

November 2015



# Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

*Published to promote compliance of pharmacy and drug law*

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## **A Message From Secretary Schneider**

Greetings,

Welcome to the November issue of the *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter*.

I hope that everyone's fall season is off to a good start. I encourage you to check out the new Illinois Department of Financial and Professional Regulation (IDFPR) website at [www.idfpr.com](http://www.idfpr.com) if you have not done so already. The website enhancements reflect the IDFPR's focus on being responsive, innovative, transparent, and efficient.

The website is mobile friendly and contains direct tabs to each division. In addition to containing a visible search tool, the website also contains new quick links to the pages where users can fill out a new licensing application, look up licensed professionals throughout Illinois, renew their professional licenses, and file a complaint with the appropriate divisions within the IDFPR.

I hope that you find the new website and this *Newsletter* beneficial to your practice. Please feel free to reach out to me if you have thoughts concerning how IDFPR can better carry out its mission.

Very truly yours,

Bryan A. Schneider  
Secretary, IDFPR  
[bryan.schneider@illinois.gov](mailto:bryan.schneider@illinois.gov)  
312/793-3676

## **Upcoming Board Meetings**

The IDFPR, Division of Professional Regulation – State Board of Pharmacy is scheduled to meet:

- ◆ November 10, 2015 – Chicago, IL, Room 9-040
- ◆ January 12, 2016 – Chicago, Room 9-040
- ◆ March 8, 2016 – Springfield, IL, Room 202N
- ◆ May 10, 2016 – Chicago, Room 9-040

Chicago location: 100 W Randolph St 9<sup>th</sup> Floor

Springfield location: 320 W Washington St

## **Pharmacy Legislation Update**

*By Garth K. Reynolds, RPh, IPhA Executive Director*

The following is a summary of new pharmacy legislation, as of October 6, 2015.

### **Public Act (PA) 099-0480/House Bill (HB) 0001 – Heroin Crisis Act: Effective September 9, 2015**

Sponsor: Representative Lou Lang (D-Skokie, IL)

- ◆ Medication take-back program to be established by June 1, 2016. Pharmacy participation will be voluntary. All pharmacies will display a sign of local State-approved drop-off sites.
- ◆ Pharmacies need to have in place and post a policy regarding the type of identification, if any, necessary to receive a prescription.
- ◆ For sequential Schedule II prescriptions, prescribers must document reason of medical necessity for the two additional 30-day prescriptions in the patient's medical record.
- ◆ Additional data element of days supply is required to be transmitted to the Illinois Prescription Monitoring Program (PMP).
- ◆ Reporting to the PMP changes from within seven days to the end of the next business day.
- ◆ Statewide standing order, developed by the IDFPR with the Illinois Department of Public Health and the Illinois Department of Human Services, for pharmacists to dispense an opioid antagonist (naloxone). Pharmacists will need to complete a training program before dispensing.
- ◆ Exemption of civil liability for dispensing or administering an opioid antagonist without fee or compensation.

### **PA 099-0270/HB 1335 – Right to Try Act: Effective January 1, 2016**

Sponsor: Representative Greg Harris (D-Chicago)

- ◆ Creates the Right to Try Act.
- ◆ Allows patients who are terminally ill to obtain an investigational medication that has completed Phase I clinical trials, but is not yet approved by the United States Food and Drug Administration (FDA).
- ◆ Manufacturers may charge the patient for the medication. Manufacturers are not required to make the medication available.
- ◆ Insurers are not required to cover the medication, but are encouraged to do so.

### **PA 099-0226/HB 3137 – Topical Eye Medication Prescription Act: Effective January 1, 2016**

Sponsor: Representative Dan Brady (R-Normal, IL)

- ◆ Amends Insurance Code.
- ◆ Removes early refill restrictions, in individual and group policies, for eye drops being used to treat a chronic condition of the eye.
- ◆ Refill to be requested prior to the last day of prescribed eye drops or after 75% of predicted days of use.

*continued on page 4*



## **FDA Issues Warning About Name Confusion for Brintellix and Brilinta**

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm).

## **Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!**

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting [www.ismp.org](http://www.ismp.org). ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at [www.ismp.org](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

This is part two of a three-part series on seven persistent safety gaffes of 2014.

### **3) Vaccine Errors: Repetitive Errors Reported in the Last Decade**

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when

vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

### **4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale**

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

### **5) Disrespectful Behavior: A History of Tolerance in Health Care**

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

## **FDA Advises Caution Against Codeine for Treating Colds in Young Patients**

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm).



## **Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns**

In June 2015, FDA warned health care providers and consumers that Daytrana<sup>®</sup>, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm).

## **FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke**

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at [www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm) provides more details.

## **Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter**

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm).

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to

customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs." More information about this recall is available in an FDA safety alert at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm).

## **FDA Warns Against Unapproved Prescription Ear Drops**

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- ◆ benzocaine;
- ◆ benzocaine and antipyrine;
- ◆ benzocaine, antipyrine, and zinc acetate;
- ◆ benzocaine, chloroxylenol, and hydrocortisone;
- ◆ chloroxylenol and pramoxine; and
- ◆ chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm).

## **Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25**

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm).

- ◆ Number of early refills may not exceed total number of refills prescribed.

### **PA 099-0473/HB3219 – Pharmacy Technician CPE, Pharmacy Inspectors, and Medication Locking Caps**

Sponsor: Representative Michael Zalewski (D-Riverside, IL)

#### **Pharmacy technician continuing pharmacy education (CPE) requirements:**

- ◆ CPE requirements (20 hours every two years) for registered certified pharmacy technicians (CPhTs). (One contact hour in pharmacy law and one contact hour in patient safety.)
- ◆ Clarifies when a pharmacy technician must register as a CPhT.
- ◆ **Effective January 1, 2017.**

#### **Pharmacy Inspectors:**

- ◆ Amends requirements to state that pharmacy inspectors shall be registered pharmacists.
- ◆ Does not impact any currently employed non-pharmacist inspectors.
- ◆ **Effective August 27, 2015.**

#### **Medication Locking Caps**

- ◆ Creates a one-year pilot program for hydrocodone-containing Schedule II prescriptions – voluntary participation by pharmacies.
- ◆ Medicaid, Medicare Part D, and long-term care patients are exempt from pilot program.
- ◆ Prescribers may exempt any patient from the pilot program by indicating on the prescription order.
- ◆ Program is subject to appropriation.
- ◆ **Effective January 1, 2016.**

### **PA 099-0200/Senate Bill (SB) 455 – Biological Products: Effective January 1, 2016**

Sponsor: Senator Antonio Muñoz (D-Chicago)

- ◆ Amends Pharmacy Practice Act.
- ◆ Adds definitions for biologics and interchangeables.
- ◆ Requires pharmacists to notify patient of interchange.
- ◆ Communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through:
  - ◇ An interoperable electronic medical records system;
  - ◇ An electronic prescribing technology;
  - ◇ A pharmacy benefit management system; or
  - ◇ A pharmacy record.
- ◆ Entry into an electronic records system is presumed to provide notice. Otherwise, the pharmacist shall communicate using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required where:
  - ◇ There is no FDA-approved interchangeable biological product for the product prescribed; or
  - ◇ A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

### **PA 099-0163/SB 689 – Controlled Substances/ APNs and PAs: Effective January 1, 2016**

Sponsor: Senator Matt Murphy (R-Palatine, IL)

- ◆ Amends Pharmacy Practice Act and Controlled Substances Act.
- ◆ Allows advanced practice nurses (APNs)/practical nurses/registered nurses/physician assistants (PAs) to pick up, deliver, and possess controlled substances for a patient utilizing hospice services or home health services.

*Garth K. Reynolds, RPh, is the executive director of the Illinois Pharmacists Association (IPhA). The IPhA is dedicated to enhancing the professional competency of pharmacists, advancing the standards of pharmacy practice, improving pharmacists' effectiveness in assuring rational drug use in society, and leading in the resolution of public policy issues affecting pharmacists.*

### **Improving Tdap Vaccination Rates Among Infant Caregivers**

*Authors: Zachary Pentoney, PharmD, RPh, and Despina Kotis, PharmD, RPh, FASHP*

#### **Introduction**

The advent of vaccines ushered in a new era for public health. When the pertussis vaccine was introduced in the 1940s, the case rate of pertussis was roughly 150,000 cases per year. By the 1980s, the case rate had fallen to less than 5,000 per year. Since the 1980s, the number of reported cases of pertussis has slowly increased, with over 28,000 cases reported for 2014.<sup>1</sup> The incidence of pertussis is highest for infants younger than 12 months of age, and infants two months of age or younger are particularly vulnerable as they are ineligible for vaccination because of their young age. In fact, seven of the nine pertussis-related deaths in 2014 were infants less than three months of age.<sup>2</sup>

In 2011, the Advisory Committee on Immunization Practices recommended that mothers and close contacts of neonates (eg, siblings, grandparents) be vaccinated with the tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine to protect neonates. This strategy is called “cocooning,” as the process of vaccinating the infant’s closest contacts creates a protective cocoon around the infant, helping to insulate him or her from pertussis. Cocooning initiatives have had mixed results. According to a 2011 *Morbidity and Mortality Weekly Report* from the Centers for Disease Control and Prevention, these programs have been most successful among postpartum mothers, but there is still room for growth in reaching other family members, like fathers.<sup>3</sup>

#### **Process**

In November 2013, Northwestern Memorial Hospital (NMH) implemented a caregiver Tdap vaccine initiative to improve caregiver access to this vaccine. NMH is an 894-bed academic medical center with 12,497 live births in fiscal year 2014. The initiative was targeted at parents and other caregivers expected to have close contact with the neonate. The process is as follows:

- 1) Caregivers present to NMH to visit the neonate.
- 2) Nursing staff identify which caregivers have “close contact” with the neonate and provide education regarding the importance of the vaccine.
- 3) Willing caregivers sign a consent form.
- 4) Nursing staff administer the vaccine and document administration in the neonate’s electronic health record.
- 5) Pharmacy staff document caregiver receipt of vaccination in the Illinois Department of Public Health’s Illinois Comprehensive Automated Immunization Registry Exchange database. The program is currently funded with grant money donated by the Northwestern Medical Faculty Foundation, which covers the cost of the vaccine.<sup>4</sup>

As can be seen in Figure 1 (page 5), there was considerable variation in the number of doses dispensed monthly from November 2013 to April 2015. The average number of doses dispensed during this time frame was approximately 70 per month. It is important to note that these figures represent electronic records of doses dispensed, not actual doses administered. Figure 2 (page 5) shows the number of doses administered based on the relationship to the infant for the time period of August 2014 to

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March 2015. The majority of the doses administered were to fathers. Grandparents were the second most common relation to be vaccinated in the postpartum period. From August 2014 to April 2015, the vaccination rate among fathers declined and then leveled off at about 50% of the August 2014 rate.

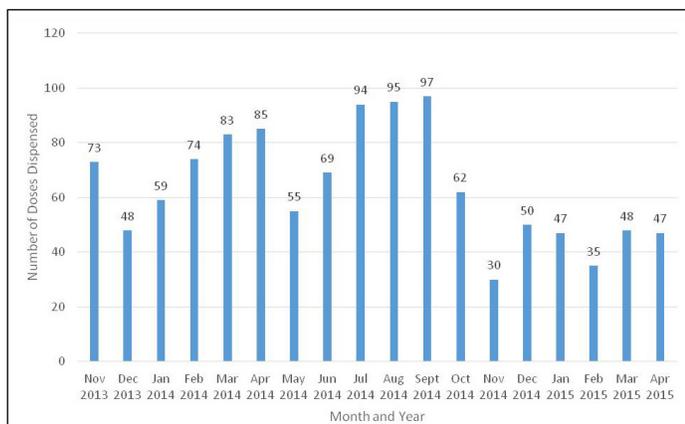


Figure 1. Total number of postpartum Tdap doses dispensed from automated dispensing cabinets.

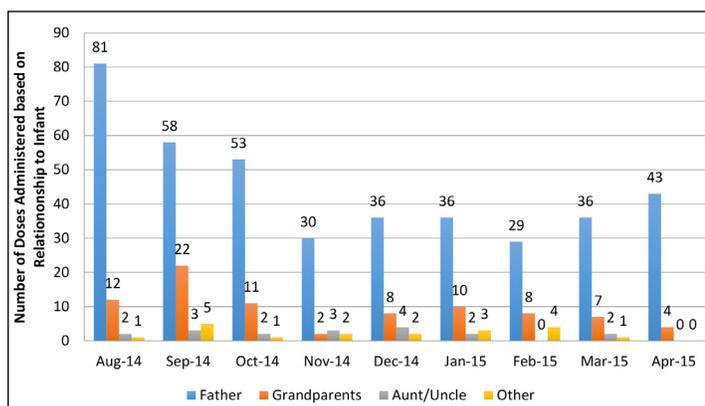


Figure 2. Total number of postpartum Tdap doses administered to caregivers over time based on caregiver relationship to the neonate. Data are taken from paper copies of vaccine administration paperwork. "Other" category includes: nanny, great grandparent, godparent, grandnephew, and not otherwise specified.

## Lessons Learned

A hospital-based cocooning program requires a multidisciplinary approach to be successful. Physicians agree to provide a standing order so that nurses and pharmacists can evaluate patient vaccine eligibility and administer the vaccine. Those on the front lines – nurses – serve as the initial resource for answering caregiver questions about the vaccine. Additionally, nurses administer the vaccine and perform preliminary documentation. All of this is incorporated into the nursing workflow. The pharmacy department agrees to provide the vaccines and finalize the documentation. An initial challenge for the program was workflow adjustments during busy periods.

The apparent decline in vaccination rate of fathers between August 2014 and April 2015 could be due to a variety of factors. Some nurses at NMH have speculated that fathers may be getting vaccinated elsewhere (eg, community pharmacies) prior to coming to the hospital. Additionally, some have suggested that seasonal variation in birthing rates (higher in the summer months compared to the winter months) may account for part of the variation seen. Although the program currently tracks which caregivers receive the Tdap vaccine, there is no process in place to capture how many caregivers are not reached or have refused the vaccine. This would be valuable information as it could indicate how effective the program is in facilitating a "complete" cocoon

(ie, all caregivers with close contact vaccinated). Furthermore, this new data would provide insight into the apparent decline in vaccination rates and illuminate opportunities for improvement.

Another key aspect of the program is ensuring the safety of caregivers and health care professionals during the vaccine administration process. On one occasion, a nurse sustained a needlestick injury while administering the vaccine to a caregiver. Although the hospital had policies in place regarding vaccine safety and accidental needlesticks, there was no clear provision for how to handle a needlestick when a "non-patient" was involved. Consequently, new language was proposed for the caregiver consent form so that in the event of a needlestick accident, the hospital would be permitted to obtain blood samples from the caregiver to provide adequate care for the injured worker.

## Future Initiatives

Moving forward, a revised consent form will be brought to NMH's medication safety subcommittee. Additionally, a survey is being developed that could potentially help capture reasons why caregivers may decline the Tdap vaccine. Lastly, funding is being sought to sustain the program.

## Conclusion

A hospital-based Tdap program aimed at vaccinating close contacts of neonates can successfully reach close relations, such as fathers of the neonate. The success of such a program hinges on collaboration between members of the health care team. Even if caregivers decline the vaccine, they are receiving education and may decide to get vaccinated later. By implementing an inpatient-based Tdap program, institutions can give back to the community and contribute to public health.

## References

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