Improving Pediatric Influenza Vaccination Rates
in the Primary Care Setting
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#### Abstract

**Background and Significance**: Caregiver vaccine hesitancy (VH) is a barrier to pediatric health. Current pediatric vaccination rates nationwide fall below the national recommendations. Understanding contributors to individualized hesitancy while employing motivational interviewing (MI) techniques can reduce caregiver hesitancy, improve influenza vaccination rates, decrease pediatric disparities, improve community health, and reduce healthcare costs. **Purpose**: The purpose of this quality improvement (QI) project was to reduce caregiver influenza vaccine hesitancy through provider education and the use of MI techniques with the MOTIVE-Flu (Motivational Interview Tool to Improve Vaccination Adherence) algorithm point of care tool. The intended outcome goal was to increase seasonal influenza vaccination rates by 10% when comparing the participating providers 2020 (without the intervention) to the 2021 (with the intervention) vaccination acceptance rate. **Methods**: A literature review guided the selection of the tools and techniques selected, which substantiated the effectiveness of MI within the pediatric population in the primary care setting. De-identified aggregate data was reviewed and provided by the organizational data manager and the participating Medical Assistant (MA). Statistical analysis was provided via Michigan State University (MSU). To assist with MI techniques and the MOTIVE-Flu tool use education was completed by the participating MA's, provider, and nurse practitioner student. **Implementation**: Implementation occurred from October 2021 to December 2021 within peak influenza vaccine administration season. The intervention occurred during all pediatric primary care visits for children aged six months through seventeen years. The Knowledge into Action Framework guided the development and monitoring process with bi-weekly clinical staff progress, evaluation, and support.

Implications: Practical implications include reducing pediatric influenza morbidity and

mortality, reducing the spread of influenza within the community, and decreasing healthcare costs.

Keywords: Vaccine, Hesitancy, Motivational Interviewing, Pediatric, Primary Care

## Improving Pediatric Influenza Vaccination Rates in the Primary Care Setting

Influenza viruses are orthomyxoviruses that result in acute respiratory illness (World Health Organization [WHO], n.d.). The Centers for Disease Control and Prevention currently identify the best way to prevent an influenza illness is to obtain an annual influenza vaccination (Centers for Disease Control and Prevention [CDC], 2021a). Data reveals that among vaccine-preventable diseases, influenza is responsible for the most hospitalizations (CDC, 2021b). Caregiver vaccine hesitancy is an ongoing barrier to pediatric health as evidenced by the most recent 2019-2020 CDC data identifying only 54.9% of children between the ages of six months and seventeen years were immunized for influenza (CDC, 2020b). Current pediatric influenza vaccine rates fall below the Healthy People 2030 influenza vaccination goal of 80% (Office of Disease Prevention & Health Promotion, n.d.). The World Health Organization defines vaccine hesitancy as "...delay in acceptance or refusal of vaccines despite availability of vaccine services" (WHO, 2016).

#### **Purpose of the Project**

The purpose of this quality improvement project was to reduce caregiver influenza vaccine hesitancy through provider education and implementation of motivational interviewing techniques with the point of care MOTIVE-Flu tool, The outcome intention was a ten percent improvement of seasonal influenza vaccination rates compared to the participating providers previous 2020 rates. The intervention occurred during all pediatric primary care visits for children aged six months through seventeen years. Implementation occurred from October 2021 to December 2021 within the peak influenza vaccine administration season.

#### **Problem Statement & Clinical Question**

Data reveals an increase in pediatric influenza vaccine hesitancy from a macro to micro

level with significant community and individual health consequences. This quality improvement project evaluates if the MOTIVE-Flu algorithm tool could help to reduce caregiver hesitancy and improve pediatric influenza vaccination rates.

## **Background**

There has been a longstanding paradigm between vaccinations and hesitancy (Marshall, 2019). Recent vaccine hesitancy behaviors can be traced to a 1998 article by Wakefield that attempted to link autism to the measles, mumps, and rubella vaccination (Marshall, 2019). The article has been found scientifically invalid and removed from circulation but has contributed to a significant increase in vaccine hesitancy (Marshall, 2019). Additionally, the ease of access to readily available mixed content lacks credibility and contributes to caregivers' fatigue, confusion, and skepticism of vaccinations (Marshall, 2019). To transition caregivers from vaccine hesitant to vaccine compliant, there are evolutionary thought processes and characteristics within human nature that have the potential to evolve and can be applied to aid in this transition (Marshall, 2019). The constructs are rooted in MI techniques and include moving from anecdotal thinking to scientific thinking, from risk versus benefit to analysis and analytical thinking, and from heuristics thought to deductive reasoning (Marshall, 2019). Understanding perceived barriers and grasping the disease burden can assist in reducing caregiver VH and improve vaccination rates resulting in decreased influenza-related morbidity and mortality within the pediatric population (Marshall, 2019).

The pediatric population is especially vulnerable to respiratory conditions and complications because of their decreased adaptability to potential rapid concomitant conditions such as pyrexia, dehydration, croup, and/or epistaxis (Sanderson & Gaylord, 2020). Severe influenza infections can be fatal resulting from atelectasis, myocarditis, pneumonia, and/or sepsis

(Sanderson & Gaylord, 2020; WHO, n.d.). In the United States (U.S.) during the 2017-2018 influenza season 188 children died of influenza, while 199 died of influenza during the 2019-2020 season (CDC, 2021f). Comparing U.S. 2010-2011 seasonal rates to the 2017-2018 seasonal rates, the incidence of symptomatic illness, medical visits required, and deaths doubled, while hospitalizations more than tripled (CDC, 2020a). The State of Michigan and Kalamazoo County mirror this increase in influenza cases (CDC, 2021b; LiveStories, n.d.). In 2018, the influenza and pneumonia mortality rate per 100,000 persons within the U.S. was 15.2 persons, within the State of Michigan 14.5 persons. In Kalamazoo County, the location of the clinical site where this quality improvement project was performed, was above the state and national average at 67 deaths per 100,000 (CDC, 2021d; CDC, 2021c; LiveStories, n.d.). Improving vaccination rates at any age including the pediatric population will decrease community spread resulting in reduced influenza-related mortality and improve community health.

## **Significance**

Many factors contribute to caregivers' hesitancy of the pediatric influenza vaccination. The World Health Organization, Immunization Strategic Advisory Group of Experts, or SAGE outlined a Vaccine Hesitancy Model (WHO, 2016). The Vaccine Hesitancy Model identifies three contributing factors: complacency, confidence, and convenience (WHO, 2016). Hesitancy is multifactorial and varies across geographical locations, populations, cultures, socioeconomic conditions and is rooted in social determinants of health (WHO, 2013). Exploring community driven contextual influences such as poor-quality information provided on social media, political climates, and historical experiences can help to identify the degree of each vaccine hesitancy contributor (WHO, 2013).

The growing trend of pediatric influenza infections, coupled with vaccine hesitancy in the general population, contributes to a substantial healthcare-associated economic burden. A 2018 study found within the U.S. healthcare system the estimated total economic burden of influenza was \$11.2 billion annually (Putri, Muscatello, Stockwell, & Newall, 2018). Annual average influenza-related direct medical costs were estimated to be \$3.2 billion and indirect costs resulted in \$8 billion in expenses (Putri, Muscatello, Stockwell, & Newall, 2018). The CDC reviewed the cost-effectiveness associated with annual vaccination of children with average health risk with an inactivated influenza vaccine (IIV) ranged from \$12,000 per quality-adjusted life year (QALY) savings for children aged six to 23 months, to \$119,000 per QALY saved for children ages 12 through 17 years, further quantifying and substantiating the need for annual pediatric influenza vaccinations (Prosser, Bridges, Uyeki, Hinrichsen, Meltzer, Molinari, .... Lieu, 2006). Understanding individualized hesitancy factors while employing MI can reduce hesitancy and improve influenza vaccination rates resulting in reduced influenza-related pediatric disparities and reduced healthcare costs.

## **Description of the Clinical Organization**

The participating pediatric primary care clinical practice is a part of a larger university's school of medicine, located in Kalamazoo County, Michigan. The university school of medicine has a dual-purpose micro system with a focus on education and providing quality patient care. The overarching school of medicines mission statement is to: "Inspire lifelong learners to be exceptional clinicians, leaders, educators, advocates, and researchers of tomorrow" (Western Michigan University Homer Stryker School of Medicine, 2021). There is not a separate defined mission statement for the pediatric primary care subspecialty. The clinic exemplified their dual purpose through inspiring learners in various stages of training including residents, medical

students, and nurse practitioner students. The organization utilizes a model of care that emphasized care coordination and communication to meet the needs of patients and their families (A. Sheehan, personal communication, June 10, 2021).

The pediatric population served by the clinic site was defined as 'newborn to early adulthood' (WMed Health, 2020). The population served was composed of insured, underinsured, and uninsured patients including self-pay (A. Sheehan, personal communication, June 10, 2021). The clinic does not discriminate against patients based on their ability to pay or vaccination status, race, sex, religion, or gender preferences (A. Sheehan, personal communication, June 10, 2021; WMed Health, 2020;).

The participating pediatric primary care microsystem team was composed of two certified Medical Assistants, a doctorly prepared Pediatric Nurse Practitioner and a senior Family Nurse Practitioner student in training. The macrosystem support team consisted of a data manager, clinic support staff, and two senior Family Nurse Practitioner students completing a doctoral project who helped facilitate the project. The participating staff were eager to learn the new technique via the MOTIV-Flu tool and provide support to the project.

The clinic provided core processes include a wide variety of acute, chronic, and well-child medical services. Services were available in person and through telemedicine visits when appropriate. Acute services included any non-emergent pediatric care needs with follow-up. Well-child services included an overview of health and safety with immunization status review and administration. The primary care office also partnered with the local health department to participate in a low-cost or free Vaccines for Children program (VFC) (A. Sheehan, personal communication, June 10, 2021).

Before this quality improvement project, the immunization status review, education and administration process was driven by the MAs. It included generating the patient's individualized Michigan Care Improvement Registry (MCIR) report for review, assessing vaccine acceptance with the caregivers, followed by provider education reinforcement if needed and MA vaccine administration (A. Sheehan, personal communication, June 10, 2021). A clinic wide data review identified a steady decline in pediatric influenza vaccinations since 2018, as evidenced by 46.8 % acceptance in 2018, compared to the 2019 acceptance rate of 32.9% (A. Sheehan, personal communication, June 10, 2021).

## Strengths, Weaknesses, Opportunities, & Threats

Prior to project implementation, a strength, weaknesses, opportunities, and threats (SWOT) analysis was performed with key stakeholders of the pediatric primary care clinic to better understand how to best implement the intervention. The purpose of performing a SWOT analysis is to show positive and negative factors that could affect project outcomes (Harris, 2020). Appendix A provides a comprehensive SWOT analysis based on factors specific to the participating primary care clinic setting.

Strengths related to the primary care clinic included a well-documented electronic health record (EHR) that provided detailed accounts of when vaccines were provided and what vaccinations were outstanding. Vaccine status was further substantiated by a clinic report from the state of Michigan database MCIR that indicated the up-to-date status of the patient's immunizations on record regardless of the location it was administered. An additional strength for implementation included no conflicting QI projects within the location setting within the same time frame. Weaknesses identified included a narrow window for vaccine administration, potential staff turnover, and no motivational interviewing technique training for support staff

outside of the clinical setting. An additional weakness revealed there was no previous required vaccination training for the MA or provider (A. Sheehan, personal communication, June 10, 2021). The evaluation of opportunities revealed that the primary care setting was an ideal place to implement the use of motivational interviewing. When considering the World Health Organization Vaccine Hesitancy Model's three contributing factors; complacency, confidence and convenience, the primary care setting allowed for status review, education, and immediate vaccine administration, reducing all three contributing barriers at once (WHO, 2016).

Additionally, an opportunity existed related to the partnership with the local health department for free vaccines for at-risk or underprivileged children reducing potential financial barriers for caregivers. Threats related to the success of the project included potential missed opportunities for vaccination education related to telemedicine visits and a loss to follow up for patients who were inconsistent with care. Potential threats considered included staff fatigue and turnover of unrelated nature.

#### Fishbone Diagram

A fishbone analysis is a diagram data tool that provides significant value by revealing cause and effect relationships (Riley & Harris, 2020). Appendix D provides a visual representation and understanding of the reciprocal relationships within the practice to assist in identifying vulnerabilities during the improvement process.

## **Synthesis of the Evidence**

#### **Search Strategy**

A systematic research review was conducted to explore established literature and data available regarding vaccine hesitancy and motivational interviewing. The search was completed on June 25, 2021, via the Cumulative Index to Nursing and Allied Health Literature (CINAHL),

PubMed of the U.S. National Library of Medicine National Institutes of Health, and Cochrane Review database (Appendix B). Motivational interviewing is defined by employing and activating each patient's individual motivation for change (Rollnick, Miller, & Buttler, 2008). The CINAHL and PubMed reviews were guided by limitations including: the English language and articles published within the last five years. The Cochrane review limitation included: within the last 5 years. Truncation and Boolean key phrases for all three searches included: Vaccin\*, "Motivational Interviewing" OR "Motivational Interview". CINAHL search query yielded 37 results, PubMed yielded 52, and Cochrane yielded 27 query matches. After eliminating duplicates, a title and abstract review was completed resulting in further elimination of 97 articles. Full article review was completed on 19 articles with final appropriateness selection based on level of evidence, and outcomes analysis with MI, resulting in nine articles for the literature review (Appendix C).

### **Selection Criteria**

All studies were reviewed based on the reciprocal relationship of vaccine hesitancy and motivational interviewing. Upon conclusion of each database review, all articles underwent a title and abstract review. Inclusion required to vaccine hesitant caregivers, the outpatient setting, and educational components of MI. Studies were excluded based on their geographical location. Those not conducted or published within the United States were eliminated. Additional exclusion criteria were based on population discrepancies such as postpartum mothers, men who have sex with men, studies related to the novel Corona 19 virus, and studies not completed within the last five years. Final selection of applicable studies yielded nine relevant articles (Appendix C). These nine articles highlighted common themes and gaps within the literature. A common theme identified included the appropriateness of the primary care setting for employing

motivational interviewing to overcome vaccine hesitancy. Gaps within the literature identified: a lack of influenza specific content related VH, discrepancies among confounding variables contributing to VH, and a variety of educational techniques employed for MI.

## **Literature Synthesis Review**

#### **Settings Related to Motivational Interviewing**

The literature review revealed a consistent theme confirming that reducing vaccine hesitancy is ideal for the primary care setting and can be facilitated by MI techniques. Two studies identified in the literature review substantiated that the primary care setting serves as an ideal opportunity to implement MI and foster trust with caregivers (Mical, Martin-Velez, Blackstone, & Derouin, 2021; Wermers, Ostroski, & Hagler, 2021). A benefit to the primary care setting is that it allows providers to build rapport with patients which reduces VH in caregivers (Bernstein, Bocchini, & Committee on Infectious Diseases, 2017). Dempsey et al. (2018), note that there was an increased opportunity for employing MI with adolescents if vaccination status was addressed during all visits, as opposed to only well-child visits. The primary care setting can facilitate provider/caregiver autonomy when establishing a vaccine schedule when used in conjunction with MI. This allows for a cost effective and convenient way to address concerns related to vaccine safety (Gagneur et al., 2019). According to Tokish and Solanto (2020), 80% of caregivers stated that their decision to vaccinate their children was influenced by a positive trusting provider relationship within the primary care setting. This further indicates that the primary care setting is beneficial for reducing vaccine hesitancy.

## **Gap Analysis**

The literature review highlighted the lack of available content regarding overcoming vaccine hesitancy in relation to seasonal influenza vaccinations. Of the nine articles reviewed,

three specifically reviewed improving Human Papillomavirus (HVP) (Dempsey & O'Leary, 2017; Reno, O'Leary, Garrett, Pyrazanowski, Lockhart, Campagna, Barnard, J., & Dempsey, 2018; Dempsey et. al., 2018) and five reviewed improving all acceptance of vaccinations (Bernstein, Bocchini, & Committee on Infectious Diseases, 2017; Cole, Berman, Gardner, McGuire & Chen, 2020); Gagneur et al., 2019; Mical, Martin-Velez, Blackstone, & Derouin, 2021; Tokish & Solanto, 2020). The final article reviewed vaccine outcome improvement data for influenza, Human Papillomavirus (HPV), and meningitis B (MenB) rates within a university health care setting (Wermers, Ostroski, & Hagler, 2021). In the primary care setting, fostering positive influenza vaccination interventions through patient/provider conversations creates a unique opportunity to provide education and support vaccine positivity on an annual consistent basis. Tokish & Solanto, (2020) reveal that approaching the influenza vaccination with MI techniques facilitates communication that is built on trust and empathy. Employing this technique annually with the seasonal influenza vaccine could foster consistency and reduce overall hesitancy.

## **Vaccine Hesitancy**

Each article reviewed vaccine hesitancy and echoed the World Health Organization definition of Vaccine Hesitancy as a "...delay in acceptance or refusal of vaccines despite availability of vaccine services" (WHO, 2016). Individualized variables reiterate specific factors that contribute to the complex problem of vaccine hesitancy. In accordance with the Vaccine Hesitancy Model provided by the World Health Organization, the variables reviewed consistently align with the three significant contributors: complacency, confidence, and convenience (WHO, 2016). Tokish and Solanto (2020) reviewed concerns regarding complacency, they identified that many caregivers consider the perceived disease risk as

minimal. Caregivers also inaccurately believed that becoming naturally infected with a disease will increase immunity contributing to complacency (Tokish & Solanto, 2020). Cole et al. (2020) reviewed VH related to confidence, citing the 2011 National Immunization Survey, indicating that health beliefs such as vaccine safety influenced caregivers to refuse or delay immunizations. Bernstein, Bocchini, & Committee on Infectious Diseases (2017) reviewed convenience concerns based on pediatric healthcare utilization trends which decreased as the pediatric population grew older. Ensuring that consistent and convenient care is established and continued with one provider allowed providers to foster a congruent reciprocal relationship (Bernstein & Bocchini, 2017). Allowing provider/caregiver autonomy with implementation schedules can create convenience and improved acceptance rates (Bernstein & Bocchini, 2017).

## **Motivational Interviewing**

The use of motivational interviewing is consistently noted in the literature review to improve vaccination rates. Wermers, Ostroski, and Hagler (2021) found that when MI was applied continuously over time by primary care providers in a university clinic, it led to higher rates of influenza vaccination. Bernstein, Bocchini, and Committee on Infectious Diseases (2017) and Bernstein, Bocchini, & Committee on Infectious Diseases, (2017) identify that when MI was employed with proper technique it encouraged caregivers to reflect on why their adolescent child needed to be protected against vaccine preventable diseases. Mical, Martin-Velez, Blackstone, and Derouin (2021) noted that for MI to be effective, certain attributes like compassion and understanding must be engaged to overcome VH. Additionally, Tokish and Solanto (2020), noted that MI is a powerful technique to overcoming VH, as it emphasizes a dialogue with the patient's caregiver based on their individual values and specific concerns. Establishing, promoting, and maintaining trust with consistent communication was vital with

vaccine hesitant caregivers, and cited to be the most important factor as caregivers made decisions related to vaccinations (Tokish & Solanto, 2020). Dempsey and O'Leary (2017), noted that when providers were trained and utilized motivational interviewing, the vaccination rates improved and became significantly higher, demonstrating that MI is an impactful resource available to providers. Cole et al. (2020) noted the lack of clinical tools available to assist health care professionals with caregiver motivational interviewing conversations. MOTIVE-Flu (Motivational Interview Tool to Improve Vaccination Adherence) created by Cole, Berman, Gardner, McGuire, and Chen in 2020, established a point of care algorithm specifically for influenza vaccine conversations (Appendix I). The tool guides clinicians through difficult vaccine hesitant conversations with the use of open-ended questions, affirming the patient's ability to change and summarizing the caregivers' thoughts and goals while moving toward vaccination compliance (Cole et. al., 2020).

## **Quality Improvement Framework**

The pediatric influenza vaccination quality improvement project was based on the Knowledge into Action Framework developed by Graham, Logan, Harrison, Straus, Tetroe, Caswell, and Robinson (2006). The framework was created to improve understanding and implementation of the "concepts of knowledge translation, knowledge transfer, knowledge exchange, research utilization, implementation, diffusion, and dissemination" (Graham et al., p. 13., 2006). The framework has two distinct components; first a funnel of Knowledge Creation which is dynamic and influential to the second component, the Action Cycle (Graham et al, 2006). The Knowledge Inquiry component of the Knowledge into Action Framework identified data indicating a decreased acceptance rate of seasonal influenza vaccine administration within the pediatric population from a micro to macro level, from the clinic wide, to Kalamazoo

County, the State of Michigan and on a national level (A. Sheehan, personal communication, June 10, 2021; CDC, 2021d; CDC, 2021e; LiveStories, n.d.). The Knowledge Inquiry set the stage for the intention of the selected intervention to reduce vaccine hesitancy. This was facilitated by improved provider knowledge and employing the MOTIVE-Flu tool to foster motivational interviewing techniques in the pediatric primary care setting. The intervention selection was evidenced by and supported through the literature review. Following the Knowledge Inquiry portion of the framework was step two the Action Cycle. This process served as a guide for data collection, analysis, sustainability, further development, and continued research.

#### Goals, Objectives, & Expected Outcomes

Success of the quality improvement project was evaluated by a ten percent increase in the participating providers' influenza vaccination acceptance compared to the previous year. The objective was to provide MA and provider education and the MOTIVE-Flu point of care tool when working with identified vaccine hesitant caregivers. The expected outcome is an increase in influenza vaccination acceptance with the use of the MOTIVE-Flu tool. Practical implications for the project outcome included improving morbidity and mortality related to the influenza within the pediatric population, reducing the spread of influenza within the community, and decreasing healthcare costs related to influenza.

The timeline for the project was based on the release of the 2021-2022 seasonal influenza vaccine during the months of October through December (Appendix E). Following the intervention, implementation data was collected and reviewed. During the implementation process data was collected via the Clinical Data Collection Chart (Appendix G), where it was reviewed bi-weekly by the project facilitators, then verbally reviewed with stakeholders for

ongoing feedback and process improvement. Following the implementation process data was collected via the organization's data manager via the EPIC Slicer Dicer to compare 2020 to 2021 acceptance rate of the participating provider. Within the spring of 2022, the project facilitators synthesized the data to better understand the results compared to the expected outcomes, to determine if the expected outcome was achieved.

#### Methods

#### **Ethical Considerations**

Prior to project implementation or data collection, the project was submitted for review and approved by the Michigan State University's Institutional Review Board (Appendix P). The review board's approval satisfied the ethical requirements for the clinical site standards. The project was determined to be quality improvement without human subjects. The intervention reinforced the use of MI with the provider and MA through a structured learning opportunity and the using the MOTIVE-Flu tool was intended to decrease vaccine hesitancy in caregivers, resulting in improved influenza vaccination rates at a pediatric primary care clinic. Motivational interviewing is standard practice within many clinics, the use of the MOTIVE-Flu tool was facilitated as intended and approved by the creators (Appendix J). The project focused on improving the current procedure to reflect the healthcare industry norms. All data provided to the project facilitators was aggregated and de-identified.

## **Setting Facilitators**

The pediatric primary care setting was structured as part of a larger university medical institution, located in Kalamazoo County, Michigan. This specific primary care site was a standalone clinic with a mix of providers that were both faculty and non-faculty of the university. They included five physicians and one pediatric nurse practitioner. Additional support staff at

the clinic included social work, MAs, a Family Nurse Practitioner senior student, office assistants and administrative staff (A. Sheehan, personal communication, June 10, 2021). Services offered included acute and non-acute pediatric care, well child visits, immunization, and care coordination (WMed Health, 2020). Interactions with site staff personnel were facilitated through in person coordination that was pre-approved and structured to the project. The project did not require patient interaction by the project facilitators. The project was supported by the facility and administration within the site organization as evidenced by the Letter of Support (Appendix F). Careful considerations were reviewed within the SWOT Analysis (Appendix A) including the resources, constraints, facilitators, and barriers that influenced the implementation of the project.

#### **Barriers**

Barriers to implementation of the project included: resource limitations of competing universities, the Covid-19 global pandemic, and provider scheduling limitations (A. Sheehan, personal communication, June 10, 2021). The project facilitators and the clinical site were represented by two competing universities with limited resources resulting in logistical challenges. An additional non-modifiable barrier included the political and social climate related to the Covid 19 pandemic and vaccination status. Consideration was given to the time constraints of the staff as well as the participating provider who facilitated the intervention. This provider was limited to patient interaction two days per week, which created an accessibility barrier and limited sample size (A. Sheehan, personal communication, June 10, 2021).

#### **Intervention & Data Collection Procedure**

Provider education was the foundation of the intervention for the project. Education and employing the MOTIVE-Flu tool with MI techniques was used to reduce caregiver vaccine

hesitancy, resulting in the expected outcome of a ten percent increased acceptance of the seasonal influenza vaccination compared to the previous year. The tool and technique were selected based on the literature review substantiating effectiveness of MI within the pediatric population in the primary care setting. The MOTIVE-Flu tool was created by Cole, Berman, Gardner, McGuire, and Chen with the support of Cedarville University in 2020 (Cole et.al., 2020). The use of this tool was approved by the creators (Appendix J) and agreed upon by the participating provider and the project facilitators (Appendix K), approval included agency stakeholders such as the organizations Pediatric and Adolescent Medicine Department Chair, and the participating provider and the Medical Assistants. The MOTIVE-Flu is specifically designed as a guide for provider use during difficult vaccine hesitant caregiver conversations, focusing on caregiver engagement (Cole et.al., 2020).

The MOTIVE-Flu tool education presentation was facilitated by a four-part module. This education presentation was completed by the provider, the FNP student and MA's. The educational presentation was developed by the MOTIVE-Flu creators Cole, Berman, Gardner, McGuire, and Chen (Cole et al, 2020). Each module session was 30 to 45 minutes long with active learning opportunities (Cole et.al., 2020). The four learning modules including: Module One: Vaccine Health Beliefs and Current Vaccine Rates, Module Two: Motivational Interviewing, Module Three: Introduction to the MOTIVE Tool and Module Four: Role Playing using the MOTIVE-Flu tool and motivational interviewing (Cole et al., 2020). Provider education was geared toward tool use and MI simulation. Education for the MA was geared toward identifying VH caregivers (Cole et al. 2020). The Family Nurse Practitioner student completing a clinical rotation during the time of intervention implementation and data collection was willing to participate in the project and participation was approved by the participating

provider who also served as the student's preceptor (A. Sheehan, personal communication, June 10, 2021). The MOTIVE-Flu education tool was shared with the student and a review session was completed to ensure the student was comfortable with implementing the tool with patients' caregivers. All implementation by the student was reviewed, supervised, and reinforced with the preceptor/participating provider (A. Sheehan, personal communication, June 10, 2021).

Following the education implementation, the influenza vaccination process within the clinic was altered. After MA identification of vaccine hesitant caregivers, the MOTIVE-Flu point of care algorithm reference tool (Appendix I) was provided with the MICR documentation for the provider to reference through difficult VH conversations. The MAs no longer fostered VH conversations. The provider initiated the MOTIVE-Flu tool with open ended questions to facilitate vaccination acceptance. The MA recorded if the patient accepted the vaccination, refused the vaccination, or was not applicable if the vaccination was not due on the Clinical Data Collection Chart (Appendix G). Throughout the implementation process, data was analyzed by the investigators bi-weekly to review project development within the clinic. The information was verbally shared with key stakeholders to provide updates, receive feedback, and instill team enthusiasm and encouragement.

In December 2021, after completion of the intervention, project facilitators began data analysis. Data collection strategies were facilitated by the medical assistant Clinical Data Collection Chart and the organization's Data Manager using the EPIC Slicer Dicer. Data was collected and reviewed in accordance with the ethical considerations (Appendix G). A potential budget of the project is reviewed in Appendix H.

#### Timeline

A timeline was established with participating project facilitators, faculty, and the community liaison for project implementation (Appendix E). Project creation began in May of 2021, intervention implementation began in October of 2021, conclusion and data collection occurred in December of 2021, data analysis began in January of 2022. At the conclusion of the project in April 2022, dissemination was approved and presented via an executive summary to all participating agency stakeholders, including the Pediatric and Adolescent Medicine Department Chair, data managers, the participating provider, and the MAs as well as other clinic staff at the site location, the Michigan State College of Nursing and Cedarville University MOTIVE-Flu creators.

#### **Measurement Instruments & Tools**

Outcome's measurement was facilitated in two forms, the Medical Assistant's anecdotal Clinical Data Collection Chart during the project implementation and via the Data Managers EPIC Electronic Medical Record, Slicer Dicer post project. All data was collected in accordance with the IRB approval (Appendix P). The Epic slicer data was statistically reviewed by Michigan State University for difference in proportion hypothesis testing.

#### **Analysis**

## **Epic Slicer Dicer Data**

Evaluation and analysis were completed based on EMAR ICD-10 code Z23 'Encounter for Immunization' at all appointments from October 4, 2021, to December 13, 2021. Total use of the Z23 use was collected via the EPIC slicer dicer and compared to the same dates from the previous year's total visit ICD10 code. The participating provider previous 2020-year ICD 10 code Z23.0 was utilized during 73 of the 177 visits resulting in 43% of the visits (Appendix L). During the 2021 dates while the intervention was being employed the ICD 10 code Z23 was

employed at 96 of the 177 visits resulting in 54% of visits, a 11% improvement (Appendix L). Additionally, 2021 data was compared via the EMAR Slicer Dicer ICD-10 codes with the participating provider using the intervention results in Z23 code use during 54% of visits compared to all other providers, not using the intervention, use of the Z23 code during the same time frame was 37% (Appendix M). This comparison was reviewed for statistical analysis by Michigan State University and yielded statistically significant difference in proportion hypothesis testing results. The proportion of those who accepted vaccines in the intervention group was significantly higher (p-value = 0.003) as compared to the proportion of patients who accepted the vaccination within the nonintervention group.

#### Limitations

Limitations were identified with the Epic Slicer Dicer tool data collection including the inability to decipher which patients were up to date with their influenza vaccination resulting in no need to employ the ICD 10 Z23 code. Of the anecdotal data collected via the Clinical Data Collection Chart, it is indicated that up to 28% of patients seen within the clinic were up to date with their immunizations (Appendix N). An additional limitation of the Slicer Dicer is the ICD 10 code can be employed for other vaccinations.

#### **Anecdotal Clinical Data**

Based on the limitations identified above, the clinical data collection by the Medical Assistants provided anecdotal inference for context. Data indicated that within the 2021 defined time frame time 28% of the total patients seen by the participating provider were up to date and did not need the influenza vaccination at that time (Appendix N). An inference can be drawn by eliminating the 28% that were up to date, resulting in an acceptance rate of 65.3% and refusal rate of 34.6% (Appendix O).

#### Sustainability Plan

In accordance with the selected quality improvement Knowledge into Action Framework, the Action Cycle guided the sustainability plan (Graham et al., 2006). At the conclusion of the project implementation and analysis, dissemination occurred to seek recommendations, feedback, and sustainability potential. The first meeting was completed with the two MAs who identified that they felt the intervention was impactful and warranted the allocation of their time as a resource within the clinical setting (L. Ebbitt, personal communication, December 15, 2021). During their reflection the MAs noted that the intervention reduced their workload and streamlined the communication with the provider for who needed vaccinations and who was vaccine hesitant (L. Ebbitt, personal communication, December 15, 2021). The second sustainability meeting was completed at the conclusion of the project with the participating provider who identified that the intervention was useful and improved her communication with vaccine hesitant caregivers to foster evidence-based knowledge during the decision-making process (L. Ebbitt, personal communication, December 15, 2021). The provider noted that she felt some of her colleagues may be looking to improve their pediatric influenza vaccination rates (A. Sheehan, personal communication, December 15, 2021). Project dissemination to drake holders, clinic providers and the facility medical staff was completed during a staff lunch in April 2022. During the staff meeting an executive summary reviewed project intervention, outcome, tools, and training options. The providers and their support staff who indicated interest were given the intervention education and MOTIVE-Flu tool to employ with their patient population. Clinical sharing of the MOTIVE-Flu tool, and training was approved by the creators (Appendix J). The third dissemination was provided via an executive summary to the participating facility overarching leadership including the medical chair and the organization's

data manager. The content covered included a review of the intervention, data results, project outcomes, implication potential and a final statement of encouragement to consider implementation site wide. The executive summary was also provided to the MOTIVE-Flu creators with participant's feedback. Final dissemination and project presentation was provided by the project facilitators to Michigan State University College of Nursing.

## **Discussion/Implications for Nursing**

Vaccine hesitancy is a growing concern among providers and community health leaders. The MOTIVE-FLU can serve as a guide for medical professionals with difficult vaccine hesitant conversations. This tool can have lasting health benefits for the pediatric population and community health. Project results support the use of the MOTIVE-Flu tool to reduce caregiver vaccination hesitancy and improve pediatric influenza acceptance rates. Practical implications for the project include increased provider use of the tool to reduce morbidity and mortality related to the influenza within the pediatric population, while reducing the spread of influenza within the community and decreasing healthcare costs related to influenza. The Healthy People 2030 pediatric influenza vaccination goal is 80% (Office of Disease Prevention & Health Promotion, n.d.). Employing this tool can help providers to move toward this goal and improve trust between patients, their caregivers, and the clinician. This quality improvement project validated the use of a motivation interviewing algorithm within the clinical setting to overcome vaccine hesitancy. Related additional potential implications of the MOTIVE-Flu tool's success warrant consideration of developing this tool to guide pediatric COVID 19 vaccine hesitant caregivers could be a powerful tool as this novice vaccination requires overcoming educational barriers. The use of the MOTIVE-Flu tool was with permission (Appendix J) at no cost to the organization and required minimal time allocation for implementation further warrants expansion of this asset site wide. Kalamazoo County Michigan's pediatric influenza mortality rate is higher than the state and national average indicating that improved influenza rates within the pediatric population will slow the spread of influenza within the community to save lives (CDC, 2021d; CDC, 2021c; LiveStories, n.d).

#### **Cost-Benefit Analysis/Budget**

Cost considerations during this quality improvement project included both financial implications and time allocation (Appendix H). Donations were provided in the form of refreshments brought to the clinic during the bi-weekly monitoring process by the project facilitators and three lunches, at the beginning, conclusion, and dissemination of the project, totaling \$284 (Appendix H). This cost was not required but provided an opportunity for the project facilitators to connect with members of the intervention team. Potential budget considerations were provided for donations and time compensation totaling \$13,687.32 including project facilitators involved and training time for the intervention team members (Appendix H). Each compensation estimate was taken from the 2020 median pay estimate statistics of the U.S. Bureau of Labor Statistics, 2021a; U.S. Bureau of Labor Statistics 2021b; U.S. Bureau of Labor Statistics, 2021c). This QI project was implemented through volunteer participation and at no personnel or resource costs to the organization. No official cost to benefit ratio was implemented due to IRB limitations that prevented further depth to show the economic benefit.

#### Conclusion

Utilizing the influenza vaccine is a proven primary prevention strategy that is useful in protecting pediatric patients, their peers, family members, and the community from the seasonal influenza virus and its spread. Motivational interviewing is a helpful, low-cost technique that

can effectively reduce vaccine hesitancy and increase influenza vaccine administration as evidenced by the data conclusion in this quality improvement project. Time allocation and resources required to employ MI are minimal, demonstrating that MI is a strategic approach for providers in the pediatric primary care setting. Despite the data collection limitations identified, evidence in this project demonstrates that in the pediatric primary care setting, when providers employ the MOTIVE-Flu tool with motivational interviewing techniques, caregiver vaccination hesitancy decreases and rates of influenza vaccination acceptance increase. The use of motivational interviewing has a long-standing presence within healthcare. Employing this technique with the MOTIVE-Flu algorithm tool in the primary care setting has proven decreased VH and increase in vaccine acceptance. Project facilitators encourage additional research and development of specific tools to serve as an educational guide to vaccine hesitant caregivers within pediatric primary care. Vaccination education for immunizations such as the novel Covid-19 series could be applied within any clinic setting globally to achieve improved pediatric vaccine adherence rates.

#### References

- Bernstein, H. H., Bocchini, J. A., Jr, & COMMITTEE ON INFECTIOUS DISEASES (2017).

  Practical Approaches to Optimize Adolescent Immunization. *Pediatrics*, *139*(3),
  e20164187. https://doi.org/10.1542/peds.2016-4187
- Centers for Disease Control and Prevention. (2018). Influenza. How Flu Spreads (Centers for \Disease Control and Prevention, n.d.). Retrieved from \https://www.cdc.gov/flu/about/disease/spread.htm#:~:text=Person%20to%20Person,be%20inhaled%20into%20the%20lungs.
- Centers for Disease Control and Prevention. (2020a). Estimated Influenza Disease Burden, by Season. United States, 2010-11 through 2018-20 Influenza Season. Retrieved from https://www.cdc.gov/flu/about/burden/index.html
- Centers for Disease Control and Prevention. (2020b). Influenza vaccination coverage for persons six months and older. Retrieved from https://www.cdc.gov/flu/fluvaxview/interactive-general-population.htm?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fflu%2Ffluvaxview%2Freportshtml%2Freporti1920%2Freportii%2Findex.html
- Centers for Disease Control and Prevention. (2021a). Influenza: Information for Schools & Childcare Providers. Retrieved from https://www.cdc.gov/flu/school/index.htm
- Centers for Disease Control and Prevention. (2021b). Healthy Habits to Help Prevent Flu.

  Retrieved from https://www.cdc.gov/flu/prevent/actions-prevent-flu.htm
- Centers for Disease Control and Prevention. (2021c). National, Regional, and State Level
  Outpatient Illness and Viral Surveillance. Retrieved from
  https://gis.cdc.gov/grasp/fluview/fluportaldashboard.html

- Centers for Disease Control and Prevention. (2021d). National Center for Health Statistics.

  Influenza. Data for the U.S. Retrieved from https://www.cdc.gov/nchs/fastats/flu.htm
- Centers for Disease Control and Prevention. (2021e). National Center for Health Statistics.

  Influenza and Mortality by State. Retrieved from

  https://www.cdc.gov/nchs/pressroom/sosmap/flu\_pneumonia\_mortality/flu\_pneumonia.h

  tm
- Centers for Disease Control and Prevention. (2021f). Influenza Associated Pediatric Mortality.

  Retrieved from https://gis.cdc.gov/grasp/fluview/pedfludeath.html
- Cole, J., Berman, S., Gardner, J., McGuire, K., & Chen, A. (2021). Implementation of a motivational interviewing-based decision tool to improve childhood vaccination rates:
   Pilot study protocol. *Research in social & administrative pharmacy: RSAP, 17*(3), 619–624. https://doi.org/10.1016/j.sapharm.2020.04.021
- Dempsey, A. F., & O'Leary, S. T. (2018). Human Papillomavirus Vaccination: Narrative Review of Studies on How Providers' Vaccine Communication Affects Attitudes and Uptake.

  \*\*Academic pediatrics\*, 18(2S), S23–S27. https://doi.org/10.1016/j.acap.2017.09.001
- Dempsey, A. F., Pyrznawoski, J., Lockhart, S., Barnard, J., Campagna, E. J., Garrett, K., Fisher,
  A., Dickinson, L. M., & O'Leary, S. T. (2018). Effect of a Health Care Professional
  Communication Training Intervention on Adolescent Human Papillomavirus
  Vaccination: A Cluster Randomized Clinical Trial. *JAMA pediatrics*, 172(5), e180016.
  https://doi.org/10.1001/jamapediatrics.2018.0016
- Gagneur, A., Gosselin, V., Bergeron, J., Farrands, A., & Baron, G. (2019). Development of motivational interviewing skills in immunization (MISI): a questionnaire to assess MI learning, knowledge and skills for vaccination promotion. *Human vaccines* &

- immunotherapeutics, 15(10), 2446–2452https://doi.org/10.1080/21645515.2019.1586030
- Graham, I., Logan, J., Harrison, M., Straus, S., Tetroe, J., Caswell, W., & Robinson, N. (2006).

  Lost in knowledge translation: time for a map? Journal of Continuing Education in the Health Professions, 26 (1), 13-24. doi: 10.1002/chp.47.
- Harris, J. (2020). Key foundations of successful project planning and management. In J. Harris,L. Roussel, C. Dearman, P. Thomas (Eds.), *Project planning and management* (3rd ed.,pp. 1-22). Burlington, MA: Jones & Bartlett Learning.
- Live Stories. (n.d.) Kalamazoo County Influenza (Flu) & Pneumonia Death Statistics. Retrieved from https://www.livestories.com/statistics/michigan/kalamazoo-county-influenza-flu-pneumonia-deaths-mortality
- Marshall, G. S. (2019). Vaccine Hesitancy, History, and Human Nature: The 2018 Stanley A. Plotkin Lecture. Journal of the Pediatric Infectious Diseases Society, 8(1), 1–8. https://doi-org.proxy2.cl.msu.edu/10.1093/jpids/piy082
- Mical, R., Martin-Velez, J., Blackstone, T., & Derouin, A. (2021). Vaccine Hesitancy in Rural Pediatric Primary Care. *Journal of Pediatric Healthcare*, *35*(1), 16–22. https://doi-org.proxy1.cl.msu.edu/10.1016/j.pedhc.2020.07.003
- MindTools. (2020). SWOT Analysis. Retrieved from https://www.mindtools.com/pages/article/newTMC 05.htm
- Office of Disease Prevention and Health Promotion. (n.d.). Vaccinations. Retrieved from https://health.gov/healthypeople/objectives-and-data/browse-objectives/vaccination
- Prosser, L. A., Bridges, C. B., Uyeki, T. M., Hinrichsen, V. L., Meltzer, M. I., Molinari, N. M....Lieu, T. A. (2006). Health Benefits, Risks, and Cost-Effectiveness of Influenza

- Vaccination of Children. *Emerging Infectious Diseases, 12*(10), 1548-1558. https://doi.org/10.3201/eid1210.051015
- Putri, W., Muscatello, D. J., Stockwell, M. S., & Newall, A. T. (2018). Economic burden of seasonal influenza in the United States. *Vaccine*, *36*(27), 3960–3966. https://doi.org/10.1016/j.vaccine.2018.05.057
- Reno, J. E., O'Leary, S., Garrett, K., Pyrzanowski, J., Lockhart, S., Campagna, E., Barnard, J., & Dempsey, A. F. (2018). Improving Provider Communication about HPV Vaccines for
- Vaccine-Hesitant Parents Through the Use of Motivational Interviewing. *Journal of health communication*, *23*(4), 313–320. https://doi.org/10.1080/10810730.2018.1442530
- Riley, B. & Harris, J. (2020). Influences and determinants of quality improvement projects. In J. Harris, L. Roussel, C. Dearman, P. Thomas (Eds.), *Project planning and management* (3rd ed., pp. 23-38). Burlington, MA: Jones & Bartlett Learning.
- Rollnick, S., Miller, W., & Butler, C. (2008). *Motivational Interviewing in Health Care: Helping patients change behavior*. New York, NY: The Guilford Press
- Sanderson, S., & Gaylord, N. (2020). Infectious Diseases. In Maaks, D., Starr, N., Brady, M., Gaylord, N., Driessnack, M., & Duderstadt, K. (7th ed.) *Pediatric Primary Care*. Saint Louis, Missouri: Elsevier
- Schmid, P., Rauber, D., Betsch, C., Lidolt, G., & Denker, M. L. (2017). Barriers of Influenza Vaccination Intention and Behavior A Systematic Review of Influenza Vaccine Hesitancy, 2005 2016. *PloS one*, *12*(1), e0170550. https://doi.org/10.1371/journal.pone.0170550
- Tokish, H., & Solanto, M. V. (2020). The problem of vaccination refusal: a review with guidance

- for pediatricians. *Current opinion in pediatrics*, *32*(5), 683–693. https://doi.org/10.1097/MOP.0000000000000937
- U.S. Bureau of Labor Statistics. (2021a). *Medical Assistants*. Retrieved from https://www.bls.gov/ooh/healthcare/medical-assistants.htm
  U.S. Bureau of Labor Statistics. (2021b). *Nurse Anesthetists, Nurse Midwives, and Nurse Practitioners*. Retrieved from https://www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm
  - U.S. Bureau of Labor Statistics. (2021c). *Registered Nurses*. Retrieved from https://www.bls.gov/ooh/healthcare/registered-nurses.htm
- Wermers, R., Ostroski, T., & Hagler, D. (2021). Health care provider use of motivational interviewing to address vaccine hesitancy in college students. *Journal of the American Association of Nurse Practitioners*, 33(1), 86-93. https://doi-org.proxy1.cl.msu.edu/10.1097/JXX.000000000000281
- Western Michigan University Homer Stryker School of Medicine. (2021). *Mission, Vision, and Values*. https://med.wmich.edu/node/277.
- WMed Health. (2020). *Pediatric and Adolescent Medicine*.

  https://med.wmich.edu/sites/default/files/Pediatrics%20Mall%20Drive%20practice.pdf.
- World Health Organization. (2013). The SAGE Vaccine Hesitancy Working Group. What influences vaccine acceptance: A model of determinants of vaccine hesitancy. Retrieved from
  - https://www.who.int/immunization/sage/meetings/2013/april/1\_Model\_analyze\_driversof vaccineConfidence\_22\_March.pdf
- World Health Organization. (n.d.). Influenza. Vaccine Preventable Diseases. Surveillance

Standards. Retrieved from

at Child Health gvirf16.pdf

https://www.who.int/immunization/monitoring\_surveillance/burden/vpd/WHO\_SurveillanceVaccinePreventable\_09\_Influenza\_R1.pdf?ua=1

World Health Organization. (2016). Vaccine Hesitancy: What it means and what we need to know in order to tackle it. Retrieved from <a href="https://www.who.int/immunization/research/forums\_and\_initiatives/1\_RButler\_VH\_Thre">https://www.who.int/immunization/research/forums\_and\_initiatives/1\_RButler\_VH\_Thre</a>

World Health Organization. (2017). Estimate of Respiratory Death due to Seasonal Influenza 290,000 - 650,000 Annually. Retrieved from

https://www.who.int/influenza/surveillance\_monitoring/bod/WHO-INFLUENZA-MortalityEstimate.pdf?ua=1

# Appendix A

Gap Analysis: Clinic SWOT Matrix Analysis

Strengths What do you do well? What unique resources can you draw on? What do others see as your strengths?	Weaknesses What could you improve? Where do you have fewer resources? What are others likely to see as weaknesses?
- Support from providers and staff towards increasing the influenza vaccine administration due to decreased numbers from the year before related to the Covid-19 Pandemic and access to care.  -Access to comprehensive data from the clinic EHR showing previous influenza rates to measure the effectiveness of the intervention  -Well trained staff specifically trained in motivational interviewing related to vaccine hesitancy  -Consistent pediatric population within clinic allows for focus on this community  -The Michigan Care Improvement Registry, MCIR, is printed for every patient encounter to ensure review by the providers vaccinations are being met  -No limitation of time frame related to covid vaccine  -No other vaccine education program being rolled competing for staff attention  - Monthly staff meetings are pre planned to allow for education  -Quarterly faculty meetings with the clinic where teaching and announcements can be made.  -Covid restrictions have loosened at clinic site allowing researchers and stakeholders to come into the clinic	-Time constraints of when to administer the vaccine due to it being seasonal and predicted availability of August 2021 -Hesitancy of caregivers due to the Covid vaccine becoming available with specific parameters for administration -Inconsistent lack of providers due to the various providers seeing other provider's patients -Lack of staff training related to motivational interviewing -Staff turnover -Lack of reminders for pediatric patients and their caregivers -The pediatric clinic being studied does not give covid vaccine which brings up less encounters for other vaccinations -Lack of notifications within EHR for patients who have not been to the clinic and in need of vaccinations Lack of MA or Provider clinic specific training for vaccination education or administration

-Clinic being studied has strong relationship with the local health department and Vaccine For Children program	
Opportunities What opportunities are open to you? What trends could you take advantage of? How can you turn your strengths into opportunities?	Threats What threats could harm you? What is your competition doing? What threats do your weaknesses expose to you?
-Direct access to primary care where majority of influenza vaccines are administered -Forecasted higher prevalence of influenza related to predictions of more in person gatherings -A specific MA who is willing to assist and develop research team -Participate in Vaccines for Children from the local health department allowing free vaccinations for low-income patientsPatients do not have to go to another location for immunizations - Increased risk for infection related to return-to-work school and sports transition post covid	-Fear of seeking primary care due to COVID-19 pandemic -Unknown amount of provider turnover within the clinic -Lack of education about consequences of flu from providers and staff -Media inconsistency regarding influenza and its risks -Staff fatigue -Telemed is not appropriate for administration but is appropriate for screening and MI as well as vaccination scheduling -Inconsistent follow up for prevention of missed vaccinations

(MindTools, 2020)

Appendix B

# June 25, 2021, Literature Inquiry Method Table

Database Searched	Keyword Truncation	Limitations	# of Results
CINAHL	Vaccin*, "Motivational Interviewing" OR "Motivational Interview"	English Language Within the last 5 years	37
PUBMED	Vaccin*, "Motivational Interviewing" OR "Motivational Interview"	English Language Within the last 5 years	52
COCHRANE LIBRARY	Vaccin*, "Motivational Interviewing" OR "Motivational Interview"	Within the last 5 years	27

## Appendix C

## Literature Review Table

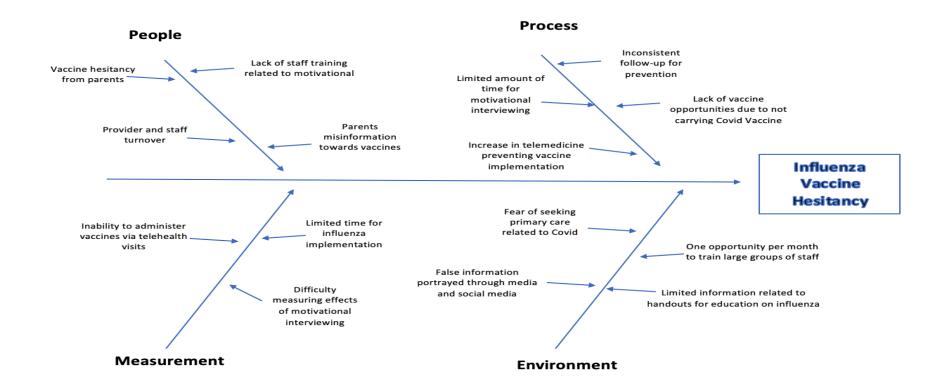
Title	Authors	Level of evidence/ Design	Purpose of the project/research	Framework (Theoretical)	Results Outcomes	Relation to our project	Implications for Practice/ Intervention(s)
Health care provider use of motivational interviewing to address vaccine hesitancy in college students.	Wermers, R., Ostroski, T., & Hagler, D.		Although vaccination decisions are complex, a recommendation from a health care provider is one of the key motivators for individuals receiving a vaccine.	Theory of Planned Behavior	MI can be an effective part of a strategy to increase vaccination rates.	Influenza Provider Edu MI	Provider Education MI
Communication about HPV Vaccines for Vaccine-Hesitant	Reno, J.E., O'Leary, S., Garrett, K., Pyrazanowski, J., Lockhart, S., Campagna, E., Barnard, J., & Dempsey, A.F.		Providers and staff at eight pediatric and family medicine clinics received communication training that included MI techniques. Assessed the perceived efficacy of the intervention.	Not identified		HPV but RCT with MI	Provider Edu with MI intervention
Vaccine Hesitancy n Rural Pediatric Primary Care.	Mical, R., Martin- Velez, J., Blackstone, T., & Derouin, A.,	Qualitative	The study determined if early identification of parental VH via a survey could decrease VH scores.	Not identified		Motivational Interview Peds Primary Care Setting	Presumptive Language MI

					improved vaccine compliance.		
The problem of vaccination refusal: a review with guidance for pediatricians.	Tokish, H. & Solanto, M.V.,	Level 3 - Literature Review	The purpose of this literature review was to demonstrate that pediatricians can apply research from cognitive behavioral research to reduce vaccine hesitancy in caregivers	Not identified	MI was successful in reducing vaccine hesitancy (HPV) Rated by providers as more effective than other communication techniques, without increasing the length of the appointment.	MI	MI Primary care, Resources to overcome vaccine hesitancy
Human Papillomavirus Vaccination: Narrative Review of Studies on How Providers' Vaccine Communication Affects Attitudes and Uptake.	Dempsey, A. F. & O'Leary, S. T.	Level 4, Literature Review	The purpose of this literature review was to provide up to date, well designed information regarding communication related to vaccines, specifically the HPV vaccine.	Not identified	Using self-affirmation to improve VH caregivers' willingness to hear provaccine messages. Creative communication strategies	MI among vaccine hesitant caregivers	MI
Development of motivational interviewing skills in immunization (MISI): a questionnaire to assess MI learning, knowledge and skills for vaccination promotion.	Gagneur, A., Gosselin, V., Bergeron, J., Farrands, A., & Baron, G.	Level 3, Control Trial	The purpose of this questionnaire was to evaluate the effectiveness of MI training related to immunizations.	Questionnaire	The MISI questionnaire to assess MI training specific to immunization. Psychometric measures showed high reliability.	МІ	Evaluation of MI

Practical Approaches to Optimize Adolescent Immunization.	Bernstein, H. H., Bocchini, J. A., Jr, & Committee on Infectious Diseases	Level 5, Literature Review	The purpose of the literature review was to examine current guidelines and literature in order to empower providers to overcome vaccine hesitancy predominantly in adolescents. However, the information could be applied to all pediatric populations.	Not identified	Authors used literature to address vaccine hesitancy within the adolescent population, and also gave evidence-based suggestions to help overcome vaccine hesitancy with any caregiver.	MI	American Academy of Pediatric guidelines to help promote vaccines
Effect of a Health Care Professional Communication Training Intervention on Adolescent Human Papillomavirus Vaccination: A Cluster Randomized Clinical Trial.	Dempsey, A., Pyrznawoski, J., Lockhart, S., Barnard, J., Campagna, E. J., Garrett, K., Fisher, A., Dickinson, L. M., & O'Leary, S.	Level 2 Cluster Randomized Clinical Trial	A health care professional communication intervention significantly improved HPV vaccine series initiation and completion among adolescent patients.	Survey	The study of 43,152 patients showed that when providers had improved training related to communication techniques related to HPV, the vaccination rates improved significantly	Provider training, adolescent immunizatio n	Using communication to increase adherence
Implementation of a motivational interviewing-based decision tool to improve childhood vaccination rates: Pilot study protocol.	Cole, J., Berman, S., Gardner, J., McGuire, K., & Chen, A.M.H.	Level 3 Pilot Study	This study aims to develop a validated parental communication tool utilizing motivational interviewing to increase vaccination adherence in children ages 6 years and younger.	Pilot study based on the Health Belief Model	Outcome results were not provided because this was a pilot study. However, the researchers were hopeful for positive results.	motivational	Implementation of MI, great information related to using MI in infants and toddlers.

## Appendix D

## Fishbone Diagram



# Appendix E

## Timeline

		Summer	Semester 2	2021	Fall Semester 2021				Spring Semester 2022			
Task	May	June	July	August	September	October	November	December	January	February	March	April
Meet with Agency												
Clinical Question												
Literature Review												
Project model, SWOT, and Fishbone Diagram												
Develop Methodology												
IRB Presentation and Submission												
Meet with Clinic Staff												
Implement Project and Data Collection												

Analyze Data						
Interpret Results						
Finalize Project						
Disseminate Project						

## Appendix F Letter of Support



#### DEPARTMENT OF PEDIATRIC & ADOLESCENT MEDICINE GENERAL PEDIATRICS

Dilip R. Patel, MD, MBA, MPH Chair

Kelly A. Brown, MD Program Director Pediatric Residency Program

Erica VanderKooy, MD Associate Program Director Pediatric Residency Program

Cheryl A. Dickson, MD, MPH Associate Dean for Community Affairs

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Natalie Behrle, MD, MS M4 Clerkship Director

Jayce Deleon, MD

Mahesh Shrestha, MD, FAAP

Priscilla Woodhams, MD Medical Director, Pediatric Clinic Scholar Advisor

Ann Sheehan, DNP

Jayne Barr, MD, MPH

Theo Gomes, MD

Nic Helmstetter, MD

Tom Melgar, MD

May 25, 2021



Dear Kara,

It is my pleasure to work with Channan Kositzke and Luke Linscheid on their DNP project regarding vaccine hesitancy in pediatric primary care and the related impact on population health. I understand that my involvement with Western Michigan University's School of Medicine WMed Pediatrics will include facilitation of participants regarding vaccine hesitancy and subsequent interventions.

I have reviewed the project with the students and am comfortable with the project taking place in our facility. I understand that the project will be carried out following sound, ethical principles and MSU IRB approval.

As a contracted provider of WMed Pediatrics, I agree that the project proposed by Channan Kositzke and Luke Linscheid may be conducted within the Mall Dr. facility. I understand with the conclusion of this project dissemination of results will occur with Michigan State University College of Nursing in order for the students to achieve course completion.

Sincerely,



1000 Oakland Drive, D48G Kalamazoo, MI 49008 Clinic: (269) 337-6400 Office: (269) 337-6450 Fax: (269) 337-6474 www.med.wmich.edu

Appendix G

## Clinical Data Collection Chart

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
10/4/21	U	U	Y	Y	Y	U	U	R	U	Y	U	U		
10/8/21	Y	Y	Y	U	R	Y	Y	Y	R	R	R	Y	R	
10/11/21	R	Y	U	U	Y	U	R	R	Y	Y	U	R	U	Y
10/13/21	Y	Y	U	Y	U	R	Y	Y	Y					
10/18/21	U	Y	U	Y	U	R								
10/19/21	U	R	R	R	U									
10/20/21	U	U	Y	R	R									
10-25-21	Y	R	Y	R	R	R	U	Y	Y					
10-27-21	Y	U	Y	Y	Y	Y	U	Y						
11-1-21	Y	R	R	R	Y	R	Y	Y	Y	R	U	Y	Y	U
11-3-21	Y	R	R	Y										
11-8-21	Y	U	U	Y	Y	U	Y	Y	R	U	R	U		
11-10-21	Y	Y	Y	R	U	Y	U	U						
11-15-21	Y	Y	Y	U	Y	R	U	U	R	R	U			
11-17-21	Y	Y	R	Y	R	R								
11-22-21	Y	Y	Y	Y	U	R	R							
11-24-21	Y	Y	Y	Y	U	R	U							
11-29-21	U	Y	Y	Y	U	Y	Y	Y	Y	U	R			
12-13-21	Y	U	Y	Y	Y	Y	U	U	Y	U	R	R		

Key Y = Influenza Vaccination Acceptance R = Vaccination Refusal N/A = Vaccination not due
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Appendix H

## Potential Budget Considerations

Personnel	Pay	Total	
Luke Linscheid RN BSN	\$36.22/hour x 180 hours	\$6,519.60	
Channan Kositzke RN BSN	\$36.22/hour x 180 hours	\$6,519.60	
2 Medical Assistant module training	\$17.23/hour x 4 hours	\$137.84	
Nurse Practitioner module training	\$56.57/hour x 4 hours	\$226.28	
Facilitator Food Donation	Lunch x 3, Snacks x 3	\$284.00	
TOTAL	\$13,687.32		

## Appendix I

#### MOTIVE-Flu Tool

MOtivational interviewing <u>T</u>ool to <u>Improve</u> <u>Vaccine</u> Adherenc<u>E</u> (MOTIVE)- Flu Vaccine Adherence in Pediatric **Patients** 

Note: Refer to MOTIVE Tool for childhood vaccines regarding vaccines other than influenza.

#### Step 1

Use a participatory approach and ask the parent to share their personal perspective on the fluvaccine.

#### Step 2

If the parent verbalize hesitation or refusal, ensure the patient has no medical contraindication to a vaccine or vaccine component.

Step 3
If no medical contraindications, utilize the MOTIVE-Flu tool for pediatric patients.

Question to Parent	Parent Answer: Open-Ended					
"We have flu vaccines available. What are your thoughts on receiving the vaccine today?"	Consider using A (safety), B (efficacy), and C (ethical/social) to discover and overcome barriers.					
Question to Parent	Parent Answer: Yes	Parent Answer: No				
Do you think the flu vaccine could cause side effects or illness that would make you not want to vaccinate your child?	Parent has safety concerns. Proceed to A	Proceed to the next question.				
Do you feel as though the flu vaccine is effective in preventing the flu?	Proceed to the next question.	Parent has efficacy concerns. Proceed to <b>B</b>				
Do you have any ethical or religious concerns about the flu vaccine?	Parent has social/ethical concerns. Proceed to C	Proceed to the next question				
Have you ever delayed or denied a vaccination for your child for reasons other than illness or allergy?	The parent may have other health beliefs that are creating a barrier to vaccination.  Proceed to <b>D</b> .	Ask clarifying questions if no specific safety, efficacy, ethical or care coordination concerns are identified				

#### A. SAFETY

Questions to Ask	Common Health Beliefs	Ways to Address Beliefs						
Tell me your concerns related to the safety of the flu vaccine.     What have you been told about how the flu shot is made and how it works?	Getting the flu from the flu shot: The flu vaccine can cause the flu.	Getting the flu from the flu shot:  How the flu shot works: The flu vaccine helps the body to develop antibodies against the flu over a two-week period. Often people who get sick after getting the flu shot experienced an overlap of the flu shot and sickness they would have gotten anyway.  How the flu shot is made: To develop the flu shot, heat or chemicals are used to kill the virus and make it non-infectious. The virus cannot make copies, so it cannot change back to the form that makes you sick and causes the flu. The immune system is able to recognize and respond to this inactivated virus to prevent sickness.						

What can you tell me about the side effects the flu shot can cause?	Side effects: The flu shot has too many serious side effects.	Side effects: Common side effects from the flu shot: There are no live flu viruses in the flu vaccine, so it cannot cause the flu. Achiness or tiredness can be caused by your immune system responding to the vaccine. Side effects from the flu vaccine are generally mild and include headache, fever, nausea, muscle aches, and swelling at the injection site. These symptoms are proof that your body is responding well to the vaccine.
	Egg allergies: My child has egg allergies, so they cannot get a flu shot.	Egg allergies: Most patients with egg allergies can still get a flu shot. Patients with egg allergies that only result in hives can get a flu shot without special monitoring. If the egg allergy results in swelling, breathing problems, lightheadedness, or repeated vomiting, flu shots appropriate for age and health can be given in a setting within the clinic where any adverse effects could be monitored for. The only true allergy that would prevent a patient from getting a flu vaccine is a previous severe reaction to a flu vaccine.

#### B. EFFICACY

Ques	stions to Ask	Common Beliefs	Ways to Address Beliefs
	What do you know about how the flu shot prevents the flu? What are the potential problems your	Not all types of the flu are covered: The flu shot isn't always effective against all types of the flu, so my child will still get the flu anyway.	Not all types of the flu are covered: Research is done to predict which types of the flu will be the most common during the upcoming flu season. Traditional flu vaccines protect against three different strains of the flu: H1N1, H3N2, and Influenza B. Quadrivalent flu vaccines protect against the same three types as the traditional vaccine plus an additional type of Influenza B. While it is not possible to protect against every type of flu, protecting from these types can prevent serious illness.
3.	child could have if unvaccinated?  Who benefits from your child receiving the flu vaccine?	Herd immunity: My child is not around sick children or babies, so it's not that important to be immunized.	Herd Immunity: To avoid the spread of diseases, 80-95% of people need to be vaccinated to protect others who cannot be vaccinated such as newborns and people at high risk for developing problems from the flu. By getting the vaccine, we can all do our part in protecting children and others that are more at risk for the flu.
		Antibiotics for the flu: If I do get the flu, I can just get antibiotics to treat it instead of preventing it.	Antibiotics to treat the flu: Antibiotics do not work to treat the flu. The flu is a virus, and antibiotics are only effective against infections caused by bacteria. Antivirals are available but are not shown to work for treating the flu. Antivirals only relieve symptoms one day earlier than not taking an antiviral at all when given within 48 hours of the start of your symptoms.
		Flu shots are too frequent: You don't need to get a flu shot every year.	Flu shots are too frequent: Over the course of the year, the influenza virus changes so that previous flu vaccines are no longer effective. Getting a vaccination every year ensures you are protected against the types most likely to cause infection for that specific year.
		Getting the flu anyway: My child will get the flu whether her/she gets the flu shot or not.	Getting the flu anyway: If your child gets an influenza vaccination and still gets the flu in the same year, the immune system is ready to fight off the infection. This reduces the severity of the illness and reduces the risk of bad outcomes including death and the need to go to the hospital.
		It's not that bad: The flu isn't going to harm my child, so it is not worth being vaccinated against.	It's not that bad: The flu can cause serious health problems and be dangerous for those at <a href="high-risk">high-risk</a> , but even healthy people can get the flu. Children are one of the groups at greatest risk of bad outcomes from the flu. Some of these include lung infections,

sinus and ear infections, and swelling of the heart or brain, which can be potentially life-threatening.

People at high risk of developing serious health problems from the flu: children younger than five years, adults older than 65 years, pregnant women, American Indians, and Alaskan Natives, residents of nursing homes, people with immune system suppression, asthma, neurological disorders, chronic lung disease, heart disease, blood disorders, diabetes, kidney or liver disorders, cancer, or people under the age of 19 taking salicylates like aspirin or Pepto Bismol.

#### C. SOCIAL / ETHICAL

Concerns	Solutions
Parent indicates that vaccinations interfere with divine providence, i.e., God's plan for them.     Parent indicates hesitancy due to pork products in immunizations (maybe of Jewish or Islamic faith).     Parent indicates hesitancy due to concerns with the use of fetal tissue in the development of immunizations.	Religious Objections:  Use MI to explore: How do you view the difference between vaccines and other medical interventions?  Share information about vaccines and how they are derived. Refer to local religious leaders who are informed about vaccines  Pork products: There are statements from Islamic and Jewish groups allowing for the use of injectable products with porcine gelatin Thus, individuals from these faith communities can receive vaccinations without compromising their beliefs.  Of note, the FluMist vaccine contains porcine gelatin.  Fetal tissue: Today, about {10 vaccines} are created using human cell lines. These originated from two fetuses electively aborted (not for financial gain) in the 1960s. These fetal cells made copies grown in a lab, which were used to grow viruses that then became vaccines.  The actual cells from the abortions died long ago, because human cells only replicate so many times before dying. The copies of these cells continue to be used today for vaccine production.  The vaccines themselves do not contain the cells. Vaccines do not truly contain aborted body parts as some claim.

#### D. COORDINATION OF CARE

Questions to Ask		Solutions	
atter appo 2. Can abou	at barriers have you faced in nding your child's ointments? you tell me what you know ut the importance of well-child s and immunizations?	<ul> <li>Schedule the next appointment with the patient considering patient factors and barriers.</li> <li>Consult the <u>catch-up schedule</u>.</li> <li>Consult a social worker (if available) to address barriers to care.</li> <li>If a catch-up is planned, discuss with parent/caregiver timelines and goals.</li> <li>If you uncover safety or efficacy concerns, please see A and B.</li> </ul>	

#### E. OTHER

Who is paying for my vaccine?  If you are insured through the Affordable Care Act, Medicare Part B, or most other insurance plans, should be able to get your flu shot for free at your doctor's office or at your local community pharm	
Is the vaccine mandatory?  The vaccine is not mandatory, and you are free to make your own decision regarding vaccination. However, depending on the type of work you do (e.g. healthcare workers, first responders), your employer may require the vaccine.	
Who can/should CDC recommends annual flu vaccination for all individuals 6 months and older as Flu vaccines are safe	

get the vaccine?	and effective and the primary means of preventing Flu and its complications.	
Who should not get vaccinated against Flu?	Children younger than 6 month old and people with severe life threatening allergies to Flu vaccine or an ingredient in the vaccine should not get the Flu vaccine.	
What types of vaccines are available?	Flu vaccines are updated annually to protect against Flu strains that are most likely to be circulated in the season. There are different types of Flu vaccines offered. Different types of Flu vaccines are approved for different age groups. Your health care provider will determine the suitable flu vaccine for your age group.	
When should I get vaccinated against Flu?	In the U.S., flu season may begin in October and end in May. The best time to receive the vaccine is before you get the Flu. Therefore, it is better to take the vaccine early in the fall, before the beginning of the Flu season, as it takes two weeks to develop protection against the virus. But getting the vaccine any time during the Flu season is still beneficial.	
How long does Influenza protection last?	As the virus strains causing Flu can change each season, the vaccine is only effective for the particular season. Therefore, getting vaccinated every year is important.	
How many vaccinations are necessary to be protective?	Children from 6 months to 8 years who are receiving the flu vaccine for the first time should receive two doses of the vaccine at least one month apart. Everybody else needs only one dose every year to get protection against the Flu.	
Is the FLU vaccine the same every year?	Virus strains causing Flu can change each year. Therefore, new vaccines are made each year to give protection against the circulating strains. Because of this, getting vaccinated each year is very important.	
Will this help the vulnerable?	Yes. Flu is a very serious and potentially deadly disease that spreads very easily. Vaccination against Flu is beneficial to both children and adults with chronic conditions like asthma, diabetes, heart disease and for those who are immunocompromised because flu can exacerbate these conditions and they are at high risk of getting complications from Flu.	

Resources for Healthcare Providers: Talking about Vaccine Hesitancy, Tips for effective communication

#### Appendix J

#### Cedarville University MOTIVE-Flu Tool Approval



Chen, Aleda M <amchen@cedarville.edu>

Wed 8/4/2021 8:00 AM

To: Kositzke, Channan Marie

Cc: Linscheid, Luke William; jwcole@cedarville.edu

Thank you for your patience while we had some discussions about this.

We are willing to share our MOTIVE tool with you - I am assuming you would like to use the MOTIVE-Flu? Here are the conditions for use:

- 1. You would need to cite us in any publication or presentation that discusses the Tool.
- 2. The tool is copyrighted, so it can be used for the study and by clinicians, but it cannot be made available publicly (i.e., included as a whole in a publication, posted on a public website, etc.)
- 3. We do ask that you and anyone using the tool complete a training (online video module) about the tool itself in order to prepare for use. We will make it available at no charge.

If you are amenable, I can start the process of this. I'm also happy to answer any questions you may have.

Aleda

• • •

#### Appendix K

### Participating Provider and Tool Agreement



Kositzke, Channan Marie Wed 8/4/2021 5:33 PM

To: Chen, Aleda M <amchen@cedarville.edu>

Cc: Linscheid, Luke William; jwcole@cedarville.edu; Sheehan, Ann

Dr. Chen,

Thank you so much for your prompt response to our request. We appreciate your consideration.

We have spoken with the provider that we are looking to implement this quality improvement intervention with and have shared your publications with her to review.

We have reviewed your conditions for use of the MOTIVE-Flu tool and can agree to the conditions you have outlined. We are thankful for this opportunity.

With that said, we are wondering if we can review the tool and education to ensure that it is clinically appropriate for this QI project?

Please let us know what information you need from us to facilitate this process.

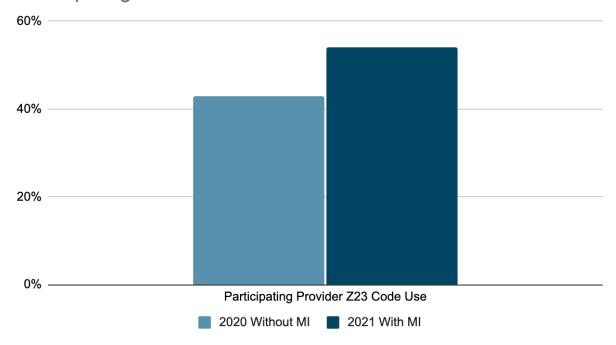
Best,

Channan Kositzke BSN DNP-S Luke Linscheid BSN DNP-S

Appendix L

Participating Provider 2020 vs 2021 Z 23 Code Use

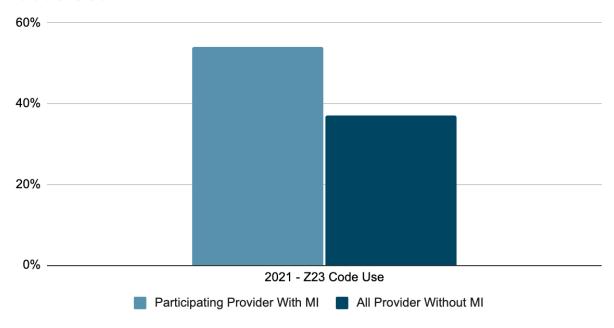
# Participating Provider 2020 vs 2021 Z 23 Code Use



Appendix M

Participating Provider 2021 vs All Practice Provider 2021 Z 23 Code Use

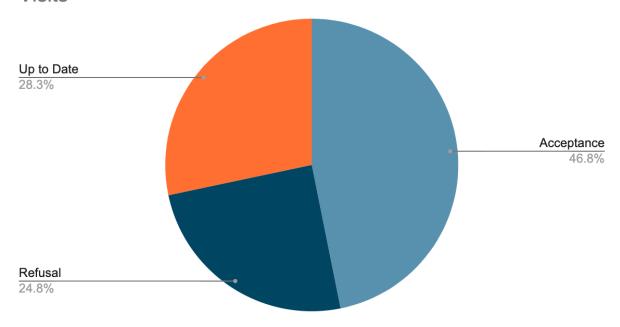




Appendix N

Participating Provider 2021 Anecdotal Clinical Data - Total Visits

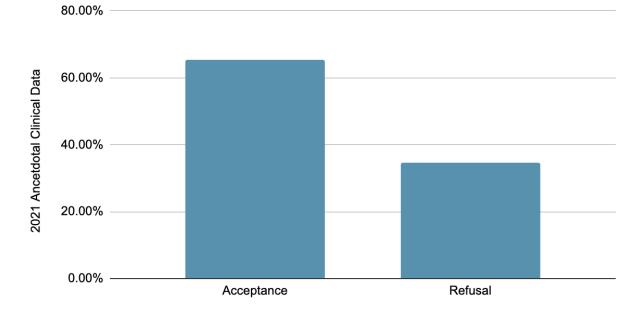
# Participating Provider 2021 Anecdotal Clinical Data - Total Visits



Appendix O

Participating Provider 2021 Anecdotal Clinical Data - Eliminating Up to Date





#### Appendix P

#### Michigan State University Institutional Review Board Approval

# MICHIGAN STATE

# DETERMINED NOT "RESEARCH" Revised Common Rule

September 8, 2021

To: Luke Linscheid

Re: MSU Study ID: STUDY00006624

Principal Investigator: Luke Linscheid

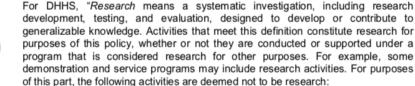
**Determination Date: 9/8/2021** 

Title: DNP Project: Improving Pediatric Influenza Vaccination Rates in the Primary

Care Setting

The activity described in this submission was determined not to be "research" as defined by the Common Rule as codified in the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human research subjects.

#### **Definition of Research**





Office of Regulatory Affairs Human Research Protection Program

> 4000 Collins Road Suite 136 Lansing, MI 48910

517-355-2180 Fax: 517-432-4503 Email: irb@msu.edu www.hrpp.msu.edu

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

MSU is an affirmative-action, equal-opportunity employer. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions." [45 CFR 46.102(I)]

#### Determination

Based upon your application this activity is quality improvement involving healthcare operations. Hence, the activity does not involve research.

Therefore, the federal regulations for the protection of human subjects would not apply to this activity and Michigan State University (MSU) Institutional Review Board (IRB) approval is not needed to proceed. However, please note that while MSU IRB approval is not required, other federal, state, or local regulations or requirements or ethical or professional standards may still be applicable based on the activity.

**Modifications:** If any of the activities described in this submission change, please contact the IRB office as the activity may involve human subject research and require IRB approval. For example, this determination is not applicable to activities that may be regulated by U.S. Food & Drug Administration (FDA), such as those involving drugs, medical devices, human food additives, color additives, electronic products, or any other test articles regulated by the FDA.

Modifications to Funding: Changes in funding may alter this determination. For example, MSU IRB review and approval is required if MSU receives an award through a grant, contract, or cooperative agreement directly from a federal agency, even where all non-exempt research involving human subjects are carried out by employees or agents of another institution. In addition, the new funding source may have additional or different requirements.

**For More Information:** See HRPP Manual Section 4-3, Determination of Human Subject Research (available at <a href="https://hrpp.msu.edu">hrpp.msu.edu</a>).

**Contact Information:** If we can be of further assistance or if you have questions, please contact us at 517-355-2180 or via email at <a href="IRB@msu.edu">IRB@msu.edu</a>. Please visit <a href="httpp://hrpp.msu.edu">hrpp.msu.edu</a> to access the HRPP Manual, templates, etc.