

Gaining Commitment: Advocacy Tools



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The Need

- * What is the problem you are addressing?
- * Why is this problem significant?
 - * Market size
 - * Market growth
 - * People Affected
 - * Incidence, prevalence, etc.
- * What are the current methods for solving this problem?
 - * include pictures & diagrams, as appropriate, along with the strengths and weaknesses of each existing approach.

A way to reduce the number of failed catheter line insertions

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Team 4 – BME 790

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The Need

A way to reduce the number of failed catheter line insertions.

- * What is the problem?
 - * Inserting catheters into veins and arteries is difficult
- * Why do we need catheters?
 - * Administer medication, fluids, blood samples, mean arterial pressure
- * Why fix the problem?
 - * Reduce complications associated with catheter line insertions
 - * Blood loss, infection, pain, pneumothorax, thrombosis
- * **Need Statement – A way to reduce the number of failed attempts during catheter line insertion**

Background

Notebook Entry: February 20, 2013

7:40 AM Right hepatic resection (510 min. procedure)
 8:36 AM Timeout is performed
 8:45 AM **Resident is going to insert CVC, but can't find the vein. Ultrasound is requested.**
 9:20 AM Ultrasound machine is brought in by tech. Resident begins to insert CVC into right jugular vein with ultrasound.
 9:50 AM Resident cannot ensure proper insertion.
 9:55 AM The attending scrubs in to assist. Attending uses landmark technique and complains about how the ultrasound transducer is hard to control.
 10:00 AM **Patients neck is covered in blood. CVC is still unsuccessful after many pokes.**
 10:03 AM Meanwhile the surgery is occurring. Surgeon asks resident if the CVC has been placed yet.
 10:05 AM New attempt at CVC placement in left jugular vein.
 10:10 AM Despite clear JV visualization in ultrasound the resident is unsuccessful again.
 10:20 AM **Attending steps in and is able to insert CVC after multiple attempts.**
 10:22 AM Attending scrubs out and resident begins to clean up the mess.
 10:25 AM **Patients head is soaking in a pool of blood that has clotted overtime.**
 11:05 AM Resident finishes cleaning up the mess.
 12:00 PM Surgeons question the amount of blood that was lost for CVC insertion.
 3:30 PM **Attending anesthesiologist comes in to talk to resident. They are considering ordering 2 units of blood to compensate for that lost during the CVC insertion.**

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Market Assessment

Funders will want to know that the market is sizable enough to build a big business around.

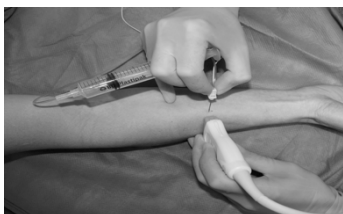
- * Sizing the Total Market: How big is the problem you are solving? Can you quantify it?
- * Segmentation
- * Competition

Market Assessment

- * Infection
 - * 80,000 catheter related bloodstream infections (ICU/year)
 - * \$25,000 - \$56,000 in additional healthcare costs per episode
- * **Large potential market**
 - * 5 million CVC, 8 million arterial catheters (US/year)
 - * CVC projected revenue for 2013: \$220 million
- * 20% of initial attempts are unsuccessful
- * 61.6% of initial CVC attempts were unsuccessful before ultrasound (22%)
- * CVC procedure time with ultrasound: from 10 to 3.3 minutes

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Current Approaches



<http://www.respond2articles.com/ANA/>



<http://www.equip.nl>



<http://www.eradimaging.com>



<http://learn.accuvein.com>



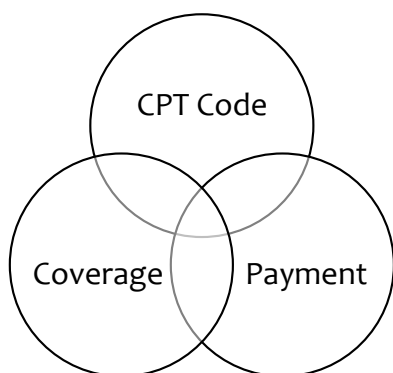
<http://www.veinlite.com/veinlite/>

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Reimbursement

- * Will the existing healthcare payment infrastructure accommodate a solution to the need?
- * Will insurance coverage be applicable to a large enough segment of the target market to make the development of the solution financially viable?

Reimbursement



CPT codes:

- 76937: Ultrasonic guidance for vascular access - \$36
- 36556: Insertion of CVC (adults) - \$120

			Stakeholder		
Musts & Wants			Hospital Administration	Anesthesiologists	Insurance Payer
Category	No	Statement			
MUST	1	<i>Reduces number of attempts to access blood vessel</i>	X	X	X
	2	<i>FDA Approved</i>	X	X	X
	3	<i>No IP infringement</i>	X		
WANTS	4	<i>Reduces time to insert catheter line</i>	X	X	X
	5	<i>Device is easy to use</i>		X	
	6	<i>Simple to train how to use the device</i>	X	X	
	7	<i>Low procedure cost</i>	X		X
	8	<i>Reusable</i>	X		X
	9	<i>Usable on different blood vessels</i>		X	
	10	<i>Provide visualization of needle position</i>		X	
	11	<i>Compatible with existing technologies</i>	X	X	X

Priority
0.373
0.075
0.101
0.020
0.021
0.234
0.123
0.054
1.000

CONCEPTUAL DESIGN

PROVIDE VISUAL SHOWING HOW YOUR DESIGN WORKS

Solution

- * What stage are you at?
- * Provide pictures of your product in action and a visual showing how your solution works
- * What will your solution enable?
- * How does it meet the “must haves” and prioritized “wants” of key stakeholder groups? (reference your *Stakeholder Assessment*)
- * How is this an improvement (e.g. “this will allow a savings of 30 minutes/day for every pediatric NP”)
- * Is your solution patentable?

Freedom to Operate

- * If government regulations (ex. U.S. Food & Drug Administration approval) and associated constraints pertain to this need and its resolution, identify them here.
- * If other certifications are necessary (ex. regulatory approval in non-U.S. countries, Institutional Review Board approval, independent regulatory body approval, et al.) provide an outline of what will be necessary to obtain those approvals.

Customers

- * Who are your customers?
- * What is your pricing model and why?
- * How profitable are these customers?
- * How will you reach your customers in a low-cost way?
- * Have you developed partnerships that help you reach customers and distribute product (i.e. channel partners)?

Marketing Strategy and the Unique Value Proposition

Marketing to customers and attaining the “buy-in” of those affected by the use of your product, process or service begins with an understanding of key stakeholder groups and the unique value proposition your solution represents, particularly for those in a position to purchase your product and champion its use.

- * Confirm that you know who really has the purchasing power and the best “sales channels” through which to reach those people with your product or service.
- * Test various value propositions on your trusted advisors and representative stakeholders to decide which will appeal best to which key stakeholder group.
- * Revisit the clinical literature and get insight from the statements of professional societies, trade groups, patient advocacy and support groups, online patient blogs, and insurance websites to make sure that you are on the right track.

Comparables

A competitive advantage is something a company does well that other companies cannot imitate easily.

- * What are the competitive advantages each of the established and emerging competitors in the market have developed and the business strategies they have used to capitalize on those advantages?
- * What weaknesses in these competitor companies can a new company exploit in order to establish a foothold in the market by addressing those gaps?

Competitive Advantage

- * What is your company's competitive advantage?
 - * Convey in one or two sentences what your company does, for whom it does this, how this *uniquely* solves an urgent clinical need in the market, and *why competitors cannot easily replicate this distinctive advantage*.

Operating & Staffing Plans

- * Make sure you have realistic answers to the following questions:
 1. What steps will you need to take in order to build your innovation?
 2. If the innovation is regulated in any way, how will the regulatory process impact the timeline?
 3. If your innovation is a product, how will you sell it (sales and distribution) and when will the first sale take place?
 4. Other critical milestones?
 5. What are the staffing requirements for achieving these milestones and how will you measure progress toward goals?

Cash Flow Statement

Funders will want to see historical data that can predict financial trends for a new business or program.

The cash flow statement shows the cumulative cash the business will spend over a period of time, and therefore it is the amount of money that needs to be raised or allocated to the project.

Questions you'll need to answer:

- * In the case of a start-up company, base your projections on comparable companies or programs (known as "benchmarking").
- * Find comparable companies and ask the following questions: What is the company's most recent income statement, the number of employees, estimates of the cash spent per employee, cash spent on equipment and estimates of inventory required?

Summary

Hit the highlights of the story; focus on the key elements of the opportunity that would lead an investor to ask you back for a second meeting:

- * What problem you are solving
- * Why it's such a significant problem
- * Why you have the best solution
- * Why you and your team are the right people to solve this problem
- * Why your audience is the right investor for this opportunity