Assessing Barriers and Increasing Use of Immunization Information Systems in Pharmacies: A Randomized Controlled Trial

by

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Abstract

The role of pharmacists as immunization providers is increasingly common. However, as the number of providers administering vaccines increases, there is a concern of fragmented immunization records in state and regional immunization information systems (IIS). In order for IIS to have complete records, it is critical that each provider administering vaccines participate and update the IIS each time a vaccine is administered to a patient. In Alabama, participation in the IIS is not mandatory; as a result, less than 25% of adults over the age of 19 have immunization data recorded in the state IIS. Limited pharmacy participation may have contributed to these incomplete IIS records.

The purpose of this study was to identify barriers to utilization of IIS within a pharmacy context and tailor the information learned about barriers into a novel IIS training program. The research design was a mixed methods approach to qualitatively identify contextual barriers and facilitators to IIS utilization and quantitatively assess effectiveness of the training program on pharmacists' knowledge, attitudes, intention, enrollment in the IIS, and actual participation in the IIS. The specific aims were to 1) identify barriers and best practices of IIS implementation through qualitative interviews of Alabama pharmacists as well as IIS representatives and participating pharmacists in states identified as having high IIS participation rates, 2) use a participatory design approach to develop an IIS training program, and 3) assess the impact of the IIS training program among community pharmacies' IIS participation rates.

Analysis of qualitative interviews identified multiple factors influencing implementation of IIS in the community pharmacy setting, aligning well with CFIR domains. Results of the randomized controlled trial phase showed a significant effect of the intervention on participants' awareness, knowledge, and attitudes toward innovation characteristics. The intervention was shown to significantly affect enrollment in IIS. However this effect was not seen when examining participation in the IIS. This pharmacist-centered training program focused on practical strategies to integrate IIS into pharmacy workflow. While this program contains some information specific to the Alabama IIS, it could be adapted and disseminated to other states, incorporating strategies to improve sustainment of the intervention effect over time.

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List of Abbreviations

ACIP	Advisory Committee on Immunization Practices
ADPH	Alabama Department of Public Health
AIRA	American Immunization information system Association
ARRA	American Reinvestment & Recovery Act
CE	Continuing Education
CFIR	Consolidated Framework for Implementation Research
EHR	Electronic Health Record
IIS	Immunization Information System
ImmPRINT	Immunization Patient IIS with Internet Technology
NVAC	National Vaccine Advisory Committee
TAM	Technology Acceptance Model
UTAUT	Unified Theory of Acceptance and Use of Technology
VFC	Vaccines for Children

Chapter 1. Introduction

As vaccine-preventable diseases remain leading causes of illness and death in the United States, improving immunization rates, particularly for adults, is a Healthy People 2020 goal. One way to reach this goal is by increasing the utilization of pharmacists as non-traditional vaccine providers, allowing for convenient access and the ability to reach underserved populations (Healthy People 2020, 2015). Now, pharmacists in all 50 states can administer vaccines, with varying degree of state law/regulations restrictions (U.S. Department of Health and Human Services, 2013). In fact, a recent national survey shows that over 90% of pharmacies offer the herpes zoster vaccine, 88% offer pneumococcal vaccine, 85% offer the Tdap vaccine, and over 52% offer the Hepatitis B vaccine (Westrick SC et al., 2018). Patients identify pharmacies as the second most preferred setting for receiving vaccinations, with 25% of flu shots being delivered in pharmacies in 2015 (Randall C. Burson, Alison M. Buttenheim, Allison Armstrong, & Kristen A. Feemster, 2016; Kennedy, Santibanez, Bridges, & Singleton, 2012). At the same time, the complexity of immunization schedules has increased, spanning the whole life course. This increase in immunization program complexity, along with an increase in the number and type of providers administering vaccines, has created the need for accurate immunization records. This will allow providers, in real time, to determine which individuals received particular vaccines, as well as when and by whom.

Incomplete immunization records are a concern both at the population level and at the point of clinical care. At the population level, complete immunization records are needed in order to track immunization rates as well as identify and target areas with inadequate coverage (Centers for Disease Control and Prevention, 2012). Aggregate data on vaccination is also essential in planning outbreak response efforts (Centers for Disease Control and Prevention, 2012). At the point of clinical care, complete records are necessary to identify which vaccinations are due for an individual so that opportunities are not missed and individuals are not over-vaccinated, ultimately improving patient care coordination (Centers for Disease Control and Prevention, 2012).

Immunization information systems (IIS), or immunization registries, have been developed to help mitigate the concern of incomplete and fragmented immunization records by consolidating vaccination information for individuals within a defined geographic area (National Vaccine Advisory Committee, 2015). These IIS are computerized databases that record and consolidate immunization doses that are administered by participating providers (National Vaccine Advisory Committee, 2015). In the early 1990s, legislation was proposed to create a national IIS as part of the Comprehensive Child Immunization Act of 1993. However Congress did not pass this legislation and thus individual states were charged with the responsibility of creating and maintaining their own immunization information systems. Today, we have more than 50 IIS across the U.S. with states, territories, and some local jurisdictions maintaining their own IIS (National Vaccine Advisory Committee, 2015). With each IIS operating individually, there are differences in policies surrounding IIS that impact how patients and providers interact and participate in the immunization information system. This can include the age groups of patients that are included, whether or not consent must be obtained from patients prior to enrollment, how data is shared between IIS, whether or not provider participation is mandatory, and the types of providers who must participate in IIS. While some states such as Georgia and North Dakota mandate that providers report this information to their respective state IIS, many states do not. When providers do not participate in the IIS this results in incomplete records. In many states where reporting is not mandatory, like Alabama, less than 25% of adults over the age of 19 have immunization data recorded in the state IIS. Further, the accuracy and completeness of the individuals' data who are included in the IIS is unknown.

While policies surrounding IIS may have some impact on participation, IIS information is only useful if all providers participate. This includes any healthcare professional administering vaccines, especially pharmacists. Perceived inability of pharmacies to keep accurate and complete records of immunizations has been identified as a barrier to the acceptance of vaccination in community pharmacies by patients and physicians (Bergus, Ernst, & Sorofman, 2001; S Postema & Breiman, 2000; SC. Westrick et al., 2017; S. C. Westrick et al., 2017). Currently, the majority of pharmacists, 91%, maintain vaccination documentation within their pharmacy and 64% provide vaccination documentation directly to the patient's physician after an immunization is provided. However only 35-50% of pharmacies report vaccinations to their IIS (U.S. Department of Health and Human Services, 2013; Westrick SC et al., 2018).

IIS have the potential to benefit patients, caregivers, providers, public health officials, and communities. Patients are provided with an accurate immunization history they can use to ensure that they have received all their needed immunizations. This also provides timely immunization when a patient moves or switches providers. Additionally, some IIS have patient portals so that patients can access their records at any time. Further, public health officials are able to use IIS to evaluate immunization programs and initiatives as well as monitor adverse events and identify under-immunized populations. Finally, IIS are beneficial to providers in that they are able to access a reliable, consolidated record from all providers and confidently recommend needed vaccines to their patients. Previous studies have demonstrated the usefulness of IIS within these contexts (Boom, Dragsbaek, & Nelson, 2007; Groom et al., 2015; Placzek & Madoff, 2011). However, provider participation is key in developing complete and accurate IIS that can be used in a meaningful way.

While some studies have examined physician perceptions and barriers related to IIS (D. A. Christakis et al., 1999; K. J. Dombkowski, S. W. Leung, & S. J. Clark, 2007; S. T. O'Leary et al., 2016; Rask, Wells, Kohler, Rust, & Cangialose, 2000), there is a gap in the literature surrounding pharmacists' experiences in implementing and using IIS. That is, limited information is available as to why community pharmacies do or do not participate in IIS. This could be because many pharmacists are not aware of IIS and their importance (Hastings, Fox, & Westrick, 2016; Westrick SC et al., 2018). Among those that are aware, they may choose not to participate based on perceptions of data incompleteness and inaccuracy when retrieving information to identify immunization gaps. Additionally, once pharmacists become aware of the IIS and enroll, they often experience difficulty implementing the IIS into their daily workflow. Participating in an IIS does require additional effort on the part of the pharmacy. Typically, larger chain pharmacies have technology that is compatible with the IIS; as such data is being reported at the corporate level to the state IIS with individual pharmacists being unaware (American Immunization Registry Association, 2015). However, this does require substantial technological upgrades required to support transferring information between systems that aren't capable for many smaller and independently owned pharmacies. To participate in the IIS, these smaller independently owned pharmacies would have to manually enter immunization data via the online IIS each time a vaccine is administered (American Immunization Registry Association, 2015). As such, it is time consuming and interrupts pharmacy workflow. Only 352 of 1,282 total pharmacies in Alabama are currently enrolled in the state IIS. When examining independent pharmacies specifically, only 27% are enrolled. Enrolling and obtaining data from independent pharmacies has been identified by the American Immunization Registry Association as a significant challenge (American Immunization Registry Association, 2015).

Problem Statement

The need for complete immunization data is essential to any immunization provider. IIS have the potential to address this need through the provision of complete and accurate immunization data provided by all immunization providers. However only 35% of pharmacists nationwide report ever entering immunization information into their respective IIS, and even less so in states like Alabama where reporting is not mandatory (U.S. Department of Health and Human Services, 2013). Causes of this low rate of participation by pharmacists have yet to be identified. While some studies have examined physician perceptions and barriers experienced related to IIS (D. A. Christakis et al., 1999; K. J. Dombkowski et al., 2007; S. T. O'Leary et al., 2016; Rask et al., 2000), there is a gap in the literature surrounding pharmacists' experiences in implementing and using IIS in the community pharmacy. In order to improve the completeness of IIS data, barriers to pharmacist participation need to be explored so that strategies can be designed to address these issues and improve participation.

The overall goal of this dissertation is to increase the use of IIS in community pharmacies. This study addresses a gap in the literature by assessing Alabama pharmacists' awareness, barriers, and attitudes toward IIS. Alabama was selected as the study state as it has one of the lowest rates of adult patient enrollment in the state IIS (Centers for Disease Control and Prevention, 2013), and about half of community pharmacies are independently owned with no technology that interfaces with the state IIS. Best practices were compiled from IIS in successful states with high participation rates. Combining the best practice strategies with identified barriers, a training program was developed to assist Alabama pharmacists in implementing IIS in their workplace. This program serves the purpose of increasing awareness and addressing pharmacists' perceived barriers related to IIS. The impact of this program on participation rates was assessed. This program can be adapted and applied to other struggling states that seek to increase pharmacy participation in the utilization of IIS.

Specific Aims

Specific Aim 1

Identify barriers of and best practices in implementing immunization information systems in independent community pharmacies.

This aim was accomplished through qualitative interviews of pharmacists and immunization information system representatives. This aim has two purposes. The first purpose was to identify motivational factors and contextual barriers from the Alabama IIS representatives and Alabama pharmacist perspectives. The second purpose was to identify best practices of IIS representatives and pharmacists in states with high IIS participation rates.

Specifically, semi-structured, in person or telephonic qualitative interviews with IIS representatives and pharmacists were conducted. Interview scripts contained open-ended questions designed to elicit barriers the IIS representatives experience in recruiting, onboarding, and working with pharmacies, as well as barriers pharmacists experience in implementing the immunization information system. The second set of interviews were designed to elicit best practices in recruiting, onboarding and working with pharmacists learned by IIS representatives in states with high participation rates, as well as best practices in implementing the IIS among community pharmacists. Open-ended interview questions were informed by the Consolidated Framework for Implementation Research (CFIR) domains including intervention characteristics, inner setting, outer setting, characteristics of individuals, and implementation process (L. Damschroder et al., 2009).

Specific Aim 2

Develop an immunization information system training program using a participatory design approach.

The purpose of this aim was to design an IIS training program tailored to the needs of pharmacists using the information gained in specific aim one. A participatory design approach was used to solicit feedback from a review panel of pharmacists and IIS representatives to refine the training program (Israel et al., 2010). This approach ensured that the training program meets the needs of end users, which are community pharmacists.

Select specific aim one interview participants were asked to join a review panel to help the researchers refine the training program. Once developed, the program was shared among the panel members. Panel members were asked to review the program and provide feedback in terms of depth and breadth of content as well as the program format. After the first round of panel review, the program was modified and sent back to the panel for review. This process continued until all panel members were satisfied with the finished product.

Specific Aim 3

Assess the impact of the immunization information system training program on community pharmacies' IIS participation rates.

The purpose of this aim was to assess the impact of the training program on pharmacists' awareness, knowledge, attitudes, intention to participate in the immunization information system, enrollment decision, and actual participation in the immunization information system. A randomized controlled trial design was employed targeting rural, independent, community pharmacies in Alabama.

Alabama pharmacists were invited to participate in the randomized controlled trial with two groups – control and intervention groups. The proposed intervention was the training program, developed in specific aim two, which consisted of an educational component to improve pharmacies' willingness to adopt the IIS and practical strategies to improve their ability to integrate the IIS into their pharmacy workflow. The intervention also included an easy to follow implementation guide to assist pharmacies in the manual data submission process and how to retrieve data to identify an immunization gap. Pharmacists' awareness, knowledge, attitudes, intention to participate in the immunization information system, enrollment, and actual participation in the IIS were assessed at various time points including baseline, one month and three months.

Study Significance

The proposed study has the potential to make significant contributions to both pharmacy practice and public health. To my knowledge, this is the first theory-based research that seeks to understand contextual barriers to participation in IIS within a pharmacy context and identify issues that may be more prevalent for specific cases. Investigating implementation factors that may influence the success of IIS uptake among community pharmacies informs this training and helps to develop a better understanding of pharmacy-based implementation decisions. As pharmacists become more involved in immunization efforts, they need to be aware of and prepared to participate in responsible immunization documentation, including use of immunization information systems. The results of this study enhance our understanding of the issues pharmacies face in incorporating IIS into daily workflow in order to inform training programs to meet the specific needs of community pharmacies. Further, no prior research has sought to intervene on pharmacists' behavior to improve IIS participation. As such, this is the first study to develop and assess the impact of a training program on pharmacist participation in state IIS reporting.

This study also has a significant impact on public health. Improving the use of IIS among pharmacies will significantly impact the ability of public health officials to assess vaccination rates. This allows public health officials to accurately track immunization coverage and develop targeted interventions to improve vaccination rates in areas with the greatest need. Improved access to consolidated vaccine information will also facilitate response efforts in the event of an outbreak or vaccine recall.

While this study aimed to improve IIS use among community pharmacies in Alabama, these resources can be replicated and used to significantly impact the completeness and accuracy of IIS across the U.S., providing the potential for IIS to be used consistently in assessing immunization status and recommending additional vaccines in the pharmacy setting, thereby improving vaccination coverage and vaccine safety.

Chapter 2. Literature Review

The literature reviewed in this chapter is separated into six key areas. First, the importance of immunizations is discussed including the history of vaccines, impact of vaccine legislation, and current immunization coverage in the United States. Second, immunization barriers including patient, provider, and healthcare-system related barriers are presented. Third, pharmacists' role in the provision of immunizations is reviewed. This includes a discussion of pharmacists as immunization providers, improved immunization coverage, and documentation of immunizations in the pharmacy setting. The fourth section describes immunization records including recommendations for immunization documentation, the benefit of consolidated and accurate immunization records, and the role of health information technology. The fifth section discusses the literature surrounding IIS including their development, benefits, accuracy of data contained within IIS, recommended processes for utilization, participation rates, policies, and implementation barriers. Finally, the literature on the Consolidated Framework for Implementation Research (CFIR) is reviewed. This includes domains included within the framework, its use in implementation research, and application of the CFIR to IIS implementation.

Importance of Immunizations

History of Vaccines

Over the past two centuries, humans have benefited from immunizations decreasing outbreaks of infectious diseases. The history of immunization begins with Dr. Edward Jenner, who administered the first smallpox vaccination in 1796 (Helfert, 2015; Jenner, 1800; Parish, 1965). Prior to this discovery, physicians attempted to reduce the risk of severe and life-threatening smallpox attacks by deliberately transmitting the disease from an infected individual to a healthy individual (Parish, 1965). This procedure, called variolation, did reduce the number of small-pox related deaths but was very risky. Healthy individuals who underwent variolation were at risk of death and of infecting other individuals in their community (Helfert, 2015; Parish, 1965). Jenner's new method, known as vaccination, proved to be superior to variolation in that side-effects and risk of becoming severely ill were minimized, and there was no risk of infecting third-persons (Parish, 1965). Thus, when Edward Jenner published his book, "An inquiry into the causes and effects of the variolae vaccinae" in 1798 (Jenner, 1800), vaccination uptake spread rapidly and was being used in most of Europe and the Americas by 1801 (Parish, 1965).

Vaccine Legislation

With vaccination becoming the officially recommended procedure, the 1800s brought the first examples of mandatory vaccination policies. In England this began with The Vaccination Act of 1853, imposing fines or imprisonment on parents who did not vaccinate their children by three months of age (Porter & Porter, 1988). In 1867, this law was expanded to include all children under 14 years of age. These policies didn't reach the United States until the early 1900s when the Supreme Court ruled that states had the right to impose and enforce mandatory vaccination policies (Omer, Salmon, Orenstein, Dehart, & Halsey, 2009). As new vaccines were developed, the United States relied on ad hoc committees to advise on the safety and use of individual vaccines (J. C. Smith, Hinman, & Pickering, 2014). In the 1960s, it was decided that a single committee should be developed to provide expert advice on national immunization policy. The Surgeon General of the U.S. Public Health Service created the Advisory Committee on Immunization Practices (ACIP) in 1964 (Advisory Committee on Immunization Practices, 2012;

J. C. Smith et al., 2014). This committee brought together experts from public health, epidemiology, immunology, preventive medicine, and pediatrics to advise on immunization schedules and recommendations (J. C. Smith et al., 2014). The number of available vaccines has increased tremendously from six recommended for children and adolescents when the committee was established in 1964, to 16 today, in addition to those recommended for adults (Table 2.1) (Advisory Committee on Immunization Practices, 2017a, 2017b; J. C. Smith et al., 2014).

Table 2.1 Available vaccines for all ages by disease, 2018 (Advisory Committee on Immunization Practices, 2017a, 2017b)

Disease	Types of vaccines available	Disease spread by	Disease symptoms
Adenovirus	Adenovirus vaccine	Air, direct contact	Sore throat, bronchitis, pneumonia, diarrhea, pink eye, fever, bladder infection
Anthrax	AVA (BioThrax)	Contact or inhaling spores	Skin ulcer, difficulty breathing
Diphtheria	DTaP (Daptacel, Infanrix) Td (Tenivac, generic) DT (-generic-) Tdap (Adacel, Boostrix) DTaP-IPV (Kinrix, Quadracel) DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel)	Air, direct contact	Sore throat, mild fever, weakness, swollen glands in neck
Hib	Hib (ActHIB, PedvaxHIB, Hiberix) MenCY-Hib (MenHibrix) DTaP-IPV/Hib (Pentacel)	Air, direct contact	May be no symptoms unless bacteria enter the blood
Hepatitis A	HepA (Havrix, Vaqta) HepA-HepB (Twinrix)	Direct contact, contaminated food or water	May be no symptoms, fever, stomach pain, appetite loss, fatigue, vomiting, jaundice, dark urine
Hepatitis B	HepB (Engerix-B, Recombivax HB) DTaP-HepB-IPV (Pediarix)	Contact with blood or body fluids	May be no symptoms, fever, headache, weakness, vomiting, jaundice (yellowing of skin and eyes), joint pain

	HepA-HepB (Twinrix)		
Human Papillomavirus	HPV9 (Gardasil 9) HPV4 (Gardasil) HPV2 (Cervarix)	Intimate skin-to-skin contact	May be no symptoms, genital warts, cancer
Influenza (Flu)	IIV (Afluria, Fluad, Flublok, Flucelvax, FluLaval, Fluarix, Fluvirin, Fluzone, Fluzone High-Dose, Fluzone Intradermal) LAIV (FluMist)	Air, direct contact	Fever, muscle pain, sore throat, cough, extreme fatigue
Japanese Encephalitis	JE (Ixiaro)	Infected mosquito bite	Fever, headache, brain infection
Measles	MMR (M-M-R II) MMRV (ProQuad)	Air, direct contact	Rash, fever, cough, runny nose, pinkeye
Meningococcal	MenACWY (Menactra, Menveo) MPSV4 (Menomune) MenCY-Hib (MenHibrix) MenB (Bexsero, Trumenba)	Exchange of respiratory and throat secretions	Fever, headache, stiff neck, nausea, vomiting, photophobia, altered mental status
Mumps	MMR (M-M-R II) MMRV (ProQuad0	Air, direct contact	Swollen salivary glands (under the jaw), fever, headache, tiredness, muscle pain
Pertussis	DTaP (Daptacel, Infanrix) Tdap (Adacel, Boostrix) DTaP-IPV (Kinrix, Quadracel) DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel)	Air, direct contact	Severe cough, runny nose, apnea (a pause in breathing in infants)
Pneumococcal	PCV13 (Prevnar13) PPSV23 (Pneumovax 23)	Air, direct contact	May be no symptoms, pneumonia (infection in the lungs)
Polio	Polio (Ipol) DTaP-IPV (Kinrix, Quadracel) DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel)	Air, direct contact, through the mouth	May be no symptoms, sore throat, fever, nausea, headache
Rabies	Rabies (Imovax Rabies, RabAvert)	Saliva of infected animals	Fever, headache, excess salivation, muscle spasms, paralysis, mental confusion
Rotavirus	RV1 (Rotarix) RV5 (RotaTeq)	Through the mouth	Diarrhea, fever, vomiting

Rubella	MMR (M-M-R II) MMRV (ProQuad)	Air, direct contact	Children infected with rubella virus sometimes have a rash, fever, swollen lymph nodes
Shingles	Shingrix (recombinant zoster vaccine, RZV) Zostavax (live-attenuated vaccine, ZVL)	Reactivated chickenpox virus	Painful rash with blisters
Smallpox	Vaccinia (ACAM2000):	Air, direct contact, through the mouth	Fever, body aches, vomiting, rash
Tetanus	DTaP (Daptacel, Infanrix) Td (Tenivac, generic) DT (-generic-) Tdap (Adacel, Boostrix) DTaP-IPV (Kinrix, Quadracel) DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel)	Exposure through cuts in skin	Stiffness in neck and abdominal muscles, difficulty swallowing, muscle spasms, fever
Tuberculosis	BCG vaccine	Air, direct contact	May be no symptoms, cough, weight loss, night sweats, fever
Typhoid Fever	Ty21a Vi capsular polysaccharide	Contaminated food or water	High fever, headache, stomach pain, constipation, diarrhea
Varicella (Chickenpox)	VAR (Varivax) MMRV (ProQuad):	Air, direct contact	Rash, tiredness, headache, fever
Yellow Fever	YF (YF-Vax)	Infected mosquito bite	Fever, chills, headache, backpain, body aches, nausea, vomiting, fatigue

The majority of recommended vaccines are administered before a child reaches six years of age (Advisory Committee on Immunization Practices, 2017b). At birth, a newborn will receive the first dose of the vaccine protecting against Hepatitis B. Once they have reached one to two months, they will receive the second dose of the Hepatitis B vaccine, as well as diptheria, tetanus, and whooping cough (pertussis) (DTaP), Haemophilus influenza type b (Hib), polio (IPV), pneumococcal (PCV), and rotavirus (RV) (Table 2.2).

Table 2.2 Recommended vaccines by age, 2018 (Advisory Committee on Immunization Practices, 2017b)

Age	Recommended vaccines
Birth	Hep B
1 month	Hep B
2 months	RV, DTap, Hib, PCV, IPV
4 months	RV, DTaP, Hib, PCV, IPV
6 months	RV, DTaP, Hib, PCV, IPV, Influenza (yearly)
12-23 months	Hib, PCV, MMR, Varicella, Hep A, Hep B, DTaP, IPV, Influenza (yearly)
2-3 years	Influenza (yearly)
4-6 years	DTaP, IPV, MMR, Varicella, Inluenza (yearly)
7-10 years	Influenza (yearly)
11-12 years	Meningococcal conjugate, HPV Tdap, Influenza (yearly)
13-18 years	Influenza (yearly)
19-26 years	Influenza (yearly), Td or Tdap, HPV, any vaccines recommended for job or school related requirements
27-60 years	Influenza (yearly), Td booster every 10 years, any vaccines recommended for job or school related requirements, Zoster (2 doses of RZV at age 50 or older preferred OR 1 dose of ZVL at age 60 or older)
60 years or older	Influenza (yearly), Td booster every 10 years, pneumococcal (65 or older),

Immunization Coverage in the U.S.

As a result of the widespread availability of these vaccines, significant declines in vaccine-preventable diseases have been observed. Smallpox averaged 48,164 cases and 1,528 deaths per year in the early 1900s (Centers for Disease Control and Prevention, 1999). Today, smallpox has been eradicated and routine vaccination efforts have ceased (Fenner, Henderson, Arita, Jezek, & Ladnyi, 1988). The polio vaccine became available in the United States in 1955 (Centers for Disease Control and Prevention, 1999). Prior to this, an average of 16,316 paralytic polio cases and 1,879 deaths resulted from polio each year (Centers for Disease Control and Prevention, 1981, 1999). Polio has been eliminated in the U.S. since 1979, when the last case of polio originating in the U.S. was observed (Centers for Disease Control and Prevention, 1994). Polio can be brought into the U.S. by foreign travelers, the last known occurrence being 1993 (Centers for Disease Control and Prevention, 1999). Global efforts to eradicate polio have made progress in recent years, with a 79% decrease in the number of polio cases worldwide in 2015 compared to 2014 (Morales, 2016). The measles and hib vaccines have also led to significant improvements in morbidity in the U.S. (Centers for Disease Control and Prevention, 1999). However, despite these accomplishments, vaccine-preventable diseases still exist.

U.S. vaccination rates for the population as a whole look promising, especially for routine childhood vaccinations (Figures 2.1 and 2.2) (Centers for Disease Control and Prevention, 2016b). However this coverage can vary substantially depending on the location.

Figure 2.1 Routine childhood vaccination coverage rates (Centers for Disease Control and Prevention, 2016b)

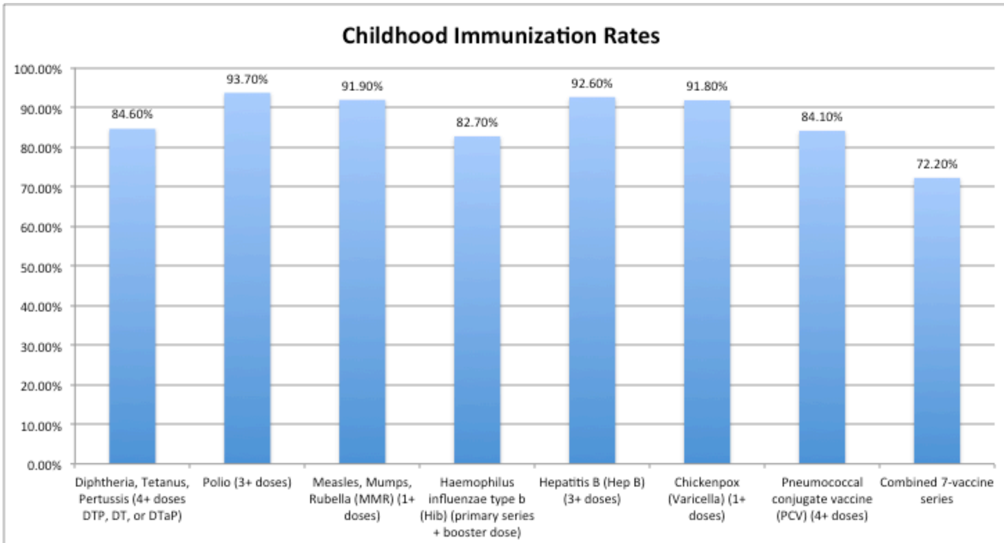
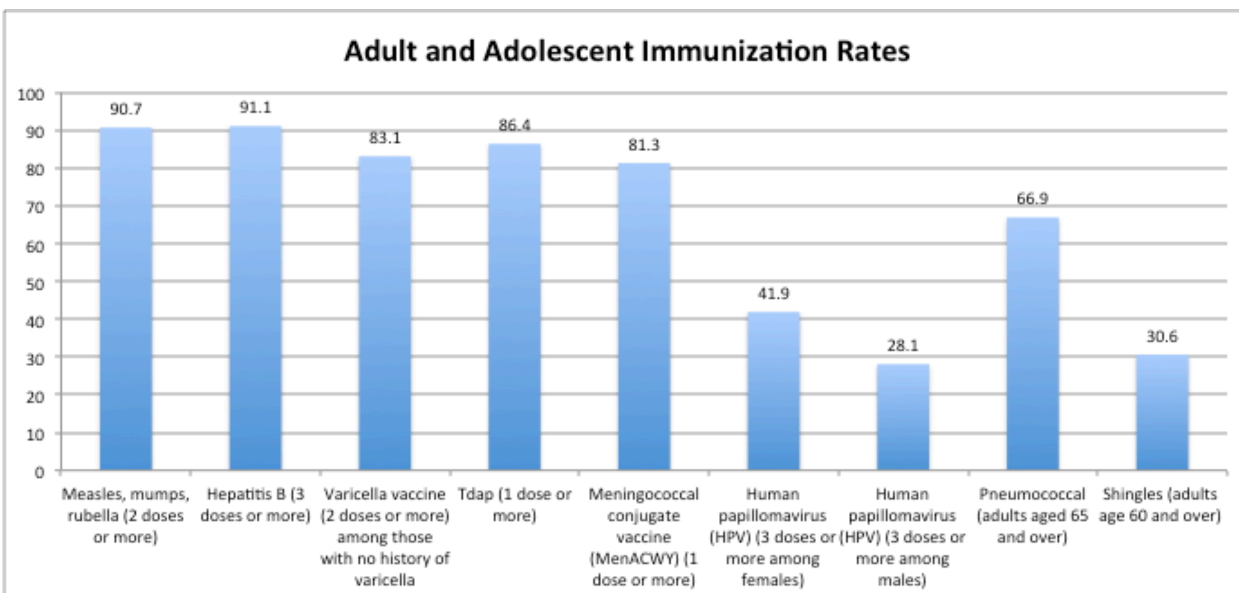


Figure 2.2 Adolescent and adult vaccination coverage rates (Centers for Disease Control and Prevention, 2016b)



Barriers to Immunization

A number of barriers may contribute to inadequate immunization coverage. These barriers impact immunization coverage in the U.S. and the burden of vaccine-preventable diseases. The barriers described in the following sections can be classified into three categories: 1) patient barriers, 2) provider barriers, and 3) healthcare system barriers (Burns & Zimmerman, 2005).

Patient Barriers

Acceptance of vaccination is a complicated decision-making process that is influenced by a number of factors. Vaccine hesitancy, also referred to as vaccine confidence, is defined by the Strategic Advisory Group of Experts (SAGE) Working Group on Vaccine Hesitancy as "a delay in acceptance or refusal of vaccination despite availability of vaccination services." (MacDonald, 2015). The "3 Cs" model of vaccine hesitancy suggests three primary factors influencing vaccine hesitancy including confidence, complacency, and convenience (MacDonald, 2015). Confidence is defined as trust in the safety and effectiveness of the vaccine and in the healthcare providers and policymakers who recommend them. Barriers related to patients or parents of children who need immunization are most often attributed to fear and lack of knowledge. In order for a patient to receive a vaccine they must be comfortable with the evidence provided that the vaccine is safe and effective. Vaccine complacency refers to low perceived risk of vaccine-preventable diseases, deeming the vaccine as unnecessary. Studies have shown that parents perceive non-immunization to be less risky for their children than immunization, and that natural immunity resulting from exposure to disease is superior to vaccination (Prislin, Dyer, Blakely, & Johnson, 1998; Smailbegovic, Laing, & Bedford, 2003). The third factor, convenience, is related to the ability of the patient to understand immunization services and their appeal. In order to accept vaccination, the patient must first be aware that the vaccine is needed. Parents often make these decisions for their children and lack of immunization has been shown to be correlated with low health literacy and parental confusion regarding complex vaccination schedules (Taylor et al., 2002). In addition to the 3 C's, lack of physician recommendation has been found to be associated with lower rates of vaccination (Johnson, Nichol, & Lipczynski, 2008). Most patients report that they are likely to follow provider recommendations regarding vaccination (Johnson et al., 2008; Nichol, Mac Donald, & Hauge, 1996). However, providers face a number of barriers themselves in recommending and providing appropriate vaccines.

Provider Barriers

Providers may also face barriers related to lack of knowledge. This can include indications for and contraindications to specific vaccines (Burns & Zimmerman, 2005). Frequently changing recommendations and schedules for an increasing number of vaccines can be difficult for providers to maintain (Burns & Zimmerman, 2005). This is compounded by specific recommendations for high-risk categories of individuals. Studies have shown that physicians often lack the knowledge necessary to recommend vaccines according to immunization schedules (Prislin et al., 2002; Zimmerman, Mieczkowski, Mainzer, Medsger, & Nowalk, 2002). Another barrier faced by providers is a lack of adequate information regarding patients' immunization status (Burns & Zimmerman, 2005). Providers may not have complete immunization records for their patients due to increasing fragmentation of care (Burns & Zimmerman, 2005). This often makes it difficult for providers to determine which vaccines a patient needs, leading to over and under-immunization. IIS can provide the complete immunization records that are needed to make appropriate recommendations, but most physicians do not take advantage of this resource (Schaffer, Humiston, Shone, Averhoff, &

Szilagyi, 2001). Missed opportunities can also occur due to lack of or incorrect assessment of immunization status by providers when they in fact do have the necessary information. Studies show that most providers assess immunization status during well-child visits but fail to complete this task during sick-child visits (Schaffer et al., 2001; S. W. Smith et al., 1999). Both physicians and office nurses have reported lack of time as the greatest barrier to assessing immunization status at all visits (T. C. Davis et al., 2001).

Healthcare System Barriers

In addition to patient and provider-related barriers, there are a number of barriers to immunization related to the healthcare system. These can include difficulties in finding available vaccine providers, lack of transportation, vaccine unavailability, and vaccine affordability. Difficulty accessing vaccine providers is of particular concern for patients in rural areas who must travel further distances to reach a provider able to administer needed vaccines (Gore et al., 1999). This can be especially difficult for patients who have difficulty finding adequate transportation (Gore et al., 1999). Clinics that are difficult to reach, with limited hours and long wait times leave many children with minimal preventive care visits (Gore et al., 1999; Yawn, Xia, Edmonson, Jacobson, & Jacobsen, 2000). In contrast, some providers fail to offer immunizations, citing low reimbursement rates that often do not cover the cost of providing the vaccine (Burns & Zimmerman, 2005). Further, cost is a concern for many parents who may be uninsured or who do not have a plan covering the cost of routine vaccines (Burns & Zimmerman, 2005). Under the Affordable Care Act most health plans are required to cover vaccinations recommended by the Advisory Committee on Immunization Practice (ACIP) with no cost-sharing for the patient (The Henry J. Kaiser Family Foundation, 2015). In addition, the federally-funded Vaccines for Children Program (VFC) provides immunizations for children who are either uninsured or insured through Medicaid (Brenner, Simons-Morton, Bhaskar, Das, & Clemens, 2001). However not all eligible children are aware of this program, and those who are aware may still face barriers previously discussed such as transportation problems that prevent them from obtaining needed vaccines. In order to address some of these barriers, the use of non-traditional settings and providers has been suggested as a means to improving vaccination coverage.

Pharmacists' Role in the Provision of Immunizations

Pharmacists as Immunization Providers

Over the past few decades, the role of pharmacy has shifted from dispensing and compounding to a greater focus on patient care services. Pharmacists are now working with physicians, nurses, and other healthcare providers to perform medication therapy management, preventive care screenings, smoking cessation, health education, and immunizations among other patient care services (Abramowitz, 2009; Chisholm-Burns, 2012; Gable, 1998). One of the most successful expansions of the pharmacists' role is in the area of immunization (Hogue, Grabenstein, Foster, & Rothholz, 2006). Given their accessibility within the community, being located in almost every town in the U.S., with 93% of American citizens living within five miles of a pharmacy, pharmacists are uniquely positioned to serve as immunization providers (Seib et al., 2013). In addition to their ease of access, pharmacies also do not require appointments and maintain longer hours of operation than traditional providers. Further, pharmacists are perceived as trustworthy by patients, possibly even more trustworthy than physicians (Meyerson, Ryder, & Richey-Smith, 2013). Because of this, many patients identify pharmacies as a preferred setting for receiving immunizations (R. C. Burson, A. M. Buttenheim, A. Armstrong, & K. A. Feemster, 2016; Ernst, Bergus, & Sorofman, 2001; SC Westrick et al., 2017).

Pharmacists have been providing immunizations in the community setting since the 1990s. This expansion in pharmacists' role led many states to develop legislation allowing collaborative practice agreements between pharmacists and physicians, expanding their capacity as immunization providers (Hammond et al., 2003). Currently all 50 U.S. states allow pharmacists to provide immunizations in some capacity (Brewer, Chung, Baker, Rothholz, & Smith, 2014). However laws vary from state to state in terms of the age of vaccine recipient, vaccine type, reporting and documentation, pharmacist training, and the ability of pharmacists to furnish the vaccine.

Pharmacists Improve Immunization Coverage

Pharmacists have become more involved in the provision of vaccines from 6% of adults receiving immunizations in a community pharmacy setting during the 2004-2005 season to 25% during the 2015-2016 season (R. C. Burson et al., 2016; Kennedy et al., 2012). Research has shown that with increasing pharmacist involvement, vaccination coverage improves. A review assessing pharmacists as immunization providers found a significant difference in immunization rates when pharmacists were used as vaccine administrators (Isenor et al., 2016). One such study specifically found that allowing pharmacists to provide immunizations led to higher rates of influenza vaccination in a population of patients aged 65 and older (Steyer, Ragucci, Pearson, & Mainous, 2004). A second study found that pharmacists can have a substantial impact on the provision of vaccinations specifically in rural locations (Bearden & Holt, 2005). As the success of pharmacists as immunization providers becomes more apparent and the number and type of vaccine providers continues to expand, accurate documentation of immunization records is critical to providing safe and effective vaccination.

Pharmacy Documentation of Immunizations

As pharmacies become more prominent as a setting for the provision of immunizations, their documentation practices must be considered. Recommendations are provided by the National Vaccine Advisory Committee (NVAC) Standards for Adult Immunization Practice to ensure that administered vaccinations are adequately documented (National Vaccine Advisory Committee, 2014). The recommendations specific to community pharmacies include 1) providing the patient with a record of the vaccines administered, 2) reporting to the patient's primary care provider, and 3) recording administered vaccines in the state or regional immunization information system. A survey examining pharmacists' immunization practices found that 91% of pharmacists maintain documentation within the pharmacy (U.S. Department of Health and Human Services, 2013). About 69% of these pharmacists also provide patients with a record of the immunization. However, pharmacists report that only 58% of patients provide them with the contact information necessary to notify the patient's primary care provider. About 3 of 5 pharmacists (63%) do manage to provide this documentation to the patient's physician, but the remaining 37% who do not are contributing to the issue of incomplete immunization information among providers. Further, only 35% report recording administered vaccines in their state or regional immunization information system. Inadequate documentation of immunizations within the pharmacy setting, including lack of reporting to physicians and the immunization information system, has been cited as a concern among both patients and primary care providers. This has led patients to forego seeking immunization in the community pharmacy setting due to perceived improper documentation (S. C. Westrick et al., 2017). Physicians also report inadequate pharmacy documentation practices as a barrier to collaboration in the provision of immunizations (Bergus et al., 2001; S Postema & Breiman, 2000). Improving documentation within the pharmacy setting is critical to not only improving immunization delivery in the community pharmacy setting, but also in ensuring that appropriate vaccines are administered in a safe and effective manner.

Immunization Records

Traditionally, immunizations have been documented in the medical record of the physician's office where they were administered. As discussed, this method alone has become problematic with the increased fragmentation of information coinciding with a greater number of immunization providers. Not having complete immunization history due to lack of record sharing between settings prevents healthcare providers from making timely and accurate decisions (Centers for Disease Control and Prevention, 2012). Further, redundant vaccination adds to unnecessary healthcare spending and may not be reimbursed by payers (Theuns, 2015).

Benefits of Consolidated and Accurate Immunization Records

Consolidated immunization records benefit patients, caregivers, providers, public health officials, and communities (Centers for Disease Control and Prevention, 2012). Patients with access to accurate immunization records can ensure that they have received all their needed immunizations and will therefore be protected from vaccine-preventable diseases (American Academy of Pediatrics, 2018). This also enables patients to receive timely immunization if they move or switch providers. Further, complete immunization records that are accessible in one location allow for patients to obtain official documentation that is often needed for school or daycare registration.

Immunization records containing accurate, up-to-date information are essential at the point of clinical care. Providers need a reliable history of patients' immunization in order to determine which immunization a patient may need and which have already been obtained elsewhere. Without this information it becomes nearly impossible for providers to determine appropriate vaccinations a patient may need and ensure that individuals are not over or under-vaccinated. Consolidated records equip providers with this information so they are able to reliably assess a patient's immunization status and recommend additional needed vaccines, thereby improving the care provided in their practice (American Academy of Pediatrics, 2018). Further, reducing missed opportunities to immunize will improve patient immunization rates, which may be linked with HEDIS scores and Pay for Performance programs (American Academy of Pediatrics, 2018). Finally, consolidated vaccine information reduces the provision of redundant vaccines, for which the provider is unable to be reimbursed (Theuns, 2015).

Accurate immunization data is also a necessity in the field of public health. Public health officials are tasked with evaluating immunization programs and initiatives. Consolidated records allow them to monitor vaccination rates and ensure that providers are following up to date recommendations (Groom et al., 2015). This technology also allows for the facilitation of response efforts and recalls at the population level during times of outbreak. The safety and effectiveness of vaccines are continuously monitored and without complete records, it becomes difficult for public health officials to track adverse events and identify under-immunized populations (Groom et al., 2015).

The identification of under-immunized populations and tracking of outbreaks is also an important benefit of complete vaccination records from the community perspective. Accurate immunization information helps to prevent disease outbreaks by ensuring that community residents are up-to-date on immunizations. An example of the impact of under-immunization on community health is the occurrence of several measles outbreaks in recent years (Gahr et al., 2014; Gastañaduy et al., 2016; Hall et al., 2017). Consolidated immunization data, which improves immunization rates, not only reduces the potential for outbreaks, but also protects vulnerable individuals within communities who are unable to be vaccinated including infants, elderly, and those with weakened immune systems (Jordan et al., 2006).

Health Information Technology

Technology has been used as a means to connect health information across providers for decades. Technology specific to immunization delivery gained momentum in the healthcare world in the early 1990s, after a nationwide measles epidemic. Approximately 46,000 cases of measles were reported in the U.S. After the outbreak, it was determined that the inability of the healthcare system to determine if individual patients had been immunized contributed to the severity of this outbreak (Henderson, Dunston, Fedson, & et al., 1991). In order to prevent future outbreaks such as this, the National Vaccine Advisory Committee (NVAC) recommended improving electronic immunization records through the use of IIS (Henderson et al., 1991).

In 2009, this effort was supported by the American Reinvestment & Recovery Act (ARRA) (Centers for Disease Control and Prevention, 2016a). The ARRA included a goal of increasing the “meaningful” use of Electronic Health Record (EHR) systems among various healthcare professionals. To achieve this goal, ARRA funds were used to establish an incentive program to encourage providers to adopt EHR systems. In order to receive these incentives, providers must meet various criteria related to immunization documentation. For example, one criterion is to establish a connection between the provider’s EHR and the IIS within the provider’s jurisdiction. These provisions have encouraged healthcare providers to work with public health officials in improving the documentation of immunizations through immunization information systems.

Immunization Information Systems

Also known as immunization registries, immunization information systems (IIS) are confidential computerized databases that record and consolidate immunization doses administered by participating providers within a defined geographic area (Count & Poliomyelitis, 2001). Among their many attributes, IIS make outreach efforts to reach under immunized populations much more effective. Some IIS are able to integrate recall notices sent either by mail or telephonically to patients who are missing an immunization (Wood, Saarlas, Inkelas, & Matyas, 1999). Twelve key attributes of IIS have been identified by the National Vaccine Advisory Committee (Table 2.3) (Wood et al., 1999).

Table 2.3 Key functions of immunization information systems

1. Consolidate all immunization records from multiple providers.
2. Permit providers to electronically retrieve information on all immunization records at the time of encounter.
3. Permit providers to electronically submit information on all immunization encounters on the same day as vaccine administration.
4. Protect confidentiality and security of the IIS's medical information.
5. Recover lost data.
6. Exchange immunization records between IIS using Health Level 7 (HL7) standards.
7. Forecast immunizations needed at medical encounters, based on recommendations from the Advisory Committee on Immunization Practices.
8. Produce recalls for individuals who are late for immunizations.
9. Produce immunization coverage reports.
10. Print official immunization records and certificates of immunization for patients.
11. Electronically store data on all National Vaccine Advisory Committee—approved core data elements.
12. Link electronically with birth certificate data to automatically populate the IIS

As stated previously, consolidated immunization information is beneficial to healthcare providers, patients, and the healthcare system as a whole. As such, the most prominent function of IIS is their ability to consolidate all immunization records from any provider who has administered a vaccine for a particular patient. However, this function does rely on the participating providers to have up-to-date technology to automatically upload or to manually enter vaccination information to the specific IIS in the case of incompatible technology. For example, most IIS are able to link to birth certificate IIS and automatically create a patient profile for newborns (Wood et al., 1999). In 2012, 83% of IIS were able to establish newborn records within six weeks of birth (Centers for Disease Control and Prevention, 2013). However this is also reliant on hospitals having up to date technology, otherwise this information must be manually entered in order to ensure up-to-date information in the IIS.

Development of IIS

It should be noted that there is not a national IIS in the United States. Thus, each of the attributes listed in Table 2.3 above are dependent on the individual IIS's capabilities. In 1993 legislation was proposed as part of the Comprehensive Child Immunization Act to create a national IIS (Count & Poliomyelitis, 2001). When this legislation was not passed, each state was left to develop and maintain their own IIS to monitor immunization status. State IIS function independently and states have the authority to develop legislation surrounding the function of their IIS as they see fit. Policies that vary between IIS are focused on the privacy, confidentiality, and security of patient information. However in order to allow for the exchange of records between states, all states must include core data elements in their IIS (Robyn et al., 1997; Wood et al., 1999). These elements are categorized as either required or optional (Table 2.4).

Table 2.4 Immunization information system core data elements (Wood et al., 1999)

Required vs. Optional	**Data Item**
Required	Patient name: first, middle, last
	Patient birth date
	Patient sex
	Patient race
	Patient ethnicity
	Patient birth order
	Patient birth State/country
	Mother's name: First, middle, last, maiden
	Vaccine Type
	Vaccine Manufacturer
	Vaccination date
	Vaccine lot number
Optional	Patient status indicators (active/inactive)
	Patient alias name: first, middle, last
	Patient address, phone number
	Birthing facility
	Patient Social Security number (SSN)
	Patient birth registration number
	Patient Primary language
	Patient Medicaid number
	Mother's SSN
	Father's name: first, middle, last
	Father's SSN
	Vaccine dose number
	Vaccine expiration date
	Vaccine injection site
	Vaccine provider
	Historical vaccination flag indicator
	VFC eligibility
	History of varicella disease indicator

Benefits of Immunization information systems

IIS are active or in development in every state in the U.S. While many are still being developed, significant achievements have already been reported resulting from the use of more advanced immunization information systems. For example, in the days following Hurricane Katrina nearly 200,000 New Orleans residents evacuated to Houston, Texas. The personal records for most of these individuals had been left behind or lost in the catastrophe. In order to assist public health officials and healthcare workers caring for the evacuees in temporary shelters, the Houston-Harris County IIS and the Louisiana Immunization Network for Kids Statewide were able to be linked, allowing healthcare workers in Houston to access evacuees' records (Boom et al., 2007). This effort allowed for the immunization status of children with a record in the IIS to be verified, meaning that they did not have to be revaccinated, saving approximately $3.04 million (Boom et al., 2007). Several other studies have also demonstrated the critical role IIS have played in outbreaks and responses to public health emergencies (Boom et al., 2007; Bronson-Lowe, Gosney, Goodykoontz, Fredrickson, & Anderson, 2007; Centers for Disease Control and Prevention, 2006; Crielly & Castora, 2006; Denious, 2006; Gosney, Conklin, & Fredrickson, 2006; Groom et al., 2015; Wilson, Gaudino, Dumont, Carlson, & Skiles, 2006).

When examining the potential of immunization information systems, one systematic review found that providers' use of IIS has impacted a range of health outcomes (Groom et al., 2015). One study found that in Australia the implementation of the IIS in 1996, coupled with provider incentives, led to an improvement in the percentage of children at two years of age who had reached full immunization status; from 64% in 1997 to 92.7% in 2007 (Hull, Deeks, & McIntyre, 2009). Among several studies examining the impact of the reminder and recall functionalities of IIS on vaccination rates, the median improvement was 6% (Daley et al., 2004; Daley et al., 2002; Dombkowski, Harrington, Dong, & Clark, 2012; Groom et al., 2015; Hambidge et al., 2004; Hambidge, Phibbs, Chandramouli, Fairclough, & Steiner, 2009; Irigoyen et al., 2006; Kempe et al., 2005; LeBaron, Starnes, & Rask, 2004; Stockwell, Kharbanda, & Martinez, 2010). Studies examining how the ability of providers to assess immunization status using an IIS impacted vaccination rates found that rates improved by a median of 9%, ranging from 5-15% (Groom et al., 2015). One such study evaluated the use of provider reminder systems within an immunization information system, finding that this function increased vaccination rates by over 14% (Groom et al., 2015). IIS have also been used to evaluate vaccine safety and effectiveness (Allison et al., 2006; Boom et al., 2010; Gold, Dugdale, Woodman, & McCaul, 2010; Guh & Hadler, 2011). Countless more studies have evaluated IIS in the context of public health decision support (Centers for Disease Control and Prevention, 2007, 2008, 2009; Daskalaki, Spain, Long, & Watson, 2008; Dombkowski et al., 2012; Feemster, Spain, Eberhart, Pati, & Watson, 2009; Phibbs, Hambidge, Steiner, & Davidson, 2006; Robison, Kurosky, Young, Gallia, & Arbor, 2010; "Seasonal influenza vaccination coverage among children aged 6 months-18 years --- eight immunization information system sentinel sites, United States, 2009-10 influenza season," 2010).

Completeness and Accuracy of IIS Data

While the positive outcomes of IIS in terms of increasing vaccination rates have been confirmed by a great deal of research, a concern has been raised about the quality of data stored in these IIS. The data available in IIS is only complete and accurate if all providers are participating and providing this information accurately and in a timely manner. The literature shows mixed results when assessing the completeness and accuracy of IIS (Bosch-Capblanch, Ronveaux, Doyle, Remedios, & Bchir, 2009; Groom et al., 2015; Hastings et al., 2017). A systematic review comparing the completeness of IIS data to other sources of information found that IIS data was more complete than medical records in four of the nine comparisons and more complete than patient personal records in only three of six comparisons (Hastings et al., 2017). These results show that the completeness of IIS needs to be improved in order for providers to rely on this data to make decisions. Improving provider participation is key to reaching complete and accurate IIS data. This confirms the need for additional research to improve the adoption of IIS by providers.

Recommended Process for IIS Utilization

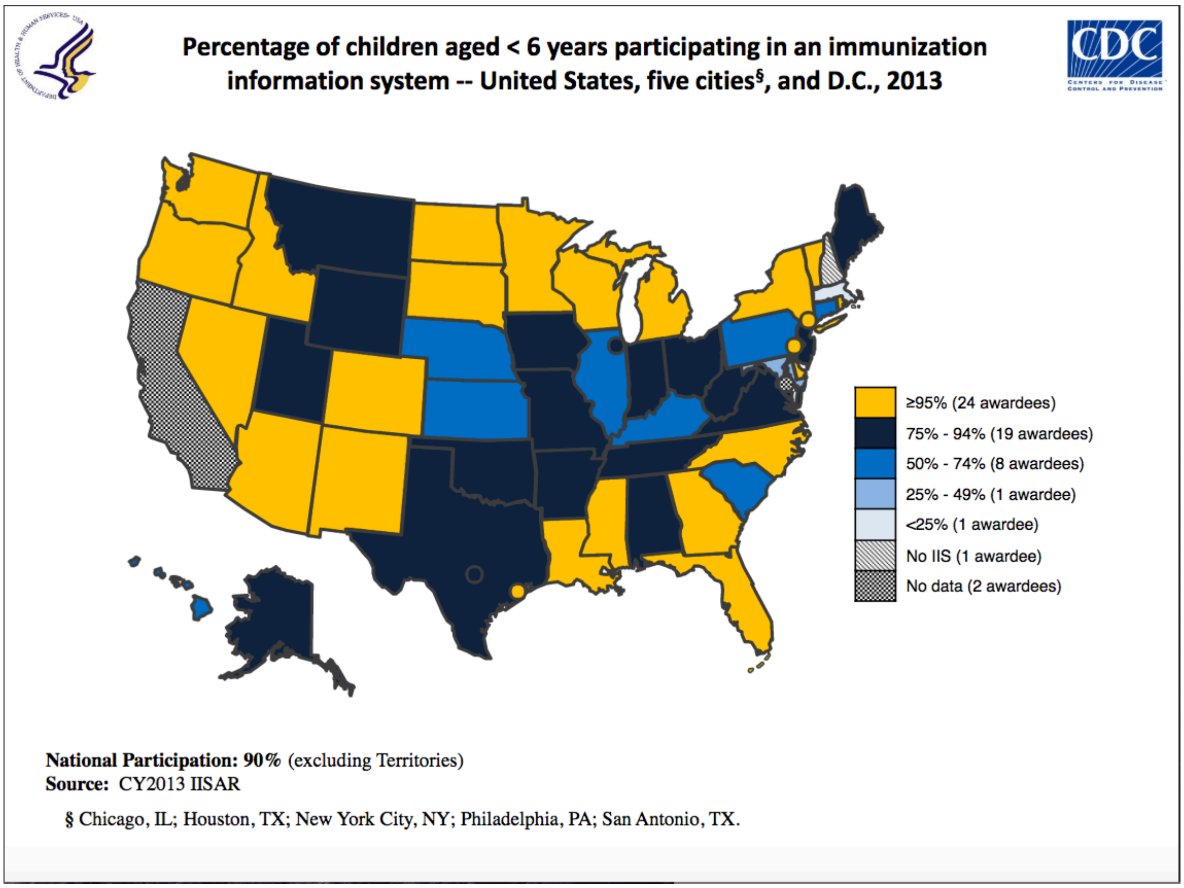
Ideally, when providers participate in an immunization information system, their process would flow as described in Figure 2.3. First, when a patient is identified the provider would check the IIS and identify any needed vaccines that have not been administered elsewhere. After discussing the need of being vaccinated with the patient, the provider would then administer the needed vaccine(s). Finally, the provider would document the vaccine(s) administered including updating the immunization information system. However, in reality most providers don't utilize their IIS in this manner, if at all, leading to missed opportunities and low IIS participation rates, particularly for adolescents and adults.

Figure 2.3 Ideal IIS utilization

IIS Participation Rates

The success of an IIS is measured primarily by the percentage of patients within the IIS's jurisdiction who have a patient profile in the immunization information system. This includes any patient with at least one immunization recorded in the IIS. It is important to note that this measure does not consider the completeness or accuracy of the patient's record. Currently, the percentage of children with patient profiles in their respective IIS is promising, with the majority of states having more than 95% of children enrolled (Figure 2.4) (Centers for Disease Control and Prevention, 2013). This can likely be attributed to the ability of most IIS to link to birth certificate IIS, automatically creating a patient profile for most newborns.

Figure 2.4 Percentage of children participating in an IIS (Centers for Disease Control and Prevention, 2013)



However the participation for adolescents and adults is much lower, with the majority of states having 50-74% and 25-49% of adolescents and adults enrolled, respectively (Figures 2.5 and 2.6). In Alabama, less than 25% of adults have a patient profile in the Alabama state immunization information system.

Figure 2.5 Percentage of adolescents participating in an IIS (Centers for Disease Control and Prevention, 2013)

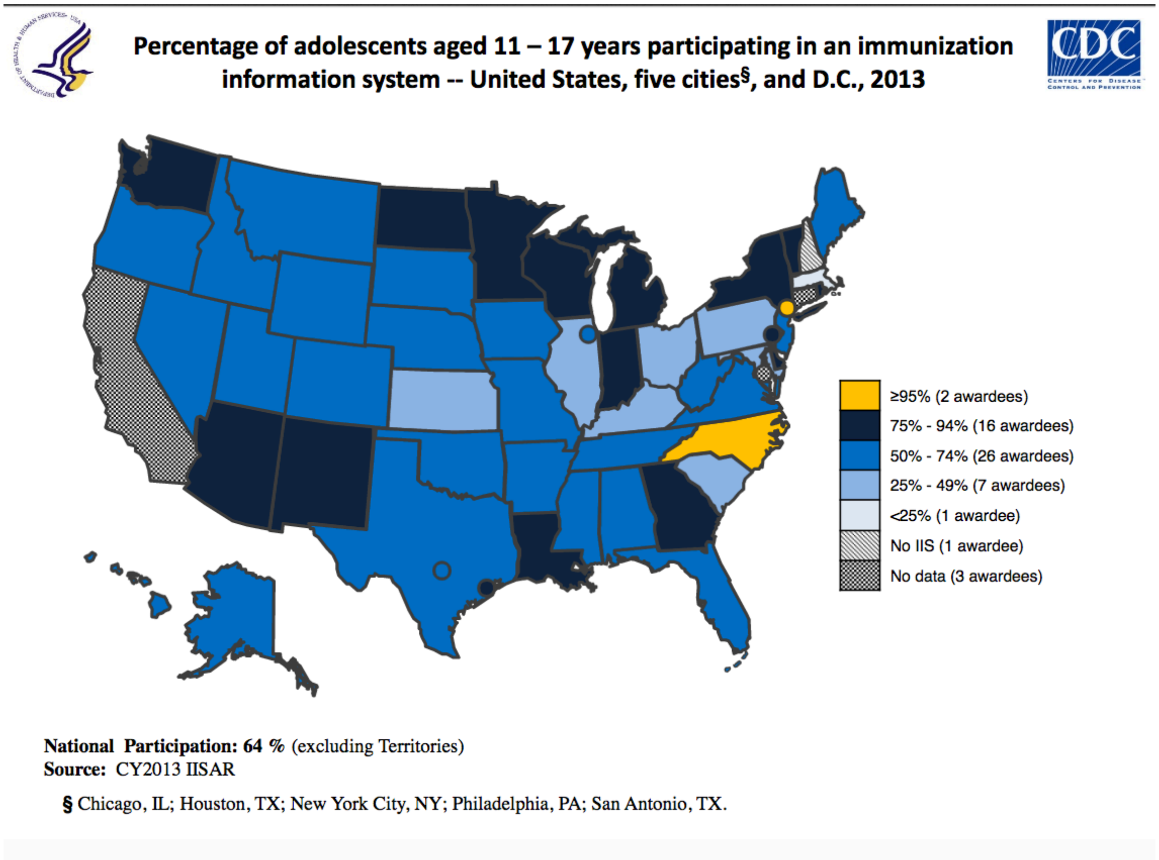
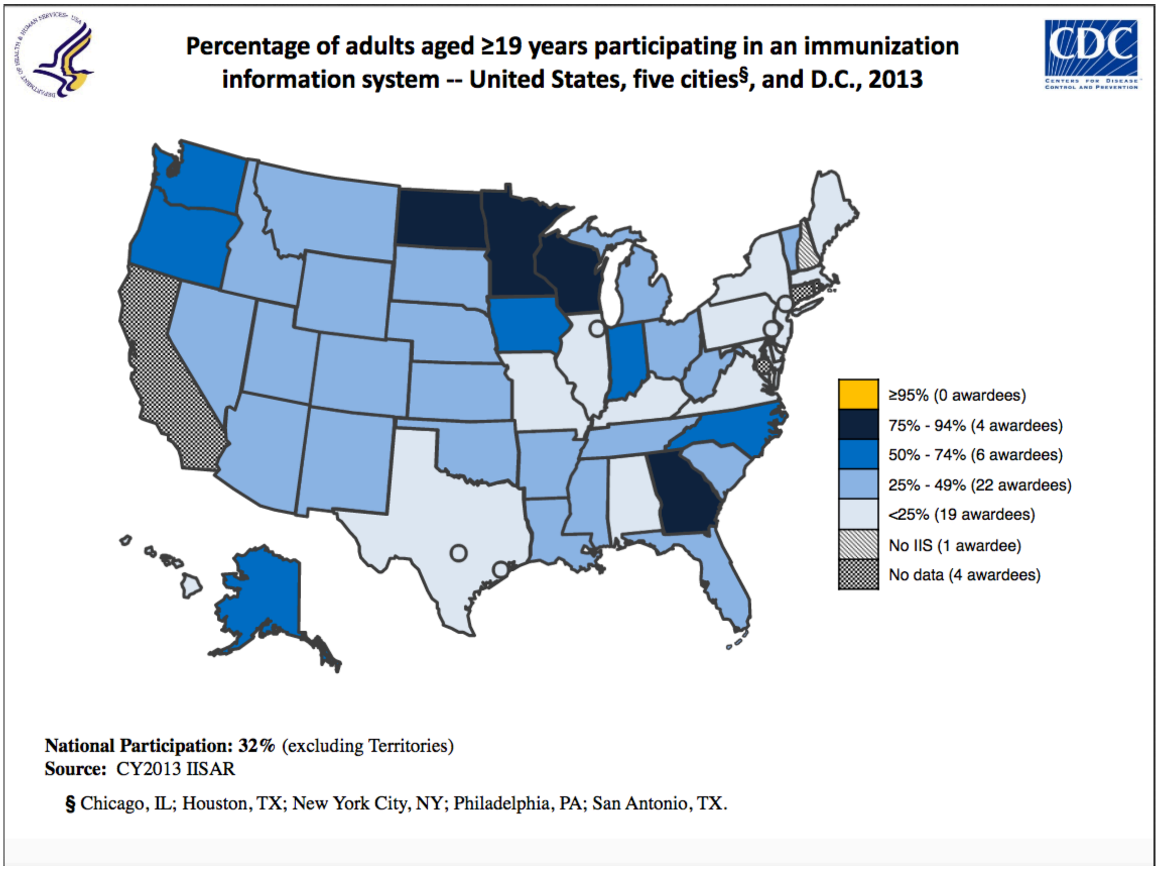


Figure 2.6 Percentage of adults participating in an IIS (Centers for Disease Control and Prevention, 2013)

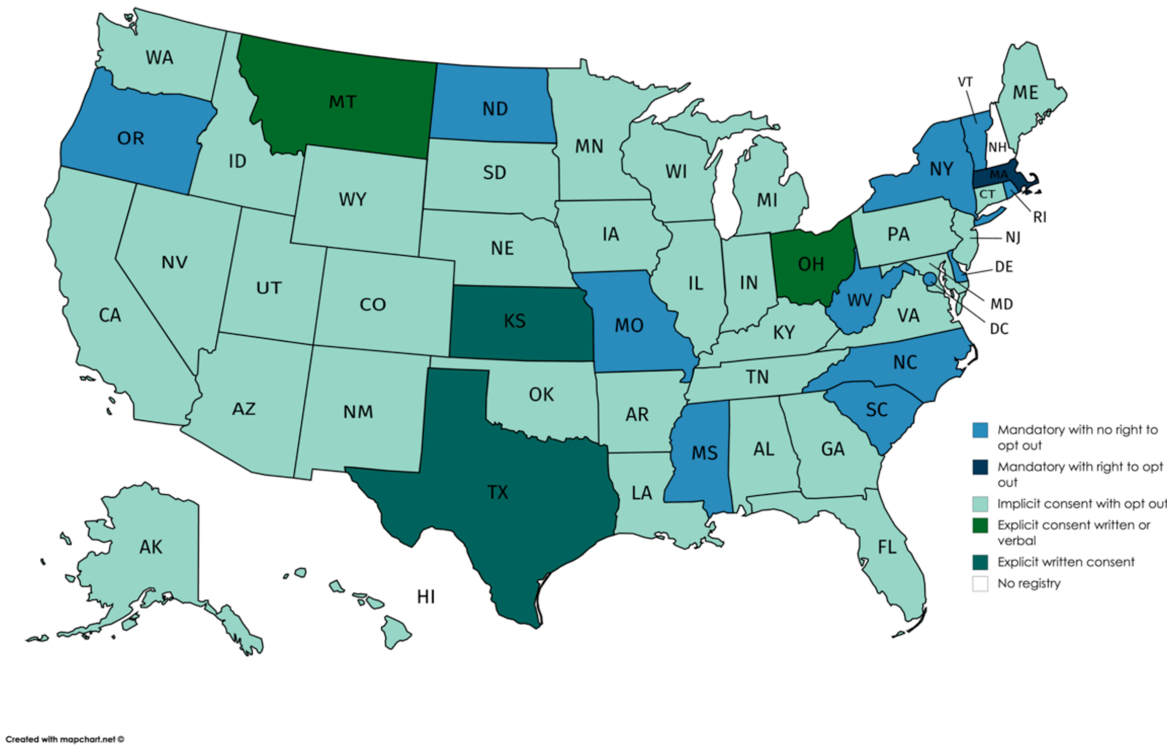


IIS Policies

Much of this variation in participation has been attributed to policies surrounding IIS that vary by state. These policies include the types of consent for different age groups that are required to be obtained from patients prior to entering their data, and whether or not provider participation is mandatory. A 2015 survey conducted by Martin and colleagues described the differences in policies used by each state in terms of patient consent requirement and type of provider mandate (Martin, Lowery, Brand, Gold, & Horlick, 2015).

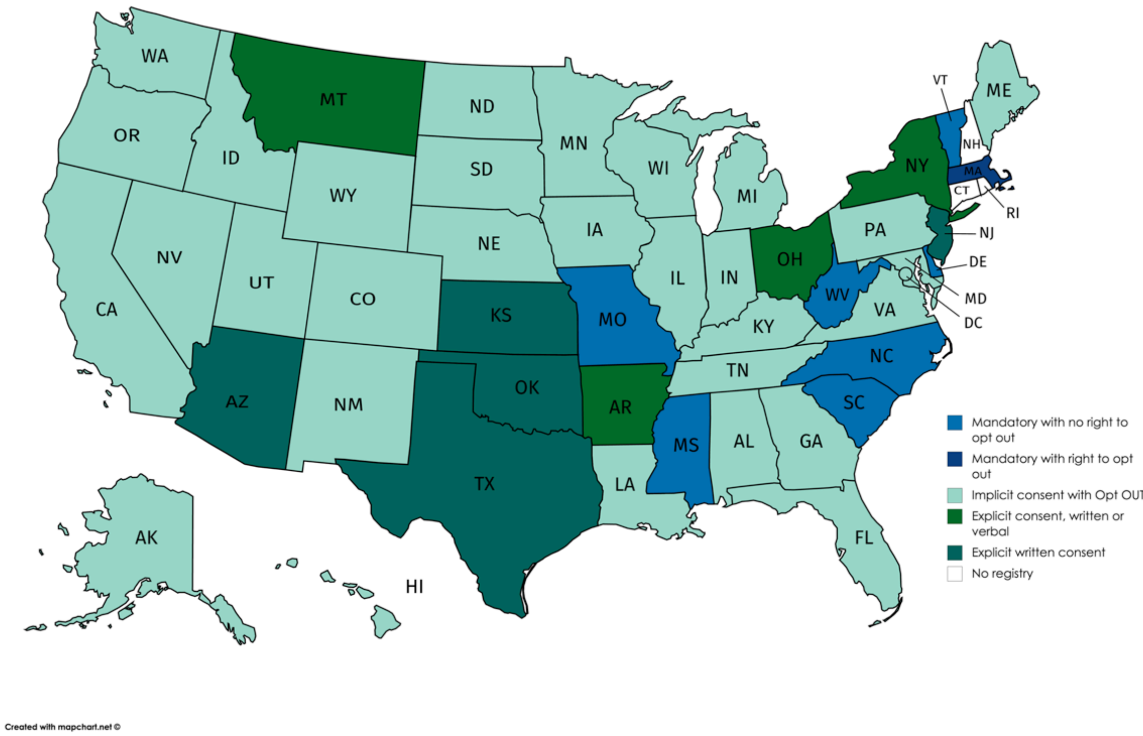
Patient Consent

Figure 2.7 Type of consent required for child enrollment in an IIS (Martin et al., 2015)



There are differences between most states in the type of consent required for children and adults to be enrolled in the immunization information system. For children, the majority of states allow implicit consent with an opt-out condition, such as Alabama (Figure 2.7) (Martin et al., 2015). In these states, consent is implied, but individuals do have the option to opt out of the IIS if they do not wish to be included. In other states, like Mississippi, participation for children is mandatory, meaning they have no right to opt-out. In states like Texas and Montana, providers must obtain explicit consent, either written or verbal, prior to enrolling a patient in the immunization information system. The same types of consent apply to adult enrollment. However many more states require explicit consent from adults than for children (Figure 2.8) (Martin et al., 2015).

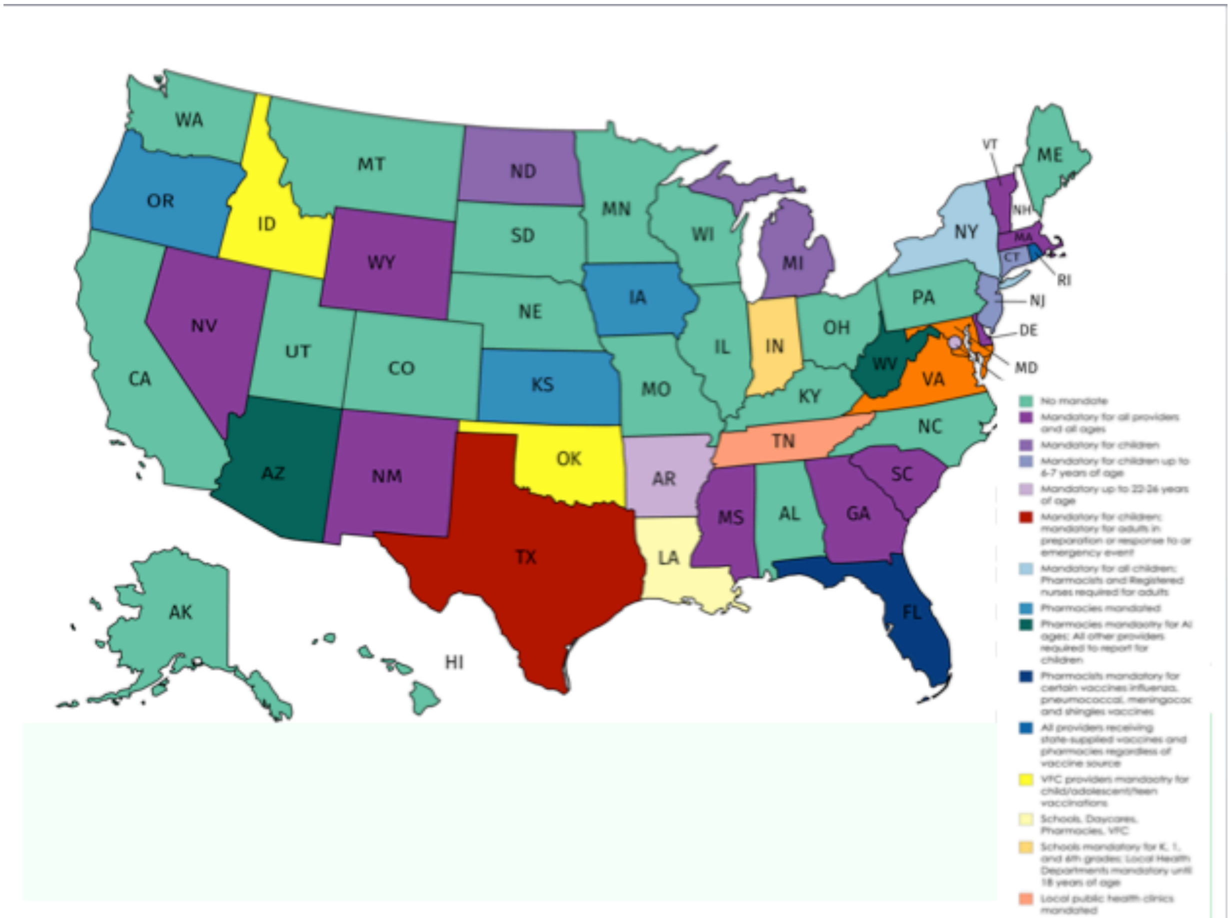
Figure 2.8 Type of consent required for adult enrollment in an IIS (Martin et al., 2015)



<u>Mandatory Provider Participation</u>

Provider participation mandates refer to whether or not any type of providers are required to provide data to the IIS and under which circumstances (Figure 2.9) (Martin et al., 2015). For the majority of states like Alabama and Ohio, no provider is required to enter any patients information in the IIS, it is considered a voluntary act. However in other states like Mississippi and Georgia it is mandatory for all providers to enter immunization data for patients of any age. A number of states have policies in which pharmacists are singled out in some form. For example, in Kansas, pharmacists are the only provider mandated to enter information. All other providers participate on a voluntary basis. In Arizona pharmacists are mandated for patients of all ages, while other providers are only mandated to enter data for children. The policies surrounding mandatory participation vary widely between state IIS.

Figure 2.9 Type of provider participation mandate (Martin et al., 2015)



Provider-level Implementation Barriers

While state-level policies may impact the success of immunization information systems, there are a number of barriers associated with implementation at the provider level that are equally critical to the success of immunization information systems. As depicted in the figures above, there are states which mandate provider participation, such as Mississippi, and still have low rates of participation in the immunization information system. This suggests the importance of examining factors at the provider level to understand barriers and facilitators to implementation of the immunization information system, including uploading and retrieving data, in individual practices.

It has been suggested that IIS are more likely to be implemented in larger practices that can accommodate the technology needed to facilitate automatic uploading of immunization data. Larger practices will typically have the ability to interface with the IIS and automatically upload data (American Immunization Registry Association, 2015). However, this does require substantial technological upgrades required to support transferring information between systems that aren't capable for many smaller practices. To participate in the IIS, these smaller practices would have to manually enter immunization data via the online IIS each time a vaccine is administered (American Immunization Registry Association, 2015). As such, it is time consuming and interrupts workflow.

Several studies were conducted to assess primary care providers' perceptions of IIS as well as implementation barriers in terms of both uploading and retrieving data from the immunization information system. While the majority of physicians reported positive perceptions of immunization information systems, they reported technological upgrades, perceptions of data inaccuracy and incompleteness, access, and patient consent as barriers to participation (D. A. Christakis et al., 1999; K. J. Dombkowski et al., 2007; S. T. O'Leary et al., 2016; Rask et al., 2000). Further, interruption to physicians' established workflow, as well as cost associated with implementation were also reported as major barriers (K. J. Dombkowski et al., 2007; Rask et al., 2000). These barriers have been identified through studies of physician perceptions to immunization information systems; little research has explored the barriers faced by pharmacists. Understanding the barriers and facilitators associated with the adoption of IIS in the community pharmacy setting is critical.

Consolidated Framework for Implementation Research

Given that the decision to adopt IIS is made at the organizational level, the Consolidated Framework for Implementation Research (CFIR) will be used as guidance to examine this phenomenon (L. Damschroder et al., 2009). The CFIR is a framework designed to inform the implementation process. Included in this framework are constructs determined to be important in the successful implementation of an innovation.

CFIR Domains

The domains and constructs included within the CFIR were informed by Everett Rogers' Diffusion of Innovations Theory (Rogers, 2003), as well as results from a review of over 500 published sources across a range of scientific disciplines completed by Greenhalgh and colleagues (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004). In 2009, implementation scientists within the Veterans Affairs Diabetes Quality Enhancement Research Initiative combined these sources and developed the CFIR (L. Damschroder et al., 2009). The 39 constructs included in the CFIR are categorized into five domains: 1) Intervention characteristics, 2) Outer setting, 3) Inner setting), 4) Characteristics of individuals, and 5) Process (L. Damschroder et al., 2009) (Table 2.5).

Intervention Characteristics

The first domain, intervention characteristics, describes aspects of the intervention itself that may influence implementation. These key attributes of interventions have been found to impact the success of implementation across a number of disciplines (L. Damschroder et al., 2009; Greenhalgh, Robert, Macfarlane, et al., 2004; Rabin, Brownson, Haire-Joshu, Kreuter, & Weaver, 2008). Many implementation theories lend support to the constructs of the intervention characteristics domain. These constructs include intervention source, evidence strength and quality, relative advantage, adaptability, trialability, complexity, design quality and packaging, and cost.

Intervention source refers to the perception of stakeholders regarding the development of the intervention as external or internal to the organization (L. Damschroder et al., 2009). An intervention developed internally in response to a problem may be more or less accepted by individuals within the organization as compared to those developed by an external entity (Edmondson, Bohmer, & Pisano, 2001; Grol, Bosch, Hulscher, Eccles, & Wensing, 2007; Stetler, 2001). Perceptions of the supporting evidence for the intervention, *Evidence Strength and Quality*, from credible sources such as peer-reviewed literature, published guidelines, or trustworthy colleagues can also influence the acceptance of an intervention (L. Damschroder et al., 2009; Stetler, 2001).

The constructs of *relative advantage, adaptability, trialiability*, and *complexity* are supported in the literature by a number of theories, including Rogers' Diffusion of Innovations (Rogers, 2003). *Relative advantage* refers to advantages of implementing an intervention in comparison to an alternative solution, and is imperative to implementation. *Adaptability*, or the ability to adapt and tailor the intervention to meet the specific needs of the organization, is often difficult to balance. This construct is relevant to Rogers' construct of compatibility, or the degree to which the innovation is perceived as being consistent with the values, past experiences, and needs of the organization (Rogers, 2003). Determining the intervention's adaptability requires a clear definition of the core components that cannot be changed to maintain integrity of the intervention compared to the adaptable "periphery components" that are more flexible and able to be changed across settings. Further, the *trialability* of the intervention, or the ability to test the intervention prior to full-scale implementation is another important component of successful implementation. Small scale piloting of an intervention allows users to build expertise and confidence, leading to successful implementation. *Complexity* of the intervention, or the perceived difficulty is a construct supported across numerous implementation theories. Rogers suggests that the complexity of an intervention has a negative relationship with the rate of adoption of the intervention (Rogers, 2003). While complexity may not be as critical to adoption as relative advantage or other key constructs, it can be a major barrier to implementation. The influence of perceived complexity of an intervention is also supported by theories specific to technology such as the Unified Theory of Acceptance and Use of Technology (UTAUT) and the Technology Acceptance Model (TAM) (F. D. Davis, 1989; Venkatesh, Morris, Davis, & Davis, 2003).

The final two constructs of the intervention characteristics domain, *design quality and packaging* and *cost,* are not included within diffusion theories (Greenhalgh, Robert, Macfarlane, et al., 2004; Rogers, 2003). The inclusion of these constructs in the CFIR intervention characteristics domain was informed by Grol et al's *Implementation of Change: A Model* (Grol et al., 2007). *Design quality and packaging* is defined as the perception of how well the intervention is bundled, presented, and assembled (L. Damschroder et al., 2009). *Costs* of implementing the intervention are negatively associated with successful implementation (L. Damschroder et al., 2009). These costs can include the actual cost of the intervention itself as well as implementation costs such as investment, supply, and opportunity cost. It is important to note that this "costs" constructs may be associated with the complexity construct as identified by Rogers (Rogers, 2003).

Outer Setting

The outer setting domain includes factors external to the organization that may impact the extent to which the innovation is implemented. The influence of constructs within the outer setting on implementation, specifically within healthcare systems is evident in the literature (L. Damschroder et al., 2009; Greenhalgh, Robert, Macfarlane, et al., 2004). Changes within the setting can have either positive or negative influences on implementation and are most often mediated through the inner setting (L. Damschroder et al., 2009). Four constructs comprise the outer setting domain including patient needs and resources, cosmopolitanism, peer pressure, and external policy and incentives.

Patient needs and resources refers to how well the organization recognizes and prioritizes the needs of patients, and the barriers and facilitators to meeting those needs (L. Damschroder et al., 2009). Many theories suggest that failing to account for the needs of patients results in less effective implementation, with greater success observed among more patient-centered healthcare entities (Ian D Graham & Logan, 2004; Kitson, Harvey, & McCormack, 1998; Rycroft-Malone et al., 2002). The degree of networking an organization has with other external organizations is referred to as *cosmopolitanism* (L. Damschroder et al., 2009). This networking makes it more likely that an organization will implement an intervention rapidly, when the intervention is accepted as the norm within the organization's external network (L. Damschroder et al., 2009; Greenhalgh, Robert, Macfarlane, et al., 2004). Further, when the intervention is accepted as the norm, this can create *peer pressure* or competitive pressure to implement the intervention because other competing organizations have already done so, or the organization wants to develop a competitive advantage (L. Damschroder et al., 2009). This construct can be particularly strong within highly cosmopolitan as well as late-adopting organizations (Greenhalgh, Robert, Macfarlane, et al., 2004; Walston, Kimberly, & Burns, 2001). The final construct within the outer setting domain, *external policy and initiatives*, refers to strategies and policies outside the organization designed to spread the intervention (L. Damschroder et al., 2009). These can include governmental policies, mandates, guidelines, pay-for-performance programs, and/or public reporting (Mendel, Meredith, Schoenbaum, Sherbourne, & Wells, 2008).

Inner Setting

The inner setting domain is comprised of characteristics internal to the organization that can influence implementation, such as the culture or learning climate. While some implementation theories describe the inner setting as background factors needed for implementation, the CFIR recognizes the inner setting as an active and interacting component of implementation (L. Damschroder et al., 2009). This domain includes five constructs, structural characteristics, networks and communication, culture, implementation climate, and readiness for implementation.

Structural characteristics are defined as an organization's social architecture, age, maturity, and size (L. Damschroder et al., 2009). Social architecture refers to the clustering of large groups of individuals within the organization into smaller groups and how these groups are coordinated and function within the organization. This construct is informed by Damanpour's organizational innovation research (Damanpour, 1991). A meta-analysis conducted by Damanpour identified structural characteristics that have an influence on organizational innovation, which Damschroder and colleagues extend to implementation within the CFIR

(Damanpour, 1991; L. Damschroder et al., 2009). In addition to the structural characteristics of an organization, the quality and nature of social networks and informal or formal communication within the organization has a complex role in implementation. This construct is referred to as *networks and communication*. Damschroder et al consolidate several of the domains described within Greenhalgh, et al's review including organizational structure, intraorganizational communication, and intraorganizational networks to create the *networks and communication* construct (Greenhalgh, Robert, Macfarlane, et al., 2004).

The *culture* of an organization has been described throughout the literature as having a significant impact on the effectiveness of implementation (Helfrich, Li, Mohr, Meterko, & Sales, 2007; Shortell et al., 2001). The definition of culture within the literature varies widely. Within the CFIR, this construct is defined as the norms, values, and basic assumptions of an organization (L. Damschroder et al., 2009). Culture is a critical component of the inner setting domain and implementation failure can often be attributed to overlooking the culture of an organization and the impact it can have on implementation success (L. Damschroder et al., 2009; Kitson et al., 1998; Rycroft-Malone et al., 2002).

The final two constructs in the inner setting domain, *implementation climate* and *readiness for implementation*, have been used to varying degrees and defined inconsistently throughout implementation models in the literature. Greenhalgh et al's model, the PARiHS framework, Lehman et al's Organizational Readiness for Change tool, Weiner's Theory of Organizational Readiness for Change, and Klein and Sorra's Conceptual Model for Implementation Effectiveness all incorporate these constructs in some form (Greenhalgh, Robert, Macfarlane, et al., 2004; Klein, Conn, & Sorra, 2001; Klein & Sorra, 1996; Lehman, Greener, & Simpson, 2002; Rycroft-Malone et al., 2002; Weiner, 2009). The CFIR expands upon Klein and

Sorra's model to include the construct of *implementation climate*, which is defined as the organization's capacity for change, shared receptivity, and the extent to which use of the implementation will be rewarded, supported, and expected within the organization (L. Damschroder et al., 2009). Implementation climate incorporates several sub-constructs including tension for change, compatibility, relative priority, organizational incentives and rewards, goals and feedback, and learning climate, which are described in Table 2.5 below (L. Damschroder et al., 2009). *Readiness for implementation* is composed of more tangible and observable characteristics of an organization's commitment to implement an intervention and includes leadership engagement, available resources, and access to knowledge and information (L. Damschroder et al., 2009).

<u>Characteristics of Individuals</u>

The fourth domain, characteristics of individuals, describes how attributes of individuals within the organization such as their knowledge or self-efficacy might impact implementation (L. Damschroder et al., 2009). While characteristics of the organization have a significant impact on implementation, individuals do have the freedom to make their own choices, which can influence the success of the implementation within the organization. A number of theories examine change within individuals from the Theory of Planned Behavior to Prochaska's Transtheoretical Model of Stages of Change (Ajzen, 1991; Grol et al., 2007; Prochaska & Velicer, 1997). These models form the basis for the constructs included within the characteristics of individuals domain of the CFIR. This domain includes five constructs: knowledge and beliefs about the intervention, self-efficacy, individual stage of change, individual identification with the organization, and other personal attributes.

The first construct, *knowledge and beliefs* is defined as individuals' attitudes toward the intervention and their familiarity with facts, truths, and principles related to the intervention (L. Damschroder et al., 2009). Without knowledge and the skills necessary to use the intervention prior to implementation, individuals often reject the intervention and discontinue its use (Ajzen, 1991; Klein et al., 2001; Rogers, 2003). *Self-efficacy* is defined as individuals' belief in their own ability to execute the necessary actions to achieve implementation goals (L. Damschroder et al., 2009). This construct is a component within most theories of behavior change, the most recognizable of which being The Health Belief Model and Social Cognitive Theory which define self-efficacy as the belief that one can achieve desired action leading to health behavior change and the confidence in one's ability to take action and overcome barriers, respectively (Bandura, 1986; Hochbaum, Rosenstock, & Kegels, 1952). The third construct, *individual stage of change*, is defined as the phase of an individual as they move towards skilled, enthusiastic, and sustained use of the intervention (L. Damschroder et al., 2009). The CFIR does not assign a specific model of stages to be used in assessing stages of change. However, Prochaska's transtheoretical model, Roger's diffusion theory, and Grol's five-stage model are suggested as possibilities depending on the purpose of the study (Grol et al., 2007; Prochaska & Velicer, 1997; Rogers, 2003). *Individual identification with the organization* is defined as how individuals perceive the organization and their relationship and commitment to the organization (L. Damschroder et al., 2009). An individual's perception of the organization and how they fit within can affect their willingness to implement the intervention (Abraham, 2000; Greenberg, 1990). *Other personal attributes* is included as the final construct which is a broad category including characteristics such as intellectual ability, motivation, innovativeness, and learning style among others (L. Damschroder et al., 2009).

Process

The final domain, process, includes systems and pathways within the organization itself. The CFIR incorporates four constructs that are common across most theories investigating implementation or change (Grol et al., 2007). These four constructs include planning, engaging, executing, and reflecting and evaluating. Damschroder et al describe these four activities as a spiral or incremental approach rather than a sequential process completed in order (L. Damschroder et al., 2009).

The first construct, *planning*, is the degree to which a method of behavior and tasks necessary to implement an intervention are developed in advance (L. Damschroder et al., 2009). The purpose of this construct is to create an action plan, building capacity on an individual and collective basis, which will result in successful implementation (Mendel et al., 2008). The second construct, *engaging*, describes the activity of involving the appropriate individuals in the implementation and use of the intervention (L. Damschroder et al., 2009). This is accomplished through social marketing, education, role modeling, and training strategies (L. Damschroder et al., 2009). The CFIR identifies four types of individuals that should be engaged in the implementation process including opinion leaders, formally appointed implementation leaders, champions, and external change agents (L. Damschroder et al., 2009). These types of individuals can be found in the implementation literature in various models and theories (Feldstein & Glasgow, 2008; Flodgren et al., 2007; Greenhalgh, Robert, Bate, et al., 2004; Greenhalgh, Robert, Macfarlane, et al., 2004; Locock, Dopson, Chambers, & Gabbay, 2001; Rogers, 2003; Rycroft-Malone et al., 2002). The *executing* construct refers to carrying out or accomplishing the implementation according to plan (L. Damschroder et al., 2009). As stated above, the completion of activities within this domain are not necessarily in order. Meaning that execution may take place without any formal planning, making it difficult to measure. The quality of execution can be defined as the fidelity, intensity, timeliness, and degree of engagement of key stakeholders (L. Damschroder et al., 2009). The final construct, *reflecting and evaluating*, is defined by Damschroder et al. as quantitative and qualitative feedback about the implementation progress and quality as well as regular debriefing about progress and experience for both teams and individuals (L. Damschroder et al., 2009). The importance of reflecting and evaluating the implementation process is overlooked in most implementation theories, especially the need for debriefing (L. Damschroder et al., 2009). Reflecting and evaluating is an important activity, even in the event of implementation failure so that problems can be identified and addressed (Edmondson et al., 2001; Klein & Sorra, 1996; Simpson & Dansereau, 2007).

Table 2.5 Consolidated Framework for Implementation Research (CFIR) Constructs

Construct	Description
Intervention Characteristics	
Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
Outer Setting	
Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
Cosmopolitanism	The degree to which an organization is networked with other external organizations.
Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
Inner Setting	
Structural Characteristics	The social architecture, age, maturity, and size of an organization.
Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
Culture	Norms, values, and basic assumptions of a given organization.

Implementation Climate 1. Tension for Change 2. Compatibility 3. Relative Priority 4. Organizational Incentives and Rewards 5. Goals and Feedback 6. Learning Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
	1. The degree to which stakeholders perceive the current situation as intolerable or needing change.
	2. The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
	3. Individuals' shared perception of the importance of the implementation within the organization.
	4. Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.
	5. The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
	6. A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.
Readiness for Implementation 1. Leadership Engagement 2. Available Resources 3. Access to Knowledge & Information	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
	1. Commitment, involvement, and accountability of leaders and managers with the implementation.
	2. The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
	3. Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
Characteristics of Individuals	
Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
Individual Identification with Organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.

Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.
Process	
Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
Engaging 1. Opinion Leaders 2. Formally Appointed Internal Implementation Leaders 3. Champions 4. External Change Agents	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
	1. Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.
	2. Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
	3. Individuals who dedicate themselves to supporting, marketing, and 'driving through' an implementation, overcoming indifference or resistance that the intervention may provoke in an organization.
	4. Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
Executing	Carrying out or accomplishing the implementation according to plan.
Reflecting and Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

The Use of CFIR in Implementation Research

The CFIR has been used as a guiding framework in a number of studies to assess potential barriers and facilitators to successful implementation. The majority of these studies have applied the CFIR to health-related interventions. For example, Damschroder and Lowery conducted a post-implementation assessment of a weight management program implemented in Veteran Affairs Medical Centers (L. J. Damschroder & Lowery, 2013). A qualitative approach was used to assess 31 of the 39 CFIR constructs. Ten of these constructs were found to be different between settings with high program implementation effectiveness and those with low program implementation effectiveness. Meaning that these differentiating constructs were important attributes for successful implementation. The majority of these distinguishing constructs were within the inner setting domain. Rather than completing a post-implementation assessment, Connell and colleagues completed a pre-implementation assessment to explore therapists' perceptions of implementing a stroke rehabilitation intervention in the United Kingdom prior to implementing the intervention (Connell, McMahon, Watkins, & Eng, 2014). Using a cross-sectional design, therapists who were classified as early adopters of the intervention were found to have higher positive perceptions related to the intervention characteristics domain than those who did not implement the intervention. Specifically, perceived relative advantage was found to be a strong predictor of successful implementation. This study also examined the characteristics of individuals domain, finding that individuals who had experience using the intervention displayed greater knowledge and confidence in implementation. A study of the adoption of buprenorphine for opioid addiction treatment using qualitative methods found that the interaction between the inner setting and characteristics of the individual clinician and the intervention affect organizational acceptance (Green et al., 2014).

These studies point to the importance of the inner setting, intervention characteristics, and characteristics of individuals domains specifically in the successful implementation of health-related innovations. This finding is consistent among studies in non-clinical settings. A systematic review of implementation measures for public health and community settings found that the inner setting, characteristics of individuals, and intervention characteristics were most likely to be assessed, specifically the constructs of relative advantage, networks and communications, culture, implementation climate, learning climate, readiness for implementation, and available resources (Clinton-McHarg et al., 2016). A critical review of 45 articles on services provided in the community pharmacy setting identified constructs within these domains that are most relevant in the pharmacy setting (Shoemaker, Curran, Swan, Teeter, & Thomas). Within the intervention characteristics domain, relative advantage and complexity were found to be of particular importance in the pharmacy setting. The outer setting constructs that are most likely to impact pharmacies include patient needs as well as external policies and incentives. Structural characteristics such as pharmacy type (independent vs. chain), size, and staff, as well as pharmacists' perceptions of their role and available resources were the most relevant constructs identified within the inner setting domain. Within the characteristics of individuals domain, the training, preparedness, and self-efficacy of the pharmacist were most important to implementing a new service. While very few studies were identified that incorporated the process domain, those that did primarily focused on engaging champions in this process.

Applying the CFIR to IIS

The factors related to the successful implementation of IIS have been examined primarily among physicians (D. A. Christakis et al., 1999; K. J. Dombkowski et al., 2007; S. T. O'Leary et al., 2016; Rask et al., 2000). However no such studies examining IIS implementation or utilization have been explicitly guided by theory. Applying implementation theory, including the CFIR, can help to guide IIS implementation leading to more successful and effective implementation. The most commonly reported factors include the need for software, information technology support, computer equipment, etc. all of which could be classified within the inner setting domain, specifically the setting's readiness for implementation and available resources (Sean T. O'Leary et al., 2016). Within the intervention characteristics domain, cost was a barrier that was identified as a primary concern for physicians (Sean T. O'Leary et al., 2016; Rask et al., 2000). The strength and quality of evidence supporting the innovation is a sub-construct of the intervention characteristics domain that has not frequently been assessed. However some physicians identified this as a perceived barrier. The incompleteness and inaccuracy of IIS was seen as a deterrent for implementation (Dimitri A. Christakis et al., 1999; K. Dombkowski, S. Leung, & S. Clark, 2007).

One study utilized qualitative interviews with the five largest chains that have implemented IIS in their pharmacies, including Walgreens, CVS, Rite Aid, and Kroger to assess pharmacy-related factors of IIS use (American Immunization Registry Association, 2015). The barriers described in this study fall into the intervention characteristics domain as well as the inner setting domain. Participants reported that the lack of standardization and complexity surrounding the IIS were major barriers to successful implementation that were compounded by limitations of typical pharmacy systems. Further, they reported that the resources available in their settings were not adequate to handle the volume of data required by the immunization information system. However the benefits perceived by these participants were primarily related to the outer setting, with the improvement of patient care and patient relationships as the most prominent perceived benefit. The applicability of these barriers to CFIR constructs suggest that studies guided by implementation theory may be successful in increasing the use of immunization information systems. While the implementation factors identified by physicians can be applied primarily to the intervention characteristics and inner setting domains, factors related to pharmacy implementation may differ and need to be examined.

Table 2.6 Application of the Consolidated Framework for Implementation Research to IIS Implementation Factors

Reference	IIS Implementation Factors Identified	Associated CFIR Domains
Christakis et al (Dimitri A. Christakis et al., 1999)	Incompleteness of IIS data	Intervention Characteristics
Dombkowski et al (K. Dombkowski et al., 2007)	Patient identification features, limited patients included, completeness of data	Intervention Characteristics
O'Leary et al (Sean T. O'Leary et al., 2016)	Software needs, information technology support, computer equipment, cost	Inner Setting
Rask et al (Rask et al., 2000)	Cost	Intervention Characteristics
AIRA (American Immunization Registry Association, 2015)	Perceived barriers: Complexity, lack of standardization, volume of data required to be submitted Perceived benefits: improvement of patient care	Intervention Characteristics Inner Setting Outer Setting

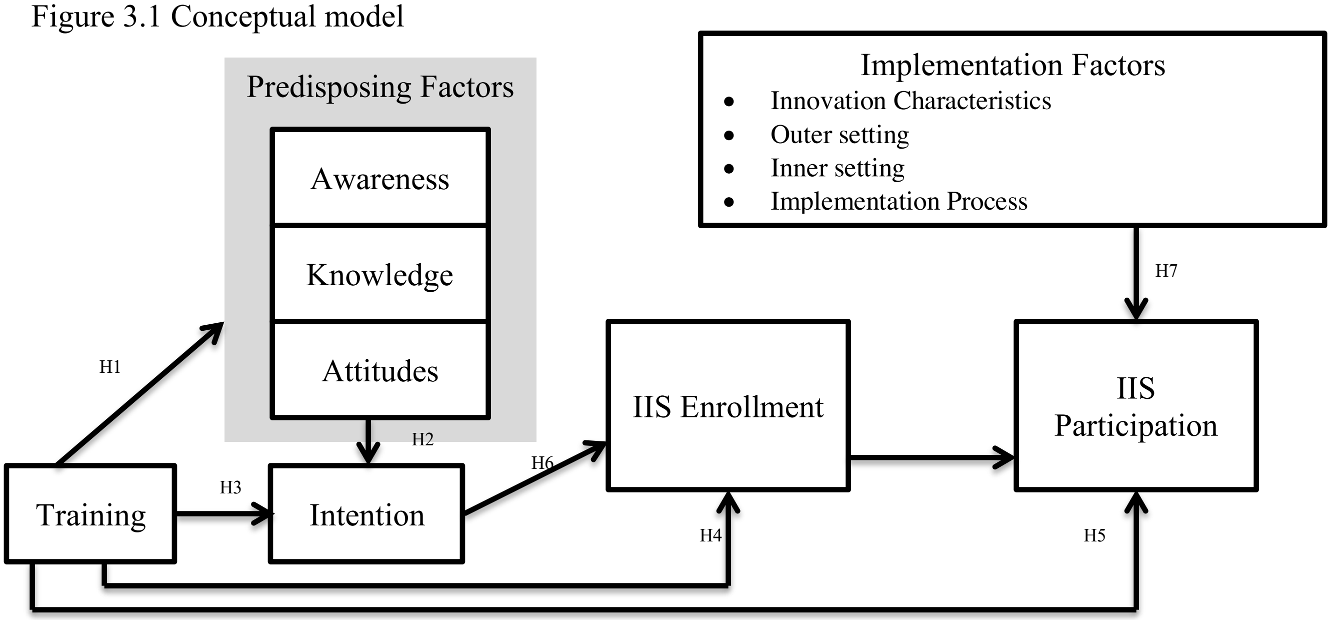
Chapter 3. Methods

The specific aims of this dissertation were to 1) identify barriers and best practices of Immunization Information System (IIS) implementation among community pharmacists, 2) use a participatory design approach to develop an IIS training program, and 3) assess the impact of the IIS training program on community pharmacies' IIS enrollment rates. The research questions and hypotheses associated with these aims are provided in the following section.

Research Questions and Study Hypotheses

The overall goal of this dissertation was to increase the use of IIS in community pharmacies. This study used the Consolidated Framework for Implementation Research (CFIR) as a guide to allow us to explore the proposed relationship between factors that influence IIS use as proposed in Figure 3.1. This section lists the specific research questions and study hypotheses.

Figure 3.1 Conceptual model



Research Questions

The research questions listed below are addressed in this dissertation. RQ1-RQ4 are addressed in phase one through qualitative interviews with pharmacists and IIS staff. After development of the training program in phase two, RQ5- RQ11 were tested using a randomized controlled trial design in phase three.

RQ1. What motivational factors and contextual barriers influence Alabama pharmacists' decision to enroll and participate in the IIS?

RQ2. What barriers do Alabama IIS staff experience in recruiting pharmacists to enroll in the IIS?

RQ3. What are best practices implemented by pharmacists in states with high IIS participation rates?

RQ4. What are best practices observed by IIS staff in states with high IIS participation rates?

RQ5. What is the impact of a training intervention on the awareness, knowledge, and attitudes of Alabama pharmacists?

RQ6. What is the relationship between predisposing factors (awareness, knowledge, and attitudes) and intention to implement the IIS?

RQ7. What is the impact of a training intervention on the intention of Alabama pharmacists to implement the IIS?

RQ8. What is the impact of a training intervention on the enrollment of Alabama pharmacists in the IIS?

RQ9. What is the impact of a training intervention on the participation of Alabama pharmacists in the IIS?

RQ10. What is the relationship between intention and decision to enroll in the IIS?

RQ11. What is the relationship between implementation factors and IIS participation?

Study Hypotheses

The following hypotheses were tested in phase three using a randomized controlled trial study design:

H1. An increase in pharmacists' predisposing factors will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.

> **H1a.** An increase in pharmacists' awareness will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.
>
> **H1b.** An increase in pharmacists' knowledge will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.
>
> **H1c.** An increase in pharmacists' positive attitudes will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.

H2. An increase in pharmacists' intention to enroll in the IIS will be observed among intervention and control pharmacies who demonstrate greater awareness, knowledge, and positive attitudes across baseline and one-month.

H3. An increase in pharmacists' intention to enroll in the IIS will be observed among participants in the intervention group when compared to the control group across baseline and one-month.

H4. An increase in pharmacists' enrollment in the IIS will be observed from baseline to three-months among participants in the intervention group when compared to the control group.

H5. An increase in pharmacists' participation in the IIS will be observed among participants in the intervention compared to the control group at three-months.

H6. An increase in pharmacists' enrollment in the IIS at three months will be observed among participants who demonstrate intention to implement the IIS.

H7. Implementation factors including innovation characteristics, inner setting, outer setting, characteristics of individuals, and process will have a relationship with IIS participation.

Study Design

A mixed-methods study design incorporating qualitative and quantitative aspects was used to address the research questions and test the hypotheses described above. This was conducted in three phases. In Phase I, semi-structured telephone interviews were conducted to explore barriers and best practices of IIS implementation among community pharmacists. The second phase utilized a participatory design approach to develop an IIS training program. Lastly, the third phase used a randomized controlled trial study design to assess the impact of the IIS training program on participants' awareness, knowledge, attitudes, intention, enrollment, and participation.

All procedures were approved by the Auburn University Institutional Review Board as expedited review. Phases one and two were approved first. Once the format, content, and details of the training program were determined, a second application was submitted for phase three, the randomized controlled trial.

Phase I: Qualitative Study

Phase I was used to address specific aim 1 which was to identify barriers and best practices of IIS implementation. Qualitative interviews of pharmacists and IIS representatives identified barriers and best practices that were used in the development of an IIS training program in phase two.

Motivational Factors and Contextual Barrier Interviews

Research Design, Participants and Setting

The first step in this phase was to identify motivational factors and contextual barriers from the Alabama IIS and Alabama pharmacist perspectives. Semi-structured, in person or telephonic qualitative interviews with Alabama IIS representatives and Alabama pharmacists were conducted. Interview scripts contained open-ended questions designed to elicit barriers the IIS representatives experience in recruiting, onboarding, and working with pharmacies, as well as motivational factors and barriers pharmacists experience in implementing the immunization information system.

This study began with a purposive sample of four Alabama state IIS (ImmPRINT) staff and 10 Alabama pharmacists. IIS staff were selected based on their position and experience with the IIS and their expertise in recruiting and working with pharmacy participants. Pharmacy personnel were selected who were practicing in pharmacies currently enrolled in the IIS and providing at least one type of non-seasonal vaccine. Pharmacy personnel were also required to be practicing in rural, independent community pharmacies. Only one participant per pharmacy was permitted. Independent pharmacy contact information was obtained from Hayes Directory, a listing of pharmacies, containing pharmacy name, address, phone number, etc. ImmPRINT enrollment status was verified by Alabama Department of Public Health Immunization Division personnel prior to scheduling interviews. An incentive of $40 per pharmacist was provided to participants to compensate for their time spent participating in these interviews.

The Alabama Rural Health Association's definition of rural was used to determine rurality of pharmacies (Alabama Rural Health Association, 2011). This definition uses four variables to determine rurality including 1) the percentage of total county employment that is comprised by public school systems, 2) the dollar value of agricultural production per square mile, 3) the population per square mile, and 4) the population of the largest city in the county. Using this methodology, there are 55 counties in Alabama that are classified as rural and 12 classified as urban. Independent pharmacies in rural areas are likely to experience the most barriers and greatest need in implementing IIS and thus will be the focus of these interviews. Typically, larger chain pharmacies have the ability to interface with the IIS and automatically upload data (American Immunization Registry Association, 2015). In fact, many chain pharmacies have technology that is compatible with the immunization information system; as such data is being reported at the corporate level to the state IIS with individual pharmacists being unaware. However, this does require substantial technological upgrades required to support transferring information between systems that aren't capable for many smaller and independently owned pharmacies. To participate in the IIS, these smaller/independently owned pharmacies would have to manually enter immunization data via the online IIS each time a vaccine is administered (American Immunization Registry Association, 2015). Further, pharmacies in rural communities with fewer primary care providers are more likely to be used as vaccination providers, thereby increasing the need for their IIS participation, and thus will be the focus of these interviews.

Best Practice Interviews

Research Design, Participants and Setting

The second step was to identify best practices of IIS representatives and pharmacists in states with high IIS participation rates. This was accomplished through semi-structured, telephonic qualitative interviews with an initial purposive sample (see Data Collection for description of final sample) of one IIS representative and one pharmacist participant per state from those with high participation rates including Minnesota, Wisconsin, North Dakota, and Georgia. States with high rates of participation were identified as those with at least 75% of adults over the age of 19 recorded in an IIS (Centers for Disease Control and Prevention, 2013).

All IIS representatives were identified and contacted via publicly available online department of public health websites for their respective states. With the request from TH, in high participation states, the IIS representatives identified and contacted high-performing pharmacists in their state to participate. In order to protect participant confidentiality, the IIS staff reached out to potential pharmacist participants and provided them with contact information if they were interested in participating. The same incentive amount of $40 per pharmacist was provided to participants to compensate for their time spent participating in these interviews. The best practices from these states were used to inform the training program development and can be applied to other states, specifically Alabama.

Data Collection

Interviews were conducted by TH using open-ended questions to elicit participants' views, beliefs, and perceptions regarding implementation of IIS in community pharmacies. The interviews were conducted between August and October 2018 and ranged from 28 minutes and

43 seconds to 57 minutes and 20 seconds in length. All interviews were transcribed verbatim using Rev.com. The open-ended interview questions for pharmacists were informed by the Consolidated Framework for Implementation Research (CFIR) domains including intervention characteristics, inner setting, outer setting, characteristics of individuals, and implementation process (Table 3.1) (L. Damschroder et al., 2009). A full list of interview questions for each type of interview can be found in Appendices 1-4, with mapping to CFIR domains and constructs supplied in Appendix 5. After development, the interview script was pre-tested for content validity among a sample of graduate students.

All interviews were audio-recorded and transcribed verbatim. Participants were informed that all identifying information would remain confidential. To ensure confidentiality, file names were de-identified using a unique identification number. Recordings were destroyed immediately after transcription and de-identified transcripts maintained.

Interviews were conducted until the point of saturation was reached. The point of saturation occurs when no new information is being gained by the interviews. While the point of saturation, and thus the desired sample size, could not be determined prior to beginning the study, previous research provided suggestions of the number of participants to initially include. Data collection began with interviews of 4 Alabama IIS personnel, 10 Alabama pharmacists, 4 high participation state IIS personnel, and 4 high participation state pharmacists. These estimations were based on characteristics of both the participants and study and used to guide the anticipated sample size in this study (Bonde, 2013). The ability to reach saturation with the planned sample size was due to a number of factors. First, IIS implementation in Alabama independent community pharmacies is a narrow and focused topic in a specific setting. Second, saturation was able to be reached with four Alabama IIS personnel due to their high level of knowledge and expertise in relation to the topic of inquiry, barriers to IIS implementation in Alabama community pharmacies. We found that after interviewing four Alabama IIS personnel, saturation had been reached, no new information was being conveyed. Regarding the Alabama pharmacist sample, all were actively engaged in immunization delivery and enrolled in ImmPRINT. This population had a variety of practice experience (chain, independent, academic), varying prescription volume, years in business, and years of experience. This dense sample and focused topic allowed saturation to be reached after conducting the planned ten interviews.

While the planned sample size was adequate for the Motivational Factors and Contextual Barrier Interviews among Alabama IIS and pharmacy personnel, additional interviews were conducted to reach saturation among high participation states IIS and pharmacy participants. An initial sample of four IIS staff and four pharmacist participants total (one IIS staff and one pharmacist per state) were planned to be interviewed. Additional interviews were conducted using snowball sampling until the saturation point was reached. A total of five IIS representatives and six pharmacists were interviewed. Data collection and analysis were conducted simultaneously so that this point of saturation could be identified.

Table 3.1 Consolidated Framework for Implementation Research (CFIR) Domains and Constructs Mapped to Example Interview Questions

Domain	Example Construct	Example Interview Question
Intervention Characteristics	Relative Advantage	How does the IIS add value to immunization services in your setting? a) What advantages does the IIS have? b) What disadvantages does the IIS have?
	Complexity	How complex is the IIS to understand? How complicated is it for you to use the IIS in your pharmacy?
	Cost	What cost or expenses were considered when deciding to utilize the immunization information system? Which is the most significant cost for your pharmacy?
Outer Setting	Patient/Physician Needs and Resources	How might participating in the IIS help meet the needs of the patients served by your pharmacy? a) In what ways will the IIS meet their needs? How well do you think the IIS will meet the needs of your patients' primary care providers? a) In what ways will the IIS meet their needs?
	Normative Pressure	Are you aware of any other pharmacies that implement the immunization information system? a) How does this (other pharmacies extent of implementation) affect the decision to use (or not use) IIS in your setting? b) How does implementing the IIS provide an advantage for your

		organization compared to other pharmacies in your area? c) Is there something about the IIS that would bring more individuals into your pharmacy, instead of another one in your area?
	External Policy & Initiatives	What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced the decision to implement the immunization information system?
Inner Setting	Structural Characteristics	What kinds of changes in the pharmacy setting will be needed to accommodate the IIS in your pharmacy?
	Networks and Communication	How do you typically find out about new information, such as new initiatives, accomplishments, issues? a) Are meetings, such as staff meetings, held regularly?
	Culture	How would you describe the culture of your pharmacy? a) To what extent are new ideas embraced and used to make improvements in your pharmacy?
	Readiness for Implementation	Do you expect to have sufficient resources to implement and administer the immunization information system? a) [If Yes] What resources are you counting on? Are there any other resources that you received, or would have liked to receive? b) [If no] What resources will not be available?
Characteristics of Individuals	Knowledge and Beliefs about the Innovation	What do you know about the immunization information system?

	Self-Efficacy	How confident are you in using the immunization information system?
Process	Engaging	Who led or is leading implementation of the IIS in your pharmacy? a) How did/will this person come into this role? Appointed? Volunteered? Voluntold?
	Reflecting and Evaluating	Will feedback be elicited from pharmacy staff? From the patient served by your pharmacy?

Data Analysis

Atlas.ti qualitative data analysis software version 11.4 was employed to deductively code the transcripts using the 39 CFIR constructs. Pharmacist and IIS representatives were coded separately. A second researcher then independently coded 25% of the transcripts. All transcripts were initially coded by TH. Upon completion of coding and finalization of the codebook, the second coder independently coded one transcript. TH and the second coder met to review their independent coding schemes and resolve any discrepancies via discourse and consensus. The second coder then proceeded to code six transcripts. TH compiled a total of 1,522 codes for 25 transcripts while the second coder compiled a total of 302 codes for 6 transcripts (TH 357 for the same transcripts). The overall inter-rater reliability was good (Krippendorff's alpha = 0.9). Krippendorff's alpha was also determined for each domain and ranged from 0.637 to 0.685. A value of 0.60 or above is considered acceptable.

Upon completion of coding, the CFIR Rating Rules (L. Damschroder et al., 2009), were applied to the coded data to allow for identification of constructs that have the greatest impact on implementation. Ratings are based on valence and strength of comments. Valence of the construct is defined as either a positive or negative influence on implementation. Strength of the construct is defined as the level of influence the construct has on implementation, either weak or strong. This is identified through factors including the level of agreement between multiple participants and examples provided by participants. A summary rating (valence and strength) was applied to each construct.

Phase II: Training Program Development

Phase two was to develop an IIS training program (specific aim 2) using a participatory design approach. This approach solicited feedback from a review panel of pharmacists and IIS representatives to refine the training program, which was then offered as a continuing education credit for pharmacists in phase three. Using a participatory design approach ensured that the training program meets the needs of community pharmacists.

Program Development

Using information gathered through qualitative interviews in phase one, a pharmacist training program was developed; its content was reviewed and approved by ImmPRINT. Panel input was solicited throughout the development process to ensure that information was relevant and useful and that the Continuing Education (CE) format was acceptable. Based on prior CE development experience and suggested topics, it was anticipated that the program format would be either online video modules, live webinar, or article with a range of 1-2 hours of continuing education credit. Information gathered through qualitative interviews and review panel feedback resulted in a two credit hour online article with accompanying demonstration videos and a concise implementation guide. The intent of the program is to make pharmacists aware of the importance of the IIS and equip them with basic information about enrollment and participation. This program was offered to Alabama pharmacists as CE credit, in addition to the face-to-face training provided by ImmPRINT when a pharmacy requests to enroll in the immunization information system. The in-depth face-to-face training provided by ImmPRINT is a necessary step in the enrollment process to ensure pharmacists and pharmacy staff are comfortable with all aspects of the ImmPRINT system and will not be altered. Once the review panel finalized the newly developed training program, it was pilot tested among a sample of five independent community pharmacists to ensure that the program is feasible and acceptable to the target population.

Review Panel

Select phase one interview participants were asked to join a review panel to refine the training program. Participants were selected based on their level of expertise demonstrated in aim 1. Additionally, maximal variation was used to ensure diversity of the panel. This included two Alabama IIS personnel, two Alabama pharmacy personnel, and two pharmacists from high participation states. Participants were diverse in terms of their age, race, sex, years of experience, geographic location, and position. Once the program was developed, the product was shared with the panel via email and feedback gathered via the Delphi method (Dalkey, Brown, & Cochran, 1969). Panel members were asked to review the program and provide feedback via questionnaire in terms of depth and breadth of content as well as the program format. After the first round of panel review, the program was modified and comments summarized before sending back to the panel for a second round of review. Adherence to the Delphi method strengthened reviews of the training program and ensured validity and reproducibility. Each pharmacist panel member received $100 to compensate for their time spent participating in this panel review process.

Phase III: Randomized Controlled Trial

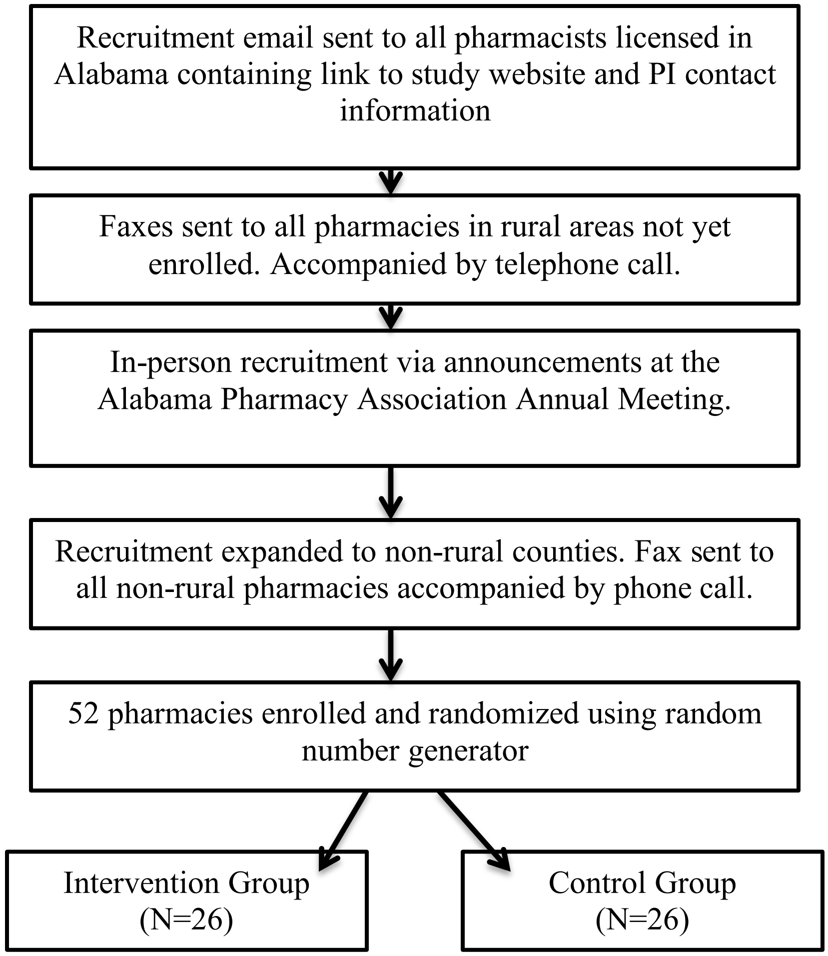
This phase addressed specific aim 3, which is to assess the impact of the IIS training program on community pharmacies' IIS participation rates. The training program was distributed among pharmacists in rural, independent Alabama pharmacies to increase awareness of IIS and educate community pharmacies on successful implementation strategies with the goal to increase pharmacy participation in the IIS. A randomized controlled trial design was used to evaluate the impact of the program on participants' awareness, knowledge, attitudes, intention, enrollment, and participation.

Research Design, Participants and Setting

A randomized controlled trial design targeting community pharmacies in Alabama was used to assess the impact of the training program on pharmacists' awareness, knowledge, attitude, intention to participate, enrollment, and actual participation in the immunization information system. Alabama pharmacists practicing in rural, independent pharmacies were invited to participate in the randomized controlled trial portion of this study.

At the time of study recruitment, there were 1,282 pharmacies in Alabama. Recruitment was focused on the 523 independent Alabama pharmacies, first targeting the 309 independent pharmacies in rural areas. Rural areas were selected using the Alabama Rural Health Association methodology described in phase one (Alabama Rural Health Association, 2011). Recruitment efforts in rural areas were exhausted, and the remaining 244 independent pharmacies in non-rural areas were contacted and invited to participate. Those pharmacies currently enrolled in the IIS were excluded. Multiple methods of recruitment were employed including emails, telephone calls, and fax. Recruitment materials informed potential participants that they were eligible to participate in a study exploring pharmacist participation in immunization information systems. Materials stated that participants would receive continuing education credit and be reimbursed $50 for their time. The materials instructed interested participants to enroll in the study by contacting the PI via telephone, email, or the study website. Pharmacy contact information was obtained from Hayes Directory, a listing of pharmacies, containing pharmacy name, address, phone number, etc to distribute recruitment materials. A study website (www.alabamaimmunizers.com) was developed to facilitate recruitment and enrollment efforts. Once potential participants indicated their interest via telephone, email, or study website, they were screened and those that met the following inclusion criteria were included: 1) not enrolled in the IIS (verified with ImmPRINT), 2) currently providing at least one type of vaccination, 3) independently owned, and 5) agreed to provide requested data for assessment.

Figure 3.2 Enrollment, Randomization, and Data Collection Process



Sample Size Calculation

The appropriate sample size for this study was determined through a power analysis. A total of 52 interested community pharmacists were enrolled and randomly assigned into either the intervention or control group. This sample size was determined using a Cohen's d effect size of 0.8 (Deyo et al., 2014) and 80% power at an alpha level of 0.05 (Hulley, Cummings, Browner, Grady, & Newman, 2013), using chi-square test on the primary outcome of proportion of IIS enrollment and accounting for at least 20% loss to follow-up based on prior research (randomized pharmacies that do not complete the final three month questionnaire) (Gheewala et al., 2016). A random number generator was used to assign pharmacies to either the intervention or control group as they were enrolled. A three-month rolling recruitment was used with pharmacists enrolling and being randomized on a weekly basis.

Intervention

The intervention was the training program, developed in phase two. This training program consists of an educational component focusing on practical strategies to improve pharmacies' willingness to adopt the IIS and their ability to integrate the IIS into their pharmacy workflow. Training program topics are described in chapter four. The intervention also included an easy to follow implementation guide to assist pharmacies in the manual data submission process and how to retrieve data to identify an immunization gap.

Intervention pharmacists were sent training program instructions via email immediately after study enrollment. Upon completion of the training (approximately one month), intervention pharmacists received CE credit and were asked to provide data as described below.

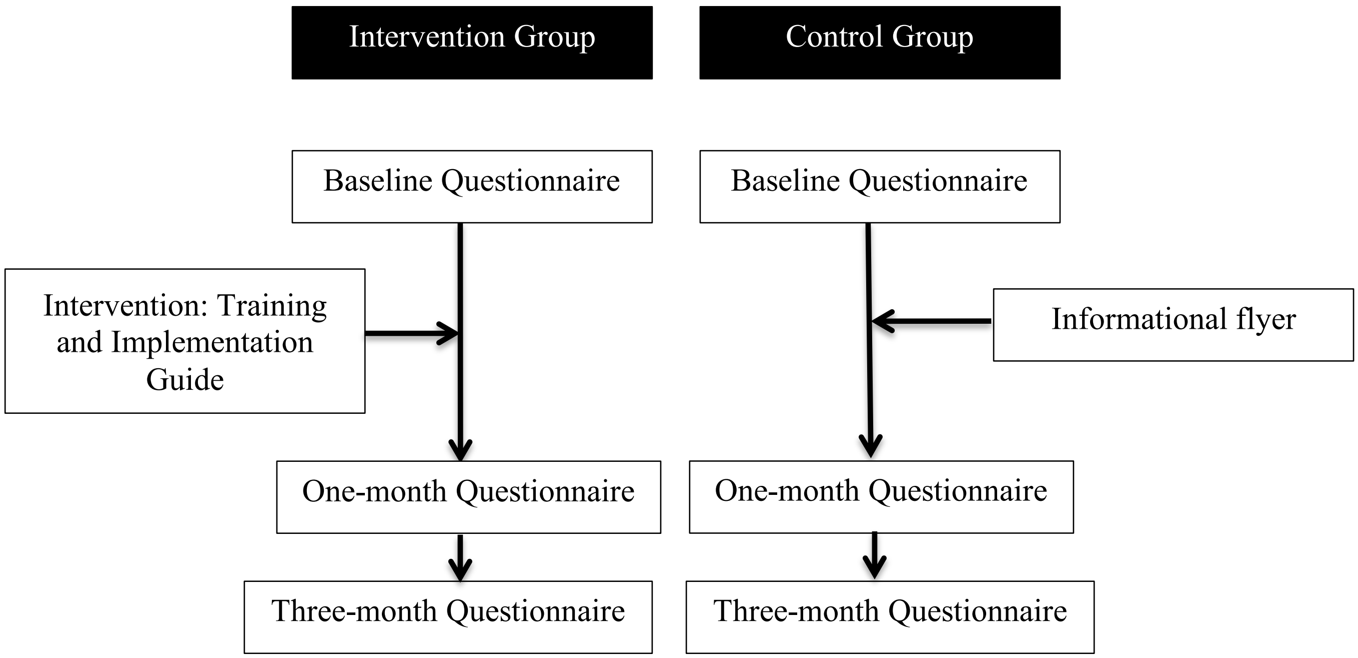
Control Group

Control pharmacists received an informational flyer briefly describing the IIS and providing the ImmPRINT contact information for IIS enrollment. Upon completion of data collection, control pharmacists were also offered the training program for CE credit.

Data Collection

Baseline awareness, knowledge, attitude, and intention of intervention and control participants were obtained via an online Qualtrics questionnaire emailed to participants after randomization was complete. Upon completion of the training program and CE credit receipt, a questionnaire was again administered to the intervention group to assess any changes in these items immediately post-program and at three months. Control pharmacies again completed a questionnaire one-month after enrollment and again three months later. Additionally, through an agreement with ImmPRINT the researchers had access to ImmPRINT data. ImmPRINT provided data indicating which pharmacies had enrolled in the IIS as well as the number and type of all vaccines entered into the IIS by each pharmacy. The IIS maintains this data and removed all patient identifying information before providing files to the researcher. As part of the three months post-CE questionnaire, pharmacies were asked to query the immunization records within their pharmacy system and indicated the actual number of each vaccine administered. This allowed for comparison of the accuracy and completion of pharmacies' reporting to the IIS by comparing the number actually administered to the number of vaccines recorded in the IIS per pharmacy. Discrepancies between the IIS data and pharmacy- reported vaccines indicate that pharmacists have signed up for the IIS, but have not yet begun to implement reporting into their workflow.

Figure 3.3 Data Collection Process



Questionnaire Development

Questionnaires were constructed using newly developed questions informed by both the IIS representative and pharmacist interviews. Questions included: 1) Pharmacist and Pharmacy Characteristics, 2) Awareness and Knowledge of Immunization Information Systems, 3) Attitudes toward Immunization Information Systems, 4) Current Documentation Practices, and 5) Intention to Enroll in the Immunization Information System. The baseline questionnaire included pharmacist and pharmacy characteristics, awareness, knowledge, attitudes, and intention. The second questionnaire was administered as a post-CE assessment and included awareness, knowledge, attitudes, and intention related items. The final questionnaire was administered three months after CE completion and included awareness, knowledge, attitudes, implementation factors, and the number and type of vaccines administered in the past three months. Questionnaires are included in Appendices 6-8. The variables included in each questionnaire are described in Table 3.2 below.

Pre-test of Questionnaire

All questionnaires were pre-tested among a convenience sample of five independent community pharmacists prior to distribution. Information gained through this pre-test was used to revise the questionnaires.

Validity

Validity is defined as the degree to which evidence and theory support the interpretations made from an instrument. To accumulate evidence evaluating the validity of measures used in this study, two types of validity were assessed: 1) content and 2) internal structure. Content validity was assessed during the development of the questionnaire. Internal structure of the questionnaire was assessed after baseline data is collected and is described within the Data Analyses and multi-item measures section in chapter four.

Variables

This study measured multiple variables including awareness, knowledge, attitudes, intention, IIS enrollment, IIS participation, and implementation factors including intervention characteristics, inner setting, outer setting, and process. Each variable is included in Table 3.2 and described below.

Table 3.2 Variables

Variable	Definition	Source	Measurement
Awareness	The extent to which participant is aware of immunization information systems	Questionnaire Baseline: Section II Q2.3-2.5 (3 items) One month: Section I Q1.3-1.5 (3 items) Three months: Section I Q1.4-1.6 (3 items)	Each item is scored, 0 for an incorrect answer and 1 for a correct answer. Index is the sum of 3 items.
Knowledge	The extent to which participant is familiar with and understands immunization information systems	Questionnaire Baseline: Section II Q2.2,2.6-2.12 (8 items) One month: Section I Q1.2, 1.6-1.12 (8 items) Three months: Section I Q1.3, 1.6-1.13 (8 items)	Each item is scored, 0 for an incorrect answer and 1 for a correct answer. Index is the sum of 8 items.
Attitudes/ Implementation Factors: Intervention Characteristics	Participant's perceptions toward attributes of the immunization information system	Questionnaire Baseline: Section III Q3.1-3.25 (25 items) One month: Section III Q3.1-3.25 (25 items) Three months: Section II Q2.1-2.25 (25 items)	Each item is scored ranging from 0 for strongly disagree to 6 for strongly agree. Scale is the mean of 25 items. 10 items are reverse coded (Baseline Q3.1, 3.3, 3.4, 3.9, 3.11-3.15, 3.25; Three months Q2.1, 2.3, 2.4, 2.9, 2.11-2.15, 2.25).
Intention	Participant's likelihood to enroll their pharmacy in the IIS	Questionnaire Baseline: Section V Q5.1-5.3 (3 items) One month: Section II Q2.1-2.3 (3 items)	Each item is scored ranging from 0 for strongly disagree to 6 for strongly agree. Scale is the mean of 3 items.
IIS Enrollment	Participant's pharmacy enrollment in the Alabama IIS (ImmPRINT)	Data provided by ImmPRINT obtained at baseline and three months	Scored 0 for "did not enroll in IIS" to 1 for "did enroll in IIS".
IIS Participation	Extent to which the participant's pharmacy's	Questionnaire Three months: Section V (16 items)	Proportion of doses administered that are reported in the

	immunization data is accurate and complete in the immunization information system	ImmPRINT data obtained at three months	immunization information system.
Implementation Factors: Characteristics of Individuals	Attributes of individuals that influence implementation of the immunization information system	Questionnaire Three months: Section VI Q6.28-6.29 (2 items)	Each item is scored ranging from 0 for strongly disagree to 6 for strongly agree. Scale is the mean of 2 items. 1 item (Q6.28) is reverse coded.
Implementation Factors: Inner Setting	Internal characteristics of the pharmacy that influence implementation of the immunization information system	Questionnaire Three months: Section VI Q6.7-6.27 (21 items)	Each item is scored ranging from 0 for strongly disagree to 6 for strongly agree. Scale is the mean of 21 items. 1 item (Q6.26) is reverse coded.
Implementation Factors: Outer Setting	Factors external to the pharmacy that influence implementation of the immunization information system	Questionnaire Three months: Section VI Q6.1-6.6 (6 items)	Each item is scored ranging from 0 for strongly disagree to 6 for strongly agree. Scale is the mean of 6 items.
Implementation Factors: Process	Systems and pathways within the pharmacy that influence implementation of the immunization information system	Questionnaire Three months: Section VI Q6.30-6.42 (13 items)	Each item is scored ranging from 0 for strongly disagree to 6 for strongly agree. Scale is the mean of 13 items.

Awareness

Awareness is defined as the extent to which the participant is aware of general information regarding immunization information systems. The first step in making a behavior change is for an individual to become aware of the need to change. Individuals who are aware and interested in adopting a change are better prepared to then receive the information and skills needed to take action (Contento, 2007). Awareness was measured using three items. Participants were asked to indicate whether they believe the following statements to be true or false: 1) IIS consolidate vaccination data for patients within a defined geographic area, 2) pharmacies can record administered vaccinations in immunization information systems, and 3) other providers can retrieve immunization information in real time. Awareness was measured at baseline (questionnaire Section II Q2.3-2.5), one month (questionnaire Section I Q1.3-1.5), and three months (questionnaire Section I Q1.4-1.6). Each item was scored, 0 for an incorrect answer and 1 for a correct answer. Awareness index is the sum of the 3 items and could range from 0-3.

Knowledge

Knowledge and awareness are often used interchangeably or together without making a distinction between the two. The literature cites a need for definitional clarity between the constructs of knowledge and awareness (Trevethan, 2017). While awareness is often referred to as having general information, knowledge is typically defined as having more factual information (Trevethan, 2017). Knowledge is defined in this study as the extent to which the participant is familiar with and understands immunization information systems. Eight items were used to measure knowledge. Participants were asked to respond to the following six true or false statements (correct response): 1) IIS are also known as immunization registries (T), 2) each state maintains its own IIS (T), 3) IIS consolidate immunization doses from all providers regardless of participation (F), 4) IIS can share data between states (F), 5) IIS reporting is mandatory in Alabama (F), and 6) IIS reporting is mandatory in all states (F). Participants were also asked to respond to two multiple answer questions, 1) which of the following are methods of documenting immunizations and 2) IIS typically include which of the following. Knowledge was measured at baseline (questionnaire Section II Q2.2,2.6-2.12), one month (questionnaire Section I Q1.2, 1.6-1.12), and three months (questionnaire Section I Q1.3, 1.6-1.13). Each item was scored, 0 for an incorrect answer and 1 for a correct answer. Knowledge is the sum of the 8 items and could range from 0-8.

Attitudes

Attitudes are defined in this study as the participant's attitude toward attributes of the immunization information system. Attitudes can also be defined as the participant's perception of the intervention characteristics, a domain within the CFIR (L. Damschroder et al., 2009). This domain examines key attributes of interventions and their influence on the successful implementation of the intervention. This domain includes several constructs assessing various attributes of the intervention including adaptability, complexity, cost, design quality and packaging, evidence strength and quality, intervention source, relative advantage, and trialability (L. Damschroder et al., 2009). Research has shown support for the influence of intervention characteristics on implementation across a number of disciplines (Greenhalgh, Robert, Macfarlane, et al., 2004). A 25-item scale was developed to measure attitudes, informed by previous research examining intervention characteristics (Atkinson, 2007; Chang & Pan, 2011; Gustafson et al., 2003; Moore & Benbasat, 1991; Peltier, Schibrowsky, & Zhao, 2009; Venkatesh & Davis, 2000). Participants were asked to rate their level of agreement with 25 statements from strongly disagree to strongly agree. Examples of items include: 1) IIS are not standardized in terms of data required, 2) current systems of reporting immunizations are sufficient to determine immunization status, 3) data recorded in IIS is inaccurate, and 4) IIS provide patients with consolidated immunization records. Attitudes were measured at baseline (questionnaire Section III Q3.1-3.25), one month (questionnaire Section III Q3.1-3.25), and three months (questionnaire Section II Q2.1-2.25). Each Likert-type item was scored, ranging from 0 for strongly disagree to 6 for strongly agree. Ten items were reverse coded due to negative wording (baseline and one month questionnaires: Q3.1, 3.3, 3.4, 3.9, 3.11-3.15, 3.25; three months questionnaire: Q2.1, 2.3, 2.4, 2.9, 2.11-2.15, 2.25). Mean scores were calculated for the 25 items in the scale so that attitudes score range from 0 to 6.

Intention

In this study, intention is defined as the participant's likelihood to enroll their pharmacy in the IIS (ImmPRINT). Theories including intention argue that it is the immediate antecedent and most proximate predictor of behavior change (Ajzen, 1991; Fishbein & Ajzen, 1975). Research has found that intention explains 19-38% of variance in behavior (Armitage & Conner, 2001; Sheeran & Orbell, 1998; Sheppard, Hartwick, & Warshaw, 1988; Van den Putte). In this study, the primary behavior of interest is enrollment in the IIS and intention was measured as a predictor of enrollment. While many studies utilize a single item measure of intention, this approach has been criticized as it limits the ability to measure internal reliability (Peter, 1979). In 2002, Ajzen developed an instructional guide on the construction of a Theory of Planned Behavior questionnaire, in which he suggests the use of multiple Likert-type items to measure intention (Ajzen, 2002). Therefore, a three-item scale was developed to measure intention in this study, informed by Ajzen's work (Ajzen, 2002). Participants were asked to rate their level of agreement with three statements with response options ranging from strongly disagree to strongly agree. Items included: 1) I plan to enroll my pharmacy in the IIS within 30 days, 2) I will make an effort to enroll my pharmacy in the IIS in the next 30 days, and 3) I intend to enroll my pharmacy in the immunization information system. Intention was measured at baseline (questionnaire Section V Q5.1-5.3) and one month (questionnaire Section II Q2.1-2.3). Each Likert-type item was scored, ranging from 0 for strongly disagree to 6 for strongly agree. Mean scores were calculated for the three items in the scale so that intention score ranges from 0 to 6.

IIS Enrollment

The primary outcome, IIS enrollment, is defined in this study as the participant's pharmacy enrollment in the Alabama IIS (ImmPRINT). Pharmacies enroll in the Alabama IIS by contacting ImmPRINT or the Alabama Department of Public Health's (ADPH) Immunization Division. In order to enroll, pharmacies must complete a site enrollment agreement and new user registration. Pharmacies are then scheduled for an on-site face-to-face ImmPRINT training session with ADPH Immunization Division staff. Pharmacy enrollment status was provided by ImmPRINT through a data sharing agreement. Pharmacies who have completed the site enrollment agreement were classified as enrolled. Enrollment was categorized as 0 for "did not enroll in the IIS" and 1 for "did enroll in the IIS". This information was obtained at two time points throughout the study including baseline and three months.

IIS Participation

IIS participation is defined as the extent to which the participant's pharmacy immunization data is accurate and complete in the immunization information system. In order to obtain a degree of accuracy, pharmacy immunization data was compared to data recorded in ImmPRINT. Pharmacy immunization data, including the number and types of vaccines administered was self-reported by each pharmacy. Pharmacies were asked to query the immunization records within their pharmacy system and indicate the actual number of each type of vaccine administered within the three month questionnaire (Section V). This was then compared to the number and types of vaccines recorded in the IIS for each pharmacy. The number and types of vaccines recorded were provided by the Alabama Immunization information system, ImmPRINT. This data was collected from ImmPRINT at three months. Participation was calculated as the proportion of doses administered that were reported in the immunization information system.

Implementation Factors

Implementation factors informed by the Consolidated Framework for Implementation Research (CFIR) were measured including: 1) Characteristics of Individuals, 2) Inner Setting, 3) Outer Setting, and 4) Process. Questionnaire items were mapped to each CFIR domain and construct in Appendix 9.

Characteristics of individuals are defined in this study as attributes of individuals that influence implementation of the immunization information system. This CFIR domain includes five constructs that are related to the individuals involved in the implementation of the intervention. These include knowledge and beliefs about the intervention, self-efficacy, individual stage of change, individual identification with the organization, and other personal attributes which can include motivation, competence, intellectual ability, etc. (L. Damschroder et al., 2009). The outcome of interest in this study, pharmacy enrollment in the immunization information system, is a decision made at the organizational level; however, characteristics of the pharmacy staff interacting with the IIS and involved in the decision making process will impact its success. A three-item scale was developed to measure individual characteristics, informed by previous research measuring CFIR domains including individual characteristics (Gustafson et al., 2003; Kansanaho, Puumalainen, Varunki, Airaksinen, & Aslani, 2004). Participants were asked to rate their level of agreement with two statements from strongly disagree to strongly agree. Items include: 1) our staff's knowledge and beliefs are barriers to implementing the IIS and 2) our staff are confident that they can use the immunization information system, and 3) our staff have a sense of personal responsibility for improving patient care and outcomes. These individual characteristics were measured at three months (questionnaire Section VI Q6.28-6.29). Each Likert-type item was scored, ranging from 0 for strongly disagree to 6 for strongly agree.

One item was reverse coded due to negative wording (Q6.28). Mean scores were calculated so that individual characteristics score ranges from 0 to 6.

The Inner Setting domain is defined in this study as internal characteristics of the pharmacy that influence implementation of the immunization information system. This CFIR domain includes five constructs that are related to internal characteristics of the organization that will influence implementation. These constructs include structural characteristics, networks and communication, culture, implementation climate, and readiness for implementation (L. Damschroder et al., 2009). A 21-item scale was developed to measure the inner setting domain, informed by previous research (Fang, Yang, Feng, Ni, & Zhang, 2011; Gustafson et al., 2003; Helfrich, Li, Sharp, & Sales, 2009; Roberts, Benrimoj, Chen, Williams, & Aslani, 2008). Participants were asked to rate their level of agreement with the 21 statements from strongly disagree to strongly agree. Examples of items in this scale include: 1) our pharmacy owner/manager rewards innovation and creativity to improve patient care, 2) staff members in our pharmacy cooperate to maintain and improve effectiveness of patient care, and 3) successful implementation of the IIS will help us meet our organization's mission and goals. These inner setting items were measured at three months (questionnaire Section VI Q6.7-6.27). Each Likert-type item was scored, ranging from 0 for strongly disagree to 6 for strongly agree. One item was reverse coded due to negative wording (Q6.26). Mean scores were calculated so that individual characteristics score ranges from 0 to 6.

Outer setting is defined in this study as factors external to the pharmacy that influence implementation of the immunization information system. This CFIR domain includes four constructs that are related to factors of influence that are external to the organization. These constructs include patient needs and resources, cosmopolitanism, peer pressure, and external policy and initiatives (L. Damschroder et al., 2009). A six-item scale was developed to measure the outer setting, informed by previous research (Gustafson et al., 2003; Helfrich et al., 2009; Peltier et al., 2009; Roberts et al., 2008). Participants were asked to rate their level of agreement with six statements from strongly disagree to strongly agree. Items include: 1) the IIS incorporates the needs and preferences of patients, 2) it is helpful to have people external to the pharmacy who can provide support when needed, 3) it is helpful to have access to someone from outside the pharmacy when implementing the immunization information system, 4) most pharmacies are using the immunization information system, 5) using the IIS helps my pharmacy maintain a competitive advantage over other pharmacies, and 6) external organizations or individuals have pressured our pharmacy to implement the immunization information system. The outer setting domain was measured at three months (questionnaire Section VI Q6.1-6.6). Each Likert-type item was scored, ranging from 0 for strongly disagree to 6 for strongly agree. Mean scores will be calculated so that the outer setting score ranges from 0 to 6.

Process is defined in this study as systems and pathways within the pharmacy that influence implementation of the immunization information system. This CFIR domain includes eight constructs that are related to activities within the implementation process. These constructs include planning, engaging, executing, and reflecting and evaluating (L. Damschroder et al., 2009). A 13-item scale was developed to measure process, informed by previous research (Gustafson et al., 2003; Helfrich et al., 2009). Participants were asked to rate their level of agreement with 13 statements from strongly disagree to strongly agree. Examples of these items include: 1) our plan for implementing the IIS clearly describes tasks and timelines, 2) staff opinion leaders are supportive of the immunization information system, and 3) we've spoken with patients and considered their opinion regarding the immunization information system. The process domain was measured at three months (questionnaire Section VI Q6.30-6.42). Each Likert-type item was scored, ranging from 0 for strongly disagree to 6 for strongly agree. Mean scores were calculated so that the process score ranges from 0 to 6.

Data Analyses

All statistical analyses were conducted using SPSS version 21.0. Descriptive statistics including means, standard deviations, and frequencies are reported for all key variables including demographic characteristics of participants.

Validity and Reliability

To ensure that the intended structure and actual structure of items are consistent, exploratory factor analysis of data using principal components and varimax rotation will be used. Reliability is defined as the consistency of a measure. Internal consistency is one measure of reliability that will be used in this study. Internal consistency measures the correlations between items within a measure. Cronbach's alpha is a commonly used measure of internal consistency. The Cronbach's alpha of each scale was measured with 0.7 as the acceptable reliability threshold.

Hypothesis 1a

The first hypothesis in this study is that an increase in pharmacists' awareness will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months. To test this hypothesis, two-way mixed ANOVA was used to compare awareness as a continuous dependent variable between time-points (baseline, one month, and three months) and between groups (intervention or control).

Hypothesis 1b

Hypothesis 1b in this study is that an increase in pharmacists' knowledge will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months. To test this hypothesis, two-way mixed ANOVA was used to compare knowledge as a continuous dependent variable between time-points (baseline, one month, and three months) and between groups (intervention or control).

Hypothesis 1c

An increase in pharmacists' positive attitudes observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months is hypothesis 1c. To test this hypothesis, two-way mixed ANOVA was used to compare attitudes as a continuous dependent variable between time-points (baseline, one month, and three months) and between groups (intervention or control).

Hypothesis 2

The second hypothesis in this study is that an increase in pharmacists' intention to enroll in the IIS will be observed among intervention and control pharmacies who demonstrate greater awareness, knowledge, and positive attitudes at one-month. To test this hypothesis, multiple linear regression was used with intention as a continuous dependent variable and awareness, knowledge, and attitudes measured at one-month as predictors of intention.

Hypothesis 3

The third hypothesis in this study is that an increase in pharmacists' intention to enroll in the IIS will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months. To test this hypothesis, two-way mixed ANOVA was used to compare intention as a continuous dependent variable between time-points (baseline, one month, and three months) and between groups (intervention or control).

Hypothesis 4

That an increase in pharmacists' enrollment in the IIS will be observed among participants in the intervention group when compared to the control group measured at three months is the fourth hypothesis tested in this study. A chi-squared test was used to explore this hypothesis, with enrollment as a dichotomous dependent variable and group as the independent variable.

Hypothesis 5

The fifth hypothesis explored in this study is that an increase in pharmacists' participation in the IIS will be observed among participants in the intervention compared to the control group at three-months. An independent t-test was used to test this hypothesis, with degree of participation as a continuous dependent variable and group as the independent variable at three months.

Hypothesis 6

The sixth hypothesis is that an increase in pharmacists' enrollment in the IIS at three months will be observed among participants who demonstrate greater intention to implement the immunization information system. Logistic regression was used to test this hypothesis, with enrollment as a dichotomous dependent variable and intention as the continuous independent variable at three months.

Hypothesis 7

In this study, hypothesis 7 is that there will be a relationship between implementation factors and IIS participation. The implementation factors include innovation characteristics, inner setting, outer setting, characteristics of individuals, and process. Multiple linear regression was used to test this hypothesis, with participation as a continuous dependent variable and implementation factors (innovation characteristics, inner setting, outer setting, characteristics of individuals, and process) as predictor variables at three months.

Table 3.3 Data Analysis Plan

RQ	Hypothesis	Dependent Variable	Independent Variable(s)	Time point(s)	Data Analysis
RQ5	H1a	Awareness (continuous)	Group (Intervention/control)	1.Baseline 2. One month 3. Three months	Two-way mixed ANOVA
RQ5	H1b	Knowledge (continuous)	Group (Intervention/control)	1.Baseline 2. One month 3. Three months	Two-way mixed ANOVA
RQ5	H1c	Attitude (continuous)	Group (Intervention/control)	1.Baseline 2. One month 3. Three months	Two-way mixed ANOVA
RQ6	H2	Intention (continuous)	Awareness Knowledge Attitudes	1. One month	Multiple linear regression
RQ7	H3	Intention (continuous)	Group (Intervention/control)	1.Baseline 2. One month 3. Three months	Two-way mixed ANOVA
RQ8	H4	Enrollment (dichotomous)	Group (Intervention/control)	1.Three months	Chi-squared test
RQ9	H5	Participation (continuous)	Group (Intervention/control)	1. Three months	Independent t-test
RQ10	H6	Enrollment (dichotomous)	Intention (continuous)	1. Three months	Logistic Regression
RQ11	H7	Participation (continuous)	Implementation Factors (continuous) • Innovation Characteristics • Inner Setting • Outer Setting • Process	1. Three months	Multiple Linear Regression

Chapter 4. Results

Phase I: Qualitative Results

The first phase of this dissertation explored motivational factors and contextual barriers, as well as best practices used in implementing Immunization Information Systems (IIS) in community pharmacies. Pharmacy personnel from pharmacies already enrolled in IIS and IIS representatives in Alabama and high IIS participation states (North Dakota, Wisconsin, Minnesota, and Georgia) were interviewed to gain a greater understanding of IIS implementation.

Participant characteristics

A total of 25 interviews were conducted including 16 pharmacy personnel and nine IIS representatives. Of the 16 pharmacy personnel, 12 were from Alabama. Participant characteristics can be found in tables 4.1- 4.3. All pharmacist participants were white and the majority of pharmacy personnel were female (62.5%) and with a PharmD (56.3%). About half (50.0%) were working in a multi-store independent pharmacy. The mean age of pharmacy personnel participants was 42 (SD= 10.4) with 17.7 (10.1) years of experience in their current role. Participants were working in locations with an average of 2.83 (1.1) pharmacists trained in vaccination administration. Participating pharmacies were offering a wide range of vaccinations, with 1) influenza, 2) Pneumococcal polysaccharide (PPSV23), 3) Pneumococcal 13-valent conjugate (PCV13), 4) Tetanus/ Diptheria/ Pertussis (Tdap), and 5) Herpes Zoster being the most offered (Table 4.2). Of the 9 IIS representatives from 5 states, the majority (83.3%) of

IIS representatives were also female, with an equal representation of white and black participants (Table 4.3). The mean number of years employed with their respective state's department of public health was 10.7 (2.9).

Table 4.1 Pharmacy Participant Characteristics (N=16)

Pharmacy Participant Characteristics (N=16)	Number (%)
Sex	
Female	10 (62.5)
Male	6 (37.5)
Race	16 (100)
White	
Ethnicity	
Not Hispanic or Latino	15 (93.8)
Position	
Staff Pharmacist	6 (37.5)
Pharmacy Manager	6 (37.5)
Pharmacy Owner/Partner	6 (37.5)
Pharmacy Technician	1 (6.3)
Other	1 (6.3)
Education	
PharmD	9 (56.3)
B.S. Pharmacy	6 (37.5)
Nationally Certified	1 (6.3)
Practice Site	
Multi store independent pharmacy	8 (50.0)
Single store independent pharmacy	6 (37.5)
Other*	2 (12.5)
	Mean (SD)
Age	42.3 (10.4)
Number of Years Registered as a Pharmacist/Pharmacy Technician	17.7 (10.1)
FTE staff pharmacists	4.7 (9.5)
FTE pharmacy technicians	7.5 (14.2)
Average prescription volume per day	253.0 (135.6)
Staff pharmacists trained in vaccination administration per pharmacy	2.8 (1.1)
Staff pharmacists actively administering vaccines per pharmacy	2.6 (1.2)

*Dual appointment with academic institution

Table 4.2 Number of pharmacies offering each type of vaccine in the past 12 months (N=16)

Vaccine type	Number of pharmacies (%)
Influenza	15 (93.8)
Pneumococcal polysaccharide (PPSV23)	15 (93.8)
Pneumococcal 13-valent conjugate (PCV13)	14 (87.5)
Tetanus/ Diptheria/ Pertussis (Tdap)	14 (87.5)
Herpes Zoster	11 (68.8)
Meningococcal	7 (43.8)
Hepatitis B	7 (43.8)
Hepatitis A	6 (37.5)
Measles, Mumps, Rubella (MMR)	4 (25.0)
Varicella	4 (25.0)
Travel vaccines (Yellow fever, typhoid, etc.)	3 (18.8)
Haemophilus influenza	2 (12.5)
Human Papillomavirus (HPV)	2 (12.5)
Rotavirus (RV)	2 (12.5)
Tetanus/ Diptheria (Td)	2 (12.5)
Other	2 (12.5)

Table 4.3 IIS Participant Characteristics (N=6)

IIS Participant Characteristics (N=6)	N (%)
Sex	
Female	5 (83.3)
Male	1 (16.7)
Race	
White	3 (50)
Black	3 (50)
Ethnicity	
Not Hispanic or Latino	6 (100)
Education	
Masters	4 (66.7)
PhD	1 (16.7)
Bachelors	1 (16.7)
	Mean (SD)
Age	40.5 (6.8)
Number of years employed by state department of health	10.7 (2.9)

Consolidated Framework for Implementation Research (CFIR) Ratings

Upon completion of coding, the CFIR rating rules were used to apply a summary rating to each construct to allow for identification of constructs that will have the greatest impact on implementation among Alabama pharmacists (Table 4.4). This includes the construct's valence (positive vs. negative) and strength (weak or strong). Valence is whether the construct had a positive or negative influence on implementation. Strength describes whether that influence was weak or strong. This is identified through factors including the level of agreement between multiple participants and examples provided by participants. Following CFIR Rating Rules, mixed comments were applied a weak positive or weak negative rating based on the aggregate of comments. For example, some pharmacists indicated that cost was not a barrier to implementation of IIS in their pharmacy. However, more indicated that it was a factor negatively influencing their implementation. Therefore, cost was applied a weak negative summary rating (-1) to reflect this mixture of comments. For pharmacist interviews, TH applied a summary rating (valence and strength) to each construct. Ratings were then discussed and verified with the second coder through peer debriefing. The constructs that were identified as having a strong negative (-2) or strong positive (+2) influence are described in the following sections by CFIR domain.

Table 4.4 Consolidated Framework for Implementation Research Summary Ratings

Domain	Construct	Summary Rating[a]
Innovation Characteristics	A. Innovation Source	n/a
	B. Evidence Strength & Quality	n/a
	C. Relative Advantage	0
	D. Adaptability	**-2**
	E. Trialability	n/a
	F. Complexity	**-2**
	G. Design Quality & Packaging	0
	H. Cost	-1
Inner Setting	A. Structural Characteristics	-1
	B. Networks & Communications	+1
	C. Culture	+1
	D. Implementation Climate	
	1. Tension for Change	+1
	2. Compatibility	**-2**
	3. Relative Priority	0
	4. Organizational Incentives & Rewards	n/a
	5. Goals & Feedback	0
	6. Learning Climate	+1
	E. Readiness for Implementation	
	1. Leadership Engagement	+1
	2. Available Resources	**-2**
	3. Access to Knowledge & Information	**-2**
Outer Setting	**A. Needs & Resources of Those Served by the Organization**	**+2**
	B. Cosmopolitanism	+1
	C. Peer Pressure	**+2**
	D. External Policy & Incentives	**+2**
Characteristics of Individuals	**A. Knowledge & Beliefs about the Innovation**	**-2**
	B. Self-Efficacy	+1
	C. Individual Stage of Change	0
	D. Individual Identification with Organization	+1
	E. Other Personal Attributes	n/a
Process	A. Planning	0
	B. Engaging	
	1. Opinion Leaders	+1
	2. Formally Appointed Internal Implementation Leaders	n/a
	3. Champions	+1
	4. External Change Agents	+1
	5. Key Stakeholders	**-2**
	6. Innovation Participants	**-2**
	C. Executing	0
	D. Reflecting & Evaluating	n/a

aThe influence ratings range from -2 to 2 where 2 represents 'strong', 1 represents 'weak' and 0 represents neutral. Negative influence means the construct hinders implementation, while positive means the construct facilitates implementation.
n/a- Not mentioned during interviews

Consolidated Framework for Implementation Research Domains

A total of 32 of 39 CFIR constructs were mentioned during interviews and experiences of participants in implementing immunization registries appeared to align well with the CFIR domains including innovation characteristics, inner setting, outer setting, characteristics of individuals, and process. Within each domain, the constructs with a strong influence (+2 or -2) are indicated in bold in Table 4.4.

Innovation Characteristics

The first domain, innovation characteristics, describes key attributes of the innovation itself that may influence the success of implementation. In this study, the innovation is the IIS. The constructs within this domain that demonstrated a strong negative influence included Adaptability and Complexity.

Table 4.5 Excerpts from interviews demonstrating innovation characteristics constructs

Construct	**Excerpt from interviews**
Adaptability	*"It doesn't fit into our flow because you have to, you log in separately to the system and then you have to enter it separate, you know. You can't go to it from like the prescription screen while you're filling it; not on our system."*
Complexity	*"If they're not born in Alabama after '89 or '90-something, they're not in there. So you either have to add them or just not put one in. That happens occasionally. It just depends on what's going on and whether or not they want to be added in. Then you got to get all their information like mother's maiden name and all this kind of stuff. It's kind of crazy."*

Adaptability

Adaptability was defined as the degree to which the innovation could be adapted, tailored, refined, or reinvented to meet organization's needs (L. Damschroder et al., 2009). Statements regarding the ability or inability of the IIS to be adapted to the pharmacy context were included. Alabama pharmacists described the IIS as being disruptive and not easily adapted to fit into their daily workflow. For example, one Alabama pharmacist said, *"It doesn't fit into our flow because you have to, you log in separately to the system and then you have to enter it separate, you know. You can't go to it from like the prescription screen while you're filling it; not on our system."* Many pharmacists expressed the need for automatic exchange of information between the dispensing software and ImmPRINT, *"Instead of taking the data from our software system, like it does on every other piece of information that it gathers, it cannot take the vaccine data from RX-30 and send it to ImmPRINT. So it's either me enter the data into Prescribe Wellness and Prescribe Wellness send it on to ImmPRINT, or me enter it into ImmPRINT. To me that doesn't make any sense."* However, their willingness to pay for such a feature is unclear. For example one Alabama pharmacist said, *"If it were a minimal charge of, say, 20, 30 bucks a month, something like that. I mean, much more than that, I don't know."* Hesitancy to pay for an automatic connection between the dispensing software and IIS was not unique to Alabama pharmacists. For example, a pharmacist from a high participation state said, *"It was too expensive for our blood, because it's $80 a month no matter what. You had to stay active all year. I know my comfort level would not be $80 a month. Vaccines, I mean immunizations, that's one of the reasons why so many chains have become such a huge, huge advocate for immunizations is because it's also a huge profit for the company. So they can afford to do a lot of the giving away vaccine things and stuff like that. But when you're talking about like small, independent community pharmacies, where you're not making money on prescriptions, so I'd love to immunize the world because it's the right thing to do, but at the end of the day, we're also a business and if the thing that's making you money is actually immunizations, you try to do everything possible to maximize your gross profit. So that involves using students and having our pharmacist just upload that spreadsheet instead of spending $80 to interface with a computer."*

Complexity

Complexity was defined as the perceived difficulty of the innovation, reflected by duration, scope, radicalness, disruptiveness, centrality, intricacy, and number of steps required to implement (L. Damschroder et al., 2009). Statements regarding the complexity of the innovation itself were included while statements regarding the complexity of implementation were excluded. In summary, participants reported that IIS process is time consuming with many required fields, missing populated lot number which could interrupt the workflow, and adding new patient is problematic. For example, this Alabama pharmacist describes the process, *"So we log into the ImmPRINT system and I'm trying to picture it in my mind. And you search for the patient, a lot of times if they're older I've noticed that we have to add them to the system. That they're not in it, like if they're younger most of them are in there because I guess of all their school vaccines and everything. And so add them in and then there's an option to administer a vaccine. So we do that, and you pick which vaccine it was, what the NDC number was and then where you injected it, were there any adverse effects and then you submit it."* Another Alabama pharmacist said, *"To tell you the truth, I don't worry about it [entering information into ImmPRINT] too much just because of the time involved in it and then all of the questions you have to ask them."*

The process of entering new lot numbers was described by pharmacists as being particularly troublesome. For example on Alabama pharmacist said, *"You should not have to go through their ridiculous process to enter a lot number that they don't have on file yet. If you do a Prevnar for example, or any vaccine, and it's a lot number from the manufacturer that hasn't been officially entered into ImmPRINT, you can't choose it from the drop-down menu. And so there's no such thing as a free text box for you to put in a lot number that ImmPRINT doesn't recognize yet. Well, that's ridiculous. If they're interested in keeping up with a lot number, let me enter it. You know what I mean?"* IIS representatives interviewed described the lot number request process within ImmPRINT, *"There's a feature in ImmPRINT where you make your lot number request. It comes to me. If there's nothing wrong with the request, I approve it and I send them an email back* *letting them know the lot number is active. If something's wrong with it, I tell them what's wrong with it so they can fix it and resubmit it. Then I approve it and send them an email back letting them know that that lot number is active."* However, many of the pharmacists interviewed were not aware of this feature within ImmPRINT and stated that they would not enter vaccines they administered without an approved lot number into ImmPRINT, *"No. No, no, no. I'm not wasting my time. I just don't put it in there. You know? If they really want to know and they want access to the data, then they need to make that easier, you know what I mean?"* or *"No, I don't do anything. I consider that to be their problem."*

Creating a new patient profile was described by Alabama pharmacy personnel as being especially complex and requiring detailed information that they may not have readily accessible. For example, one Alabama pharmacist said, *"If they're not born in Alabama after '89 or '90-something, they're not in there. So you either have to add them or just not put one in. That happens occasionally. It just depends on what's going on and whether or not they want to be added in. Then you got to get all their information like mother's maiden name and all this kind of stuff. It's kind of crazy."*

Inner Setting

The third domain of the CFIR is the inner setting. This domain describes the structural, political, and cultural context through which the intervention proceeds and the relationship between these elements. The constructs within this domain that demonstrated a strong negative influence included Compatibility, Available Resources, and Access to Knowledge and Information. When considering IIS features and its primary purpose (for public health), it makes sense that constructs within the inner setting domain show negative influence over the utilization of IIS, as resources from the adopting organization are required to make implementation successful.

Table 4.6 Excerpts from interviews demonstrating inner setting constructs

Construct	Excerpt from interviews
Compatibility	*"I think that using ImmPRINT is basically something that does not pay off for you personally in any way, shape, or form. It's an appeal to the greater good, if you're interested. And quite frankly, there are a lot of business owners who, if it doesn't benefit them in some way that's tangible to them, are just not going to care ever."*
Available Resources	*"You have to make the time and make it a priority. You have to make sure you've got a space to do it and a computer to use. You have to make concessions, or you would have to put it in your workflow, like a prescription, so that it gets processed."*
Access to Knowledge and Information	*"I guess if I ever had a question I would just ask the other pharmacist and then if we couldn't figure it out I'm sure there's some kind of help me tab somewhere."*

Compatibility

Compatibility was defined as the degree of fit between meaning and values attached to the innovation by involved individuals, and how those align with individuals' own norms, values, and perceived risks and needs (L. Damschroder et al., 2009). Statements that demonstrate the level of compatibility the innovation has with organizational values and work processes were included.

While some pharmacists reported a desire to participate in ImmPRINT for the good of their patients, others expressed concerns about the lack of benefit to the pharmacists or pharmacy. For example, one Alabama pharmacist stated, "*I think that using ImmPRINT is basically something that does not pay off for you personally in any way, shape, or form. It's an appeal to the greater good, if you're interested. And quite frankly, there are a lot of business owners who, if it doesn't benefit them in some way that's tangible to them, are just not going to care ever.*"

Available Resources

Available resources were defined as the level of resources the organization has dedicated for implementation including physical space and time (L. Damschroder et al., 2009). Statements were included that related to the presence or absence of resources specific to the innovation that is being implemented. Many Alabama pharmacists described lack of resources to support implementation. For example, one Alabama pharmacist said, *"You have to make the time and make it a priority. You have to make sure you've got a space to do it and a computer to use. You have to make concessions, or you would have to put it in your workflow, like a prescription, so that it gets processed."*

Access to Knowledge and Information

Access to Knowledge and Information was defined as the ease of access to digestible information and knowledge about the innovation (L. Damschroder et al., 2009). Statements were included that related to implementation leaders' and users' access to knowledge and information regarding use of the program. Over the course of the interviews conducted with Alabama pharmacists, it was evident that most were not aware how or who they could contact to obtain assistance with ImmPRINT. For example, one

Alabama pharmacist describes not being sure where to find information if needed, *"I guess if I ever had a question I would just ask the other pharmacist and then if we couldn't figure it out I'm sure there's some kind of help me tab somewhere."*

Outer Setting

The second domain, outer setting, describes the external environment in which the pharmacy resides. The constructs within this domain that demonstrated a strong influence included: Needs and Resources of Those Served by the Organization, Peer Pressure, and External Policy & Initiatives.

Table 4.7 Excerpts from interviews demonstrating outer setting constructs

Construct	Excerpt from interviews
Needs and Resources of Those Served by the Organization	*"You're helping the patient and you're also helping others in your profession. Cause I mean, like I said, if they go somewhere else next time for a shot that requires a series of them. Then that pharmacist knows or if they go to the doctor's office, they can look on and they would know. So it's not just helping the patient, also helping other healthcare professionals so the patient doesn't overall get too much of an injection."*
Peer Pressure	*"She [nearby physician] had called me and said, 'When you give the new Shingrix, will you please let us know?' And I'm like, 'Oh, sure.' Then she said, 'I'm going in the database and making sure we update it and this and that.' I said, 'Oh well, we do that as well.' She said, 'Oh, that's great!'"*
External Policy and Initiatives	*"Honestly, I am waiting for something like ImmPRINT to be almost like a mandatory type thing, and at that point I think it would be a really good thing. I almost feel like it's going to require that for it to actually be a useful tool."*

Needs and Resources of Those Served by the Organization

Needs and Resources of Those Served by the Organization was defined as the extent to which the needs of patients are known and prioritized by the pharmacy (L. Damschroder et al., 2009).

Most pharmacists recognized the need to provide a complete immunization record for patients to avoid over- or under-immunization. For example, an Alabama pharmacist stated, *"You're helping the patient and you're also helping others in your profession. Cause I mean, like I said, if they go somewhere else next time for a shot that requires a series of them. Then that pharmacist knows or if they go to the doctor's office, they can look on and they would know. So it's not just helping the patient, also helping other healthcare professionals so the patient doesn't overall get too much of an injection."*

Peer Pressure

Peer pressure was defined as mimetic or competitive pressure to implement the innovation (L. Damschroder et al., 2009). Statements were included that described perceived pressure or motivation from other entities or organizations in the local geographic area to implement the innovation. Pharmacists identified physicians as the main source of pressure to implement the IIS. For example, one Alabama pharmacist described a conversation between himself and a neighboring physician, *"She [nearby physician] had called me and said, 'When you give the new Shingrix, will you please let us know?' And I'm like, 'Oh, sure.' Then she said, 'I'm going in the database and making sure we update it and this and that.' I said, 'Oh well, we do that as well.' She said, 'Oh, that's great!'"* Another Alabama pharmacist stated, *"But we enter everything into*

ImmPRINT except for flu shots. And we're very good about it. And the doctors around here, they appreciate that because honestly, I'm the only one who does it. We don't do flu shots because A, it becomes extremely tedious, and B, if you can't remember if you got a flu shot, we really do have a problem. You know what I mean?" While pharmacists recognize the pressure from physicians, they were not influenced by pressure from other independent pharmacies. When asked if they know of any nearby pharmacies that are also using the IIS, most pharmacists were under the impression that chain pharmacies may be, but other independent pharmacies were not using the IIS. For example, one Alabama pharmacist stated, *"I know Wal-Mart and Walgreens and all that are, but independent-wise ... Not that I know of, but that doesn't mean they aren't."*

External Policy and Initiatives

External Policy and Initiatives was defined as external strategies to spread innovations including policy and regulations, external mandates, or recommendations and guidelines (L. Damschroder et al., 2009). The majority of statements coded included references to mandates to report vaccinations administered to the state IIS. At this time, no healthcare professionals in Alabama are mandated to use the state IIS. Among the high participation states, two out of four states had mandates for pharmacy participation.

Interview participants from high participation states spoke of the positive influence of state policies. For example, this pharmacist from a high participation state said, *"I think if it wasn't mandated, especially working in an independent where our computer systems didn't have the upload capabilities automatically on the back end and we had to physically key in every vaccine we give, I don't think it (using IIS) would* *happen unless it was mandated by law."* Another pharmacist from a high participation state said, *"We also by statute are required to document any vaccines we give into the IIS. We are the only medical group within our state, or the medical professionals within our state, that it's legislated in statute that we have to record into the IIS. We have a very high, about a 97% usage of IIS amongst pharmacists in the state, which is pretty remarkable."*

In high participation states without a statewide mandate, there were still some cases, such as participation in the Vaccines for Children (VFC) or a standing order, where a pharmacist would be required to participate in the IIS. For example, this high participation state IIS representative said, *"Yeah so it is an optional system. The few exceptions that we have is as of, I think 2015 or so, vaccine for children providers are required to use the registry not only to order vaccines for that program but also to go ahead and report the immunizations that they give. So that's one group and that's programmatic, that's not a state law. There is an administrative rule here that was passed a couple of years ago that says that pharmacists who immunize children, and they can immunize children six and up, need to submit that information to the registry I think within seven days. So that is an administrative rule for pharmacists only. Those are the only instances where there are requirements for reporting to the registry. Everything else is voluntary."* Another immunization registry representative from a high participation state said, *"Once a quarter we evaluate the data entry, and like I said, that requirement for reporting is just for those pharmacies whose standing orders are signed by our State Health Officer. So we have that list of those pharmacies, and then we evaluate their data* *entry every quarter to see if it remained at least somewhat consistent from quarter to quarter, year to year."*

In Alabama, most pharmacists expressed the need for a mandate of some kind in order for the IIS to become a reliable and useful tool, and lack of external policies was a barrier to their implementation. For example, one Alabama pharmacist said, *"No, no. I just think it's the right thing to do. It doesn't make any sense. I think the thing ought to be mandatory. How can we possibly do the best job? And I'm talking about "we" as in physicians and nurses and all of us. How can we possibly do the best job with vaccines if it's not mandatory?"* Another Alabama pharmacist said, *"Honestly, I am waiting for something like ImmPRINT to be almost like a mandatory type thing, and at that point I think it would be a really good thing. I almost feel like it's going to require that for it to actually be a useful tool."* These Alabama pharmacists did recognize the barriers pharmacists would face resulting from a mandate. For example, one Alabama pharmacist said, *"If everybody was just reporting to ImmPRINT, just like PDMP is mandatory. I know if anybody has filled a controlled substance, it's the law. Every pharmacy has to report every single night to the PDMP, the controlled substances that you filled that day. So, I feel 100% confident that when I run a PDMP, that if somebody filled a controlled substance, I'm going to see it no matter where they filled it. I just think it should be the same way for vaccines. I should be able to pull up the database, and if you got a vaccine, then I should be able to see that. I know logistically for pharmacies it's a lot to manually enter all of that. It's going to be an enormous pushback, so I would like to see that the pharmacy dispensing systems have the ability to be able to report that data into ImmPRINT like the EMR systems."*

Overall, participating pharmacists in Alabama as well as high participation states, regardless of their respective laws surrounding IIS, welcome policies that mandate pharmacy reporting.

Characteristics of Individuals

The fourth domain of the CFIR includes the characteristics of individuals involved with the implementation. This domain describes how attributes of individuals within the organization such as their knowledge or self-efficacy might impact implementation. One construct, Knowledge and Beliefs about the Innovation, within this domain demonstrated a strong negative influence on implementation.

Table 4.8 Excerpts from interviews demonstrating characteristics of individuals constructs

Construct	Excerpt from interviews
Knowledge and beliefs about the innovation	*"Honestly, I just really don't know a whole lot about it. Because I've always assumed that it probably is not a system that at this point is working very well, because it does take time to implement and it is a voluntary basis."*

Knowledge and Beliefs about the Innovation

Knowledge and Beliefs about the Innovation was defined as the involved individuals' attitudes toward and value placed on the innovation, as well as familiarity with facts, truths, and principles related to the innovation (L. Damschroder et al., 2009). This construct was one that seemed to distinguish between Alabama pharmacy personnel and those in other states. Knowledge and beliefs about IIS appeared to more negatively influence implementation among Alabama pharmacists. For example, one Alabama pharmacist enrolled in ImmPRINT states that they don't know much about it and that it is not reliable. This pharmacist stated, "*Honestly, I just really don't know a whole lot about it. Because I've always assumed that it probably is not a system that at this point is working very well, because it does take time to implement and it is a voluntary basis."* However, pharmacists in high participation states demonstrated greater knowledge and positive beliefs about their respective IIS. For example, a pharmacist in a high participation state said, *"Well, we keep on talking about wanting to immunize more and more people and to be equal with other providers, and if we want to be the leaders, why don't we act like the leaders and actually put it in our rules as a requirement."*

Process

Process is the fifth and the final domain of the CFIR. This domain describes the process through which desired changes are achieved. Two constructs within this domain demonstrated a strong influence on implementation. These constructs include Engaging Key Stakeholders and Engaging Innovation Participants.

Table 4.9 Excerpts from interviews demonstrating process constructs

Construct	**Excerpt from interviews**
Engaging Key Stakeholders	"*I've either been putting it in or my technicians. I threatened [the registry] I would not put them in anymore because it was ridiculous that a technician couldn't do that. Finally, after about two months, they decided to let technicians do it again. We were the first store."*
Engaging Innovation Participants	*"Most patients, they have no clue what you're talking about. I'm sure we've mentioned it [the immunization registry] in passing in that particular conversation, but it's not something that we have a regular conversation about."*

Engaging Key Stakeholders

Key Stakeholders were defined as individuals from within the organization that are directly impacted by the innovation, e.g., staff responsible for implementing ImmPRINT (L. Damschroder et al., 2009). Statements were included that related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation. Lack of engagement with key stakeholders demonstrated a strong negative influence among Alabama pharmacists. For example, one Alabama pharmacist describes wanting to have their technician involved, "*I've either been putting it in or my technicians. I threatened [the registry] I would not put them in anymore because it was ridiculous that a technician couldn't do that. Finally, after about two months, they decided to let technicians do it again. We were the first store."*

Throughout the high participation state interviews IIS representatives discussed how they engaged pharmacy in the development and continued improvement of their respective IIS. For example, one high participation state IIS representative described creating a stakeholder group that included pharmacists, *"Very early on we were in conversation with the Board of Pharmacy. Basically, we sort of became, the host if you will of a multi ... kind of stakeholder group that came together to really talk about the pros and cons of the expansion of pharmacists scope of practice."* Other high participation state representatives described engaging student pharmacists and educating them regarding IIS early in the curriculum, "*We worked to make sure that the state immunization registry is at least one of the lectures or part of a lecture in that* *immunization delivery course. So for the College of Pharmacy we actually give that talk."*

Engaging Innovation Participants

Innovation Participants were defined as individuals served by the organization, e.g., patients served by the pharmacy (L. Damschroder et al., 2009). Patients in Alabama were described as not being aware of ImmPRINT, whereas patients in other states were described as either being able to access their records themselves or frequently requesting printed IIS immunization records from their pharmacist. For example, one pharmacist in a high participation state said, *"You put in your name, date of birth, social security number and it will pull up your record if all of those pieces are on file and that they match. You can pull up your own record and see what you've had and what you're due for."* While a pharmacist from Alabama said, *"Most patients, they have no clue what you're talking about. I'm sure we've mentioned it [the immunization registry] in passing in that particular conversation, but it's not something that we have a regular conversation about."*

Phase II: Program Development

This section describes development of the training program, addressing specific aim two. A participatory design approach was used to develop and refine the training program. A review panel comprised of six pharmacists and IIS representatives reviewed the program and provided feedback using the Delphi method to ensure content was relevant and the format was acceptable. The final format of the program was an online article, demonstration videos, and an implementation guide.

Training Program Components

The training program included an online article, demonstration videos, and a implementation guide, each described below.

Online Article

Topics addressed within the CE article included: 1) IIS Introduction, 2) IIS policies, 3) Benefits of participation, 3) Enrollment, 4) Documentation of historical and administered vaccines, 5) Assessment and recommendation of additional vaccines, 6) Using IIS to provide patient records, 7) Vaccines for children, and 8) Recommendations for pharmacies. The article in full is included in Appendix 23, it could be downloaded or viewed on the study website and consisted of 15 pages. Throughout the article cases were presented to provide specific examples.

Demonstration Videos

Demonstration videos were recorded using Camtasia and hosted using TechSmith Smart Player. A quiz question was inserted in each video to assess completion. Results were recorded and monitored using screencast.com. The videos demonstrated common tasks that users would need to complete to enroll in ImmPRINT and use it on a regular basis. Ten videos were created, ranging from 28 seconds to 3 minutes and 25 seconds in length. Video Topics included: 1) Site Enrollment Agreement, 2) User Registration, 3) Patient Search, 4) Add a New Patient, 5) Establish Patient List, 6) Document Historical and Administered Vaccines, 7) Add New Lot Number, 8) Forecast Needed Vaccines, 9) Print Certificate of Immunization and Patient/Parent Card, and 10) Doses Administered Report.

Implementation Guide

The program also included a concise implementation guide to assist pharmacies with the manual data submission process that could be easily referenced in the pharmacy as needed. The guide can be found in Appendix 24.

Once the training program was developed, a website, www.alabama immunizers.com, was created to host the training program. The estimated time to complete was 120 minutes. Therefore, the training program was accredited by the Accreditation Council for Pharmacy Education (ACPE) for 2.0 hours (0.2 CEU). To earn credit, participants were required to 1) read the learning objectives and author disclosures; 2) review the educational activity including CE article and videos; and 3) complete the post-test online via Qualtrics. Participants were required to score 75% or higher on the post-test to be awarded CE credit. Participants were notified of this requirement and their score after submission of the second survey. Those scoring lower than 75% were offered an opportunity to retake the test. Participants' first attempt only was retained for analyses described in phase three results below.

Phase III: RCT Results

This section presents results from the randomized controlled trial phase of this study. Findings address specific aim three and study hypotheses one through seven. First, psychometric evaluation of multi-item measures are discussed. Next, characteristics of participating pharmacists are presented. Following this, RCT results are presented in order of corresponding hypothesis.

Multi-Item Measures

Psychometric evaluation of eight scales was conducted. Exploratory factor analysis using principal components and varimax rotation was used to ensure that the intended structure and actual structure of items were consistent, for five implementation factor scales and intention. The Cronbach's alpha of each scale was measured with 0.7 as the minimum acceptable reliability. Kudar-Richardson 20 (KR-20) was used to assess the reliability of awareness and knowledge. Attitudes toward innovation characteristics, awareness, knowledge, and intention were collected at baseline, one month, and three months. Thus, reliability was assessed at all three time points for these variables. The remaining implementation factor scales including inner setting, outer setting, characteristics of individuals, and process were only collected at the three-month time point.

Implementation Factors

Attitudes Toward Innovation characteristics

The attitudes toward innovation characteristics scale was examined using baseline data. Initial exploratory factor analysis revealed seven factors with eigenvalues greater than one, explaining 29.4%, 17.20%, 9.54%, 7.52%, 4.84%, 4.17%, and 4.09%, respectively. Upon visual inspection of the scree plots, and employing a parsimonious approach, three components were retained. This three-component solution explained 56.1% of the total variance. The three components focus on improving patient care, intervention source support, and ease of use. Table 4.10 describes the factor loading matrix for these three components. Factor loadings of greater than 0.3 are displayed. Reliability analyses for the overall innovation characteristics scale at baseline indicated acceptable reliability. Cronbach's alpha at baseline was high at 0.871 with a per item mean of 4.55 (0.77) (Table 4.11). The subscales, improving patient care, intervention source support, and ease of use also demonstrated high reliability with Cronbach's alpha of 0.903, 0.817, and 0.748, respectively. Reliability analyses for data collected at one month and three months are also described in Table 4.11.

Table 4.10 Attitudes toward innovation characteristics factor loadings and communalities[a,b]

Item	Components			Communalities
	Improving Patient Care	Intervention Source Support	Ease of Use	
Immunization registries are a realistic method of consolidating immunization data.	**.865**			.762
Immunization registries allow pharmacies to assess immunization status.	**.828**			.702
Using the immunization registry enables pharmacy staff to accomplish tasks related to the provision of immunizations more effectively	**.825**			.734
Using the immunization registry is more reliable than patient self-report when checking immunization status	**.822**			.677
The immunization registry appears to have more advantages than disadvantages	**.788**			.685
Immunization registries improve patient care coordination.	**.786**			.622
Using the immunization registry enables pharmacy staff to accomplish tasks related to the provision of immunizations more quickly	**.777**			.625
Use of the immunization registry can be adapted to fit our pharmacy's current situation	**.706**			.555
Immunization registries provide patients with consolidated immunization records.	**.555**	-.314	.356	.534
The immunization registry helps to manage vaccine inventory more effectively	**.520**	.320	-.362	.503
Immunization registries compromise patient confidentiality.*	**.431**			.342

It is difficult to obtain immunization registries IT support.*		**.887**		.827
It is difficult to obtain immunization registries software.*		**.768**		.602
Data recorded in immunization registries is incomplete.*	-.310	**.647**		.530
Immunization registries are not standardized in terms of data required.*		**.643**		.450
Immunization registries are too time consuming.*	.411	**.630**		.584
It is difficult to obtain patient consent for immunization registries.*		**.609**		.434
Data recorded in immunization registries is inaccurate.*		**.476**		.317
Implementing the immunization registry is too much of a financial burden.*		**.437**	.326	.345
The immunization registry fits easily into pharmacy workflow.		**.430**		.324
Interacting with the immunization registry is clear and understandable			**.809**	.766
Interacting with the immunization registry does not require a lot of mental effort			**.768**	.721
Current systems of reporting immunizations are sufficient to determine immunization status.			**.710**	.516
It is difficult to obtain access to the immunization registry.*		.303	**.601**	.454
I've had the opportunity to test various applications of the immunization registry		.328	**.599**	.516

[a]Extraction Method: Principal Component Analysis; Rotation Method; Varimax with Kaiser Normalization.
[b]Rotation convereged in 5 iterations.
*Items were reverse coded

Table 4.11 Internal consistency of attitudes toward innovation characteristics scale and subscales measured at three time points[a]

Scale	Items	Baseline		One Month		Three Months	
		Cronbach's alpha	Mean (SD)	Cronbach's alpha	Mean (SD)	Cronbach's alpha	Mean (SD)
Attitudes toward innovation characteristics	25	0.871	4.55 (0.77)	0.838	4.46 (1.18)	0.862	4.37 (1.15)
Improving patient care	11	0.903	5.23 (0.46)	0.771	5.36 (1.07)	0.892	5.23 (0.96)
Intervention Source Support	9	0.817	4.11 (0.36)	0.798	3.60 (0.51)	0.622	3.42 (0.61)
Ease of Use	5	0.748	3.84 (0.69)	0.691	4.00 (0.88)	0.767	4.18 (0.88)

[a]Each item is scored ranging from 0 for strongly disagree to 7 for strongly agree.

Inner Setting

The inner setting scale was examined using three months data. Initial exploratory factor analysis revealed five factors with eigenvalues greater than one, explaining 35.4%, 23.69%, 11.66%, 9.24%, and 6.41%, respectively. Upon visual inspection of the scree plots, and employing a parsimonious approach, three components were retained. This three-component solution explained 70.7% of the total variance. The three components focus on the readiness for implementation, implementation climate, and culture of the pharmacy. Table 4.12 describes the factor loading matrix for these three components. Factor loadings greater than 0.3 are displayed. Reliability analyses for the overall innovation characteristics scale indicated acceptable reliability. Cronbach's alpha was high at 0.905 with a per item mean of 4.92 (0.53). The readiness for implementation, implementation climate, and culture subscales also demonstrated high reliability with Cronbach's alpha of 0.838, 0.853, and 0.870 respectively (Table 4.13).

Table 4.12 Inner Setting factor loadings and communalities[a,b]

Item	Readiness	Component Implementation Climate	Culture	Communalities
All staff will work together as a team when implementing the immunization registry.		**.863**		.800
The changes that will be occurring in the pharmacy when implementing the immunization registry have been communicated to all pharmacy staff.	.645		**.565**	.756
Mechanisms for communication, such as staff meetings, are important when implementing the immunization registry.			**.670**	.493
Our pharmacy has proven that we are able to adapt ideas from outside to fit our organization's way of doing things.			**.762**	.602
Our pharmacy owner/manager rewards innovation and creativity to improve patient care.	**.560**		.523	.588
Staff members in our pharmacy have a sense of personal responsibility for improving patient care and outcomes.		**.891**		.832
Staff members in our pharmacy cooperate to maintain and improve effectiveness of patient care.		-.329	**.712**	.693
Staff members in our pharmacy are willing to innovate and/or experiment to improve patient care.			**.878**	.842
Staff members in our pharmacy are receptive to change.		-.413	**.764**	.761

Some of our pharmacy staff believe that implementing the immunization registry is essential.	**.722**			.602
Successfully implementing the immunization registry will meet staff needs..	**.820**			.717
Our pharmacy owner/manager has set a high priority on the success of the immunization registry in our pharmacy.	**.845**		.300	.815
Staff incentives are likely to be set up to engage them in using the immunization registry.	.673	**.467**		.671
Successful implementation of the immunization registry will help us meet our organization's mission and goals.	.517	**.735**		.876
The pharmacy owner/ manager/ staff opinion leaders agree on the goals for the implementation of the immunization registry.	.882	**.325**		.885
Our pharmacy owner/manager has set a deadline for enrollment in the immunization registry.	**.805**		.331	.758
Our pharmacy owner/manager has designated an individual to be responsible for enrolling our pharmacy in the immunization registry.	.346	**.713**		.675
Our pharmacy owner/manager has openly endorsed the immunization registry.	**.823**			.741
Our pharmacy owner/manager has committed to spending time and resources to remove obstacles related to implementation of the registry if they arise.	**.899**			.816

Our staff do not have the time required to update the immunization registry when an immunization is provided.*	**-.382**			.252
Our staff has access to immunization registry training and training materials.		**.763**		.677

[a]Extraction Method: Principal Component Analysis; Rotation Method; Varimax with Kaiser Normalization.
[b]Rotation converged in 6 iterations.
*Items were reverse coded

Table 4.13 Internal consistency of inner setting scale and subscales measured at three month[a]

Scale	**Items**	**Cronbach's alpha**	**Mean (SD)**
Inner Setting	21	0.905	4.92 (0.53)
Readiness for Implementation	8	0.838	4.71 (0.45)
Implementation Climate	7	0.853	4.69 (0.43)
Culture	6	0.870	5.46 (0.33)

[a]Each item is scored ranging from 0 for strongly disagree to 7 for strongly agree.

Outer Setting

The outer setting scale was examined using three months data. Exploratory factor analysis revealed two factors with eigenvalues greater than one, explaining 55.08% and 24.33% of the total variance, respectively. The two-component solution explained 79.42% of the total variance. The two components focus on external support and peer pressure. Table 4.14 describes the factor loading matrix for these two components. Factor loadings greater than 0.3 are displayed. Reliability analyses for the overall innovation characteristics scale indicated low reliability (Table 4.15). Cronbach's alpha was 0.591 with a per item mean of 4.41 (0.83). However, individual subscales were acceptable. The external support subscale demonstrated high reliability with Cronbach's alpha of 0.798 and per item mean of 5.01 (0.44). The peer pressure subscale demonstrated moderate reliability with a Cronbach's alpha of 0.621 and a per item mean of 3.97 (0.39). The moderate reliability of the peer pressure subscale is likely due to the inclusion of only three items.

Table 4.14 Outer Setting factor loadings and communalities[a,b]

Item	Component: External support	Component: Peer pressure	Communalities
The immunization registry incorporates the needs and preferences of patients	**.889**		.794
It is helpful to have people external to the pharmacy who can provide support when needed	**.879**		.784
It is helpful to have access to someone from outside the pharmacy when implementing the immunization registry	**.851**		.747
Most pharmacies are using the immunization registry	-.684	**.497**	.715
Using the immunization registry helps my pharmacy maintain a competitive advantage over other pharmacies		**.873**	.841
External organizations or individuals have pressured our pharmacy to implement the immunization registry	-.570	**.747**	.883

[a]Extraction Method: Principal Component Analysis; Rotation Method; Varimax with Kaiser Normalization.
[b]Rotation converged in 3 iterations.

Table 4.15 Internal consistency of outer setting scale and subscales measured at three month[a]

Scale	**Items**	**Cronbach's alpha**	**Mean (SD)**
Outer Setting	6	0.591	4.41 (0.83)
External Support	3	0.798	5.01 (0.44)
Peer pressure	3	0.621	3.97 (0.39)

[a]Each item is scored ranging from 0 for strongly disagree to 7 for strongly agree.

Characteristics of Individuals

The characteristics of individuals scale was examined using three months data. Exploratory factor analysis revealed only one eigenvalue greater than one, explaining 58.5% of the total variance. Table 4.16 describes the factor loading matrix for this component. The scale demonstrated moderate reliability with a Cronbach's alpha of 0.661 and a per item mean of 4.39 (0.92) (Table 4.17). This is moderate level of reliability is likely due to the inclusion of only three items.

Table 4.16 Characteristics of individuals factor loadings and communalities[a]

Item	Component	Communalities
Our staff have a sense of personal responsibility for improving patient care and outcomes.	**.852**	.726
Our staff's knowledge and beliefs are barriers to implementing the immunization registry.*	**.673**	.453
Our staff are confident that they can use the immunization registry.	**.759**	.577

[a]Extraction Method: Principal Component Analysis.
*Items are reverse coded.

Table 4.17 Internal consistency of characteristics of individuals scale at three months[a]

Scale	**Items**	**Cronbach's alpha**	**Mean (SD)**
Characteristics of Individuals	3	0.661	4.39 (0.92)

[a] Each item is scored ranging from 0 for strongly disagree to 7 for strongly agree.

Process

The process scale was examined using three months data. Exploratory factor analysis revealed three factors with eigenvalues greater than one, explaining 43.11%, 22.92%, and 9.18% of the total variance, respectively. Upon visual inspection of the scree plots, and employing a parsimonious approach, two components were retained. This two-component solution explained 66.03% of the total variance. The two components focus on Engaging and Planning, and Executing. Table 4.18 describes the factor loading matrix for these two components. Factor loadings greater than 0.3 are displayed. Reliability analyses for the overall process scale indicated high reliability (Table 4.19). Cronbach's alpha was 0.892 with a per item mean of 4.71 (0.46). The subscales, improving engaging and planning, and executing also demonstrated high reliability with Cronbach's alpha of 0.896 and 0.924, respectively.

Table 4.18 Process factor loadings and communalities

Item	Engaging and Planning	Executing	Communalities
Our plan for implementing the immunization registry identifies specific roles and responsibilities.	**.883**		.792
Our plan for implementing the immunization registry acknowledges staff input and opinions.	**.880**		.776
Our plan for implementing the immunization registry clearly describes tasks and timelines.	**.863**		.814
Our plan for implementing the immunization registry includes appropriate staff education.	**.854**	.374	.869
Staff opinion leaders are supportive of the immunization registry.	**.850**		.725
The individual responsible for overseeing implementation of the immunization registry is committed to making this successful.	**.712**	.332	.616
We've spoken with patients and considered their opinion regarding the immunization registry.	**.614**	-.338	.491
The majority of our pharmacy staff have been involved in the decision to implement the immunization registry.	**.572**		.329
We have retrieved data from the immunization registry to determine a patient's needed vaccines.		**.899**	.809
We have uploaded data to the immunization registry successfully.		**.897**	.811
We have completed the immunization registry face-to-face training.		**.789**	.623
We have enrolled in the immunization registry.		**.719**	.534

We plan to collect honest reactions from staff regarding use of the immunization registry.	**.340**	.529	.396

[a]Extraction Method: Principal Component Analysis; Rotation Method; Varimax with Kaiser Normalization.
[b]Rotation convereged in 3 iterations.

Table 4.19 Internal consistency of process scale and subscales

Scale	**Items**	**Cronbach's alpha**	**Mean (SD)**
Process	13	0.892	4.71 (0.46)
Engaging and Planning	9	0.896	4.76 (0.52)
Executing	4	0.924	4.58 (0.29)

[a] Each item is scored ranging from 0 for strongly disagree to 7 for strongly agree.

Awareness and Knowledge

Reliability of awareness and knowledge items were assessed using Kuder-Richardson 20 (KR-20). At baseline, awareness included 3 items with a KR-20 of 0.626. Knowledge included 8 items with a KR-20 of 0.781 at baseline. Analyses at one and three months are also described in Table 4.20.

Table 4.20 Reliability of Awareness and Knowledge variables

	Items	**Baseline**	**One Month**	**Three Months**
		KR-20	**KR-20**	**KR-20**
Awareness	3	0.626	0.638	0.676
Knowledge	8	0.781	0.716	0.755

Intention

The *intention* scale was examined using baseline, one month, and three months data. Exploratory factor analysis revealed only one eigenvalue greater than one, explaining 85% of the total variance. Table 4.21 describes the factor loading matrix for these two components. At baseline, Cronbach's alpha was 0.909 with a per item mean of 4.43 (0.53). Reliability at one month and three months were also excellent and described in Table 4.22.

Table 4.21 Intention factor loadings and communalities

Item	Component	Communalities
I plan to enroll my pharmacy in the immunization registry within 30 days.	**.953**	.909
I will make an effort to enroll my pharmacy in the immunization registry in the next 30 days.	**.921**	.849
I intend to enroll my pharmacy in the immunization registry.	**.890**	.793

[a]Extraction Method: Principal Component Analysis.

Table 4.22 Internal consistency of intention scale at three time points

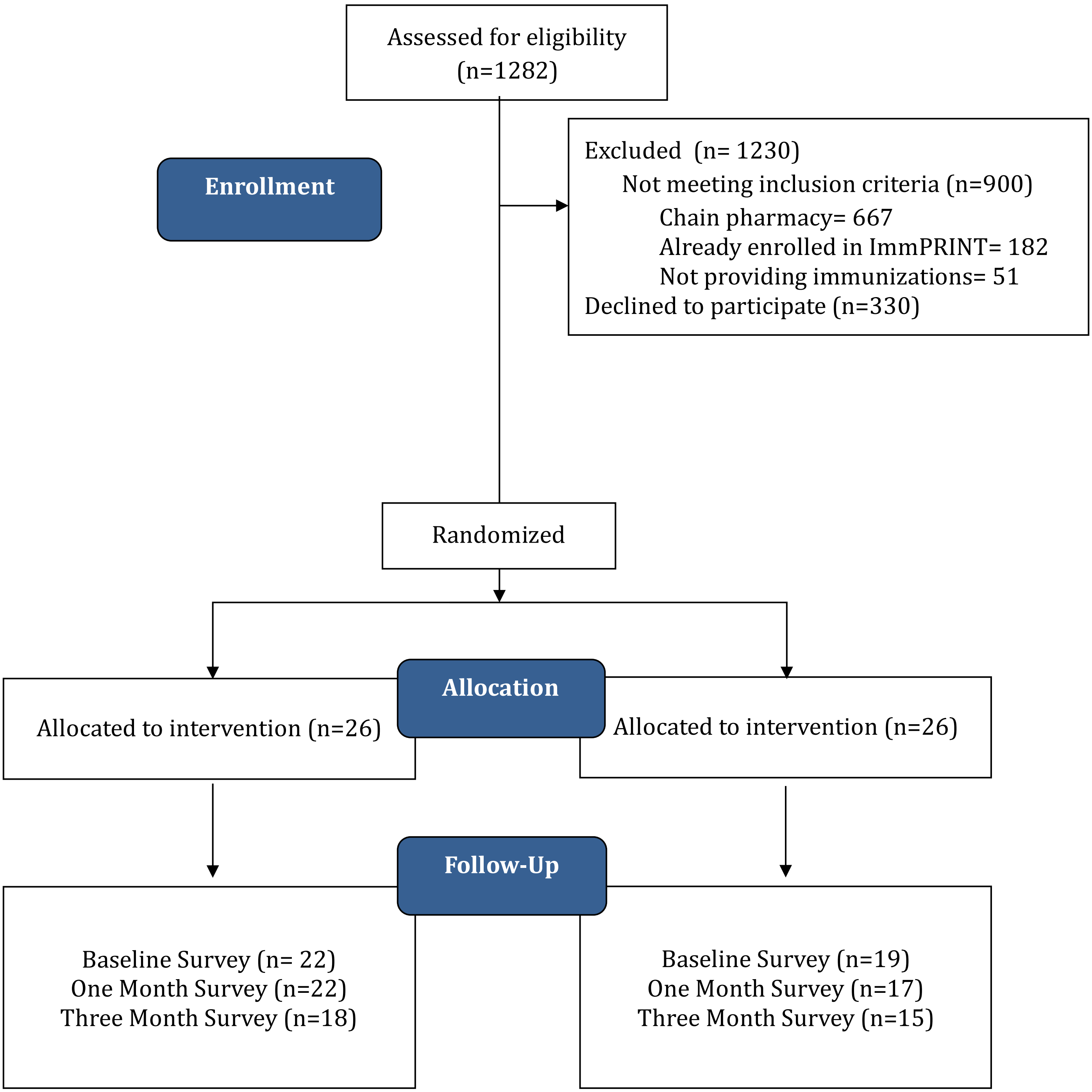
Scale	**Items**	**Baseline**		**One Month**		**Three Months**	
		Cronbach's alpha	**Mean (SD)**	**Cronbach's alpha**	**Mean (SD)**	**Cronbach's alpha**	**Mean (SD)**
Intention	3	0.909	5.15 (0.23)	0.939	5.37 (0.22)	0.914	5.08 (0.10)

[a] Each item is scored ranging from 0 for strongly disagree to 6 for strongly agree.

Recruitment Results

Figure 4.1 describes the study recruitment, enrollment, and randomization process. At the time study recruitment began there were 1,282 pharmacies in Alabama. A total of 667 chain pharmacies and 182 pharmacies already enrolled in ImmPRINT were eliminated. The 433 independent pharmacies not enrolled in ImmPRINT were contacted. Of these pharmacies, 51 were determined to be interested but not currently providing immunizations and therefore ineligible. A total of 330 pharmacists contacted declined to participate. Therefore, 52 pharmacists were enrolled in the randomized controlled trial with 26 randomized to the intervention group and 26 to the control group using a computerized random number generator. Eleven pharmacists were lost to drop-out prior to completion of the baseline survey. A total of 41 pharmacists, including 22 in the intervention group and 19 in the control group completed the baseline survey. A total of 40 (22 intervention; 18 control) and 33 (18 intervention; 15 control) pharmacists completed the one-month and three-month surveys, respectively. Demographic characteristics and baseline immunization documentation practices were compared between the three-month survey responders and non-responders to assess any differences. Results are presented in Appendix 25. The number of years the pharmacist had been practicing at their current practice site were significantly different between the responders and non-responders ($p=0.009$). The mean number of years at current practice site for the responders was 7.84 (10.4) and the non-responders was 20 (11.1).

Figure 4.1 Study CONSORT Flow Diagram



Pharmacist Baseline Characteristics

Table 4.23 describes the characteristics of the 41 pharmacists. Participants were primarily white (100%) males (53.7%) not of non-Hispanic ethnicity (2.4%). The majority of participants were staff pharmacists (53.7%) with a PharmD degree (78.0%). The mean number of years practicing as a pharmacist was 15.40 (11.8) with a mean of 10.03 (11.4) years at the current pharmacy site. The majority of pharmacies were located in non-rural counties (73.2%). No statistically significant differences in demographic characteristics were found between groups at baseline. There were also no significant differences found in participants' awareness, knowledge, intention or attitudes at baseline.

Table 4.23 Pharmacist and Pharmacy Characteristics (N=41)

Characteristic	Intervention (N=22)	Control (N=19)	Total (N=41)	p-value [a]
	n (%)			
Sex				
Male	13 (59.1)	9 (47.4)	22 (53.7)	
Female	9 (40.9)	10 (52.6)	19 (46.3)	0.538
Race				
White	22 (100)	19 (100)	41 (100)	-
Ethnicity				
Hispanic	0 (0)	1 (5.3)	1 (2.4)	
Non-Hispanic	22 (100)	18 (94.7)	40 (97.6)	0.475
Job Title				
Staff Pharmacist	9 (40.9)	13 (68.4)	22 (53.7)	
Manager	13 (59.1)	3 (15.8)	16 (39.0)	
Owner/Partner	7 (31.8)	7 (36.8)	14 (34.1)	0.142
Pharmacist Education				
B.S. Pharm	4 (18.2)	6 (31.6)	10 (24.4)	
PharmD	17 (77.3)	15 (78.9)	32 (78.0)	
Residency	1 (4.5)	1 (5.3)	2 (4.9)	
Masters	1 (4.5)	1 (5.3)	2 (4.9)	
Other	1 (4.5)	0 (0)	1 (2.4)	0.525
Rurality[b]				
Rural	6 (27.3)	5 (26.3)	11 (26.8)	
Non-Rural	16 (72.7)	14 (73.7)	30 (73.2)	0.945
	Mean (SD)			**p-value [a]**
Pharmacist Age	43.41 (12.8)	40.58 (9.4)	42.09 (11.3)	0.667
Number of years practicing as a pharmacist	15.90 (13.1)	14.87 (10.6)	15.40 (11.8)	0.967
Number of years practicing at current site	12.23 (13.0)	7.71 (9.2)	10.03 (11.4)	0.270

[a] Analyzed using Fisher's exact and Chi-square test of homogeneity and two-tailed Mann-Whitney U tests for categorical and continuous data, respectively.
[b] Pharmacies classified as rural vs. urban using the Alabama Rural Health Association definition (Alabama Rural Health Association, 2011).

Immunization documentation practices at baseline are described in Table 4.24. In order to enroll in the RCT portion of the study, the investigator checked with ImmPRINT to ensure that no participating pharmacists' pharmacies were enrolled in ImmPRINT at baseline. Interestingly, of the participating pharmacists, 12 reported being unsure if their pharmacy was enrolled in ImmPRINT and seven pharmacists indicated that their pharmacy was enrolled in ImmPRINT, when in fact they were not. Only 22 pharmacists (53.7%) correctly indicated that their pharmacy was not enrolled in ImmPRINT. The majority of pharmacists (97.6%) indicated that they maintain documentation of vaccination within their pharmacy when providing immunizations. However, only 14 pharmacists (34.1%) indicated that they share this information with their patients' physician. Of these, the most common method of delivery was fax.

Table 4.24 Baseline immunization documentation practices (N=41)

Characteristic	Intervention (N=22)	Control (N=19)	Total (N=41)	p-value[a]
	n (%)			
ImmPRINT Enrollment Status				0.306
Correctly identified	12 (54.5)	10 (52.6)	22 (53.7)	
Incorrectly identified	2 (9.1)	5 (26.3)	7 (17.1)	
Don't Know/ Not sure	8 (36.4)	4 (21.1)	12 (29.2)	
Maintain documentation in pharmacy				0.383
Yes	21 (95.5)	19 (100)	40 (97.6)	
No	1 (4.5)	0 (0)	1 (2.4)	
Provide documentation to physician				0.551
Yes	6 (27.3)	8 (42.1)	14 (34.1)	
No	15 (68.2)	10 (52.6)	25 (61.0)	
Don't Know/ Not sure	1 (4.55)	1 (5.3)	2 (4.9)	
Method of providing documentation to physician				0.191
Fax	5 (22.7)	8 (42.1)	13 (31.7)	
Phone	0 (0)	2 (10.5)	2 (4.9)	
Delivered by patient	3 (13.6)	0 (0)	3 (7.3)	

[a] Analyzed using Chi-square test of homogeneity

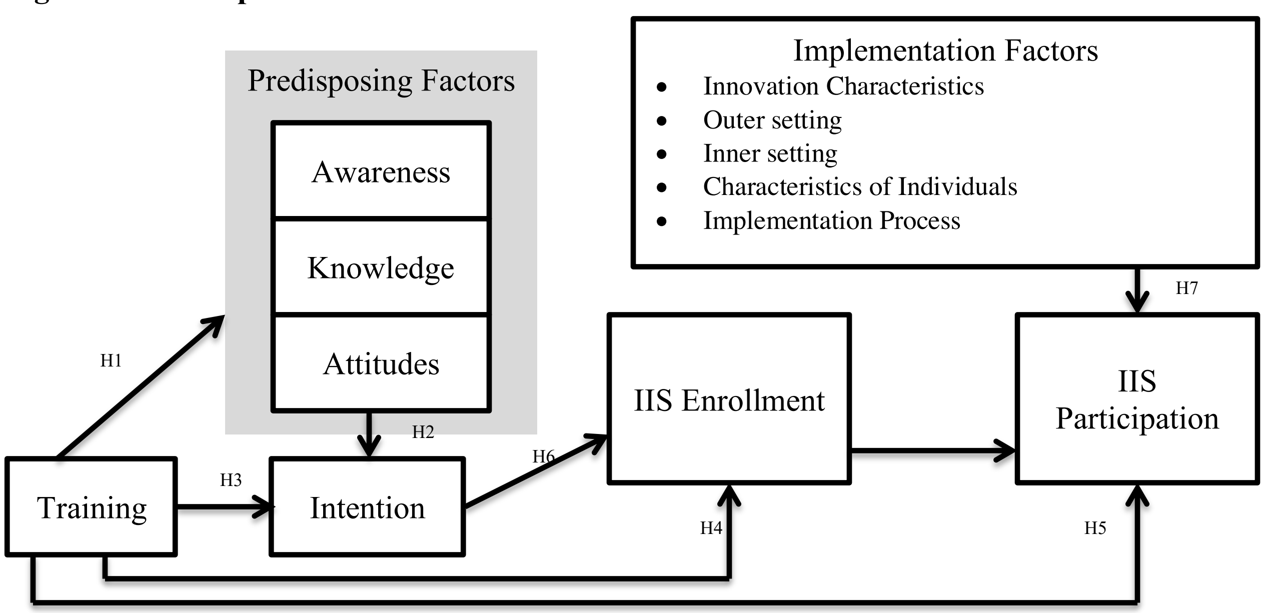
Video Completion

The number of individuals who viewed each video and completed the quiz are reported in Appendix 26. The average percentage of content viewed and average score for each quiz are also reported. In summary 13 to 15 individuals completed each quiz. The average content viewed ranged from 61% for the Site Enrollment Agreement video to 74% for the Establish Patient List video. The average score ranged from 31% for the Establish Patient List video to 100% for the Site Enrollment Agreement video. Only participants who watched at least one video were included in further analyses.

Hypothesis Testing

This section describes the results of analyses conducted to test hypotheses H1-H7. This first includes two-way mixed ANOVAs to examine the effect of the intervention on predisposing factors including participant awareness, knowledge, and attitudes (H1a-H1c). Second, the relationship between predisposing factors and intention to implement the IIS is analyzed (H2). Next, the impact of the intervention on pharmacist intention to implement the IIS is also examined (H3). Next, the primary outcomes, impact of the intervention on pharmacy enrollment (H4) and participation (H5) in the Alabama IIS, ImmPRINT is assessed along with the relationship between these two (H6). Finally, the relationship between implementation factors and IIS participation is analyzed (H7).

Figure 4.2 Conceptual Model



Predisposing Factors

The first set of hypotheses, H1a-H1c, examine the effect of the intervention on pharmacists' predisposing factors. Predisposing factors include awareness (H1a), knowledge (H1b), and attitudes toward innovation characteristics (H1c). Only alternative hypotheses are displayed.

H1. An increase in pharmacists' predisposing factors will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.

Awareness

H1a. An increase in pharmacists' awareness will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.

The mean (SD) awareness of participants in the intervention group was 2.3 (1.03) at baseline, 2.9 (0.32) at one month, and 2.9 (0.32) at three months. Among control group participants, the mean (SD) awareness at baseline, one month, and three months, was 2.1 (0.92), 2.4 (0.83), and 2.7 (0.82), respectively (Table 4.25). A total of 33 individuals responded to the baseline, one-month, and three-month assessments.

Two-way mixed ANOVA was used to test hypothesis H1a. A summary of the results of the two-way mixed ANOVA are presented in Table 4.26. Tables 4.25, 4.27, and 4.28 include results from the Bonferroni post-hoc tests conducted as part of the mixed

ANOVA. Mauchly's test of sphericity indicated that the assumption of sphericity was not met for the two-way interaction, therefore the Greenhouse-Geisser correction was used.

There was no statistically significant interaction between the intervention and time on mean participant awareness, $F(1.514) = 0.391$, $p = 0.621$ (Table 4.26). The main effect of group also did not show a statistically significant difference in mean awareness index between groups, $F(1) = 3.748$, p =0.062 (Table 4.26). The main effect of time showed that there was a statistically significant difference in mean awareness index at the different time points $F(1.514) = 4.879$, p = 0.019 (Table 4.26). The mean awareness index was slightly greater in the intervention group than the control group at all three time points (Table 4.25). This difference was statistically significant between the intervention and control groups at the one-month (post-intervention) time point (p=0.028) (Table 4.25). Awareness at baseline (p=0.563) and three months (p=0.297) were not significant. As stated above, the mean (SD) awareness index for the intervention group was 2.9 (0.32) at one month while the control group was 2.7 (0.82).

Table 4.25 Mean awareness index at baseline, one month, and three months[a] (N=33)

Timepoints	Intervention (N=18)	Control (N=15)
	Mean Awareness Index (SD)	
Baseline	2.3 (1.03)	2.1 (0.92)
One Month*	**2.9 (0.32)**	**2.4 (0.83)**
Three Months	2.9 (0.32)	2.7 (0.82)

[a] Mixed ANOVA with Bonferroni post-hoc tests.
*Significant at the 0.05 level

Table 4.26 Summary of the effect of the intervention on awareness (N=33)

	df	*MS*	*F*	*Sig.*
Group	1	0.755	3.748	0.062
Time	1.514	3.481	4.879	**0.019***
Time*Group	1.514	0.279	0.391	0.621

[a] Mixed ANOVA with Bonferroni post-hoc tests.
*Significant at the 0.05 level

Table 4.27 Change in awareness within groups over time (N=33)

Change in Awareness Within Groups				
	Intervention (N=18)		Control (N=15)	
Timepoints	**Mean Difference (SE)**	**p-value [a]**	**Mean Difference (SE)**	**p-value [a]**
Baseline - One Month	-0.56 (0.27)	0.134	-0.27 (0.29)	1.000
One Month – Three Months	0.000 (0.16)	1.000	-0.27 (0.18)	0.441
Overall		0.131		0.191

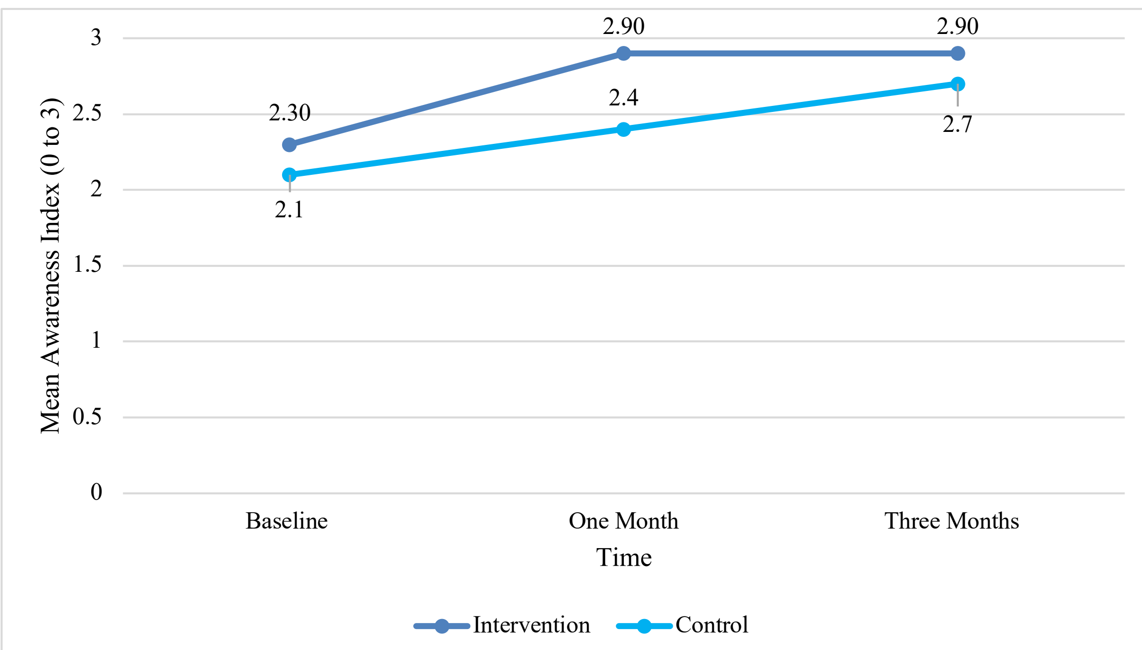
[a]Mixed ANOVA with Bonferroni post-hoc tests

Table 4.28 Change in awareness between groups over time (N=33)

	Change in Awareness Between Groups	
Timepoints	**F**	**p-value[a]**
Baseline - One Month	0.538	0.469
One Month – Three Months	1.208	0.280
Overall	0.391	0.621

[a]Mixed ANOVA with Bonferroni post-hoc tests

Figure 4.3 Change in awareness over time by group



In summary, results of the two-way mixed ANOVA indicate that while there was no significant interaction between group and time, the mean awareness of the intervention group was significantly greater than the control group at one-month post intervention and this difference was not seen at baseline. Therefore, the results support hypothesis H1a; the null hypothesis is rejected, and we conclude that the intervention had an effect on participants' awareness. Also, results suggest that no differences were detected statistically from one month to three month; therefore we concluded that the awareness was sustained during this period.

Knowledge

H1b. An increase in pharmacists' knowledge will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.

The mean (SD) knowledge of participants in the intervention group was 3.00 (1.71) at baseline, 5.89 (1.13) at one month, and 4.89 (1.45) at three months. Among control group participants, the mean (SD) knowledge at baseline, one month, and three months, was 3.53 (2.61), 4.53 (1.85), and 4.87 (2.23), respectively (Table 4.29).

Two-way mixed ANOVA was used to test hypothesis H1b. A summary of the results of the two-way mixed ANOVA are presented in Table 4.30. Tables 4.29, 4.31, and 4.32 include results from the Bonferroni post-hoc tests conducted as part of the mixed ANOVA. Mauchly's test of sphericity indicated that the assumption of sphericity was not met for the two-way interaction, therefore the Greenhouse-Geisser correction was used.

According to Table 4.30, the interaction between the intervention and time on mean participant knowledge was significant, $F(1.606) = 4.118$, $p = 0.030$. The main effect of time also showed that there was a statistically significant difference in mean knowledge index over time, $F(1.606) = 18.902$, $p < 0.001$ (Table 4.30). However, the main effect of group showed that there was not a statistically significant difference in mean knowledge index between intervention and control groups $F(1) = 0.295$, $p = 0.591$ (Table 4.30). The mean knowledge index difference was significant in the intervention group from baseline to one month ($p < 0.001$), one month to three months ($p = 0.041$), and overall ($p < 0.001$) (Table 4.31). There was a significant effect between groups from baseline to one month ($p = 0.004$) and one month to three months ($p = 0.025$) (Table 4.32). At baseline, the mean knowledge index was slightly greater in the control group than the intervention group (Table 4.25). This difference was not statistically significant ($p= 0.487$). However at the one-month (post-intervention) time point, the mean knowledge index is statistically significantly greater in the intervention group compared to the control group ($p=0.015$) (Table 4.25). Knowledge at three months ($p=0.973$) was not significant. As stated above, the mean (SD) knowledge index for the intervention group was 5.89 (1.13) at one month while the control group was 4.53 (1.85).

Table 4.29 Mean knowledge index at baseline, one month, and three months[a] (N=33)

Timepoints	Intervention (N=18)	Control (N=15)
	Mean Knowledge Index (SD)	
Baseline	3.00 (1.71)	3.53 (2.61)
One Month*	**5.89 (1.13)**	**4.53 (1.85)**
Three Months	4.89 (1.45)	4.87 (2.23)

[a] Mixed ANOVA with Bonferroni post-hoc tests.

Table 4.30 Summary of the effect of the intervention on knowledge (N=33)

	df	*MS*	*F*	*Sig.*
Group	1	0.648	0.295	0.591
Time	1.606	44.067	18.902	**<0.001***
Time*Group	1.606	2.331	4.118	**0.030***

[a] Mixed ANOVA with Bonferroni post-hoc tests.
*Significant at the 0.05 level

Table 4.31 Change in knowledge within groups over time (N=33)

Change in Knowledge Within Groups				
	Intervention (N=18)		Control (N=15)	
Timepoints	Mean Difference (SE)	p-value [a]	Mean Difference (SE)	p-value [a]
Baseline - One Month	**-2.89 (0.41)**	**<0.001***	-1.00 (0.45)	0.100
One Month – Three Months	**1.00 (0.38)**	**0.041***	-0.33 (0.42)	1.000
Overall		**<0.001***		0.082

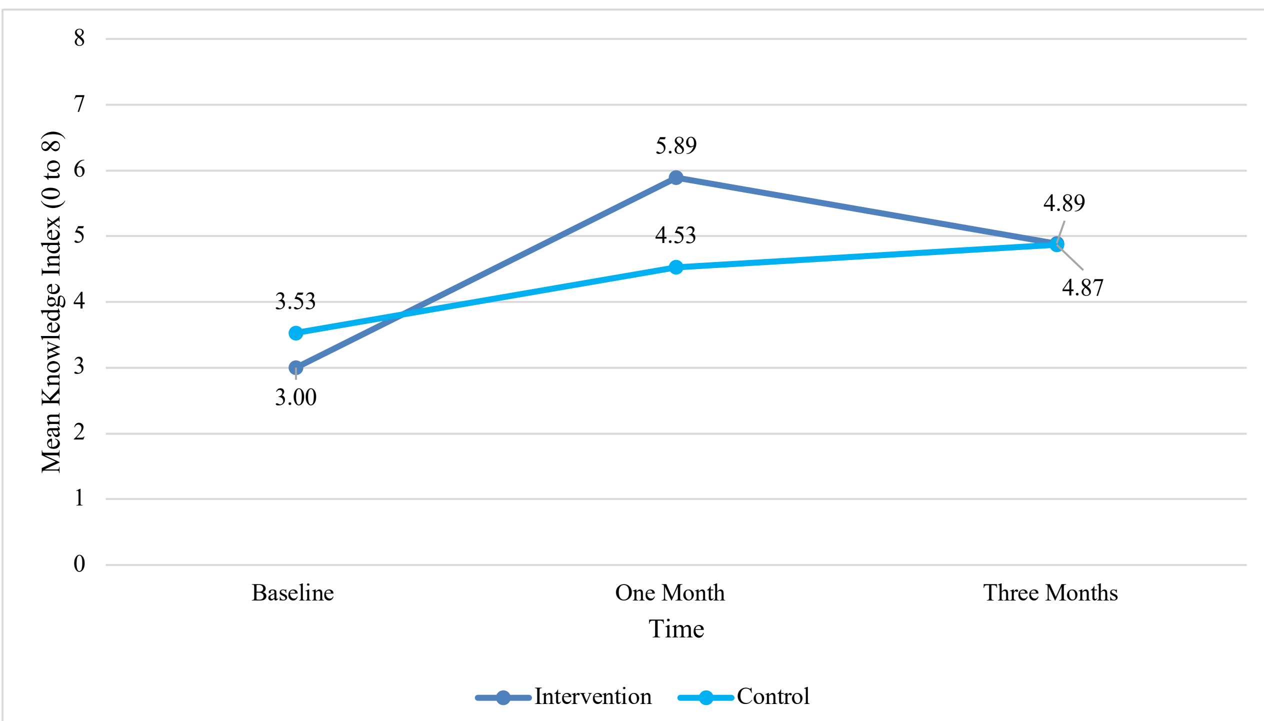
[a]Mixed ANOVA with Bonferroni post-hoc tests
*Significant at the 0.05 level

Table 4.32 Change in knowledge between groups over time (N=33)

	Change in Knowledge Between Groups	
Timepoints	**F**	**p-value[a]**
Baseline - One Month	9.650	**0.004***
One Month – Three Months	5.544	**0.025***
Overall	4.118	**0.030***

[a]Mixed ANOVA with Bonferroni post-hoc tests
*Significant at the 0.05 level

Figure 4.4 Change in knowledge over time by group



In summary, results of the two-way mixed ANOVA indicate that knowledge was significantly improved in the intervention group, the interaction of time and group as significant with the mean knowledge of the intervention group was significantly greater at one-month post intervention compared to baseline. Therefore, the results support hypothesis H1b; the null hypothesis is rejected and we conclude that the intervention did have an effect on participants' knowledge.

Attitudes toward Innovation characteristics

H1c. An increase in pharmacists' positive attitudes will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.

The mean (SD) of intervention participants' attitudes toward characteristics of the IIS was 4.44 (0.38) at baseline, 5.11 (0.62) at one month, and 5.16 (0.92) at three months. Among control group participants, the mean (SD) attitudes at baseline, one month, and three months, was 4.55 (0.41), 4.57 (0.56), and 4.76 (0.55), respectively (Table 4.33).

Two-way mixed ANOVA was used to test hypothesis H1c. A summary of the results of the two-way mixed ANOVA are presented in Table 4.34. Tables 4.33, 4.35, and 4.36 include results from the Bonferroni post-hoc tests conducted as part of the mixed ANOVA. Mauchly's test of sphericity indicated that the assumption of sphericity was met for the two-way interaction.

The effect of the interaction between the intervention and time on mean participant attitudes was significant, $F(2) = 4.424$, $p = 0.016$ (Table 4.34). The main effect of time also showed that there was a statistically significant difference in mean scale score over time, $F(2) = 8.628$, $p < 0.001$ (Table 4.34). However, the main effect of group showed that there was not a statistically significant difference in mean scale score between intervention and control groups $F(1) = 2.785$, $p = 0.105$ (Table 4.34). Post-hoc tests reveal that the mean attitudes scale score difference was significant in the intervention group from baseline to one month ($p < 0.001$). Also results suggest that no differences were detected statistically from one month to three month; therefore we concluded that the attitudes were sustained during this period (Table 4.35).

Table 4.33 Attitudes toward innovation characteristics at baseline, one month, and three months[a] (N=33)

Timepoints	Intervention (N=18)	Control (N=15)
	Mean Scale Score (SD)	
Baseline	4.44 (0.38)	4.55 (0.41)
One Month*	**5.11 (0.62)**	**4.57 (0.56)**
Three Months	5.16 (0.92)	4.76 (0.55)

[a] Mixed ANOVA with Bonferroni post-hoc tests.

Table 4.34 Mixed ANOVA summary table for change in attitudes toward intervention between groups over time (N=33)

	df	*MS*	*F*	*p-value* [a]
Group	1	0.631	2.785	0.105
Time	2	1.866	8.628	**<0.001***
Time*Group	2	0.957	4.424	**0.016***

[a] Mixed ANOVA with Bonferroni post-hoc tests.
*Significant at the 0.05 level

Table 4.35 Change in attitudes toward innovation characteristics within groups over time (N=33)

Change in Mean Scale Score Within Groups				
	Intervention (N=18)		Control (N=15)	
Timepoints	**Mean Difference (SE)**	**p-value** [a]	**Mean Difference (SE)**	**p-value** [a]
Baseline - One Month	**-0.669 (0.13)**	**<0.001***	-0.016 (0.14)	1.000
One Month – Three Months	-0.042 (0.167)	1.000	-0.192 (0.18)	0.906
Overall		**<0.001***		0.508

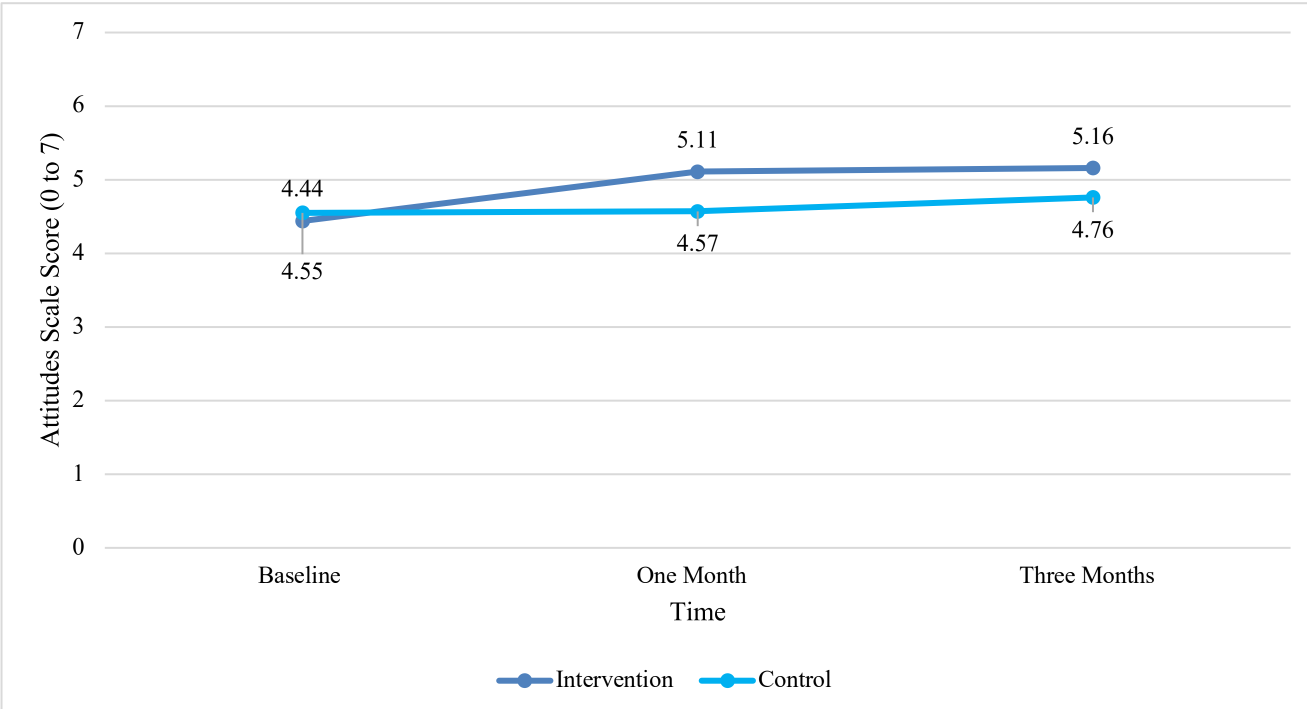
[a]Mixed ANOVA with Bonferroni post-hoc tests
*Significant at the 0.05 level

Table 4.36 Change in attitudes toward innovation characteristics between groups over time (N=33)

	Change in Mean Scale Score Between Groups	
Timepoints	**F**	**p-value** [a]
Baseline - One Month	11.588	**0.002***
One Month – Three Months	0.366	0.550
Overall	4.424	**0.016***

[a]Mixed ANOVA with Bonferroni post-hoc tests
*Significant at the 0.05 level

Figure 4.5 Change in attitudes toward innovation characteristics over time by group



The effect of the intervention on each of the three subscales within attitudes toward innovation characteristics was also analyzed. Two-way mixed ANOVA was used to test the effect of the intervention. Mauchly's test of sphericity indicated that the assumption of sphericity was met for the two-way interaction of all three subscale analyses. Results from Bonferroni post-hoc tests conducted as part of the mixed ANOVA are presented where there are significant main effects.

Subscale 1: Improving Patient Care

The first subscale was Improving Patient Care. The mean (SD) of the intervention group was 5.528 (0.87) at baseline, 5.77 (0.76) at one month, and 5.62 (1.10) at three months. Among control group participants, the mean (SD) at baseline, one month, and three months, was 5.10 (0.67), 5.31 (0.64), and 5.28 (0.84), respectively (Table 4.37).

A summary of the results of the two-way mixed ANOVA are presented in Table 4.38. There was no statistically significant interaction between the intervention and time, $F(2) = 0.418$, $p = 0.660$ (Table 4.33). The main effect of group also did not show a statistically significant difference in mean scale score, F(1) = 2.000, p =0.167 (Table 4.38). Finally, the main effect of time also did not show a statistically significant difference at the different time points, F(2) = 2.684, p =0.076 (Table 4.38). No differences were detected across time nor groups in terms of "Improving Patient Care" attitudes.

Table 4.37 Subscale 1: Improving Patient Care at baseline, one month, and three months[a] (N=33)

Timepoints	Intervention (N=18)	Control (N=15)
	Mean Scale Score (SD)	
Baseline	5.28 (0.87)	5.10 (0.67)
One Month	5.77 (0.76)	5.31 (0.64)
Three Months	5.62 (1.10)	5.28 (0.84)

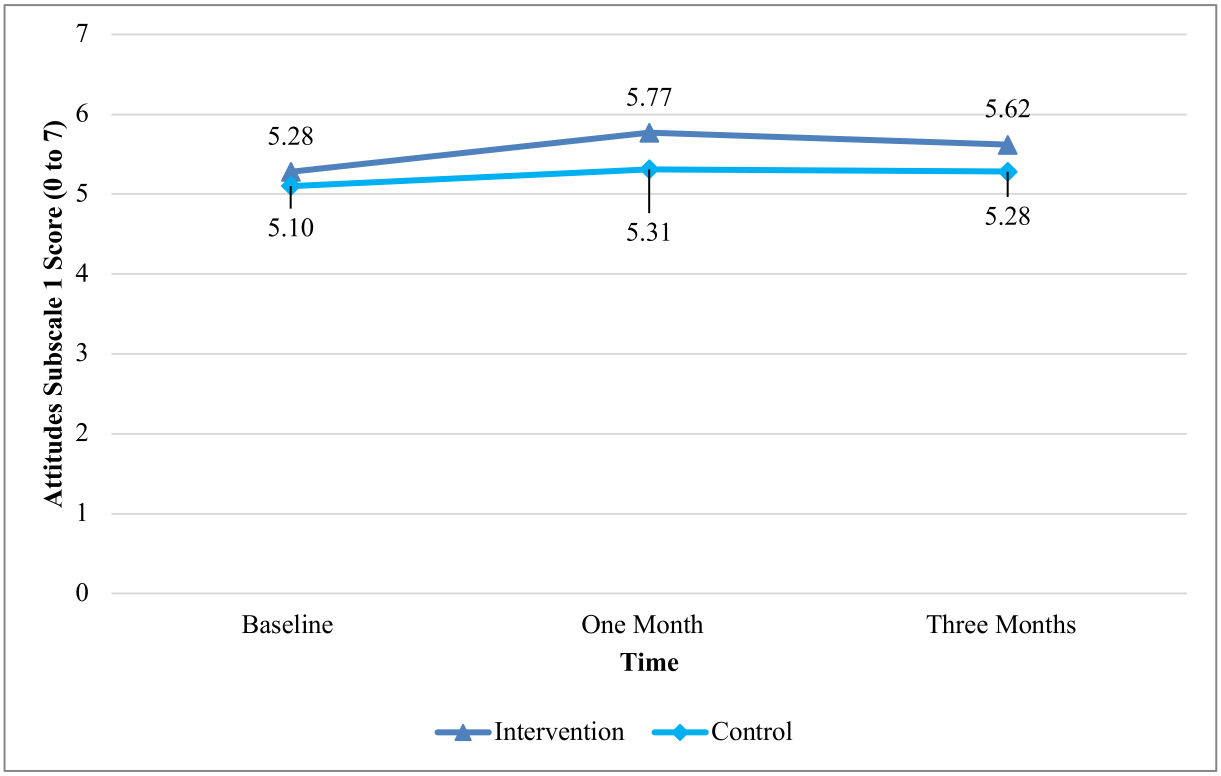
[a] Mixed ANOVA with Bonferroni post-hoc tests.

Table 4.38 Mixed ANOVA summary table for change in Subscale 1: Improving Patient Care between groups over time (N=33)

	df	*MS*	*F*	*p-value* [a]
Group	1	0.875	2.000	0.167
Time	2	1.062	2.684	0.076
Time*Group	2	0.165	0.418	0.660

[a] Mixed ANOVA with Bonferroni post-hoc tests.
*Significant at the 0.05 level

Figure 4.6 Change in Subscale 1: Improving Patient Care over time by group



Subscale 2: Intervention Source Support

The second subscale was Intervention Source Support. The mean (SD) of the intervention group was 3.86 (0.53) at baseline, 4.64 (0.64) at one month, and 4.79 (1.05) at three months. Among control group participants, the mean (SD) at baseline, one month, and three months, was 4.19 (0.33), 4.02 (0.76), and 4.39 (0.62), respectively (Table 4.39). The mean was significantly greater among control participants at baseline ($p=0.047$). However, the mean of the intervention group was significantly greater at the one month (post-intervention) time point ($p=0.017$).

A summary of the results of the two-way mixed ANOVA are presented in Table 4.40. The main effect of group did not show a statistically significant difference in mean scale score, $F(1) = 1.424$, $p = 0.242$ (Table 4.40). However, there was a statistically significant interaction between the intervention and time, $F(2) = 7.209$, $p = 0.002$ (Table 4.40). The main effect of time also showed a statistically significant difference in mean scale score, $F(2) = 9.487$, $p < 0.001$ (Table 4.40). Bonferroni post-hoc tests revealed that intervention participants' mean perceived intervention source support increased significantly from baseline to one month ($p<0.001$) (Table 4.41). The overall change within the intervention group from baseline to three months was also significant ($p< 0.001$). Furthermore, there was a significant effect between groups from baseline to one month ($p < 0.001$) (Table 4.42).

Table 4.39 Subscale 2: Intervention Source Support at baseline, one month, and three months[a] (N=33)

Timepoints	Intervention (N=18)	Control (N=15)
	Mean Scale Score (SD)	
Baseline*	**3.86 (0.53)**	**4.19 (0.33)**
One Month*	**4.64 (0.64)**	**4.02 (0.76)**
Three Months	4.79 (1.05)	4.39 (0.62)

[a] Mixed ANOVA with Bonferroni post-hoc tests.

Table 4.40 Mixed ANOVA summary table for change in Subscale 2: Intervention Source Support between groups over time (N=33)

	df	*MS*	*F*	*p-value* [a]
Group	1	0.435	1.424	0.242
Time	2	2.628	9.487	**<0.001***
Time*Group	2	1.997	7.209	**0.002***

[a] Mixed ANOVA with Bonferroni post-hoc tests.
*Significant at the 0.05 level

Table 4.41 Change in Subscale 2: Intervention Source Support within groups over time (N=33)

Change in Mean Scale Score Within Groups				
	Intervention (N=18)		Control (N=15)	
Timepoints	**Mean Difference (SE)**	**p-value** [a]	**Mean Difference (SE)**	**p-value** [a]
Baseline - One Month	**-0.778**	**<0.001***	0.163	0.935
One Month – Three Months	-0.154	1.000	-0.363	0.261
Overall		**<0.001***		0.220

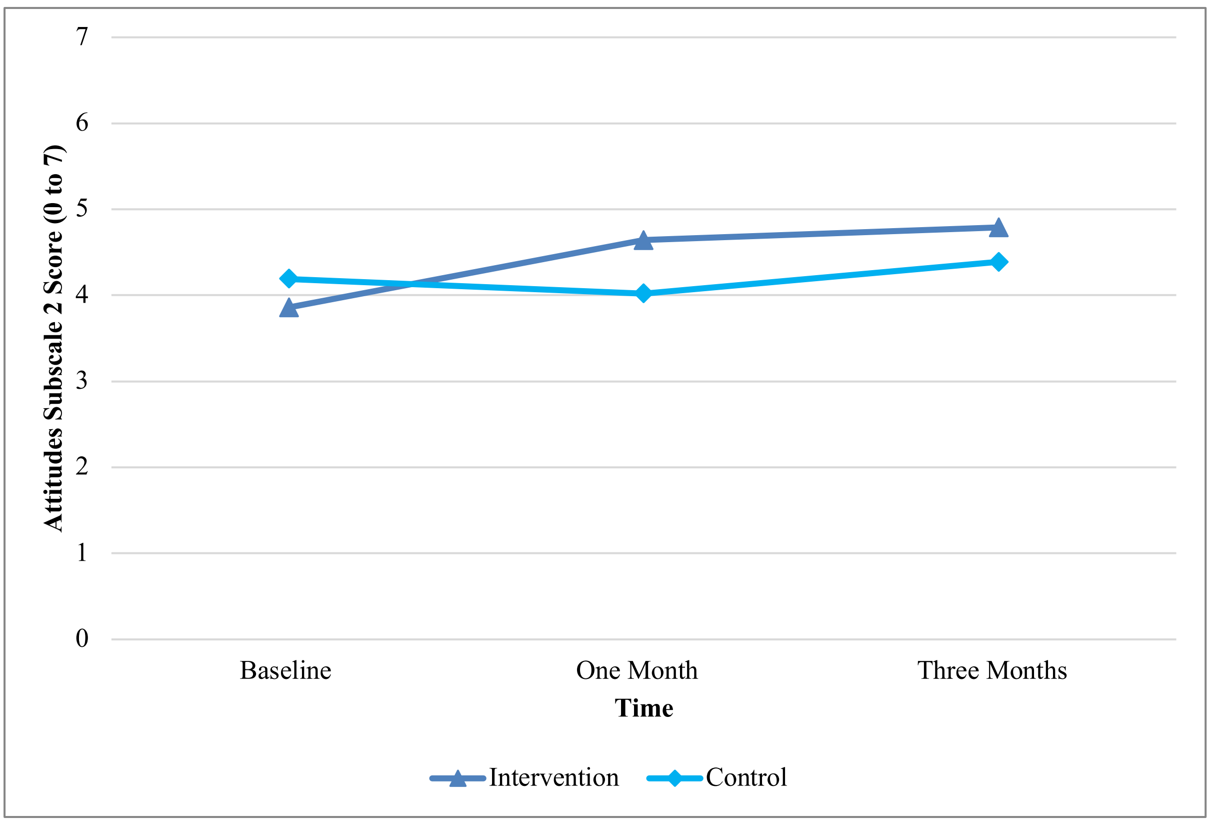
[a]Mixed ANOVA with Bonferroni post-hoc tests
*Significant at the 0.05 level

Table 4.42 Change in Subscale 2: Intervention Source Support between groups over time (N=33)

	Change in Mean Scale Score Between Groups	
Timepoints	**F**	**p-value [a]**
Baseline - One Month	19.225	**<0.001***
One Month – Three Months	0.563	0.459
Overall	7.209	**0.002***

[a]Mixed ANOVA with Bonferroni post-hoc tests
*Significant at the 0.05 level

Figure 4.7 Change in Subscale 2: Intervention Source Support over time by group



Subscale 3: Ease of Use

The third subscale analyzed was Ease of Use. The mean (SD) of the intervention group was 3.66 (0.67) at baseline, 4.52 (0.93) at one month, and 4.80 (0.95) at three months. Among control group participants, the mean (SD) at baseline, one month, and three months, was 4.00 (0.69), 3.92 (0.90), and 4.29 (0.89), respectively (Table 4.43).

A summary of the results of the two-way mixed ANOVA are presented in Table 4.44. The interaction between the intervention and time was statistically significant, $F(2) = 3.787$, $p = 0.028$ (Table 4.44). The main effect of time also showed a statistically significant difference in mean scale score, F(2) = 7.226, p =0.002 (Table 4.44). However, the main effect of group did not show a statistically significant difference in mean scale score, F(1) = 1.630, p =0.211 (Table 4.44). Bonferroni post-hoc tests revealed that intervention participants' mean perceived ease of use increased significantly from baseline to three months (p=0.009) (Table 4.45).

Table 4.43 Subscale 3: Ease of Use at baseline, one month, and three months[a] (N=33)

Timepoints	Intervention (N=18)	Control (N=15)
	Mean Scale Score (SD)	
Baseline	3.66 (0.67)	4.00 (0.69)
One Month	4.52 (0.93)	3.92 (0.90)
Three Months	4.80 (0.95)	4.29 (0.89)

[a] Mixed ANOVA with Bonferroni post-hoc tests.

Table 4.44 Mixed ANOVA summary table for change in Subscale 3: Ease of Use between groups over time (N=33)

	df	*MS*	*F*	*p-value* [a]
Group	1	0.531	1.630	0.211
Time	2	4.241	7.226	**0.002***
Time*Group	2	2.222	3.787	**0.028***

[a] Mixed ANOVA with Bonferroni post-hoc tests.
*Significant at the 0.05 level

Table 4.45 Change in Subscale 3: Ease of Use within groups over time (N=33)

Change in Mean Scale Score Within Groups				
	Intervention (N=18)		**Control (N=15)**	
Timepoints	**Mean Difference (SE)**	**p-value** [a]	**Mean Difference (SE)**	**p-value** [a]
Baseline - One Month	**-0.867**	**0.009***	0.080	1.000
One Month – Three Months	-0.278	0.879	-0.373	0.597
Overall		**<0.001***		0.372

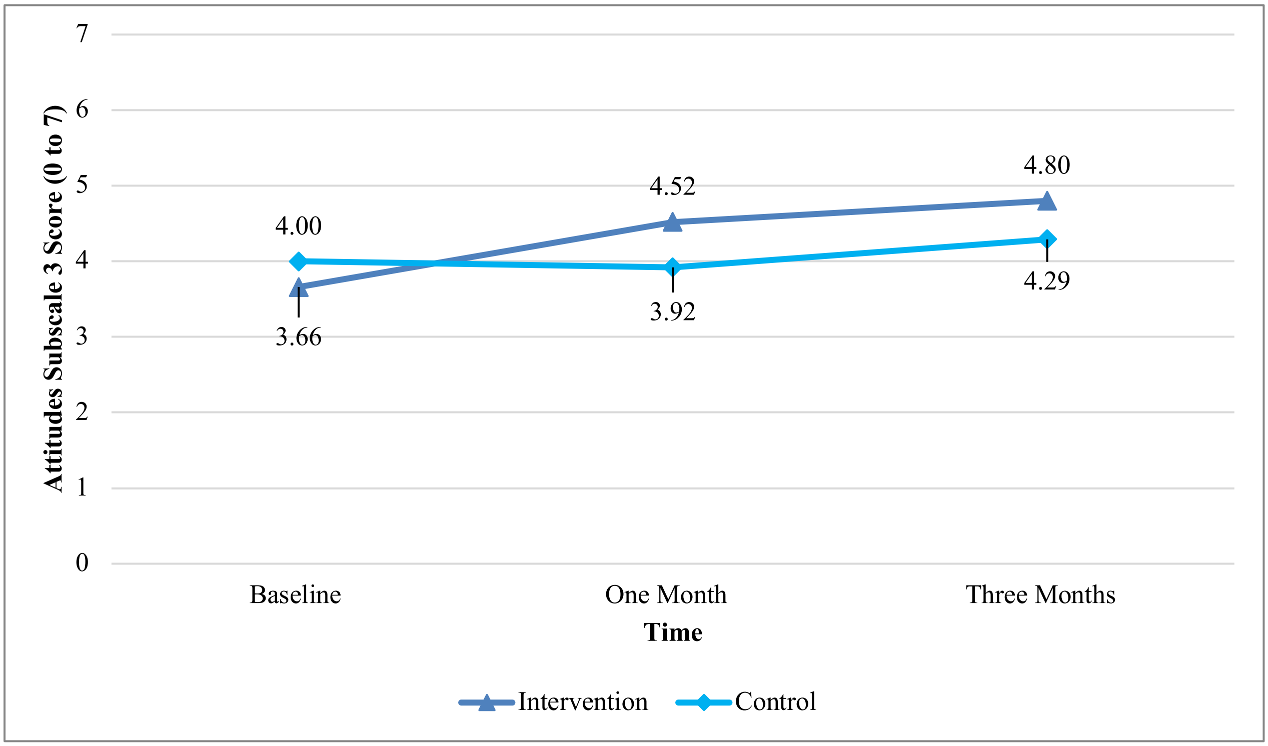
[a]Mixed ANOVA with Bonferroni post-hoc tests
*Significant at the 0.05 level

Table 4.46 Change in Subscale 3: Ease of Use between groups over time (N=33)

	Change in Mean Scale Score Between Groups	
Timepoints	**F**	**p-value** [a]
Baseline - One Month	5.696	**0.023***
One Month – Three Months	0.062	0.806
Overall	3.787	**0.028***

[a]Mixed ANOVA with Bonferroni post-hoc tests

Figure 4.8 Change in Subscale 3: Ease of Use over time by group



In summary, results of the two-way mixed ANOVA indicate that attitudes toward innovation characteristics, the overall scale, were significantly improved in the intervention group. When evaluating the subscales, this effect was significant within the intervention source support and ease of use subscales. Therefore, the results support hypothesis H1c; the null hypothesis is rejected and we conclude that the intervention had an effect on participants' attitudes toward innovation characteristics. Specifically, the aspects that were affected are intervention source support and ease of use.

Relationship between predisposing factors and intention

H2. An increase in pharmacists' intention to enroll in the IIS at one-month will be observed among intervention and control pharmacies who demonstrate greater awareness, knowledge, and positive attitudes across baseline and one-month.

Liner regression was used to test hypothesis H2. The results are presented in Table 4.47. Bivariate analyses were used to test demographic characteristics as potential control variables. None of the demographic characteristics were significant, and therefore no control variables were included in the models. Model one includes the predisposing factors awareness, knowledge, and attitudes toward innovation characteristics. Analysis of this regression model indicate that predisposing factors are not associated with intention to enroll in IIS, $R^2 = 0.032$, $F= 0.319$, $p = 0.811$.

In addition to the regression model testing H2, Table 4.47 also presents Model 2. In model two, attitudes toward innovation characteristics was removed and replaced with the three subscales, improving patient care, intervention source support, and ease of use. Analysis of this regression model indicated that including the subscales did not significantly improve the model, $R^2 = 0.143$, $F= 0.903$, $p = 0.493$.

Table 4.47 Linear Regression Models Analyzing Intention to Enroll in IIS (N=33)

Variables	Model 1		Model 2	
	β	p-value	β	p-value
Awareness	-0.100	0.634	-0.225	0.304
Knowledge	-0.111	0.598	-0.099	0.643
Attitudes toward IIS	0.076	0.689		
Improving Patient Care			0.421	0.074
Intervention Source Support			-0.273	0.337
Ease of Use			-0.045	0.863
Model R^2	0.032		0.143	
Model F	0.319		0.903	
Sig.	0.811		0.493	

In summary, results of the linear regression indicate that predisposing factors, including awareness, knowledge, and attitudes toward innovation characteristics were not predictors of intention to enroll in the immunization information system. Therefore, the results do not support hypothesis H2; the null hypothesis is not rejected and we conclude that predisposing factors do not predict intention.

Intention

H3. An increase in pharmacists' intention to enroll in the immunization registry will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.

The mean (SD) of intervention participants' intention to enroll in the IIS was 5.28 (1.13) at baseline, 5.81 (1.25) at one month, and 5.20 (1.46) at three months. Among control group participants, the mean (SD) intention at baseline, one month, and three months, was 4.78 (1.15), 5.00 (1.20), and 4.93 (1.11), respectively (Table 4.48).

Two-way mixed ANOVA was used to test hypothesis H3. A summary of the results of the two-way mixed ANOVA are presented in Table 4.49. Mauchly's test of sphericity indicated that the assumption of sphericity was not met for the two-way interaction, therefore the Greenhouse-Geisser correction was used.

There was no statistically significant interaction between the intervention and time on intention, $F(1.640) = 0.850$, $p = 0.413$ (Table 4.49). The main effect of time also did not show a statistically significant difference in mean intention at the different time points, $F(1.640) = 1978$, $p = 0.156$ (Table 4.49). Finally, the main effect of group also did not show a statistically significant difference in mean intention between intervention and control groups $F(1) = 2.219$, $p = 0.146$ (Table 4.49). Mean intention was slightly greater in the intervention group than the control group at all three time points, however this was not statistically significant at baseline ($p=0.217$), one month ($p=0.067$), or three months (0.561) (Table 4.48).

Table 4.48 Intention to enroll in ImmPRINT at baseline, one month, and three months[a] (N=33)

Timepoints	Intervention (N=18)	Control (N=15)
	Mean Scale Score (SD)	
Baseline	5.28 (1.13)	4.78 (1.15)
One Month	5.81 (1.25)	5.00 (1.20)
Three Months	5.20 (1.46)	4.93 (1.11)

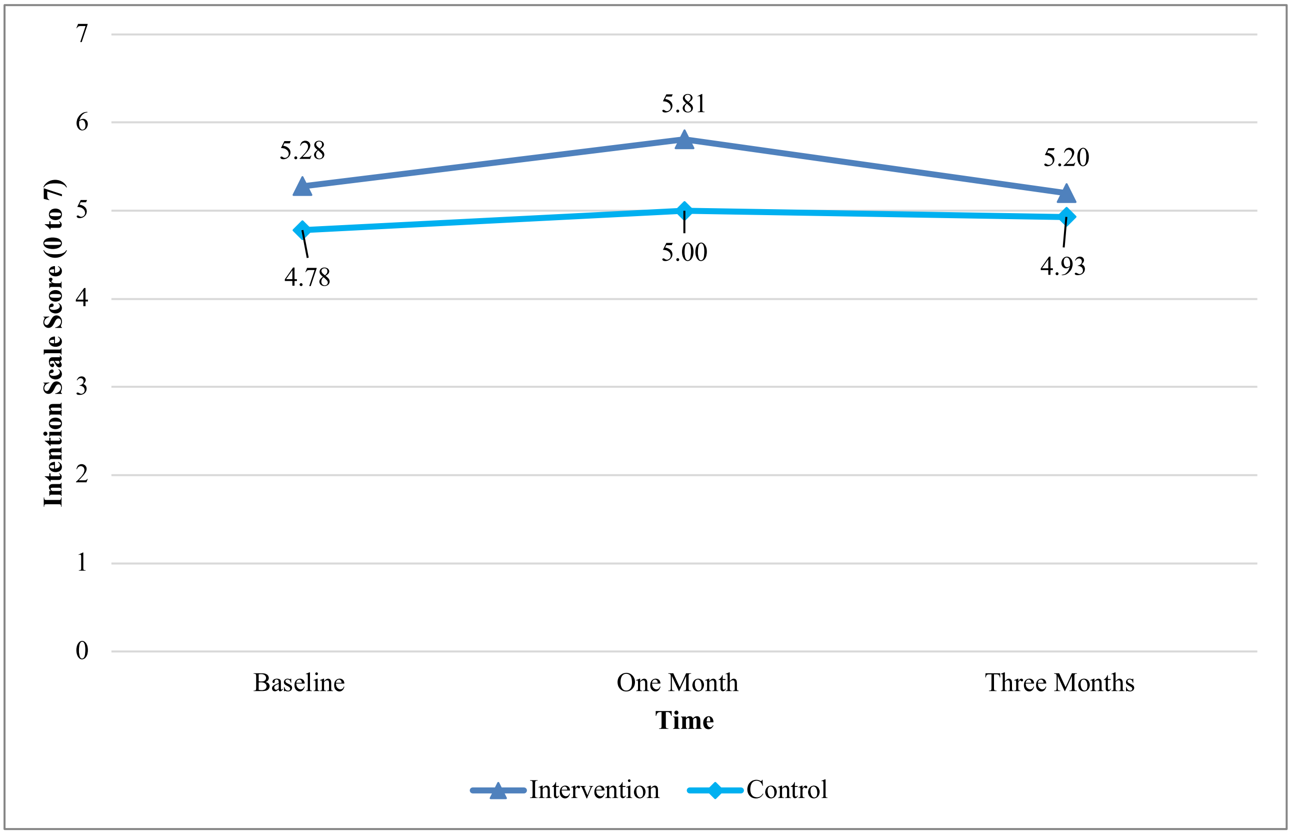
[a] Mixed ANOVA with Bonferroni post-hoc tests.
*Significant at the 0.05 level

Table 4.49 Mixed ANOVA summary table for change in intention to enroll in ImmPRINT between groups over time (N=33)

	df	*MS*	*F*	*p-value* [a]
Group	1	2.284	2.219	0.146
Time	1.640	1.733	1.978	0.156
Time*Group	1.640	0.745	0.850	0.413

[a] Mixed ANOVA with Bonferroni post-hoc tests.
*Significant at the 0.05 level

Figure 4.9 Change in intention to enroll in ImmPRINT over time by group



In summary, results of the two-way mixed ANOVA indicate that intention to enroll in ImmPRINT was not significantly improved in the intervention group. Therefore, the results do not support hypothesis H3; the null hypothesis is not rejected and we conclude that the intervention did not have an effect on participants' intention to enroll in ImmPRINT.

Enrollment

H4. An increase in pharmacists' enrollment in the immunization registry will be observed from baseline to three-months among participants in the intervention group when compared to the control group.

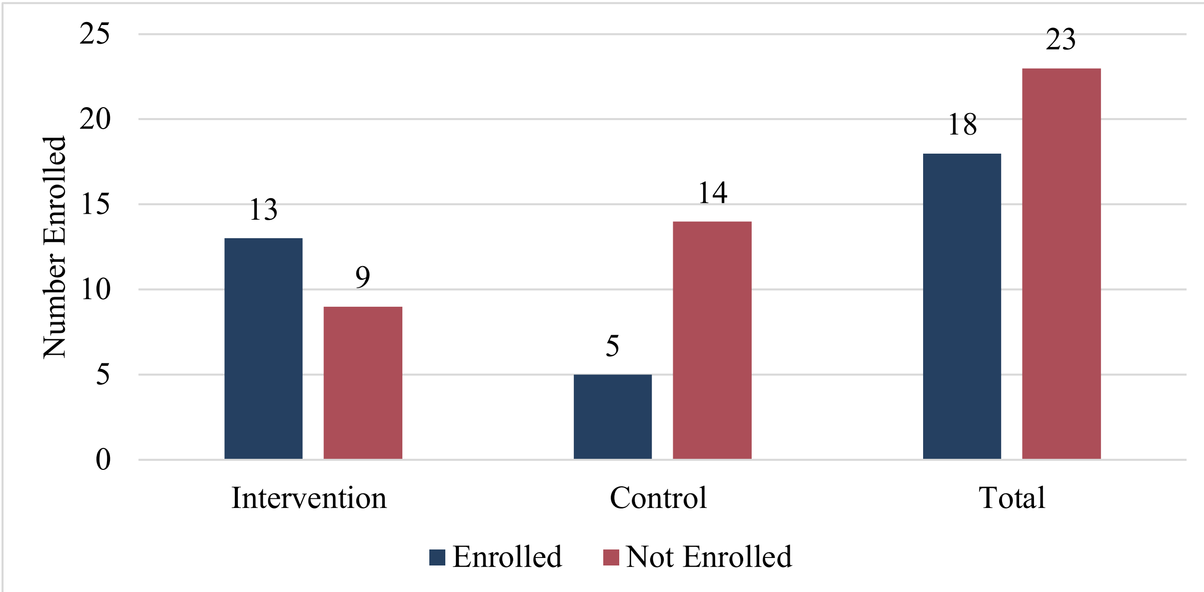
A chi-square test of independence was conducted between group and enrollment status. There was a statistically significant association between group and enrollment status, $\chi^2(1) = 4.447$, $p = 0.035$. Specifically, at three months 13 (59.1%) participants in the intervention group were enrolled in ImmPRINT compared to only 5 (26.3%) control group participants (Table 4.50).

Table 4.50 Chi-square analysis of enrollment status

	Enrolled N(%)	**Not Enrolled N(%)**	**Chi-square (df)**	**p-value**
Intervention (n=22)			4.447 (1)	**0.035***
Control (N=19)		14 (73.7)		
Total (N=41)		23 (56.1)		

*Significant at the 0.05 level

Figure 4.10 ImmPRINT enrollment status by group at three months



In summary, results of the chi-square test indicate that enrollment in ImmPRINT at three months was significantly different in the intervention group compared to the control group. Therefore, the results support hypothesis H4; the null hypothesis is rejected and we conclude that the intervention had an effect on participants' enrollment in ImmPRINT.

Participation

H5. An increase in pharmacists' participation in the immunization registry will be observed among participants in the intervention compared to the control group at three-months.

There were 13 intervention and 5 control participants enrolled in ImmPRINT at three months. Among these participants, the proportion of doses administered compared to the number of doses recorded in ImmPRINT, between groups was analyzed. An independent-samples t-test was run to determine if there were differences in the proportion of doses recorded between intervention and control participants. There were no statistically significant differences between groups (Table 4.51). The total number of doses recorded in ImmPRINT by participating pharmacies during the study period was 350 doses, with 227 and 123 doses contributed by the intervention and control groups, respectively.

Table 4.51 Participation between groups (N=18)

	Mean (SD)		p-value [a]
Self-reported doses administered	20.67 (21.37)	26.6 (21.37)	0.615
Doses recorded in ImmPRINT	18.92 (45.03)	24.60 (25.37)	0.797
Proportion of doses recorded	0.83 (0.85)	0.79 (0.53)	0.923

[a]Independent samples t-test

In summary, results of the independent samples t-test indicate that participation in ImmPRINT at three months was not significantly different in the intervention group compared to the control group. Therefore, the results do not support hypothesis H5; the null hypothesis is not rejected and we conclude that the intervention did not have an effect on participants' participation in ImmPRINT.

Relationship between Intention and Enrollment

H6. An increase in pharmacists' enrollment in the immunization registry at three months will be observed among participants who demonstrate intention to implement the immunization registry.

Binomial logistic regression was used to test hypothesis H6. The results of this logistic regression model are presented in Table 4.52. The logistic regression model H6 was used to determine the relationship between intention measured at one month and enrollment in the immunization information system. Analysis of this regression model indicate that intention did not predict enrollment, X^2 = 6.287; df=1; p= 0.790.

Table 4.52 Logistic Regression Models Analyzing Enrollment in IIS (N=39)

	B	**SE**	**Wald**	**DF**	**p-value**	**Odds Ratio**
Intention	0.064	0.240	0.070	1	0.791	1.066
Model Chi-square	0.071					
Degrees of freedom	1					
-2 log likelihood	52.731					
Cases correctly classified (%)	59.0%					
Sig.	0.790					

In summary, results of the logistic regression indicate that intention did not predict enrollment in the immunization information system. Therefore, the results do not support hypothesis H6; the null hypothesis is not rejected and we conclude that there is no significant association between intention and enrollment.

Implementation Factors

H7. Implementation factors including innovation characteristics, inner setting, outer setting, characteristics of individuals, and process will have a relationship with IIS participation.

Five domains of the CFIR were measured at three months. The first domain, innovation characteristics was also measured at baseline and one month and is described under H1c, *Attitudes toward innovation characteristics*. The mean scale score for all five domains including innovation characteristics, inner setting, outer setting, characteristics of individuals, and process, for both intervention and control groups are described in Table 4.53. At three months, independent samples t-tests indicate that there was a significant difference between intervention and control groups related to the first inner setting subscale, Readiness for Implementation($p=0.003$). Specifically, the Readiness for Implementation mean scale scores were 5.15 (0.75) and 4.19 (0.97) for the intervention and control groups, respectively.

Table 4.53 Implementation Factors at three months by group

		Intervention (N=18)	Control (N=15)	Total (N=33)	p-value [a]
		Mean Scale Score (SD)			
Innovation characteristics	Overall	5.16 (0.92)	4.76 (0.55)	4.98 (0.79)	0.155
	Improving Patient Care	5.62 (1.10)	5.28 (0.84)	5.46 (0.99)	0.338
	Intervention Source Support	4.79 (1.05)	4.39 (0.62)	4.61 (0.89)	0.199
	Ease of Use	4.80 (0.95)	4.29 (0.89)	4.57 (0.94)	0.127
Inner Setting	Overall	5.14 (0.69)	4.65 (0.78)	4.92 (0.77)	0.064
	Readiness for Implementation	5.15 (0.75)	4.19 (0.97)	4.71 (0.97)	**0.003***
	Implementation Climate	4.82 (1.07)	4.53 (0.94)	4.69 (1.01)	0.430
	Culture	5.51 (0.88)	5.39 (0.73)	5.45 (0.8)	0.675
Outer Setting	Overall	4.62 (0.67)	4.38 (0.49)	4.51 (0.59)	0.257
	External Support	5.12 (0.81)	5.01 (0.65)	5.07 (0.73)	0.676
	Peer Pressure	4.15 (0.73)	3.76 (1.12)	3.97 (0.93)	0.235
Characteristics of Individuals		4.56 (1.52)	4.80 (1.15)	4.67 (1.35)	0.612
Process	Overall	5.03 (1.09)	4.32 (1.00)	4.71 (1.1)	0.067
	Engaging and Planning	5.06 (0.96)	4.41 (1.08)	4.76 (1.05)	0.075
	Executing	4.94 (2.02)	4.13 (1.73)	4.58 (1.91)	0.229

[a] Independent samples t-test
*Significant at the 0.05 level

Hierarchical linear regression was used to test hypothesis H7, that implementation factors including innovation characteristics (H7a), inner setting (H7b), outer setting (H7c), characteristics of individuals (H7d), and process (H7e) have a relationship with participation. Bivariate analyses were used to test demographic characteristics as potential control variables. None of the demographic characteristics were significant, and therefore no control variables were included in the models. Model one includes all five

CFIR domains as implementation factors: innovation characteristics, inner setting, outer setting, characteristics of individuals, and process (Table 4.54). Analysis of this regression model indicate that implementation factors are associated with participation in IIS, $R^2 = 0.599$, $F= 3.884$, $p = 0.023$.

This analysis was then repeated within each domain to explore the relationship between each domain's subscales and IIS participation. These results are presented in Models H7a- H7d in Table 4.54. In model H7a, attitudes toward innovation characteristics was removed and replaced with the three subscales, improving patient care, intervention source support, and ease of use. Analysis of this regression model indicated that Ease of Use was a predictor of participation (p=0.038), $R^2 = 0.419$, $F= 3.599$, $p = 0.039$. Additionally, model H7d indicates that the process domain is associated with participation, $R^2 = 0.430$, $F= 6.043$, $p = 0.011$, with Executing being a significant predictor (p=0.003).

Table 4.54 Linear Regression Models Analyzing Implementation Factors and Participation in IIS (N=33)

Variables	Model H7		Model H7a		Model H7b		Model H7c		Model H7d	
	β	p-value	β	p-value	β	p-value	β	p-value	β	p-value
Innovation characteristics	0.607	**0.021***	-	-	-	-	-	-	-	-
Inner Setting	-0.064	0.873	-	-	-	-	-	-	-	-
Outer Setting	-0.557	0.052	-	-	-	-	-	-	-	-
Characteristics of Individuals	-0.240	0.312	-	-	-	-	-	-	-	-
Process	0.432	0.181	-	-	-	-	-	-	-	-
Innovation Characteristics										
Improving Patient Care	-	-	-0.110	0.676	-	-	-	-	-	-
Intervention Source Support	-	-	0.243	0.357	-	-	-	-	-	-
Ease of Use	-	-	0.551	**0.038***	-	-	-	-	-	-
Inner Setting										
Readiness for Implementation	-	-	-	-	0.002	0.996	-	-	-	-
Implementation Climate	-	-	-	-	0.218	0.572	-	-	-	-
Culture	-	-	-	-	-0.106	0.729	-	-	-	-
Outer Setting										
External Support	-	-	-	-	-	-	-4.43	0.176	-	-
Peer Pressure	-	-	-	-	-	-	-6.93	0.178	-	-
Process										
Engaging and Planning	-	-	-	-	-	-	-	-	-0.228	0.294
Executing	-	-	-	-	-	-	-	-	0.725	**0.003***
Model R^2	0.599		0.419		0.035		0.196		0.430	
Model F	3.884		3.599		0.183		1.221		6.043	
Sig.	**0.023***		**0.039***		0.906		0.336		**0.011***	

*Significant at the 0.05 level

In summary, implementation factors were found to be associated with IIS participation. Specifically, Ease of Use and Executing are predictors of participation. As such, the null hypothesis was rejected, there is a relationship between implementation factors and participation in ImmPRINT

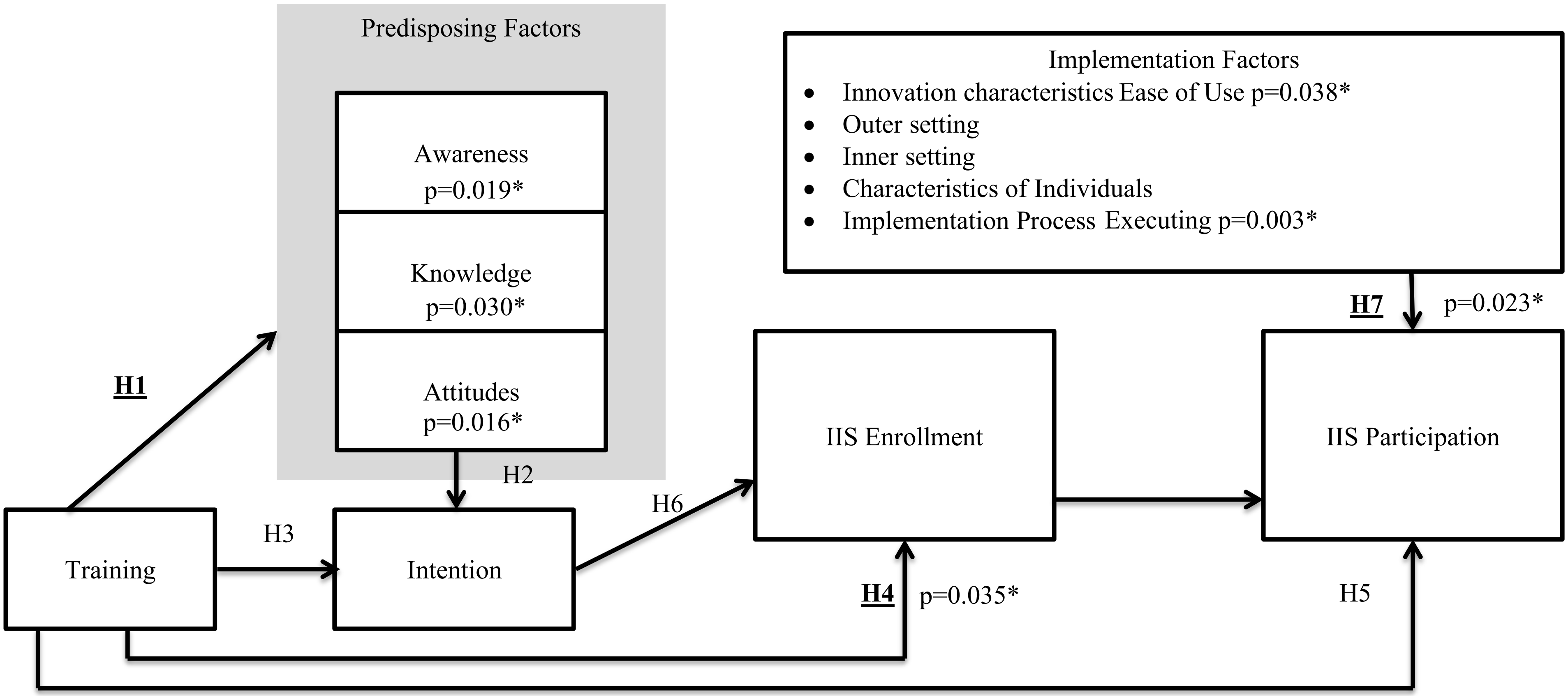
Summary

In summary, the intervention was shown to affect participants' awareness, knowledge, and attitudes toward innovation characteristics. The intervention did not significantly improve intention to enroll in IIS, and predisposing factors did not predict intention to enroll in IIS. While intention was not shown to predict enrollment, the intervention was shown to affect enrollment in IIS. However this effect was not seen when examining participation in the IIS. Finally, a relationship was found between implementation factors and IIS participation. Table 4.55 below summarizes the results and supported and unsupported hypotheses.

Table 4.55 Summary of supported and unsupported hypotheses

Hypothesis	Result	Supported
H1a. An increase in pharmacists' awareness will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.	Mean awareness of the intervention group was significantly greater than the control group at one-month post intervention.	YES
H1b. An increase in pharmacists' knowledge will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.	Mean knowledge of the intervention group was significantly greater at one-month post intervention compared to baseline.	YES
H1c. An increase in pharmacists' positive attitudes will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.	Mean attitudes toward innovation characteristics of the intervention group was significantly greater at one-month post intervention compared to baseline.	YES
H2. An increase in pharmacists' intention to enroll in the immunization information system at one-month will be observed among intervention and control pharmacies who demonstrate greater awareness, knowledge, and positive attitudes across baseline and one-month.	Predisposing factors, including awareness, knowledge, and attitudes toward innovation characteristics were not associated with intention to enroll in the immunization information system.	NO
H3. An increase in pharmacists' intention to enroll in the immunization registry will be observed among participants in the intervention group when compared to the control group across baseline, one-month, and three-months.	Intention to enroll in ImmPRINT was not significantly different in the intervention group compared to the control group.	NO
H4. An increase in pharmacists' enrollment in the immunization registry will be observed from baseline to three-months among participants in the intervention group when compared to the control group.	Enrollment in ImmPRINT at three months was significantly different in the intervention group compared to the control group.	YES
H5. An increase in pharmacists' participation in the immunization registry will be observed among participants in the intervention compared to the control group at three-months.	Participation in ImmPRINT at three months was not significantly different in the intervention group compared to the control group.	NO
H6. An increase in pharmacists' enrollment in the immunization registry at three months will be observed among participants who demonstrate intention to implement the immunization registry.	Intention did not predict enrollment in the immunization information system.	NO
H7. Implementation factors including innovation characteristics, inner setting, outer setting, characteristics of individuals, and process will have a relationship with IIS participation.	Implementation Factors, specifically Ease of Use and Executing were found to predict participation in the Alabama IIS, ImmPRINT.	YES

Figure 4.11 Conceptual model with supported hypotheses indicated*



*Supported hypotheses are indicated in bold and underlined.

Chapter 5: Discussion

This mixed-methods, randomized controlled trial examined the impact of a training program on implementation of Immunization Information Systems (IIS) in independent community pharmacies in Alabama. This chapter summarizes and explains the results, discusses the significance of the study's finding, and outlines limitations of this work. Finally, implications and directions for future research are presented.

Summary and Discussion of Qualitative Findings

Studying the factors that influence uptake and use of IIS in independent community pharmacies will contribute to successful implementation of IIS. Multiple Consolidated Framework for Implementation Research (CFIR) constructs were identified by interviewees as factors having a strong influence on implementation of IIS in community pharmacies.

Innovation Characteristics

Within the innovation characteristics domain, complexity was a critical factor. Requirements to complete tasks within the IIS can be overly complicated and burdensome for pharmacists working under already difficult time constraints. Furthermore, the adaptability of IIS is limited. Specifically, IIS use is disruptive and does not easily fit in the pharmacy workflow. Pharmacies need access to technology that allows the IIS to be easily integrated with their dispensing software. The ability to automatically exchange immunization information through the pharmacy dispensing software allows pharmacy staff to remain within their typical workflow when providing vaccinations. Some software vendors do have this functionality that can be made available to individual pharmacies for a fee. Pharmacists should be made aware of this option so they can consider whether this added benefit is worth the additional costs.

Inner Setting

Factors within the inner setting domain that were identified as having a strong influence on implementation included access to information, compatibility, and available resources. In order to successfully implement IIS, independent community pharmacists need access to knowledge and information about the IIS and how to incorporate it into their workflow. This is unsurprising, as independent pharmacies likely do not have access to the same resources and corporate support provided to large chain pharmacies. These independent pharmacists, many of whom own the business they work in, identified that the goals of the IIS are not always aligned with the business mindset required to maintain a successful independent pharmacy. Participating in the IIS takes time and resources that are limited for smaller, independent pharmacies. While manually documenting vaccinations can be time-consuming, many pharmacies have successfully incorporated ImmPRINT into their pharmacy workflow. Determining the ideal time for documentation in the individual pharmacy's workflow can make the process more efficient. It is up to the individual pharmacy or pharmacist to decide their optimal method of documenting the vaccination records into IIS. Some pharmacies have become successful integrating documentation so that it is done immediately after the vaccine is administered. Others might find that storing administered vaccine information in a designated location and inputting all information once per day, during downtime is ideal. Pharmacy personnel should work as a team to identify their needs and determine which strategy might be the right fit for the pharmacy.

Outer Setting

Needs of patients, peer pressure, and external policies were key factors within the outer setting domain. Pharmacists are compelled to participate in the IIS to meet the needs of their patients. Furthermore, physicians expect pharmacists to responsibly participate in IIS if they are serving as immunization providers. Some may expect opposition to policies mandating this participation among pharmacists. However, pharmacists participating in this study expressed positive perceptions toward a mandate, even stating that one is needed so that more providers participate and they can reliably use the IIS themselves.

Characteristics of Individuals

In order to successfully implement the IIS, characteristics of individual pharmacy personnel must also be considered. Pharmacy staff should be knowledgeable and hold positive attitudes toward ImmPRINT. However, lack of knowledge and negative beliefs about IIS were observed among Alabama pharmacists. These pharmacists may place a low value on IIS and/or are not familiar enough with the IIS in order to enroll and use it. Improving pharmacists' knowledge and beliefs is critical to increasing the number of pharmacies participating in IIS.

Process

Engaging the correct individuals was observed to have a strong influence on IIS implementation. Participants from high participation states stressed the importance of including pharmacy representatives in the initial and continuing development and decision-making stages regarding IIS at the state level. Alabama participants echoed the importance of this inclusion. Some reported feeling as if their unique needs were not always being met, or were not immediately considered. This includes recognizing the importance of engaging pharmacy technicians in the implementation of IIS, and thus allowing technicians to access the IIS and all of its components. One strategy that was reported to lessen the burden of documentation is developing a team-based approach within the pharmacy. The pharmacist does not necessarily have to be the only individual responsible for assessing immunization status and documenting vaccines administered in ImmPRINT. Many pharmacies have had success engaging other pharmacy team members in this role. Pharmacy technicians can gather immunization history from ImmPRINT and also document the information after a vaccine has been administered. This team-based approach divides the labor among staff, making the process more efficient. Outer setting stakeholders, individuals external to the pharmacy, should also be involved in IIS implementation. Academic institutions should be engaged to develop and deliver IIS related content in pharmacy curricula, so that future pharmacists are prepared to immediately begin using the IIS as they enter the workforce.

In Alabama, lack of patient engagement with the IIS had a negative influence on implementation. Some participants in other states reported that patient involvement in the IIS had a positive impact on implementation. This was the case when patients had access to their own patient portal. Allowing patients to check their own immunization records is a valuable tool. Patient access creates a level of accountability to ensure that data is entered accurately and in a timely manner. In some states, where enforcement of IIS mandates has proved difficult, accountability to patients is one method by which State

Departments of Public Health are notified of providers not adhering to the mandate. In states without mandates, patient access to and awareness of IIS could still motivate providers to participate. Prior research has shown that patients may avoid receiving immunizations in a pharmacy setting due to perceived improper documentation of administered immunizations (SC Westrick et al., 2017). Advertisement of pharmacy participation in IIS may improve these perceptions and increase immunization in individual pharmacy settings. States without current patient portals should consider the addition and future research should explore patient-related strategies to improve IIS participation.

Discussion

The results of these qualitative interviews address a gap in the literature specific to factors that influence implementation of IIS in an independent pharmacy setting. The research surrounding IIS implementation is limited, and the few studies that do examine these factors primarily do so among physicians using survey methods (D. A. Christakis et al., 1999; K. J. Dombkowski et al., 2007; S. T. O'Leary et al., 2016). Using survey methods allows for the ability to capture a representative sample of a larger population, however they are limited in the level of detail and unexpected information that can be gathered. Further, two of the three studies were published 12 and 20 years ago. One study did explore pharmacy barriers, but only included the five largest pharmacy chains that had implemented IIS (American Immunization Registry Association, 2015). These studies found that perceived incompleteness of IIS data, available resources (software, IT support, computer equipment, cost, etc.), complexity of IIS, and needs of patients were key factors influencing implementation. These factors fall within the intervention characteristics, inner setting, and outer setting domains and align well with the qualitative results reported here. However, many factors found to be critical in this study appear to be unique to independent pharmacies. These include adaptability, compatibility between IIS and workflow, knowledge and beliefs of IIS, peer pressure, external policies, and engaging stakeholders. This is unsurprising given the lack of external support provided to small independent pharmacies compared to larger chains. Further, the disruption to pharmacy workflow that takes place when personnel are required to change their routine and log on to the IIS website to manually enter vaccine information is often not an issue among physicians and chain pharmacists, whose data is automatically uploaded. These factors should be acknowledged and addressed in future studies aiming to implement IIS and other similar innovations in the community pharmacy setting.

The results of this dissertation are consistent with other research examining factors influencing innovation adoption. Health services innovations involving organization level technological change, are often characterized by non-adoption and abandonment (Greenhalgh et al., 2017). In this dissertation, complexity was found to be a key factor leading to this non-adoption and abandonment, which is consistent with previous literature (F. D. Davis, 1989; Greenhalgh, Robert, Macfarlane, et al., 2004; Greenhalgh et al., 2017; Rogers, 2003; Venkatesh et al., 2003). Greenhalgh and colleagues developed the non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework through a systematic review of 28 published technology implementation frameworks as well as empirical case studies of technology implementation. The NASSS framework helps to predict and evaluate the success specifically of technology based healthcare programs. Greenhalgh and colleagues highlight the role of complexity in the NASSS framework, suggesting that innovations perceived as being highly complex rarely become mainstreamed (Greenhalgh et al., 2017). The NASSS framework also discusses the important roles knowledge and support play in innovation adoption. Lack of knowledge and perceived lack of support were key issues that many pharmacists mentioned as barriers to implementation. The value proposition, including alignment of the technology with the organization's business model was also key. The results of our study showed that the pharmacists care about their patients and want to engage in activities that will offer them the best care possible, but independent pharmacy owners also have a business mindset, and in order to remain successful they must consider the value proposition of participating in IIS. NASSS also outlines the impact external policy issues can have on implementation. The results of our qualitative interviews described the need for policies to regulate IIS participation among pharmacists and other providers. Future training programs should be able to address these factors, particularly complexity and knowledge. Pairing this with an explanation of the current policies and potential for added revenue should be successful in reducing these barriers so that pharmacies are more likely to successfully implement and sustain IIS.

Summary and Discussion of Randomized Controlled Trial Findings

This randomized controlled trial demonstrated that a training program can improve independent community pharmacists enrollment in IIS which is a success as only 27% were enrolled at the beginning of the study period. A total of 18 independent pharmacies participating in this study enrolled in the Alabama IIS, ImmPRINT during the study period. Total enrollment of independent pharmacies in Alabama improved from 27% to 30%. While encouraging, there is still much room for improvement, as 70% of independent pharmacies in Alabama are still not enrolled in ImmPRINT. The enrollment of these 18 pharmacies resulted in the reporting of 350 vaccines doses in ImmPRINT over the course of the study period. Recording of these doses in ImmPRINT is critical at the population level, so that immunization rates in Alabama can be tracked and target areas with inadequate coverage can be identified (Centers for Disease Control and Prevention, 2012). This is especially critical in planning outbreak response efforts. A concern that is timely given the recent outbreak of vaccine preventable diseases such as measles across the U.S. At the point of clinical care, these additional vaccine doses added to patients' records can help other providers to accurately assess immunization status and identify which vaccinations are due for an individual so that opportunities are not missed and individuals are not over-vaccinated, ultimately improving patient care coordination (Centers for Disease Control and Prevention, 2012).

This is the first identifiable study with an aim to improve implementation of IIS in independent community pharmacies. No other studies have sought to improve pharmacy enrollment and participation in IIS. Providers may be provided with training materials upon enrollment in their state IIS. However, these materials are often generalized and not specific to their setting and are often provided after they have made the decision to enroll. The training intervention tested in this study was developed using a participatory design approach to ensure that the content was tailored and useful specifically for pharmacists. Furthermore, while this training program could be used to improve participation among enrolled, but inactive pharmacists, the training was designed to target pharmacists who have not yet made the decision to enroll or participate in the IIS on a regular basis. This study is strengthened by the inclusion of actual enrollment and participation data in addition to self-report as well as the inclusion of the CFIR as a guiding framework.

The results of the randomized controlled trial phase of this study demonstrate the ability of tailored training to improve pharmacists' awareness, knowledge, and attitudes toward IIS. Improving pharmacists' knowledge and beliefs, which was identified as a key factor in phase one qualitative interviews, was successful in improving pharmacy enrollment in IIS. Because there are no similar studies examining the impact of training on pharmacy enrollment and participation in IIS, in this discussion, we will compare and contrast the results with studies exploring the utilization of Prescription Drug Monitoring Programs (PDMPs), given some similarities shared between IIS and PDMPs. PDMPs are state-based electronic reporting systems similar to IIS. PDMPs consolidate data from outpatient and community pharmacies on controlled prescription drugs dispensed (Marc L. Fleming, Phan, Ferries, & Hatfield, 2015). Regulations vary by state with not all states mandating reporting. The improvement in participation rates of PDMPs is partly due to intervention research, with continuing education being used as one such intervention specifically for pharmacists (M. L. Fleming et al., 2014; Marc L. Fleming et al., 2015; Johnston et al., 2018). In 2018, Johnston and colleagues conducted a scoping review of pharmacists' knowledge, attitudes, registration, and utilization related to PDMPs (Johnston et al., 2018). Through this scoping review, they found that attitudes and knowledge were key factors influencing pharmacists likelihood to register and ultimately use the PDMP, and that targeted training substantially improved knowledge, training, and utilization. Similar to the results of this dissertation, the studies included in Johnston's scoping review identified that behavior change related to implementation of a healthcare technology was motivated through attitudes and knowledge. Pharmacists who received PDMP training were found to have improved opioid safety knowledge, more favorable attitudes, and higher PDMP registration rates. While the PDMP and IIS are different technological platforms, targeting very different public health needs, the use of training programs to improve knowledge, attitudes, and enrollment/registration in technology implementation is evident.

As demonstrated in this study, pharmacies have needs unique to those of other, more traditional immunization providers. Qualitative interview findings of this study, which identified CFIR constructs that were key factors in implementation, appear to align with the RCT results. Implementation factors including the inner setting, outer setting, characteristics of individuals, and process domains were not tracked over time. However, at three months we see that participants in intervention and control groups differed in terms of their characteristics related to Readiness for Implementation within the inner setting domain of the CFIR. This suggests that the training program impacted their readiness to implement the IIS. While the qualitative interviews identified a number of factors in the outer setting domain affecting IIS utilization, it is unsurprising that there was no effect seen within these domains between groups as these domains are not within the pharmacy's control. Pharmacy personnel are not able to change characteristics of the IIS itself, or the outer setting impacting their use of IIS. These factors should be considered during the course of IIS development and improvement to ensure that needs are not overlooked, negatively impacting their involvement. The results of this study enhance our understanding of the issues independently owned pharmacies face in incorporating IIS into daily workflow. This improved understanding can be used to inform expanded training programs to meet the specific needs of community pharmacies in Alabama and other states.

While this intervention was successful in improving awareness, knowledge, attitudes, and enrollment, sustainability remains a challenge. Sustainability is defined as "the extent to which an evidence-based intervention can deliver its intended benefits over an extended period of time after external support is terminated" (Hailemariam et al., 2019). The improvement of these outcomes at the one month timepoint demonstrates the immediate impact of the training program. However, the decrease in knowledge and lack of participation at three months demonstrate that the effect was not sustained. Sustainment of IIS implementation, creating and supporting structures and processes that will allow the IIS to be maintained in the pharmacy setting is needed for IIS to be useful as a reliable tool (Hailemariam et al., 2019).

Limitations

This dissertation used a mixed-methods qualitative and quantitative approach. The randomized controlled trial study design is a strength that limits potential threats to internal validity. During the study period, it is possible that participants were exposed to information about ImmPRINT from other sources. This could include the Alabama Pharmacy Association's Mid Winter Meeting, during which there was a CE session on ImmPRINT. Also, legislation was proposed during the study period that would make reporting to the IIS mandatory for all providers in Alabama, including pharmacists. Discussion surrounding this proposed legislation may have increased awareness of study participants during the study period. Furthermore, the study recruitment itself may have improved awareness of IIS. However, the experimental design of this study controls for these potential threats to internal validity and we can conclude that the effects seen between groups were due to the intervention itself and not outside factors. Within the control group, there were no statistically significant changes in awareness, knowledge, attitudes, or intention. However, 20% of control pharmacists did enroll in the IIS. Receipt of surveys and reminder emails could have contributed to a Hawthorne effect, whereby control pharmacists were aware they were participating in a study and being observed, and thus altered their behavior. Further, a question-behavior effect may have impacted the results. The surveys completed by both intervention and control participants may have served as reminders to complete the behaviors in question. While the RCT design strengthens the internal validity of this study, there is a need to test external validity. The study was limited to independent pharmacists in Alabama and may not be generalizable to other populations. The small sample size due to pharmacist drop out is another limitation that should be considered when interpreting the results of this study. Further, responders to the three month survey were found to be significantly different from non-responders in terms of their number of years practicing at their current practice site. The perceptions reported in this study are those of the individual pharmacist and may not represent the perceptions of the pharmacy staff as a whole. While this study included only one pharmacist per pharmacy, training of all personnel should be conducted in the future. The pharmacists participating in this study may not be the only personnel administering vaccines at their respective pharmacies, and without IIS training, these personnel may not be reporting the administered vaccines to ImmPRINT. Through training of all pharmacy personnel, improved participation of the pharmacy in IIS might be observed. Implementation of IIS is a change that requires support of all pharmacy staff, including the pharmacy owner, manager, staff pharmacists, and pharmacy technicians. As such, opinions of all personnel should be studied in the future. This study included staff pharmacists, pharmacy managers, and pharmacy owners. The varying levels of influence and authority these participants may or may not have could have impacted the decision to enroll their pharmacy in ImmPRINT and their ability to affect other pharmacy personnel's behavior. majority of data collected was self-reported and could be subject to associated biases including recall and social desirability bias. The IIS participation rate was calculated based on self-reported doses administered and doses reported in IIS. It is possible that self-reported doses administered were inaccurate, thus affecting the interpretation of the level of participation. None of the pharmacies participating in this study were enrolled in the Alabama IIS, ImmPRINT, at baseline. However, many believed that they were enrolled. This may have affected their reported intention to enroll in the IIS. The short, three month time frame for this study limited the amount of participation data that could be collected. Furthermore, IIS face-to-face training conducted by the Alabama Department of Public Health is required to be completed before pharmacists can begin using ImmPRINT. ImmPRINT typically completes this training within one month, but with the increase in number of pharmacies enrolling, the delay in training may have limited the level of participation, if any, that could be observed.

Future Directions

There is a strong base of evidence supporting the use of IIS to improve vaccination coverage (Daley et al., 2004; Daley et al., 2002; Dombkowski et al., 2012; Groom et al., 2015; Hambidge et al., 2004; Hambidge et al., 2009; Hull et al., 2009; Irigoyen et al., 2006; Kempe et al., 2005; LeBaron et al., 2004; Stockwell et al., 2010). However, in order to achieve these outcomes, high levels of participation are required. While the training program developed in this study improved enrollment in the IIS, there was no significant effect observed on participation. This may be due to the limited time frame and sample size. However, future research should incorporate a greater focus on participation.

Participation includes reporting data to the IIS, but also use of the IIS to assess and recommend additional vaccines. While not possible in this study, future research might track this participation through website analytic tools. The number of times pharmacy personnel access the IIS to check the vaccination status of a patient could be an important indicator of participation that ought to be measured. An increased focus on participation and tracking of assessment activities may improve IIS use in independent pharmacies. This could be accomplished through the integration of immunization interface and forecaster technologies into pharmacy dispensing software, and adjusting workflow so that patients with age or medical indications are flagged. Vaccine forecasts are then run for the patient, and this forecast used to initiate a conversation about their needed vaccines ending with the provision of a strong recommendation, and hopefully vaccine administration. The use of an interface and forecaster tool such as this, resulted in a 15% increase in the total number of influenza, pneumococcal, herpes zoster, and pertussis vaccines among participating pharmacies in Washington (Bacci et al., 2019).

While bi-directionally integrated technology would be ideal, some independent pharmacies may not have the resources to obtain this technology. This process could still be achieved with some pharmacies simply querying the state IIS, but integrating this into routine workflow as described above. A number of implementation strategies have been tested to sustain implementation outcomes. The Expert Recommendations for Implementing Change (ERIC) provides a compilation of 73 implementation strategies mapped to CFIR constructs based on context assessment (Powell et al., 2015; Waltz et al., 2015). This tool can be used to query implementation strategies that will be successful in addressing the implementation barriers identified throughout this study. Future research to improve IIS implementation among pharmacists might begin with a planning phase. Numerous studies of innovation implementation have emphasized the importance of the planning phase, including assessing the context, engaging key stakeholders, prioritizing goals and objectives, and adapting the innovation to fit the organization (Chinman et al., 2004; Ian D. Graham et al., 2006; Jennifer Leeman, Birken, Powell, Rohweder, & Shea, 2017; Meyers, Durlak, & Wandersman, 2012). For IIS implementation, this phase might include discussions with all pharmacy personnel to 1) assess readiness for implementation; 2) prioritize IIS participation as an area in need of improvement; 3) identify and engage champions; 4) identify barriers; 5) select implementation strategies that best fit the identified barriers to IIS participation; and 6) adapt the use of IIS to fit the pharmacy workflow. Throughout this planning phase, an implementation blueprint should be developed alongside educational materials.

The implementation phase should incorporate capacity-building implementation strategies, such as training, technical assistance, tools, and support systems, which could be tested using the factorial stepped wedge design (Jennifer Leeman et al., 2017). These strategies should increase individual's motivation and capability to engage in implementation process strategies (Jacobs et al., 2014; J. Leeman et al., 2015; Wandersman, Chien, & Katz, 2012). For IIS, capacity-building strategies could include 1) distribution of educational materials and ongoing educational training; 2) consultation and technical assistance as needed; 3) reminder systems; and 4) audit and feedback. Educational materials should address perceived complexity of the IIS, knowledge, and beliefs. Consultation and technical assistance on an as needed basis will address the lack of support reported by pharmacists in regard to IIS. An audit and feedback implementation strategy could be done on a weekly or monthly basis, either by the implementation facilitator or as an automated process. The creation of individualized reports to alert pharmacies to the number of administered doses reported in the IIS could serve this purpose. Including comparisons of the pharmacy's administered doses report to reports of the number of doses in their immediate surrounding area, county, or state could also increase peer pressure to actively participate in IIS, a factor identified in the qualitative interviews as a facilitator of IIS implementation. Further, automated feedback could extend beyond the study period in order to improve sustainability.

When developing these future programs, methods to improve sustainability should be incorporated. Factors have been identified that hinder sustainment of innovations which may be applicable to pharmacy implementation of IIS. These include lack of resources, competing demands, lack of support from organizational leadership, lack of trained personnel to continue use of innovation, and inability to adapt the innovation (Hailemariam et al., 2019). To improve sustainment of IIS, future research should attempt to go beyond improving knowledge and beliefs and incorporate implementation strategies to address these factors. Providing independent pharmacies with resources to support the communication between their pharmacy dispensing software and state IIS, automatically uploading data, would address many of the barriers to sustainment including lack of time and competing demands. As demonstrated in this study, most pharmacies are not willing to pay for this and alternative mechanisms should be explored. Training should be extended to all pharmacy personnel including owners and pharmacy technicians, this will ensure that all personnel are trained and prepared to participate in the IIS. Costs associated with implementation strategies to improve sustainability should be collected to inform future efforts. While more difficult to accomplish, states with low participation should consider legislation to mandate participation among all providers. Initial planning stages for these efforts should engage representatives from all key stakeholder groups, including pharmacists. Furthermore, these states should incorporate meaningful ways of assessing and enforcing this mandated participation.

Organizations seeking to adopt IIS into their pharmacy workflow should consider using a sustainability framework. Several frameworks have been developed to guide sustainment efforts in the design and implementation of innovations. These include 1) Exploration, Preparation, Implementation, and Sustainment (EPIS) Framework, 2) Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM), 3) Program Sustainability Assessment Tool (PSAT), and 4) a framework developed by Shediac-Rizkallah and Bone (Aarons, Hurlburt, & Horwitz, 2011; Glasgow, Vogt, & Boles, 1999; Hailemariam et al., 2019; Luke, Calhoun, Robichaux, Elliott, & Moreland-Russell, 2014;

Shediac-Rizkallah & Bone, 1998). These frameworks will help to guide and monitor the implementation of IIS in a pharmacy setting, ensuring long term success.

Conclusions

Despite documented effectiveness of Immunization Information Systems, uptake remains low. Inadequate documentation of immunizations by pharmacy personnel within the pharmacy setting has been cited as a concern among both patients and primary care providers. In Alabama less than 25% of adults over the age of 19 have immunization data recorded in the state immunization information system, ImmPRINT (Centers for Disease Control and Prevention, 2013). Lack of pharmacy participation is a contributing factor as only 27% of Alabama pharmacies were enrolled at the beginning of this study. Improving documentation within the pharmacy setting is critical to not only improving immunization delivery in the community pharmacy setting, but also in ensuring that appropriate vaccines are administered in a safe and effective manner. This pharmacist-centered training program focused on practical strategies to integrate IIS into pharmacy workflow. Results show that pharmacists' awareness, knowledge, attitudes toward IIS, and enrollment significantly improved as a result of this training. While this program contains some information specific to the Alabama IIS, it could be adapted and disseminated to other states, incorporating strategies to improve sustainment of the intervention effect over time.

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Appendix 1: Motivational Factors and Contextual Barriers Interview Questions (Pharmacy Personnel)

1. Can you tell me about how your pharmacy documents immunizations?
2. What do you know about the immunization information system?
3. What kinds of changes or alterations do you think you will need to make to the IIS so it will work effectively in your setting?
    a. Do you think you will be able to make these changes? Why or why not?
4. How complicated is the immunization information system?
    a. What is your perception of the quality of the supporting materials, packaging, and bundling of the IIS for implementation?
    b. What supports, such as online resources, marketing materials, or a toolkit, have you used to help you implement and use the immunization information system?
5. What costs were considered when deciding to implement the immunization information system?
6. How well do you think the IIS will meet the needs of the patients served by your pharmacy?
    a. In what ways will the IIS meet their needs?
7. What kind of information exchange do you have with others outside your setting, either related to the immunization information system, or more generally about your profession?
    a. What professional networking do you engage in? Listservs? Local or national conferences? Trainings?
8. To what extent are other pharmacies implementing the immunization information system?

a. How does this affect support for implementing the IIS in your setting?
b. Does implementing the IIS provide an advantage for your organization compared to other pharmacies in your area?
c. Is there something about the IIS that would bring more individuals into your pharmacy, instead of another one in your area?

9. How would you describe the culture of your pharmacy?
    a. To what extent are new ideas embraced and used to make improvements in your pharmacy?
    b. How do you typically find out about new information, such as new initiatives, accomplishments, issues?
        i. Are meetings, such as staff meetings, held regularly?
10. What is the general level of receptivity in your organization to implementing the immunization information system?
    a. Why?
11. How well does the IIS fit with existing work processes and practices in your setting?
    a. What are likely issues or complications that may arise?
    b. How will it interact or conflict with current programs or processes?
12. How will you juggle competing priorities in your own work? How will your colleagues juggle these priorities?
    a. How does the priority of implementing the IIS compare to other priorities in your organization? For your own work?

13. What level of involvement has leadership at your organization had so far with the immunization information system?
    a. Do they know about the intention to implement the immunization information system?
    b. What kind of support have they given you? Can you provide specific examples?
14. Do you expect to have sufficient resources to implement and administer the intervention?
    a. [If Yes] What resources are you counting on? Are there any other resources that you received, or would have liked to receive?
    b. [If no] What resources will not be available?
15. Who do you ask if you have questions about the IIS or its implementation?
    a. How available are these individuals?
16. How confident are you in using the immunization information system?
    a. What gives you that level of confidence (or lack of confidence)?
    b. How confident do you think your colleagues feel about using the immunization information system?
        i. What gives them that level of confidence (or lack of confidence)?
17. Who will lead implementation of the immunization information system?
    a. How did/will this person come into this role? Appointed? Volunteered? Voluntold?
18. What steps have been taken to encourage individuals to commit to using the immunization information system?

19. I think I’ve asked all my questions, do you have any questions for me?

20. Is there anything else you’d like to tell me about?

Appendix 2: Contextual Barrier Interview Questions (IIS Staff)

1. How long has your IIS been in place?
2. Can you tell me about the types of providers currently participating in your immunization information system?
3. What kind of consent do providers need to obtain before enrolling a patient in your IIS?
4. Are there any mandates for providers to participate?
5. How do you enforce these? How do pharmacists participate in your immunization information system?
6. What methods do you use to recruit new pharmacies to participate in your IIS?
7. Tell me about the enrollment process.
8. Do you provide training to new pharmacies?
    a. In person, online, over the phone?
9. What has your experience been working with pharmacies?
10. What challenges have you experienced?

Appendix 3: Best Practice Interview Questions (Pharmacy Personnel)

1. Can you tell me about how your pharmacy documents immunizations?
2. What do you know about the immunization information system?
3. What kinds of changes or alterations do you think you will need to make to the IIS so it will work effectively in your setting?
    a. Do you think you will be able to make these changes? Why or why not?
4. How complicated is the immunization information system?
    a. What is your perception of the quality of the supporting materials, packaging, and bundling of the IIS for implementation?
    b. What supports, such as online resources, marketing materials, or a toolkit, have you used to help you implement and use the immunization information system?
5. What costs or expenses were considered when deciding to implement the immunization information system?
6. How well do you think the IIS will meet the needs of the patients served by your pharmacy?
    a. In what ways will the IIS meet their needs?
7. What kind of information exchange do you have with others outside your setting, either related to the immunization information system, or more generally about your profession?
    a. What professional networking do you engage in? Listservs? Local or national conferences? Trainings?
8. To what extent are you aware of other pharmacies implementing the immunization information system?

    a. How does this affect your pharmacy's decision to use (or not use) the IIS in your setting?
    b. Does implementing the IIS provide an advantage for your organization compared to other pharmacies in your area?
    c. Is there something about the IIS that would bring more individuals into your pharmacy, instead of another one in your area?
9. How would you describe the culture of your pharmacy?
    a. To what extent are new ideas embraced and used to make improvements in your pharmacy?
    b. How do you typically find out about new information, such as new initiatives, accomplishments, issues?
        i. Are meetings, such as staff meetings, held regularly?
10. What is the general level of receptivity in your organization to implementing the immunization information system?
    a. Why?
11. How well does the IIS fit with existing work processes and practices in your setting?
    a. What are likely issues or complications that may arise?
    b. How will it interact or conflict with current programs or processes?
12. How will you juggle competing priorities in your own work? How will your colleagues juggle these priorities?
    a. How does the priority of implementing the IIS compare to other priorities in your organization? For your own work?

13. What level of involvement has leadership at your organization had so far with the immunization information system?
    a. Do they know about the intention to implement the immunization information system?
    b. What kind of support have they given you? Can you provide specific examples?
14. Do you expect to have sufficient resources to implement and administer the intervention?
    a. [If Yes] What resources are you counting on? Are there any other resources that you received, or would have liked to receive?
    b. [If no] What resources will not be available?
15. Who do you ask if you have questions about the IIS or its implementation?
    a. How available are these individuals?
16. How confident are you in using the immunization information system?
    a. What gives you that level of confidence (or lack of confidence)?
    b. How confident do you think your colleagues feel about using the immunization information system?
        i. What gives them that level of confidence (or lack of confidence)?
17. Who will lead implementation of the immunization information system?
    a. How did/will this person come into this role? Appointed? Volunteered? Voluntold?
18. What steps have been taken to encourage individuals to commit to using the immunization information system?

19. Does your pharmacy use the IIS to assess and recommend additional vaccines?
    a. Tell me more about that.
    b. Are there any difficulties you've experienced with this?
    c. Successful strategies?
    d. Have you personally experienced viewing the IIS to assess vaccination status?
20. What do you think has made your pharmacy successful in using the immunization information system?
21. What benefits do you think using the IIS presents to independent pharmacies?
22. I think I've asked all my questions, do you have any questions for me?
23. Is there anything else you'd like to tell me about?

Appendix 4: Best Practice Interview Questions (IIS Staff)

1. How long has your IIS been in place?
2. Can you tell me about the types of providers currently participating in your immunization information system?
3. Are there any mandates for providers to participate?
    a. How do you enforce these?
4. What kind of consent do providers need to obtain before enrolling a patient in your IIS?
5. How do pharmacists participate in your immunization information system?
6. What methods do you use to recruit new pharmacies to participate in your IIS?
7. Tell me about the enrollment process.
8. Do you provide training to new pharmacies?
    a. In person, online, over the phone?
9. What has your experience been working with pharmacies?
10. What do you believe makes your program successful?

Appendix 5: Ordered List of CFIR Constructs Mapped to Interview Questions

Domain	Construct	Sub-Construct	Interview Question
Intervention Characteristics	Intervention Source		
	Evidence Strength and Quality		
	Relative Advantage		1. How does the immunization information system add value to immunization services in your setting? a. What advantages does the immunization information system have? b. What disadvantages does the immunization information system have?
	Adaptability		1. What kinds of changes or alterations do you think you will need to make to the immunization information system so it will work effectively in your setting? a. Do you think you will be able to make these changes? Why or why not?
	Trialability		
	Complexity		1. How complex is the immunization information system to understand? 2. How complicated is it for you to use the immunization information system in your pharmacy?
	Design Quality and Packaging		1. What is your perception of the quality of the supporting materials, packaging, and bundling of the immunization information system for implementation? a. Why? b. What supports, such as online resources, marketing materials, or a toolkit, have

			you used to help you implement and use the immunization information system?
	Cost		1. What cost or expenses were considered when deciding to utilize the immunization information system? 2. Which is the most significant cost for your pharmacy?
Outer Setting	Patient/Physician Needs and Resources		1. How well do you think the immunization information system will meet the needs of the patients served by your pharmacy? a. In what ways will the immunization information system meet their needs? 2. How well do you think the immunization information system will meet the needs of your patients' primary care providers? a. In what ways will the immunization information system meet their needs?
	Cosmopolitanism		1. What kind of information exchange do you have with others outside your setting, either related to the immunization information system, or more generally about your profession? a. What professional networking do you engage in?

			Listservs? Local or national conferences? Trainings?
	Normative/Peer Pressure		1. Are you aware of any other pharmacies that implement the immunization information system? a. How does this (other pharmacies extent of implementation) affect the decision to use (or not use) the immunization information system in your setting? b. How does implementing the immunization information system provide an advantage for your organization compared to other pharmacies in your area? c. Is there something about the immunization information system that would bring more individuals into your pharmacy, instead of another one in your area?
	External Policy & Incentives		1. What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced the decision to implement the immunization information system?

			a. How will the intervention affect your pharmacies ability to meet these measures, policies, regulations, or guidelines?
Inner Setting	Structural Characteristics (age, size of pharmacy)		1. What kinds of changes in the pharmacy setting will be needed to accommodate the immunization information system in your pharmacy? o Changes in formal policies? Changes in software systems? Other? o What kind of approvals will be needed? Who will need to be involved? o Can you describe the process that will be needed to make these changes?
	Networks and Communication		1. How do you typically find out about new information, such as new initiatives, accomplishments, issues? a. Are meetings, such as staff meetings, held regularly?
	Culture		1. How would you describe the culture of your pharmacy? a. To what extent are new ideas embraced and used to make improvements in your pharmacy?
	Implementation Climate	Tension for Change	1. What is the general level of receptivity in your organization to implementing the

			immunization information system? o Why?
		Compatibility	1. How well does the immunization information system fit with existing work processes and practices in your setting? a. What are likely issues or complications that may arise? b. How will it interact or conflict with current programs or processes?
		Relative Priority	1. How will you juggle competing priorities in your own work? How will your colleagues juggle these priorities? a. How does the priority of implementing the immunization information system compare to other priorities in your organization? For your own work?
		Org. Incentives and Rewards	
		Goals and Feedback	
		Learning Climate	
	Readiness for Implementation	Leadership Engagement	1. What level of involvement has leadership at your organization had so far with the immunization information system? a. Do they know about the intention to implement the

			immunization information system? b. What kind of support have they given you? Can you provide specific examples?
		Available Resources	a) Do you expect to have sufficient resources to implement and administer the immunization information system in? a. [If Yes] What resources are you counting on? Are there any other resources that you received, or would have liked to receive? b. [If no] What resources will not be available?
		Access to Knowledge & Information	1. Who do you ask if you have questions about the immunization information system or its implementation? a. How available are these individuals?
Characteristics of Individuals	Knowledge and Beliefs about the Innovation		1. What do you know about the immunization information system?
	Self-efficacy		1. How confident are you in using the immunization information system? a. What gives you that level of confidence (or lack of confidence)?

			2. How confident do you think your colleagues feel about using the immunization information system? a. What gives them that level of confidence (or lack of confidence)?
	Individual stage of change		
	Individual Identification with Organization		
	Other Personal Attributes		
Process	Planning		1. What have you done (or what do you plan to do) to get a plan in place to implement the immunization information system?
	Engaging	Opinion Leaders	1. What are influential individuals saying about the immunization information system? a. Who are these influential individuals? b. To what extent will they influence others' use of the intervention? The success of the implementation?
		Formally Appointed Internal Implementation Leaders	1. Who lead or is leading implementation of the immunization information system in your pharmacy? o How did/will this person come into this role? Appointed? Volunteered? Voluntold?

		Champions	1. Other than the formal implementation leader, are there people in your organization who are likely to champion (go above and beyond what might be expected) the immunization information system? o Were they formally appointed in this position, or was it an informal role? o What position do these champions have in your pharmacy? o How do you think they will help with implementation? Getting people to use the intervention?
		External Change Agents	
		Key Stakeholders including staff	1. What steps have been taken to encourage individuals to commit to using the immunization information system?
		Patients/Customers	
	Executing		1. Has the immunization information system been implemented according to the implementation plan? a. [If Yes] Can you describe this? b. [If No] Why not?
	Reflecting and Evaluating		1. How will you assess progress towards

			immunization information system goals? 2. Will feedback be elicited from pharmacy staff? From the patient served by your pharmacy? a. [If yes] What kind of feedback?

Appendix 6: Baseline Questionnaire

Section I: Pharmacist and Pharmacy Characteristics

1.1) Please indicate your sex:

❒ Male

❒ Female

1.2) Please indicate your race:

❒ White

❒ Black or African American

❒ Asian

❒ Native Hawaiian or Other Pacific Islander

❒ American Indian or Alaska Native

❒ Other (please specify):

____

1.3) Please indicate your ethnicity:

❒ Hispanic or Latino

❒ Not Hispanic or Latino

1.4) Please indicate your age: _________

1.5) Please indicate the number of years you have been practicing as a pharmacist:

____

1.6) Please indicate the number of years you have been practicing at your current site:

____

1.7) Please indicate your title (select all that apply):

❒ Staff pharmacist

❒ Pharmacy manager

❒ Owner/partner

❒ Other (please specify):____________

1.8) Please indicate your education (select all that apply):

❒ B.S. Pharmacy

❒ PharmD

❒ Residency

❒ Masters

❒ Other (please specify):_____________

1.9) Please indicate the average number of immunizations you provide per week:_______

Section II: Awareness and Knowledge

2.1) Is your pharmacy enrolled in the Alabama immunization information system (ImmPRINT)?

❒ Yes

❒ No

❒ Don't know/ Not sure

2.2) Which of the following are methods of documenting immunizations (select all that apply):

❒ Maintaining documentation in the pharmacy

❒ Providing documentation to the patient's physician

❒ Entering vaccination into the patient's medical record

❒ Recording vaccination in an immunization information system

Please indicate whether you believe the following statements are true, false, or if you are unsure.

	True	False
2.3) Immunization information systems consolidate vaccination data for patients within a defined geographic area.	❒	❒

2.4) Pharmacies can record administered vaccinations in immunization information systems.	❒	❒
2.5) Other providers can retrieve immunization information in real time.	❒	❒
2.6) Immunization information systems are also known as Immunization Information Systems.	❒	❒
2.7) Each state maintains its own Immunization Information System.	❒	❒
2.8) Immunization information systems consolidate immunization doses from all providers regardless of participation.	❒	❒
2.9) Immunization information systems can share data between states.	❒	❒
2.10) Immunization information system reporting is mandatory in Alabama.	❒	❒
2.11) Immunization information system reporting is mandatory in all states.	❒	❒

2.12) Immunization information systems typically include which of the following (select all that apply):

❒ Patient Name

❒ Patient DOB

❒ Vaccine lot number

Section III: Attitudes

How strongly do you agree or disagree with the following statements?

	Strongly Disagree (1)	(2)	(3)	(4)	**(5)**	**(6)**	Strongly Agree (7)
3.1) **Immunization information systems are not standardized in terms of data required.**	❒	❒	❒	❒	❒	❒	❒
3.2) **Current systems of reporting immunizations are sufficient to determine immunization status.**	❒	❒	❒	❒	❒	❒	❒
3.3) **Data recorded in immunization information systems is inaccurate.**	❒	❒	❒	❒	❒	❒	❒

3.4) **Data recorded in immunization information systems is incomplete.**	❒	❒	❒	❒	❒	❒	❒
3.5) **Immunization information systems provide patients with consolidated immunization records.**	❒	❒	❒	❒	❒	❒	❒
3.6) **Immunization information systems improve patient care coordination.**	❒	❒	❒	❒	❒	❒	❒
3.7) **Immunization information systems allow pharmacies to assess immunization status.**	❒	❒	❒	❒	❒	❒	❒
3.8) **Immunization information systems are a realistic method of consolidating immunization data.**	❒	❒	❒	❒	❒	❒	❒
3.9) **Immunization information systems are too time consuming.**	❒	❒	❒	❒	❒	❒	❒
3.10) **The immunization information system fits easily into pharmacy workflow.**	❒	❒	❒	❒	❒	❒	❒
3.11) **It is difficult to obtain access to the immunization information system.**	❒	❒	❒	❒	❒	❒	❒
3.12) **It is difficult to obtain immunization information systems software.**	❒	❒	❒	❒	❒	❒	❒
3.13) **It is difficult to obtain immunization information systems IT support.**	❒	❒	❒	❒	❒	❒	❒
3.14) **It is difficult to obtain patient consent for immunization information systems.**	❒	❒	❒	❒	❒	❒	❒
3.15) **Immunization information systems compromise patient confidentiality.**	❒	❒	❒	❒	❒	❒	❒
3.16) **The immunization information system appears to have more advantages than disadvantages**	❒	❒	❒	❒	❒	❒	❒
3.17) **Using the immunization information system is more reliable than patient self-report when checking immunization status**	❒	❒	❒	❒	❒	❒	❒
3.18) **Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more quickly**	❒	❒	❒	❒	❒	❒	❒
3.19) **Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more effectively**	❒	❒	❒	❒	❒	❒	❒
3.20) **The immunization information system helps to manage vaccine inventory more effectively**	❒	❒	❒	❒	❒	❒	❒
3.21) **Use of the immunization information system can be adapted to fit our pharmacy's current situation**	❒	❒	❒	❒	❒	❒	❒
3.22) **I've had the opportunity to test various applications of the immunization information system**	❒	❒	❒	❒	❒	❒	❒

3.23) **Interacting with the immunization information system is clear and understandable**	❒	❒	❒	❒	❒	❒	❒
3.24) **Interacting with the immunization information system does not require a lot of mental effort**	❒	❒	❒	❒	❒	❒	❒
3.25) **Implementing the immunization information system is too much of a financial burden**	❒	❒	❒	❒	❒	❒	❒

Section IV: Current Documentation Practices

4.1) When providing immunizations in my pharmacy, I maintain a documentation of the vaccination at my pharmacy.

❒ Yes
❒ No
❒ Don't know/ Not sure

4.2) When providing immunizations in my pharmacy, I provide the vaccination documentation directly to the patient's physician.

❒ Yes
❒ No
❒ Don't know/ Not sure

4.3) If you answered yes to the previous question, how do you provide the documentation to the physician:

❒ Fax
❒ Phone
❒ Delivered by patient
❒ Other (please specify):_________________

Section V: Intention

	Strongly Disagree	(2)	(3)	(4)	**(5)**	**(6)**	Strongly Agree (7)

	(1)						
5.1) **I plan to enroll my pharmacy in the immunization information system within 30 days.**	❒	❒	❒	❒	❒	❒	❒
5.2) **I will make an effort to enroll my pharmacy in the immunization information system in the next 30 days.**	❒	❒	❒	❒	❒	❒	❒
5.3) **I intend to enroll my pharmacy in the immunization information system.**	❒	❒	❒	❒	❒	❒	❒

Appendix 7: One-Month Assessment

Section I: Awareness and Knowledge

1.1) Is your pharmacy enrolled in the Alabama immunization information system (ImmPRINT)?

❒ Yes

❒ No

❒ Don't know/ Not sure

1.2) Which of the following are methods of documenting immunizations (select all that apply):

❒ Maintaining documentation in the pharmacy

❒ Providing documentation to the patient's physician

❒ Entering vaccination into the patient's medical record

❒ Recording vaccination in an immunization information system

Please indicate whether you believe the following statements are true, false, or if you are unsure.

	True	False
1.3) Immunization information systems consolidate vaccination data for patients within a defined geographic area.	❒	❒
1.4) Pharmacies can record administered vaccinations in immunization information systems.	❒	❒
1.5) Other providers can retrieve immunization information in real time.	❒	❒
1.6) Immunization information systems are also known as Immunization Information Systems.	❒	❒
1.7) Each state maintains its own Immunization Information System.	❒	❒
1.8) Immunization information systems consolidate immunization doses from all providers regardless of participation.	❒	❒
1.9) Immunization information systems can share data between states.	❒	❒

1.10) Immunization information system reporting is mandatory in Alabama.	❒	❒
1.11) Immunization information system reporting is mandatory in all states.	❒	❒

1.12) Immunization information systems typically include which of the following (select all that apply):

❒ Patient Name

❒ Patient DOB

❒ Vaccine lot number

Section II: Intention

	Strongly Disagree (1)	(2)	(3)	(4)	**(5)**	**(6)**	Strongly Agree (7)
2.1) **I plan to enroll my pharmacy in the immunization information system within 30 days.**	❒	❒	❒	❒	❒	❒	❒
2.2) **I will make an effort to enroll my pharmacy in the immunization information system in the next 30 days.**	❒	❒	❒	❒	❒	❒	❒
2.3) **I intend to enroll my pharmacy in the immunization information system.**	❒	❒	❒	❒	❒	❒	❒

Section III: Attitudes

How strongly do you agree or disagree with the following statements?

	Strongly Disagree (1)	(2)	(3)	(4)	**(5)**	**(6)**	Strongly Agree (7)
3.26) **Immunization information systems are not standardized in terms of data required.**	❒	❒	❒	❒	❒	❒	❒

3.27) **Current systems of reporting immunizations are sufficient to determine immunization status.**	❒	❒	❒	❒	❒	❒	❒
3.28) **Data recorded in immunization information systems is inaccurate.**	❒	❒	❒	❒	❒	❒	❒
3.29) **Data recorded in immunization information systems is incomplete.**	❒	❒	❒	❒	❒	❒	❒
3.30) **Immunization information systems provide patients with consolidated immunization records.**	❒	❒	❒	❒	❒	❒	❒
3.31) **Immunization information systems improve patient care coordination.**	❒	❒	❒	❒	❒	❒	❒
3.32) **Immunization information systems allow pharmacies to assess immunization status.**	❒	❒	❒	❒	❒	❒	❒
3.33) **Immunization information systems are a realistic method of consolidating immunization data.**	❒	❒	❒	❒	❒	❒	❒
3.34) **Immunization information systems are too time consuming.**	❒	❒	❒	❒	❒	❒	❒
3.35) **The immunization information system fits easily into pharmacy workflow.**	❒	❒	❒	❒	❒	❒	❒
3.36) **It is difficult to obtain access to the immunization information system.**	❒	❒	❒	❒	❒	❒	❒
3.37) **It is difficult to obtain immunization information systems software.**	❒	❒	❒	❒	❒	❒	❒
3.38) **It is difficult to obtain immunization information systems IT support.**	❒	❒	❒	❒	❒	❒	❒
3.39) **It is difficult to obtain patient consent for immunization information systems.**	❒	❒	❒	❒	❒	❒	❒
3.40) **Immunization information systems compromise patient confidentiality.**	❒	❒	❒	❒	❒	❒	❒
3.41) **The immunization information system appears to have more advantages than disadvantages**	❒	❒	❒	❒	❒	❒	❒
3.42) **Using the immunization information system is more reliable than patient self-report when checking immunization status**	❒	❒	❒	❒	❒	❒	❒
3.43) **Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more quickly**	❒	❒	❒	❒	❒	❒	❒
3.44) **Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more effectively**	❒	❒	❒	❒	❒	❒	❒
3.45) **The immunization information system helps to manage vaccine inventory more effectively**	❒	❒	❒	❒	❒	❒	❒

3.46) **Use of the immunization information system can be adapted to fit our pharmacy's current situation**	❒	❒	❒	❒	❒	❒	❒
3.47) **I've had the opportunity to test various applications of the immunization information system**	❒	❒	❒	❒	❒	❒	❒
3.48) **Interacting with the immunization information system is clear and understandable**	❒	❒	❒	❒	❒	❒	❒
3.49) **Interacting with the immunization information system does not require a lot of mental effort**	❒	❒	❒	❒	❒	❒	❒
3.50) **Implementing the immunization information system is too much of a financial burden**	❒	❒	❒	❒	❒	❒	❒

Appendix 8: Three-Month Questionnaire

Section I: Awareness and Knowledge

1.1) Is your pharmacy enrolled in the Alabama immunization information system (ImmPRINT)?

❐ Yes

❐ No

❐ Don't know/ Not sure

1.2) Have you personally reported immunization data to Alabama's immunization information system (ImmPRINT)?

❐ Yes

❐ No

❐ Don't know/ Not sure

1.3) Which of the following are methods of documenting immunizations (select all that apply):

❐ Maintaining documentation in the pharmacy

❐ Providing documentation to the patient's physician

❐ Entering vaccination into the patient's medical record

❐ Recording vaccination in an immunization information system

Please indicate whether you believe the following statements are true, false, or if you are unsure.

	True	False
1.4) Immunization information systems consolidate vaccination data for patients within a defined geographic area.	❐	❐
1.5) Pharmacies can record administered vaccinations in immunization information systems.	❐	❐
1.6) Other providers can retrieve immunization information in real time.	❐	❐

1.7) Immunization information systems are also known as Immunization Information Systems.	❒	❒
1.8) Each state maintains its own Immunization Information System.	❒	❒
1.9) Immunization information systems consolidate immunization doses from all providers regardless of participation.	❒	❒
1.10) Immunization information systems can share data between states.	❒	❒
1.11) Immunization information system reporting is mandatory in Alabama.	❒	❒
1.12) Immunization information system reporting is mandatory in all states.	❒	❒

1.13) Immunization information systems typically include which of the following (select all that apply):

❒ Patient Name

❒ Patient DOB

❒ Vaccine lot number

Section II: Attitudes

How strongly do you agree or disagree with the following statements?

	Strongly Disagree (1)	(2)	(3)	(4)	**(5)**	**(6)**	Strongly Agree (7)
2.1) **Immunization information systems are not standardized in terms of data required.**	❒	❒	❒	❒	❒	❒	❒
2.2) **Current systems of reporting immunizations are sufficient to determine immunization status.**	❒	❒	❒	❒	❒	❒	❒
2.3) **Data recorded in immunization information systems is inaccurate.**	❒	❒	❒	❒	❒	❒	❒
2.4) **Data recorded in immunization information systems is incomplete.**	❒	❒	❒	❒	❒	❒	❒

2.5) **Immunization information systems provide patients with consolidated immunization records.**	❒	❒	❒	❒	❒	❒	❒
2.6) **Immunization information systems improve patient care coordination.**	❒	❒	❒	❒	❒	❒	❒
2.7) **Immunization information systems allow pharmacies to assess immunization status.**	❒	❒	❒	❒	❒	❒	❒
2.8) **Immunization information systems are a realistic method of consolidating immunization data.**	❒	❒	❒	❒	❒	❒	❒
2.9) **Immunization information systems are too time consuming.**	❒	❒	❒	❒	❒	❒	❒
2.10) **The immunization information system fits easily into pharmacy workflow.**	❒	❒	❒	❒	❒	❒	❒
2.11) **It is difficult to obtain access to the immunization information system.**	❒	❒	❒	❒	❒	❒	❒
2.12) **It is difficult to obtain immunization information systems software.**	❒	❒	❒	❒	❒	❒	❒
2.13) **It is difficult to obtain immunization information systems IT support.**	❒	❒	❒	❒	❒	❒	❒
2.14) **It is difficult to obtain patient consent for immunization information systems.**	❒	❒	❒	❒	❒	❒	❒
2.15) **Immunization information systems compromise patient confidentiality.**	❒	❒	❒	❒	❒	❒	❒
2.16) **The immunization information system appears to have more advantages than disadvantages**	❒	❒	❒	❒	❒	❒	❒
2.17) **Using the immunization information system is more reliable than patient self-report when checking immunization status**	❒	❒	❒	❒	❒	❒	❒
2.18) **Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more quickly**	❒	❒	❒	❒	❒	❒	❒

2.19) **Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more effectively**	❒	❒	❒	❒	❒	❒	❒
2.20) **The immunization information system helps to manage vaccine inventory more effectively**	❒	❒	❒	❒	❒	❒	❒
2.21) **Use of the immunization information system can be adapted to fit our pharmacy's current situation**	❒	❒	❒	❒	❒	❒	❒
2.22) **I've had the opportunity to test various applications of the immunization information system**	❒	❒	❒	❒	❒	❒	❒
2.23) **Interacting with the immunization information system is clear and understandable**	❒	❒	❒	❒	❒	❒	❒
2.24) **Interacting with the immunization information system does not require a lot of mental effort**	❒	❒	❒	❒	❒	❒	❒
2.25) **Implementing the immunization information system is too much of a financial burden**	❒	❒	❒	❒	❒	❒	❒

2.26)	**Strongly Disagree**	**Somewhat Disagree**	**Neutral**	**Somewhat Agree**	**Strongly Agree**
2.27) **The training provided surrounding how to use immunization information systems is adequate.**	❒	❒	❒	❒	❒
2.28) **It is difficult to obtain immunization information systems software.**	❒	❒	❒	❒	❒
2.29) **It is difficult to obtain immunization information systems IT support.**	❒	❒	❒	❒	❒
2.30) **The opinions of my superiors influence my use of immunization information systems**	❒	❒	❒	❒	❒
2.31) **The opinions of my peers influence my use of immunization information systems.**	❒	❒	❒	❒	❒

2.32) **It is difficult to obtain patient consent for immunization information systems.**	❐	❐	❐	❐	❐
2.33) **Immunization information systems compromise patient confidentiality.**	❐	❐	❐	❐	❐
2.34) **Immunization information systems are too costly.**	❐	❐	❐	❐	❐

Section III: Current Documentation Practices

3.1) When providing immunizations in my pharmacy, I maintain a documentation of the vaccination at my pharmacy.

❐ Yes
❐ No
❐ Don't know/ Not sure

3.2) When providing immunizations in my pharmacy, I provide the vaccination documentation directly to the patient's physician.

❐ Yes
❐ No
❐ Don't know/ Not sure

3.3) If you answered yes to the previous question, how do you provide the documentation to the physician:

❐ Fax
❐ Phone
❐ Delivered by patient
❐ Other (please specify):_________________

3.4) When providing immunizations in my pharmacy, I enter the vaccination information into an immunization information system (or immunization information system).

❐ Yes
❐ No
❐ Don't know/ Not sure

3.5) If you answered yes to the previous question, how is data transmitted to the immunization information system?

❒ Automatic uploads
❒ Manually entering data
❒ Fax data
❒ Don't know/ Not sure

3.6) Prior to administering a vaccine, do you check the patient's history in the immunization information system?

❒ Yes, I check (select all that apply):
  ❒ To ensure that the patient is eligible for the vaccine
  ❒ To ensure that the patient has not received the vaccine somewhere else
  ❒ To see if there are any additional vaccines the patient may need
❒ No

Section IV: Intention

	Strongly Disagree (1)	(2)	(3)	(4)	(5)	(6)	Strongly Agree (7)
4.1) **I plan to enroll my pharmacy in the immunization information system within 30 days.**	❒	❒	❒	❒	❒	❒	❒
4.2) **I will make an effort to contribute to the immunization information system on a regular basis.**	❒	❒	❒	❒	❒	❒	❒
4.3) **I intend to enroll my pharmacy in the immunization information system.**	❒	❒	❒	❒	❒	❒	❒

Section V: Vaccines Administered

In this section please indicate the number of each type of vaccine your pharmacy has provided in the past three months.

Type of Vaccine	Number Administered	Check if this vaccine has not been provided in your pharmacy in the past 3 months
5.1) Haemophilus influenza (Hib)		❒
5.2) Hepatitis A		❒
5.3) Hepatitis B		❒
5.4) Herpes Zoster		❒
5.5) Human Papillomavirus (HPV)		❒
5.6) Influenza		❒
5.7) Measles, Mumps, Rubella (MMR)		❒
5.8) Meningococcal		❒
5.9) Pneumococcal polysaccharide (PPSV23)		❒
5.10) Pneumococcal 13-valent conjugate (PCV13)		❒
5.11) Rotavirus (RV)		❒
5.12) Tetanus/ Diptheria/ Pertussis (Tdap)		❒
5.13) Tetanus/ Diptheria (Td)		❒
5.14) Travle vaccines (Yellow fever, typhoid, etc.)		❒
5.15) Varicella		❒
5.16) Other (Specify):		❒

Section VI: Implementation Factors

How strongly do you agree or disagree with the following statements?

	Strongly Disagree (1)	(2)	(3)	(4)	(5)	(6)	Strongly Agree (7)
6.1) **The immunization information system incorporates the needs and preferences of patients**	❒	❒	❒	❒	❒	❒	❒
6.2) **It is helpful to have people external to the pharmacy who can provide support when needed**	❒	❒	❒	❒	❒	❒	❒
6.3) **It is helpful to have access to someone from outside the pharmacy when implementing the immunization information system**	❒	❒	❒	❒	❒	❒	❒
6.4) **Most pharmacies are using the immunization information system**	❒	❒	❒	❒	❒	❒	❒
6.5) **Using the immunization information system helps my pharmacy maintain a competitive advantage over other pharmacies**	❒	❒	❒	❒	❒	❒	❒
6.6) **External organizations or individuals have pressured our pharmacy to implement the immunization information system**	❒	❒	❒	❒	❒	❒	❒
6.7) **All staff will work together as a team when implementing the immunization information system**	❒	❒	❒	❒	❒	❒	❒
6.8) **The changes that will be occurring in the pharmacy when implementing the immunization information system have been communicated to all pharmacy staff**	❒	❒	❒	❒	❒	❒	❒
6.9) **Mechanisms for communication, such as staff meetings, are important when implementing the immunization information system**	❒	❒	❒	❒	❒	❒	❒
6.10) **Our pharmacy has proven that we are able to adapt ideas from outside to fit our organization's way of doing things**	❒	❒	❒	❒	❒	❒	❒
6.11) **Our pharmacy owner/manager rewards innovation and creativity to improve patient care**	❒	❒	❒	❒	❒	❒	❒

6.12) Staff members in our pharmacy have a sense of personal responsibility for improving patient care and outcomes	❒	❒	❒	❒	❒	❒	❒
6.13) Staff members in our pharmacy cooperate to maintain and improve effectiveness of patient care	❒	❒	❒	❒	❒	❒	❒
6.14) Staff members in our pharmacy are willing to innovate and/or experiment to improve patient care	❒	❒	❒	❒	❒	❒	❒
6.15) Staff members in our pharmacy are receptive to change	❒	❒	❒	❒	❒	❒	❒
6.16) Some of our pharmacy staff believe that implementing the immunization information system is essential	❒	❒	❒	❒	❒	❒	❒
6.17) Successfully implementing the immunization information system will meet staff needs.	❒	❒	❒	❒	❒	❒	❒
6.18) Our pharmacy owner/manager has set a high priority on the success of the immunization information system in our pharmacy	❒	❒	❒	❒	❒	❒	❒
6.19) Staff incentives are likely to be set up to engage them in using the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.20) Successful implementation of the immunization information system will help us meet our organization's mission and goals	❒	❒	❒	❒	❒	❒	❒
6.21) The pharmacy owner/ manager/ staff opinion leaders agree on the goals for the implementation of the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.22) Our pharmacy owner/manager has set a deadline for enrollment in the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.23) Our pharmacy owner/manager has designated an individual to be responsible for enrolling our pharmacy in the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.24) Our pharmacy owner/manager has openly endorsed the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.25) Our pharmacy owner/manager has committed to spending time and resources to remove obstacles related to implementation of the IIS if they arise	❒	❒	❒	❒	❒	❒	❒

6.26) Our staff do not have the time required to update the immunization information system when an immunization is provided	❒	❒	❒	❒	❒	❒	❒
6.27) Our staff has access to immunization information system training and training materials	❒	❒	❒	❒	❒	❒	❒
6.28) Our staff's knowledge and beliefs are barriers to implementing the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.29) Our staff are confident that they can use the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.30) Our plan for implementing the immunization information system identifies specific roles and responsibilities	❒	❒	❒	❒	❒	❒	❒
6.31) Our plan for implementing the immunization information system clearly describes tasks and timelines	❒	❒	❒	❒	❒	❒	❒
6.32) Our plan for implementing the immunization information system includes appropriate staff education	❒	❒	❒	❒	❒	❒	❒
6.33) Our plan for implementing the immunization information system acknowledges staff input and opinions	❒	❒	❒	❒	❒	❒	❒
6.34) Staff opinion leaders are supportive of the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.35) The individual responsible for overseeing implementation of the immunization information system is committed to making this successful	❒	❒	❒	❒	❒	❒	❒
6.36) The majority of our pharmacy staff have been involved in the decision to implement the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.37) We've spoken with patients and considered their opinion regarding the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.38) We have enrolled in the immunization information system	❒	❒	❒	❒	❒	❒	❒
6.39) We have completed the immunization information system face-to-face training	❒	❒	❒	❒	❒	❒	❒
6.40) We have uploaded data to the immunization information system successfully	❒	❒	❒	❒	❒	❒	❒

6.41) We have retrieved data from the immunization information system to determine a patient's needed vaccines	❒	❒	❒	❒	❒	❒	❒
6.42) We plan to collect honest reactions from staff regarding use of the immunization information system	❒	❒	❒	❒	❒	❒	❒

Appendix 9: Ordered List of Implementation Factors (CFIR Constructs) Mapped to Questionnaire Items

Domain	Construct	Sub-Construct	Potential Question	Source
Intervention Characteristics	Intervention Source			
	Evidence Strength and Quality			
	Relative Advantage		*c.* The immunization information system appears to have more advantages than disadvantages *d.* The immunization information system is likely to be supported by staff because they believe that the advantages outweigh the disadvantages *e.* Using the immunization information system is more reliable than patient self-report when checking	1-2. OCM 3. Perceived Attributes of eHealth Innovations Questionnaire 4-5. PCI Scale 6. Adoption of Customer Relationship Management Technology Scale

			immunization status ***f.*** Using the immunization information system enables me to accomplish tasks related to the provision of immunizations more quickly ***g.*** Using the immunization information system enables me to accomplish tasks related to the provision of immunizations more effectively ***h.*** The immunization information system helps to manage my vaccine inventory more effectively	

	Adaptability		3. Use of the immunization information system can be adapted to fit our current situation	OCM
	Trialability		1. I've had the opportunity to test various applications of the immunization information system 2. Before deciding whether or not to use the immunization information system, I was able to properly try it out	PCI Scale
	Complexity		1. Interacting with the immunization information system is clear and understandabl e 2. Interacting with the immunization information system does not require a lot of mental effort 3. I find the immunization information system to be easy to use	TAM2 Scale

			4. I find it easy to get the immunization information system to do what I want it to do	
	Design Quality and Packaging		*3.* The immunization information system interface is attractive *4.* The immunization information system interface is user friendly	Intention to Adopt Multimedia Messaging Service Scale
	Cost		1. Implementing the immunization information system is too much of a financial burden	Adoption of Customer Relationship Management Technology Scale
Outer Setting	Patient Needs and Resources		1. The immunization information system incorporates the needs and preferences of patients	ORCA
	Cosmopolitanism		2. It is helpful to have people external to the pharmacy who can provide support when needed 3. It is helpful to have access to someone from outside the pharmacy	Facilitators of Practice Change Scale

			when implementing the immunization information system	
	Peer Pressure		2. Most pharmacies are using the immunization information system 3. Using the immunization information system helps my pharmacy maintain a competitive advantage over other pharmacies	Adoption of Customer Relationship Management Technology Scale
	External Policy & Incentives		2. External organizations or individuals have pressured our pharmacy to implement the immunization information system	OCM
Inner Setting	Structural Characteristics (age, size of pharmacy)			
	Networks and Communication		2. All staff will work together as a team when implementing the immunization information system	Facilitators of Practice Change Scale

			3. The changes that will be occurring in the pharmacy when implementing the immunization information system have been communicated to all pharmacy staff 4. Mechanisms for communication, such as staff meetings, are important when implementing the immunization information system	
	Culture		2. Our pharmacy has proven that we are able to adapt ideas from outside to fit our organization's way of doing things 3. Our pharmacy owner/manager rewards innovation and creativity to improve patient care 4. Staff members in our pharmacy	1. OCM 2-6. ORCA

			have a sense of personal responsibility for improving patient care and outcomes 5. Staff members in our pharmacy cooperate to maintain and improve effectiveness of patient care 6. Staff members in our pharmacy are willing to innovate and/or experiment to improve patient care 7. Staff members in our pharmacy are receptive to change	
	Implementation Climate	Tension for Change	1. Some of our pharmacy staff believe that implementing the immunization information system is essential	OCM
		Compatibility	2. Successfully implementing the immunization information system will meet staff needs.	OCM

		Relative Priority	2. Our pharmacy owner/manager has set a high priority on the success of the immunization information system in our pharmacy	ORCA
		Org. Incentives and Rewards	1. Staff incentives are likely to be set up to engage them in using the immunization information system	OCM
		Goals and Feedback	1. Successful implementation of the immunization information system will help us meet our organization's mission and goals 2. The pharmacy owner/ manager/ staff opinion leaders agree on the goals for the implementation of the immunization information system	1. OCM 2. ORCA
		Learning Climate		
	Readiness for Implementation	Leadership Engagement	2. Our pharmacy owner/manager has set a	OCM

			deadline for enrollment in the immunization information system 3. Our pharmacy owner/manager has designated an individual to be responsible for enrolling our pharmacy in the immunization information system 4. Our pharmacy owner/manager has openly endorsed the immunization information system	
		Available Resources	b) Our pharmacy owner/manager has committed to spending time and resources to remove obstacles related to implementation of the IIS if they arise c) Our staff do not have the time required to update the immunization information system when an	1. OCM 2. Perceived Barriers to the Provision of Pharmaceutical Care Questionnaire

			immunization is provided	
		Access to Knowledge & Information	2. Our staff has access to immunization information system training and training materials	OCM
Characteristics of Individuals	Knowledge and Beliefs about the Innovation		1. Our staff's knowledge and beliefs are barriers to implementing the immunization information system	LATCon
	Self-efficacy		3. Our staff are confident that they can use the immunization information system	OCM
	Individual stage of change			
	Individual Identification with Organization			
	Other Personal Attributes			
Process	Planning		2. Our plan for implementing the immunization information system identifies specific roles and responsibilities	ORCA

			3. Our plan for implementing the immunization information system clearly describes tasks and timelines 4. Our plan for implementing the immunization information system includes appropriate staff education 5. Our plan for implementing the immunization information system acknowledges staff input and opinions	
	Engaging	Opinion Leaders	2. Staff opinion leaders are supportive of the immunization information system	OCM
		Formally Appointed Internal Implementation Leaders	2. The individual responsible for overseeing implementation of the immunization information system is committed to making this successful	?
		Champions		

		External Change Agents		
		Key Stakeholders including staff	2. The majority of our pharmacy staff have been involved in the decision to implement the immunization information system	OCM
		Patients/Customers	1. We've spoken with patients and considered their opinion regarding the immunization information system	OCM
	Executing		1. We have enrolled in the immunization information system 2. We have completed the immunization information system face-to-face training 3. We have uploaded data to the immunization information system successfully 4. We have retrieved data from the immunization information system to determine a	OCM

			patient's needed vaccines	
	Reflecting and Evaluating		3. We plan to collect honest reactions from staff regarding use of the immunization information system	OCM

Appendix 10: Awareness of Immunization Information Systems Frequency of Responses to Items

Item	Group	Baseline (N=41)			One Month (N=39)			Three Months (N=33)		
		Answered Correctly	Answered Incorrectly	Don't Know	Answered Correctly	Answered Incorrectly	Don't Know	Answered Correctly	Answered Incorrectly	Don't Know
		n (%)			n (%)			n (%)		
Immunization information systems consolidate vaccination data for patients within a defined geographic area	**Intervention** **Control**	**18 (81.8)** **12 (63.2)**	0 (0) 1 (5.3)	4 (18.2) 6 (31.6)	**22 (100.0)** **12 (70.6)**	0 (0) 1 (5.9)	0 (0) 4 (23.5)	**16 (88.9)** **13 (86.7)**	0 (0) 1 (6.7)	2 (11.1) 1 (6.7)
Pharmacies can record administered vaccinations in immunization information systems	**Intervention** **Control**	**19 (86.4)** **16 (84.2)**	0 (0) 1 (5.3)	3 (13.6) 2 (10.5)	**22 (100.0)** **17 (100.0)**	0 (0) 0 (0)	0 (0) 0 (0)	**18 (100.0)** **14 (93.3)**	0 (0) 0 (0)	0 (0) 1 (6.7)
Other providers can retrieve immunization information in real time	**Intervention** **Control**	**16 (72.7)** **15 (78.9)**	0 (0) 0 (0)	6 (27.3) 4 (21.1)	**20 (90.9)** **13 (76.5)**	1 (4.5) 0 (0)	1 (4.5) 4 (23.5)	**18 (100.0)** **13 (86.7)**	0 (0) 0 (0)	0 (0) 2 (13.3)

Appendix 11: Knowledge of Immunization Information Systems Frequency of Responses to Items

Item	Group	Baseline (N=41)			One Month (N=39)			Three Months (N=33)		
		Answered Correctly	Answered Incorrectly	Don't Know	Answered Correctly	Answered Incorrectly	Don't Know	Answered Correctly	Answered Incorrectly	Don't Know
		n (%)			n (%)			n (%)		
Which of the following are methods of documenting immunizations (select all that apply)	**Intervention** **Control**	6 (27.3) 8 (42.1)	**16 (72.7)** **10 (52.6)**	0 (0) 1 (5.3)	**12 (54.5)** 8 (47.1)	10 (45.5) **9 (52.9)**	0 (0) 0 (0)	8 (44.4) **6 (40.0)**	**10 (55.6)** **9 (60.0)**	0 (0) 0 (0)
Immunization Information Systems are also known as immunization registries	**Intervention** **Control**	**15 (68.2)** **11 (57.9)**	7 (31.8) 0 (0)	0 (0) 8 (42.1)	**22 (100.0)** **12 (70.6)**	0 (0) 5 (29.4)	0 (0) 0 (0)	**18 (100.0)** **12 (80.0)**	0 (0) 0 (0)	0 (0) 3 (20.0)
Each state maintains its own Immunization Information System	**Intervention** **Control**	5 (22.7) **10 (52.6)**	2 (9.1) 0 (0)	**15 (68.2)** 9 (47.4)	**21 (95.5)** **9 (52.9)**	0 (0) 0 (0)	3 (4.5) **8 (47.1)**	**9 (50.0)** 8 (53.3)	1 (5.6) 1 (6.7)	8 (44.4) **6 (40.0)**
Immunization information systems consolidate immunization doses from all	**Intervention** **Control**	6 (27.3) 8 (42.1)	5 (22.7) 1 (5.3)	**11 (50.0)** **10 (52.6)**	**13 (59.1)** **10 (58.8)**	6 (27.3) 1 (5.9)	3 (13.6) 5 (29.4)	**10 (55.6)** **9 (60.0)**	5 (27.8) 2 (13.3)	3 (16.7) 4 (26.7)

providers regardless of participation										
Immunization information systems share data between states	**Intervention** **Control**	2 (9.1) 2 (10.5)	3 (13.6) 5 (26.3)	**17 (77.3)** **12 (63.2)**	3 (13.6) 3 (17.6)	**16 (72.7)** 5 (29.4)	3 (13.6) **8 (47.1)**	2 (11.1) 4 (26.7)	**10 (55.6)** 4 (26.7)	6 (33.3) **7 (46.7)**
Immunization information system reporting is mandatory in Alabama	**Intervention** **Control**	**11 (50.0)** **11 (57.9)**	2 (9.1) 1 (5.3)	9 (40.9) 7 (36.8)	**19 (86.4)** **9 (52.9)**	2 (9.1) 1 (5.9)	1 (4.5) 7 (41.2)	**11 (61.1)** **10 (66.7)**	2 (11.1) 1 (6.7)	5 (27.8) 4 (26.7)
Immunization information system reporting is mandatory in all states	**Intervention** **Control**	**12 (54.5)** **10 (52.6)**	1 (4.5) 1 (5.3)	9 (40.9) 8 (42.1)	**20 (90.9)** **12 (70.6)**	1 (4.5) 0 (0)	1 (4.5) 5 (29.4)	**14 (77.8)** **10 (66.7)**	0 (0) 1 (6.7)	4 (22.2) 4 (26.7)
Immunization information systems typically include which of the following (select all that apply)	**Intervention** **Control**	**18 (81.8)** **11 (57.9)**	1 (4.5) 2 (10.5)	3 (13.6) 6 (31.6)	**20 (90.9)** **15 (88.2)**	2 (9.1) 1 (5.9)	0 (0) 0 (0)	**16 (88.9)** **14 (93.3)**	2 (11.1) 1 (6.7)	0 (0) 0 (0)

Appendix 12: Attitudes Toward characteristics of Immunization Information Systems Frequency of Responses to Items

Item	Group	Baseline (N=41; Intervention= 22, Control= 19)						
		Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Somewhat Agree	Agree	Strongly Agree
		n (%)						
Immunization information systems are not standardized in terms of data required.	Intervention Control	1 (4.5) 1 (5.3)	2 (9.1) 1 (5.3)	2 (9.1) 1 (5.3)	10 (45.5) 10 (52.6)	2 (9.1) 5 (26.3)	4 (18.2) 1 (5.3)	1 (4.5) 0 (0)
Current systems of reporting immunizations are sufficient to determine immunization status.	Intervention Control	2 (9.1) 0 (0)	6 (27.3) 3 (15.8)	3 (13.6) 3 (15.8)	6 (27.3) 8 (42.1)	4 (18.2) 2 (10.5)	1 (4.5) 2 (10.5)	0 (0) 1 (5.3)
Data recorded in immunization information systems is inaccurate.	Intervention Control	0 (0) 1 (5.3)	3 (13.6) 3 (15.8)	5 (22.7) 7 (36.8)	9 (40.9) 8 (42.1)	5 (22.7) 0 (0)	-	-
Data recorded in immunization information systems is incomplete.	Intervention Control	0 (0) 1 (5.3)	1 (4.5) 1 (5.3)	2 (9.1) 2 (10.5)	8 (36.4) 6 (31.6)	1 (4.5) 5 (26.3)	8 (36.4) 3 (15.8)	2 (9.1) 1 (5.3)
Immunization information systems provide patients with consolidated immunization records.	Intervention Control	1 (4.5) 0 (0)	-	-	8 (36.4) 5 (26.3)	4 (18.2) 6 (31.6)	9 (40.9) 7 (36.8)	0 (0) 1 (5.3)
Immunization information systems improve patient care coordination.	Intervention Control	-	-	0 (0) 1 (5.3)	4 (18.2) 2 (10.5)	3 (13.6) 3 (15.8)	6 (27.3) 8 (42.1)	9 (40.9) 5 (26.3)

Immunization information systems allow pharmacies to assess immunization status.	Intervention Control	-	1 (4.5) 0 (0)	-	5 (22.7) 6 (31.6)	2 (9.1) 5 (26.3)	9 (40.9) 3 (15.8)	5 (22.7) 5 (26.3)
Immunization information systems are a realistic method of consolidating immunization data.	Intervention Control	-	-	-	6 (27.3) 3 (15.8)	1 (4.5) 4 (21.1)	11(50.0) 10(52.6)	4 (18.2) 2 (10.5)
Immunization information systems are too time consuming.	Intervention Control	0 (0) 1 (5.3)	5 (22.7) 3 (15.8)	3 (13.6) 3 (15.8)	11 (50.0) 10 (52.6)	2 (9.1) 2 (10.5)	1 (4.5) 0 (0)	-
The immunization information system fits easily into pharmacy workflow.	Intervention Control	-	2 (9.1) 1 (5.3)	5 (22.7) 2 (10.5)	11 (50.0) 10 (52.6)	2 (9.1) 3 (15.8)	2 (9.1) 2 (10.5)	0 (0) 1 (5.3)
It is difficult to obtain access to the immunization information system.	Intervention Control	0 (0) 1 (5.3)	0 (0) 3 (15.8)	3 (13.6) 2 (10.5)	12 (54.5) 12 (63.2)	5 (22.7) 1 (5.3)	2 (9.1) 0 (0)	-
It is difficult to obtain immunization information systems software.	Intervention Control	0 (0) 1 (5.3)	3 (13.6) 0 (0)	-	15 (68.2) 14 (73.7)	2 (9.1) 3 (15.8)	2 (9.1) 1 (5.3)	-
It is difficult to obtain immunization information systems IT support.	Intervention Control	0 (0) 1 (5.3)	1 (4.5) 0 (0)	0 (0) 1 (5.3)	17 (77.3) 17 (89.5)	2 (9.1) 0 (0)	2 (9.1) 0 (0)	-
It is difficult to obtain patient consent for immunization information systems.	Intervention Control	1 (4.5) 1 (5.3)	0 (0) 2 (10.5)	4 (18.2) 5 (26.3)	14 (63.6) 11 (57.9)	2 (9.1) 0 (0)	1 (4.5) 0 (0)	-
Immunization information systems compromise patient confidentiality.	Intervention Control	1 (4.5) 3 (15.8)	9 (40.9) 9 (47.4)	4 (18.2) 2 (10.5)	7 (31.8) 3 (15.8)	1 (4.5) 1 (5.3)	0 (0) 1 (5.3)	-
The immunization information system appears to have more advantages than disadvantages	Intervention Control	-	-	-	7 (31.8) 4 (21.1)	3 (13.6) 6 (31.6)	10 (45.5) 8 (42.1)	2 (9.1) 1 (5.3)

Using the immunization information system is more reliable than patient self-report when checking immunization status	Intervention Control	-	-	0 (0) 1 (5.3)	5 (22.7) 5 (26.3)	2 (9.1) 2 (10.5)	7 (31.8) 5 (26.3)	8 (36.4) 6 (31.6)
Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more quickly	Intervention Control	-	-	0 (0) 3 (15.8)	7 (31.8) 9 (47.4)	6 (27.3) 1 (5.3)	7 (31.8) 5 (26.3)	2 (9.1) 1 (5.3)
Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more effectively	Intervention Control	-	-	-	7 (31.8) 7 (36.8)	6 (27.3) 6 (31.6)	6 (27.3) 5 (26.3)	3 (13.6) 1 (5.3)
The immunization information system helps to manage vaccine inventory more effectively	Intervention Control	1 (4.5) 1 (5.3)	1 (4.5) 3 (15.8)	2 (9.1) 4 (21.1)	10 (45.5) 7 (36.8)	1 (4.5) 1 (5.3)	5 (22.7) 2 (10.5)	2 (9.1) 1 (5.3)
Use of the immunization information system can be adapted to fit our pharmacy's current situation	Intervention Control	-	-	-	8 (36.4) 5 (26.3)	5 (22.7) 3 (15.8)	7 (31.8) 10 (52.6)	2 (9.1) 1 (5.3)
I've had the opportunity to test various applications of the immunization information system	Intervention Control	7 (31.8) 4 (21.1)	7 (31.8) 5 (26.3)	0 (0) 2 (10.5)	7 (31.8) 6 (31.6)	-	1 (4.5) 1 (5.3)	0 (0) 1 (5.3)

Interacting with the immunization information system is clear and understandable	Intervention Control	-	-	0 (0) 1 (5.3)	18 (81.8) 11 (57.9)	2 (9.1) 4 (21.1)	2 (9.1) 2 (10.5)	0 (0) 1 (5.3)
Interacting with the immunization information system does not require a lot of mental effort	Intervention Control	-	-	-	18 (81.8) 14 (73.7)	3 (13.6) 1 (5.3)	1 (4.5) 3 (15.8)	0 (0) 1 (5.3)
Implementing the immunization information system is too much of a financial burden	Intervention Control	0 (0) 2 (10.5)	3 (13.6) 3 (15.8)	-	16 (72.7) 13 (68.4)	3 (13.6) 0 (0)	0 (0) 1 (5.3)	-
		One Month (N=39; Intervention= 22, Control= 17)						
		Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Somewhat Agree	Agree	Strongly Agree
		n (%)						
Immunization information systems are not standardized in terms of data required.	Intervention Control	2 (9.1) 1 (5.9)	5 (22.7) 4 (23.5)	2 (9.1) 2 (11.8)	3 (13.6) 5 (29.4)	3 (13.6) 2 (11.8)	6 (27.3) 1 (5.9)	1 (4.5) 2 (11.8)
Current systems of reporting immunizations are sufficient to determine immunization status.	Intervention Control	2 (9.1) 1 (5.9)	9 (40.9) 1 (5.9)	5 (22.7) 5 (29.4)	2 (9.1) 4 (23.5)	1 (4.5) 4 (23.5)	2 (9.1) 1 (5.9)	1 (4.5) 1 (5.9)
Data recorded in immunization information systems is inaccurate.	Intervention Control	1 (4.5) 1 (5.9)	10 (45.5) 4 (23.5)	4 (18.2) 1 (5.9)	4 (18.2) 8 (47.1)	2 (9.1) 3 (17.6)	-	1 (4.5) 0 (0)
Data recorded in immunization information systems is incomplete.	Intervention Control	1 (4.5) 1 (5.9)	2 (9.1) 3 (17.6)	3 (13.6) 1 (5.9)	6 (27.3) 5 (29.4)	8 (36.4) 5 (29.4)	1 (4.5) 1 (5.9)	1 (4.5) 1 (5.9)

Immunization information systems provide patients with consolidated immunization records.	Intervention Control	-	0 (0) 1 (5.9)	1 (4.5) 2 (11.8)	2 (9.1) 3 (17.6)	4 (18.2) 3 (17.6)	10 (45.5) 6 (35.3)	5 (22.7) 2 (11.8)
Immunization information systems improve patient care coordination.	Intervention Control	-	-	-	1 (4.5) 3 (17.6)	3 (13.6) 0 (0)	11 (50.0) 9 (52.9)	7 (31.8) 5 (29.4)
Immunization information systems allow pharmacies to assess immunization status.	Intervention Control	-	-	-	2 (9.1) 1 (5.9)	2 (9.1) 3 (17.6)	10 (45.5) 7 (41.2)	8 (36.4) 6 (35.3)
Immunization information systems are a realistic method of consolidating immunization data.	Intervention Control	-	-	-	2 (9.1) 2 (11.8)	1 (4.5) 5 (29.4)	12 (54.5) 7 (41.2)	7 (31.8) 3 (17.6)
Immunization information systems are too time consuming.	Intervention Control	2 (9.1) 0 (0)	4 (18.2) 2 (11.8)	6 (27.3) 5 (29.4)	5 (22.7) 5 (29.4)	5 (22.7) 3 (17.6)	0 (0) 1 (5.9)	0 (0) 1 (5.9)
The immunization information system fits easily into pharmacy workflow.	Intervention Control	0 (0) 2 (11.8)	0 (0) 2 (11.8)	2 (9.1) 4 (23.5)	6 (27.3) 6 (35.3)	9 (40.9) 3 (17.6)	2 (9.1) 0 (0)	3 (13.6) 0 (0)
It is difficult to obtain access to the immunization information system.	Intervention Control	3 (13.6) 0 (0)	7 (31.8) 3 (17.6)	7 (31.8) 3 (17.6)	3 (13.6) 6 (35.3)	2 (9.1) 5 (29.4)	-	-
It is difficult to obtain immunization information systems software.	Intervention Control	1 (4.5) 0 (0)	6 (27.3) 1 (5.9)	4 (18.2) 2 (11.8)	8 (36.4) 8 (47.1)	2 (9.1) 2 (11.8)	1 (4.5) 3 (17.6)	0 (0) 1 (5.9)
It is difficult to obtain immunization information systems IT support.	Intervention Control	1 (4.5) 0 (0)	2 (9.1) 2 (11.8)	3 (13.6) 1 (5.9)	14 (63.6) 10 (58.8)	1 (4.5) 2 (11.8)	1 (4.5) 2 (11.8)	-

It is difficult to obtain patient consent for immunization information systems.	Intervention Control	8 (36.4) 1 (5.9)	6 (27.3) 1 (5.9)	2 (9.1) 5 (29.4)	5 (22.7) 8 (47.1)	1 (4.5) 1 (5.9)	0 (0) 1 (5.9)	-
Immunization information systems compromise patient confidentiality.	Intervention Control	7 (31.8) 3 (17.6)	9 (40.9) 6 (35.3)	4 (18.2) 0 (0)	1 (4.5) 5 (29.4)	1 (4.5) 1 (5.9)	0 (0) 2 (11.8)	-
The immunization information system appears to have more advantages than disadvantages	Intervention Control	1 (4.5) 0 (0)	-	-	2 (9.1) 3 (17.6)	2 (9.1) 2 (11.8)	12 (54.5) 11 (64.7)	5 (22.7) 1 (5.9)
Using the immunization information system is more reliable than patient self-report when checking immunization status	Intervention Control	-	-	-	2 (9.1) 0 (0)	1 (4.5) 1 (5.9)	9 (40.9) 9 (52.9)	10 (45.5) 7 (41.2)
Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more quickly	Intervention Control	-	0 (0) 1 (5.9)	1 (4.5) 2 (11.8)	2 (9.1) 3 (17.6)	5 (22.7) 4 (23.5)	8 (36.4) 6 (35.3)	6 (27.3) 1 (5.9)
Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more effectively	Intervention Control	-	-	-	2 (9.1) 2 (11.8)	3 (13.6) 5 (29.4)	10 (45.5) 8 (47.1)	7 (31.8) 2 (11.8)

The immunization information system helps to manage vaccine inventory more effectively	Intervention Control	-	1 (4.5) 5 (29.4)	2 (9.1) 3 (17.6)	6 (27.3) 3 (17.6)	6 (27.3) 2 (11.8)	4 (18.2) 3 (17.6)	3 (13.6) 1 (5.9)
Use of the immunization information system can be adapted to fit our pharmacy's current situation	Intervention Control	-	0 (0) 1 (5.9)	-	3 (13.6) 2 (11.8)	2 (9.1) 7 (41.2)	14 (63.6) 6 (35.3)	3 (13.6) 1 (5.9)
I've had the opportunity to test various applications of the immunization information system	Intervention Control	1 (4.5) 5 (29.4)	8 (36.4) 3 (17.6)	2 (9.1) 2 (11.8)	2 (9.1) 3 (17.6)	4 (18.2) 1 (5.9)	3 (13.6) 3 (17.6)	2 (9.1) 0 (0)
Interacting with the immunization information system is clear and understandable	Intervention Control	-	0 (0) 1 (5.9)	0 (0) 3 (17.6)	3 (13.6) 7 (41.2)	9 (40.9) 1 (5.9)	8 (36.4) 5 (29.4)	2 (9.1) 0 (0)
Interacting with the immunization information system does not require a lot of mental effort	Intervention Control	-	-	1 (4.5) 3 (17.6)	4 (18.2) 7 (41.2)	6 (27.3) 2 (11.8)	9 (40.9) 5 (29.4)	2 (9.1) 0 (0)
Implementing the immunization information system is too much of a financial burden	Intervention Control	4 (18.2) 0 (0)	9 (40.9) 6 (35.3)	3 (13.6) 3 (17.6)	5 (22.7) 6 (35.3)	1 (4.5) 1 (5.9)	0 (0) 1 (5.9)	-
		Three Months (N=33; Intervention= 18, Control= 15)						
		Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Somewhat Agree	Agree	Strongly Agree
		n (%)						

Immunization information systems are not standardized in terms of data required.	Intervention Control	1 (5.6) 1 (6.7)	2 (11.1) 3 (20.0)	2 (11.1) 1 (6.7)	5 (27.8) 3 (20.0)	3 (16.7) 4 (26.7)	5 (27.8) 3 (20.0)	-
Current systems of reporting immunizations are sufficient to determine immunization status.	Intervention Control	1 (5.6) 1 (6.7)	6 (33.3) 2 (13.3)	4 (22.2) 2 (13.3)	1 (5.6) 2 (13.3)	2 (11.1) 5 (33.3)	3 (16.7) 3 (20.0)	1 (5.6) 0 (0)
Data recorded in immunization information systems is inaccurate.	Intervention Control	2 (11.1) 0 (0)	7 (38.9) 7 (46.7)	3 (16.7) 4 (26.7)	4 (22.2) 3 (20.0)	2 (11.1) 1 (6.7)	-	-
Data recorded in immunization information systems is incomplete.	Intervention Control	2 (11.1) 0 (0)	1 (5.6) 4 (26.7)	3 (16.7) 2 (13.3)	2 (11.1) 2 (13.3)	6 (33.3) 3 (20.0)	3 (16.7) 2 (13.3)	1 (5.6) 2 (13.3)
Immunization information systems provide patients with consolidated immunization records.	Intervention Control	-	-	1 (5.6) 0 (0)	2 (11.1) 2 (13.3)	3 (16.7) 4 (26.7)	7 (38.9) 7 (46.7)	5 (27.8) 2 (13.3)
Immunization information systems improve patient care coordination.	Intervention Control	1 (5.6) 0 (0)	-	-	1 (5.6) 1 (6.7)	2 (11.1) 2 (13.3)	6 (33.3) 8 (53.3)	8 (44.4) 4 (26.7)
Immunization information systems allow pharmacies to assess immunization status.	Intervention Control	1 (5.6) 0 (0)	-	0 (0) 1 (6.7)	1 (5.6) 1 (6.7)	3 (16.7) 2 (13.3)	7 (38.9) 6 (40.0)	6 (33.3) 5 (33.3)
Immunization information systems are a realistic method of consolidating immunization data.	Intervention Control	1 (5.6) 0 (0)	0 (0) 1 (6.7)	0 (0) 1 (6.7)	0 (0) 2 (13.3)	2 (11.1) 1 (6.7)	7 (38.9) 8 (53.3)	8 (44.4) 2 (13.3)
Immunization information systems are too time consuming.	Intervention Control	2 (11.1) 0 (0)	3 (16.7) 2 (13.3)	8 (44.4) 2 (13.3)	2 (11.1) 5 (33.3)	2 (11.1) 4 (26.7)	1 (5.6) 1 (6.7)	0 1 (6.7)

The immunization information system fits easily into pharmacy workflow.	Intervention Control	0 (0) 1 (6.7)	1 (5.6) 1 (6.7)	5 (27.8) 5 (33.3)	3 (16.7) 4 (26.7)	4 (22.2) 3 (20.0)	3 (16.7) 1 (6.7)	2 (11.1) 0 (0)
It is difficult to obtain access to the immunization information system.	Intervention Control	4 (22.2) 0 (0)	6 (33.3) 5 (33.3)	3 (16.7) 2 (13.3)	2 (11.1) 6 (40.0)	2 (11.1) 1 (6.7)	1 (5.6) 1 (6.7)	-
It is difficult to obtain immunization information systems software.	Intervention Control	4 (22.2) 0 (0)	5 (27.8) 5 (33.3)	2 (11.1) 3 (20.0)	5 (27.8) 7 (46.7)	1 (5.6) 0 (0)	1 (5.6) 0 (0)	-
It is difficult to obtain immunization information systems IT support.	Intervention Control	2 (11.1) 0 (0)	7 (38.9) 3 (20.0)	1 (5.6) 3 (20.0)	6 (33.3) 6 (40.0)	1 (5.6) 3 (20.0)	1 (5.6) 0 (0)	-
It is difficult to obtain patient consent for immunization information systems.	Intervention Control	3 (16.7) 2 (13.3)	7 (38.9) 7 (46.7)	2 (11.1) 1 (6.7)	5 (27.8) 4 (26.7)	1 (5.6) 1 (6.7)	-	-
Immunization information systems compromise patient confidentiality.	Intervention Control	4 (22.2) 1 (6.7)	5 (27.8) 9 (60.0)	4 (22.2) 1 (6.7)	4 (22.2) 2 (13.3)	0 (0) 2 (13.3)	-	1 (5.6) 0 (0)
The immunization information system appears to have more advantages than disadvantages	Intervention Control	1 (5.6) 0 (0)	-	-	1 (5.6) 1 (6.7)	3 (16.7) 5 (33.3)	6 (33.3) 7 (46.7)	7 (38.9) 2 (13.3)
Using the immunization information system is more reliable than patient self-report when checking immunization status	Intervention Control	-	-	-	2 (11.1) 4 (26.7)	3 (16.7) 1 (6.7)	6 (33.3) 7 (46.7)	7 (38.9) 3 (20.0)
Using the immunization information system enables	Intervention Control	1 (5.6) 1 (6.7)	-	2 (11.1) 1 (6.7)	1 (5.6) 5 (33.3)	6 (33.3) 5 (33.3)	4 (22.2) 2 (13.3)	4 (22.2) 1 (6.7)

pharmacy staff to accomplish tasks related to the provision of immunizations more quickly								
Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more effectively	Intervention Control	1 (5.6) 0 (0)	-	1 (5.6) 1 (6.7)	0 (0) 5 (33.3)	4 (22.2) 3 (20.0)	8 (44.4) 4 (26.7)	4 (22.2) 2 (13.3)
The immunization information system helps to manage vaccine inventory more effectively	Intervention Control	-	0 (0) 5 (33.3)	2 (11.1) 1 (6.7)	7 (38.9) 3 (20.0)	4 (22.2) 2 (13.3)	3 (16.7) 3 (20.0)	2 (11.1) 1 (6.7)
Use of the immunization information system can be adapted to fit our pharmacy's current situation	Intervention Control	-	0 (0) 2 (13.3)	-	1 (5.6) 0 (0)	7 (38.9) 6 (40.0)	7 (38.9) 7 (46.7)	3 (16.7) 0 (0)
I've had the opportunity to test various applications of the immunization information system	Intervention Control	1 (5.6) 3 (20.0)	2 (11.1) 6 (40.0)	-	4 (22.2) 2 (13.3)	4 (22.2) 1 (6.7)	6 (33.3) 3 (20.0)	1 (5.6) 0 (0)
Interacting with the immunization information system is clear and understandable	Intervention Control	-	1 (5.6) 0 (0)	1 (5.6) 1 (6.7)	2 (11.1) 7 (46.7)	5 (27.8) 1 (6.7)	8 (44.4) 6 (40.0)	1 (5.6) 0 (0)
Interacting with the immunization information system does not require a lot of mental effort	Intervention Control	-	-	0 (0) 1 (6.7)	4 (22.2) 6 (40.0)	5 (27.8) 2 (13.3)	8 (44.4) 6 (40.0)	1 (5.6) 0 (0)

Implementing the immunization information system is too much of a financial burden	Intervention Control	0 (0) 1 (6.7)	4 (22.2) 5 (33.3)	5 (27.8) 1 (6.7)	5 (27.8) 4 (26.7)	4 (22.2) 1 (6.7)	0 (0) 3 (20.0)	-

Appendix 13: Intention to Enroll in ImmPRINT Frequency of Responses to Items

		Baseline (N=41; Intervention=22, Control= 19)						
		Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Somewhat Agree	Agree	Strongly Agree
		n (%)						
I plan to enroll my pharmacy in the immunization information system within 30 days	Intervention Control	0 1 (5.3)	1 (4.5) 1 (5.3)	-	6 (27.3) 8 (42.1)	8 (36.4) 3 (15.8)	3 (13.6) 3 (15.8)	4 (18.2) 3 (15.8)
I will make an effort to enroll my pharmacy in the immunization information system in the next 30 days	Intervention Control	-	1 (4.5) 1 (5.3)	-	4 (18.2) 3 (15.8)	10 (45.5) 7 (36.8)	4 (18.2) 5 (26.3)	3 (13.6) 3 (15.8)
I intend to enroll my pharmacy in the immunization information system	Intervention Control	-	-	-	4 (18.2) 8 (42.1)	8 (36.4) 4 (21.1)	4 (18.2) 3 (15.8)	6 (27.3) 4 (21.1)
		One Month (N=39; Intervention = 22, Control= 17)						
		Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Somewhat Agree	Agree	Strongly Agree
		n (%)						
I plan to enroll my pharmacy in the immunization information system within 30 days	Intervention Control	1 (4.5) 0 (0)	1 (4.5) 1 (5.9)	1 (4.5) 1 (5.9)	1 (4.5) 8 (47.1)	2 (9.1) 1 (5.9)	10 (45.5) 4 (23.5)	6 (27.3) 2 (11.8)
I will make an effort to enroll my pharmacy in the	Intervention Control	1 (4.5) 0 (0)	1 (4.5) 0 (0)	0 (0) 1 (5.9)	1 (4.5) 6 (35.3)	4 (18.2) 4 (23.5)	10 (45.5)	5 (22.7) 2 (11.8)

immunization information system in the next 30 days							4 (23.5)	
I intend to enroll my pharmacy in the immunization information system	Intervention Control	1 (4.5) 0 (0)	1 (4.5) 0 (0)	-	1 (4.5) 6 (35.3)	1 (4.5) 2 (11.8)	11 (50.0) 5 (29.4)	7 (31.8) 4 (23.5)
		Three Months (N=33; Intervention= 18, Control= 15)						
		Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Somewhat Agree	Agree	Strongly Agree
		n (%)						
I plan to enroll my pharmacy in the immunization information system within 30 days	Intervention Control	-	1 (5.6) 2 (13.3)	1 (5.6) 1 (6.7)	5 (27.8) 3 (20.0)	4 (22.2) 2 (13.3)	3 (16.7) 5 (33.3)	4 (22.2) 2 (13.3)
I will make an effort to enroll my pharmacy in the immunization information system in the next 30 days	Intervention Control	-	1 (5.6) 1 (6.7)	-	6 (33.3) 5 (33.3)	2 (11.1) 4 (26.7)	4 (22.2) 4 (26.7)	5 (27.8) 1 (6.7)
I intend to enroll my pharmacy in the immunization information system	Intervention Control	-	1 (5.6) 0 (0)	-	6 (33.3) 6 (40.0)	3 (16.7) 3 (20.0)	2 (11.1) 5 (33.3)	6 (33.3) 1 (6.7)

Appendix 14: Awareness Index and Item Means

Item	Baseline (N=41)	One Month (N=39)	Three Months (N=33)
	Mean (SD)		
Overall Awareness Index	2.34 (0.91)	2.72 (0.60)	2.79 (0.59)
Immunization information systems consolidate vaccination data for patients within a defined geographic area	1.22 (0.48)	1.08 (0.35)	1.06 (0.35)
Pharmacies can record administered vaccinations in immunization information systems	1.10 (0.37)	1.00 (0.00)	1.03 (0.17)
Other providers can retrieve immunization information in real time	1.24 (0.44)	1.10 (0.38)	1.06 (0.24)

Appendix 15: Knowledge Index and Item Means

	Baseline (N=41)	One Month (N=39)	Three Months (N=33)
	Mean (SD)		
Overall Knowledge Index	3.56 (2.19)	5.43 (1.61)	4.88 (1.82)
Which of the following are methods of documenting immunizations (select all that apply)	0.39 (0.54)	0.51 (0.51)	0.42 (0.50)
Immunization Information Systems are also known as immunization information systems	1.37 (0.49)	1.13 (0.34)	1.09 (0.29)
Each state maintains its own Immunization Information System	1.54 (0.59)	1.26 (0.49)	1.36 (0.60)
Immunization information systems consolidate immunization doses from all providers regardless of participation	1.17 (0.92)	0.67 (0.89)	0.64 (0.82)
Immunization information systems share data between states	1.61 (0.67)	1.18 (0.72)	1.21 (0.74)
Immunization information system reporting is mandatory in Alabama	0.85 (0.96)	0.49 (0.82)	0.64 (0.89)
Immunization information system reporting is mandatory in all states	0.88 (0.98)	0.33 (0.74)	0.52 (0.87)
Immunization information systems typically include which of the following (select all that apply)	1.15 (0.53)	0.95 (0.32)	0.91 (0.29)

Appendix 16: Attitudes Toward Intervention Characteristics Scale, Subscale, and Item Means

	Baseline (N=41)	One Month (N=39)	Three Months (N=33)
	Mean (SD)		
Attitudes Toward Innovation Characteristics Scale	4.55 (0.56)	4.95 (0.67)	4.98 (0.79)
Improving Patient Care Subscale	5.23 (0.83)	5.63 (0.72)	5.46 (0.99)
Intervention Source Support Subscale	4.11 (0.69)	4.45 (0.82)	4.61 (0.89)
Ease of Use Subscale	3.84 (0.82)	4.33 (0.94)	4.57 (0.94)
Immunization information systems are not standardized in terms of data required.	4.12 (1.31)	3.92 (1.83)	4.12 (1.57)
Current systems of reporting immunizations are sufficient to determine immunization status.	3.63 (1.43)	3.44 (1.62)	3.82 (1.72)
Data recorded in immunization information systems is inaccurate.	3.46 (0.98)	3.21 (1.34)	2.85 (1.12)
Data recorded in immunization information systems is incomplete.	4.63 (1.43)	4.08 (1.46)	4.21 (1.75)
Immunization information systems provide patients with consolidated immunization records.	5.02 (1.11)	5.41 (1.29)	5.67 (1.05)
Immunization information systems improve patient care coordination.	5.83 (1.14)	6.03 (0.90)	5.97 (1.24)
Immunization information systems allow pharmacies to assess immunization status.	5.44 (1.27)	6.08 (0.90)	5.82 (1.33)
Immunization information systems are a realistic method of consolidating immunization data.	5.59 (0.99)	5.90 (0.91)	5.73 (1.46)
Immunization information systems are too time consuming.	3.54 (1.08)	3.59 (1.33)	3.61 (1.44)
The immunization information system fits easily into pharmacy workflow.	4.07 (1.10)	4.23 (1.42)	4.12 (1.46)
It is difficult to obtain access to the immunization information system.	3.9 (0.99)	3.18 (1.23)	3.03 (1.43)
It is difficult to obtain immunization information systems software.	4.05 (0.97)	3.79 (1.36)	2.97 (1.26)
It is difficult to obtain immunization information systems IT support.	4 (0.78)	3.85 (1.07)	3.27 (1.28)
It is difficult to obtain patient consent for immunization information systems.	3.63 (0.94)	2.87 (1.38)	2.67 (1.22)
Immunization information systems compromise patient confidentiality.	2.78 (1.22)	2.51 (1.43)	2.7 (1.38)
The immunization information system appears to have more advantages than disadvantages.	5.32 (0.96)	5.67 (1.16)	5.76 (1.23)

Using the immunization information system is more reliable than patient self-report when checking immunization status.	5.68 (1.25)	6.28 (0.79)	5.82 (1.07)
Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more quickly.	4.9 (1.14)	5.36 (1.29)	4.88 (1.54)
Using the immunization information system enables pharmacy staff to accomplish tasks related to the provision of immunizations more effectively.	5.12 (1.01)	5.82 (0.91)	5.33 (1.38)
The immunization information system helps to manage vaccine inventory more effectively.	4.12 (1.55)	4.44 (1.57)	4.42 (1.52)
Use of the immunization information system can be adapted to fit our pharmacy's current situation.	5.24 (0.99)	5.51 (1.02)	5.39 (1.12)
I've had the opportunity to test various applications of the immunization information system.	2.73 (1.58)	3.46 (1.90)	3.94 (1.92)
Interacting with the immunization information system is clear and understandable.	4.39 (0.80)	4.95 (1.17)	5 (1.17)
Interacting with the immunization information system does not require a lot of mental effort.	4.37 (0.77)	4.97 (1.14)	5.12 (0.99)
Implementing the immunization information system is too much of a financial burden.	3.68 (1.06)	2.87 (1.24)	2.97 (1.47)

Appendix 17: Intention Scale and Item Means

	Baseline (N=41)	One Month (N=39)	Three Months (N=33)
		Mean (SD)	
Intention Scale	5.15 (1.16)	5.37 (1.39)	5.08 (1.30)
I plan to enroll my pharmacy in the immunization information system within 30 days	4.90 (1.43)	5.18 (1.59)	4.97 (1.53)
I will make an effort to enroll my pharmacy in the immunization information system in the next 30 days	5.20 (1.19)	5.31 (1.39)	5.09 (1.38)
I intend to enroll my pharmacy in the immunization information system	5.37 (1.16)	5.62 (1.43)	5.18 (1.31)

Appendix 18: Inner Setting Scale, Subscale, and Item Means

	Three Months (N=33) Mean (SD)
Inner Setting Scale	4.92 (0.77)
Readiness for Implementation Subscale	4.71 (0.97)
Implementation Climate Subscale	4.69 (1.01)
Culture Subscale	5.45 (0.80)
All staff will work together as a team when implementing the immunization information system	5.00 (1.32)
The changes that will be occurring in the pharmacy when implementing the immunization information system have been communicated to all pharmacy staff	5.03 (1.26)
Mechanisms for communication, such as staff meetings, are important when implementing the immunization information system	5.06 (1.12)
Our pharmacy has proven that we are able to adapt ideas from outside to fit our organization's way of doing things	5.48 (1.06)
Our pharmacy owner/manager rewards innovation and creativity to improve patient care	4.79 (1.64)
Staff members in our pharmacy have a sense of personal responsibility for improving patient care and outcomes	5.12 (1.17)
Staff members in our pharmacy cooperate to maintain and improve effectiveness of patient care	5.76 (0.87)
Staff members in our pharmacy are willing to innovate and/or experiment to improve patient care	5.76 (0.90)
Staff members in our pharmacy are receptive to change	5.64 (0.93)
Some of our pharmacy staff believe that implementing the immunization information system is essential	5.18 (1.13)
Successfully implementing the immunization information system will meet staff needs.	5.03 (1.16)

Our pharmacy owner/manager has set a high priority on the success of the immunization information system in our pharmacy	4.82 (1.42)
Staff incentives are likely to be set up to engage them in using the immunization information system	3.82 (1.63)
Successful implementation of the immunization information system will help us meet our organization's mission and goals	4.55 (1.28)
The pharmacy owner/ manager/ staff opinion leaders agree on the goals for the implementation of the immunization information system	4.88 (1.14)
Our pharmacy owner/manager has set a deadline for enrollment in the immunization information system	4.03 (1.74)
Our pharmacy owner/manager has designated an individual to be responsible for enrolling our pharmacy in the immunization information system	4.67 (1.76)
Our pharmacy owner/manager has openly endorsed the immunization information system	5.03 (1.38)
Our pharmacy owner/manager has committed to spending time and resources to remove obstacles related to implementation of the IIS if they arise	4.82 (1.38)
Our staff do not have the time required to update the immunization information system when an immunization is provided	4.00 (1.62)
Our staff has access to immunization information system training and training materials	4.79 (1.29)

Appendix 19: Outer Setting Scale, Subscale, and Item Means

	Three Months (N=17) Mean (SD)
Outer Setting Scale	4.51 (0.59)
External Support Subscale	5.07 (0.73)
Peer pressure Subscale	3.97 (0.93)
The immunization information system incorporates the needs and preferences of patients	4.52 (1.12)
It is helpful to have people external to the pharmacy who can provide support when needed	5.30 (0.77)
It is helpful to have access to someone from outside the pharmacy when implementing the immunization information system	5.24 (1.12)
Most pharmacies are using the immunization information system	3.97 (1.45)
Using the immunization information system helps my pharmacy maintain a competitive advantage over other pharmacies	4.36 (1.37)
External organizations or individuals have pressured our pharmacy to implement the immunization information system	3.58 (1.60)

Appendix 20: Characteristics of Individuals Scale, Subscale, and Item Means

	Three Months (N=17) Mean (SD)
Characteristics of Individuals Scale	4.67 (1.35)
Our staff have a sense of personal responsibility for improving patient care and outcomes.	5.12 (1.17)
Our staff's knowledge and beliefs are barriers to implementing the immunization information system	3.36 (1.58)
Our staff are confident that they can use the immunization information system	4.70 (1.65)

Appendix 21: Process Scale, Subscale, and Item Means

	Three Months (N=17) Mean (SD)
Process Scale	4.71 (1.09)
Engaging and Planning Subscale	4.76 (1.05)
Executing Subscale	4.58 (1.91)
Our plan for implementing the immunization information system identifies specific roles and responsibilities	4.61 (1.32)
Our plan for implementing the immunization information system clearly describes tasks and timelines	4.45 (1.50)
Our plan for implementing the immunization information system includes appropriate staff education	4.82 (1.38)
Our plan for implementing the immunization information system acknowledges staff input and opinions	5.06 (1.19)
Staff opinion leaders are supportive of the immunization information system	5.18 (1.26)
The individual responsible for overseeing implementation of the immunization information system is committed to making this successful	5.39 (1.29)
The majority of our pharmacy staff have been involved in the decision to implement the immunization information system	4.79 (1.41)
We've spoken with patients and considered their opinion regarding the immunization information system	3.61 (1.60)
We have enrolled in the immunization information system	4.97 (2.02)
We have completed the immunization information system face-to-face training	4.61 (2.22)
We have uploaded data to the immunization information system successfully	4.36 (1.98)
We have retrieved data from the immunization information system to determine a patient's needed vaccines	4.36 (2.21)
We plan to collect honest reactions from staff regarding use of the immunization information system	4.97 (1.76)

Appendix 22: Phase I Informed Consent and Information Letters for Pharmacy and IIS Personnel

DEPARTMENT OF HEALTH OUTCOMES RESEARCH AND POLICY

AUBURN UNIVERSITY

HARRISON SCHOOL OF PHARMACY

INFORMATION LETTER

Dear Pharmacy Staff,

We are currently recruiting community pharmacy staff to participate in a study that aims to explore pharmacy participation in immunization registries. This study involves community pharmacy staff in Alabama, Georgia, North Dakota, Wisconsin, and Minnesota. Approximately 18 pharmacists in these states will participate in this study.

What is the purpose of this study?
The purpose of this study is to increase the use of immunization registries in community pharmacies. Through interviewing community pharmacy staff we hope to gain a better understanding of the facilitators and barriers to immunization registry participation in a pharmacy setting. These findings will assist us in the development of an immunization registry training program specifically for pharmacists in Alabama.

What will my participation involve?
If you agree to participate in this study, you will be asked to complete a 30-60 minute interview. You may also be asked to join a review panel to provide 2-3 rounds of feedback via email and online questionnaire regarding the development of an immunization registry training program.

What do I do to participate?
Contact Tessa Hastings at **tjh0043@auburn.edu** or 330-904-8231

Tessa Hastings, MS	Salisa Westrick, PhD
PhD Candidate	Sterling Professor
Health Outcomes Research and Policy	Health Outcomes Research and Policy
Harrison School of Pharmacy	Harrison School of Pharmacy
Auburn University	Auburn University
Principal Investigator	Advisor

Sincerely,

Tessa Hastings, MS
PhD Candidate
tjh0043@auburn.edu

DEPARTMENT OF
HEALTH
OUTCOMES
RESEARCH AND
POLICY

AUBURN UNIVERSITY

HARRISON SCHOOL OF
PHARMACY

Assessing Barriers and Increasing Use of Immunization Registries in Pharmacies- Phase I Interest Form

After reading the enclosed information, if you are interested in participating in this study or would like to learn more, please contact me (Tessa Hastings) via email at tjh0043@auburn.edu or phone at 330-904-8231(cell). After receiving your interest, I will be happy to review the details of the study with you before you enroll by signing and returning the informed consent document to me. We can then schedule a telephone interview at a time that is most convenient for you.

Alternatively, you may also indicate your interest in participating or learning more about the study by filling out the questions below and returning this page to me via fax (1-334-323-6194) or email (tjh0043@auburn.edu). I will then contact you within 48 business hours to review the study or answer any questions you may have. If you decide to participate, I will ask you to please also sign and fax or scan the informed consent document back to me.

1. Your name: ____
First *Last*

2. The name of your pharmacy practice site:
____

3. The street address of your pharmacy practice site:
____
Street Address *City, State* *Zip*

4. The most convenient phone number to reach you: ______________________

5. Your preferred email address: ______________________________

6. Is your pharmacy enrolled in the state immunization registry?
❒ Yes
❒ No
❒ Don't know/ Not sure

Thank you so much in advance for your help with my dissertation study! I look forward to hearing from you soon.

Tessa Hastings, MS, PhD Candidate
Health Outcomes Research and Policy
Harrison School of Pharmacy
Auburn University
Principal Investigator
tjh0043@auburn.edu | Fax: 1-334-323-6194

DEPARTMENT OF HEALTH OUTCOMES RESEARCH AND POLICY

AUBURN UNIVERSITY

HARRISON SCHOOL OF PHARMACY

INFORMED CONSENT
for a Research Study entitled
Assessing Barriers and Increasing Use of Immunization Registries in Pharmacies

You are invited to participate in a research study to understand the barriers of and best practices for implementing immunization registries in independent community pharmacies. The study is being conducted by Tessa Hastings, a PhD Candidate, as her final dissertation project under the direction and supervision of Salisa Westrick, PhD in the Auburn University Department of Health Outcomes Research and Policy. Eligible participants are community pharmacy personnel at least 19 years of age, employed full-time in pharmacies providing immunization services and currently enrolled in the state immunization registry.

What will be involved if you participate? Your participation is completely voluntary. If you decide to participate in this research study, you will be asked to complete an interview either in person or telephonically which may last approximately 60 minutes and will be recorded. You may also be asked to participate on a review panel to provide feedback on an immunization registry training program via email and questionnaire.

Are there any risks or discomforts? The risks involved in this study are minimal. Responses including audio-recorded files, transcripts, and questionnaires will be assigned a code number, which will allow for follow-up, if any questions arise. All codes will be stored in a secured file and kept separate from the information collected. Upon completion of the study, lists with names and code numbers will be destroyed. Study results will be presented in aggregate form only.

Are there any benefits to yourself or others? There are no direct benefits associated with participating in this study. As for indirect benefits, the study findings may inform how to increase pharmacy participation in immunization registries, thereby improving the safe and effective delivery of vaccinations.

Will you receive compensation for participating? You will receive a $40 gift card for your participation in the interview. If you participate on the review panel, you will also receive one $100 gift card.

Are there any costs? There are no costs associated with this study.

If you change your mind about participating, you can withdraw at any time during the study. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University or the Department of Health Outcomes Research and Policy.

Participant's initials ______

The Auburn University Institutional Review Board has approved this Document for use from 06/22/2018 to 06/21/2019 Protocol # 18-203 EP 1806

Any data obtained in connection with this study will remain anonymous. Your privacy will be protected. Your data will be stored securely with access granted only to researchers involved in this study.

If you have questions about this study, please contact me at 334-844-5152 or tjh0043@auburn.edu.

If you have questions about your rights as a research participant, you may contact the Auburn University Office Human Subjects Research or the Institutional Review Board by phone (334) 844-5966 or e-mail at hsubjec@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO PARTICIPATE.

Participant's signature Date	Investigator obtaining consent Date
Printed Name	Printed Name
	Co-Investigator Date
	Printed Name

The Auburn University Institutional Review Board has approved this Document for use from 06/22/2018 to 06/21/2019 Protocol # 18-203 EP 1806

Page 2 of 2

DEPARTMENT OF HEALTH OUTCOMES RESEARCH AND POLICY

AUBURN UNIVERSITY

HARRISON SCHOOL OF PHARMACY

Dear Immunization registry representative,

We are currently recruiting immunization registry representatives to participate in a study that aims to explore pharmacy participation in immunization registries. This study involves immunization registry representatives in Alabama, Georgia, North Dakota, Wisconsin, and Minnesota. A total of 8 immunization registry representatives in these states will participate in this study.

What is the purpose of this study?
The purpose of this study is to increase the use of immunization registries in community pharmacies. Through interviewing registry representatives we hope to gain a better understanding of the facilitators and barriers to the recruitment of community pharmacies and the implementation of immunization registries in a pharmacy setting. These findings will assist us in the development of an immunization registry training program specifically for pharmacy personnel in Alabama.

What will my participation involve?
If you agree to participate in this study, you will be asked to complete a 30-60 minute interview. You may also be asked to join a review panel to provide 2-3 rounds of feedback via email and online questionnaire regarding the development of an immunization registry training program.

What do I do to participate?
Contact Tessa Hastings at tjh0043@auburn.edu or 334-844-5152

Tessa Hastings, MS	Salisa Westrick, PhD
PhD Candidate	Sterling Professor
Health Outcomes Research and Policy	Health Outcomes Research and Policy
Harrison School of Pharmacy	Harrison School of Pharmacy
Auburn University	Auburn University
Principal Investigator	Advisor

Sincerely,

Tessa Hastings, MS
PhD Candidate
tjh0043@auburn.edu

AUBURN UNIVERSITY

HARRISON SCHOOL OF PHARMACY

Assessing Barriers and Increasing Use of Immunization Registries in Pharmacies- Phase I Interest Form

After reading the enclosed information, if you are interested in participating in this study or would like to learn more, please contact me (Tessa Hastings) via email at tjh0043@auburn.edu or phone at 330-904-8231(cell). After receiving your interest, I will be happy to review the details of the study with you before you enroll by signing and returning the informed consent document to me. We can then schedule a telephone interview at a time that is most convenient for you.

Alternatively, you may also indicate your interest in participating or learning more about the study by filling out the questions below and returning this page to me via fax (1-334-323-6194) or email (tjh0043@auburn.edu). I will then contact you within 48 business hours to review the study or answer any questions you may have. If you decide to participate, I will ask you to please also sign and fax or scan the informed consent document back to me.

1. Your name:

____

First *Last*

2. District:

____

3. The most convenient phone number to reach you:

____

4. Your preferred email address:

____

Thank you so much in advance for your help with my dissertation study! I look forward to hearing from you soon.

Tessa Hastings, MS, PhD Candidate
Health Outcomes Research and Policy
Harrison School of Pharmacy
Auburn University
Principal Investigator
tjh0043@auburn.edu | Fax: 1-334-323-6194

Appendix 23: Phase III Recruitment Materials

DEPARTMENT OF HEALTH OUTCOMES RESEARCH AND POLICY

AUBURN UNIVERSITY

HARRISON SCHOOL OF PHARMACY

Dear Pharmacist,

Immunization registries allow healthcare providers to share immunization records for their patients. Even though providers' participation in the registry is free, enrollment is low (4%) among independently owned pharmacies. Therefore, this study is seeking to recruit 50 pharmacists practicing in a community setting to participate in a study that aims to improve the use of immunization registries.

What will my participation involve?

If you agree to your pharmacy's participation in the study, you will be randomly assigned to either receive the intervention or to participate in the control group, and you will complete a brief 10-15 minute online survey. If you are assigned to the intervention, you will receive an online continuing education program. You will also complete two online follow-up surveys, one immediately after completion of the CE and again at three months. Control pharmacies will complete a questionnaire one-month after enrollment and again three months later. In addition, by agreeing to participate, you agree that the Alabama immunization registry (ImmPRINT) will provide data including your pharmacy's enrollment status and the number and types of vaccines uploaded to the registry during the study period.

What are the benefits?

- 2 ACPE approve credit hours
    - Intervention group receives CE hours immediately
    - Control group receives after 6 months
- $50 compensation

What do I do to participate?

Complete and return the attached documents to 334-844-8307 (Fax) or **tjh0043@auburn.edu**.
For more information please visit the study website at www.alabamaimmunizers.com

Tessa Hastings, MS
PhD Candidate
Health Outcomes Research and Policy
Harrison School of Pharmacy
Auburn University
Principal Investigator

Salisa Westrick, PhD
Professor and Department Head
Health Outcomes Research and Policy
Harrison School of Pharmacy
Auburn University
Dissertation Advisor

Sincerely,

Tessa Hastings

Tessa Hastings, MS
PhD Candidate
tjh0043@auburn.edu

DEPARTMENT OF HEALTH OUTCOMES RESEARCH AND POLICY

AUBURN UNIVERSITY

HARRISON SCHOOL OF PHARMACY

INFORMED CONSENT

for a Research Study entitled

Assessing Barriers and Increasing Use of Immunization Registries in Pharmacies

You are invited to participate in a research study to improve the use of immunization registries in independent community pharmacies. The study is being conducted by Tessa Hastings, a PhD Candidate, as her final dissertation project under the direction and supervision of Salisa Westrick, PhD in the Auburn University Department of Health Outcomes Research and Policy. Alabama pharmacy personnel practicing in community pharmacies that meet the following criteria are eligible to enroll: 1) are not currently enrolled in the immunization registry (ImmPRINT), 2) currently provide at least one type of vaccination, 3) are independently owned, 4) are located in rural counties, and 5) agree to provide requested data for assessment. Approximately 50 pharmacy personnel will be enrolled and randomly assigned into either the intervention or control group.

What will be involved if you participate? If you agree to participate in the study, you will be randomly assigned to either receive the intervention or to participate as a control. You will complete a brief 10-15 minute baseline survey online. If you are assigned to the intervention, you will participate in an online continuing education program consisting of an article, series of videos, and a printable quick reference guide. You will also complete two follow-up surveys online immediately after completing the CE program and again at 3 months. If you are assigned to the control group, you will receive only an informational flyer at the beginning of the study and will complete two follow-up surveys at 1 month and 3 months. You will be able to receive the full continuing education program at the end of the study. In addition, by agreeing to participate, you agree that the Alabama immunization registry (ImmPRINT) will provide data including your pharmacy's enrollment status and the number and types of vaccines uploaded to the registry during the study period.

Are there any risks or discomforts? The risks involved in this study are minimal. No information about individual respondents, pharmacies, or patients will be released. Surveys will be conducted online. Your responses will be assigned a code number which will allow us to monitor responses and to follow-up, if any questions arise. All codes will be stored in a secured file and kept separate from the information collected. Upon completion of the study, lists with names and code numbers will be destroyed. Study results will be presented in aggregate form only.

Are there any benefits to yourself or others? There are no direct benefits associated with participating in this study. As for indirect benefits, the study findings may inform how to increase pharmacy participation in immunization registries, thereby improving the safe and effective delivery of vaccinations.

Will you receive compensation for participating? You will receive two $25 gift cards for your participation in this study, which will be provided after the two follow-up surveys at one and three months. The total direct compensation is $50.

Are there any costs? There are no costs associated with this study.

Participant's initials ______

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Page 1 of 2

If you change your mind about participating, you can withdraw at any time during the study. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University or the Department of Health Outcomes Research and Policy.

Any data obtained in connection with this study will remain anonymous. Your privacy will be protected. Your data will be stored securely with access granted only to researchers involved in this study. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you have questions about this study, please contact me at 334-844-5152 or tjh0043@auburn.edu.

If you have questions about your rights as a research participant, you may contact the Auburn University Office Human Subjects Research or the Institutional Review Board by phone (334) 844-5966 or e-mail at hsubjec@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO PARTICIPATE.

____________________________ ____________________________
Participant's signature Date Investigator obtaining consent Date

____________________________ ____________________________
Printed Name Printed Name

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Protocol # 18-511 EP 1901

AUBURN UNIVERSITY

HARRISON SCHOOL OF PHARMACY

Assessing Barriers and Increasing Use of Immunization Registries in Pharmacies
Interest Form

1. Your name: ____
First *Last*

2. The name of your pharmacy practice site:
____

3. The street address of your pharmacy practice site:
____
Street Address *City, State* *Zip*

4. The county in which your pharmacy is located: ____________________

5. The most convenient phone number to reach you: ____________________

6. Your preferred email address: ____________________

7. Is your pharmacy enrolled in the state immunization registry?
- ☐ Yes
- ☐ No
- ☐ Don't know/ Not sure

8. Is your pharmacy independently owned?
- ☐ Yes
- ☐ No
- ☐ Don't know/ Not sure

9. Does your pharmacy currently administer at least one type of vaccination?
- ☐ Yes, we administer Influenza + other types of vaccinations
- ☐ Yes, we only administer Influenza
- ☐ No, we don't administer any vaccinations
- ☐ Don't know/ Not sure

Thank you so much in advance for your help with my dissertation study! I look forward to hearing from you soon.

Tessa Hastings, MS, PhD Candidate
Health Outcomes Research and Policy
Harrison School of Pharmacy
Auburn University
Principal Investigator
tjh0043@auburn.edu | Fax: 334-844-8307

Appendix 23: Continuing Education Article

Improving Immunization Information System Implementation in Community Pharmacies

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Introduction

Immunization rates among adults in the United States remain unacceptably low. To address these low rates, the importance of collaboration between healthcare professionals is more important than ever. The "immunization neighborhood", a term coined by the American Pharmacists Association (APhA), has been used to model collaboration among healthcare providers and is defined as "collaboration, coordination, and communication among immunization stakeholders dedicated to meeting the immunization needs of the patient and protecting the community from vaccine-preventable diseases".[1] Pharmacists play a central role in the immunization neighborhood and pharmacy-based immunization services have been shown to improve immunization rates. In fact, the CDC estimates that 28% of all influenza vaccines in the 2017–2018 influenza season were administered by pharmacists.[2] Immunization services also present a financial opportunity for pharmacies, with a 25% immunization rate expected to drive a 6% increase in front-end sales.[3]

As a substantial number of patients receive vaccines from a pharmacist, it is imperative that documentation of these interventions be made available to all members of the healthcare team. The National Vaccine Advisory Committee (NVAC) Standards for Adult Immunization Practice provide recommendations to ensure that administered vaccines are adequately documented. The recommendations specific to community pharmacies include 1) providing the patient with a record of the vaccines administered, 2) reporting to the patient's primary care provider, and 3) recording administered vaccines in the state or regional immunization information system (IIS).[4]

Inadequate documentation of immunizations by pharmacy personnel within the pharmacy setting, including lack of reporting to physicians and IIS, has been cited as a concern among both patients and primary care providers. This has led patients to forego seeking immunization in the community pharmacy setting due to perceived improper documentation.[5] Physicians also report inadequate pharmacy documentation practices as a barrier to collaboration in the provision of immunizations.[6,7] Consolidated vaccine information reduces the provision of redundant vaccines, for which physicians are unable to be reimbursed.[8] In Alabama less than 25% of adults over the age of 19 have immunization data recorded in the state immunization information system, ImmPRINT.[9] Lack of pharmacy participation is a contributing factor as only 27% of Alabama pharmacies are enrolled. Participation of independent pharmacies is of particular concern as approximately 40% of Alabama pharmacies are independent, but only 4% of independent pharmacies are enrolled in the ImmPRINT. Improving documentation within the pharmacy setting is critical to not only improving immunization delivery in the community pharmacy setting, but also in ensuring that appropriate vaccines are administered in a safe and effective manner.

Therefore, after reading this continuing education article and reviewing the short demonstration videos online, the learner should be able to:

1. Describe the benefits of consolidated immunization documentation through immunization information systems.

2. Describe the steps to enroll in the Alabama immunization information system (ImmPRINT).

3. Identify the features of ImmPRINT used to assess, document, and provide patient records of immunizations.

Case

AJ, a 66-year old patient comes into your pharmacy saying, "my doctor said I need a tetanus shot". You gather from the Alabama immunization information system (ImmPRINT) that AJ has no documented Td or TDaP vaccines administered and he cannot recall ever getting one. Thus, you are able to determine that AJ does indeed need a tetanus shot and specifically which one: a TDaP.

What are Immunization Information Systems?

The above case illustrates how immunization information systems can be useful when patients' recall is unreliable. Also known as immunization registries, IIS are confidential, computerized databases that record and consolidate immunization doses administered by participating providers within a defined geographic area.[10] In the early 1990s, legislation was proposed to create a national registry as part of the Comprehensive Child Immunization Act of 1993. However Congress did not pass this legislation and thus individual states were charged with the responsibility of creating and maintaining their own IIS. Today, there are more than 50 IIS across the U.S. with states, territories, and some local jurisdictions maintaining their own system.[11] The Alabama IIS, Immunization Patient Registry with Integrated Technology, is known as ImmPRINT and is owned and managed by the Alabama Department of Public Health (ADPH). State systems function independently and have the authority to develop legislation surrounding the function of their IIS as they see fit. As such, the policies surrounding IIS vary by state.[12]

Immunization Information System Policies

Immunization information system policies vary from one state to another in terms of the types of patient consent required and provider participation mandates. The majority of states allow implicit patient consent with an opt-out condition, such as Alabama.[13] This means that in Alabama, consent by individual patient is implied. That is, it is not necessary to ask your patients' permission before entering their information in ImmPRINT.

Provider participation mandates refer to whether or not any type of providers are required to provide data to the IIS and under which circumstances.[13] In some states, including Mississippi and Georgia, it is mandatory for all providers to enter immunization data for patients.[12] A number of states have policies in which pharmacists are the only provider required to participate in the IIS. For example, in Kansas pharmacists are the only provider mandated to enter information, all other providers participate on a voluntary basis.[12] In Arizona pharmacists are mandated to document immunizations in the IIS for patients of all ages, while other providers are only mandated to enter data for children.[12] Recently, the California Board of Pharmacy approved regulations mandating pharmacy reporting to the California Immunization Registry.[14] In Alabama, providers are not currently required to enter patient information in ImmPRINT. However, as many states are moving toward mandatory provider participation Alabama providers, including pharmacists, should be participating in ImmPRINT to better prepare themselves for their role in the future.

Policies in different states vary in terms of whether providers are required to document vaccinations in the immunization information system. Pharmacist Avery who practices in both Alabama and Georgia needs to know the requirements. When she practices in Columbus, GA, she is required to document vaccinations. Even though it is optional in Alabama, she made it a habit to document vaccinations in Alabama's immunization information system.

Benefits of Provider Participation in Immunization Information Systems

Consolidated immunization records benefit patients, caregivers, providers, public health officials, and communities.[15] First, patients with access to accurate immunization records can ensure that they have received all their needed immunizations and will therefore be protected from vaccine-preventable diseases.[16] This also enables patients to receive timely immunization if they move or switch providers. Further, complete immunization records that are accessible in one location allow for patients to obtain official documentation that is often needed for school or childcare registration.

Immunization records containing accurate, up-to-date information are essential for providers, including pharmacists, to make decisions at the point of clinical care. Because patients' self-reported immunization history often is inaccurate, reliable history of patients' immunization is needed in order to determine which vaccine a patient may need and which have already been obtained elsewhere.[17] Without this information it becomes nearly impossible for providers to determine appropriate vaccinations a patient may need and ensure that individuals are not over or under-vaccinated. Consolidated records in immunization information systems equip providers with this information so they are able to reliably assess a patient's immunization status and recommend additional needed vaccines, thereby improving the care provided in their practice.[16] Finally, consolidated immunization information reduces the provision of redundant vaccines, for which the provider is unable to be reimbursed.[8]

The safety and effectiveness of vaccines are continuously monitored. Without complete records, it becomes difficult for public health officials to track adverse events and identify individuals affected in the event of a vaccine recall. Accurate immunization information is also critical in facilitating timely response efforts in the event of an outbreak. Immunization information systems also help prevent outbreaks by ensuring that community residents are up-to-date on immunizations. Consolidated immunization records allow public health officials to evaluate immunization coverage and identifying under-immunized populations before an outbreak occurs.[18] An example of the impact of under-immunization on community health is the occurrence of several measles outbreaks in recent years.[19-21]

To illustrate how immunization information systems can be used to benefit a community, an example from Hurricane Katrina will be used. In the days following Hurricane Katrina nearly 200,000 New Orleans residents evacuated to Houston, Texas. The personal records for most of these individuals had been left behind or lost in the catastrophe. In order to assist public health officials and healthcare workers caring for the evacuees in temporary shelters, the Houston-Harris County immunization information system and the Louisiana immunization information system were able to be linked, allowing healthcare workers in

Houston to access evacuees' records.[22] This effort allowed for the immunization status of children with a record in the immunization information system to be verified, meaning that they did not have to be revaccinated, saving approximately $3.04 million.[22]

Case

After you looked up 66-year old AJ's TDaP vaccination history documented in ImmPRINT, you notice that he has not received a zoster nor pneumococcal vaccine. You discuss the need for these vaccines with AJ and recommend Shingrix and PCV13. You tell him that in one year he will also need to get the PPSV23 and that he can get it at your pharmacy.

The Alabama immunization information system, also known as ImmPRINT, has the potential to be used in a similar manner if necessary, but the usefulness is dependent on the participation of all providers. The data available in immunization information systems is only complete and accurate if all providers are participating and providing this information accurately and in a timely manner. Because of pharmacists' increased role in immunization services, it is more important than ever that we enroll in ImmPRINT and properly document vaccinations to achieve the benefits described above.

Alabama Immunization Information System (ImmPRINT)

The Immunization Patient Registry with Integrated Technology, or ImmPRINT is the Alabama statewide electronic immunization information system. ImmPRINT is a population-based registry including all children born in Alabama since January 1993. Patients of all ages and those born outside Alabama may also be included in the system if they have visited a county health department or if their provider(s) are enrolled and participating in ImmPRINT. The purpose of ImmPRINT is "to be a reliable source for providing an accurate summary of vaccine histories for all Alabama patients".[23] ADPH provides assistance with provider enrollment, training, and support. Enrollment in ImmPRINT is at no cost for all providers. Additional ImmPRINT information can be found in the ADPH ImmPRINT Manual at https://www.alabamapublichealth.gov/immunization/immprint-manual%20.html.

ImmPRINT Site Enrollment and User Registration

Participation in ImmPRINT requires both enrollment at the site (pharmacy) level and registration at the individual user level (pharmacist or pharmacy technician). During the enrollment process, each pharmacy must designate a Site Administrator. The Site Administrator for independent pharmacies is required to be a pharmacist. The Site Administrator is responsible for ensuring that all pharmacy staff using ImmPRINT are properly trained and that users are activated and deactivated as appropriate. Once a Site Administrator has been designated, this individual should complete the Site Enrollment Agreement (SEA) at https://siis.state.al.us/ImmPrint/login/login.aspx. Upon completion of the SEA, an ADPH Immunization Compliance Manager (ICM) will contact the Site Administrator to activate the site and schedule a time to visit the pharmacy and conduct a face-to-face training session.

Prior to the face-to-face training session, individual pharmacy staff members should complete the user registration at https://siis.state.al.us/ImmPRINT/user/mou.aspx. During this process, new users will review and accept a Memorandum of Understanding and provide both user and primary site information. Individuals will select their "user type". Three types of users are included in ImmPRINT: Medical Authority, Vaccinator, and User. As vaccine administrators, pharmacists should select "Vaccinator/User". Pharmacy technicians who are using ImmPRINT to enter or review vaccination information and do not administer vaccinations should select "User". Once an individual has submitted their registration, the Site Administrator will be able to activate the individual from within their account or by contacting their local ICM.

All authorized users have a duty to maintain the integrity of the patient data contained within ImmPRINT. This responsibility includes protecting passwords and login information, and verifying user and site information each time the system is accessed. This is particularly important for users who are authorized to access ImmPRINT at more than one pharmacy location. Each time ImmPRINT is accessed, be sure that the correct site is selected and switch to a different site when appropriate. It is important to always remember to protect your account and patient data by logging out when your session is complete.

ImmPRINT Features

This section will describe how to document administered vaccines, how to identify needed vaccines, and how to print patient immunization records.

Documentation of Historical and Administered Vaccines

The most prominent function of ImmPRINT is the ability to consolidate all immunization records from any participating provider who has administered a vaccine for a particular patient in Alabama. As such, the primary feature is the Vaccination History. Within this function, users can view and update a patient's immunization history. In order to use this feature, users must first conduct a patient search. The first three letters of the patient's first name and their date of birth can be used to search for a patient. When necessary, unique identifiers inducing social security number, registry ID, or chart number can also be used. If your initial search is unsuccessful, repeat using different search criteria. All patients born in Alabama after January 1st, 1993 have profiles in ImmPRINT. If after multiple search attempts using a variety of search criteria you are still unsuccessful in locating the patient, you may create a new patient profile. Once the correct patient has been identified, the ImmPRINT user can proceed to the patient's chart to review details and update the patient's immunizations.

The Vaccine History page allows users to review the patient's immunization history and document provided vaccines. Two types of vaccines can be documented in ImmPRINT including historical and administered vaccines. Historical vaccines are defined as vaccines that were provided at another facility or on a previous date. Administered vaccines are defined as vaccines entered in ImmPRINT on the same day, by the site that administered the vaccine to the patient.

Example #1

Mrs. Smith is 68-year old patient picking up her prescriptions Monday morning at Main Street Pharmacy. Pharmacist Avery asks her about shingles vaccine, and Mrs. Smith says she already got one. Pharmacist Avery checks ImmPRINT and sees that it is the older shingles vaccine (Zostavax) and recommends Mrs. Smith get the first dose of Shingrix vaccine per CDC guidance. She also schedules an appointment for Mrs. Smith to come back in two months to get the second dose. That afternoon, Sarah Beth, a pharmacy technician at Main Street Pharmacy enters Mrs. Smith's Shingrix vaccine into ImmPRINT as an **administered vaccine**.

Example #2

During flu season, Main Street Pharmacy provides a number of influenza vaccines. Friday of each week Sarah Beth enters all of the influenza vaccines administered at Main Street Pharmacy for the week. Mr. James received an influenza vaccine on Tuesday of this week. When Sarah Beth enters his vaccination into ImmPRINT, she does so as a **historical vaccine**.

Example #3

Mrs. Hall visits Main Street Pharmacy to receive her pneumococcal vaccine. As Pharmacist Avery checks her vaccination history on ImmPRINT, she notices that Mrs. Hall hasn't received the influenza vaccine yet this year. Mrs. Hall informs Pharmacist Avery that she got her flu shot at a pharmacy across town last month. After calling the pharmacy to confirm that this vaccine was in fact received, Pharmacist Avery enters Mrs. Hall's influenza vaccine in ImmPRINT as a **historical vaccine** and the pneumococcal vaccine he administered that day as an **administered vaccine.**

When documenting historical vaccines, ImmPRINT users will need the date the vaccine was administered and the administered vaccine product's CVX description. Pharmacy staff should verify any patient self-reported immunizations prior to entering them in ImmPRINT as a historical vaccine. When documenting an administered vaccine, users will: 1) select the appropriate vaccine, 2) select the appropriate vaccinator and medical authority, 3) select the correct NDC code, and 4) provide other information such as administration site, route, and any adverse reactions.

Assessment and Recommendation of Additional Vaccines

Appropriately documenting historical and administered vaccinations is a responsibility of all providers who offer immunization services. In addition to this documentation function, providers are encouraged to use ImmPRINT to identify additional vaccines that their patients might need. The Vaccine Forecaster is a function of ImmPRINT that was developed to support this goal.

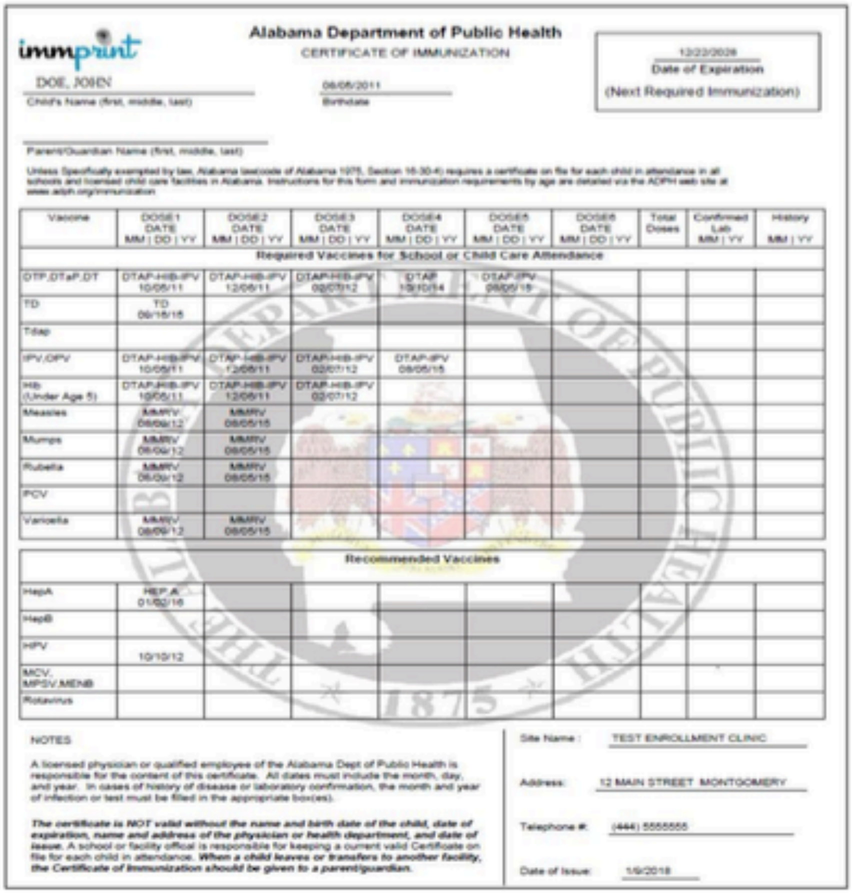
The Vaccine Forecaster is a tool to identify recommended vaccines as well as valid and invalid doses for a patient based on their immunization history recorded in ImmPRINT. The recommended vaccines in the Vaccine Forecaster are suggested according to the Advisory Committee on Immunization Practices (ACIP). Recommendations are updated in ImmPRINT as guidelines are revised and patient information displayed in the Vaccine Forecaster is updated in real time. As soon as an administered vaccine is documented in ImmPRINT, the forecaster is updated. This feature allows pharmacists and other providers, in real time, to determine which individuals received particular vaccines, as well as when and by whom.

A resource guide is available through APhA that describes best practices for applying the patient care process to pharmacy-based immunization services.[1] When a patient requests or is identified as potentially needing a vaccination, the pharmacist or pharmacy technician should first check ImmPRINT to ensure that this particular vaccine has not already been administered elsewhere. The Vaccine Forecaster can then also be checked to identify any additional vaccines the patient might need. After discussing the need of being vaccinated with the patient, the pharmacist would then administer the needed vaccine(s) and document the immunization in ImmPRINT as described above.

Certificate of Immunization and Parent/Patient Card

Patients may at times request immunization records from the pharmacy. Pharmacies are able to provide valid Certificates of Immunization (COI) through ImmPRINT. The COI is issued according to Alabama State Vaccine Requirements and is mandatory for all patients attending public or private schools. A COI may also be requested for children registering for childcare. However, the COI is only available to be printed from ImmPRINT if the patient is up to date on all school-required vaccines. When making this assessment, ImmPRINT evaluates the student's age, grade-level, documented vaccines in ImmPRINT, and any recorded exemptions. If all of the requirements have been met, ImmPRINT will generate an official COI with the ADPH seal transposed and ImmPRINT logo (Figure 1). Pharmacists and pharmacy technicians can then print this document for their patient. This is the only official document accepted by schools and childcare facilities in the state of Alabama, and it can only be accessed through ImmPRINT.

Figure 1. ADPH Official Certificate of Immunization



immprint

Alabama Department of Public Health

CERTIFICATE OF IMMUNIZATION

DOE, JOHN
Child's Name (first, middle, last)

08/08/2011
Birthdate

12/22/2028
Date of Expiration
(Next Required Immunization)

Parent/Guardian Name (first, middle, last)

Unless Specifically exempted by law, Alabama law(code of Alabama 1975, Section 16-30-4) requires a certificate on file for each child in attendance in all schools and licensed child care facilities in Alabama. Instructions for this form and immunization requirements by age are detailed via the ADPH web site at www.adph.org/immunization

Vaccine	DOSE1 DATE MM | DD | YY	DOSE2 DATE MM | DD | YY	DOSE3 DATE MM | DD | YY	DOSE4 DATE MM | DD | YY	DOSE5 DATE MM | DD | YY	DOSE6 DATE MM | DD | YY	Total Doses	Confirmed Lab MM | YY	History MM | YY
Required Vaccines for School or Child Care Attendance									
DTP,DTaP,DT	DTAP-HIB-IPV 10/05/11	DTAP-HIB-IPV 12/06/11	DTAP-HIB-IPV 02/07/12	DTAP 10/10/14	DTAP-IPV 08/05/15				
TD	TD 09/16/15								
Tdap									
IPV,OPV	DTAP-HIB-IPV 10/05/11	DTAP-HIB-IPV 12/06/11	DTAP-HIB-IPV 02/07/12	DTAP-IPV 08/05/15					
Hib (Under Age 5)	DTAP-HIB-IPV 10/05/11	DTAP-HIB-IPV 12/06/11	DTAP-HIB-IPV 02/07/12						
Measles	MMRV 08/09/12	MMRV 08/05/15							
Mumps	MMRV 08/09/12	MMRV 08/05/15							
Rubella	MMRV 08/09/12	MMRV 08/05/15							
PCV									
Varicella	MMRV 08/09/12	MMRV 08/05/15							
Recommended Vaccines									
HepA	HEP A 01/02/16								
HepB									
HPV	10/10/12								
MCV, MPSV,MENB									
Rotavirus									

NOTES

A licensed physician or qualified employee of the Alabama Dept of Public Health is responsible for the content of this certificate. All dates must include the month, day, and year. In cases of history of disease or laboratory confirmation, the month and year of infection or test must be filled in the appropriate box(es).

The certificate is NOT valid without the name and birth date of the child, date of expiration, name and address of the physician or health department, and date of issue. A school or facility offical is responsible for keeping a current valid Certificate on file for each child in attendance. ***When a child leaves or transfers to another facility, the Certificate of Immunization should be given to a parent/guardian.***

Site Name : TEST ENROLLMENT CLINIC

Address: 12 MAIN STREET MONTGOMERY

Telephone #: (444) 5555555

Date of Issue: 1/9/2018

When printing a COI for school or childcare, it is recommended to also print a parent/ patient card for the patient's own record. The patient/parent card includes similar information as the COI and Vaccine Forecaster. This card lists vaccines administered, the date administered, and vaccines recommended in the future with anticipated due dates. An example of the patient/parent card is provided in Figure 2.

Figure 2. Patient/Parent Card

immprint

Alabama Immunization Record

Patient Name: TEST, TEST
Date of Birth: 03/20/2017 **Chart No.:**
Parent(s) Name: OUTSIDEAL TEST

AUBURN UNIVERSITY
PHARMACEUTICAL CARE CENTER
2155 WALKER BUILDING
AUBURN, AL 36849-5501
334 8444099

Vaccine	Vaccine Given	Date Given	Physician or Clinic
Diphtheria, Tetanus, Pertussis (DTaP, DTaP-Hib, DTaP-HepB-IPV, DT, Tdap, Td, DTaP-Hib-IPV)	DTAP	08/01/18	OUTSIDE CLINIC
	DTAP-IPV	12/06/18	OUTSIDE CLINIC
	DTAP (DAPTACEL)	12/11/18	OUTSIDE CLINIC
	DTAP-HEP B-IPV	12/11/18	OUTSIDE CLINIC
Polio (IPV, DTaP-HepB-Hib, DTaP-Hib-IPV)	DTAP-IPV	12/06/18	OUTSIDE CLINIC
	DTAP-HEP B-IPV	12/11/18	OUTSIDE CLINIC
***Haemophilus influenzae* type b** (Hib, HepB-Hib, DTaP-Hib, DTaP-Hib-IPV)	HIB (PRP-T)	08/09/18	OUTSIDE CLINIC
Measles, Mumps, Rubella (MMR, MMRV)			
Varicella (Var, MMRV)			
Hepatitis A (HepA, HepA-HepB)			
Hepatitis B (HepB, HepB-Hib, DTaP-HepB-IPV, HepA-HepB)	HEP B UNS	03/20/14	OUTSIDE CLINIC
	DTAP-HEP B-IPV	12/11/18	OUTSIDE CLINIC
Human Papillomavirus(HPV)			
Meningococcal (MCV4, MPSV4)			
Pneumococcal (PCV, PPV)			
Rotavirus (Rota)			
Influenza (TIV, LAIV)	IIV4 P-FREE PED	11/05/18	OUTSIDE CLINIC
	INFLUENZA UNS	12/10/18	OUTSIDE CLINIC

Case

AJ wants to talk with his primary care physician first about Pharmacist Avery's recommendations for the Shingrix and PCV13 vaccines. Pharmacist Avery then printed the patient card from ImmPRINT for AJ so that he can take it to his primary care physician.

Doses Administered Report

All pharmacy ImmPRINT users are able to establish patient lists and run reports to assess the status of their patient population. The Doses Administered Report (Figure 3) provides a summary of the number of doses of each vaccine administered to the pharmacy's patients by age group. Community pharmacists should find this feature useful as it provides an aggregate report to assess the number of vaccine doses administered to their patients for each vaccine within a given timeframe. This data can be used to assess the effectiveness of specific initiatives (eg, marketing, personal recommendation) on increasing vaccine doses administered.

Figure 3. Doses Administered Report

REGISTRY DOSES ADMINISTERED REPORT

TEST PHARMACY

1/1/2018 - 5/18/2018

Run Date: 05/18/2018

East Central District

MONTGOMERY

TEST PHARMACY

Vaccines	Age in Months			Age in Years							
	<12	12-23	24-35	3-6	7-12	13-18	19-29	30-49	50-64	65+	All
DTAP	1	0	0	0	0	0	0	0	0	0	1
HPV9	0	0	0	0	0	1	0	0	0	0	1
IIV4	0	0	0	0	0	0	0	1	0	0	1

Vaccines for Children

Providers who enroll in ImmPRINT are eligible to participate as Vaccines for Children (VFC) program providers. The VFC program provides ACIP recommended vaccines at no cost to children who meet eligibility requirements including those who are Medicaid eligible, uninsured, underinsured, or American Indian or Alaskan Native ethnicity. Community pharmacies are currently permitted to provide immunizations through the VFC program in many states, and starting from 2018 community pharmacies have been authorized to become VFC providers in Alabama. Free vaccines are shipped to pharmacies enrolled as VFC providers to be provided at no cost for VFC-eligible patients. This reduces the cost of purchasing the vaccine and provides the opportunity to build relationships with new patients who might not otherwise have visited your pharmacy. All VFC providers must enroll and actively participate in ImmPRINT. For those who are interested and would like to know more information and apply to become a VFC provider, please visit http://www.alabamapublichealth.gov/immunization/vaccines-for-children.html.

Recommendations for Pharmacies

Proper documentation of provided immunizations is necessary to identify which vaccines are needed for individual patients so that opportunities are not missed and individuals are not over-vaccinated. However, IIS information is only useful if all providers participate. This includes any healthcare professional administering vaccines, especially pharmacists. While manually documenting vaccinations can be time-consuming, many pharmacies have successfully incorporated ImmPRINT into their pharmacy workflow.

One approach to lessen the burden of documentation is developing a team-based approach. The pharmacist does not necessarily have to be the only individual responsible for assessing immunization status and documenting vaccines administered in ImmPRINT. Many pharmacies have had success incorporating other pharmacy team members in this role. Pharmacy technicians can gather immunization history from ImmPRINT and also document the information after a vaccine has been administered. This team-based approach divides the labor among staff, making the process more efficient. Further, determining the ideal time for documentation in your pharmacy's workflow can also make the process more efficient. Some pharmacies have become quite successful integrating documentation so that it is done immediately after the vaccine is administered. Others might find that storing administered vaccine information in a designated location and inputting all information once per day, during downtime is ideal. Examine your needs and determine which strategy might be the right fit for your pharmacy.

For those who wish to shift from a manual to an automatic process in documentation, we encourage you to discuss this with your vendor. The ability to automatically exchange immunization information through the pharmacy dispensing software allows pharmacy staff to remain within their typical workflow when providing vaccinations. Some software vendors do have this functionality that can be made available to your pharmacy for a fee. To learn more, contact your vendor to determine individual costs and requirements.

Conclusion

Incomplete immunization records are a concern both at the population level and at the point of clinical care. Alabama's immunization information system, ImmPRINT, has been developed to help mitigate the concern of incomplete immunization records by consolidating immunization information from participating providers. However, pharmacy participation is critical in maintaining a complete and accurate immunization information system among Alabamians that can be used in the safe and effective administration of vaccines.

Next Steps:

1. **Review the accompanying videos**
2. **Complete the post-assessment at https://auburn.qualtrics.com/jfe/form/SV_7WcunQ3YpzsveVn**
3. **Register your pharmacy as an ImmPRINT site at: https://siis.state.al.us/ImmPrint/login/login.aspx**

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Appendix 24: Implementation Quick Start Guide

ImmPRINT Quick Start Guide

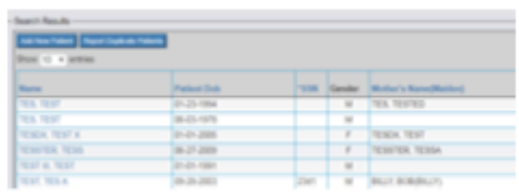
ImmPRINT Site Enrollment and User Registration

Step 1: Complete the Site Enrollment Agreement at https://siis.state.al.us

Step 2: Each pharmacy user complete the New User Registration

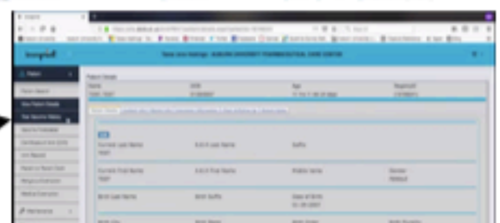
Patient Search

Step 1: Enter the first three letters of the patient's first name and their DOB and click "Search" at the bottom right of the page



Step 2: Click on your patient's name to proceed to their chart

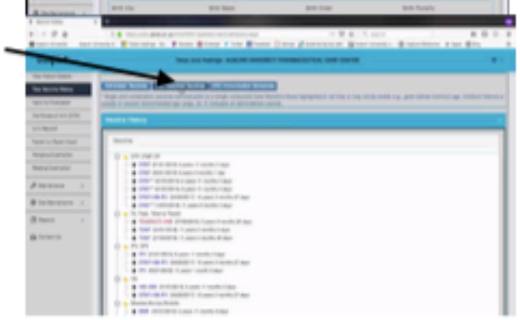
Document Vaccines



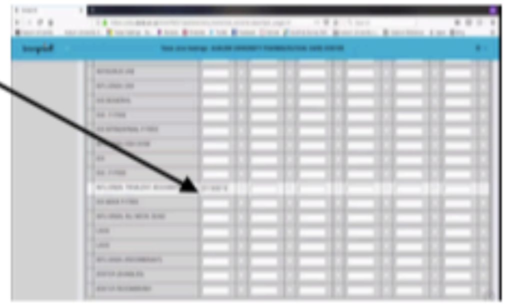
Step 1: Click Tree Vaccine History

Historical Vaccines

Step 2: To document vaccines provided at another location OR on a previous date, click "Add Historical Vaccines".



Step 3: Find the vaccine you wish to document and enter the date administered in the text box.



Step 4: If the vaccine was administered at your pharmacy on a previous date click the check box to the right of the text box. If the vaccine was administered at another location, do not click the check box.

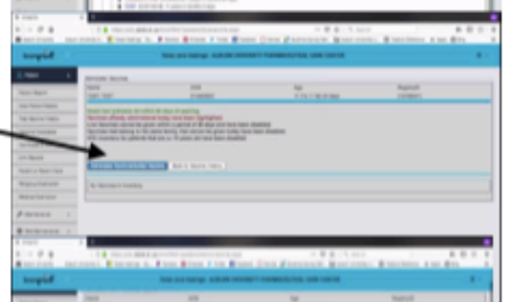
Step 5: Proceed to the next page and select the appropriate CVX description.

Step 6: Submit

Administered Vaccines

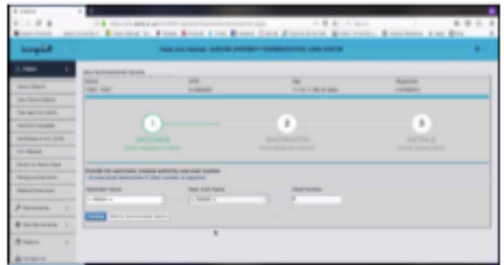
Step 2: To document vaccines provided at your location on the same day you are documenting the information in ImmPRINT, click "Administer Vaccines"

Step 3: Click "Administer Non-Inventoried Vaccine" (unless your vaccines are inventoried in ImmPRINT)



Step 4: Select the Vaccine and click continue

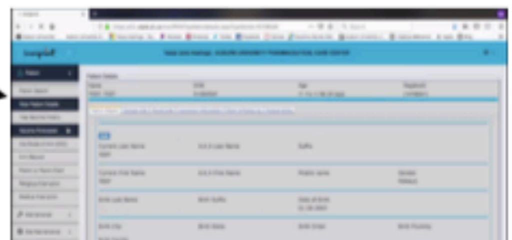
Step 5: Add Vaccinator name and Medical Authority Name



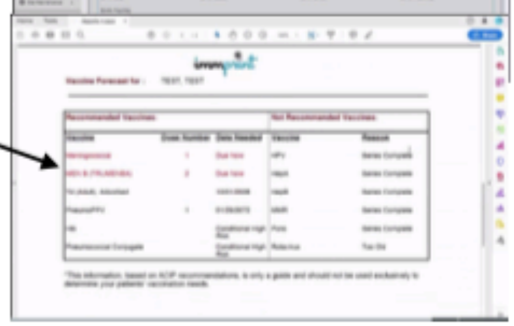
Step 6: Select NDC Code and add details including site, route, etc. and "Save"

Check for Needed Vaccines

Step 1: Click "Vaccine Forecaster" on the left hand side of the homepage.



Step 2: A pdf of the Forecast will download. At the bottom of this pdf, you will find a list of the recommended vaccines in red.



For more detailed information, watch the demonstration videos at https://www.alabamaimmunizers.com/videos or visit the ADPH ImmPRINT manual at https://www.alabamapublichealth.gov/immunization/immprint-manual%20.html

Appendix 25: Comparison of Three Month Responder and Non-Responder Characteristics

Demographic comparison of three month responders and non-responders

Characteristic	Three Month Responders (N=33)	Three Month Non-Responders (N=8)	p-value [a]
	N (%)		
Sex			
Male	17 (51.5)	5 (62.5)	
Female	16 (48.5)	3 (37.5)	0.703
Race			
White	33 (100)	8 (100)	-
Ethnicity			
Hispanic	0 (0)	1 (12.5)	
Non-Hispanic	32 (100)	7 (87.5)	0.200
Job Title			
Staff Pharmacist	17 (51.5)	5 (62.5)	
Manager	14 (42.4)	2 (25)	
Owner/Partner	11 (33.3)	3 (37.5)	0.721
Pharmacist Education			
B.S. Pharm	6 (18.2)	4 (50.0)	
PharmD	27 (81.8)	5 (62.5)	
Residency	2 (6.1)	0 (0)	
Masters	0 (0)	1 (12.5)	
Other	2 (6.1)	0 (0)	0.185
Rurality[b]			
Rural	8 (24.2)	3 (37.5)	
Non-Rural	25 (75.8)	5 (62.5)	0.658
	Mean (SD)		**p-value [a]**
Pharmacist Age	40.64 (11.5)	48.13 (8.7)	0.094
Number of years practicing as a pharmacist	13.86 (11.6)	22.43 (10.6)	0.081
Number of years practicing at current site	7.84 (10.4)	20.00 (11.1)	**0.009***

[a] Analyzed using Fisher's exact and Chi-square test of homogeneity and two-tailed Mann-Whitney U tests for categorical and continuous data, respectively.

[b]Pharmacies classified as rural vs. urban using the Alabama Rural Health Association definition (Alabama Rural Health Association, 2011).

Immunization documentation practices comparison of three month responders and non-responders

Characteristic	Three Month Responders (N=33)	Three Month Non-Responders (N=8)	p-value[a]
	n (%)		
ImmPRINT Enrollment Status			
Correctly identified	17 (51.5)	5 (62.5)	0.849
Incorrectly identified	6 (18.2)	1 (12.5)	
Don't Know/ Not sure	10 (30.3)	2 (25.0)	
Maintain documentation in pharmacy			0.195
Yes	33 (100)	7 (87.5)	
No	0 (0)	1 (12.5)	
Provide documentation to physician			
Yes	10 (30.3)	4 (50.0)	0.493
No	21 (63.6)	4 (50.0)	
Don't Know/ Not sure	2 (6.1)	0 (0)	
Method of providing documentation to physician			0.184
Fax	10 (30.3)	3 (37.5)	
Phone	1 (3.0)	1 (12.5)	
Delivered by patient	2 (6.1)	1 (12.5)	

[a] Analyzed using Chi-square test of homogeneity

Appendix 26: Video Completion

Video	Number of Quizzes Taken	Average Content Viewed	Average Score
Site Enrollment Agreement	14	61%	100%
User Registration	15	64%	80%
Patient Search	14	65%	100%
Add a New Patient	13	69%	92%
Establish Patient List	13	74%	31%
Document Historical and Administered Vaccines	13	68%	100%
Add New Lot Number	13	71%	92%
Forecast Needed Vaccines	13	72%	92%
Print Certificate of Immunization and Patient/Parent Card	13	73%	92%