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Clinical Medical Informed Consent: More than a form

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- Col (Dr.) Kerry Latham is the Deputy Chair of the Department of Surgery at USUHS, her alma mater. She is committed to service, education and student and faculty development. She is the Plastic Surgery Consultant to the AF/SG and serves as the Chair of the Surgical Services Clinical Communities for DHA medical affairs. She previously served as the 316th and11th Surgical Operations Squadron Commander, Malcolm Grow Medical Clinics and Surgery Center, Joint Base Andrews, Maryland. She oversaw 200 active duty and civilian doctors, nurses, technicians and administrators to deliver safe, timely, and effective health care while accomplishing the readiness mission. The service lines include Ambulatory Surgery Center services, Radiology, ENT, Orthopedics, Urology, Plastic Surgery, General Surgery, Podiatry, Ophthalmology, Warrior Refractive Surgery, and Women's Health.

- Col. Latham entered the Air Force through Uniformed Services University of Health Sciences (USUHS) in 1996 after graduating Princeton University. She is a national speaker and educator on trauma and has authored more than 20 peer review journals, and a book chapter. She is active in global health engagement and has participated in 19 missions, leading 5 of them in both military and civilian organizations. She pioneered and directs the Plastic Surgery Visiting Surgeon Program, overseeing 50 missions with $8M recaptured. She is a dedicated teacher and academic mentor and Associate Professor of Surgery and Pediatrics at USU department of Surgery. She had developed and sustained several critical Training Affiliation Agreements to sustain trauma readiness and is faculty on the facial trauma and reconstruction team at University of Maryland Baltimore Shock Trauma. Additionally, Col Latham created the Expeditionary Craniofacial Trauma Course for multidisciplinary surgeons.

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Learning Objectives

At the conclusion of this activity, participants will be able to:

1. Explain Informed Consent and why it is important in modern clinical practice.
2. Discuss the importance of respect for others, patient autonomy, and the doctor- patient relationship.
3. Apply informed consent to clinical practice in the Defense Health Agency.

History of medical informed consent (not research)

- Mohr v. Williams - 95 Minnesota 261, 104 N.W. 12 (1905)
- Pratt v. Davis, 224 Ill. 300 (1906)
- Schoendorff v. Society of New York Hospital, 105 N.E. 92, 93 (N.Y. 1914) Self - Determination
- Salgo v. Leland Stanford JR University Board Of Trustees (1957)
- Canterbury v. Spence, 464 F. 2d 772 (D.C. Cir. 1972)
- Miller-McGee v Washington Hospital Center (2007)

Has the patient been informed of the R/B/A, understood this information and given consent?

- Diagnosis and Treatment
- Risks
- Benefits (Likely Success)
- Alternatives

- Understood
- Given Consent (Voluntary)

R/B/A – Risks, benefits, alternatives

Disclosure

- Definitions
  - Prudent Physician
  - Reasonable Patient
  - Subjective Standard
- Scope
  - (1) patient's current medical status, including if no treatment is provided
  - (2) interventions that might improve prognosis, including a description of the risks and benefits of those procedures, and some estimation of probabilities and uncertainties associated with the interventions
  - (3) professional opinion about alternatives open to the patient; and
  - (4) a recommendation based on best clinical judgment.

Comprehension

- Many studies show comprehension is limited or inadequate
- Patient may be distracted or distressed

- Clear and simple explanations
- Questions to assess understanding
- Decision aids
- Educational programs
- Team approach

Documentation- written consent

- Form
- Note
- Food and Drug Administration (FDA) required patient decision checklists
- State required written consent items (Texas)

- Informed consent is a PROCESS not a form. The process is documented in a variety of ways based on the nature of the treatment, organizational requirements and law.

Oral and implied consent

- Emergency Implied Consent
- In life-threatening emergencies, patients may be unable to express their preferences or give their consent because they are unconscious or in shock. No surrogate may be available. In such situations, it has become customary for physicians to presume that the patient would give consent if able to do so, because the alternative would be death or severe disability.

- Minimal Risk
  - Organization determines what requires oral v written consent
  - Oral consent generally satisfactory for minimal risk and written for other than minimal risk (The Joint Commission) organization further clarifies
  - Generally - labs, many routine immunizations, X-ray, minor diagnostics like joint aspiration, routine medications
  - Oral consent is generally still documented in the notes

Challenges of Informed Consent

- **Patient**
- Limited understanding
- Misinformation (internet; social media)
- Inattentive; selective listening, distracted
- Cultural and language barriers
- When the patient does not agree with the recommendation
- Disruptive patient: Failure to comply with therapeutic treatment plan

- **Provider**
- Overly technical
- Busy/ pressed by multiple duties: one-sided; bureaucracy
- Delegation
- Worried about scaring patient
- May not know what needs to be included by org/ state law

Special Topics in Informed Consent

- Industry Influence – speaker for a vendor - Conflict of Interest (COI)
- Use of Non- FDA approved or off-label treatments, products, implants or medication
- Tricare covered benefits/ Services available to patient but not available at Military Treatment Facilities (MTF) (e.g. tissue)
- Be Truthful – patient questions
  - Residents/ medical students
  - # of cases performed / experience
  - Military career impact

Decision Making Capacity

- the law, the terms *competence* and *incompetence* indicate whether persons have the legal authority to effect certain personal choices, such as managing their finances or making health care decision
- medical care, however, persons who are legally competent may have their mental capacities compromised by illness, anxiety, and/or pain: *decisional capacity* or *incapacity:* It is necessary to assess decisional capacity as an essential part of the informed consent process.

LAR and Surrogate Decision Makers

- State Law – review organization and state law

- LAR – Legally Authorized Representative
- Surrogate - Crucial clinical decisions must often be made when a patient is very sick and unable to communicate his or her desires about care. Other persons speak on behalf of these patients. Such persons are called *surrogates*. (substituted judgement and best interest)

Advanced Care Planning

- Living Wills
- Physician Orders for Life Sustaining Treatment (POLST) – portable medical orders
- Medical Power of Attorney
- Uniform Health-Care Decisions Act in 1993
- 10 U.S. Code § 1044c. (1996)

Resources

- MTF Policy
- Market Policy
- DHA procedural instruction in development but not published
- Ethics Committee for concerns about capacity; or ethical concerns with informed consent
- DoD Medical Ethics Center (DMEC) – defense medical ethics center
- Publications on Clinical Medical Ethics

Key Takeaways

- Informed Consent is a process not just a form
- Documentation is critical
- Follow local policy on informed consent and documentation.
- State Law guides local policy (MTF and Market policy reflects State Law)

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