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Design Foundation, Part 2

BME 590L

What is your problem/need statement?

"A way to address (Problem) in (Population) that (Outcome)"

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What's the worst design you've encountered?

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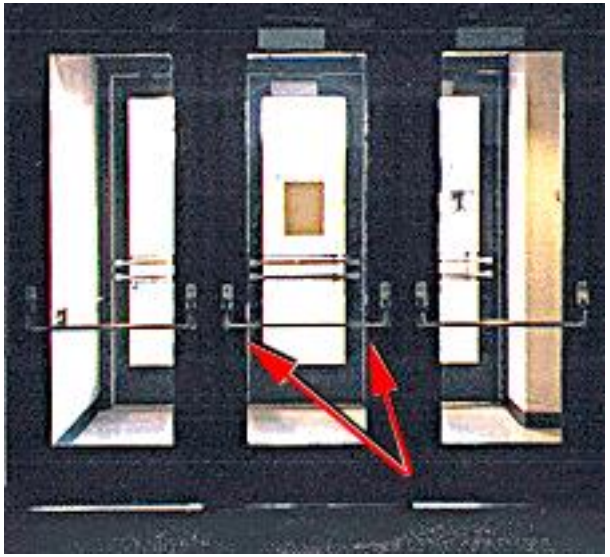
Bad Designs.



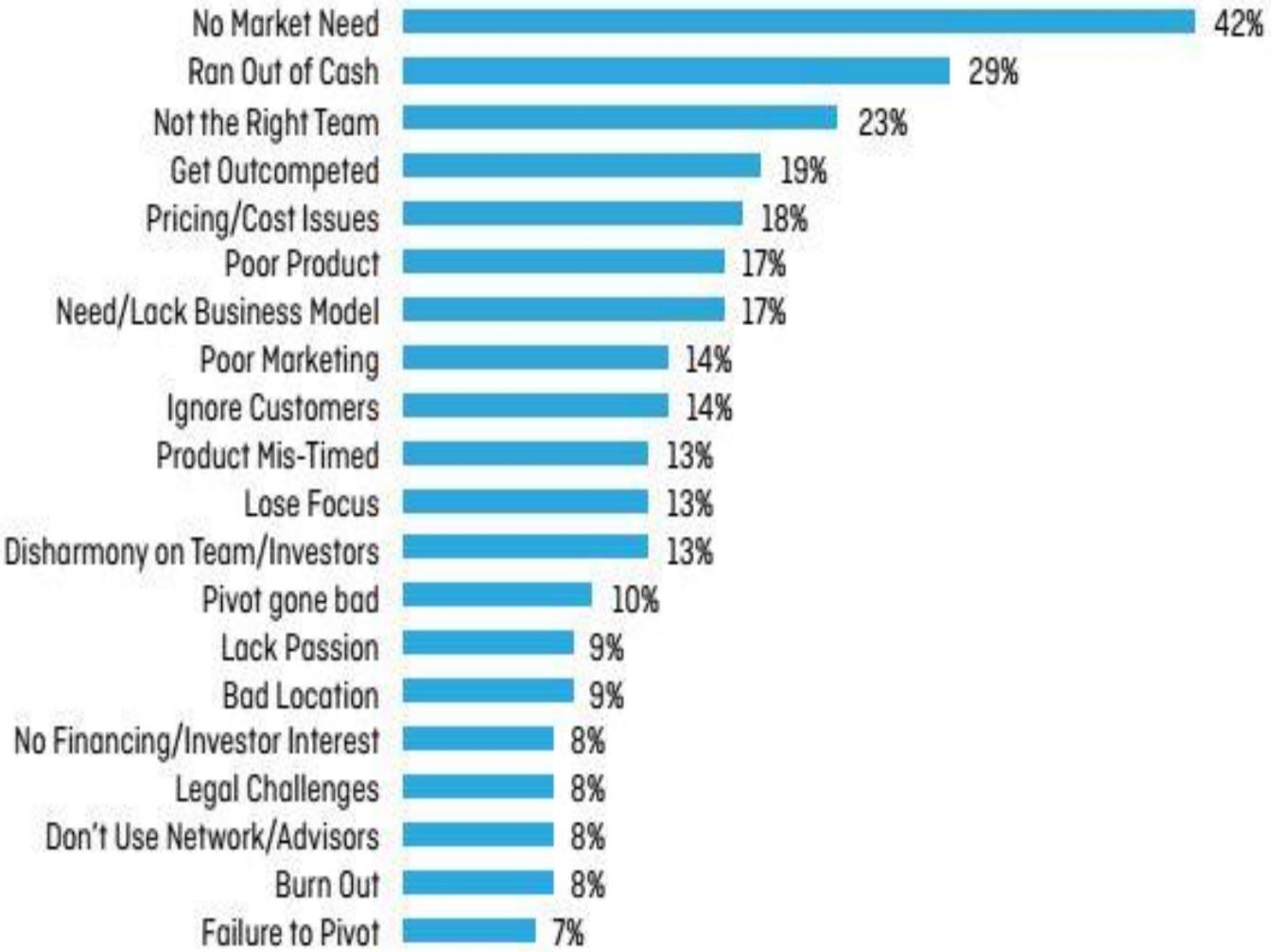
http://baddesigns.com/

What are major sources of bad designs?

A disconnect with the customer.

Top 20 Reasons Startups Fail

Based on an Analysis of 101 Startup Post-Mortems



Source: The Top 20 Reasons Startups Fail, CB Insights, 2014.

No More Absorb BVS: Abbott Puts a Stop to Sales

The company announced its intention to stop selling the bioresorbable scaffold in all countries but said follow-up of existing studies will continue.

By Caitlin E. Cox | September 08, 2017

Abbott Vascular is calling a halt to sales of the Absorb bioresorbable vascular scaffold as of September 14, 2017, attributing the decision to "low commercial sales."

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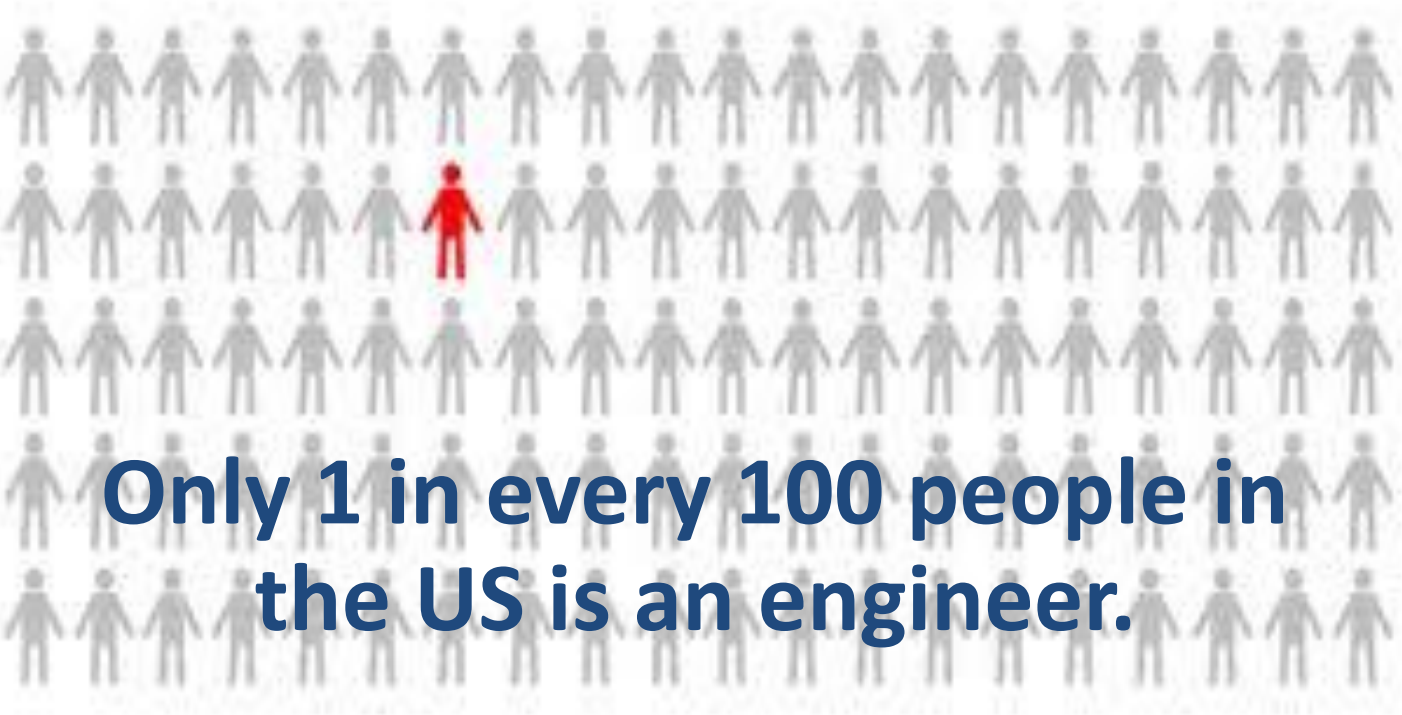
Engineers think differently.

And speak a different language.



http://www.nspe.org/resources/media/resources/frequently-asked-questions-about-engineering

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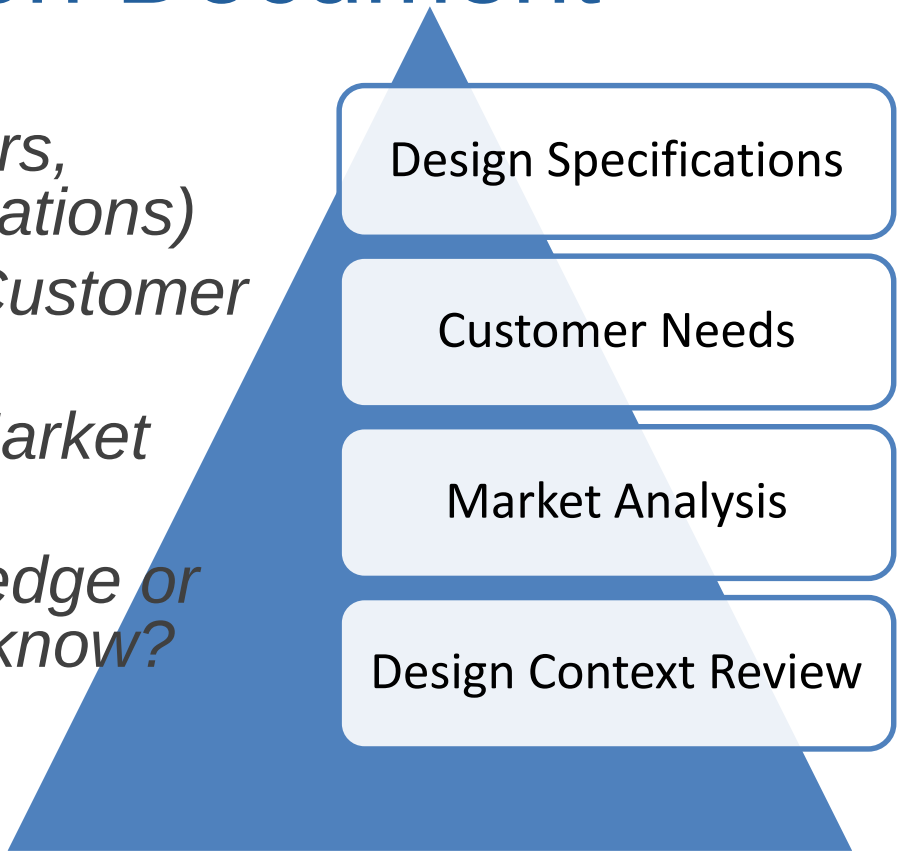
Design Foundation Document

- *What will we, as engineers, deliver? (Design Specifications)*
- *What are their needs? (Customer Needs)*
- *Who is my customer? (Market Analysis)*
- *What background knowledge or information do I need to know? (Design Context Review)*



IN SHORT, UNDERSTAND YOUR CUSTOMER AND TRANSLATE THEIR NEEDS INTO YOUR LANGUAGE.

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Design Foundation Document

- Outlined in greater detail in Ulrich and Eppinger, Chapters 5 and 6
- Will help you strengthen and finalize your team's need statement
- Will be the meat of your mid-semester Project Intro Presentations (October)
- **Output: Clear, quantifiable, and agreed-upon target specifications to begin the engineering design process**

	Start of Course	Cycle 1 - PREP/ID	Fall Break	Cycle 2- DESIGN	Winter Break	Cycle 3 - PROTOTYPE	Spring Break	Cycle 4 - TESTING	End of Course
Lecture Topics		Disease State Analysis, Patient Flow Competitive Options, including IP landscape Market Analysis Customer Needs Specifications, Constraints (including Standards/reg)		Functional Decomposition and System-level Design Concept Generation Concept Selection Testing strategies Two "concept feedback" lectures		DFM, LBM Quality: DOE, Statistics, FMEA Clin/Reg Strategy and IRB IP Disclosure and Strategy		Design Poster Presentations Oral Presentation Tips & Tricks Final Presentation Dry-runs	
Written Delieverables		Design Foundation Document, which includes DSA, Patient Flow, IP, Market Analysis (Basically the intro section to the final report) HOQ (Customer needs mapped to preliminary specifications and constraints)		Functional Decomposition (Appendix 1 of Final Report) Sketches/CAD of top designs (Appendix 2 of Final Report) Pugh Matrices (Appendix 3 of Final Report) Updated HOQ/specs Testing Strategy (rough proposal) Rev 2 of DFD		Final design desciption (both form and function, including CAD/photos of prototype) Testing proposal (essentially the methods section of final report) Implementation Strategies (LBM, FMEA, Clin/reg strategy and IRB proposal (if needed)) Updated, Final HOQ/specs Rev 2 of Appendices Competition Submission Plan		Final Report, which includes: 1) DFD 2) HOQ 3) Final Design Document 4) Test Methods and Results 5) Implementation Strategies 6) Appendices Competition Submission IP Disclosure (if applicable) IRB documentation (if applicable)	
Presentation Deliverables		Project Intro slides (content of DFD, up to specs), 10 slides		Intro slides, plus five slides showing top 3 concepts/prototypes/subfunctions (Video/photos/CAD encouraged)		Intro slides, final design slides (3-4 slides showing final prototype), and implementation slides (3-4 slides showing LBM, FMEA, Clin/reg strategy)		Final Presentation (Intro slides, final design slides, tesing results, implementation slides, conclusion slides - polished) Poster Presentation (leveraging their existing slide deck and final report)	
Presentation Format		10 minutes in-class presentation		30 minute time slot, with mentors and part of class (four other teams?)		15-20 minute in-class presentation		30 minute time slot, with mentors and part of class (four other teams?)	
Prototyping		Prototyping skills introduced		Initial prototyping; low to medium fidelity prototype and/or working subfunctions completed by winter break		Prototype refinement; functional, integrated prototype ready by spring break		Prototype tested against all specs in a statistically-driven approach	

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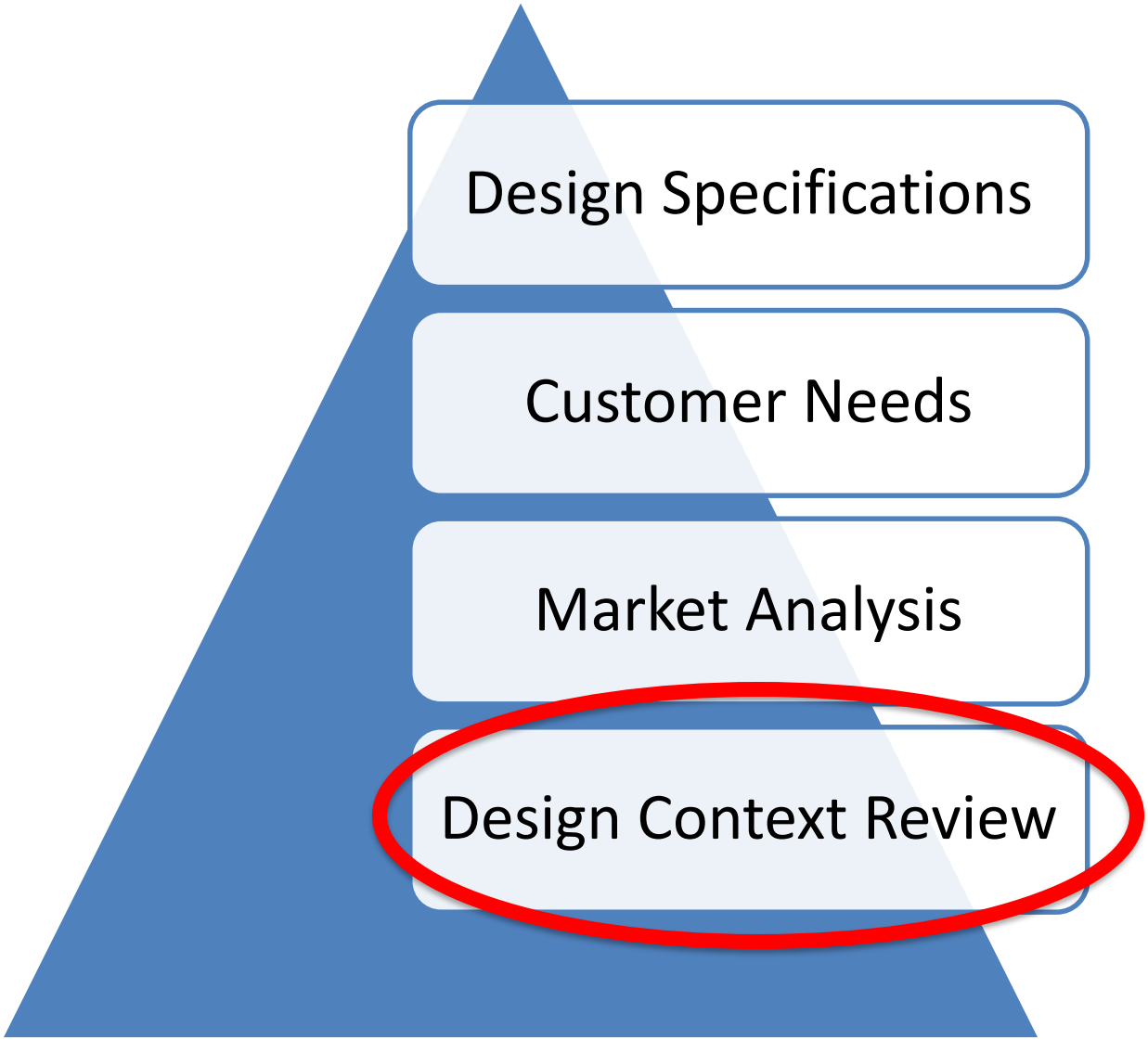
Design Foundation Document



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Step 1: What do you NOT know?

- Necessary background information about the environment of your design
  - Physiology, Pathophysiology and Anatomy
  - Epidemiology (Prevalence)
- Identification of customers that will use, pay for, or authorize the use your design
- References to applicable standards in the area of your project
- Descriptions of current technologies you might use in your design
- Current competitive products or existing intellectual property (especially patents) in the area related to your product

Cease and Desist

“Good Morning:

Please note that this device presented was plagiarised.

We developed and patented the product which is currently marketed as (…).

Articles with regard to this product are well-published.

The award and merit granted should be rescinded and any attempt to develop will be prosecuted

Please inform me of actions taken.”

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Getting Started on the DCR

- Product Development Worksheet –email sent today
- Begin filling out the prioritized need-to-know list for the 5 listed areas (5 min)

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Design Context Review

- Your path to become the world's expert on your product starts here
- Two purposes of the DCR:
  - Assures profs, sponsors, and yourselves that you have the foundational knowledge necessary for success
  - Establish a common language with your sponsor, and educate him/her

More info to be posted on intro section (see github repo)

Patient and Money Flow

Where does the patient go, and where does the money go?

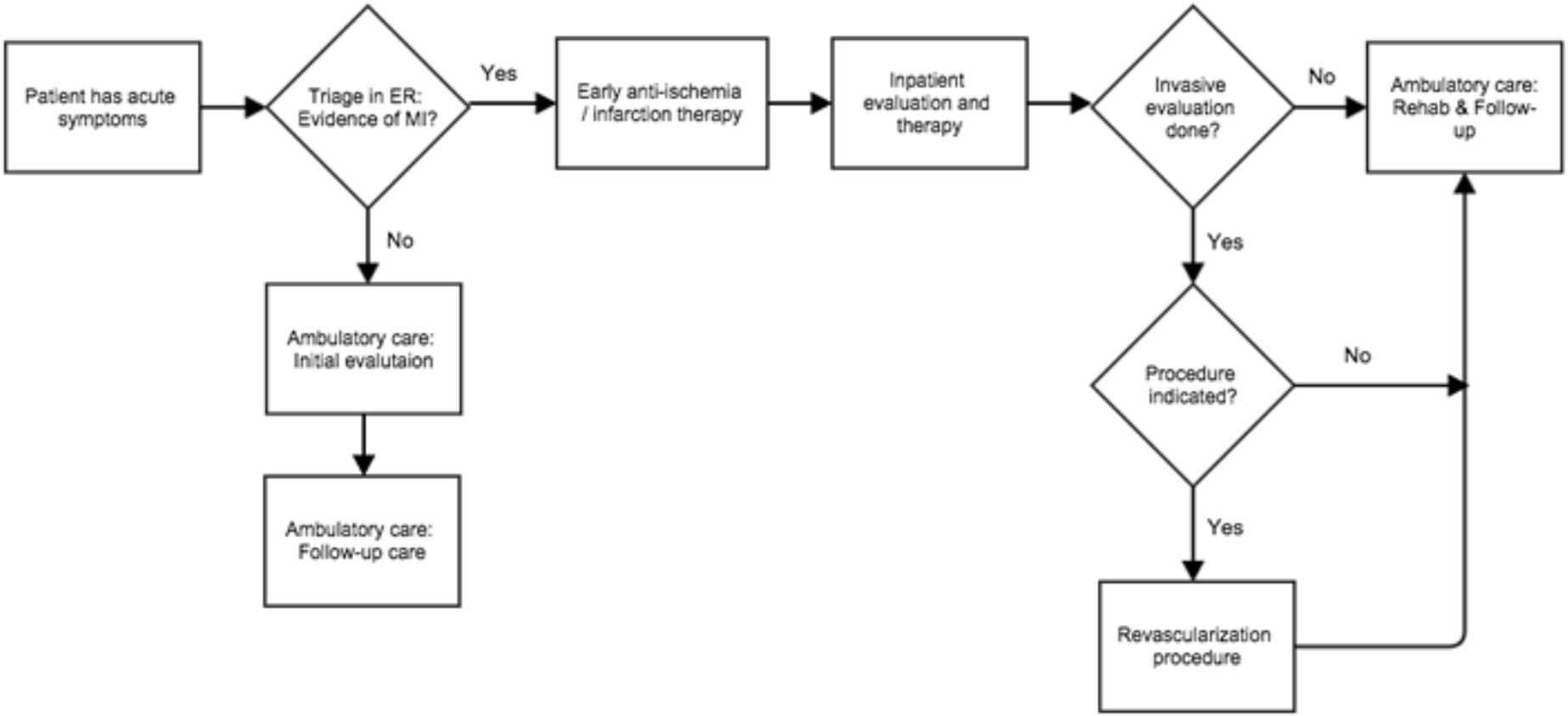
Draw a block diagram to show how a patient goes through the healthcare system to be treated

Discuss how the money flows to pay for the patient's treatment – this can be complicated, no need to do a diagram

Example

Ischematic Heart Disease Patient Flow

"[Ischematic Heart Disease Patient Flow]. Cambridge, Massachusetts: Institute for Healthcare Improvement; [2004]. (Available on www.ihi.org)



Worktime

- Spend 5 minutes as a team drawing a flow diagram of what happens before, during and after your need

Design Foundation Document

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Market Analysis: Who is my customer?

1. Identifying Market Segments
2. Estimating Market Sizes
3. Assessing Competitive Products/Solutions
4. Estimate Total Addressable Market (TAM)

Market Analysis: Who is my Customer?

Market Segments: Groups of people that share common needs (or need a common job to be done)

Market Segments: Getting Started

- Brainstorm at least three possible market segments for your product (5 min)
- If your product is non-traditional, be creative!

Market Sizing: The art of estimation

Estimation of how many people are in each segment.

Use online market reports, volumes of competitive products sold, population estimates, and other rationales to give a best guess.

Know that market sizes are an estimation and may be way off ….

at&t

McKinsey&Company

900,000/3 days

http://www.economist.com/node/246152

Market Segments: Getting Started

- Provide a size estimation and rationale for your top market segment (5 min)

Assessing Competitive Products/Solutions and Willingness to Pay

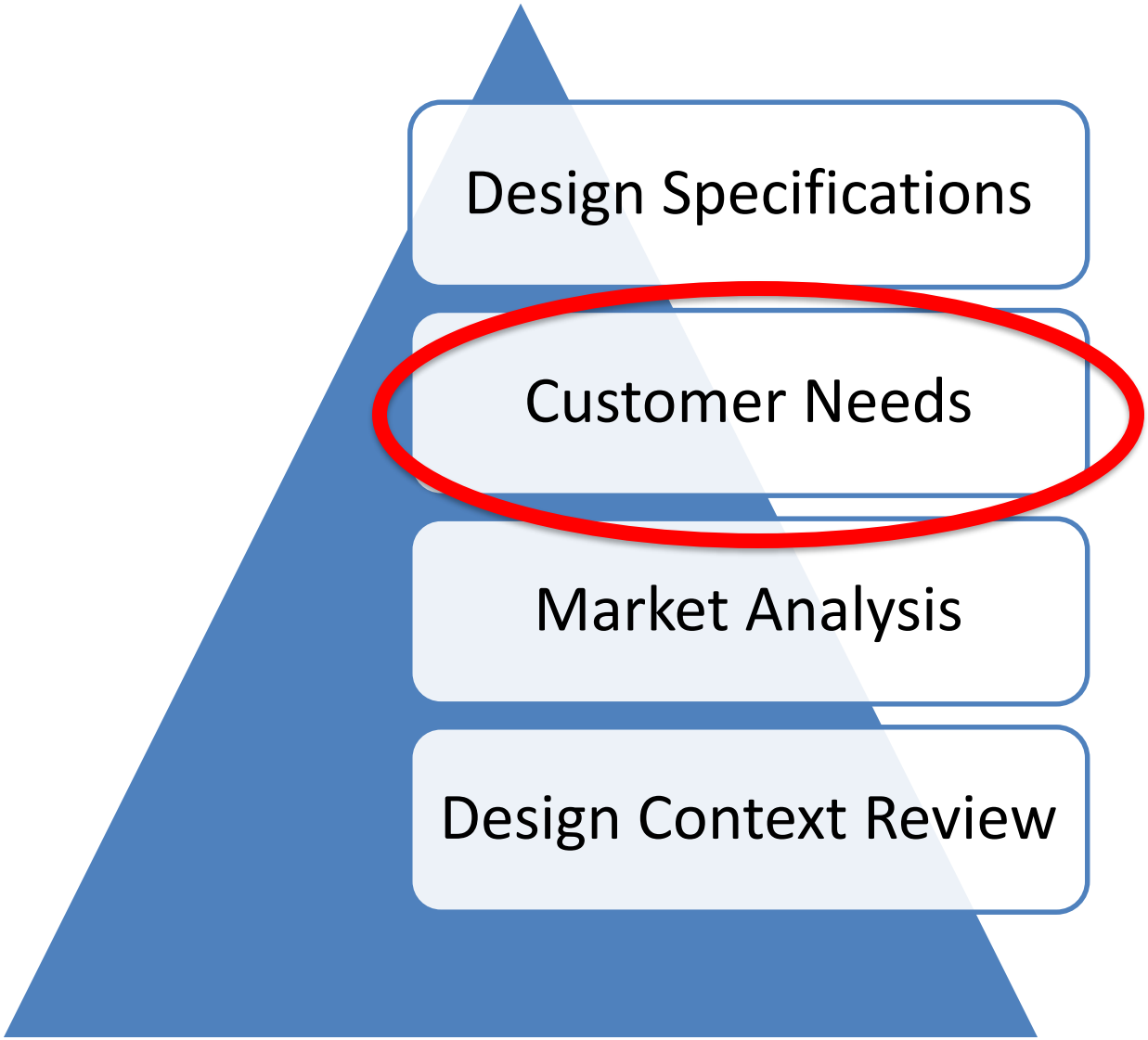
- List as many competitive products or alternative solutions that your top market segments uses to get the job done
- Estimate how much your customer might be willing to pay for your product. Consider:
  - How much they are paying or how much time they are spending on competitive solutions
  - Their **ability** to pay
- Get started! (Spreadsheet - 5 min)

Estimating your TAM

TAM = Total Addressable Market (or Total Available Market = total revenue you could theoretically generate (usually per year)

TAM = (Market Size)X ($$ Willing to Pay)

Design Foundation Document



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Customer Needs

Steps from Ulrich & Eppinger, Chapter 5:

1. Gather raw data from Customers
2. Interpret raw data in terms of customer needs
3. Organize these needs into a hierarchy
4. Establish the relative importance of the needs

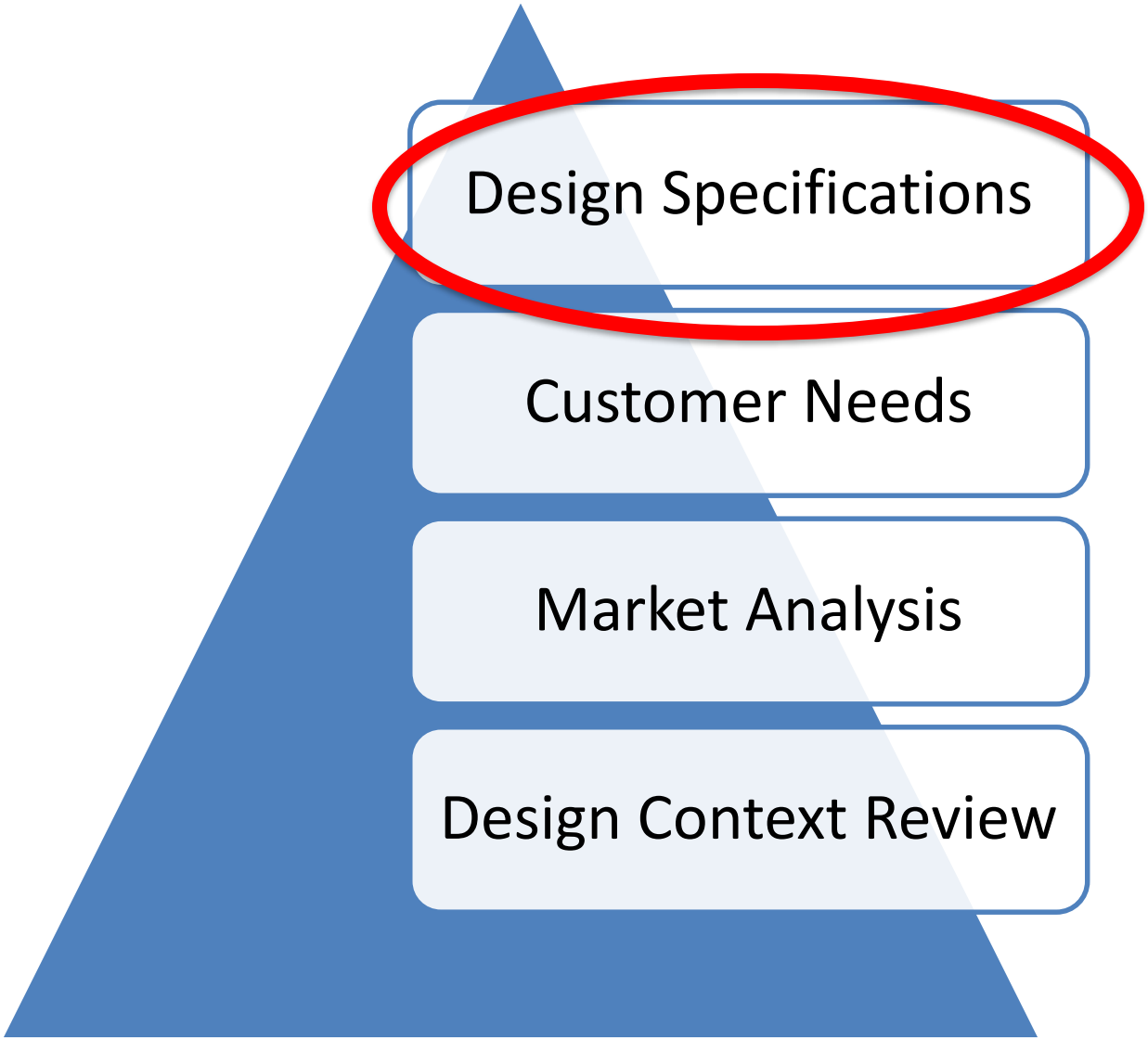
Customer Needs: Users, Payers, and Regulators

- Who USES, PAYS FOR, and AUTHORIZES the use of your product or service? Usually different people who care about different things!

Customer Needs: Interpreting, Organizing, Prioritizing

- Getting Started: Given your current knowledge of the project, craft one customer needs statement for the user, payer and regulator.
- Importantly, when you craft your need statements, don’t embed a solution!

Design Foundation Document



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Target Specifications: What you will deliver in Engineering Language

- Translation from Customer Language to Engineering Language
- Target specifications should:
  - Be measurable (with a method that is available to you)
  - Be independent of the solution
  - Map to a customer need
  - Have an ideal value, and a target value, informed by your competitive products
- Choose wisely!
  - This is the criteria that you will be judged on at the end of the year
  - It acts as a contract and negotiation tool for you and your sponsor

House of Quality: A Translation Tool

- HOQ is a common tool for mapping customer needs to specifications
- It's a part of Quality Functional Deployment (QFD)

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Systems2win

Getting Started

- Create at least one target specification that maps to one customer need in your PD Worksheet

Design Foundation Document

- Tentatively due Oct 4 (Cycle 1)
  - Design Context Review
  - Patient Flow Diagram
  - Market Analysis
  - Customer Needs
  - Specification Proposal
- Presentation
  - 10-slide version of DFD (“Pitch”)

Product Development Worksheet

- Fill out first four tabs, develop patient flow diagram and submit to Sakai by 9/18, midnight
- Continue work on Design Foundation Document – will be revisited on 9/25

Conclusion

- Carefully completing these documents will:
  - Provide a foundation of knowledge for the team
  - Prevent customer disconnects and ensure you are meeting their needs
  - Clarify expectations between students, profs, and sponsors for product performance