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Joint Implantation Outcomes: The Need for Broad Monitoring

LARGE SCALE MECHANISMS TO MONITOR JOINT IMPLANTATION OUTCOMES

Our presidential election is only days away, 48 million people in America are uninsured and healthcare costs are rising two to three times faster than our nation's GDP. Where will America's healthcare system be in five years?

Welcome to ReachMD's monthly series focus on public health policy. This month we explore the many questions facing healthcare today.

One of your patients undergoes routine hip replacement surgery. Months later you learn that they are now suffering with significant pain that appears to be secondary to the procedure. What is next for this patient? Is there a bona fide mechanism through which we can report both positive and negative procedural outcomes?

You are listening to ReachMD XM 157, the channel for medical professionals.

Welcome to a special segment focused on healthcare policy.

I am your host, Dr. Mark Nolan Hill, professor of surgery and practicing general surgeon and our guest is Dr. William Jiranek, Associate Professor of Orthopedics and Chief of the Adult Reconstruction Section of Orthopedic Surgery at the Virginia Commonwealth University School of Medicine. Dr. Jiranek. currently leads a campaign across the State of Virginia to create a statewide joint registry.

Dr. HILL:

Welcome Dr. Jiranek.

Dr. JIRANEK:

Thanks for having me, Mark, great to be with you.

Dr. HILL:

Dr. Jiranek, you hear about these incidences where patients are in agony months after a hip replacement. What are your thoughts about this? Why do they have pain?

Dr. JIRANEK:

I think there are a lot of reasons that people have pain and not all of them have to do with the implants. Some of them have to do with the patients; some of them have to do with the surgeon, I am sure. The reason that we are interested in this is there is not a good mechanism to track those problems in aggregate and so people hear about an isolated problem that patient A has, but they do not see how all the patients in the state or a country are doing and that's where we think that picking up on those trends in certain types of surgery and certain implants may help us protect patients. That's why we are trying to put this thing together.

Dr. HILL:

When you look at a patient and they have certain symptoms, how can you differentiate between a defective implant or some other process going on that has nothing to do with the prosthetic itself?

Dr. JIRANEK:

Well, I think that's why people go to medical school and why they train the orthopedist and they are fairly straightforward algorithms that we use to help diagnose a patient's pain. Certainly, history has always been the first thing you do, we all know that, and then physical exam and then radiographic studies. So certainly we learn a lot just from the history and the physical exam and that's often corroborated just by plain x-rays. We occasionally use more advanced studies CT, MRI, or nuclear studies.

Dr. HILL:

When we talk about a defective device, what is the defect we are referring to?

Dr. JIRANEK:

Well, I think there can be many manifestations of defective devices and what our registry hopes to collect is people who end up having to have repeat surgery as a result of some problem with their replacement and that can be everything from an infection to recurrent dislocations to an actual problem with the implant that causes failure of the implant become fixed to the bone or premature loosening or an allergic reaction to some of the materials. There are lots of things that can happen to implants.

Dr. HILL:

You know I can only speak from the general surgery perspective, but when we are learning and training about new prosthetic devices that we use in general surgery, the training we receive is actually from the manufacturer. Is this the same way in orthopedics and is this the best way to do it?

Dr. JIRANEK:

Yeah! I don't think that, the training is largely what we learn as residents and fellows and then from our patients; I would say that industry-sponsored training programs are part of an orthopedic surgeon's learning process, but I would not say that they are the most important and in some cases, they are not very important at all.

Dr. HILL:

How common are prosthetic device problems?

Dr. JIRANEK:

Well, that's a very good question, and I think without a registry it's hard to know. You know our reporting system thus far has been reporting adverse outcomes to the FDA and I think both the FDA and most surgeons agree that the process by which we report that is not a good one and consequently the adverse responses are under reported.

Dr. HILL:

What about when you talk to other orthopedic surgeons?

Dr. JIRANEK:

Well, when we look in other registries and other countries, Australia, England, Sweden, for example; I can't give you a specific percentage like 5% of all joint implants are defective and are bad, but they have been able to identify implants that don't work as well as our Gold Standard Implants and therefore questioned whether those implants should be on the market and have induced changes from manufacturers of those implants.

Dr. HILL:

Doctor, what if we need a widespread device review. Who would lead the review? Would it be the manufacturer or would there be other organizations that lead this and guide us?

Dr. JIRANEK:

It's my personal feeling that it should be led by the patient's advocate and I think the patient's advocate is foremost their physician. So I strongly feel that review of registry data should be done by physician organizations.

Dr. HILL:

Is there a database for this?

Dr. JIRANEK:

There isn't currently, which is why we are trying to get one started in the State of Virginia and hopefully in other states across the US. There are databases that exist in other countries.

Dr. HILL:

Well how does this information then get transmitted from orthopedic surgeon to orthopedic surgeon?

Dr. JIRANEK:

The idea is that the way it is transmitted in other countries, it is posted on a website available for the general public as well as other surgeons and that's what we envision happening in this country as well.

Dr. HILL:

How do the manufacturers feel about this national registry?

Dr. JIRANEK:

Well, I think that manufacturers have had some interest in supporting this kind of initiative, but it has not been well organized thus far. I wouldn't say that they have taken steps to try and avoid the development of a registry at all, but they have not developed internal registries within their companies.

Dr. HILL:

How did you personally deal with the first time or multiple times that you have had defective devices with respect to your communications with the manufacturer?

Dr. JIRANEK:

The current process is to report it to the FDA and we have done that. We have given feedback when there is not a gross adverse response to the manufacturer of things that are not working well and I think that generally they are quite responsive.

Dr. HILL:

They do not try to fight you and say that it's indeed not the device itself?

Dr. JIRANEK:

Well, in some cases, and we could run through a litany of products that the manufacturer felt that perhaps the problem was not with the product, but with the surgeon and how it was implanted and that is the impasse that we often find ourselves and that delay while that is figured out causes lots of the other patients to have the same device and potentially with the same problem.

Dr. HILL:

What do you tell to the patients?

Dr. JIRANEK:

About a device that we think is abnormal; it depends if it's a patient who has that device and is not doing well, we give them the diagnosis and talk about a solution problem and what we think caused the problem and I think then it's up to the patient to decide what they are doing from there?

Dr. HILL:

Now Medicare has recently released what they call “never events,” is this a “never event?”

Dr. JIRANEK:

I kind of disagree with the current Medicare “never events.” For example, two of the things that they say are “never events” are infection of a hip prosthesis and deep vein thrombosis, both of which we know even in the best of circumstances or best of hospitals still exist and will continue to exist, so never does it really make sense. How do you apply 'never' to a prosthesis. A prosthesis would never ingrow, or if a prosthesis didn't ingrow, didn't become fixed to the bone is that a “never event?” Well, there are a lot of things that can lead to a bone not fixing to a prosthesis other than a defect in the manufacturing and that's where it gets sticky. So I don't think they could really say that an adverse response to a prosthesis is a “never event.” I think there would be too many individual differing circumstances to be able to come up with a blanket "never" rule. I think the whole concept of a "never" is pretty crazy in medicine because both you and I and everybody else listening have seen everything that can happen, does happen.

Dr. HILL:

I think everyone listening agrees with you 100% on that, but when we talk about the times when patients have to have their prosthetics changed because of a defect, who covers this cost of surgery?

Dr. JIRANEK:

Well, it's interesting if a manufacturer has issued a recall, the manufacturer covers the problem or a settlement is developed. If the problem is not identified, then the insurer covers the problem, which is why a lot of insurers including HIPAA are very interested in this problem and how big a problem it actually is.

Dr. HILL:

Now, do we have plaintiff lawyers breathing down the neck of the patients who might require this type of surgery?

Dr. JIRANEK:

Well, it's interesting. There was an article in the New York Times about registries that mentioned specific companies, specific product and that week after that article I googled the name of the product and the first four pages were attorney websites. So I think it's a real problem and it highlights how we deal with this data. If we do identify a problem that is more common with the specific prosthesis, how do we induce a change without driving everybody into bankruptcy?

Dr. HILL:

In general surgery, one of the most common procedures that I do obviously are hernias, and as you are well aware, there was a prosthetic that had significant problems. I received, when this became public, many, many calls from patients over the ensuing months asking if they had this type of mesh implanted and I could tell by their demeanor and their tone that they were potentially very, very worried. When you have had a device that has been made public as one that has been recalled and such like that, do you get calls like that from the patients and you implanted them?

Dr. JIRANEK:

Oh, very commonly a lot of those calls and lot of it is reassurance, but you are right, it's something that induces a lot of apprehension.

Dr. HILL:

Well, what do you say to the patient who has one of these devices, but not having a problem?

Dr. JIRANEK:

Well, exactly that. I tell them that it is the prosthesis under question, but not all of these prostheses have had problems and that we would continue to monitor their status.

Dr. HILL:

I want to thank our guest, Dr. William Jiranek.

We have been discussing large scale mechanisms to monitor joint implantation outcomes.

I am Dr. Mark Nolan Hill and you have been listening to a special segment focused on healthcare policy on ReachMD XM 157, the channel for medical professionals.

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