Comment Report

HF 632
A bill for an act relating to information to be provided, recorded, and reported by health care providers relative to certain vaccinations, and providing penalties.(See HF 769.)

Subcommittee Members: Osmundson-CH, Forbes, Meyer, A.

Date: 02/25/2021
Time: 01:00 PM
Location: RM 15

Name: Sally Gaer

Comment: Our daughter Margaret is vaccine unjured. 4 hours after her 4 month DPT and oral polio vaccines in 1990 she went into a status seizure that required an ambulance ride and stay in the pediatric ICU. As you can imagine our world was shattered. When we arrived in the ER the doctor said, "We see more of this on the third round of shots." We were dumbfounded that doctors knew this could happen.Not ONE doctor in the next few years of Margaret's life told us about VAERS or the National Vaccine Injury Compensation Act. It was an attorney in the law firm where Steve worked that told him about the program.We filed her injury just within the 3 year limit. Steve represented Margaret, and after our experience, which took YEARS, he served on the Advisory Commission on Childhood Vaccines. NOT ONE of his recommendations was considered.Even though this program has been gutted it is the responsibility of anyone who administers vaccines to advise people of VAERS and the National Vaccine Injury Compensation Program.We live a lifetime of vaccine injury. Vote yes on HF 632, because obviously the Federal Law has not been followed in Iowa for over 30 years.

Name: emily lewis

Comment: SUPPORT HF632.This bill is extremely important to me. Our oldest son had a severe adverse reaction to the vaccines given to him at 6 months old. In the days following that appointment our son seemed to go deaf, he stopped responding to his name, he stopped attempting to mimic anything we said when he was previously mimicking us a lot. Even his doctor said he would most likely be an early talker. Our son was hitting every milestone prior to that appointment. When I took him back out of concern of the change the doctor denied that it had anything to do with the vaccines he had just had and he told me "its its normal for boys to regress." Our son continued to regress further and was making very little progression as he got older. We found a doctor that would help us. She was confident he had been having a severe reaction to those vaccines after she looked through his medical file, did her own testing, and spoke at length with us. Our son suffered a neurological injury. Hes been diagnosed with severe mixed expressive receptive language disorder, intellectual delay, cognitive delay, and sensory processing disorder. Our son is 5.5 years old now but he tests out at 2.5 years old in many ways. He is unable to speak for the most part and he has a very hard time understanding what is being said to him. he lacks the ability to reason and very easily gets into dangerous situations. He requires a one on one para at school all day long. Hes been in speech and occupational therapy since he was 2 with very slow progress. His doctors and therapists are unsure if he will ever speak properly or move beyond the intellectual or cognitive age of 3. Neither the doctor that we were originally seeing (who kicked us out of his practice when we decided to stop vaccinating our son after the adverse reaction) nor the doctor that was able to help us told us about VAERS or the VICP. I didnt learn about either of those until I was told about Informed Choice Iowa. By the time I learned about VAERS we were just past the cut off for reporting our sons

reaction. Im not sure of the reason for the second doctor not telling us about VAERS was, she possibly didn't know abour it which is what I have found to be a common thing for doctors and nurses over the last few years. If a medical professional is made aware of a reaction they should be required by law to report it to VAERS. Less that 1% of reactions are ever reported to VAERS and this is hurting vaccine safety severely. PLEASE SUPPORT THIS BILL!

Name: Tara Truex

Comment: I fully support HF 632. And urge you to vote yes. Any type of medical procedure that can result in serious injury should have FULL disclosure of any reactions from previous persons undergoing treatment. Medical personnel should have full knowledge and instructions how to use VAERS to benefit the patient. Patients should be given the VAERS information prior to any type of vaccination.

Name: Keith L

Comment: Support HF632. Vaccine safety reporting practices need to be improved urgently. Surveillance for safety is lacking if reporting isn't mandatory, and this is the system used to determine long term safety. Vaccine injuries are common and severely under reported, with less than 1% of adverse events even making it into the VAERS system.As an actuary, data and numbers are important to me. Having real, comprehensive data, affects the results and greatly influences credibility. Mandatory reporting fixes a broken vaccine adverse event data system.

Name: Jim Kelli

Comment: I fully support HF 632. We can not continue to claim all vaccines are safe and effective if we are not reporting on possible injuries and reactions caused by them.

Name: Tanya Humphrey

Comment: Why wouldnt you want to support this bill? We all know risk associated with taking certain medications. Shouldnt vaccines be held to the same standards?

Name: Amansa Friedl

Comment: Hearing that you are now considering this bill helps my heart, my son had a reaction to a vaccine 20 years ago.. the side effect is listed in the flyer I got. (Not the insert, but a 1 page colored paper). I called the nurse and she said to monitor it. I didnt know it could have long lasting effects. I really believe that not all medical professionals understand that this should be reported. I believe if we dont report adverse reactions we are inflating safety numbers. Please help support this bill.

Name: Ashlee Tyler

Comment: Please support HF 632You, as a medical provider have an obligation to protect your patients and that includes anything that happens to YOUR patients after a vaccination has been administered. Please be responsible and please protect your current patients and future patients.

Name: Kate Giebeck

Comment: Doctors must do better at informing patients of the reporting systems for adverse reactions to vaccines. So many times there is such a disconnect that there is even a possibility of a link and it leaves us as parents feeling like we're being gaslighted and ignored. It was only when I found another PCP for my child outside of the doctor that was covered by her insurance that we saw the link between her MMR shot and her inability to walk for 2 weeks afterwards. Reporting these reactions is so important. If we aren't tracking the data accurately, than how do we truly know how these shots are affecting our children and if they truly are "safe". Doctors need to be held to a higher standard for TRUE INFORMED CONSENT.

Name: Jennifer Leonhard

Comment: After I recieved childhood vaccinations required for elementary school my pediatrician witnessed that I had many adverse effects. He recommended that I not continue to receive vaccines, and upon reexamination in high school still did not think it would be safe for me to get the vaccines generally required for college. Despite witnessing the adverse health effects and telling my parents to stop vaccinating me he never informed them of VAERS or reported anything on our behalf. This information would have been significantly helpful.

Name: Shanon Epley

Comment: We are in full support of HF 632. Vaccines need to be held to the same standard as any medication given to patients...with full knowledge of possible risks. We have a son who is vaccine injured. Right after getting his 9 month shots, he developed hydrocephalus. He imediately had to have surgery to place a shunt in his brain to drain the fluid building up. If let go, it would've been fatal. He has had 2 shunt replacements so far, and will have this the rest of his life. Because of the neurological damage from hydrocephalus, he has struggled with seizures, eczema, delayed motor skills, depression, anxiety, gut issues and has been diagnosed with aspergers. He is now 21 yrs old, still struggling with these conditions. I had no idea until 2 yrs ago about VAERS and adverse reactions due to vaccines. I wish we would've known back then what we know now...

Name: Shalyn Donofro

Comment: Please support this bill. No one should vaccinate without knowing the real risk of adverse reactions, and should always be made aware of VAERS if an injury occurs. My son only had the Vit K shot and suffered from seizures 3 days after. We took him to the emergency room and he had numerous tests done, but the doctor sent us home with no answers. She never even brought up the Vit K shot as a possible reason for the seizures, and I only learned about VAERS months later from a friend. This is not responsible at all for doctors to not know how to handle vaccine reactions and injuries. Parents have been left to deal with this on their own with little to no support from the medical community. Let's take steps towards fixing that.

Name: Megan B

Comment: Support HF632!This bill should be important to everyone. As a healthcare professional, I want to make sure I'm giving the best care to our patients. We give vaccines in our office and have never handed out a VIS or has anyone reported to VAERS. (I know this for fact as I've have asked others since learning this information myself.) If we truly want absolute transparency & decrease vaccine hesitancy, then all information should be made available so parents,, guardians and patients themselves and make an informed decision regarding their healthcare and feel empowered doing so. Providers & support staff should be made aware of the actual info patients need to know & both should be educated on how to report adverse events no matter how small it may be. We as healthcare professionals are already mandatory reports for abuse, so it should make sense to be mandatory reporters adverse events related to vaccines. (Or any medication for that matter) Thank you!

Name: Margo Ellis

Comment: As a mother of two and Informed Choice Iowa member, it is appalling that a bill like this wasn't passed DECADES AGO!How can we protect our children when adverse events are rarely ever reported?Get this bill passed NOW!!!

Name: Britni Graham

Comment: There is only one question you should be asking yourselves right now, and that is "why wouldn't someone support this bill?"In a day and age where many are being forced and pressured, both directly and indirectly, to have medical procedures that they don't want, enforcing this sort of reporting is the very least that should be done.

Name: Elizabeth K

Comment: Please support this bikl. I had an adverse reaction to a vaccine while pregnant. I had never heard of VAERS and wasn't told about it by my Dr. There needs to be accountability to ensure doctors are taking these reactions seriously and patients are truly getting the care they deserve.

Name: Jaime Griffis

Comment: I am in SUPPORT of this bill. Why wouldnt someone be in support of this bill? VAERS was set up as a system for people to report reactions to. But people cannot report a reaction if they dont know about the system. Also, if someone calls their provider or the health department where they received the vaccination it should be required that the reaction is reported to VAERS. In my personal experience, when a question is brought up about a reaction, the reaction is blamed on something else and therefore not reported and that is not how it should be handled. PLEASE support this bill.

Name: Miranda B

Comment: Please support this bill HF 632. All medications and medical procedures have potential risks and benefits. It is up to the Doctor prescribing such things to know these and convey them to their patients. Getting their informed consent is imperative. Knowing how to file any reactions is also part of their follow up care. Harvard did a study showing VAERS is grossly underutilized. Making sure doctors file this report is currently the only way to track its safety. Vote yes

Name: Emily Cole

Comment: I support this bill. It should be required to report any reactions to vaccines.

Name: Danielle ten Hoeve

Comment: Support HF632!If medication needs to notice patience of all possible side effects, so should vaccines. Therefore health professionals should have to report any possible side effect.

Name: brooke schefers

Comment: I strongly support HF 632. The National Childhood Vaccine Injury Act, passed in 1986 in response to calls from the Pharmaceutical companies, AAP, and other medical groups to shield vaccine manufacturers and doctors from liability for vaccine related deaths and injuries, ACKNOWLEGES THAT VACCINES CAN CAUSE INJURY AND DEATH. The Vaccine Injury Compensation Program was initiated by Congress in response to that acknowledgement. Understanding that there cannot be a liability free market impacting millions of children, the NVIC founders worked with Congress to secure vaccine informing, improving Informed Consent, recording and monitoring injuries and deaths to the federal Vaccine Adverse Events Reporting System (VAERS), and created a safety task force to report to Congress every 2 years. This has not been complied with for 32 years!Reporting injury and death associated with a vaccine is REQUIRED by federal law, but it is NOT enforced at a state level. There are no legal sanctions for pediatricians and/or other vaccine providers who fail to obey the federal law. Furthermore, there is no legal repercussion for NOT reporting serious health problems following vaccination to federal health officials, for NOT providing written vaccine risk/benefit information to parents or patients, or for NOT recording vaccine adverse reactions in the patients permanent medical record. I urge you to investigate the 1986 original law objectives laid out for informed consent and what adverse reactions were included to gain compensation from the VICP. Compare to what happened in 1993 and how drastically the safety precautions were cut. We know that it is estimated that between 1 and 10 percent of injury and death are reported to VAERS by pediatricians and health care providers. This lack of reporting has a ripple affect as far as inaccurate and incomplete data to evaluate safety of current and future vaccines, as well as an

inaccurate portrayal of risk/benefit which impacts a patient/s right to Informed Consent. This is an ethical violation of a principal that has guided the medical community since the mid20th century. we must put in place accountability at a state level to ensure proper safety to all. That is the hope and goal of this bill, period.

Name: Teri Schloss

Comment: I am not in favor of supporting SF632; there is no need for this bill. The current vaccine information sheet (VIS) that is required by law to be given to parents prior to all vaccines, contains information regarding adverse events. I looked at the VIS for DTaP and found the information there, plain as day. It is the parents responsibility to read the VIS and ask questions prior to their child receiving a vaccine. At my childs pediatrician, I must sign that I have received the VIS prior to administration of a vaccine. This bill assumes that vaccines are not safe or tested, neither of which is true. Vaccines are among the most rigorously tested and safest medical products on the market. Vaccines are one of the greatest public health contributions to the world. Our society has developed amnesia to the diseases that vaccines protect us from. We need to maintain a strong vaccination rate in Iowa to protect our citizens. I work in a public elementary school where children share nearly everything. I am thankful that Iowas children remain vaccinated so they do not share diseases. This bill will create undue vaccination hesitancy which could lead to us battling another epidemic of diseases that we thought were vanquished. My grandfather nearly died of tetanus from a small scratch. My daughter and myself have suffered the consequences of having chickenpox as a child. Not only do we have scars but we both have suffered through painful episodes of shingles. My youngest children had the benefit of receiving the chickenpox vaccine and will never have to endure the excruciating misery of shingles. Please do support this unnecessary bill. Laws are already in place for this issue.

Name: Danielle Pettit-Majewski

Comment: DO NOT SUPPORTThe focus of this bill, similar to the others, is to fix a problem that is not there. The Boards do not receive complaints about this issue. There is a federal law, that requires information to be provided and vaccine injuries to be reported.The bill promotes the false assumption that vaccines are harmful enough that they must be singled out more than other clinical patient care approaches in regards to patient safety and education. That is simply not the case. Since vaccines are administered to otherwise healthy people, they are among the most rigorously tested and safest medical products on the market. In fact, it can take 15 to 20 years or more and approximately $1 billion dollars to thoroughly test a new vaccine before it is licensed and made available to the public.Vaccine providers are already required to give Vaccine Information Statements to patients and parents BEFORE administering vaccine to ensure they are making an informed choice. We have just lived through a year without ONE vaccine and the impact on our country was horrendous. Vaccines keep our public healthy. They save lives.

Name: Deborah Thompson

Comment: The focus of this bill, similar to the others that have been filed this year, is to fix a problem that is not there. The Professional Licensure Boards do not receive complaints about this issue. There is a federal law, that requires information to be provided and vaccine injuries to be reported. The bill promotes the false assumption that vaccines are harmful enough that they must be singled out more than other clinical patient care approaches in regards to patient safety and education. That is simply not the case and no amount of information lends itself to having a crystal ball that predicts the outcome. The overwhelming data we have, however, gets us as close to understanding probability of adverse reactions. The probability is LOW. That is why is it CLEAR that the point is to scare people away from vaccinations and nothing else. Since vaccines are administered to otherwise healthy people, they are among the most rigorously tested and safest medical products on the market. In fact, it can take 15 to 20 years or more and approximately $1 billion dollars to thoroughly

test a new vaccine before it is licensed and made available to the public.No medical intervention is 100% perfect and neither is any one policy or process however, the amount of time being spent by the General Assembly on behalf of people (mostly from out of the state) who are small in numbers and who are promoting vaccine hesitancy is concerning. Vaccines are effective, safe, and administered by people who care about their patients, own children, and community. Please focus on the public health issues of the 21st Century like chronic conditions caused by Iowa's obesity and preventable cancers that are decreasing life expectancy.

Name: Bettina Hewitt

Comment: Please support HF 632. Our health care providers need to be informing all patients about VAERS with all vaccinations. The pediatric nurses in my life that I have asked about it do not know what it even is, what it is for or how to report to VAERS. This needs to utilized more than the approximately 1% shown in the Harvard study.

Name: Elizabeth Faber

Comment: Please vote NO on this bill. There is not a problem. This bill is searching for one. There is a process in place to report concerns already. Vaccines are not harmful. They are safe an effective and necessary. As we've seen with the COVID19 pandemic, we need vaccines to get back to our lives, get our economy back and thrive. We do not want to decrease vaccine confidence and have the rates of other vaccinepreventable diseases increase. Please vote NO on this bill and all others that are aimed to decrease vaccine confidence. They are a package of antivax bills promoted in other states as well and do not reflect Iowa.

Name: Kerry Crouch

Comment: PLEASE, support HF 632. What's the purpose of VAERS? The government website,https://vaers.hhs.gov/about.htmlSAYS:"Established in 1990, the Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in U.S.licensed vaccines. VAERS is comanaged by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention." The GOVERNMENT website says doctors AND vaccine manufacturers are supposed to report injuries to be able to track the info vsccines and problems caused by them. This is not being done except for 1% of all injuries because it's not being enforced. VAERS was established to be a helpful tool to collect data to help fix issues. It's not being utilized correctly. Vaccine injuries and deaths are common knowledge now. However, doctors are telling their injured patients they are believing lies, people aren't getting the help they need, damage keeps happening. Now look at the mess we are in. Most people don't trust the government anymore because of issues like this. PLEASE. Help us get this mess straightened out. Support HF 632.Thank you for your time and consideration of this very important bill.Kerry Crouch

Name: Mary Kelly

Comment: DO NOT support HF 632 which is to fix a problem that doesn't exist. There is a federal law, that requires information to be provided and vaccine injuries to be reported. The bill promotes the false assumption that vaccines are harmful which is not the case. I have always received Vaccine Information Statements for myself and my kids BEFORE consenting to vaccine administration to make an informed choice. Vaccines save lives and protect Iowans.

Name: Jenna Anthofer

Comment: SUPPORT HF 632 Please support and pass this bill! It's appalling that reporting

adverse events and reactions is a choice. An HHS investigation revealed that reactions and adverse events are severely underreported. How can the claim that vaccines are completely safe and effective be true if these reactions and adverse events are not properly documented and reported? This bill is integral to the health and safety of Iowa's children, and a vote against it tells me which politicians in Iowa aren't supporting the children of our state. Thank you for voting yes!

Name: Pamela Duffy

Comment: Oppose this legislation because of the important individual and community benefits of preventing infectious diseases which are not just an inconvenience to those afflicted. Serious illness resulting in missed school and work is likely the least of the consequences of contracting anything from childhood illnesses, to influenza, to COVID19. For many, there is disability, impairment, or death. All of these sequelae impact not just individuals, but also families and community and society. The risk is great.There is already sufficient opportunity for Iowans to consult with their physicians on what is best for them related to vaccines and there is no need to change what currently exists. The danger of spread of communicable, infectious diseases is great.

Name: Laci Minard

Comment: Please support this bill. We have four children, one of whom was injured by a vaccine. We had no idea that it was even a possibility, and our provider did not educate us on the possibility of an injury or reporting to VAERS once it happened. Our son will suffer for the rest of his life because of his injury.

Name: Jon Crosbie

Comment: Vote no. Aside from promoting vaccine hesitancy and likely continuing the effects of the pandemic, this bill also singles out vaccines among other medical treatments as being more unsafe than others (which is flatly not true). Where were you on a bill like this during the opioid crisis (which is still going on)? Why wasn't there a bill like this introduced for benzodiazepines? Why hasn't everybody fallen all over themselves writing a bill like this for stimulant ADHD medications? Why did you decide to introduce a bill like this for the thing that will most likely pull us out of a pandemic that cost 500,000 Americans their lives and did incalculable economic damage?Moreover, this bill seeks to add more work onto an already overworked population of healthcare providers primary care providers. What this bill does is levy fines and financial penalties to providers for something that isn't a problem in the first place. It's another set of hoops to jump through, more paperwork, more documentation, more busy work that keeps us away from our patients. Basically, this bill makes everybody's job harder. If the government wants to inform the public about socalled vaccine damage in order to get votes, then YOU DO IT. Don't punt it to healthcare providers.

Name: Coreena Kinney

Comment: I support HF 632. While the National Childhood Vaccine Injury Act requires that health care professionals report ANY adverse event following vaccination, it does not provide any punishment for those who fail to report. It is critical to have the information collected in a timely matter, so as to limit harm in cases such as a particular vaccine lot being contaminated. VAERS is an early warning system, but it isn't being used. Studies show that less than 1% of severe adverse events are being reported. A family member suffered a dramatic change in her health shortly after a vaccine that her work required her to get. She now has multiple chronic conditions and cannot work. She asked the doctor to report it, and even handed a blank copy of the form to him. On the next visit, he denied that she had mentioned the vaccine or given him the reporting form. He refused to fill it out when she offered to give him a new one. We are continually told that vaccines are very safe. Those statements are based in part on how many reports are made to VAERS. With doctors refusing to report adverse events to VAERS, we can't actually be sure vaccines are safe.

Name: Victoria Bates

Comment: Please do the right thing and let peoples voices be heard.

Name: Amy Kimball

Comment: As a pediatrician, a parent, and an Iowan, I strongly urge you to oppose HF632. Vaccine Information Safety statements, including information about VAERS and required reporting, are already provided and discussed as standard of practice. Vaccine providers are required to discuss this information and record the VIS document date provided as part of the immunization documentation. This information is provided to patients and families at the time of immunization and immunizing providers discuss these with families. Any reported side effects are entered into the VAERS system through processes already in place in clinics and hospitals. This is an unfunded mandate without a source problem. Vaccines save lives. They are regulated, investigated, and researched more than any other medication or supplement. Vaccines are essential to the public health of all Iowans. Any regulations that increase fear and imposes penalties without scientific or factual basis stand to undermine the integrity of our health care system and our health. Please oppose HF632.

Name: Donald Shepherd

Comment: There is no need for this bill. Vaccinations are a wonderful tool for improving public health and all have been thoroughly investigated for safety and efficacy. Furthermore, this process is ongoing. Any bill which might cause some people to needlessly think otherwise will have the unintended effect of lowering the use of these vaccinations and thereby harming the health of Iowa citizens.

Name: Chris Crew

Comment: Support! This does not discourage vaccination; it encourages providers to do their job. My son had a reaction to a vaccine as a toddler. I reported the reaction to his Dr at the time. His Dr did not file a report in the Vaccine Adverse Event Reporting System (VAERS). No one told me about VAERS; I discovered it on my own, researching after my son's reaction. VAERS is important for monitoring for trends. If reactions aren't reported, we can't see these trends. Vaccines need to be safe, but if reactions aren't reported, we can't ensure that they are. We're supposed be able to trust doctors. If their education and licencing isn't enough to get them to consistently report to VAERS as federally required, we need some teeth to grease the wheels.

Name: Alexi Dawson

Comment: Informed. Consent.

Name: Maya Carneiro

Comment: SUPPORT HF632 The attached report commissioned by HHS states on page 6: "Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 113% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported." The VAERS system is a primary source for long term safety, and it is BROKEN. Mandatory reporting fixes the problem.

Grant Final Report

Grant ID: R18 HS 017045

Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)

Inclusive dates: 12/01/07 - 09/30/10

Principal Investigator:
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Abstract

Purpose: To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

Scope: To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

Methods: Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

Results: Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

Key Words: electronic health records, vaccinations, adverse event reporting

Final Report

Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

Aim 1. Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

Aim 2. Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

Aim 3. Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

Aim 4. Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values

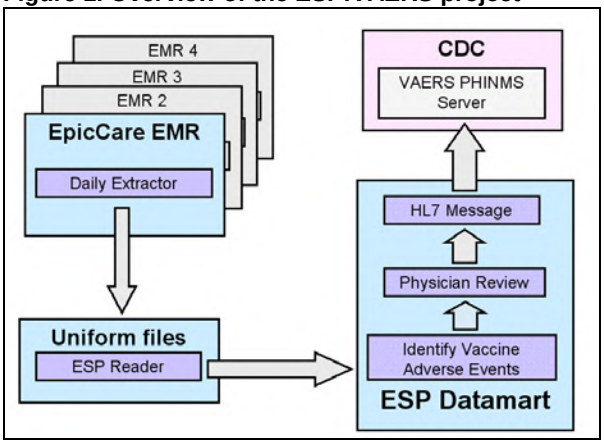
suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

Methods

The goal of Aim 1: *Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration,* and Aim 2: *Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS),* was to construct the below flow of data in order to support the first two Aims:

Figure 1. Overview of the ESP:VAERS project



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect.* A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS*. The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to *Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.*

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 *Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems* has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center http://esphealth.org, specifically, the Subversion repository available at:
http://esphealth.org/trac/ESP/wiki/ESPVAERS.

Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atruis currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atruis physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atruis was included in our adverse event surveillance system (ESP:VAERS). Atruis serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atruis is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atruis population is under age 18.

List of Publications and Products

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: http://esphealth.org.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

Lazarus R, Klompas M Automated vaccine adverse event detection and reporting from electronic medical records. CDC Public Health Informatics Network (PHIN) Conference August 27, 2008.

Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.