Clinical Problem Selection

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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.
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.”

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?
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*.