

Doctors yes, assistants no

Laurance Jerrold

Brooklyn, NY

Can a qualified member of a doctor's staff obtain a patient's informed consent, or should that task be done by the practitioner himself? This question was recently addressed by the Supreme Court of Pennsylvania Middle District in *Shinal v Toms*, No. 31 MAP 2016. (Pa. Sup. Ct. June 20, 2017)

The facts of the case reveal that the plaintiff (the patient) had a 20-minute consultation with the defendant (the surgeon) concerning the regrowth of a pituitary tumor that had been partially removed years earlier. The tumor was now encroaching on her carotid artery, affecting her hormone function, jeopardizing her eyesight, and causing her severe headaches. If left untreated it would become life threatening. The patient expressed that she had a 9-year-old child who she wanted to "be there" for. The defendant took that to mean that if he believed he had a reasonable chance to successfully remove the tumor in its entirety, with reasonable downside risk, he should go ahead. The defendant claimed that he discussed the risks and possible consequences of both a partial and total resection, with the latter obviously carrying more risk of an adverse outcome. The partial resection offered the least risk of any significant injury, the best short-term outcome, but with a good chance of regrowth, whereas the total resection offered the best chance for long-term survival but could result in blindness or complications regarding the carotid artery. The patient agreed to have the surgery but at that point in time did not decide on total versus partial resection.

A few weeks later, the plaintiff had a telephone conversation with the surgeon's physician's assistant asking about scarring, the need for radiation, and the craniotomy incision. A month later, she went to the hospital and signed an informed consent form for the surgery, a resection of recurrent craniopharyngioma, acknowledging the risks of "pain, scarring, bleeding, infection, breathing problems, heart attack, stroke, and death." The consent form also stated that the plaintiff had been made aware of the advantages and disadvantages

of alternate treatments, that she understood the form, and that she had the opportunity to ask and have answered any questions.

During the surgery, a total resection, the carotid artery was perforated resulting in hemorrhage, stroke, brain injury, and partial blindness. The plaintiff sued for lack of informed consent, claiming that she had never been offered the alternative of partial resection with the lowered risk potential followed by radiation. She claimed that the only thing she could recall about the 20-minute conversation was that she could go into a coma or die.

After the trial closed, the court issued the following jury instruction: "In considering whether Dr Toms provided consent to Mrs Shinal, you may consider any relevant information you find was communicated to Mrs Shinal by any qualified person acting as an assistant to Dr Toms." The jury returned a verdict for the defense. The plaintiff asked for post-trial relief, opining that the jury instruction was an incorrect statement of the law. The Court denied the request. The plaintiff appealed, and the Appellate Court upheld the Trial Court's ruling in favor of Dr Toms, stating that "information communicated to a patient for purposes of obtaining informed consent may be conveyed by a qualified professional acting under the attending doctor's supervision." The plaintiff then brought this appeal to the state Supreme Court.

The Supreme Court looked at the trial transcript of the objected-to instruction that the judge gave to the jury. His words exactly were:

Now, I phrased it that way because it's within your province to determine a recollection of the evidence you heard, who said what, who those people were that said these things, and whether they were assistants to Dr Toms, you know, working under him. And I said qualified person. There are different types of qualifications of medical personnel. And it is up to you to determine whoever you remember provided information to Mrs Shinal, it's up to you to determine whether they were a qualified person working as an assistant to Dr Toms ...

The plaintiff's claim was that the instruction given was in violation of Pennsylvania Statutory Law (40 Pa. C.S. § 1303.504) known as the MCARE Act. This statute

Chair, Division of Orthodontics, and Program Director, Orthodontics and Dentofacial Orthopedics, NYU Langone Hospital, Brooklyn, NY.

Am J Orthod Dentofacial Orthop 2019;155:600-3
0889-5406/\$36.00

© 2019 by the American Association of Orthodontists. All rights reserved.
<https://doi.org/10.1016/j.ajodo.2019.01.007>

deals with informed consent in Pennsylvania.

The act mandates:

- (a) **Duty of physicians.**—Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:
- (1) Performing surgery, including the related administration of anesthesia
 - (2) Administering radiation or chemotherapy.
 - (3) Administering a blood transfusion.
 - (4) Inserting a surgical device or appliance.
 - (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.
- (b) **Description of procedure.**—Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted medical standards of medical practice would provide.
- (c) **Expert testimony.**—Expert testimony is required to determine whether the procedure constituted the type of procedure set forth in subsection (a) and to identify the risks of that procedure, the alternatives to that procedure and the risks of these alternatives.
- (d) **Liability.**—
- (1) A physician is liable for failure to obtain the informed consent only if the patient proves that receiving such information would have been a substantial factor in the patient's decision whether to undergo a procedure set forth in subsection (a).
 - (2) A physician may be held liable for failure to seek a patient's informed consent if the physician knowingly misrepresents to the patient his or her professional credentials, training or experience.

The defendant, on the other hand, argued that yes, a doctor has a duty to obtain a patient's informed consent but that the physician is not required to do this personally. The defendant proposed that "it is the information conveyed, rather than the person conveying it, that determines informed consent."

When functioning in an appellate capacity, the reviewing court has to determine whether the trial court

"committed a clear abuse of discretion or error of law controlling the outcome of a case." This is because an erroneous charge to the jury could be "wholly inadequate, unclear, or [have] a tendency to mislead or confuse a material issue." In addition, in matters of statutory construction and interpretation, the reviewing court "cannot ignore the plain meaning of a statute when the words ... are unambiguous, ... nor can we disregard the plain meaning of an unambiguous statute in order to pursue its spirit."

The legal issue to be resolved was whether or not a doctor can fulfill his duty to obtain informed consent, in whole or in part, through members of his staff. The court noted that to ensure informed consent is obtained, the practitioner has a duty to "inform the patient about the risks, benefits, likelihood of success, and alternatives ... [by providing patients with] ... sufficient information to give the patient a true understanding of the nature of the operation to be performed, the seriousness of it, the organs of the body involved, the disease or incapacity sought to be cured, and the possible results." (Cits. Omit.)

The court noted that this responsibility comes into being only through the existence of a doctor-patient relationship resulting in the establishment of a pseudo-contract wherein both parties "understand the nature of the undertaking and what the possible as well as the expected results might be." Up until this point in time, established case law had held that "the validity of a surgical patient's informed consent depends on the pre-treatment information relayed to the patient, regardless of whether the disclosures are made by the treating physician or another qualified person such as a nurse or other assistant." (Cit. Omit.)

A prior case had decided that doctors, not hospitals, had the duty to obtain a patient's informed consent. A portion of that decision stated:

It is the surgeon and not the hospital who has the education, training and experience necessary to advise each patient of the risks associated with the proposed surgery. Likewise, by virtue of his relationship with the patient, the physician is in the best position to know the patient's medical history and to evaluate and explain the risks of a particular operation in light of the particular medical history. (Cit. Omit.)

The Pennsylvania Supreme Court used the same logic, based on common law principles, to overrule prior case law in Pennsylvania and decide that moving forward,

... a physician cannot rely upon a subordinate to disclose the information required to obtain informed consent. Without direct dialogue and a two-way exchange between physician and patient, the physician cannot be confident that the patient comprehends

the risks, benefits, likelihood of success, and alternatives. Informed consent is a product of the physician-patient relationship. The patient is in the vulnerable position of entrusting his or her care and well-being to the physician based upon the physician's education, training, and expertise. It is incumbent upon the physician to cultivate a relationship with the patient and to familiarize himself or herself with the patient's understanding and expectations. Were the law to permit physicians to delegate the provision of critical information to staff, it would undermine patient autonomy and bodily integrity by depriving the patient of the opportunity to engage in a dialogue with his or her chosen health care provider. A regime that would countenance delegation of the informed consent process would undermine the primacy of the physician patient relationship. Only by personally satisfying the duty of disclosure may the physician ensure that consent is truly informed.

... Thus, we hold that a physician may not delegate to others his or her obligation to provide sufficient information in order to obtain a patient's informed consent. Informed consent requires direct communication between physician and patient, and contemplates a back-and-forth, face-to-face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent. The duty to obtain the patient's informed consent belongs solely to the physician.

The appellate decision was reversed, and the case remanded for a new trial.

COMMENTARY

To be honest, this case left me quite conflicted. There is no question that the court got it right. The statute is quite clear; except that it is not—at least as far as orthodontics is concerned. It holds that the doctor should obtain informed consent before “conducting the following procedures,” but orthodontics is not one of the listed procedures. Then, just to cover all of the bases, the statute requires expert testimony to determine if the procedure performed, let's say orthodontics, fits in to one of the enumerated categories. It's easy to visualize a few hundred orthodontists lined up on the steps outside of the courthouse waiting to come in and testify that (A) orthodontics is not one of the enumerated medical conditions covered by the statute and (B) it's okay for an orthodontist to delegate obtaining informed consent to a qualified subordinate. If I were the President of the Pennsylvania Association of Orthodontists, I would be seeking a declaratory opinion from the state's Attorney General clarifying the fact that informed consent, at least in the arena of orthodontics, is not governed by the

statute but does fall under the umbrella of the prior precedential decisions allowing delegation of this task. After all, if the statute has to be taken at face value and is unambiguous and clear in its language and intent, then only those 5 procedures, and any others as determined by expert witnesses, require a physician to personally obtain the patient's informed consent. In all other areas, a qualified person should legally be allowed to obtain the required consent.

Ah, but what about my internal conflict? The court alluded to it: It was the spirit of the statute. The bioethicist in me (yes, I am one) firmly believes that informed consent should be obtained by the practitioner. To me, this is where the rubber meets the road. I cannot imagine a more opportune time to solidify and enhance a doctor-patient relationship than by directly participating in the informed consent process. This is where you have the opportunity to show the patient how much you care. Oh, and nothing for nothing, if you don't care enough or place enough importance on demonstrating your concern to the patient, the bioethicist in me questions your values and motivations as a health care practitioner. Informed consent is what patient autonomy is all about.

As to what characteristics or training is required for one to be considered a “qualified person” under the Pennsylvania statute, that is another matter altogether. For decades, practice management gurus have been touting the virtues of using a treatment coordinator to explain the need for treatment, what the doctor proposes to do to address the clinical situation, the need for any ancillary or interdisciplinary treatment that may be required, and those nasty things such as time and money and cooperation needs, as well as to answer any questions the patient may have. I know that many states have provisions for licensing assistants, but treatment coordinators? I'm not so sure. So what makes somebody qualified to obtain informed consent under the law? No clue, unless on-the-job training and having attended specific staff programs at our various national, constituent, or component meetings count. There are tons of research reports out there showing just how little patients recall from an informed consent discussion, and if I as the doctor might be held responsible for not telling a patient about X, Y, or Z, then I want it to be because I, not my treatment coordinator, did not tell them.

However, as an orthodontics entrepreneur, which I was for a long time, I really don't have a problem with delegating the informed consent process; but you have to be willing to put your money where your mouth is. What I mean by that is, in the end, only you are responsible for the quality of the information given and the

sufficiency of the consent obtained. I feel that way as an attorney and as a risk-management educator too. But, if you are going to delegate it, the process had better be good and it has to stand up to scrutiny. And finally, all you guys and gals have to stop believing that merely handing somebody a booklet or a form and having

them sign it constitutes fulfilling your legal and moral obligations regarding this issue. If you believe this ... well, you were misinformed.

In the end, we will all have to paraphrase William Shakespeare and ask: "To delegate or not to delegate, that is the question." I told you I was conflicted.