



O&P Risk Advisor

RISK MANAGEMENT NEWSLETTER FOR THE ORTHOTICS & PROSTHETICS BUSINESS OWNER

FAQs about informed consent

Informed consent is an integral part of the practitioner/patient relationship. In addition to its legal function of protecting practitioners and businesses from malpractice lawsuits, it also plays an ethical role by recognizing the patient's autonomy and dignity, and demonstrating respect for the patient's right to make treatment decisions.

Informed consent is particularly important for orthotics and prosthetics practitioners, where the proper fit often takes time to achieve and where new products are frequently used. Not all fittings are successful. Fulfilling informed consent requirements through discussions with your patients helps you manage their expectations and avoid anger and disappointment. Follow your organization's policy for informed consent, and review these frequently asked questions (FAQs) to ensure your knowledge is up to date.

What is informed consent?

Informed consent isn't simply a signed piece of paper. It's the process of explaining treatment options, including no treatment at all, to patients so they can weigh the risks and benefits of each before making a decision to accept—or not accept—treatment. According to *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and still used as guidance today, informed consent has three principles: adequate information is provided, participants comprehend the information, and consent is given voluntarily.

When should I obtain informed consent?

Most orthotics and prosthetics practitioners understand the need to obtain consent before treating a new patient. However, you also should obtain consent when fitting patients with new devices, when making major fitting adjustments, when a patient's cognitive status changes, and when you update your records.

Don't make the mistake of having an outdated consent form on file. Much can happen, for example, in just 2 years of a patient's life. He or she may develop dementia, which a court hearing a malpractice claim will say invalidates the original consent. You can avoid this situation by obtaining consent with the designated patient representative.

If possible, don't wait until right before you are ready to fit a new prosthesis or make a significant change before you obtain consent. The patient may feel pressured to sign the form and not ask all of his or her questions.

How should I obtain informed consent?

Allow plenty of time to talk with the patient so you establish a connection and fully answer any questions. Explain options to patients before they read the form. To increase their understanding, explain why the care team recommended different options. For instance, you might say that research supports using a specific type of prosthesis in the patient's particular situation. Help patients understand that fitting an orthotic or prosthesis often involves "trial and error." Reassure patients that although an initial fitting might not be successful, you will work with them to attain the comfort and mobility they need.

Use the strategy called "teach-back" to

ensure the patient's understanding. In this method, patients state their understanding of key elements of the information they receive. This gives you the opportunity to correct misunderstandings.

Most practices have patients sign a paper consent form. There should be a space for you to sign as well. Some organizations use electronic signatures and file the forms electronically. Place the form in the medical record and document you obtained informed consent, including the method used to give the patient the information, who was present during the discussion, and that you gave the patient a copy of the consent form.

What should I do if...?

Special situations may arise when obtaining informed consent. The consent form needs to be in a language that the patient—or his or her authorized representative—understands. You'll also need an interpreter to translate the information you are exchanging with a non-English speaking patient.

Obtain consent from parents of children under age 18, but for children older than 6, you may want to use an age-specific form to obtain the child's consent. Check state guidelines for situations when you only need the child's signature on the consent form such as an emancipated minor.

Providing informed consent promotes a respectful, effective relationship between practitioners and patients. It can help avoid a day in court and protect patients from harm.

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Caution: Telephone advice

As an orthotics and prosthetics business owner, you or your employees may give telephone advice. Whether it is responding to clients calling about the fit of their new device, their treatment options, or making an appointment, you're in a position to provide valuable information.

But in your eagerness to help clients, you and your employees must be careful not to expose your business to legal risks. Here are some tips to protect yourself while providing clients with quality information.

Consistency counts

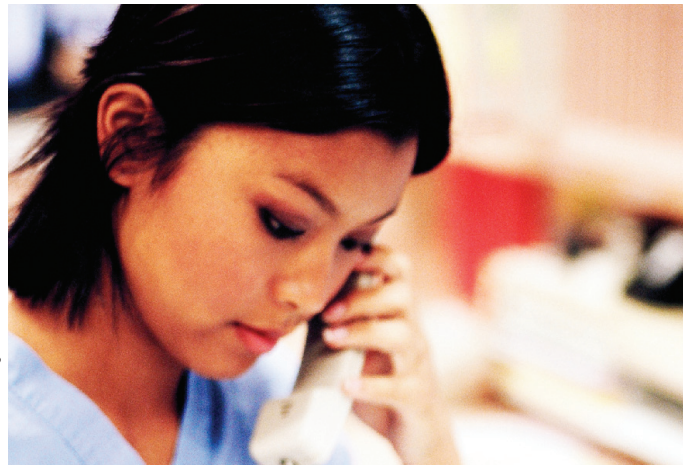
Consistency helps ensure that questions are answered completely and effectively. Protocols and responses to frequently asked questions are useful tools that also reduce legal risk.

Tools should be predicated on current stan-

dards, so be sure to review them on a regular basis and update as needed. Anyone who will be responding to questions should receive special training in how to speak with clients over the phone.

If it isn't written...

In the hectic rush of the day, it's easy to neglect documenting telephone calls. Treat each client-related telephone call the same way you would a face-to-face visit: Document the conversation, the advice given, and any follow-up instructions. Regular review of documentation will help maintain quality and identify areas of improvement.



Building relationships

Remember that giving advice over the phone establishes a relationship with your clients. Keep your telephone skills sharp so the relationship yields positive results.

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