Malpractice Risk Assessment Among Different Approaches For Informed Consent

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Abstract

Introduction: The standards for obtaining informed consent, set forth by the Hawaii Revised Statutes, establish that it is the physician's duty to disclose what a reasonable person objectively needs to hear in order to make an informed decision. It is the purpose of this study to report the opinions of medical malpractice attorneys to survey their opinion whether full or limited disclosure of alternative treatments in informed consent is viewed as having a lower malpractice risk.

Methods: Hawaii medical malpractice attorneys viewed a compilation of arguments for and against both full and limited disclosure, and completed an opinion survey after reading samples of disclosure statements in two different case scenarios: 1) a pediatric emergency department case involving a febrile child at risk for occult bacteremia, and 2) an obstetrics case involving a woman with a postdate pregnancy.

Results: A vast majority of respondents believe that, in general and in the obstetrics case, full disclosure results in less liability. In the pediatrics ED case, 46% chose full disclosure as having less liability, 38% believe that the same liability exists with both full and limited disclosure, and 15% believe that limited disclosure is associated with less liability in this case.

Conclusions: Hawaii attorneys with medical malpractice experience overwhelmingly agree that, in general, full disclosure is associated will less medical legal liability. Full disclosure was also the option selected as associated with less liability by a majority of attorneys in a sample obstetrical case. Opinions were more diverse in the pediatrics ED case. Many attorneys stressed that judging the risk of liability in general is difficult, and should be done on a case by case basis.

Introduction

Throughout much of the history of medicine, the authority to make medical decisions rested solely with the physician. This paternalism was justified by two factors, 1) the belief that patients did not have the ability to fully understand the complexities of medical decision-making, and 2) the physician has a duty to protect the patient from serious harm.[1] Although these factors are still valid, it is now considered unacceptable for the physician to make medical decisions without obtaining informed consent from the patient[2]. In *Schloendorff v. New York Hospital* (1914), Justice Cardozo wrote, "Every human being of adult years and sound of mind has a right to determine what shall be done with his own body"[3] This opinion has been supported by medical literature[4-7] and court decisions.[7] In 1983, Hawaii State law regarding standards of informed consent was written as follows, in the Hawaii Revised Statutes §671-3(b)[8]:

> "If the standards established by the board of medical examiners include provisions which are designed to reasonably inform a patient, or patient's guardian, of:
> 1) The condition being treated;
> 2) The nature and character of the proposed treatment or surgical procedure;
> 3) The anticipated results;
> 4) The recognized possible alternative forms of treatment; and
> 5) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment or surgical procedure, and in the recognized possible alternative forms of treatment, including nontreatment,
>
> then the standards shall be admissible as evidence of the standard of care required of health care providers."

On the topic of informed consent, §671-3 HRS states that standards must be designed to "*reasonably inform* a patient or patient's guardian." Further, it specifies that the provider must inform a patient of the "recognized possible alternative forms of treatment; and the recognized serious possible risks, complications, and anticipated benefits involved..." Physicians are not required to inform a patient of all treatments, all risks, and all benefits of each, but are required to disclose "what a reasonable patient needs to hear from his or her physician in order for the patient to make an informed and intelligent decision regarding the course of treatment or surgery."[9,10,11] The intention of the law was not only to protect patient autonomy, but also to establish "a defense to the action" for physicians, thereby lessening liability[12] (i.e. a physician who complied with the requirements set forth in the statute could present this evidence at a malpractice trial as proof that he or she had complied with the standard of care). The difficulty with the statute arises from the ambiguity of the term "reasonably inform". It is logical to assume that nearly every person believes that he or she is reasonable, thereby transforming the reasonable person standard to an individual person standard – the physician must tell each individual what that person subjectively needs to know in order to make an informed decision. A proposed solution to the ambiguity of the reasonable person standard is for the physician to provide full disclosure to all patients.

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In theory, full disclosure should completely protect the physician from any liability stemming from a patient's claim of lack of informed consent. However, some studies have found that when presented with more information, and a greater variety of options, some patients choose options that may not be in their best medical interest[13]. In a recent study involving febrile children at risk for occult bacteremia, in 81% of cases, parents opted for no tests and no treatment if the physician made no recommendations (left the decision up to the parents). Published survey results of a hypothetical case scenario involving a 6-week old febrile infant reveal that, when given a choice, parents often opted for fewer tests and less treatment[14]. These studies demonstrate that when presented with more information, parents often choose the less aggressive option, even if that choice subjects their children to greater risk. It is unclear whether fully involving patients in medical decisions (i.e. fully informed consent) may subject the physician to greater risk of liability. Common arguments for and against full disclosure and limited disclosure are summarized in Table 1.

Table 1.— Medical arguments comparing limited and full disclosure

Arguments for limited disclosure

1. Patients do not have the ability to fully understand the complexities of the medical decision making process.
2. This is a medical decision which should be made by medical professionals and patients should not be making this decision.
3. Patients do not want to make medical decisions. This is why they seek the expertise of physicians to make this decision for them.

Arguments against limited disclosure

1. This is a high liability situation, since if a bad outcome occurs, it will be argued that the physician failed to adequately disclose the availability of other medical management options which the patient may have preferred.
2. This approach fails to respect patient autonomy and is inconsistent with currently accepted doctrines of informed consent which must include the disclosure of alternative medical management options.

Arguments for full disclosure

1. Patients prefer to be informed of all the medical options even if they have difficulty fully understanding the complexities of the decision making process.
2. Patients prefer to be involved (have the right of choice or veto) in medical decision making.
3. Physicians are responsible for the patient's comprehension of their medical care.
4. This approach respects patient autonomy and is consistent with currently accepted doctrines of informed consent which must include the disclosure of alternative medical management options.

Arguments against full disclosure

1. This takes too much time; more time than a physician realistically has. An in depth discussion of all the medical options for some medical conditions may take 30 minutes to 2 hours depending on the depth of understanding desired and the previous educational background of the patient.
2. Patients may have several conflicting goals. They may avoid the benefits of a certain choice because of an irrational fear of some of the other aspects of this choice. Physicians fear that providing information about rare and unexpected risks may cause patients to refuse medical care which is most likely to be beneficial.
3. This is a high liability situation, since if a bad outcome occurs, it will be argued that the doctor let the patient (who is not a medical professional) choose the medical management option. The patient will argue that he/she is not a medical professional and thus, is incapable of truly understanding everything about all the medical management options.

It is the purpose of this report to determine whether, in practice, full disclosure or limited disclosure is associated with a higher risk of liability, by drawing on the expertise of Hawaii attorneys with experience in medical malpractice cases.

Methods

A pediatrician drafted an "Emergency Department Pediatric Case" for this survey. This scenario involves the case of a 14-month-old female child presenting to the ED with a fever of 40° C and a suspected viral infection. Full and limited disclosure explanations of the child's condition were presented exactly as would be explained to the child's parents. The limited disclosure explanation included a succinct discussion of the child's medical condition and possible complications, but only included the doctor's recommendation for treatment with the mention that other treatment options exist. The full disclosure explanation included a detailed explanation of the child's medical condition, including percentage risks of even minor complications, all treatments options and the advantages and disadvantages of each option.

An obstetrician drafted an "Obstetrical Case" for this survey. This scenario involves a 23-year-old primiparous female presenting to the labor and delivery unit at 41-1/2 weeks with weak contractions and a cervical condition unfavorable for delivery. Full and limited disclosure explanations were presented exactly as would be explained to the patient. The limited disclosure explanation included a discussion of the options for labor induction and the mention that the patient has the option of being discharged home to await the spontaneous progression of labor. The full disclosure explanation included a more detailed explanation of the risks and benefits of inducing labor, a discussion of each drug used including side effects, and mentions the option of a cesarean section, which is not recommended.

A list of 53 attorneys with experience in medical malpractice law was compiled from phone book listings and from the working knowledge of a medical malpractice paralegal. Surveys were delivered to each attorney's office with a cover letter explaining the purpose of the study. Attorneys were asked to read the introductory summary, which provided background information on the problem of informed consent in medicine, and a summary of medical arguments comparing limited and full disclosure. The terms 'Limited Disclosure' and 'Full Disclosure' were defined in this section. A discussion of legal and medical arguments was provided as optional reading. Following this section, attorneys were asked to give their opinion *in general* by checking off one of three options:

1) I believe that the limited disclosure option is associated with less medical legal liability.
2) I believe that the full disclosure option is associated with less medical legal liability.
3) I believe that the degree of medical legal liability is similar with both options, thus I have no preference.

The attorneys were then presented with the pediatric ED case and asked to give their opinion on the liability specific to the circumstances in that particular case, by selecting one of the same three options as listed above. Next, the attorneys were presented with the obstetric case and asked to give their opinion on the liability specific to the circumstances in that particular case, by selecting one of the

three options listed above. Attorneys then rated possible decision-making factors on a scale of 1 to 5 with 5 being an extremely important factor in their decision-making and 1 being not important in affecting their decision.

Results

Three surveys were undeliverable. Out of the 50 surveys delivered, the response rate was 28% (n=14). One respondent was only able to respond to part 1 of the survey, and did not complete the case-specific survey questions. The respondents had an average of 23 years of legal experience (median 25; range = 3.5-32), with an average of 16 years of experience with medical malpractice law (median 15; range = 2.5-29). 57% had practices devoted solely or primarily (>50% of caseload) to medical malpractice law. 21% devoted 25%-50% of their caseload to medical malpractice, and 21% handled medical malpractice cases as <25% of their caseload. 50% of respondents were solely or primarily defense attorneys, and 50% were solely or primarily plaintiffs' personal injury attorneys.

The results of the survey are summarized in Table 2. Table 3 presents the various decision-making factors commonly used in the assessment of liability risk and the average rating given to each factor. Explanations of each factor are presented exactly as they were provided to respondents. Respondents rated "potential for bad outcome" and "patient autonomy" as the most important factors in comparing liability risk between full and limited disclosure. Respondents who chose full disclosure in the pediatrics case did not differ in their ratings of decision-factors from those who chose limited disclosure and similar liability, by more than 0.9 points in any category (Table 4). A comparison of responses given by defense vs. plaintiffs' attorneys found no difference in recommended disclosure options (Table 5). Defense attorneys rated "potential for bad outcome" and "autonomy" higher than plaintiffs' attorneys by 0.4 and 1.0 points respectively, but these factors still received the highest ratings from both groups. "Time" was rated 1.0 point higher by defense attorneys, and was ranked 3rd in importance, while plaintiff's attorneys considered "time" as less important (Table 6). None of these differences were statistically significant.

Respondents were able to write in any other factors which were not listed, but which they felt were important factors in making their assessment. Some of the comments made by respondents included: *"An understanding of the common law of informed consent allows for both an abbreviated version and a lengthy version to satisfy the legal requirements." "Strong recommendation by treating doctor is important in full disclosure." "As a general rule, in a non-*

Table 2.— Method of disclosure with lower legal liability

	N	Full	Limited	Same
In General:	n=14	86%	0%	14%
Pediatrics ED Case:	n=13	46%	15%	38%
Obstetrics Case:	n=13	85%	0%	15%

Table 3.— Ratings of Importance of Decision-Making Factors in Determinations of Liability Assessment

n = 13	Average Rating	#Ratings (4.0-4.5)	#Ratings >4.5
Potential for Bad Outcome	3.9	3	6
Patient Autonomy	3.6	6	3
Dr./Pt. Relationship	3.0	3	2
Time Available for Explanation	2.9	2	2
Commonness of the Case	2.3	3	0
Complexity of the Explanation	2.3	2	0
Age of the Patient	1.8	2	0

*Explanations of each option as provided to respondents.

- Potential for bad outcome: The pediatric case is very unlikely to result in a bad outcome, while the obstetric case has a modest, but small potential to result in a bad outcome.
- Patient Autonomy: The limited disclosure option offers less patient autonomy and puts the physician in the role of the decision-maker more than the full disclosure option.
- The doctor/patient relationship: The pediatric case involves an emergency physician who is seeing the patient for the first time, while the obstetric case involves an obstetrician who has an ongoing established relationship with her since this obstetrician has been seeing this patient throughout her pregnancy.
- Amount of time available to explain options: Full disclosure takes more time than limited disclosure. There is less time available in the pediatric case to explain options. More time is available in the obstetric case.
- Commonness of the case: The pediatric case occurs very commonly while the obstetric case is less common.
- Complexity of the explanation: Limited disclosure offers a simpler explanation than full disclosure, and is often easier to understand. Full disclosure is more complex and involves giving the patient more information.
- Age of the patient: The pediatric case involves a child, so the parent is in charge, while the obstetric case involves an adult.

Table 4.— Comparision of decision factors for respondents in the Pediatrics ED case.

Decision Factor	Full Disclosure (n=6)	Limited Disclosure & Similar Liability (n=7)	P Value
Time Available	2.7	3.1	NS
Commonness of Case	1.8	2.7	NS
Autonomy	3.5	3.6	NS
Potential for Bad Outcome	3.7	4.1	NS
Age of the Patient	2.2	1.6	NS
Dr/Pt Relationship	2.5	3.4	NS
Complexity of Explanation	2.0	2.6	NS

Table 5.— Comparison of preferred options by attorney specialty

	Primarily or Solely Defense		Primarily or Solely Plaintiff/Personal Injury	
	Full	Limited & Same	Full	Limited & Same
In General (n=14)	6 (43%)	1 (7%)	6 (43%)	1 (7%)
Pediatrics ED Case (n=13)	3 (23%)	3 (23%)	3 (23%)	4 (31%)
Obstetrics Case (n=13)	5 (38%)	1 (8%)	6 (46%)	1 (8%)

Table 6.— Comparision of decision factors by attorney specialty

n=13	Primarily or Solely Defense	Primarily or Solely Plaintiff/Personal Injury	P Value
Time Available	3.4	2.4	NS
Commonness of Case	2.0	2.6	NS
Autonomy	4.1	3.1	NS
Potential for Bad Outcome	4.1	3.7	NS
Age of the Patient	1.6	2.1	NS
Dr/Pt Relationship	3.2	2.9	NS
Complexity of Explanation	2.3	2.4	NS

emergency situation, more disclosure probably exposes a doctor to less liability." "Full disclosure, by definition, is less likely to result in liability for lack of informed consent." "If a private medical doctor fails to appreciate the severity of a problem...[the mistake] cannot be passed off to the patient by telling the patient what the options are...and then asking the patient to select from the menu of options." "Generally it is easier to defend a case when there has been a full disclosure, assuming you can prove that."

Two attorneys mentioned the recommendation of an expert physician as an important factor in informed consent cases, especially in full disclosure where the patient is presented with a wider variety of options. One respondent wrote that how closely the physician's disclosure matches the criteria set forth in the Hawaii Revised Statutes and recent case law is an extremely important factor. Other factors mentioned were the urgency of the situation and the ability to prove what was disclosed.

Discussion

Our results demonstrate that, based on the experiences of medical malpractice attorneys, full disclosure is the option associated with less liability in general. The possibility that the wording of the arguments, used for and against limited and full disclosure, may have been biased, is acknowledged. The arguments were compiled by researchers with medical backgrounds and may have been biased towards supporting the choice favored by medical personnel. Although not proven conclusively by scientific study, many medical personnel seem to favor limited disclosure because of the time involved in full disclosure explanations, the difficulty in ensuring that the patient fully understands everything that is involved, and the fear that the patient will select an option different from what is medically recommended. No respondents chose limited disclosure as the choice associated with less liability in general. This pattern of responses matches our expectation that attorneys would, in general, believe that greater disclosure of information lessens the risk of liability.

The obstetrical and pediatric cases were presented in order to give respondents a sample of what limited disclosure and full disclosure explanations would entail. It is possible to believe that full disclosure is associated with less liability in general, but to have a different opinion when the theory is implemented in specific actual cases. It was crucial to select cases, therefore, that provided a wide range of variable factors which might influence the type of disclosure that is provided. It is recognized that there are medical situations in which disclosure is much less of a concern. Such a case occurs with emergency situations in which there is little time to provide adequate disclosure. Disclosure is also less of a concern in cases with few options available, where one option is clearly superior, for example, most patients with appendicitis will consent to an appendectomy. Although it would have been preferable to include more scenarios with a wider variety of situational factors, due to the length of the survey and the time required for attorneys to voluntarily complete the surveys, it was not possible to do so.

The results of the obstetrical case mirror the responses for liability in general, with the vast majority of respondents choosing full disclosure as associated with less liability. The limited disclosure explanation in this case was very similar to the full disclosure explanation. It is possible that more information was provided in the limited disclosure explanation than is typically given to an obstetrical patient. This may have been a confounding factor if any of the respondents had selected the limited disclosure option because the responses may have been based on a non-representative explanation. However, even with the increased details provided in the limited disclosure explanation, respondents still chose full disclosure as the option associated with less liability.

The OB case also illustrated two key points that medical personnel are concerned with when full disclosure is given. First of all, unappealing side effects for the medications are described, increasing the probability that the patient will refuse the induction option. Secondly, a cesarean section is described as an option, although the patient is warned that there are no accepted indications for performing a cesarean at that time. Offering the patient an option that is inferior or not recommended opens up the possibility that the patient will choose that option even if it is not in her best interest. This endangers the welfare of the patient and exposes the physician to greater liability. In spite of these possibilities, the respondents still felt that full disclosure was the best option for reduced liability.

The most variation in responses was seen in the pediatrics ED case. This case, like the OB case, was presented in order to give respondents a sample of the explanations that might be given in a

real-life situation. It also contrasted with the OB case in a number of ways. Because this case takes place in an emergency department, less time is available for explanation. In all likelihood, the child is being treated by an emergency physician whom the parents have never met before, unlike the OB patient who has an established relationship with her physician over the course of her pregnancy. Since the patient is a child, medical decisions are being made by the parents, making patient autonomy somewhat less of a factor. The pediatrics case also occurs more frequently, making this situation more common than the OB case. In this pediatrics case, several respondents felt limited disclosure was associated with less liability and several felt the liability risk was the same with both options, but there was no clear explanation that could account for their responses. On the survey of decision-making factors, the respondents who selected limited disclosure or same liability gave a similar pattern of ratings as those who chose full disclosure.

This may be an indication that these respondents felt that full disclosure was associated with less liability in any situation regardless of the different variables involved in any individual situation. This case was also notable for a large contrast in the limited and full disclosure explanations. The limited disclosure explanation was very brief, consisting mainly of the physician's recommendation for tests and treatment. The full disclosure explanation was considerably longer and more detailed, with percentage risks of improbable complications, a list of all treatment options, including options not recommended, and the percentage risks and benefits of each. Although previous studies have shown that most parents are willing to digest substantial amounts of medical information in a reasonably short period of time, the degree to which they understand this information is unknown.[13] It is doubtful that a non-medically trained parent would be capable of remembering such details. It is even questionable whether such detail serves to make a decision-maker more informed or more confused. Patients often do not recall information they have discussed with their physicians; even basic information about the proposed treatment. In a study of cancer patients who had just consented to treatment, only 60% understood the purpose and nature of the treatment, only 55% could list even one complication, and only 27% could name a single alternative.[15]

It is possible that in this case the volume of information that would need to be provided for full disclosure, coupled with the fact that the patient is in the emergency department, may have played a factor in influencing respondents' opinions. One recognized exception for obtaining informed consent is in emergent cases, where consent is implied. This exception does not fit perfectly in this case, as the parents are present and the child is not in imminent danger of harm. There is sufficient time to discourse with the parents and attempt to enlist their preferences in their child's treatment. However, in general, emergency cases do provide justification for more paternalistic action on the part of physicians than is normally acceptable in non-emergent situations.

Of the factors involved in decision-making, respondents rated "age" as the lowest in importance and "autonomy" as the second highest, indicating that preserving a patient's decision-making authority is still a strong consideration, even if the patient does not have any autonomy because of their age. Complexity of the explanation" was rated as low in importance. As one respondent pointed out, "although limited disclosure is easier to understand, it is also easier to mislead." Likewise,"commonness of the case" was rated as low in importance. A respondent commented that, "the case may be common to the physician, but it is probably not common to the patient." "Potential for bad outcome" was rated the most important factor, as expected. It was also expected that the higher ratings for "potential for bad outcome" would correspond to a greater recommendation for full disclosure. This was not seen in the pediatrics ED case, where half of respondents chose limited disclosure or same liability, despite rating "potential for bad outcome" the highest of all factors, probably because the actual potential for a bad outcome in this case is very low.

A final comparison of options preferred by attorneys with differing specialties showed that there was no difference in opinions provided by defense attorneys versus the opinions provided by plaintiffs' attorneys in any of the case scenarios. This demonstrates a general consensus among attorneys on what actions may expose a physician to greater liability that is independent of their plaintiff/ defense inclinations.

In summary, medical malpractice attorneys chose full disclosure as the option associated with less liability in all situations, regardless of the different variables in each patient's individual situation. More variability in responses was noted in the pediatrics ED case, although it was not clearly correlated with variability in decision-factors. Finally, although many attorneys stressed that liability must be judged on a case by case basis, many of the write-in responses supported full disclosure as associated with less liability. As one attorney noted, 'if all doctors [gave full disclosure] I wouldn't have as much business.'

Acknowledgments

Thank you to the following attorneys who participated in our research study: L. Richard Fried, Jr., Esq., Mal Gillan, Esq., Mark Davis, Esq., Peter C.P. Char, Esq., Jeff Portnoy, Esq., and to all the attorneys who responded anonymously. Thanks to Joseph F. Kotowski III, paralegal, for legal research assistance and summaries of informed consent cases. Thanks to the attorneys who provided copies of recent Hawaii State Supreme Court rulings on informed consent cases.

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