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DO WE REALLY NEED VACCINES?

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I am asked this question often along with many other vaccine questions regarding safety. The media is full of conflicting information. Vaccine use, numbers and timing change yearly. It is no surprise that both parents and patients are confused and worried. One hundred years ago children received one vaccine, the smallpox vaccine. Then, 40 years ago, the vaccines included five: diphtheria, tetanus, pertussis (also known as whooping cough), polio and smallpox which equaled about eight shots in the first two years of life. Today there are eleven vaccines that are given prior to the age of two equaling approximately 20 shots.

Before all these vaccines were available, the following statistics were true for the United States:

- Polio would paralyze 10,000 children
- Rubella or German measles, caused birth defects with mental retardation in as many as 20,000 newborns.
- Measles would kill 3,000 children a year.
- Diphtheria at that time was one of the most common causes of death in school-aged children.
- Pertussis would kill 8,000 children prior to the age of one year.
- The bacteria hemophilus (Hib) would cause meningitis in 25,000 leaving most with brain damage and many deaths.

When the question is asked, "Are vaccines safe?" that definition is usually free from negative effects and the answer is "no, there are side effects." All vaccines have possible side effects, most are very mild: pain, tenderness at the site, fever. Although most reactions can be treated, it is sometimes frightening. So, if there are some side effects, why not just avoid vaccines? Because you simply trade one risk for another, and it is not necessarily a better risk. Unvaccinated children are at risk for death, infection, blindness, deafness, seizures, scarring, pneumonia, liver cancer, sterility and birth defects to name a few. When you compare the risk of a vaccine versus the disease, the vaccines are clearly a much safer choice and one has to weigh the difference.

Children and adults, who are not immunized due to disease or illness that precludes vaccines, are part of what is called "protection by herd immunity." As long as the largest group is covered, the small numbers who cannot be vaccinated are relatively safe. The risk for this small group rises as more people choose not to get vaccines.

Another question raised is "Do children have a good immune system?" Absolutely! From the moment of birth newborns are challenged by thousands of different bacteria that start to live on

the intestinal surface and on their skin surface. By quickly making an immune response to these bacteria, babies keep disease from invading their bloodstream and causing serious infection. In fact, they are capable of responding to millions of different viruses and bacteria because they have billions of immunologic cells circulating in their body, thus vaccines given in the first two years of life are literally a rain drop in the ocean of what infants' immune systems successfully encounter in their environment.

Natural infection generally causes good immunity, sometimes more long-lived than immunity from vaccines, but the price paid for that immunity after a natural infection is quite high. From death to pneumonia to encephalitis, shingles, seizures and birth defects, those are all the side effects from natural immunity compared to vaccine side effects which are primarily soreness, fever and irritability.

There are some newer vaccines that are available now that not everyone is aware of. The old standbys most people know are tetanus, diphtheria, pertussis, polio, measles, mumps, rubella, chickenpox, even hepatitis B and haemophilus influenza B, as well as pneumonia.

The newer vaccines include hepatitis A which is a liver disease caused by contamination from poor hand-washing and frequently is spread in food. Zostrix is an adult booster vaccine for chickenpox recommended once you are 60 years of age.

The **HPV** vaccine, human papilloma virus, prevents the spread of papilloma virus responsible for causing cervical cancer and is recommended for the ages of 9 to 26. **Menactra**, a meningitis vaccine that replaces the old one given to young adults when they went off to college, is now recommended to start as early as two years of age. **Rotavirus** vaccine is for infants against a common cause of severe diarrhea, vomiting and fever in children. **Influenza** vaccine now comes in two forms; an injectable form which most people are familiar with, and an intranasal spray which is used for patients 2 to 49 years of age who do not have asthma or are immunosuppressed.

Lastly, but one that I think most people need to be very aware of, is the Tdap vaccine, which is the new booster vaccine for tetanus as well as for whooping cough for adults, anybody 18 up to 65. This vaccine replaces the old Td vaccine which we used to give as the booster for tetanus. We now booster whooping cough as adults are the primary source and spread of this illness.

Your care provider, physician, nurse practitioner, doctor, should give you a vaccine information sheet on any vaccine that you or your child will get. In addition, the Centers for Disease Control has a website at (www.cdc.gov) that you can go to for more information. The American Academy of Pediatrics has a great website (www.aap.org) with links about vaccines. There are websites that are not science or evidence-based, be wary of those.

For a very readable book that talks in greater depth about vaccines, I would recommend "Vaccines: What Every Parent Should Know" by Paul A. Offit and Louis M. Bell.



CONTROVERSIES IN THE TREATMENT OF OSTEOPOROSIS

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With dramatic media coverage of jaw necrosis, TV ads promoting osteoporosis drugs, and dentists and oral surgeons asking their patients to stop taking Fosamax or one of its cousins; it is difficult to know what the right thing is to do.

We have learned more about how to fine-tune the treatment of osteoporosis, and its less severe form, osteopenia, in the last couple of years. The DEXA or bone density scan and the new drugs to treat osteoporosis evolved together, but we are just now understanding how to use these tools better. The whole point of checking for osteoporosis and treating it is to prevent fractures, prevent loss of spine integrity (Dowager's hump), improve functioning and pain in those with fractures, and prevent crippling that can ruin a person's independence. The following will try to clarify some recent points of interest, controversy, and new data in this field. As always, if you are unsure how any of this may apply to you, please make an appointment with your health care provider to discuss your particular situation.

What are the risk factors for osteoporosis-related fractures?

Female, thin, caucasian ethnicity, smoking, family history, use of steroids past and/or present, some anti-cancer and anti-rheumatologic drugs, malnutrition, sedentary lifestyle, anorexia, amenorrhea (prolonged loss of menses when not pregnant, lactating or on hormones) poor intake or poor absorption of calcium and vitamin D, early loss of normal hormone support (like early menopause).

Should I take medication in the first place?

This is an important question. In the past, decisions for treatment with medication or not were made mostly on the basis of a person's bone density scan results. We now know that there are people out there with bone density scan result that normally would prompt a recommendation for medication who probably don't need it. What really needs to be taken into consideration is the person's whole risk profile, not just the T score (the bone density score). For example- a woman who is overweight, has no family history of osteoporosis, never smoked, but has an abnormal T score may not need to be treated. There is a new fracture risk tool developed by the World Health Organization (WHO) that takes all of these factors into consideration when producing a recommendation for treatment or not. This computer-based calculator will soon be incorporated with a person's bone density score. You can also view and use the risk assessment tool on-line at www.shef.ac.uk/FRAX

Men can get osteoporosis, too!

How long should I take medication?

Until recently, there was little data to guide how long to treat with one of the bisphosphonate medications. It now appears that 3-5 years of therapy should be followed by a 1-2 year break from the medication. After this 1-2 year hiatus, a repeat bone density scan and risk assessment should be done with your health care provider. Depending on your particular risk level going into treatment, this recommendation could be modified; for example during the 1-2 year break from Actonel or one of its cousins, a patient may need to take something like Evista to maintain the bone density he or she had regained.

What about jaw necrosis?

The press, as usual, has thrown out dramatic headlines about this relatively rare occurrence without really presenting the data. The jaw necrosis risk question only needs to be asked if you are taking one of the osteoporosis medications of the "bisphosphonate" type like Fosamax, Actonel, or Boniva. In addition, jaw necrosis is a risk if you take one of these medications and have recently had or are having a dental procedure which affects the jawbone itself, like dental implants or extractions. Dental cleaning or fillings are not risk factors. The risk also varies by type of medication. If you take one of the oral (by mouth) medications in the family of "bisphosphonates"; your risk of jaw necrosis is approximately 1 in 50,000. If you are getting one of the IV infusion drugs which include, Reclast or Zometa; your risk is approximately 1 in 5,000. This is a significant difference which highlights that even though there are ad campaigns in magazines and on TV about the convenience of once-yearly IV infusions, it might not be advisable to make a decision purely based on convenience. A small percentage of people cannot tolerate the by-mouth medications, and for these people the IV medications may be the best option. The IV version is also preferable for those with recent spinal fractures as the infusion may greatly reduce pain.

My oral surgeon told me to stop my medication and get a test called CTX – what is that about?

Oral surgeons are the ones who actually see and care for jaw necrosis, so they are cautious. The CTX test may help your oral surgeon and physician know where you are at with normal bone activity. However, it is still hard to know how long a person needs to be off of their osteoporosis medication before they are "safe" to have oral surgery because the medications have very long-lasting (many months) effects on bones. The best we can do is to give at least several months buffer between taking one of the medications and having oral surgery.

What other treatment options are there?

As usual, the foundation of bone health is in eating well, getting enough calcium and Vitamin D (1500 mg calcium and 800-1000 IU Vitamin D a day) through diet and/or supplements, getting some sunshine, and getting daily weight-bearing exercise. If you have one of the risk factors listed above which can be altered, alter it (like stop smoking). Beyond this foundation there are a couple of other options to treat high-risk individuals that are not bisphosphonates (Fosamax, Actonel, or Boniva). Two of these other options include Evista, a daily medication which acts on the bones like estrogen, but is an "anti-estrogen" for the rest of the body, and Forteo, a daily injection that works a bit differently than bisphosphonates.

CURRENT CLINICAL TRIALS

You may be eligible to participate!

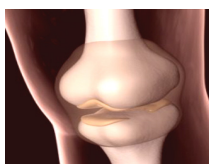
June / July 2008

For information, call: Josh Sallin, Research Coordinator
(406) 329-7386



TYPE 2 DIABETES—This study involves taking a study medication daily to see if the medication helps with diabetes control.

Eligibility Criteria: HbA1C > 7.5 Ages Eligible for Study: 18-79 years old Currently taking 2-3 medications for your diabetes for at least 3 months. **Note:** If you qualify, all visits and procedures are paid by the study. You will need to come to the clinic once a month and this study lasts for 7 months. Patients will be paid for time & travel.



OSTEOARTHRITIS (OA) OF THE KNEE—This study involves injecting a study medication or placebo into your affected knee.

Eligibility Criteria: Ages Eligible for Study: 35 -75 yrs old History of symptomatic OA of the knee for at least 6 months. No previous injections into the knee for the past 3 months. Have one bad knee and one good knee. **Note:** If you qualify, all visits and procedures are paid by the study. You will need to come to the clinic once a month and this study lasts for 6 months.



RHEUMATOID ARTHRITIS—This study involves receiving an infusion of a study medication or placebo.

Eligibility Criteria: Diagnosis of active rheumatoid arthritis of greater than 6 months duration. 6 or more swollen joints and 6 or more tender joints. **Note:** If you qualify, all visits and procedures are paid by the study. You will need to come to the clinic once a month and this study lasts for 6 months.



DEEP VEIN THROMBOSIS (DVT) or PULMONARY EMBOLISM (PE) - This study involves taking a study medication or placebo daily to see if the medication prevents the recurrence of a DVT or PE.

Eligibility Criteria: Currently being treated with Coumadin for the past 6-18 months and your physician is planning to stop coumadin. **Note:** If you qualify, all visits and procedures are paid by the study. You will need to come to the clinic once a month and this study lasts for 6 months. Patients will be paid for time & travel.

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