Exploration of Measles immunization acceptability in the Emergency Department

PRINCIPAL INVESTIGATOR:

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A. STUDY BACKGROUND AND PURPOSE

Under-immunization rates for childhood immunizations in the United States ranges from 8-20%.[1] Previous studies have demonstrated that pediatric patients are most likely to be under-immunized for seasonal immunizations.[2] The aim of this study is to explore the factors and facilitators contributing to measles immunization hesitancy. Secondly, we aim to explore the impact of hypothetical contexts on measles immunization hesitancy. The results of this study may identify potential disparities in measles immunization coverage and potential solutions for resolving those disparities.

B. STUDY DESIGN

This will be a cross sectional RCT study conducted through web-based surveys to determine factors and facilitators contributing to measles immunization confidence in the ED.

Aim 1: Identify the characteristics of the measles under-immunized population. Parents of patients aged 1 year up to and including 6 years of age who present to the AMC pediatric ED between 6/1/2025 and 6/1/2026 will be screened for the below exclusion criteria:

-The patient is critically ill- Any life-threatening condition that requires pharmacological and/or mechanical support of vital organ functions, i.e. shock, moderate to severe asthma exacerbation, airway obstruction, anaphylaxis, etc.
-The patient presents with major (i.e. leveled) trauma
-The patient presents with concern for physical or sexual assault
-The patient presents with need for child protective service evaluation
-The patient or guardian are not English speaking
-The patient presents in custody of a juvenile detention center or law enforcement
-The patient presents without a consenting parent or legal guardian present at time of evaluation

Parents of children meeting the above inclusion and exclusion criteria will be approached for consent to participate in the study by convenience sampling weekdays 0900-1700. All consenting guardians will complete a brief survey to assess parental demographics and child immunization history. The below questions will be included in the brief survey:

- Age of caregiver
- Age of child
- Race of caregiver
- Ethnicity of caregiver
- Education level of caregiver
  - High school degree
  - College/University/technical school degree
  - Post-graduate college/university degree
- Household income level of caregiver
  - <24,000
  - 24,001-53,000
  - 53,001-89,000
  - 89,001-136,000
  - ≥136,001
  - Unknown
- What source do you find to be the most effective at communicating vaccine information
  - Social media
  - PCP (Primary care physician)

        - Personal communication with friends/families
        - Government agencies (i.e. Center for Disease Control and Prevention)
        - Pharmaceutical companies
    - On average, how many minutes do you (the guardian) spend on social media outlets per day?
        - 0-30 minutes
        - 31-60 minutes
        - 61-120 minutes
        - 121-180 minutes
        - 181-240 minutes
        - ≥241 minutes
    - Is your child up to date with all routine (Not including influenza, COVID-19, RSV) immunizations at this time?
    - Is your child immunized against Influenza for this season?
    - Is your child immunized against COVID-19 for this season?
    - Is your child immunized against RSV for this season?
        - Yes, the mother was immunized for RSV during pregnancy.
        - Yes, the child was immunized for RSV as an infant.
        - No
        - Unsure

All participants who identify that their child is under-immunized for measles (i.e. did not receive 1st MMR immunization at 1 year of age OR 2nd MMR immunization at 4 years of age) will go on to complete a comprehensive survey to assess immunization beliefs, to include:

- Please indicate that you agree or disagree with the below statements when thinking about getting your child up to date with all of their recommended immunizations?
    - Receiving all the recommended vaccines would significantly reduce my child's risk of getting sick (Vaccine Efficacy)
        - Agree or Disagree
    - Receiving all the recommended vaccines would be safe for my child (Vaccine Safety)
        - Agree or Disagree
    - Receiving all the recommended vaccines would be like performing an experiment on them (Vaccine Distrust)
        - Agree or Disagree
    - Receiving all the recommended vaccine will lead to long-term health problems for my child (Vaccine Long-Term Health Problems)
        - Agree or Disagree
    - Receiving all the recommended vaccines would be harmful to my child because of their current medical condition (Child's Medical Condition)

    - Agree or Disagree

- Receiving all the recommended vaccines is unnecessary because there is less risk now that young children will be infected with the virus or bacteria (Low Risk of Infection)
    - Agree or Disagree
- Receiving all the recommended vaccines is unnecessary because America has reached herd immunity for the virus or bacteria (low risk for infection)
    - Agree or Disagree
- The opinion of my child's doctor or healthcare provider will influence my decision about getting my young child vaccinated (Nt recommended by Provider)
    - Agree or Disagree
- Getting children vaccinated against infectious diseases supports the community by stopping the spread of the disease among other children and adults (Stopping Community Spread)
    - Agree or Disagree
- I do not have enough information about all the recommended vaccines to be comfortable giving them to my child (lack of information)
    - Agree or Disagree
- I do not have a health care provider who has offered my child the vaccine (lack of healthcare access)
    - Agree or Disagree
- I cannot miss work (have my child miss school) for a doctor's appointment to receive the vaccine (Social barriers)
    - Agree or Disagree
- I do not have transportation to get my child to the doctor's appointment to receive the vaccine (social barriers)
    - Agree or Disagree

- "Do you plan to get your child fully immunized for measles?"
    - "Definitely not"
    - "Probably not"
    - "Unsure"
    - "Yes"

Aim 2: Explore the impact of favorable immunization messaging on parental confidence in the measles in the under-immunized population.
All guardians who complete the comprehensive survey will be randomized to receive one of four patient-centered immunization messages. The guardian will then be asked again if they plan to immunize their child against RSV this season and if they would accept the immunization if we administer it at the current visit.

- "Would you give your child the measles vaccination at this visit. This vaccine is known to prevent pneumonia that could lead to death and brain swelling that could lead to seizures or deafness?"
    - "Definitely not"
    - "Probably not"
    - "Unsure"
    - "Yes"
- "Would you give your child the measles immunization at this visit. This immunization is known to prevent pneumonia that could lead to death and brain swelling that could lead to seizures or deafness?"
    - "Definitely not"
    - "Probably not"
    - "Unsure"
    - "Yes"
- "Would you give your child the measles shot at this visit. This shot is known to prevent pneumonia that could lead to death and brain swelling that could lead to seizures or deafness?"
    - "Definitely not"
    - "Probably not"
    - "Unsure"
    - "Yes"
- "Would you give your child the measles medicine at this visit. This medicine is known to prevent pneumonia that could lead to death and brain swelling that could lead to seizures or deafness?"
    - "Definitely not"
    - "Probably not"
    - "Unsure"
    - "Yes"

C. SUBJECT POPULATION (WHO, WHAT, WHERE)

Aim 1: Guardians of patients 1 year to 6 years old presenting to the pediatric emergency department 6/1/2025 and 6/1/2026 will be eligible. I expect that we will enroll ~800 parental encounters here at AMC. Parents of children meeting the above inclusion and exclusion criteria will be approached for consent to participate in the study by convenience sampling weekdays 0900-1700. All consenting guardians will complete a brief survey to assess parental demographics and child immunization history. All participants who identify that their child is under-immunized for measles (i.e. did not receive 1st MMR immunization at 1 year of age OR 2nd MMR immunization at 4 years of age) will go on to complete a comprehensive survey to assess immunization beliefs.

Aim 2: In a private location, research assistants (RA) will randomly sample patients between 1 and 6 years of age in the pediatric ED and approach the patient's caregivers for participation in the survey if

eligible. Caregivers will give written consent to participate in the survey. Caregivers will complete this survey in the ED on a private tablet. All guardians who complete the comprehensive survey will be randomized to receive one of four patient-centered immunization messages. The guardian will then be asked again if they plan to immunize their child against RSV this season and if they would accept the immunization if we administer it at the current visit.

Patient Sampling

The RA will screen patients using convenience sampling methodology.

Patient recruitment, enrollment, and progress through the study

Once a patient is screened and determined to be eligible, the RA will review the patient's ED electronic health record (dashboard or face sheet) and record (on a redcap database) the following de-identified information: race/ethnicity, gender, ESI level, insurance status, and chief complaints. [Please see data collection form/survey for further details collected.]

Collecting de-identified data from patient's charts poses no or minimal risk to the patient and it is generally considered acceptable to do this without previously consenting patients. We will keep this information on all patients, even if they refuse to participate in the survey portion, as this information is helpful to understand who are the patients that refused to participate in the study and who are the patients who did participate in the study to comment on the potential sampling bias. These demographic data are (a) de-identified, (b) readily available, (c) can be collected as a chart review without individual patient consent, (d) are not sensitive information, and (e) for patients who do not want to participate in the survey, are not linked in any way with the study questions. The information collected allows the investigators to compare the demographics of participants and non-participants; and therefore, to ensure that the sample is not biased.

If a patient meets the inclusion criteria, a RA will administer the consent for collection of their name, medical record number, and survey responses.

D. DATA ANALYSIS

We will collect the following data: Age, Gender, Race, Ethnicity, State of residence, parental age, parental education level, household income, insurance status, parental report of immunization status and the reason for under-immunization if applicable. The sub-investigators will perform the data analysis at Albany Medical Center (AMC) with an AMC approved password protected PC. Storage of files will be on a password protected departmental drive. Use of a password protected master key document to store identifiers separately from other study variables, which will be collected and stored through REDCAPs.

Our primary outcome is the demographic variables and immunization beliefs that are associated with RSV under-immunization. Survey responses will be used to stratify outcomes according to child's age, Gender, Race, Ethnicity, State of residence, parental age, parental education level, household income, insurance status, and sources of health information. The secondary outcome is the improvement in immunization confidence (defined as converting from "definitely not intent, unsure about intent, or probably not intent" to "intent") stratified by patient-centered immunization messaging.

Sample Size Considerations

We plan to enroll ~800 patients at AMC.

E. RISKS

The primary risk to individuals whose data are being used in this study is the potential breach of confidentiality of research data. We recognize that confidentiality is of foremost importance and we will use a series of standard practices to protect the confidentiality of study participants. We believe that the risk of loss of confidentiality should be a high priority in any project and have effective safeguards in place to assure that confidentiality is not breached in the proposed project.

F. BENEFITS

This research project aims to better understand a patient's potential risk for vaccine preventable infections. All patients stand to benefit from these advances in health care quality, safety, and efficiency. We believe risks to study subjects are minimal. The projected increase in the value of health care is exponentially higher than the investment.
It will enable:
a) Standardized communication of vital history elements,
b) Electronic surveillance,
c) Error-prevention,
d) Reporting of quality metrics, cost and outcomes

G. CONFIDENTIALITY

Only project personnel directly involved in the study will have access to identified patient data and medical charts at their respective site. All project personnel with access to patient data will be trained in the proper handling of such data. Each study subject will be assigned a unique study identification number linked to his or her medical record number. We will use existing procedures to ensure that individual patient identifiers are kept separate from analysis files and are available to project personnel on a need-to-know basis. PHI linked (patient name and MR number) to study number will be kept in a separate password-protected excel file from the remaining data points This file will be on a secure AMC server with user permission access. This 'master key' will be destroyed once data collection is closed and the adjudication process completed for enrolled subjects. Data collection forms not including PHI will be recorded in REDCap on a secure AMC server. This de-identified data set is all that will remain following the completion of subject enrollment and adjudication. The data will be analyzed by Dr. Ashar Ata (AMC biostatistician).

H. OPTIONS

Parents of patients can refuse participation without impact on their care in the ED.

I. REFERENCES

1. Vaccination coverage for selected diseases by age 24 months, by race and Hispanic origin, poverty level, and location of residence: United States, birth years 2010–2016
2. Patel A WM, Woll C. Accuracy of pediatric vaccination status assessment in the emergency department. 2024.