



Consent, Disclosure & Apology

Christopher Church, MD



Informed Consent in ENT

- Up to 37% alleged lack of informed consent in ESS lawsuits (Lynn-Macrae et al, 2004)

Informed Consent - History

- Hippocrates (460-370 BC)
- Schloendorff v. Society of New York Hospital (1914)
 - "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages." -Justice Cardozo
- Nuremberg Code (1947)



Informed Consent - History

- Salgo v. Leland Stanford Jr. University Board of Trustees (1957)
 - Introduced term "informed consent"
- Natanson v. Kline (1960)
 - Reasonable physician standard
- Canterbury v. Spence (1972)
 - Reasonable patient standard



Shared Decision Making (SDM)

- Phrase first used by Veach in 1972
- Shared decision-making in the medical encounter: what does it mean? Charles et al, 1997
- Intersection of patient-centered communication skills and EBM

What makes a consent an *Informed Consent*?

- A process, not an event
- Physician documentation
- Criteria for valid consent
 - Decision-making capacity
 - Adequate information
 - Voluntary



Capacity

- Different from “competence”, which is a legal term
- Patient knows a decision must be made
- Can understand the pros and cons
- Able to apply own values in reaching a decision

Adequate Information

- Understandable language/words
- Reason for the proposed procedure
- Expected outcomes (benefits)
- Burdens and risks
- Alternatives
- Likely outcome without intervention
- Physician's recommendation

Voluntary

- **No**
 - Manipulation, deception and coercion
- **Yes**
 - Education and persuasion

Exceptions to informed consent

- Implied consent
 - “Simple and Common”
- Emergency consent
- Refusal of information
- “Therapeutic privilege” - no



Which Complications?

- No set standard
- Exhaustive lists
- >1% or catastrophic
- Surgeon's own complication rates vs. literature
- Don't just list potential complications

Who Should Obtain Consent?

- ACS - the surgeon “responsible for obtaining consent from the patient...need not personally obtain the patient's signature....”
- Greater inaccuracy of risk estimation with nurses, students or residents vs. attending staff
- Many patients expect physician obtaining consent will be the one performing the procedure

Educational Tools

- In addition to discussion with physician...
 - Handouts
 - Videos
 - Trained educators
 - Teach-back
 - aka "shared decision-making tools"



Cultural & Religious Differences

- Paternalistic relationship with physician
- Corporate/family decision
- Unique medical beliefs



Communication after a Complication

- Unexpected outcomes are distressing for everyone
- Physician as "second victim"
- Most surgeons make first disclosure without guidance

Appropriate Level of Communication

- Extremes
 - Avoidance
 - Smothering
- Appropriate
 - Education
 - Access



Disclosure

- When? - As soon as possible
- Who? - Don't delegate
- What? - Facts only - don't speculate
- Assure that this is an ongoing conversation
- Don't ignore family

Apology

- Patients desire apology
- An admission of guilt?
- "I'm sorry" laws



Saying, "I'm sorry" is the same as saying, "I apologize" ... except at a funeral.

-Demetri Martin

Apology vs. Disclosure

- Disclosure is an ethical (and legal) right
- Apology is a therapeutic necessity
 - Shows humanity and remorse
 - Helps patients with forgiveness and emotional healing

Apology Works

- Lexington VA - 1987
 - "unanticipated financial benefits"
- Michigan Model - 2001
 - Fewer claims, faster resolution, reduced costs
- Stanford PEARL program - 2005
 - 36% reduction in claims; 32% reduction in premiums

A Good Apology

- An insincere apology is worse than no apology at all
- Demonstrate sincerity through:
 - Specific acknowledgement of event and pain
 - Participate in root cause analysis
 - Learn from the mistake
- Idea of recompense – making the injured whole

Summary

Do to others as you would have them do to you.
-Luke 6:31

Snissarenko EP & Church CA
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