Medical Oncologists' Self-Reported Practices and Opinions Regarding Cancer Chemotherapy Informed Consent Procedures

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MEDICAL ONCOLOGISTS' SELF-REPORTED
PRACTICES AND OPINIONS
REGARDING CANCER CHEMOTHERAPY
INFORMED CONSENT PROCEDURES

by

George Walter Rakowsky

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Faculty of The Graduate College
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requirements for the
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MEDICAL ONCOLOGISTS' SELF-REPORTED PRACTICES AND OPINIONS REGARDING CANCER CHEMOTHERAPY INFORMED CONSENT PROCEDURES

George Walter Rakowsky, M.A.
Western Michigan University, 1983

This study gathered descriptive data on the parameters of informed consent with cancer chemotherapy patients from the medical oncologists' point of view. A review of the literature suggested that no such research has previously been attempted. A description of disclosure practices would clarify current procedures and would also serve as a guide for further research in the area.

Six hundred questionnaires were mailed to medical oncologists, and thirty percent of these were returned. Data were analyzed primarily using descriptive statistics. Additionally, relationships between demographic variables and different disclosure practices were investigated.

Significant relationships were observed between variables reflecting the size of the facility, proportion of patients put on research treatments, and disclosure practices. The medical practice standard and the reasonable person rule of informed consent were discussed in the light of these findings.
ACKNOWLEDGEMENTS

I would like to express my appreciation to three women without whose participation completion of this thesis would have been impossible: My wife, Teresa, for her patience and understanding; my adviser, Nancy Petty, for her inspiration and fervor; and my typist, Marcia Veld, for her skill and humor.

George Walter Rakowsky
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INTRODUCTION

This study was primarily concerned with an investigation of how medical oncologists subjectively view and practice the informed consent process with cancer chemotherapy patients and how these opinions and practices relate to a number of demographic variables. Previous research on informed consent from a physician's perspective (Faden, Lewis, Becker, Faden & Freeman, 1981; Hershey & Bushkoff, 1969; Rosoff, 1981) has been quite minimal. Moreover, there have been no studies from the physician's perspective specific to medical oncology. Considering the implications that such research (or the lack thereof) can have on the evolution of the doctrine of informed consent, the dearth of empirical research in this area is quite surprising.

Nonetheless, since 1762, there have been published more than 5,000 articles related to informed consent and ethics in human experimentation. However, the greatest proportion of these articles came after 1960, with the total number being multiplied six-fold between that year and 1975 (Woodward, 1979). Historically, physicians, nurses, other health-care professionals, lawyers, professional bioethicists, and consumer advocates have debated what to disclose to patients and how to disclose

The approaches have ranged from the pedantic to the inflammatory, the quality from the impenetrable to the flatly erroneous. Many of the conclusions reached have been little more than opinions, seldom buttressed with facts or objective observations. (Woodward, 1979, p. 248)

Reasons for relying on opinions and beliefs rather than research are many. First, the seeming encroachment of law into medicine is, by its very nature, a conflict bound to arouse vociferous, emotional charges and defenses. With ever-increasing lawsuits, monetary settlements, and malpractice insurance premiums, empirical data may be more threatening than simply continuing with idealogical and philosophical arguments. Second, the informed consent issue is quite complex. For example, one may describe what occurs during a consent session from three different but equally valid points of view, i.e. the patient's, the physician's, and the independent observer's (Meisel & Roth, in press). Third, it's simpler not to do research.
The first judicial case bearing on informed consent occurred in 1767—Slater vs. Baker and Stapleton—and the doctrine has been evolving ever since. Today there are two somewhat conflicting major standards by which informed consent disclosure may be judged to be adequate or not—the medical practice standard and the reasonable person standard. The medical practice standard is the older of the two and

... obligates physicians to disclose information in accordance with the custom of physicians within the community. This reflects the view that physicians' duty to disclose must be weighted against their right to withhold information. This duty to withhold is based on the assumption that physicians, because of their superior knowledge, are better equipped than patients to determine what is best for them, and that therefore, physicians' duty to disclose is secondary to the obligation to act in their patients' best interests. (Faden, Lewis, Becker, Faden & Freeman, 1981, p. 256)

This medical practice rule has been the time-honored one usually held up by physicians as a shield against litigious probings into the reasons why some aspects of treatment were disclosed to a patient and why others (usually the risks) were withheld.

1Slater vs. Baker and Stapleton, 2 Wils 359, 95 Eng Rep 860 (KB 1767).
More recently it has been determined that while the medical standard may protect physicians from legal incursions, it may also inadvertently obstruct the patient's rights to self-determination in treatment choice. In 1972 with the Canterbury vs. Spence decision, the reasonable person standard was set:

In our view, the patient's right to self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then must be measured by the patient's need, and that need is the information material to the decision. Thus, the test for determining whether a particular peril must be divulged is its materiality to the patient decision: All risks potentially affecting the decision must be unmasked. (Canterbury vs. Spence\textsuperscript{2}, 1972, pp. 786-787).

While this decision, and similar ones in California and Rhode Island--Cobbs vs. Grant\textsuperscript{3} and Wilkinson vs. Vesey\textsuperscript{4}, respectively--have established the reasonable

\textsuperscript{2}Canterbury vs. Spence (D.C. Cir. 1972) 464 F. 2d 772.

\textsuperscript{3}Cobbs vs. Grant (Cal. 1972) 8 Cal. 3d 229, 104 Cal./Rptr. 505, 502 P. 2d 1.

\textsuperscript{4}Wilkinson vs. Vesey (R.I. 1972) 295 A. 2d 676.
person standard in some jurisdictions, other courts have not judged it necessary to strike down the medical practice doctrine in favor of the newer standard. The medical practice standard is still dominant throughout most of the country today (Faden et al., 1981).

Meisel, Roth, and Lidz (1977) provide an excellent model of the necessary elements of a valid informed consent. They state that as a precondition to the start of the consent process, the patient's voluntariness must be assured. Any coercive influence on the patient's decision negates the intent of the informed consent doctrine and renders the decision invalid. In order to produce a valid consent, the patient must be competent and must be provided with all of the necessary information.

They must be informed of 1) the risks, discomforts and side effects of proposed treatment, 2) the anticipated benefits of such treatments, 3) the available alternative treatments and their attendant risks, discomforts, and side-effects, and 4) the likely consequences of a failure to be treated at all (Meisel et al., 1977, p. 286).

Finally, the patient must comprehend this information, and make the decision itself, that is, consent to or refuse the proposed treatment.

While the spirit of the consent doctrine implies that every effort should be made to obtain a valid consent before treatment, there are legally recognized
extenuating circumstances where informed consent may be foregone. Specifically, informed consent may not be required where the patient is incompetent, is in a life-threatening emergency situation, or waives his right to informed consent prior to treatment, or where the physician invokes so-called "therapeutic privilege" and intentionally withholds all or partial information from the patient for his or her own good (Meisel, 1981). Both patient waiver and therapeutic privilege point to the sensitivity of the courts in recognizing the possibility that full disclosure may be psychologically harmful to some patients and that either patient or physician may decide to limit disclosure.

While the patient's right not to know has generated little controversy, physicians' therapeutic privilege has been opened to the greatest scrutiny. This scrutiny has come about as the result of physicians using therapeutic privilege as a defense strategy in litigation involving non-disclosure of risks. Therapeutic privilege may also have become suspect because by its very nature it is against egalitarian values found in this country. In our culture, it is distasteful to grant that any individual has a wisdom so superior to that of others that it would allow him or her to censor information having a direct bearing on the fate of those same others.
Studies on Informed Consent

A great number of studies have been published on informed consent as it relates specifically to the psychiatric patient's competence in understanding and giving consent to treatment or research (Appelbaum, Mirkin, & Bateman, 1981; Geller, 1982; Grossman & Summers, 1980; Kaufmann & Roth, 1981; Olin & Olin, 1975; Roth, Lidz, Meisel, Soloff, Kaufman, Spiker, & Foster, 1982; Stanley, Stanley, Lautin, Kane & Schwartz, 1981; Stanley, Stanley, Peselow, Wolkin, Deutsch, Platt, Speicher, Golash, & Kaufman, 1982). These studies will not be reviewed, however, since competency in a psychiatric population is rather tangential to informed consent with medical patients.

What Patients Want To Be Told. There have been a group of studies which investigated what the general public and average patient wants to know in medical treatment situations. It has been traditionally believed that the patient would not want to know the truth about his condition and treatment. Moreover, the harsher the reality of the situation, the less likely the patient would want to be told of it. However, most research has not supported this belief. For example, looking at the type of consumer information that is inserted within prescribed packets of diazepam (Valium), Fisher, Mansbridge,
and Lankford (1982), found that lay consumers and medical information experts who had designed the inserts had a high degree of accordance as to what they had independently found to be especially important and meaningful in the insert. Where disagreements did arise

... the public attached even greater importance to warnings and "bad news" about diazepam than to information providing reassurances, benign general education, and "good news". (Fisher et al., 1982, p. 707)

While attaching importance to "bad news" does not necessarily translate into a desire to be told of it if it in fact existed, that implication is still clearly there.

Alfidi (1971, 1973) investigated whether patients about to undergo arteriography wanted to know about possible complications. The majority of patients (87-89%) said that they were pleased with having been given such information. Working independently and using a similar population and methodology, Rosenberg (1973) replicated these findings.

However, Alfidi (1975), in a subsequent study, found that when patients were asked in advance of the consent if they wanted to be told of possible complications from arteriography, only a small minority wanted to be given such information.
As has been discussed elsewhere it is possible that the disparity in these findings was due to the fact that

...patients are inclined to view a fait accompli as a good thing, because there is nothing that can be done to erase the experience. An alternative explanation is that the first study is more likely to be valid because it measures patients' attitudes toward a real past event, whereas the second study is hypothetical in that patients are asked not whether they were grateful for information received, but whether they wanted information at all, and information that was characterized as relating to "significant hazards", a phrase with negative connotations. (Meisel & Roth, in press, pp. 23-24)

As to the question of whether patients wanted to be informed of "bad news", a national survey of 1518 adults determined that 92% would want to be told if they had a terminal disease (Blumenfield, Levy, & Kaufman, 1978). The authors cautioned, however, that because the survey polled the general population, some care must be taken in concluding that the terminally ill desire to be informed of their prognosis.

Hartwich (1979) interviewed 56 terminally ill patients and concluded that three factors correlated with willingness to be told and subsequent positive adjustment: 1) advanced years, 2) a good social network, and 3) a nonpathologic personality. Where the terminally
ill patient is young, socially withdrawn, and/or markedly neurotic, particular care against negative reactions to disclosure should be taken, if disclosure is attempted at all.

With findings such as the above, there has been seen a reversal in physicians' attitudes about disclosing terminal illness to patients. While in 1961, 90% of the physicians reported that they would not reveal a terminal prognosis to a cancer patient (Oken, 1961), in 1979, 97% of similarly questioned physicians indicated that they would (Novack, Plumer, Smith, Ochitill, Morrow, & Bennett, 1979).

*Communication In Informed Consent.* With the determination that most patients desire all information concerning their treatment (and the realization that they were willing to insure the fulfillment of such desires with lawsuits), there have begun to appear articles on such topics as how to disclose the complications of specific medical procedures (Buchwald, 1980) e.g. how to increase retention of imparted information through the use of quizzes (Williams, Trenholme, Rieckman, Frischer, & Carson, 1977; Woodward, 1979) videotapes (Barbour & Blumenkrantz, 1978), and instructions to the patient to take written information home before signing the forms (Morrow, Gootnick, & Schmald, 1978). This trend
to increase the informativeness of informed consent comes after findings that although patients and the general public claim that they want to hear all there is about the medical treatment to which they are about to be subjected, the numbers of those who actually do hear and understand, is actually small (Robinson & Merav, 1976; Priluck, Robertson, & Büttner, 1979). This lack of understanding in turn could promote litigation.

Part of the problem in patients' misunderstanding lies in the way consent information is typically presented. In explanations to patients, physicians tend to overuse medical jargon and to be too technical without sufficiently translating what they mean into lay terms. For example, in a study which reported on how pediatricians communicated to the parents of their young patients, it was found that

Terms such as nares, peristalsis and Coombs titre were Greek to patients. A "lumbar puncture" was interpreted as meaning an operation to drain the lungs, and a reference to "incubation period" was taken to signify the length of time the sick child was to be kept in bed. A mother who was told that her child would be "admitted for a work-up" did not realize that he was to be hospitalized; when another mother was told by the physician that he would have to "explore", she had no idea he was talking about surgery. (Korsch & Negrete, 1972, p. 71)
Similarly, in studies on the readability of consent forms, analyses have shown that they are usually written at least on the college level (Riecken & Ravich, 1982) and sometimes as high a level as that found in medical journals or specialized academic magazines (Grundner, 1980; Morrow, 1980). Consequently, it is not surprising that patients after reading consent forms and/or listening to physicians sometimes grossly misunderstand. For example, various patients after consent did not ever realize that they were consenting to be research subjects (Riecken & Ravich, 1982), that the research had no curative intent (McCollum & Schwartz, 1969), or that there was a possible fatal reaction to treatment (Epstein & Lasagna, 1969). Furthermore, this lack of comprehension tends to be compounded by the patients' own reluctance to ask questions of physicians (Boreham & Gibson, 1978; Korsch & Negrete, 1972).

**Patient recall.** A number of articles have not focussed on comprehension as such, but rather on what patients recall of the information presented during the informed consent discussion. One of the earliest studies along this line found that all 20 patients questioned 4-6 months postoperatively failed to remember significant portions of the consent content (Robinson & Merav, 1976). Based on the belief that those patients understood the
information at time of delivery, but simply forgot it, the authors recommended that physicians insure themselves against possible lawsuits generated by faulty patient memory by documenting all that had transpired during consent sessions.

Similar findings have been reported by others (Muss, Priluck, White, Michielutte, Richards, Cooper, Williams, Stuart, & Spurr, 1979). In the Muss et al. study 100 breast cancer patients were asked a variety of questions to measure their recall of the information presented during the consent given prior to the start of chemotherapy. Up to about 30% of the patients could not remember the names of the drugs they were being administered. More significantly, the great majority were able to name distressing yet non-life-threatening side effects such as nausea and hair loss; however, only about 50% recalled the possibility of occurrence of such potentially lethal complications as infections and bleeding. The authors hypothesized that the reason for this paradoxical discrepancy in recall rates for minor vs. major side effects may be due to the fact that although the more frequently recalled side-effects were less serious, they were also much more common in occurrence. It is possible therefore that patients recalled the more probable minor side effects because they had experienced such side effects to some degree. Conversely, the
potentially lethal side-effects, were rarely experienced and were therefore not salient consequences of chemotherapy. It is also possible that information on life-threatening risks was qualified by statements pointing out the rarity of their occurrence. In addition to softening the blow of such news, qualifying statements may have modified the extent to which a patient attended and consequently modified what he remembered.

A major flaw of the Muss et al. study is that the questions posed by the researchers were asked anywhere from 0-24 months after the start of chemotherapy. Consequently, it is hard to determine what is remembered by patients at what time post the consent. Such data would be of some interest both in and of itself, and for comparison to typical learning retention curves.

**Patient Variables.** In addition to the informed consent content and format (the use of jargon, readability of forms, etc.), research has also looked at patient variables that may account for differences in comprehension and recall. In light of the previously discussed findings that most consent forms are written at the college level of readability, it is to no one's surprise that the level of education of the patient is a factor found to be most strongly related to later recall
and comprehension (Cassileth, Zupkis, Smith, & March, 1980; Freeman, Pichard, & Smith, 1981; Golden & Johnston, 1970; Howard & DeMets, 1981; Taub, 1980; Taub, Kline, & Baker, 1981). Only one study has not found such a correlation (Bergler, Pennington, Metcalfe, & Fries, 1980), and that observation seemed due to exceptional circumstances. First, an unusually high percentage of recall was seen (71.6% at 2 hours post consent and 61.2% at three months post consent). Second, the procedure for which consent was sought was a relatively simple two drug trial and consequently, only a very brief, concise consent form was presented. Third, special care was exercised to use a clear style in the vernacular. Finally, all potential participants were allowed 15 undisturbed minutes to read and think over the information presented in the form. In addition to education, various of the above cited authors found a relationship between degree of recall and age (Howard et al., 1981; Taub, 1980; Taub et al., 1981), race (Howard et al., 1981), medical status, the attention with which patients read consent forms (Cassileth et al., 1980), and the number of opportunities to question the medical information provider (Golden et al., 1970).
As has been pointed out by Meisel and Roth (in press), the major drawback in studying recall as a measure of comprehension, is that the two are not equivalent.

There are difficulties inherent, however, in any attempt to extrapolate "understanding" from recall. That patients do not recall information several days, weeks, or months after treatment is simply not relevant or at best only marginally relevant - to whether or not they can be said to have rendered an informed consent at or near the time of the procedure. Thus, to conclude that patients have not given informed consent, because they have had difficulty remembering even for a short period of time, exhibits a fundamental misunderstanding of informed consent. (Meisel & Roth, in press, pp. 39-40)

A further criticism of studies on recall is that there rarely was any control on what actually was said to patients in addition to the information presented in the form. This fact may make evaluating recall difficult, if not impossible, since what actually is said sometimes falls far short of what should have been said. For example, Beecher (1966b) found that of the 50 medical research studies he reviewed, only two mentioned consent. He ends up dismissing even these on the grounds that,
In any precise sense statements regarding consent are meaningless unless one knows how fully the patient was informed of all risks, and if these are not known, that fact should be made clear. (Beecher, 1966b, p. 1355)

While it may be true that such findings were the norm in 1966 and that there is no basis to suspect that such a cavalier attitude toward consent exists among physicians and researchers today, it would also be a mistake to assume that disclosure is fully and comprehensibly made. Unfortunately, this error is made by the recall studies. Writing with regard to the Cassileth et al. (1980) findings, Meisel and Roth remark:

> The most critical and poorly researched question about informed consent is, 'what exactly are patients told by their doctors?' Unless we treat this topic as one for investigation rather than assumption, findings about what patients subsequently understand are not meaningful. (Meisel & Roth, 1980, pp. 459-460)

**Descriptive Studies On Informed Consent.** After more than 5000 published articles spanning more than 200 years of thought on the matter, the crucial question is finally asked, "What exactly are patients told by their doctors?" At first glance this may seem to be a simple query. However, its answer, not unlike the informed consent issue itself, is quite complex and difficult to attain.
The difficulty lies first with the potential methodology one could use, and second with the interpretation that one may make of findings produced by that particular methodology.

Meisel and Roth (in press), conceive that the issue of what is told to patients can be potentially studied in three ways: 1) by asking patients, 2) by asking physicians, and 3) by observing actual consents. They further stress that each method has its faults. Simply asking patients relies on their imprecise memories of what transpired. As was noted above, patients' verbal reports cannot be taken at face value as a valid and accurate record of what actually did happen. Furthermore, each patient's consent process is idiosyncratic. Nonetheless, collecting data from patients allows inferences and probability statements about informed consent procedures. Finally, with descriptive statistics, one may also quickly lose the ability to define variables controlling the content and extent of what was disclosed.

By asking physicians, one obviates the idiosyncratic data of patients' one-occurrence reports. It is a safe assumption that the vast majority of physicians have engaged in the consent process more than once in their professional careers and most probably do so on a routine daily basis. The pitfall here is the subjective
nature of this type of data. Researchers must be careful of a potential pro-medical bias, possibly influenced by a "them-against-us" stance.

Finally, using unbiased and independent third-party observers may at the outset, seem like the perfect solution. The on-the-spot recording and independence of the observers attenuates problems of faulty recall and potential bias that plague methods relying on the verbal reports of patients and physicians. However, direct observation approaches to consent procedures are difficult to accomplish. For example, experimental rigor demands that such observations be limited to one type of medical procedure. Consents with simple, frequently occurring procedures are not appropriate because of the restriction of range of possible content in such cases. More complicated treatment on the other hand, occurs much less frequently; therefore, low rates of occurrence necessitate observers to either waste a great deal of time by waiting for the consent of interest to occur and/or to be on call at all hours. Furthermore, direct observations are always open to the criticism that the observer is not a natural part of the consent process environment and may produce a reactive effect in the physician. Use of a one-way mirror, of course, would have to be disclosed to the participants on the other side (Meisel and Roth, in press), but to do so
would tend to defeat the purpose of preventing an audience effect. Another possible route to take would be to invest the necessary time to become a regular fixture of the physician's environment whenever he/she obtains consent. However, habituating the physician to one's presence would be extremely time-consuming. It is not surprising therefore, that to date only one informed consent study has been reported that utilized a direct observation methodology (Hershey and Bushkoff, 1969).

In addition to the recall comprehension studies reviewed above, Hawkins (1979) utilized the "ask-the-patient" methodology to ascertain whether patients were satisfied with what they had been told of investigative procedures prior to their undergoing treatment. Of the 504 subjects interviewed, findings were that tests were satisfactorily explained in 74% of the cases, and that more complicated procedures produced a greater degree of disclosure than the less complicated ones. However, Hawkins himself admitted his findings were limited only to what patients were able to recall.

To date, there have appeared three studies on what physicians report disclosing to patients as part of the consent process. Using two methodologies, Hershey and Bushkoff (1969) attempted to determine the disclosure standards of orthopedic surgeons. This question is important to the validity of the notion that there are
uniform disclosure practices within identifiable medical specialties - a key assumption of the medical practice standard. First, 21 physicians were asked to describe the information they would give to patients who were about to undergo one or two hypothetical orthopedic surgery procedures. Second, they tried to observe these same physicians actually giving informed consents. In the final analysis, however, interviews did not yield any data which could be described as reflecting a definite disclosure standard. While there was great variability as to what was disclosed and to what extent, the authors suspect this variation was no greater than one would expect to find with any other specialty group of physicians. Observing actual informed consents also failed to produce any standards for any one procedure.

Rosoff (1981) used a 39-item questionnaire to examine the disclosure standards of approximately 3,400 internists and surgeons. Although only 800 usable questionnaires were returned, several interesting general conclusions were reached. The great majority of physicians claimed that they revealed most of the legally mandated topics and that few thought that anything approaching a "professional standard" for disclosure existed. Most surprising was that the majority of respondents could not state whether the
medical practice rule or the reasonable person rule was the legal standard in their own states of practice. This was in spite of the fact that approximately 75% of the respondents indicated that they considered themselves fairly knowledgeable about informed consent law.

Finally, a study in 1981 by Faden et al., compared what physicians reported that they routinely told patients with what they thought patients wanted to be told. Results indicated that physicians disclosed as much information as they thought patients wanted to hear. However, when these findings were compared with those of an earlier study looking at what patients said they wanted to be told, it was clear that the extent of physicians' disclosure did not match those of patients' desires.

The purpose of the present study was to gather descriptive data on the parameters of informed consent with cancer chemotherapy patients from the medical oncologists' point of view. Only 4% of Rosoff's (1981) somewhat heterogeneous group of respondents were medical oncologists. Gathering descriptive data on informed consents with cancer patients is important, since such data will guide further research in this area.
METHOD

Subjects

The subjects were 600 medical oncologists who were randomly selected from the 1982-83 Membership Directory of the American Society of Clinical Oncology. Instructions in the cover letter specified that only those oncologists who have placed at least five patients on chemotherapy regimens during the course of the last year should complete the survey.

Materials

All materials used were mailed to oncologists in a packet. Included were a cover letter, questionnaire, postage-paid business reply envelope, and a postage-paid business reply card. The cover letter briefly described the purpose of the survey, defined "informed consent process" as used by the author, and provided instructions for completion of the questionnaire. The letter also contained a guarantee of anonymity for respondents and instructions on how oncologists should go about requesting copies of the results without jeopardizing anonymity. For that purpose, the business reply card was to be returned separately from the business reply envelope containing the questionnaire.
The questionnaire (Appendix A) consisted of 35 multiple-choice items and was divided into two parts. The first part focused on demographic characteristics and informed consent procedures as they are usually practiced within the treatment setting with which the oncologist is primarily affiliated. For example, items queried type of facility, program size, credentials of individuals most actively involved in the informed consent process, and availability of patient information sheets and instructional aids. The second part of the questionnaire assessed the physicians' personal preferences and practices in conducting informed consents.

Procedure

Oncologists were asked to go through the questionnaire and mark their answers from the choices provided for each question asked. For five items a ranking task was presented where subjects had to rank order the options provided from most to least. Respondents were asked to return completed questionnaires within four weeks; however, due to a low initial accrual rate, late arriving questionnaires were accepted for two weeks beyond this deadline.

Completed questionnaires were transcribed onto Mark-Sense sheets and fed into a computer. All analyses were completed using the Minitab Statistical Program (Ryan, Joiner, & Ryan, 1981).
RESULTS

Of the 600 questionnaires distributed, 182 usable, completed questionnaires (30%) were returned. A little over half of responding oncologists (56%) were primarily affiliated with a university and/or teaching hospital. Slightly over a quarter of remaining respondents (26%) worked in local community hospitals. The remainder worked in private clinics (14%) and other facilities (3%). Of these facilities, few (27%) were federally designated regional oncological centers, but more than three fourths (78%) were affiliated with one or more cooperative oncological research groups.

Approximately half of physicians were affiliated with rather small operations as was reflected in their answers pertaining to the number of nurses specialized in medical oncology, number of medical oncologists, and number of surgical oncologists working at these facilities.

The vast majority of respondents (94%) placed 50 or more new cancer patients on chemotherapy last year, and 30% placed at least 300 patients. Better than 80% of these new patients were treated using conventional non-research protocol regimens.

Respondents split pretty evenly on whether the informed consent process was usually seen as a
collaborative one or mainly the responsibility of one individual. However, at 75% of the facilities there was no one person who routinely conducted the informed consent process. Nonetheless, where there was such an individual, she/he was most likely (72%) to have had some sort of special training in communicating this type of information.

When oncologists ranked the importance of variables determining style and content of the verbal component of the informed consent process, the personal preference of the physician getting the consent was ranked first by the majority of respondents, and current legal considerations were ranked second. Hospital/clinic traditions and in-house-generated rules played a relatively minor role (Appendix A, Questions 12 & 13). However, respondents were most likely to see informed consent as practiced with chemotherapy patients to be either a combination educative and legal process (57%) or primarily an educative one (35%).

Patient information sheets specifying possible drug side-effects were provided to patients in 83% of the settings. While the information sheet was separate from the consent form in only about half of the cases, the patient usually got to keep the information sheet during the entire time she/he deliberated on whether or not to grant consent (93%). In addition to patient
information sheets, approximately 75% provided supplementary brochures and pamphlets. Only 10% reported having audio-visual equipment available for consents.

Literature on drug effects was the most popular instructional aid used by physicians (64%). However, printed materials were ranked third in importance to helping patients understand about their treatment. The oncologist-patient interaction was seen to be the most effective element in patient comprehension in 95% of the cases, followed by other personnel communicating information (65%).

Prior to the first treatment, the majority of physicians met with patients twice (56%), three times (20%), or more (11%), and 83% of oncologists participated in more than one of these sessions. In addition to the responding oncologist, nurses take part in the consent process approximately 70% of the time. Fellows and/or other oncologists (36%) and interns and/or residents (23%) also are involved in the consent process.

About half of respondents reported usually taking less than an hour to complete the entire informed consent process. An additional third usually took 1-3 hours time. Where informed consent did run overtime, oncologists indicated the most likely reason to be lack of patient sophistication in medical matters (33%) closely followed
by family involvement (31%) and patients asking many questions (18%).

Only 12% of physicians routinely limited themselves to the information contained in the consent form during the verbal components of the process. The majority (58%) indicated covering other topics depending on the individual treatment and patient involved. Topics usually covered included possible negative side-effects (97%), rationale for treatment (96%), possible positive effects of treatment (96%), drug action (70%), and history of chemotherapy for cancer patients (62%). Half of the physicians said that they usually cover all possible negative side-effects, no matter how remote are the chances for their occurrence. But only 17% said that they typically use as much time and detail in covering remote side-effects as they do the more likely side-effects. Most oncologists are also guided on extent of disclosure by the patient's reactions (31%, sometimes; 30%, usually; and 17%, always).

Only 8% of respondents indicated that they usually suggest that the patient seek a second opinion before deciding whether or not to grant consent. However, depending upon the circumstances, the majority (60%) sometimes make such a suggestion.

Surveyed physicians typically (90%) encouraged patients to have members of their family present when
consent information was imparted. Furthermore, they ranked the most important role of such family members as being individuals who will be able to understand and remember more than the patient, and later help him/her reach a decision (54%). They ranked family members as emotional support providers second (56%) and witnesses third (64%) (Appendix A, Questions 31 & 32).

A little over half of the responding oncologists indicated they used only clinical judgement in determining whether the patient understood the information that they had given him/her. Forty-two percent made a specific effort to verbally determine patient comprehension. Seventy percent believed that a majority of their patients understood the information to the degree that their decision could be called "knowledgeable", with 30 of those 70% indicating that the vast majority of their patients' decisions were "knowledgeable".

In addition to the descriptive data reported above, \( \chi^2 \) was used to explore primarily between questions on demographic variables and questions about the consent process itself (Appendix D). Given a significant \( \chi^2 \), post hoc statistical analyses were not performed; however, in the event of a significant \( \chi^2 \), data were visually inspected.

Type of facility interacted with whether or not it was a usual practice to seek a second opinion.
(\chi^2(6) = 14.813, p < .05). Table 1 shows that physicians affiliated with a private clinic were less likely to suggest a second opinion than physicians affiliated with university or community hospitals.

The extent to which remote negative side-effects are covered was a function of the number of medical oncologists at the site (\chi^2(4) = 9.819, p < .05). Table 2 shows that the great majority of medical oncologists do not cover remote negative side-effects as extensively as they do common side-effects. However, half of responding oncologists in facilities where there are 20 or more other medical oncologists indicated they use as much time and detail in covering remote side-effects as they do the more likely side-effects.

A significant relationship was found between the annual number of new patients started either on chemotherapy regimens or on research protocols, and whether there was one person who was routinely assigned the task of conducting the informed consent prior to chemotherapy (\chi^2(12) = 32.475, p < .01, and \chi^2(15) = 33.933, p < .01, respectively). Tables 3 and 4 show that the more new cancer patients, the less likely there is to be a specially designated informed consent provider.

The proportion of patients put on research protocol treatments also interacted with the number of informed consent meetings with patients (\chi^2(15) = 27.531, p < .05).
Table 1
Percent of Oncologists Usually Suggesting that Patients Seek a Second Opinion Before Granting Consent as a Function of Type of Facility

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>n</th>
<th>Yes</th>
<th>No</th>
<th>Sometimes</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Affiliated and/or Teaching Hospital</td>
<td>102</td>
<td>7.84</td>
<td>30.39</td>
<td>61.76</td>
</tr>
<tr>
<td>Community Hospital</td>
<td>47</td>
<td>4.26</td>
<td>23.40</td>
<td>72.34</td>
</tr>
<tr>
<td>Private Clinic</td>
<td>26</td>
<td>7.69</td>
<td>53.85</td>
<td>38.46</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>33.33</td>
<td>33.33</td>
<td>33.33</td>
</tr>
</tbody>
</table>
Table 2

Whether Extent of Disclosure of Remote Side-Effects Matches that of More Likely Side-Effects as a Function of Total Number of Medical Oncologists in a Facility

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-4</td>
<td>49</td>
<td>14.29</td>
<td>85.17</td>
</tr>
<tr>
<td>5-9</td>
<td>32</td>
<td>9.37</td>
<td>90.62</td>
</tr>
<tr>
<td>10-14</td>
<td>11</td>
<td>27.27</td>
<td>72.73</td>
</tr>
<tr>
<td>15-19</td>
<td>6</td>
<td>16.67</td>
<td>83.33</td>
</tr>
<tr>
<td>20 or more</td>
<td>10</td>
<td>50.00</td>
<td>50.00</td>
</tr>
</tbody>
</table>
Table 3

Whether One Person Is Routinely Assigned Task of Getting Consent Prior to Chemotherapy as a Function of the Number of New Patients

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Research protocols only</th>
<th>Non-research protocols only</th>
<th>Both research and non-research</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 50</td>
<td>10</td>
<td>10.00</td>
<td>—</td>
<td>50.00</td>
<td>40.00</td>
</tr>
<tr>
<td>50-99</td>
<td>42</td>
<td>14.29</td>
<td>2.38</td>
<td>26.19</td>
<td>57.14</td>
</tr>
<tr>
<td>100-199</td>
<td>42</td>
<td>7.14</td>
<td>4.76</td>
<td>4.76</td>
<td>83.33</td>
</tr>
<tr>
<td>200-299</td>
<td>29</td>
<td>10.34</td>
<td>—</td>
<td>17.24</td>
<td>72.41</td>
</tr>
<tr>
<td>300 or more</td>
<td>51</td>
<td>3.92</td>
<td>—</td>
<td>3.92</td>
<td>92.16</td>
</tr>
<tr>
<td>Proportion of Patients Going on Research Protocol Treatments</td>
<td>n</td>
<td>Research protocols only</td>
<td>Non-research protocols only</td>
<td>Both research and non-research</td>
<td>No</td>
</tr>
<tr>
<td>------------------------------------------------------------</td>
<td>---</td>
<td>-------------------------</td>
<td>-----------------------------</td>
<td>--------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>0</td>
<td>9</td>
<td>22.22</td>
<td>22.22</td>
<td>55.56</td>
<td></td>
</tr>
<tr>
<td>1-9%</td>
<td>57</td>
<td>8.77</td>
<td>15.79</td>
<td>75.44</td>
<td></td>
</tr>
<tr>
<td>10-24%</td>
<td>49</td>
<td>14.29</td>
<td>69.39</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25-49%</td>
<td>35</td>
<td>2.86</td>
<td>82.86</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-74%</td>
<td>16</td>
<td>12.50</td>
<td>87.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>75% or more</td>
<td>10</td>
<td>10.00</td>
<td>90.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 5 reveals that oncologists were most likely to attend all such meetings if they were affiliated with facilities where less than a quarter of cancer patients were placed on research protocols.

Whether or not all possible remote side-effects were discussed was also a function of the proportion of patients going on research protocol treatments \( \chi^2 (5) = 21.939, p < .01 \). Table 6 indicated that the highest proportion of affirmatives to the question of whether all possible negative side-effects are disclosed came from physicians affiliated with facilities placing no patients on research protocols, and those that place three quarters or more of their patients on such treatments.

Significant \( \chi^2 \)'s were also seen between the proportion of patients going on research protocol and the degree to which patients' reactions were used to determine extent of disclosure \( \chi^2 (20) = 32.919, p < .05 \), and also between the number of medical oncologists in a given facility and whether there was any one person routinely assigned the task of conducting the informed consent process \( \chi^2 (12) = 21.560, p < .05 \).
Table 5  
Number of Informed Consent Sessions Attended by Medical Oncologists as a Function of Proportion of Patients Placed on Research Protocols

<table>
<thead>
<tr>
<th>Proportion of Patients</th>
<th>n</th>
<th>None</th>
<th>One</th>
<th>More than one, but not all</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>9</td>
<td></td>
<td>44.44</td>
<td>33.33</td>
</tr>
<tr>
<td>1-9%</td>
<td>57</td>
<td>1.75</td>
<td>10.53</td>
<td>26.32</td>
<td>61.40</td>
</tr>
<tr>
<td>10-24%</td>
<td>50</td>
<td></td>
<td>20.00</td>
<td>18.00</td>
<td>62.00</td>
</tr>
<tr>
<td>25-49%</td>
<td>35</td>
<td>5.71</td>
<td>11.43</td>
<td>42.86</td>
<td>40.00</td>
</tr>
<tr>
<td>50-74%</td>
<td>16</td>
<td></td>
<td>25.00</td>
<td>50.00</td>
<td>25.00</td>
</tr>
<tr>
<td>75% or more</td>
<td>11</td>
<td></td>
<td></td>
<td>45.45</td>
<td>54.55</td>
</tr>
</tbody>
</table>
Table 6

Whether All Possible Remote Negative Side-Effects are Disclosed, as a Function of the Proportion of Patients Going on Research Protocol Treatment

<table>
<thead>
<tr>
<th>Proportion</th>
<th>n</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>9</td>
<td>88.89</td>
<td>11.11</td>
</tr>
<tr>
<td>1-9%</td>
<td>56</td>
<td>28.57</td>
<td>71.43</td>
</tr>
<tr>
<td>10-24%</td>
<td>49</td>
<td>46.94</td>
<td>53.06</td>
</tr>
<tr>
<td>25-49%</td>
<td>35</td>
<td>60.00</td>
<td>40.00</td>
</tr>
<tr>
<td>50-74%</td>
<td>16</td>
<td>56.25</td>
<td>43.75</td>
</tr>
<tr>
<td>75% or more</td>
<td>11</td>
<td>81.82</td>
<td>18.18</td>
</tr>
</tbody>
</table>
DISCUSSION

While Rosoff's (1981) book is a major comprehensive, data-based analysis of informed consent practices in medicine, the present study differs in that (1) it was limited to medical oncologists and (2) it was limited to one type of medical treatment, chemotherapy. Both surveys were similar in that they both achieved a rather low response rate (Rosoff 24%, and the present research, 30%).

A judicially produced dichotomy between the medical practice standard and the reasonable person standard may have been valid in describing common and ideal disclosure practices in the past. However, results of this study as well as Rosoff's findings suggest that in present day application, the more extensive disclosure standards usually associated with the reasonable person rule have clearly infused physicians' perceptions of common medical practice. Physicians ranked personal preference as the most important variable in determining what is disclosed and how it is disclosed, but they also indicated that they usually cover many topics and include great detail. A related point is that physicians' opinions on disclosure of terminal prognoses underwent complete reversal from non-disclosure to disclosure in the span
of twenty years (Novack et al., 1979; Oken, 1961). The trend, therefore, seems to be toward incorporating the standards for disclosure as set by the reasonable person rule into the medical practice standard. Such a trend would ultimately leave the medical practice standard prevailing, as it historically has in most jurisdictions (Faden et al., 1981), and delegate the reasonable person standard into the position of a moot point. Before the conclusion that the medical practice standard and the reasonable person rule are drifting in the direction of being one and the same can be taken as fact, however, findings showing physicians' inclination to extensive disclosure must be corroborated by observations of actual informed consent procedures.

Both the size of the facility and the amount of oncological research conducted there seem to have a strong relationship to how informed consents are done. For example, the larger the facility (Table 3), and the greater the proportion of patients placed on research protocols (Table 4), the less likely that any one person is designated to routinely attain the informed consent. The reason for this finding may be that oncologists, if at all possible, prefer to do the disclosing themselves, but in the case of small hospitals or practices where the workload per oncologist is great, they cannot afford to do so, and therefore delegate the task to another individual.
Also, but with one exception, the greater the proportion of patients placed on research protocols, the greater was the probability that all possible remote side-effects would be disclosed (Table 6). The one exception occurred in the case where no patients were treated on research protocol. Where no research was done, almost all of the physicians said that they covered all side-effects. This anomaly may be understood if it is assumed that non-research protocol treatment is usually less complex and with fewer remote negative side-effects. Therefore, the physician can disclose the few remote side-effects that there are without placing constraints on his/her time or memory. In those facilities where a large proportion of patients are placed on research protocol, physicians may have initially disclosed more due to federal regulations requiring them to do so, which with time and practice developed into standard procedure.

Several problems with the questionnaire were discovered in the course of the study. First, questions with an "other (please specify)" category may have confounded some of the results. In some instances, the "others" specified were interesting. However, commonly "other" was not checked, or when it was marked, it either went unspecified or was occasionally filled in with an answer choice already available.
Second, with respect to the question on the role of family members, an inadvertent inconsistency in format may have attenuated its reliability and validity. Specifically, while most of the questions calling for ranking instructed #1 to be used for "most", this particular question asked that #1 be used for "least". The effect of this deviation is not known. However, one letter pointed out the error and asked if this were a "cute psychological trick".

Future research should supplement and contrast the findings here with descriptive data collected on this question using other methodology. For example, studies should directly observe actual informed consent procedures and study their effects upon patients.
Appendix A

Questionnaire
May 9, 1983

Dear Doctor:

We are currently conducting a survey of physicians practicing medical oncology in order to better describe informed consent procedures performed with cancer chemotherapy patients. Of particular interest to us are: 1) the style of presentation and content of the informed consent process and, 2) how style and content interact with type of treatment setting. Our usage of the term "informed consent process" refers to whatever interaction of an informative nature that occurs between medical staff and patient, from the time a treatment regimen is proposed to the time it is either accepted or rejected.

Your name was randomly selected from the 1982-83 Membership Directory of the American Society of Clinical Oncology. If you have placed at least five patients on chemotherapy regimens for the treatment of cancer during the past year, we would very much appreciate your cooperation in filling out the enclosed questionnaire. Please return the latter in the self-addressed, stamped envelope provided by June 6th, 1983. If you wish a copy of our completed study, please return the enclosed postcard under separate cover.

We wish to assure all respondents of the total anonymity of their participation. No attempt has been made to code or mark the enclosed material in any way which would enable identification of particular participants, the treatment setting with which they are affiliated, or their geographical location.

Thank you for your cooperation.

Yours truly,

George W. Rakowsky, B. Sc.

Nancy E. Petty, Ph. D.
Part I

The following questions pertain to the treatment setting which is your primary affiliation, and the informed consent process as is usually practiced there. (Please check all appropriate boxes.)

1. The type of facility you are primarily affiliated with:
   - a) university affiliated and/or teaching hospital
   - b) local community hospital
   - c) private clinic
   - d) other (please specify) ________________________

2. Is this facility a federally designated regional oncological center?
   - a) yes
   - b) no

3. Is your oncology unit affiliated with a cooperative oncological research group?
   - a) yes, one
   - b) yes, more than one
   - c) no

4. Number of nurses specialized in medical oncology:
   - a) 1-4
   - b) 5-9
   - c) 10-14
   - d) 15-19
   - e) 20 or more

5. Number of medical oncologists:
   - a) 1-4
   - b) 5-9
   - c) 10-14
   - d) 15-19
   - e) 20 or more

6. Number of surgical oncologists:
   - a) 1-4
   - b) 5-9
   - c) 10-14
   - d) 15-19
   - e) 20 or more
7. Approximately how many new cancer patients were started on chemotherapy regimens last year?

- a) less than 50
- b) 50-99
- c) 100-199
- d) 200-299
- e) 300 or more

8. Approximately what proportion of the above new cancer patients were placed on research protocol treatments?

- a) 0
- b) 1-9%
- c) 10-24%
- d) 25-49%
- e) 50-74%
- f) 75% or more

9. Is there any one person who is routinely assigned the task of conducting the informed consent process prior to chemotherapy?

- a) yes, but only for research protocols
- b) yes, but only for non-research protocols
- c) yes, for both research and non-research protocols
- d) no (if no, go to Question #11)

10. Does this person have any special training in communicating this type of information?

- a) yes
- b) no
- c) don't know

11. Is the informed consent process usually a collaborative one (i.e., do you see it as a group responsibility in which all personnel take part?) or is it mainly the job of one individual?

- a) it's a collaborative process
- b) mainly the responsibility of one individual

12. Rank order from (1) most to (5) least influencing the following variables as they relate to the style of the verbal component of the informed consent process at your facility.

- a) personal preference of person getting consent
- b) current legal considerations
- c) hospital or clinic traditions
- d) hospital or clinic generated rules and regulations (eg. IRB rulings)
- e) other (please specify) __________________________
13. Rank order from (1) most to (5) least influencing the following variables as they relate to the content of the verbal component of the informed consent process.

- a) personal preference of person getting consent
- b) current legal considerations
- c) hospital or clinic traditions
- d) hospital or clinic generated rules and regulations (eg. IRB rulings)
- e) other (please specify) ____________________________

14. Is a patient information sheet specifying possible drug side-effects usually provided to the patient?

☐ a) yes
☐ b) no (if no, go to Question #17)

15. Is the patient information sheet usually separate from the consent form itself?

☐ a) yes
☐ b) no

16. Does the patient get to keep the patient information sheet during the entire time she/he deliberates on whether or not to grant consent?

☐ a) yes
☐ b) no

17. Which of the following instructional aids are available for use in the consent process?

☐ a) brochures/pamphlets on drug effects
☐ b) audio/visual equipment (eg. a video tape describing a treatment regimen)
☐ c) other (please specify) ____________________________
☐ d) no aids available

Part II

The following questions pertain to the informed consent process as is usually practiced by you with your cancer chemotherapy patients.

18. Approximately how many times do you and/or your staff meet with the typical patient before the first chemotherapy treatment is administered?

☐ a) once
☐ b) twice
☐ c) three times
☐ d) more than three times
19. At how many of these meetings do you usually take part?

- □ a) none
- □ b) one
- □ c) more than one, but not all
- □ d) all

20. In addition to yourself, what other personnel usually take part in the consent process?

- □ a) nurses
- □ b) interns and/or residents
- □ c) fellows and/or other oncologists
- □ d) others (please specify) ____________________________
- □ e) no other personnel involved

21. Which of the following aids do you routinely use in the informed consent process?

- □ a) literature on drug effects
- □ b) audio/visual equipment
- □ c) other (please specify) ____________________________
- □ d) none

22. Rank order the following from (1)most to (6)least useful in helping your patients understand the information contained within the informed consent process.

- a) oncologist-patient interaction
- b) other personnel communicating information
- c) patient-cancer support group interaction
- d) printed materials
- e) audio/visual presentation
- f) other (please specify) ____________________________

23. What is the usual amount of time it takes you to complete the entire informed consent process?

- □ a) less than an hour
- □ b) 1 to 3 hours
- □ c) more than 3 hours but less than 24 hours
- □ d) 1-3 days
- □ e) 4 days to a week
- □ f) more than a week
24. From your experience, rank order the following factors from (1) most to (5) least common in accounting for excessive time in taking to complete an informed consent procedure:

- a) patient asking many questions
- b) lack of patient sophistication in medical matters
- c) denial on the part of the patient
- d) family involvement
- e) other (please specify) ____________________________

25. Does your verbal component of the informed consent process cover only information already contained in the consent form, or is more information routinely added?

- a) only consent form information is presented
- b) only consent form information is presented, but in greater detail
- c) other topics are covered
- d) varies from patient to patient, and from treatment to treatment.

26. What topics do you usually cover in the consent process for chemotherapy patients? (Check all that apply).

- a) brief history of chemotherapy with cancer patients
- b) rationale for treatment
- c) drug action
- d) possible positive effects of treatment
- e) possible negative effects of treatment

27. Do you usually cover all possible negative side-effects, no matter how remote the chances for their occurrence are?

- a) yes
- b) no, (if no, go to Question #29)

28. Do you usually use as much time and detail in covering remote negative side-effects, as you do the more likely side-effects?

- a) yes
- b) no

29. Do you use your patient's reactions to the information you are giving them as a guide as to what is to be further disclosed and to what extent?

- a) never
- b) rarely
- c) sometimes
- d) usually
- e) always
30. During the informed consent process do you usually suggest that the patient seek a second opinion before determining whether or not to grant consent?

- a) yes
- b) no
- c) sometimes, depending on the circumstances

31. Do you encourage patients to have members of their family present when consent information is imparted?

- a) yes
- b) no (go to Question #33)

32. Rank order in importance from (1) least to (4) most important, the following roles you see family members as playing in the informed consent process.

- a) emotional support providers
- b) witnesses
- c) individuals who will be able to understand and remember more than the patient, and later help him/her reach a decision.
- d) other (please specify) _____________________________

33. How do you determine that the patient understands the information you have given?

- a) clinical judgement and experience
- b) a specific effort is made to verbally determine patient comprehension
- c) a standardized quiz is used to determine patient comprehension
- d) other (please specify) _____________________________
- e) no effort is made to determine patient comprehension

34. What proportion of your patients would you say understand the information contained in your informed consent process to the degree that their decision could be called "knowledgeable"?

- a) the vast majority
- b) a majority
- c) about 50%
- d) a minority
- e) a small minority

35. Do you see informed consent with chemotherapy patients to be primarily an educational or legal process?

- a) educational
- b) legal
- c) a combination of both

Thank-you.
Appendix B

Raw Data
1. The type of facility you are primarily affiliated with:

<table>
<thead>
<tr>
<th>Type</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>university affiliated</td>
<td>102</td>
<td>56.04</td>
</tr>
<tr>
<td>and/or teaching hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>local community hospital</td>
<td>48</td>
<td>26.37</td>
</tr>
<tr>
<td>private clinic</td>
<td>26</td>
<td>14.29</td>
</tr>
<tr>
<td>other (please specify)</td>
<td>6</td>
<td>3.30</td>
</tr>
</tbody>
</table>

Each * represents 5 observations

<table>
<thead>
<tr>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
</tr>
<tr>
<td>b)</td>
</tr>
<tr>
<td>c)</td>
</tr>
<tr>
<td>d)</td>
</tr>
</tbody>
</table>

2. Is this facility a federally designated regional oncological center?

<table>
<thead>
<tr>
<th>Type</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>49</td>
<td>27.22</td>
</tr>
<tr>
<td>no</td>
<td>131</td>
<td>72.78</td>
</tr>
</tbody>
</table>

Each * represents 5 observations

<table>
<thead>
<tr>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
</tr>
<tr>
<td>b)</td>
</tr>
</tbody>
</table>
3. Is your oncology unit affiliated with a cooperative oncological research group?

<table>
<thead>
<tr>
<th></th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes, one</strong></td>
<td>80</td>
<td>44.44</td>
</tr>
<tr>
<td><strong>Yes, more than one</strong></td>
<td>61</td>
<td>33.89</td>
</tr>
<tr>
<td><strong>No</strong></td>
<td>39</td>
<td>21.67</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

a) **********************************************
   b) ************************************************
   c) ****************************************

4. Number of nurses specialized in medical oncology:

<table>
<thead>
<tr>
<th></th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1-4</strong></td>
<td>93</td>
<td>52.54</td>
</tr>
<tr>
<td><strong>5-9</strong></td>
<td>40</td>
<td>22.60</td>
</tr>
<tr>
<td><strong>10-14</strong></td>
<td>19</td>
<td>10.73</td>
</tr>
<tr>
<td><strong>15-19</strong></td>
<td>5</td>
<td>2.82</td>
</tr>
<tr>
<td><strong>20 or more</strong></td>
<td>20</td>
<td>11.30</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

a) **********************************************
   b) ************************************************
   c) *************
   d) ***
   e) **********
5. Number of medical oncologists:

<table>
<thead>
<tr>
<th>Category</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) 1-4</td>
<td>89</td>
<td>(49.44)</td>
</tr>
<tr>
<td>b) 5-9</td>
<td>52</td>
<td>(28.89)</td>
</tr>
<tr>
<td>c) 10-14</td>
<td>13</td>
<td>(7.22)</td>
</tr>
<tr>
<td>c) 15-19</td>
<td>9</td>
<td>(5.00)</td>
</tr>
<tr>
<td>e) 20 or more</td>
<td>17</td>
<td>(9.44)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

6. Number of surgical oncologists:

<table>
<thead>
<tr>
<th>Category</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) 1-4</td>
<td>121</td>
<td>(80.13)</td>
</tr>
<tr>
<td>b) 5-9</td>
<td>15</td>
<td>(9.93)</td>
</tr>
<tr>
<td>c) 10-14</td>
<td>2</td>
<td>(1.32)</td>
</tr>
<tr>
<td>d) 15-19</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>e) 20 or more</td>
<td>13</td>
<td>(8.61)</td>
</tr>
</tbody>
</table>

Each * represents 5 observations
7. Approximately how many new cancer patients were started on chemotherapy regimens last year?

<table>
<thead>
<tr>
<th>Range</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 50</td>
<td>10</td>
<td>(5.68)</td>
</tr>
<tr>
<td>50-99</td>
<td>42</td>
<td>(23.86)</td>
</tr>
<tr>
<td>100-199</td>
<td>42</td>
<td>(23.86)</td>
</tr>
<tr>
<td>200-299</td>
<td>29</td>
<td>(16.48)</td>
</tr>
<tr>
<td>300 or more</td>
<td>53</td>
<td>(30.11)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

8. Approximately what proportion of the above new cancer patients were placed on research protocol treatments?

<table>
<thead>
<tr>
<th>Range</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>9</td>
<td>(5.06)</td>
</tr>
<tr>
<td>1-9%</td>
<td>57</td>
<td>(32.02)</td>
</tr>
<tr>
<td>10-24%</td>
<td>50</td>
<td>(28.09)</td>
</tr>
<tr>
<td>25-49%</td>
<td>35</td>
<td>(19.66)</td>
</tr>
<tr>
<td>50-74%</td>
<td>16</td>
<td>(8.99)</td>
</tr>
<tr>
<td>75% or more</td>
<td>11</td>
<td>(6.18)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations
9. Is there any one person who is routinely assigned the task of conducting the informed consent process prior to chemotherapy?

<table>
<thead>
<tr>
<th>No.</th>
<th>(% )</th>
<th>Responding</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) yes, but only for research protocols</td>
<td>15</td>
<td>(8.38)</td>
<td></td>
</tr>
<tr>
<td>b) yes, but only for non-research protocols</td>
<td>3</td>
<td>(1.68)</td>
<td></td>
</tr>
<tr>
<td>c) yes, for both research and non-research protocols</td>
<td>25</td>
<td>(13.97)</td>
<td></td>
</tr>
<tr>
<td>d) no (if no, go to Question #11)</td>
<td>136</td>
<td>(75.98)</td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 5 observations

a) ***
b) *
c) *****
d) *********************

10. Does this person have any special training in communicating this type of information?

<table>
<thead>
<tr>
<th>No.</th>
<th>(% )</th>
<th>Responding</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) yes</td>
<td>36</td>
<td>(72.00)</td>
<td></td>
</tr>
<tr>
<td>b) no</td>
<td>11</td>
<td>(22.00)</td>
<td></td>
</tr>
<tr>
<td>c) don't know</td>
<td>3</td>
<td>(6.00)</td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 1 observation

a) *********************
b) ************
c) ***
11. Is the informed consent process usually a collaborative one (i.e., Do you see it as a group responsibility in which all personnel take part?) or is it mainly the job of one individual?

<table>
<thead>
<tr>
<th></th>
<th>No.</th>
<th>(%)</th>
<th>Responding</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) it's a collaborative process</td>
<td>86</td>
<td>(47.78)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) mainly the responsibility of one individual</td>
<td>94</td>
<td>(52.22)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 2 observations
12. Rank order from (1) most to (5) least influencing the following variables as they relate to the style of the verbal component of the informed consent process at your facility.

a) personal preference of person getting consent

<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>****************************115</td>
<td>(66.09)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>****************************21</td>
<td>(12.07)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>****************************21</td>
<td>(12.07)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>****************************16</td>
<td>(9.20)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>(0.57)</td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 5 observations

b) current legal considerations

<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>****************************16</td>
<td>(9.47)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>****************************62</td>
<td>(36.69)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>****************************43</td>
<td>(25.44)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>****************************38</td>
<td>(22.49)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>10</td>
<td>(5.92)</td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 2 observations

c) hospital or clinic traditions

<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>****************************8</td>
<td>(4.82)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>****************************41</td>
<td>(24.70)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>****************************47</td>
<td>(28.31)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>****************************60</td>
<td>(36.14)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>10</td>
<td>(6.02)</td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 2 observations
12. (Continued)

d) hospital or clinic generated rules and regulations

<table>
<thead>
<tr>
<th>No. Responding</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>(7.14)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

1. *********************** 32 (18.93)
2. *********************** 38 (22.49)
3. *********************** 53 (31.36)
4. *********************** * 41 (24.26)
5. *** 5 (2.96)

e) other

<table>
<thead>
<tr>
<th>No. Responding</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>129</td>
<td>(70.88)</td>
</tr>
</tbody>
</table>

Each * represents 1 observation

1. *************** 12 (22.64)
2. ** 2 (3.77)
3. ** 2 (3.77)
4. ** 2 (3.77)
5. *********************** 35 (66.04)

13. Rank order from (1) most to (5) least influencing the following variables as they relate to the content of the verbal component of the informed consent process.

a) personal preference of person getting consent

<table>
<thead>
<tr>
<th>No. Responding</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>(7.14)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

1. ***********************
2. 93 (55.03)
2. 22 (13.02)
3. 22 (13.02)
4. 27 (15.98)
5. *** 5 (2.96)
13. (Continued)

b) current legal considerations

<table>
<thead>
<tr>
<th>No.</th>
<th>(%)</th>
<th>No. Not Responding</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>(7.69)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 2 observations

1. 24 (14.29)
2. 65 (38.69)
3. 44 (26.19)
4. 26 (15.48)
5.  9 (5.36)

c) hospital or clinic traditions

<table>
<thead>
<tr>
<th>No.</th>
<th>(%)</th>
<th>No. Not Responding</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>(9.89)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 2 observations

1. 9 (5.49)
2. 28 (17.07)
3. 57 (34.76)
4. 60 (36.59)
5. 10 (6.10)

d) hospital or clinic generated rules and regulations (eg. IRB rulings)

<table>
<thead>
<tr>
<th>No.</th>
<th>(%)</th>
<th>No. Not Responding</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>(8.79)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 1 observation

1. 39 (23.49)
2. 43 (25.90)
3. 42 (25.30)
4. 38 (22.89)
5.  4 (2.41)
13. (Continued)
e) other

<table>
<thead>
<tr>
<th></th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>e) other</td>
<td>30 (71.43)</td>
</tr>
</tbody>
</table>

Each * represents 1 observation

1. ********** 11 (21.15)
2. ********* 8 (15.38)
3. * 1 (1.92)
4. * 1 (1.92)
5. ***************** 31 (59.62)

14. Is a patient information sheet specifying possible drug side-effects usually provided to the patient?

<table>
<thead>
<tr>
<th></th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) yes</td>
<td>151 (83.43)</td>
</tr>
<tr>
<td>b) no (if no, to to Question #17)</td>
<td>30 (16.57)</td>
</tr>
</tbody>
</table>

Each * represents 5 observations

a) ********************
b) *****

15. Is the patient information sheet usually separate from the consent form itself?

<table>
<thead>
<tr>
<th></th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) yes</td>
<td>77 (50.66)</td>
</tr>
<tr>
<td>b) no</td>
<td>75 (49.34)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

a) ********************
b) ********************

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<table>
<thead>
<tr>
<th>16.</th>
<th>Does the patient get to keep the patient information sheet during the entire time she/he deliberates on whether or not to grant consent?</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) yes</td>
<td>141 (92.76)</td>
</tr>
<tr>
<td>b) no</td>
<td>11 (7.24)</td>
</tr>
</tbody>
</table>

Each * represents 5 observations

a) ..........................
b) **

<table>
<thead>
<tr>
<th>17.</th>
<th>Which of the following instructional aids are available for use in the consent process?</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) brochures/pamphlets on drug effects</td>
<td>131 (73.18)</td>
</tr>
<tr>
<td>b) audio/visual equipment (eg. a video tape describing a treatment regimen)</td>
<td>17 (9.50)</td>
</tr>
<tr>
<td>c) other (please specify)</td>
<td>5 (2.79)</td>
</tr>
<tr>
<td>d) no aids available</td>
<td>26 (14.53)</td>
</tr>
</tbody>
</table>

Each * represents 5 observations

a) ..........................
b) ****
c)  
d) *****
18. Approximately how many times do you and/or your staff meet with the typical patient before the first chemotherapy treatment is administered?

<table>
<thead>
<tr>
<th>Option</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) once</td>
<td>23 (12.85)</td>
</tr>
<tr>
<td>b) twice</td>
<td>100 (55.87)</td>
</tr>
<tr>
<td>c) three times</td>
<td>36 (20.11)</td>
</tr>
<tr>
<td>d) more than three times</td>
<td>20 (11.17)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

19. At how many of these meetings do you usually take part?

<table>
<thead>
<tr>
<th>Option</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) none</td>
<td>3 (1.65)</td>
</tr>
<tr>
<td>b) one</td>
<td>28 (15.38)</td>
</tr>
<tr>
<td>c) more than one,</td>
<td>55 (30.22)</td>
</tr>
<tr>
<td>but not all</td>
<td></td>
</tr>
<tr>
<td>d) all</td>
<td>96 (52.75)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations
20. In addition to yourself, what other personnel usually take part in the consent process?

Each * represents 5 observations

<table>
<thead>
<tr>
<th></th>
<th>No. (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a) nurses</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>126 (69.23)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>56 (30.77)</td>
<td></td>
</tr>
<tr>
<td>b) interns and/or residents</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>41 (22.53)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>141 (77.47)</td>
<td></td>
</tr>
<tr>
<td>c) fellows and/or other oncologists</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>65 (35.71)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>117 (64.29)</td>
<td></td>
</tr>
<tr>
<td>d) others (please specify)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>23 (12.64)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>159 (87.36)</td>
<td></td>
</tr>
<tr>
<td>e) no other personnel involved</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>30 (16.48)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>152 (83.52)</td>
<td></td>
</tr>
</tbody>
</table>
21. Which of the following aids do you routinely use in the informed consent process?

<table>
<thead>
<tr>
<th></th>
<th>No.</th>
<th>(%%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>116</td>
<td>64.09</td>
</tr>
<tr>
<td>b)</td>
<td>8</td>
<td>4.42</td>
</tr>
<tr>
<td>c)</td>
<td>2</td>
<td>1.10</td>
</tr>
<tr>
<td>d)</td>
<td>55</td>
<td>30.39</td>
</tr>
</tbody>
</table>

Each * represents 5 observations

a) ****************************
b)  **
c)  *
d)  ************

22. Rank order the following from (1) most to (6) least useful in helping your patients understand the information contained within the informed consent process.

a) oncologist-patient interaction

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>171</td>
<td>95.00</td>
</tr>
<tr>
<td>b)</td>
<td>6</td>
<td>3.33</td>
</tr>
<tr>
<td>c)</td>
<td>3</td>
<td>1.67</td>
</tr>
<tr>
<td>d)</td>
<td>0</td>
<td>-----</td>
</tr>
<tr>
<td>e)</td>
<td>0</td>
<td>-----</td>
</tr>
<tr>
<td>f)</td>
<td>0</td>
<td>-----</td>
</tr>
</tbody>
</table>

Each * represents 5 observations

b) other personnel communicating information

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>11</td>
<td>6.55</td>
</tr>
<tr>
<td>b)</td>
<td>109</td>
<td>64.88</td>
</tr>
<tr>
<td>c)</td>
<td>31</td>
<td>18.45</td>
</tr>
<tr>
<td>d)</td>
<td>12</td>
<td>7.14</td>
</tr>
<tr>
<td>e)</td>
<td>2</td>
<td>1.19</td>
</tr>
<tr>
<td>f)</td>
<td>3</td>
<td>1.79</td>
</tr>
</tbody>
</table>
22. (Continued)

<table>
<thead>
<tr>
<th></th>
<th>No. (%)</th>
<th>No. Not Responding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) patient-cancer support group interaction</td>
<td>33</td>
<td>(18.13)</td>
</tr>
<tr>
<td></td>
<td>Each * represents 2 observations</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>0</td>
<td>(—)</td>
</tr>
<tr>
<td>2.</td>
<td>17</td>
<td>(11.41)</td>
</tr>
<tr>
<td>3.</td>
<td>24</td>
<td>(16.11)</td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>21</td>
<td>(14.09)</td>
</tr>
<tr>
<td>6.</td>
<td>5</td>
<td>(3.36)</td>
</tr>
</tbody>
</table>

d) printed materials | 15 | (8.24) |
| Each * represents 2 observations |
| 1. | 4 | (2.40) |
| 2. | 43 | (25.75) |
| 3. |                     |
|   |                     |
| 4. | 19 | (11.38) |
| 5. | 4 | (2.40) |
| 6. | 2 | (1.20) |

e) audio/visual presentation | 80 | (43.96) |
| Each * represents 2 observations |
| 1. | 1 | (0.98) |
| 2. | 2 | (1.96) |
| 3. | 3 | (2.94) |
| 4. | 22 | (21.57) |
| 5. | 64 | (62.75) |
| 6. | 10 | (9.80) |
f) other (please specify) | 152 | (83.52) |
| Each * represents 1 observation |
| 1. | 0 | (—) |
| 2. | 1 | (3.33) |
| 3. | 1 | (3.33) |
| 4. | 0 | (—) |
| 5. | 3 | (10.00) |
| 6. | 25 | (83.33) |

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23. What is the usual amount of time it takes you to complete the entire informed consent process?

<table>
<thead>
<tr>
<th>Option</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) less than an hour</td>
<td>94</td>
<td>(52.22)</td>
</tr>
<tr>
<td>b) 1 to 3 hours</td>
<td>58</td>
<td>(32.22)</td>
</tr>
<tr>
<td>c) more than 3 hours but less than 24 hours</td>
<td>6</td>
<td>(3.33)</td>
</tr>
<tr>
<td>d) 1-3 days</td>
<td>19</td>
<td>(10.56)</td>
</tr>
<tr>
<td>e) 4 days to a week</td>
<td>3</td>
<td>(1.67)</td>
</tr>
<tr>
<td>f) more than a week</td>
<td>0</td>
<td>(----)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

a) *******************************
b) ****************************** c) ***
d) **********
e) **
f)

24. From your experience, rank order the following factors from (1) most to (5) least common in accounting for excessive time in taking to complete an informed consent procedure:

<table>
<thead>
<tr>
<th>Factor</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) patient asking many questions</td>
<td>9</td>
<td>(4.95)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

1. *******************************
   51  (29.48)
2. *******************************
   52  (30.06)
3. *******************************
   31  (17.92)
4. *******************************
   34  (19.65)
5. ***
   5   (2.89)

b) lack of patient sophistication in medical matters
   12  (6.59)

Each * represents 2 observations

1. *******************************
   56  (32.94)
2. *******************************
   39  (22.94)
3. *******************************
   46  (27.06)
4. *******************************
   28  (16.47)
5. *
   1   (0.59)
24. (continued)

<table>
<thead>
<tr>
<th></th>
<th>No. (%)</th>
<th>No. Not Responding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>c) denial on the part of the patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Each * represents 2 observations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. ..........................</td>
<td>27 (16.67)</td>
<td></td>
</tr>
<tr>
<td>2. ..........................</td>
<td>31 (19.14)</td>
<td></td>
</tr>
<tr>
<td>3. ..........................</td>
<td>28 (17.28)</td>
<td></td>
</tr>
<tr>
<td>4. ..........................</td>
<td>66 (40.74)</td>
<td></td>
</tr>
<tr>
<td>5. *****</td>
<td>10 (6.17)</td>
<td></td>
</tr>
<tr>
<td>d) family involvement</td>
<td>13 (7.14)</td>
<td></td>
</tr>
<tr>
<td>Each * represents 2 observations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. ..........................</td>
<td>40 (23.67)</td>
<td></td>
</tr>
<tr>
<td>2. ..........................</td>
<td>52 (30.77)</td>
<td></td>
</tr>
<tr>
<td>3. ..........................</td>
<td>54 (31.95)</td>
<td></td>
</tr>
<tr>
<td>4. ..........................</td>
<td>20 (11.83)</td>
<td></td>
</tr>
<tr>
<td>5. **)</td>
<td>3 (1.78)</td>
<td></td>
</tr>
<tr>
<td>d) other (please specify)</td>
<td>141 (77.47)</td>
<td></td>
</tr>
<tr>
<td>Each * represents 1 observation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. ..........................</td>
<td>12 (29.27)</td>
<td></td>
</tr>
<tr>
<td>2. *</td>
<td>1 (2.44)</td>
<td></td>
</tr>
<tr>
<td>3. **)</td>
<td>2 (4.88)</td>
<td></td>
</tr>
<tr>
<td>4. **)</td>
<td>2 (4.88)</td>
<td></td>
</tr>
<tr>
<td>5. ..........................</td>
<td>24 (58.54)</td>
<td></td>
</tr>
</tbody>
</table>

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25. Does your verbal component of the informed consent process cover only information already contained in the consent form, or is more information routinely added?

<table>
<thead>
<tr>
<th>Option</th>
<th>No. (%)</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) only consent form information is presented</td>
<td>7</td>
<td>(3.91)</td>
</tr>
<tr>
<td>b) only consent form information is presented, but in greater detail</td>
<td>15</td>
<td>(8.38)</td>
</tr>
<tr>
<td>c) other topics are covered</td>
<td>54</td>
<td>(30.17)</td>
</tr>
<tr>
<td>d) varies from patient to patient, and from treatment to treatment.</td>
<td>103</td>
<td>(57.54)</td>
</tr>
</tbody>
</table>

Each * represents 5 observations

a) **
b) ****
c) ***********
d) ************************

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26. What topics do you usually cover in the consent process for chemotherapy patients. (Check all that apply).

Each * represents 5 observations

<table>
<thead>
<tr>
<th>Topic</th>
<th>Yes</th>
<th>No</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Brief history of chemotherapy with cancer patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>112</td>
<td>70</td>
<td>(61.54)</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>38.46</td>
<td></td>
</tr>
<tr>
<td>b) Rationale for treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>175</td>
<td>7</td>
<td>(96.15)</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>3.85</td>
<td></td>
</tr>
<tr>
<td>c) Drug action</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>128</td>
<td>54</td>
<td>(70.33)</td>
</tr>
<tr>
<td></td>
<td>54</td>
<td>29.67</td>
<td></td>
</tr>
<tr>
<td>d) Possible positive effects of treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>174</td>
<td>8</td>
<td>(95.60)</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>4.40</td>
<td></td>
</tr>
<tr>
<td>e) Possible negative effects of treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>177</td>
<td>5</td>
<td>(97.25)</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>2.75</td>
<td></td>
</tr>
</tbody>
</table>

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27. Do you usually cover all possible negative side-effects, no matter how remote the chances for their occurrence are?

<table>
<thead>
<tr>
<th></th>
<th>No. (%) Responding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) yes</td>
<td>2 (1.10)</td>
</tr>
<tr>
<td>b) no, (if no, go to Question #29)</td>
<td>92 (51.11)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

a) ********************************************
b) ********************************************

28. Do you usually use as much time and detail in covering remote negative side-effects, as you do the more likely side-effects?

<table>
<thead>
<tr>
<th></th>
<th>No. (%) Responding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) yes</td>
<td>73 (40.11)</td>
</tr>
<tr>
<td>b) no</td>
<td>90 (82.57)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

a) ************
b) ********************************************

c) ********************************************

d) ****************

e) ********************************************

29. Do you use your patient's reactions to the information you are giving them as a guide as to what is to be further disclosed and to what extent?

<table>
<thead>
<tr>
<th></th>
<th>No. (%) Responding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) never</td>
<td>3 (1.65)</td>
</tr>
<tr>
<td>b) rarely</td>
<td>16 (8.94)</td>
</tr>
<tr>
<td>c) sometimes</td>
<td>21 (11.73)</td>
</tr>
<tr>
<td>d) usually</td>
<td>56 (31.28)</td>
</tr>
<tr>
<td>e) always</td>
<td>55 (30.73)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

a) ************
b) ************
c) ********************************************
d) ****************
e) ********************************************

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30. During the informed consent process do you usually suggest that the patient seek a second opinion before determining whether or not to grant consent?

<table>
<thead>
<tr>
<th></th>
<th>No. (%)</th>
<th>No. Not Responding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) yes</td>
<td>14 (7.73)</td>
<td>1 (0.55)</td>
</tr>
<tr>
<td>b) no</td>
<td>58 (32.04)</td>
<td></td>
</tr>
<tr>
<td>c) sometimes, depending on the circumstances</td>
<td>109 (60.22)</td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 5 observations

a) ***
b) ***********
c) *******************

31. Do you encourage patients to have members of their family present when consent information is imparted?

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a) yes</td>
<td>161 (89.44)</td>
<td>2 (1.10)</td>
</tr>
<tr>
<td>b) no (go to Question #33)</td>
<td>19 (10.56)</td>
<td></td>
</tr>
</tbody>
</table>

Each * represents 5 observations

a) ******************************
b) ****
32. Rank order in importance from (1) least to (4) most important, the following roles you see family members as playing in the informed consent process.

a) emotional support providers

Each * represents 2 observations

1. **************************** 42 (25.00)
2. **************************** 94 (55.95)
3. **************************** 20 (11.90)
4. **************************** 12 (7.14)

b) witnesses

Each * represents 5 observations

1. ***** 22 (13.75)
2. ***** 28 (17.50)
3. **************************** 103 (64.38)
4. ** 7 (4.37)

c) individuals who will be able to understand and remember more than the patient, and later help him/her reach a decision

Each * represents 2 observations

1. **************************** 90 (53.57)
2. **************************** 40 (23.81)
3. **************************** 20 (11.90)
4. **************************** 18 (10.71)

d) other

Each * represents 1 observation

1. **************************** 11 (30.56)
2. **************************** 0 (___)
3. **************************** 7 (19.44)
4. **************************** 18 (50.00)

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33. How do you determine that the patient understands the information you have given?  

<table>
<thead>
<tr>
<th>Option</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) clinical judgement and experience</td>
<td>93</td>
<td>(51.38)</td>
</tr>
<tr>
<td>b) a specific effort is made to verbally determine patient comprehension</td>
<td>76</td>
<td>(41.99)</td>
</tr>
<tr>
<td>c) a standardized quiz is used to determine patient comprehension</td>
<td>4</td>
<td>(2.21)</td>
</tr>
<tr>
<td>d) other (please specify)</td>
<td>5</td>
<td>(2.76)</td>
</tr>
<tr>
<td>e) no effort is made to determine patient comprehension</td>
<td>3</td>
<td>(1.66)</td>
</tr>
</tbody>
</table>

Each * represents 2 observations

- a) ****************************
- b) ****************************
- c) **
- d) ***
- e) **
34. What proportion of your patients would you say understand the information contained in your informed consent process to the degree that their decision could be called "knowledgeable"?

<table>
<thead>
<tr>
<th>No.</th>
<th>(%)</th>
<th>Responding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>(1.10)</td>
<td></td>
</tr>
</tbody>
</table>

- **a)** the vast majority 53 (29.44)
- **b)** a majority 73 (40.56)
- **c)** about 50% 38 (21.11)
- **d)** a minority 12 (6.67)
- **e)** a small minority 4 (2.22)

Each * represents 2 observations

a) ****************************
b) ****************************
c) **************************
d) ******
e) **

35. Do you see informed consent with chemotherapy patients to be primarily an educational or legal process?

<table>
<thead>
<tr>
<th>No.</th>
<th>(%)</th>
<th>Responding</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>(0.55)</td>
<td></td>
</tr>
</tbody>
</table>

- **a)** educational 63 (34.81)
- **b)** legal 14 (7.73)
- **c)** a combination of both 104 (57.46)

Each * represents 5 observations

a) ****************************
b) ****************************
c) ****************************
Appendix C

Respondents' Comments
1. The type of facility you are primarily affiliated with:
   a) university affiliated and/or teaching hospital - No comments.
   b) local community hospital - No comments.
   c) private clinic - No comments.
   d) other (please specify) - 068: "Multi-specialty group practice."
      143: "Armed Forces Teaching Hospital."
      149: "Group Practice."
      162: "Cancer Research Institute."
      181: "Group practice and voluntary Medical School faculty."

2. Is this facility a federally designated regional oncological center?
   a) yes - 093: "but I am a private physician in the community and do not practice at the regional oncological center."
   b) no - No comments.

3. Is your oncology unit affiliated with a cooperative oncological research group?
   a) yes, one - 093: "yes, but I enter few patients."
   b) yes, more than one - No comments.
   c) no - No comments.
4. Number of nurses specialized in medical oncology:
   a) to e) - No comments.

5. Number of medical oncologists:
   a) to e) - No comments.

6. Number of surgical oncologists:
   a) to e) - No comments.
   090: "all surgeons claim to be surgical oncologists."

7. Approximately how many new cancer patients were started on chemotherapy regimens last year?
   a) less than 50 - No comments.
   b) 50-99 - 093: "by me."
   c) 100-199 - No comments.
   d) 200-299 - No comments.
   e) 300 or more - No comments.

8. Approximately what proportion of the above new cancer patients were placed on research protocol treatments?
   a) to f) - No comments.
9. Is there any one person who is routinely assigned the task of conducting the informed consent process prior to chemotherapy?
   a) yes, but only for research protocols - No comments.
   b) yes, but only for non-research protocols - No comments.
   c) yes, for both research and non-research protocols - 124: "I give all consents."

10. Does this person have any special training in communicating this type of information?
    a) yes - 025: "M.D."
    b) no - 113: "experience but no special training."
    c) don't know - No comments.

11. Is the informed consent process usually a collaborative one (i.e., Do you see it as a group responsibility in which all personnel take part?) or is it mainly the job of one individual?
    a) it's a collaborative process - No comments.
    b) mainly the responsibility of one individual: 061: "physician."
       104: "depends on the patient, but usually b."
       124: "ME!"
       144: "The attending M.D.!"
12. Rank order from (1) most to (5) least influencing the following variables as they relate to the style of the verbal component of the informed consent process at your facility.

a) personal preference of person getting consent - No comments.

b) current legal considerations - No comments.

c) hospital or clinic traditions - No comments.

d) hospital or clinic generated rules and regulations (eg. IRB rulings) - 113: "IRB regulations govern only written informed consent."

  e) other (please specify) - 040: "Insuring that the patient understands on his/her own terms."
    047: "patients' attitudes toward chemotherapy."
    054: "My feeling toward patient having complete information."
    057: "Personality of patient."
    061: "depending on patient personality and degree to which he/she can understand."
    066: "type of protocol."
    067: "My personal style."
    073: "Patient's language."
    079: "Personality of patient."
    080: "Clarification purpose."
    '93: "the patient and family's ability to be involved in decision and consent."

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12. (Continued)

97: "FDA guidelines."
124: "Psychosocial status of patient and family."
135: "Personality and understanding of the patient receiving the consent information."
139: "Patient's (and Family's) capacity to understand."
149: "Patient's intellectual capacity and insight."
152: "Patient's status psychologically and emotionally as well as intellectually."
161: "Nature of patient and disease."
175: "Patient's intellect."

13. Rank order from (1) most to (5) least influencing the following variables as they relate to the content of the verbal component of the informed consent process.

a) to d) - No comments.

e) other (please specify) - 040: "Insuring that the patient understands fully."
052: "protocol."
054: "My form or research form."
057: "patient characteristics."
066: "protocol."
067: "My style."
077: "operation of, protocol/risks, benefits."
080: "patient's comprehension level."

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13. (Continued)

093: "patient and family's background for understanding."

097: "FDA guidelines."

120: "patient information."

123: "Scientific information about disease/protocol."

124: "psychosoical status of patient and family."

152: "Status of patient."

177: "Experience and judgement of physician."

14. Is a patient information sheet specifying possible drug side-effects usually provided to the patient?

a) and b) - No comments.

15. Is the patient information sheet usually separate from the consent form itself?

a) yes - 029: "We have separate information forms for each drug with no mention of protocol. The consent form describes the protocol and reiterates the drug toxicities alone and in combination."

b) no - No comments.
16. Does the patient get to keep the patient information sheet during the entire time she/he deliberates on whether or not to grant consent?
   a) yes - 096: "Federal regulation require that a patient receive a copy of consent!"
   b) no - 152: "Unless specifically requested."

17. Which of the following instructional aids are available for use in the consent process?
   a) brochures/pamphlets on drug effects - No comments.
   b) audio/visual equipment (eg. a video tape describing a treatment regimen) - No comments.
   c) other (please specify) - 016: "Information sheets on Clinical Research in general; Information sheets on specific regimens/schedules.
      018: "repeat verbal procedure by chemotherapy nurses."
      027: "specific quiz, letters, flip chart."
      054: "Family conference."
      056: "Cansurmount-cancer support group."
      064: "Conference is taped for patient to play back."
      075: "oncology nurse."
      088: "other patients."
      110: "teaching, nurse."
      114: "doctor and nurse instruction."
      121: "discussion with oncology nurse."
      154: "Nurses."
17. (Continued)

159: "patient education, one on one."
161: "interview with nurse oncologist."
163: "copy of treatment plan (protocol)."
165: "personal description and informed consent form."
170: "consent form."
172: "Classes."
173: "repeated availability of staff to answer questions."
175: "repeated contact with the oncologist allowing patient to communicate feeling."

D) no aids available - No comments.

18. Approximately how many times do you and/or your staff meet with the typical patient before the first chemotherapy treatment is administered?

a) once - No comments.

b) twice - 124: "this varies greatly from case to case, referral source, hospital vs. office setting."
152: "if consultative."

c) three times - No comments.

d) more than three times - 113: "In the office - once or twice. In the hospital - daily visits from 3-7 times, depending on the nature of the work-up involved."
19. At how many of these meetings do you usually take part?
   a) none - No comments.
   b) one - No comments.
   c) more than one, but not all - 097: "initial proposal for new Rx, later question and answer session."
   d) all - No comments.

20. In addition to yourself, what other personnel usually take part in the consent process?
   a) nurses - 061: "Majority - explaining further if needed - expanding."
   b) interns and/or residents - No comments.
   c) fellows and/or other oncologists - No comments.
   d) others (please specify) - 004: "occasionally medical students."
      016: "Data manager."
      021: "Secretary."
      020: "hospital pharmacist."
      045: "physician assistant."
      052: "research secretary."
      060: "private M.D.'s."
      064: "social worker."
      065: "medical students."
      073: "Social Worker, preacher."
      086: "clinical research nurses."
20. (Continued)

096: "physician assistant."
097: "physician's assistant."
111: "social worker, chaplain."
112: "hospice personnel."
113: "physician assistant."
126: "physician assistant."
137: "research nurse for oncology."
148: "social service and psychologists."
164: "Protocol monitor."
165: "Data clerks."
166: "physician assistant."
181: "Research pharmacists."

e) no other personnel involved - 093: "family are asked to be involved."

21. Which of the following aids do you routinely use in the informed consent process?

a) literature on drug effects - No comments.
b) audio/visual equipment - No comments.
c) other (please specify) - 008: "Nurses provide written info."
   009: "Talk."
   016: "patient information sheets for specific protocols; the consent form itself."
   042: "Oral explanations."
21. (Continued)

054: "Verbal with patient and family."
056: "Cansurmount."
063: "Protocol abstract."
066: "Conversing with patient."
091: "drug information sheets."
112: "person to person."
116: "chemotherapy side-effects booklet which we prepared ourselves."
132: "discussions."
151: "drawings."
163: "provide contact with other patients."
165: "specific informed consent form."
173: "patient information sheet."
175: "ample time for discussion, participation of spouse or other family members."

d) none - No comments.

22. Rank order the following from (1) most to (6) least useful in helping your patients understand the information contained within the informed consent process.

a) oncologist-patient interaction - No comments.
b) other personnel communicating information - 075: "often detrimental."
c) patient-cancer support group interaction - No comments.
22. (Continued)

d) printed materials - No comments.
e) audio/visual presentation - No comments.
f) other (please specify) - 030: "contact with other
patients."
080: "lay magazines."

23. What is the usual amount of time it takes you to complete the entire informed consent process?

a) less than an hour - 016: "but patients may think about it for a long time."
077: "per patient."
097: "(over two to three units)."
b) 1 to 3 hours - 104: "depending on patient and their emotional and educational background."
c) more than 3 hours but less than 24 hours - No comments.
d) 1-3 days - No comments.
e) 4 days to a week - No comments.
f) more than a week - No comments.

24. From your experience, rank order the following factors from (1)most to (5)least common in accounting for excessive time in taking to complete an informed consent procedure:

a) patient asking many questions - No comments.
24. (Continued)

b) lack of patient sophistication in medical matters -
   No comments.

c) denial on the part of the patient - No comments.

d) family involvement - No comments.

e) other (please specify) - 007: "the intrinsic nature
   of the treatment."

   021: "My feeling that the patient and primary
   physician need time to understand."

   048: "Patient wants extra time to think it over."

   050: "type of protocol."

   057: "Distrust of chemotherapy."

   061: "Complicated radical situation difficult to
   grasp."

   071: "time spent in general discussion with patient."

   074: "complexity of therapy."

   078: "explaining randomization."

   090: "Friends' talking to patient."

   094: "Fear."

   100: "misunderstandings and misconceptions regarding
   chemotherapy and cancer."

   123: "complete the work-up, ineligibility criteria,
   etc."

   126: "helping patient understand complex medical
   data and then making a "life choice.""
24. (Continued)

143: "having heard 'horror stories' about chemotherapy."
145: "the time is not excessive."
151: "complicated program."
167: "Old Wives Tales re: chemotherapy."
177: "complexity of care and treatment."

25. Does your verbal component of the informed consent process cover only information already contained in the consent form, or is more information routinely added?

a) only consent form information is presented - No comments.
b) only consent form information is presented, but in greater detail - No comments.
c) other topics are covered - 144: "as the patient may request."
d) varies from patient to patient, and from treatment to treatment - No comments.

26. What topics do you usually cover in the consent process for chemotherapy patients? (Check all that apply).

a) to e) - No comments.
27. Do you usually cover all possible negative side-effects, no matter how remote the chances for their occurrence?
   a) yes - 144: "as far as is possible."
   b) no, (if no, go to Question #29) - 009: "no, but most side-effects."

28. Do you usually use as much time and detail in covering remote negative side-effects, as you do the more likely side-effects?
   a) yes - 144: "Have to for drugs like Adriamyecin. ... is rare but a real problem."
   b) no - 097: "these are described as uncommon."

29. Do you use your patient's reactions to the information you are giving them as a guide as to what is to be further disclosed and to what extent?
   a) never - 017: "For chemotherapy."
   b) rarely - No comments.
   c) sometimes - 124: "more of effect on how information is disclosed rather than what is disclosed."
   d) usually - No comments.
   e) always - 017: "For disease prognosis, course, etc."
30. During the informed consent process do you usually suggest that the patient seek a second opinion before determining whether or not to grant consent?
   a) yes - 019: "1-2%.
   054: "always tell them it is available."
   b) no - No comments.
   c) sometimes, depending on the circumstances - No comments.

31. Do you encourage patients to have members of their family present when consent information is imparted?
   a) yes - 097: "if they wish."
   b) no (go to Question #33) - No comments.

32. Rank order in importance from (1) least to (4) most important, the following roles you see family members as playing in the informed consent process.
   a) emotional support providers - No comments.
   b) witnesses - No comments.
   c) individuals who will be able to understand and remember more than the patient, and later help him/her reach a decision - 019: "essential."
   d) other (please specify) - 005: "Relieve anxiety of family members."
   023: "They can't say they didn't hear or couldn't talk."
32. (Continued)

026: "Someone else for the patient to discuss the treatment with and it lets the family know what to expect."

039: "Asking questions to clarify what information is given."

054: "asking questions."

057: "to provide a familiar background for the patient."

062: "this depends very much on the level of sophistication and in tactness of the family."

066: "to ask questions."

167: "Resources of what was told."

177: "part of educational process."

33. How do you determine that the patient understands the information you have given?

a) clinical judgement and experience - No comments.

b) a specific effort is made to verbally determine patient comprehension - No comments.

c) a standardized quiz is used to determine patient comprehension - No comments.

d) other (please specify) - 012: "go over information at subsequent visits."

018: "Ask patient if he needs further explanation and if he has questions."
33. (Continued)

030: "I ask."

040: "I ask the patient to relate what the tx is and what benefits or options of treatment the patient has (alternative)."

066: "___wk. later ask questions on side effects, etc."

097: "briefly summarize what is to be done and review possible toxicities, then ask if there are further questions."

124: "Encourage patient and family to ask questions and answer them."

143: "Given opportunity to ask questions."

e) no effort is made to determine patient comprehension - No comments.

34. What proportion of your patients would you say understand the information contained in your informed consent process to the degree that their decision could be called "knowledgeable"?

a) the vast majority - No comments.

b) a majority - No comments.

c) about 50% - No comments.

d) a minority - No comments.

e) a small minority - 013: "Note: 'Knowledge' used in standard non-medical English usage."
35. Do you see informed consent with chemotherapy patients to be primarily an educational or legal process?
   a) educational - 167: "for most. Legal for experimental protocols (a minimal part of my practice).
      Written consent is only obtained for experimental study protocols. Above answers reflect verbal."
   b) legal - 073: "(and useless)."
   c) a combination of both - No comments.
Extended Comments:

011:
Checked 1st 3 questions. Then wrote - "All following questions relate to Lombardi Cancer Center at Georgetown - I frankly couldn't get the answers" - See Part II. Then answered Q's 18-35 in Part II.

012:
At end of survey wrote: "We only use informed consent forms for experimental protocols - verbal discussion only (without consent form) is the rule - forms are the exception."

013:
At end of survey wrote: "Note: In days past, informed consent had no legal meaning and it was a standard part of my practice. I still do what I did then to make sure my ethical ideals are followed but in addition go through the legal ritual of "informed consent". The process is now more complex because human experimentation committee approval bears no relationship to whether a protocol is 'ethical' (in the old non-legal sense of that now-altered word); thus, many unethical protocols now are approved. One must teach young physicians how to weed those out. Also, how to be sure your patient understands (as best as is possible) what is planned - and to do this while going through the legal mickey mouse..."
(013 - Continued):
of informed consent - a process which we know does not work
at all. (For example, patients remember hair loss a higher
% of the time than they remember risk of infection).
On balance, of course as one would expect, things are worse
now that committees and professional "ethicists" are in-
volved. But it is still possible to make the system work."

014:
At end of survey wrote: "The requirements of our Human Studies
Committee are burdensome and unnecessary for patient's
education; i.e. chemotherapy side effects. Many patients say
'Whatever you think, Doctor' after reading the 2-page,
single-spaced, typewritten, encyclopedic consent form man-
dated by the IRB and the Federal Government. As a direct
consequence of these and other burdensome Federal regulations
regarding medical clinical research, we are steadily re-
ducing our involvement in clinical research. It is getting
to be too much hassle and time, compliments of bureaucratic
regulation of consents and necessary record-keeping."

023:
Before survey; i.e. front page: "N.B. - I do not obtain
written informed consent for chemotherapy other than:
1) VP 16 - consent comes with NCI forms. 2) U. of Iowa etc.
Protocol - They get informed consent."
At end of survey wrote: "Most patients prefer us to make the decision: 'Whatever you think is best, Doc.' When almost forced to make a decision themselves, they choose what they guess is our preference. Understanding seems less important than trust."

At end of survey wrote: "Written consent form is primarily a legal coverage for the institution or physician."

At end of Q-34 wrote: "The only ones who do not [understand] are emotionally disturbed or mentally incompetent, in which case a family member or guardian is informed to be 'knowledgeable.'"

At beginning wrote: "I have been out of full-time practice since Jan. 4, 1982, but I am still involved with an oncology program in a large hospital. Prior to this I was in practice 17.5 years. My answers apply to Dec. '81 and prior."

At end of Q-32 wrote: "Important for family to feel a part of the process."
159: At end of Q-24 wrote: "None can get all the time they require."

074: Re: Q-25 wrote: "Consent form not used."
Appendix D

Chi-Square Values
Generated by Interactive Effects
Between Selected Questions
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Table of chi-square values generated by interactive effects between selected questions.

* \( p < .05 \)

** \( p < .01 \)
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