THE IMPACT OF LANGUAGE BARRIERS ON DOCUMENTATION OF INFORMED CONSENT

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Informed consent . . . is ethically required of healthcare practitioners in their relationships with all patients, not a luxury for a few.

President's commission for the study of ethical problems in medicine and biomedical and behavioral research, 1982.

Background

- IC is central to the practice of ethical, safe, and patient-centered healthcare.
- Process of shared decision making.
- When patient and provider speak different languages, the process becomes more complex.

Background

- Informed consent is the law.
- Documentation of informed consent is the legal standard.
  - Informed consent discussion
  - Signed consent form
- Informed consent documentation policies have been developed by most U.S. hospitals.

Study Aim

Determine the impact of language barriers on documentation of informed consent among patients in a teaching hospital with on-site interpreter services.

Methods

- Study design

  Retrospective chart review

- Setting

  Large public teaching hospital in San Francisco with 24-hr interpreter services. Procedures performed by residents.

- Procedures

  Thoracentesis, Paracentesis, Lumbar puncture

- Data

  Electronic database and paper charts

Subjects

- Subjects

  Chinese and Spanish-speaking patients with LEP and English-speaking patients who received a procedure while hospitalized during 2004 and 2005.

- Exclusion Criteria

  - Altered mental status
  - Inability to participate in IC for any clinical reason
  - Intubated patients
  - Consent Form signed by surrogate
  - IR/OR

- Matching

  Procedure, Service, Date of procedure

Components of Informed Consent

1. Procedure note documenting consent discussion

2. Signed consent form

3. Evidence of interpretation
   - Documentation of consent discussion through interpreter or in pt's primary language
   - Interpreter signature on consent form
   - Consent form in pt's primary language

Study Sample

- 74 LEP and 74 English procedures
- 54% Medicine Service
  - 28% Emergency Room
  - 18% Neurology/Family Practice
- 54% Lumbar Punctures
  - 32% Paracenteses
  - 14% Thoracenteses

Patient Characteristics

	LEP (n=74)	English (n=74)	p value
Mean age +/- SD, yrs	50 +/- 16	47 +/- 12	0.3
Male N (%)	44 (59)	58 (78)	0.01
Race N (%)			<0.001
White	--	28 (38)	
Black	--	26 (35)	
Latino	51 (69)	10 (14)	
Asian	23 (31)	10 (14)	
Diagnosis			0.5
Infection	29 (39)	32 (43)	
Malignancy	12 (16)	7 (9)	
Other	33 (45)	35 (47)	

Documentation of Informed Consent

	LEP (n=74)	English (n=74)	p
Procedure note documenting IC discussion	44 (59)	43 (58)	0.9
Signed Consent Form - any language	52 (70)	63 (85)	0.03
Consent Form - pt's language or signed by an interpreter	30 (41)	63 (85)	<0.001
Informed Consent	21 (28)	39 (53)	0.003

Predictors of Documentation of Informed Consent

	OR	CI	Adj OR	CI
Language (Eng vs LEP)	**2.8**	**1.4-5.6**	**3.1**	**1.5-6.5**
Age	1.0	0.9-1.0	1.0	1.0-1.1
Gender – ref men	0.7	0.3-1.5	0.7	0.3-1.5
Infection Malignancy	1.0 1.4	0.5-2.0 0.5-4.0	0.9 1.5	0.4-2.1 0.5-4.7
LP Paracentesis	1.1 1.0	0.4-2.9 0.3-2.9	2.0 1.1	0.6-6.5 0.3-3.4
ED vs Wards	0.5	0.2-1.1	0.5	0.2-1.2

Discussion

- Documentation of IC was low for English-speakers and LEP pts.
- LEP patients were less likely to have evidence of IC documentation.
- Residents underutilize professional interpreters when caring for LEP pts.
- Differences in the documentation of IC suggest differences in the process of informed consent.

Limitations

- Documentation, not practice or quality of the informed consent process.
- One hospital.
- Patient language ability was not directly measured.

Implications

- Informed consent may constitute a healthcare disparity for LEP patients.
- Hospitals may wish to monitor informed consent for pts with LEP as a measure of quality.
- Resident physicians need more training in the care of LEP pts, the use of interpreters, and the process and documentation of informed consent.

SFGH Response

- Study reviewed by relevant committees including risk management, ethics, quality improvement, med-executive.
- Results confirmed by another chart review
- Results championed by CEO as example of valuable QI and disparities assessment
- Consent process revisited

COMMUNITY HEALTH NETWORK

SAN FRANCISCO GENERAL HOSPITAL
MEDICAL CENTER

CONSENT FOR A TREATMENT OR PROCEDURE

NAME

DOB

MRN

PCP

Patient ID / Addressograph

MY RIGHTS--

I understand that I have the right to make decisions about my health care. I also understand that my doctor or other health care provider will give me information about the treatment or procedure he or she recommends. This information will include:

1. What the doctor/provider plans to do
2. Who will do the treatment or procedure
3. How it may help me
4. Possible unplanned problems
5. Other things that could be done instead

WHAT--

My doctor or provider recommends that I have the following treatment or procedure:

____

During the procedure my doctor or provider **may** need to do an additional or different procedure. My doctor or provider will only do this in an **emergency** to save my life or protect some important body function.

WHO--

The **attending doctor or doctors** responsible for the treatment or procedure are ____.

The **resident doctor(s) or provider(s)** involved in the treatment or procedure are ____.

I understand that San Francisco General Hospital is a teaching hospital. Resident doctors and other doctors in training may perform important parts of the treatment or procedure. Attending doctors supervise the resident doctors and other doctors in training. Other licensed health care workers (such as nurse practitioners or physician assistants) may also perform some procedures or tasks, but only when permitted by California law and hospital policy.

WHY--

The reason for the treatment or procedure is____.

OTHER OPTIONS--

Instead of this procedure, the following could be done:

☐ Nothing ☐ Other: ____

OUTCOME--

The chance of a successful outcome is

☐ Excellent ☐ Good ☐ Fair ☐ Poor ☐ ________________________________

There is a possibility that the treatment or procedure will not be successful or that it may cause an unexpected, new problem.

RISKS--

My doctor or provider has explained that there is some risk in all medical treatments and procedures. She or he has explained to me some of the common and serious risks associated with the recommended treatment or procedure. Some (**but not all**) of these risks may include bleeding; infection; damage to close-by blood vessels, nerves, organs or other tissue; disability or death. Other risks: ____

TISSUE STUDY--

I understand that any tissue removed during surgery will first be studied to better understand my medical condition and how best to treat it. Any tissue that is left over may be appropriately disposed of or saved for future study. If the tissue is saved for future study:

- My privacy will be protected.
- I may not receive any direct benefit, but the study may lead to discoveries that will help others in the future.
- I will not receive any payment for the study.

I agree that my tissue may be saved for future study, but with the following conditions (**if any**):

____.

Before you sign, do you have any questions?

✓ **MY CONSENT--**

I have received the information described above. My doctor or provider has answered my questions. I wish to have the recommended treatment or procedure.

- Patient / Representative: Signature:____

  Print Name______________________________________ Date: ______________

  If a surrogate, relationship: ☐ Spouse/Domestic Partner, ☐Parent, ☐ Adult Child ☐Other Family Member: ____________________, ☐ Power of Attorney for Health Care, ☐Conservator, ☐ Surrogate orally designated by patient during this admission

- Interpreter: Signature:____

  Print Name ___________________________ Date: _________ Time: __________

- Witness (Member of Healthcare Team): Signature:_____________________________

  Print Name ___________________________ Date: _________ Time: __________

Complete 1, 2 *OR* 3 below

1. CONSENT DISCUSSION WITH PATIENT OR SURROGATE (Complete this section together with the consent form which is signed by the patient or surrogate.)

a. As indicated on the **Consent Form** I explained the following to the patient or her/his surrogate:

--nature of the procedure or treatment,
--why it's recommended and the possible benefits,
--risks and complications (most common and serious),
--alternative treatments and the risks of each (including no treatment), and
--who will perform the procedure or treatment.

☐ At the patient's request, a friend(s) or family member(s) was present during the discussion ____.

b. ☐ An interpreter was involved. [Use a trained medical interpreter (**ext. 5133**) except in urgent situations or if a patient specifically requests that an adult family member serve as the interpreter.]

c. ☐ Patient has **DNAR/DNI** order; I explained to the patient or surrogate that the order will be suspended during the procedure.

d. ☐ Teach-Back (The patient or surrogate was able to tell me what treatment / procedure is planned, why it's needed, the benefits and some of the risks that s/he might expect.)

________________________________ ________________ ________________
(Physician/Provider) (Provider ID No.) (Date & Time)

2. EMERGENCY [Complete this section when neither the patient nor a surrogate can give consent and clinically the procedure cannot be delayed to allow the hospital to petition the court for an order authorizing treatment--"*medical probate*". The consent form (*pages 1 & 2*) is not completed.]

In my clinical judgment the patient emergently needs the following treatment or procedure to alleviate severe pain or to diagnose and treat a condition that may lead to a serious disability or death; **AND** ☐The urgency of the situation precluded getting the patient's consent in advance; **OR** ☐ I have assessed the patient and determined that s/he lacks the capacity to make health care decisions and have not been able to readily identify or locate a surrogate decision maker.

Treatment/Procedure: ____

________________________________ ________________ ________________
(Physician/Provider) (Provider ID No.) (Date & Time)

3. **TELEPHONE CONSENT** **[Complete this section when a surrogate gives consent by telephone. The consent form (*pages 1 & 2*) is not completed.]**
I assessed the patient and determined that (1) s/he lacks the capacity to make health care decisions or (2) s/he is a minor. I have located a family member or other authorized representative who is willing to act as the patient's surrogate health care decision-maker, but who cannot be physically present to sign the consent form. By telephone I discussed the nature of the treatment/procedure, expected outcome, risks and benefits and alternatives with the patient's surrogate.

- **Treatment/Procedure**:

  ____

- **Risks explained**:
  I explained that some (**but not all**) of these risks may include bleeding; infection; damage to close-by blood vessels, organs or other tissue; disability or death.

  Other risks:____

- The surrogate has consented to the treatment/procedure on behalf of the patient.

  ____ ______________________
  (Surrogate's Name) (Telephone No.)

- Surrogate's relationship to patient:

  ☐ Spouse/Domestic Partner, ☐ Parent, ☐ Adult Child, ☐ Other Family Member (relationship): _____________________________, ☐ Power of Attorney for Health Care, ☐ Conservator, ☐ Surrogate orally designated by patient during this admission

____ ______________________ ____________
(Physician/Provider) (Provider ID No.) (Date & Time)

- Staff who was a **witness** to the telephone call:

____ ______________________ ___________
(Name) (Title) (Date)

New SFGH Consent Form

- Low literate reading level
- Signals physicians to
  - Call interpreters (gives phone number)
  - Assess patient comprehension “teach back”
- Space for interpreter signature
- Longer– 4 pages
- English/Spanish/Russian/Chinese/Vietnamese/Tagalog

Projects

- Qualitative study of resident decision making on interpreter use
- Evaluation of new consent forms
- Improving ability to capture use of interpreter services
- Novel technology to lower barriers to interpreter use