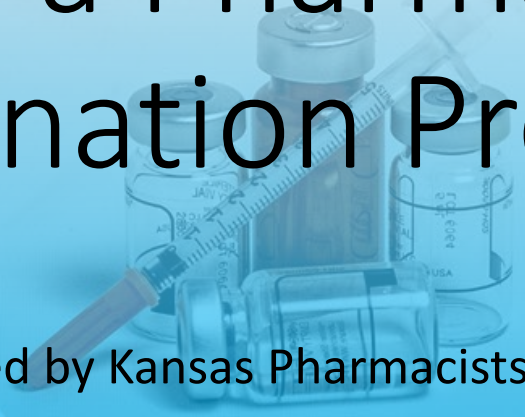
The Details - How to Start and Maintain a Pharmacy-Based Vaccination Program



Sponsored by Kansas Pharmacists Association

Provided Through a Grant from the Kansas Department of Health and Environment – Immunization Program

Objectives

Program Attendees will:

- Understand what steps to take to prepare to begin a vaccination program at a pharmacy
- Recognize the requirements of storage maintenance, including the importance of temperature control for vaccines
- Be aware of the reporting and documentation requirements at the state and federal level for vaccines
- Be informed on basics of WebIZ

Pre-Test

Of the items below, which one do you do last when beginning a vaccination program?

A. Assign a vaccination coordinator

B. Determine where to store the vaccine

C. Buy emergency response supplies

D. Order vaccines

Pre-Test

An effective cold chain relies on which of the following?

A. Well-trained staff
B. Reliable storage
C. Accurate temperature monitoring equipment
D. All of the above

Pre-Test

When must you give a patient you vaccinate the Vaccine Information Statement for the appropriate vaccine?

A. Before administering the vaccine
B. At the time of vaccination
C. Before the patient leaves
D. Within two weeks of giving the vaccination
E. Never

Pre-Test

WebIZ, the Kansas Immunization Information System, was designed to not do which of the following?

1. Consolidate immunization information among health care professionals
2. Assure adequate immunization levels
3. Avoid unnecessary immunizations
4. Identify providers that are not administering vaccinations

Things to Do Before You Begin a Vaccination Program

- Seek out community resources
  - Obtain protocol from a partnering physician
- Assign a vaccination coordinator and a back-up
- Determine how and where vaccines will be stored and buy equipment
- Purchase vaccine administration supplies
- Purchase emergency response supplies
- Identify who will be providing vaccinations
- Train all staff working with the program
- Organize documentation and reference materials
- Order vaccines

Clinical and Staff Support

- Meet face-to-face and support program through messaging
- Frontline staff must be supportive of the program for it to be successful
- Provide them positive reinforcement
- This will change your workflow and daily activities

Clinical and Staff Support - ?s to Consider

- How do we make sure all patients are assessed and offered appropriate vaccines?
- Will we offer vaccines everyday, all day, or will we have designated days and/or times?
- Do have the right electronic record system and paperwork to support the program?
- How will we track patients and provide them notices of vaccinations coming due?
- Who will be monitoring temperatures in the vaccine storage units?
- Who will manage vaccine and supply inventory?
- How and from whom will reimbursement be obtained?

Community Resources

- Identify go-to resources at KDHE and local health departments
- Discuss referrals and process with medical partners in the area
  - This can be a two-way street!
- Obtain a vaccine protocol from a partnering physician (MUST HAVE)

Vaccination Coordinator and Back-Up

- Responsibilities might include:
  - Ordering and maintaining inventory
    - Vaccines
    - Administration materials
  - Developing or acquiring:
    - Screening checklist
    - Procedural guidelines
    - Protocols
    - Staff training
  - Ensuring proper storage and handling
  - Monitoring compliance with recordkeeping requirements
  - Evaluating the program

Supplies

- Vaccine supplies include:
  - Vaccines
  - Clinical documentation (consent forms)
  - Medical emergency supplies
  - Refrigerator
  - Freezer
  - Temperature monitoring equipment
  - Sharps and waste disposal containers
  - Administration materials (i.e. needles, syringes, gloves, bandaids, etc.)
  - VISs

Documentation and Reference Materials

- You should have onsite or have access to the following online:
  - Vaccine Information Statements (VISs) – federally required documents explain benefits and risks of each vaccine, available at: https://www.cdc.gov/vaccines/hcp/vis/current-vis.html
  - Screening checklist for contraindications to vaccines for adults (http://www.immunize.org/catg.d/p4065.pdf)
  - Screening checklist for contraindications to inactivated influenza vaccine (http://www.immunize.org/catg.d/p4066.pdf)
  - Temperature log for refrigerator

Documentation and Reference Materials (Con't)

- You should have onsite:
  - Temperature log for freezer (if applicable)
  - Vaccine storage troubleshooting record (http://www.immunize.org/catg.d/p3041.pdf)
  - Vaccine Adverse Event Reporting System (VAERS) – www.vaers.hhs.gov/index - website to report adverse events after vaccination, whether vaccine caused the adverse event or not
  - WebIZ user handbook and reporting schedule

Vaccine Storage

- Handling and storing vaccines
- The cold chain
- Pink Book
- Storage plan
- Equipment
- Monitoring temperature
- Documentation

Handling and Storing Vaccines

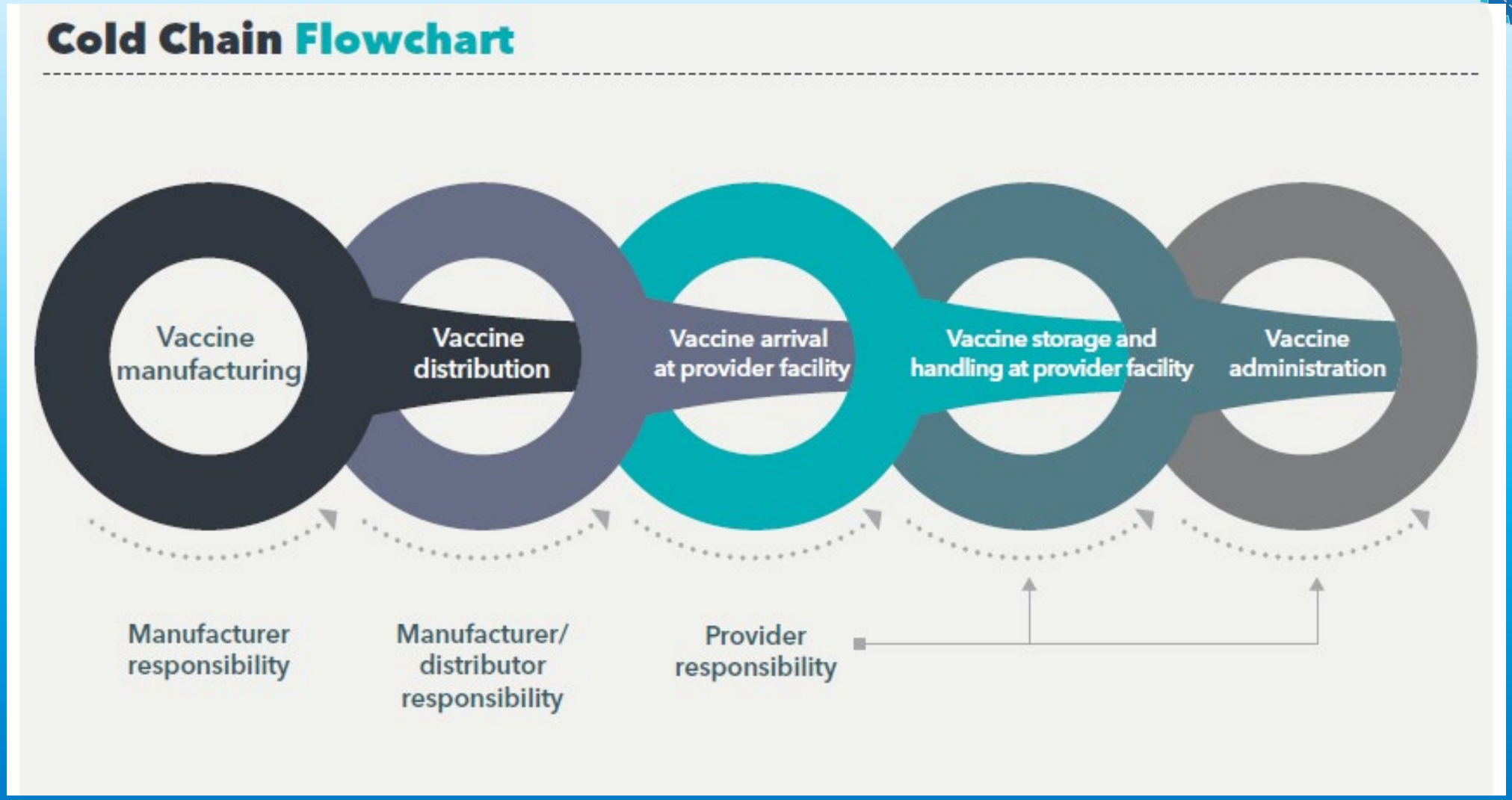
- The CDC provides information and recommendations for appropriate storage and handling of vaccines

- Objectives:
  - Understand who is responsible during the cold chain process
  - Understand proper storage and temperature monitoring
  - Understand how to manage vaccine inventory and how to transport vaccines off site

Vaccine Cold Chain

- It begins with manufacturing of the vaccine, which is the responsibility of the manufacturer
- Ultimately, it has to be distributed through the supply chain down to the pharmacy and depending on contracting this is the manufacturer or distributers responsibility
- It arrives at your pharmacy and up to the moment it is administered it is your responsibility to ensure proper cold storage is maintained

Vaccine Cold Chain



Vaccine Cold Chain

- Effective cold chain relies on three main elements:
  - Well-trained staff
  - Reliable storage
  - Accurate temperature monitoring equipment

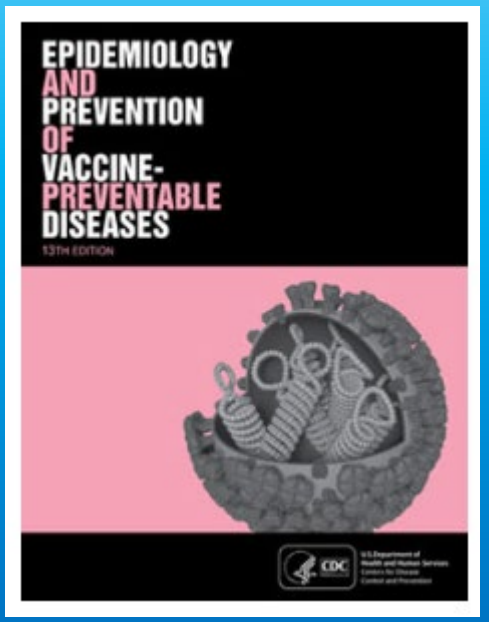
- A break in the cold chain means:
  - Extra doses for the patients
  - Increased costs for the providers
  - Damage to public confidence in vaccines

The Pink Book

- CDC guidelines for specific vaccines, storage and handling procedures, and other information related to vaccines

- The following slides take excerpts from the Pink Book to describe proper technique in storage and handling

- https://www.cdc.gov/vaccines/pubs/pinkbook/index.html



A Proper Storage Plan

- Vaccine management, including proper storage and handling standard operating procedures (SOPs), is the basis on which good immunization practices are built and should include:
  - General information – contact info for manufacturers, equipment service providers, and facility staff, as well as job descriptions, forms, and staff training requirements
  - Routine storage SOPs – inventory management and monitoring storage conditions
  - Emergency SOPs – procedure to follow in case of a equipment failure, power failure, natural disaster, or other emergency

- Every facility should have detailed written protocols for routine and emergency vaccine storage and handling, and they should be updated annually

A Proper Storage Plan

- Staff should receive training on storage and handling:
  - As part of new employee orientation
  - Annually as a refresher for all staff involved in vaccination program
  - Whenever new vaccines are added to the inventory
  - Whenever recommendations for storage and handling of vaccines are updated

- A routine storage and handling plan provides guidelines for daily activities, such as:
  - Ordering and accepting vaccine deliveries
  - Storing and handling vaccines
  - Managing inventory
  - Managing potentially compromised vaccines

Required Equipment

- Stand-alone, purpose-built units that only freeze or refrigerate
  - can vary in size from compact, counter-top or under-the-counter to large, pharmaceutical grade
  - maintain required temperatures better than combination units, particularly the freezer section of these units

- If existing equipment is a household, combination refrigerator/freezer
  - only use refrigerator for vaccine storage
  - use a stand-alone freezer for frozen vaccines
  - applies to both temporary and long-term storage

- Able to maintain required temperature range throughout year

Other Equipment Considerations

- Large enough to hold year's largest vaccine inventory without crowding (including flu vaccine)
- If stand-alone freezer is manual defrost, must defrost regularly and have another storage unit that maintains appropriate temperatures for temporary storage during defrosting
- Frost-free or automatic defrost cycle may be preferred

Vaccine Placement

- Promote good air circulation around fridge/freezer
  - place in well-ventilated room
  - allow for space on all sides and top
  - allow at least 4 inches between storage unit and a wall
  - do not block motor cover
  - ensure unit stands level with at least 1 to 2 inches between bottom of unit and floor

Monitoring Temperature

- Use only calibrated temperature monitoring devices with a certificate of calibration testing (Report of Calibration) from an accredited laboratory
  - required for providers who receive VFC vaccines or vaccines purchased with public funds
  - CDC recommends a temperature monitoring device (TMD) that is a “digital data logger” (DDL)
    - Provides the most accurate storage unit temperature information, including details on how long unit is outside of recommended temperature range
    - Provides detailed information on all temperatures recorded at preset intervals

- Freezer
  - between -58°F and +5°F (between -50°C and -15°C)
- Refrigerator
  - between 35°F and 46°F (between 2°C and 8°C) average: 40°F (5°C)

Monitoring Temperature - DDLs

- Need DDL or appropriate temperature monitoring device for each vaccine storage unit and each transport unit

- Should use DDL with the following features:
  - Detachable/remote probe
  - Alarm for out-of-range temperatures
  - Low-battery indicator
  - Current, minimum, and maximum temperature display
  - Recommended uncertainty of +/-0.5°C (+/-1°F) or less

- Calibration testing should be done every one to two years according to manufacturer's suggested timeline

Documentation

- Review and record temperatures in both freezer and refrigerator units 2 times each day, once in the morning and once before leaving at the end of the workday
- Post temperature log on the door of each storage unit
- If using a DDL, download temperature data and review weekly
- Keep temperature logs (hard copies and downloaded data) 3 years or according to individual state record retention requirements

Unit Power Supplies

- Recommendations:
  - Only one unit per outlet
  - Use safety-lock plug or an outlet cover to prevent unit being unplugged
  - Post “DO NOT UNPLUG” signs at outlets and on storage units
  - Label fuses and circuit breakers to alert people not to turn off power to a storage unit
  - Use caution when using power outlets that can be tripped or switched off and avoid using:
    - Built-in circuit switches
    - Outlets that are controlled by a wall switch
    - Multioutlet power strips

Vaccine Inventory Management – Deliveries

- Must maintain the cold chain
- Should always be immediately checked and stored upon arrival
- Never leave a vaccine shipping container unpacked and unattended
  - Vaccines and diluents must be unpacked, stored at recommended temperatures, and documented immediately after they arrive
  - Immediately examine shipments for:
    - Signs of damage
    - Guarantee right vaccine and quantities are included

Organizing and Storing – Best Practices

- To confirm vaccines are stored correctly and to minimize the risk of administration errors, implement the following practices:
  - Store each type of vaccine or diluent in its original packaging and in a separate container
  - Position vaccines and diluents two to three inches from the unit walls, ceiling, floor, and door
  - If using a household-grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in deli, fruit, or vegetable drawers, or on refrigerator door shelves
  - The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures

Organizing and Storing – Best Practices

- Arrange vaccines and diluents in rows and allow space between them to promote air circulation

- Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates

Organizing and Storing – Best Practices

- Label shelves and containers to clearly identify where each type of vaccine and diluent is stored
- Store vaccines and diluents with similar packaging or names or with pediatric and adult formulations on different shelves (Look-alike/Sound-alike)
- Whenever possible, store diluent with the corresponding vaccine

Organizing and Storing – Best Practices

- Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units
  - If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccines
  - Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks

- The freezer of a household-grade unit may be used for non-vaccine, medical storage, so long as "use does not compromise the temperature range within the refrigerator compartment where vaccine is stored"
  - i.e. doesn't get accessed frequently

Temperature Excursions

- Any temperature reading outside of the recommended ranges is considered a temperature excursion
- CDC recommends:
  - Any staff who hears and alarm or notices a temperature excursion should notify the vaccine coordinator, or supervisor, immediately
  - Notify staff by labeling exposed vaccines “DO NOT USE” and place them in a separate container apart from other vaccines (do not discard)

Temperature Excursions

- CDC recommends:
  - The vaccine coordinator, supervisor, or if necessary, the person reporting the problem should begin to document the event with the following information:
    - Date and time of the temperature excursion
    - Storage unit temperature as well as room temperature, if available (including minimum/maximum temperatures during the time of the event, if available)
    - Name of the person completing the report and description of the event:
      - General description of what happened
      - The length of time vaccine may have been affected, if using a DDL
      - Inventory of affected vaccines
      - List of items in the unit (including water bottles) other than vaccines
      - Any problems with the storage unit and/or affected vaccines before the event
      - Other relevant information

Temperature Excursions

- CDC recommends:
  - Implement your facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the TMD to make sure it is appropriately placed in the center of the vaccines.
  - Contact your immunization program and/or vaccine manufacturer(s) per your SOPs for further guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for revaccination. Be prepared to provide documentation of the event (e.g., temperature log data) to ensure you receive the best guidance.
  - Complete your documentation of the event, including:
    - Action taken
      - What you did with vaccine and how long it took to take action
      - Whom you contacted and instructions received
      - What you did to prevent a similar future event
    - Results
      - Final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned)
      - Other comments

Vaccine Inventory Management – Stock Management

- Only order as much vaccine as you need to meet patient needs
- Rotate stock and for expired doses regularly
- Remove expired product immediately to avoid risk of administering them by mistake

Vaccine Preparation – Best Practices

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed
- Only prepare vaccines when you are ready to administer them
- Always check expiration dates and confirm that you have selected the correct vaccine
- Never use sterile water or saline to reconstitute a vaccine or administer a vaccine reconstituted with the wrong diluent

Deciding Whom to Vaccinate – Assessment and Screening

- Determine the patient's previous vaccination history
  - Patient interview, clinical records, immunization registries
- Determine which vaccines are recommended
- Screen for contraindications and precautions to vaccines
- Advise the patient if he or she should be vaccinated
- Educate your patients about diseases for which they may be at risk and the vaccines that can prevent them

Documentation

- Record federally required information about your patient's vaccinations in the patient's permanent medical record or in an office log
  - Follow CDC guidelines for documenting that you gave the patient current VISs
  - Record specific information about each administered vaccine in your clinic's vaccine administration record
  - Report adverse events that occur after vaccination in the Vaccine Adverse Event Reporting System (VAERS)
  - Subject to Section 2125 of the Public Health Service Act (42 U.S.C. §300aa-25) and the National Childhood Vaccine Injury Act (NCVIA) of 1986 created by the National Vaccine Injury Compensation Program (NVCIP)
- Update your patient's personal vaccination record card or provide a record to your patient
- Update your patient's vaccination record in immunization registry (KSWebIZ)

Documentation - NVCIP

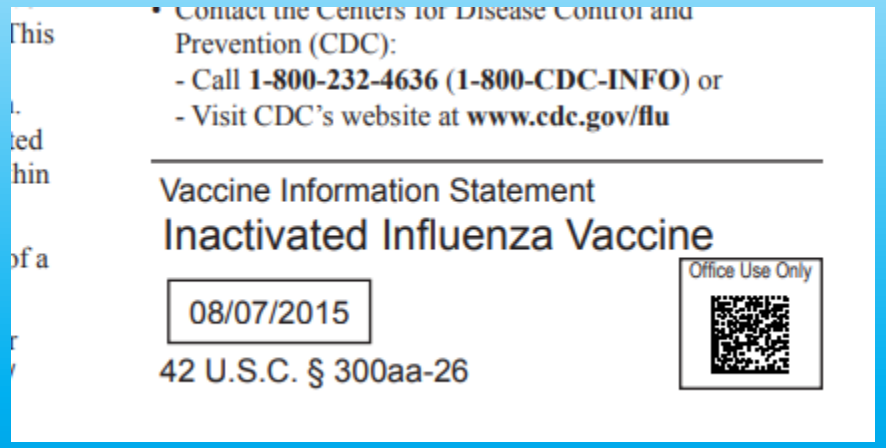
- Covered vaccines include:
  - Diphtheria
  - Tetanus
  - Pertussis
  - Measles
  - Mumps
  - Rubella
  - Polio
  - Hepatitis A
  - Hepatitis B
  - *Haemophilus influenza* type b
  - Seasonal influenza
  - Pneumococcal conjugate
  - Meningococcal ACWY and B
  - Human papillomavirus
  - Varicella

Documentation - VISs

- Developed by the CDC
- Must be given to patient for every vaccination received
- Contains:
  - Information on the disease the vaccine prevents
  - The vaccine
  - Possible side effects
  - What to do about serious reactions
  - Phone number of the NVICP
- You can provide:
  - a paper copy
  - laminated version
  - electronic version
- The patient always has to be offered a copy to take home BEFORE vaccine is administered

Documentation - What to Record

- In your clinic vaccine record you must record:
  - Date the vaccination was given
  - Vaccine manufacturer and lot number of the vaccine administered
  - Name, address (location where the information will be stored), and title of the individual who administered the vaccine
  - Edition (date of publication) of the VIS (found at the bottom of the back page of the VIS)
  - Date the VIS was given to the patient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Prevention (CDC):
- Call **1-800-232-4636 (1-800-CDC-INFO)** or
- Visit CDC's website at **www.cdc.gov/flu**

Vaccine Information Statement
Inactivated Influenza Vaccine

Office Use Only

08/07/2015

42 U.S.C. § 300aa-26

Documentation - VAERS

- In the case of an adverse reaction you must report to VAERS
  - National database gathering adverse event data
  - Epidemiological tool for the FDA and CDC
  - Required reporting events can be found at https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf and is included in your handouts
  - Available at https://vaers.hhs.gov/index

WebIZ – What is It

- The Kansas Immunization Registry, referred to as KSWebIZ is a statewide registry for vaccinations/immunizations

- It is web-based and contains lifespan immunization records that are complete, accurate, and secure for Kansas residents

- Its purpose is to:
  - consolidate immunization information among health care professionals
  - assure adequate immunization levels
  - avoid unnecessary immunizations

WebIZ – Data Use

- Registry data is used by healthcare professionals to:
  - Monitor the immunization status of children and adults
  - Assure compliance with state statutes on immunization requirements for individuals
  - Identify geographic areas at high risk due to low immunization rates
  - Document and assess vaccination coverage during disease outbreaks

WebIZ – Users

- Security measures comply with Health Insurance Portability and Accountability Act (HIPAA) and Kansas statutes

- Access is limited to individuals and entities that either provide immunization services or are required to ensure that persons are immunized

- “Authorized users” are any one of the following:
  - An employee of a public agency or department
  - Health records staff of child care facilities and family day care homes
  - A person other than a public employee who is entrusted with the regular care of those under the care and custody of a state agency including, but not limited to, operators of day care facilities, group homes, residential care facilities adoptive or foster homes
  - A health care professional (KSA 65-531)

WebIZ – Data Sources

- Data comes from:
  - Vital Statistics – birth data and consent to be included in the registry, including demographics and birth dose of HepB
  - Medical billing systems – vaccinations billed to Medicaid
  - Historical data imports – when available from new users
  - Direct entry providers – demographic data, vaccination history, new doses
  - Schools - demographic data, vaccination history, new doses
  - Interface providers - demographic data, vaccination history, new doses

WebIZ – Functionality

- KSWebIZ allows users to generate:
  - Kansas Certificate of Immunizations (KCIs)
  - Pink Cards
  - Vaccine Documentation & Consent forms electronically
- The system has a recommender function that assists the provider in determining immunizations needed by the patient and can generate a reminder for immunizations that are due or past due
- The system is web-based and secure, making patient records mobile wherever the internet is accessible

WebIZ – Signing Up

- To participate you must:
  - Complete the site enrollment agreement at http://www.kdheks.gov/immunize/download/Site_Enrollment_Agreement.pdf
  - Complete the pharmacy screening form located at http://www.kdheks.gov/immunize/download/KSWebIZ_New_Pharmacy_Screening.pdf
  - Forms can be returned to KDHE by fax (785-559-4227) or by email (kdhe.immunizationregistry@ks.gov)

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