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What Form of Informed Consent? A Nationwide Pilot Survey

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Abstract

Background: Informed consent practices in dermatology are unknown.

Objective: Assess informed consent practices and opinions regarding minimum standards of care for dermatologic procedures.

Methods/materials: 500 randomly-selected, American dermatologists received mailed surveys, listing 19 dermatologic procedures. For each procedure, responders selected the informed consent method-none, verbal only, written only, or written and verbal representing their usual practice and opinion regarding minimum standard of care.

Procedures were grouped into: Destruction of non-malignant lesions, biopsy, electrodessication and curettage (ED&C), cosmetic, and excision (including Mohs surgery).

Results: Among 97 responders, mean age (SD) was 50 years (10.7). The most common informed consent practice (*) and opinion regarding standard of care (+) was verbal only for destructive procedures (66.5%*, 67.8%+), biopsy(46%*, 55.7%+), and ED&C (49.6%*, 53.9%+). Written and verbal informed consent was most common for excision (62.1%*, 41.1%+) and cosmetics (70.7%*, 51.6%+). No consent was in frequent (6.2% of responses), more common for destruction (11.9%) than biopsy (5.8%), ED&C (6.6%), cosmetic (3.3%) or excision (2.9%) (p=0.0002). Multivariate regression analysis revealed factors predicting no consent (odds ratio>5, 95% confidence interval) including practice <5 years (234.9, 11.2-999.9), surgical subspecialty (8.7, 2.9-25.8), solo private practice (14.7, 1.2-200), and destructive procedures (10, 3-33.3). Informed consent practice responses frequently equaled opinions about minimum standard (78.7%). Factors predicting practice exceeding opinion (estimate, p-value) included practice in Western US (-0.35, <0.0001) and academia (-0.67, <0.0001), practice >25years (0.16, 0.018), and history of malpractice litigation (-0.13, 0.008).

Conclusion: Numerous factors influence informed consent practices and opinions, including procedure type.

Keywords: Informed consent; Dermatologic procedures

Introduction

Informed consent is an ethical obligation for physicians and required by law prior to treatment in most states [1-3]. Consequences of failure to pursue informed consent may be grave not only for the patient but also the physician. The National Practioner Data Bank, which houses data on adverse actions taken against physicians in the US such as liability settlements or licensure revocation, reports 130 instances in which "lack of informed consent" was a basis for action [4]. Further, the Physician Insurers Association of America, an organization that collects professional liability claim data from insurance companies for a variety of medical specialties, reports that, over the last 25 years, "consent issues" was the second most common legal matter reported in claims made against dermatologists [5]. An indemnity payment to the plaintiff resulted from 42% of those claims, a considerably higher proportion than the 29% average for all claims made against dermatologists.

Given the importance of informed consent, research exploring current practice in dermatology is lacking. Fleischman and Garcia demonstrated exceedingly poor recall of potential complications by patients 20 minutes and 1 week after thorough informed consent for Mohs micrographic surgery [6]. Migden et al. investigated the use of video modules to expedite informed consent on a small group of patients undergoing Mohs micrographic surgery [7].

Representative dermatologic organizations, such as the American Society for Dermatologic Surgery (ASDS), have placed increasing emphasis on patient safety and guidelines of care [8]. Indeed, the American Academy of Dermatology (AAD) has recently recommended the use of a consent form for skin biopsy [9]. However, a broad range of other procedures commonly employed by dermatologists, ranging from cryosurgery to cosmetic procedures, lack formal guidelines. Survey data demonstrate a sharp rise in the utilization of many of these procedures [10].

The aims of the current work are to assess the method by which practicing dermatologists in the US pursue informed consent for common dermatologic procedures and to measure opinions regarding minimum standards of care for informed consent for these procedures. We hypothesized that more rigorous practices and opinions exist

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for more cosmetic and/or invasive procedures. Further, we sought to determine relevant factors that predict failure to obtain informed consent, as well as those that predict a discrepancy between opinions regarding standard of care and usual practice. Finally, we assessed the interest among respondents in the creation of published guidelines for informed consent.

Materials and Methods

The study protocol was approved by the Emory University Institutional Review Board. A survey was constructed by the investigators using Survey Monkey™. In addition to several demographic and miscellaneous items, the survey listed 19 common dermatologic procedures, based on a well-regarded dermatology textbook [11]. Responders were asked to indicate their usual practice for informed consent – none, verbal only, written only, or written and verbal – for each procedure, as well as the method that they believed to constitute the minimum standard of care.

The AAD provided the investigators with a mailing list comprised of a random sample of 1500 of its members, including only those that were practicing in the US. A randomly-selected sample of 500 from this list was mailed a paper copy of the survey, with options to complete it on line or by hand and return it through mail. Data was collected from March to November 2009.

For the purposes of data analyses, procedures were grouped according to level of invasiveness and cosmetic nature into the following: (1) destruction of nonmalignant lesions (including cryosurgery, intralesional corticosteroid injection, and medical chemical peel), (2) biopsy (including incisional and excisional shave, punch, and scalpel-based techniques], (3) electrodessication and curettage (ED&C), (4) excision of benign or malignant lesions [including Mohs micrographic surgery), and (5) cosmetic (including injection of botulinum toxin, injection of soft tissue filler, cosmetic chemical peel, laser, sclerotherapy, and liposuction).

Primary endpoints were the most common usual practice for informed consent [none, verbal only, written only, or written and verbal] for each procedure group and the most common opinion regarding minimum standard of care for each procedure group.

Other variables were codified as follows: Ethnicity as Caucasian 1 and non-Caucasian 2 (reference case for regression models Caucasian), age in years as continuous variable (reference 0), region of practice as west 1, south 2, northeast 3, and mid west 4 (reference west), practice duration as <5years 1, 5-15years 2, 16-25years 3, >25years 4 (reference >25 years), subspecialty as medical 1 and surgical 2 (reference medical), practice setting as solo private practice 1, group private practice 2, and academic 3 (reference solo private practice), procedure type as destruction 1, biopsy 2, ED&C 3, cosmetic procedures 4, and excision 5 (reference destruction), construct most influential to informed consent as ethics 1, law 2, and medicine 3 (reference ethics), and history of malpractice litigation as none 0 and having been used for malpractice 1 (reference none).

Statistical analyses were performed with SAS version 9.2 [12] and a p-value<0.05 was considered significant. All continuous variables were expressed as means with standard deviations and all categorical variables were expressed as proportions. Proportions were compared using chi-squared analysis.

We calculated the proportion of each type of consent response for each procedure group. However, we summarized our findings by dichotomizing the respondents into those who failed to obtain informed consent (answer: none) versus those who obtained consent by any means (answer: verbal only, written only, or written and verbal). We also performed a logistic regression model with an outcome variable of failure to obtain informed consent. Possible predictor variables included those listed above.

We captured the discrepancy (if any) between usual practice and opinion regarding minimum standard of care by subtracting the scores for minimum standard from usual practice (range -3 to +3). For example, a responder indicates that her usual practice for biopsy is written and verbal informed consent (score 4) but her opinion about minimum standard for biopsy is verbal only (score 2). This would result in a positive discrepancy (+2). We justified this approach because the responses are ordinal with regard to intensity or rigor of informed consent process.

We performed a linear regression model using the discrepancy score as the outcome variable and the factors listed above as possible predictors. We justified the linear regression approach because outcome scores could range between -3 to +3.

Results

Demographics

In all, 97 completed surveys were returned (response rate 19.4%), including 94 by mail and only 3 on-line. Responder demographics are presented in table 1, corresponding reasonably well to those of the AAD [13]. Responses to additional survey items revealed that only 73% of

Variable	Survey Responders	AAD
Mean Age (SD)	50 (10.7)	51 (*)
Gender	60% Female	39% Female
Race	92% Caucasian	*
	8% Noncaucasian	*
Years in Practice	7% <5 yrs	10% <5 yrs
	41% 5-15 yrs	15% 5-10 yrs
	19% 16-25 yrs	29% 11-20 yrs
	33% >25 yrs	24% 21-30 yrs
		22% >30 yrs
Type of Practice	42% Group Derm	40% Group Derm
	38% Solo	40% Solo
	11% Multispec	9% Multispec
	8% Academic	8% Academic
Region of Practice	38% South	32% South
	27% NE	26% NE
	29% MW	19% MW
	16% Pacific	22% Pacific
Subspecialty	72% Medical	*
	25% Surgical	*
	3% Pediatric	*

*Data not reported by AAD
SD = standard deviation
Group Derm = group private practice composed of only dermatologists
Solo = dermatologist in solo private practice
Solo = dermatologist in solo private practice
NE = northeastern US
MW = midwestern US
Medical = dermatologists who spend the majority of their time practicing medical dermatology
Surgical = dermatologists who spend the majority of their time practicing surgical dermatology

Table 1: Demographics of responders compared to members of the AAD.

responders pursue informed consent with patients themselves (versus delegating the duty to someone else). When verbal informed consent only is obtained, the conversation is documented in nearly every case or every case (76-100% of the time) for 47% of responders, the majority of cases (51-75% of the time) for 15%, less than half of cases (25-50% of the time) in 11%, and rarely (<25% of the time) in 27%. Ethics (44%) was considered more influential to responders in their conception of informed consent than law (29%) or medicine (27%). Surprisingly, 39% of responders reported a history of litigation for malpractice. 58% did not support the creation of published guidelines for informed consent by dermatologic organizations, such as the AAD and ASDS.

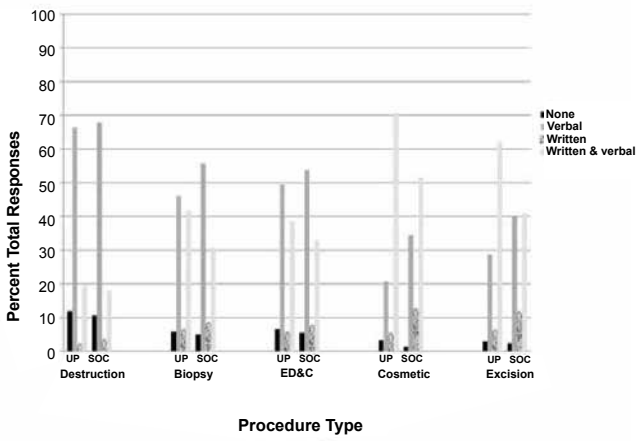
Informed consent type and procedure type

The most common usual practice and opinion regarding minimum standard for each procedure type were as follows: verbal only for destruction of nonmalignant lesions (66.5% practice, 67.8% opinion), biopsy (46% practice, 55.7% opinion), and ED&C (49.6% practice, 53.9% opinion). A combination of written and verbal informed consent was most common for excision (62.1% practice, 41.1% opinion) and cosmetic procedures (70.7% practice, 51.6% opinion) (Figure 1).

Lack of informed consent

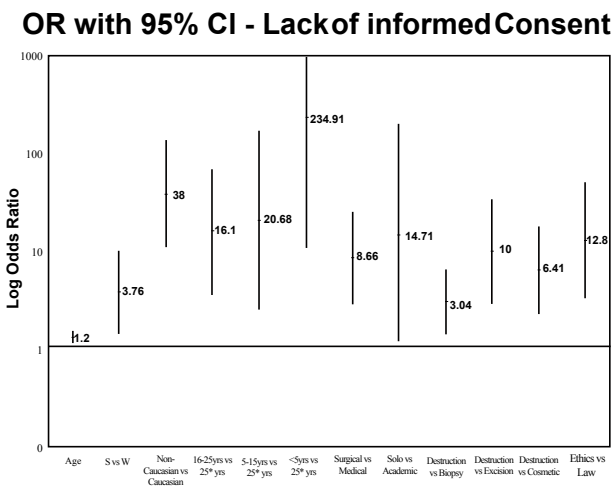
Failure to pursue informed consent was uncommon in general, comprising 6.2% of all responses for usual practice. Lack of informed consent was more common in practice for destruction of non-malignant lesions (11.9%) than for biopsy (5.8%), ED&C (6.6%), cosmetic procedures (3.3%) and excision (2.9%) (p=0.0002). Multivariate logistic regression analysis revealed that all variables, except practice setting and history of litigation, were significant predictors of failure to obtain informed consent. Those categories with adjusted odd ratios greater than 5 for lack

of informed consent (odds ratio, 95% confidence interval) included: surgical vs. medical subspecialty (8.7, 2.9-25.8), destruction vs. excision procedure type (10, 3-33.3), ethics vs. law as primary influence on informed consent (12.8, 3.3-50), solo private vs. academic practice setting (14.7, 1.2-200), non-Caucasian vs. Caucasian ethnicity (38.1, 10.8-134.1), practice duration <5years vs. >25years (234.9, 11.2-999.9) (Figure 2).



UP: Usual Practice; SOC: standard of Care

Figure 1: Frequencies of informed consent method in usual practice and in opinion regarding standard of care for each procedure type.



Adjusted odds ratios (OR) with 95% confidence intervals (CI). Non-significant comparisons omitted
S = practice is southern US
W = practice in western US
yrs = years in practice
Surgical vs Medical = subspecialty
Solo vs Academic = practice setting
Ethics vs Law = construct most influential to attitudes related to informed consent

Figure 2: Multivariate logistic regression model for failure to obtain informed consent.

Usual practice versus opinion about standard of care

Usual practice and opinion regarding minimum standard of care agreed in 78.7% of responses. Practice responses tended to exceed opinions regarding standard of care (i.e. demonstrated more rigorous method of informed consent) with more invasive or cosmetically-oriented procedures (Figure 1). In the case of destruction of nonmalignant lesions, for example, the frequency of written and verbal informed consent in practice (19.4%) was similar to frequency with which this method was believed to be the standard of care (18.1%). For cosmetic procedures, however, written and verbal informed consent was much more common in practice (70.7%) than in standard of care opinion (51.6%) (p<0.001).

The multivariate linear regression model predicting responses in which usual practice exceeded standard of care opinion demonstrated that all variables were significant, except age and subspecialty. Categories most predictive of this positive discrepancy [estimate, p-value] included: practice in Western US versus Northeast (-0.35, <0.0001), Caucasian ethnicity (-0.53, <0.0001), academic practice setting versus solo private practice (-0.67, <0.0001), practice duration >25years versus <5years (0.16, 0.018), and positive history of litigation (0.13, 0.008) (Table 2).

Discussion

Our results suggest that informed consent practices in dermatology vary by procedure type, with a tendency toward more stringent informed consent for more invasive and/or cosmetic procedures. Interestingly, despite recommendations by the AAD to pursue written informed consent prior to skin biopsies, less than 50% of responders engage in this practice.

Linear Regression
Usual Practice – Standard of Care= ++

Variable		Compared To:	Estimate	Pr>[t]
Age			0.009	0.109
Practice Region	NE	West	-0.351	<0.0001
	MW	*West*	*-0.225*	*0.743*
	S	West	-0.212	0.001
Ethnicity	Caucasian	non Caucasian	0.525	<0.0001
Practice Duration	5-15y	<5 yrs	-0.225	0.002
	16-25y	<5yrs	-0.135	0.255
	25 yrs	<5yrs	0.160	0.018
Subspecialty	*Med Derm*	*Surgical*	*0.114*	*0.062*
Practice Setting	Solo Private Practice	Academic	-0.666	<0.0001
	Group, single specialty	Academic	-0.636	<0.0001
Procedure Group	Destruction	Excision	-0.254	0.000
	Biopsy	*Excision*	*-0.060*	*0.289*
	Cosmetic	*Excision*	*-0.179*	*0.056*
	ED&C	*Excision*	*-0.003*	*0.969*
Construct	*Law*	*Medicine*	*-0.067*	*0.330*
	Ethics	Medicine	-0.213	0.001
Sued	Yes	No	0.130	0.008

Categories in *italics* = non-significant.
Column labeled "Compared To" = reference case
SOC = minimum standard of care

Table 2: Multivariate linear regression model for positive discrepancy between usual practice and opinion regarding minimum standard of care for informed consent: Point estimates with Pr>[t] (analogous to *p* value).

While failure to pursue informed consent was rare, this failure occurred more frequently with minimally invasive procedures, such as cryosurgery and intralesional corticosteroid injection, than with more invasive procedures, such as excision. Factors most strongly predicting lack of informed consent included short practice duration, non-Caucasian ethnicity, surgical subspecialty, solo private practice setting, and less invasive procedure type.

In the vast majority of cases, the usual informed consent practice enacted by a given responder was precisely that which she believed was the minimum standard of care. There were instances in which informed consent method used in practice was more rigorous than that considered the minimum standard, a discrepancy associated with practicing in the Western US and in an academic setting, as well as Caucasian ethnicity, longer practice duration, and history of malpractice litigation.

We were pleased to find that most dermatologists consider ethics the most influential construct with regard to informed practice. Indeed, preservation of autonomy, or freedom from external constraints and capacity for self determination, should be intrinsic to all medical decision making [1].

We also found intriguing the potential influence of the law on informed consent practices and opinions. When asked directly, 29% of responders declared that the law influenced them most. Indeed, history of litigation was a significant predictor of responders whose practices exceeded their opinions about minimum standard of care.

A deeper understanding of the law governing informed consent may also aid in understanding the results. In most states, informed consent for minimally-invasive procedures falls under the legal rubric of negligence [3]. To be deemed negligent, a physician must have a duty to a given patient, that duty must be breached, the breach must be the proximate cause of an untoward event, and that event must constitute harm to the patient [14]. Without harm, therefore, there is no negligence. As risk is defined as the potential for harm, then perhaps it is the avoidance of legal risk that, in part, drives dermatologists' behavior and beliefs regarding informed consent.

Most consistent with this theory was the finding of more rigorous informed consent for more invasive and/or cosmetic procedures. Those procedures that were most prone to cause harm, either because they were most invasive and/or involved patients perhaps most sensitive to harm, were associated with more stringent informed consent practices.

To illustrate this phenomenon further, consider the most predictive factor for lack of informed consent: practice duration <5years vs. >25years. Prior work demonstrates that longer practice duration is associated with greater risk aversion [15]. Therefore, those in practice for shorter periods may be expected to be less risk averse. The less risk averse, the more likely one may be to neglect their duty to pursue informed consent. In keeping with this notion, our results suggest that longer practice duration is associated with a greater likelihood for usual informed consent practice to exceed opinion about minimum standard of care. The longer physicians are in practice, that is, the more likely they are to do more than they believe is necessary when pursuing informed consent.

Surgical subspecialty was also associated with lack of informed consent. Although less well substantiated, it is conceivable predominantly surgical dermatologists who perform procedures regularly might consider a given procedure less prone to harm than those who don't. In such a case, surgeons may be less likely to pursue informed consent.

Also intriguing was the finding that academic practice setting was associated with a greater tendency toward usual practice exceeding standard of care opinion. We speculate that additional practice standards imparted by an academic institution, coupled with legal and ethical requirements, may contribute to this finding. Perhaps those in the solo private practice setting have fewer administrative standards to

which to adhere and are therefore less likely to do more than they deem necessary, as demonstrated in the linear regression analysis.

Finally, we were surprised to discover that the majority of responders were not in favor of the creation of published guidelines for informed consent by representative organizations, such as the ASDS and AAD. Perhaps this sentiment stems from the ever-increasing regulatory burden shouldered by physicians or from a perceived threat to autonomous practice that such guidelines may impart. An opposing position may hold that better defining the standard of care regarding informed consent through such guidelines may serve to mitigate uncertainty on the part of physicians. To return to the legal realm, standards of care related to informed consent are often determined by an expert witness [16]. Were published guidelines available, the expert witness and practicing dermatologist may find less ambiguity in defining best practice.

Limitations

As with much survey research, low response rate may have biased results in this study. The low response rate also resulted in very small numbers of subjects in each subgroup, leading to odds ratios with wide confidence intervals. Further, although randomly-selected and ostensibly similar to AAD membership, our sample may not have been truly representative of practicing dermatologists in the United States. The proportion of responders reporting a history of litigation for malpractice, nearly 40%, highlights the potential role of this bias. Unfortunately, the AAD and ASDS do not publish data on litigation rates among their respective memberships. Professional liability claims data collected over the last 25 years suggests that dermatology accounts for only 1.4% of all claims filed [5]. It would seem likely, therefore, that dermatologists with direct exposure to litigation were more likely to complete the survey than those without such exposure, further demonstrating the influence of the law in dermatologists' conception of informed consent. Response bias, which may occur when responders perceive certain answers as "correct," may have distorted results as well.

Perhaps more important, our survey failed to assess the content of informed consent. Although we operationalized informed consent as an ordinal variable, this may not reflect reality. For instance, a thorough discussion with a patient (considered verbal only in this study) may be superior at conveying informed consent than the use of a poorly constructed consent form (considered written only and more rigorous informed consent than verbal only in this study). Indeed, many studies have demonstrated poor understanding by patients of the content and role of consent forms [17,18].

Future Directions

Future research is needed to validate the results of this pilot study on larger numbers of dermatologists. As such, we plan to undertake further data collection and analyses. Assuming a power of 80% and alpha of 5%, we will seek to test, for example, the null hypothesis for the distribution of written informed consent by procedure type. Having 5 procedural categories and assuming effect size of 0.05, we will need 239 participants. This sample size seems reasonably attainable based on the number of dermatologists practicing in the United States. As discussed above, it is also crucial to access the content of informed consent, as well as outcomes for patients, in terms of understanding and voluntariness.

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