Section II: DISCLOSURE

1-14. DISCLOSURE STANDARDS FOR INFORMED CONSENT

a. Two Different Standards Plus Hybrids. It is neither feasible nor desirable to tell the patient everything that could possibly happen as a result of treatment decisions (in other words, full disclosure). Therefore, the courts have developed two standards for determining the adequacy of a physician's disclosure: the professional practice standard and the reasonable person (material risk) standard, with two variations (the objective and subjective tests). Some states have developed hybrids of these tests. Although a number of disclosure standards do exist, the physician must comply with disclosure requirements of state law.

b. Professional Practice Standard. The courts in many states use the professional practice standard. In those states, the physician's duty is to disclose what any reasonable medical practitioner would disclose in the same or similar affair. (This standard supports the institutional model of consent, discussed earlier, in which the physician transmits a body of information in an essentially one-way communication.) Medical standards, rather than the patient's rights, are the operative guidelines for disclosure under this standard.

Professional practice standard of disclosure: a standard of disclosure that requires the physician to disclose what any reasonable health care provider would communicate in the same or a similar circumstance.

There are some problems with this standard. First, it assumes that a customary standard exists. In many medical situations a standard may not exist regarding the communication of information. Secondly, if a standard of disclosure does exist for a certain procedure but is set too low, then the patient's right to information is undermined by the legal standard. And finally, and most importantly, the professional practice standard can undermine the patient's right of autonomous choice. This standard reflects the assumptions, values, and goals of a medical mindset. But, decisions for or against medical care are, in large measure, no medical judgments made by the patient, and are rightly the domain of the patient. It may also be questioned whether physicians really know what information is in the best interests of the patient. The weighing of risks against a patient's unique set of subjective beliefs, fears, and hopes cannot be measured through a professional standard. What is important to one patient may not be important to another.
c. **Reasonable Person (Material Risk) Standard.** For the reasons stated above, the reasonable person standard has gained acceptance in 60 percent of the states in the United States. Under this standard, the kind and amount of information are determined by reference to a hypothetical reasonable person. The relevance (materiality) of a piece of information is measured by the significance a reasonable person would attach to it in deciding whether to undergo a procedure. By this standard, informational needs are determined by the *patient*, not the physician. The underlying basis for this standard is the belief that informed consent is a doctrine, designed to permit patients to be the agents of decision making and authorization. (Thus, this standard supports the autonomy choice model of consent discussed earlier.)

---

**Reasonable Person Standard of Disclosure**

- The kind and amount of information are determined by reference to:
  - A hypothetical reasonable person (the objective test).

**OR**

- The unique informational needs of the actual person (the subjective test)
- It supports the autonomy model of consent.
- There is a two-way dialogue.

---

Figure 1-11. The reasonable person model supports the patient's right to self-determination in making health care decisions.
PROFESSIONAL PRACTICE STANDARD OF DISCLOSURE

In *Natanson vs. Kline* (Kansas, 1960), cobalt radiation (a relatively new procedure for the time) was administered following a radical mastectomy. After suffering serious side effects from the therapy (injuries to the chest, skin, and cartilage), the patient sued the physician. The physician acknowledged that he had failed to warn the patient of the risks that were inherent in this procedure. This case established a category of risks that must be disclosed to the patient. The question of how disclosure should best be made was judged to be primarily one of medical judgment. The duty of the physician is to make "those disclosures which a reasonable medical practitioner would make under the same or similar circumstances." This is the standard established in the early cases and the one that is still law in the majority of jurisdictions.

REASONABLE PERSON (MATERIAL RISK) STANDARD OF DISCLOSURE

In *Canterbury vs. Spence* (Wash. D.C., 1972), a laminectomy (surgical removal of the posterior arch of a vertebra) was performed for severe back pain. On the following day, the patient fell out of bed causing major paralysis. The patient had not been warned that a laminectomy might increase the danger of paralysis as a result of such eventualities as falling out of bed. A second operation failed to relieve the paralysis, and though the patient did improve, he never returned to normal. The court ruled that information "material" to the decision must be disclosed. It said that a risk was material "when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy." The court went on to say: "...the patient's right of self-decision... can be exercised only if the patient possesses enough information to enable an intelligent choice."

(1) **Objective test.** The original reasonable person standard applies an *objective* test, which measures the individual patient against a *reasonable person* standard. It asks what information a reasonably prudent person in the patient's position would consider material if informed of the same risks. This standard is not without its problems. "Material information" and the concept of a reasonable person have never been thoroughly defined. (Who, exactly, is this prototype of the reasonable person?) It is difficult, at times, for physicians to anticipate what a reasonable person might need to know. But, for all its shortcomings, the reasonable person standard better serves the patient's needs in coming to a personal decision on treatment procedures than the professional practice standard.
(2) **Subjective test.** A subjective test of the reasonable person standard was later developed. The subjective test goes one step farther by recognizing that the informational needs of an *objective* reasonable person may not meet the unique and specific needs of a *real* patient.

**subjective test of the reasonable person standard of disclosure:** the standard whereby the physician's duty to disclose information material to the decision is determined by the informational needs of the *individual* patient.

The reasonable person standard of disclosure (subjective test) goes the farthest to support the autonomy choice model of informed consent, discussed earlier, in which a two-way dialogue establishes the unique informational needs of the patient. Informational needs can differ. For example, a person may have unorthodox beliefs, unusual health problems, or a unique family history that requires a different information base than the hypothetical objective reasonable person.

---

**INFORMATIONAL NEEDS CAN DIFFER**

In *Hales v. Pitman* (Ariz., 1978), the patient told the physician that his ability to work was crucial, so the court ruled that the physician should have informed him of the risks that could affect his ability to work. This ruling illustrates that when a patient indicates a need for special information, unique to his or her situation, there can be a duty to provide it. A female employee with a family history of reproductive problems might need information that other persons would not need, before becoming involved in research on sexual and family relations or before accepting employment in certain industries.

d. **Hybrid Standards.** Some states have developed hybrid standards. For instance, in Texas there is the "A list" which delineates certain procedures and what the patient must be told about them. The "B list" contains another group of procedures for which there is no obligation to inform the patient about potential risks, unless the physician so desires. Interestingly, there are no gynecological procedures on the "A list," even though the obstetrics-gynecology (OB-GYN) specialty is recognized as having a high incidence of malpractice suits.
- **FULL DISCLOSURE**
  All risks, likely and remote, are disclosed. (Impossible/undesirable standard.)

- **PROFESSIONAL PRACTICE STANDARD**
  What a reasonable physician would disclose under the same or similar circumstances.

- **REASONABLE PERSON (MATERIAL RISK) STANDARD**
  - **OBJECTIVE TEST**
    What a hypothetical reasonable patient would view as "material" is disclosed.
  - **SUBJECTIVE TEST**
    The unique informational needs of the particular patient determine what is disclosed.

- **HYBRID STANDARDS**
  Example:
  List A (Required disclosures).
  List B (Optional disclosures).

**Figure 1-12. Standards of disclosure.**

**REASONABLE PERSON STANDARD OF DISCLOSURE AND UNIQUE INFORMATIONAL NEEDS**

While it is not necessary or desirable to outline all possible risks, it is important to take into account the unique informational needs of each patient. For example, a concert pianist requiring surgery would need to know about the possible risks of a 10 percent loss of motion in the hand, that could result from an operation. For the pianist, such a risk, however remote, would be crucial since the pianist's livelihood and creative fulfillment require full range of fine motor skills of the hand. On the other hand, a day laborer, undergoing the same surgery, would probably not consider this risk particularly relevant. (Other information might be crucial based, perhaps, on family health history or other factors.) Less severe or less probable risks may be relevant and important to a particular patient. Thus, the dialogue between physician and patient is important in ascertaining the patient's unique informational needs.
1-15. ELEMENTS OF DISCLOSURE

a. Providing the Information That Will Facilitate The Patient's Decision Making. Professionals are obliged to disclose a core body of information. Without an adequate transfer of information, many patients will have insufficient information for decision-making. The health care professional's perspective, opinions, and recommendations are often useful and relevant for the patient's consideration, as well as for mutual understanding. Even if not always essential, the provider's input is certainly useful and relevant.

b. What to Disclose. The purpose and nature of authorization as an act of consent should be explained. The facts that patients usually consider relevant in deciding whether to refuse or consent to intervention should be covered. And, any information that the physician believes to be relevant, together with the clinician's own recommendations, should be outlined. All explanations should be made in layman's terms, so that they can be easily understood. The usual elements of an explanation are summarized below.

(1) The purpose and nature of authorization as an act of consent. (Self-explanatory; see paras 1-2 and 1-5.)

(2) The nature of the treatment. This is a statement of the patient's condition or problem and an explanation of the nature and purpose of the proposed treatment.

(3) Possible and probable benefits of treatment. (Self-explanatory.)

(4) Probable risks and consequences (seriousness and frequency). A reasonable disclosure of the dangers that are possible is required. This does not mean that the physician is obliged to describe in detail all of the possible consequences of treatment. In fact, full disclosure (an explanation of all facts, diagnoses, complications, and alternatives) would be bad medical practice, as it would unduly alarm and confuse the patient. Only risks that are known (or should be known) by the physician to occur without negligence must be disclosed. Nearly all courts recognize that not all risks can be disclosed. One useful guideline is to disclose the risks that have a large probability of occurring and those with the most severe consequences. The seriousness of the risk (for example, temporary paralysis) and the frequency of occurrences (for example, a 75 percent chance) should be discussed. Under the reasonable person standard (subjective test), the unique informational needs of the patient should also be taken into account. A remote risk that is not relevant to most patients might be crucial to some, depending on the patient's beliefs, medical history, lifestyle, and so forth.

(5) Feasible treatment alternatives and their likelihood of success. Accepted alternatives that are reasonable should be discussed.
6. Consequences of not treating. (Self-explanatory.)

7. Names of person(s) responsible for treatment or procedure. (Self-explanatory.)

1. The purpose and nature of authorization as an act of consent.
2. The nature of the treatment (surgical procedure or drug therapy).
3. Possible and probable benefits of the proposed treatment.
4. Probable risks and consequences.
   a. Seriousness (temporary paralysis of the arm)
   b. Frequency (a 75 percent chance).
5. The feasible alternative treatments and their likelihood of success.
6. The consequences of not treating.
7. Name(s) of person(s) responsible for treatment or procedure.

Figure 1-13. Element of disclosure.

1-16. PURPOSE OF DISCLOSURE

The disclosure requirements were not designed to protect the physician from medical malpractice suits. Thus, the elements of disclosure cannot simply be viewed as a handy laundry list of "right things" to cover to ensure protection from medical malpractice suits. Rather, the goal of disclosure is patient-centered. The intent is to support the patient's right to self-determination (autonomy) in decision making by enabling patients to exercise their autonomy rationally and intelligently. The emphasis should be on options rather than risks (although failure to advise of the risks could definitely get the physician in trouble).

Continue with Exercises, Section II
It is recommended that you work the following exercises (1 through 11) before beginning the next section of the lesson. After you have completed the exercises, check your answers against the solutions following the exercises. For any answer missed, reread the material referenced in the solution.

MULTIPLE-CHOICE. Select the ONE response (a, b, c, or d) that BEST completes the statement or BEST answers the question.

1. Which standard of disclosure reflects the assumptions, goals, and values of a medical mindset rather than the patient's beliefs, fears, and hopes?
   a. The professional practice standard.
   b. The reasonable person standard (objective test).
   c. Hybrid standards.
   d. The material risk standard (subjective test).

2. Which of the following shifts the determination of informational needs from the physician to the patient?
   a. The professional practice standard of disclosure.
   b. The reasonable person (material risk) standard of disclosure.
   c. Professional codes of ethics.
   d. "The thing speaks for itself" doctrine.

3. Which standard of disclosure does the most to take into account unorthodox beliefs, unusual health problems, and unique family histories?
   a. The professional practice standard.
   b. The objective test of the reasonable person standard.
   c. Hybrid standards.
   d. The subjective test of the reasonable person standard.

4. When disclosing risks and consequences to the patient, the physician should, at a minimum, outline:
   a. All risks known by the physician.
   b. Risks resulting from negligence.
   c. Probable risks, those with the most severe consequences and those particularly relevant to the patient.
   d. All risks known to medical science.
5. The purpose of disclosure is to:
   a. Protect the physician from medical malpractice.
   b. Enable patients to exercise their autonomy by intelligently selecting treatment options.
   c. Foster paternalism in health care, and give the patient the benefit of full disclosure.
   d. Emphasize the potential risks rather than treatment options.

6. The professional practice standard assumes that:
   a. A customary standard of disclosure exists for the communication of information.
   b. The physician can put him- or herself in the patient’s place.
   c. Patient autonomy is the most important consideration.
   d. The standard of disclosure can never be set too high.

7. According to the material risk standard of disclosure, the materiality (relevance) of a piece of medical information is measured by the significance that a _________ would attach to it in deciding whether or not to undergo a medical procedure.
   a. Physician.
   b. Hospital administrator.
   c. Medical ethicist.
   d. Hypothetical reasonable person.

8. The problem with the objective test of the reasonable person standard is that:
   a. Material information and the concept of the reasonable person have never been thoroughly defined.
   b. It is doctor-centered.
   c. It meets the unique needs of any patient.
   d. It goes too far in supporting the ethical principle of the patient’s right to self-determination.
9. Which is NOT an element of disclosure?

   a. Treatment options (recommendations and alternatives).
   b. The benefits and risks of treatment; risks of not treating.
   c. The purpose and nature of authorization as an act of consent.
   d. The name(s) of person(s) responsible for the treatment or procedure.
   e. All possible risks and complications.

10. A female patient, who is a single working parent, consents to repeat surgery on a hiatus hernia. The physician does not mention that it may be necessary to open the patient's chest during surgery. (He won't know if this is necessary until she is on the operating table.) It turns out that there is no need to open her chest, and the operation and recovery are uneventful. In view of the general trend toward patient's rights and the reasonable person standard of disclosure, what would the patient's likely reaction be to such an omission of information, had it been necessary to open her chest?

   a. She would be glad not to know. Even if she consented to having her chest opened, informing her would have caused unnecessary worry, a kind of harm.
   b. If it turned out that opening the chest wasn't necessary, the doctor would have saved her needless worry by not telling her about that possibility in the first place.
   c. Even if the chest had to be opened, the patient would be so grateful for the relief from hernia pain, that she would not resent having not been told.
   d. Horrified by the size and pain of the incision and unprepared for a long absence from work, she might sue the surgeon and hospital for failing to disclose relevant information.

11. The professional practice standard of disclosure requires that the physician tell the patient:

   a. All possible risks and benefits, likely and remote.
   b. What an objective reasonable person in the same or similar circumstances would need to know.
   c. What any reasonable medical practitioner would disclose in the same or similar circumstances.
   d. What the particular patient in question needs to know.

Check Your Answers on Next Page
SOLUTIONS TO EXERCISES, LESSON 1, SECTION II

1. a (para 1-14b)
2. b (para 1-14c)
3. d (para 1-14c(2))
4. c (para 1-15b(4))
5. b (para 1-16)
6. a (para 1-14b)
7. d (para 1-14c)
8. a (para 1-14c(1))
9. a (para 1-15b(4))
10. d (para 1-14c)
11. c (para 1-14b)

Go to Section III