Introducing 9-Valent Human Papilloma Virus Vaccine

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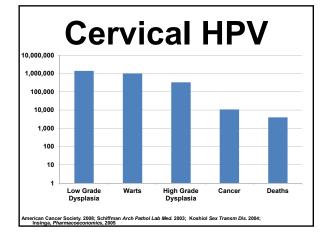
Conflicts of Interest

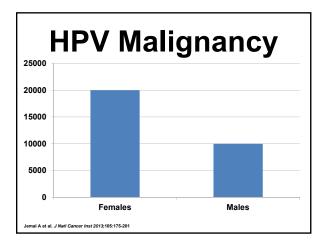
None



HPV's Significance

US Population: 320 Million HPV Infected: 80 Million





Total Burden

3 million cases costing \$7 billion

HPV Vaccine Coverage

65-70% cervical cancers are secondary to HPV 16 and 18 infection

An additional 15-20% are secondary to HPV 31, 33, 45, 52, and 58

Familiar HPV Vaccines

2 valent HPV Vaccine Cervarix Glaxo Smith Klein (2vHPV)

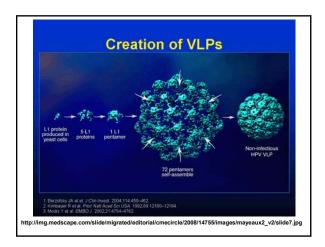
4 valent HPV Vaccine Gardasil Merck (4vHPV)

Unfamiliar HPV Vaccine

9 valent HPV Vaccine Gardasil 9 Merck (9vHPV)

FDA Approved December 2014. ACIP Recommended February 2015. MMWR publication March 2015.

| 2vHPV <i>vs</i> 4vł | IPV <i>vs</i> 4vHPV <i>vs</i> 9vHPV | |
|---------------------|-------------------------------------|--|
| Vaccine | Strains Covered | |
| 2vHPV | 16, 18 | |
| 4vHPV | 6, 11, 16, 18 | |
| 9vHPV | 6, 11, 16, 18, 31, 33, 45, 52, 58 | |
| | | |

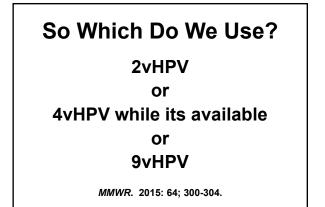


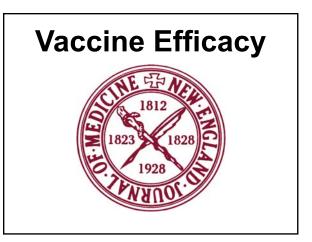
Routine Indications

| Vaccine | Females | Males |
|---------|----------|----------|
| 2vHPV | 11-26 уо | N/A |
| 4vHPV | 11-26 уо | 11-21 уо |
| 9vHPV | 11-26 yo | 11-21 yo |
| | | |

Schedules

| Vaccine | Schedule |
|---------|----------------|
| 2vHPV | 0, 1, 6 months |
| 4vHPV | 0, 2, 6 months |
| 9vHPV | 0, 2, 6 months |
| | |





FUTURE 98%

vaccine efficacy in prevention of HPV 16/18 High-Grade Cervical Lesions

NEJM 2007; 356:1915-1927

FUTURE 100%

vaccine efficacy in prevention of cervical intraepithelial neoplasia, adenocarcinoma in situ, or cancer associated with HPV type 6, 11, 16, or 18

NEJM 2007; 356:1928-1943

Broad Spectrum HPV Vaccine Study

14,215 women randomized to 9v- or 4v-HPV

Rate of high grade HPV disease secondary to HPV 31,33,45,52,58 4vHPV = 1.6/1000 person years 9vHPV = 0.1/1000 person years 96.7% efficacy (80.9-99.8)

9vHPV was non-inferior to 4vHPV in prevention of HPV 6,11,16,18 disease

NEJM. 2015: 372; 711-723

Safety

Adverse events related to injection site: 9v: 90.7% and 4v: 84.9%

Systemic adverse events: 9v: 55.8% and 4v: 54.9%

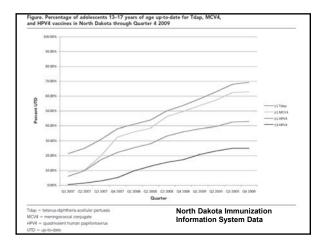
Is Sanford Ready for 9vHPV?

The Enterprise Immunization Committee has made a formal recommendation to the Enterprise Formulary Committee and the Enterprise Clinical Practice Committee to adopt 9vHPV.

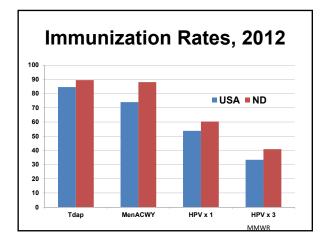
9vHPV is now added to formulary.

How is ND Doing?

LoMurray and Sander. Using the North Dakota Immunization Information System to determine adolescent vaccination rates and uptake. *Public Health Reports*. 2011 (126): Supplement 2.



| ND Rates 2009 | | | |
|---------------|-------|----------|--|
| Vaccine | Doses | Coverage | |
| Tdap | ≥1 | 69.2% | |
| MCV4 | ≥1 | 62.8% | |
| HPV4 | ≥1 | 42.8% | |
| HPV4 | 3 | 24.9% | |
| | | | |



Conclusion 1

Selling HPV vaccination must be hard.

Conclusion 2

This is not just a North Dakota problem.

Conclusion 3

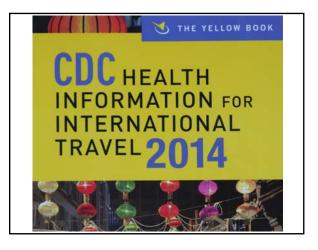
Starting is a lot easier than finishing.

Missed Opportunities 2009

Only 11.5% of FEMALES received MCV4, Tdap, and HPV4 at the first visit. **Missed Opportunities 2009**

Only 48.9% of MALES received MCV4 and Tdap at the first visit.

Unfamiliar vaccines can be a very hard sell.





Familiar vaccines can be a hard sell too.



A Question

What do you tell people who believe vaccination is unnecessary?

The Answer

You don't know what you are talking about.

Statement

My child is NOT having sex.

Reply 1

Your child might be having sex.

Reply 2

Your child will have sex someday.

Simple Math

79 million with HPV ≈ 80 million
319 million total ≈ 320 million
80 million/320 million = ¼
Your child has a ¼ chance of marrying someone with HPV.

Statement

If I vaccinate my children they will have sex.

Reply

They will have sex, but not because you vaccinated them. **Risk Perception Following Vaccination**

Mayhew et al. Pediatrics 2014;133:404-411

Risk perceptions for both sexually experienced and inexperienced adolescents were unchanged when measured before and 6 months after HPV vaccination.

Barriers to Vaccination

Providers in general are not comfortable talking to adolescents about sexual health.

Question

They still don't want to be vaccinated, so now what do I do?

Answer

Leave them with the thought that the patient is at risk for death and disability.