecting a decision to one’s identity or core values. MI explores ambivalence to behavioural change; is empathetic, informative, non-judgmental and conversational; and involves restating or clarifying a patient’s own statements. This process promotes autonomy, builds a sense of competence (self-efficacy), and enhances relatedness between the patient and the provider. It is theorised that these affect internal motivation, thus increasing the likelihood of the positive behaviour change.<sup>70 72</sup> We will assess patient perspectives on self-determination theory concepts of autonomy, competence, and relatedness in qualitative interviews with patients.

The Enhanced Reach Effectiveness Adoption Implementation Maintenance (RE-AIM)/Practical Robust Implementation and Sustainability Model (PRISM)<sup>74 75</sup> (see figure 1) of dissemination and implementation (D&I) will guide development, implementation and assessment of the intervention. PRISM identifies key contextual factors related to the widely used RE-AIM implementation outcomes. We will assess organisational perspective in intervention development and implementation strategies (provider focus groups) and include contextual factors and organisational and patient perspectives in assessing implementation of the intervention (provider focus groups, audiorecorded visit observations and surveys, patient interviews). Future studies will build on this intervention pilot study to address the remaining PRISM elements (sustainability infrastructure and maintenance). For RE-AIM outcomes, we will assess adoption with provider surveys and implementation with

**Table 1** MI4MI trial specifications

Data category	Information
Registry and trial no	ClinicalTrials.gov: NCT04302675
Date of registration	10 March to 2020
Secondary identifying numbers	19–1312
Initial IRB approval date	June 6 to 2019
Financial support	National Institutes of Health
Contact for queries	sean.oleary@cuanschutz.edu
Title	Adapting MI4MI
Countries of recruitment	USA
Health condition studied	Maternal vaccination
Intervention(s)	clinician vaccine communication strategy
Key inclusion and exclusion criteria	Inclusion: patient who is receiving care during pregnancy at a participating practice; exclusion: none
Study type	Implementation feasibility evaluation; pre–postpilot evaluation
Date of first enrolment	Providers: 1 May to 2020 Patients: 1 September to 2020
Target sample size	500 patients with 2+ prenatal care visits for chart reviews 40 audiorecorded visits with audioelicitation interviews, 20 follow-up interviews
Trial status	Preintervention
Primary outcomes	Adoption and implementation of the MI4MI intervention implementation
Key secondary outcomes	Provider time spent; use of communication techniques; provider self-efficacy in discussing maternal immunisations with patients; patient experience of vaccine discussions in prenatal care visits; uptake of maternal vaccines during pregnancy.

IRB: Institutional Review Board;  
MI4MI, Motivational Interviewing for Maternal Immunisation.

audiorecordings and provider reports, and effectiveness with patient interviews and measurement of vaccination rates.

### Aim and hypothesis

The main objective of this study is to evaluate adoption and implementation and pilot test the effectiveness of the MI4MI intervention on maternal immunisation status using a predesign and postdesign. We hypothesise that adoption and implementation of the MI4MI intervention among prenatal care providers will be consistent, feasible and acceptable. We will also test the exploratory hypothesis that the intervention will increase autonomy, competence and connectedness among patients and increase uptake of Tdap and influenza vaccine among pregnant patients.

### METHODS

A summary of the trial's specifications is presented in [table 1](#).

#### Study design and registration

We will conduct a pragmatic pilot study implementing the MI4MI intervention in five Colorado prenatal care practices. This study includes implementation of

maternal vaccination communication strategies as well as a preimplementation and postimplementation evaluation of the use of this package of communication strategies. This study is registered with ClinicalTrials.gov ([table 1](#)).

#### Study overview and setting

The MI4MI intervention will be implemented in five Colorado practices purposively selected to reflect a diversity of practice, provider and patient population characteristics. MI4MI intervention implementation and assessment will involve the same practices and providers who participate in intervention development. Pregnant patients will be recruited from participating practices to assess acceptability of MI among patients. We will time the intervention to occur during influenza season to maximise recruitment. Colorado is the ideal setting for our intervention. Parental vaccine hesitancy is highly prevalent, which is reflected in attitudes towards maternal immunisations.<sup>38 42</sup> Colorado consistently ranks in the top quintile of US states for non-medical exemptions for childhood vaccination,<sup>76</sup> and our prior project found that 45% of pregnant patients surveyed worried about the safety of Tdap and influenza vaccines.<sup>38</sup>

### Study population and inclusion/exclusion criteria

All English-speaking and Spanish-speaking patients who receive prenatal care visits at a participating practice during the intervention period of August 2020 to April 2021 will be eligible. All patients included in this study will be pregnant patients. Providers who participate in provider focus groups, surveys and the MI4MI communication training intervention will be men and women. The study settings proposed serve a racially and ethnically diverse population.

Pregnant patients who are less than 18 years of age will be included in the MI4MI intervention because providers may use MI communication techniques in their clinical encounters and no parental permission is required for this portion of the study. Because the interventions include provider communication techniques about recommended vaccinations, the interventions do not fall outside of usual care. Pregnant patients who are less than 18 years of age will also be eligible to participate in audiorecorded encounters and audioelicitation interviews and assent will be obtained. No parental permission is required for this portion of the study.

### Recruitment

#### Practices

Practices will be recruited from among prenatal care providers located in Colorado, including urban, suburban and rural communities. Practices will be invited to participate if they have more than two providers (physicians or nurse midwives), are not affiliated with large corporate health systems and stock both influenza and Tdap vaccine routinely. Attempts will be made to recruit a diverse group of five practices, by practice size, setting (urban, suburban and rural), and type of clinicians (ob-gyn physicians, certified nurse midwives, physician assistants and nurse practitioners). The intervention strategies of the MI4MI project will be implemented in participating practices based on their input. These strategies will be performed as part of quality improvement around immunisation delivery within the study practices and are considered evidence-based and the optimal standard of care by the ACIP and Task Force on Community Preventive Services.

#### Providers

Providers will be recruited from participating practices for focus groups and provider surveys. All practicing providers will be invited to receive MI4MI trainings and associated maintenance of certification (MOC) and/or continuing medical education (CME)/continuing nursing education (CNE) credit for participation.

#### Patients

We will obtain individual informed consent for audiorecording and audioelicitation patient interviews. Eligible patients will be identified through a brief screening survey assessing vaccine hesitancy, adapted from the paediatric setting,<sup>77</sup> administered prior to their prenatal care visit. A subset of enrolled patients at participating clinics will

have their prenatal care visit with a participating clinician audiotaped to assess clinician–patient vaccine communication practices, including adherence to the MI4MI communication strategy among intervention clinicians (ie, intervention fidelity).

### Blinding

Given our intervention and study design, it is not possible to blind practices or investigators. We will minimise selection bias by approaching all patients who are pregnant and receiving prenatal care at participating practices and by including those who receive prenatal care in the analysis.

### Sample size calculations

This study will implement the MI4MI intervention in five prenatal care practices with between 30 and 45 providers to gather diverse input on adoption and implementation in multiple settings. As a preliminary study, the findings will not be wholly generalisable to all prenatal care settings, but will provide important information for a broader trial.

With 500 charts per sample (100 charts x 5 practices) and an assumed baseline 50% vaccination rate, we will have 80% power to detect a 9% increase in vaccination rates.

We will audiorecord a total of 40 prenatal care visits in which we anticipate maternal vaccination will be recommended. Through audioelicitation interviews with the patients of these visits, we anticipate we will reach thematic saturation with this number of visits.

### Intervention

We will use adult learning theory techniques<sup>78</sup> that have been found effective in changing provider behaviour<sup>79 80</sup> to develop a multifaceted MI training programme.<sup>81–83</sup> These approaches include interactive tailored educational outreach,<sup>84</sup> rehearsal and coaching,<sup>85</sup> booster learning sessions<sup>85</sup> and change agents.<sup>86</sup> The MI4MI intervention and implementation strategy will include: (1) a video training module introducing presumptive recommendations and the MI4MI communication strategy including rationale and model vaccine discussions; (2) an in-person training session for providers with a brief didactic session followed by provider role-playing and coaching; (3) one-page reference sheets summarising strategies used in MI4MI and examples of key messages; (4) a refresher training sessions 3 months after initial training including question/answer sessions, role-playing and coaching; (5) a study champion identified at each practice to support intervention implementation and liaise with the study team. These components are described in detail in [table 2](#).

### Outcomes

Our primary outcomes will be adoption and implementation of the MI4MI intervention implementation in prenatal care settings. Secondary outcomes include provider time spent, communication technique and

**Table 2** MI4MI intervention components

Intervention component	Description
Online video module	Introduces the MI4MI communication strategy and its rationale
One 60 min in-person interactive clinician training session	(1) a brief didactic session on vaccine hesitancy, how the MI4MI strategy addresses vaccine hesitancy, and practice data on vaccination coverage and vaccine hesitancy prevalence (2) baseline assessments of clinician skills using the presumptive format and MI (3) modelling the MI4MI intervention followed by clinician rehearsal through role-playing and coaching by the study team
Reference sheets	Provides brief and accessible summaries of the communication behaviours that comprise MI4MI and example scripted language for key steps in the MI4MI strategy
60 min in-person refresher trainings at 3 months after the start of the intervention	Includes a question and answer session regarding barriers to implementing the MI4MI intervention followed by role-playing and coaching. Refresher training will include review of audiotaped encounters to provide feedback for how to improve incorporation of MI4MI into the vaccine discussion.
Practice study champion	Staff liaison who routinely solicits feedback from intervention clinicians regarding the MI4MI intervention and communicates with the study team at regular intervals to coordinate implementation data collection and assist with implementation issues

MI, motivational interviewing ; MI4MI, Motivational Interviewing for Maternal Immunisation.

self-efficacy in discussing maternal immunisations with patients. Exploratory outcomes include the patient experience of vaccine discussions in prenatal care visits and uptake of maternal vaccines.

### Data collection methods

A summary of measures organised by the Enhanced RE-AIM/PRISM dimensions is provided in [table 3](#).

### Adoption and implementation

To assess MI4MI implementation, we will audiorecord clinical encounters between study providers and pregnant patients. Practice personnel (nurses and medical assistants) will help a study research assistant (RA) identify patients attending prenatal visits. Potential participants will be asked to complete a brief screening questionnaire composed of a validated tool to assess vaccine hesitancy, developed by Oladejo *et al.*,<sup>77</sup> with additional items about attitudes toward vaccination during pregnancy and influenza vaccine. Hesitant patients will be invited to participate in a study of provider–patient communication at ob-gyn visits in which their clinic visit will be audiorecorded and they will complete 1–2 interviews after the visit. We will describe the study generally to minimise alterations in patient behaviour to meet observer expectations. The RA will obtain written informed consent for recording of the clinic visit. While similar studies have used videorecording,<sup>43 87</sup> we will use audiorecording without video given the sensitive nature of some elements of the physical exam at prenatal visits. Audiorecorded visits will be analysed for fidelity and adaptation of MI4MI implementation using a structured coding scheme for the key behavioural components of the MI approach in the vaccine discussion. We will recruit throughout the intervention period to assess for waning of intervention implementation over time.

To provide a mixed-methods assessment of adoption and implementation of the MI4MI intervention among providers, we will conduct postintervention focus groups and baseline and postintervention surveys. A postintervention provider focus group with 4–6 providers per practice will be conducted with each practice 9 months after baseline training to assess provider experience using MI, including barriers to applying MI, use of and usefulness of each component of MI4MI training, and how providers adapted the intervention as well as contextual factors. We will conduct postintervention focus groups using the same methods as baseline focus groups.

We will also assess adoption by collecting data on number of providers in each practice, proportion of providers who completed online modules and training session and focus group attendance and reasons for not participating. Surveys will also assess self-reported provider time spent on MI4MI as a preliminary way to investigate intervention cost.

Finally, we will assess organisational contextual factors and practice characteristics using a validated scale for evidence-based vaccination strategies conducted both pre-implementation and at 9 months later with an practice representative.<sup>88</sup>

### Provider surveys

A provider survey will assess provider time and self-efficacy in discussing maternal immunisations with patients. Surveys will be administered by paper or electronically immediately prior to baseline provider training, at 3 months after the initial provider training, and postintervention surveys will be administered at the time of the postintervention provider focus groups approximately 9 months after initial training. Preintervention surveys will collect provider demographic and practice characteristics. The 3-month and 9-month surveys will assess intervention

**Table 3** Outcome measures by RE-AIM/PRISM dimensions

	Definition	Specific measure(S)	Instrument(S)
<b>RE-AIM dimension</b>			
Reach	Proportion of patients with whom trained providers used MI	# of and characteristics of patients with whom provider used MI versus those not used MI % of patient visits in which provider used MI	Survey Brief interviews with providers about patients with whom they did not use MI
Adoption	Proportion and representativeness of providers willing to participate in MI4MI programme	% of and characteristics of providers who completed online modules % and characteristics of providers who completed training session % and characteristics of providers who completed follow-up focus group	Administrative records Brief interview with those who did not participate about reasons
Effectiveness	Average and consistency of improvement in clinical outcomes and any generalisation effects	% of pregnant patients receiving influenza and Tdap vaccines during 2020–2021 influenza season. Change in patient perceived autonomy, competence and relatedness Change in provider autonomy and self-efficacy On all of above, relationship of patient and provider characteristics to these outcomes of	EHR records Audio-elicitation interviews Survey
Implementation	Consistency of delivery of key intervention components; adaptations made to implementation process; and costs of the delivery	Counts of MI4MI behavioural components used in vaccine conversations Reported changes to MI4MI strategy Representativeness of those with high versus low levels of implementation Time spent on MI in visits	Audiorecorded visits Focus groups, individual interviews, and review of audio recorded visits Survey Survey
Maintenance	Provider and setting intention (in this short term study) to continue or adapt the intervention	End of intervention assessment of intentions: Providers End of intervention assessment of intentions: Setting Reasons why or why not	Focus Groups Immunisation Delivery Scale <sup>88</sup> Provider focus groups
<b>Other</b>			
PRISM contextual factors	Setting and institutional factors supporting or hindering RE-AIM dimensions	Perceived barriers, facilitators; procedural incompatibilities, extent to which other evidence-based practices, training and resources are already implemented, practice culture	Immunisation Delivery Scale <sup>88</sup> Focus groups
Patient hesitancy	The extent to which a patient is hesitant to receive maternal vaccines	% of patients screened with high hesitancy	Screening
Pragmatism	The ability of the MI4MI strategy to be scaled to other settings	PRECIS-2 score by study team at three time points	PRECIS-2

EHR, electronic health record; MI, motivational interviewing; PRECIS-2, Pragmatic-Explanatory Continuum Indicator Summary-2; PRISM, practical robust implementation and sustainability model; RE-AIM, Reach, Effectiveness, Adoption, Implementation, Maintenance.

reach by asking providers to estimate the number and proportion of patients with whom they used MI, and reasons for not when they did not. The survey tool will be modified from one used in two prior studies.<sup>68 89</sup> Completion of both preintervention and postintervention surveys will be required for MOC/CME/CNE credit. The survey will also capture key demographics to be used to understand to what extent provider differences may influence their likelihood to adopt and implement the approach.

### Patient interviews

We will audiorecord a sample of provider visits with vaccine-hesitant patients to assess MI4MI implementation (see above). Audioelicitation interviews<sup>90</sup> will be conducted using the recorded visits to assess the patient perspective of intervention acceptability, perceived autonomy, competence and relatedness. These semistructured audioelicitation interviews will be conducted within 30 days of the index encounter. The study team member will play portions of the recording for the participant to guide the interview. A screening questionnaire will be used to identify and recruit vaccine hesitant patients who may refuse vaccination at their visit, even if MI techniques are used. Participants who do not receive all recommended immunisations at the index visit will be invited to participate in a second interview 3 months later. We will recruit up to 20 participants (50%) for follow-up interviews, which will be conducted by phone or in person to assess for change over time in patient perception of maternal immunisations and provider communication.

### Vaccine uptake

To assess preliminary effectiveness of the intervention, we will measure rates of Tdap and influenza vaccination among pregnant patients at study practices using chart review. A study RA will review 100 charts per practice for the preintervention and postintervention influenza seasons (1 October–31 March). Study champions will help the RA identify patients with prenatal visits during the study period and a sample will be selected by a random number generator. Patient demographics, number of clinic visits and Tdap and influenza vaccine eligibility, refusal and receipt will be recorded.<sup>91</sup>

### Pragmatic trial design

Finally, the study team will rate the MI4MI study on its pragmatism for D&I using the Pragmatic-Explanatory Continuum Indicator Summary-2 instrument at three time points during the project: preimplementation, 3 months after the initial training and at the conclusion of the study.<sup>92</sup>

### Participant retention

Patient participants will receive a US\$50 gift card for participating in an audio-elicitation interview about their audiotaped visit and a second US\$50 gift card for completing a follow-up interview.

Retention of participating clinicians will be supported by the opportunity to earn MOC part IV credit from the

American Board of Obstetrics and Gynaecology and CME or CNE credits. Providers will receive a US\$75 gift card for participation in postintervention focus groups. Providers who complete preintervention and postintervention surveys and attend all training sessions will receive MOC/CME/CNE credit.

Retention of practices is supported by the study champion. This staff person receives additional support from the study team and compensation to assist with data collection coordination and liaising with the research team.

### Data security and storage

We will create unique study IDs for each patient participant and de-identified data will be stored on a secure and password-protected server. All linkages between the unique study ID and the individual-level data will be destroyed on completion of the study. We will adhere to all Health Insurance Portability and Accountability Act (HIPAA) requirements as required by the law. Data access is limited to study staff, and data are backed up automatically nightly. We will maintain each dataset separately and index records using unique encrypted identifiers to facilitate linkages between files while maintaining confidentiality of personal health information. Analysis of this audiotaped data will be conducted on password-protected computers with access restricted to research team members.

### Statistical methods

We will use Pearson's  $\chi^2$  tests in unadjusted analyses to compare preintervention and postintervention proportions of providers who (1) spent  $\geq 5$  min discussing vaccines at typical visits and during visits with pregnant patients who had concerns; (2) used MI techniques in vaccine discussions with pregnant patients (always, frequently, sometimes, never) and (3) perceived they were able to influence patients' vaccine decisions.

Audioelicitation interview and provider focus group data will be analysed using a content analysis approach<sup>93 94</sup> using both deductive and inductive approaches. An a priori codebook will be developed based on the constructs of the self-determination theory and the Enhanced RE-AIM/PRISM dimensions. Emergent codes will be developed by team consensus.

We will use Pearson's  $\chi^2$  test in an unadjusted pooled comparison of influenza and Tdap vaccination rates among eligible pregnant patients during preintervention and postintervention periods and logistic regression to adjust for potential covariates, including race, insurance type, number of prenatal care visits and prior vaccination acceptance when available.

### Missing data

We will compare patient and provider characteristics by missing data as well as missing outcome data in all participating practices. We will apply sensitivity analyses techniques to address missing data.

### Patient and public involvement

Patients involved in this study are pregnant patients seeking prenatal care at participating practices and are only involved in this study as research participants. Patients will not be involved in recruitment, data analysis or dissemination. Clinicians will be involved in the refinement of the MI4MI intervention.

### ETHICS AND DISSEMINATION

All study activities described in this protocol have been approved by the Colorado Multiple IRB. Any protocol modifications will be reviewed and approved by the same.

#### Informed consent

Providers who complete the baseline experience survey will be considered to have consented to participation. This survey will contain information about the study and its risks and benefits. For provider focus groups, verbal consent will be performed and a waiver of documentation of consent will be obtained. The only risks to providers are potential loss of confidentiality. Written informed consent will be obtained from patients and clinicians who participate in the audiotaped visits substudy. The study team will record the names of persons participating in the focus group, in order to follow up on themes or issues raised. However, all study results will be published and presented in aggregate form only, with no individual responses identified. The study team will record the names of persons participating in provider surveys in order to track completion for MOC/CME/CNE credit.

Because the entire patient–provider clinical encounter will be audiorecorded, there is potential to capture personal health related information that is unrelated to maternal immunisations and may be considered more private and sensitive in nature. The risks to participants relate to a potential loss of confidentiality. The study team will record the names of persons participating in audiorecording and audioelicitation interviews, in order to facilitate scheduling of interviews after recording.

Individual informed consent will not be required for completion of the chart review portion of the study. This is a retrospective chart review will collect already existing immunisation data recorded as part of routine clinical care.

#### Monitoring

The principal investigator of this study (O’Leary) will be responsible for participant safety monitoring. Oversight of study data safety and monitoring will be conducted by a faculty member at UCD who is not involved in the project. This individual will provide independent observation and verification of protocol compliance, recruitment and study progress, and data completeness. The individual will review draft annual reports. They will also monitor the study for adverse events, and the study team’s response to these events, should any occur. A letter summarising findings will be included in annual project

reports for NIH. Though not anticipated, adverse events will be reported to the IRB promptly, should any occur.

#### Dissemination plans

Study materials will be developed so that they may be easily adapted to other prenatal care settings, with particular focus on having the online video module available for use by others immediately. Should this intervention prove effective, we intend to collaborate with other national sites to test the intervention on a broader scale. Results of the study will be presented at national and international research conferences and through peer-reviewed publications. Likely of greater impact, we will conduct trainings at key national meetings (eg, ACOG Annual Meeting, Annual Conference on the Science of Dissemination and Implementation in Health, Infectious Diseases Society For Obstetrics And Gynecology Annual Meeting), make our protocol and measures publicly available and seek to have our programme listed on credible sources for Evidence-Based Programmes (eg, Research-Tested Intervention Programs (RTIPS), etc)

#### Strengths and limitations

This strength of this study to address the lack of interventions for increasing maternal vaccine uptake include the mixed-methods assessment of adoption and implementation of the MI4MI intervention, a pragmatic model, interventions and measures, the novel implementation of audioelicitation interviews to assess RE-AIM dimensions, and the use of a practice study champion to inform sustainability of implementation in the practice setting.

This study’s limitations include a small number of practices and providers in one region of the USA. Practices and providers are not randomised to intervention or control arms and patients are not randomised to receive the MI4MI communication strategy. As such, our sample may not be representative of all practices and those practices that opt to participate may differ from others in immunisation rate or other factors. Additionally, there are limitations to our observation and measurement methods that should be pointed out. First, if providers are aware of being observed they may behave differently than for their other patient visits (Hawthorne effect), which could lead to overestimating adherence to the MI4MI intervention communication strategy in this case. However, evidence suggests that there is little impact on provider or patient behaviour of recording clinical encounters.<sup>95–97</sup> Second, provider outcomes on survey measures are self-report and at risk for recall and testing biases because they will know the research team is looking for improvement over time and because they will be asked to report on activities over the last 30–60 days without documentation of their activities. Our experience in prior physicians surveys suggests testing bias is minimal. To reduce recall bias, we will also use audiorecorded visits to assess fidelity to the MI4MI communication strategy



and validate reports of time spent on vaccination conversations. Third, because pregnancy is a periodic event, we are unable to conduct a longitudinal assessment of women's vaccination uptake across multiple opportunities for vaccination during pregnancy with and without MI approaches. Fourth, immunisation decisions may differ during influenza season, limiting the generalisability of our findings to this portion of the year. Our prior experience with maternal vaccination suggests this is not the case. However, follow-up evaluation of the maintenance of the MI4MI intervention during the summer months warrants future examination. Finally, the lack of a control group hinders our ability to account for secular trends in vaccination uptake and the impact of other simultaneous efforts to improve vaccination uptake in the practices. Once the MI4MI communication strategy has been adapted to the ob-gyn setting, future studies will be better situated to evaluate the effectiveness of the approach on vaccination uptake. Despite these limitations, this preliminary study will provide important knowledge for scaling an MI intervention for maternal vaccination to other prenatal care settings nationally.

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