

Anderson TN, Kaba A, Gros E, et al. A novel blended curriculum for communication of informed consent with surgical interns. *J Grad Med Educ.* 2021;13(3):411–416. <http://dx.doi.org/10.4300/JGME-D-20-01057.1>

Informed Consent

The Discussion

Objectives

Review

Review of landmark historical events that shaped the current environment.

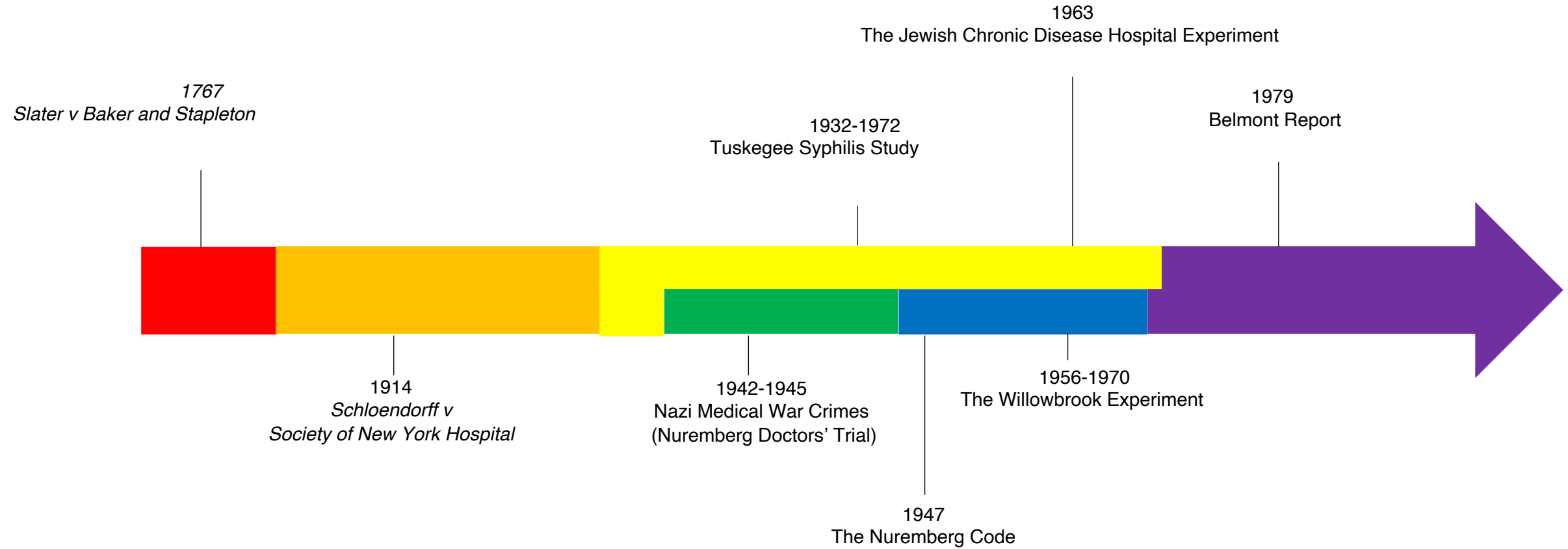
Discuss

Discuss ethical concepts related to: autonomy, beneficence, justice and capacity

Examine

Examine the components that help to create an effective informed consent discussion using the PICR system

Historical development



Slater v Baker and Stapleton

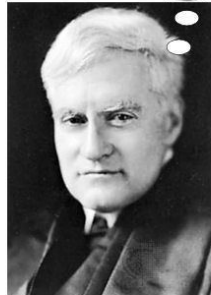
- 1767 - The physician refractured the patient's healing leg as part of an experimental external fixation method, patient claimed that he was not informed. Court ruled in favor of the patient, reasoning that a radical experiment could itself be considered malpractice, at least in the absence of the patient's consent. *Slater v Baker* 95 Eng. 860, 2Wils. KB 359 (1767).
- Established that a **patient is a person who has a right of self-determination**. ... The third cornerstone is consent: registration of the patient's decision and (written) consent [11, 24, 25].





Mary Schloendorff

Every human being of adult years
and sound mind has the right to
determine what shall be done with
his own body.....

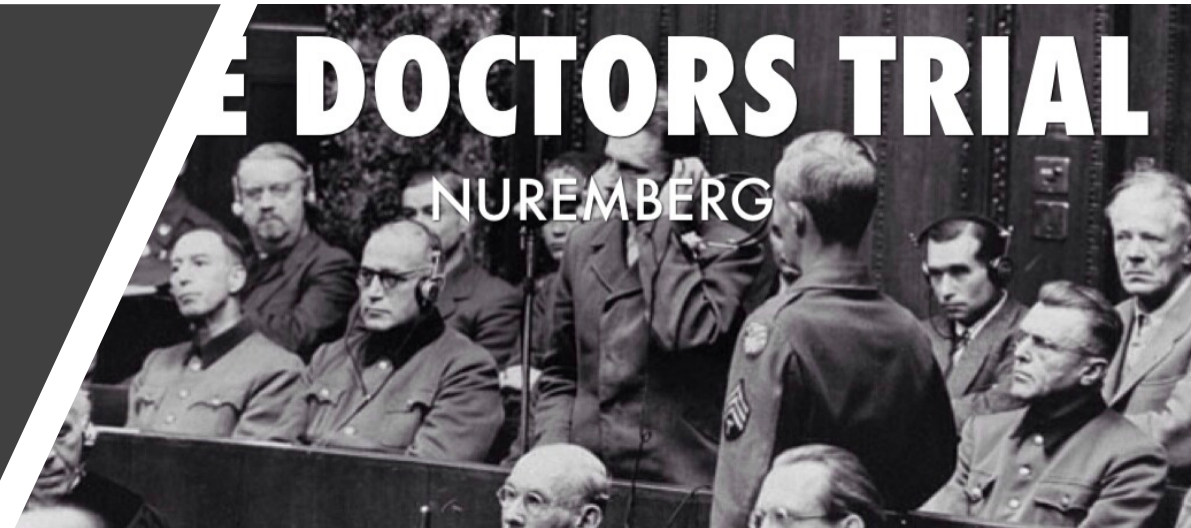


Schloendorff v Society of New York Hospital

- 1914 – *Mary Schloendorff*, the patient, was admitted to the hospital and diagnosed with a fibroid tumor. The physician recommended surgery, but the patient ***adamantly declined***.
- However, she *DID* consent to an examination under anesthesia (EUA).
- During the EUA, the physician elected to convert to open surgery to remove the tumor.
- Due to the anesthesia and time required for the the surgery it was thought that the patient developed gangrene leading to the amputation of several fingers
- *Schloendorff v Society of New York Hospital* was filed by the patient and the Court concluded that the operation to which plaintiff did not consent ***constituted medical battery*** ruling in favor of the patient

Nazi Medical War Crimes (Nuremberg Doctors' Trial)

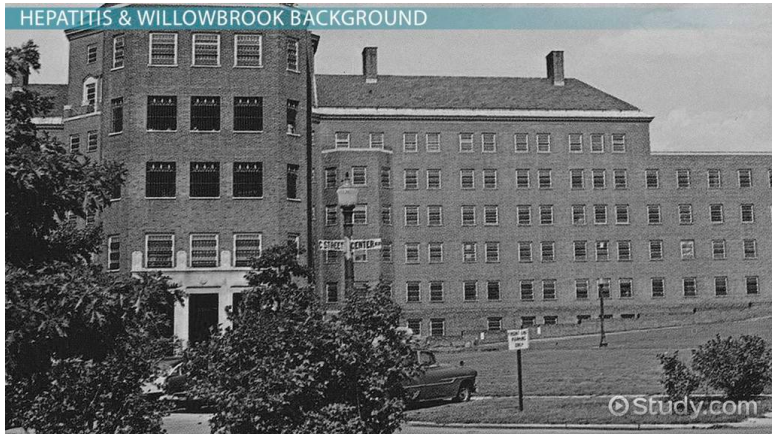
- 1942-1945 – “Medical experiments” were performed on thousands of concentration camp prisoners and included deadly studies and tortures such as injecting people with gasoline and live viruses, immersing people in ice water, and forcing people to ingest poisons.
- The accused faced four charges, including:
 - 1. Conspiracy to commit **war crimes and crimes against humanities**. Specified in counts 2 and 3.
 - 2. War crimes: performing medical experiments, without the subjects' consent, on prisoners of war and civilians of occupied countries, in the course of which experiments the defendants committed murders, brutalities, cruelties, tortures, atrocities, and other **inhuman acts**. Also planning and performing the mass murder of prisoners of war and civilians of occupied countries, stigmatized as aged, insane, incurably ill, deformed, and so on in nursing homes, hospitals, and asylums during the Euthanasia Program and participating in the mass murder of concentration camp inmates.
 - 3. Crimes against humanity: committing crimes described under count 2 also on German nationals.
 - 4. Membership in a criminal organization
- All of the criminals sentenced to death were hanged on June 2, 1948 in Landsberg prison, Bavaria.



Tuskegee Syphilis Study

- 1932-1972 – This study was initiated in the 1930s as an examination of the natural history of untreated syphilis.
- More than 400 black men with syphilis participated, and about 200 men without syphilis served as controls.
- The men were recruited *without informed consent*
- *And misinformed* that some of the procedures done in the interest of research (e.g., spinal taps) were actually “special free treatment.”
- The victims of the study, all African American, included numerous men who died of syphilis, 40 wives who contracted the disease, and 19 children born with congenital syphilis.
- Led to the 1979 Belmont Report and to the establishment of the Office for Human Research Protection (OHRP).





The Willowbrook Experiment

- 1956-1970 –mentally delayed **children** housed at the Willowbrook State School in Staten Island, New York, were **intentionally** given hepatitis in an attempt to track the development of the viral infection.
- The study began in 1956 and lasted for 14 years.
- Although parents were asked to give consent for experimentation, this was deemed a serious violation of **beneficence**.

Jewish Chronic Disease Hospital Experiment

- 1963 – These studies involved the injection of foreign, live cancer cells into patients who were hospitalized with various chronic debilitating diseases.
- **Consent** had been **given orally**, but **did not include a discussion** on the injection of cancer cells, and consent was **not documented**.
- The researchers felt that documentation was unnecessary because it was customary to undertake much more dangerous medical procedures without the use of consent forms.
- Further, patients **were not told that they would receive cancer cells**, because the researchers felt it would unnecessarily frighten them.



Guiding Principles...

In 1979 the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote the report entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research, commonly called the “**Belmont Report.**”

1. Autonomy

- Respect for persons demands that participants enter into the research voluntarily and with adequate information.
- For those in which In some cases, respect for persons may require seeking the permission of other parties, such as a parent or legal guardian when at all possible assent should be obtained.

2. Beneficence - The principle of beneficence obligates the provider to maximize possible benefits and minimize possible harm. The goal of much research is societal benefit; however, in the interest of securing societal benefits; no individual shall be intentionally injured.

3. Justice – This principle requires that participants be treated fairly and involves questions such as: Who should bear the risks, and who should receive its benefits?

Capacity to Consent



Often called “decision-making capacity”



“capacity” as the medical terminology



“competence” as the legal terminology




Patient must have the ability to understand the problem, options of treatment, and risks/benefits of each approach



Patient must understand and select the appropriate approach for him/her



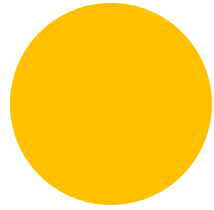
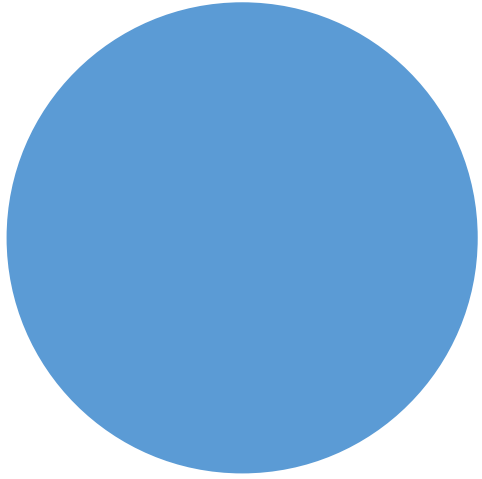
Cannot be under duress or feel coerced



How Much to Inform?

Four standards

1. Professional practice standard
 - Communities accepted practice
2. Reasonable person standard
 - “Material information” for “reasonable person”
3. Subjective standard
 - Different individuals want/need different amounts of information
4. State legal standards
 - Standards vary from state to state



The Discussion





Preparation

- Look at the chart:
- Why are they in the hospital?
- What are the relevant images/labs/data?
- Who are they as a person? Family? Social Situation? Religious considerations? Capacity?
- Will you need an interpreter? A family member or friend does NOT count



Setting the Stage - Environment

- Quiet area and away from others
 - Patient's support should be present (if available)
- Face the patient (and his/her support)
- If using interpreter;
 - Interpreter should be facing the patient and the physician obtaining consent
 - If video interpreter;
 - Camera facing patient, support, and physician
 - Audio up
 - Frame the discussion with the interpreter first
- Talk to the patient directly (regardless of support or interpreter)
- Speak slowly and in small chunks
- Leave time in between statements for questions or clarifications
- OK to come back after the discussion to obtain signature



Introduction

- Identify yourself, what role you play in their overall health care.
- Who will be present for the discussion?
- Ask about current understanding of their situation
- Ask about values, goals, expectations
- Encourage the patient to ask questions throughout and clearly explain that this is a conversation/discussion

Core



Discuss the patient's current health problem as it relates to the proposed procedure.



Explain the procedure, how it will be performed, by whom, and how long.



Describe the benefits as relates to the patient's condition.



Describe the risks, including that the results are not guaranteed.



Alternatives, including the option to refuse surgery.



Describe the postop course (e.g amount and duration of pain, length of recuperation, limitations on activities of daily living, quality of life).

Review

Elicit questions and concerns

Teach back

If there is a written form go through it with them

Allow time for discussion with family

Emphasize that it is a choice

1) Preparation:

- Review the patient's medical record including pertinent laboratory tests, imaging, and other data. Learn cultural background, personal and social history.
- Determine if the patient needs an interpreter or other communication aid.

2) Introduction:

- Introduce yourself and state your role in the patient's care including the proposed procedure.
- Encourage **active patient participation** and **shared communication** with open-ended questions.
- Ask about values, goals and expectations.

3) Core:

- Discuss the patient's current health problem as it relates to the proposed procedure.
- Explain the procedure, including how it will be performed, by whom, and how long it might take.
- Describe the **benefits** of the procedure as they relate to the patient's condition and the risk of not having the procedure.
- Describe the **risks** of the procedure; include the risk that the procedure may not achieve the desired goal.
- Describe the **alternatives** to the proposed procedure.
- Describe what to expect following the procedure (e.g., amount and duration of pain, length of recuperation, limitations on activities of daily living, quality of life).

4) Review:

- Elicit **questions and concerns**.
- Check for patient **understanding** through "teach back".
- Review the written consent form with the patient; consider reading the form out loud or giving the patient the opportunity to read the form alone.
- Allow time for additional discussion with family members.
- Emphasize that it is the patient's **choice** whether or not to consent to the procedure; make sure the patient understands that the procedure cannot occur without their consent.

Consider inviting the patient to follow along with a copy of this checklist.

Parting Thoughts..

- Fundamentals of an appropriate discussion
 - Capacity
 - Understanding
 - Authorization
- Setting the stage
 - Not rushed
 - No pressure
 - Support system present (if possible)
 - Digestible chunks
 - Make the patient feel part of the process
- Remember to consider Interpreter Services

Objectives

Review

- Review of landmark historical events that shaped the current environment.

Discuss

- Discuss ethical concepts related to: autonomy, beneficence, justice and capacity

Examine

- Examine the components that help to create an effective informed consent discussion using the PICR system

References

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Informed Consent Evaluation

Ethically valid consent is a process of shared decision making based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of a particular treatment (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982)

Effective and informed decision-making acknowledges patients' central role in making decisions about their own health care. The clinician's primary role is to make recommendations based on evidence as an adjunct to patients' well-being. The clinician's second obligation is to help patients obtain and understand the information relevant to a particular health decision and to facilitate their active participation in making the most informed decision possible before consenting to interventions and procedures. The most relevant, and perhaps complex, example is a surgical procedure, in which there is substantial risk and clear alternatives. Here, the need for exploration and explanation is greater. For these surgical procedures, explicit discussion of alternatives, risks and benefits, and a full exploration of the patient's level of understanding is essential.

In demonstrating proficiency for obtaining informed consent, residents should be able to:

1. Demonstrate confidence and effective communication skills when communicating with patient and family.
 1. Introduces themselves and explains resident involvement in patient care, as well as attending surgeon who will be performing procedure.
 2. Practices shared decision making, eliciting patient and family preferences
 3. Responds to emotional cues in real time
 4. Enlists interpreters collaboratively (when appropriate)
2. Check patient's perspective and understanding of the procedure and its indication.
 1. Confirms correct procedure, indication and key elements of the procedure using provided patient information as guide and preparation.
 2. Clearly asks for patient's perspective by eliciting questions
3. Discusses basic steps of the procedure, risks and benefits of the given procedure, as well as peri-operative care and potential complications
 1. Clearly describes the benefits of the proposed procedure.
 2. Clearly describes the risks of the proposed procedure.
 3. Describes what to expect following the procedure (e.g., amount and duration of pain, length of recuperation, limitations on activities of daily living, quality of life).
 4. Clearly describes alternatives to the proposed procedure. Also, explaining that there is the option to not undergo procedure.
4. Fill out informed consent document correctly.
 1. Review the written consent form with the patient
5. Allow patient to ask clarifying questions and demonstrate further understanding before willingly signing informed consent.
 1. Check for patient understanding through "teach back".

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2. Seeks timely and appropriate help in answering patient questions as needed

Evaluation Scenarios:

1. Proposed verification of proficiency (VOP) scenarios for assessment: laparoscopic appendectomy and central venous line placement
2. Residents are provided with patient H&P, cognitive aid specific for the procedure, and consent form
INSTRUCTIONS FOR LAPAROSCOPIC APPENDECTOMY INFORMED CONSENT

RESIDENT INSTRUCTIONS (Outside the Door)

Ms Gonzalez is an English speaking 32-year old female with no reported PMH that presents to the ED with worsening abdominal pain. She indicates pain started vaguely around her bellybutton yesterday and migrated to her right lower quadrant and became sharper in character. Pain is currently constant 8/10 and localized to her right lower abdomen. She denies fevers or chills, but endorses nausea and multiple episodes of non-bloody, non-bilious emesis. She cannot recall her last bowel movement or her last menstrual period. She denies any previous similar pain.

The patient's chart is available for review outside of the door.

1. **Discuss** the diagnosis, surgery and obtain informed consent for the planned procedure. This should be conducted at the “reasonable patient level.”
2. Consent for blood transfusion has already been obtained.
3. You do **not** need to confirm the history or do a physical exam on the patient (see H&P attached).
4. After you have completed the station, leave the completed informed consent form in the envelope.
5. You will have a total of **15 minutes** to perform the station. A maximum of 5 minutes may be used to review the information outside of the door prior to the patient encounter.
6. The remaining **10 minutes** are allotted for the consent discussion.
7. You will hear a **2 min** warning knock on the door and an announcement when the scenario is over.

APPENDICITIS INFORMATION SHEET

BACKGROUND:

Overall US incidence is approximately 7%, with a mortality of 0.2-0.8%. The morbidity and mortality are related to the presenting stage of disease and are higher in cases of perforation.

Presentation: anorexia and periumbilical pain, followed by nausea, right-lower-quadrant (RLQ) pain, and vomiting, as well as leukocytosis.

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Diagnosis: clinical diagnosis, the accuracy of which has improved with CT scan, which has an accuracy of 90%. The diagnosis is made using a combination of history, physical examination, and laboratory tests plus an elevated temperature and white blood cell count.

Pathophysiology: Attributed to luminal obstruction, causing distention, ineffective venous and lymphatic drainage, bacterial invasion, and, finally, perforation with associated leakage of contents into the peritoneal cavity.

Indications:

- Laparoscopic appendectomy is appropriate for virtually all patients
- Preferred in obese patients, who require longer open incisions with increased manipulation and the resultant increase in surgical-site infections.
- Indicated in females, especially during the reproductive years, when adnexal pathology may mimic appendicitis.
- Pregnancy: Laparoscopic appendectomy has been shown to be as safe as open appendectomy in the first trimester of pregnancy; however, there is always risk to the fetus with any anesthesia or operation. Later or third-trimester pregnancies as well as any process that creates intestinal distention will make entering the intraperitoneal space more difficult and leave no room for maneuvering the instruments for a safe operation.

Contraindications:

Absolute contraindications for laparoscopic appendectomy are as follows:

Hemodynamic instability

Lack of surgical expertise

Relative contraindications include the following:

Severe abdominal distention that causes operative view obstruction or complicates abdominal entry and bowel manipulation

Generalized peritonitis

Multiple previous surgical procedures

Severe pulmonary disease

Pregnancy (depending on trimester)

Operative vs Non-operative management

- Approximately 70 percent of those successfully treated with antibiotics during the initial admission are able to avoid surgery during the first year. The other 30 percent eventually require appendectomy for recurrent appendicitis or symptoms of abdominal pain (mean time to appendectomy 4.2 to 7 months)

Antibiotic/Nonoperative treatment data:

- Patients respond clinically with a reduction in white blood cell count, avoidance of peritonitis, and general symptom reduction. Have lower or similar pain scores, require fewer doses of narcotics.

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- Quicker return to work and do **NOT** have a higher perforation rate.
- 90 percent of patients treated with antibiotics are able to avoid surgery during the initial admission.
- 10 percent that fail to respond to antibiotics require a rescue appendectomy. *However, there is no reliable way of predicting who will or will not respond to antibiotics.*
- Follow-up data beyond the first year are not available for any but one of the six trials. In the only five-year observational follow-up of 257 patients initially treated with antibiotics for uncomplicated acute appendicitis, the cumulative incidence of recurrent appendicitis was 27.3 percent at 1, 34.0 percent at 2, 35.2 percent at 3, 37.1 percent at 4, and 39.1 percent at 5 years. No patients suffered a major complication.

Open vs Laparoscopic

The laparoscopic approach was superior for:

- A lower rate of wound infections
- Less pain on postoperative day 1
- Shorter duration of hospital stay
- A lower rate of intra-abdominal abscesses
- A shorter operative time

If intraoperative complications that cannot be handled with laparoscopy arise during laparoscopic appendectomy, conversion to an open appendectomy is indicated. It is crucial to understand the circumstances in which such conversion is warranted.

Relative indications to convert from laparoscopic to open include the following:

Dense adhesions due to inflammation or prior surgical procedures

Perforated or gangrenous appendicitis

Gangrenous or necrotic base

Generalized peritonitis

Retrocecal appendix

Inability to visualize the appendix

Uncontrolled bleeding

Tumor of the appendix extending into base

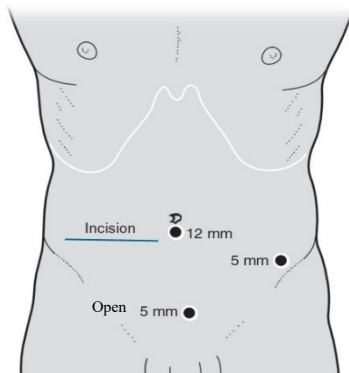
Other pathology, including malrotation, carcinoma, diverticula of cecum, endometriosis, pelvic inflammatory diseases, torsion of tubo-ovarian cyst Unexpected diagnosis

INTRAOPERATIVE STEPS:

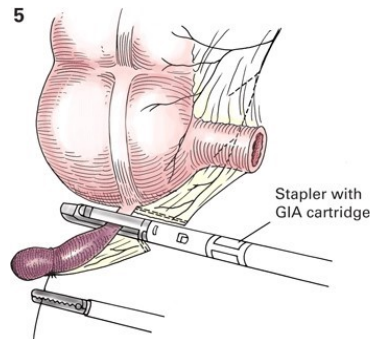
- The patient is placed in a supine position with arms out.
- Typical placement for access ports is shown at the umbilicus, left lower quadrant, and lower midline
- A hole is made in the mesoappendix and a stapling device ligates the vessel and then the appendix at the base near the cecum.

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- The appendix is usually placed into a plastic bag for removal through the abdominal wall. This lessens the chances of infection at the surgical site.
- Each of the 5-mm ports is removed under direct vision with the videoscope to make sure that there are no bleeding abdominal wall vessels.



Source: Wintter RM, Doherty GM: *Current Procedures: Surgery*; <http://www.accesssurgery.com>
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Source: Zollinger RM, Ellison EC: *Zollinger's Atlas of Surgical Operations, 9th Edition*; <http://www.accesssurgery.com>
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Complications:

Early Complications:

Normal appendix

Bleeding

Surgical-site infection (<2-5% if simple, 20% in perforated)

Intra-abdominal abscess (fevers, diarrhea may be a sign, higher risk in lap and perf)

Unrecognized enteric injury

Fistula formation (rare)

Late Complications:

Incisional hernia

Stump appendicitis

Recurrent infections from a retained appendiceal stump

Small-bowel obstruction (<1% in simple and <3% with perforated)

Post-operative care:

The patient is awakened from anesthesia. Postoperative pain can be controlled with oral medications. There may be some transient nausea, but most patients can be weaned from intravenous fluid to simple oral intake within a day. Antibiotic therapy is often perioperative but may continue for a few days, depending on the operative findings. Most patients are discharged home within a day or two.

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SCENARIO: LAPAROSCOPIC APPENDECTOMY

GONZALEZ, Elia
MRN 1127826
DOB 2/17/1987

HISTORY AND PHYSICAL

Admitting Service: Acute Care Surgery
Date of Admission: 07/01/2016

HPI: Ms Gonzalez is an English speaking 32 year-old female with no reported PMH who presents to the ED with worsening abdominal pain. She indicates pain started vaguely around her umbilical area yesterday and migrated to her right lower quadrant and became sharper in character. Pain is currently a constant 8/10 and localized to her right lower abdomen. She denies fevers or chills, but endorses nausea and multiple episodes of non-bloody, non-bilious emesis. She cannot recall her last bowel movement or her last menstrual period. She denies any previous similar pain.

PMH: denies
PSH: denies
Meds: denies
Allergies: penicillin
Social: social ETOH, denies smoking or illicit drugs
ROS: negative unless otherwise specified in HPI

Physical Exam:

T 38.3 HR 101 BP 117/88 RR 16 SpO2 99%
BMI 27
Gen: No acute distress, awake and alert
RV: RRR
Pulm: clear to auscultation bilaterally
Abd: soft, tender to palpation in RLQ and suprapubis with rebound and voluntary guarding
Ext: WWP, nontender, no edema

Labs:

140 104 20	11
_____ < 188	17 > — < 255
4.4 23 0.8	36
INR 1.0, PT 12, PTT 32	

UA: negative for leukocyte esterase, negative for beta hCG

Imaging:

CT abdomen/pelvis: Moderately inflamed appendix, thickened to 1.1 cm with surrounding fat stranding. No discrete fluid collection or abscess

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Assessment:

Ms. Gonzalez is a 32 y.o. healthy woman with acute appendicitis

Plan:

NPO/IVF

Abx

To OR for laparoscopic appendectomy

INSTRUCTIONS FOR CENTRAL VENOUS CATHETER INSERTION INFORMED CONSENT

RESIDENT INSTRUCTIONS (Outside the Door)

Mr. Beale is a 74 yo man with PMH significant for CHF, COPD, and CAD s/p MI 15 years ago. He is brought into the ED from a nursing home with worsening SOB consistent with a COPD exacerbation. He has required hospitalization for COPD exacerbation 3 times in the past year, and on one occasion required intubation. Shortly after presenting to the ED, his breathing deteriorated and he was intubated for pending respiratory failure. Chest Xray in the ICU indicated that the patient likely had respiratory failure secondary to severe pneumonia. His cultures are growing resistant organisms and will require viscous IV antibiotics.

The patient's chart is available for review outside of the door.

1. You will need to conduct a **Phone** consent with the patient's healthcare proxy.
2. **Discuss** the diagnosis, treatment plan, and procedure. Obtain informed consent for the planned procedure. This should be conducted at the "reasonable patient level."
3. Consent for blood transfusion has already been obtained and not specifically needed for this procedure.
4. You do **not** need to confirm the history or do a physical exam on the patient (see H&P attached).
5. In this testing environment, you do not need a witness signature, although in actual (not simulated) circumstances, you will always need a witness for phone consents.
6. After you have completed the station, leave the completed informed consent form in the envelope.
7. You will have a total of **15 minutes** to perform the station. A maximum of 5 minutes may be used to review the information outside of the door prior to the patient encounter.
8. The remaining **10 minutes** are allotted for the consent discussion.
9. You will hear a **2 min** warning knock on the door and an announcement when the scenario is over.

CENTRAL VENOUS CATHETER INSERTION COGNITIVE AID

Background

Central venous access is a commonly performed procedure with approximately 8 percent of hospitalized patients requiring central venous access during the course of their hospital stay. More than five million central venous catheters are inserted in the United States each year.

A central venous access device is defined as a catheter whose tip is located in the superior vena cava, in the right atrium, or in the inferior vena cava. Access is typically obtained at different anatomic sites by percutaneous puncture to cannulate the vein, ideally with dynamic ultrasound guidance.

Classified based on duration of catheter use (ie, dwell time; short-term, mid-term, long-term), type of insertion (ie, central, peripheral), location of insertion (eg, jugular, subclavian, femoral, brachial), number of lumens (ie, single, double, triple), as well as whether the catheter implanted or not, and to what extent (eg, tunneled, totally implanted [ie, port]). The basic features of the various types of catheters and the manner in which these features influence catheter selection is discussed separately.

Indications

- Inadequate peripheral venous access (unable to obtain, or complex infusion regimen).
- Peripherally incompatible infusions – Long-term intermittent or continuous administration of medications such as vasopressors, chemotherapy, highly viscous antibiotics, and parenteral nutrition are typically administered by central venous catheters because they can cause phlebitis
- Hemodynamic monitoring –permits measurement of central venous pressure, venous oxyhemoglobin saturation (ScvO₂), and cardiac parameters (via pulmonary artery catheter).
- Extracorporeal therapies – Large-bore venous access is required to support high-volume flow required for many extracorporeal therapies, including hemodialysis, continuous renal replacement therapy, and plasmapheresis.
- Transvenous cardiac pacing.
- Inferior vena cava filter placement.
- Venous thrombolytic therapy.
- Venous stenting (eg, iliac vein, vena cava).
- Extracorporeal life support (ECLS) cannulation.

Relative contraindications — Contraindications to central venous catheterization are relative and depend upon the urgency and alternatives for venous access.

- Coagulopathy and/or thrombocytopenia — Moderate-to-severe coagulopathy is a relative contraindication to central venous catheterization, although major bleeding is uncommon
- Cannulation is generally avoided at sites with anatomic distortion or other indwelling intravascular hardware, such as a pacemaker or hemodialysis catheter. Vascular injury proximal to the insertion site represents another relative contraindication
- Access sites with altered local anatomy (eg, prior clavicle fracture), sites with multiple scars from prior access, and the presence of another central venous catheter or device (such as a pacemaker or internal defibrillator) are associated with higher rates of access failure, malposition, dysrhythmia, and other complications and should be avoided if alternative sites are available. If a patient has significant unilateral lung disease, the hemithorax ipsilateral should be cannulated, for internal jugular and subclavian access, to minimize respiratory decompensation in the event of a procedure-related pneumothorax.

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Benefits/risk for specific sites:

Jugular — The jugular veins (external, internal) are reliable access sites for temporary and permanent (eg, tunneled central catheters and subcutaneous ports) venous cannulation to support hemodynamic monitoring, fluid and medication administration, and parenteral nutrition.

Internal jugular venous access (especially right-sided) is associated with a low rate of catheter malposition and is commonly used in situations that require reliable tip positioning for immediate use, such as drug administration or transvenous pacing. Similarly, the direct route from the right internal jugular vein to the superior vena cava facilitates hemodialysis access and pulmonary artery catheter placement.

Specific relative contraindications to jugular venous catheterization: neck surgery, or neck irradiation.

Subclavian — The subclavian veins are reliable access points for temporary and permanent (eg, tunneled central catheters and subcutaneous ports) venous cannulation to support hemodynamic monitoring, fluid and medication administration, and parenteral nutrition. The left subclavian access site is particularly well suited for cardiac access, including placement of pulmonary artery catheters, temporary transvenous pacer leads, and implantable pacers and defibrillators. Subclavian venous access may be preferred for subcutaneous port placement due to the short distance between the subclavian vein and chest wall, making the catheter less prone to kinking.

Specific relative contraindications to subclavian venous catheterization: Subclavian access should be avoided, if possible, at sites with altered local anatomy (eg, previous clavicle fracture), prior access, or the presence of an indwelling pacemaker or internal defibrillator because these are associated with a higher risk of failure, complication, and malposition. In patients with significant unilateral lung disease, cannulation of the vessel ipsilateral to the compromised lung is preferred to avoid decompensation in the event of a procedure-related pneumothorax.

Femoral — The femoral veins are commonly viewed as an alternative access site for central venous access due to a higher incidence of catheter-related deep vein thrombosis compared with jugular or subclavian access, and a perceived higher risk for infection. With contemporary skin preparation and proper routine catheter maintenance, infection rates appear to be comparable to other sites.

Compared with subclavian and jugular access sites, the femoral veins may be preferred in the face of coagulopathy due to the ability to provide direct pressure at this access site. The femoral veins are also frequently preferred when other access sites are exhausted or there is increased risk for complications such as with emergency access, or in the uncooperative patient. The femoral veins are generally easier to cannulate and provide dependable access for less experienced operators or when there is concern for arterial injury at upper extremity sites because of altered local anatomy.

General Technique

- Obtain the equipment and devices needed for catheter placement
- Prepare (consent, sedation, antibiotics) and position the patient. Prepare the ultrasound machine and probe.
- Using sterile technique, prepare the skin and drape the patient.
- Identify the vein with ultrasound (preferred). Otherwise, identify pertinent anatomic landmarks.
- Infiltrate the skin with local anesthetic.
- Cannulate the vein using dynamic ultrasound imaging (preferred) via standard introducer needle and confirm the intravenous location of the needle.
- Insert the guidewire into the vein through the access needle.

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- Remove the needle while controlling the guidewire.
- Make a small stab incision in the skin at the puncture site adjacent to the guidewire.
- Advance the dilator over the guidewire into the vein, taking care to control the guidewire, then remove the dilator.
- Thread the catheter over the guidewire, taking care to control the guidewire.
- Remove the guidewire, taking care to control the catheter.
- Sequentially aspirate blood from each access hub and flush with saline to ensure functioning of the catheter.
- Suture the catheter into place and dress the site using sterile technique.
- Confirm the position of the tip of the catheter with chest radiography (jugular, subclavian approaches).

SCENARIO: CENTRAL VENOUS CATHETER INSERTION

BEALE, William
MRN 1625437
DOB 7/26/41

HISTORY AND PHYSICAL

Admitting service: MICU
Date of Admission: 7/26/19

HPI:

Mr. Beale is a 74 yo English speaking man with PMH significant for CHF, COPD, and CAD s/p MI 15 years ago. He presented to the ED with worsening SOB consistent with a COPD exacerbation. He has required hospitalization for COPD exacerbation 3 times in the past year, and on one occasion required intubation. Shortly after presenting to the ED, his breathing deteriorated and he was intubated for pending respiratory failure. Chest X-ray indicates respiratory failure secondary to severe pneumonia. His cultures are growing *Klebsiella pneumoniae* and an un-specified gram positive organism.

PMH:

CHF, COPD, CAD s/p MI 15 years ago with stent placement, HTN, PVD, GERD, BPH, gout

PSH:

Laparoscopic appendectomy (2007), Left Heart Cardiac Catheterization (15 years ago)

MAH:

Atrovent, Spiriva, Metoprolol 25'', Allopurinol, Nexium, multivitamin

ALL:

None

ROS:

Unable to obtain, patient intubated

Physical Exam:

T 37.0 HR 84 BP 110/60 RR 15 SpO2 98%

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Gen: intubated, sedated; responds to pain

CV: RRR

Pulm: Diffuse wheezes throughout, prolonged expiration

Abd: soft, NT ND, no palpable masses

Ext: WWP, brisk capillary refill, trace pedal edema

Labs:

137|100|22

12.2

-----< 167

11.2 >----< 345 INR 1.1 PT 12 PTT 27

4.9 | 20 | 1.4

37

Micro:

ESBL positive *Klebsiella pneumoniae* sensitivities pending

Gram positive organism culture speciation pending

Assessment / Plan:

-

Meropene

m

- F/u culture speciation
- Central line placement for IV antibiotic administration
- ID consult

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Informed Consent Verification of Proficiency Assessment Tool

Expectation	Poor	Fair	Good	Very Good	Excellent
1. Prepared in advance about the patient's medical record including pertinent labs, imaging, cultural background, personal and social history.	1 Resident did not review patient chart prior to entering room	2	3 Reviewed the patient's chart, but could not accurately answer family specific question, but did not make up information	4	5 Resident Reviewed Chart and was able to accurately answer specific questions posed by Patient/surrogate
2. Introduces themselves and their role in the patient's care.	1 Did not say their name and/or role in patient care	2	3 Stated their name and who will be performing procedure	4	5 Stated their name, who will be performing procedure and name their supervisor (attending)
3. Clearly explains patient's current health problem as it relates to the proposed procedure.	1 Does not ask/explain/indications conditional status	2	3 Explains the indication/diagnosis without preamble	4	5 Asks the patient/surrogate their understanding of the patient's condition, and feels in gaps in knowledge
4. Clearly describes the benefits of the proposed procedure.	1 Does not describe benefits	2	3 Explains "superficial" benefits (see attached specific to procedure)	4	5 Explains more advanced benefits and scenarios
5. Clearly describes the risks of the proposed procedure.	1 Does not describe risks	2	3 Explains superficial risks of infection, bleeding, hematoma, death	4	5 Explains that the procedure/treatment may not be successful in specific ways
6. Clearly describes alternatives to the proposed procedure. Also, explaining that there is the option to not undergo procedure.	1 Does not Explain Alternatives	2	3 Explains that there are alternatives, gives superficial options	4	5 Explains that they have the right to refuse or change their mind at anytime

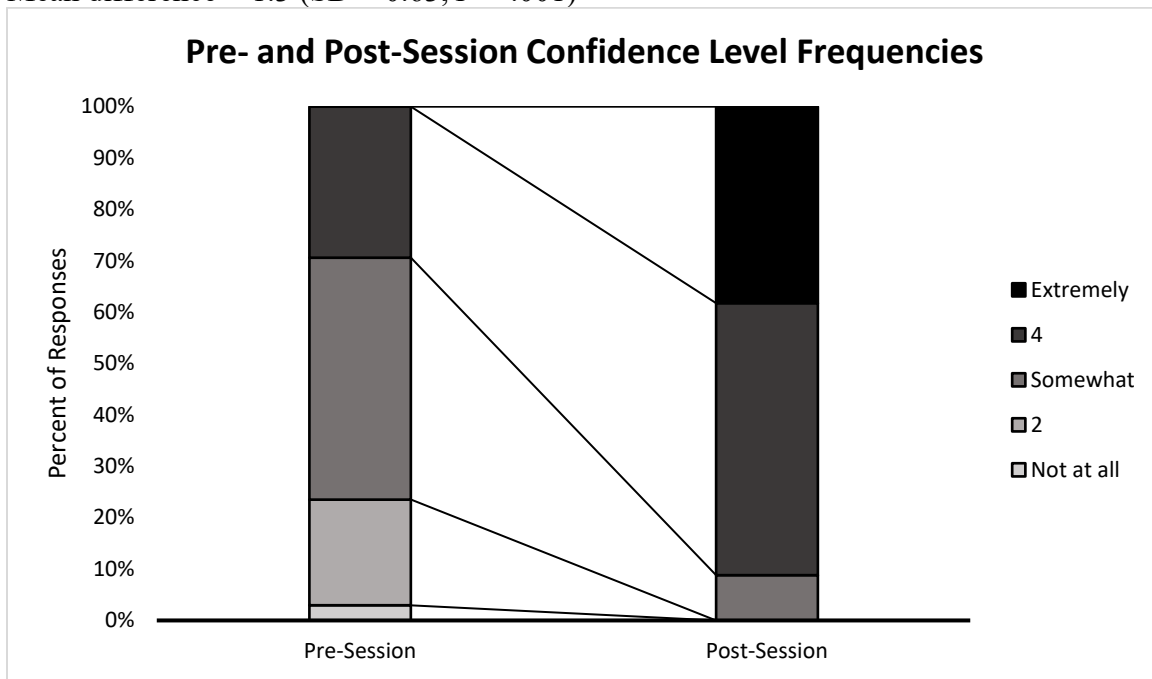
7. Describes what to expect following the procedure (e.g., amount and duration of pain, length of recuperation, limitations on activities of daily living, quality of life).	1 Does not explain postprocedure plans	2	3 Explains superficial immediate post-procedure care	4	5 Explains long term outcomes and care
8. Elicits questions and concerns.	1 Does not ask about questions or concerns	2	3 Asks about questions and concerns, but does not exhaust patient's questions	4	5 Exhausts patient's line of questioning
9. Check for patient understanding through "teach back".	1 Does not ask the patient to explain their understanding	2	3 Asks patient to explain their understanding, does not correct misinformation	4	5 Asks patient to explain their understanding and corrects misinformation
10. Review the written consent form with the patient.	1 Does not discuss the consent form	2	3 Presents consent form for signature, does not explain the different parts	4	5 Walks the patient through the consent form

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FIGURE

Frequency Distribution of Reported Confidence Levels

Mean difference = 1.3 (SD = 0.63, $P < .001$)



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Specific Data on Recording

Recording Number	Scenario	Total Time (Minutes:Seconds)	Onsite Rater Score	Remote Rater Score Average (SD, agreement)
1	CVC	9:50	44	34.7 (5.1, 0)
2	CVC	10:16	31	27.7 (4.7, 0)
3	LA	8:33	43	31.7 (7.6, 0)
4	LA	10:57	47	36.3 (7.4, 0)
5	CVC	8:40	30	27.7 (3.8, 0)
6	CVC	16:36	46	43.3 (2.5, 0)
7	CVC	11:05	45	40.7 (4, 0)
8	LA	12:07	46	39.7 (3.2, 0)
9	CVC	9:37	48	36 (2, 0)
10	CVC	7:21	31	25.3 (4.7, 0)
11	CVC	8:14	38	30 (4.6, 0)
12	CVC	13:07	41	31.7 (2.3, 0.33)
13	CVC	10:51	37	35.7 (2.9, 0.33)
14	CVC	16:47	32	32.7 (6.1, 0)
15	CVC	12:21	37	34.3 (4.5, 0)
16	LA	7:30	45	36.7 (1.2, 0.33)
17	CVC	15:03	45	42 (3.5, 0.33)
18	LA	8:59	47	35 (1, 0)
19	LA	11:01	48	40.7 (2.3, 0.33)
20	LA	11:05	44	41.3 (4.2, 0)
21	CVC	13:37	43	39.3 (0.6, 0.33)
22	CVC	11:20	41	35 (4.4, 0)
23	CVC	10:08	43	31.3 (3.5, 0)
24	CVC	9:57	30	25.7 (1.5, 0)