1992

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INFORMED CONSENT AND RISK MANAGEMENT IN DERMATOLOGY: TO WHAT EXTENT DO DERMATOLOGISTS DISCLOSE ALTERNATE DIAGNOSTIC AND TREATMENT OPTIONS TO THEIR PATIENTS?*

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I. INTRODUCTION

Informed consent in general and the disclosure of treatment options by physicians in particular have received little attention in clinical medical literature despite the increasing legal emphasis on these issues.¹ Patients in the

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¹ Presented in part at the 49th Annual Meeting of the American Academy of Dermatology, Atlanta, Georgia, December 1990. The material presented is intended as a general presentation of medicolegal issues of interest to dermatologists in the United States. Specific legal advice should be sought with a licensed attorney in your jurisdiction. The opinions or assertions herein are those of the authors and do not necessarily reflect the view of the Department of Army or the Department of Defense.

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1. In 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research sought to document emerging legal and medical trends which relate to informed consent. In discussing the tension between "medical paternalism" and "patient sovereignty," the Commission noted that "[b]oth positions attempt to vest exclusive moral agency, ethical wisdom, and decisionmaking authority on one side of the relationship, while assigning the other side a dependent role." 1 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: A REPORT ON THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 36
United States are demanding more information about their diagnoses and treatment options before physicians begin case management. Implicit in the encounters between physician and patient lies a mixture of different communication styles and expectations for participation in the therapeutic relationship. It has been suggested that physicians refuse to share information in order to maintain power over their patients. However, this Article proposes that the maximum exchange of information enhances patient autonomy and facilitates the therapeutic process.

Disclosure of relevant diagnostic facts and treatment options is essential to the informed consent process by which the physician and patient both arrive at medical management decisions. Yet, the practice of informed consent is compromised if reasonable diagnostic or treatment options are withheld by the physician. This survey was designed to document the extent to which disclosure practices within the specialty of dermatology meet the ideal of shared decision-making. Following a brief summary of the methods used and results obtained, the evaluation of informed consent is divided into two


2. A continually developing consumerism in health care has been linked to the important, yet poorly advocated, value of patient autonomy. See Patrick A. Malone, Granting Informed Consent: How Patients Can Protect Themselves, WASH. POST, July 10, 1990, Health Magazine, at 11. In fact, it has been suggested that there exists a "bill of rights" for patients in dealing with physicians. See Morton Hunt, Patients' Rights, N.Y. TIMES, Mar. 5, 1989, Magazine, at 55. Because of this increased interest in patient autonomy, physicians have been more responsive to disclosing potential risks associated with treatment. In the 1960s, only 1 out of 10 doctors would tell patients they had cancer; by the late 1970s, 97% of the doctors surveyed preferred to disclose cancer diagnoses. Miriam Shuchman & Michael S. Wilkes, Asking—and Telling, N.Y. TIMES, Feb. 12, 1989, Magazine, at 45.


6. It is here that many commentators draw the nexus between a valid informed consent and the disclosure of a requisite quantum of information. For example, informed consent is interpreted as "a law of disclosure based on a general obligation to exercise reasonable care by giving information." Tom L. Beauchamp & James F. Childress, PRINCIPLES OF BIOMEDICAL ETHICS 86 (3d ed. 1989).

7. Rather than abrogating patient autonomy in favor of professional control, a "'participatory' model . . . rests on the belief that both the professional and his client benefit from a
sections. First, various legal doctrines are examined in tracing the development of the requirements of disclosure. Second, the results of the survey are analyzed, with particular attention to those areas in which there was a lack of consensus in disclosure. By discussing informed consent with the goal of meeting patients' expectations for information, this study attempts to bridge the gap between the theory and practice of informed consent.8

II. METHODS

One hundred dermatologists were surveyed at random from the 1989-1990 Directory of the American Academy of Dermatology.9 Only those categorized as fellows practicing within the United States were included. The selection was based on random numbers generated by the Hewlett Packard 11C calculator. One dermatologist was selected at random from each page of the ninety-five page directory, and five additional dermatologists were selected at random from five more randomly selected pages.

The questionnaire used in the survey described clinical case presentations and called for the respondents to select any of the diagnostic and treatment options for each case presentation from a listing of options that they would disclose to a patient. Cases included the dysplastic nevus syndrome, recurrent basal cell carcinoma, malignant melanoma, and neonatal port-wine stain. Respondents were encouraged to suggest alternative diagnostic or treatment options that were not offered on the list by filling in the blank spaces provided.

III. RESULTS

Forty-eight percent of dermatologists representing twenty-five states responded to the survey. All the dermatologists practiced in cities with populations greater than 10,000 people and 44% were in a city with a population greater than 500,000. Seventy-five percent of the physicians were in the thirty to forty-nine-year-old range. The responding physicians completed their dermatology residencies between 1956 and 1988. The most common type of practice was a solo private practice (48%), with 33% in a group practice and 17% in an academic practice.

Seventy-seven percent of the respondents were situated less than ten miles

from a Mohs micrographic surgeon, and ninety percent were located less than fifty miles away. Thirty-eight percent of the respondents were less than ten miles away from a pigmented lesion clinic; forty-eight percent were less than fifty miles away; and twenty-five percent were over two hundred miles away. Forty-four percent of respondents were less than ten miles away from the nearest pulsed dye laser, fifty-eight percent were less than fifty miles away, and fifteen percent were more than two hundred miles away.

The four case presentations and the survey responses are presented in Tables 1-4. The mean number of options disclosed for each case presentation is presented in Figure 1. No correlation patterns were found between the demographic data and responses to the case presentations.

IV. DISCUSSION

This study revealed startling differences in disclosure practices of the surveyed dermatologists. Despite the degree of consensus about disclosure of some treatment options, those instances of nondisclosure have important ramifications for the process of informed consent in the practice of dermatology. This analysis will be divided into three sections. First, a review of the traditional standards for medical disclosure reveals that progress in advanc-

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10. In 1988, The American College of Mohs Micrographic Surgery and Cutaneous Oncology approved 21 fellowships of 1 year duration in Mohs micrographic surgery. Willis J. Cottel et al., Essentials of Mohs Micrographic Surgery, 14 J. DERMATOLOGIC SURGERY & ONCOLOGY 11, 12 (1988). This training program focuses on mastering the techniques of skin cancer excision, color coding, and the freezing of tissue samples. Id. at 11. Accurate microscopic evaluation of frozen tissue samples is essential in determining whether tumor removal is successful and a “well-trained Mohs micrographic surgeon... is often required to interpret over 100...” specimens daily. Id. at 12.

11. Of the many pigmented lesions that are diagnosed and treated at one of these facilities, malignant melanoma and dysplastic nevus syndrome are the most important. For a discussion of the experience with pigmented lesions at Massachusetts General Hospital see Raymond L. Barnhill et al., Frequency of Dysplastic Nevi Among Nevomelanocytic Lesions Submitted for Histopathologic Examination, 126 ARCHIVES DERMATOLOGY 463 (1990) (reporting the increased diagnosis of dysplastic nevi over a 37-year interval).

12. Currently, the pulsed dye laser is very expensive to purchase and maintain, and few sole practitioners and university medical centers are able to provide this service. For a brief survey of various surgical techniques, including the pulsed-eye laser, see Christopher B. Zachary, Surgical Therapy, in PRINCIPLES AND PRACTICE OF DERMATOLOGY 63 (W. M. Sams, Jr. & Peter J. Lynch eds., 1990).

13. Only if a doctor is willing to provide information concerning treatment options, including the risks associated with each, can the patient make an autonomous treatment choice. See Joyce C. Billue, Who Owns the Patient?, 18 HEART & LUNG 530 (1989). See also David L. Cohen et al., A National Survey Concerning the Ethical Aspects of Informed Consent and Role of Medical Students, 63 J. MED. EDUC. 821, 828 (1988) (proposing that deficiencies in informed consent may be traced to the medical education process).
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Second, two categories of disclosure are proposed to be integrated into physician practice on a uniform basis. While treatment practices differ within the profession of dermatology, the data collected below can provide professionals with a baseline for future comparison and promote greater awareness of emerging therapies.

A. Current Disclosure Standards

Commenting on the international differences in informed consent, the Secretary of the British Medical Association stated that a patient in America “must be informed of every possible adverse consequence of submitting to treatment, whereas under English law the patient needs to be told about only such risks as a responsible body of medical opinion would consider relevant.” However, this evaluation oversimplifies the current state of the law in this country and reflects a widespread view that informed consent is an unfortunate appendage of defensive medicine. Rather, the doctrine serves as a vehicle for both the mutual exchange of information and a recognition

14. The early development of informed consent focused on the physician’s duty to disclose the attendant risks of a specific procedure once it had been selected for the patient. In referring to this practice, the California Court of Appeal stated, “A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.” Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957) (emphasis added).


17. In response, one physician noted that “the importance of informed consent to risk management lies in the contributions it makes to the doctor-patient relationship and overall clinical care, much more so than in any future defense it may provide.” Schouten, supra note 3, at 1360.
of the reciprocal rights and duties that enable patients to trust their physicians and participate in their own health care decisions.\textsuperscript{18}

The roots of informed consent in this country can be traced to a series of opinions recognizing a patient’s right to bodily autonomy.\textsuperscript{19} The frequently quoted statement that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body” is an appealing endorsement of the right to self-determination.\textsuperscript{20} Yet, an analysis of these early cases reveals the very limited nature of a patient’s involvement in his own health care. The evolution of informed consent began with a recognition of the right to “simple consent,”\textsuperscript{21} exercised through a poorly defined veto power over a proposed treatment.

In *Mohr v. Williams*,\textsuperscript{22} the patient submitted to an operation on her right ear for the removal of a polyp. It was also suspected that the bones in the middle ear were infected and should be removed as well.\textsuperscript{23} The patient awoke from the operation to discover that the attending surgeon, with the concurrence of the patient’s family physician, had operated on the left ear after determining that it was in greater need of care.\textsuperscript{24} While the facts of this case and others like it\textsuperscript{25} are well known, the opinion of the Minnesota Supreme Court established two points of departure for the nascent doctrine of informed consent. First, the consent of the patient would be invoked only

\begin{footnotes}
\item\textsuperscript{18} Charles W. Lidz et al., *Two Models of Implementing Informed Consent*, 148 ARCHIVES INTERNAL MED. 1385, 1386 (1988).
\item\textsuperscript{19} Pratt v. Davis, 79 N.E. 562 (Ill. 1906); Mohr v. Williams, 104 N.W. 12 (Minn. 1905); Schloendorff v. Society of N.Y. Hosp., 105 N.E. 92 (N.Y. 1914); Rolater v. Strain, 137 P. 96 (Okla. 1913); Hunter v. Burroughs, 96 S.E. 360 (Va. 1918).
\item\textsuperscript{20} See, e.g., *Schloendorff*, 105 N.E. at 93.
\item\textsuperscript{21} See Paul S. Appelbaum et al., *Informed Consent: Legal Theory and Clinical Practice* 38 (1987) (discussing the historical background of the legal requirements for disclosure and consent).
\item\textsuperscript{22} 104 N.W. 12 (Minn. 1905).
\item\textsuperscript{23} *Id.* at 13.
\item\textsuperscript{24} *Id.*
\item\textsuperscript{25} There is an unfortunate legacy of outright deceit by physicians in obtaining consent to treatment that far outstrips the well-intentioned actions of the doctor in *Mohr*. See Pratt v. Davis, 79 N.E. 562 (Ill. 1906) (affirming judgment for patient when physician removed patient’s uterus with full knowledge that no consent was obtained for the procedure); Bang v. Charles T. Miller Hosp., 88 N.W.2d 186 (Minn. 1958) (questioning whether the patient was informed that a bladder resection operation would lead to sterility); Corn v. French, 289 P.2d 173 (Nev. 1955) (leaving as a question of fact for the jury whether physician performed a mastectomy when only given consent to perform a biopsy). One commentator noted that *Bang* has been frequently used in informed consent litigation “because the injury suffered was not a collateral hazard of the operation, but a part of the procedure to be accomplished.” William H. Karchmer, *Informed Consent: A Plaintiff’s Medical Malpractice “Wonder Drug.”* 31 MO. L. REV. 29, 38 (1966).
\end{footnotes}
when the physician’s care involved surgery. Once the surgical remedy is proposed, the patient decides “whether he will take his chances . . . of living without [the operation].” Second, the physician retains near absolute discretion as to the “methods of treatment.”

The Supreme Court of Oklahoma elaborated on the second point in Rolater v. Strain. In an attempt to distinguish Mohr, the defendant physician in Rolater contended that “consent was given to an operation upon the [plaintiff’s] right foot, where it was performed.” The court affirmed a judgment for the plaintiff based on lack of consent because the nonremoval of any bones was an express condition of the operation, and “the patient had the right to insist upon a strict performance” of the agreed parameters of consent.

These early cases present a curious mixture of competing values at a time when physician paternalism remained very entrenched. At the time, doctors were allowed to effect their chosen treatments with little input from their patients. In effect, the patient’s right to redress under the law was limited by the extent to which she was able to set the conditions of the doctor’s performance. However, the physician, because of his superior knowledge, effectively controlled the parameters of the relationship.

One precedent from this era “contained the seeds of the requirement of an affirmative duty of disclosure.” In Hunter v. Burroughs, the patient submitted to X-ray treatment to cure eczema, and this treatment damaged the patient’s skin. The court upheld “the duty of a physician in the exercise of ordinary care to warn a patient of the danger of possible bad consequences of using a remedy” only in a very limited sense. Normally, the failure to

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26. Mohr, 104 N.W. at 14; see also Pratt, 79 N.E. at 565; Rolater v. Strain, 137 P. 96, 97 (Okla. 1913).
27. Mohr, 104 N.W. at 15 (citation omitted).
28. Id. However, the court stated that the doctor did not have “free license respecting surgical operations.” Id.
29. 137 P. 96 (Okla. 1913).
30. Id. at 98. The procedure called for surgically draining an existing wound in the plaintiff’s foot but resulted in the removal of the foot’s sesamoid bone. Id. at 97.
31. Id. at 98.
33. Id. at 7. The paternalistic doctor would view consent as acceptance of the proposed treatment and refusal as an indication that the patient is incompetent. Id.
35. Appelbaum et al., supra note 21, at 38.
37. Id. at 362.
38. Id. at 366.
warn was "not per se an act of negligence," but the physician in this case "misled the plaintiff by not only not giving him the warning aforesaid, but by affirmatively assuring him" that the X-ray treatment would be efficacious.\textsuperscript{39}

An affirmative duty of disclosure was recognized in \textit{Salgo v. Leland Stanford Jr. University Board of Trustees.}\textsuperscript{40} In this negligence action, the plaintiff alleged that the doctor failed to competently perform a translumbar aortography,\textsuperscript{41} which allegedly caused paralysis of the lower extremities.\textsuperscript{42} On appeal, the defendant physicians challenged a jury instruction mandating that the duty of a physician is "to disclose to the patient 'all the facts which mutually affect his rights and interests and of the surgical risk, hazard and danger . . . .' "\textsuperscript{43} Finding that the instruction should be modified, the court held that the physician rightfully retains a certain amount of discretion that must be consistent with the full disclosure of facts necessary to an informed consent.\textsuperscript{44} In "coin[ing] the term informed consent,"\textsuperscript{45} the court recognized the physician's two alternative courses of action: disclosing every possible risk to a patient or revealing the maximum amount needed before causing a patient undue apprehension when there is, in fact, minimal risk involved.\textsuperscript{46}

Two courts had occasion to comment on this curious standard promulgated in \textit{Salgo}.\textsuperscript{47} In \textit{Natanson v. Kline}, the Supreme Court of Kansas found that the \textit{Salgo} rule provided a balance "between the two extremes of absolute silence on the part of the physician relative to the treatment of a patient and exhaustive discussion" of every conceivable danger of the treatment.\textsuperscript{48} The court provided some guidance in this area by stating that disclosure "is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances."\textsuperscript{49} The Supreme Court of

\textsuperscript{39} \textit{Id.} 366-67.
\textsuperscript{40} 317 P.2d 170 (Cal. Dist. Ct. App. 1957).
\textsuperscript{41} \textit{Id.} at 173. This procedure involves the injection of contrast dye material into the patient's abdominal aorta and the taking of X-ray pictures of the area to locate any blockage of blood flow. \textit{Id.} at 174.
\textsuperscript{42} \textit{Id.} at 175.
\textsuperscript{43} \textit{Id.} at 181.
\textsuperscript{44} \textit{Id.}
\textsuperscript{45} \textsc{Appelbaum et al., supra} note 21, at 39.
\textsuperscript{46} \textit{Id.} See generally Edmund Pellegrino, \textit{The Relationship of Autonomy and Integrity in Medical Ethics}, 24 \textsc{Bull. Pan Am. Health Organization} 361, 371 (1990) (finding that the physician has a heightened responsibility to be sensitive to the vulnerable, frightened state of the patient).
\textsuperscript{48} \textit{Natanson}, 350 P.2d at 1104.
\textsuperscript{49} \textit{Id.} at 1106.
Missouri in *Mitchell v. Robinson* proposed that the duty to warn of hazards and risks arose because the doctors knew of the high incidence of injury associated with insulin shock therapy.\(^5\) In essence, *Mitchell* also endorsed the emerging professional standard of disclosure approved of in *Natanson* by recognizing that patient consent could be coupled with an understanding of established medical practices.

This policy governing disclosure allowed the medical profession to set its own standards for what was considered to be the appropriate disclosure of information.\(^5\) As early as 1960, courts stated that a plaintiff's recovery depended upon whether the physician's disclosure "squared with professional custom."\(^5\) In questioning this custom or professional standard of care, the United States Court of Appeals for the District of Columbia Circuit noted in *Canterbury v. Spence*\(^5\) that "the reality of any discernible custom reflecting a professional consensus [sic] on communication of option and risk information to patients is open to serious doubt."\(^5\) The *Canterbury* court further reasoned that the duty to disclose arose "from phenomena apart from medical custom" and that the professional standard was "at odds with the patient's prerogative to decide on projected therapy himself."\(^5\) The court ultimately held that all material risks must be disclosed to a patient prior to

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\(^{50}\) 334 S.W.2d at 19.


\(^{52}\) Id. at 89 (crediting Natanson v. Kline, 350 P.2d 1093 (Kan. 1960) with this new theory of recovery for injured patients who can show neither negligent diagnosis nor treatment). For an analysis of the present requirements of a cause of action based on the negligent failure to obtain informed consent, see Richard E. Shugrue & Kathryn Linstromberg, *The Practitioner's Guide to Informed Consent*, 24 CREIGHTON L. REV. 881 (1990-91). Informed consent now forms the basis of two separate causes of action:

In a claim of battery . . . [i]t need only be shown that the medical procedure performed was substantially different than that to which the patient consented. In negligent nondisclosure cases . . . [t]he patient must prove that a reasonable person in the patient's position would have refused the treatment had the physician disclosed the risk.


\(^{53}\) 464 F.2d 772 (D.C. Cir. 1972).

\(^{54}\) Id. at 783 (footnote omitted). There are a number of factors which, in their totality, cast doubt on the possibility of a uniform standard of practice, including "locality of the physician, availability of facilities, specialized or general practice, and proximity of specialists and special facilities . . . ." Blair v. Eblen, 461 S.W.2d 370, 373 (Ky. Ct. App. 1970). These various elements are presently subsumed in the debate over whether standards of care are measured by local geography or by reliance on national standards. For medical specialists, the majority of courts have imposed national standards of professional competence. See Jay M. Zitter, *Annotation, Standard of Care Owed to Patient by Medical Specialist as Determined by Local, "Like Community," State, National, or Other Standards*, 18 A.L.R.4TH 603, 608-20 (1982).

\(^{55}\) *Canterbury*, 464 F.2d at 786.
consenting to surgery.56

Canterbury and its progeny reaffirmed that self-determination is the principal goal of informed consent and that the patient’s needs for information, rather than the physician’s practices, must form the basis of any adequate standard of disclosure.57 However, use of the “reasonable person” to judge the legitimacy of patient demands still compromises the amount of information that may be given to individual patients.58 James Childress, known for his autonomy-based ethics, suggests that “the rule of informed consent has become too formalistic and that following it has become mechanical sometimes to the extent of violating its spirit.”59 The following analysis attempts to discover how these rules can positively guide medical practice, rather than restrict it.

B. Improving Disclosure Practices

In classifying the duty to disclose standard as “the professional-oriented”60 or the “patient-oriented”61 standard, one commentator has suggested that both focuses should yield the same practical result.62 However, deficiencies in disclosure persist in daily practice, regardless of which legal standard the physician feels obliged to follow.63 Two areas of disclosure warrant attention: the disclosure of treatment alternatives and the presenta-

56. Id. at 787. The court defined a risk as 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.” (quoting Jon R. Walz & Thomas W. Scheuneman, Informed Consent to Therapy, 64 NW. U.L. REV. 628, 640 (1970)). See also Cobbs v. Grant, 502 P.2d 1, 11 (1972).
58. Id.
59. See Childress, supra note 32, at 135.
60. Under this traditional approach, the physician must disclose to each patient as much information as a reasonably prudent physician would disclose in the same situation. Marshall B. Kapp, Informed Consent for Federal Clinicians, 154 MIL. MED. 238, 239 (1989); see also supra note 34 and accompanying text.
61. This growing trend focuses on the materiality aspect of informed consent, questioning how much information a patient would require to make an intelligent decision on a proposed treatment that is consistent with personal values and preferences. Kapp, supra note 60, at 239; see also supra note 46 and accompanying text.
62. Kapp, supra note 60, at 239.
63. Commentators note:
Many physicians feel the informed consent requirement imposes upon them an undesirable and perhaps impossible task. It is considered undesirable because adequately informing a patient takes too long and might create unnecessary anxiety. It is considered impossible because no medically uneducated and clinically inexperienced patient can truly grasp the significance of the information the physician must disclose.
ALBERT R. JONSEN ET AL., CLINICAL ETHICS: A PRACTICAL APPROACH TO ETHICAL DECISIONS IN CLINICAL MEDICINE 64 (2d ed. 1986).
tion of the possible risks and benefits of a procedure.⁶⁴

1. Treatment Alternatives

In an area of practice particularly important to this survey, the disclosure of treatment alternatives is a necessary part of a patient's informed consent.⁶⁵ As noted above, informed consent developed from a milieu of physician paternalism. The patient would simply ratify or decline the doctor's proposed treatment. However, the Natanson court gave official recognition to the disclosure of treatment alternatives.⁶⁶ While Natanson would not properly stand as the progenitor of a new duty of disclosure, it recognized that "[i]f the physician fails to disclose alternative forms of treatment, the patient is precluded from expressing a preference among them."⁶⁷

Essential to this analysis will be an understanding of what are considered reasonable alternative procedures,⁶⁸ which currently depend on the standard adopted in the particular jurisdiction.⁶⁹ Yet, it has been argued that some congruence exists between the professional and reasonably prudent patient standards. That is, physicians will be aware "that patients want to know about more than what their physicians recommend" and recognize "that greater disclosure is almost always preferable."⁷⁰

A review of cases and statutes referencing the duty to disclose alternate treatments reveals that the determination of reasonableness belies convenient

⁶⁴. The practice of informed consent usually combines disclosure of all benefits as well as all risks. See Fay A. Rozovsky, Consent to Treatment: A Practical Guide 45 (2d ed. 1990). However, there are instances where benefits deserve separate treatment from that of risks, particularly when the procedure is diagnostic rather than therapeutic or otherwise provides something less than full relief of the patient's suffering. See Appelbaum et al., supra note 21, at 55.

⁶⁵. Appelbaum et al., supra note 21, at 54.


The term alternatives suggests that the physician has already determined what is best for the patient, and that any other procedures are secondary in value. . . . Physicians ought to suggest what they deem to be the medically preferable course. However, if decision making about care were simply a matter of what is preferable on medical grounds alone, there would be no need for the informed consent doctrine; simple consent would do just as well if not better.

Appelbaum et al., supra note 21, at 54.

⁶⁷. Jonsen et al., supra note 63, at 50.

In an early discussion of what is reasonableness, one author advocated a "middle course" between wanton experimentation and a failure to keep up with widely accepted medical advances. Angela R. Holder, Alternative Medical Procedures, 212 JAMA 385, 386 (1970).


application of either standard of disclosure. In applying Utah law, a federal district court held that the state's standard of disclosure must be judged by materiality and concluded that the disclosure of material information included "any alternative treatments and the risk of no treatment at all." A similarly vague standard was adopted in the Indiana informed consent statute which speaks only of the "reasonable" alternatives to a proposed treatment.

In Florida, a more specific standard has focused on what is considered to be a medically "viable" or "accepted" alternative. The statutory definition approves of those alternatives "generally considered by the medical profession to be within the scope of current, accepted standards" and inherently adopts a professional standard of practice to determine if the treatment option should be disclosed. This approach was also employed in Logan v. Greenwich Hospital Ass'n, which considered whether a treatment alternative that was more risky than the chosen method was in fact a viable alternative. The court held that to exclude the more difficult option would vitiate any meaningful communication with a patient by automatically recommending the "safest procedure."

For the practice of dermatology, advances in treatment are being made in laser therapy and skin cancer management at a startling rate. The survey responses indicate an overall willingness to refer patients with difficult problems to modern facilities instead of effecting treatment with traditional methods. Standards similar to that promulgated in Logan have been criti-

71. This determination is made with the goal of discerning trends in clinical practice which are defined by the law rather than of evaluating the requirements for maintaining a negligent informed consent cause of action.
72. Unthank v. United States, 732 F.2d 1517, 1521 (10th Cir. 1984) (seeking recovery for injuries sustained from swine flu inoculation).
73. IND. CODE ANN. § 16-9.5-1-4.(c)(5) (Burns 1990).
74. See FLA. STAT. ANN. § 458.324 (West 1991).
75. Id. § 458.324(1). The Florida statute specifically considers informed consent with regard to the treatment of breast cancer. Compare ME. REV. STAT. ANN. tit. 24, § 2905-A (West 1991) (requiring disclosure of "alternative efficacious methods of treatment of breast cancer, including surgical, radiological or chemotherapeutic treatment or any other generally accepted medical treatment"); PA. STAT. ANN. tit. 35, § 5641 (1991) (requiring patient to attest that "I have been informed of the currently medically accepted alternatives to radical mastectomy."). For a history of the development of modern treatments for this condition and their impact on the informed consent process, see KATZ, supra note 8, at 175-84.
76. Prillaman, supra note 69, at 48 (stating that the determination of whether other practitioners in the relevant community would have disclosed the alternative is made by comparing the testimony of competing medical experts).
77. 465 A.2d 294, 301 (Conn. 1983).
78. Id.
79. See Tables 1-4.
cized for not guiding physicians in the course of disclosure.\textsuperscript{80} However, the apparent tendency of courts to adopt a professional standard of disclosure protects physicians from "having to describe the theories of quacks or to explain treatments too new to have a track record," while retaining the "duty to keep up with the relevant literature and other sources of information, and to inform patients of new treatments as they meet the criteria of acceptance."\textsuperscript{81}

2. Risk-Benefit Information

One difficulty with requiring physicians to thoroughly disclose both the risks and benefits of treatment alternatives is that the language used in characterizing these alternatives "may not be solely descriptive" and may convey the physician's "own positive or negative evaluation of various alternatives."\textsuperscript{82} In the disclosure of benefits, the "greatest risk lies in the impulse to improve the patient's morale by exaggerating the potential for benefits."\textsuperscript{83} There is the added risk that by failing to detail fully the expected benefits of a procedure the patient would be unable to adequately weigh the advantages of choosing a particular treatment. For example, management of recurrent basal cell carcinoma can be achieved by radiation therapy or Mohs micrographic surgery. The advantages and disadvantages for each procedure could be determinative for different patients, depending on their concerns about cosmetic ramifications and long-term treatment goals.\textsuperscript{84}

Case law and statutes are virtually silent on the issue of disclosing potential treatment benefits.\textsuperscript{85} The Hawaii informed consent statute does make reference to the "anticipated results" of treatment as one criteria of complete disclosure.\textsuperscript{86} Most patients would equate this standard, or the "purpose of the procedure," with its "anticipated benefits."\textsuperscript{87} Yet, even in a jurisdiction

\textsuperscript{80.} ROZOVSKY, supra note 64, at 51.

\textsuperscript{81.} Prillaman, supra note 69, at 58. The author describes official recognition as those objective manifestations of approval by such institutional bodies as the Food and Drug Administration and the American Medical Association. \textit{Id.} at 52-57. The use of the professional standard of disclosure in this case is not at odds with the general theme of promoting the patient's autonomy because the profession of dermatology has the ability to establish good care practices which reflect the emerging technologies.


\textsuperscript{84.} See infra note 108 and accompanying text.

\textsuperscript{85.} APPELBAUM ET AL., supra note 21, at 55.

\textsuperscript{86.} HAW. REV. STAT. § 671-3 (1985).

\textsuperscript{87.} APPELBAUM ET AL., supra note 21, at 55. See, e.g., Gray v. Grunnagle, 223 A.2d 663, 674 (Pa. 1966) (requiring "understanding of the nature of the operation to be performed, the
lacking a positive duty to disclose benefits information,\textsuperscript{88} such information should be disclosed in an effort to engage the patient in the therapeutic process.

While the physician should make recommendations as to the course of treatment, the ability of patients to make informed choices is enhanced if they are also apprised of the potential risks associated with each procedure.\textsuperscript{89} Realistically, all risks and options simply cannot be discussed. Should the remote possibility of a needle breaking off in a vein or the rare possibility of sepsis be discussed before every blood sample is ordered? To address these concerns, four considerations have been proposed as a guide for physicians trying to determine if disclosure is warranted: 1) the nature of the risk; 2) the magnitude of the risk; 3) the probability that the risk might materialize; and 4) the imminence of risk materialization.\textsuperscript{90} In addition to these guidelines, the law in each jurisdiction determines precisely how much disclosure is required.\textsuperscript{91}

Disclosure of risk-benefit information ranked well for each case presentation surveyed.\textsuperscript{92} However, further study will be needed to determine the actual content of that disclosure.

V. CASE PRESENTATIONS

The results of this study suggest that disclosure practices differ widely, perhaps inappropriately, with regard to the four case presentations in the survey questionnaires. At a minimum, informed consent requires disclosure and an understanding on the part of the patient of the significant alternative diagnostic and treatment options and the potential risks and benefits of each option. This information should also include the natural history of the disease if it remains untreated. In evaluating the responses below, practitioners are admonished to determine the specific details of disclosure on an individual patient basis because a particular patient may have greater susceptibility

\textsuperscript{88} See \textsc{Ga. Code Ann.} § 31-9-6(d) (Michie 1991) (requiring disclosure in general terms the treatment in connection with which consent is given).

\textsuperscript{89} A national survey of patient injury claims against dermatology residency programs revealed that 50\% of these claims "related to therapeutic or surgical complications." Eric S. Hollabaugh et al., \textit{Patient Personal Injury Litigation Against Dermatology Residency Programs in the United States, 1964-1988: Implications for Future Risk-Management Programs in Dermatology and Dermatologic Surgery}, 126 \textsc{Archives Dermatology} 618, 618 (1990).

\textsuperscript{90} \textsc{Appelbaum et al.}, \textit{supra} note 21, at 51.

\textsuperscript{91} For an excellent survey of the law in each state, whether adopted by statute of judicial opinion, see \textsc{Rozovsky}, \textit{supra} note 64.

\textsuperscript{92} See Tables 1-4.
to more serious complications or have an increased likelihood of injury from complications due to the presence of predisposing risk factors.

A. Dysplastic Nevus Syndrome

Although controversy exists regarding the diagnosis and management of the dysplastic nevus syndrome, this survey revealed a consensus regarding some diagnostic and management tools for the specific case presentation. One hundred percent of the respondents indicated they would disclose the options of routine physician follow-up examinations, sun avoidance, and use of sun protection strategies. The vast majority of respondents would disclose routine self-examination of the skin (97.9%), surgical removal of selected pigmented lesions (95.8%), and explain the familial component of the syndrome so that blood relatives could be examined (91.7%). Less than one-half of the respondents would discuss other patient management options such as the surgical removal of all pigmented lesions (20.8%), patient referral to a specialized pigmented lesion clinic for further evaluation and treatment (33.3%), genetic counseling (39.6%), or limited photography for suspicious lesions (41.7%).

The clinical option for excising all lesions in the dysplastic nevus syndrome is recognized. This surgery may meet the legitimate needs of certain patients. For example, a person with the dysplastic nevus syndrome and a strong family history of malignant melanoma who is working in an area of the world without available medical care might well consider this option. Although the excision of all nevi is rarely recommended by dermatologists as the best management choice for patients with the dysplastic nevus syndrome, it is recognized that the least invasive management option is a routine skin examination. Removal of all nevi may lead to a false sense of security, causing the patient to forgo periodic medical examination. David L. Shrinier et al., *Techniques of Full-Scale Colour Total Body Photography: A Useful Tool in the Management of Patients with the Dysplastic Nevus Syndrome*, I J. DERMATOLOGICAL TREATMENT 181, 184 (1990). The false sense of security is potentially deadly for the patient who no longer finds it necessary to examine his skin for problematic lesions. Telephone Interview with Dr. Margaret Tucker, Director of Family
vis syndrome, if the option is not disclosed, it cannot be selected.

Due to the apparent genetic component in this case presentation, genetic counseling may allow the patient to exercise a choice in fathering a child who could also inherit the dysplastic nevus syndrome. Failure to warn this patient of the genetic component of his medical condition may lead to later allegations of wrongful birth if his child develops the dysplastic nevus syndrome. However, most patients do not desire genetic counseling and view the dysplastic nevus syndrome as a manageable condition. Because negligent genetic counseling is the focus of much attention in the legal community and the potential for costly litigation is high, it would seem prudent to inform the patient of the possibility of transmitting the disease to any offspring and offer the option of genetic counseling.

Of the dermatologists surveyed, 60.4% would disclose this patient's risk of death from malignant melanoma regardless of which patient management strategy was employed. Discussion of the risk of death in most instances helps the patient to understand the nature of the condition and choose realistic management options. The early detection and treatment of malignant melanoma is strongly predictive of a good prognosis.

Many of the respondents would disclose the option of an eye examination (60.4%). In fact, it has been recommended that all patients with dysplastic nevus syndrome and their families should be evaluated ophthalmologically because of the possible association with ocular melanoma. One

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97. In the DNS-familial case presentation there is a high risk of dying from melanoma unless changing lesions (i.e., those which turn dark, become scaly in texture, or irregular in size) are removed and the patient is educated about recognizing melanoma through regular self-examination and warned to avoid exposure to the sun. Id.

98. See, e.g., Gallagher v. Duke Univ., 852 F.2d 773 (4th Cir. 1988) (action against cytogeneticist after second child was born with severe physical and mental defects); Viccaro v. Milunsky, 551 N.E.2d 8 (Mass. 1990) (action against physician after second child was born with anhidrotic ectodermal dysplasia); Azzolino v. Dingfelder, 337 S.E.2d 528 (N.C. 1985) (action against health service, doctor, and nurse when child was born with Down's Syndrome).

99. The low response rate for genetic counseling in the survey may be attributable to the fact that it would take about two hours for a practitioner to effectively counsel this patient. Therefore, referral to a genetics clinic may be more efficient. Tucker Interview, supra note 95. See also Robin J. Caldwell & Walter E. Nance, Genetic Counseling for Problems Affecting Older Children and Adults, in Counseling in Genetics 121, 121-22 (Y. Edward Hsia et al. eds., 1979).

100. Rene S. Rodriguez-Sains, Ocular Findings in Patients with Dysplastic Nevus Syndrome, 93 Ophthalmology 661, 661 (1986) ("Dysplastic nevus syndrome patients may acquire melanomas at an earlier age than the general population, and have multiple cutaneous melanomas
ophthalmologist reported that there are no instances of a patient having both primary ocular and cutaneous malignant melanoma absent the dysplastic nevus syndrome.101

Limited photography for isolated suspicious lesions is difficult to support because any lesion initially suspected as malignant melanoma should be managed by biopsy,102 not photography. There is significant medicolegal risk for the clinician who photographs an isolated suspicious pigmented lesion only to later discover that it is a malignant melanoma. Regional photography is a useful type of limited photography when most of the dysplastic nevi are located in one area, such as the back. In this situation, photographing the back only will be less expensive for the patient and will also serve as an objective standard during future examinations of the back lesions. The reason for obtaining complete photodocumentation in the dysplastic nevus syndrome is to provide a baseline for later objective comparison.103

Over 70% of the respondents would discuss the option of obtaining photodocumentation of all of the lesions. This approach is useful as a clinical tool for physicians attempting to diagnose early malignant melanoma in patients with the dysplastic nevus syndrome.104 The photodocumentation of high risk patients under surveillance for malignant melanoma led to the detection of 23.1% new tumors.105 As more evidence mounts in support of photodocumentation, it is likely that more dermatologists will disclose this option.

B. Recurrent Basal Cell Carcinoma106

In the recurrent basal cell carcinoma case presentation, 97.9% of the res-
spondents would disclose the option of Mohs micrographic surgery while only 16.7% would disclose the option of treatment by radiation therapy.\textsuperscript{107} This finding is surprising given the wide availability and historic use of radiation therapy for skin cancer. Although Mohs micrographic surgery enjoys a statistically superior cure rate for recurrent basal cell carcinoma when compared to radiation therapy,\textsuperscript{108} the ultimate decision regarding the choice of treatment must rest with the patient. Therefore, the option of radiation therapy should be explained to the patient along with its advantages and disadvantages.\textsuperscript{109} Similarly, the advantages and disadvantages of other treatment options such as cryotherapy,\textsuperscript{110} curettage,\textsuperscript{111} and electrosurgery\textsuperscript{112} should be disclosed, even if they are not recommended.

\textbf{C. Malignant Melanoma}

In the case presentation of malignant melanoma, only 52.1% of the respondents would discuss an elective lymph node dissection. Controversy exists in the medical literature regarding whether an elective lymph node dissection will benefit the type of patient described in the case.\textsuperscript{113} The decision to employ this surgical operation is

\textsuperscript{107} For a comparison of cure and recurrence rates for basal cell carcinoma by radiation therapy, see Perry Robins & Blas A. Reyes, Cure Rates of Skin Cancer Treated by Mohs Micrographic Surgery, in \textit{DERMATOLOGIC SURGERY: PRINCIPLES AND PRACTICE} 853, 855 (Randall K. Roenigk & Henry H. Roenigk, Jr. eds., 1989). It is encouraging to the profession that dermatologists who do not practice Mohs surgery will refer patients for this therapy when they could perform treatment with less effective (and fee generating) methods.


\textsuperscript{109} One advantage is that there are no surgical risks involved and, therefore, no cosmetic reconstruction is needed. Disadvantages include a lower cure rate than Mohs micrographic surgery, the necessity for frequent radiation treatments, local and regional side effects, future management problems should radiation fail, and increased risk of a second primary tumor in the radiation portal.

\textsuperscript{110} Cryotherapy destroys cutaneous lesions by freezing with liquid nitrogen. The amount of freezing time will depend on the size of the lesion. Zachary, \textit{supra} note 12, at 67. For a discussion of possible complications associated with this procedure, see Setrag A. Zacarian, \textit{Complications, Indications, and Contraindications in Cryosurgery}, in \textit{CRYOSURGERY FOR SKIN CANCER AND CUTANEOUS DISORDERS} 283 (Setrag A. Zacarian ed., 1985).

\textsuperscript{111} Curettage involves the use of a curette, a sharp round instrument, which scoops the lesion in one movement of the hand, while the skin is stabilized with the other hand. Roy C. Grekin, \textit{Physical Modalities of Dermatologic Therapy}, in \textit{ANDREWS' DISEASES OF THE SKIN: CLINICAL DERMATOLOGY} 1008, 1009 (Harry L. Arnold et al. eds., 1990).

\textsuperscript{112} Destruction of tumor tissue is achieved by an electrical current. There are two types of electrosurgery: electrofulguration and electrodesiccation. In electrofulguration, an electric arc applied to the carcinoma "induces a superficial injury with charring, relatively fast healing, and low scar formation potential." Zachary, \textit{supra} note 12, at 67. In electrodesiccation, a treatment electrode must contact the skin. \textit{Id}. The latter type of electrosurgery is associated with a deeper tissue injury. \textit{Id}.

\textsuperscript{113} HABIF, \textit{supra} note 93, at 579. The determination to employ this surgical operation is
sion of many respondents not to discuss elective lymph node dissection with this patient may be related to the selected management option of referring the patient to another physician for additional surgery. Nonetheless, the survey shows that dermatologists are likely to discuss a regional lymph node dissection as an option in this setting. Similarly, 56.3% of the respondents would disclose the option of a medical oncology consultation to the patient which otherwise may be left to the physician performing the definitive surgery.

A small minority of the respondents would disclose experimental options for the management of this malignant melanoma such as hyperthermia (6.3%) and immunotherapy (4.2%). However, liability for failure to disclose experimental options is unusual.

D. Neonatal Port-Wine Stain

With respect to the newborn girl who has a neonatal port-wine stain, 70.8% of the respondents would discuss with the parents the option of evaluating whether metastasis has occurred into a nearby lymph node drainage pathway. One study has shown that 28% to 38% of patients with stage I melanoma of greater than .76 mm thick had prophylactic or elective lymph node dissections. See Yeu-Tsum Lee, Loco-Regional Primary and Recurrent Melanoma: III. Update of Natural History and Non-Systemic Treatments, (1980-1987), 15 CANCER TREATMENT REVIEWS 135, 140-41 (1988).

For a discussion of the latest developments in marshalling the body's immune system to fight cancerous cells, see Robin Herman, The New Weapons, WASH. POST, Dec. 3, 1991, at 14. To date, it is unclear whether the therapeutic elevation of body temperature or hyperthermia is clinically efficacious in the treatment of melanoma.

For a comparison of the role of informed consent in the experimental trial, see Paul Ramsey, The Patient as Person—Explorations in Medical Ethics, in EXPERIMENTATION WITH HUMAN BEINGS 589 (Jay Katz ed., 1972).

Both the neonatal port-wine stain and the Sturge-Weber syndrome are characterized by capillary hemangiomas. The skin discoloration associated with these cases usually occurs on the face and head. Specifically, the port-wine stain usually "involves the face in the distribution of the sensory branches of the fifth cranial nerve." R. F. Stevenson et al., Unrecognized Ocular Problems Associated with Port-Wine Stain of the Face in Children, 111 CANADIAN MED. ASS'N J. 953, 953 (1974). The Sturge-Weber syndrome typically follows the first branch of the trigeminal nerve. John Y.M. Koo, Neurocutaneous Disorders, in PRINCIPLES AND PRACTICE OF DERMATOLOGY 867, 873 (W. Mitchell Sams & Peter J. Lynch eds., 1990). Some patients with port-wine stains will also have Sturge-Weber Syndrome.
uation for possible treatment by a pulsed dye laser. Fewer respondents would discuss treatment with the argon laser (25%) or the carbon dioxide laser (4.2%) despite the plea by one physician to let the patient decide about the acceptable risks and benefits of using these two methods for treating a port-wine stain.

Of the dermatologists surveyed, 72.9% would discuss getting an eye evaluation and a neurology consultation. Since glaucoma and seizures are associated with the Sturge-Weber syndrome, evaluation along these lines is prudent. If glaucoma is discovered, intervention might prevent loss of vision. One physician recommends that patients having a port-wine covering the entire cranial nerve V₁ distribution associated with V₂ involvement should receive serial ophthalmologic examinations. Other ophthalmologists have suggested that all patients with any type of facial port-wine stain should have routine eye examinations because of the risk of glaucoma.

Early neurologic evaluation may be able to discern which infants with port-wine stains are at risk for subsequent neurological complications.

VI. CONCLUSION

This study has endeavored to show that the goal of preserving patient autonomy in the context of informed consent does not diminish the efficacy of the therapeutic process. The physician must be prepared to disclose significant alternative treatment options to the patient and provide the amount of information necessary to the patient's understanding of the potential risks and benefits of each option. On the basis of this survey, dermatologists should be concerned on two levels. First, a review of disclosure practices should be undertaken to determine whether they satisfy the legal requirements of their particular jurisdiction. Second, the legal requirements for disclosure should not serve as the outer limit of acceptable disclosure.

119. The pulsed dye laser is regarded as the best treatment tool for the port-wine stain with the advantages of high response rates, slight damage to surrounding healthy tissue, little or no pain during the procedure, and a small risk of scarring. Grekin, supra note 111, at 1015.
120. There is a high risk of scarring associated with using an argon laser on the port-wine stain. Id. at 1014.
123. See id. at 303.
124. Id.
125. Stevenson et al., supra note 118, at 954.
126. There is the added goal of providing some guidance of what physicians might routinely tell their patients in day-to-day practice, and it is hoped that this survey may help begin to address the perceived lack of study in this area.
practices. That is, dermatologists should endeavor to recognize those areas where the profession can promote more efficacious treatment.

Contrary to those who propose that informed consent cannot accommodate the perceived competing values of autonomy and physicians’ delivery of health care services, this survey has shown that these values can be complementary. If advances in dermatological medicine and surgery are to continue, doctors must avoid the tendency of focusing on the “institutional rules of informed consent” to the exclusion of developing a conscientious understanding of an individual patient’s needs.

FIGURE 1

Mean (\(\bar{X}\)) and standard deviation (SD) for the number of options disclosed for case presentations of dysplastic nevus syndrome, recurrent basal cell carcinoma, malignant melanoma and neonatal port-wine stain.
Case 1

A 34 year-old man presents to your office with several hundred unusual pigmented lesions scattered over his body. Most lesions are on sun-exposed areas. He relates to you that his mother, father, sister, and paternal grandfather died of malignant melanoma.

You decide to sample several of the nevi and the pathology report shows “moderate to severe dysplastic pattern.” You diagnose dysplastic nevus syndrome, familial type.

Please circle all the patient management options that you would discuss with this patient. Choose as many as apply to this case.

Survey Responses

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<td>48</td>
<td>routine physician follow-up examinations</td>
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<td>100</td>
<td>48</td>
<td>sun avoidance and use of sun protection strategies</td>
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<td>routine self-examination of the skin</td>
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<td>surgical removal of selected pigmented lesions</td>
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<td>follow-up of blood relatives</td>
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<td>natural history of disease if no medical intervention</td>
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<td>79.2</td>
<td>38</td>
<td>risks and benefits of various patient management strategies</td>
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<td>70.8</td>
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<td>total-body photographs</td>
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<td>60.4</td>
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<td>eye examination</td>
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<td>risk of patient death from malignant melanoma</td>
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<td>limited photography</td>
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CASE 2 — RECURRENT BASAL CELL CARCINOMA

A 45 year-old woman presents to you with a red sclerotic 0.8 x 0.9 cm plaque on the right ala. Three years ago she had a primary basal cell carcinoma at the same location treated by cryosurgery. Your biopsy shows a basal cell carcinoma. You diagnose a recurrent basal cell carcinoma.

Please circle all the patient management options that you would discuss with this patient. Choose as many as apply to this case.

Survey Responses

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<td>Natural history of disease if no medical intervention</td>
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<td>34</td>
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<td>25</td>
<td>Routine follow-up</td>
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<td>Local (conventional) excision of the lesion yourself</td>
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<td>12</td>
<td>Local (conventional) excision by other surgeon</td>
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<td>22.9</td>
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<td>Local (conventional) excision by another dermatologic surgeon</td>
</tr>
<tr>
<td>16.7</td>
<td>8</td>
<td>Radiation therapy</td>
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<td>14.6</td>
<td>7</td>
<td>Curettage and electrosurgery</td>
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<td>10.4</td>
<td>5</td>
<td>Cryotherapy</td>
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<td>Excision with frozen section control</td>
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TABLE 3 — MALIGNANT MELANOMA

Case 3

A 25 year-old man presents to you with a 0.5 x 0.7 cm diameter pigmented nodule on the right anterior thigh. Your excisional biopsy with 0.30 cm margins shows a malignant melanoma, 2.5 mm thick. There are no clinical lymph nodes present and metastatic evaluation is otherwise negative.

Please circle all the patient management options that you would discuss with this patient. Choose as many as apply to this case.

**Survey Responses**

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<td>re-excising the lesion yourself</td>
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<td>re-excision by another dermatologic surgeon</td>
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<td>immunology consultation</td>
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<td>periodic dermatologic follow-up exams</td>
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<td>refer to university because of potential medicolegal liability</td>
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<td>total skin exam, remove suspicious nevi, obtain family history, routine follow-up</td>
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<td>pigmented lesion conference with panel of specialists</td>
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</table>
You are called to the hospital to consult on a newborn girl who has a large macular port-wine stain involving the right forehead, upper and lower eyelids, cheek and nose.

Please circle all the patient management options that you would discuss with this patient’s parents. Choose as many as apply to this case.

**Survey Responses**

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