

Kansas Vaccination Training for Pharmacists

Sponsored by Kansas Pharmacists Association

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

Welcome



- Our programming is funded by a grant from the Kansas Department of Health and Environment, Bureau of Disease Control and Prevention, Immunization Program
- Our presenters have no disclosures

Logistics

- Breaks
- Bathrooms
- Drinks
- Snacks





Outline

- **Block 1** – Kansas Immunization Law, Adolescent and Adult Vaccinations, Protocols, and Rates
 - Review of Kansas law
 - Protocols
 - ACIP schedules
 - Clinical info for various vaccines and immunization rates for US and Kansas



Outline

- **Block 2** – How to Start and Maintain a Pharmacy-Based Vaccination Program
 - Things to do before you begin a vaccination program
 - Storage
 - Documentation
 - WebIZ

Outline



- **Block 3**

- Vaccine administration
 - Vaccine Information Statement (VIS)
 - Injection site
 - Preparing the vaccine
 - Infection control
 - IM
 - Subcutaneous
 - Intradermal
 - Intranasal
 - Jet
 - Patient factors
 - Appointments for subsequent doses



Vaccinations, the Law and Rates

- Objectives

- Review foundational laws that give pharmacists authorization to immunize in Kansas
- Know the fundamentals of a vaccination protocol
- Comprehend documentation required for pharmacies to initiate a vaccination program
- Understand vaccination standards set by governing bodies
- Clarify which patients may be vaccinated and which vaccines are permitted in Kansas
- Know the ACIP schedules
- Understand clinical information for each recommended adolescent and adult vaccine
- Be aware of the vaccination rates in the United States and Kansas



The Law – Pre-Test

When should an employer make hepatitis B vaccinations available to workers with occupational exposure risk?

- A. Immediately prior to initial exposure risk
- B. Within 10 days of initial assignment to a job with occupational exposure
- C. Within 30 days of initial assignment to a job with occupational exposure
- D. Employees are not required to offer Hepatitis B vaccinations



The Law – Pre-Test

What documentation authorizes a pharmacies to give vaccinations in Kansas?

- A. Protocol/Standing order
- B. Collaborative Practice agreement
- C. Verbal authorization from prescriber
- D. No authorization is required



The Law – Pre-Test

With an appropriate protocol in place, which of the following immunizations are pharmacists permitted to give in Kansas?

- A. Haemophilus influenzae type B
- B. Human papillomavirus (Gardasil 9)
- C. Varicella
- D. All of the above
- E. None of the above



Kansas Statute Annotated (K.S.A.) § 65-1626a.

Practice of pharmacy defined; persons engaged as pharmacists.

(b)(1) “Practice of pharmacy” means the interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; **the administering of vaccine pursuant to a vaccination protocol...**



Kansas Statute Annotated (K.S.A.) § 65-1626

(uuu) "Vaccination protocol" means a written protocol, agreed to by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts, that establishes procedures and recordkeeping and reporting requirements for administering a vaccine by the pharmacist for a period of time specified therein, not to exceed two years.



Kansas Statute Annotated (K.S.A.) § 65-1635a

- What is allowed:
 - **Flu vaccine to those ≥ 6 years**
 - **All vaccines to those ≥ 12 years**
- Who can give vaccine:
 - Pharmacist
 - Pharmacy Student/Intern (supervised by a pharmacist)
- Requirements:
 - Vaccination protocol in place
 - Completed course of study or training approved by ACPE or Kansas Board of Pharmacy
 - Maintain proof of completion of training and provide to Board upon request
 - Current BLS or CPR certificate
- You cannot:
 - Delegate to anyone the authority to give immunizations

Kansas Statute Annotated (K.S.A.) § 65-1635a, continued



- Completed course of study or training approved by ACPE or Kansas Board of Pharmacy must include the following subjects, at a minimum:
 - Vaccination storage
 - Protocols
 - Injection technique
 - Emergency procedures
 - Recordkeeping



Vaccination Protocols

- Written protocol is required for pharmacist vaccination
- Protocols are agreed to by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts
- Protocol must establish procedures, recordkeeping, and reporting requirements for vaccine administration by a pharmacist for 2 years and then must be re-established
- A CPA (collaborative practice agreement) shall not authorize a pharmacist to administer influenza vaccine except pursuant to K.S.A. § 65-1635a, and amendments thereto



Information to Include in Protocol

- Physician authorization
- Qualifications of persons administering vaccines
- Vaccines covered in protocol
- Policies
- Process for screening patients for indications/contraindications
- How to administer vaccine (e.g. dose, route, anatomic location)
- Documentation requirements
- Communication to physician and reporting requirements
- Emergency precautions including specific protocols



Who can Kansas pharmacists vaccinate?

- A pharmacist or a pharmacy student or intern who is working under the direct supervision and control of a pharmacist may administer influenza vaccine to a person six years of age or older and may administer vaccine,
 - All other than influenza vaccine, to a person 12 years of age or older; including (but not limited to) Tdap, MMR, VAR, RZV/ZVL, HPV, PCV13, PPSV23, HepA, HepB, MenACWY, MenB, Hib

Required accreditation: Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard



- Requires training with annual updates
 - Must reflect changes that affect exposure
 - Employers must document beginning or considering using safer medical devices and that they have solicited input from frontline workers
- Requires use of engineering/work practice controls
 - Mandates use of safer devices (safety needles), sharps disposal, labels and signs for hazards
- Requires an exposure control plan (ECP)
 - Written plan to minimize employee exposure to BP

OSHA Bloodborne Pathogens Standard (continued)



- Requires employer to provide hepatitis B vaccine to employees with potential risk
 - Within 10 days of initial assignment to a job with occupational exposure
- Requires documentation of injuries
- Implement the use of universal precautions
 - Treating all blood and other potentially infectious material as if it is known to be infection for BP
- Provide personal protective equipment
 - Gloves, gowns, eye protections, mask as applicable
 - No cost to the employee

OSHA Bloodborne Pathogens Standard (continued)



- Make available post-exposure evaluation and follow-up to any occupationally exposed worker who experiences an exposure incident
 - Specific eye, mouth, mucus membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials (OPIM)
 - Evaluation/ follow-up should be at no cost to employee documenting exposure with source testing (consent required)
 - Testing of workers blood (if consenting) and offering post-exposure prophylaxis



OSHA: Kansas Source Testing Laws

- If possible, the supervisor will obtain and supply the health care provider with the identity, risk levels, and sero-status of the source person for HBV, HCV, and HIV (refer to Appendix H). If the source person's blood is at the state laboratory, it will be tested for HIV, HCV, and HBV only after obtaining consent for testing and release of information since there is no provision in Kansas law for testing a patient or release of testing results without consent. It will be the responsibility of the supervisor to notify the source individual, obtain written permission, obtain additional blood if necessary, and return signed consent forms and blood to the Virology/Serology Lab.

OSHA Bloodborne Pathogens Standard (continued)



- Use labels and signs to communicate hazards
- Provide information and training to workers (at least annually)
- Maintain worker medical training records
 - Also must maintain sharps injury log



National Vaccine Advisory Committee (NVAC) Standards for Adult Immunizations Recommendations

- Stay up-to-date
- Assess every patient for needed vaccines
- Strongly recommend needed vaccines
- Administer or refer
- Document
- Report to state registries (immunization information systems)
- Provide patients with an immunization record
- Notify other providers (primary-care provider)
- Follow-up for future vaccines



Federal Requirements for Documentation

- National Vaccine Injury Compensation Program (VICP) established in 1986
- Required documentation for all vaccines covered by VICP:
 - Patient name
 - Date vaccine administered
 - Vaccine manufacturer and lot number
 - Name, address, title of person administering the vaccine
 - Date printed on the VIS
 - Date the VIS is given to the vaccine recipient or the recipient's legal representative
- Signature is not required by federal law
 - Verify local or state requirements



VAERS

- Vaccine Adverse Event Reporting System (VAERS) established in 1990
- National early warning system to detect possible safety problems in U.S. licensed vaccines
- Co-managed by the CDC and the FDA
- Pharmacists should report any adverse reactions



VAERS

The primary objectives of VAERS are:

- Detect new, unusual, or rare vaccine adverse events
- Monitor increases in known adverse events
- Identify potential patient risk factors for particular types of adverse events
- Assess the safety of newly licensed vaccines
- Determine and address possible reporting clusters (e.g., suspected localized [temporally or geographically] or product-/batch-/lot-specific adverse event reporting)
- Recognize persistent safe-use problems and administration errors
- Provide a national safety monitoring system that extends to the entire general population for response to public health emergencies, such as a large-scale pandemic influenza vaccination program



Vaccination reporting

- All vaccinees will be given a written immunization record for their personal files.
 - If the vaccinee has a primary care provider(PCP):
 - The administering pharmacist or pharmacist supervising an administering pharmacy student or intern shall promptly report a record of the immunization to the vaccinee's primary care provider by mail, electronic facsimile, e-mail or other electronic means.
 - If the vaccinee does not have a PCP:
 - The administering pharmacist or pharmacist supervising an administering pharmacy student or intern shall promptly report a record of the immunization to the person licensed to practice medicine and surgery by the state board of healing arts who has entered into the vaccination protocol with the pharmacist.
 - The immunization will **also** be reported to appropriate county or state immunization registries, except that if the person vaccinated or, if the person is a minor, the parent or guardian of the minor, objects to the report, the report shall not be made.
 - In Kansas, the state immunization registry is WebIZ.



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Vaccines and Schedules Pre-Test

When considering vaccines and deliberating on recommendations the Advisory Committee on Vaccine Practices considers which of the following?

- A. Consideration of disease epidemiology and burden of disease
- B. Vaccine efficacy and effectiveness
- C. Vaccine safety
- D. The quality of evidence reviewed
- E. Economic analyses and implementation issues
- F. All of the above



Vaccines and Schedules Pre-Test

A male, age 54 who has a diagnosis of diabetes has not had a shingles vaccine. Is the preferred ACIP recommendation:

- A. 1 dose of live zoster vaccine
- B. No vaccination due to diagnosis of diabetes
- C. 2 doses of adjuvanted zoster vaccine
- D. No vaccine recommended until age 60



Vaccines and Schedules Pre-Test

For all otherwise healthy patients, a flu vaccination is recommended:

- A. Every 6 months
- B. Every year
- C. Every 2 years
- D. When the vaccine is determined to be effective for that year's strains of influenza



Vaccines and Schedules Pre-Test

Effective August 2, 2019, which of the following vaccines was added to the required immunizations for 11th graders in Kansas?

- A. Additional varicella immunization
- B. Additional MMR immunization
- C. Additional dose of Tdap
- D. A meningococcal immunization for serogroup type A, C, W, and Y



Vaccines – A Very Brief History

- Edward Jenner discovered the small pox inoculation in 1796, which was endorsed in 1802 and termed “vaccine” in 1803
- U.S. Vaccine Agency established by the Vaccine Act of 1813 to encourage vaccination. The act was repealed in 1822 to give regulatory authority of vaccines to the states
- 1855 - Massachusetts becomes first state in the U.S. to mandate vaccinations for schoolchildren



Vaccines – A Very Brief History

- In 1905, U.S. Supreme Court determines in *Jacobson v. Massachusetts*, that states could require vaccination in the best interest of the public but did allow for a medical exemption in extreme circumstances
- In 1938, the Committee on Infections Procedures publishes “Red Book,” an 8-page pamphlet on eighteen vaccines for children and adults
- The Advisory Committee on Immunization Practices (ACIP) was established in 1964



Vaccine Recommendations

- Prior to the Advisory Committee on Immunization Practices, public health services and various academies (such as American Academy of Pediatrics) made recommendations to the public concerning vaccines
- These recommendations lacked any specified form or organization. Policies were not in place to standardize or even assess the efficacy of recommendations
- In 1964 the Advisory Committee on Immunization Practices (ACIP) was established by the U.S. Surgeon General

ACIP



- The ACIP is tasked with advising on best practices for administering and handling vaccines
- The advisory committee informs immunizers of established technique used to administer immunizing agents which prevent communicable diseases



ACIP – What it Does

- ACIP was established under Section 222 of the Public Health Service Act
- ACIP comprises medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States
 - The recommendations stand as public health guidance for safe use of vaccines and related biological products
 - ACIP provides advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States
 - Recommendations made by the ACIP are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR)



ACIP - Deliberations

- Committee deliberations on use of vaccines to control disease in the U.S. shall include:
 - Consideration of disease epidemiology and burden of disease
 - Vaccine efficacy and effectiveness
 - Vaccine safety
 - The quality of evidence reviewed
 - Economic analyses and implementation issues
- The committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations or other data become available



Why do we need oversight from ACIP?

TABLE. Diseases prevented by vaccines in the child/adolescent immunization schedule — United States, 1964–2014*

1964 (6 diseases)	1985 (7 diseases)	1995 (10 diseases)	2014 (16 diseases)
Polio	Polio	Polio	Polio
Diphtheria	Diphtheria	Diphtheria	Diphtheria
Pertussis	Pertussis	Pertussis	Pertussis
Tetanus	Tetanus	Tetanus	Tetanus
Measles	Measles	Measles	Measles
Smallpox	Rubella	Rubella	Rubella
	Mumps	Mumps	Mumps
		Hib	Hib
		Hepatitis B	
		Varicella	
			Hepatitis B
			Hepatitis A
			Varicella
			Pneumococcal
			Influenza
			Meningococcal
			Rotavirus
			HPV

Abbreviations: Hib = *Haemophilus influenzae* type b; HPV = human papillomavirus.

* Current child/adolescent immunization schedule available at <http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html>.



ACIP Guidelines

- <https://www.cdc.gov/vaccines/acip/index.html>
- The guidelines can be found at the above link on the CDC website
- This CDC page breaks the guidelines down into age groups or into disease state categories for simplicity



CDC Adolescent Vaccination Schedule

	Flu Influenza	Tdap Tetanus, diphtheria, pertussis	HPV Human papillomavirus	Meningococcal		Pneumococcal	Hepatitis B	Hepatitis A	Polio	MMR Measles, mumps, rubella	Chickenpox Varicella
				MenACWY	MenB						
7-8 Years											
9-10 Years											
11-12 Years											
13-15 Years											
16-18 Years											
More Information:	Everyone 6 months and older should get a flu vaccine every year.	All 11- through 12-year-olds should get one shot of Tdap.	All 11- through 12- year olds should get a 2- shot series of HPV vaccine. A 3-shot series is needed for those with weakened immune systems and those who start the series at 15 years or older.	All 11- through 12- year olds should get one shot of meningococcal conjugate (MenACWY). A booster shot is recommended at age 16.	Teens 16-18 years old may be vaccinated with a serogroup B meningococcal (MenB) vaccine.						

CDC Adult Vaccination Schedule – Vaccines in the Schedule

Vaccines	Abbreviations	Trade names
<i>Haemophilus influenzae</i> type b	Hib	ActHIB Hiberix
Hepatitis A vaccine	HepA	Havrix Vaqta
Hepatitis A and hepatitis B vaccine	HepA-HepB	Twinrix
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB Hepilisav-B
Human papillomavirus vaccine	HPV vaccine	Gardasil 9
Influenza vaccine, inactivated	IIV	Many brands
Influenza vaccine, live attenuated	LAIV	FluMist Quadrivalent
Influenza vaccine, recombinant	RIV	Flublok Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R II
Meningococcal serogroups A, C, W, Y vaccine	MenACWY	Menactra Menveo
Meningococcal serogroup B vaccine	MenB-4C MenB-FHbp	Bexsero Trumenba
Pneumococcal 13-valent conjugate vaccine	PCV13	Prennar 13
Pneumococcal 23-valent polysaccharide vaccine	PPSV23	Pneumovax
Tetanus and diphtheria toxoids	Td	Tenivac Td vaccine
Tetanus and diphtheria toxoids and acellular pertussis vaccine	Tdap	Adacel Boostrix
Varicella vaccine	VAR	Varivax
Zoster vaccine, recombinant	RZV	Shingrix
Zoster vaccine live	ZVL	Zostavax

CDC Adult Vaccination Schedule – By Age



Table 1 Recommended Adult Immunization Schedule by Age Group
United States, 2019

Vaccine	19–21 years	22–26 years	27–49 years	50–64 years	≥65 years
Influenza inactivated (IIV) or Influenza recombinant (RIV) ^{or} Influenza live attenuated (LAIV)	1 dose annually				
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap, then Td booster every 10 yrs				
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)				
Varicella (VAR)	2 doses (if born in 1980 or later)				
Zoster recombinant (RZV) (preferred) ^{or} Zoster live (ZVL)	2 doses ^{or} 1 dose				
Human papillomavirus (HPV) Female	2 or 3 doses depending on age at initial vaccination				
Human papillomavirus (HPV) Male	2 or 3 doses depending on age at initial vaccination				
Pneumococcal conjugate (PCV13)	1 dose				
Pneumococcal polysaccharide (PPSV23)	1 or 2 doses depending on indication				
Hepatitis A (HepA)	2 or 3 doses depending on vaccine				
Hepatitis B (HepB)	2 or 3 doses depending on vaccine				
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, then booster every 5 yrs if risk remains				
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication				
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication				

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection
 Recommended vaccination for adults with an additional risk factor or another indication
 No recommendation

CDC Adult Vaccination Schedule – By Medical Condition and Other Indications



Table 2 Recommended Adult Immunization Schedule by Medical Condition and Other Indications
United States, 2019

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease, on hemodialysis	Heart or lung disease, alcoholism ¹	Chronic liver disease	Diabetes	Health care personnel ²	Men who have sex with men	
			<200	≥200								
IIV or RIV or LAIV	1 dose annually											
	CONTRAINDICATED					PRECAUTION				1 dose annually		
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td booster every 10 yrs										
MMR	CONTRAINDICATED			1 or 2 doses depending on indication								
VAR	CONTRAINDICATED			2 doses								
RZV (preferred) or ZVL	DELAY				2 doses at age ≥50 yrs							
	CONTRAINDICATED			1 dose at age ≥60 yrs								
HPV Female	DELAY	3 doses through age 26 yrs			2 or 3 doses through age 26 yrs							
HPV Male		3 doses through age 26 yrs			2 or 3 doses through age 21 yrs						2 or 3 doses through age 26 yrs	
PCV13	1 dose											
PPSV23	1, 2, or 3 doses depending on age and indication											
HepA	2 or 3 doses depending on vaccine											
HepB	2 or 3 doses depending on vaccine											
MenACWY	1 or 2 doses depending on indication, then booster every 5 yrs if risk remains											
MenB	PRECAUTION	2 or 3 doses depending on vaccine and indication										
Hib		3 doses HSCT ³ recipients only		1 dose								

 Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection
 Recommended vaccination for adults with an additional risk factor or another indication
 Precaution—vaccine might be indicated if benefit of protection outweighs risk of adverse reaction
 Delay vaccination until after pregnancy if vaccine is indicated
 Contraindicated—vaccine should not be administered because of risk for serious adverse reaction
 No recommendation



Vaccine Information

- In your packet we have sheets for each vaccine on the adolescent and adult immunization schedule.
- Vaccine review

- **Note: Be careful! Always be aware of the vaccines you have on hand or when ordering. Double check their name and contents prior to administering to a patient.**



Vaccines and Schedules Post-Test

When considering vaccines and deliberating on recommendations the Advisory Committee on Vaccine Practices considers which of the following?

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A male, age 54 who has a diagnosis of diabetes has not had a shingles vaccine. Is the preferred ACIP recommendation:

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For all otherwise healthy patients, a flu vaccination is recommended:

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- C. Every 2 years
- D. When the vaccine is determined to be effective for that year's strains of influenza



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Effective August 2, 2019, which of the following vaccines was added to the required immunizations for 11th graders in Kansas?

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Immunization Data Pre-Test

For which group does Kansas have a better HPV immunization rate for 13-17-year olds than the rest of the United States?

- A. 1 or more immunizations
- B. 2 or more immunizations
- C. 3 or more immunizations
- D. Up to date on immunizations
- E. All the above
- F. None of the above



Immunization Data Pre-Test

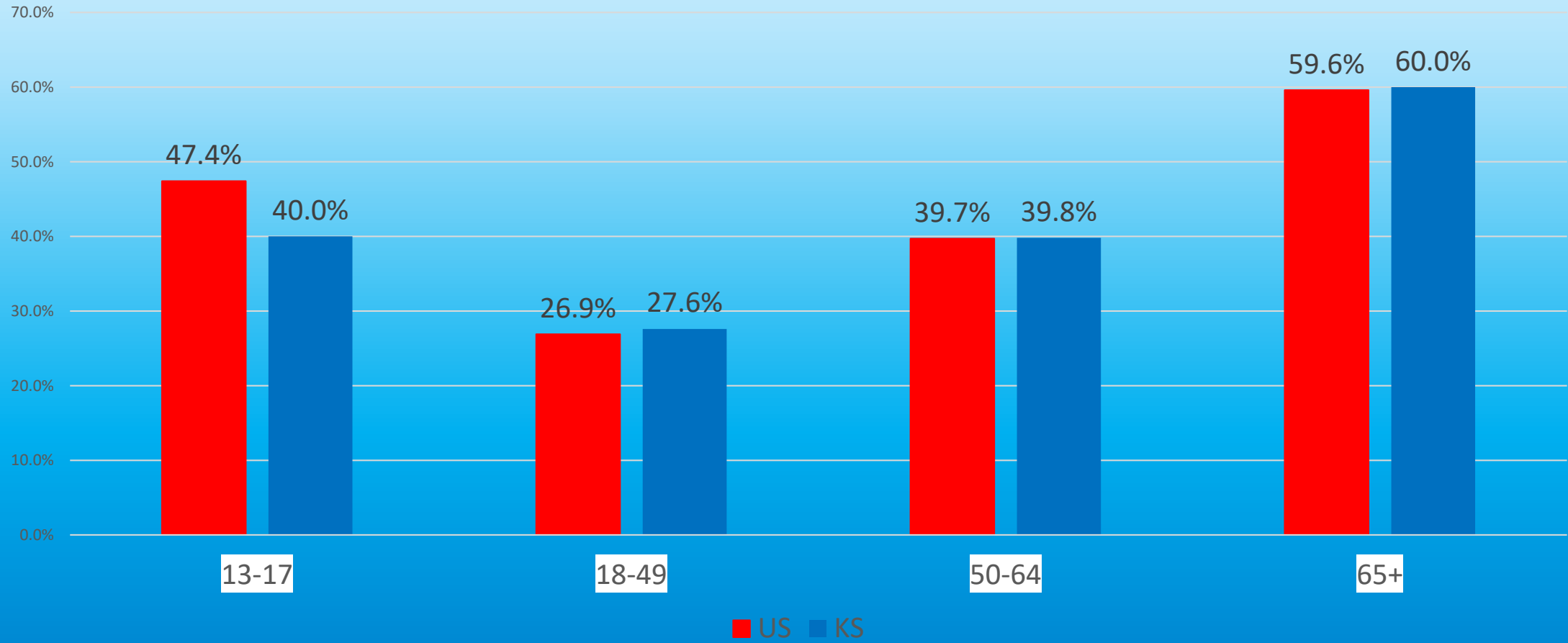
For which of the following immunizations does Kansas have a better rate than the rest of the United States?

- A. Pneumococcal age 65+
- B. HepB for 13-17-year olds
- C. Men ACWY for 13-17-year olds
- D. Varicella zoster in 13-17-year olds with no history of the disease
- E. All the above
- F. None of the above



The Data – Influenza Vaccine Rates

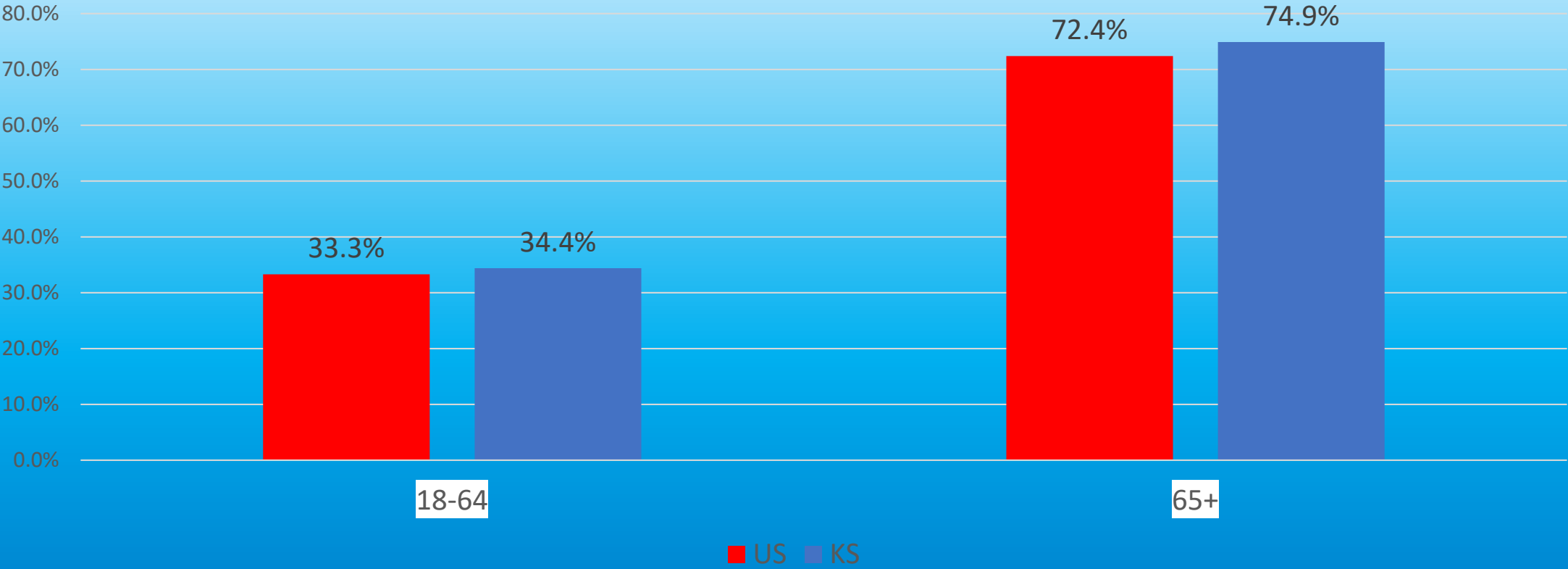
Influenza Vaccine Coverage by Age and Location, 2017





The Data – Pneumococcal Vaccine Rates

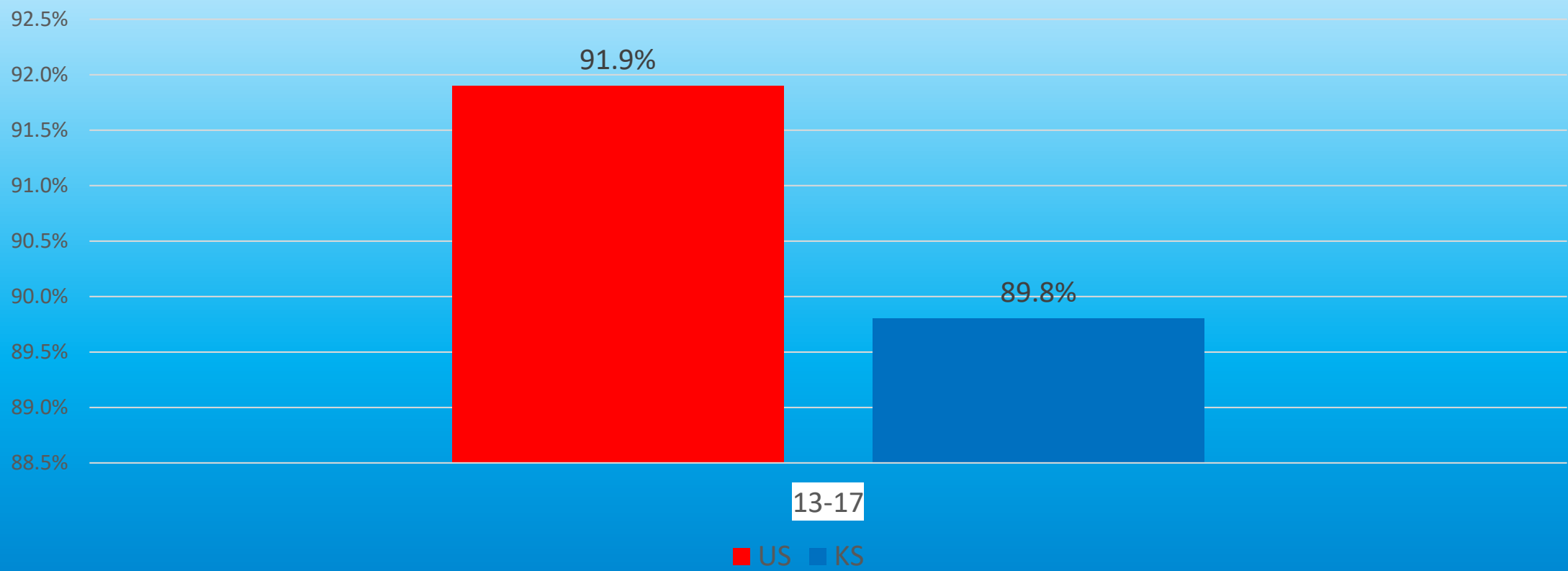
Pneumococcal Vaccination Rates by Age and Location, 2017





The Data – HepB Vaccine Rates

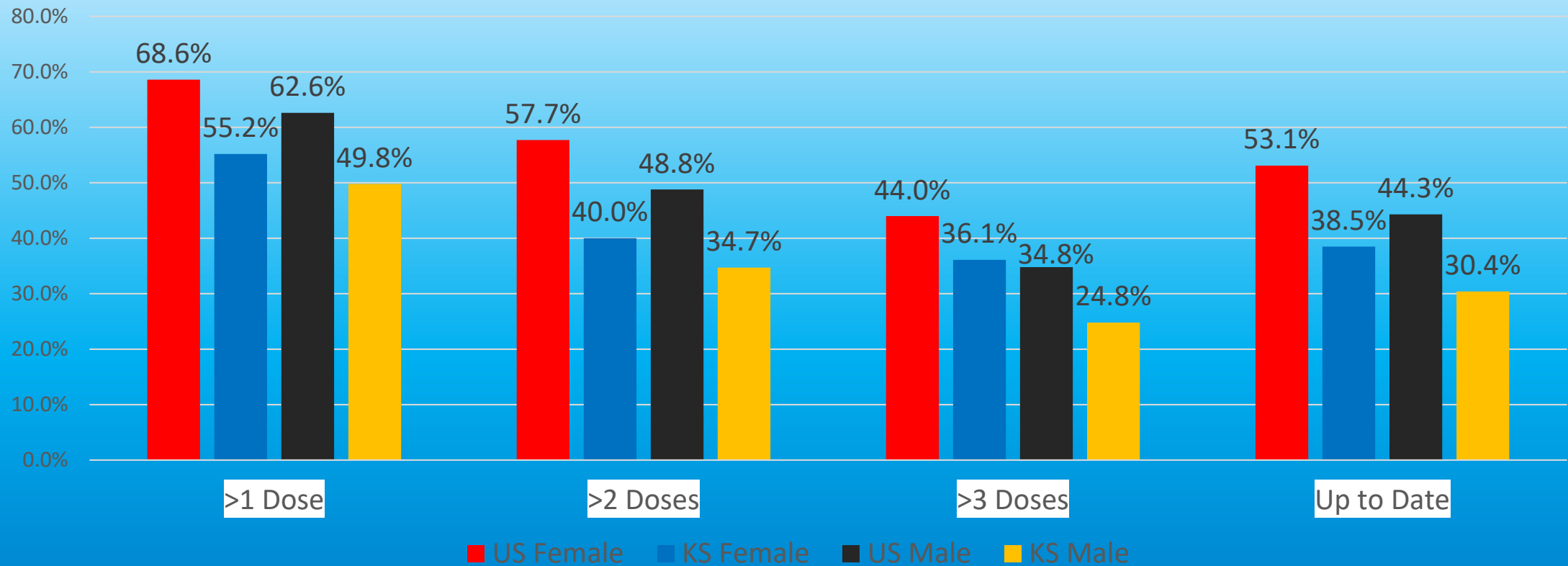
Hep B Vaccine Rate 13-17 Year-olds, 2017





The Data – HPV Vaccine Rates

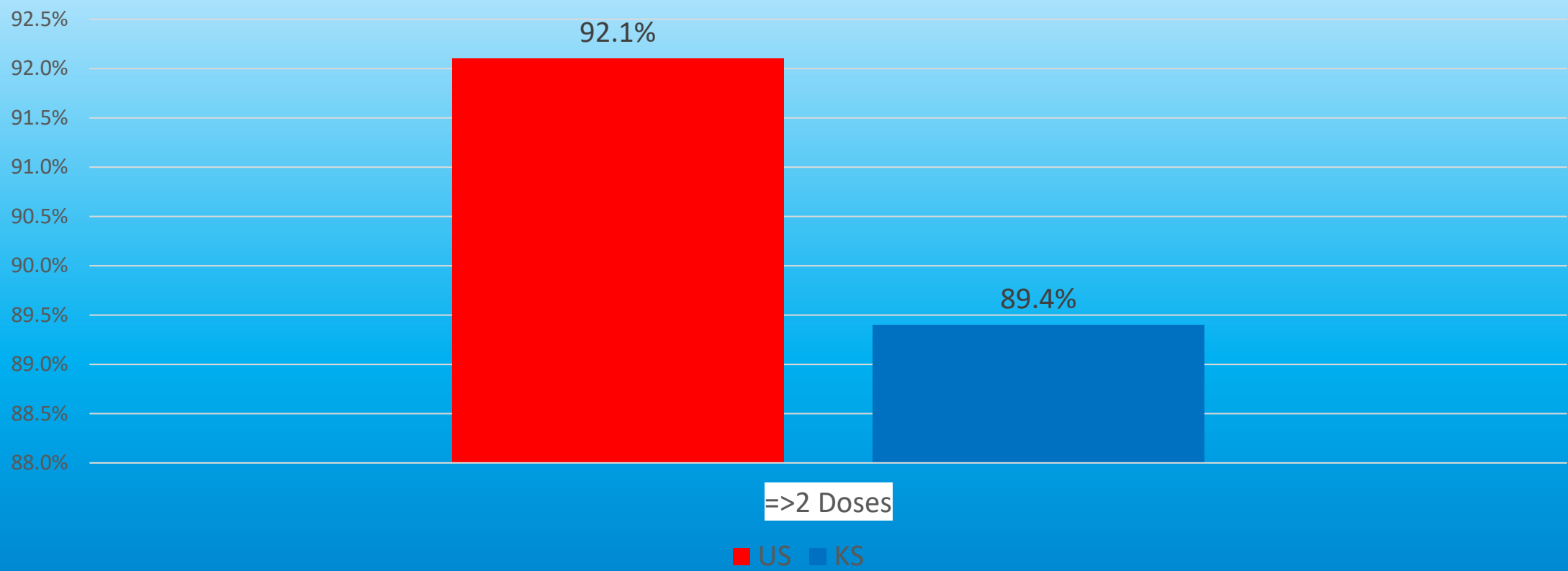
HPV Vaccine Rate 13-17 Year-olds, 2017





The Data – MMR Vaccine Rates

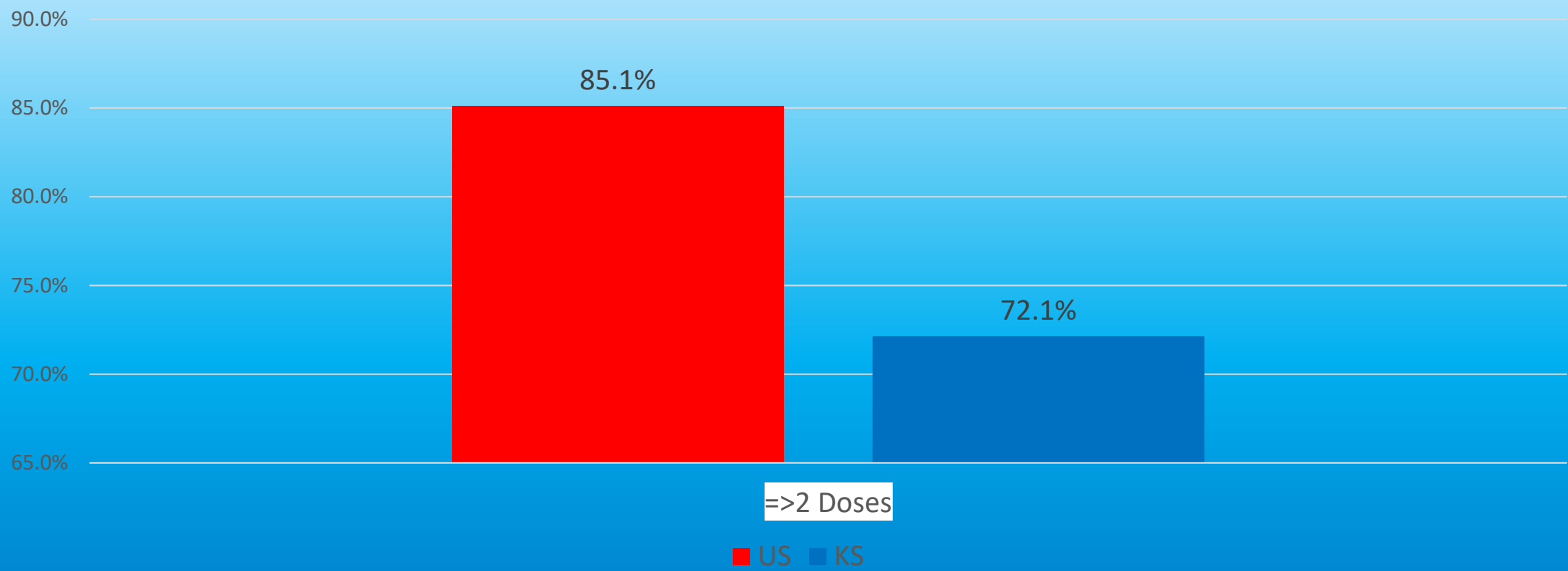
MMR Vaccine Rate 13-17 Year-olds, 2017





The Data – MenACWY Vaccine Rates

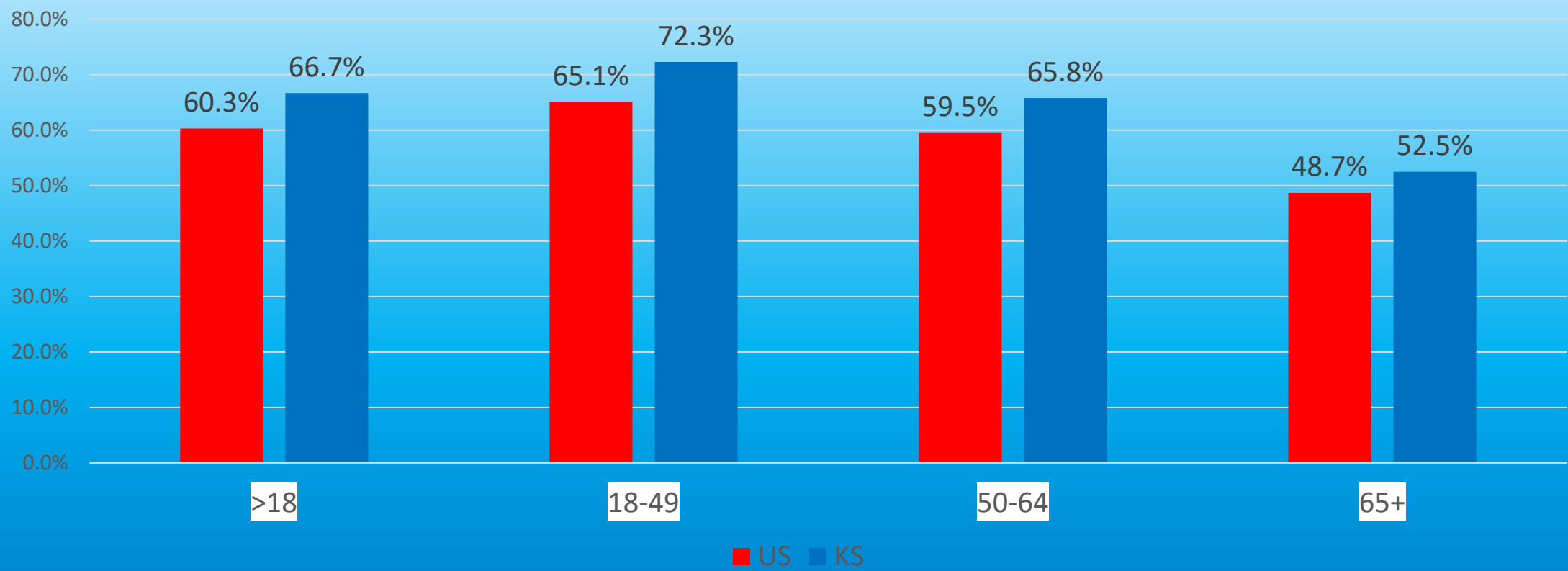
MenACWY Vaccine Rate 13-17 Year-olds, 2016





The Data – Tdap or Td Vaccine Rates

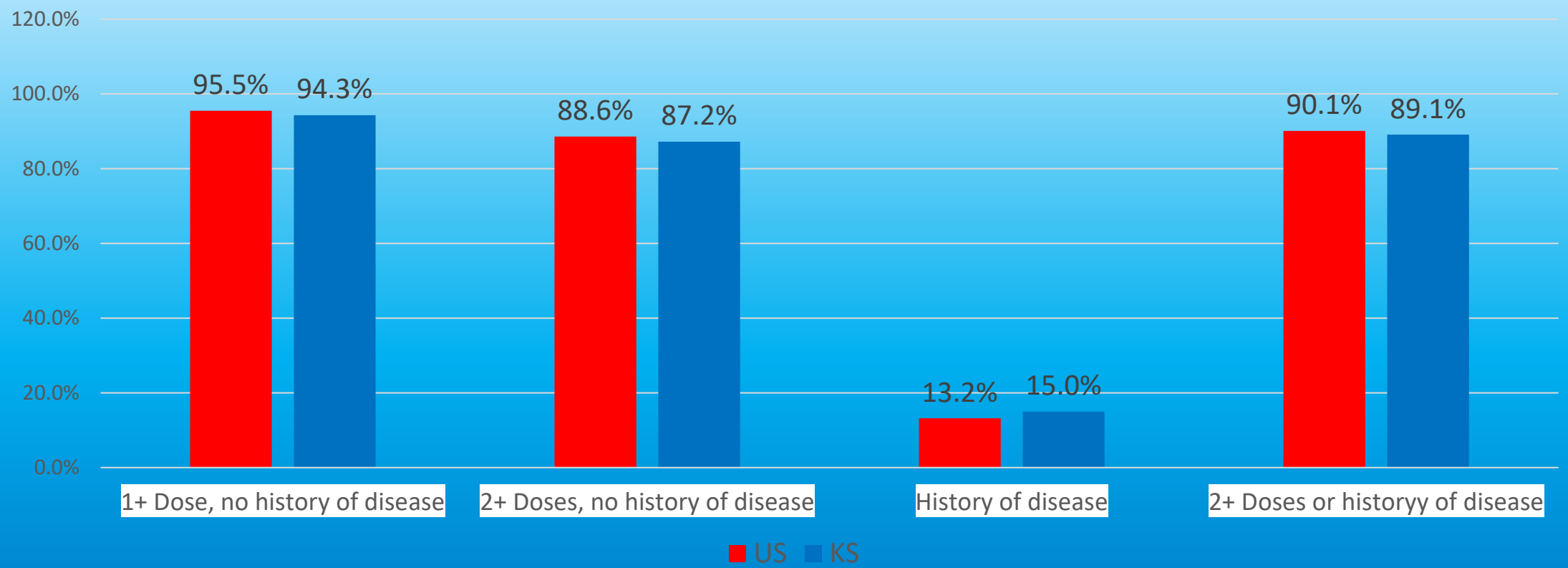
Tdap or Td Vaccine Rate ≥18 Year-olds, 2016





The Data – Varicella Zoster Vaccine Rates

Varicella Zoster Vaccine Rate 13-17 Year-olds, 2017





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- C. Men ACWY for 13-17-year olds
- D. Varicella zoster in 13-17-year olds with no history of the disease
- E. All the above
- F. None of the above