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Immunization Adverse Reactions: Educate, Prevent, Respond, Report

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Objectives

- Review patient/parent education approaches as part of immunization procedures that promote vaccine acceptance
- Review processes involved in recognition of adverse events occurring post-immunization and appropriate response
- Review reporting requirements once adverse events are identified

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Scenario

MC and KC are parents of three children aged 6, 9, and 12 years of age. During a provider visit, there is discussion of vaccines for all three children. One of the vaccines mentioned is Human Papillomavirus (HPV).

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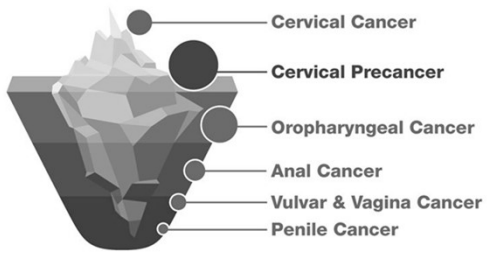
Screening Won't Protect Your Patients from Most HPV Cancers



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MOUS

Every year in the U.S., there are:

13,500 Oropharyngeal Cancer cases
6,200 Anal Cancer cases
3,400 Vulvar & Vaginal Cancer cases
800 Penile Cancer cases

Over 90% of HPV cancers can be prevented by HPV vaccination

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MOU5 No screening tools for these cancers

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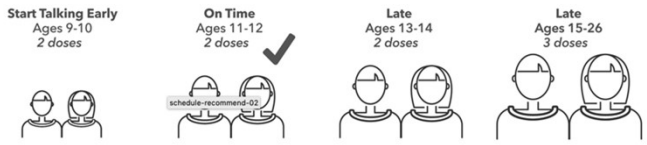
HPV Vaccine Schedule and Dosing



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Scenario

Parents do not want to discuss this vaccine. They state they are aware of HPV and its transmission. Their feeling is that the vaccine is not necessary for their 9 year old daughter or their 11 year old son.

What are the considerations behind their hesitance?

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Vaccine Hesitance

- Defined by the World Health Organization (WHO) as "delay in acceptance or refusal of vaccines despite availability of vaccination services"
- Hesitance may be due to concerns about safety of the vaccine or vaccine schedule AND/OR concerns about whether or not the vaccine is needed or will be helpful in preventing the disease

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Vaccine Safety


Ensuring the Safety of Vaccines in the United States

Before vaccines are approved by the Food and Drug Administration (FDA), they are tested extensively by scientists to ensure they are effective and safe. Vaccines are the best defense we have against infectious diseases; however, **no vaccine is actually 100% safe or effective** for everyone because each person's body reacts to vaccines differently

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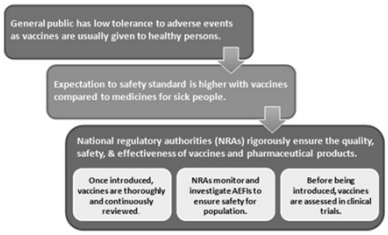
Vaccine Safety



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Pharmacovigilance of Vaccines

The science and activities relating to:

- Detection
- Assessment
- Understanding and
- Communication of adverse events following immunization and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization.

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Thalidomide was **not** approved or licensed for use in the USA between 1957 and 1962, despite pressure to do so. An FDA physician, Frances Kelsey, responsible for approving drug licenses, had co
The thalidomide disaster demonstrated for the first time that **species differences exist in drug reaction/response.** Mice, traditionally used to screen for drug action, are less sensitive to thalidomi

Origins of Pharmacovigilance:

- The WHO Programme for International Drug Monitoring--established in 1968
- Response to the thalidomide disaster in which thousands of infants were born with congenital deformities
- Medicine that had been used to treat morning sickness in pregnancy.

Currently, 136 countries are full members of the WHO Programme for International Drug Monitoring

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Member Countries

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Pharmacovigilance centers:

Have a significant role in post-licensure surveillance—They may conduct:

- Post-licensure surveillance of ADRs
- Data collection on AEFIs using standardized methodologies
- Data analysis
- Regular communications with National Regulatory Authority to update safety profiles.

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National Regulatory Authority Functions

FUNCTION 1 Marketing authorization and licensing activities	Issuing a market authorization, and licensing vaccine production facilities and vaccine distribution facilities.
FUNCTION 2 Post-marketing surveillance (including AEFI surveillance)	Ensuring that post-marketing surveillance is carried out, with a focus on detecting, investigating, and responding to unexpected AEFIs.
FUNCTION 3 Vaccine lot release	Verifying consistency of the safety and quality of different batches of vaccine coming off the production line (lot release).
FUNCTION 4 Laboratory access	Accessing, as needed, a national control laboratory in order to test vaccine samples.
FUNCTION 5 Regulatory inspections	Inspecting vaccine manufacturing sites and distribution channels.
FUNCTION 6 Oversight of clinical trials	Authorizing and monitoring clinical trials to be held in the country.

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Role of Immunization safety surveillance system

- Vaccine quality
- Adverse events
- Vaccine storage and handling
- Vaccine administration
- Disposal of sharps
- Management of waste

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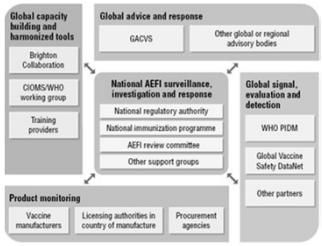
Organizations in Vaccine Safety



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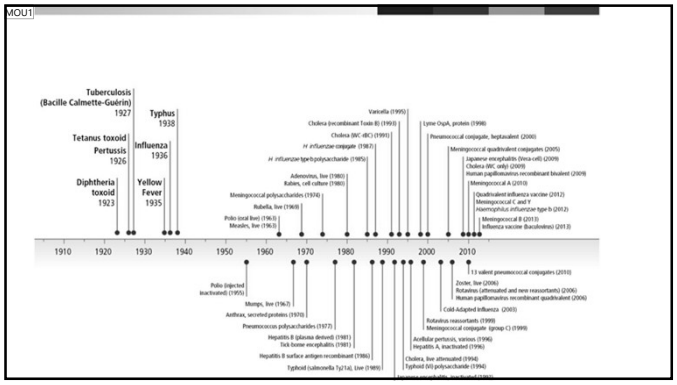

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Vaccine Efficacy

Involves the study of the vaccine impact under strict conditions of a clinical trial (e.g., vaccine given only to healthy individuals in order to measure the impact under ideal circumstances).

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Shingrix Vaccine Efficacy—Licensed 2017 (GSK)

- Efficacy against rash –mid to high 90% range- for all age groups (even over age 70) (compared to Zostavax 51%)
- Efficacy against post-herpetic neuralgic—high 80% to low 90% range (compared to 67%)
- Duration—after 4 years, still about 85% (compared to Zostavax 30%)

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Slide 19

MOU1 This slide is very busy but it shows all of the vaccines that have been developed that prevent disease. Shingrix is not on the list-2017

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Vaccine effectiveness

- The probability that a vaccine will provide immunity to prevent disease in the "real world".

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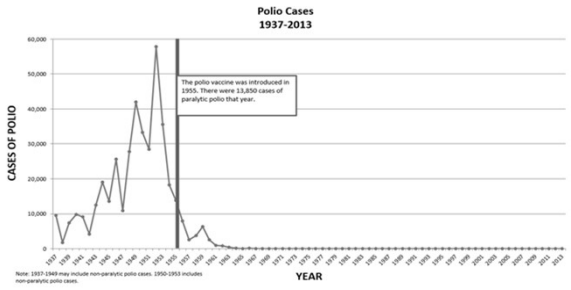
MOU2

Polio Vaccine Effectiveness



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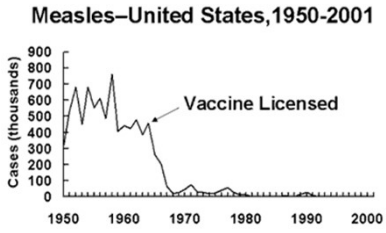
Vaccine Effectiveness



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Slide 23

MOU2 1956 oral Polio

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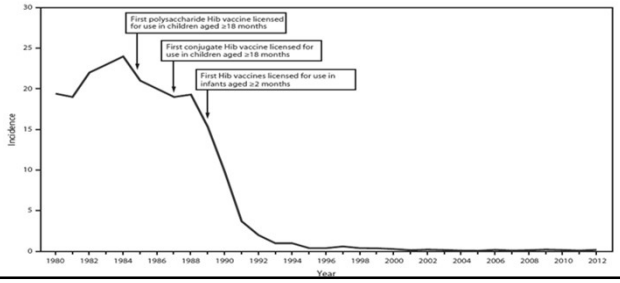
HIB Vaccine Effectiveness



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Adverse Events Following Immunization

- Any untoward medical occurrence that follows immunization
- May not have a causal relationship with the vaccine
- Five categories of reactions:

Vaccine product-related reaction
Vaccine quality defect-related reaction
Immunization error-related reaction
Immunization anxiety-related reaction
Coincidental event

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What is a Serious Adverse Event?

- Results in death,
- Life-threatening,
- Requires in-patient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity,
- Congenital anomaly/birth defect
- Requires intervention to prevent permanent impairment or damage.

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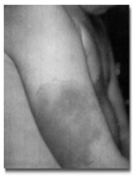
Product Related Reaction

- An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.



Arthus-type reaction following diphtheria- or tetanus-containing vaccine.

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Vaccine Quality Defect Related Reaction

- Caused by or precipitated by a vaccine due to one or more quality defects in the product.
- Includes the administration device (e.g., air jet gun)

Example–

Vaccine-associated paralytic poliomyelitis: rare serious event occurring in recipients of oral polio virus vaccine or a close contact

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Immunization Error Related Reaction

- An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.

- Contamination of vaccine vial, vaccine degradation due to temperature excursion, non-sterile technique, incorrect injection site, reuse of needles or syringes

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Immunization Anxiety-Related Reaction-- Related to the Injection, not the Vaccine

- Fainting (usually affects older children and adults)
  - reduced by minimizing stress in those awaiting injection, through short waiting times, comfortable room temperatures, preparation of vaccine out of recipient's view, and privacy during the procedure.
- Hyperventilation
- Vomiting (common anxiety symptom in children)
- Breath holding
- Convulsions (RARE) –do not need investigation. Provide reassurance

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Coincidental Event

- An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.
- Coincidental event reflecting natural occurrences or community problems that occur close in time of vaccination
- For example, sudden infant death syndrome (SIDS) incidence peaks around the age of early childhood immunization.

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What About Adverse Events?

- Low acceptance of risk.
- All severe, even if rare, AEFIs require intensive investigation
- Minor AEFIs require carefully monitored because they may suggest a potentially larger problem with the vaccine or immunization, or have an impact on the acceptability of immunization in general.

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What About an Immediate Adverse Event

- Rapid recognition
- Rapid response
- Monitoring
- Follow-up
- Reporting

Are you prepared?

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Vaccine Adverse Event Reporting System (VAERS)

- National vaccine safety surveillance program co-sponsored by FDA and CDC
- Purpose is to detect possible signals of adverse events associated with vaccines.
- Reports are welcome from all concerned individuals: patients, parents, health care providers, pharmacists and vaccine manufacturers.

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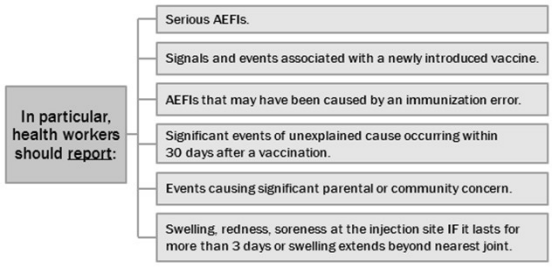
Reporting



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