Enhancing Efficiency and Patient Satisfaction – Automating the Informed Consent Process

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Tulane Medical School
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Background
Necessary Elements of Informed Consent (AMA)

- Diagnosis
- Purpose of treatment or procedure
- Risks and benefits of treatment or procedure
- Alternatives includes risk and benefits
- The risks and benefits of not receiving treatment
Standards Applicable to Informed Consent

- JCAHO
- CMS
- Individual Hospital Policy
- State Law
  - Texas and Louisiana require disclosure of specific risks
How Are We Doing?

- Physicians typically do a good job with the *verbal communication* aspects
- Documentation is usually inadequate
Traditional Informed Consent
Traditional Written Consent Form

- **Note:**
  - Limited descriptions
  - Illegible handwriting
  - Use of unacceptable abbreviations
Limitations of Traditional Informed Consent Documents

- A review of 540 written consent forms, from 157 hospitals, found the necessary elements of informed consent (purpose, risks, benefits, & alternatives) in only 26% of the documents.

*Archives of Surgery. 2000;135:26-33.*
Challenges with the Traditional Current Consent Form

- Time-consuming
- Details may be limited
- Content varies from provider to provider
- Risk of missing sections, signatures or dates
- Involves paper
  - Often lost or misplaced
Legal Implications
Potential Legal Impact of Informed Consent

- **Study of medical malpractice claims against urologists**
  - Postoperative complications most common claim of negligence

- **Malpractice premiums for urologists have increased 57% during the past three years**

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“One of the strongest is the doctor's ability to communicate effectively with the patient. Informed consent problems are more likely to arise for a doctor who doesn't communicate well. But perhaps even more importantly, a doctor who doesn't communicate well is not likely to build a healthy relationship with a patient such that if a bad outcome did happen in medical care, the patient would be inclined to forgive rather than sue.”

Michelle Mello, PhD, JD, Assistant Professor of Health Policy and Law, Harvard School of Public Health. NPR Radio Interview: January 15, 2005.
Patient Safety
Patient Safety

- Incomplete or not fully comprehended informed consent is a significant patient safety issue.
- Better informed patients “are less likely to experience medical errors by acting as another layer of protection”

Patient Safety

- Providing informed consent information to patients in **written form** increases the patients’ comprehension of the procedure


- Better informed patients are more compliant, are less anxious and are more satisfied

Cost of Lost or Misplaced Consent Documents
Take Home Message:

8% of the time the consent document was lost or missing from the patient’s chart!
Cost of Lost or Misplaced Consent Documents

- Cost of OR time = $20 per minute
- Time to find or re-obtain lost consent document ~ 10 minutes
- Cost per case = $200!
## Annual Cost of Lost or Misplaced Consent Documents

<table>
<thead>
<tr>
<th>Item</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures performed in the U.S. each year</td>
<td>212,000,000</td>
</tr>
<tr>
<td>Percentage of consents that are lost or misplaced</td>
<td>8%</td>
</tr>
<tr>
<td>Approx. number of lost or misplaced documents</td>
<td>16,960,000</td>
</tr>
<tr>
<td>OR time spent replacing a lost/misplaced consent</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Hours of wasted OR time each year</td>
<td>2,826,667</td>
</tr>
<tr>
<td>Average cost of OR time per hour</td>
<td>$1,200</td>
</tr>
<tr>
<td>Cost of lost or misplaced consent documents in U.S.</td>
<td>$3,392,000,000</td>
</tr>
<tr>
<td>Number of U.S. hospitals</td>
<td>5,764</td>
</tr>
<tr>
<td>Average Cost per U.S. hospital due to lost or misplaced consent documents</td>
<td>$588,480</td>
</tr>
</tbody>
</table>

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1. Inpatient Surgery, Data for the U.S. for 2002, National Center for Health Statistics (NCHS)  
2. Pilot Study of iMedConsent - Report to the Health Systems Committee and the Informatics and Data Management Committee, Veterans Health Administration. (Data on File, Dialog Medical)
Automating the Informed Consent Process
iMedConsent™ Application

- Automatically generates procedure-specific consents for every urologic procedure
- Comprehensive libraries
  - Education documents
  - Patient instructions
  - Anatomical diagrams and images
- Standard of Care in all 158 VA Medical Centers
Demonstration
Select Specialty
Patient Selected from Database
Provider Selected from Database
Consent is Populated

Consent for Blood Products

You must obtain the patient's (or surrogate's) consent to use blood products in the event they are needed for this treatment/procedure.

- The patient (or surrogate) consents to the use of blood products.
- The patient (or surrogate) refuses the use of blood products.
CONSENT TO OPERATION OR OTHER PROCEDURE

Patient: Smith, Robert
Medical Record Number: 806259749
Birth Date: 08/04/1972
Date: May 16, 2006
Time: 5:32 PM
Diagnosis: Prostate cancer.

Procedure: PROSTATE - RADICAL PERINEAL PROSTATECTOMY

1. In conjunction with the procedure identified above, I understand the following:
   a. Nature and purpose of the procedure: Removal of entire prostate & seminal
Benefits and Risks are Automatically Populated

1. In conjunction with the procedure identified above, I understand the following:
   b. Benefits of procedure: Possible cure of tumor or cancer.
   c. Risks of the procedure:
      1. Impotence (inability to achieve adequate erections).
      2. Incontinence (loss of urinary control).
      3. Stricture (narrowing) of bladder and/or urethra requiring stretching or further procedures.
      4. Severe blood loss, possibly requiring transfusions.
      5. Damage to rectal wall possibly requiring temporary colostomy.
      6. No guarantee of cancer cure and need for further cancer treatment such as hormone or radiation therapy.
      7. Fecal incontinence (inability to maintain control of stool).
      8. Nerve damage to legs or pelvis from position required to do surgical procedure, with permanent injury or side effects.
      10. Emboli (blood clots) from veins traveling into the lung.
      11. Anesthetic or cardiovascular problems during or after surgery.
Alternative and Prognosis-if-Rejected are Automatically Added

Additional material risks of the procedure include: death, cardiac arrest, brain damage, disfiguring scar, paralysis or partial paralysis, loss or loss of function of a limb or organ, severe loss of blood, allergic reaction and infection.

d. Practical alternatives to procedure: Radiation therapy, radioactive implant, removal of all male hormones, different surgical approach, observation (no immediate treatment).

e. Prognosis if procedure rejected: Continued growth and possible spread of malignant (cancerous) tumor, making the tumor incurable or later removal impossible.

2. PROCEDURE CONSENT: The procedure identified above has been explained to me and all of my questions have been answered. I acknowledge that no guarantees have been made concerning the outcome of the procedure. I hereby consent to the performance of this procedure by Neil Baum, MD and/or any assistants selected by this physician/surgeon.

3. ANESTHESIA CONSENT (if applicable): IT IS EXPECTED that an anesthesia practitioner will be involved in this treatment/procedure.

A member of the anesthesia care team will visit me before my treatment/procedure to discuss the type(s) of anesthesia I may need. The specific anesthetic plan may be
Signatures are Digitally Captured
Patient Signature

By signing below, I attest to the following:
- Someone has explained this treatment/procedure and its purpose.
- Someone has explained how this treatment/procedure could help me, and things that could go wrong.
- Someone has told me about other treatments or procedures that might be done instead, and what would happen if I have no treatment or procedure.
- Someone has answered all my questions.
- I choose to have this treatment/procedure.

Signature:

5/16/2005 5:49:22 PM

Patient: Smith, Robert

Consentor Signature
Signature Informed Consent for
PROSTATE - RADICAL PERINEAL PROSTATECTOMY
to be performed at St. Ashlyn Medical Center

1. Patient name: Smith, Robert
2. Medical Record Number: 806259749
3. Patient Birth Date: 03/04/1972
4. Informed consent was obtained at 8:32 PM on May 16, 2005.
The full consent document can be accessed through the St. Ashlyn Medical Center document management system.
5. Capacity Assessment
6. Surrogate (if applicable):
7. Condition or diagnosis: Prostate cancer.
8. Treatment/procedure: Removal of entire prostate & seminal vesicles. (Radical Perineal Prostatectomy)
10. IT IS EXPECTED that an anesthesia practitioner will be involved in this treatment/procedure.
11. Patient or surrogate's statement about consent or refusal of blood

Victorino

Date 2005-05-16
Education Documents are Available to Provide to the Patient
Kidney Cancer

Definition

Kidney cancer, or renal cell cancer, is a disease in which cancer (malignant) cells are found in certain tissues of the kidney.

Kidney cancer is also called renal adenocarcinoma, clear-cell cancer, or hypernephroma.

There are over 30,000 new cases of kidney cancer each year in the United States.

The kidneys are a "matched" pair of organs found on
Patient Instructions are Available to Provide to the Patient

Neil Baum, M.D.
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Suite 614
New Orleans, LA 70115
Tel: 504.891.8454
Fax: 504.891.8505

Discharge Instructions
Cystoscopy

After your office cystoscopy you will be able to return home. How you will feel will depend on the reasons that the cystoscopy was performed. In most instances, you will have no problems urinating and will have little or no symptoms.

Some patients will feel mild irritation or a sense of “burning” with urination that will last one to two voids. If irritation continues, a warm bath may help.

However, if the irritation is new and continues more than 24 hours, please let us know. For the first day, you should drink 2-3 glasses of water in the first hour or two after the procedure. Stay away from irritating foods or liquids until all the symptoms have resolved. Such liquids and foods include coffee, soft drinks, cranberry juice and spicy foods.

Some patients will notice a speck of blood in the urine or in their underwear for the first day. If the bleeding is more severe and continues, let us know.

Medication
Pictures and Diagrams are Available to Explain Procedures
Kidney stones in the minor and major calyces of the kidney

Kidney stone in the ureter
Annotated Diagram, Inserted in Document, with Patient Signature

Kidney stones in the minor and major calyces of the kidney

Kidney stone in the ureter

You have a stone located here.

4/21/2005 12:25:03 PM
Sildenafil
(silden-a-fil)

Brand Name(s): Viagra

WHY is this medicine prescribed?

Sildenafil is used to treat impotence in men. Sildenafil increases the body’s ability to achieve and maintain an erection during sexual stimulation.

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

HOW should this medicine be used?

Sildenafil comes as a tablet to take by mouth. It should be taken as needed about 1 hour before sexual activity. However, sildenafil can be taken anytime from 4 hours to 30 minutes before sexual activity. Sildenafil should not be taken more than once a day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take sildenafil exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

What SPECIAL PRECAUTIONS should I follow?

Before taking sildenafil,

- tell your doctor and pharmacist if you are allergic to sildenafil or any other drugs,
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially amiodarone (Norpace) or other medications for high blood pressure, cimetidine (Tagamet, Tagamet HB), erythromycin, HIV protease inhibitors such as ritonavir (Norvir) and saquinavir (Invirase), isosorbide (Imdur, Ismo, Isordil, and others),itraconazole (Sporanox), ketoconazole (Nizoral), nitroglycerin (Nitro-Bid, Nitrodot, Nitrostat, and others), other medications to treat impotence, phenobarbital, rifampin (Rifadin, Rimactane), and vitamins,
- tell your doctor if you have or have ever had a bleeding disorder, heart, kidney, or liver disease, a heart attack, irregular heartbeat, angina, a stroke, high or low blood pressure, sickle cell anemia, multiple myeloma, leukemia, conditions affecting the shape of the penis (e.g., angulation, cavernosal fibrosis, or Peyronie’s disease); or a condition known as reticuloid pigments,
- if you are having surgery, including dental surgery, tell your doctor or dentist that you take sildenafil,
- tell your doctor if you use amyl nitrate, amyl nitrite, or butyl nitrite.
Response to the Imed Consent Application
M.D. Satisfaction and Ease of Learning (Emory Outpatient Urology Clinic)

- Very Satisfied/Very Easy: 5
- Somewhat Satisfied/Easy: 4.7
- Neither Satisfied/Easy nor Dissatisfied/Difficult: 3
- Somewhat Dissatisfied/Difficult: 2
- Very Dissatisfied/Very Difficult: 1

Overall Satisfaction: 4.7
Ease of Learning: 4.9

Patient Satisfaction
(Emory Outpatient Urology Clinic)

Very Satisfied
Somewhat Satisfied
Neither Satisfied nor Dissatisfied
Somewhat Dissatisfied
Very Dissatisfied

4.5
4.7

Satisfaction Compared to Traditional Consent
Overall Satisfaction

Conclusions

- An automated informed consent solution can benefit your practice by:
  - Ensuring more complete informed consent documentation
  - Enhancing patient safety
  - Avoiding lost or misplaced consent documents
  - Improving patient satisfaction
  - Improve your efficiency and efficiency of your OR...AND
May or likely to protect you from a malpractice suite

AND

IT’S GOOD MEDICINE!