The Essentials of Informed Consent

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Medow: The three critical elements of informed consent are to explain the risks, benefits, and alternatives to performing a surgical procedure or treatment. Case 1 is a 1-year-old boy with a congenital 60 to 70 prism diopter alternating cross-fixing esotropia. You have seen him two or three times. He has no need for prescriptions and you’ve decided that it’s time to consider surgery. What do you tell the patient’s parents?

Grigorian: I would tell the parents that surgery is the best option to reestablish the eye alignment and develop binocularity. There are risks involved in surgery, but they are minimal compared to the benefits.

Medow: Do you discuss the anesthetic complications?

Grigorian: I mention it but I let the anesthesiologists provide specific information. The risk of blindness often comes up in the discussions with the parents. As in any surgery, there is risk of decreased vision in strabismus surgery. This can be caused by endogenous infection, such as a simple sore throat, or may be exogenous during or after the procedure. This is why I emphasize to the parents that surgery cannot take place if the child has a fever or any sign of infection. I also warn the parents of possible signs of postoperative infection and see them all in follow-up 3 days after the surgery.

Medow: Do you talk about perforation?

Grigorian: Yes. Perforation is another risk, but it’s minimal and we will try to avoid it.

Hoehn: Usually I have already discussed the option of surgery with the parents, so by this point it’s not a new concept and the parents are at least somewhat receptive to it. I recommend that this would be the child’s best chance of achieving binocular vision. Studies show that if the child is surgically aligned before 2 years of age or before the strabismus has existed for more than a year, then the chances are much better. So early surgery does seem to correlate with better sensory outcomes, better depth perception, and better binocular vision. At this point, because the child doesn’t need glasses, there’s really no other way to align the eyes but with surgery.

Medow: Do you tell them about anesthetic complications?

Hoehn: If they ask.

Medow: If they don’t ask, you leave it to the anesthesiologist to discuss that.

Hoehn: Yes, which they do at my hospital.

Medow: Suppose the parents say they assume only one operation will be necessary.

Rosenberg: I always discuss the possibility of overcorrection and undercorrection. In this case, I think it likely that the child will need another surgery. So I mention that this may require more surgery in the future.

Medow: Then the parents ask, how often does that occur?

Rosenberg: I try to avoid using percentages because they can be confusing for patients. I usually just say we’re going to take it one step at a time and see how things go, but I am fairly confident in this case that I can make it significantly better even if it’s not perfect.

Medow: Do you give them the informed consent and ask
them to go home and discuss it or do you have them sign it right then and there?

Rosenberg: I have them sign it then. I find that the text we have regarding the risks is not at an appropriate level for our patients or their parents, so I summarize each paragraph and then I tell them to take their time and look through it. Most of the parents do not read it at all and they sign on the spot. If there is another parent who can't be there, I offer them the opportunity to come back with the other parent or I can speak to them on the phone.

Medow: What do you write in your chart regarding the consent process? Do you write each item that you discussed or just a general statement?

Rosenberg: I write everything on the consent form and then I just refer to the consent in the chart. “The consent was signed. All risks, benefits, and alternatives were discussed.” I don't rewrite it in detail.

Hoehn: I have two main children's hospitals where I operate and one of the consent forms doesn't allow me to write in specific risks, benefits, and alternatives. The other one does.

Medow: What about in the chart?

Hoehn: We use electronic medical records, so we click on a button that spells everything out in detail, including further surgery, diplopia, infection, loss of vision, and loss of the eye.

Medow: Is there anything that the university has not included that could occur?

Hoehn: It does not specifically mention perforation.

Grigorian: I refer patients to the AAPOS web site and tell them what to look for regarding strabismus surgery. They can call me with questions, but usually it's on the day of surgery that they ask me questions and they sign the form.

Medow: So you give them time to digest what you've talked about.

Grigorian: Yes.

Medow: Case 2 is a 4-month-old infant with a congenital cataract. There is no family history or genetic work-up. The eye is normal size and B-scan is normal. You think surgery is indicated. Do you discuss the same risks, benefits, and alternatives that you did for strabismus surgery or are they different?

Grigorian: I tell the patients that surgery is indicated and there are risks that go with it. The risks include glaucoma, infection, and loss of the eye. However, the benefits of having vision in that eye outweigh the risks.

Medow: What if the parents say they don't want to have surgery? They know someone who had an operation and doesn't see with that eye.

Grigorian: Many times when the parents hear the word surgery they want to back off, but we have to educate them.

Medow: You've educated them and on the day of surgery they call you in the morning and say that they've decided to wait. You've told them that the longer you wait the poorer the results are going to be, but they've decided they don't want to have surgery now.

Grigorian: We have to do a better job of informing them because this is something that has to do with knowing about the condition. If you don't know, you cannot make the right choice.

Medow: Do you call the social service staff?

Rosenberg: This is not a case where I think child protection is necessary. I agree about educating the family and doing your best to make sure they understand, but unlike a case of congenital glaucoma, which you really can't let go, this patient has one normal seeing eye.

Medow: Should you allow the parents to make the decision even after informed consent? You've discussed it with them, they appear to understand everything, and they tell you they want to wait or that they don't want to do the surgery.

Rosenberg: The next step may be to encourage them to get a second opinion from someone I respect. Sometimes just hearing the same things from another person is helpful.

Medow: What else do you discuss with the parents of this child?

Hoehn: I agree with everything that's been said, but I really try to stress how important surgery is and basically tell them in no uncertain terms that the eye will not see if you don't take the cataract out. It may still not see well, but it's not going to see anything better unless we do surgery now.

With strabismus, you don't know if the patient is going to develop binocular vision or that the outcome is going to be any different if you wait a year, but you know with the cataract that it certainly will be. I'm much more definitive about surgery being necessary with cataract. I describe all of the potential risks, including the lifelong risk of retinal detachment and glaucoma, but I go back to the fact that if we don't do it now, the eye will never see.
**Medow:** Case 3 is a 30-year-old man with a 60 prism diopter alternating congenital esotropia who has never had surgery. He’s been single all his life but wants to find a partner so he decides to have his eyes straightened. Do you recommend surgery?  

**Grigorian:** Definitely. I would do that.  

**Medow:** You’re not going to tell him he’s going to fuse?  

**Grigorian:** No. I’m going to help him find a partner.

**Medow:** Case 4 is a 35-year-old woman who has had three previous strabismus operations. She’s a 9 diopter myope. She comes to you having been esotropic and then had a consecutive exotropia that was operated on 2 or 3 years ago. The records of the previous surgeries are not available. You look at the four horizontal muscles under the slit lamp and they all have scars on them. In your informed consent, is there something different that you might discuss with this patient rather than the patient with congenital esotropia at the age of 1 year or the 4 year old with an exotropia that was intermittent and now is constant?  

**Grigorian:** She would have a high risk of reoperation and also perforation because of being myopic.

**Medow:** She’s already had three surgeries and you are proposing a fourth surgery with a high risk of needing more. When you operate and take off the muscle you might find thin sclera or uvea or you might perforate the globe. Would you hang back the muscles in those cases or do you put them in the sclera?  

**Grigorian:** Depending on how it looks, I like to put them in the sclera.  

**Rosenberg:** Right.

**Hoehn:** I also like to put them in the sclera.

**Rosenberg:** Right.

**Hoehn:** I tell the patient that because she’s already had three surgeries there’s a higher risk that her muscles may not be as expected and there may be intraoperative complications that we can’t foresee, such as perforation. Sometimes when hooking the muscle in a very thin sclera, it can come off or the tip of the muscle hook can go into the eye. So I would be very frank with that patient in that situation because she’s going to have extensive scarring with that many surgeries.

**Medow:** You talk about the risks of infection, perforation, and needing other operations, but you don’t necessarily spell each of those out because you don’t know.  

**Hoehn:** Right. That’s why I would say there are some risks that we can foresee and some that we might not be able to foresee.

**Medow:** Are there any pearls that we can impart to our readers on informed consent? I think the important element is that the patient understands exactly what we plan on doing. There’s an art to talking to patients because each patient is different in terms of their intellectual abilities to understand. We’re all used to talking one particular way, but sometimes we have to modify how we talk because of who we are talking to.

**Rosenberg:** One other thing that has been shown to be effective with informed consent is doing a teach back where you ask the patient or the parents to repeat what you just told them. I often find when I do that they didn’t get the message at all.

**Medow:** For 5 years I taped the consent with my fellow or my associate present. These were all intraocular cases (glaucoma, corneal transplant, and cataract), not strabismus cases. Then 5 months later, after the cataract was removed and the child’s vision improved and there were no complications, I would go back and ask them whether they remembered the consent and the possible poor outcomes I mentioned. They said they didn’t remember so I turned the tape on and they’d say, “Oh, we did discuss that.” They never remembered the worst potential outcomes unless it happened, and then they’d always say I never told them that might happen, even if I did. I abandoned the taping because it was so adversarial.

This Eye to Eye session was conducted on Thursday, April 3, 2014, during the annual meeting of the American Association for Pediatric Ophthalmology & Strabismus.

Drs. Grigorian, Hoehn, Medow, and Rosenberg have no financial or proprietary interest in the materials presented herein.

doi: 10.3928/01913913-20140819-03