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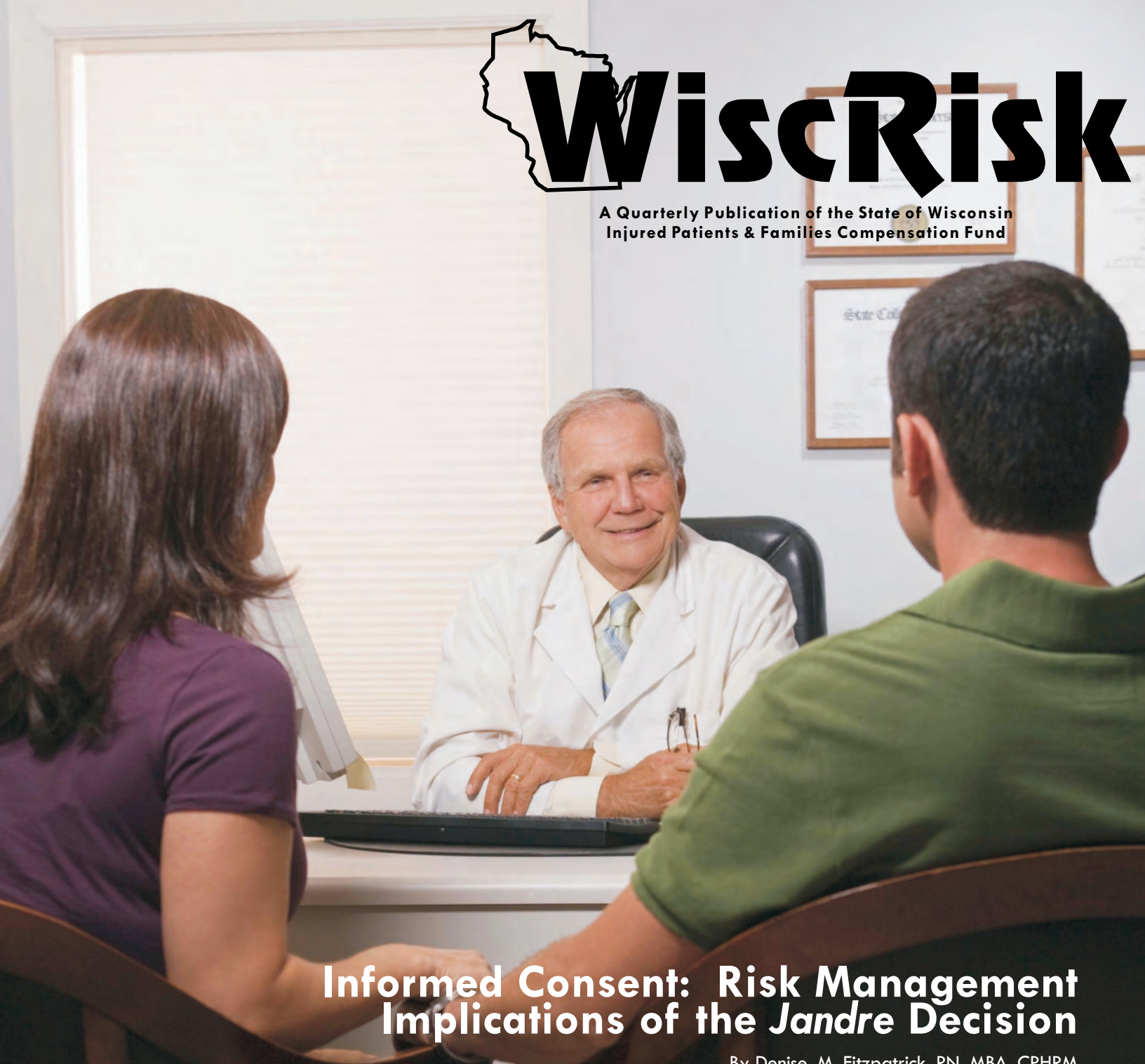
A Quarterly Publication of the State of Wisconsin
Injured Patients & Families Compensation Fund



Informed Consent: Risk Management Implications of the *Jandre* Decision

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In previous issues of this newsletter we have discussed the physician's responsibilities associated with providing informed consent to patients as it relates to medical treatments and procedures. However in April 2012 the Wisconsin Supreme Court expanded the idea of informed consent to include a physician's duty to inform patients about treatment and diagnostic options that the physician does not recommend. This ruling appears to expand the responsibility of the physician to include informing the patient of diagnostic tests and procedures for aspects of the differential diagnosis that they believe they have already ruled out. While the facts of the *Jandre* case involve a physician in the emergency room setting, the court's interpretation of the statute applies to all practice settings.

Informed consent is defined by Webster as consent to surgery by a patient or to participation in a medical experiment by a subject after achieving an understanding of what is involved.

The Wisconsin Supreme Court issued its decision in *Jandre v. Wisconsin Injured Patients and Families Compensation Fund* on April 17, 2012. The key issue was whether the emergency department physician in this case had a duty to inform the patient about the availability of a carotid ultrasound. The carotid ultrasound would have been part of the evaluation for a stroke/transient ischemic attack (TIA), conditions the physician believed she had sufficiently ruled out. It is not a test for Bell's palsy, which was her final diagnosis of the patient. The Court of Appeals concluded that the physician had a duty to inform the patient about the test. The Supreme Court affirmed the decision of the Court of Appeals. [1]

The patient, Thomas Jandre, presented to the emergency room after experiencing a variety of symptoms, including slurred speech, drooping of the left side of his face, unsteadiness and weakness in his legs. The emergency room physician evaluated the patient. Her differential diagnosis included Bell's palsy, stroke, TIA, tumor, Guillian-Barre and multiple sclerosis. After examining the patient and conducting various tests (including a CT scan), the physician ruled out stroke, TIA, and several other conditions and diagnosed the patient with Bell's palsy. The emergency room physician's diagnosis was confirmed three days later by the patient's family medicine physician. Eight days after the patient's visit to the emergency room, he suffered a stroke.

Informed consent is defined by Webster as *consent to surgery by a patient or to participation in a medical experiment by a subject after achieving an understanding of what is involved*. Prudent risk management strategies encourage physicians to obtain a patient's informed consent for non-routine and higher risk treatments and procedures. Unfortunately, with the *Jandre* decision the law of informed consent is being expanded beyond its original scope and purpose to include not only treatments and procedures but also *evaluation*.

[1] Wisconsin Medical Society – Wisconsin Supreme Court Issues Decision in the *Jandre* Informed Consent Case, 2012.
[2] Wis.Stat. §448.30 *Information on Alternate Modes of Treatment.*

In Wisconsin physicians have a statutory obligation to obtain patients' informed consent. However, this decision expands the physicians' obligation and raises questions about the scope of informed consent and how much treatment information doctors should provide about conditions for which patients are not diagnosed. Wis. Stat. §448.30, *Information on Alternate Modes of Treatment* provides that: *Any physician who treats a patient shall inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. The physician's duty to inform the patient under this section does not require disclosure of:*

1. *information beyond what a reasonably well-qualified physician in a similar medical classification would know.*
2. *detailed technical information that in all probability a patient would not understand.*
3. *risk apparent or known to the patient.*
4. *extremely remote possibilities that might falsely or detrimentally alarm the patient.*
5. *information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.*
6. *information in cases where the patient is incapable of consenting.*[2]

In the *Jandre* decision the court has declared that it is the patient's symptoms, not the diagnosis that drives the duty to "inform" in a case. While the language of Wis. Stat. §448.30 focuses on informing the patient of treatment, the Court read into this language both **evaluation** and treatment for possible differential diagnoses regardless of whether it is the end diagnosis the physician arrives at. For example, a carotid ultrasound is not a treatment for stroke/TIA but can be part of the evaluation. So based on this decision a physician would not only need to inform the patient about treatment options for stroke but also options for additional diagnostic tests that the physician doesn't feel are necessary.

From a risk management perspective the fundamentals of the informed consent process consists of two equally important elements: communication and documentation. Prudent risk management suggests that the following information should be included in the informed consent process:

- Communicating the information that any patient in similar circumstances would reasonably wish to know
- Describing the recommended evaluation, treatment or procedure clearly and simply, avoiding medical jargon and providing a qualified interpreter if necessary
- Explaining how the recommended evaluation, treatment or procedure relates to the patient's condition or diagnosis, why it is indicated and what are the risks
- Discussing reasonable alternatives, including receiving no treatment, and describing the material risks and benefits of each option
- Informing the patient if the recommended treatment is experimental, unconventional or unusually hazardous
- Ensuring that the patient understands the information provided by encouraging questions and asking the patient to describe the treatment/procedure in his/her own words.

Sometimes missing in the communication aspect of informed consent is confirmation of the successful exchange of information. Studies have shown most patients retain less than 30 percent of the information initially shared with them. Prior to discharging a patient they should have an opportunity, as appropriate, to review and process the information provided, reflect on their values and interest, to ask questions and to make an informed decision.

Processes and tools to help demonstrate that communication has transpired include the following:

- **Simple discharge instructions**—use discharge instructions that are understandable across all levels of health literacy and address differential diagnoses. As such, the instructions should be written in simple sentences and in the primary language of the patient. There should be virtually no question that the information being communicated can be easily understood and details can be recalled about the diagnosis and evaluation/treatments.
- **Support materials**—use non-technical language when explaining a diagnosis and evaluation/treatment options. Use written materials, models, or audiovisual aids to supplement your discussions.
- **Engage patients**—engage patients in discussion regarding the diagnosis and differential diagnosis that have been ruled out. Such interactions are appreciated by the patient and facilitate their care decisions.
- **Interpreters**—where deemed necessary, use an interpreter. Moreover, translated discharge instructions should be utilized for segments of your non-English-speaking patient population. The guidance promulgated through the U.S. Department of Health and Human Services is to translate "vital written materials" in languages spoken by 5 percent of your patient population.
- **"Teach Back" method**—ask the patient to restate the salient aspects of information that has been imparted through the diagnosis discussion process. The patient should be able to accurately repeat back the diagnosis and treatments, the risks involved the consequences of not having the treatment or procedure and the treatment/procedure's benefits.

Medical record documentation should convey the essence of the communication between the practitioner and patient. Documentation should be sufficiently explicit so that another person reviewing the record will be able to derive both what the patient was told and whether the patient had a reasonable understanding of the implications. Documentation should also record the presence of all individuals present – including family, friends, guardians and or significant others. While the *Jandre* decision appears to have expanded potential liability against providers clear communication and detailed documentation are the best risk management strategy.

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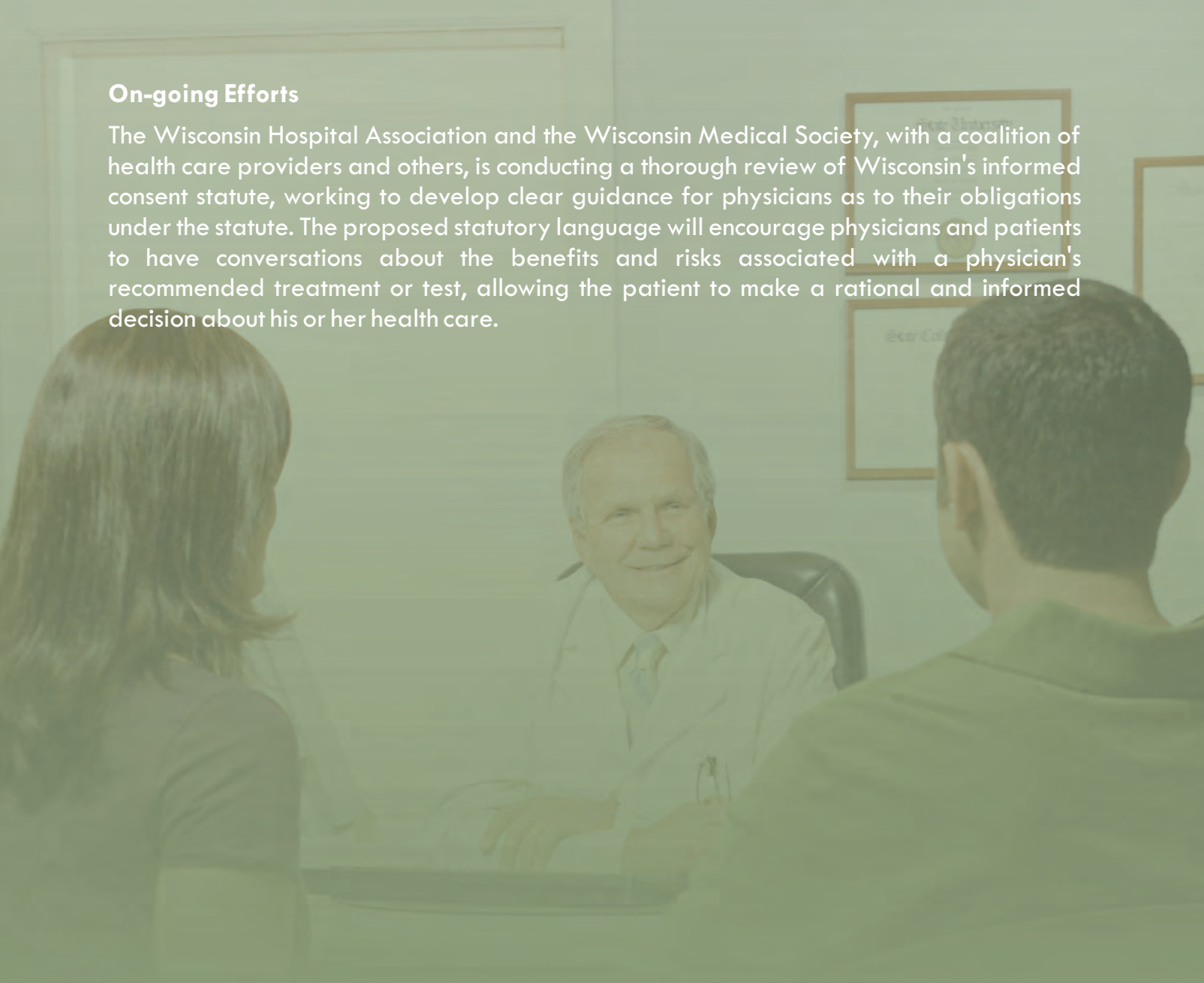
On-going Efforts

The Wisconsin Hospital Association and the Wisconsin Medical Society, with a coalition of health care providers and others, is conducting a thorough review of Wisconsin's informed consent statute, working to develop clear guidance for physicians as to their obligations under the statute. The proposed statutory language will encourage physicians and patients to have conversations about the benefits and risks associated with a physician's recommended treatment or test, allowing the patient to make a rational and informed decision about his or her health care.



About WiscRisk

WiscRisk is published quarterly and circulated to more than 14,000 healthcare providers statewide. Designed to keep readers informed of trends in liability claims and loss prevention, this publication is prepared by the Risk Management Steering Committee for the Injured Patients & Families Compensation Fund.

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