Clinical Problem Selection

Prof. Steven S. Saliterman
Department of Biomedical Engineering, University of Minnesota
http://saliterman.umn.edu/

First Steps

- Have a lab notebook for assignments, readings notes, minutes of meetings, ideas, and drawings.
- Divide into teams of 1 to 3.
- Select a *clinical problem* (we will do this together).
- In your notebook, list your team members and emails, team name, *clinical problem*, and identify your team strengths and weaknesses.

Suggestions

1. Allergy
    a. Early detection and treatment of anaphylactic reactions.

2. Cardiovascular Diseases
    a. Monitoring and recording angina episodes.
    b. Arrhythmia monitoring.
    c. Cardiomyopathy monitoring.
    d. Minimally invasive treatment methods and tools.
    e. Pacing and defibrillation.
    f. Peripheral arterial disease assessment and/or monitoring.
    g. Stents and other implanted devices.
    h. Thrombophlebitis diagnosis and/or treatment.

3. Dermatology
    a. Deep learning computer application to diagnosis of skin lesions.

4. Ear, Nose and Throat (ENT)
    a. Prosthetics and implants.
    b. Surgical tools.

5. Emergency Medicine
    a. Applications for trauma.

6. Endocrinology
    a. Continuous glucose monitoring
    b. Insulin adminstration

7. Infectious Disease
    a. Rapid diagnosis of pathogens.
    b. Sample collection.
    c. Sterilization methods.
    d. Transport and handling of specimens.

8. Gastroenterology
    a. Biopsy instruments.
    b. Video capsule for visualization of the digestive tract.

9. Nephrology
    a. Home dialysis

10. Neurological Diseases
    a. Thoracic back pain diagnosis.
    b. Parkinson's disease monitoring.
    c. Peripheral nerve disease assessment.
    d. Seizure monitoring.
    e. Sensory and motor function assessment tools.

11. Orthopedics
    a. Rehabilitation devices.
    b. Surgical tools.

12. Pharmacology
    a. Enhanced drug delivery systems.
    b. Infusion Pumps

13. Plastic Surgery
    a. Restorative/cosmetic prosthesis and implants.

14. Psychiatry
    a. Alert systems for Depression and/or Anxiety
    b. Suicide Prevention

15. Pulmonary
    a. Diagnosing drug-induced respiratory depression.
    b. Low cost sleep apnea monitoring.

Investigate the Clinical Problem

- Resources
  - University libraries – topic search, journal articles.
  - Bio-Medical Library in Diehl Hall – medical books.
  - Interview physicians if able – ie. Prof. Saliterman.
  - Interview patients if able – friends & relatives.
- Study the disease
  - What is the clinical presentation and progression?
  - What anatomy and pathophysiology are involved?
  - What are the incidence, prevalence, morbidity and mortality of the disease?
  - What are the causes, treatments, and outcomes?

Impact

- What is the cost/impact of the clinical problem to the patient and society?
  - Healthcare costs
  - Emotional impact
  - Loss of wages
  - Global issues like opioid addiction
- Are there Medicare or other insurance coverage issues?
- Are patient expectations realistic?

Formulate a "Needs Statement"

- **"A process for determining and addressing the gaps between the current situation or condition, and the desired one."[1]**
- Consider ie. ***Chronic Pain Management:***
  - "Lessen the amount and duration of knee pain in elderly adults with osteoarthritis."
  - "Reduce the number of visits to the emergency room for low back pain."
  - "Reduce the use of opioid medications for chronic pain among Appalachian residents."
  - "Improve sleep disturbance due to pain."

[1] *Needs assessment for medical devices*. World Health Organization, 2011

Solutions

- What are the *existing and emerging solutions* for diagnosis, treatment and management?
- Do you see an *opportunity* – "gap analysis" to create value within existing solutions?
- Can you identify a totally *unique solution*, based on yours or someone else's research?
  - ***It is not the discoverer, but the first to patent an invention based on the discovery, that ultimately owns the intellectual property.***

Stakeholder Analysis

- Identify the stakeholders, including potential conflicts of interest and alignments.
- Identify market segments.
  - For example, in *Stroke Management*, this includes:
    - Pre-hospital – family and EMS.
    - Emergency Department – all personnel.
    - Hospital – nurses, doctors, pharmacists, physical therapists.
    - Recovery – rehabilitation centers, nursing homes.

Market Analysis

- What is your target population/market?
- What is the current market landscape (for example competitors)?
- What is the size and demographics of your market (patients, first responders, nurses etc.)?
- Is the market growing or shrinking?
- Are there regional or international considerations?

Clinical Problem Worksheet

Team

1. Team members and contact information.

2. Team member's individual strengths and weaknesses.

Discovery & Ideation

1. Clinical problem chosen.

2. Resource list – websites, places and people.

3. Understanding of the disease:
   - Clinical presentation and progression,
   - Anatomy and pathophysiology,
   - Incidence, prevalence, morbidity and mortality,
   - Causes, treatments and outcomes

4. Impact of the Disease:
   - To the patient,
   - To society,
   - Insurance coverage,
   - Patient expectations

5. Needs Statement

6. Solutions

7. Stakeholder analysis.

8. Market analysis.

Investigation Phase Invention & Prototype

1. Medical device solution.

2. Prototype requirements:
   - Costs, timeline and other resources needed.

3. Plans for completion and presentation.

Summary

- Keep a lab *notebook*.
- Select a *clinical problem*.
- *Investigate* the clinical problem and its impact.
- Identify a specific *need*.
- Consider all *solutions*.
- Describe the *stakeholders*.
- Complete a *market analysis*.
- Propose a *medical device solution*.