Translational Medicine Connects the Problem to the Solution

• Every step in developing a device or drug must be evaluated in light of the clinical problem
Translational Medicine Symposium 2013

Identifying the Clinical Problem

Bench to Business to Bedside: The Roller Coaster Ride to the Clinic
Introductions

• Moderator:
  – John Langell, MD, PhD, MPH
    (Executive Director, Center for Medical Innovation)

• Panelists:
  – Kathy Peterson, MD
    (Associate Professor of Gastroenterology, University of Utah)
  – Robert Hitchcock, PhD
    (Associate Professor of Bioengineering, University of Utah)
Introductions

HOW DO I IDENTIFY A VALID CLINICAL PROBLEM?
Clinical Problem Identification

- **Methodology**
  - Observation
    - Watch the entire care pathway
    - Create an observation statement
      (what you saw...not what perceive to be the problem)
  - Problem Identification and Validation
    - Create a Problem statement from recurring observations
    - Is it really a problem?
    - Stakeholder validation
  - Need Shaping
    - Identifies a desired change in outcome
    - Stay out of the Solution Space
Conducting Observations

• Ethnographic Research
  – “Way of life of living human beings”
  – Immersion to obtain an in-depth perspective

• Become part of the team
  – Gain acceptance and credibility
  – Reduce “observer Effect” through repetition
  – Do not attempt to make treatment recommendations

• Watch for unexpected clues
  – Times of struggle
  – Identify “Work-Arounds”
  – DOGMA: “It’s how I was trained”
  – DOGMA: “It's how I've always done it”
  – Look for variation
  – Look for delays and impediments
Observational Perspectives

• Observe each component of care
  – 360 degree cycle of care

• Have a foundational knowledge
  – Anatomy, physiology, treatment concepts

• Know who the stakeholders are
  – Observe first, then ask basic question
  – Do not bias your observation or the question!

• Stakeholders have different perspectives
  • The Patient
  • The Family
  • The Physician
  • The Trainee
  • The Nurse
  • The Facility
  • The Payer
Conducting Observation

• Critical Clues
  – Patient Perspective: Pain, Death, Stress
  – Provider Perspective: Risk, Malfunction, Uncertainty, Dogma
  – System Perspective: Cost, Inefficiency, Work absence

• Documentation of Observations
  – Innovation notebook
    • Format, process, authentication, additions, blank space, deletions
  – Do not editorialize
  – Note: questions/answers, times, procedure details, observations
Conducting Observation

- Study all Possible Scenarios
  - Different patient types with different needs
  - Different provider stakeholders
  - Different treatment approaches
  - Different Treatment Settings
Conducting Observation

• Study Team Assignment
  – How do we increase Patient Compliance?
  – Foundational knowledge
  – Ethnographic research
    • Clinical immersion
  – Ideation

Result: Three personas....not one solution

1) The Hipster- Young, single, socially motivated, appearance-driven
2) The Metro- Health conscious, spiritual, personal fulfillment focused
3) The Dude- non-hygienic, unconcerned with appearance, convenience focused