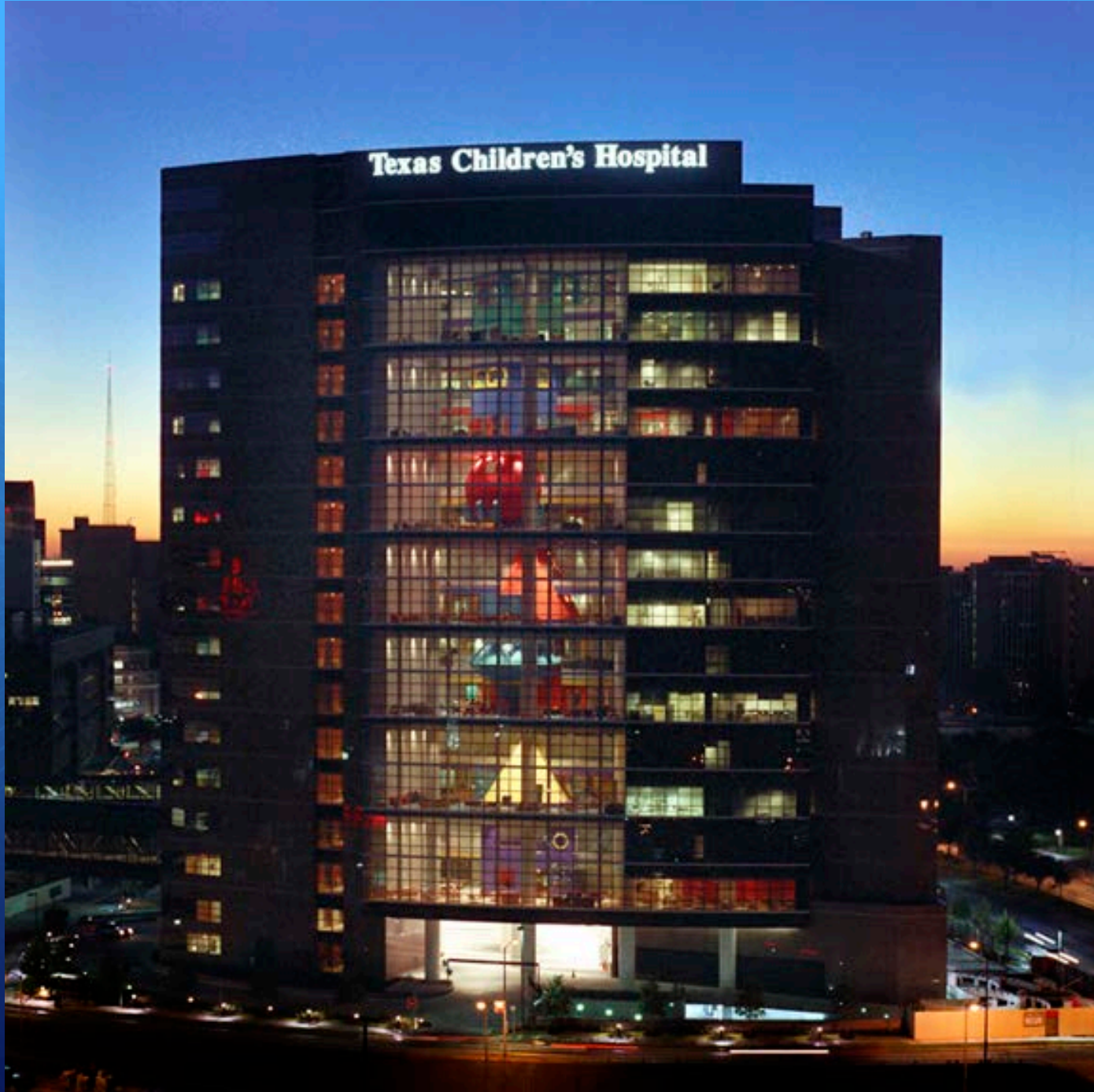




Common Reservations: Vaccine Safety

Julie A. Boom, M.D.
June 18, 2015



HPV vaccine safety concerns are common

TABLE 2. Top five reasons for not vaccinating adolescents with human papillomavirus (HPV) vaccine* – National Immunization Survey-Teen, United States, 2013

Parents of girls			Parents of boys		
Reason	%	(95% CI)	Reason	%	(95% CI)
Lack of knowledge	15.5	(13.0–18.5)	Not recommended	22.8	(20.6–25.0)
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Not recommended	13.0	(10.8–15.5)	Not sexually active	7.7	(6.4–9.2)
Not sexually active	11.3	(9.1–13.9)	Safety concern/Side effects	6.9	(5.6–8.5)

Abbreviation: CI = confidence interval.

* Analysis limited to parents reporting that they were not likely to seek HPV vaccination for their teen in the next 12 months or were unsure of their HPV vaccination plans.

HPV Vaccine Gardasil®

What You Need to Know

1 What is HPV?

Genital **human papillomavirus (HPV)** is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

5

What are the risks from this vaccine?

This HPV vaccine has been used in the U.S. and around the world for about six years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild to moderate** problems are known to occur with this HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:
 - Pain (about 8 people in 10)
 - Redness or swelling (about 1 person in 4)
- Fever:
 - Mild (100° F) (about 1 person in 10)
 - Moderate (102° F) (about 1 person in 65)
- Other problems:
 - Headache (about 1 person in 3)
- Fainting: Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls. Tell your doctor if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.



What am I up against?



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Scholarly articles for hpv vaccine safety

... of infection with human papillomavirus types 16 and ... - Harper - Cited by 1669
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Human papillomavirus vaccination coverage among ... - Centers for Disease ... - Cited by 85

CDC - HPV Vaccine Safety - Vaccine Safety

www.cdc.gov/vaccl... ▾ United States Centers for Disease Control and Preve... ▾
Mar 30, 2015 - This page summarizes **safety** issues regarding the Human Papillomavirus (HPV) Vaccine and mentions two HPV vaccines available to protect ...
FAQ: Gardasil Vaccine recall - FAQs about HPV Vaccine Safety

CDC - FAQ HPV Vaccine Safety - Vaccine Safety

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Mar 30, 2015 - This page includes frequently asked questions about HPV vaccine **safety**, including questions about availability, adverse events, side effects, ...

HPV Vaccine for Children: Gardasil and Cervarix Pros and ...

www.webmd.com/.../vaccines/.../should-your-child-get-hpv-vac... ▾ WebMD ▾
WebMD discusses the arguments for and against HPV vaccination and explains the risks and benefits associated with it.

Myth-busting Gardasil safety and efficacy—Skeptical Raptor

www.skepticalraptor.com/.../one-stop-shop-science-myth-debunking-gar... ▾
May 13, 2015 - Original HPV quadrivalent vaccine, known as Gardasil, can prevent infection by human papillomavirus, substantially reducing the risk of certain ...

How Accurate Are the Recent Claims of the Dangers of the ...

www.huffingtonpost.com/.../how-accurate-are-the-r... ▾ The Huffington Post ▾
Oct 25, 2013 - The HPV vaccine is at least as safe, if not safer, than the other recommended vaccines in use today in the U.S. Is it 100% safe? Of course not.

HPV Vaccine Is Associated with Serious Health Risks

articles.mercola.com/sites/articles/.../07/.../hpv-vaccine-effectiveness.aspx ▾
Jul 16, 2013 - An oncology dietitian reveals that there are significant discrepancies in the result of the recent HPV vaccine effectiveness study.

Oncology Dietitian Exposes Fraud in CDC's HPV Vaccine Effectiveness Study

July 16, 2013 | 589,739 views

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By Dr. Mercola

There are currently two HPV vaccines on the market, but if there was any regard for sound scientific evidence, neither would be promoted as heavily as they are. The first, Gardasil, was licensed by the US Food and Drug Administration (FDA) in 2006. It is now recommended as a routine vaccination for girls and women between the ages of 9-26 in the US.

On October 25, 2011, the CDC's Advisory Committee on Immunization Practices also voted to recommend giving the HPV vaccine to males between the ages of 11 and 21. The second HPV vaccine, Cervarix, was licensed in 2009.

Most recently, an oncology dietitian pointed out significant discrepancies² in a new HPV vaccine effectiveness study published in the *Journal of Infectious Diseases*³, which evaluated data from the National Health and Nutrition Examination Surveys (NHANES), 2003-2006 and 2007-2010.

The study pointed out that HPV vaccine uptake among young girls in the US has been low but concluded that:

"Within four years of vaccine introduction, the vaccine-type HPV prevalence decreased among females aged 14-19 years despite low vaccine uptake. The estimated vaccine effectiveness was high."

Assessing the Overall Impact of the HPV Vaccine

Story at-a-glance

- An oncology dietitian has pointed out significant discrepancies in a new HPV vaccine effectiveness study that claims the vaccine's effectiveness is "high"
- Recent reductions in HPV infection prevalence among young women in the US cannot be said to be due to introduction of Gardasil vaccine in 2006 and use of HPV vaccines by pre-teen and teenage girls since then; the data clearly shows that unvaccinated girls had the best outcome
- In 2007-2010, HPV prevalence dropped 27.3 percent in the unvaccinated girls, but only declined by 5.8 percent in the vaccinated group. In four out of five different measures, the unvaccinated girls had a lower incidence of HPV
- According to Merck's own research before Gardasil was licensed, if you've been exposed to HPV strains 16 or 18 prior to receiving Gardasil vaccine, you could increase your risk of precancerous lesions by 44.6 percent.

Case Report of a Gardasil Death Confirms Presence of HPV DNA Fragments

Earlier this year, a lab scientist, who discovered HPV DNA fragments in the blood of a teenage girl who died after receiving the Gardasil vaccine, published a case report in the peer reviewed journal *Advances in Bioscience and Biotechnology*⁵. The otherwise healthy girl died in her sleep six months after receiving her third and final dose of the HPV vaccine. A full autopsy revealed no cause of death.

Sin Hang Lee with the Milford Molecular Laboratory in Connecticut confirmed the presence of HPV-16 L1 gene DNA in the girl's postmortem blood and spleen tissue. These DNA fragments are also found in the vaccine. The fragments were protected from degradation by binding firmly to the particulate aluminum adjuvant used in the vaccine.

"The significance of these HPV DNA fragments of a vaccine origin found in post-mortem materials is not clear and warrants further investigation," he wrote.

Lee suggests the presence of HPV DNA fragments of vaccine origin might offer a plausible explanation for the high immunogenicity of Gardasil, meaning that the vaccine has the ability to provoke an exaggerated immune response. He points out that the rate of anaphylaxis in girls receiving Gardasil is far higher than normal—reportedly five to 20 times higher than any other school-based vaccination program!

HPV Vaccine Is Associated with Serious Health Risks, Including Sudden Death

Many women are not aware that the HPV vaccine Gardasil might actually *increase* your risk of cervical cancer. Initially, that information came straight from Merck and was presented to the FDA prior to approval⁶. According to Merck's own research, if you have been exposed to HPV strains 16 or 18 prior to receipt of Gardasil vaccine, you could increase your risk of precancerous lesions, or worse, by 44.6 percent.

Other health problems associated with Gardasil vaccine include immune-based inflammatory neurodegenerative disorders, suggesting that something is causing the immune system to overreact in a detrimental way—sometimes fatally.

- Between June 1, 2006 and December 31, 2008, there were 12,424 reported adverse events following Gardasil vaccination, including 32 deaths. The girls, who were on average 18 years old, died within two to 405 days after their last Gardasil injection
- Between May 2009 and September 2010, 16 additional deaths after Gardasil vaccination were reported. For that timeframe, there were also 789 reports of "serious" Gardasil adverse reactions, including 213 cases of permanent disability and 25 diagnosed cases of Guillain-Barre Syndrome
- Between September 1, 2010 and September 15, 2011, another 26 deaths were reported following HPV vaccination

snopes.com: Urgent Warning About Gardasil

www.snopes.com › Home › Medical › Drugs - Snopes.com -

Aug 5, 2014 - Has the Gardasil HPV vaccine been proved to have caused the deaths of 32 ... to help track the safety and efficacy of various vaccines.

Parents' Worries About HPV Vaccine on the Rise: Study ...

health.usnews.com/.../parents-worries-about-... - U.S. News & World Report -

Mar 18, 2013 - "It's really concerning that parents think the HPV vaccine isn't safe," said Dr. Dennis Cunningham, an infectious disease specialist at ...

Japan withdraws support of controversial HPV vaccine over ...

<https://www.lifesitenews.com/.../japan-withdraws-support-of-cont...> - LifeSite -

Oct 16, 2013 - Japan withdraws support of controversial HPV vaccine over safety concerns. Thaddeus ... "HPV vaccination programs began in 2010 under a ...



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[Gardasil Vaccine Witnessing & The Public Flogging of Katie Couric](#)

Jan 14, 2014 ... NVIC's Barbara Loe Fisher reveals facts on **HPV** and public criticism of ... the **safety** or effectiveness of a government recommended vaccine.
www.nvic.org

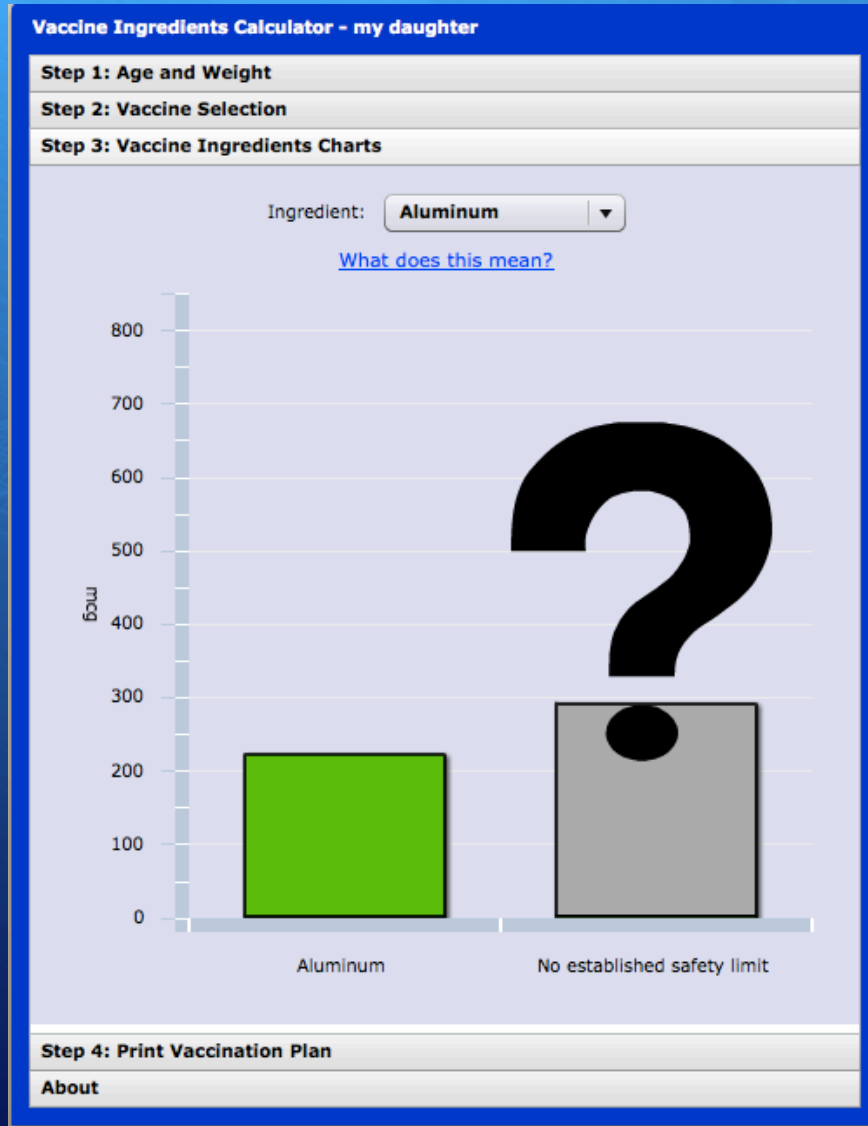
[Human Papillioavirus \(HPV\) - National Vaccine Information Center](#)

Read reports, articles and press releases provided by NVIC about **HPV** ... a true placebo to study **safety** but compared Gardasil against a bioactive aluminum ...
www.nvic.org

[Human Papillioavirus \(HPV\) - National Vaccine Information Center](#)

Human Papilloma Virus Vaccine **Safety**. Analysis of Vaccine Adverse Events Reporting System Reports: Adverse Reactions, Concerns and Implications.
www.nvic.org

I found the ingredients calculator and typed in HPV for "My Daughter"



What is a young adult or parent supposed to think?

If parents and teens don't immediately accept HPV vaccine, they likely have questions or beliefs based on misinformation

When talking with teens, be honest HPV vaccine hurts

Table 3: Rates (%) of Solicited and Unsolicited* Injection-Site and Systemic Adverse Reactions among Boys 9 through 15 Years of Age who Received Gardasil 9

	GARDASIL 9 N=639	Girls
Solicited Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)		
Injection-Site Pain	71.5	89.3
Injection-Site Erythema	24.9	34.1
Injection-Site Swelling	26.9	47.8
Oral Temperature $\geq 100.0^{\circ}\text{F}^{\dagger}$	10.4	6.7
Unsolicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)		
Injection-Site Hematoma	1.3	3.7
Injection-Site Induration	1.1	2.0
Unsolicited Systemic Adverse Reactions (1-15 Days Post-Vaccination, Any Dose)		
Headache	9.4	11.4
Pyrexia	8.9	5.0
Nausea	1.3	3.0

When talking to parents explain that:

- + Pain occurs in almost everyone (90%)
- + Swelling and redness are common too (30-40%)
- + Fever and hematomas are uncommon (3-5%)
- + Headache may occur in about 20%
- + SAEs are very rare – science does not support the scary stories on the internet
- + If there is any concern about an anxious teen, vaccinate in the supine position; insist on observation for 15 min

What about fainting (syncope)?

- Yes, it can occur
- Remember teens know shots hurt
- Explain you will take precautions

What about other rare disorders?

HPV has not been shown to be associated with:

- + Guillan Barre syndrome
- + stroke,
- + seizures,
- + venous thromboembolism
- + Autoimmune disorders

Ultimately, is it all a matter of vaccine safety?

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As a vaccine provider, you must be able to :

- Answer HPV safety questions calmly and accurately
- Remove these sources of concern so other potential concerns can be addressed
- After addressing the concerns, be ready to address other concerns

Use the “CASE” model



Corroborate

About me

Science

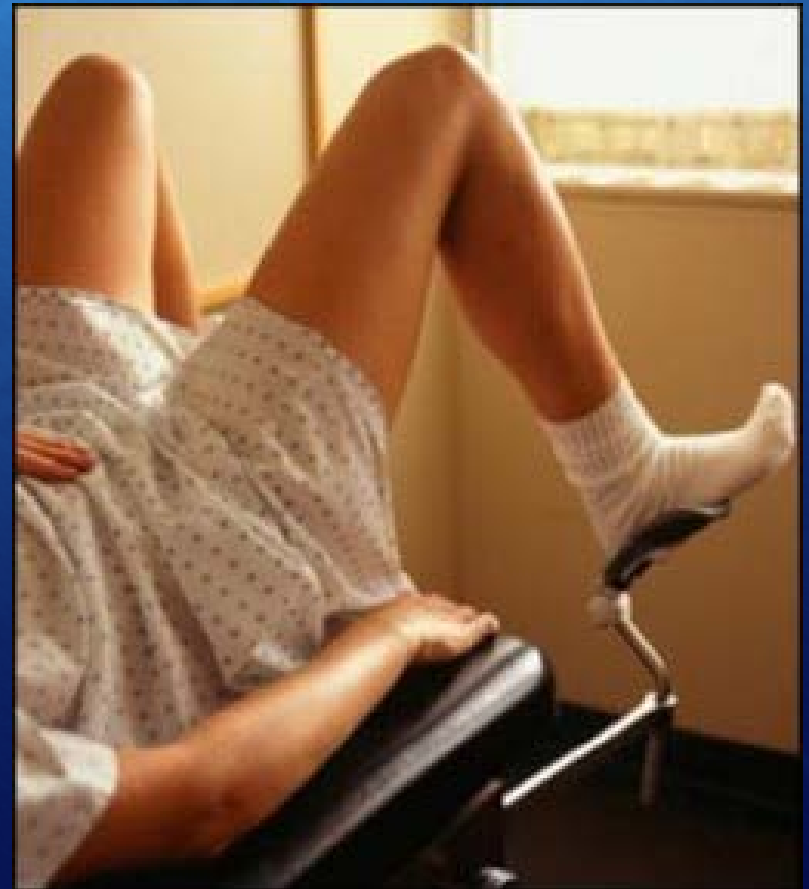
Explain/advise

Singer A. Autism Science Foundation. Texas Immunization Summit. www.immunizeusa.org/2010-summit-update/

Jacobsen R, et al. The C.A.S.E. approach: guidance for talking to vaccine-hesitant parents. Minn Medicine: 49-50.

Ultimately, I don't think any parent wants cancer for their child later in life....

Be patient and spend the time that it takes to move the parent past their vaccine safety concerns



Help them to understand that vaccinating their teen is truly in their best interests

