Pharmacists as Immunizers: Increasing Non-Influenza Adult Immunization Rates

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Kimberly Mace Plumly Drew University Madison, New Jersey August 2020

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<u>Abstract</u>

Currently adult immunization rates in the United States are low. According to the Centers for Disease Control (CDC), in 2016, ~26.6% of adults have received the Tdap vaccine, ~33.4% of adults over 60 have received Herpes Zoster vaccine, and only 23.7% and 24.5% of adults \geq 19 years of age received hepatitis A vaccination and hepatitis B vaccination respectively in 2016.¹

This dissertation aims to examine non-influenza adult vaccination rates in the United States and the barriers to administration across healthcare settings and stakeholders. These settings include the physician office and pharmacy while stakeholders include HCPs in these settings and consumers.

I aimed to understand where adults are getting their information about vaccines. And who and what would influence them to be vaccinated. Due to various challenges, office-based Health Care Providers are resistant to stocking vaccines in their office. Furthermore, these HCPs are focused on disease management rather than prevention.

I hypothesized that the community pharmacist can help improve adult immunization awareness and administration. However, pharmacists in most states are licensed to administer adult vaccines yet the rates are still low indicating barriers to address in this healthcare setting.

This dissertation references the CDC and Advisory Committee on Immunization Practices as the vaccine sources of truth. In order to best understand the current situation for adult immunizations in the Unites States, next to a review of the literature, I engaged

¹ CDC, "Vaccine Coverage Among Adults in the United States, National Health Interview Survey, 2016," AdultVaxView, accessed January 20, 2020, <u>https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2016.html</u>.

in qualitative research and developed a survey shared with practicing bench pharmacists and retail pharmacy decision makers. I asked questions to understand their connectivity to being an immunizer and what the biggest barriers to increasing adult immunizations in the pharmacy are. The responses confirmed my suspicions that through the support of ancillary staff, like the Pharmacy Technician, and via visual culture there is an opportunity to improve the process and experience of receiving an immunization in the pharmacy. With some simple adjustments, pharmacies are well poised to help raise the rates. This dissertation is dedicated to Penn and Bentley Plumly Set intentions, be courageous, have persistence If you believe in yourself, you will achieve your dreams

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Vita

Forward

Having spent eleven years in the Drew University Medical Humanities program as a part-time student, I've come to realize that medical humanities influences the way I think about progress, time, relationships, and vaccines. I originally decided to pursue medical humanities in 2009, having spent two and half years as a pharmaceutical sales representative in northern New Jersey I started to notice patterns of behavior across patients, Health Care Practitioner (HCP) offices, and physician prescribing habits. The conversations I had led me to believe that doctors were being squeezed for time, their schedules were triple, or quadruple booked all day every day. Primary Care Physicians (PCPs) were no longer able to complete hospital rounds to check in on critical patients. Hospitalists were introduced to keep an eye on those patients requiring hospitalizations, taking the burden from the PCP. The physician patient relationship started to become strained as these new practitioners appeared when patients are in the direct medical need. Practices that were traditionally the responsibility of physicians were delegated to ancillary office staff starting with nurses and medical assistants. An explosion of other kinds of prescribers like nurse practitioners and physician assistants began substituting for the physician. Blood draws were delegated to lab phlebotomists rather than in the physician office, other tests became available in small clinics and urgent care facilities where you did not need an existing history or relationship to receive a diagnosis.

Vaccines became a seasonal phenomenon as flu immunizations became widely available even beyond the walls of the physician office in places like the pharmacy and even the place of work during health clinics. The standard of care became more aligned

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to outcomes defined by the Affordable Care Act and less about physician clinical experience. All of these changes became overwhelming as I traveled from office to office and across multiple hospitals and health systems in northern New Jersey. I began to hear a reoccurring conversation about selling independent practices as health systems vertically integrated becoming big entities to foster better negotiations with wholesalers, distributors, insurers, and pharmaceutical manufacturers. These large systems continued to redefine the physician patient relationship, limiting access and continuing to confuse the patient with new advanced practice players, group practices, and multiple office locations. I was witnessing a healthcare revolution and I was wondering where the voice of the patient, i.e. the consumer, was in this process.

For this reason, I was drawn to my humanities background having studied anthropology and women's studies as an undergraduate. As someone concerned about marginalization, equality, and cultural values I felt humanities could provide a lens as the healthcare revolution evolved. Rather than pursue an MBA or even MPH as many of my counterparts were exploring, I wanted to draw on my humanities passion and background to make a difference.

I began the Drew Medical Humanities program in the fall of 2009 and completed a masters by May 2012. I was thrilled to take elective courses across many areas in the multidiscipline approach that the humanities embrace. The somewhat unpopular biomedical ethics course was standout to me. Here was a discipline designed to discuss the problems I was noticing. What are the ethical dilemmas with healthcare reform? The introduction of genetic modifications and Invitro Fertilization raises ethical concerns that need a forum for discussion and policy making.

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I was also struck during medical narrative where I saw the value of narrative from multiple perspectives, the patient story and the physician story. Western Medicine, in my experience, is ripe with metaphors and dichotomies; diseases are described metaphorically to help us make sense of complicated biological and physiology processes. Organisms are described in the context of machines, partly for reductionist simplicity, but also in alignment with modernization and the industrial revolution. The consequence, simply stated, is the separation of the mind from the body. I practice yoga and try to practice balance in my life. I believe in the mind body connection. Western medicine in its subspecialty approach defines illness via disease and not an entire state of being. Medical narrative is an example where these thoughts and connections can be reestablished. The physician writer can articulate the metaphors and experience them in new ways. Here is an avenue to bring humanities into the practice of modern medicine!

Ancient medicine was also a favorite class for me. Going back to Asclepius and Hippocrates, learning about horrific human experimentation in vivisection that provides us the anatomical knowledge we use today was fascinating. Modern medicine is derivative of these philosophies. Surgeons, once called butchers and hacks, evolved into the hierarchy of physicians and sub specialties known today. Over time the practice of medicine changes. Physicians of the past placed their ears on their patient's chests to hear the heartbeat. Now there are stethoscopes and even 3-D imaging of the heart. The medical evolution through technology is not necessarily in favor of the patient, who loses the human connection with their physician through touch. The context of medicine as prevention is also blurred as the physician patient relationship is separated through technology and advanced practice healthcare extenders. If patients are looking for

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preventative advice, who are they seeking this from? Is it the internet or one of the many different HCPs they encounter? Is the advice as meaningful when it comes from someone they do not have a continuous relationship with? What does this mean for preventative interventions like vaccines, mammograms, PSA tests? Will a patient act on a preventative or diagnostic recommendation, that may be unpleasant for them, from someone they have not established trust with?

I also took courses in healthcare leadership and board work. As I continued to have the conversations with physicians and other health care providers during my daywork and apply the theoretical and humanities during my schoolwork I began to see myself as a healthcare leader. At the same time, I was very interested in further studies in biomedical ethics, particularly in the context of clinical trials and human subject research. Working for a pharmaceutical company, clinical research is paramount to bringing medications and biologics, like vaccines, to market. How are we making sure patients are protected in these studies? What codes and conduct are expected and monitored to make sure there is informed consent? How do you define informed consent for patients who may not have full decision making? Is it appropriate to delegate decision making on these things to someone else, even a loved one? These topics were important for me to start seeing the end to end process of bringing the therapies I was selling, and soon to be marketing to patients.

I decided to write my master's thesis on the implementation of Electronic Medical Records (EMR). I argued that EMR contributed to increased computer gazing and separation of HCP from the patient. What is the right intersection of technology with the art of medicine?

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Perhaps one of the most interesting courses to me was Art and Medicine. In this class I saw the history of medicine via visual arts, the progression of disease through the eyes of the artist, discussed how art can influence therapy, and finally began to think about how art positively impacts my life. For example, during my father's fight with myelofibrosis, a rare blood cancer, I gravitated to drawing. I bought colored pencils and sketch books and brought them with me to his hospital bedside. The time of stress induced me to flex the creative elements in my brain. I walked through the halls of the oncology center at Dartmouth Hitchcock and began to examine what was on the walls and in the hallways. Portraits of important physicians and former patients mixed with watercolors and landscapes. A life-sized sculpture of a Moose, colorful carpets, turquois handrails and stairs, golden frames, and fountains in a courtyard greeted my investigation. Art can make us comfortable. It established a connection with creativity and encourages positivity. Visual art can relay a narrative without sounds. I took note of these things and thought about how I could infuse art into vaccine conversations with pharmacy decision makers.

I went back to my marketing job in Philadelphia inspired to bring visual art into my next presentation. Images that promote the positive aspects of vaccines and partnership. The result was a presentation our customers had never experienced before. It made the presentation memorable and stand out from others. It kept the topic of vaccines top of mind, an important step as we continued to ask for more opportunities to provide resources and education to their pharmacists to help them become better equipped as vaccinators.

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I have included this reflection on my medical humanities highlights to showcase how medical humanities can even influence pharmaceutical marketing. There is important work to be done to repair the physician patient relationship and to bring vaccines into the wellness paradigm. In my dissertation I will address the later. I hope you as my reader will pick up the medical humanities threads throughout my work. Vaccines is usually a topic of public health. My position is that medical humanities can influence and impact all aspects of medicine, including raising adult immunization rates.

Introduction

As a mother, a concerned citizen, a medical humanist, and a marketer for the largest vaccine manufacturer in the world, I am passionate about educating those in my life and the general public about the importance of vaccination. I believe we must vaccinate to protect ourselves, those we are responsible for, and the community against vaccine preventable diseases. Working exclusively in the adult vaccine space, I am privy to know how poor the immunization rates are for adults in the United States. The rates are even poor for Center for Disease Control (CDC) recommended adult vaccines like flu, pneumococcal, Tdap, and shingles. Having worked as regional director in the sales organization with our childhood vaccines I am aware of state programs and mandates driving vaccine utilization at much higher rates in children than in adults in the US. Despite recent years having shown an increase in the number of vaccine preventable disease cases in children, due to the anti-vaccine movement and vaccine hesitancy, the childhood vaccine schedule and mandates have modeled success at raising the rates and vaccine awareness in this country. I have set out to learn more about the drivers and barriers impacting the low adult immunization rates and what can be done to improve them.

Focus and Scope

This dissertation will examine adult vaccine rates in the United States and the barriers to administration across healthcare settings and stakeholders. These settings include the physician office and pharmacy while stakeholders are the physician, nurse, pharmacist, pharmacy technician, and patient/consumer. This work is mostly concerned

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with non-influenza adult vaccines because flu immunizations are a unique market that does not represent other adult vaccines in the United states.

According to the Centers for Disease Control (CDC), in 2016, ~26.6% of adults have received the Tdap vaccine, ~33.4% of adults over 60 have received Herpes Zoster vaccine, and only 23.7% and 24.5% of adults \geq 19 years of age received hepatitis A vaccination and hepatitis B vaccination respectively in 2016.² These rates are low because of several barriers that may be addressed with education and practical solutions provided in this dissertation.

Current barriers impacting adult vaccines in the US include misinformed or uneducated consumers and unwilling office-based Health Care Providers (HCPs.) I have set out to understand where adults are getting their information about vaccines. Where and why do they choose to receive a vaccine? And what would influence them to do so. Due to difficulties with storage, administration, reimbursement, and cash flow impacts of the buy and bill model, office-based Health Care Providers are resistant to stocking vaccines in their office. Vaccine hesitancy makes it easier to ignore the problem of low adult immunization rates while focusing on disease management rather than prevention.

Research Question

My hypothesis is that the community pharmacist can help improve adult vaccine awareness and administration. Unlike the physician office, the community pharmacy offers an easy and convenient option, no appointment necessary. Pharmacies are well

² CDC, "Vaccine Coverage Among Adults in the United States, National Health Interview Survey, 2016," AdultVaxView, accessed January 20, 2020, <u>https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2016.html</u>.

equipped in handling adult vaccines and storing temperature-controlled products. Pharmacists in most states are licensed to administer adult vaccines yet the rates are still low. My primary research questions are:

How can the community pharmacist contribute to improving the adult immunization rates in the United States? How can the community pharmacist assist in overcoming the barriers to adult immunization?

There are current efforts to increase immunization rates through programs like Vaccines For Children (VFC) and state specific school mandates, yet there is still work to do to understand application to adults. I hypothesize that there is more than one solution to improve low adult immunization rates. Although this dissertation hypothesizes the community pharmacy as the primary solution to increasing adult immunization rates, I also seek to understand the ethical implications surrounding adult vaccine mandates.

Other areas of consideration are access to vaccines, including healthcare coverage and logistics, and vaccine perceptions and fears for different generations of adults. Celebrity and political figures representing the anti-vaccine movement influence parents about their decisions to vaccinate their children and themselves. Ideas that vaccines don't work or give you the disease you are planning to protect with the vaccine continue to mystify the value of getting vaccinated. Popular culture influences how we perceive vaccines. We call them shots. The nurse stabs or jabs you with a vaccine. Images from the history portraying Jenner inoculating children show the patient curling away in terror or pain as unwilling subjects. These examples contribute to the continued controversy regarding vaccines and to low adult acceptance of vaccines.

In this dissertation I explore solutions surrounding how to better leverage the community pharmacy as the destination for adult vaccines. I address this in two ways;

pharmacist activation and consumer awareness. I also report the current policies in place regarding the pharmacist's scope of practice and make recommendations for policy reform that will enhance the efforts of the pharmacist. This dissertation has practical application and aims to speak to a wide audience including the CDC, consumers, patients, pharmacists, and non-pharmacy Health Care Providers (HCPs.) It is a rally cry to improve the currently very low adult vaccine rates.

Overview of Controlling Argument and Approach

In order to demonstrate that adult vaccination rates can be improved, I hypothesize that increasing comfort in administering vaccinations in the community pharmacy for both pharmacy personnel and consumers is the best use of existing resources. While most experts in this subject primarily focus on educating pharmacists around engaging patients in the pharmacy,³ I believe that educating the pharmacy technician is just as important. I also postulate that activating the consumer is critical. Because adult immunization rates are very low, I suppose a combined effort from the community pharmacy as well as the United States government. Furthermore, I suppose to increase adult immunizations, it will take a community effort, including the CDC and local governments, vaccine manufacturers, pharmacist organizations, and collaboration with large pharmacy chains. This collaboration will flow from headquarters to bench staff.

³ Nathan Spann, "Patient Engagement Strategies for Immunization in a Community Pharmacy Setting," *Pharmacy Times* (August 1, 2018), accessed May 9, 2020, <u>https://www.pharmacytimes.com/publications/supplementals/2018/zosteraugust2018/patient-</u> engagement-strategies-for-immunization-in-a-community-pharmacy-setting.

Methodology

Approach and Survey of existing discussions

In this dissertation I used the CDC and Advisory Committee on Immunization Practices (ACIP) as the vaccine sources of truth in the United States. CDC is charged with oversight for infectious diseases and immunization practices in the US. ACIP is an arm of CDC comprised of "medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States. The recommendations stand as public health guidance for safe use of vaccines and related biological products."⁴ The ACIP guidelines are the governing guidance on the safe use of immunizations for children and adults. In my experience physicians and pharmacists use these guidelines to help them make the best vaccine recommendations for patients. They will also use the guidelines to determine catch up schedules and booster guidance.

I was also interested in what vaccine enthusiasts and subject matter experts are saying about the current adult immunization rates and how the community pharmacy can intervene. I initially reviewed articles produced by the American Pharmacists Association (APhA) by Michael D. Hogue, Bruce Berger, and JD Grabenstein, three of the most prominent voices in driving awareness around vaccines in the pharmacy. Articles date back to the early 2000s through the present and offer advice for the pharmacist yet still leave us with low adult immunization rates. The Pharmacy Times publishes an immunization special report annually that taps into insights from pharmacist

⁴ CDC, "General Committee Related Information," ACIP, accessed Mary 9, 2020, <u>https://www.cdc.gov/vaccines/acip/committee/index.html</u>.

educators and pharmacist decision makers from leading industry chains. I believe this is the best source to understand the current conversation and what ideas are circulating to improve adult immunization rates.

Journals such as Pharmacy Today and Drug Topics also provide ideas about how pharmacists can implement vaccine protocols into their practice. They focus on business models and reimbursement and less on the problems related to fitting vaccination into the workflow. Many of the articles offer ideas but do not offer instruction. For example, a recent special report in the Pharmacy Times includes insights around the value in tapping into the Immunization Information Systems (IIS) but fails to address how to accomplish this.

The biggest gap in the current conversation is a lack of acknowledgement that proactively identifying patients through their pharmacy record or by conversation requires time and effort outside of the pharmacy workload. I have not yet read an article that speaks to the value of the pharmacy technician and their role in bridging the gap. I suspect the technician can help by identifying and educating patients and transferring them to the pharmacist for vaccine administration. I also do not find robust discussion around consumer activation and how to create awareness of adult vaccines other than flu in the pharmacy. It is evident these subject matter experts are leaving out a critical stakeholder in driving awareness in the pharmacy setting, the pharmacy technician. The existing literature fails to consider how to drive awareness to the consumer outside of the pharmacy.

Summary of research materials and methods

In order to best understand the current situation for adult immunizations in the Unites States as well as the barriers to improving the rates, next to a review of the literature, I engaged in qualitative research to arrive at my conclusions. I surveyed existing materials in journals, Centers for Disease Control (CDC) and National Institute of Health (NIH) studies and reports, and internet searches and sites for anti-vaccine sentiments. For the qualitative research, I conducted an online survey via Google Forms with licensed pharmacists to understand more about their biases, beliefs, and barriers to providing adult immunizations.

Methods

I wanted to know more about the pharmacist and the pharmacy technician and if they are ready for activation according to my hypothesis. I sought to understand what it takes to remove current barriers that stand in the way of their successful execution of administering vaccines in the pharmacy. In order to answer these questions, I conducted original qualitative research approaching the subject matter from multiple angles.

First, to uncover the current state of adult immunization practice and policy I explored the conversation in journals. Pharmacy journals offer many ideas around how to incorporate vaccine protocols in the pharmacy. Second, I conducted extensive qualitative and quantitative research to better understand the thoughts, beliefs, and behaviours that pharmacists have around administering vaccines in the pharmacy. I sought to understand the barriers from their perspectives. Third, I explored physician journals and research to better understand vaccine hesitancy in physician practice as well as beliefs and behaviours influencing physician referrals to the pharmacy.

As for the pharmacist data, I created a 15 minute to complete, online, real world survey using Google Forms, with drop down and free form questions for licensed pharmacists to answer at their convenience. I disclosed my employment position and dissertation research and asked the pharmacists for their time to complete to help improve adult immunizations based on their insights. The pharmacists were not paid for their participation.

Survey

As I thought more about how to improve the low adult immunization rates in this country, I realized there are many perceived barriers and thus many questions to address as I work towards potential solutions or future areas of research. Questions I sought to answer include:

Situational Questions	Barrier Related Questions	
Why are adult vaccination rates currently low and what	Do misconceptions about pediatric vaccines influence	
is currently done to improve rates?	adults' decisions to vaccinate themselves?	
What are the drivers and motivators for those adults who	How has the anti-vaccine movement influenced adult	
do get vaccinated?	immunizations?	
How are adults educated about vaccines? Is it through	Is the anti-vaccine movement the biggest barrier to	
their physician? Pharmacist? The internet? Other trusted	increasing adult immunization rates?	
sources like friends and family?		
What are the best approaches to educate and create	Is vaccine hesitancy something to solve for?	
positive awareness about adult vaccines?		
Where is the best place for adults to be immunized?	Is there time in the pharmacist's day to do more	
How does the community pharmacy fit in?	immunizations?	
Do pharmacists see themselves as a solution?	Are doctors talking about vaccines with their patients?	
Are pharmacists willing vaccinators?	What is the experience like to receive a vaccine? In a	
	physician setting? In a pharmacy?	
Do pharmacy chains set up pharmacists for success?	Are biases influencing pharmacist behaviors towards	
	immunizations?	
What policies are in place to support adult	Are we set up for success with vulnerable populations	
immunizations? Are they effective?	like the homeless or the poor?	

The answers to these questions derive from research from sources including the CDC, NIH, The Journal Vaccines, The New England Journal of Medicine, the voices of those who support Dr. Wakefield, the physician who first linked MMR vaccine to autism and was later disbarred, and internet sites aligned with the anti-vaccine movement.

Sampling survey

Working with pharmacists on a day to day basis I was able to identify a key stakeholder who shared my online survey with their former colleagues and current bench and decision-making pharmacists. Although the sample size is eight participants, the fill in the blank forms provided deep insights and I was able to segment and draw correlations amongst the participants.

Data analysis survey

The survey was emailed to respondents based on inclusion criteria. Data was collected once all surveys were returned via Google Forms. Data was pooled based on segmentation for current vaccine behaviors and beliefs about vaccines. I looked for correlations across these areas when creating the segments. Conclusions and recommendations were drawn based on the pooled analysis and fill in the blank insights from research participants.

Marrying up patterns and conclusions from my survey to existing sources found in Journals and Pharmacist Association communications I was able to further define my segments. In addition, this approach helped to determine if pharmacy chains are delivering top down success in administering vaccines or if the bench pharamcsits are individually motivated. This also helped determine if solutions should be oriented to

decision makers, vaccinators or both.

The analysis focused on the following:

- Prior experience administering vaccines
- Perceived barriers to increasing vaccine administration
- Perceptions of patient receptivity to pharmacy vaccine administration
- Decision criteria involved in undertaking vaccine administration
- Pharmacist motivation to vaccinate
- Information (topics), resources and messages required to motivate action.
- Beliefs about the level of financial benefit associated with vaccine services
- Beliefs about other in-direct benefits of offering vaccine services
- Other barriers to adoption

The combined results of the qualitative study with existing research provides deep insights into the perceptions and behaviors of retail pharmacists and their staff and gave me a platform to make recommendations based on the current state and what is required to see improved adult immunization rates.

Some of the other resources I am reviewing will help me further develop my argument that the pharmacy, rather than the doctor's office, is the best destination for adult vaccines. These include articles about physician practices lowering vaccine costs or not vaccinating at all because of decreased reimbursement as well as research around the convenience the pharmacy provides to adults in need of vaccines.

Quality Criteria

Reliability and validity are the two quality criteria I use to assess the quality of my qualitative research. Having a small sample size of 8 individuals, I am assuming trustworthiness of my sample based on some segmentation characteristics I assess early in my survey. All participants are practicing pharmacists and seven of the eight are current immunizers. Their insights and experiences are authentic and credible due to the inclusion criteria I established for them to participate. I cannot validate their morality however; I am using external surveys of existing resources and institutional knowledge I bring to this subject to validate their responses. In this sense there is internal validity supporting my hypothesis and external validity wherein the results can be generalized beyond the scope of my research sample.

It is an important consideration that qualitative studies are inherently subjective. I tried to balance this with the upfront segmentation questions, quantitative in nature. To apply quantitative data, such as how many immunizations the participants give in a month to their qualitative answers, helps me understand if there are behavior or bias related problems to solve. I am cognizant that there is the potential for Hawthorne effect and social desirability bias⁵ where the participants are aware they are in a study and potentially modify their responses based on an expectation that the study is seeking a particular response. However, in my introduction to the research I asked for honesty in their responses to help me confirm if my hypothesis stands and how to address barriers to this hypothesis if it does.

Ethical Considerations

Research is subject to the lens of the investigator. It may be argued that there is a conflict of interest in me conducting this research and writing this dissertation as a commercial employee of a pharmaceutical company. I began this work as a retail strategy marketing manager in the vaccines division and transitioned onto an adult

⁵ Psychology Concepts, "Social Desirability Bias," accessed April 17, 2020, http://www.psychologyconcepts.com/social-desirability-bias/.

vaccine brand team as a pharmacy brand director. Prior to my marketing experience I led the state of New Jersey sales team for pediatric and adult vaccines across the private and public business sectors. These experiences and positions gave me insights and understanding into how vaccines are manufactured, delivered to the market, marketed, sold, and used. Countless conversations and research studies were conducted for me to become a true subject matter expert in understanding how we can help physicians and pharamcsits become better vaccinators. I have been involved in market research to better understand how consumers or patients make decisions to either vaccinate or not to.

I would not have spent six years in the commercialization of vaccines if I did not believe in the work. As Chapter One will illustrate, there is value in vaccines. They have been proven to eradicate and eliminate diseases. As the current COVID-19 pandemic spreads across the world, panicked populations cling to the hope of a vaccine and a cure to address the crisis. I am writing this from a position of someone who believes in the science of vaccines, the positive impact they have to healthcare in the United States and around the globe, and the role they have in improving humanity. This standpoint is present throughout my writing. It is my lens; my worldview and I acknowledge that. I hope my voice on the topic does not dissuade the reader and bring you back to my potential conflict of interest, but rather invoke curiosity and the desire to be part of the vaccination conversation.

Epistemological Standpoints

Epistemology is essentially the study of knowledge or having to do with knowing. Standpoint theory is often used in feminism to define a social point of view. For the purpose of this dissertation I will refer to standpoint as an academic or experience-based point of view. For example, my standpoint as a vaccine marketer, as described above, provides a filter for me to absorb vaccine knowledge through as I process that information from that position. My standpoint as a medical humanities student also influences this research. In the forward I describe the course work I took on my journey through a masters and now doctorate in the medical humanities curriculum. I was drawn to the concept of applying the humanities, particularly the arts, to the practice and concept of Western medicine. The intersection of art and vaccines is a concept that influenced this dissertation and is only lightly touched on towards the conclusions. It is an area that should be explored further.

Medical humanities also incorporates theory and knowledge from medical anthropology, another discipline that inspires my thinking and beliefs. Nancy Scheper Hughes and Margret Locke's⁶ mindful body influences my thinking about vaccine perception and barriers in relationship to the individual self, the social self, and the body politic. Their theory of the mindful body is woven into my discourse on barriers to immunization, particularly as it relates to vaccine hesitancy.

Overview of the Dissertation

⁶ Nancy Scheper-Hughes and Margaret M. Lock, "The Mindful Body: A Prolegomenon to Future Work in Medical Anthropology." In *Understanding and Applying Medical Anthropology*, ed. Peter J. Brown (Mountain View, Mayfield Publishing Company, 1998). 208-25.

In the remainder of this introduction I will provide a brief overview of the content and chapters you will read. This overview is provided to guide your journey through my research and connect the content to my conclusions.

Chapter One: The Value of Vaccines

In this chapter I discuss why adult vaccines are important and what their impact is on health outcomes and spending. I develop an argument for the values of vaccines and highlight programs that are currently working to drive immunization rates in children and adolescents and what we can and cannot apply from these examples to adults. This chapter focuses on the positive aspects of vaccines and discusses the impact improving immunization rates can have on public health and wellness in the US. In this chapter I am laying the foundation for why improving adult immunizations is a pharmacoeconomically efficient way to address prevention and I leverage the CDC guidance and recommendations on vaccines as the source of credibility and truth for immunizing health care providers as well as for those consuming vaccines.

Chapter Two: Barriers and Beliefs Around Adult Immunizations

In this chapter I will introduce the current situation on adult vaccines in the United States and provide the theoretical framework around why rates are low. There are several areas I consider, including: philosophical barriers to vaccinating including vaccine hesitancy, misconceptions about the safety of vaccines and potential concerns about the spread of infectious disease through the use of needles, ACIP recommendations and lack of adult mandates, current policies limiting pharmacists from administering vaccines in the pharmacy, logistical problems in vaccinating vulnerable and at risk populations like the homeless and the poor, the ethical considerations of adult mandates, and the barriers that currently exist for pharmacists and non-pharmacists Health Care Providers (HCPs) to administer vaccines including cost, time, and coverage. Chapter Two outlines the barriers that are driving poor adult immunization rates.

In Chapter Two I introduce medical anthropological theory to several barriers related to vaccine hesitancy. This is included to bring the conversation to a conceptual level. It is helpful to position one's self in the worldview of someone deliberating on the positive and negative aspects of immunizations to fully understand the barriers blocking them from activation.

Chapter Three: The Anti-Vaccine Movement

Originally part of Chapter Two as its own barrier, the anti-vaccine movement contains a robust set of history, information, and debate deserving its own chapter. It is my intention to highlight what is driving this movement and how it has such powerful momentum in the United States. It is not my intention to imply that the community pharmacy is designed to address the anti-vaccine movement, however to highlight that the anti-vaccine movement is a deep root cause influencing other barriers to immunizations. The anti-vaccine movement is linked to many other adult immunization barriers such as vaccine hesitancy, mis-information and myths, and physician burnout in having the difficult immunization conversation. Parents may have anti-vaccine sentiment around childhood immunizations preventing them receiving important adult immunizations. Important epidemiology concepts like herd immunity are at risk due to this movement, therefore it is important to be aware of the various factors and think about how pro-vaccination efforts can rise above what anti-vaxers are saying and doing. The community pharmacist can and should be aware and involved in the pro-vaccine effort.

Chapter Four: Belief and Behavior Shifts: Getting Pharmacists and Consumers Proactive

In this chapter I present the original research I conducted to identify current vaccination beliefs and behaviors. I conducted the online survey to learn more about the group of HCPs I am proposing as the solution to low immunization rates. I asked pharmacists specifically what they think are the biggest barriers to vaccinating adults in the pharmacy and how things could be improved. This chapter includes the results and analysis of my qualitative research with community pharmacists. In the discussion I pair the research results with the concepts reviewed in Chapter One, Two and, Three to identify the most pressing barriers and the most urgent opportunities to address in order to improve adult vaccination rates.

<u>Chapter Five: The Visual Culture of Vaccination: A Medical Humanities</u> <u>Perspective</u>

This chapter defines the visual culture of vaccines from historical images, world health campaign posters, and pharmacy immunization advertising. It also discusses the vaccine experience or ritual and how a patient experiences a vaccine in the pharmacy. Understanding the visual culture of vaccines and accompanying narrative is critical as new vaccinators like the pharmacist and even pharmacy technician emerge. If patients want to experience vaccines in a different way, perhaps in a more natural way, these should be discussed in the context of visual culture.

Chapter Six: Vaccines Policy, Advocacy, and Prescriptions for Change

Taking the insights from the previous chapters, I discuss how to make an impact and what policies, resources, and educational efforts can be used to address an improvement in adult vaccination rates. I offer a simplified plan for pharmacies to implement by engaging their pharmacy technicians as well as the consumer. I propose tools that can be used to drive awareness and engage the staff with the patient. I also offer other insights around professional partnerships and potential policy changes that can impact vaccination rates.

Having spent 11 years studying medical humanities as a part-time student, I elected to incorporate a very specific aspect into this body of work. My recommendation to improve adult immunization rates through the community pharmacist is an example of applied medical humanities. As the healthcare landscape evolves and patient behavior changes; new avenues for prevention need to be explored. Services traditionally provided in the physician office are now offered in other locations like a mini-clinic or a pharmacy. Services that doctors provided are now offered by other kinds of HCPs, like Nurse Practitioners (NPs) or pharmacists. As the scope of practice continues to evolve for these healthcare extenders, a medical humanities lens can be applied to help with the practical implications and assimilation to this new healthcare landscape for patients and providers alike. Vaccines have made an impact, there is a gap for adults, how can we take a humanities lens to fill this gap? My suggestion is using visual stimuli, essentially visual culture, as a medium that speaks to most and can have a positive influence on the public. Visual mediums can help shift the paradigm, so consumers see vaccines as the valuable preventative tool that they are. Creating a positive vaccination ritual with positive visual stimuli will help create a pleasant experience that adults will encourage to replicate. I also propose using appreciative inquiry in how we discuss and think about vaccines. Shifting the paradigm of vaccines from shots to tools that foster wellbeing and prevention takes vaccination from a negative experience to part of the wellness paradigm for adults. In this chapter I review how vaccines have been portrayed negatively in art and the media and how to change the paradigm to a more positive light.

In conclusion, I discuss what I hope will happen once these tools and protocols are implemented and what next steps need consideration to make a lasting impact on adult immunization rates. I will also discuss any gaps that may exist in this research and why exploring those gaps may prove important for future considerations.

Chapter One: "The Value of Vaccines"

Introduction

Vaccines are a notable medical intervention that have had an impact on our lives. In this chapter, I will discuss the value of vaccines, their cost benefit ratio, and vaccine impact on disease eradication and public health. Diseases like smallpox, polio, measles, and rubella have been eliminated due to vaccine efficacy. Consider the impact those diseases could have on modern society, especially since some, like measles, have been reintroduced into the United States as the value of vaccinating is under threat with miscommunication and influence by the anti-vaccine movement. As a counter to this movement and to encourage the use of vaccines in the United States, mandates support efforts to vaccinate children. While adults also benefit from immunizations, no mandates are in place to foster adult immunizations, therefore rates are low. By examining the historical impact vaccines have made as they became available during epidemics and the benefit of current vaccine mandates for children, I will illuminate the value of vaccines and expose the danger of the currently low adult immunization rates.

To show that vaccines are a necessary and cost-efficient tool for public health, I will first introduce the cost benefit ratio of several vaccines currently available for children and adults. Next, I will offer a brief history of how vaccines have eradicated pandemics over time. Lastly, in the second half of this chapter, I will review the impact current mandates have on Vaccine Preventable Diseases (VPDs).

Vaccines are a cost-effective, high impact intervention that should get the attention of medical economists and policy makers. The United States healthcare system is in economic

crisis. In December 2019 I attended a meeting at the American College of Physicians (ACP) headquarters in Philadelphia, PA. Their government affairs and public health policy representative, Bob Doherty, shared the astronomical costs associated with US healthcare spending⁷. At the start of his presentation he reiterated that ACP is committed to a new vision for healthcare with a focus on cost and coverage, payment and delivery systems, and social detriments and other barriers to care. He stated, "Our New Vision will be based on a comprehensive review of the economic, public health, public policy, and social sciences literature on the biggest challenges facing U.S. health care, and policies likely to be effective in improving it." With the nod to social science literature there was a lot of questions about medical humanities that I will address in a later chapter. In this section I will focus on how out of balance US healthcare spend and delivery is and how vaccines can help.

The Peterson Center for Healthcare projects totaled US healthcare spending, both public and private, to be 1/5 of the US economy by 2025.⁸ United States Healthcare spending per capita is more than 2 times the average of other developed countries at \$10,209 in the US versus the Organization for Economic Cooperation and Development (OECD) countries average at \$4,069. Below is the breakdown by developed country from Peterson Center. The Center goes on to show that US healthcare costs are the number one driver of increased government spending, above both social security and defense. Additionally, health system and hospital consolidation are on the rise with more than 1,400 US hospital mergers occurring between 2009 and 2015. This consolidation results in higher healthcare prices. Decreased competition leads to

⁷ Bob Doherty, "Public Health Policy Update" (American College of Physicians Corporate Membership Roundtable, ACP HQ, Philadelphia December,9, 2019).

⁸ Peterson Center for Healthcare, "Infographic: U.S. Healthcare Spending," Peter G. Peterson Foundation, accessed December 17, 2019, <u>https://www.pgpf.org/sites/default/files/Healthcare-Spending-Infographic.pdf</u>.

increased prices. And perhaps most frustrating is that higher prices do not yield better outcomes. US outcomes are usually not better than those of other developed countries and in some cases even worse! Below is a snapshot of US spending and US outcomes for select disease states and milestones from the Peterson Center for Healthcare.⁹



When put into context, public health economists are eager to find cost effective solutions to drive healthcare outcomes and health system efficiency. This excludes the administrative burden our \$3 Trillion health system generates. Invasive interventions provided as reactive care lead to increased costs, increased mortality, increased admin, and decreased patient satisfaction. The widespread adoption of vaccines for both children and adults can help alleviate these pressures.

For minimal upfront cost, vaccines provide valuable outcomes that can be measured in healthcare dollars spent and quality of life. During the 20th century, life expectancy for U.S.

⁹ Ibid.

residents increased by 67%, from 47.3 years in 1900 to 78.8 in 2015.¹⁰ Although many significant achievements in public health emerged during this time, vaccines are at the top of this list. VPD is on the Center for Disease Control's (CDC) list of "10 Great Public Health Achievements -United States 2001-2010."¹¹ The CDC recognizes that advances in vaccine availability and immunization opportunities have resulted in declines in the number of health care dollars spent, disease burden cases and related hospitalizations as well as fatal outcomes of several VPDs.

According to the CDC, "vaccination of each U.S. birth cohort with the current childhood immunization schedule prevents approximately 42,000 deaths and 20 million cases of disease, with net savings of nearly \$14 billion in direct costs and \$69 billion in total societal costs."¹² Direct costs include medical expenses affiliated with disease management like physician visits, prescription drugs, hospitalization, and medical testing and procedures. These expenses contribute to the increasing cost of healthcare in the United States and impact insurance premiums and tax spending affiliated with government funded healthcare like Medicare and Medicaid. Indirect costs include time missed from work, travel expenses, and childcare. These costs also hurt the tax payer and contribute to an over reliance on social programs when individuals become too ill to continue to work and maintain benefits. The combined \$83 billion impact is almost unmatched with any other great public health achievement.

¹⁰ US Department of Health and Human Services Center for Disease Control and Prevention National Center forHealth Services, "Health, United States, 2016: With Chartbook on Long-term Trends in Health," *DHHS*, no.2017-1232:4, accessed October 22, 2017, <u>https://www.cdc.gov/nchs/data/hus/hus16.pdf</u>.

¹¹ CDC,, "10 Great Public Health Achievements-United States, 2001-2010," MMWR, accessed October 22, 2017, <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6019a5.htm.</u>

¹² Zhou F., "Updated economic evaluation of the routine childhood immunization schedule in the United States," (Presented at the 45th National Immunization Conference, Washington, DC; March 28--31, 2011).

Public health policy is concerned with the pharmaco-economic value that

pharmacological interventions may or may not provide. In almost all cases, the cost benefit ratio is favorable for vaccines. For example, the Wholesale Acquisition Cost (WAC) for the Tetanus, Diphtheria, Pertussis (Tdap) vaccine is \$37. The hospitalization costs in 2013 for Tetanus were \$102,584 per case, Diphtheria were \$16,982, and Pertussis were \$10,765-22,410.¹³ Additionally, the indirect costs such as time missed from work, follow up care, and transportation are also important figures to factor into the cost of disease. The risk to vaccinating is minimal. Vaccines are safe and tolerable with injection site reaction presenting as the most common adverse event.¹⁴ Most of the time statistics confirm that vaccinating is cost effective and the benefits outweigh any potential risks.

A 2018 systemic review¹⁵ of 78 publications about vaccine costs yielded positive results for several adult vaccines' cost effectiveness. Researchers found that a substantial amount of influenza, pneumococcal, and Tdap outcomes are cost-saving. Specifically, influenza and pneumococcal vaccination outcomes yielded a cost-effectiveness ratio of <=\$50,000/qualityadjusted life-year (QALY) saved. For the human papilloma virus and zoster vaccines, the outcomes yielded a cost-effectiveness ratio of <=\$100,000/QALY saved.¹⁶ These findings support increasing the low adult immunizations rates for influenza, pneumococcal, zoster, and Tdap.

¹³ CDC, Vaccines for Children Program, "Appendix: Methods for the cost-benefit analyses presented in <u>Benefits from Immunization during the Vaccines for Children Program Era — United States,</u> <u>1994–2013(https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm)</u>", *MMWR* 2014;63:352-5, accessed October 22, 2017, https://www.cdc.gov/vaccines/programs/vfc/pubs/methods/index.html. ¹⁴ CDC, "Possible Side Effects from Vaccines," Vaccines and Immunizations, accessed May 9,

^{2020, &}lt;u>https://www.cdc.gov/vaccines/vac-gen/side-effects.htm</u>.

¹⁵Leidner et al., "Cost-Effectiveness of Adult Vaccinations: A Systemic Review," *Vaccine* 37 (2019) 229.

¹⁶ Ibid.
Unfortunately, new vaccines to market have made the news as potentially too costly for the potential benefit. The following example regarding the Meningococcal B (MenB) vaccine illustrates when the statistical or financial analysis indicates that vaccinating may not be the most cost-effective intervention. A recent article in the NY Times questions the value of MenB vaccines with high prices tags between \$300-\$350/series for a very rare disease that mostly impacts college-age students in the university setting. The article entitled, "For Meningitis B Vaccines, Climbing Revenue, Plenty of Skepticism," claims that MenB vaccines are a" lucrative new business: persuading parents that pricey vaccines are a loving investment for their collegebound children."¹⁷ The article suggests that drug companies are pulling in excessive profits using scare tactics with mothers of college-age children.

This article is an example of the perpetuation of vaccine misinformation through mainstream media. Meningitis B is a rare but incredibly fast acting and deadly serotype of Meningococcal Meningitis. Someone who contracts the serotype, typically spread through sharing a drink, smoke, or kissing, has only about 4 hours to start intravenous antibiotics once the rash appears. MenB can kill an adolescent or young adult within 24 hours or sooner. If caught early, there can still be debilitating and lasting effects, such as arm and leg amputations. The article states that less than 300 cases occur in the United States per year. Because of the low number of cases and the high cost of the vaccine series, MenB vaccines lose the pharmacoeconomic analysis.

¹⁷ Luthra, Shefali, "For Meningitis B Vaccines, Climbing Revenue, and Plenty of Skepticism", *NYTimes* Business Day Sept 7, 2017, accessed October 29, 2017, https://www.nytimes.com/2017/09/07/business/meningitis-b-vaccines.html.

Despite the argument in this example, I maintain it is still difficult to deny the value of vaccinating. Ask any parent who has lost their child to MenB if they could have prevented the death through a \$320 vaccination series and I believe the answer is obvious. Why wait until MenB is more prevalent before instituting a mandate? Vaccines are preventative medicine. The NY Times article promotes reactive medicine by diminishing the value of a vaccine that prevents a rare but deadly VPD. As the article states, "In a world where there aren't enough health care dollars to address every possible harm, many experts noted, other health concerns might be a smarter investment."¹⁸

As a result of my literature review of current and historical immunization mandates, I challenge this thinking. Mandates can be carefully crafted to speak to specific populations. For example, the ACIP recommendation for MenB vaccines can be worded more proactively and states can mandate their own recommendations for summer camp or university entry. The ACIP recommendation for MenB vaccines suggests 2 uses. The Category A recommendation for persons ten years and older, captures the attention of health care professionals and usually results in adherence. This recommendation states, "For persons at increased risk for meningococcal disease and for use during serogroup B meningococcal disease outbreaks, 3 doses of MenB-FHbp should be administered at 0, 1–2, and 6 months to provide earlier protection and maximize short-term immunogenicity."¹⁹ The Category B recommendation, one that is not widely adopted is for young adults aged 16-23 years. The Category B recommendation states, "when given to

¹⁸ Ibid.

¹⁹Monica E Patton, MD et al., "Updated Recommendations for Use of MenB-FHbp Serogroup B Meningococcal Vaccine — Advisory Committee on Immunization Practices, 2016," *MMWR Weekly* 66, no 19 (May 19, 2017)509–513, accessed October 29, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6619a6.htm

healthy adolescents who are not at increased risk for meningococcal disease, 2 doses of MenB-FHbp should be administered at 0 and 6 months."²⁰

In this instance, I would not challenge the Category B recommendation, one that is taken less seriously and often ignored in practice, if the Category A recommendation was stronger and more detailed. "At increased risk" is not defined. The definition is critical to help health care providers understand appropriate patients for the vaccine. Instead, risk is left to interpretation. Perhaps someone in a dorm setting at university or summer camp or anyone attending school and potentially sharing a drink. A health care provider may take a less aggressive approach and only reserve the vaccine for students in an outbreak setting. The loose recommendation is a result of the poor pharmaco-economic analysis. Without school mandates and a more detailed description of who is at risk, MenB will continue to threaten children in the United States. The science exists to eradicate MenB. Vaccinators can use that science and potentially save 300 lives in the US each year. From the medical humanities perspectives of beneficence and justice, is it not ethical to challenge widespread use of a vaccine that saves lives because the "n" is small.

I argue an "n" of one is enough. Even the 300 cases a year referenced earlier are important to prevent. The concepts of beneficence and justice should be applied to vaccination decisions when lives are at stake. Physicians have a deontological duty to protect their patients and offer vaccines that may save their lives. To offer the vaccine is an example of beneficence and to not can be considered negligence, particularly if the patient goes on to acquire the disease. Seen from this perspective, this is also a matter of justice in that, every life is equal. With the current ACIP recommendation, there is limited use of this vaccine. Parents who are educated and insured have the best potential to vaccinate their children. It may be considered unjust that uninsured 16-18-year-old adolescents, although covered for free vaccines under the Vaccines For Children (VFC) program, are left unvaccinated if their physician chooses not to stock the vaccine. The most at-risk population is this cohort since crowded living conditions increases risk for acquiring MenB. If every college aged student were to be vaccinated with a MenB vaccine, there would be a decreased risk of spreading the bacteria. Vaccinating protects the person receiving the vaccines and even those who have not been vaccinated yet by eliminating the opportunity to spread disease.

When examining the history of vaccines, one can easily identify how vaccines impact public health by eliminating disease. Prior to exploring the historical timeline of vaccines, I will introduce three concepts to examine how vaccines impact public health. The first is that vaccine efficacy can wane over time. Vaccine efficacy may last just long enough to eradicate an epidemic if the entire population is vaccinated at the same time. However, that is less likely to occur today unless there is an epidemic; therefore, many vaccines are given as boosters to boost immunity over time. Tdap is an example. The CDC recommends and many states require Tdap at age 10. The CDC also recommends Tdap for adults aged 19 and older, even if already administered at age 10, to boost immunity. Because the recommendation is not a mandate, many adults do not get vaccinated after age 19. This is one of the reasons whooping cough still exists.

The second concept I will introduce is also relevant to the Tdap example. Vaccines offer protection to the individual vaccinated but also to those around them. In the instance of infants, the protection to others is referred to as cocooning. Unfortunately, the most vulnerable population at risk to die from whooping cough are infants less than 6 months of age. Babies do not receive their first dose of Dtap (Diptheria, Tetanus, and Pertussis) until 6 months of age. To protect infant's in their lives, adults can proactively choose the Tdap vaccine over Td (Tetanus).

Some adults may not make the connection between receiving a Tdap vaccine and altruism. Tdap vaccines protect others beyond merely protecting the person vaccinated. This altruism protects those who are unprotected, like babies under 6 months of age. To choose a Td vaccine, one chooses to protect only themselves. To choose Tdap, there is an act of altruism involved.

The final concept I would like to introduce is herd immunity. Similar to cocooning, herd immunity implies that vaccinating offers protection beyond the individual. I will further develop the impact of herd immunity or presumed herd immunity when discussing measles. For now, herd immunity can be described when a community is free of an infectious disease because of a high vaccination rate. If an unvaccinated person were to enter this community, they would have herd protection since there are no individuals carrying that disease, thus they are protected by herd immunity.

The history and impact of vaccination is fast and furious, particularly towards the end of the Twentieth Century. In this analysis of why vaccines are important and necessary tools for public health, I will discuss a brief history of vaccination and why the CDC touts it as one of the top ten achievements to public health. In reviewing this history some of the root causes behind vaccine mistrust will surface. These will be further developed in chapter two. In this chapter my intention is to reinforce the importance and necessity of vaccinating everyone, including adults and to support public policy that stands behind this initiative.

A Brief History of Vaccines and Their Impact on Disease

Four key figures emerge when considering how vaccines have impacted public health over time. Vaccine impact begins with the Father of Immunology, Edward Jenner; the first lab scientist to discover live vaccines, Louis Pasteur; the eradicator of polio, Jonas Salk; and John Enders and colleagues who discovered the measles vaccine.

During the late 18th century, immunology began with Edward Jenner and his, "innovative contribution to immunization" and the "eradication of smallpox."²¹ Stefan Riedel provides a detailed overview in "Edward Jenner and The History of Smallpox and Vaccination."²² As early as 430BC, common knowledge existed that smallpox survivors were immune to the disease. Throughout time, various methods were used to inoculate individuals against smallpox, but it was not until 1796 when Jenner made the connection between cowpox and smallpox. Jenner had heard stories that dairy maids were protected from smallpox due to exposure to cowpox. He concluded that cowpox could be transmitted between individuals as a "deliberate mechanism of protection" against smallpox. ²³ By 1800, Jenner had all of England and most of Europe vaccinating for smallpox. Jenner's contribution represents the "first scientific attempt to control an infectious disease by the deliberate use of vaccination."²⁴ The term vaccination originates with Jenner's discovery; *vacca* is Latin for cow.²⁵

Ultimately Jenner's contribution led to the eradication of smallpox.²⁶ Eradicating a disease has enormous benefit to public health. The impact goes beyond increased life expectancy. Easing disease burden allows improved quality of life, more productivity, and

²¹ Stefan Riedel MD, "Edward Jenner and The History of Smallpox and Vaccination," *Baylor University Medical Center Proceedings*, Vol 18.1(Jan 2005):21.

²² Ibid, p 22.

²³ Ibid, p 24.

²⁴ Ibid, p 25.

²⁵ Michael D Hogue et al., "A Decade of Advancement in Pharmacy Immunizations," *Journal of the American Pharmacists Association*, Vol 46, No2 (March/April 2006):168-82.

²⁶ The College of Physician's of Philadelphia, "The History of Vaccines," accessed October 22, 2017, <u>http://www.historyofvaccines.org/content/timelines/all.</u>

societal benefits affiliated with these improvements. Jenner proved that human intervention can defy natural selection.

However, Jenner's work was controversial and for all the honors he received, he also met great ridicule.²⁷ Even the very start of the vaccine movement was met with controversy. One can imagine the controversy inoculation created in Europe during that time. Those who had seen the consequences of smallpox and lost relatives and children to the disease were probably desperate for the vaccine. Those unaffected by smallpox were disgusted by the idea of taking a virus and injecting it into the body. This first group influenced the vaccination movement, a movement that, unlike today, was focused on vaccinating not just children, but everyone. That is how disease is eradicated. However, as this example may illustrate, it may take desperate times, like an outbreak of smallpox, to influence that kind of policy. Despite ridicule and difficulty Jenner persevered as did the history of vaccination.

The next major player in vaccine history is Louis Pasteur. Famous for discovering the rabies and anthrax vaccines, Pasteur is the first scientist to use live viruses in vaccinations.²⁸ Pasteur drew from Jenner's example and executed science that persists today and influences adult vaccines. The first vaccine created in a laboratory was Pasteur's vaccine for chicken cholera in 1879.²⁹ Pasteur's next project involved a vaccine that could benefit animals and humans. He understood that rabies caused symptoms only after it had made its way to the brain. He therefore used dried nervous tissue of animals that had died from rabies and thus was able to

²⁷ Stefan Riedel MD, "Edward Jenner and The History of Smallpox and Vaccination," *Baylor University Medical Center Proceedings*, Vol 18.1(Jan 2005):21.

²⁸ Louis Pasteur, "Anthrax and Rabies," Passport Health USA, accessed October 22, 2017, https://www.passporthealthusa.com/2015/08/louis-pasteur-anthrax-and-rabies/.

²⁹ The College of Physician's of Philadelphia, "The History of Vaccines," accessed October 22, 2017, <u>http://www.historyofvaccines.org/content/timelines/all.</u>

vaccinate living animals against the disease.³⁰ When a mother brought him her son who had been bitten by a rabid dog, Pasteur's next move was highly controversial because he was not a medical doctor, and he had never used the rabies vaccine on a human. According to the College of Physicians of Philadelphia, he believed that the boy was going to die, so he administered the vaccine to the child. The boy lived and thus Pasteur had a working rabies vaccine.³¹

Pasteur opened the door to an array of vaccines that are available to adults today. After Pasteur, vaccines for diphtheria, tetanus, anthrax, cholera, plague, typhoid, tuberculosis, and others were developed into the 1930s.³²

Yet availability does not lead to use as the low adult immunization rates indicate. Adults need to feel the impact from VPDs, and most modern adults do not. Other than scattered flu pandemics and more recently Zika, there had been no diseases of epidemic proportions in the US since the elimination of polio. This drastically changed suddenly in January 2020 with the introduction of the novel corona virus, COVID-19 in the United States. By early May 2020 over 1.2 million people in the US were infected and over 75,000 people died³³. Until COVID -19, disease was not a primary concern in our civilization. Only when a flu epidemic or a global pandemic occurs, are adults motivated to act. Without those triggers, proactive adult vaccinating is minimal.

To illustrate further, flu vaccines currently have the highest immunization rates amongst adults at $41.7\%^{34}$ for the 2016-17 season. Flu rates are higher than other adult immunization

³⁰ Ibid.

³¹ Ibid.

³² Ibid.

³³ Johns Hopkins University and Medicine, "Cases and Mortality By Country," Corona Virus Resource Center, accessed May 9, 2020, <u>https://coronavirus.jhu.edu/data/mortality</u>.

³⁴ CDC, "Flu Vaccination Coverage, United States, 2015-16 Influenza Season," FluVaxView, accessed January 20, 2020, https://www.cdc.gov/flu/fluvaxview/coverage-1516estimates.htm.

rates because there have been flu pandemics in recent years (as recently as a worldwide pandemic in 2009). Yet, a vaccination rate of 42% is still too low to produce herd immunity. However, a higher immunization rate for flu compared to other adult vaccines does prove the point that adults are more motivated to vaccinate themselves when confronted with a real threat to their health. Vaccinating when there is an imminent disease threat exemplifies a reactive, rather than a proactive approach. The historical examples I have reviewed also exemplify a reactive approach. This is a warped way to utilize a product that is designed for preventative or proactive use.

The next significant period in vaccine history brings the timeline to the mid-20th century: a busy time for medical research and development, including vaccines. Laboratory innovation was producing science and technology for immediate impact including the creation of polio vaccines.³⁵ In 1952, polio was at an epidemic level. Individuals in the Baby Boomer generation remember and can speak to the impact of this disease. Polio was part of growing up in this time period. Most older adults can relate to the disease also known as "infant paralysis." Polio created panic and urgency to do something about it. 58,000 new polio cases were reported in the United States and more than 3,000 people died as a result of poliomyelitis.³⁶ In response, on March 26, 1953, American Jonas Salk announced he had successfully tested a vaccine against polio.

Salk's procedure was to kill several strains of the virus and then inject the viruses into a healthy person's bloodstream. The person's immune system would then form antibodies designed to fend off poliomyelitis. Salk³⁷ conducted the first human experiments on polio

³⁵ Ibid.

³⁶ History, "Dr. Jonas Salk Announces Polio Vaccine," This Day in History March 26, accessed October 22, 2017, <u>http://www.history.com/this-day-in-history/salk-announces-polio-vaccine</u>. ³⁷ Ibid.

patients and on himself and his family. Next, two million American schoolchildren were vaccinated with Salk's polio vaccine in 1954. One year later, the vaccine was advertised as effective and tolerable. In 1955, a nationwide inoculation campaign began. The reported cases of polio dropped to under 6,000 in 1957.³⁸ Salk became a household name after his discovery and has made a giant contribution to improved quality and longevity of life with his vaccine. Unlike Jenner, Salk was widely celebrated. Vaccines were proven to make a big difference. Since 1979 there have been no cases of polio in the US.³⁹

Measles Vaccines: An Example of Success Followed By the Anti-vax Influence

After Salk, researchers investigated other common childhood diseases including measles, mumps, and rubella. According to the CDC, in the 1950s, almost all children were afflicted with measles by the time they were 15 years of age. The CDC describes the 1950s measles endemic and its impact on public health in the US on their webpage. According to the CDC, about 3 to 4 million individuals in the United States were infected each year during the 1950s and about 400 to 500 people died. 48,000 people were hospitalized, and 4,000 suffered encephalitis from measles. In 1954, John F. Enders and Dr. Thomas C. Peebles collected blood samples from a few students during a measles outbreak in Boston. They were interested in using the blood samples to create a vaccine. By isolating measles in 13-year-old David Edmonston's blood, in 1963, John Enders and colleagues successfully incorporated their Edmonston-B strain of measles virus into a vaccine and licensed it in the United States. ⁴⁰

³⁸ Ibid.

³⁹ CDC, "Polio Elimination in the United States," Polio, accessed January 20, 2020, https://www.cdc.gov/polio/us/.

⁴⁰ CDC, "Measles History," Measles Home, accessed November 14, 2017, <u>http://www.cdc.gov/measles/about/history.html</u>.

To address other common childhood diseases, the measles vaccine evolved into the MMR (Measles, Mumps, Rubella) vaccine currently used in children today. In 1963, inactivated measles vaccine and live virus vaccine were licensed in the United States. The live vaccine prevailed and eventually the inactivated vaccine was withdrawn from the market.⁴¹ In 1964, a rubella epidemic swept across the United States resulting in "12.5 million cases of rubella infection, an estimated 20,000 newborns with congenital rubella syndrome (CRS), and excess fetal and neonatal deaths in the thousands."⁴² Two years later the rubella virus was attenuated by Paul Parkman and Harry Meyer, Jr. and the CDC announced the first national measles eradication campaign. By 1968, the incidence of measles had decreased more than 90% compared with pre-vaccine era levels and the mumps vaccine was first licensed, developed by Maurice Hilleman.⁴³ In April of 1971 Hilleman and colleagues developed a combined measles, mumps, and rubella vaccine (MMR) and it was licensed by Merck.

With the newly created MMR vaccine, in 1978, the CDC created the goal to eliminate measles from the United States by 1982. By 1981 there was an 80% reduction in the number of reported cases from 1980, although the end goal was not met. Measles was eliminated from the United States by 2000.⁴⁴ It is important to note the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) recommendations changed after a 1989 outbreak. A second dose of MMR was recommended for all children resulting in further measles cases declining.⁴⁵ The

 ⁴¹ Immunization Action Coalition, "Historic Dates and Events Related to Vaccines and Immunization," Vaccine Timeline, accessed November 14, 2017,<u>http://www.immunize.org/timeline/</u>.
 ⁴² Ibid.

⁴³ Ibid.

⁴⁴CDC, "Measles Cases and Outbreaks," Measles Home, accessed November 14, 2017, <u>http://www.cdc.gov/measles/about/history.html</u>.

⁴⁵ Ibid.

booster recommendation set the tone for further first dose compliance and bolstered further protection for those with waning immunity. In essence, this recommendation provided results.

Although the goal to eliminate measles from the United States was met, herd immunity was not able to keep it away. In 2000 measles was eliminated in the United States however, 2014 saw a whopping 667 cases in the US across 27 states stemming from an outbreak in the Philippines. The CDC website states that in 2014 the U.S. experienced 23 measles outbreaks, including a large outbreak of 383 cases, occurring among unvaccinated Amish communities in Ohio.⁴⁶ Many of the additional cases were brought in from the Philippines, which also experienced a large measles outbreak.⁴⁷ Ultimately, lack of vaccinating was the primary reason for the return of measles in 2014. Herd immunity failed and unvaccinated, hence unprotected, individuals were exposed to and contracted measles.

The following year, in 2015, there were 189 reported cases of measles. The CDC website mentions the US saw a large multi-state measles outbreak linked to an amusement park in California. This outbreak most likely began with an infected traveler from overseas coming from a country that had an outbreak. CDC scientists analyzed the virus from California showing that the measles virus type in this outbreak (B3) was an identical match to the virus type that caused the large measles outbreak in the Philippines in 2014.⁴⁸ Thus, international travel played a key role in the 2015 outbreak as well. Between the growing number of unvaccinated individuals and the spread of measles from international travelers coming from countries with measles outbreaks, the incidence of

⁴⁶ Ibid.

⁴⁷ Ibid.

⁴⁸ Ihid

measles in the US had hit all-time highs in 2014 and 2015 combined since the elimination of the disease in 2000. This was until the 2018-2019 outbreaks, again the result of international travel and linked to the wild type D8 and B3 strains.⁴⁹

CDC states that From January 1 to November 7, 2019, 1,261 individual cases of measles have been confirmed in 31 states⁵⁰. CDC goes on to state that this is the highest number of cases reported in the U.S. since 1992. Greater than 75% of the cases in 2019 are linked to outbreaks in New York state. And CDC reminds the public that measles is more likely to outbreak in communities where groups of people are unvaccinated and that most of the recent cases are among people who were not vaccinated against measles. Furthermore, measles can cause serious complications for individuals and strain on the healthcare ecosystem. Of the reported cases from January 1 – November 7, 2019, 123 of the people who got measles were hospitalized and 61 reported having complications, inclusive of pneumonia and encephalitis.⁵¹

According to the CDC, areas reporting outbreaks in 2019 include: California, Georgia, Illinois, Michigan, New Jersey, New York City, New York State, Oregon, Pennsylvania, Texas, and Washington. The 2019 cases are spillover from seventeen outbreaks from 2018. CDC confirms that three outbreaks in New York State, New York City, and New Jersey, contributed to most of the cases and occurred primarily among unvaccinated people in Orthodox Jewish communities. These outbreaks are the result of travelers bringing measles back from Israel, where a large outbreak was occurring and continues to occur. Eighty-two people brought measles to the U.S. from other countries in

⁴⁹ CDC, "Measles Cases and Outbreak," Measles Home, accessed November 24, 2019, <u>https://www.cdc.gov/measles/cases-outbreaks.html</u>.

⁵¹ Ibid.

2018, the greatest number of imported cases since measles was eliminated from the U.S. in $2000.^{52}$ Clearly measles continues to be a public health issue that is worsening as outbreaks spread internationally.

The CDC firmly encourages MMR vaccines for everyone and specifically attributes the re-occurrence of measles with the following:

- o The majority of people who got measles were unvaccinated.
- Measles is still common in many parts of the world including some countries in Europe, Asia, the Pacific, and Africa.
- \circ Travelers with measles continue to bring the disease into the U.S.
- Measles can spread when it reaches a community in the U.S. where groups of people are unvaccinated.⁵³

Herd Immunity Revisited

The common thread in the re-emergence of measles, involves the risk associated with those individuals who are unvaccinated. This is where the vaccine debate comes into play. Essentially vaccination, as a public health issue, must balance societal needs versus individual needs. Vaccines themselves are designed to offer collective and individual protection. Collectively, all individually vaccinated persons offer community or herd protection. Ideally, from a scientific and economic viewpoint, everyone within a given geography under a state or federal jurisdiction should be vaccinated. However, that situation does not exist. The antivaccine movement has gained momentum over the last 15 years as celebrity parents and politicians have created fear and misconceptions linking vaccines with autism. This link was

⁵² Ibid.

⁵³ CDC, "Measles Cases and Outbreaks," Measles Home, accessed November 14, 2017, <u>http://www.cdc.gov/measles/about/history.html</u>.

originally illuminated by the former Dr. Wakefield, since barred from practicing medicine. Chapter Three will explore this movement and the dangers affiliated with it further.

The concept of herd immunity factors into decisions on vaccination. As previously mentioned, herd immunity can be described when a community is free of an infectious disease because of a high vaccination rate or high communicable exposure to the disease. If an unvaccinated person were to enter this community, they would have herd protection since there are no individuals carrying that disease, thus they are protected by herd immunity. The percentage of the population that must be immune to provide herd immunity varies according to how infectious the disease is. For poliomyelitis, that percentage is ~80%, whereas for measles it exceeds 90%.⁵⁴

The people who take herd immunity for granted could be seen as selfish since herd immunity reduces disease risk for the non-immunized person. At the same time, that person also reduces their risk of side effects associated with vaccination since they choose not to vaccinate and to take advantage of the herd. Herd immunity should be reserved for vulnerable groups who do not have access to vaccines, like the homeless. Herd immunity should not be assumed by individuals who have a choice and the means to vaccinate themselves. When diseases like measles come back, everyone who is unvaccinated is at risk, adults and children alike.

Hepatitis A Outbreaks in 2016-2019:

The current Hepatitis A outbreaks can also be considered in the context of herd immunity. According to the CDC, since March of 2017 there have been ongoing Hepatitis A

⁵⁴ Kevin M. Malone and Alan Hinman, "Vaccine Mandates, The Public Health Imperative and Individual Rights," For Immunization Managers, accessed November 14, 2017, <u>http://www.cdc.gov/vaccines/imz-managers/guides-pubs/downloads/vacc_mandates_chptr13.pdf</u>, p.264.

(Hep A) outbreaks in California, Michigan, Kentucky and Utah. The primary demographic is vulnerable populations including: homeless individuals, intravenous drug users, and non-intravenous drug users in the afflicted areas. The secondary demographic is immunosuppressed individuals who cannot be vaccinated due to their condition. Prior to the current outbreaks, between 2015 and 2016, reported cases of Hepatitis A increased by 44.4% from 1,390 in 2015 to 2,007 cases in 2016. The 2016 increase was due to two hepatitis A outbreaks, each linked to imported foods.⁵⁵ The CDC has responded with vaccine clinics for individuals who may have been in contact with people reported to have acquired Hepatitis A. However, Hepatitis A is not only transmitted through drug use; it can be transmitted through the preparation of food, sexual contact, and caregivers of any at risk group. At risk populations also include those who have chronic liver disease, including cirrhosis, hepatitis B, or hepatitis C.⁵⁶

Although the 2019 surveillance data for Hepatitis A outbreaks has not been published yet, the CDC registers states with outbreaks on their website. Since the beginning of this string of outbreaks in late 2016 there have been 28,269 reported cases in the US with 60% of cases leading to hospitalizations. Of the 17,078 hospitalizations, there have been 285 reported deaths.⁵⁷ Again, aside from the deaths and quality of life impact to infected individuals, these cases are a significant burden to the healthcare ecosystem that is preventable via vaccination. CDC.gov states that just one dose of single-antigen hepatitis A vaccine has been shown to control outbreaks of hepatitis A. The single dose provides up to 95% sero-protection in healthy individuals for up to 11 years. Typically, hepatitis A vaccines are 2 doses (both Havrix and

⁵⁵ CDC, "Hepatitis A Outbreaks in the US," Viral Hepatitis, accessed November 24, 2019, <u>https://www.cdc.gov/hepatitis/outbreaks/hepatitisaoutbreaks.htm</u>.

⁵⁷ Ibid.

Vaqta), however during outbreaks, many individuals only receive one dose and data suggests sero-protection enough for a significant period.

When outbreaks are reported to the CDC, there are measures taken from a public health perspective to help support containing and controlling the outbreak. According to the CDC website,⁵⁸ in response to all hepatitis outbreaks, they provide ongoing epidemiology and laboratory support. CDC also works closely with vaccine manufactures for updates on vaccine supply and utilization across age groups, insured segments, and other demographics. They receive regular updates on manufacturer outbreak support and series completion statistics. The CDC also works with the ACIP and other governing bodies on vaccine policy development. Upon request, CDC sends "disease detectives" to affected areas to evaluate and assist in an outbreak response. CDC will alert other public health departments of increases in cases. All states are encouraged to be vigilant for cases. CDC also works with state and local health officials to ensure vaccines are targeted to the correct at-risk populations and that access to the vaccine supply is sufficient.

Because of the nature of how Hepatitis A is spread, the current 2019 outbreaks are not confined to one specific geographic area as indicated in the US Outbreak Map on the next page.⁵⁹

The CDC recommends anyone over the age of 1 year to be vaccinated against Hepatitis A. The current adult immunization rate for hepatitis A is only 9.5% for adults aged great than or equal to 19.⁶⁰ At that rate, there is no herd immunity to protect vulnerable groups who may not

⁵⁸ CDC, "Hepatitis A Outbreaks in the United State," Viral Hepatitis, accessed February 22, 2020, <u>https://www.cdc.gov/hepatitis/outbreaks/hepatitisaoutbreaks.htm</u>.

⁵⁹ Ibid.

⁶⁰ CDC, "2016 Adult Vaccination Coverage General Population Report, Adult Vaxview, accessed November 24, 2019. <u>https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-</u><u>resources/NHIS-2016.html</u>.

have access to vaccines, like the homeless. Herd immunity offers utility to protect vulnerable groups. It is unfair when herd immunity offers protection to those who choose not to vaccinate.



The 2014 Measles outbreak and current Hepatitis A outbreak are both examples of herd immunity failing. Despite the potential utility herd immunity may play in protecting vulnerable groups, adult vaccine rates would have to be much higher for there to be any potential value. In contrast, for the non-vulnerable groups, taking advantage of herd immunity is at conflict with utilitarian public health initiatives. And as in the case of measles, taking advantage of herd immunity is also doomed to fail.

One of the most successful tools in improving vaccination rates are vaccine requirements or mandates. School mandates for vaccinations have tremendously helped immunization rates over the last few decades. However, laws are different state by state. There are still opportunities for children to enter school despite the mandates. While all states allow medical exemptions, some states also offer religious and/or philosophical exemptions. Each state establishes their own mechanisms for enforcement of school vaccination requirements and exemptions.⁶¹ This category of exemptions falling under "philosophical reasons" may pose the biggest danger to herd protection of infectious disease. For example, in New Jersey, the state only allows temporary and permanent physical exemptions and religious exemptions. Pennsylvania, a bordering state, allows philosophical exemptions as well. The percentage of unvaccinated children in Pennsylvania is very high due to the philosophical exclusion. Only 86.9% of Kindergarten aged children in PA were vaccinated for MMR during the 2011-2012 school year.⁶² This is the second lowest in the US, only beat by Colorado, another state that allows philosophical vaccine exemptions. Note that 86.9% is less than the 90% required for herd immunity. Herd immunity does not exist for measles in the state of Pennsylvania.

The list of current 2017 philosophical state exemptions is long with 19 states allowing exemptions. Unlike Medical exemptions, allowing children with rare conditions that cannot be exposed to vaccines an out, the philosophical exemptions allow parents to refuse vaccines because they do not believe in the science or have been influenced by the anti-vaccine movement. Interesting to note that both Pennsylvania and California, where the two largest outbreaks in recent years occurred, are on this list. This is not a coincidence but the result of waning herd immunity as more parents take advantage of the philosophical exemption category in these states. Below is a snapshot⁶³ from the CDC website for current 2017 philosophical state exemptions.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6133a2.htm#tab1.

⁶¹ CDC, "State Vaccination Requirements," For Immunization Managers, accessed November 14, 2017, <u>http://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html</u>.

⁶² CDC, "Vaccine Coverage Among Children in Kindergarten – United States, 2011-12 School Year," MMWR, accessed November 7, 2020,

⁶³ CDC, "School Vaccination Requirements, Exemptions, and Weblinks," SchoolVaxView, accessed Novemeber 14, 2017,

http://www2a.cdc.gov/nip/schoolsurv/schImmRqmtReport.asp?s=Philosophical,%20grantee&d=10&w=% 20&t=2.

<u>State</u>	Medical		Doligious	Dhilocophical
	Temporary	Permanent	Keligious	Philosophical
Arizona	√	√		✓
Arkansas	√		√	\checkmark
California	√	 ✓ 		\checkmark
Colorado	√	 ✓ 	√	\checkmark
Idaho	√	 ✓ 	√	\checkmark
Louisiana	√	✓	√	\checkmark
Maine	\checkmark		√	\checkmark
Michigan	√	✓	√	\checkmark
Minnesota	\checkmark	√	√	\checkmark
New Mexico	√	✓	√	\checkmark
North Dakota		✓	√	\checkmark
Ohio	√	✓	√	\checkmark
Oklahoma	√	✓	√	\checkmark
Pennsylvania	√	✓	√	\checkmark
Texas	√	✓	√	\checkmark
Utah	√	✓	√	\checkmark
Vermont	\checkmark	✓	~	\checkmark
Washington	\checkmark	✓	~	\checkmark
Wisconsin	\checkmark	✓	~	\checkmark

Until philosophical exemptions are eliminated, the population is at risk to experience the re-emergence of VPDs. Dr. Steven Novella⁶⁴ supports eliminating the philosophical state exemptions. In a 2015 article⁶⁵, Novella asserts that Mississippi has the highest vaccination rates, close to 100%, and does not allow any exemptions other than medical. He goes on to mention that states with philosophical exemptions have 2.5 times the vaccine refusal rate than states with no philosophical exemptions. The exemption allows parents the right to refuse vaccines and take advantage of herd immunity. As more states allow these kinds of exemptions and more parents exercise their rights to choose not to vaccinate the herd protection will

 ⁶⁴Novella, Steven, "Personal Belief Exemptions for Vaccines," Science Based Medicine, accessed
 Novemeber 26, 2017, <u>https://sciencebasedmedicine.org/personal-belief-exemptions-for-vaccines/</u>.
 ⁶⁵ Ibid.

continue to diminish and will offer no effect. It may be considered unfair to allow other parents to vaccinate while asking for a philosophical exemption for your own child. Vaccine policies are in place to protect everyone and should therefore be respected and implemented by everyone.

Vaccine programs exist to protect us, our children, grandchildren, and future generations. The risks when we stop vaccinating are serious to public health as is evidenced by the re-emergence of measles and the related consequences. The re-emergence of pertusis in Japan in the 1980s is an insightful example. In 1974, Japan had a successful pertussis vaccination program, with nearly 80% of children vaccinated. That year only 393 cases of pertussis were reported in Japan, and no deaths were reported. In just 2 years, the pertussis program success was undone as safety of the vaccine became questionable and misinformation was disseminated that the vaccine was no longer necessary due to herd immunity. By 1976, only 10% of infants were getting vaccinated. In 1979 Japan experienced a major pertussis epidemic, with greater than 13,000 cases of whooping cough and 41 deaths. In 1981 the government course corrected and began vaccinating with acellular pertussis vaccine. The number of pertussis cases dropped again as the vaccination rates rose.⁶⁶ This exemplifies an important lesson to not take herd immunity for granted and to not assume herd immunity when it is not there.

As it pertains to measles, the MMR vaccine is still part of the ACIP childhood vaccine schedule. It is a required vaccine because measles is still prominent around the globe and with the reintroduction in recent years in the US, there is no herd protection here either.

⁶⁶CDC, "A Final Example: What Could Happen," Vaccines and Immunizations, accessed April 5, 2020, <u>https://www.cdc.gov/vaccines/vac-gen/whatifstop.htm</u>.

Vaccine Policy

Vaccine policy is designed to encourage childhood immunizations and is not specific to adult immunizations. Currently, over 17 diseases are targeted by US immunization policy. ⁶⁷ Policy is in place to vaccinate children from Vaccine Preventable Disease. The impact to children is great, yet the incidence of illness attributable to VPD is greatest among adults.⁶⁸ The most recent National Health Institute Survey (NHIS) reports ~23% of adults have received the Tdap vaccine, ~30.6% of adults over 60 have received Herpes Zoster vaccine, and only 9% and 24.5% of adults \geq 19 years of age received hepatitis A vaccination and hepatitis B vaccination respectively in 2015.⁶⁹ The rates are low and the government is responsible for taking action. However, the rates have held steady here for the last several NHISs. This indicates that the actions taken may not be strong enough.

The benefits of vaccinating against all VPDs are impactful and necessary. However, even though the results of vaccination are promising, as mentioned, immunization rates among adults are low. The lowest rates are among minorities and the poor in the United States despite 317 funding for state specific programs like Vaccines for Adults (VFA). VFA programs are publicly funded programs, similar to VFC. Adults aged 19 and older who are uninsured or under-insured will receive free vaccines and will not be billed for the vaccine administration by the provider if the patient is unable to pay.

⁶⁷ CDC, "Vaccine Coverage Among Children in Kindergarten – United States, 2011-12 School Year," MMWR, accessed November 7, 2017,

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6133a2.htm#tab1.

⁶⁸ Walter W. Williams, MD et al., "Surveillance of Vaccination Coverage Among Adult Populations — United States, 2014," *MMWR Surveillance Summaries* 65, no. 1 (February 5, 2016):1, accessed October 22, 2017, https://www.cdc.gov/mmwr/volumes/65/ss/ss6501a1.htm.

⁶⁹ Ibid

Only select states like New York and California have 317 funding set aside to support VFA programs. Vermont is an example of a universal state where the state provides free vaccines to providers for all children and adults via the VFC and 317 funds. Because the population in Vermont is small, this program is manageable financially and logistically. It is also showing success, Vermont has the highest adult immunization rates for zoster in the US. Vermont's rates for all 3 HPV vaccines are higher than the US averages.⁷⁰ Other smaller states can leverage the Vermont program as a case study in implementing a universal program, taking the guesswork out of "are the vaccines covered?"

Programs like VFA help increase adult vaccine rates, particularly among the poor, however they are the exception and not the norm. Ideally, immunization rates should be consistent across all groups and collectively above the Healthy People 2020 goal. Healthy People 2020 intends to increase immunizations rates in all adults including those difficult to reach, like the poor.

With that stated it is important to acknowledge how disease prevention improves quality of life, increases life expectancy, and reduces cost associated with disease burden and ill health. The increase in life expectancy experienced during the 20th century is in part due to improvements in childhood survival. Per Healthy People 2020, this increased life expectancy is associated with "reductions in infectious disease mortality, due largely to immunization."⁷¹ However, infectious diseases remain a major cause of disease

⁷⁰ Vermont Department of Health. "Vermont Immunization Program 107 Annual Report," Health Vermont, accessed January 4, 2020, <u>https://www.healthvermont.gov/sites/default/files/documents/pdf/ID_IZ_RATES_annual_report_2017.p</u> df.

⁷¹ Healthy People 20/20, "Immunization and Infectious Diseases," *20/20 Topics and Objectives*, accessed October 30, 2017, https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases.

burden, disability, and mortality particularly for the poor. The Healthy People 2020 website explains, in the US we continue to see and monitor diseases that are vaccine preventable. "Viral hepatitis, influenza, and tuberculosis (TB) remain among the leading causes of illness and death in the United States and account for substantial spending on the related consequences of infection.⁷²" For these reasons the Healthy People 2020 goal to "Increase immunization rates and reduce preventable infectious diseases⁷³" is in place to protect all people regardless of their race/ethnicity, socio-economic and health insurance status.

While policy is in place to encourage childhood immunizations, goals are set to achieve adult immunization rates. Goals are softer and unenforceable; they are less effective in achieving results than mandates. The Healthy People Goals are the most robust goals specific to adult immunizations. Healthy People 2020 is an Office of Disease Prevention and Health Promotion program that sets population-based health goals to progress US health statistics every 10 years. Some practitioners embrace the goals and make them part of their practice protocols, others do not even acknowledge their existence as they are not requirements or policy, only milestones set to decrease the incidence of infectious disease.

Outside of the Healthy People immunization goals and adult immunization recommendations, the US government has taken a passive approach to improving adult immunization rates. Healthy People 20/20's goal is to improve immunization rates and reduce preventable infectious disease as stated on their website.⁷⁴ The effort has evolved from Healthy

⁷² Healthy People 20/20, "Immunization and Infectious Diseases," *20/20 Topics and Objectives*, accessed October 30, 2017, https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases.

⁷³ Ibid

⁷⁴ Ibid

People 2010 to focus on community activities and technological advancements in creating a better partnership between the government and immunization goals. The reality is despite significant efforts to improve childhood vaccination rates, approximately 42,000 adults and 300 children in the United States die each year from VPDs.⁷⁵ Measures taken to improve the childhood vaccine rates have made an impact. There should be research to understand why the CDC is not applying these learnings to adults.

The next set of objectives beyond Healthy People 2020 is Healthy People 2030. Healthy People 2030 has 16 Core Objectives and 1 developmental objective related to Immunization and Infectious Disease. The goals are macro-level without specific metrics tied to them.

Although the list is ambitious in favor of vaccines; there is only one out of sixteen goals specific to adult immunizations. This goal is specific to all people over the age of 6 months including adults. It is only for influenza vaccine. The optional goal is also specific to adults but only to pregnant women, and it is in interest of protecting the fetus. There are no other adult specific vaccinations goals. Adult vaccination may be inferred in numbers one and two relevant to hepatitis B and C respectively however; the goal of reducing the number of persons with these diseases is very loose. It would have been strategic for Healthy People to draw from the Healthcare Effectiveness Data and Information Set (HEDIS) adult composite measure for adult vaccines. I will discuss HEDIS further in Chapter Six.

Finally, my last insight around these objectives concerns the lack of specific metrics. It is surprising that the objectives are not more outcome oriented. I would expect to see goals defined as reduce the rate by x percent or increase the number vaccinated by x percent. I imagine the vagueness may be related to these being proposed objectives and not finalized however,

75 Ibid

proposed objectives can be more specific in what the goal is and how to measure success. Again, since Healthy People is only a guideline and not a mandate it is left to be seen how many practitioners decide to follow these objectives.

HPV Vaccine and Cancer Prevention Programs

Policy advances are needed for adult immunizations. For example, in a recent article on reasons why adults do not get vaccinated, Dr. Sangini S. Sheth, ⁷⁶ references catch-up vaccination against the human papillomavirus (HPV). HPV can cause cancers of the cervix, vulva, vagina, penis, anus, and throat. Catch up vaccines for adult women could be included in the federally funded National Breast and Cervical Cancer Early Detection Program. This program was developed in the 1990s to reduce deaths from breast and cervical cancer. According to Dr Seth's article,⁷⁷ "Adult Vaccinations Save Lives, Why Do So Few Adults Get Vaccinated?" the detection program has provided access to cervical cancer screening for thousands of women. This program could be an excellent vehicle for supporting and implementing HPV vaccination.

In many states, the early detection program provides access to Pap screens and HPV testing for uninsured women and undocumented women. The women can benefit from HPV immunization offered through this program, particularly if they are within the catch-up immunization ages of 13 to 26 years. They can even benefit if they are older and between the ages of 27 and 45 years. Inclusion of the HPV vaccine in the early detection program for uninsured adults, who are not eligible for the Vaccines For

⁷⁶ Sheth, Sangini S. MD. "Adult Vaccinations Save Lives. Why Do so Few Adults Get Vaccinated?," STAT Nov 15, 2019, accessed January 4, 2020, https://www.statnews.com/2019/11/15/vaccinationsaves-adult-lives/. 77 Ibid

Children program, would save money according to Dr. Sheth, ⁷⁸ "by reducing the number of abnormal cervical cancer screening results later on that require follow-up and procedures."

Chapter One Conclusions

In this chapter I have demonstrated the value of vaccines as lifesaving and disease eradicating preventative measures. I have reviewed a brief history of the impact vaccines have made from the advent of immunization. I have started to address one of the major barriers to vaccination, the anti-vaccine influencers and the negative impact their propaganda achieves. Measles had been eradicated however, in 2019 there were 1,261 cases in the United States through November 7. Hepatis A outbreaks continue to occur despite the CDC recommendation that all persons over the age of 1 year be vaccinated against hepatitis A.

Currently, adult immunizations rates in the United States are very low and ideally should be improved. The United States spends an immense amount of money on reactive medical care contributing to over \$3.4 Trillion dollars spent in the healthcare ecosystem.⁷⁹ Vaccines are a cost-effective and simple measure to help reduce the economic burden our healthcare system continues to perpetuate. This dissertation examines how the ACIP and CDC can support increased utilization of adult vaccines through the pharmacist. These governing bodies should ask which policies would support

⁷⁸ Ibid.

⁷⁹ Tony Abraham, "US Healthcare Spending Estimated to Grow to \$3.6MT This Year." HealthCareDive, accessed January 9, 2020, <u>https://www.healthcaredive.com/news/us-healthcare-spending-estimated-to-grow-to-36t-this-year/555658/</u>.

immunizations and how to set strategic, aligned, and incentivized goals to help achieve higher adult immunization rates.

Like Dr. Sangini Sheth, I question why if vaccines save lives, so few adults get vaccinated. Vaccines prevent death and the side effects affiliated with preventing death are mostly benign including pain at the injection site and muscle soreness. In the next chapter I will explore the barriers to adult immunizations including the lack of focus on prevention in the US healthcare landscape, questions about vaccine efficacy, the beliefs and behaviors of primary care physicians specific to vaccines, the vaccine hesitant, and vaccine myths and misconceptions influencing consumers. Chapter Three will address the anti-vaccine movement and its affiliated barriers.

In 2019, the World Health Organization (WHO)⁸⁰ ranked vaccine hesitancy, a "reluctance or refusal to vaccinate despite the availability of vaccines," among the top 10 health threats worldwide, alongside Ebola, H.I.V. and drug-resistant infections. WHO characterizes vaccines as "one of the most cost-effective ways of avoiding disease – it currently prevents 2-3 million deaths a year, and a further 1.5 million could be avoided if global coverage of vaccinations improved."⁸¹ The United States can contribute by improving adult immunization rates. The barriers to immunization limit the benefits to the individual and to the public as outlined throughout this chapter. The next chapter will outline and review the most common barriers to adult immunizations in the United States. Once the barriers are defined it becomes more clear how to move forward in driving vaccine uptake and utilization.

⁸⁰WHO, "Ten Threats to global health in 2019," Feature Stories, accessed January 9, 2020, <u>https://www.who.int/emergencies/ten-threats-to-global-health-in-2019</u>.

⁸¹ Ibid.

Chapter 2: Barriers and Beliefs Around Adult Immunizations

Introduction

In this chapter I will elaborate further on the current situation of adult vaccines in the United States and provide the theoretical framework around why rates are low. There are several areas I will consider:

- The language used to describe vaccines
- The foundation of biomedicine and the lack of focus on prevention
- Philosophical barriers to vaccinating including vaccine hesitancy
- Myths and misconceptions about the safety of vaccines and potential concerns about the spread of infectious disease through the use of needles
- Logistical barriers for the uninsured
- Advisory Committee on Immunization Practices (ACIP) recommendations and the lack of adult mandates
- The ethical considerations of adult mandates
- Adult vaccine efficacy
- The barriers that currently exist for pharmacists and non-pharmacists Health Care Providers (HCPs) to administer vaccines including cost, time, and coverage

I will incorporate the concept of the self and Scheper-Hughes and Lock's individual body and the social body⁸² as they relate to barriers within primary care and vaccine hesitancy. These concepts are borrowed from medical anthropology, bringing a unique analysis to the multi-layered barriers behind adult immunizations in the United States. There may not be one barrier that stands out against others, however there are

⁸² Nancy Scheper-Hughes and Margaret M. Lock, "The Mindful Body: A Prolegomenon to Future Work in Medical Anthropology." In *Understanding and Applying Medical Anthropology*, ed. Peter J. Brown (Mountain View, Mayfield Publishing Company, 1998). 208-25.

several that can be broken down and prioritized to improve public health through increasing adult immunizations.

Vaccine Language

Perhaps first and foremost are the terms associated with the word vaccination.⁸³ I hypothesize that negative terminology influences the way we perceive many things, including vaccines. I am reminded in the fall as I drive past a grocery store and pharmacy of "flu shots". Outdoor signage advertising "Flu shots are here" seem to be placed strategically on every pharmacy corner. I am in favor of vaccination and still cringe when I see these signs. The term shot does not correlate in a positive way for me. Shot sounds like something coming out of a gun; something that has the potential to kill someone. I am not aware of anyone proactively signing up for gun shots. Anecdotally, when I have asked major retail chain leadership in the past about the terminology on these signs, I am met with the simple fact that consumers refer to vaccines as shots. They ask for a flu shot; not a flu immunization. Seeing how influenza immunization rates are only 26.9% for adults aged 19-49 for the 2017-2018 season, I am not surprised that the term flu shot could be influencing the other ~73% not to partake.

I am also struck by some of the other terms used in reference to vaccines. When I was a regional vaccines sales director in New Jersey, I challenged my team to help us think of a creative team name incorporating some vaccination language. Terms like stab, jab, and shot rose to the top of the suggestions. Ironically, we landed on Jersey Jabbers. Cute, but perpetuating the violence associated with the way we describe a live saving

⁸³ Eula Biss, *On Immunity: An Inoculation* (Minneapolis: Graywolf Press, 2014):12-13.

tool. Eula Biss⁸⁴ summarizes the violence in *On Immunity: An Inoculation*. "If we source our understanding of the world from our own bodies, it seems inevitable that vaccination would become emblematic: a needle breaks the skin, a sight so profound that is causes some people to faint, and a foreign substance is injected directly into the flesh. The metaphors we find in this gesture are so overwhelmingly fearful, and almost always suggest violation, corruption, and pollution."⁸⁵ If we want the public to embrace vaccination, we need to start to change the paradigm and offer some positive overtures as I will discuss in Chapter 5.

Nevertheless, I hypothesize the negative tone and terminology exists and serves the individuals involved in undoing significant benefits of vaccination. The anti-vaccine movement leverages these negative associations and uses them to continue to perpetuate fear, myths, and mistruths around vaccination. They proliferate misinformation through celebrity and political influencers, grabbing the attention of the lay person who may be hovering on the fence about vaccines. It is imperative the pro-vaccine movement educates the lay people who are hovering first, those that are vaccine hesitant.

Lack of Focus on Prevention

The underutilization of prevention is a health concern in the United States. Our medical system is designed to work reactively. A common scenario includes insured individuals waiting for illness prior to seeking medical care. Doctors are educated in medical school to treat disease; often to what is considered heroic measures leading to

⁸⁴ Eula Biss, On Immunity: An Inoculation (Minneapolis: Graywolf Press, 2014).

⁸⁵ Biss, On Immunity: An Inoculation, 12.

increased costs to the healthcare system. In my opinion and experience with the United States health system, many patients in the U S seem to take their health for granted. Based on my experience as a researcher and marketeer, they do not take accountability for being proactive and preventative in the medical setting. However, a more modern movement on healthy aging has shifted the mindset to a healthier lifestyle with a focus on eating right, getting rest, exercise, and balancing activity with rest⁸⁶. Doctors may prescribe some of these items but usually after someone has come in to react to another condition.

The focus on prevention exists outside of the doctor's office and in the health food store or vitamin shop; often a place where anti-vaccine materials are commonly found. Whole Foods, whose mission is "to nourish people and the planet,"⁸⁷ is a common household name associated with healthy living. Whole Foods Market has been charged with promoting anti-vaccine material in their checkout lines. ⁸⁸ Adjacent to magazines promoting yoga and healthy cooking are titles like *Well Being Journal*, a bi-monthly publication sold at Whole Foods stores in many locations. According to Insider, this journal has published articles about homeopathic therapies as "non-toxic" alternatives to vaccination. Other articles in this publication promote the disproven link between the MMR vaccine and autism. One article in a 2017 issue, adapted from a defunct anti-

⁸⁶ As a vaccine marketer, I spent years doing market research understanding consumer behavior around health and wellness. Many adults believe that eating right, exercising, and getting rest is enough. They see those activities in the realm of prevention and fail to see medical interventions like vaccines in the same scope.

⁸⁷ Whole Foods, "Mission & Values," Home, accessed April 10, 2020, www.wholefoodsmarket.com.

⁸⁸ Maddie Stone, "Whole Foods is Selling Dangerous Anti-Vaccine Propaganda in it's checkout Aisles," *Insider*, (Dec 10, 2019), accessed January 2, 2020, <u>https://www.insider.com/whole-foods-amazon-anti-vaxxer-vaccines-2019-12</u>.

vaccine website, is titled "MMR Vaccine Causes Autism."⁸⁹ The Well Being Journal can also be found at Sprouts, a similar wholistic grocer with a healthy living focus.

The Insider article refers to several anti-vaccine stories appearing in the Well Being Journal over the years. The journal has quoted Dr. Sherri Tenpenny, a prominent naturopath and very outspoken anti-vaccine physician in Ohio. In an Interview with Dr Hotze, from the Hotze Wellness Center International, Tenpenny says, "I stand firmly on the fact that vaccines are not safe. That schedule has never been proven to be safe. The interaction between all the different chemicals and antigens, effective is not a synonym for protection and vaccines are causing irreparable harm to the human DNA and human genetics at all age groups, from babies all the way through seniors."⁹⁰ I address the antivaccine movement in the following chapter however, I would like to comment now on some of the other misinformation found in this interview.

Dr. Hotze and Dr. Tenpenny begin to discuss the hepatitis B birth dose. After Dr. Tenpenny explains the incidence of hepatitis B in infants in the US, Dr. Hotze states, "and Hepatitis B can only be transmitted by blood or by perverted sexual acts. That's the only way it can be. So, there's no way that little baby, a one or two day old baby or a young child is going to have any problem with hepatitis."⁹¹ What they are failing to acknowledge in this interview is that babies born in the US are given this vaccine while they are in the hospital. They could need a blood transfusion which could expose them to contaminated blood with hepatitis B. Also, during their time in the hospital they could be

⁸⁹ Ibid.

⁹⁰ Hotze Health," Dr Sherri Tenpenny on the Dangers of Vaccination," Accessed January 2020, <u>https://www.hotzehwc.com/2018/07/dr-sherri-tenpenny-on-the-dangers-of-vaccinations/</u>July 27, 2018.. ⁹¹ Ibid.

inadvertently stuck with a needle also putting them at risk. Most likely, an infant could become infected with hepatitis B from their birth mother. Infants are at significant risk for the infection to become chronic and without treatment can die.⁹² It is therefore CDC recommended that all infants receive the vaccine in the first 24 hours of their life.⁹³ Since Dr. Hotze and Dr. Tenpenny do not acknowledge the CDC recommendation rationale and argue that an infant is not at risk for this disease. Their claim that the CDC and medical community perpetuate misinformation about vaccines is inaccurate and inconsistent with the World Health Organization (WHO).

Now, back to the problem of the US lack of a medical focus on prevention. Limited accessibility, high costs, and time are all barriers to the physician focus on prevention, including vaccines. Physicians should be rewarded through incentives to focus on prevention. Patients need to put prevention into their own hands as well. They will need the proper education to do so. If we leave prevention up to the healthy lifestyle magazines found in Whole Foods and other wellness centers, vaccines will be left out of the paradigm as evidenced above. It should be considered to include vaccines in what it takes to lead a healthy lifestyle, preventing vaccine preventable disease is an easy step towards health and wellness that does not require long term maintenance like diet and exercise.

An interesting conversation led me back to thinking about Whole Foods in the context of vaccines. Since Whole Foods was purchased by Amazon there is the potential

⁹² World Health Organization, "Who is at Risk of Chronic Disease?," Hepatitis B, accessed April 10, 2020, https://www.who.int/news-room/fact-sheets/detail/hepatitis-b.

⁹³ CDC, "Prevention of Hepatitis B Virus Infection In the United States: Recommendations of the Advisory Committee on Immunization Practices," *MMWR*, accessed April 10, 2020, https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm.

for pharmacy product distribution. Whole foods allows for cold chain distribution and storage as well being a grocery store. In this conversation I was asked if vaccines are safe to sell over the counter in whole foods. I was asked if vaccines are safe in the context of self-administration, like a diabetes medication. In theory, yes. However, vaccines are prescribed so they are not misused, overused, or administered incorrectly. Many vaccines require a process called reconstitution before you administer them into the body. If not stored properly (either refrigerated or frozen, specific to the vaccine) the vaccine is not effective. There could be potential on the self-administer concept, however at this point it is illegal. If vaccines were made available to purchase and selfadminister over the counter, then there could be partnerships with places like Whole Foods and they could become part of the wellness paradigm in their store. In Chapter 6 I will discuss another more practical and realistic solution that can be executed in the current environment. The community pharmacy can be useful in bridging this gap.

Adult Vaccine Policy: Is There Adult Vaccine Policy?

The ACIP issues guidelines and recommendations for childhood and adolescent immunizations. The recommended schedule has been adopted by public school systems as a requirement to public school entry. However, there are state specific exemptions for religious, philosophical, and medical reasons as has been outlined earlier in this dissertation. Yet, for the most part children are required to be immunized and even those who have access barriers are covered under the Vaccines For Children (VFC) program,⁹⁴

⁹⁴ CDC, "Vaccines For Children Program (VFC), Vaccines For Children Home, accessed April 10, 2020, https://www.cdc.gov/vaccines/programs/vfc/index.html.

receiving free vaccines, paid by state tax payers, from VFC providers. The ACIP also issues an adult vaccine schedule of recommended adult immunizations. Physicians are encouraged to provide these recommended immunizations to their adult patients however there are no school requirements or standard work requirements pulling through the recommendations like the childhood schedule. Furthermore, measures, like the National Committee for Quality Association (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS),⁹⁵ which has an adult composite vaccine goal, including Tdap, Pneumococcal, influenza, and shingles are not required but rather voluntary as uptake is measured.

Because there are no policies in place requiring adult immunizations, adults are essentially left to make their own decisions on their immunizations. Without the proper education on the need to receive the recommended vaccines; most adults do not include vaccines in their wellness and prevention paradigm. This is problematic because adults who do not vaccinate are suffering from diseases like pertussis, hepatitis, and shingles unnecessarily. Worse, they may be spreading diseases like pertussis to vulnerable populations, like infants. Furthermore, if a physician does not initiate the discussion, the patient is unlikely to proactively seek a vaccine. The pharmacy offers a convenient location for adults to receive vaccines however more education needs to be delivered to create awareness on the role of the pharmacist as a vaccinator and clinical expert in helping adults make vaccine decisions. One of the biggest barriers in the pharmacy setting is that even when the pharmacist proactively offers a vaccine to adult patients,

⁹⁵ NCQA, "Proposed Changes to Existing Measure for HEIDIS MY 2020 Adult Immunization Status (AIS)," accessed January 10, 2020, https://www.ncqa.org/wp-content/uploads/2020/02/20200212 16 AIS.pdf.
they are mostly unsuccessful⁹⁶. If that patient has not already had the vaccine conversation with their physician, they are unwilling to receive the vaccine. Chapter Four reviews my original research with pharmacists for this dissertation. 75% of my respondents confirmed that patients want to speak with their doctor before receiving the vaccine the pharmacist recommended. Most patients see the physician as their guide to these kinds of decisions. Without adult mandates or the physician recommendation, adults do not make vaccine choices for themselves.

I will discuss more about current immunization policies in the United States in Chapter Six. Most interesting is looking at the rich history of the anti-vaccine movement and the strong tie to personal liberties as a driver in keeping the government from making vaccine mandates. Would adult vaccine mandates interfere with our constitution? How much can the government intervene in our health-related decisions? Is it ethical for the government to enforce vaccine regulations on adults in the interest of public health? These are ethical questions to consider when discussing adult immunization mandates.

The very recent COVID-19 pandemic in 2020 is an interesting case study. As vaccine manufacturers offer adjuvant technologies to scientific research partners to quickly manufacture a corona virus vaccine; people all over the world wait in anticipation. If the United States government were to make corona-virus vaccination mandatory would there be an outcry of resistance or placid acceptance? We are witnessing the impact this disease has on the greater population in real time. For many potential immunizers this is when vaccines matter.

⁹⁶ This will be further explored in Chapter 4 and is captured in my research. Many conversations I have had with pharmacists go down this path as well confirming that patients are either too busy to receive a vaccine that day and/or need validation from their physician first.

Vaccine Access: A Barrier for the Poor

Perhaps the most at-risk for vaccine preventable disease in the United States is the under or uninsured. Those who are economically disadvantaged suffer from crowded living conditions, poor nutrition, limited or no access to healthcare, and unclean sanitary conditions. This creates the perfect storm for diseases to spread. Furthermore, due to complications that more heavily impact the poor such as limited access to transportation, less flexible work schedules, and frequent telephone number and address changes, access to vaccines and completing an immunization series is limited. Health Care Providers communicate challenges in getting series completion rates higher especially in less affluent populations⁹⁷ that are more transient and have fewer resources to come back to the clinic to continue or complete a vaccine series. It is pertinent that solutions to improve vaccination rates are focused on completing the entire series.

There is much discussion on lower immunization rates and lower series completion in poor children. Many of the findings can be applied to poor adults as well. For example, Schempf et al.⁹⁸ have presented a host of reasons for lower rates in the indignant attributed to missed opportunities within the healthcare system including: "inappropriate contraindications, failure to administer simultaneous vaccinations, and failure or inability to assess immunization status at every contact.⁹⁹" This last piece is

⁹⁷ K.E. Gallagher, et al., "Factors influencing completion of multi-dose vaccine schedules in adolescents: a systemic review," BMC Public Health, 2016; 16:172, published online February 19, 2016, accessed April 11, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4759915/.

⁹⁸ Ashley H. Schempf, Robert M. Politzer, and John Wulu, "Immunization Coverage of Vulnerable Children: A Comparison of Health Center and National Rate," *Medical Care Research and Review* 60 No.1, (March 2003).

⁹⁹ Ibid, 86.

largely due to poor children and adults having multiple vaccine providers and scattered records.

The Importance of Vaccinating Vulnerable Populations

Poverty is one of the largest risk factors for acquiring and living with disease worldwide. Historically when compared to other risk factors such as the environment and genetics, poverty has received less attention from the health care community. According to an article¹⁰⁰ entitled "Poverty, Global Health and Infectious Disease: Lessons from Haiti and Rwanda," several reasons contribute to this lack of attention.

First, being poor is not considered a disruption of normal physiologic function. Physicians and basic scientists viewed themselves as ill-equipped to understand or manipulate an individual's socioeconomic status. Second, unlike the largesse dedicated to finding technical solutions for population health problems, funding for research dedicated to understanding and alleviating poverty was sparse. Third, although some acknowledged that poverty plays a pivotal role in determining disease vulnerability and outcomes, the resultant solutions aimed at redressing poverty were often wrongheaded. For example, structural adjustment programs (SAPs) aimed at increasing GDP growth often involved austerity measures, such as cuts in government spending, currency devaluation, and privatization. These macroeconomic shifts involved intertemporal tradeoffs— "temporary pain for long-term gains"—and completely ignored the path-dependent nature of healthcare. If a child does not get vaccinated, a pregnant mother lacks antenatal care, or a TB clinic goes without drugs, the health consequences can reverberate for generations¹⁰¹.

The last sentence speaks specifically to the importance of vaccinating the poor;

the "consequences" can be felt for generations. What are the potential consequences?

¹⁰⁰ Marcella M. Alsan, Michael Westerhaus, Nichael Herce, Koji Nakashima, and Paul E. Farmer, "Poverty, Global Health and Infectious Disease: Lessons from Haiti and Rwanda," *Infect Dis Clin North Am*. 3 (Sept25, 2011).

¹⁰¹ Ibid, 612.

First, everyone including, the poor, the middle class and the rich are at risk if the poor are left unvaccinated. Diseases are communicable and evidence¹⁰² suggests that the under-privileged are at a greater risk for acquiring and succumbing to illness and disease. Therefore, the poor are at the greatest risk themselves to transmit disease to each other and the least able to get the proper medical attention required to treat disease. Second, according to Mazlow's Hierarchy of Needs¹⁰³ safety, including health, is one of the fundamental building blocks required to be able to reach self-actualization. Once this occurs the poor would be better able to contribute to society and have the real opportunity to move from below the Federal Poverty Level (FPL) to above the FPL.

Good health provides the ability to work, to earn, to start a family and to move the poor towards the middle class. An example of a non-health related consequence is the loss of productivity. Someone who belongs to a low socio-economic working class, may not have sick days or paid time off to compensate for missed time. Related financial impacts could be the difference between making a rent payment and being able to feed the family. The above consequences are public health and national concerns and make it imperative for the poor to have access to vaccines to protect against preventable diseases. The impact is felt by everyone when a group like the poor is unprotected and left to fend for themselves.

Communicable diseases do not exist in geographic silos within a given community. In a similar vein they do not remain within a given country. In our global

¹⁰² Poor Health, "Poor Health: Barriers to Healthcare for Low Income America," Home, accessed April 11, 2020, https://newsinteractive.post-gazette.com/longform/stories/poorhealth/1/.

¹⁰³Seul McLoud, "Maslow's Heirarchy of Needs," Simple Psychology, accessed November 15, 2020, <u>http://www.simplypsychology.org/maslow.html</u>.

economy and society, it is evident that diseases do not stop at geopolitical borders. For example, in 2014 outbreaks of Ebola in West Africa¹⁰⁴ spread across the globe to the United States due to international travel and U.S. Health Care Provider volunteer efforts in Africa. As illustrated in this example, "awareness of disease, prevention and treatment courses remain essential components for reducing infectious disease transmission."¹⁰⁵ Despite progress with interventions in the spread of infectious disease, nearly "42,000 adults and 300 children in the United States die each year from vaccine-preventable diseases."¹⁰⁶ Furthermore, specific communities, such as underprivileged communities with unvaccinated and under vaccinated populations are at increased risk for outbreaks of vaccine-preventable diseases.

"In 2008, imported measles resulted in 140 reported cases—nearly a 3-fold increase over the previous year."¹⁰⁷ In 2019, 1,282 cases of measles were reported in 31 states of the United States¹⁰⁸. According to the CDC, 128 resulted in hospitalizations of which 61 had complications including pneumonia and encephalitis. The re-emergence of vaccine-preventable disease can result in undesirable outcomes such as increased illness, disability, or death in these communities. According to the CDC website measles continues to be a common disease in many parts of the world. "Anyone who is not protected against measles is at risk of getting infected when they travel

¹⁰⁴ CDC, "2014 Ebola Outbreak in West Africa," Ebola Virus Disease, accessed November 8, 2015, <u>http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html#areas</u>.

¹⁰⁵ ODPHD, "Immunization and Infectious Disease," Healthy People, accessed November 8, 2015, <u>http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases</u>.

¹⁰⁶ Ibid.

¹⁰⁷ Ibid.

¹⁰⁸ CDC, "Measles Cases and Outbreaks," Measles Home, accessed February 22, 2020, https://www.cdc.gov/measles/cases-outbreaks.html.

internationally.¹⁰⁹ Many patients that are part of the Vaccines For Children (VFC) program travel internationally in their infancy and are at risk for contracting and carrying measles into the United States. It is pertinent that these infants receive a full series of MMR at the appropriate time to protect themselves, their families, and everyone else they encounter. Additionally, MMR coverage is needed to sustain elimination of the disease in this country, although over 1,000 cases in 2019 suggest that it has not been eliminated.

The re-emergence of diseases such as measles, once non-existent in the United States makes an excellent case for complete vaccination programs that address all populations, particularly those most at risk such as the poor. In an article titled, "Immunization Coverage of Vulnerable Children: A Comparison of Health Center and National Rates," Schempf et al. discuss that "poor, minority, and uninsured children use only half to two-thirds as many physician services and are at least twice as likely to be inadequately vaccinated for measles."¹¹⁰ Inadequate coverage can come from several complicating factors including inadequate vaccination series record keeping in this transient population. Schempf et al. continue to illuminate that poor and minority children are inadequately immunized because of structural obstacles and barriers such as long wait times, inflexible schedules, inadequate transportation, work barriers as well as cultural and language barriers.¹¹¹ To Schempf et al.'s point, transportation to health care facilities is yet another obstacle for the under-privileged; even if there is a Federally Qualified Health Care Center (FQHC) in the area, how does this patient arrive? Suppose

¹⁰⁹ CDC, "Prevent Measles with Measles Vaccine," Measles (Rubeola) accessed November 9, 2015, <u>http://www.cdc.gov/measles/index.html</u>.

¹¹⁰ Schempf, "Immunization Coverage of Vulnerable Children: A Comparison of Health Center and National Rates,"86.

¹¹¹ Ibid, 87.

they have access to transportation do they have time off from work? Culture and language are also roadblocks in improving vaccination rates.

Another example emphasizing the importance of vaccinating at-risk groups is influenza. The Advisory Committee on Immunization Practices (ACIP) has included the following in high risk groups for influenza: adults aged 65 years of age and older, children 6-23 months of age, pregnant women, and individuals with chronic medical conditions, especially pulmonary or cardiovascular disorders¹¹². Additionally, vaccination coverage is not evenly concentrated across diverse groups. "Data from the National Health Interview Study revealed significant differences in influenza vaccination coverage among elderly adults by race/ethnicity, with rates being higher among Whites, followed by Hispanics, and Blacks (66 percent vs. 50 percent and 46 percent, respectively.)¹¹³" The same article goes on to identify there is a gap in the literature concerning vaccination uptake across race/ethnicity and socioeconomic status.

One more crucial point to consider in evaluating why it is important to vaccinate the underprivileged, concerns the rate of communicable disease patterns and spread among the increasing number of urban poor. Close living quarters allows for more rapid spread of disease and a higher potential for unsanitary conditions making the urban poor more vulnerable and at a higher risk than those above the FPL for contracting disease. Atkinson and Cheyne¹¹⁴ note the following about the urban poor:

In urban areas vaccine-preventable diseases have higher potential transmission rates than in rural areas, and cases have a lower age and may serve as reservoirs

¹¹²Danielle C. Ompad, Sandro Galea, and David Vlahov. "Distribution of Influenza Vaccine to High-Risk Groups." <u>Epidemiologic Reviews</u> 28 (2006):54.

¹¹³ Ibid, 55.

¹¹⁴ S.J. Atkinson and J. Cheyne. "Immunization in Urban Areas: Issues and Strategies." <u>Bulletin of</u> the World Health Organization 72.2 (1994).

of disease for the general population. The population groups most often underimmunized are those in slum areas, illegal squatter settlements, and newly expanding peri urban zones. These areas are also densely populated, are environmentally poor, and have few public services, including health care.¹¹⁵

The impact creates under protection and heightened risk for the urban poor. This is particularly alarming since the urban population continues to increase thus increasing the risk for everyone, even for those not residing in urban areas but in contact with them for work or travel.

Adults Vaccines: What are they really preventing and how effective are they?

Yet another barrier to adult vaccinations is the kinds of vaccines available to adults. Currently, the most common kinds of vaccines available to adults are influenza, pneumococcal, shingles, Tdap, travel vaccines such as hepatitis A & B, yellow fever, and Japanese encephalitis. It is widely known that the flu vaccine is only about 40-65% effective depending on the year. Tdap vaccine efficacy has recently been reported to wane significantly after initial vaccination, questioning the need for a booster. A resurgence of pertussis cases among both vaccinated and unvaccinated people raised questions about vaccine effectiveness over time, prompting researchers to investigate Tdap efficacy.

Schwartz, et al. published the following regarding acellular pertussis vaccine effectiveness, "Between Dec. 7, 2009, and Mar. 31, 2013, data on 5867 individuals (486 test-positive cases and 5381 test-negative controls) were available for analysis. Adjusted vaccine effectiveness was 80% (95% confidence interval [CI] 71% to 86%) at 15–364

¹¹⁵ Ibid, 183.

days, 84% (95% CI 77% to 89%) at 1–3 years, 62% (95% CI 42% to 75%) at 4–7 years and 41% (95% CI 0% to 66%) at 8 or more years since last vaccination. We observed waning immunity with the acellular vaccine."¹¹⁶ These findings suggest there is a high Confidence Interval (CI), over 95%, that vaccine effectiveness for acellular pertussis vaccine wanes from 80-84% in years 1-3 to 62% in years 4-7 and down to 41% in year 8 and beyond.

In January 2019, Adacel (Tetanus, Diptheria, Pertussis vaccine manufactured by Sanofi Pasteur) was approved by the FDA for a booster dose 8-12 years after the initial dose. "A single Tdap immunization does not offer lifetime protection against pertussis due to waning immunity," said David P. Greenberg, M.D., Regional Medical Head North America at Sanofi Pasteur¹¹⁷. This acknowledgement does not discredit the value and use of the Tdap vaccine; however, it suggests we can leverage the vaccine even better by providing a booster dose.

Adacel was marketed as a once in a lifetime vaccine for 14 years, since entering the market in 2005. The last few years is when waning efficacy has come to the attention of health care professionals and consumers. When vaccines are reported to be 50% efficacious or wane after several years with no recommended booster, the patient loses confidence in the need to vaccinate themselves. There is the perception that "you get the vaccines you need as a child". Even if titers wane, the risk of acquiring childhood diseases seems to dissipate as you grow to adulthood.

¹¹⁶ Kevin R. Schwartz, et al., "Effectiveness of Pertussis Vaccination and Duration of Immunity," *CMAJ* 188,16. (September 26, 2016):10.1503/cmaj.160193.

¹¹⁷Don Ward Hackett, "1st Tdap Vaccine Approved for a 2nd Dose," Precision Vaccinations, accessed January 25, 2019, <u>https://www.precisionvaccinations.com/sanofi-adacel-vaccine-now-fda-approved-prevent-tetanus-diphtheria-and-pertussis-whooping-cough-when</u>.

When speaking with a physician colleague¹¹⁸ who is very proactive about vaccines, he said "there just hasn't been good adult vaccines on the market, look at Zostavax and Prevnar 13." Prevnar is an interesting case, since HCPs started vaccinating children, the need to vaccinate adults has come into question. At the June 2019 ACIP meeting there was a decision to change the Prevnar 13 recommendation. ACIP confirmed that "PCV13 use in children has led to sharp declines in pneumococcal disease among adults and children."¹¹⁹ The official ACIP recommendation¹²⁰ follows:

"ACIP recommends a routine single dose of PPSV23 for adults aged ≥ 65 years. Shared clinical decision-making is recommended regarding administration of PCV13 to persons aged ≥ 65 years who do not have an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant and who have not previously received PCV13. If a decision to administer PCV13 is made, PCV13 should be administered first, followed by PPSV23 at least 1 year later."

Because ACIP made the decision to change their recommendation to a shared decision, following a decrease in the incidence of this strain of pneumococcal disease in adults, some individuals misinterpret the change to reflect that the vaccine is ineffective. It is because the vaccine is so effective in younger groups that the incidence of the disease has decreased. These changes, although reflecting the positive impacts vaccines contribute to health, complicate adult vaccine decisions for adults and health care professionals. The conversation changes from a recommendation to questions from the patient, "isn't that the vaccine that is no longer needed because it is ineffective?" The time and energy necessary

¹¹⁸ Conversation with Leonard Friedland, MD in Philadelphia PA, spring 2018.

¹¹⁹ Amela Matanock, MD et al., "Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Ages >=65 Years: Updated Recommendations of the Advisory Committee on Immunization Practices," *Weekly* Nov 22, 2019, 68(46); 1069. <u>https://www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm</u>..

to invest in these discussions overrides the conversation. Essentially vaccines are designed to put themselves out of business. When the incidence of disease is no longer an imminent threat, vaccine recommendations are revised to fit the need of public health.

Many people believe that you can get the flu from the flu vaccine. This is a common vaccine myth. Even some nurses in health systems believe this¹²¹. If nurses are opting against the flu vaccine each year, claiming they get the flu from it; they are negatively influencing patients. Education and awareness are required to counter this vaccine myth. There is a lack of awareness around efficacy and design that influences public opinion surrounding vaccine need. When public confidence about vaccine safety and effectiveness begins to decline; the anti-vaccine conspiracy theories begin to take root and start filling in the gaps in knowledge.

My hypothesis surrounding adult vaccine education is that pro-vaccine campaigns can be aggressive and factual in their messaging to strongly encourage more immunizations. The public should understand that influenza vaccine efficacy is only 60% at best each year. 60% is better than 0% if left unvaccinated. But they should also realize if they acquire the flu it isn't because the vaccine did not work, it is because it is 60% effective and only works against specific strains contained in the vaccine¹²². Each flu season the strain has the potential to change. It is also important for adults to understand

¹²¹ I learned this from my experience as a hospital account manager. Every flu season there would be an effort to have 100% influenza immunization rates amongst hospital staff in Northern NJ health systems. Unfortunately, these health systems would not achieve these rates since many nurses would refuse to be vaccinated. They were required to wear a mask during the entire flu season to protect patients. This became like a scarlet letter for them, branding them as non-vaccinators. This was in 2012-2014, I hope things are moving in a more positive direction now.

¹²² CDC, "What are the Factors that Influence How Well the Vaccines Work," Seasonal Influenza Flu, accessed April 11, 2020, https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm.

that Tdap immunizations are only a little more than 40% effective 8 years in. This will help them understand the importance of re-vaccination.

Zostavax is another interesting example of a vaccine that was debated due to low efficacy. According to the CDC, Zostavax, a single vaccine used to prevent shingles, provides 51% efficacy for patients over the age of 60-year-old¹²³. It lowers the chance of Post Herpetic Neuralgia (PHN) by 67%. PHN is a painful complication of shingles. Since over 99% of US adults over the age of 40 had chicken pox, they are at risk for developing shingles. The CDC therefore advises that all adults over 50 years of age¹²⁴ receive the shingles vaccine, Shingrix. While Zostavax was the only vaccine on the market to prevent shingles, physicians and patients often weighed the benefit/risk ratio since the vaccine was not as effective as other kinds of vaccines available. Now a new shingles vaccine, called Shingrix is over 90% effective and available to adults over the age of 50. The ACIP made a preferential recommendation for adults to receive Shingrix over Zostavax due to the improved efficacy. With the advent of Shingrix there is no longer the risk/benefit debate in terms of efficacy. The vaccine has become so popular that due to extraordinary demand it is difficult to stock.

The zoster vaccine story illustrates the importance of vaccine efficacy in public opinion and decision making for adult vaccines. When the vaccine offered was only 50% effective, the number of people interested in immunization was lower and the conversation

¹²³ CDC," Routine Vaccination of People 60 Years Old and Older," Vaccines and Preventable Diseases Home, accessed April 11, 2020,

https://www.cdc.gov/vaccines/vpd/shingles/hcp/zostavax/recommendations.html.

¹²⁴ CDC, "What Everyone Should Know About Shingles Vaccine (SHINGRIX)," Vaccine and Preventable Diseases Home, accessed April 11, 2020,

https://www.cdc.gov/vaccines/vpd/shingles/public/shingrix/index.html.

was not urgent. When a newer more efficacious vaccine became available, the conversation shifted and demand outpaced supply.

Primary Care Physicians and Adult Vaccines: The Self and the Individual Body

Barriers to adult immunizations in the US can be broken down into 3 primary categories for primary care physicians. The first is logistical issues including time, a lack of focus on prevention, and incomplete data on a patient's immunization history. Second, is a lack of knowledge on the adult immunization schedule. Third, is financial complications with the buy and bill model.

American Family Physician is a well- known family practice journal and resource for physicians. The front cover of the periodical highlights articles and popular sections of the journal. In the December 2019 edition, "Page 751 Influenza Diagnosis and Treatment" is called to attention as well as 771 "Putting Prevention into Practice." I opened to page 751 and quickly scanned for any mention on the Influenza vaccine ACIP guidelines from the CDC. I admit, I was surprised to find a section entitled "Prevention" on page 752. The section reviews the CDC, ACIP, and American Academy of Family Practice (AAFP) recommendation for an annual flu vaccine for all individuals over the age of six months who do not have contraindications.¹²⁵

Even though there is a section on prevention in the early part of this article, I am still dismayed and concerned that the title is about diagnosis and treatment only. Why not include prevention in the title? I speculate this has something to do with the way

¹²⁵ David Y. Gaitonde, Cpt., Faith C. Morre, USA, MC, and Maj. Mackenzie K. Morgan, USA, MC. "Influenza: Diagnosis and Treatment." *American Family Physician* Vol 100.12 (Dec 15, 2019):752-3.

doctors are trained and practice medicine in the United States. It is my belief that Western medicine demonstrates dichotomies and reductionism. Biomedicine has a long history of creating definitive dichotomies, including mind/body, male/female, nature/nurture, and technology/nature. To draw from medical anthropology, there is a further metaphysical layer when describing one's physical body versus the self under the concept of medical anthropologists, Nancy Scheper Hughes and Margaret Locke's¹²⁶, individual body. The concept of the self is more than just the physical body. "Anthropology offers potent theoretical paradigms for analyzing the significance of the body as a cultural construct and the manner in which embodiment shapes identity over time."¹²⁷ The self as current cultural anthropologists see it is a very narrow view of a culturally shaped construct that one applies to one's self. The totality of the self can be viewed in a larger context including the psychological, biological, physiological, sociological, and cultural aspect of personhood.¹²⁸

The distinction of the self versus the individual body influences how doctors treat patients. In order to fully understand the dynamics behind the representation of the self, it is useful to look at the construction of "the self" and "the other" under liberal law. There is the general assumption that "personhood is characterized by ownership of one's body." This idea comes out of Cartesian mind/body dualism, which in turn creates "a division between the self that owns and the object that is owned. This division is not

¹²⁶ Nancy Scheper-Hughes and Margaret M. Lock, "The Mindful Body: A Prolegomenon to Future Work in Medical Anthropology." In *Understanding and Applying Medical Anthropology*, ed. Peter J. Brown (Mountain View, Mayfield Publishing Company, 1998). 208-25.

 ¹²⁷ Lesley A. Sharp, "Organ Transplantation as a Transformative Experience: Anthropological Insights into the Restructuring of the Self." Medical Anthropology Quarterly 9.3 (1995): 358.
 ¹²⁸ Naomi Quinn, "The Self," accessed December 21, 2019,

http://ant.sagepub.com/cgi/content/abstract/6/3/362.

value-free, rather the self, the rational legal subject, maintains primacy over the object which is its body."¹²⁹ This division emphasizes the objectified body from the self. The body needs to be reduced to parts to reinforce the notion that objectified pieces can be manipulated and treated, not actual parts of an individual self.

To further separate the self from the body, medicine turns to metaphors, particularly comparing the human body to a machine. The body is made up of parts and medicine is sub-specialized into those parts, cardiology, neurology, podiatry, hematology, etc. When the body is compared to a machine and reduced to parts, the specialists focused on those parts lose sight of the big picture and stop seeing the whole patient. The other problem is that the "special part physicians" are reactive, *diagnosing and treating* for their respective parts rather than acting proactively for the good of the entire body.

Now, one can argue that the primary care physician (PCP) is in place to see the big picture and treat the entire patient. Unfortunately, they are not set up for success to do this for several reasons. First, they undergo the same foundational pre-medical and medical school education and training those specialists encounter. The text books and clinical rotations employ the reductionist philosophy by focusing on specific parts and diseases. Second, the healthcare eco-system, including payers influence how the PCP operates. The PCP serves as the quarterback for all the specialists, they are the gatekeeper sending patients as referrals to different specialists rather than treating them in house. Because they are looking for serious diseases to react to, such as hypertension, a silent killer, and diabetes; there is no time or focus on prevention and vaccines.

¹²⁹ Megan Crowley, "Troubling Boundaries: Organ Transplantation and Liberal Law," *PoLAR* 21.1 (1998): 27.

Furthermore, patients expect the system to work this way. If they are diagnosed with a neurological disorder, they expect the PCP to refer them to a neurologist. No one proactively visits with a neurologist to make sure everything is ok. Patients are also trained to be reactive, rather than proactive about their health. Even, if a patient is interested in receiving a vaccine; where do they truly expect to have the conversation and receive the vaccine. If they only go to the PCP in reaction to a problem; when does this topic even come up? A study conducted in 2018 to determine US clinicians' and pharmacists; barriers to vaccine implementation confirms patient reactivity. "There may be missed opportunities to vaccinate adults, because many adults do not seek healthcare unless they have an acute medical problem that is prioritized over preventative services such as vaccination by providers."¹³⁰ Unfortunately, the vaccine conversation either does not happen or it comes up in the last few moments of a physical exam with the PCP.

Having participated in market research that records the conversation between physicians and patients, I have heard the quick connect at the end of the appointment on vaccines. It usually goes like this hypothetical conversation:

Doctor: Are you up to date on your vaccines?
Patient: I'm not sure; I think I had a flu shot
Doctor: Ok great, I am in your record and see you are due for the pneumonia vaccine. This is CDC recommended for patients your age.
Patient: What about the new shingles vaccine?
Doctor: It is out of stock, you can try to see if your pharmacy has it but call ahead.

In the same study concerning clinician and pharmacist barriers, 40.2% of

clinicians claim they could not spend the time to assess adults for vaccination due to

¹³⁰ Anup Srivastav, et al., "U.S. Clinician's and Pharmacists Reported Barriers to Implementation of the Standards for Adult Immunization Practice," *Vaccine* 36 (2018) 6778.

inadequate reimbursement for these services. 66.3% reported they do not assess patients for vaccines because they prioritize acute and chronic medical conditions over vaccines.¹³¹ Furthermore, as far back as 2005, the vaccine conversation between physician and patient, or the lack there of, was reported in another article suggesting a physician reminder tool for adult immunizations. The article states that "practitioners lack the time to deliver the most strongly recommended services."¹³² They list eight recommended adult vaccines, influenza, pneumococcal polysaccharide (PPV), tetanusdiptheria (TD) which is now replaced with tetanus, diptheria, pertussis (TDaP), measlesmumps-rubella (MMR), hepatitis A, hepatitis B, or the combo vaccine Twinrix, varicella (or zoster), and meningococcal polysaccharide. The authors note through investigation they learned that determining which of these vaccines is indicated is complicated and time consuming since "it requires knowledge about the patient's demographics, health conditions, occupation, avocations, travel plans, sexual behaviors, use of street drugs, as well as the age and health condition of family members."¹³³

To complicate it further, the practitioner must also determine if the patient has already received these vaccines. If the patient started the series, the physician must determine where they are in the series and when they are due for their next dose. Ideally this information should be housed in the Immunization Information System (IIS); "confidential, population-based computerized databases that record all immunization doses administered by participating providers to persons residing within a given

¹³¹ Ibid.

 ¹³² Daniel B. Fishbein et al., "A Comprehensive Patient Assessment and Physician Reminder Tool for Adult Immunization: Effect on Vaccine Administration." *Vaccine* 24 (2006): 3971.
 ¹³³ Ibid.

geopolitical area."¹³⁴ At the point of care, the physician can log into the IIS and determine the consolidated vaccination history for the patient.

The IIS is designed to connect with pharmacy software and electronic medical records (EMR) however it requires the practitioner to send the data to the IIS. In many situations, particularly for adult vaccines, the physician or pharmacist will not record the immunization in the IIS as this step is not required and rewarded through any incentive. Srivastav et al. report that only one third of clinicians and pharmacists who administer vaccines use the IIS. Barriers to using the IIS were lack of knowledge if the state they practice in has an IIS and how to link up to and report into the registry. The HCPs in this study reported a lack of interoperability between their EMR and the IIS. They claim it is very expensive and time consuming to report the data into the IIS via their EMR or an alternative system. "Thirty-four states have an opt-in policy for adult vaccination data to be included in IIS...providers are required to obtain patient consent before submitting patient vaccination data to IIS."135 This adds complexity to the conversation and takes time. Finally, they claimed that using the IIS is not required by law or standard of practice. Without a carrot or a stick, the behavior is not likely to change. Like rewarding physicians for becoming more proactive in preventative conversations during a patient interaction; practitioners should be rewarded for taking the extra step to complete the record in the IIS. Using the IIS at a minimum should become part of the clinical standard of practice.

¹³⁴ CDC, , "About Immunization Information Systems," IIS Home, accessed January 3, 2020, https://www.cdc.gov/vaccines/programs/iis/about.html.

¹³⁵ Anup Srivastav, et al., "U.S. Clinician's and Pharmacists Reported Barriers to Implementation of the Standards for Adult Immunization Practice," *Vaccine* 36 (2018) 6779.

Even though technology through the EMR exists to remind or alert the practitioner that an immunization is due, these reminders are effective with one or 2 immunizations but not for 8. When the list of adult immunizations becomes so long, the reminders become common place and ineffective. Office staff could be used to help with the reminders and the conversation with patients however, in the article by Srivastav et al. one of the primary conclusions was that there are major administrative burdens to vaccinating. These burdens include a lack of staff to help support immunizations in the practice. Another common barrier reported was a lack of the proper storage and handling equipment.¹³⁶ Because vaccines need to be refrigerated or frozen, a vaccine fridge/freezer is required to keep vaccines. These refrigerators need back up generators in case of power outages or the inventory will be lost. Many physician practices see this as a burden to implementing a vaccine protocol and opt to refer patients to the pharmacy for adult immunizations instead. Regardless if a physician decides to store and administer vaccines in their practice or refer the patient to the pharmacy, the vaccine conversation and verification in the IIS need to happen.

In a different article¹³⁷ that appeared in the publication Vaccine reporting physician perspectives on providing adult vaccines, it becomes even more clear that there are additional belief and behavior barriers in this space. First, patients report that physicians do not actively recommend vaccines to them. This is in part due to physician lack of awareness about the adult immunization schedule. The *Annals of Internal*

¹³⁶ Ibid, 6678.

¹³⁷ Freed, Gary L., Sarah J. Clark, Anne E. Cowan, and Margaret S. Coleman. "Primary Care Physician Perspectives on Providing Adult Vaccines." *Vaccine* Vol 29 (2011).

Medicine did not publish the adult immunization schedule until 2007.¹³⁸ Creating physician awareness of the adult immunization recommendations and schedule is paramount to increasing conversations between doctor and patient about vaccines. Regardless if the physician wants to stock vaccines in their office or not, the conversation triggers the patient to believe they are at risk and should take the preventative measure. The conversation is so critical to improving adult immunizations rates because the physician recommendation is the dominant driver to motivate adults to vaccinate themselves.¹³⁹

Back to the article¹⁴⁰ I referenced earlier about diagnosing and treating influenza, the CDC guidelines are referenced however the follow up sentence muddies the recommendation. "Vaccination efforts should target people at increased risk of complicated or severe influenza."¹⁴¹ In Table 1 the article lists those at increased risk: any condition that may compromise the handling of respiratory secretions, asthma or COPD, chronic kidney disease, chronic liver disease, heart disease, immunosuppression, long term aspirin therapy in patients younger than 19 years, metabolic disorders, morbid obesity, and sickle cell anemia and other hemoglobinopathies. The table is referenced from another American Family Physician journal. There are also special groups considered high risk listed in table 1. It can be considered problematic that these instructions seem to select certain individuals for influenza vaccines and most of the

¹³⁸ Ibid, 1850.

¹³⁹ Ilene Timko Burns MD, MPH and Richard Kent Zimmerman, MD, MPH. "Immunization Barriers and Solutions." *The Journal of Family Practice* January 2005 Vol 54.1: S60.

¹⁴⁰ David Y. Gaitonde, Cpt., Faith C. Morre, USA, MC, and Maj. Mackenzie K. Morgan, USA, MC. "Influenza: Diagnosis and Treatment." *American Family Physician* Vol 100.12 (Dec 15, 2019):752-3.

section reviews who these at-risk groups are. The first sentence in the paragraph drawing attention to the CDC recommendation to vaccinate all individuals over the age of six months is forgotten and minimized. If a physician reader were to dissect these instructions; they would only vaccinate the special groups from table 1 and not proactively discuss influenza vaccine with all their patients, even the healthy ones. To confirm, I decided to review the CDC influenza recommendations for the 2019-2020 flu season on their website and I encountered verbatim, "Routine annual influenza vaccination is recommended for all persons aged ≥ 6 months who do not have contraindications."142 This exact sentence appears at least three times on the site and special populations are reviewed as not to be "targeted" as the American Family Physician article¹⁴³ directs but rather to be prioritized when there is a supply shortage. The CDC states, "All persons aged ≥ 6 months who do not have contraindications should be vaccinated annually. However, vaccination to prevent influenza is particularly important for persons who are at increased risk for severe illness and complications from influenza and for influenza-related outpatient, emergency department, or hospital visits. When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to persons at higher risk for medical complications attributable to severe influenza who do not have contraindications."¹⁴⁴ Therefore, if educating physicians on the CDC Immunization recommendations is a barrier to increasing adult immunizations,

¹⁴² Lisa A. Grohskopf, MD et al., "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2019–20 Influenza Season." *Recommendations and Reports* Vol 68.3 (August 23, 2019): 1.

¹⁴³ David Y. Gaitonde, Cpt., Faith C. Morre, USA, MC, and Maj. Mackenzie K. Morgan, USA, MC. "Influenza: Diagnosis and Treatment." *American Family Physician* Vol 100.12 (Dec 15, 2019):752-3.

¹⁴⁴ Grohskopf, "Prevention and Control of Seasonal Influenza: Diagnosis and Treatment," 6.

the American Family Physician journal should do just that and leave the recommendation verbatim from the CDC without further muddying the waters.

There are two more barriers I would like to include in this section. The first is specific to the buy and bill model of vaccines. As I mentioned earlier, implementing a vaccine administration protocol in the physician practice is a costly endeavor. The refrigerator/freezer offers its own set of costs and challenges, training staff on the proper technique requires time and resources, and after all this you need to pay for the vaccines up front. In Srivastav et al.'s ¹⁴⁵ study less than half of the clinician and pharmacist respondents believe adults have awareness of the vaccines they need and greater than two thirds reported they believe adult patients are resistant to being vaccinated. If doctors feel it is too difficult to convince the patient to be vaccinated, they are less likely to want to pay upfront for vaccines to stock in an expensive refrigerator. If they cannot move the vaccines purchased, they have lost the money for the upfront buy.

In an article about financing and system barriers to seasonal influenza vaccines, Penfold et al., ¹⁴⁶ find that "limited purchasing power, the uncertain nature of public demand, and unpredictable timing of influenza vaccine supply were important barriers to enhance delivery in community settings."¹⁴⁷ The article also mentions the uncertainty of reimbursement as another barrier. Unlike the Point of Sale setting that a pharmacy offers, the physician office cannot do a quick look up to determine if the vaccine is reimbursed

¹⁴⁵ Srivastav, et al., "U.S. Clinician's and Pharmacists Reported Barriers to Implementation of the Standards for Adult Immunization Practice," *Vaccine* 36 (2018) 6781.

¹⁴⁶ Robert B. Penfold, et al., "Financing and System Barriers to Seasonal Influenza Vaccine Delivery in Community Settings," *Vaccine* 29 (2011) 9632.

¹⁴⁷ Penfold, ibid.

and for how much. Not knowing if the patient's insurance will cover the vaccine offers significant financial uncertainty as well.

Vaccine Manufacturers have tried to overcome these barriers with programs like Novartis' Menveo on Demand. Essentially, Novartis dropped off "free" refrigerators stocked with Menveo at physician offices. The physician would not pay for any of the inventory until they used a dose. It was an expensive and complicated program for Novartis to execute and it did not lead to the increased vaccine utilization they were seeking. The physician practice needs to be bought into the importance of vaccinating in their office before implementing the protocol and buying the vaccines. The strong believe that they are offering a life-saving service to their patients will drive the behavior change to move the vaccines out of the fridge and into their patients' arms.

The final point I would like to address in this section is another belief that is driving physician behavior. When I would join my vaccine sales representatives in the field, I heard many doctors complaining during flu season that the pharmacies are taking their business. They would claim that the big chains buy in bulk and not only receive better prices but earlier supply driving the patient out of the physician office and into the pharmacy. This competitive point of view was very common. The physician did not see the pharmacy as a partner in prevention but rather as a threat.

I have heard related sentiments in the market research I have participate in. Physicians will state that they do not want to refer patients to the pharmacy because they do not trust the pharmacist to have the clinical acumen to administer the vaccines correctly. They also claim they lose control of the patient by referring them out. If the patient were to start a vaccine series in the pharmacy the doctor claims they have no way of following up to learn if they finished the series. Not all physicians exhibit this sentiment but the ones who do imply the information is not being exchanged and they believe they are losing control of the patient and the information.

Interestingly, pharmacy partners I engage with let me know they make every effort to inform the physicians when one of their patients receives a vaccine. Many patients arrive at the pharmacy with a prescription for the vaccine from their physician. This immediately triggers a follow up either via telephone call or fax to the physician office that the prescription was filled. Insurers also share back this prescription data with the prescribing physician several months after the event in this case, the immunization. This is not the cleanest feedback loop, but it is a start. In Chapter 6 I will address additional ideas on how to foster a better working relationship between the physicians and the pharmacists while putting the patient first and at the center. The goal should be to vaccinate the patient, where it happens is in the nuance.

Vaccine Hesitancy

According to the Strategic Advisory Group of Experts on Immunization (SAGE) Working Group on Vaccine Hesitancy, vaccine hesitancy can be defined as the "delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence."¹⁴⁸ Another report on vaccine hesitancy from Dube et al. describes "contextual determinants (broad

¹⁴⁸MacDonald, NE, SAGE Working Group on Vaccine Hesitancy, <u>https://www.ncbi.nlm.nih.gov/pubmed/25896383</u> (accessed Dec 21, 2019).

influences such as communication and media, religious values, social norms, health policies, etc.); organizational determinants (or factors related to the accessibility and quality of vaccination services) and individual determinants (such as parent' knowledge, attitudes and beliefs or sociodemographic characteristics)."¹⁴⁹ The SAGE work group came together in 2011 when an uptick in the presentation of several vaccine preventable diseases was noticed. An Op Editorial in *The New York* Times on January 9[,] 2020 by Dr. Peter J. Hotez states in the US, vaccine hesitancy is leading to an increase in influenza related deaths and future cervical cancer as well as the reappearance of measles.¹⁵⁰ For measles, herd immunity has diminished because the population is not vaccinated at the level to achieve immunity.

The SAGE work group noted outbreaks or resurgence of measles, mumps, Haemophilus influenzae b, pertussis and polio in places where these diseases had previously been controlled via herd protection.¹⁵¹ The geographic specific outbreaks are not surprising given that unvaccinated or under-vaccinated individuals tend to cluster together resulting in the increased transmission and incidence of vaccine preventable diseases.¹⁵²

Most interesting in the SAGE definition of vaccine hesitancy is the inclusion of vaccine specificity. A few years ago, in 2017, I conducted what is called shopper

¹⁴⁹ Eve Dube, Maryline Vivion, and Noni E MacDonald, "Vaccine Hesitancy, Vaccine Refusal and the Anti-Vaccine Movement: Influence, Impact and Implications," *Expert Review of Vaccines* 14:1. Pg99-100.

¹⁵⁰Peter J. Hotez, "Without a Vaccine, These are Your Odds," *The NY Times* Opinion Jan 9, 2020, <u>https://www.nytimes.com/2020/01/09/opinion/vaccine-hesitancy.html</u>.

¹⁵¹ Report of the SAGE Working Group on Vaccine Hesitancy, accessed December 21, 2019, <u>https://www.who.int/immunization/sage/meetings/2014/october/1 Report WORKING GROUP vaccine hesitancy final.pdf</u>.

¹⁵² SB Omer et al., "Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Disease," *New England Journal of Medicine* 2009;360 (19): 1981-8.

research to understand why or why not a consumer would receive a vaccine in the pharmacy. It was clearly apparent that the handful of consumers interviewed considered flu vaccines in a different context than other adult vaccines. Flu vaccines were viewed as a commodity; it was normal to receive one spontaneously at a pharmacy without consultation with a physician. A vaccine like Tdap for pertussis and hepatitis vaccines were not considered in the same context. Many of the research participants claimed their physician would have to drive the decision on those vaccines. They did not see themselves as owning the decision like they do for a flu vaccine but rather the physician as the owner and the person who would be recommending and initiating the conversation.

So here was a group of people, in the focus group setting, discussing how one vaccine is different from another. Their hesitancy on the other adult vaccines is complex and varies across time and place. Their confidence waivered outside of the influenza vaccine, a vaccine they receive annually and feel empowered to receive without consultation with their physician (PCP). They were willing with one vaccine and hesitant on the others. This is consistent with vaccine hesitant parents, they may be willing to have their children receive some vaccines and disagree to others. Dube and colleagues explain that while a small number of parents are anti-vaccine at less than 5%, about one third of US parents are vaccine hesitant.¹⁵³

Vaccines have often been considered victims of their own success. You know the vaccine worked because nothing happens, you don't get sick. Furthermore, vaccines, as outlined in Chapter One, have done a terrific job eradicating several diseases. When this

¹⁵³ Eve Dube, Maryline Vivion, and Noni E MacDonald, "Vaccine Hesitancy, Vaccine Refusal and the Anti-Vaccine Movement: Influence, Impact and Implications," *Expert Review of Vaccines* 14:1,100.

happens, individuals have no direct experience with the diseases anymore. Eula Biss in her book "On Immunity: An Inoculation" tells us that her extended family suffered deaths from infectious disease. Her grandmother and her grandfather lost siblings to disease like pertussis, measles, and tetanus.¹⁵⁴ Even though she was not alive at the time to experience these loses, the stories from her grandparents confirm the cruel reality of infectious diseases. These stories in part inspired her to write her pro-vaccination book. For other younger generations; where the stories of infectious disease are not as close to home; the incentive to vaccinate is not as strong. "Thus, fear of risks of vaccine maybe more prominent than fear of the diseases vaccines prevent."¹⁵⁵

The SAGE Working Group goes on to discuss how inadequate or poor communication about vaccines (e.g., why they are recommended and their safety and effectiveness) can also contribute to vaccine hesitancy.¹⁵⁶ Perhaps the individuals in the focus group received an initial permission from their PCP for flu vaccine and felt that supported the annual administration. Since there was no discussion on the other adult vaccines, they did not hear the compelling points around safety, efficacy, and most important of all why they need it. I distinctly remember a female participant state; my doctor would have told me if I needed this vaccine when asked about the hepatitis A vaccine.

To further support the spectrum of vaccine comfort, the SAGE work group acknowledges the following: "Vaccine attitudes can be seen on a continuum, ranging from total acceptance to complete refusal. Vaccine-hesitant individuals are a

 ¹⁵⁴Eula Biss, On Immunity: An Inoculation (Minneapolis: Graywolf Press, 2014).
 ¹⁵⁵ Biss, On Immunity: An Inoculation, 110.

¹⁵⁶ Biss, On Immunity: An Inoculation, 7.

heterogeneous group in the middle of this continuum. Vaccine hesitant individuals may refuse some vaccines but agree to others; delay vaccines or accept vaccines but are unsure in doing so."¹⁵⁷ Therefore, there is still hope, through educational efforts, to vaccinate the hesitant group unlike the anti-vaccine group. The anti-vaccine group is the biggest threat to the vaccine hesitant as their myths and misinformation can influence them to choose in favor of not vaccinating.

An interesting aspect to consider is around the idea of delaying vaccines. Why wait? Eula Biss discusses the idea of American excess. "Too much too soon" is often a tagline for the vaccine hesitant. The idea that grandparents received a small number of vaccines, parents received a slightly larger number, and now children are receiving 15 recommended vaccines in the childhood schedule enables those who are unsure to start making excuses as to why vaccines may be problematic and overloading the immune system. Eula Biss herself admits to questioning her pediatrician when her son was offered the varicella vaccine to protect against chicken pox. She asked the physician to limit the vaccines to those protecting against diseases that kill you. Here is someone who wrote a book about the value of vaccines exhibiting vaccine hesitancy. Her pediatrician explained that although chicken pox is unlikely to kill her son, it can cause a flesh-eating bacteria, pneumonia, and encephalitis. About 10,000 children were hospitalized each year due to complications from chicken pox prior to the vaccine being introduced, this included about 70 annual deaths.¹⁵⁸

¹⁵⁷Biss, On Immunity: An Inoculation, 8.

¹⁵⁸Biss, On Immunity: An Inoculation, 114-115.

Biss goes on to explain how the zoster virus will live dormant in your body once you contract chicken pox and manifest again later in life as the painful and debilitating shingles virus. Although it is still too soon to determine if the varicella vaccine protects against shingles if administered to children, there is a strong suspicion that it could prevent shingles in the future or at a minimum reduce the severity of shingles and the accompanying postherpetic neuralgia (PHN) for those who were vaccinated. Therefore, although vaccines like varicella most likely do not prevent death, they prevent other awful complications and potentially help protect you from other viruses that impact you in adulthood. Wavering on the varicella vaccine, because chicken pox does not sound serious is probably more common than reported. These are the kinds of deep-rooted beliefs that pediatricians need to acknowledge and be prepared to address when discussing immunizations with their patients. These are also the kinds of examples that influence the same parents as they think about vaccinating themselves.

In the next section I will apply medical anthropological epistemology to the attitudinal and behavioral drivers behind the vaccine hesitant. Beliefs and behaviors influence human decisions. Many times, beliefs are driving the behaviors as well as social norms. In their work surrounding the 3 bodies, Nancy Scheper-Hughes and Margaret Locke discuss the individual body, the social body, and the body politic. I have already introduced the individual body in the section on primary care physicians and adult immunizations, next I will apply the concept of the social body as a driver behind vaccine hesitancy.

Vaccine Hesitancy and The Social Body

Before diving into the social body portion and its' relationship to vaccine hesitancy, it is important to recognize the concept of disgust in relationship to the body and the self as it crosses the boundary between the individual and the social bodies. For many individuals, external organs are more closely associated with the self, compared to internal organs. There is a simple reason, you see your exterior self or reflection in the mirror. There is a greater degree of disgust injecting something through the skin, the protective barrier to the inside of the body than taking for example an oral medication that is consumed through an orifice and entered into the internal system. This inner/outer dichotomy is a feature of the relationship between the self and the body. The Cartesian mind/body dualism separates the inner self, usually portrayed through the mind from the physical self, the body.

However, as Daniel Fessler uncovered in his research surrounding disgust, the external features of the body enable the self to tactically communicate with the world. The external organs give the self the capacity to interface with the environment.¹⁵⁹ External organs are also those that strangers, friends, and family see at first glance; they relate the external features through recognition to the inner self or personhood of that individual. The outer or social self is the gateway to the inner true self. Therefore, for those adults that are vaccine hesitant, there may be a strong belief in the social self, driving their hesitancy. In this sense, vaccines are more tied to the social value of the self through the process of administration.

¹⁵⁹ Daniel M. T. Fessler and Kevin J. Haley, "Guarding the Perimeter: The Outside-Inside Dichotomy in Disgust and Bodily Experience," *Cognition and Emotion* 20.1 (2006): 3.

The social body in its metaphoric representation of the natural and structural worlds becomes displaced when science has a hand in adjusting this symbolism. According to Megan Crowley, "The body and its parts have long been recognized as a potent site and source of social meaning [...] Biomedicine, as a body of knowledge about and practices for the body, offers social scientists a strategic site from which to explore both cultural values and meanings at the symbolic level, as well as issues of power and inequality at the material level."¹⁶⁰ Receiving a vaccine may transcend the view of the body as healthy in its organic wholeness from two perspectives. One is the introduction of killed or live virus into the healthy body and two is the administration process; the penetration of the skin.

In a more boiled down version vaccine hesitant patients are either afraid of the contents of the vaccine (a dangerous disease from the outside invited in or unnatural chemicals introduced into the body), the administration of a needle, or both. The "outside-In" analysis to this piece is the underlying assumption that cultural constructions regarding the body perpetuate certain assumptions and views regarding social relations and values. This is evident in the concept of the healthy body perceived as superior to the unhealthy body. And, as the natural body being superior to the unnatural body.

In the mind of some vaccine hesitant persons, you are taking a perfectly good and healthy body and injecting it with something potentially harmful that can cause ill health; this is unnatural. Without explicit direction from their physician, the risk outweighs the benefit. Furthermore, there could be preservatives and other chemicals in that injection

¹⁶⁰ Megan Crowley, "Culture, Class, and Bodily Meaning: An Ethnographic Study of Organ Transplantation in Mexico," *PoLAR* 22.2 (1999):130.

introducing an unnatural substance into the physical body. The risk benefit ratio is not viewed in the same way that someone who trusts and believes in vaccines views it. It is almost as if the Western sense of entitlement has infiltrated the minds of the vaccine hesitant. This is a social construction placing natural bodies as superior to unnatural Western bodies. Hence, the social body in the context of vaccine hesitancy is an example of the metaphor "us versus them". Vaccines have the potential to reconceptualize the human body and the relationship between the external and internal self and of people and bodies to each other.

These vaccine hesitancy narratives shape the cultural and social construction of people who challenge the biomedical technological interventions between the self and other, life and death, science and nature as well as the impeding influence of biomedicine and Westernization. In the spirit of medical anthropologists Nancy Scheper-Hughes and Margaret Lock's theme of the social body as "the representational uses of the body as a natural symbol with which to think about nature, society, and culture,"¹⁶¹ it is interesting to see how vaccine myths and misinformation is used to identify certain groups within a socio-cultural framework. In the context of the social body we can analyze the valuations of the body that manifest in both medical and popular discourses of vaccinations.

"The cultural analysis of visual, textual, popular, discursive, and national forms of representation of the body requires paying attention to not only embodiment itself but also to biology as a site of knowledge production, moral dispute, and economic worth. It

¹⁶¹ Nancy Scheper-Hughes and Margaret M. Lock, "The Mindful Body: A Prolegomenon to Future Work in Medical Anthropology." In *Understanding and Applying Medical Anthropology*, ed. Peter J. Brown (Mountain View, Mayfield Publishing Company, 1998). 209.

is [...] a site of aesthetic spectacle, heroic narrative, and imagined future."¹⁶² However, this ideology is a product of biomedicine itself. For others, on the fringe like the extreme anti-vaccinators or some of the vaccine hesitant, heroic narratives are replaced with narratives that represent oppression, economic and political exploitation, and conspiracy theories. One particularly useful form of popular discourse on this subject is the link between vaccines and autism. The cultural construction of anti-vaccine narrative portrays these tales as weapons of the weak, challenging medicine and the third body; the body politic¹⁶³.

Science and technology such as immunizations give us as humans great hope for the improvement of life but at the expense of society as we know it "for it is now possible to manipulate nature/culture and self/other dichotomies."¹⁶⁴ Margaret Locke states that "mortality—victorious nature, in the form of the dying patient—is hidden, made anonymous, so that immortality—the triumph of culture—can take center stage." ¹⁶⁵ Therefore, one can make the claim that via biomedical technology we have altered the state of being to the point that culture has dominated nature, this is a sociological phenomenon that only a complex society could imagine. Spawning from the scientific technology of vaccines another metaphorical dichotomy is conjured culture/nature; where science and technology represent culture and nature is represented by the human body.

¹⁶² Sarah Franklin and Margaret Lock, eds. Remaking Life and Death: Toward an Anthropology of the Biosciences (Santa Fe, School of American Research Press, 2003).120.

¹⁶³ Nancy Scheper-Hughes and Margaret M. Lock, "The Mindful Body: A Prolegomenon to Future Work in Medical Anthropology." In *Understanding and Applying Medical Anthropology*, ed. Peter J. Brown (Mountain View, Mayfield Publishing Company, 1998). 208-25.

¹⁶⁴ Margaret Lock, "Transcending Mortality: Organ Transplantation and the Practice of Contradictions," *Medical Anthropology Quarterly* 9.3 (1995): 391.

The contextual intricacies of how individuals experience their *individual bodies*, are influenced by the perceptions of their *social bodies*, and are asked to do things for the *body politic* are all contributing factors behind vaccine hesitancy. The body politic is less involved in mandating vaccines for adults, like it is in the childhood immunization requirements. However, the public health benefit of vaccines is an example of how the body politic benefits from both childhood and adult immunization programs. The utilitarian aspect of vaccination, taking a small potential risk for the benefit of the self and the greater population is an example of how vaccines can be applied to the body politic. It is with the anti-vaccine movement that the body politic is most applicable as I will highlight in the next chapter.

Chapter 3: The Anti-Vaccine Movement

Introduction

As I began to explore the many barriers to increasing adult immunization rates, I realized that the anti-vaccine movement was an important consideration even though my hypothesis to increase rates does not directly address individuals' beliefs affiliated with this movement. The tension in the vaccine conversation is most widely felt between vaccine enthusiasts and the anti-vaxers. The extremes of information can be confusing for those seeking guidance on vaccines, particularly for the vaccine hesitant. It is my belief and hypothesis that education backed by science and evidence can help those outside this debate make informed choices about immunizations. This chapter explores the relationship between the anti-vaccine movement and the body politic.

For others who do not identify as vaccine hesitant but rather anti-vaccine; biomedicine is on the periphery. Heroic narratives of vaccines eradicating disease are replaced with narratives that represent oppression, political exploitation, capitalism, conspiracy theories, and corporate greed. Anti-vaccinators claim that we do not need to vaccinate since disease rates are so low¹⁶⁶. They also claim that vaccines weaken or overwhelm the immune system, particularly in young children.¹⁶⁷ There is also the mistaken philosophy that natural immunity is superior to immunity via vaccination and that vaccines contain unsafe toxins and preservatives that are more harmful

¹⁶⁶ Most frustrating is that disease rates are low because we do vaccinate! As more parents opt to delay or not vaccinate their children, we continue to see a rise in the incidence of diseases, like measles, that were once eradicated because of the value of vaccines. The anti-vaccine arguments are often rationalized to fit the purpose rather than demonstrated through objective scientific methods.

¹⁶⁷ Paul A. Offit et al., "Addressing Parents Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System," Pediatrics January 2002, 109 (1) 124-129; DOI: <u>https://doi.org/10.1542/peds.109.1.124</u>

than the diseases vaccines are designed to protect against.¹⁶⁸ Finally, and most pronounced is the scientifically debunked theory that vaccines cause autism.¹⁶⁹

One example of popular discourse on this subject is the link between the MMR vaccine and autism. The cultural construction of the vaccine and autism narrative portrays these tales as a weapon of the weak and misinformed, challenging medicine and the state. However, vaccines causing autism stories serve as a set of narratives that echo "current themes in popular cultures, where the mad scientist and the evil doctor have played major roles since the early 1800s and have evolved into widespread genres such as the medical thriller."¹⁷⁰ The evil doctors then serve the evil pharmaceutical empires that are supported by the government. Any scientific evidence is overshadowed by the conspiracy theory and rejected. These narratives shape the cultural and social construction of people who challenge the biomedical technological interventions between the self and other, life and death, science and nature as well as the impeding influence of biomedicine and Westernization.

<u>A History of the Anti-Vaccine Movement</u>

The anti-vaccine movement is not a new phenomenon, even though the advent of the internet has ignited more fuel to its fire. As far back as the 1790s there are those who stood opposed to vaccination. Once widespread vaccination began in the early 1800s with Jenner's

¹⁶⁸ Medical News Today, "Debunking the Anti-Vaccine Myths," Newsletter, accessed April 17, 2020, https://www.medicalnewstoday.com/articles/325371.

¹⁶⁹ Ibid.

¹⁷⁰ Campion-Vincent, Veronique. "On Organ Theft Narratives." <u>Current Anthropology</u> 42.4 (2001): 555.
smallpox vaccine; anti-vaccine sentiment began to creep in. According to Dube et al. ¹⁷¹, in 1802, the popular British weekly magazine, *The Punch* published a satirical drawing of vaccine recipients at an inoculation hospital with cow parts coming out of their bodies. The illustration was to depict a possible side effect of cowpox used to prevent smallpox. For many Victorian parents, the smallpox vaccination created fear and protest. The inoculation required scoring the flesh on a child's arm and inserting "lymph" from the blister of a person who had been vaccinated a week earlier.¹⁷² Local clergy believed that the vaccine was unchristian because it came from an animal and convinced their congregations as such. Other early anti-vaccinators demonstrated their general distrust in medicine and in Jenner's ideas about how disease spreads.¹⁷³

Later, after the 1840s the UK issued vaccination acts to help control smallpox. "The Vaccination Act of 1853 ordered mandatory vaccination for infants up to 3 months old, and the Act of 1867 extended this age requirement to 14 years, adding penalties for vaccine refusal."¹⁷⁴ The acts made vaccination "compulsory, with cumulative penalties for noncompliance." ¹⁷⁵ Dube¹⁷⁶ explains, the acts were not popular and resisted by groups disliking state control over their bodies. They claimed the acts were inconsistent with personal liberty. Groups were formed against vaccination, like the Leicester Anti-Vaccination League promoting

¹⁷¹ Eve Dube, Maryline Vivion, and Noni E. MacDonald, "Vaccine Hesitancy, Vaccine Refusal, and the Anti-Vaccine Movement: Influence, Impact, and Implications," *Expert Review of Vaccines* 2015;14:1, Pg 104.

¹⁷² The College of Physicians of Philadelphia, "History of Anti-Vaccination Movements," *The History of Vaccines: An Educational Resources By the College of Physicians of Philadelphia*, accessed January 7, 2020, <u>https://www.historyofvaccines.org/content/articles/history-anti-vaccination-movements</u>.

¹⁷³ Ibid.

¹⁷⁴ Ibid.

¹⁷⁵ Ibid, 100.

¹⁷⁶ Eve Dube, Maryline Vivion, and Noni E. MacDonald, "Vaccine Hesitancy, Vaccine Refusal and the Anti Vaccine Movement: Influence, Impact, and, Implications," ibid.

anti-vaccine propaganda using literature such as tracts, pamphlets, and books during the 1870s and 1880s.¹⁷⁷ The Leicester Demonstration in March of 1885 was one of the most infamous anti-vaccination demonstrations. 80,000-100,000 anti-vaccinators led a march, complete with banners and a child's coffin.¹⁷⁸ This was the first of many anti-vaccine movements across Europe.

The demonstrations and rallies prompted law makers to revisit the initial mandatory vaccination acts. In 1898, vaccination law was amended to appease the anti-vaccine movement allowing exemption for parents based on conscience. The Vaccination Act of 1898 removed the penalties of earlier mandatory vaccination acts and included a "conscientious objector" clause. This allowed parents who did not believe in vaccination's safety or efficacy an exemption certificate.¹⁷⁹ This act also introduced the concept of "conscience objector" into English laws.¹⁸⁰ This law represents the first chink in vaccine legislative armor allowing parentally determined exemptions to vaccinations. The conscious objector law sounds like the philosophical exemption current laws allow parents to exercise.

In the early 1900s, the United States exhibited similar anti-vaccine sentiments using similar vehicles. At the end of the 19th century, there were smallpox outbreaks in the United States prompting vaccine campaigns and anti-vaccine activity. First, the Anti Vaccination Society of America was founded in 1879 by British anti-vaccination leader William Tebb. The

¹⁷⁷ JD Swales, "The Leicester Anti-Vaccination Movement," *The Lancet* 1992;340:1019-21.

¹⁷⁸ The College of Physicians of Philadelphia, "History of Anti-Vaccination Movements," *The History of Vaccines: An Educational Resources By the College of Physicians of Philadelphia*, accessed January 7, 2020, <u>https://www.historyofvaccines.org/content/articles/history-anti-vaccination-</u> movements.

¹⁷⁹ Ibid.

¹⁸⁰ Robert M Wolfe and Lisa K. Sharp, "Anti-Vaccinationists Past and Present," *BMJ* vol 325, August 24, 2002:430-2.

New England Anti Compulsory Vaccination League, founded in 1882 and the Anti-vaccination League of New York City founded in 1885 followed.¹⁸¹ The early anti-vaccination movement in the US was characterized by court battles to repeal vaccination laws in several states including California, Illinois, and Wisconsin.¹⁸² A landmark court case in 1905, *Johnson v. Massachusetts* ruled in favor of vaccine legislature allowing the state of Massachusetts to implement laws mandating vaccines against communicable diseases.¹⁸³ Anti-vaccine sentiment in the past is very similar to the present. The arguments for personal liberty still influence vaccine hesitancy and anti-vaccine beliefs today. What is most different is the platform that the anti-vaccine movement has today with the advent of the internet.

In present times, we still observe states favoring the anti-vaccine position. In December 2019 New Jersey tried to pass a bill, after having recent measles outbreaks in the state¹⁸⁴, to end religious exemptions to vaccination for children to attend public and private schools in the state. This included all schools, even universities and colleges. The bill was not passed, failing to get enough votes. If approved, this would have been one of the strictest vaccine laws in the US. In response to the bill, dozens of anti-vaccine parents and children stood outside the state senate's doors chanting, "Do not touch my child." In response to the cheers when the bill was not passed, Senate President, Peter M Sweeney said, "They can cheer all they want, we're not walking away from it." He added, "It's just remarkable how people are

¹⁸¹ Ibid.

¹⁸² Ibid.

¹⁸³ Justia US Supreme Court, "Jacobson v Massachusetts 197 US 11.1905" accessed May 3, 2020, https://supreme.justia.com/cases/federal/us/197/11/.

¹⁸⁴Robert McDonald, MD. Et al, "*Notes from the Field*: Measles Outbreaks from Imported Cases in Orthodox Jewish Communities — New York and New Jersey, 2018–2019," CDC *MMWR*, accessed January 12, 2020, <u>https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a4.htm</u>.

looking at this and not trusting the science on it at all. They're trusting the internet."¹⁸⁵ The internet has become a game changer in spreading mis-information about many topics, including vaccines. The internet has eased the delivery of anti-vaccine information into the hands of the vaccine hesitant, influencing and persuading them to not vaccinate. It is interesting that the science of vaccines does not motivate the anti-vaxers protesting this bill. This group generally does not trust the science but is portrayed as trusting the information found on the internet. Or perhaps, the infringement of their personal liberties is driving their courtroom chants. The availability to choose might be the primary concern; it may not all be the lack of trust in vaccines.

Most interesting is the strong religious thread in the NJ decision. Lakewood, New Jersey hosts the largest Orthodox Jewish Yeshiva in the country with over 7,000 students. The recent measles cases in NJ centered mainly around the Orthodox Jewish community in Ocean County. The CDC reports, from Oct 17-Nov 30, 2018 there were 33 reported measles cases in this community. A second outbreak occurred in the same community in March 2019¹⁸⁶. Most orthodox Jewish families vaccinate their children; however, several Rabbis have expressed concern that the state of New Jersey is interfering in a potential rabbinical decision. The ultra-orthodox follow the specific interpretations of Jewish law by their rabbis. Furthermore, a rabbi may decide a third child in a family should not be vaccinated if the first two children were

¹⁸⁵ Sharon Otterman and Tracy Tulley, "Strict Vaccine Law Stumbles in N.J. Legislature," *The NY Times* Dec. 16, 2020, accessed January 9, 2020,

https://www.nytimes.com/2019/12/16/nyregion/vaccines-measles-nj-religious-exemptions.html.

¹⁸⁶ Robert McDonald, MD. et al, "*Notes from the Field*: Measles Outbreaks from Imported Cases in Orthodox Jewish Communities — New York and New Jersey, 2018–2019," CDC *MMWR*, accessed January 12, 2020, <u>https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a4.htm</u>.

injured by vaccines. Based on the statistics, the serious adverse events that would dictate a sibling child from not receiving a vaccine is incredibly small.

For example, Dr. Peter Hotez¹⁸⁷ outlines the risk for vaccine related adverse events compared to the risks associated with acquiring measles. For every 10,000 children 6 months to 5 years of age receiving a measles vaccine, the risk of fever related seizure is 2-5% (200-500). There were only .25 to .4 cases out of 10,000 children vaccinated against measles developing abnormal blood clotting and 93% of these cases resolve within six months. That is 1 in 25,000-40,000 cases. For every 10,000 unvaccinated children who get measles, there are 1,000 child ear infections with potential for hearing loss, more than 3 cases of abnormal blood clotting, 2,000 hospitalizations, 10 cases of childhood encephalitis, 500 cases of child pneumonia and 10 to 30 child deaths from respiratory or neurological complications.¹⁸⁸Based on these numbers, the risk affiliated with the measles vaccine is significantly less than the risk affiliated with acquiring the disease. Rabbi's may want the opportunity to exercise religious decision making for clinical reasons however the state of New Jersey does not agree.

The New Jersey story has had more traction over time. The bill was approved in the house and then stalled in the senate in December 2019. The bill went once again to senate on January 13, 2020 with confidence in approval. However, after approval from the senate the governor needed to approve, and his position was unclear. What was clear was the anti-vaccine protesters shouting "Murderer!" and "Traitor!" while the bill was being discussed again at the

¹⁸⁷ Peter J. Hotez, "You Are Unvaccinated And Got Sick. These Are Your Odds," *The NY Times* Opinion Jan 9, 2020, accessed January 9, 2020, <u>https://www.nytimes.com/2020/01/09/opinion/vaccine-hesitancy.html</u>.

senate.¹⁸⁹Again, lawmakers in New Jersey were unsuccessful in passing the bill on January 13, 2020. One of the thousands of protestors who showed up to the senate that day said to a journalist, "I feel like this is a fascist overreach of the government and taking away religious and medical freedoms."¹⁹⁰ She also told reporters she has not vaccinated her three children. Her three children will not be protected from vaccine preventable diseases as herd immunity fails. Perhaps standing at the senate building near protestors that day was more dangerous than the anti-vaccinators realized. Grouping together a large crowd of unvaccinated individuals can quickly spread a disease like measles if someone was exposed.

Although the proposed bill was progress in favor of vaccines; there is still a loophole. Children may go unvaccinated at private schools, including daycares in New Jersey. "This type of amendment will once again allow the wealthy to buy their way out of a law via private schools," Sue Collins, co-founder of the New Jersey Coalition for Vaccination stated in a news article.¹⁹¹ Collins is right, but the law is important progress and the state is holding firm and making a point. The state is also making it more challenging for parents who decide not to vaccinate their children since they will now have to go the extra mile to enroll and pay for private schools. It will be interesting to see if any private schools adopt the legislation and require vaccinations like public schools. If it comes down to "vaccine" versus "no-vaccine" schools, it will be very challenging to convince parents who vaccinate their children to pay for

¹⁸⁹ Brie Stimson, "NJ Vaccine Bill Eliminating Religion As Student Exemption is Likely to Advance After Senate Deal: Reports," *Fox News Channel*, accessed January 12, 2020, <u>https://www.foxnews.com/politics/anti-vaccine-protesters-storm-new-jersey-capitol-as-bill-eliminating-religious-excuse-gets-closer-to-passing</u>.

¹⁹⁰Meg Oliver, "NJ Vaccine Bill to End Religious Exemptions Fails, But Debate Rages On," *CBS News* Jan 14, 2020, accessed January 23, 2020, <u>https://www.cbsnews.com/news/new-jersey-vaccine-bill-to-end-religious-exemptions-fails-but-debate-rages-on/</u>. private school with children who are not vaccinated. The herd protection those vaccinated children offer the usually smaller cohort of unvaccinated children will no longer be available.

Even though the religious exemption bill was not passed this time around, there is a platform and positive vaccine change will emerge from it. For example, the week of January 17, 2020, NJ Governor Phil Murphy signed legislation mandating students attending county colleges and all other NJ colleges and universities be immunized according to CDC guidelines against meningitis serogroups ACWY and B.¹⁹² The aim of this legislation is to help protect outbreaks in the state. NJ has seen outbreaks at both private and public universities, Princeton University and Rutgers University. Because college students live in close quarters, the disease is easily spread in this specific age group. The CDC estimates that there have been about 500 bacterial meningitis related deaths per year in the United states between 2003-2007.

Unlike in the ultra-orthodox Jewish community, most parents who choose to not vaccinate their children are primarily motivated by concerns over vaccine safety, particularly the much-debated link between vaccines and autism. There is also the sentiment that children are not at risk for vaccine preventable diseases due to their geographic location. In Margaret Carrerl and Patrick Bitterman's¹⁹³ study that tracked spatial clusters of Personal Belief Exemptions (PBE) for vaccinating in California, results indicated that schools with high PBEs are spatially buffered from those with low PBEs.¹⁹⁴ Therefore geographic communities tend to contain individuals who share and influence each other's personal beliefs regarding vaccination.

¹⁹² Anthony Veccione, "New Law Aims to Prevent Meningitis Outbreaks On NJ College Campuses," *NJBIZ* Jan 17, 2020, accessed January 23, 2020, <u>https://njbiz.com/governor-signs-bill-to-prevent-meningitis-outbreaks-on-college-campuses/</u>.

¹⁹³Margaret Carrerl and Patrick Bitterman, "Personal Belief Exemptions to Vaccinations in California: A Spatial Analysis," *Pediatrics* Vol 136.1 (July 2015): 81.
¹⁹⁴ Ibid.

The Internet and the Anti-Vaccine Movement

Beyond geographic community anti-vaccine influence, is the powerful and far reaching influence of the internet. The internet poses threats against vaccines for several reasons. First, anyone can post information or propaganda that is incorrect. A website can post false claims about vaccinations. The internet affords individuals the opportunity to present subjective opinions and present them as facts without consequence. All one needs is a domain name and they can post non-factual, non-scientific information for people to consume. Second, the internet has incredible reach. Current Statistics in 2019 estimate that over 4.13 billion people world-wide have access to the internet.¹⁹⁵ That is more than half the earth's population. Unlike the example in California that is contained to a geographic region of like-minded individuals, the internet makes information widely available to anyone who has access. It can band and unite anti-vaccinators across the globe. Third, when someone is searching for information, they can stumble upon something that looks valid, but contains unverified information. The internet is an important vehicle to search for healthcare related information. The biggest problem is users are searching user-generated sites for this kind of information such as online news groups and blogs over evidence-based sites¹⁹⁶ such as the CDC.gov. The concern is that "many parents may shift from vaccine hesitancy to vaccine resistance, and from vaccine resistance to out-right opposition"¹⁹⁷ as they come across more anti-vaccine sentiment than pro-vaccine facts on the internet.

¹⁹⁵Statista, "Number of Internet Users Worldwide 2005-2019," Accessed January 23, 2020, <u>https://www.statista.com/statistics/273018/number-of-internet-users-worldwide/</u>.

¹⁹⁶ Eve Dube, Maryline Vivion, and Noni E MacDonald, "Vaccine Hesitancy, Vaccine Refusal and the Anti-Vaccine Movement: Influence, Impact and Implications," *Expert Review of Vaccines* 14:1. 99-117.

¹⁹⁷JL Schwartz and A Caplan, "Vaccination Refusal: Ethics, Individual Rights, and the Common Good," *Primary Care Clinic Office Practice* 2011; 38:717-28.

A 2010 study¹⁹⁸ on emerging and continuing trends in vaccine opposition on the internet references that a simple search for the word "vaccination" resulted in more anti-vaccine content than pro-vaccine websites. Unfortunately, someone innocently looking for vaccine information is more likely to find the anti-vaccine misinformation. This is particularly troublesome for the vaccine-hesitant looking for reinforcement why they should not vaccinate. It is also problematic for individuals who are not educated and trust the misinformation they find. S.J. Bean references a German study by Betsch et al.¹⁹⁹ where "subjects viewing anti-vaccine websites for only 5-10 min increased their perceptions of vaccine risks, decreased their perceptions of the risks of avoiding vaccines, and lowered their vaccination intentions compared to viewing neutral websites."²⁰⁰ The internet has the power to influence.

After searching Google with the phrase "Vaccine Facts" the fifth website that appears is called www.naturalnews.com. This site lists "10 outrageous (but true) facts about vaccines the CDC and the vaccine industry don't want you to know"²⁰¹

Their list includes the following²⁰²:

- 1. "Mercury is still used in Vaccines and the CDC openly admits it. There is NO safe level of mercury for injecting into a human child.
- 2. Injecting any substance into the human body makes it orders of magnitude more potentially toxic because it bypasses the protections of the digestive tract or the respiratory system.

¹⁹⁹ C. Betsch, F. Renkewitz, T. Betsch, and C. Ulshofer, "The Influence of vaccine critical websites on perceiving vaccination risks," *Journal of Health Psychology* 210:15(3):446-55.

¹⁹⁸ Sandra J Bean, "Emerging and Continuing Trends in Vaccine Opposition Website Content," Vaccine 29 (2011) 1874-1880: 1875.

²⁰⁰ Ibid.

²⁰¹ Mike Adams, "10 outrageous (but true) facts about vaccines the CDC and the vaccine industry don't want you to know," Natural News, accessed April 6, 2016,

http://www.naturalnews.com/042012 vaccine facts vaccine-damaged children CDC.html#. 202 Ibid.

- 3. For decades, polio vaccines injected into tens of millions of people actually contained hidden cancer viruses (SV40 and others). This was openly admitted by a top Merck vaccine scientist named Hilleman. The CDC recently scrubbed its website of this information in a "revisionist history" purge.
- 4. Top virologists working for Merck have blown the whistle and gone public with shocking revelations that claim the company routinely fabricated lab results to claim a 95% efficacy rate of its mumps vaccine in order to continue receiving government contracts on a vaccine that didn't work.
- 5. In nearly every outbreak you hear about these days, the majority of the children affected by the outbreak have already been vaccinated against the virus! For example, outbreaks of whooping cough routinely involve children who have already been vaccinated against whooping cough. This is yet more proof that vaccines do not confer immunity.
- 6. The claimed history of vaccine "successes" against polio and other diseases is a pure fabrication.
- 7. The vaccine industry refuses to conduct scientific tests on the health outcomes of vaccinated children vs. unvaccinated children. Why? Because these tests would no doubt show unvaccinated children to be healthier, smarter and far better off than vaccinated children in terms of behavioral disorders, allergies and even autoimmune disorders.
- 8. The U.S. Supreme Court has already declared that the secret "vaccine court" is a higher power than the Supreme Court.
- 9. The mainstream media receives a significant portion of its revenues from the very same drug companies selling vaccines.
- 10. The CDC openly admits that vaccines contain additives which are known to be potent neutoxic chemicals. Those additives include: Mercury, Aluminum, Formaldehyde, and MSG."

These claims, however, are not supported by scientific evidence. They are examples of the conspiracy theory culture the anti-vaccine movement thrives on. The First claim misrepresents the fact that all childhood vaccines are now available thiomerosal free. The CDC²⁰³ explicitly states, "We want you to know that thiomerosal is no longer used in children's shots, except some

²⁰³ CDC, "Thimerosal in Vaccines," Vaccine Safety, accessed April 6, 2016, http://www.cdc.gov/vaccinesafety/concerns/thimerosal/faqs.html.

types of flu shots. You can ask for a flu shot without thiomerosal." In this statement the CDC perpetuates the use of the term shots to describe children's vaccines. This negative term is not helping their cause.

The CDC²⁰⁴ also goes on to mention, "thiomerosal is a different kind of mercury. It doesn't stay in the body and is unlikely to make us sick." Furthermore CDC²⁰⁵ states, "Thimerosal contains ethylmercury, which is cleared from the human body more quickly than methylmercury and is therefore less likely to cause any harm." Methylmercury is found in fish. The CDC acknowledges some risk by use of the term" unlikely" or the phrase "less likely" however they clearly state the intended use for thimerosal is in multidose vials. Pediatric offices will generally stock prefilled syringes in the US, and as the CDC states, parents who are concerned should explicitly ask for thimerosal free vaccines. "Measles, mumps, and rubella (MMR) vaccines do not and never did contain thimerosal. Varicella (chickenpox), inactivated polio (IPV), and pneumococcal conjugate vaccines have also never contained thimerosal. Influenza (flu) vaccines are currently available in both thimerosal-containing (for multi-dose vaccine vials) and thimerosal-free versions.²⁰⁶" In 1998 the CDC issued a recommendation to vaccine manufacturers that thiomersal containing vaccines should be removed as quickly as possible and in 2004, the US Institute of Medicine did their eighth assessment of the safety of immunizations and concluded definitively that there is no link between MMR or thiomersal vaccines and autism.²⁰⁷ It is for this reason that multidose vials continue to contain thiomersal

²⁰⁴ Ibid.

²⁰⁵ CDC, "Thimerosal in Vaccines" Vaccine Safety, accessed April 18, 2020,

https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html.

²⁰⁶ Ibid.

²⁰⁷Nayanah Siva, "Thiomersal Vaccines Debate Continues Ahead of UN Meeting," *The Lancet* Vol 37 (June 23, 2012):2328.

considering the ease of use factor for the developing world. Vaccines containing thiomersal are essential to vaccinating the developing world. They are used in more than 120 countries to immunize at least 64% of the global birth cohort annually.²⁰⁸ "WHO estimates that thiomersal-containing vaccines avert at least 1.4 million child deaths every year and the vaccines are used against fatal diseases, such as diphtheria, tetanus, and hepatits B."²⁰⁹ Additionally these vaccines protect potential international travelers coming to the US from spreading diseases like measles; a very real scenario that occurred in 2015 and again throughout 2019.

The other 9 "facts" found on the Natural News website misrepresent vaccine science, perpetuate myths, and propose conspiracies. For example, number 5 references children acquiring whooping cough after having been vaccinated. This example does not speak to the need for re-vaccination with Tdap as a booster. This website is easy to find when searching for vaccine safety. Individuals looking for information may read this list and potentially follow the "facts" which are supported by links to sites that are conspiracy theory pages and contain more misinformation. One of the most common reasons parents choose not to vaccinate, is missing from this "fact" sheet. Many parents believe that babies' fragile immune systems are not developed or ready for vaccines or multiple vaccines. The CDC dispels this concern in the following²¹⁰.

"From the moment babies are born, they are exposed to numerous bacteria and viruses on a daily basis. Eating food introduces new bacteria into the body; numerous bacteria live in the mouth and nose; and an infant places his or her hands or other objects in his or her mouth hundreds of times every hour, exposing the immune system to still more germs. When a child has a cold, he or she is exposed to up to 10 antigens, and exposure to "strep throat" is about 25 to 50 antigens. Each vaccine in the childhood vaccination

²⁰⁸ Ibid.

²⁰⁹ Ibid.

²¹⁰ CDC, "Thimerosal in Vaccines," Vaccine Safety accessed April 6, 2016, http://www.cdc.gov/vaccinesafety/concerns/thimerosal/faqs.html.

schedule has between 1-69 antigens. A child who receives all the recommended vaccines in the 2014 childhood immunization schedule may be exposed to up to 315 antigens through vaccination by the age of 2."

The number of antigens contained in childhood vaccines is within range of the normal antigen activity a child is exposed to on their own. According to CDC²¹¹ there have been many scientific studies involving concomitant use of vaccines containing multiple antigens given to infants safely. "Sometimes, certain combinations of vaccines given together can cause fever, and occasionally febrile seizures; these are temporary and do not cause any lasting damage. Based on this information, both the Advisory Committee on Immunization Practices and the American Academy of Pediatrics recommend getting all routine childhood vaccines on time.²¹²"

Like much of the content from Natural News, S.J. Bean²¹³ found in her study on antivaccine sentiment on the web, several themes the misinformation can be grouped in. Natural news touches safety and efficacy concerns as well as poison, additives and ingredients, financial motives and conspiracy theories. Other categories include, civil liberties, alternative treatment, religion, celebrity themes, and expert or parent testimonial²¹⁴. Safety and Effectiveness claims on anti-vaccine websites assert that vaccines cause illness, damage, and even death. They may also make claims that vaccine side effects are under-reported and/or missed. Civil liberties touch on government mandates as a form of control. Alternative treatments discuss homeopathy, chiropractic, and other more natural alternatives to vaccination. Web-sites selling alternative or more natural solutions to replace vaccination perpetuate fear that vaccines are unsafe containing

²¹¹ CDC, "Getting Multiple Vaccines at the Same Time Has Been Shown to Be Safe," Vaccine Safety, accessed April 18, 2020, https://www.cdc.gov/vaccinesafety/concerns/multiple-vaccines-immunity.html.

²¹² Ibid.

²¹³Sandra J. Bean, "Emerging and Continuing Trends in Vaccine Opposition Website Content," Vaccine 29 (2011) 1874-1880: 1877.

²¹⁴ Ibid.

poisons, additives, and other ingredients including the dangerous thimerosal, mercury, and aluminum preservatives.

Earlier websites from the 1990s and early 2000s also mention the incorporation of aborted fetal tissue in vaccines.²¹⁵ Financial motives allege that vaccines are given for profit at the expense of the vaccinated. Bean²¹⁶ quotes from the Douglasreport.com; a website that has since been rebranded as the Daily Dose: "Vaccines have become a billion-dollar money game, plain and simple. Drug companies have used scare tactics to convince people to be injected with junk concoctions that, in some cases, are causing far more health problems than they are preventing."

I searched for the Douglas Report and found Dr Kevin Dobrzynski's²¹⁷ Daily Dose. The list of anti-vaccine articles was expansive at over 18 pages, including titles like: "US Taxpayers Foot the Bill for Big Pharma's Ebola Vaccine," "Mumps Outbreak Definitive Proof Vaccines Have Failed," and "Another Study Links Autism to Vaccines." The titles cut across all major anti-vaccine themes outlined by Bean, including conspiracy theories and search for truth. Conspiracy theorists are looking for links between the government and large corporations. They analyze themes and reasons why the government would want to impose regulations, including vaccines, on its citizens while tying in concepts like corporate greed²¹⁸. Expert and parent testimonials also appear in anti-vaccine web content. Jenny McCarthy is an example of a

²¹⁵ Ibid.

²¹⁶ Ibid.

²¹⁷Kevin Dobrzynski, "Daily Dose," accessed January 12, 2020, https://drkevinsdailydose.com/search/vaccines.

²¹⁸ Although vaccines are manufactured by For-profit manufacturers, vaccines have very small margins compared to other pharmaceutical products. Because many vaccines are paid for through the CDC's VFC program, the government sets the price floor for vaccines. In my opinion corporate greed may exist in pharma but not in vaccines.

celebrity parent using the internet to make false claims connecting vaccines to her son's autism. In addition, there is one final category that Bean does not discuss. There are several religious groups including orthodox Jews who have clerical intervention in vaccine decision making.

The primary purpose in giving this background information regarding the debate between vaccinators and non-vaccinators is to set the stage for what occurred when former physician Andrew Wakefield published an article linking MMR with autism.

Wakefield, MMR, and Autism

In 1998 Andrew Wakefield and 11 co-authors published a study entitled: "Ileal-

lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children." The study was published in the widely respected medical journal *The Lancet*. The small study sparked widespread panic about a potential connection between the mumps-measles-rubella (MMR) vaccine and autism spectrum disorder (ASD).²¹⁹ Wakefield and colleagues drew the following hypothesis in their published article:

- "A (highly) increased risk of developing autism exists after receiving the MMR vaccine.
- The prevalence of bowel symptoms and regression should be higher in children who are autistic who had the MMR vaccine before onset than in children who are autistic (i.e., a specific "autistic enterocolitis" syndrome is associated with the MMR vaccine.)
- Ecological studies should show a close secular correspondence between the use of the MMR vaccine and the prevalence of autism in the same birth cohorts."²²⁰

²¹⁹Steven Novella, "The Lancet Retracts Andrew Wakefield's Article," Accessed April 17, 2016, <u>https://www.sciencebasedmedicine.org/lancet-retracts-wakefield-article/</u>.

²²⁰Elizabeth Miller, "Measles-Mumps-Rubella Vaccine and the Development of Autism," *Seminars in Pediatric Infectious Disease* Vol 14, no 3(July 2003):201.

In direct contrast in a 2003 paper, Miller²²¹ suggests there is no evidence of increased risk of autism occurring after receiving MMR vaccine, no evidence to suggest the MMR vaccine is associated with autistic enterocolitis syndrome, and no evidence that ecological studies show correspondence between MMR and autism. "On the basis of the available epidemiologic evidence, the suggestion that a "dramatic" increase in the incidence of autism has been caused by the MMR vaccine clearly can be rejected."²²² Further Miller concludes that any small contribution to the observed incidence of autism caused by the MMR vaccine can also be rejected.²²³

Subsequent studies also published in *The Lancet* indicate no evidence for such a connection Wakefield and colleagues claim and thus the link between the MMR vaccine and ASD has been scientifically debunked. A 14-year prospective study by Heikki Peltola et al²²⁴, debunking the link between the MMR vaccine and inflammatory bowel disease and autism was published shortly after Wakefield's original article. The conclusion states, "Over a decade's effort to detect all severe adverse events associated with MMR vaccine could find no data supporting the hypothesis that it would cause pervasive developmental disorder or inflammatory bowel disease."²²⁵ Furthermore, in correspondence on May 2, 1998, A. Rouse mentions *The Society of the Autistically Handicapped* and that some of the children's in Wakefield's study came to attention because of related activities with this society. "It is a pity that Wakefield et al do not identify the manner in which the 12 children investigated were referred [...] if some

²²⁵ Ibid.

²²¹ Ibid, p204.

²²² Ibid, p204.

²²³ Ibid.

²²⁴Heikki Peltola, et al., "No Evidence for Measles, Mumps, and Rubella Vaccine-Associated Inflammatory Bowel Disease or Autism in a 14-Year Prospective Study," *The Lancet* Vol 351 (May 2, 1998):1328.

children were referred, directly or indirectly, because of the *Society for the Autistically Handicapped*, Wakefield should have declared his cooperation with that organization."²²⁶ Interesting to note the editors of *The Lancet* missed the connection admittedly.

Lee et al.²²⁷ wrote in the Correspondence section of *The Lancet* in 1998, "We are concerned about the potential loss of confidence in the (MMR) vaccine after publication of Andrew Wakefield and colleagues' report, in which these workers postulate adverse effects of measles-containing vaccines. As a result, we fear there may be a reduction in vaccine uptake in the UK and elsewhere." David Black et al.²²⁸ wrote "The publicity generated by this paper is out of proportion to the strength of evidence presented." A J Beale²²⁹ responded, "The result of publication and the subsequent general publicity is predictable [...] Such publicity has led to parents refusing vaccination for their children and a resurgence of the disease (and deaths), and more anguish for the parents who expected recompense from the courts which usually failed for lack of evidence of causality." Helen Bedford et al. 230 voiced their concern as well, "If, as a result of this paper, parents reject MMR vaccine, this could lead to a re-emergence of measles infection with associated deaths and permanent neurological damage among children, and a resurgence of rubella infection leading to a rise in congenital rubella births and terminations of pregnancy. Has nothing been learned from the experiences with Pertussis vaccine in the 1970s?"²³¹ There were several other colleagues expressing similar concerns with Wakefield's

²²⁶ A. Rouse, "Correspondence." *The Lancet* Vol 351 (May 2, 1998):1356.

²²⁷J W Lee, et al., "Autism, Inflammatory Bowel Disease, and MMR Vaccine," *The Lancet* Vol 351 (March 21, 1998): 905

²²⁸David Black, Henry Prempeh, and Tony Baxter, "Autism, Inflammatory Bowel Disease, and MMR Vaccine," *The Lancet* Vol 351 (March 21, 1998): 906.

²²⁹A J. Beal, "Autism, Inflammatory Bowel Disease, and MMR Vaccine," *The Lancet* Vol 351 (March 21, 1998): 906.

²³⁰Helen Bedford, et al., "Autism, Inflammatory Bowel Disease, and MMR Vaccine," *The Lancet* Vol 351 (March 21, 1998): 907.

²³¹ Ibid.

paper and The Lancet. At that time in March 1998, editors of the journal responded that they

made the right decision in publishing the article. Six years later on March 6, 2004, The

Lancet²³² issued a statement regarding the allegations of research misconduct brought to the

attention of the editorial staff. Allegations included:

- "Ethics approval for the investigations conducted on the children...some of them highly invasive (lumbar puncture), had not been given."
- "That the study reported in *The Lancet* was completed under the cover of ethics approval for an entirely different study..."
- "children were invited to participate in the study by Dr Andrew Wakefield and Professor John Walker-Smith, thus biasing the selection of children in favour of families reporting an association between their child's illness and the MMR vaccine."
- The children were also part of a Legal Aid Board funded pilot project, led by Dr Wakefield – "a pilot project with the aim of investigating the grounds for pursuing a multi-party legal action on behalf of parents of allegedly vaccine-damaged children, the existence of which was not disclosed to the editors of *The Lancet*."
- The results of the published paper were passed to lawyers and "used to testify the multi-party legal action prior to publication, a fact that was not disclosed to the editors of *The Lancet*."
- "Dr Wakefield received 55,000 Pounds from the legal Aid Board to conduct this pilot project...this was a financial conflict of interest that should have been declared to the editors and was not."²³³

In the statement Richard Horton²³⁴ of *The Lancet* claims the evidence does not support

the first or second allegation. Allegation three was also dismissed based on the author's best recollection of recruitment for the study. However, allegations 4-6 were what ultimately led to retraction of the paper by the journal. The editors judge that the second study had not been disclosed and should have been disclosed, "irrespective of the number of children overlapping

²³² Richard Horton, "A Statement by the Editors of The Lancet," *The Lancet* Vol 363 (March 2, 2004): 820.

²³³ Ibid.

²³⁴ Ibid.

between the pilot project funded by the Legal Aid Board"²³⁵ and the paper published by the journal. "We regret that aspects of funding for parallel and related work and the existence of ongoing litigation that had been known during clinical evaluation of the children reported in the 1998 *Lancet* paper were not disclosed to editors."²³⁶

Wakefield's study was most damaging due to the wording in his findings, "Onset of behavioral symptoms was associated by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children $[...]^{237}$ This was enough to cause panic in the lay population. The average lay person fails to recognize the study cohort of only 12 children who were later determined to be affiliated with special interests and a conflict of interest. He continues in his discussion by stating, "Rubella virus is associated with autism and the combined measles, mumps, and rubella vaccine (rather than monovalent vaccine) has also been implicated."²³⁸ The last sentence of the article is a call for action. "In most cases, onset of symptoms was after measles, mumps, and rubella immunization. Further investigations are needed to examine this syndrome and its possible relation to this vaccine."²³⁹ This statement from a physician at the time was enough to set panic among parents who want to protect their children. When weighing the risks of autism and measles, mumps, rubella, a modern parent would opt to protect from autism since they have heard the disease is on the rise and may even know someone with the disease over measles, mumps, or rubella with much lower incidences and certainly not common diseases in conversation. Wakefield woke an anti-vaccine campaign

²³⁵ Ibid.

²³⁶ Ibid, 821.

 ²³⁷Andrew Wakefield et al., "Iileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive development disorder in children," *The Lancet* Vol 351 (February 28, 1998):637.
 ²³⁸ Ibid, 640.

²³⁹ Ibid, 641.

that spread influence across the globe and ultimately exposed US children to a disease (measles) that was eliminated from this country at just about the same time his article was published. The repercussions were felt a decade later.

On May 24, 2010, *The New York Times*²⁴⁰ published an announcement that Andrew Wakefield was barred by the British Medical Council. The council found multiple instances of unprofessional conduct including Wakefield "taking blood samples for his study from children at his son's birthday party; he paid each child 5 pounds…and joked about it later. It also noted that part of the costs of Dr. Wakefield's research was paid by lawyers for parents seeking to sue vaccine makers for damages."²⁴¹ Dr Surendra Kumar, Chairman of the Medical Council, said, "Dr. Wakefield had brought the medical profession into disrepute and that his behavior constituted multiple separate instances of professional misconduct."²⁴² Wakefield was guilty of more than 30 charges. In an interview on NBC in 2010 Wakefield said, "These parents are not going away. The children are not going away. And I am most certainly not going away."²⁴³

Wakefield has been in the news as recently as 2016. He is the director and co-writer of "Vaxxed: From Cover-Up to Catastrophe" a documentary about the link between the MMR vaccine and autism that was scheduled to be released in the Tribeca Film Festival. It is clear which side of the debate Wakefield supports. *The New York Times*²⁴⁴ reports that the trailer for the film shows Wakefield stating, "Wow, the CDC had known all along there was this MMR autism risk." The plan to show the film angered the scientific community. Dr. Mary Anne

²⁴⁰John F. Burns, "British Medical Council Bars Doctor Who Linked Vaccine with Autism," *The New York Times* May 24, 2010.

²⁴¹ Ibid.

²⁴² Ibid.

²⁴³ Ibid.

²⁴⁴Pam Belluk and Melena Ryzik, "Robert De Niro Defends Screening of Anti-Vaccine Film at Tribeca Festival," *The New York Times* March 25, 2016.

Jackson²⁴⁵, a professor of Pediatrics at the University of Missouri wrote into *The New York Times*, "Unless the Tribeca Film Festival plans to unmask Andrew Wakefield, it will be yet another disheartening chapter where scientific fraud continues to occupy a spotlight and overshadows the damage he has left behind in the important story of vaccine safety and success." One day later *The New York Times*²⁴⁶ published an article stating that Robert De Niro had pulled the anti-vaccine documentary from the Tribeca Film Festival. Pulling the film demonstrated that The Tribeca Film Festival was not a venue to foster fear mongering with discredited information that continues to perpetuate the link between MMR vaccine and autism. This link has become a major platform for the anti-vaccine movement driven by celebrity influencers like Jenny McCarthy.

Celebrity and Political Anti-vax Influencers

Although Wakefield's claims have been disproven, there is still a strong celebrity influencer movement supporting some of his disproven claims. It is unfortunate when a child is diagnosed with autism and many times there is no explanation why. With no reason supporting the diagnosis, it is easy to point a finger at vaccines since there has already been a controversial connection between the two. This is exactly what Jenny McCarthy did when her son Evan was diagnosed with autism at the age of 2. She made it her mission and calling to advocate for children with autism. She claims the reason she became famous was for this mission. She is fully aware in this claim of the public attention and influence she has. In 2007 she went on media tour to spread awareness on autism and made the claim that vaccines may be related. In a

²⁴⁵ Ibid.

²⁴⁶Stephanie Goodman, "Robert De Niro Pulls Anti-Vaccine Documentary From the Tribeca Film Festival," *The New York Times* March 26, 2016.

google search of Jenny McCarthy and vaccines I was introduced to 9 quotes that Jenny has

made in respect to vaccines, these include²⁴⁷:

- 1. "If you ask a parent of an autistic child if they want the measles or the autism, we will stand in line for fucking measles."
- "The reason why (parents) are not vaccinating is because the vaccines are not safe. Make a better product and then parents will vaccine."²⁴⁸
- 3. "I do believe sadly it's going to take some diseases coming back to realize that we need to change and develop vaccines that are safe."
- 4. "Time magazine's article on the autism debate reports that the experts are certain 'vaccines don't cause autism; they don't injure children; they are the pillar of modern public health.' I say, 'that's a lie and we're sick of it.""
- 5. "Yes, a wave of 12 children with measles in San Diego is a troubling thing. But, there are more than 20,000 children in San Diego with autism! 20,000 vs. 12?"²⁴⁹
- 6. "almost all kids get----- injected toxins----very early in life, and our own government clearly acknowledges vaccines cause brain damage in certain vulnerable kids."
- 7. "What number does it have to be for everyone to start listening to what the mothers of children who have autism have been saying for years, which is...We vaccinated our baby and SOMETHING happened. SOMETHING happened. Why won't anyone believe us?"

²⁴⁷Ellie Hall, "11 Things That Jenny McCarthy Has Said About Vaccines," *Buzzfeednews.com*, Posted April 14, 2014, 6:53pm ET, accessed December 30, 2019, <u>https://www.buzzfeednews.com/article/ellievhall/11-things-that-jenny-mccarthy-has-said-about-</u>

vaccines.

²⁴⁸ I must comment directly on this one. Jenny McCarthy has no scientific or medical background. She is not an epidemiologist or an expert in public health outcomes. She is the parent of an autistic child with a voice. Her claims that vaccines are not safe is not supported by any evidence or subject matter expertise and because of her celebrity status these claims are a threat to national and global health. Jenny McCarthy began her career in Playboy magazine as a nude model however the American public allows her opinions to influence their decision making. This is an important point to consider when thinking about strategies to educate the misinformed.

²⁴⁹ Interestingly, an article in Scientific American from 2010 states there were higher clusters of autism reported in large California cities including San Diego. The article links the increased diagnoses to parents in these cities having higher levels of education and therefore better access to healthcare providers who are able to make the diagnoses and offer services to support it. They also consider that chemicals found in household cleaning products could also be linked to the higher incidences of autism in these clusters. Before reading the article, I thought it could be the school of thought in these areas. Perhaps the University of San Diego or another institution in the area has thought leaders influencing the increase in diagnoses?

Marla Cone, "Autism Clusters Found in California's Major Cities: California Scientists had identified autism clusters where children are twice as likely to have autism and mostly have highly educated parents," *Scientific American* January 6, 2010 accessed December 30, 2019, https://www.scientificamerican.com/article/autism-clusters-californiahighly-educated-parents/.

- 8. If the vaccine companies are not listening to us, it's their fucking fault that the diseases are coming back. They're making a product that's shit. If you give us a safe vaccine, we'll use it. It shouldn't be polio versus autism."
- 9. "Moms and pregnant women are coming up to me on the street going, 'I don't know what to do'...And I don't know what to tell them, because I am surely not going to tell anyone to vaccinate. But if I had another child, there's no way in hell."

Jenny McCarthy appeals to Moms also looking for answers regarding their child's autism. When she was pregnant with her son, she wrote a book about her experience called "Belly Laughs: The Naked Truth about Pregnancy and Childbirth."²⁵⁰ This gave her credibility with Mom's; therefore, when her son was diagnosed with autism, there was already the connection that she is a caring Mom trying to do what is right for her child.

As the incidence of autism increases and there aren't good medical explanations, many parents turn to the misinformation that anti-vaccinators spread on the internet to satisfy their search for the cause. They also turn to celebrity influencers like Jenny McCarthy or Robert F. Kennedy Jr. to solve their questions. "Science has become just another voice in the room," said Dr. Paul A. Offit, an infectious disease expert at Children's Hospital of Philadelphia. "It has lost its platform. Now, you simply declare your own truth."²⁵¹ An article in the NY Times called "When Did We Start Taking Famous People Seriously?" points out a rise in celebrity activism coinciding with the fall

²⁵⁰Jessica Grosse, "When Did We start Taking Famous People Seriously?," *The NY Times* June 20, 2020, accessed January 20, 2020, <u>https://parenting.nytimes.com/childrens-health/celebrity-activism-parenting-politics</u>.

²⁵¹Jan Hoffman, "How Anti-Vaccine Sentiment Took Hold in the Untied States," *The NY Times* Sept 23, 2019, accessed January 20, 2020, <u>https://www.nytimes.com/2019/09/23/health/anti-vaccination-movement-us.html</u>.

of Americans' trust in politicians, and political institutions.²⁵² When singers and actors step into the moral and political spotlight, they already have a platform and audience to engage. When Americans lose trust in the politicians; these activists start to fill in the gaps. Paul Offit says we trust celebrities because "we think we know them, we see them in movies or on TV and we assume they are the roles they play."²⁵³

Vaccine Myths and Misconceptions

I've decided to place this section on vaccine myths and misconceptions with the anti-vaccine chapter because many of the myths are perpetuated by the anti-vaccine movement. As previously discussed, the internet is a powerful tool to continue the passing of misinformation to the over 4 billion people who access it. Tapping into storytelling, a natural human tendency traced back to cavemen, anti-vaccine websites posts stories tapping into the fears and deep-rooted beliefs and conspiracy theories that many vaccine hesitant individuals respond to.

The CDC and other governing bodies in healthcare have been trying to debunk vaccine myths for years. The myths can be categorized into several buckets including: vaccines cause autism and the unnecessary fear of other immunization related adverse events, infant immune systems can't handle so many vaccines, natural immunity is better than vaccine-acquired immunity, vaccines contain unsafe toxins, better hygiene and sanitation are actually responsible for decreased infections, not vaccines, vaccines aren't

 ²⁵²Jessica Grose, "When Did We start Taking Famous People Seriously?," *The NY Times* June 20, 2020, accessed January 20, 2020, <u>https://parenting.nytimes.com/childrens-health/celebrity-activism-parenting-politics</u>.
 ²⁵³ Ibid.

worth the risk, I received all the vaccines I needed as a child, vaccines can infect me with the disease I am trying to prevent, and we do not need to vaccinate because infection rates are already so low in the United States.²⁵⁴

I have already spent much of this chapter discussing how the link between vaccines and autism was established by Andrew Wakefield and subsequently debunked by the scientific community. I have also touched on the CDCs information supporting that infant immune systems are capable of handling multiple antigens in a given vaccine visit. Where I would like to spend the reminder of this chapter is the mistaken concepts that only children receive vaccines and therefore as an adult you do not need to continue receiving vaccines as well as the idea that since infection rates are low, vaccines are no longer necessary.

Many adults believe they received the required and complete vaccine schedule as a child. As they begin to have children of their own, they experience the rigor in multiple appointments each year with the pediatrician to meet the needs of the ACIP childhood vaccine schedule. Since this schedule is mandatory to enter public schools in the US, there is the false sense that all required vaccines occur before entering school. By the time children enter kindergarten they do not have multiple immunization appointments annually. The rigorous schedule of early childhood trails off and the immunization record seems to be complete. Therefore, many adults believe they are fully immunized and do not have the vaccine conversation with their physician until they are much older

²⁵⁴ Public Health, "Vaccine Myths Debunked," accessed January 20, 2020, https://www.publichealth.org/public-awareness/understanding-vaccines/vaccine-myths-debunked/.

when diseases like pneumococcal and influenza become significant threats requiring the vaccine conversation again. This is usually at about age 60.

What many adults do not realize is that they can benefit from hepatitis A & B vaccines that were unavailable during their childhood. Titers wane over time and TD, or Tdap is needed to prevent pertussis and related tetanus toxoid effects like lock jaw. Influenza vaccines are required annually as the vaccine components change each flu season to meet the ever-evolving flu strains. Shingles vaccines are available for adults age 50 and older now, 10 years earlier than the prior CDC recommendation. Unless, adults receive these messages, they are unaware. The vaccine myth that they are fully immunized becomes a barrier to increasing adult immunizations.

Finally, the concept that we do not need to immunize because the incidence of disease is low or gone is flawed. As previously presented, measles was eradicated and then returned once parents stopped immunizing in specific pockets of the population. Continued immunization is necessary to maintain herd immunity. We live in a global society, individuals carry diseases once eradicated from the US back into the country easily through air travel. The current COVID-19 pandemic is an excellent example of how quickly a virus can spread around the globe when there is limited to no herd immunity. This misconception can be resolved through educational efforts proposed in Chapter Six.

In the next chapter I will dig into the beliefs and behaviors of a rising immunizer HCP, the pharmacist. Chapter Four will continue to explore barriers to increasing adult vaccines in this context.

<u>Chapter 4: Belief and Behavior Shifts: Getting Pharmacists and Consumers</u> <u>Proactive</u>

Introduction

To grow adult immunization rates in the United States there needs to be significant belief and behavior changes for physicians, pharmacists, and consumers. From a behavioral perspective, physicians need to initiate the vaccination conversation with patients and encourage them to make vaccines part of their wellness and prevention paradigm. Pharmacists need to have the same kinds of conversations with patients and be better able to explain risk to patients, not just the efficacy of the vaccine.

My hypothesis is if pharmacists are proactive in pulling through the same threads of the vaccination conversation, they may be more successful in immunizing patients. I also hypothesize that consumers need to shift their behaviors to include vaccination in the same category as eating well, taking vitamins, getting the right amount of rest, and exercise. Prevention is not just lifestyle choices; it is leveraging the science and technology we have in disease prevention. However, behavior change is hard. It can take years, if ever, for someone to adopt a new behavior. Defining how to encourage behavior change is perhaps the largest issue to solve.

Behavioral Economics and Bias

As a marketer I realize that behaviors are usually connected to deep rooted beliefs based on previous experiences or an influencer. Having implemented behavioral economics into marketing campaigns; I have come to understand biases as interconnected to beliefs. Behavioral economics research adds elements of psychology to traditional economic models to better understand decision-making by investors, consumers, and other economic participants, including healthcare professionals (HCPs).

Biases are deep rooted and exist at multiple levels. If you were to put the mechanics of an HCP vaccine conversation with a patient into a funnel you would find leakage along the way to the bottom of the funnel. In marketing we map patient journeys. The leakage points are called the moments that matter, and these leaks are being fueled by conscious and unconscious biases.

According to Baba Shiv²⁵⁵, "our expectations at the time when we make decisions serve as a self-fulfilling prophecy once we get to the actual experiences." We take cognitive shortcuts when making decisions based on our experience in making decisions repeatedly. These shortcuts translate into biases based on those learned decisions. For example, loss bias is the instinctual effort to avoid loss. The path of least resistance is often chosen as an example of ease bias. Timing bias enables us to determine if the payoff is better now or later, and social and self-biases influence our behavior and choices based on the behaviors of others and the expectations for ourselves.²⁵⁶

Bias is dominant in impacting our believes and our choices, there is a plethora of bias examples defined by behavioral economics. In the following I will illustrate several

²⁵⁵ Stanford Graduate School of Business, "Baba Shiv," Voices of Stanford GSB, accessed April 5, 2020, <u>https://www.gsb.stanford.edu/faculty-research/faculty/voices/baba-shiv</u>.

²⁵⁶ Wilcox, Mathew, James Coghlan, ZS Associates, "Behavior Change Workshop," (Behavioral Economics Workshop, Penn State Navy Yard Campus, Philadelphia, December 3, 2019). These definitions are from my personal notes during the workshop.

examples of bias and how they can influence the current barriers to adult immunizations. It is important to acknowledge these biases when trying to learn about the beliefs and behaviors of others, in this context, the beliefs and behaviors of adult patients and vaccinating healthcare professionals.

Availability Heuristic

Availability Heuristic means if something can be recalled it must be important.²⁵⁷ For example, if the patient can recall having the vaccination conversation with their physician, then it becomes important enough for the patient to get the vaccine at the pharmacy.

Affect Heuristic

Affect Heuristic is when the current emotion (fear, pleasure, uncertainty) influences decisions.²⁵⁸ For example, suppose a patient reads information on an antivaccine website drawing on fear, they may be influenced in the moment. If that moment is near an event where they are offered a vaccine; they are less likely to agree.

<u>Halo Effect</u>

Halo Effect is when an initial judgment influences our perception of someone.²⁵⁹ In the context of adult immunization barriers, halo effect could happen when a patient is offered a vaccine by the pharmacist. The patient may not know the pharmacist's

257 Ibid.

²⁵⁸ Ibid.

²⁵⁹ Ibid.

qualifications to administer vaccines, they may even mistakenly identify them as a pharmacy technician, rather than as the pharmacist. In this context the patient is judging or pulling forward a halo from another unqualified person towards the immunizer.

Construal-Level Theory (CLT)

Construal-Level Theory (CLT) can be defined as the more distant something is, the more abstract it will be thought of.²⁶⁰ When the patient is in the physician office discussing a vaccine that will be administered in a different location, like the pharmacy, the benefits of the vaccination may supersede other thoughts like the pain affiliated with receiving the vaccine. The closer the patient is to the situation, the less abstract it will become and the reality of pain and potential side effects in the context of vaccines become more real.

Satisfaction of Search

Satisfaction of Search²⁶¹ is best defined through an example in radiology. Once the radiologist identifies an abnormality on the scan, they are less likely to see any additional abnormalities. In the context of vaccinations in the pharmacy; if a pharmacist offers a vaccine to a patient and they agree to receive it, the pharmacist may not be as likely to offer an additional vaccine even if the patient is in need. The mere act of

²⁶⁰ Ibid. Although I am very familiar with the other terms already introduced in this section, CTL was a new concept to me.

²⁶¹ During the same Workshop with Mathew Wilcox, ZS Associates, and Area23 we discussed the topic of satisfaction of search as a bias and they used the radiology example. I think this is the best way to define this context. Essentially once you find one element of what you are seeking, you stop seeing other things that could be related and relevant.

administering one vaccine satisfies the vaccination need. This may be true since pharmacists are incredibly busy with their workflow and priority task of filling prescriptions. To take more time with the vaccination conversation is challenging. If they have an immunization goal set to one vaccine a day; offering one is simple, efficient, less time consuming, and meets their goal. Unlike the pediatric schedule where children receive multiple vaccines at a time, adults generally seek one specific vaccine for a designated purpose. They do not generally go to the pharmacy for a catch-up immunization opportunity.

Cognitive Fluency

Cognitive Fluency is the subjective experience of the ease or difficulty in completing a task.²⁶² Therefore, if the patient or the vaccine administrator subjectively believes administering a vaccine is complicated and difficult, they are less likely to engage in the behavior based on the subjective interpretation.

Illusion of Transparency

Illusion of Transparency is a cognitive bias where the individual overestimates how well their mental state is understood by others.²⁶³ In the context of adult vaccines, the pharmacist may perceive that the patient is willing to be vaccinated because they have already spoken to their physician and they are inquiring to the pharmacist about the

²⁶² One more concept that I was less familiar with prior to the workshop in December 2019 conducted by ZS Associates, Mathew Wilcox, and Area23.
²⁶³ Ibid.

vaccine. However, the patient may not have spoken to their physician and their questions to the pharmacist may have been founded on skepticism rather than positive inquiry.

Other Forms of Bias

The Identifiable Victim Effect, Reciprocity Bias, Overconfidence Effect, Loss Aversion, Ambiguity Aversion, Social Desirability Bias, Embodied Cognition, Default Bias, Framing Outcomes, Hyperbolic Discounting, Ego Depletion, Effort Bias, Group Attribution Error, Social Norms, Better Than Average Effect, Status Quo Bias, Self-Reference, and Generation Effect all influence our beliefs and how we act.²⁶⁴ There are a multitude of biases influencing our beliefs and behaviors. When we aren't on watch or aware of them, it is very difficult to address the root cause and create the desired behavior change. Essentially, the behavior changes I investigate in this dissertation, for pharmacists to become more pro-active vaccinators, can be decided based on the shortcuts affecting those choices that pharmacists currently make.

My research hypothesis is for pharmacists to fully adopt adult immunizations in their practice, there needs to be a belief shift and a behavior change at the macro-level.²⁶⁵ Currently pharmacists are busy, they are answering calls, filling prescriptions, entering orders into their workflow system, and managing multiple therapeutic areas for as many

²⁶⁴ Ibid.

²⁶⁵ As a marketer for retail pharmacy strategy I am aware of the environment that my audience operates in. This awareness comes from multitudes of pharmaceutical sponsored market research and conversations I have had with the customer, the retail pharmacist, and their regional and head quarter level clinical decision makers.

as 600 patients a day at a busy pharmacy.²⁶⁶ In an average week there are approximately 275 million patient visits to a pharmacy in the US.²⁶⁷

Patients are more engaged with pharmacists more than ever before as pharmacists are accessible health care providers. In a study by CVS Health.²⁶⁸69 percent of respondents claimed to visit the pharmacy at least once a month. This offers many opportunities for pharmacists to counsel and advise patients on health care matters, including immunizations. Furthermore, according to Gallop,²⁶⁹ pharmacists rank at the top as being the most trusted and accessible healthcare professionals, just following nurses but ahead of physicians. Based on this ranking, credibility and trust are important aspects of their relationship with patients. Pharmacists do not want to lose those important elements of their relationships with patients.

In the next section I will introduce the qualitative survey I built to dig deeper into the motivations and biases influencing the pharmacist's role as a vaccinator. These biases may be delivered as barriers to immunization. My survey is intended to identify if there are hidden biases driving the pharmacist's behaviors with immunizations or more

²⁶⁶ Anecdotal from conversations with busy bench pharmacists in metropolitan areas. Pharmacies usually range in script volume between 150-600/day. Those pharmacies filling 600 prescriptions a day are incredibly busy, the pharmacists usually have little to no break in their day and need to balance consultations, script fills, workflow in their computers, managing pharmacy technicians and their own biological needs.

²⁶⁷ Parata, "WHOops Where's the Pharmacist?," Parata.com, accessed January 20, 2020, <u>https://parata.com/whoops-wheres-the-pharmacist/</u>.

²⁶⁸ CVS Health, "By the Numbers: How do Consumers Engage with Pharmacists?," CVSHealth.com, accessed January 20, 2020, <u>https://cvshealth.com/thought-leadership/by-the-numbers-how-do-consumers-interact-with-pharmacists</u>.

²⁶⁹ Norman, Jim, "American's Rate Healthcare Providers High on Honesty, Ethics," *Social and Policy Issues* Dec 19, 2016, accessed January 20, 2020, <u>https://news.gallup.com/poll/200057/americans-rate-healthcare-providers-high-honesty-ethics.aspx</u>.

superficial barriers like process and workflow. The biases reviewed are an important consideration when studying believes, attitudes, and behaviors.

Pharmacist Adoption of Adult Vaccines

For this study, a qualitative survey via Google Forms was developed and shared via email with a small group of retail pharmacists and clinical decision makers.²⁷⁰ These individuals were selected with guidance from a former Rite Aid clinical manager and APhA certified immunizing trainer. Since an email address was required, the respondents were known to my colleague. However, each respondent does not know me nor is there a known conflict of interest. Eight respondents participated in the 15-minute survey. Their insights and answers provide an overview of current pharmacist beliefs and behaviors as they pertain to offering and administrating adult vaccines in the pharmacy. I disclosed my employment position and dissertation research and asked the pharmacists for their time to complete this survey to help improve adult immunizations based on their insights. The pharmacists were not paid for their participation. The methodology for this study can be found in the introduction section of this dissertation.

<u>Segmentation</u>

I started the survey with some basic demographic and segmentation questions that is best described through charts. I wanted to first understand approximately how many vaccines each participant was administering in the pharmacy on a monthly basis. Each respondent offered a different number of vaccines from 0-60. 25 was the next highest

²⁷⁰ See Appendix for full survey questionnaire.

and 2 was the next lowest. On average pharmacists who participated in this survey are administering between 2-10 vaccines each month. Flu season can significantly increase the number administered. The survey was sent after the height of flu season. The respondent who entered zero is in a non-customer facing role in corporate rather than a bench pharmacist and is unable to administer vaccines in their current role.

How many total vaccinations do you personally administer in a typical non-flu month (please

The next question was designed to further segment my respondents into proactive versus active vaccinators. While all respondents like to take charge in learning about new adult vaccines with the top 2 boxes checked; one respondent answered neutral to the questions about regularly initiating conversations with customers about the appropriate vaccines they should consider and another answered, "somewhat untrue of me". There were less respondents who selected "very true of me" regarding initiating the

conversation versus learning about the vaccines. The groupings of these answers points to hesitancy in initiating the conversation, even for those pharmacists proactively seeking information.

It seems pharmacists believe vaccines are important enough to research but difficult to bring up to patients. Initiating the conversation may be intimidating to a pharmacist who by the nature of their profession are reactive. Essentially pharmacists spend most of their time filling prescriptions, orders from physicians rather than initiating orders. Being reactive may be an inherent trait for a pharmacist; it could be linked to why they selected their profession. This would be an interesting study for future consideration.

Please rate the degree to which the next two statements are "very untrue of me" to "very true of me":



From a segmentation perspective most of the respondents (62.5%) were full-time pharmacists working over 35 hours per week. As I referenced earlier, one was a full-time pharmacist in a corporate position, and another indicated they are in a leadership position. These two respondents have less opportunity to vaccinate patients themselves but are critical in leading and influencing the bench pharmacists they support in vaccine
education, encouragement, and even setting immunization goals. Their responses are important in the more qualitative portions of the survey where respondents could populate their answers in free text. One respondent indicated they are a part-time pharmacist working less than 35 hours a week. Interestingly, the part-time respondent said their biggest barrier to immunization is time. This was a free-form field and was unprompted with drop downs of potential barriers. Part-time pharmacists may have more difficulty vaccinating in the pharmacy since they have the least amount of time to initiate vaccine conversations with patients.





All the survey respondents have at least 12 years of experience as a pharmacist. Two respondents have over 20 years. The first vaccination training for pharmacists was in 1994 in Seattle Washington.²⁷¹ The American Pharmacist Association (APhA) began its formal immunization program in 1996.²⁷² Therefore, all the respondents have spent the entirety of their practice as immunizers and therefore identify as such. This is an

²⁷¹ Hogue, MD, JD Grabenstein, SL Foster, and MC Rothholz, "Pharmacist Involvement with Immunizations: A Decade of Professional Advancement," *Journal of American Pharmacist Association* May-June 2006; 46(3):308, accessed January 20, 2020, <u>https://www.ncbi.nlm.nih.gov/pubmed/16602227</u>. important distinction from older pharmacists who started prior to the APhA training. Their beliefs and behaviors are not always representative of an immunizer. There have been reports from regional decision makers that older pharmacists are unwilling to adopt immunization practices.²⁷³ Albertsons went so far as to mandate that all their pharmacists are licensed and practicing immunizers. Their website encourages patients to stop by the pharmacy for a free immunization screening, walk-ins welcome and no appointment necessary.²⁷⁴

How many years have you been a pharmacist in the U.S., excluding residency and



Most of the respondents (87.5%) have spent most of their career in the large chain setting. This includes stores from the largest pharmacy chains including CVS, Walgreens, and Rite Aid. The next group is in the Mass/Grocery category including chains like Albertsons, Kroger, Costco, and Walmart. I was unable to capture any

fellowships?

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 ²⁷³ Anecdotal from my conversations with regional decision makers at Albertsons and Rite Aid.
 ²⁷⁴ Albertsons, "Pharmacy Services, Flu Shots & Immunizations," Albertsons.com, accessed April

pharmacists having spent most of their career in a regional (examples include: Bartel's,

HEB, Meijer), or an independently owned pharmacy.



Describe the kind of pharmacy you have spent most of your career in: 8 responses

Having no representation from an independent pharmacist is an important consideration to this research and my conclusions. I have excluded independent pharmacies since they are not organized at a group level, are numerous in volume with over 22,000 in the United States, and for most do not adopt immunization practices. "Pharmacists are authorized to administer immunizations under 3 primary models: prescription from another provider, vaccination protocol, or independently without a prescriber's order or protocol."²⁷⁵ Many independent pharmacies do not have an established vaccine protocol with a local physician and therefore cannot administer vaccines.

The three models allowing pharmacists to immunize are state specific further complicating the immunization model for independent pharmacies in a protocol only

²⁷⁵ Xavioer, Sharon, PharmD; and Jeff Goad, PharmD, MPH "Authority and Scope of Vaccination: How States Differ," *Pharmacy Times*, 6/22/17 17:08:22, accessed April 4, 2020, <u>https://www.pharmacytimes.com/publications/supplementals/2017/ImmunizationSupplementJune2017/</u> <u>authority-and-scope-of-vaccination-how-states-differ</u>.

state versus an independent without a prescriber protocol state. The protocol essentially allows the pharmacist to vaccinate on the physician's behalf. Large chains negotiate protocols for their regions at a group level. Independents with a protocol must establish that in an individual scenario on their own. Therefore, in those states requiring a protocol, many independent pharmacies opt to not stock or administer vaccines.

When asked what roles the pharmacists play in administering vaccines to patients there was a wide range of responses. Only one respondent claimed they do not have a role; this is the same respondent in a corporate rather than a bench pharmacy level role. 6 of 8 (75%) respondents train staff on vaccine procedures, including the part-time respondent and 7 out of 8 (87.5%) both educate and administer vaccines to customers. 4 of the 8 (50%) decide which vaccines their pharmacy stocks.



What role(s) do you play in terms of administering vaccines to customers at your pharmacy: Please check all that apply:

8 responses

When asked about which adult vaccines their pharmacy administers, most respondents had similar answers. 100% or 8 of 8 respondents chose Flu (influenza), PPSV (Pneumococcal Polysaccharide Vaccine) or PCV13 (Pneumococcal Conjugate IП

Vaccine), Tdap (Tetanus, Diphtheria, Pertussis), Shingles, Hepatitis A & B, and Meningitis B/ACWY. 12.5% or 1 respondent chose all other approved vaccines. These would include yellow fever, Japanese encephalitis, and rabies vaccines. Another single respondent selected MMR and Gardasil in addition to the adult immunizations listed above.



Although all pharmacists report administering all the adult vaccines listed, when drilling down to the easiest and most difficult to administer, behavioral and attitudinal nuances emerge.

Based on the segmentation and demographic questions, I feel it is most impactful to segment this cohort by the number of immunizations they administer. Therefore, there is the leadership segment that administers 0 vaccines, the medium immunizers vaccinating 2-10 patients monthly and the active immunizers with 20+ immunizations administered monthly. Based on my analysis, I would call the medium group reactive and the active group proactive except it is those individuals in the medium group claiming that initiating immunization conversations is very true of them, while those in the active

group say it is somewhat true of them. It will be interesting to think more about the immunization volumes behind my segmentation and what is driving those behaviors in the discussion.

Discussion

When asked: *Do you believe in vaccinating adults against vaccine preventable diseases?* One hundred percent of the respondents replied yes. Consistent with what I know about bench pharmacists, vaccinating patients is a feel-good or win/win part of the job. The pharmacist enjoys the clinical aspect of immunizing, being closer to the patient, offering a protective service and potentially saving the patients' life and the lives of others. While the patient experiences the benefit of vaccine protection.

When prompted to respond why they chose yes or no to the question, *Do you believe in vaccinating adults against vaccine preventable diseases*? One respondent wrote, "I feel that immunizations are one of the most important advances in public health and that pharmacists are positioned to best meet the needs of adults seeking vaccines because they are the most accessible member of the health care team, have been specially trained and have developed a close relationship with their patients because they see patients more than other health care providers do yearly."

This response has several critical points, first is around immunizations being the most important advance in public health. This respondent believes in the value of vaccines and their role in providing this value to the public. Second, they mention that the pharmacist is best positioned to meet the needs of adults seeking vaccines because they are the most accessible member of the health care team. This is indeed true. As the

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Albertsons website²⁷⁶ has teed up, no appointment is necessary at the pharmacy and walkins are welcome. This is not just in the context of immunizations but across the gamut of pharmacy specific services. Patients can visit the consultation window and seek medical advice from the pharmacist, they can ask for help in selecting an over-the-counterproduct, and they can ask for counseling on their prescription medications. There is no appointment or charge for these services.

Because of their accessibility pharmacists can develop close relationships with patients as the respondent mentions. Physicians may only see patients annually or quarterly however, pharmacists may see patients at least monthly as chronic medications are filled and patients come in for consultation on seasonal events like influenza, seasonal allergies, and other conditions treated with over the counter medications like indigestion or dry eye. Therefore, patients may be even closer to their pharmacist than to their physician. This would depend on how many pharmacists staff the pharmacy counter however, even the busiest pharmacies only have an average of 2.5 pharmacists scheduled.²⁷⁷

Finally, this respondent also mentioned that pharmacists are specially trained to provide immunizations. This special certification through APhA is designed to "prepare pharmacists with comprehensive knowledge, skills, and resources necessary to provide

²⁷⁶ Albertsons, "Pharmacy Services, Flu Shots & Immunizations," Albertsons.com, accessed April 4, 2020, <u>www.albertsons.com</u>.

²⁷⁷ From my recollection of a conversation with a clinical decision maker. I asked for clarification on if this was on staff or on duty and they mentioned the busiest store would have 2 pharmacists on duty during peak times, maybe with some additional part-time help. They closely matches the staffing schedule as many busy stores only have 4 pharmacists rotating through and medium to lower volume stores have 1.5-2 pharmacists on their staffing schedule.

immunization services to patients across the life span."²⁷⁸ APhA's certification also focuses on vaccination technique and prepares pharmacists to administer intramuscular, sub-cutaneous, intradermal, and intranasal immunizations.²⁷⁹

This is a comprehensive certification program qualifying the pharmacist to immunize. If there is any doubt on the credentials of pharmacists to administer vaccines, patients can be directed to the APhA website to review the certification. Rite Aid²⁸⁰ created a pharmacist certification program and backgrounder to help patients understand the pharmacist qualifications and what it takes to undergo purposeful immunization training.

Most of the other freeform responses to the question, *Do you believe in vaccinating adults against vaccine preventable diseases*? indicate that the pharmacists believe in the science of vaccines, vaccines work, and why wait for disease when you can prevent it first. One Respondent wrote, "Because when not vaccinating (even adults) vaccine preventable diseases can rise in our population and cause adverse events even death to the patient or those around them (example- pertussis in an infant (herd immunity))." In a similar sentiment, another wrote, "Because results show efficiency and prevention of vaccine preventable diseases." Another respondent focused on prevention where there is no cure. "Protection is your best defense. Somethings you can prevent but not cure. Why take a chance."

²⁸⁰Rite Aid, "Vaccine Central," Riteaid.com, accessed April 5, 2020, <u>https://www.riteaid.com/pharmacy/services/vaccine-central</u>.

²⁷⁸ APhA, "Pharmacy-Based Immunization Delivery," APhA, accessed April 5, 2020, <u>https://www.pharmacist.com/pharmacy-based-immunization-delivery</u>.

²⁷⁹ Ibid.

The next survey question was designed to dig into the barriers behind offering vaccines. *What is the biggest barrier to being able to vaccinate all adults that need vaccines in your practice*? Respondents were asked to answer in free text, unaided. 50% of the respondents wrote time or a time related response. Some survey respondents just wrote "Time", another alluded to time in the following, "Not enough pharmacy tech help while working. Difficult to target all patients when you are also dispensing and answering calls." Although, this respondent offered a solution in the pharmacy technician freeing up time for the pharmacist to focus on other things like immunizations their tone was slightly negative. Use of the term "target" sounds forced. Upon further investigation, this respondent is employed by a grocer and administers 5 immunizations per month. It could be this respondent feels pressure from their employer to meet immunization goals, even though they believe in the value of vaccines. Feeling pressured to meet a goal when there are other important aspects of your daily responsibilities can create a bias impacting immunization behavior.

Another 38% wrote something related to patient willingness or knowledge. "Education and the fact that people tend to forget how devastating diseases are when they are not apparently present to remind them." This statement is perceptive. Once disease like measles or polio are no longer afflicting the general public, there doesn't seem to be a need to protect against them. What this logic fails to acknowledge is that the US continues to mandate vaccinations against these diseases, proliferating herd protection. Once patients begin to refuse vaccinations, like in the case of measles, the disease comes back. This respondent also acknowledges the need for education to address the barrier. Similarly, another respondent wrote, "Knowledge and patient perception of disease." One respondent mentioned state regulations as a barrier. The inconsistency in regulations for the use of a physician protocol or not across the states is problematic for a comprehensive immunization program. Requiring a protocol, as previously mentioned, can be a barrier to independent pharmacists. It also takes immunization autonomy away from the pharmacist in states where a physician prescription is required. This extra step creates more work for the patient and minimizes the clinical decision making of the pharmacist.

Seven of the eight pharmacists indicated that flu or influenza vaccines are the easiest to administer in their practice. One added pneumococcal in addition to flu and another added shingles in addition to flu. The 8th pharmacist said that pre-filled syringes are the easiest to administer. The reference to the ease of influenza vaccine does not surprise me. The conversation is easy with flu because it is a commodity, each year patients arrive at the consultation window asking proactively for the vaccine. Pharmacist become so busy with flu vaccines during flu season, immunization goals are set according to other adult vaccine disease states, excluding flu.²⁸¹

The following are the reasons why the respondents selected influenza and pneumococcal, and shingles as the easiest vaccines to administer. There is also reference to influenza vaccine being a pre-filled syringe in concurrence with the respondent who answered pre-filled syringes as the easiest to administer:

- Patients are more likely to say yes to getting it, it is pre-filled and there usually isn't a lot of counseling that needs to be done with flu.
- More people actively engage for flu vaccine

²⁸¹ Anecdotal from conversations with clinical decision makers.

- They don't require reconstitution and patients don't have to wait long (specific to pre-filled syringes)
- Billing is easy and prefilled syringe
- The hype with the new shingles shot and the lack of supply have made it easy to give when it's in stock
- Goes through insurance easily
- Easiness of administration
- Already template in computer

Two answers indicate that proactive patient engagement is driving ease of use, "more people actively engage for flu vaccine", and "the hype with the new shingles shot and the lack of supply have made it easy to give when it's in stock." This indicates that 25% of respondents feel it is easier to administer vaccines when the patient initiates the discussion. Another respondent indicates that "patients are more likely to say yes to getting it [...] there usually isn't a lot of counseling that needs to be done with flu." In this response, the pharmacist may initiate the discussion, but it is an easy discussion, not requiring a lot of counseling. Not a lot of time. The other responses related to ease of administration also suggests a time saving component. Therefore, it may be inferred that saving time through ease of use (pre-filled syringes) and limited counseling would make administering vaccines easier for pharmacists because these features save time.

Ironically when asked, *What is the most challenging vaccine to administer in your practice,* five of eight, 63%, respondents selected Shingrix or shingles vaccine. This is interesting since one respondent reported shingles vaccines to be the easiest to administer. The primary reason related to shingles vaccine being the most challenging to administer is reconstitution. The Shingrix vaccine comes with 2 vials and requires a

process called reconstitution. According to the prescribing information,²⁸² Shingrix is prepared by reconstituting the antigen, powder component, with the adjuvant suspension liquid component. There are four steps described in the package insert to properly reconstitute the product. The adjuvant must be withdrawn and inserted into the antigen, gently shaken, then the entire contents is withdrawn for administration.²⁸³ The process takes time and is more complicated than administering a pre-filled syringe.

Two other respondents mentioned high co-pays as a barrier to shingles vaccines. Patients may have been in the deductible phase of their insurance coverage at the beginning of the year when this survey was sent. Until they hit their deducible their vaccine co-pay will be the entire cost of the vaccine since most deductibles are more than the ~\$160 price of the Shingrix vaccine.²⁸⁴

Another respondent mentioned yellow fever vaccine as the most complicated to administer because of the paperwork required for the administration, the potential for serious side effects, and the time taken for screening. "Patients need to be screened to be able to receive it, you need a special stamp and special vaccination cards that are accepted all over the world to document the dose and it's very important to properly document so that the vaccination is valid. Also, there are serious side effects that have to be disclosed to the patient before they get the vaccination."

There was one respondent who selected Tdap as the most challenging vaccine to administer in their practice. The reason stated was Tdap was not on protocol at their

²⁸² GSK, "Shingrix Prescribing Information," ShingrixHCP.com, accessed April, 5, 2020, <u>https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing Information/Shin</u> <u>grix/pdf/SHINGRIX.PDF</u>.

²⁸³ Ibid.

²⁸⁴ This is knowledge I have from my position on the Shingrix brand team.

pharmacy. Not knowing where this pharmacist practices, I believe this may be a state related problem. In June of 2012 APhA²⁸⁵ published a document outlining the kinds of immunizations pharmacists could administer on a state basis. At that time there were seven states not allowing Tdap administration in the pharmacy, Florida, Maryland, Missouri, New Hampshire, New York, Puerto Rico, and South Dakota. I suppose the respondent may be in a state that still prohibits pharmacists administering Tdap, or they may believe this is still a barrier from 2012 even if it has been resolved. I tried to find more recent literature about Tdap vaccine protocol for pharmacists by state and could not find anything more up to date.

When asked, *What would make it easier for you to provide more adult vaccines in the pharmacy*, two out of seven respondents to this question mentioned having access to state registries. If registries were widely used, it is easy to look up the patient's immunization record, see their history, and assess their vaccination needs. Unfortunately, there is variability by state on the adoption of state registry utilization and required reporting. Furthermore, if a patient resides part-time in multiple states, and the registries do not speak to each other, the pharmacist would still have gaps in their immunization history. One of these two respondents wrote, "Access to patient immunization history and prefilled syringes of all vaccines. Also, more acceptance of physicians in referring patients to the pharmacy." The reference to pre-filled syringes for all vaccines is related to time and easing the burden of reconstitution as outlined for

²⁸⁵ APhA, "Pharmacist Administered Vaccines authority to Administer Tdap and TD," APhA NASPA Survey, accessed April 17, 2020,

https://www.pharmacist.com/sites/default/files/files/PharmacistIMZAuthority_June18_2012%20%5BRea d-Only%5D.pdf

Shingrix above. The physician referral component is interesting and confirms the assumption that patients state not having connected with their physician first as a barrier to pharmacist immunization.

Three additional respondents had answers related to time and support. One pharmacist wrote, "If we had more time and are not pressed for time for other pharmacist duties." Another stated, "Easy insurance billing, more tech help." While a third mentioned, "More support help while working." Administrative burden, pharmacists' regular duties, and reconstitution seem to be the most commonly reported time related complications for these pharmacists. Two even call out additional support during the workday and more help from the pharmacy technician. This acknowledgment supports my hypothesis surrounding inclusion of the pharmacy technician in vaccine related tasks and or conversations. Even more delegation of non-immunization tasks to the technician could potentially free time up for the pharmacist.

The next survey question was pointed to understand if patients see their physician as the gate keeper to immunization related decisions. When asked, *Do patients often say they need to speak to their doctor before getting a vaccine that you have recommended*, 75% or six of the eight respondents confirmed yes, while 25%, only two respondents indicated no. Most patients do indeed see their physician as the gate keeper to immunization decisions. This pie chart below indicates that needing to speak with a physician first is a barrier to pharmacist immunizations.



8 responses

6. Do patients often say they need to speak to their doctor before getting a vaccine that you have recommended?

I continued this concept by asking the six respondents who answered yes, If So, what do you feel is the best way to proceed with that patient encounter. The responses mostly pointed to connecting the patient to their physician as an immediate next step. One respondent replied, "call their doctor," another stated, "Encourage the patient on recommendations or offer to contact their doctor for consent." Another collaborative answer was, "Allow them to speak with doctor to ease mind but urge them to get vaccine whether at pharmacy or doctor's office." In this case, the pharmacist highlights the importance of getting vaccinated no matter the location. This is good approach to help the patient realize their best interests are in mind, over immunization goals or corporate pharmacy objectives. Another tactic mentioned, "Explain why they need it and that their doctor and I use the same recommendations." This approach helps the patient see that the physician and pharmacist are on the same page for immunizations, using the same guidelines and recommendations coming from the CDC. Another respondent referenced "education and motivational interviewing" as a tactic. Helping the patient come to their own realization, rather than the recommendation of a

physician. This approach helps to empower the patient in their health-related decision. It is aligned with moving vaccines into the prevention and wellness paradigm. If patients begin to recognize vaccines as part of this paradigm, they may be more willing to make the decision on their own, just like some of the other healthy decisions they make as it relates, to rest, diet, and exercise.

Finally, one pharmacist stated, "Convince them but they need to be comfortable." I checked to see how many vaccines this respondent administers in one month and the answer was 25. Perhaps this approach is successful. The term convince comes across strongly, however if substituted with educate, the approach does sound effective and patient focused.

The next survey question asked pharmacists to identify their top priority. *What is your number one priority each day while at the pharmacy*? There were several themes emerging across the eight responses. These include patient safety, filling prescriptions, patient adherence, workplace safety, and workflow demands. One respondent wrote, "survive." This response indicates the pressure, responsibility, and lack of time there is to get the job done. It is busy and demanding, pharmacists have multiple responsibilities to balance and patient safety is at risk if mistakes are made. Even though this study provides evidence that pharmacists believe in administering adult vaccines, not one mentioned immunization as a top priority. Competing priorities take precedence over providing immunizations according to the results of this question. This is a serious consideration for my hypothesis and something that needs to be accounted for as solutions are proposed.

Foreshadowing that providing immunizations may not rise to the top of the pharmacist's priorities, I next presented the following question, *What three things could you implement to make providing adult vaccines a more regular part of your practice?* The answers here are also helpful in providing solutions to support my hypothesis that pharmacists are critical in increasing adult immunization rates. Because I believe these responses are critical success factors, I will list each of the seven responses:

- Integrated vaccine recommendation tool, education of all pharmacy staff
- Identifying appropriate candidates, educating staff to ask and offer, community outreach and education
- More privacy, more tech help for forms and prep, stickers or stamps
- Dedicated time to meet with patients, training staff to talk to more patients, and detailing physicians in the area
- Train staff to talk to patients and promote vaccines, have an intern or certified tech who can be trained well to advocate for promoting more vaccines and educate patients about the effectiveness of vaccines to prevent diseases
- Time and help
- Train our tech to ask all customers while ringing up prescriptions. Train techs on how to bill all vaccines, make outbound calls on weekends to promote to pneumonia and Shingrix populations

General themes emerging from these implementation ideas include better delegation to the tech on multiple things including vaccine patient identification, light education, and billing inquiries. The suggestions about community outreach and pulling the technician into weekend phone calls to specific patient populations is also strategic to elevate the role of the pharmacist as an immunizer as well as help manage time and resources. These suggestions are almost all proactive coming from what is traditionally a reactive audience. Noting pharmacist behavior as reactive by nature, filling doctors' orders and scripts and responding to patient inquiries at the consultation counter, these proactive opportunities will take significant behavior changes. However, based on the responses to this research it seems the belief base is there to effect these changes.

The next question presented to respondents was, *What is the role of the pharmacist in community outreach regarding vaccine awareness and education?* One respondent said, "No other health care provider is better poised to teach about vaccines and or medications," Another wrote, "To educate them on why vaccines benefit them and their community around them. And explain how simple the process is to walk into a pharmacy to be vaccinated. Hold clinics for the community." Like these responses, another answer states, "Role is to provide outreach to community organizations to educate and offer vaccine clinics." Almost all respondents reference having vaccine knowledge and sharing that with the community. Vaccine advocacy and education are critical components to the role of the pharmacist.

I asked the respondents, *Is there anything holding you back from initiating a vaccine discussion with a patient when you have time and a listening ear?* Seven out of Eight or 88% of respondents said no. On respondent write, "Fear of being told no by the patient." In an early question about what could be implemented to help make adult immunizations a more regular part of the practice, a different respondent mentioned more privacy. Perhaps fear of rejection in a less open and public forum would dissipate? This is worth further exploration.

The next question is specific to resources. *What resources would be helpful to help you provide more vaccines?* One respondent mentioned a "privacy screen and more refrigerator space." The privacy screen would help patients feel more at ease

and less exposed. It may also help the pharmacist feel the same. If a pharmacist is worried the patient may say no to their vaccination recommendation and this is related to the public forum of a pharmacy, perhaps the privacy screen will provide the coveted safety of a more private conversation and a private experience for both the patient and the pharmacist. Another respondent mentioned the CDC website as a resource as well as state registry access. Several respondents discussed patient education brochures, one said, "simplified vaccine schedule charts, quick cheat sheets about vaccines and what is recommended written at a patient level." This pharmacist feels the guidelines empower the patient to make decisions. It takes the opinion of the pharmacist out of the recommendation and places the credibility on the CDC and ACIP.

Another respondent suggested training modules for technicians about vaccines and educational programs. And finally, copay coupons were recommended to help with the difficult co-pay discussions that are often presented as patient barriers.

I also wanted to know how the pharmacists surveyed are leveraging their pharmacy technician regarding vaccines. I asked the respondents, *How do you leverage the pharmacy technician in the vaccine conversation with patients?* Six of eight respondents claimed the technician either starts the vaccine conversation with patients or identifies patients. "Technicians can start the conversation with 'our pharmacists recommends you receive x vaccine' and screening the patients' profile for recommendations." Another respondent said, "I think they can start a conversation but need to consult the pharmacist before processing for requirements, so laws or requirements are followed for children. For adult vaccines they can be very helpful in advocating for vaccines." Another pharmacist takes a more paternalistic approach, "Help fill out forms and answer what vaccine we have. Comes to get me for answers." Regardless, almost all pharmacists are currently leveraging the technician to assist in the vaccine conversation. There does not seem to be a standard procedure in enlisting the technician however, there is acknowledgment that the technician is important in initiating the discussion. It would be interesting to understand further what percent of conversations are technician initiated versus pharmacist initiated and what the success rate to an immediate immunization is based on those conversations.

The final question in my research survey was designed to help me better understand how pharmacists and physicians are communicating about their patient's immunization record and needs. *How do you transfer immunization documentation back to the patient's physician*? Surprisingly, six of eight respondents indicated that fax is used to exchange data with the physician. Physicians are less responsive to faxes in modern times and more dependent on electronic health records (EMR) through technology. This most likely contributes to physicians reporting that pharmacists are not communicating immunization updates specific to their patients.

The American Reinvestment & Recovery Act (AARA)²⁸⁶ phased physician practices and health systems into required Electronic Medical Record utilization via the Health Information Technology and Clinical Health (HITECH) Act by 2018. Based on these technological changes, faxing may not be the best method to

²⁸⁶ CDC, "Introduction" Meaningful Use, accessed April 17, 2020, https://www.cdc.gov/ehrmeaningfuluse/introduction.html.

exchange information. There was a respondent who referenced electronic exchange of data, however they also wrote "fax or mail" next to this response. Another respondent mentioned reporting to the state registry. There was only one reference to state registry reporting in the eight responses.

These results, although limited by the small number in this study, give me additional insight into communication barriers between physicians and pharmacists that I will continue to explore in the final chapter.

<u>Chapter Five: The Visual Culture of Vaccination: A Medical Humanities</u> Perspective

Medical humanities is an interdisciplinary field drawing from social science, humanities, and art and their application to the practice of medicine. The terms art and medicine are often combined to represent different aspects where one may influence the other. There is art as therapy for disease, the art of medicine (is it an art or a science?), and then there is also understanding disease through art. As a medical humanities student I took a course entitled, "Art and Medicine." The course followed the progression of illness through the eyes of an artist. Although this course did not suggest using art to create awareness of a disease or another medical topic; I believe visual art can be a fantastic medium to reach various audiences and provoke thought. Vaccination art, understood as visual culture, may be a critical medium to help educate the public not only about the impact of disease but the impact of preventing disease through immunizations while creating new associations for vaccination.

Visual Culture

Visual culture, as defined by Brown University,²⁸⁷ refers to the tangible, or visible, expressions by a people, a state or a civilization, and collectively describes the characteristics of that body as a whole. It is more specific than the broader term art. Visual culture is a larger term encompassing visual arts, expression, scientific diagrams, and advertising.

²⁸⁷ Brown University, "Visual Culture," Arts and Antiquity, accessed May 6, 2020, <u>https://www.brown.edu/Departments/Joukowsky_Institute/courses/artinantiquity/7158.html</u>.

Images of vaccination can be looked at as a specific sub-genre of visual culture of medicine and pharmaceuticals. There are many negative visualizations of immunization over time. In some cases, the visualizations are not intended to evoke negativity but still come across in that tone. The process of immunization is usually captured and shown as uncomfortable and painful. Many of the images from art history instill fear, rather than the benefit of vaccination. Consideration of visual culture of vaccination, the pharmacist, and pharmacies can assist in pulling through positive imagery of immunizations and serve to reinforce the pharmacist as a vaccinator.

Vaccines as Medicine

There is art as visual culture and there is art as in the practice of doing something, such as the art of medicine. These are two distinct ways to use the same term however, both are applicable to a discussion on why adult immunization rates are low.

In another way, medicine can be thought of in the context of a skillful plan. A treatment regimen requiring the combination of art and science to culminate in the most effective outcomes. Are vaccines part of this plan? As described throughout this dissertation there is scientific evidence supporting effective outcomes from vaccines. However, there is little evidence to support vaccines as part of the art of medicine. Perhaps the art of medicine is only reactive as described in Chapter Two. Perhaps only physicians can practice the art of medicine and other HCPs, like pharmacists, are on the periphery since their relationship with patients is perceived as more fleeting.

Etymologically, medicine can be a substance, like a medication that is used in the treatment of disease. And, medicine is the discipline or field of health maintenance and

prevention; the cure of disease. Can a vaccine be considered medicine? A substance used in the prevention of disease? Considering the discipline of medicine is concerned in disease prevention; it seems logical to also define preventative tactics like vaccines to be medicinal intervention.

Perhaps nomenclature is part of the problem in advancing adult awareness and urgency for vaccines. If vaccines are not considered medicine, what are they? It is interesting that the term medicine when used in reference to a substance is reactive; used to treat disease when the discipline is defined as both reactive and proactive with the mention of prevention. How do physicians and pharmacists consider the preventative tactics, like vaccines, they have in their toolbox? It is also curious to consider, is prevention or treatment more important.

Batistatou, et al.,²⁸⁸describe the practice of medicine as "an image-related science." They go on to discuss the history of anatomy and art being closely connected all the way back to the renaissance. Doctors or students of medicine who participate in art classes have improved observational skills.²⁸⁹ The appreciation and creation of art may influence the skill of the clinician.

At the second annual Center for Bioethics and Medical Humanities Conference on May 10, 2018 a group of panelists were selected to speak to "Artful Medicine: Where Art, Medicine, and Education Meet."²⁹⁰ "The reality is that we're all artists in some shape

 ²⁸⁸ A. Batistatou, et al., "The Introduction of Medical Humanities in the Undergraduate
 Curriculum of Greek Medical Schools: Challenge and Necessity," *Hippokratia* 14, no. 4, (Oct 2010): 241-3.
 ²⁸⁹ Ibid.

²⁹⁰ Anna Williams, "Exploring Art and Medicine at Medical Humanities Conference," Northwestern Medicine Feinberg School of Medicine (May 14, 2018), accessed May 7, 2020, <u>https://news.feinberg.northwestern.edu/2018/05/exploring-art-and-medicine-at-medical-humanities-</u> conference/.

or form. Art is part of humanity — and especially in a profession like medicine, where you're dealing with human beings all the time, the human content is at the forefront," according to Kelly N. Michelson, MD, MPH.²⁹¹ She goes on to explain, "This conference is a way of formally acknowledging that link and thinking about how medicine and art can come together to enhance humanity, as well as be used as an educational component to help clinicians relate better to patients and even make better clinical diagnoses."²⁹² Even though instrumentalization of art is often criticized, from the viewpoint of this study it is interesting to consider whether art may assist the patient to better engage and relate with the clinician, whether physician or pharmacist. The Keynote speaker for the conference, Joel Katz, MD, connected the role of art in medical education and how it can "narrow the gap between bioscience and the human experience."²⁹³ It is worth considering this from the perspective of the clinician as well as the patient.

There are many examples of doctors appreciating and practicing art outside of their medical practice. For instance, the Spring/Summer 2018 edition of Pennsylvania Physician highlights retired plastic surgeon, Dr. David, Leber, MD and his work in sculpture. "I'm a detail person and that has helped me in all mediums whether it is on paper or with patients."²⁹⁴ Dr Leber's affinity for detail and aesthetic value exemplifies how art influences the beholder and can speak to someone in a positive way.

Over time there are examples of how pro-vaccine campaigns have tapped into visual culture to share a message. Posters have been an effective means to communicate

²⁹¹ Ibid.

²⁹² Ibid.

²⁹³ Ibid.

²⁹⁴ Life After Medicine, "Practicing Art with the Eye of a Surgeon," *Pennsylvania Physician*, Spring/Summer 2018:19.

immunization messages to the public. "By appealing to parental instincts of protection and responsibility, through images and text, these public health posters have been a valuable part of efforts to extend vaccination coverage."²⁹⁵ For example a poster ²⁹⁶for World Health Day 1987 depicts smiling children under a rainbow umbrella. "Immunization, A Chance for Every Child,"²⁹⁷ implies that all children are eligible for vaccines.



²⁹⁵ NIH, US National Library of Medicine, "Visual Culture and Public Health Posters," Immunization, accessed May 7, 2020,

https://www.nlm.nih.gov/exhibition/visualculture/immunization.html.

 ²⁹⁶ Ibid, A028201 from Images from the History of Medicine (IHM).
 ²⁹⁷ Ibid.

However, upon further glance, though there is a positive tone to the image and the message, there is no clear call to action. How effective is a poster if there is no call to action for the parent? If this poster had no words and only the image; it would not drive a parent to immunize their child. The only reference to protection is the large umbrella covering the children, protecting them from potential sun or rain. Even the words do not drive action or provide the why behind immunizations being important. The message and image seem to be more appropriate for an internal campaign to raise awareness of immunizations over a public campaign.

Alternatively, visual culture can be used to promote negative imagery and propaganda as well. Like the power words have in influencing one towards or away from an idea or concept, imagery can do the same. Sometimes this is intentional. Other times, the passage of time and stylistic change can produce positive or negative impact. And finally, intentional portrayals of negative imagery may produce ill effect by design. Whatever the cause, a picture may induce the wrong sentiment or message, and even confirm fear, by intervening with the imagination and displaying an image, making it real.

Vaccine Imagery

Over time there have been many images of inoculations given to patients by demonstrating a real exchange between doctor and patient. Politicians and other provaccinators like Edward Jenner, in favor of public health benefits, have used images of their own children receiving vaccines to assuage fear of the unknown and promote proactive vaccination on the part of the public. However, without careful consideration of what these images depict, the same portraits can be received negatively and cause the opposite reaction.



The image above, The First Vaccination of Edward Jenner (1879) by Melingue Gaston,²⁹⁸creates anxiety and fear of inoculation for the viewer. Rather than feeling motivated to get the smallpox vaccine like the boy in the image, the viewer feels fear seeing the unpleasant exchange between Jenner and the 8-year-old boy James Phipps.

In this image the child is slumped in the chair, while restrained by a man to his right side. Edward Jenner stands at the left side, and the child is angled away from him as if in fear. Jenner holds what appears to be a large blade or scalpel and is squeezing the

²⁹⁸ Getty Images, "The First Vaccination of Edward Jenner," accessed November 17, 2019, <u>https://www.gettyimages.com/detail/news-photo/melingue-gaston-the-first-vaccination-of-edward-jenner-in-news-photo/1048344732?adppopup=true</u>.

skin on the child's arm to make an incision. The child, glancing sideways at his arm and the large scalpel, is gripping the man who restrains him. He has an expression of pain and uncertainty on his face. Jenner looks patient and purposeful. The man standing just behind Jenner, clutches his hat and looks on the scene in anticipation and worry. The image evokes an unpleasant feeling; it does little to motivate the viewer to proactively seek the same kind of intervention. Most likely the intention is to remind the audience of Edward Jenner protecting children from smallpox however it captures what looks like a scary and painful event.



A second painting²⁹⁹ of Jenner vaccinating the same boy, James Phipps, portrays a more positive image. The same event is interpreted very differently by the two artists, thus eliciting very different viewer reactions. The painting above was painted in 1796 by

²⁹⁹ <u>https://wellcomecollection.org/works/c6774vue</u> (accessed March 29, 2020). Credit: Vaccination: "Dr Jenner performing his first vaccination, 17. Credit: <u>Wellcome Collection</u>. <u>Attribution 4.0</u> <u>International (CC BY 4.0)</u>

Ernst Board, 83 years prior to the first image reviewed and yet it appears as more vaccine accepting.

In this painting the child leans in towards the needle, Jenner is holding his arm still, not in a restraining way. The mother stands behind the child as if offering him to Jenner. She supports him with her hands, again not implying restraint. There is no audience observing the event confirming any kind of anticipation or anxiety for the viewer. This is simply the act of vaccinating and the players are all leaning in. Imagery like this offers a more positive and matter of fact tone; it is less emotive. The angle of the child's face does not allow the viewer to see his full expression but there is no indication of pain or struggle.

The same event, depicted by two different artists, creates two very different feelings from the viewer. The latter being more in favor of vaccine promotion, and the former more aligned to vaccine hesitancy. An alternative to showing a more peaceful vaccination experience is to show the audience the consequences if left unvaccinated. Rather than creating fear of vaccination, but to promote vaccine acceptance and utilization, imagery of the vaccine preventable disease and the affiliated suffering, instead of the act of being vaccinated can create impact. In this sense the disease creates fear and vaccination is the solution.

Vaccination as a Ritual

Looking into the visual culture of vaccination is related to considering the event of vaccination as a ritual. There is a culture of vaccination even beyond the visual culture. When I asked a colleague about their last experience receiving a vaccine, I used the term ritual. I asked what is your vaccine ritual? When and where do you receive vaccines? This person stopped for a moment to consider vaccines as ritual and agreed that since they try to receive a flu vaccine annually and seek vaccines if traveling internationally, they indeed do have a vaccine ritual. Ritual³⁰⁰ can be defined as an established or prescribed procedure for a religious or other rite or a system or collection of religious or other rites. Collective ritual is defined as an "[...] attempt to bring some particular part of life firmly and definitively into orderly control."³⁰¹ Ritual can be in the context of ceremony, both religious or magical rites or procedures. "Ritual not only belongs to the more structured side of social behavior, it also can be construed an as attempt to structure the way people *think* about social life."³⁰² Taking medication every day can transform from habitual to ritual. This is apparent in placebo-controlled studies or when a patient is switched from branded to generic medications and the size, shape, and or color of the medication changes. The ritual becomes broken and the patient's belief in the effect begins to waiver. Like the ritualistic effects of taking chronic medication daily, exercising the decision to receive an influenza vaccine annually or proactively vaccinate for travel purposes can be viewed as rituals as well.

When I pressed further on where they receive the vaccines, we discussed the influenza vaccine and the pharmacy. Every flu season, usually in October my colleague stops in a pharmacy to receive their influenza vaccine. They mentioned that they select the pharmacy setting because they usually do not have a doctor's appointment at this time

³⁰⁰Dictionary.com, "Ritual," accessed January 23, 2020, https://www.dictionary.com/browse/ritual.

³⁰¹ Sally F. Moore and Barbara G. Myerhoff, eds, "Chapter 1 Introduction: Secular Ritual: Forms and Meaning," *Secular Ritual*, Amsterdam: Van Gorcum, 1977:3.

and the pharmacy does not require an appointment. Therefore, the pharmacy is easy and convenient. This implies there seems to exist a ritual affiliated with receiving an influenza vaccine in the pharmacy every flu season. I next wanted to know what the experience was like. I asked my colleague to describe what the immunization area in the pharmacy looked like. He said it was dirty and out in the open. He described bandage packing littering the floor, evidence that he was not the only person partaking in this ritual. He also said he felt exposed being presented to the public, out in the open. The countertop was not clean, and it created an uncomfortable experience.

To further inquire into everyday use of the term ritual regarding vaccines, I typed "vaccine ritual" into Google to see what would appear to the general population of internet users.³⁰³ In the top 5 results I found, "The Occult Archetype Called Vaccination," "Area Wicca Practitioners Replace Vaccination with Witchcraft," and "Forced Vaccination as a Barbaric Ritual." Being slightly curious I clicked on the first article and I found the following:

"Today, as a revival of ancient symbology, vaccination is a conferred seal, a sign of moral righteousness. It's a mark on the arm, signifying tribal inclusion. No tribe member is left out. Inclusion by vaccination protects against invisible spirits (viruses).

The notion of the tribe is enforced by dire predictions of pandemics: the spirits of other tribes (from previously unknown hot zones in jungles) are attacking the good tribe, our tribe.

Mothers, the keepers of the children, are given a way to celebrate their esteemed, symbolic, animal role as "lionesses": confer the seal on their

³⁰³ This is mainly because I was curious to know if there are vaccine rituals as common practice. I suspected not but was interested to see what I would find on the topic outside of scholarly articles.

offspring through vaccination. Protect the future of the tribe. Speak out and defame and curse the mothers who don't vaccinate their children. Excommunicate them from the tribe.

The ceremony of vaccination is a rite of passage for the child. He/she is now more than the offspring of the parents. The child is in the village. The child is property of the village. As the years pass, periodic booster shots reconfirm this status.

Some ancient rituals presented dangers. The child, on his way to becoming a man, would be sent out to live alone in the forest for a brief period and survive. Vaccination symbolizes this in a passive way: the injection of disease-viruses which might be harmful are transmuted into protective spirits in the body. The injection of toxic chemicals is a passageway into immunity. If a child is damaged in the process, the parents and the tribe consider it a tragic but acceptable risk, because on the whole the tribe and the village are protected against the evil spirits (viruses).

The psychological and occult and archetypal impact of vaccination is key: modern parents are given the opportunity to feel, on a subconscious level, a return to older times, when life was more bracing and immediate and vital. That is the mythology. Modern life, for basic consumers, has fewer dimensions—but vaccination awakens sleeping memories of an age when ritual and ceremony were essential to the future of the group. No one would defect from these moments. Refusal was unthinkable. Survival was All. The mandate was powerful. On a deep level, parents today can experience that power. It is satisfying.

The doctor giving the injections is, of course, the priest of the tribe, the medicine man, the holder of secrets. He is the spiritual source of, and connection to, "unseen realms" where opposing spirits carry out warfare and struggle for supremacy. Without the medicine man, the tribe would disintegrate.

The medicine man is permitted to say and do anything. He can tell lies if lies serve a noble purpose and effect greater strength of the tribe. He can manipulate language and truth and meaning. He can turn day into night. He can present paradox and contradiction. No one can question his pronouncements. Loyalty to the medicine man is absolute. In this regard, a rebel is exiled or destroyed."³⁰⁴

I found the references to the physician as the shaman, the village to the state, and the disease to the invisible spirit all very interesting having studied anthropology. For a moment I believed this article was just an analogy and perhaps even aligned to my position that medicine including vaccines is ritualistic. However, this analogy is taken to the extreme and makes the reader uncomfortable with an occult ritual like vaccination. To make sure the audience has no question on his vaccination position, Rappoport begins the article with the statement, "In many past articles, I've taken apart the so-called science of vaccines and shown how deceptive it is. Here I take another approach: examining the archetypes and symbols that surround vaccination and give it occult power."³⁰⁵ He is using occult scare tactics with the audience. Unfortunately, fear is a driver to encourage vaccination. This is not uncommon marketing practices for vaccine manufacturers.

Visual Culture of Vaccines and Pharmaceuticals

Even within the context of driving vaccine utilization there exists a negative visual culture with immunization messaging. Merck, the manufacturer of the herpes zoster vaccine, Zostavax, indicated to prevent shingles in patients over the age of 50, uses

 ³⁰⁴Jon Rappoport, "The Occult Archetype Called Vaccination," GreenMed Info, April 21, 2017, accessed January 23, 2020, <u>https://www.greenmedinfo.com/blog/occult-archetype-called-vaccination</u>.
 ³⁰⁵ Ibid.

visual scare tactics to intimidate patients into receiving the shingles vaccine. On the Merck website,³⁰⁶the following images portray patients suffering from shingles.



Most disturbing is the image of ocular shingles; a blistering red rash that surrounds the eye and affects the eyeball. In this image, the patient's eye is closed shut by the virus. The virus can afflict the actual eyeball itself, called herpes zoster ophthalmicus. 10-20% of patients will experience eye burning and itching that cannot be relieved. In some cases, the patient may have scarring, impaired or permanent visual loss as a result. These scare tactic images do have impact to motivate patients to get vaccinated. However, they continue to frame vaccination up in a negative light.

There can be a paradigm shift from negative visual culture to a positive visual culture in the context of vaccines. An interesting experiment would be to use positive visual imagery and messaging to encourage vaccination. The closest to this in recent times is the Bill and Melinda Gates Foundation collection, "The Art of Saving a Life," designed to demonstrate the global impact of vaccines.³⁰⁷ The idea of bringing 30 artists

³⁰⁶ Merckvaccines.com, "Disease information, Herpes Zoster," accessed January 23, 2020, <u>https://www.merckvaccines.com/Disease-Information/Pages/herpes-zoster</u>.

³⁰⁷ Bill and Melinda Gates Foundation, "New Collection By More than 30 World Renowned Artists Illustrates the Global Impact of Vaccines." Press Room, accessed February 22, 2020, <u>https://www.gatesfoundation.org/Media-Center/Press-Releases/2015/01/The-Art-of-Saving-a-Life-Project</u>.

across multiple mediums including painting, film, photography, sculpture, writing, and music is to inspire positive vaccine conversation. The foundation's intention was to portray the value of vaccines and their global impact. "We hope this project will inspire conversations about the incredible value and importance of immunizations worldwide," Chris Elias, President of the Global Development Program of the Bill and Melinda Gates Foundation stated.³⁰⁸ The list of artists who participated is impressive and inspiring.³⁰⁹ Artists were given a small fee to cover time and expenses and encouraged to use their specific skill and medium to develop art that was a personal reflection and interpretation of their chosen vaccine-related story.³¹⁰ It is powerful that 30 well known artists can be commissioned to help create vaccine advocacy through personal reflection. For these artists vaccines represent something positive in the context of global health. Protecting children from diseases that are easily preventable through the simple act of vaccination is a humanitarian effort to improve the quality of lives around the world.

Another aspect of visual culture of vaccines in the pharmacy is the signage directing patients to consider a vaccine while in the pharmacy. Many pharmacies have aisle signs, also called shelf talkers, advertising different topics to consumers as they peruse the pharmacy shelf. These signs are usually placed at eye level to drive the shopper to take action, such as purchasing a seasonal product. Many of these signs promote an item on sale and vaccines are often also advertised in this fashion. The following image was taken at a Walgreens pharmacy during flu season.

³⁰⁸ Ibid.

³⁰⁹ The list includes: Angélique Kidjo, Chimamanda Ngozi Adichie, GMB Akash, Sophie Blackall, Thomas Ganter, Vik Muniz, Alexia Sinclair and others.
³¹⁰ Ibid.


The shelf talker in this example is advertising flu "shots" at no cost. It does not provide a value message or a specific call to action. It also uses the terminology" shot," popular nomenclature for flu vaccines but as reviewed in Chapter Two a negative term. This sign does not increase positive associations related to immunization, but rather it commodifies the vaccine, highlighting the cost.

My colleague who described the bandage littered floor of the pharmacy may think more positively about the experience if the pharmacy created a clean, pleasant, and private space for immunizations. I investigated the immunization area at a local Walgreens pharmacy. Although there were no bandages on the floor, there was one on the privacy screen as a marketing image. The space did not appear private or pleasant. A large screen protected the patient from the rest of the pharmacy area. This screen was not visually appealing rather was used to sell the immunization services:



This space could be revised to be more private, simple, and have positive visual imagery for the patient. Changing the pharmacy environment where patients receive vaccines is an idea that deserves further conversation and a potential pilot in the future.

In another example of vaccine advertising, also adding to visual culture of immunization is an advertisement for flu vaccines in a pharmacy circular. In this image below, taken from a Walgreens circular, you can see two smiling individuals with bandages on their biceps, representing a recent completed flu immunization. The image portrays the "get a shot, give a shot" campaign at Walgreens. The "get a shot" shows a woman in the pharmacy and the "give a shot" shows someone from another culture, outdoors. The "give a shot" image is more comforting with a green tree in the background and blue sky. There is a sense of tranquility in this setting compared to the chaos of the pharmacy aisle in the "get a shot" background. This combined image is designed to promote a positive association with influenza vaccines.

The image is interesting because it draws on the aspects of immunizations as natural. As I covered earlier, many vaccine-hesitant or anti-vaccine proponents argue that vaccines are unnatural. There is the notion that the immune system has its own way of defending against disease. Koski and Holst³¹¹ define this as the "perceived benefits of illness" and that the "body knows best." In their study participants indicate that vaccine preventable illnesses are beneficial and consistently narrate the "perceived advantages of going through the disease process."³¹² Another concept is introduced, the "body's intelligence and self-healing capacity" is actively searching for disease to go through a self-cleansing cycle.³¹³ Koski represents these beliefs as the search for something natural, "[...] but to go back to something far more intuitive, where they respond to the cycles of nature rather than to the cycles of medical intervention [...]"³¹⁴

There is also the idea that the ingredients in vaccines are harmful chemicals rather than natural substances. Showing a photograph of a person in a natural environment, like the image below, may begin to help ease the fears that vaccines are unnatural. The green tree in the background brings the viewer closer to nature over the boxes of pharmacy products cluttering shelves. The image on the left perpetuates the idea that vaccines are unnatural showing over-the-counter products, perhaps deemed also unnatural. This image

³¹¹ Kaisu Koski and Johan Holst, "Exploring Vaccine Hesitancy Through an Artist-Scientist Collaboration," *Journal of Bioethical Inquiry* 14, (2017):416-17.

³¹² Ibid, 416.

³¹³ Ibid,417.

³¹⁴ Ibid.

may reinforce the notion that vaccines are unnatural by showing other "unnatural" products in the background. It is an interesting juxtaposition to see two images together that may elicit completely different reactions. Koski and Holst³¹⁵ suggest there is more work to be done to communicate with vaccine hesitant groups who perceive a natural way of life to be a primary objective. Perhaps images of vaccines in a more natural context, like the image on the right side of the below photograph is a starting place. Defining what natural means is also important. There may be more people who are influenced by natural imagery than those who outright define their existence in that way.



A final critical comment on this advertisement relates to the narrative. In a positive aspect the advertisement is also accompanied by a direct call to action to stop by the pharmacy today. However, there isn't a clear reason why, other than "It's that easy." This is confusing, should the person reading this receive a vaccine because it is easy or because it is an important preventative action for their overall health? Part of getting the visual culture correct is also getting the accompanying narrative and vocabulary right.

Social Media and Websites

Following the Pharmacist or Pharmacy on Facebook and Twitter is an engaging and easy way for patients to get seasonal vaccine reminders as well information on wellness and immunization events.

Gavi, the Vaccine Alliance³¹⁶ is an excellent example of a pro-vaccine cause with a modern and engaging digital presence. The website uses colorful photography and powerful images to inspire and draw the viewer into the cause. At the bottom of the site is a big button to subscribe to their newsletters. It is an opt-in for content viewers but easy to find and to subscribe to. The internet can be a powerful tool to engage adults about the importance and value of immunizations. It can be a source about the kinds of vaccines available to adults and why an adult should consider them.

Pro-vaccine influencers posting on the internet to counter the anti-vaccine influence of celebrities like Jenny McCarthy would be helpful. Politicians could be influential in this space, posting photos online when they receive a vaccine. Celebrity tweets on Twitter confirming receipt of a vaccine, with a link to vaccine educational materials could also help deliver the message. Aside from politicians, a respected celebrity could provide credibility, like Tom Hanks or Oprah Winfrey. A rational and reasonable person setting the tone and delivering the value of vaccines message could make a difference.

³¹⁶ Gavi, accessed April 26, 2020, https://www.gavi.org/.

There is more work to do to assess how the visual culture and accompanying narrative of vaccines can evolve. Portraying the pharmacist as an unassuming, qualified healthcare professional in images could help the public learn to see this figure as an immunizer. More work should be done to understand if images of the natural environment could also help promote positive action and intentions around vaccines. Understanding the current immunization rituals and how to play into that in a positive way through visual imagery and narrative is an important avenue in delivering the vaccine message.

Since there are many barriers to increasing adult immunization rates, there should be multiple avenues or strategies to raise the rates. The final chapter will discuss vaccine policy in the US. These polices serve as the backbone to immunization programs and are in place to help (and sometimes potentially hurt) the pro-vaccine agenda.

Chapter 6: Vaccine Policy, Advocacy, and Prescriptions for Change

Introduction

This dissertation has examined the value of vaccines, several barriers to adult immunization uptake across multiple HCP stakeholders including physicians and pharmacists, the history and influence of the anti-vaccine movement, pharmacist belief and behaviors towards immunization practice, and the visual culture of vaccines. Finally, in this chapter, I will explore how vaccine policy, advocacy, education, and visual culture can make a positive difference to immunization rates. My hypothesis at that onset of my research was that the pharmacist may be best poised to impact adult immunization rates. By understanding the barriers across this complex eco-system as well as the practice of pharmacy I can now better define this proposal and suggest areas of continued pilot projects and exploration.

I propose to increase adult immunizations, it will take a community effort. The CDC and local governments should work together to implement policy. Vaccine manufacturers and physician and pharmacist organizations should partner to educate the consumer. Pharmacy staff should approach immunizations as a team and adjust their workflow and delegation to administer vaccines. One of the most important catalysts for these efforts is via vaccine quality measures and immunization policy. In this chapter I will discuss conventional measures to increasing immunization rates, such as policy and quality metrics as well as less conventional measures such as positive visual mediums and experiences. To raise the rates, there need to be innovative channels to make an impact.

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Quality Measurement Solutions

Adult immunizations are an under-utilized tool to help prevent disease in turn reducing health care costs. Considering the US spends about \$26.5 billion³¹⁷ annually treating four major vaccine preventable disease areas, increasing adult immunization rates will reduce costs and help improve the health of Americans. The chart below summarizes US healthcare expenditure across four adult vaccine preventable disease categories.³¹⁸



 ³¹⁷ US Centers for Disease Control and Prevention, "Surveillance of Vaccination Coverage Among
 Adult Populations – United States, 2015," MMWR Surveill Summ, 2017; 66(No. SS-11): 1-28.
 ³¹⁸ Ibid.

In recent years there has been a trend in moving away from rewarding physicians and health care entities from volume-based incentives and more towards value-based incentives. Volume-based payments reward HCPs on the number of patients treated while value-based payments reward HCPs on outcomes. The volume-to-value shift is creating ways to incentivize vaccination with an increased focus on preventative services and has been shown to improve outcomes while reducing costs and utilization over the long-term³¹⁹. The Affordable Care Act (ACA) introduced Value-Based Purchasing (VBP). VBP suggests that buyers should hold healthcare providers accountable for cost and quality of care and is a replacement for Fee-For-Service payment.³²⁰ VBP includes information on the quality of health care, including patient outcomes and health status, with data on costs applied towards health care³²¹. The goal is to reduce inappropriate care and to reward the best-performing providers based on quality metrics.

Karen Shen³²² from the US Department of Health and Human Services reminds us that quality measures, "particularly when tied to reporting and payment," serve as a "mechanism that can be leveraged to incentivize" health insurance plans or payers, providers, and health systems to improve immunization rates. Therefore, one way to help improve adult immunization rates is through this kind of quality reporting. In 2018 there

³¹⁹Angela K. Shen, "National Adult Immunization Summit", 5/18/2018, accessed October 3, 2018, <u>https://www.izsummitpartners.org/content/uploads/2018/05/QM-WG.pdf</u>, slide 4.

³²⁰ HealthCare.gov, "Value Based Purchasing (VBP)," accessed April 25, 2020, https://www.healthcare.gov/glossary/value-based-purchasing-vbp/.

³²¹Thomas Sullivan, "Getting from Volume to Value in Healthcare," Policy & Medicine, accessed October 3, 2018, <u>https://www.policymed.com/2012/07/getting-from-volume-to-value-in-healthcare.html</u>.

³²²Angela K. Shen," National Adult Immunization Summit," 5/18/2018, accessed October 3, 2018, <u>https://www.izsummitpartners.org/content/uploads/2018/05/QM-WG.pdf</u>, slide 12.

were new quality measures introduced that can help increase adult immunization rates through the Healthcare Effectiveness Data and Information Set (HEDIS).³²³

Health Effectiveness Data Information SET (HEDIS)

HEDIS is one of healthcare's most widely used performance improvement tools according to the National Committee for Quality Assurance (NCQA) website³²⁴. HEDIS currently contains over 90 measures across 6 domains of care³²⁵. The data is collected from participating health plans covering over 184 million patients³²⁶. In 2018 there were two adult immunizations captured in the HEDIS measures. One assessed adults 65 years and older who reported ever having received one or more pneumococcal vaccinations.³²⁷ The second was the percentage of adults 18–64 years of age in commercial and Medicaid plans who report receiving an influenza vaccination between July 1 of the measurement year and the date when the commercial Consumer Assessment of Healthcare Providers and Systems (CAHPS) 5.0H survey was completed³²⁸ by the Agency for Healthcare Research and Quality.

Two new adult immunization composite measures had been adopted into HEDIS 2019 for voluntary reporting and, if successful, may be transitioned to mandatory HEDIS measures in 2020. The first new measure is called the Adult Immunization Composite

³²³ NCQA, "NCQA Seeks Publics Help on New and Revised Measures," HEDIS, accessed April 26, 2020, https://www.ncqa.org/news/ncqa-seeks-publics-help-on-new-and-revised-measures-3/.

³²⁴ NCQA, "HEDIS and Performance Measurement," HEDIS, accessed April 26, 2020, https://www.ncqa.org/hedis/.

³²⁵ Ibid.

³²⁶Ibid.

 ³²⁷ NCQA, "Pneumococcal Vaccination Status for Older Adults," HEDIS, accessed September 27,
 2018, <u>https://www.ncqa.org/hedis/measures/pneumococcal-vaccination-status-for-older-adults/</u>.

³²⁸ NCQA, "Flu Vaccinations," HEDIS, accessed September 27, 20218, <u>https://www.ncqa.org/hedis/measures/flu-vaccinations/</u>.

Measure assessing whether members aged 19 and above are up to date on recommended routine vaccines including influenza, TD or Tdap, Herpes Zoster, and Pneumococcal³²⁹. The second is called the Prenatal Immunization Composite Measure, assessing the percentage of pregnancies during the measurement period when women received recommended vaccines inclusive of influenza and Tdap³³⁰. The intention is for adoption of these measures to greatly expand these vaccines use and promote broader adoption across various healthcare stakeholders, including pharmacists. HEDIS is used by 41 out of 50 states and by over 90% of US health plans to report on care provided to commercial and Medicaid, and Medicare beneficiaries.³³¹ During the voluntary reporting period it will be imperative to raise awareness of the on-going efforts to expand adoption of the measures in federal and state quality reporting initiatives. These measures have been proposed for future inclusion in various quality programs such as, NCQA's Patient Centered Medical Home (PCMH) Recognition Program and various Medicare quality reporting and payment programs (i.e., Merit Based Incentive Payment System (MIPS), Star Rating Display Measure).³³²

What is the potential impact? The adoption of these new measures, including the adult composite measure is imperative especially given the proposed change to Healthy People 2030. Essentially, there is a movement to streamline the 1300 objectives organized into 42 topic areas³³³ and eliminate many of the Healthy People goals for 2030,

³²⁹Angela K. Shen, "National Adult Immunization Summit," 5/18/2018, accessed October 3, 2018, <u>https://www.izsummitpartners.org/content/uploads/2018/05/QM-WG.pdf</u>, slide 15.

³³⁰ Ibid.

³³¹ NCQA, HEDIS, accessed September 27, 2018, <u>https://www.ncqa.org/hedis/</u>.

³³² NCQA, "MACRA and NCQA Recognition Programs," PCMH, accessed April 26, 2020, https://www.ncqa.org/programs/health-care-providers-practices/patient-centered-medical-home-pcmh/benefits-support/macra/.

³³³ CDC, "Healthy People 2020," National Center for Health Statistics, accessed May 9, 2020, <u>https://www.cdc.gov/nchs/healthy_people/hp2020.htm</u>.

vaccination goals included.³³⁴ "Instead of redoubling the commitment to disease prevention, the proposed Healthy People 2030 plan would significantly minimize and weaken immunization related activities over the coming decade [...].³³⁵" Without the Healthy People vaccination goals, there needs to be another driving source, like HEDIS to help pull through adult immunizations with providers.

What does this mean for pharmacy? The challenge will be how immunization and quality stakeholders engage with one another. It will be important to leverage existing payment mechanisms for immunizations across stakeholders. For example, PCPs are paid for immunization screening while pharmacy is not. Pharmacists can add a quick immunization screening to their consultation with patients and be rewarded with reimbursement for their efforts as part of the pull through of the new composite measure.

Current Programs and Potential Solutions

As previously presented in this dissertation, research and statistics suggest there is a strong need to make immunizations not only available to the poor but also easy for them to complete the vaccine series. There are several programs currently in place to meet this need. The two that I will focus the most attention on are the CDC's Vaccines for Children (VFC) program, and 317 Funding for the Vaccines for Adults (VFA) program. The VFC was implemented in 1994 by the Omnibus Budget Reconciliation Act of 1993.³³⁶ The VFC was designed to ensure that under-privileged children do not

³³⁴ Adult Vaccine Access Coalition, "Healthy People 2030," accessed April 26, 2020, https://adultvaccinesnow.org/blog/2019/02/04/healthy-people-2030/.

³³⁵ Ibid.

³³⁶ Omnibus Budget Reconciliation Act of 1993, "Subtitle D—group health plans," Pages 326–34, accessed November 11, 2015, http://www.gpo.gov/fdsys/pkg/BILLS-103hr2264enr/pdf/BILLS-103hr2264enr.pdf.

contract vaccine-preventable diseases because of inability to pay for vaccine or lack of health insurance and was created in response to a measles resurgence in the United States that resulted in approximately 55,000 cases reported during 1989–1991.³³⁷ The resurgence was caused by widespread failure to vaccinate uninsured children at the recommended age of 12–15 months.³³⁸ Since the conception of the VFC program childhood immunizations in the United States has experienced a huge increase across the population. Coverage with new vaccines increased quickly while coverage for older childhood vaccines remains near or above 90%.³³⁹ The benefit of a program like the VFC removes the financial and logistical burdens and barriers preventing vaccination initiation and series completion for low-income children.³⁴⁰ This benefit plays a significant role in meeting vaccination coverage goals set by the Healthy People 2020 organization.

The VFC³⁴¹ program is unique in that it relies on the participation, education, and success of many stakeholders including participation of public and private health-care providers, insurance companies, state and federal public health officials, vaccine manufacturers, and parents. The VFC program supports state-based immunization programs and allows each state to make decisions on which vaccine manufacturers will provide products to support the program. Products are purchased by the CDC from manufactures and redistributed to states based on their VFC formulary decision. Providers

340 Ibid.

³³⁷W.A. Orenstein, "The role of measles elimination in development of a national immunization program," Pediatr Infect Dis J 2006;25:1093–101.

³³⁸ CDC, "Preview," MMWR, accessed November 11, 2015, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm.

³³⁹Cyntthia Whiteny, et al., "Benefits from Immunization During the Vaccines for Children Program Era – United States 1994-2013," *MMWR* 63.16 (April 25, 2014): 352-355.

³⁴¹ The information in this paragraph comes from my institutional knowledge supporting the VFC program in the state of New Jersey as a vaccine manufacturer representative.

who accept VFC eligible children will immunize the child at no cost. These providers are required to keep a separate inventory of VFC products in a separate refrigerator from private stock for insured and cash paying patients. Children up to 18 years of age qualify for VFC vaccines based upon meeting at least one of the following criteria³⁴²:

- "Medicaid eligible: A child who is eligible for the Medicaid program. (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance covered by a state Medicaid program)
- Uninsured: A child who has no health insurance coverage
- American Indian or Alaska Native: As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
- Underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.

*Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines, even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.³⁴³"

The Vaccines for Adults (VFA)³⁴⁴ program is like the VFC except it is supported

with 317 funding at the state level and not available in every state. For example, in NJ,

specific Federally Qualified Healthcare Centers (FQHCs) offer vaccines through the VFA

to the uninsured and under privileged if they were awarded part of this grant money, in

Vermont all vaccines for children and adults are available regardless of eligibility criteria

³⁴² CDC, "VFC Eligibility Criteria," VFC, accessed November 12, 2015,

http://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html. ³⁴³ Ibid.

³⁴⁴ This is institutional knowledge having supported the VFA program in NJ as a vaccine manufacturer representative.

since it is a universal vaccine state. Because there is inconsistency between states this program is not as successful nor is there adequate funding to support the VFA for all eligible adults.

Upon reviewing the success of the two largest CDC sponsored efforts to vaccinate the under-privileged there is still an identified need for improvement in vaccination series completion for children and access for many adults. For example, although literature supports that the VFC program addresses logistical challenges in completing vaccine series these challenges are still one of the largest reasons why series remain incomplete. The primary logistical obstacle preventing many under-privileged children from starting and/or continuing a vaccination series is transportation and time. Additional funding would be necessary to support a transportation program through the VFC or Federally Qualified Healthcare Centers (FQHC).

There could be two options to improve transportation; the first is providing a free shuttle to the Health Care Facility once or twice a month; the other requires the Health Care Provider (HCP) to come to the patient to administer the vaccines. This HCP could be a pharmacist as part of a pharmacy community outreach program. This could look like a bus that parks in different parts of a city each day with several pharmacists or nurses available to administer required vaccines. Again, these programs require additional funding but would help overcome a primary challenge. The bus that travels to the patient would also help the time obstacle. The bus would only focus on administering vaccines and therefore there would be less administrative burden for other health related issues. It would be a strategic and focused approach to increasing immunization rates in a specific geographical region. Another potential idea worth further investigation would help solve for the scattering of records in indigent populations, known for frequent moves and address changes. Greater continuity of care between clinics would be a worthy approach to explore. For example, a single system or database of all Vaccine For Children patients connecting each provider could assist in creating a single patient record and immunization status. Because a majority of vaccines given to the under-privileged are sponsored and funded by the Vaccines for Children (VFC)³⁴⁵ program the solution might need to be linked to program requirements. The same can be applied to the Vaccines For Adults (VFA)³⁴⁶ program; however, funding for the VFA is state specific and varies; usually resulting in little to no VFA funds in most of the United States.

Other solutions outlined by Ompad et al. ³⁴⁷ in an analysis of distributing influenza vaccine to high risk groups included the following: advertising via provider and patient mailings, registry-based telephone calls, patient and staff education, standing orders coupled with standard forms, targeting of syringe exchange customers, and visiting nurses. The registry-based telephone calls are interesting and potentially problematic. They are problematic if the patient does not have a telephone but for those that do, a reminder call to complete the series when appropriate would be beneficial. Vaccine manufacturers currently market with Interactive Voice Response (IVR) providers who offer this kind of reminder phone call service to increase immunization

³⁴⁵ CDC, "Vaccines for Children," VFC (Home), Accessed May 14, 2020, <u>https://www.cdc.gov/vaccines/programs/vfc/index.html</u>.

³⁴⁶ CDC, "Questions Answered on Vaccines Purchased with 317 Funds," Immunization Managers Home, Accessed May 14, 2020, <u>https://www.cdc.gov/vaccines/imz-managers/guides-pubs/qa-317-funds.html</u>.

³⁴⁷Danielle C. Ompad, Sandro Galea, and David Vlahov, "Distribution of Influenza Vaccine to High-Risk Groups," <u>Epidemiologic Reviews</u> 28 (2006):68.

rates. Another solution Ompad et al.³⁴⁸ raise are patient and provider education and advertising. What they fail to consider is that print materials need to be available in multiple languages and at very basic reading levels. The Healthy People 2020 website³⁴⁹ addresses the need for cultural sensitivity and international threats that impact the incidence of infectious communicable disease that are currently vaccine preventable.

"Providing culturally appropriate preventive health care is an immediate responsibility that will grow over the decade. As the demographics of the population continue to shift, public health and health care systems will need to expand their capacity to protect the growing needs of a diverse and aging population.

New infectious agents and diseases continue to be detected. Infectious diseases must be looked at in a global context due to increasing:

- International travel and trade
- Migration
- Importation of foods and agricultural practices
- Threats of bioterrorism³⁵⁰

Interestingly, the race/ethnicity and socioeconomic disparities that exist in the overall population in regard to immunization were not observed in the public health center space. Health centers vaccinate equally regardless of insurance, race and ethnicity.³⁵¹ The VFC and VFA programs have helped ease the burden of cost associated with free vaccines at these clinics making it easy for providers to offer vaccines to the

³⁴⁸ Ibid.

³⁴⁹ Healthy People 2020, "Immunization and Infectious Disease," accessed November 8, 2015, <u>http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases</u>. ³⁵⁰ Ibid.

³⁵¹Ashley H. Schempf, Robert M. Politzer, and John Wulu, "Immunization Coverage of Vulnerable Children: A Comparison of Health Center and National Rates," <u>Medical Care Research and Review</u> 60 No.1, (March 2003) 96.

uninsured. As the Healthy People 2020 website³⁵² suggests the public health center will need to expand access and programs to meet the growing needs of immunizations in a global economy. Perhaps increasing the number of FQHCs and other public health centers will help meet this demand and continue to even the plateau of race and economic disparities.

One other potential solution is accurate record keeping. If a child is required to have a social security number to register for the VFC program, then the national registry provided by the CDC needs to be updated accurately and daily when VFC vaccines are administered to serve as an immunization information system. This can be followed up by a conversation between the HCP and the patient's parent to confirm vaccines already received and those that will be required. It is up to the HCP to take advantage of the patient's presence and administer catch up vaccines if no record is available or if vaccines were missed previously. Missed opportunities for concomitant administration of vaccines need to be eliminated. The MMWR³⁵³ focused on children aged 19-35 months, suggests several other strategies to bolster vaccination services including home visits and vaccine programs in childcare centers, schools, and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) settings. For adults, similar programs can be executed including home visits and immunization programs at adult care facilities and adult living communities. Pharmacists have the potential to lead the charge through community outreach in these settings.

³⁵² Healthy People 2020, "Immunization and Infectious Disease," accessed November 8, 2015, <u>http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases</u>.

³⁵³Holly Hill et al., "National, State, and Selected Local Area Vaccination Coverage Among Children Aged 19-35 Months United States, 2014," CDC *MMWR* 64.33 (August 28, 2015)895.

Policy and CDC programs have made an impact in protecting those who have limited access to vaccines and have made an impact in the childhood immunization schedule through school mandates. However, there is still a large part of the adult population with access to immunizations (i.e. insured) and not leveraging their access. This is in part due to misinformation, lack of awareness that vaccines are easy to receive and available at the pharmacy, and the presentation of vaccines in our society.

Conclusions

Vaccines are one of the most significant improvements to eradicate disease across the globe. Immunizing against vaccine preventable disease has eased the burden of healthcare spend, improved quality of life and decreased morbidity and mortality for a host of communicable diseases. Until programs like the VFC were introduced there were large gaps between race/ethnicity and socioeconomic demographics with regards to the administration of vaccines. Even after these programs have been successfully introduced and operating for over 20 years there is still disparity across these groups. A recent *MMWR* report suggests that black and Latino children and adolescents as well as those below the FPL are under immunized and less likely to complete the vaccines series compared to white children and adolescents and those above the FPL. These disparities are largely attributed to lack of access due to logistical obstacles but also caused by missed opportunities by physician HCPs.

If physician HCPs struggle in finding the opportunity to immunize children through state regulated interventions, it is even harder for them to focus on adult immunizations. As reviewed in Chapter Two, physicians spend most of their time with patients reacting to chronic disease and less time on prevention. The vaccine conversation is quick if at all. Many physicians do not stock vaccines and therefore are not thinking about them, even during a preventative wellness visit, unless directed by their EHR. Even then, it is easy to skip questions and focus on what they deem most important with adult patients.

For this reason, the pharmacist may be best suited to provide immunizations to adults. Aside from the anti-vaccine movement, there are other barriers that the pharmacy is poised to address. For example, the pharmacy can be deemed a wellness center. You can find vitamins and other preventative Over-the-Counter (OTC) products focused on prevention. Vaccines is another tool that fits into the paradigm. The pharmacy and grocery store pharmacy can be a center of health and wellness if marketed to patients in that light.

Adult patients are busy, there often isn't time to schedule appointments to visit physicians for an immunization. The pharmacy offers a convenient and appointment free opportunity for immunizations. As one respondent in my research stated, pharmacists are the most accessible health care providers. Patients are frequently in their pharmacy and much less frequently at their physician's office. They just need to connect the dots that the pharmacist is their immunizer.

Perhaps the biggest barrier for adults is understanding the qualifications of their pharmacist. As mentioned in Chapter Four, pharmacists undergo intense immunization certification and training. They are qualified to recommend and administer vaccines. Many patients have difficulty distinguishing between the pharmacist and the pharmacy technician. If pharmacies begin to work more closely as a team, the pharmacy technician can initiate the discussion and proactively offer the pharmacist to the patient for counseling and administration. This would be helpful for the pharmacist as well who is busy with workflow activities and has limited time to start the conversation. The team approach to immunizations could help patients understand the role of the technician versus the pharmacist and help pharmacies execute successful immunization programs.

Advanced Provider Status initiatives to increase the scope of pharmacists practice have been important in updating state legislation to expand the scope of vaccines that pharmacists provide. Recent approval for pharmacists to administer COVID-19 tests also contributes to validating their clinical expertise and ability. This will help the public recognize pharmacists as qualified HCPs, however it contributes to the pharamcsits already busy list of responsibilities thus deprioritizing immunizations based on the demands of the pandemic. The continued behavior to deprioritize vaccines could have lasting effects even when the pandemic resolves.

As Chapter Four referenced, behavior change is difficult, getting back to immunizations may not be as easy as suspected. It may take top down immunization goals and programs to get back on track. It would be an interesting study to continue to monitor the expanded practices of pharmacists and how that influences their decisions and actions in offering vaccines. Pharmacists could become like physicians, if the scope of their clinical work with patients becomes too robust, the preventive offerings, like vaccines may be squeezed out. It for this reason the pharmacy technician is particularly important to pull into the immunization conversation. As states like Idaho begin to allow technicians to vaccinate, the role of the technician will continue to evolve, and other states will jump on board. It is not unlikely the technician will become the new healthcare extender and assume the immunization role of the pharmacist. At that juncture, more work will need to be done to educate on the qualifications of the pharmacy technician.

The visual culture of vaccines is another interesting area to explore further. I found an opportunity to improve the visual culture of vaccine posters, and in pharmacy vaccine signage. Even the place where the patient receives a vaccine in the pharmacy can be visually improved and made more private. More work should be done to understand the impact of presenting images of the pharmacist as an immunizer to the public. The pharmacist can appear warm, friendly, but also qualified.

Because there is a part of the population that can be characterized as vaccine hesitant it would also be interesting to understand how important seeing vaccines as "natural" is to them. If natural foods and vitamins are aspects of the natural wellness and preventative paradigm; to shift vaccines into this category they may need to be redefined as natural. As the Walgreens circular shows us, even showing patients with elements of nature in the background might make a difference.

At the start of my research I hypothesized that the pharmacy could make a positive impact on adult immunization rates. In reviewing the barriers to adult immunizations, I do believe the pharmacist has an important role in pulling trough the physician recommendation and educating patients themselves about the need for vaccines. The less reactive and more proactive pharamcsits become, the more successful they will be at immunizing adult patients. In turn, patients will become less dependent on physicians for the immunization recommendation and begin to view the pharmacist as their immunization educator and administrator. Pharmacists can raise the adult immunization rates in the United States, one vaccine at a time.

APPENDIX

Thank you for your interest in my research study! I am inviting you to assist with a 15-minute survey regarding your experiences with vaccines as a pharmacist. The insights and information you provide will be used in my dissertation on how to improve adult immunization rates through the community pharmacy. There are a few screener questions at the start to help me understand you and your practice a little better.

Important: Please be assured that your identity will be kept confidential and not revealed in my dissertation. All information provided in the survey will be aggregated with other respondents' data for reporting purposes; any direct quotes will not disclose your name.

Screening Start:

- A. How many total vaccinations do you personally administer in a typical non-flu month (please exclude flu vaccinations from your tally): ______
- B. Please rate the degree to which the next two statements are "very untrue of me" to "very true of me":

	Very untrue of me	Untrue of me	Somewhat untrue of me	Neutral	Some what true of me	True of me	Very true of me
1. I regularly initiate conversations with customers about appropriate vaccinations they should consider.	1	2	3	4	5	6	7
2. I like to take charge in learning about new adult vaccines.	1	2	3	4	5	6	7

1. Please describe your current status:

- 1. Full-time pharmacist (35 hours or more per week)
- 2. Part time pharmacist (less than 35 hours per week)
- 3. Full or Part-time Pharmacy technician
- 4. Other_____

2. How many years have you been a pharmacist in the U.S., excluding residency and fellowships? _____

3. Describe the kind of pharmacy you have spent most of your career in:

- 1. Large Chain (CVS, Walgreens, Rite Aid)
- 2. Mass/Grocery (Kroger, Albertsons, Costco, Walmart)
- 3. Regional/Independent

4. What role(s) do you play in terms of administering vaccines to customers at your pharmacy: Please check all that apply

- 1. I administer vaccines to customers
- 2. I educate and consult customers about vaccines
- 3. I decide on which vaccines our pharmacy administers
- 4. I train staff on vaccine procedures
- 5. I do not have any role in vaccine administration
- 5. Which vaccine(s) does your pharmacy administer? Please check all that apply
 - 1. Flu
 - 2. Pneumonia (PPS or PCV)/pneumococcal
 - 3. Shingles
 - 4. Tdap
 - 5. Hepatitis A or B
 - 6. Meningitis B/ACWY

6. Please review and signify your acceptance of the terms below by completing the survey with the link provided at the bottom of this message.

- I understand that this survey is for a dissertation for the Drew University Medical Humanities program.
- I understand that the student writing the dissertation works for a large vaccine manufacturer and supports the commercial side of the business in a marketing capacity.
- I understand that the aim of this survey is to gain my views for dissertation research purposes only and is not intended to be promotional or used for marketing insights or activities.
- Information presented during the course of this survey is done to explore reactions to such information and should be assumed to be hypothetical rather than factual. This study and the information presented are not to be used to influence your opinion or decision making on the survey topic.
- I understand that my identity will be kept confidential and none of my details will be passed on to the pharmaceutical company or any 3rd party.
- I understand that the outputs of this survey will be used for the medical humanities dissertation which will be published and available in the public domain.
- I understand that any information I disclose will be treated in the strictest confidence and the results of the survey aggregated to provide an overall picture of attitudes to the areas being covered in this survey. No answers will be attributable to me as an individual.

- I understand that I have the right to withdraw from the survey at any time and to withhold information as I see fit.
- A quality issue or adverse event report will be provided to the pharmaceutical company if I mention a quality or safety issue with a branded product. The information within this report will only be used by the pharmaceutical company to satisfy its internal or regulatory requirements relating to the quality or safety of its product.

If you would like to continue please click on the link below, "Fill out Form"

Thank you for your valuable information! Your responses will help me make recommendations to help improve adult vaccination rates.

Survey Start:

- Do you believe in vaccinating adults against Vaccine Preventable Diseases? Yes______
 No______
 - Why?_____
- 2. What is the biggest barrier to being able to vaccinate all adults that need vaccines in your practice?_____
- 3. What is the easiest vaccine to administer in your practice? Why?_____
- What is the most challenging vaccine to administer in your practice? Why?______
- 5. What would make it easier for you to provide more adult vaccines in the pharmacy?
- 6. Do patients often say they need to speak to their doctor before getting a vaccine that you have recommended? ______ If so, what do you feel is the best way to proceed with that patient encounter?

- 7. What is your number one priority each day while at the pharmacy?
- 8. What three things could you implement to make providing adult vaccines a more regular part of your practice?

- 9. What is the role of the pharmacist in community outreach regarding vaccine awareness and education?
- 10. Is there anything holding you back from initiating a vaccine discussion with a patient when you have time and a listening ear?
- 11. What resources are/would be helpful to help you provide more vaccines?
- 12. How do you leverage the pharmacy technician in the vaccine conversation with patients?_____
- 13. How do you transfer immunization documentation back to the patient's physician?

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VITA

Full name: Kimberly Mace Plumly

Place and date of birth: Hackensack, New Jersey November 9, 1978

Parents Name: Peter George Mace & Lois Bandur Mace

Educational Institutions:

	School	Place	Degree	Date
Secondary:	Lakeland Regional H.S.	Wanaque, New Jersey	H.S. Diploma	6/1997
Collegiate:	Drew University	Madison, New Jersey	B.A.	5/2001
Graduate:	Drew University	Madison, New Jersey	M.P.H.	5/2012
	Drew University	Madison, New Jersey	D.M.H.	8/2020