Needs and Markets

Entrepreneurship Courselet

Why Do Needs Deserve A Lecture?
- Need Innovation → Product Innovation
  - guides brainstorming
  - facilitates concept screening
  - part of intellectual property strategy
  - focuses clinical trial protocol
  - sharpens marketing effort
- getting it wrong is really, really, really bad

Why Med-Tech’s Fail
- Product doesn’t work
- No one willing to pay for it
- Not enough patients
- Bad IP, management, luck

The Costs Of Failure
- $10-$70 million
- 20-120 people’s time
- Between 3-20 years
- 3-25% of your life

Need Identification: Step 1

Know The Customer
- Surgeon  Patient  PA/Nurse  Admin.  Payer
- GM/CEO  Sales  R&D  Reg.  Manu.  Investor

Know Yourself

Need Identification: Step 2

Pick Your Approach To Finding Needs
- Ask the customer
  - surgeon, patient, etc.
  - scientific, surgeon advisory boards
  - surveys & focus groups
- Observe the customer
  - during surgery
  - Pre-op, post-op, rounds, m&m
- Research outcomes
  - journal articles
  - conference posters & presentations
Need Identification: Observation Clues

- Customer Comment
  - “If I only had a way to...”
- Patient Morbidity
  - big incision
  - lots of blood/pain/infection
  - long recovery, long ICU
  - “inoperable candidate”
- Poor Outcomes
  - less than 85% success
  - expensive complications/failures
  - collateral damage, new problems, follow-on procedure
- High Costs
  - in-patient or long procedure
  - charges above $10K, high costs to society
  - expensive devices, many people to deliver therapy

Need Identification: Step 3

- Writing A Need Statement
  - focus on the goal, not the problem
  - avoid solutions
  - get specific
  - stay positive
  - change venue
  - do it twice

Need Statement

- Focus On Goal, Not Problem
  - Bad: “A way to close sternotomy without risk of sternal-wire breaking.”
  - Focuses on sternal-wire, closes out other approaches
  - Focuses on part of the procedure that doesn’t deliver result
  - Good: “A way to close sternotomy quickly and securely.”
  - Better: “A way to perform CABG without sternotomy.”
  - No reference to current solution, targets procedure goal

Need Statement

- Avoid Solutions
  - Bad: “A way to ultrasonically weld suture in surgery.”
  - Completely limited to one approach
  - Good: “A way to secure aortic valve prosthesis with minimal or no on-pump time.”
  - Identifies specific procedure and problem while leaving solution open

Need Statement

- Stay Positive
  - Bad: “A way not to have a nuclear conflict with N. Korea.”
  - It’s negative, I’ve always been told this is bad.
  - “A way to improve relationship with N. Korea.”
  - It’s not so negative, I’ve always been told this is good.

- Get Specific
  - Bad: “A way to improve outcome of spine surgery.”
  - Not clear which surgery, initial diagnosis, or how to improve
  - Better: “A way to reduce risk of re-herniation after lumbar disectomy for sciatica.”
  - Clear about procedure, diagnosis and complication
Need Statement

- Change Venue
  - Not bad: “A way to replace mitral valve on-pump with less risk of stroke.”
  - Procedure and complications called out, but focuses brainstorming on on-pump approach, cardiac surgeon, and open chest.
  - Different: “A way to restore function of mitral valve percutaneously.”
  - Changes venue to the catheterization lab, gives greater possible gains.
  - Consider inpatient to outpatient, general anesthesia to local/regional anesthesia, operating room to office

- Poor to slow adoption

Need Perspective: Example 1

- Congenital Dysplasia of Hip
  - Socket malformed
  - Cartilage degenerates
  - Bone degenerates
  - Pain intensifies by age 30
  - Addressed by THA
- Early dislocation in 12%
  - Extremely painful
  - Requires re-operation

De Novo Ventures

Building Value, Engineering the Market

How is it normally done

Animal → Design → Clinical Protocol → Human Input → Clinical Enrolment → Release

Poor to slow adoption

Alternative Approach

Clinical → Protocol → Human Input → Feasibility

Clarity of Clinical Problem → Data Supporting Development → Validation → Key Attributes → Key Advisors → Key Attributes → Contributors → Launch Clinical Trial
Market Assessment Shortcuts and Myths

- “Market Research” (Chinese Bridges)
- 1% of $1 Billion = $0
- Today vs. Tomorrow
- “Size Matters”

Qualitative Market Assessment Shortcuts and Myths

- Is There A Problem??
- Define Relative Product Performance
- Define Patient Population
- Define Physician Culture
- Define Problem Intensity

Is There A Problem??

- Clinical Need?
  - Improve Outcome
  - Reduce Complications
- Reduce Costs
- Help Physician

Qualitative Market Assessment Define Patient Population

- Epidemiology and DRG data (ICD – 9s) (Medline and National Inpatient Samples, National Center for Health Statistics)
- Physician Interviews
  - Ask for facts, not judgments!
  - “What percent of patients have [specified] characteristics?
- Define Patient Exclusions
  - comorbidities, incompatible therapies
  - (lytics and catheters)