

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"
- Natansan 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

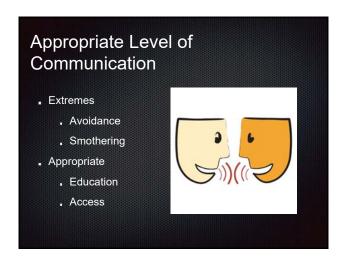
Who Should Obtain Consent?

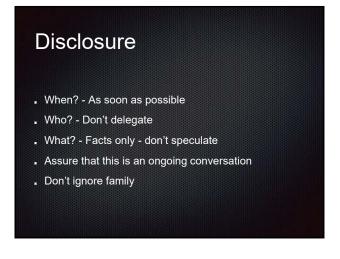
- ACS the surgeon "responsible for obtaining consent from the patient...need not personally obtain the patient's signature...."
- Greater inaccuracy of risk estimation with nurses, students or residents vs. attending staff
- Many patients expect physician obtaining consent will be the one performing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





Communication after a Complication . Unexpected outcomes are distressing for everyone . Physician as "second victim" . Most surgeons make first disclosure without guidance







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

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