Informed Consent Ruling Could Burden Physicians, Experts Say

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Excess caution after a Pennsylvania legal decision about informed consent could unnecessarily burden physicians and sideline other qualified healthcare professionals from the process of helping patients understand risks and benefits of treatments, according to lawyers who've studied the case Shinal v Toms.

Holly Fernandez Lynch, JD, MBE, and colleagues from the Department of Medical Ethics and Health Policy at the University of Pennsylvania Perelman School of Medicine in Philadelphia, examined the potential consequences of a 2017 decision from the Pennsylvania Supreme Court. In a 4-to-3 decision, the court ruled that a physician may not "fulfill through an intermediary the duty to provide sufficient information to obtain a patient's informed consent."

The court's insistence that "the treating physician personally provide all consent-related disclosures is an anachronism in a team-based health care system," Lynch and colleagues write in an article published online today in the New England Journal of Medicine.

"From the patient's perspective, physicians' time may be better spent on those specialized tasks that only they have the skill to perform, while other members of the team participate in the consent process as they do in other clinical tasks for which they are appropriately trained and supervised," they continue.

"This is not to suggest that we place efficiency above the quality of consent in terms of importance or priority; instead, we maintain that both goals can be achieved simultaneously," they add.

The Pennsylvania court's decision stemmed from a 2008 case handled by Steven Toms, MD. He perforated the carotid artery of Megan Shinal during a total resection of a recurrent craniopharyngioma, leading to permanent severe neurologic injury. Toms testified at trial that he discussed with Shinal her goals and the risks and benefits of total vs subtotal resection, including the potential harm that ultimately occurred, Lynch and colleagues explain. Shinal decided to undergo surgery, but the question of whether to proceed with total vs subtotal resection was unresolved at the time of the initial consultation with Toms, the authors note. Shinal subsequently spoke with the physician assistant about scarring, the craniotomy incision, potential radiation, and the date for surgery.

Shinal signed a consent form indicating that she had discussed the risks and benefits of alternative treatments. "However, the form did not specifically address the differential risks of the two surgical options," Lynch and colleagues write.

Shinal later sued, claiming that Toms failed to explain the surgery's risks. Shinal maintained that had she known that a lower-risk subtotal resection was an option, she would have pursued that alternative instead. In an initial ruling, a jury was instructed that it could consider information that had been communicated to Shinal by a qualified person such as the physician's assistant when assessing whether Toms had satisfied his legal duty to obtain consent.

The jury returned a verdict in favor of Toms, which an intermediate appellate court affirmed. But the Pennsylvania Supreme Court subsequently reversed that ruling.

The supreme court's deciding is now having an influence well beyond the state and beyond the specialty of surgery, said Valerie Gutmann Koch, JD, from the MacLean Center for Clinical Medical Ethics at the University of Chicago in Illinois.

Before this case, there had not been a lot of major litigation in the field of informed consent in recent decades, she told Medscape Medical News in an interview.

"It's a pretty big deal," Koch said about the Shinal case. "A lot of folks are definitely paying attention and are changing their policies and procedures to adapt to this decision, and not just in the state of Pennsylvania. There has been a lot of consideration outside of the state and in other settings."

The case is influencing clinical research as well, with institutional review boards seeing the Shinal decision as requiring that only physician investigators perform informed consent, she said.

"So this is being read quite broadly by institutions, by [institutional review boards], by physicians," she said.

Similar to Lynch and colleagues, Koch sees the Pennsylvania Supreme Court's decision as reflecting an outdated view of medicine centered on a single physician caring for patients. Many medical practices used team-based approaches. In teaching

hospitals, residents and other healthcare professionals are engaged in every step of treatment, including the informed consent process, she said.

"This is really a judicial reaction, a judicial insistence, that we go back to some extent to the traditional doctor–patient relationship, as it used to exist," she said of the Pennsylvania Supreme Court's decision.

Similar to the authors of the New England Journal of Medicine article, Koch argues against concentrating the responsibility tightly on the physician. She published an article last year in the Hasting Center Report making similar recommendations to ones offered by Lynch and colleagues.

Both papers call for the developments of systems in which qualified healthcare professionals can aid in helping patients understand risks and benefits of treatments, while still resting the responsibility for this task with the physician.

Lynch and colleagues suggest having the treating physician describe the patient's options at a high level and make a preliminary recommendation for an appropriate course of treatment. Other healthcare professionals under the physician's supervision would then educate the patient about risks and benefits of relevant alternatives, actively seeking to elicit the patient's values and goals. The treating physician would rejoin the process to address final questions and uncertainties, assisting the patient in confirming a final decision.

"We suspect that the patient would probably emerge from this process more informed and would make a decision with more confidence than would have been possible after a short office visit with the treating physician," Lynch and colleagues write.

In her paper, Koch suggested streamlining the informed consent process for complex medical or surgical interventions and designating a single individual or committee to whom the patient can go whenever a question or concern arises.

"It must be acknowledged that disclosures from multiple parties — physicians, physician assistants, hospitals, and so on — could potentially lead to increased confusion and the potential for conflicting information," she wrote.

Koch also argues for making sure that these discussions don't present a financial burden for health care providers. "[G]uaranteeing reimbursement or compensation for the informed-consent process may help ensure that these discussions do not get delegated to those who are insufficiently trained or are not well suited to the task," she wrote.

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