Immunization Update

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Pharmacist Objectives

1. Discuss recent changes to the 0-18 yr immunization schedule
2. Discuss strategies to deal with vaccine hesitancy
3. Apply key considerations for the various CDC-recommended immunizations to determine which are indicated for a given patient
4. Describe opportunities for pharmacists in utilizing the South Dakota Immunization Information System (SDIIS)
1. Discuss recent changes to the 0-18 yr immunization schedule
2. Discuss strategies to deal with vaccine hesitancy
3. Recognize the various CDC-recommended immunizations and what diseases they prevent in certain eligible patients
4. Describe opportunities for pharmacy technicians and other staff in utilizing the South Dakota Immunization Information System (SDIIS)
Adult Immunizations Overview

1. Influenza
2. Pneumococcal
3. Td/Tdap
4. Zoster
5. HPV
6. Hepatitis B
7. South Dakota Immunization Information System (SDIIS)
Influenza
Influenza

• Influenza immunization recommended for all patients 6 months of age or older on an annual basis, ideally before the end of October.

• 2017-18 Strains:
  - A/Michigan/45/2015 (H1N1)pdm09-like virus
  - A/Hong Kong/4801/2014 (H3N2)-like virus
  - B/Brisbane/60/2008 (B/Victoria lineage)-like virus
    • Quadrivalent also contains: B/Phuket/3073/2013 (B/Yamagata lineage)-like virus

• 2016-17 Strains:
  - A/California/7/2010 (H1N1)-like virus
  - A/Hong Kong/4801/2014 (H3N2)-like virus
  - B/Brisbane/60/2008 (B/Victoria lineage)-like virus
    • Quadrivalent also contains: B/Phuket/3073/2013 (B/Yamagata lineage)-like virus
Influenza Nomenclature

1. Category of influenza virus in the vaccine
   - IIV: Inactivated Influenza Vaccine
   - LAIV: Live-attenuated Influenza Vaccine
   - ccIIV: Cell-culture-based Inactivated Influenza Vaccine
   - RIV: Recombinant Influenza Vaccine

2. Number/types of strains
   - Trivalent: two influenza A viruses and one influenza B virus
   - Quadrivalent: two influenza A viruses and two influenza B virus

3. Route of administration
   - Intramuscular injection (in deltoid; most common if not otherwise specified)
     - Jet injection also available (for use with Afluria®)
   - Intradermal (Fluzone® Intradermal Quadrivalent)
   - Intranasal (FluMist® Quadrivalent)

Blanton L et al. MMWR 2017; 66: 668-676
Inactivated Influenza Vaccine (IIV)

• Contains inactivated influenza virus grown with fertilized chicken eggs
• Available IIV4 products
  • Fluarix® Quadrivalent (≥3 years)
  • FluLaval® Quadrivalent (≥6 months approved November 2016; was ≥3 years)
    • Dose of 0.5 mL is same for all ages, even infants/pediatrics
  • Fluzone® Quadrivalent
    • Pediatric (0.25 mL) pre-filled single dose syringe: 6-35 months
    • Multi-dose vial: ≥6 months
    • Single-dose vial & pre-filled single dose syringe: ≥36 months
  • Afluria® Quadrivalent (≥18 years)
    • Approved 2016 – different age recommendation than the IIV3 version
  • Fluzone® Intradermal Quadrivalent (18-64 years)

Blanton L et al. MMWR 2017; 66: 668-676
Inactivated Influenza Vaccine (IIV)

• Contains inactivated influenza virus grown with fertilized chicken eggs

• Available IIV3 products
  • Afluria® (≥5 years)
    • If given via jet injector, 18-64 years
  • Fluvirin® (≥4 years)
  • Fluzone® High-Dose (≥65 years)
  • Fluad® (≥65 years)
    • Contains MF59 adjuvant made from squalene oil intended to enhance immune response to vaccination
    • Abbreviated ‘aIIV3’

Blanton L et al. MMWR 2017; 66: 668-676
Inactivated Influenza Vaccine (IIV)

• ACIP recommendations 2017-18
  • Administer influenza vaccines to all patients age ≥6 months of age without contraindications to the vaccine
  • No influenza vaccine product preferred over another if otherwise appropriate
  • This includes no preference for patients age ≥65 in recommending Fluzone® High-Dose or Fluar® in place of any other age-appropriate vaccine product

Blanton L et al. MMWR 2017; 66: 668-676
Cell-culture-based Inactivated Influenza Vaccine (ccIIV)

• Contains inactivated influenza virus grown with cell culture technology using Madin Darby Canine Kidney (MDCK) cells (as opposed to fertilized chicken eggs)
  • Cell culture vaccines are generally quicker to produce than egg-based vaccines
  • Contains minimal amount of egg protein compared to other egg-based vaccines

• Available products
  • Flucelvax Quadrivalent® (ccIIV4)
    • Approved 05/2016
  • Previously available: Flucelvax® (ccIIV3)

• Dosing/Administration
  • Pre-filled single-dose 0.5 mL syringe

Grohskopf LA, et al. MMWR 2016; 65: 1-54
Cell-culture-based Inactivated Influenza Vaccine (ccIIV)

• Approved for ages ≥4 (ccIIV4)
  • ccIIV3 initially approved 2012 for patients ages ≥18
• ACIP recommendations
  • Interchangeable with other IIV products for approved ages
  • Despite having less egg protein due to its manufacturing process, not preferred over other IIV for patients with egg allergy

Grohskopf LA, et al. MMWR 2016; 65: 1-54
Recombinant Influenza Vaccine (RIV)

• Contains recombinant hemagglutinin proteins produced from an insect-specific virus (baculovirus) cultured in modified insect cells
  • Does not require use of the influenza virus or any eggs in the manufacturing process

• Available products
  • Flublok® Trivalent (RIV3)
  • Flublock® Quadrivalent (RIV4)
    • Approved 10/2016

• Dosing/Administration
  • Single-dose 0.5 mL vial (RIV3) or syringe (RIV4)

Grohskopf LA, et al. MMWR 2016; 65: 1-54
Recombinant Influenza Vaccine (RIV)

- FDA-approved for patients ages ≥18
  - Initially approved 2013
- ACIP recommendations
  - Interchangeable with the IIV products for appropriate ages
  - May be considered for appropriate ages in patients allergic to eggs but not officially preferred over other IIV products

Grohskopf LA, et al. MMWR 2016; 65: 1-54
Live-attenuated Influenza Vaccine (LAIV)

- Contains live influenza virus that has been modified in a variety of ways to limit its ability to cause true influenza infection
  1. **Cold-adapted**: replicates freely at 25 C (temperature of nasal passages)
  2. **Temperature-sensitive**: replicates minimally at 37-39 C (temperature of the core/lungs/lower airways where wild-type (normal) influenza virus would replicate)
  3. **Attenuated**: does not produce typical influenza symptoms

- Available products
  - FluMist® Quadrivalent® (LAIV4) Intranasal
  - Previously available: FluMist® Trivalent (LAIV3) Intranasal

- Dosing/Administration
  - Intranasally 0.2 mL in each nostril (doses are physically divided by a dose clip on syringe)
  - “Sniffing the dose up” is not necessary

Grohskopf LA, et al. MMWR 2016; 65: 1-54
Live-attenuated Influenza Vaccine (LAIV)

• FDA-approved for “healthy” patients aged 2-49
  • Contraindicated in pregnant women, immunosuppressed patients, history of egg allergy, children 2-4 with history of asthma/wheezing, use of influenza antivirals in past 48 hours
  • Precautions in patients at high risk for complications from influenza (comorbid conditions)
  • Avoid use if contact expected with immunocompromised patient due to viral shedding

• ACIP recommendations
  • 2014-15: LAIV preferred over IIV for “healthy” children 2-8 years old
  • 2015-16: no preference for LAIV or IIV for “healthy” patients
  • 2016-17: LAIV should NOT be used for this flu season
  • 2017-18: LAIV should NOT be used for this flu season

Grohskopf LA, et al. MMWR 2015; 64: 818-25
Grohskopf LA, et al. MMWR 2016; 65: 1-54
Egg Allergies and Influenza Immunization 2015-16

1. Does eating lightly cooked eggs provoke ANY allergic reaction?
   • If no allergic reaction, any usual vaccine is appropriate

2. Does eating eggs or egg-containing foods provoke ONLY hives?
   • If only hives, patient can receive
     • Appropriate IIV with 30 minutes of observation
     • RIV3 (if age ≥18)

3. Does eating eggs or egg-containing foods provoke severe allergic reaction symptoms such as hypotension/respiratory distress and/or require epinephrine or EMS to resolve?
   • If severe allergic reaction, patient can receive
     • Appropriate IIV from physician experienced in caring for patients with severe allergic reactions
     • RIV3 (if age ≥18)

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Grohskopf LA, et al. MMWR 2015; 64: 818-25
Grohskopf LA, et al. MMWR 2016; 65: 1-54
Influenza Immunization in Children

- Children (6 months to 8 years) should be given two doses of influenza vaccine their first year of receiving influenza immunizations
  - This allows for optimal antibody response to the influenza immunization
  - The two doses should be administered at least 4 weeks apart from one another

- Once the child has received two doses total of influenza vaccine they only need to receive one dose annually
  - Does not have to be two doses during the same flu season, only total number of doses

- If the child is already over age 8, normal annual vaccine recommendation

- Remember there are now two different approved vaccines/doses for children:
  - FluLaval Quadrivalent 0.5 mL IM pre-filled syringe or multi-dose vial
  - Fluzone Quadrivalent 0.25 mL IM pre-filled syringe

Groshkopf LA, et al. MMWR 2016; 65: 1-54
Guillain-Barré Syndrome & Influenza Immunization

Clinical Presentation

- More common in adults age ≥50
- Thought to be autoimmune-related triggered by a recent infection in most cases, but not well understood
- Progressive muscle weakness due to nerve damage that may progress to respiratory failure and paralysis of the limbs/face

Prognosis

- Mortality more likely if triggered by unresolved severe infection or respiratory failure without access to mechanical ventilation
- Recovery begins within one month but may take up to six months for full recovery
- Long-term nerve damage can occur
Guillain-Barré Syndrome & Influenza Immunization

**History**
- In 1976, an influenza vaccine developed to protect against swine influenza
- Increased risk of Guillain-Barré Syndrome noted in patients who received the vaccination (1 additional GBS case per 100,000 patients vaccinated) though full reasoning behind this association is not completely understood

**Current risk**
- CDC & FDA estimate risk of GBS with current influenza vaccines to be much lower (1 additional GBS case per 1,000,000 patients vaccinated)
- Risk of GBS resulting from actual influenza infection estimated to be more likely than GBS resulting from influenza immunization
- History of Guillain-Barré Syndrome within 6 weeks of receiving an influenza immunization is a precaution for receiving the immunization per ACIP
- Report any safety concerns post-vaccination on VAERS

CDC 2015
Pneumococcal
Pneumococcal Immunization Overview

Two vaccine products currently available

- Pneumovax® 23 Pneumococcal Polysaccharide Vaccine 23-valent (PPSV23)
  - Serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F
- Prevnar 13® Pneumococcal Conjugate Vaccine 13-valent (PCV13)
  - Serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F
  - Contains pneumococcal polysaccharides structures similar to PPSV23, but they are conjugated to a carrier protein which is intended to elicit a stronger immune response

Dosing/Administration

- Intramuscular injection 0.5 mL
- PCV13 vial/syringe should be shaken prior to administration until homogenous and white/cloudy (is a suspension and contains an aluminum adjuvant)

CDC 2016
Pneumococcal Immunization Overview

- Eligibility for pneumococcal immunization(s) determined by age and health status
- Divides patients into four major groups:
  1. “Healthy” – none of the underlying chronic health conditions and not immunocompromised
  2. Chronic health conditions but not immunocompromised:
     - Chronic heart disease, chronic lung disease, diabetes mellitus, alcoholism, chronic liver disease/cirrhosis, cigarette smoking
  3. Cerebrospinal fluid leaks or cochlear implants
  4. Immunocompromised OR anatomical/functional asplenia:
     - Congenital or acquired immunodeficiency, HIV infection, chronic renal failure, nephrotic syndrome, malignancy, solid organ transplant, iatrogenic immunosuppression (medications, radiation, etc.) Once the child has received two doses total of influenza vaccine they only need to receive one dose annually
     - Sickle cell disease/other hemoglobinopathies, congenital/acquired asplenia

CDC 2016
Pneumococcal Immunization Group 1: “Healthy”

- No pneumococcal vaccinations required until age ≥65

- At age ≥65
  - PCV13 ASAP; then PPSV23 ≥1 year later
  - If they received dose of PPSV23 first, give PCV13 ≥1 year later

CDC 2016
Pneumococcal Immunization Group 2: Chronic Health Conditions (but not immunocompromised)

- Age 19-64: PPSV23 ASAP

- Age ≥65: PCV13 ASAP; then PPSV23 ≥1 year later (exact same as “healthy” patients)
  - Must be at least 5 years since last PPSV23 before administering another PPSV23
  - If they received dose of PPSV23 first, give PCV13 ≥1 year later

- Timing example:
  - 64 year old patient born 11/10/1952
  - DM diagnosed 2007, has never received a pneumonia vaccine (but was eligible in 2007)
  1. Give PPSV23 ASAP today (09/2017)
  2. Give PCV13 one year later on 09/2018 (will be age 65+ then)
  3. Give PPSV23 five years later on 09/2022 (5 years since last PPSV23)
Pneumococcal Immunization Group 3: Cerebrospinal Fluid Leaks or Cochlear Implants

- Age ≥19: PCV13 ASAP; then PPSV23 ≥8 weeks later

- Age ≥65: PPSV23 at least 5 years after previous dose of PPSV23
  - No additional PCV13 needed (“moved up” the dose to the earlier age range)

CDC 2016
Pneumococcal Immunization Group 4: Immunocompromised or Asplenia Age ≥19

• Very complicated - general guidelines/intervals below:
  • Prioritize PCV13 over PPSV23
  • PCV13: ≥1 year after most recent PPSV23
  • PPSV23 first dose: ≥8 weeks after PCV13
  • PPSV23 second dose: ≥5 years after first dose PPSV23

• For all at age ≥65, administer another PPSV23 if most recent PPSV23 was received at age <65
  • Must be ≥8 weeks after PCV13 AND ≥5 years after last dose PPSV23

• Maximum number of pneumococcal vaccines based on immunization schedule:
  • One PCV13 & Three PPSV23

CDC 2016
Pneumococcal Immunization Group 4: Immunocompromised or Asplenia Age ≥19

- No pneumococcal vaccination history
  - PCV13 ASAP; then first PPSV23 ≥8 weeks later; then second PPSV23 ≥5 years later
- No PCV13, has first dose of PPSV23
  - PCV13 ASAP if ≥1 year after PPSV23; then second PPSV23 ≥8 weeks after PCV13 AND ≥5 years after first PPSV23
- No PCV13, both doses PPSV23
  - PCV13 ASAP if ≥1 year after last PPSV23
- Received PCV13, no PPSV23
  - PPSV23 first dose ASAP if ≥8 weeks after PCV13; then second PPSV23 ≥5 years later
- Received PCV13, has first dose PPSV23
  - PPSV23 second dose ASAP if ≥8 weeks after PCV13 AND ≥5 years after first dose PPSV23

CDC 2016
Tdap
Td/Tdap Immunization Overview

• Td vaccines contain tetanus and diphtheria
  • All approved ages ≥7: Decavac®; Tenivac®; “generic” available (all administered IM)

• Tdap vaccines contain tetanus, diphtheria, and acellular pertussis
  • Adacel® for ages 10-64; Boostrix® for ages ≥10 (all administered IM)

• Current ACIP Recommendations:
  • Td: Recommended interval is every 10 years; minimum interval is every 5 years
  • Tdap: All patients ages ≥11 who have not yet received Tdap immunization should receive Tdap ASAP
    • Not necessary to wait until next Td booster
    • Only one dose Tdap is necessary unless patient becomes pregnant

ACIP. MMWR 2013; 62: 131-35
CDC 2016
Tdap Immunization: Pregnancy

- Pertussis (“whooping cough”) cases have become increasingly more common in the United States
- Young infants (<12 months) are unable to use Tdap to gain protection from pertussis as their immature immune system is unable to mount a response
  - These young infants depend on existing maternal antibodies
- ACIP Recommendations (2012):
  1. Pregnant women should receive Tdap immunization with every pregnancy
     - Ideally between 27-36 weeks gestation, but can be given any time during pregnancy and regardless of previous vaccination history/intervals
  2. “Cocooning”
     - All who expect to have close contact with an infant should be up-to-date with their Tdap immunization in order to protect from pertussis specifically
     - These recommendations may change in the coming years

ACIP. MMWR 2013; 62: 131-35
CDC 2016
Herpes zoster
Herpes zoster Immunization Overview

• Zostavax® FDA-approved 2006
• Dosing/Administration
  • Vaccine must be stored frozen prior to use
  • Reconstituted with supplied diluent to form 0.65 mL of yellow/white suspension
    • Once reconstituted, must be used within 30 minutes to retain potency
  • Administer reconstituted contents into subcutaneous tissue of upper arm using 5/8” needle
• Precautions/Contraindications
  • Live vaccine – avoid use in immunosuppressed patients and caution with caregivers due to potential for viral transmission/shedding

Hales CM, et al. MMWR 2014; 63: 729-31
CDC 2016
Herpes zoster Immunization

• FDA-approved 2006 and ACIP 2008 recommended for ages ≥60
• Additional FDA approval in 2011 for ages 50-59
• However, ACIP maintained current recommendation for use in ages ≥60
  • Concerns about duration of vaccine efficacy as protection begins to wane around 5 years after immunization, and following that, actual efficacy is uncertain
  • Cost effectiveness and concerns about zoster vaccine supply also cited

• Despite concerns about duration of vaccine efficacy, revaccination is not recommended by ACIP (only one dose lifetime)
• Other options for herpes zoster vaccination are currently being studied

Hales CM, et al. MMWR 2014; 63: 729-31
CDC 2016
Other Vaccines
Human Papillomavirus (HPV) Immunization Overview

• Vaccine products available covered earlier in the presentation

• If HPV series started **before** age 15, need **only 2 doses** of HPV vaccine

• If HPV series started **after** age 15, need **3 doses** of HPV vaccine

• In adults, HPV vaccines should be received by females ≤26 and males ≤21
  • Three dose series – 0 months, 1-2 months, and 6 months
  • May consider HPV vaccines in males age 22-26 years (same dosing)

• If vaccine series was initiated prior to age 15 but not finished:
  • No third dose needed if received 2 doses that were 5+ months apart
  • Need another dose if only received 1 dose, or 2 doses less than 5 months apart

Hepatitis B Immunization Overview

• Two vaccines types, both given as a three dose series at 0, 1, and 6 months
  • Single-antigen hepatitis B vaccine: Engerix-B®; Recombivax HB®
  • Recombivax HB® adult formulation currently on shortage (dialysis formulation available)
  • Combined hepatitis A & B vaccine: Twinrix®

• A list of chronic liver disease conditions was recently added to the adult immunization schedule as routine immunization for those patients with Hepatitis B vaccination is recommended
  • Hepatitis C infection, autoimmune hepatitis
  • Cirrhosis, fatty liver disease, alcoholic liver disease
  • AST/ALT over double the upper limit of normal

• Numerous other indications, mostly focusing on patients routinely exposed to blood or blood products due to comorbid conditions, occupation, living conditions, or high-risk behaviors

CDC 2017
South Dakota Immunization Information System (SDIIS)
Overview

1. Why should pharmacists be interested in gaining access to the South Dakota Immunization Information System (SDIIS)?
2. What is the scope of practice for pharmacists with regard to immunizations in South Dakota?
3. What are the requirements for pharmacists to provide immunizations in South Dakota?
4. How do community pharmacists typically integrate immunization screening and administration into their daily practice?
5. How are community pharmacists prepared to deal with emergency situations that may result from immunization administration?
6. What other resources are available to pharmacists and other health care providers who want to work with pharmacists in providing immunizations to mutual patients?
Why should pharmacists be interested in gaining access to the South Dakota Immunization Information System (SDIIS)?
South Dakota Immunization Information System (SDIIS)

• Pharmacists are able to contact the South Dakota Department of Health Immunization Program in order to gain access to SDIIS.

• This allows pharmacists to both review vaccinations previously administered as well as document vaccinations they administer at the pharmacy.

• This SDIIS patient record is especially important to community pharmacists as they do not routinely have access to patient electronic medical records where immunization history information is typically stored.
What is the scope of practice for pharmacists with regard to immunizations in South Dakota?

1. SDCL 36-11-19.1 – Authority of Registered Pharmacists
2. ARSD 20:51:28 – Influenza Immunizations
3. SD Board of Pharmacy – Policy Statement on Immunizations
36-11-19.1. Authority of registered pharmacists. Registered pharmacists may:

• (1) **Perform drug administration pursuant to a prescription drug order.** The Board of Pharmacy shall establish standards for drug administration pursuant to chapter 1-26 with the approval of a committee composed of two persons appointed by the Board of Pharmacy, two persons appointed by the Board of Nursing and two persons appointed by the Board of Medical and Osteopathic Examiners;

• (2) Perform drug reviews;

• (3) Perform or participate in scientific or clinical drug or drug-related research as an investigator or in collaboration with other investigators;

**Source:** SL 1993, ch 278, § 2.
The Authority of Pharmacists in South Dakota

36-11-19.1. Authority of registered pharmacists. Registered pharmacists may:

• (4) **Interpret and apply** pharmacokinetic data and other pertinent **laboratory data to design safe and effective drug dosage regimens**;

• (5) Participate in drug and drug device selection pursuant to a prescription drug order;

• (6) **Initiate or modify drug therapy by protocol or other legal authority** established and approved within a licensed health care facility or **by a practitioner authorized to prescribe drugs**; and

The Authority of Pharmacists in South Dakota

36-11-19.1. Authority of registered pharmacists. Registered pharmacists may:

• (7) Provide information on prescription drugs, which may include advising, consulting, and educating, as necessary or as required, patients, the public, and other health care providers on the rational, safe and cost-effective use of drugs, including therapeutic values, content, hazards and appropriate use.

The Authority of Pharmacists in South Dakota: Influenza Immunization Administration

• 20:51:28:05. Record keeping and reporting requirements. A pharmacist granted authorization under this chapter to administer influenza immunizations shall maintain the following documentation in the pharmacy regarding each immunization administered for a minimum of five years:

1. The name, address, and date of birth of the patient;
2. The date of administration and site of injections;
3. The name, dose, manufacturer's lot number, and expiration date of the vaccine;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name of the pharmacist administering the immunization;
6. The date that the written report was sent to the patient's primary health care provider;
7. Consultation or other professional information provided to the patient; and
8. The name of the vaccine information sheet provided to the patient.

The pharmacist must provide a written report to the patient's primary health care provider of the above information within 14 days of the immunization. The required records as set forth in this section are open to inspection by the board and must be made available upon the board's request.

Source: 29 SDR 37, effective September 26, 2002.
The Authority of Pharmacists in South Dakota: Policy Statement on Immunizations (5/24/16)

- ARSD 20:51:28 outlines the authority and requirements for the administration of Influenza vaccines by pharmacists.
- The Board of Pharmacy recognizes that pharmacists are highly trained with regard to immunizations of all types and further rule change is needed to include non-influenza immunizations.
- Further, the Board recognizes that retail pharmacists provide the most convenient access point to medical care and access to immunizations is a critical component of public health and safety.
- The SD Board of Pharmacy would like to encourage pharmacists administering vaccines, pursuant to a prescription or protocol, to review patients’ eligibility on the SDIIS prior to administration. Unfortunately providers are not required to enter adult vaccines into the SDIIS.

Source: http://doh.sd.gov/boards/pharmacy/assets/Policy-Immunizations.pdf
The Authority of Pharmacists in South Dakota: Policy Statement on Immunizations (5/24/16)

• Under the current rules, pharmacists may administer Influenza vaccine if properly trained and with the required Board immunization authorization. Generally it has been felt that all other immunizations require a prescription from the prescriber. This is not the case. SDCL 36-11-19.1 allows pharmacists to “perform drug administration pursuant to a prescription drug order” and allows pharmacists to “initiate or modify drug therapy by protocol or other legal authority established and approved within a licensed health care facility or by a practitioner authorized to prescribe drugs”.

• There is no prohibition on vaccinating with all types of vaccines if they are either on a prescription or included within a signed prescriber’s protocol.

Source: http://doh.sd.gov/boards/pharmacy/assets/Policy-Immunizations.pdf
What are the requirements for pharmacists to provide immunizations in South Dakota?
Pharmacist-Provided Immunizations in South Dakota

• Pharmacists are able to administer any immunization for which they receive a prescription from a healthcare professional authorized to prescribe that immunization.

• The exception to this is influenza, for which the SD Board of Pharmacy has promulgated rules (ARSD 20:51:28) that authorize pharmacists who meet the Board’s criteria to administer without a prescription to eligible patients age 18+.

• Pharmacists may also administer immunizations as specified within a protocol signed by both a practitioner authorized to prescribe immunizations and the pharmacist(s) OR approved within a healthcare facility.
  • The SD Board of Pharmacy’s Policy Statement on Immunizations also discusses protocols and their requirements in more detail.
The protocol must be created and signed by the prescriber and pharmacist and should be valid for a period of time not to exceed two years. The protocol should follow ACIP Guidelines (http://www.cdc.gov/vaccines/hcp/acip‐recs/index.html) and be sent to the Board office for review after it has been signed by the prescriber and the pharmacists and should include:

1. Identity of the participating physician and the pharmacist;
2. Identity of the immunization or vaccination which may be administered;
3. Identity of the patient or groups of patients (age) to receive the authorized immunization or vaccination;
4. Identity of the authorized routes and sites of administration allowed;
5. Identity of the course of action the pharmacist shall follow in the case of reactions following administration;
6. Identity of the location at which the pharmacist may administer the authorized immunization or vaccination;
7. Recordkeeping and reporting requirements per ARSD 20:51:28:05 and procedures for notification of administration.
8. The statement that all immunizations will be reported to the South Dakota Immunization and Information System (SDIIS) within 14 days after administration.

Source: http://doh.sd.gov/boards/pharmacy/assets/Policy‐Immunizations.pdf
How do community pharmacists typically integrate immunization screening and administration into their daily practice?
Community Pharmacist Immunization Workflow

• Community pharmacists do not typically have a concrete medical history and indications for dispensed medications which can pose challenges when screening a patient for immunizations they may be eligible for.

• However, clinical knowledge of medication use allows community pharmacists to identify patients who should be screened for immunizations they may be eligible for in order to fill potential gaps in care:
  • Patients age 60+ are eligible for herpes zoster vaccination and most contraindications to the vaccine are due to the immune system being compromised by either medications or disease.
  • Insulin and oral hypoglycemic drugs generally indicate patients have diabetes and adults with diabetes age 18-64 are eligible for pneumococcal polysaccharide vaccine 23-valent (PPSV23).
  • Patients age 65+ are eligible for pneumococcal conjugate vaccine 13-valent (PCV13) and patients of increasing age routinely visit the community pharmacy for monthly prescriptions.
Community Pharmacist Immunization Workflow

• Once a patient is identified as potentially eligible for immunizations, the community pharmacist can review SDIIS to determine if immunizations have been previously received

• If SDIIS does not have documentation of the eligible immunization, the community pharmacist will screen the patient and counsel on immunizations the next time the patient visits the pharmacy for medications
  • Natural fit as patients are used to receiving education from pharmacists during medication counseling

• The pharmacist may choose to put a notification in the patient’s pharmacy record in order to remind pharmacy staff that the patient is potentially eligible for immunizations

• Opportunities for notifications may include:
  • An electronic alert that appears during normal dispensing workflow such as prescription drop-off, the pharmacist’s final verification of the prescription, and/or during prescription counseling
  • A physical “bag tag” that is included with the patient’s completed prescriptions that will be seen when the patient presents to the pharmacy to pick up the prescriptions
Community Pharmacist Immunization Workflow

• Patients may be poor historians on past immunizations previously received and SDIIS records may not be complete, thus the community pharmacy may contact the patient’s other health care providers to ascertain if the patient is truly eligible for the immunization
• This is also an opportunity for the pharmacist to request an immunization prescription from the other health care provider on behalf of the patient for administration at the pharmacy, thereby removing additional barriers to the patient receiving the immunization
  • Pharmacists who have a signed protocol with a prescriber have this barrier already removed

• When the patient presents for the immunization, the pharmacist will complete the required screening form with the patient, provide the patient with the Vaccine Information Statement (VIS), document vaccine-specific information, and administer the immunization
• The pharmacist will document the immunization on SDIIS as well as report the administration to the patient’s primary health care provider generally through faxing the completed screening form to the clinic for inclusion in the electronic medical record
How are community pharmacists prepared to deal with emergency situations that may result from immunization administration?
Community Pharmacist Immunization-related Emergency Management

• Pharmacists providing immunizations must have successfully completed an immunization training program approved by the South Dakota Board of Pharmacy which must contain content related to “response to an emergency situation as a result of the administration of an immunization”
• Pharmacists providing immunization administration must also maintain active certification in cardiopulmonary resuscitation

• Most pharmacies administering immunizations will have a kit with emergency medications/supplies available in the patient care area designated for immunization administration including (but not limited to):
  • Epinephrine (autoinjector most common, though other forms are appropriate)
  • Diphenhydramine (oral tablet/capsule, oral solution, injectable solution)
  • Pocket airway mask with one way valve
• If administering immunizations per protocol, an emergency management plan must be described in the signed document
What other resources are available to pharmacists and other health care providers who want to work with pharmacists in providing immunizations to mutual patients?
Immunization Resources

• The CDC’s Advisory Council on Immunization Practices (ACIP) (https://www.cdc.gov/vaccines/acip/index.html) has direct links to published immunization recommendations organized by vaccine as well as current CDC immunization schedules.

• The Immunization Action Coalition (www.immunize.org) has a variety of resources available including example immunization protocols, emergency management plans, screening documents, patient handouts, and a number of other useful documents.

• The South Dakota Board of Pharmacy website (http://doh.sd.gov/boards/pharmacy/) has links to the codified laws and administrative rules discussed previously as well as protocol templates for pharmacists and other health care providers to utilize.
References

References

Immunization Update

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Pharmacist Question #3

Which pneumococcal vaccine should be administered to a 45 year old patient with diabetes who has never received a pneumococcal vaccine and has no contraindications to vaccination?

A. Pneumococcal Conjugate Vaccine (PCV13)
B. Pneumococcal Polysaccharide Vaccine (PPSV23)
C. Either pneumococcal vaccine would be appropriate to start with
D. None of the above
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Pharmacist Question #4

All health care providers are legally required to document immunizations they administer in the South Dakota Immunization Information System (SDIIS).

A. True
B. False
Pharmacist Question #4

All health care providers are legally required to document immunizations they administer in the South Dakota Immunization Information System (SDIIS).

A. True
B. False
Technician Question #3

Which of the following vaccines needs to be stored in the freezer instead of the refrigerator?

A. Pneumococcal Polysaccharide Vaccine (PPSV23)
B. Pneumococcal Conjugate Vaccine (PCV13)
C. Herpes Zoster Vaccine (HZV)
D. None of the above
Technician Question #3

Which of the following vaccines needs to be stored in the freezer instead of the refrigerator?

A. Pneumococcal Polysaccharide Vaccine (PPSV23)
B. Pneumococcal Conjugate Vaccine (PCV13)
C. Herpes Zoster Vaccine (HZV)
D. None of the above
Technician Question #4

Community pharmacies must pay an annual fee to gain access to the South Dakota Immunization Information System (SDIIS).

A. True
B. False
Technician Question #4

Community pharmacies must pay an annual fee to gain access to the South Dakota Immunization Information System (SDIIS).

A. True
B. False
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