BIOE 301

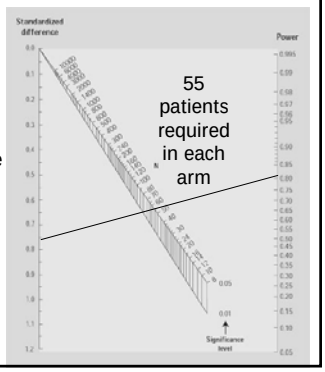
Lecture Eighteen

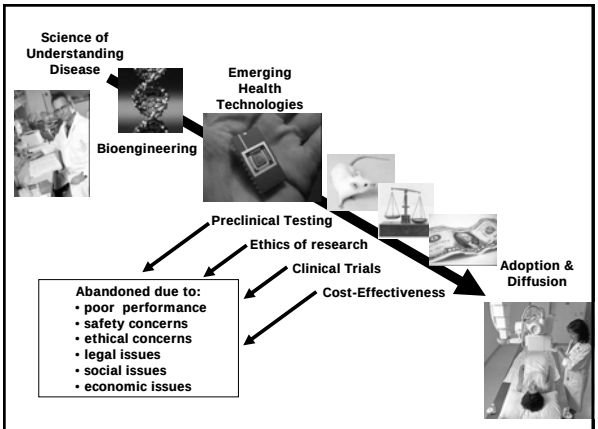
Review of Last Time

- Sample size calculations
  - Ensure differences between treatment & control group are real
- Type I Error: (False Positive)
  - Mistakenly conclude there is a difference between the two groups, when in reality there is no difference
  - p-value = probability of making type I error
- Type II Error: (False Negative)
  - Mistakenly conclude that there is not a difference between the two, when in reality there is a difference
  - Beta = probability of making type II error
- Choose our sample size:
  - Acceptable likelihood of Type I or II error
  - Enough $$ to carry out the trial

Drug Eluting Stent – Sample Size

- Treatment group:
  - Receive stent
- Control group:
  - Get angioplasty
- Primary Outcome:
  - 1 year restenosis rate
- Expected Outcomes:
  - Stent: 10%
  - Angioplasty: 45%
- Error rates:
  - p = .05
  - Beta = 0.2
- SD = 0.78





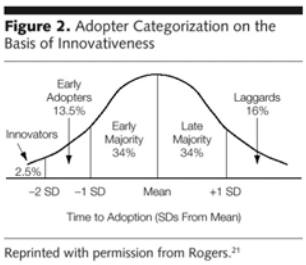
Diffusion is historically slow….

- 1497:
  - Vasco Da Gama lost 100 out of 160 crew members to scurvy sailing around Cape of Good Hope
- 1601:
  - British Navy Captain James Lancaster was in command of 4 ships traveling from England to India
    - Required sailors to take 3 tsp of lemon juice daily on 1 ship
    - The other 3 ships served as the control
  - Results:
    - 110/278 sailors died in control group
    - 0 deaths in the experimental group
- 1747:
  - British Navy Physician James Lind repeated study with similar results
- 1865:
  - British Navy finally adopted innovation, **264 years** after first recorded evidence

Berwick, Donald M., Disseminating Innovations in Health Care. JAMA April 16, 2003 – Vol 289, No. 15

Characteristics of people who adopt change

- Innovators
  - Mavericks, "willing to leave the village", weird, incautious, socially disconnected, risk takers
- Early Adopters
  - Well connected, social opinion leaders, watched by communities
- Early Majority
  - Local in perspective, follow the lead of the early adopters
- Late Majority
  - Watch for local proof
- Laggards
  - Traditional, prefer the "tried and true", archivists



Tipping Point – often between 15% - 20% adoption; spread becomes difficult to stop.

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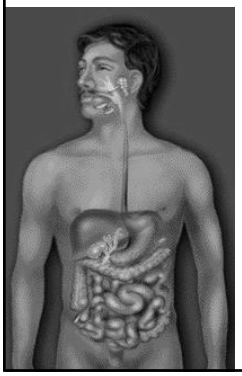
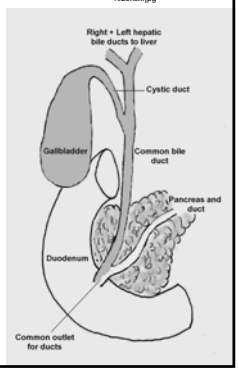
A Case Study

Cholecystectomy: Removal of the Gall Bladder

The Gall Bladder

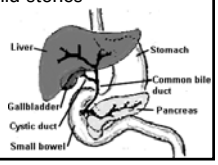
http://gensurg.co.uk/images/Biliary%20anatomy%20-%20hsk.jpg





The Gall Bladder

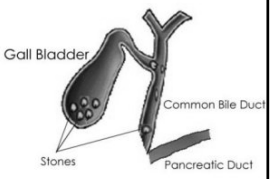
- Function:
  - Stores bile made by liver
  - After eating:
    - Gall bladder contracts
    - Secretes bile into duct which empties into small intestine
    - Aids in digestion
- Gallstones:
  - Liquid bile may precipitate into solid stones
  - Common:
  - 1/5 of North Americans and ¼ Europeans develop gallstones at some point



http://www.thaiclinic.com/images/biliary_anatomy.gif

Gallstones

- Symptoms
  - If gallstones block outflow of bile:
    - Abdominal discomfort
    - Pain
    - Heartburn
    - Indigestion
    - Acute inflammation



http://www.qualitysurgical.com/gblad.jpg

Treatment of Gallstones

- Before 1990:
  - Open surgery to remove the gall bladder
  - Effective
  - Low mortality rate (0.3-1.5%)
  - 7 day hospital stay
  - 30 days lost time from work
  - Most common non-obstetric surgical procedure in many countries

A Case Study: Laparoscopic Cholecystectomy

- Most significant major surgical advance of the 1980s
- Allows shorter hospitalization
- Rapid recovery
- Early return to work
- Significant financial savings
- Forerunner of new era of minimally invasive surgery

Laparoscopic Removal of Gall Bladder

- Patient receives general anesthesia
- Small incision is made at navel and thin tube carrying video camera is inserted
- Surgeon inflates abdomen with carbon dioxide
- Two needle-like instruments inserted; serve as tiny hands. Pick up gallbladder & move intestines around.
- Several instruments inserted to clip gallbladder artery & bile duct, to safely dissect & remove gallbladder & stones
- Gallbladder is teased out of tiny navel incision.
- Entire procedure normally takes 30 to 60 minutes.
- Three puncture wounds require no stitches; may leave very slight blemishes. Navel incision is barely visible

Laparoscopic Cholecystectomy

http://www.lapsurgery.com/gallblad.jpg

- http://www.laparoscopy.com/pictures/lap_chol.html

Advantages/Disadvantages

- Benefits:
  - Ease of recovery
    - No incision pain as occurs with standard abdominal surgery
    - Up to 90% of patients go home the same day
    - Within several days, normal activities can be resumed
    - No scar on the abdomen
- Complications:
  - Complication rate is about the same for this procedure as for standard gallbladder surgery:
    - Nausea and vomiting may occur after the surgery
    - Injury to the bile ducts, blood vessels, or intestine can occur, requiring corrective surgery
  - 5 to 10% of cases, the gallbladder cannot be safely removed by laparoscopy. Standard open abdominal surgery is then immediately performed.

Did this technology diffuse slowly or rapidly?

An Important Innovator

- Kurt Semm (1927-2003)
  - Gynecologist
  - 80 medical device inventions
    - Electronic insufflator
    - Thermocoagulation
    - Loop ligator
    - Laparoscopic suturing
  - Brother and father owned a medical instrument company which rapidly produced instruments for him
  - Allowed more complex procedures to be performed endoscopically
    - Gynecology
    - General surgery

Laparoscopic Appendectomy

- 1985:
  - Semm's techniques used to perform the world's first laparoscopic appendectomy
  - Said to reduce problem of adhesions formed during opens surgeries

Public Response

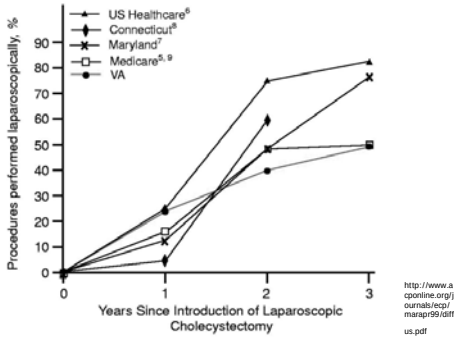
- "He's gone absolutely crazy."
- Was asked to undergo a brain scan by his colleagues
- Lectures were initially greeted with laughter and derision
  - Technique was initially viewed as too expensive and too dangerous
  - Semm exaggerated problems of adhesions
- Surgeons saw no reason to change a well established working method into a complex technical manner

Public Response

- Semm:
  - "Both surgeons and gynecologists were angry with me. All my initial attempts to publish on laparoscopic appendectomy were refused with the comment that such nonsense does not and will never belong to general surgery."
- Gynecologists have "surgeon envy"
- Semm is trying to enter into general surgery to bolster his "operation ego"

Did this technology diffuse slowly or rapidly?

Diffusion of Lap Choly



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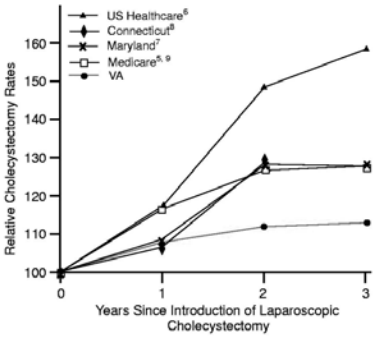
Diffusion of Lap Choly



http://www.acponline.org/journals/ecp/marapr99/diffus.pdf

Diffusion

- No technique in modern times has become so popular as rapidly as laparoscopic cholecystectomy
- Semm
  - Displayed an ability to push his ideas through despite skepticism and suspicion
  - Without Semm, the laparoscopic revolution may have been postponed by many years

Diffusion of Lap Choly

- Diffusion of laparoscopic cholecystectomy in health care is unprecedented
- Since its introduction in 1989:
  - the laparoscopic procedure has rapidly become the most widely used treatment for gallstone disease
- By 1992:
  - laparoscopic cholecystectomy accounted for 50% of all cholecystectomies in Medicare populations
  - 75% to 80% of all cholecystectomies in younger populations
- Increased overall rate of cholecystectomy

Take Home Messages

- In most settings:
  - Rate of cholecystectomy increased dramatically after introduction of the laparoscopic procedure
- Financial incentives for physicians and hospitals to use the procedure influenced the rate of diffusion
- Introduction of laparoscopic cholecystectomy:
  - Associated with a 22% decrease in the operative mortality rate for cholecystectomy