Informed Versus Uninformed Consent for Prostate Surgery: The Value of Electronic Consents

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Purpose: We evaluated the documentation of informed consent for 2 common prostate operations using current, conventional, paper based consent forms. Based on the results of the review the conventional paper based consent system was replaced with a new, standardized electronic consent system.

Materials and Methods: We retrospectively reviewed the consent forms obtained for transurethral resection of the prostate and radical prostatectomy procedures during the 6-year period 1995 to 2000 at Atlanta Veterans Affairs Medical Center. Analysis focused on the basic elements of informed consent, including a description of the proposed treatment, and the purpose, benefits, risks and alternatives. Based on these findings we standardized the procedure specific information contained in consent forms and stored it electronically in a central network accessible to all urology providers throughout the medical center.

Results: Of the 222 total procedures 204 consent forms were available for review. Senior residents, junior residents and physician assistants obtained consent for 42.2%, 30.9% and 25.5% of procedures, respectively. Information on the purpose and benefits of treatment was missing in 4.4% of cases and deficient in 22.6%. General or procedure specific risks were documented inconsistently in 0% to 96% of cases. Alternative treatment options were missing in 49% of the consent forms and they were significantly deficient in the remaining 51%. Prognosis and surgical risks were documented variably for each procedure. For example, in the radical prostatectomy group 79 patients (88.8%) had appropriate documentation regarding the potential for significant blood loss and yet only 23 (25.8%) had documented consent for blood transfusion. Following the implementation of a new standardized electronic consent program 96.1% of the patients surveyed preferred the new system.

Conclusions: Conventional nonstandardized consent forms have significant deficiencies and errors. The new system of electronic informed consent is standardized, legible and understandable, and it assists providers in fully informing patients about the treatment, risks, benefits and alternative therapies, thereby supporting ethical and legal standards, and improving the quality of care. In our opinion standardized electronic informed consent should be the new standard of care.

Key Words: prostate, prostatectomy, informed consent, complications, risks

The process of informed consent is a fundamental requirement of health care practice. More than 200 million informed consent discussions occur annually in the United states, that is more than 6 per second.[1–3]

Informed consent is a legal requirement and an ethical obligation. For consent to be informed the process must address at a minimum 5 basic elements, including a description of the proposed treatment and the diagnosis for which it is being done, and the purpose, benefits, risks and alternative therapies.[4] In addition, patients must understand the information and voluntarily agree to the proposed treatment.[5] Some groups have suggested that the informed consent process should also address the probability of treatment success, the risks of not receiving treatment and patient understanding of these issues.[6,7]

Despite the importance of informed consent in clinical practice the process remains nonstandardized, unmonitored and time-consuming. While the risks and benefits of interventions are well established in the literature, there are questions and controversies regarding the amount of information and level of details to be disclosed. Compounding this issue is variability in the levels of education and literacy among patients, and variability in the levels of training and attention to documentation detail among medical providers. The resultant inconsistency in the disclosed information compromises the educational intent of informed consent.[8] Furthermore, such disparity exposes providers and medical institutions to medicolegal risks.

Based on these concerns we examined the content and quality of written consent forms for 2 frequently performed urological procedures at our institution. Our preliminary analysis identified significant discrepancies between the information disclosed on the form and the current standard of care. We addressed these deficiencies by designing and implementing a standardized automated consent process. We present our analysis of the traditional, nonstandardized con-

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Study received approval from the Institutional Review Board at Emory University and Atlanta Veterans Affairs Medical Center.

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sent process and introduce a new standardized electronic consent system.

MATERIALS AND METHODS

We performed a retrospective review of consent forms for prostate procedures during the 6-year period 1995 to 2000 at Atlanta Veterans Affairs Medical Center. The review included 2 frequently performed prostate procedures, that is standard electrocautery and laser TURP, and retropubic and perineal RP. The study was approved by the Institutional Review Board at Emory University and Atlanta Veterans Affairs Medical Center.

The attending surgeons routinely participated in informed consent discussions, while the completion of the consent forms was usually the responsibility of nonattending providers, ie junior residents (3 or fewer years of residency training), senior residents (more than 3 years of postgraduate experience) and physician assistants. The task entailed filling in the blanks regarding the diagnosis, procedure, purpose, benefits, risks and alternatives on the generic consent form, and obtaining the signatures.

The consent forms were audited for content and clarity. Information on the procedure, purpose and benefits was categorized as acceptable, unacceptable and not documented. Information was considered acceptable when the procedure and/or its purpose/benefits were described in lay language without abbreviations or acronyms.

Risks were classified into the 2 broad categories of general (nonspecific) and procedure specific risks. The former included risks associated with anesthesia and surgery, such as bleeding, infection, deep venous thrombosis, pulmonary embolus, death, persistence, recurrence, worsening of symptoms/illness, the need for further treatment, unsatisfactory results and inability to complete the procedure. This list tended to be similar for the 2 procedures.

Procedure specific risks included those considered appropriate in all patients (mandatory) and others that only impacted individuals (optional) (table 1). For example, although urinary incontinence following TURP is rare, it is considered a serious complication because of its potential to significantly impact patient quality of life. Disclosing this complication to all patients remains the accepted standard of care. On the other hand, infertility is rarely a concern in patients following TURP and, therefore, its disclosure remains optional despite its relative common occurrence. Since the consent forms offered limited writing space for the risks, abbreviations or acronyms were routinely used and they had to be considered acceptable in this pilot study.

Treatment options listed on each consent form were counted and they are presented as a percent of the predefined accepted standard therapies. For TURP standard alternative therapies are observation, medical therapy, minimally invasive thermal therapy, open prostatectomy and management with a bladder catheter. For RP standard alternative therapies are watchful waiting (observation), radiation therapy (external beam and brachytherapy) and hormone ablation therapy.

In 1999 we initiated a project to standardize the information contained in consent forms and automate the informed consent process. An initial pilot study focused on 20 common diagnostic and therapeutic urological procedures (fig. 1). This was followed by the introduction of a formal electronic consent system. A digital consent form is displayed on a computer and automatically populated with a description of the procedure as well as with the pertinent risks, benefits and alternatives. Additional information and risks specific to the individual can be added or deleted by the provider as needed. The patient, provider and a witness sign an electronic signature pad. The completed consent is stored in the patient electronic medical record and a paper copy is given to the patient.

During the initial implementation of the new electronic consent system patients received a 4-page educational material on informed consent and the new electronic process. Following completion of the electronic informed consent patients were asked 2 questions. The first question was whether they had tried the old handwritten consent system. Those who answered yes were then surveyed with the second question, "Which system (paper or computer) do you prefer?"

TABLE 1. *Documentation of procedure specific risks in consent forms*

	No. TURP (%)	No. RP (%)
Overall	115	89
Urinary incontinence	75 (65.2)	82 (92.1)
Erectile dysfunction	76 (66.1)	86 (96.6)
Bladder neck stricture	8 (7.0)	26 (29.2)
Urethral stricture	26 (22.6)	22 (24.7)*
TURP syndrome	6 (5.2)	0*
Ejaculatory dysfunction	44 (38.3)	2 (2.2)*
Infertility	2 (1.7)	1 (1.1)*
Prolonged urinary retention	11 (9.6)*	2 (2.2)*
Bladder injury/perforation	33 (28.7)*	0
Rectal injury	10 (8.7)*	39 (43.8)
Rectal fistula	0	5 (5.6)*
Colostomy need	0	1 (1.1)*
Lymphocele	0	6 (6.7)

* Disclosure of specific risk is considered optional and disclosure of remaining risks is considered mandatory.

RESULTS

During the 6-year period 1995 to 2000, 222 prostate procedures were performed at Atlanta Veterans Affairs Medical Center, of which 18 (7.7%) were excluded due to our inability to locate the consent forms in the medical records. The remaining 204 procedures were included in the data analysis, of which 115 (56.4%) were TURP and 89 (43.6%) were RP.

Completion of the consent forms were performed by senior urology residents (42.2%), junior urology residents (30.9%) and urology physician assistants (25.5%). Table 1 shows procedure specific risks. Of the 204 consent forms information on the procedure, purpose and benefits was considered acceptable in 149 (73.0%), unacceptable (deficient) in 46 (22.6%) and not documented in 9 (4.4%).

With regard to general risks the risk of death was documented in 126 forms (61.8%), bleeding was documented in 64 (31.4%), infection was documented in 63 (30.9%) and deep venous thrombosis was documented in 2 (1.0%). No documentation was found regarding pulmonary embolus. Generic nonspecific risks were rarely documented. Persistence, recurrence and worsening of symptoms were documented in 36 forms (17.6%), the need for further treatment was documented in 3 (1.5%) and unsatisfactory results were docu-

FILE IN PATIENT'S MEDICAL RECORD

INFORMED CONSENT FOR SURGERY/INVASIVE PROCEDURES: AND/OR INFUSION OF BLOOD OR BLOOD COMPONENTS

Discussion took place with: _____
Patient or Representative's Name

On: _____ at _____
Date Time

The patient's mental status at the time of consent: Awake & Alert Yes Sedated No Mentally Compromised No

Procedure(s) Proposed: **1. Radical Retropubic Prostatectomy (RRP)**
2. Bilateral Pelvic Lymph Node Dissection (BPLND)

Physician: _____ Attending Physician: _____ **MD**

With the above named individual(s), I discussed the major:

1) Indications for the procedure(s): **Adenocarcinoma of the Prostate (Prostate Cancer)**
Clinical Stage: _____ Serum PSA: _____ ng/mL Nuclear Bone Scan: **Negative**

The patient's 'History & Physical,' laboratory/pathology findings, and all relevant information were reviewed by the urology team and discussed at the GU-Pathology clinical conference prior to recommending treatment.

2) Benefits of the procedure(s): **1. To surgically remove your prostate gland and the adjacent related structures (seminal vesicles and ejaculatory ducts). 2. To surgically remove the lymph glands on each side in your pelvis where the cancer may spread.**

The benefits in doing these procedures are to potentially cure you from your prostate cancer and to obtain tissue specimens for pathological staging (for prognosis and possible future treatment).

3) Risks including death, cardiac arrest, brain damage, disfiguring scar, paraplegia or quadriplegia, paralysis or partial paralysis, loss or loss of function of any limb or organ, severe loss of blood, allergic reaction and infection. Other risks: **bleeding, blood transfusion, infection, abscess, lymphocele (lymph fluid collection), thrombosis (clots) in limbs or lungs, anesthesia risks, impotence (no erection of the penis and no sexual intercourse), inability to ejaculate (no semen), infertility, urinary incontinence (no urine control), rectal injury, recto-urethral fistula (abnormal connection between rectum and urinary tract), need for colostomy bag (stool bag), urethral and bladder neck injury and strictures (scars), urinary obstruction (blockage), need for further surgical procedures and other treatment, cancer persistence, recurrence or worsening, inability to complete the procedure, UNSATISFACTORY RESULTS and DEATH.**

4) Alternatives: **External Radiation Therapy. Brachytherapy (radiation seeds in prostate). Hormone therapy (Elimination of your male hormone 'Testosterone'). Watchful Waiting (Observation). Others.**

5) Prognosis if procedure is rejected: ____ Good ____ Fair ____ Poor **XX** Unknown because:
It depends of the final pathology stage and the biological behavior of the your prostate cancer in the future.

6) Is the use of blood or blood components expected for this procedure? Yes **XX** No ___

If the use of blood or blood components becomes necessary, do you consent to the use of these products?

To be initialed by the Patient: Yes _____ No _____

Patient Identification

This form replaces VA-SF-522
OP 4703112 (508) 10-95 MRC# 95-005
Consent is good for 30 days

FIG. 1. Example of standardized consent form for radical RP shows 1 page of 2-page document. Form underwent further revisions and refinements, including increasing font size from 10 to 12 points.

mented in 14 (6.9%). No documentation was found regarding the inability to complete the procedure.

Of the 204 consent forms reviewed 100 (49%) were missing alternative treatment options. The remaining 104 forms (51%) had at least 1 alternative treatment documented. Overall documentation was worse in the TURP groups compared to that in the RP group (fig. 2). Of the 52 patients with TURP who were informed about alternative treatment options 16 (13.9%), 10 (8.7%) and 9 (7.8%) had documentation about medical, thermal and open surgical therapies, respectively, while 11 (9.6%) were informed about observation and 2 (1.7%) were informed about an indwelling bladder catheter. Ten consent forms (8.6%) contained "to refuse" or "to do nothing" as alternative options (fig. 2). Of the 52 patients with RP who were informed about alternative treatment options 36 (69.2%), 51 (98.1%) and 33 (63.5%) had documentation about observation, radiation and hormone ablation therapies, respectively, on the consent form. Only 4 consent forms (7.7%) mentioned brachytherapy as an alternative.

Documentation of the patient prognosis was missing in 8.3% of the consent forms (17 of 204). Overall the prognostic category chosen was highly variable and inconsistent (table 2). Only 33 consent forms (16.2%), all in the RP group, had an explanation or reason given for the prognostic category chosen.

Overall 7.4% of the consent forms (15 of 204) failed to document the risk of bleeding, the need for transfusion or risks and alternatives. In the TURP group a third of the patients were not informed about the potential for significant blood loss, nor did they provide consent for blood transfusion. Seven patients (6.1%) in the TURP group received blood transfusion, of whom 2 (1.7%) did not have the appropriate consent documentation. In the RP group 79 patients (88.8%) had the appropriate documentation in the consent forms regarding the potential for significant blood loss and yet only 23 (25.8%) had documented consent for blood transfusion. Of the 89 patients with RP 82 (92.1%) received blood transfusion (fig. 3).

TABLE 2. *Documentation of prognosis in consent forms*

	No. TURP (%)	No. RP (%)	Total No. (%)
Documentation:			
No	10 (8.7)	7 (7.9)	17 (8.3)
Yes	105 (91.3)	82 (92.1)	187 (91.7)
Prognosis:			
Good	17 (14.8)	1 (1.1)	18 (8.8)
Fair	37 (32.2)	13 (14.6)	50 (24.5)
Poor	27 (23.5)	19 (21.3)	46 (22.5)
Unknown	24 (20.9)	49 (55.1)	73 (35.8)
Explanation	0	33 (37.1)	33 (16.2)
Totals	115 (100)	89 (100)	204 (100)

Following this pilot evaluation and a number of revisions new, standardized, procedure specific consent forms were designed. The forms were stored electronically in a central network accessible by all urology providers throughout the medical center. The product was manufactured and made available as formal software (iMedConsent™ application). In addition, an extensive library of education materials and medical illustrations on various urological diseases and therapeutic options was incorporated into the software program. Providers can use this information to educate patients and answer questions during the informed consent process. In 2002 the Department of Veterans Affairs formally adopted the electronic consent system for national use at all Veterans Affairs medical centers. A total of 78 subjects participated in the patient satisfaction survey, of whom 75 (96.1%) preferred the new electronic process over the traditional paper process.

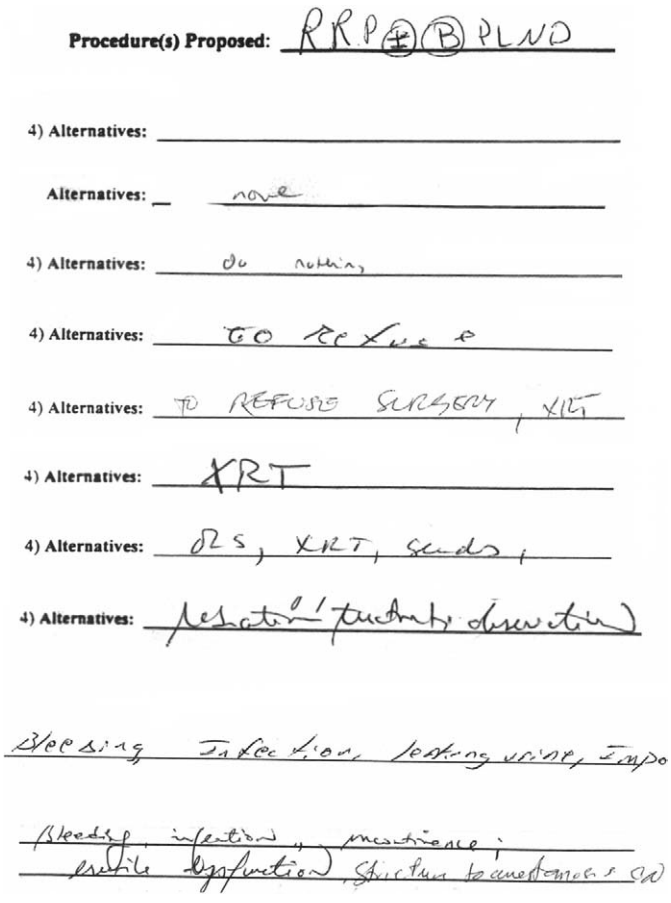

FIG. 2. Assortment of entries selected from old, conventional paper based consent forms.

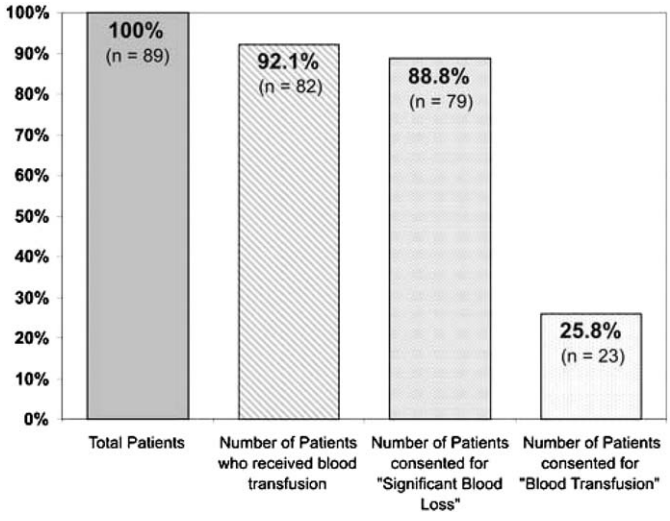

FIG. 3. Documentation of consent for blood transfusion in patients with RP.

DISCUSSION

Physicians and patients often perceive informed consent as an exercise in risk management rather than as an ethical standard of care. In reality the informed consent process is an ethical imperative often documented by a consent form for legal purposes. Ethical principles dictate that physicians should respect patient autonomy and the latter has been shown to enhance patient compliance and satisfaction.[9] From a legal standpoint a well written consent form documents that the treatment offered is in accordance with patient will. If providers fail to follow these standards, they place themselves at risk for being accused of negligence or even battery.

The presentation of factual, nonbiased and comprehensible information can be challenging, particularly given the wide variation in the level of education of health care providers and training, and the variation in patient education. A survey of written consent forms from 5 institutions in California revealed that all required a high level of literacy, similar to that required for reading a scientific journal or academically oriented magazine.[10] Much of the information normally documented on a consent form requires a college or greater level of reading ability to comprehend. Many patients fail to recall or comprehend key information, such as indications, risks and alternatives.[11] In a study of patients undergoing eye surgery 97% believed that the risks and benefits had been thoroughly discussed preoperatively, although only half of the information could be remembered postoperatively.[12] Furthermore, the psychological impact of serious and potentially fatal illness often renders patients vulnerable to misunderstanding or misinterpreting the information. Such studies highlight the current deficiencies of the system and its inability to achieve its educational goals.[10–12]

Numerous studies, including ours, have documented incomplete documentation of information by physicians.[13,14] On 1 hand, patients have the right to know about the therapies proposed, and all of the potential risks and alternatives.[14] On the other hand, many surgeons are concerned that too much information may cause unnecessary anxiety, resulting in patients electing less risky therapies that have lower efficacy.

While various guidelines are available, significant discrepancies exist among medical centers and individual providers in what information must be disclosed to patients. Several studies have demonstrated significant deficiencies that are attributable to a lack of awareness of procedural risks, poor communication skills, and lack of appropriate training and feedback on performance.[15–17]

From a legal standpoint the standards for risk disclosure have been described in 2 ways. Traditionally the prudent physician standard had been favored. It is defined by what a physician in similar practice would or would not have done in a similar situation. In the last decade the standard shifted toward the prudent patient standard, by which a physician is required to disclose information that a reasonable patient would consider important for consenting.[18] Currently half of the states use the reasonable physician standard and half use the reasonable patient standard.[14] Neither of these standards is specific about what information should be disclosed to patients. While some states, eg Texas and Louisiana, require disclosure of at least a minimum set of risks defined by a medical disclosure panel, there are currently no accepted standards regarding the threshold probability of risks that mandate their disclosure. As a result, there is significant ambiguity and discrepancies in our current nonstandardized consent process.

In our review we found the consent forms were missing from 7.7% of patient medical records. Our analysis demonstrated significant inadequacies in our traditional informed consent process/system (table 1). Much of the information was missing and, when present, it tended to be documented with illegible handwriting or in the form of abbreviations and acronyms.

The new electronic consent system implemented at our institution provides substantial benefits. The standardized information eliminates the need for handwritten information. The process is simple and user friendly for patient as well as providers. Patients were provided a legible, complete, easy to read consent form, which they can read at their leisure. Patients are more likely to actually read the consent form if it is given to them to review at their leisure.[19] Our survey demonstrates substantially improved patient preference. The new system reinforces the ethical standard of information disclosure, possibly improving compliance, while at the same time it provides excellent documentation of the informed consent encounter, decreasing legal risk. Finally, electronic storage avoids the loss of the signed consent document.

A considerable proportion of clinical negligence cases focuses on allegations relating to the absence or misleading nature of information provided to the patient during consent. For example, following prostate surgery many complications are perceived to be a result of negligence rather than accepted as adverse events.[20] Thorough disclosure of the risks in the new, standardized informed consent forms should prevent such allegations.

Informed consent is not a mere signature on a document, but rather a process of education and exchange of information relevant to the treatment proposed. The appropriate balance of information needed on the consent form is important. If a specific risk is described on the consent form, it may provide some protection against legal action. On the other hand, if the information provided is inadequate or overly complex, it may support the patient case.[14] The new, standardized electronic consent offers protection to physicians and patients by ensuring that appropriate disclosure standards have been met for the reasonable patient and the reasonable physician.

CONCLUSIONS

The information presented in traditional, paper based consent forms is frequently incomplete, illegible and/or misleading. The forms can be misplaced and absent from the medical records. Electronic informed consent is standardized, legible, understandable, and easily stored and retrieved. The system provides detailed information about the treatment, risks, benefits and alternatives, thereby supporting ethical and legal standards, and improving the quality of care. The system also improves provider autonomy and efficiency. In our opinion standardized electronic informed consent process should be the new standard of care.

Abbreviations and Acronyms

RP = radical prostatectomy
TURP = transurethral resection of prostate

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EDITORIAL COMMENT

This article highlights the problems that are associated with informed consent as it is commonly obtained. Often informed consent is somewhat of an afterthought and it does not document the thorough discussion that the surgeon has had with the patient. While there may be no repercussions 99% of the time, in the rare case when a problem leads to litigation, informed consent is the crucial pillar that the physician has to lean on. Without a well documented informed consent, which is best obtained by the operating surgeon, an otherwise invalid claim for damages may be successful because of the doctrine res ipsa loquator, that is the thing speaks for itself.

The days of the traditional, nonstandardized consent form should be over. For conventional surgical procedures a standardized consent system, which can easily be automated, would seem to provide the best assurance that the patient made a fully informed decision before surgical treatment and it also helps protect the physician to some degree from unwarranted malpractice litigation. The system as described by these authors serves these functions well.

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