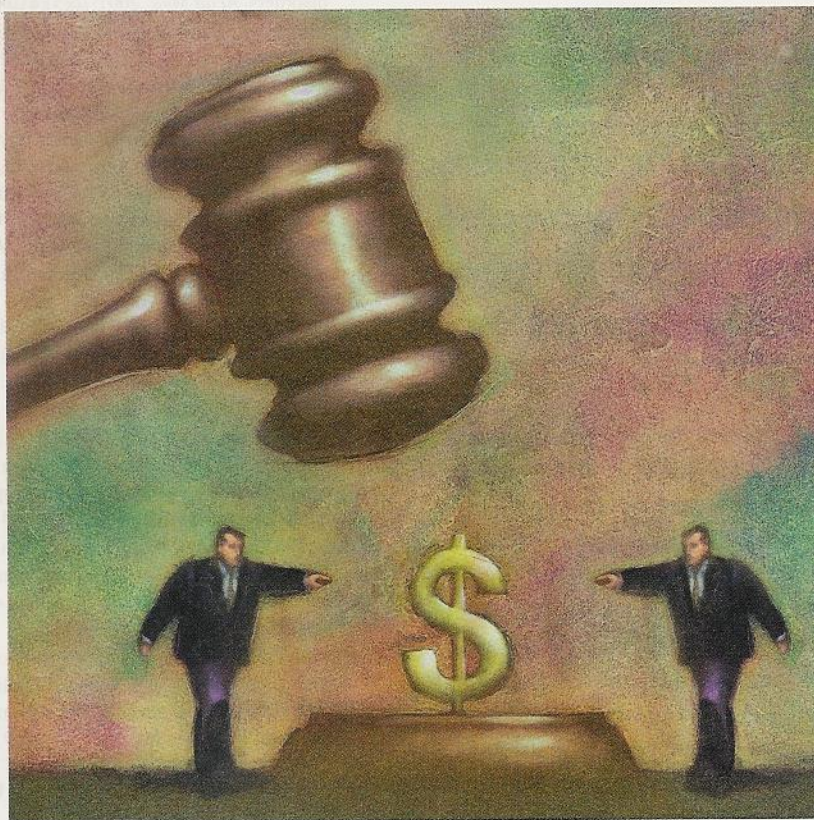


Informed Consent: Do You Know It When You See It?

Evaluating the adequacy of patient consent and the value of a lawsuit



In the modern era of medical practice, informed consent is a central tenet of the health provider-patient relationship,¹ as well as a subject of clinical research² and, under unfortunate circumstances, an

element in malpractice litigation.^{3,4} In the last context, failure to obtain proper informed consent may be an element of the claimed negligence in a malpractice suit. The classical elements of informed consent have

been noted as information — the “informed” in informed consent; voluntariness — the “consent” in informed consent; and competence — the patient’s capacity to take in and process relevant information.¹ The usual universe of information considered legally germane to decision making includes the risks and benefits of the proposed treatment, of other alternative treatments and of “no treatment.”

Informed consent could be described as a statement about the clinical and moral atmosphere of the relationship,⁵⁻⁷ expressed in an ongoing dynamic process or dialogue of openness and honesty, which begins at the moment of eye contact and endures throughout the relationship. Both parties essentially engage in mutual informing of each other over time, gradually familiarizing each other with their respective values, world views, and reasoning.

A central role and effect of good informed consent is risk management and liability prevention after a bad clinical outcome. The effect on risk management is twofold. True

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informed consent diminishes surprise, a factor that is solely responsible for a great deal of malpractice litigation.¹ In addition, informed consent fosters and underlies the therapeutic alliance, which we construe to be among the most powerful elements of prevention of liability.⁸ Informed consent requires health providers to exercise their capacity for perspective-taking by integrating the patient's point of view with that of the provider's. As this process fosters better communication and a provider-patient alliance, patients may feel less powerless and immature, and the doctor may feel more collaborative. All these factors may decrease potential liability.⁹

We infer the value of recognizing when true informed consent has occurred for all parties then or subsequently involved. Health providers would be able to self-monitor to be sure that they had communicated successfully with their patients about the medical issue. Patients would recognize that they had or had not been validly informed and would then give an authentic consent to the medical treatment in question. Finally, jurors, confronting a malpractice case in which "failure to obtain informed consent" was claimed, could render a fairer verdict on the evidence.

THE MODEL OF HIERARCHICAL COMPLEXITY: AN ADULT DEVELOPMENTAL STAGE THEORY

Formally, for a task to be more hierarchically complex than another, the new task must meet three requirements. First, a more hierarchically complex task and its required action is defined in terms of two or

more less hierarchically complex tasks and their required task actions. Second, the more hierarchically complex task organizes or coordinates two or more less complex actions; that is, the more complex action specifies the way in which the less complex actions combine. Third, the coordination of actions that occurs must be nonarbitrary; it cannot affect just any chain of actions. Each new, task-required action

options; describing their benefits and side effects; and verifying the patient's understanding. Obtaining "consent" includes four abstract propositions: offering the patient the choice of treatment plan; giving the patient the time to decide on a treatment plan; determining that the patient is competent; and obtaining the patient's assent (ie, agreement) to the execution of the chosen treatment plan. Also here, true informed consent requires

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in the hierarchy is one order more complex than the task-required actions on which it is built.¹⁰ This hierarchy has been shown to account for performance in a variety of different domains, including:

- Physics tasks: balance beam and pendulum;^{11,12}
- Kohlberg's moral interviews;^{13,14}
- Views of the "good life";^{15,16}
- Loevinger's Sentence Completion task;¹⁷
- Workplace culture and organization;^{18,19}
- Political development;²⁰
- Relationships between more and less powerful persons such as doctors and patients;^{21,22} and
- Therapists' decisions to report patients' prior crimes.²³

"Informing" in the present context includes three actions: presenting a range of possible treatment plans or

coordination between the system of "informing" and the system of obtaining "consent." Counselors must determine whether the patients are satisfied with both the amount and the quality of the information presented before soliciting their consent.

True informed consent reflects a very high order of hierarchical complexity and therefore a correspondingly high stage of performance; the less complete the informed consent process, the lower the stage that it represents. A very good counselor would perform at the systematic or metasystematic stage. These, along with the lower stages, are discussed below.

THE PRESENT STUDY

Order of hierarchical complexity of informed consent should help predict how positively mental health

TABLE 1.

Order of Hierarchical Complexity of Counselors and Degree of Informed Consent

	Brown	Jones	Corey	Kents	Bower	Spire	Flynn	Lewis	Smith	Heath
Order	8	8	9	9	10	10	11	11	12	12
Informing										
Options	0	0	0	1	0	1	1	1	1	1
Side Effects	0	0	1	0	1	1	1	1	1	1
Understanding	0	1	0	0	1	0	1	1	1	1
Consent										
Coordination1	0	0	0	0	0	0	0	1	1	1
Choice	0	0	0	0	0	1	1	1	1	1
Time	1	1	1	1	1	0	1	1	1	1
Assent	1	1	1	1	1	1	1	1	1	1
Informed Consent	2	3	3	3	4	4	6	7	7	7
Rasch Scaled Score	1.39	.86	.38	.53	.24	-.11	-.41	-1.51	-1.35	-3.65

practitioners are seen and whether or not they will be sued. This study consisted of brief vignettes of counselors obtaining informed consent. Each vignette represented an order of hierarchical complexity as explained in the introduction. Rasch²⁴ analysis was used to determine — in an objective, empirical manner — the degree of perceived effectiveness of informed consent in each vignette.

Method

The 118 participants in the study were a convenience sample of stu-

dents, friends, and relatives of a group of graduate students from Salem State College in Massachusetts. There were 74 women and 44 men, ages 18 to 74 (mean = 36.28; standard deviation = 13.253), with 10 to 26 years of education (mean = 16.35; SD = 2.928).

Instrument

The vignettes illustrate interactions between counselors and patients in a negotiation about treatment in “another country.” Interaction in the vignettes ranges down-

ward from true informed consent to varying degrees of coercion, appeals to authority and conformity, and attempts to get the patient to identify with the counselor’s viewpoint or with the counselor’s implicit values of success, fame, celebrity, morality, research, role, popular opinion, up-to-date medicine, and the like.^{20,24}

Table 1 lists the order of hierarchical complexity of each of the vignettes and how many elements of informed consent were in each of the various vignettes. Order 12, metacognitive reasoning, required participants to see which counselors made comparisons among the different “systems” of informed consent — that is, complete representations of informed consent.

For example, “Counselor Heath” describes treatment options and their side effects and ensures that the patient understands what Heath has been describing: “Then Heath asks the patient questions about the treatments, making sure the patient

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understood.” During the consent phase, Heath not only offers choices and asks if the patient is ready to make a decision but also refers back to the informing discussion: “Heath asks if the patient feels comfortable making a decision with the present information.” This comment ties the informing and consenting systems together. All lower order vignettes are more incomplete.

Concrete order counselors Brown and Jones base their ideas of what is good for the patient on what their own experience has been. The patient would not be expected to have any part in deciding which treatment to choose and would therefore not need to be well-informed about options or be expected to understand the choices in treatment and potential side effects. Participants received from five to 15 vignettes in either one, two, or three sets of five. The entire instrument is available on request.

Determining If Participants Recognized Informed Consent

First, participants rated how well the counselors obtained informed consent on a scale of 1 to 6. Then, “given that each counselor’s treatment failed, they rated how likely is it that each counselor’s method would make him or her personally liable for damages or malpractice” on a 7-item scale running from 1 to 99, where 1 = “no chance” and 99 = indicated “certainty.” Next, they rated how likely each counselor was to be sued, and finally, how much money the patient should be awarded in the event of actual legal proceedings.

Results

The participants were highly sen-

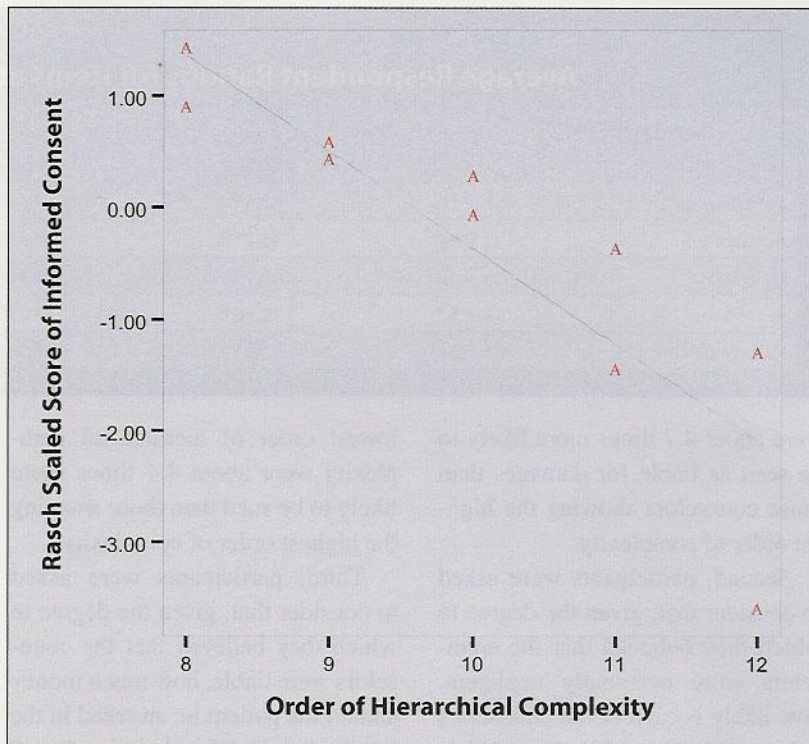


Figure 1. Regression of order of hierarchical complexity versus Rasch scaled score of informed consent [$r(8) = .879, F(1, 8) = 27.144, P < .001, r^2 = .772$].

sitive to how well informed consent was carried out. The order of hierarchical complexity of a counselor’s method of informed consent very strongly predicted its Rasch scaled

counselor’s method would make him or her personally liable for damages or malpractice. The order of hierarchical complexity of a counselor’s method of informed consent very

The counselors exhibiting the lowest order of hierarchical complexity were about 4.7 times more likely to be seen as liable for damages than those counselors showing the highest order of complexity.

stage, $r(8) = .879, F(1, 8) = 27.144, P < .001, r^2 = .772$ (Figure 1).

The answers to the second set of questions as to the likely forensic consequences were striking. Participants were told that each counselor’s treatment had failed. First, they were asked how likely it was that each

strongly predicted respondents’ raw ratings for this item, $r(8) = .957(a), F(1, 8) = 87.717, P = .0005, r^2 = .916$. Table 2 (see page 434) provides average raw ratings of this item at each order; also see Figure 2 (page 434). The counselors exhibiting the lowest order of hierarchical complexity

TABLE 2.

Average Respondent Ratings for Items at Each Order

Order of Hierarchical Complexity of Informed Consent	Average Rating of Informed Consent	Average Likelihood of Being Held Liable	Average Likelihood of Being Sued	Average Amount of Money Awarded to Patient
Concrete (8)	2.17	67.63%	64.06%	\$56,702.64
Abstract (9)	2.93	46.71%	43.45%	\$45,331.83
Formal (10)	3.30	40.23%	43.45%	\$43,775.06
Systematic (11)	4.57	16.48%	17.81%	\$32,014.63
Metasystematic (12)	5.58	14.51%	14.69%	\$28,555.73

were about 4.7 times more likely to be seen as liable for damages than those counselors showing the highest order of complexity.

Second, participants were asked to consider that, given the degree to which they believed that the counselors were personally negligent, how likely is each of the counselors to be sued? Again, the order of hierarchical complexity of a counselor's method of informed consent very strongly predicted respondents' raw ratings for this item, $r(8) = .944(a)$, $F(1, 8) = 65.658$, $P = .0005$, $r^2 = .891$. The counselors showing the

lowest order of hierarchical complexity were about 4.4 times more likely to be sued than those showing the highest order of complexity.

Third, participants were asked to consider that, given the degree to which they believed that the counselors were liable, how much money should the patient be awarded in the event of actual legal proceedings? Note that they were told that the severity of the bad outcome was the same for all of the patients. Again, the order of hierarchical complexity of a counselor's method of informed consent very strongly predicted re-

spondents' raw ratings for this item, $r(8) = .911(a)$, $F(1, 8) = 38.899$, $P = .0005$, $r^2 = .829$. Table 2 provides average raw ratings of this item at each order; also see Figure 2. The counselors showing the lowest order of hierarchical complexity would be sued for about twice the amount of the counselors showing the highest order of complexity.

DISCUSSION

The order of hierarchical complexity of the informed consent vignettes predicted the Rasch-scaled responses to those vignettes extremely well. This empirically confirmed that the vignettes accurately reflected the order of hierarchical complexity for which they were designed. Participants found it increasingly difficult to differentiate informed consent quality as the vignette order of hierarchical complexity increased. This should hold true for healthcare providers as well. Rasch-scaled scores formed a single dimension of difficulty in recognizing the quality of informed consent. This scale could be used to assess how well healthcare providers understand some fundamentals of informed consent.

Further, the results indicate that

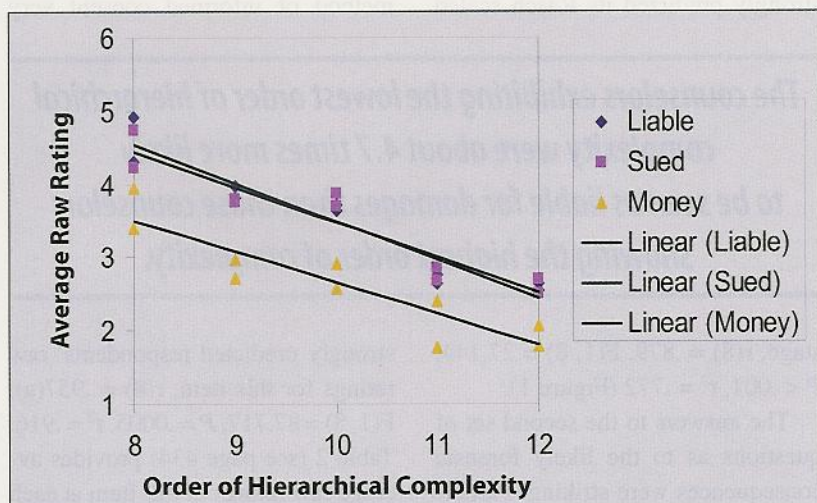


Figure 2. Regression of order of hierarchical complexity versus respondents' raw ratings of likelihood of being held liable [$r(8) = .957(a)$, $F(1, 8) = 87.717$, $P = .0005$, $r^2 = .916$]; likelihood of getting sued [$r(8) = .944(a)$, $F(1, 8) = 65.658$, $P = .0005$, $r^2 = .891$]; and amount of money likely to be awarded to patient [$r(8) = .911(a)$, $F(1, 8) = 38.899$, $P = .0005$, $r^2 = .829$].

the order of hierarchical complexity of informed consent predicts how positively counselors are viewed. Some healthcare providers would not be expected to obtain true consent from their patients without special training, which our participants lacked. Sensitivity to differences among the clinicians' methods was a powerful predictor of litigation behavior as predicted. Training could be required to increase health providers' awareness of their responsibility to inform patients of the risks and benefits of a range of treatments, as well as to raise clinicians' awareness of their own role in soliciting information and obtaining consent. The counselor-patient instrument could be used to screen new health providers to see which ones might need such training. The patient would enter the therapeutic relationship understanding the "rules," which would result in better treatment. The study offers support for the positive role of informed consent in risk management.

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