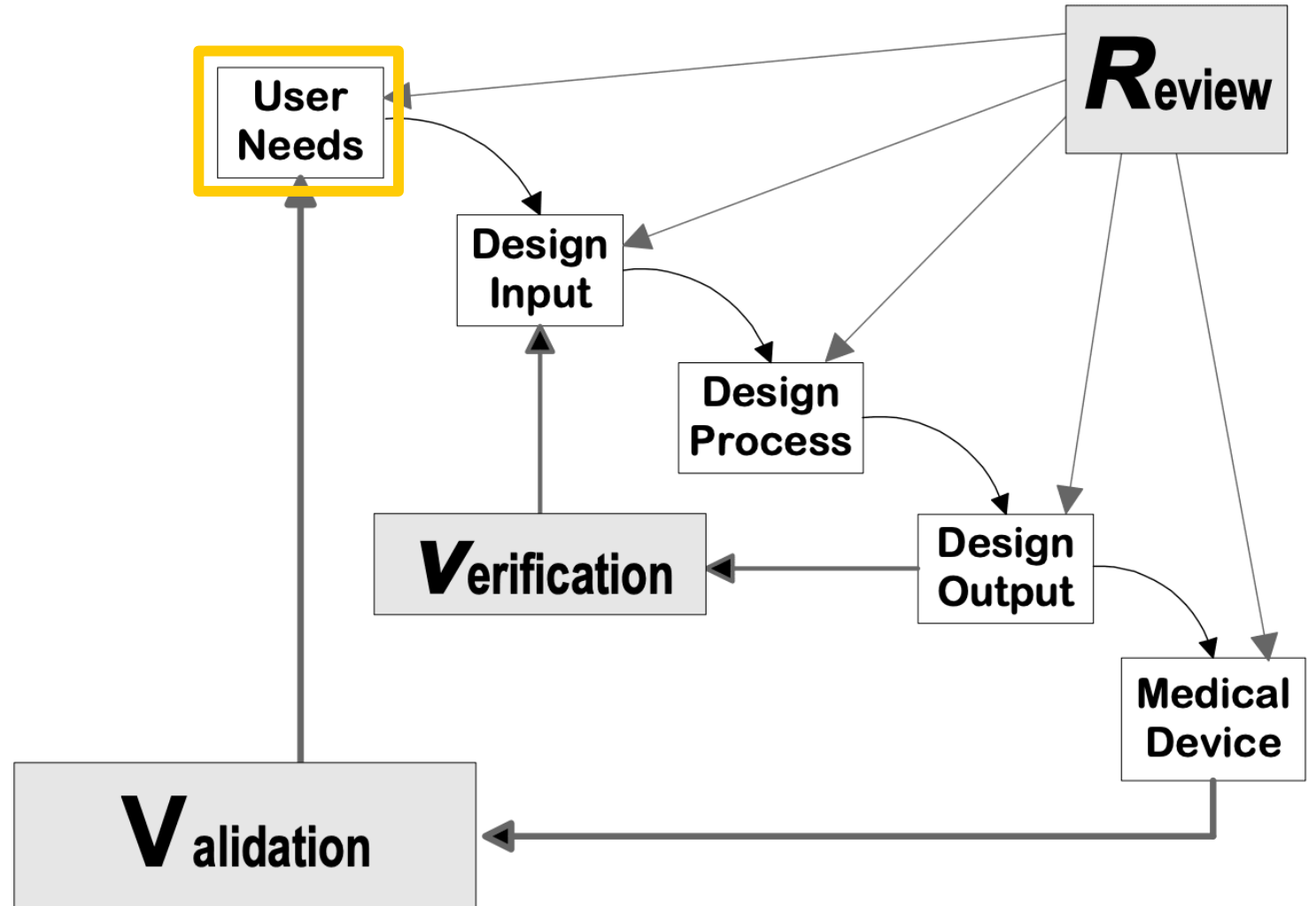


WN26 BME 350

Problem Definition & User Needs

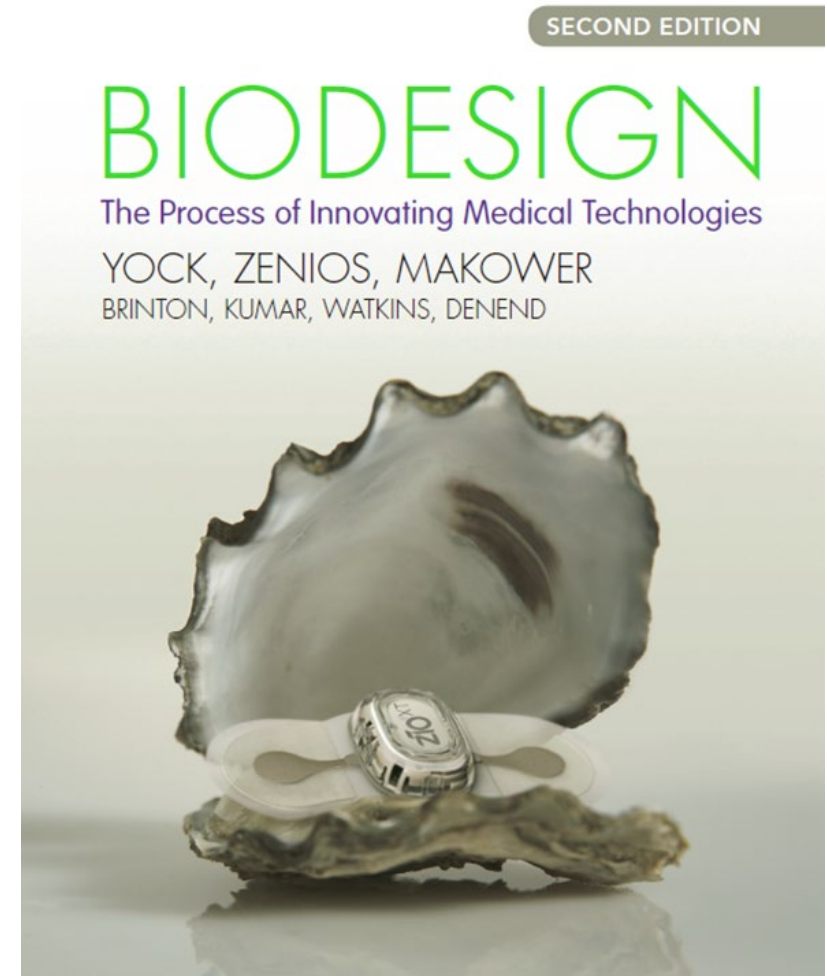
(with Intro to Library Tools + Activity)

Last Time....



Plan for today

- Problems & Needs
- The Needs Statement
 - Disease State Fundamentals
 - Existing Solutions
 - Stakeholder Analysis
- *Break at 3:20*
 - Market Analysis
 - Guest: Luesoni Kuck, BME librarian
- In-Class Activity: Resource Hunt



Companion reading for today's lecture topics:
Yock et al Sections 1.1-1.3 p. 50-109

<https://search.lib.umich.edu/catalog/record/99187447397606381>

In-Class Assignment: Reference Hunt!

Individual assignment, **5pts**, **Due:** “End of Class” or 11:59pm in two calendar days

Find a reference paper, unique within your team, related to background/disease state OR Market.

Notes should contain:

- **WHO:** Authors, Company, Inventors, or Database name
- **WHEN:** Year that information was published or created
- **WHAT:** Title of paper/patent, name of device, or other identifying label
- **WHY:** Why you think this reference/resource is credible
- **HOW** did the deep dive go?
 - Short summary of what you learned and whether this paper should be read more closely or not.
- **WHERE** does it fit in the User Needs draft?

User Needs Memo and Rubric

- Submit to Canvas, team assignment
- Assignment = Memo style overview
- Expectations & Rubric
 - Logistics, learning objectives and grading criteria

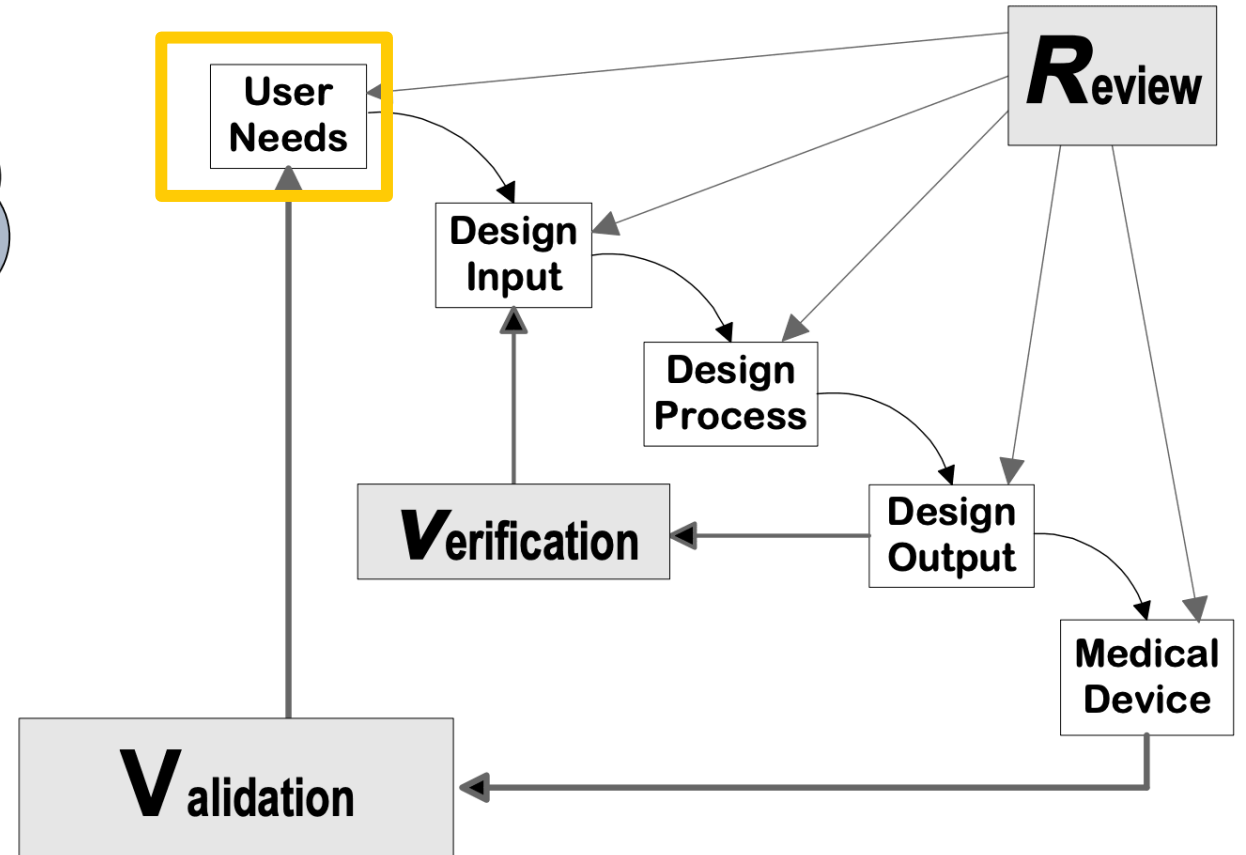
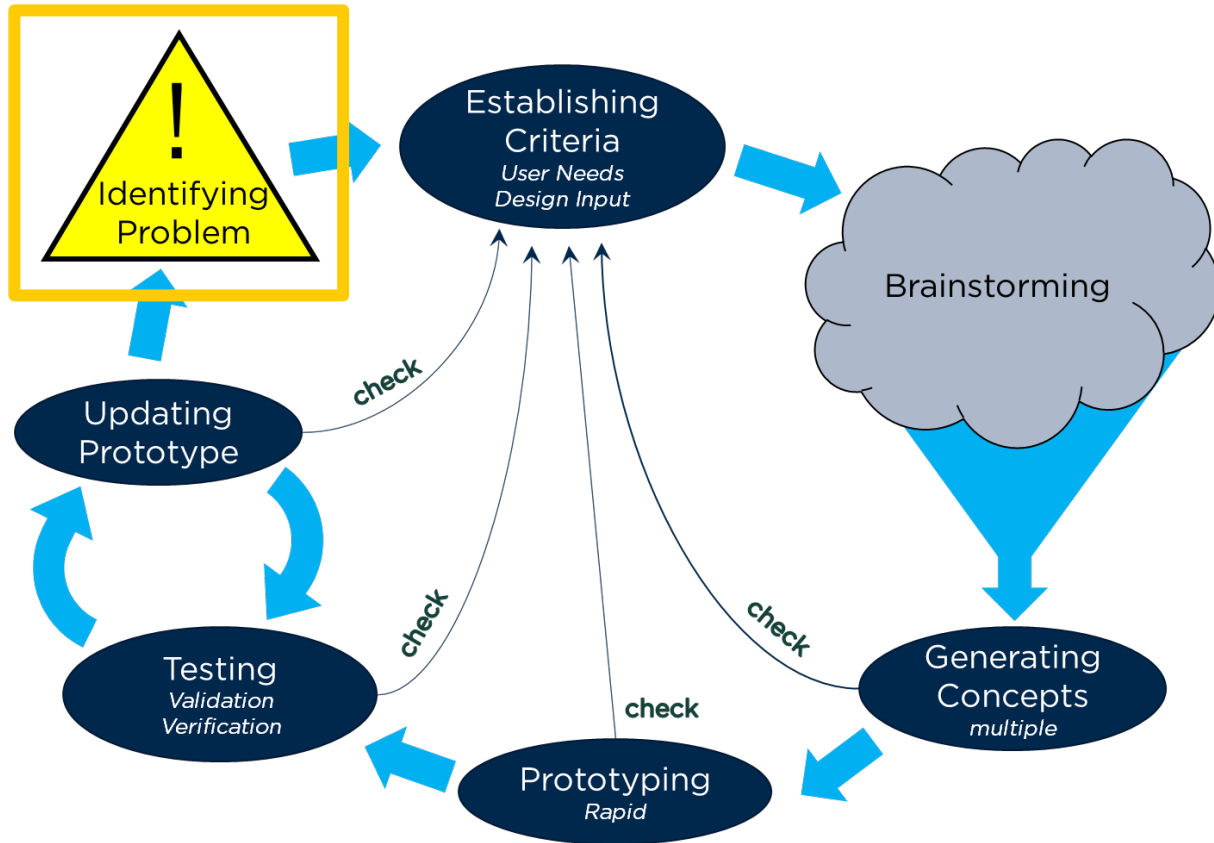
User Needs Draft: Evaluation Rubric				
Disease State Fundamentals (20%)	Excellent (typically "A" work)	Good (typically "B" work)	Fair (typically "C" work)	Needs Improvement (typically "D" work)
Content: - Definition of clinical need (i.e. disease state) - Description of scale/scope of disease (i.e. epidemiology) - Summary of patient's journey and typical treatments/outcomes - What drug or growth factors are most promising to improve patient outcomes	- Disease state is sufficiently defined for an educated outsider (e.g. not a clinician) to understand the need - Key facts about the disease and its treatment , including those related to its breadth and limitations, are presented - The pathway/experience of a patient , from the initial onset through diagnosis and treatment options, is well defined - Drugs or Growth Factors , and the healing/recovery pathway is described to highlight options for drug eluting products - Vocabulary is used which reflects a comfort with the clinical space - Citations are ample and appropriate	A few minor issues in categories such as the below: - Disease state is lacking in detail and/or does not convincingly elucidate the need - Sufficient facts and/or citations are not presented to characterize how the disease is seen from the clinical/epidemiological perspective, experienced from the patient perspective, and encountered from the clinicians' perspective - The wound healing and problem pathways are not described, and it is unclear what our future product could elute - Vocabulary demonstrates a general lack of comfort with the relevant terminology - Citations lacking or in inappropriate format	Several significant issues in categories such as the below: - Clarity and/or a few missing details of the product(s), how they work, their strengths, and/or shortcomings - Connection to the problem statement is a little unclear - Products don't fully represent the most relevant solutions in and/or outside of the field - Analysis of the gaps/opportunities are not fully convincing and/or evidence-based - Incorrect conclusions on substantial equivalence or lack of details in regulatory pathways - Citations lacking or in inappropriate format	Missing key information and/or substantial issues in categories such as the below: - Diagram either missing entirely or insufficient in extent - Claims about stakeholders present without sufficient justification/rationale - Analysis indicates overwhelming negative reaction to need being addressed without ample discussion - Analysis oversimplifies (e.g. takes "too rosy of a view") the reactions of stakeholders - Citations lacking or in inappropriate format
Existing Solutions & Regulation (20%)	- Products highlighted capture the spectrum of products / approaches available - Existing products / approaches are well described including what they are, how they work, their strengths/weaknesses - Connections are established between existing products and need statement via the identification of shortcomings - Visuals of the products effectively illustrate important aspects of said products - Products highlighted are accurately described as a predicate or not a predicate device. - Categorization of your future design (biologic, drug, device, or combination), device classification (I, II, or III) and regulatory path (510K, exempt, de novo, or PMA) are correct, clear, and thorough. - Citations are ample and appropriate	A few minor issues in categories such as the below: - Clarity and/or a few missing details of the product(s), how they work, their strengths, and/or shortcomings - Connection to the problem statement is a little unclear - Products don't fully represent the most relevant solutions in and/or outside of the field - Analysis of the gaps/opportunities are not fully convincing and/or evidence-based - Incorrect conclusions on substantial equivalence or lack of details in regulatory pathways - Citations lacking or in inappropriate format	Several significant issues in categories such as the below: - Clarity and/or a few missing details of the product(s), how they work, their strengths, and/or shortcomings - Connection to the problem statement is a little unclear - Products don't fully represent the most relevant solutions in and/or outside of the field - Analysis of the gaps/opportunities are not fully convincing and/or evidence-based - Incorrect conclusions on substantial equivalence or lack of details in regulatory pathways - Citations lacking or in inappropriate format	Missing key information and/or substantial issues in categories such as the below: - Diagram either missing entirely or insufficient in extent - Claims about stakeholders present without sufficient justification/rationale - Analysis indicates overwhelming negative reaction to need being addressed without ample discussion - Analysis oversimplifies (e.g. takes "too rosy of a view") the reactions of stakeholders - Citations lacking or in inappropriate format
Stakeholder Analysis (20%)	- Stakeholders from both cycle of care and flow of money analyses are presented are well-considered, leaving no major gaps - Analysis is balanced, conveying accurately how parties would benefit or not from the meeting of the communicated need - Chart(s) is presented which clearly indicates the connections between stakeholders and provides a visualization of their effect (e.g. by arrows, with + or -) - Citations are ample and appropriate	A few minor issues in categories such as the below: - Diagram either missing entirely or insufficient in extent - Claims about stakeholders present without sufficient justification/rationale - Analysis indicates overwhelming negative reaction to need being addressed without ample discussion - Analysis oversimplifies (e.g. takes "too rosy of a view") the reactions of stakeholders - Citations lacking or in inappropriate format	Several significant issues in categories such as the below: - Diagram either missing entirely or insufficient in extent - Claims about stakeholders present without sufficient justification/rationale - Analysis indicates overwhelming negative reaction to need being addressed without ample discussion - Analysis oversimplifies (e.g. takes "too rosy of a view") the reactions of stakeholders - Citations lacking or in inappropriate format	Missing key information and/or substantial issues in categories such as the below: - Diagram either missing entirely or insufficient in extent - Claims about stakeholders present without sufficient justification/rationale - Analysis indicates overwhelming negative reaction to need being addressed without ample discussion - Analysis oversimplifies (e.g. takes "too rosy of a view") the reactions of stakeholders - Citations lacking or in inappropriate format
Market Analysis (20%)	- TAM/SAM/SOM are justified with written rationale for their calculations - Graphics are appropriately presented which highlight both the general dynamics of the TAM and also the breakdown of the TAM/SAM/SOM - Major players are identified along with example offerings (linked to existing solution analysis above) and a breakdown of the relative dominance/party in the market - Justifications for split from Total to Available to Obtainable are reasonable and based on team's choice of selling to or competing with major players - Citations are ample and appropriate	A few minor issues in categories such as the below: - Graphics missing entirely or do not effectively communicate market dynamics - Approach to TAM/SAM/SOM lacking in justification or quantification - Missing market players and/or lacking information about their relative share of the market - Errors or missing expansion on the suitability of the market for a product with relation to the key players and future dynamics - Citations lacking or in inappropriate format	Several significant issues in categories such as the below: - Graphics missing entirely or do not effectively communicate market dynamics - Approach to TAM/SAM/SOM lacking in justification or quantification - Missing market players and/or lacking information about their relative share of the market - Errors or missing expansion on the suitability of the market for a product with relation to the key players and future dynamics - Citations lacking or in inappropriate format	Missing key information and/or substantial issues in categories such as the below: - Graphics missing entirely or do not effectively communicate market dynamics - Approach to TAM/SAM/SOM lacking in justification or quantification - Missing market players and/or lacking information about their relative share of the market - Errors or missing expansion on the suitability of the market for a product with relation to the key players and future dynamics - Citations lacking or in inappropriate format
Summary (20%)	- An overall summary that supports the Problem, Population, and Outcome to be seen in the Need Statement, which effectively establishes the design space --- summary quickly states the Problem, who is impacted/stakes of the Problem, and is backed by appropriate statistics, pulled from earlier sections of the report - Need statement is concise, well-scoped, and actionable --- Superseding needs, if present, are noted along with a discussion of the likelihood that they will be addressed by other parties - After the initial needs are defined, the scope is defined considering the constraints from VMO (bypass graft or hip implant)	A few minor issues in categories such as the below: - Lacking clarity, accuracy, and/or completeness of the problem description, existing solutions summary, or need - Impact/magnitude is not quantified but is qualitatively described (or not described at all) - Problem narrative and/or framing is somewhat unconvincing, missing some supporting evidence from the four categories presented in class - Need statement is not concise and/or introduces new information not supported by the problem - Need statement is solution biased - Scope does not match what VMO has asked the team to focus on, without compelling argument to do so	Several significant issues in categories such as the below: - Lacking clarity, accuracy, and/or completeness of the problem description, existing solutions summary, or need - Impact/magnitude is not quantified but is qualitatively described (or not described at all) - Problem narrative and/or framing is somewhat unconvincing, missing some supporting evidence from the four categories presented in class - Need statement is not concise and/or introduces new information not supported by the problem - Need statement is solution biased - Scope does not match what VMO has asked the team to focus on, without compelling argument to do so	Missing key information and/or substantial issues in categories such as the below: - Lacking clarity, accuracy, and/or completeness of the problem description, existing solutions summary, or need - Impact/magnitude is not quantified but is qualitatively described (or not described at all) - Problem narrative and/or framing is somewhat unconvincing, missing some supporting evidence from the four categories presented in class - Need statement is not concise and/or introduces new information not supported by the problem - Need statement is solution biased - Scope does not match what VMO has asked the team to focus on, without compelling argument to do so
REMINDER: Logistics (up to 10% deduction if not correct)	See assignment description	A few minor issues	Several significant issues	Missing and/or substantial issues
Font, font size, spacing, margins, page numbers, and word limits				

User Needs Draft: Evaluation Rubric				
Disease State Fundamentals (20%)	Excellent (typically "A" work)	Good (typically "B" work)	Fair (typically "C" work)	Needs Improvement (typically "D" work)
Content: - Definition of clinical need (i.e. disease state) - Description of scale/scope of disease (i.e. epidemiology) - Summary of patient's journey and typical treatments/outcomes - What drug or growth factors are most promising to improve patient outcomes	- Disease state is sufficiently defined for an educated outsider (e.g. not a clinician) to understand the need - Key facts about the disease and its treatment , including those related to its breadth and limitations, are presented - The pathway/experience of a patient , from the initial onset through diagnosis and treatment options, is well defined - Drugs or Growth Factors , and the healing/recovery pathway is described to highlight options for drug eluting products - Vocabulary is used which reflects a comfort with the clinical space - Citations are ample and appropriate	A few minor issues in categories such as the below: - Disease state is lacking in detail and/or does not convincingly elucidate the need - Sufficient facts and/or citations are not presented to characterize how the disease is seen from the clinical/epidemiological perspective, experienced from the patient perspective, and encountered from the clinicians' perspective - The wound healing and problem pathways are not described, and it is unclear what our future product could elute - Vocabulary demonstrates a general lack of comfort with the relevant terminology - Citations lacking or in inappropriate format	Several significant issues in categories such as the below: - Disease state is lacking in detail and/or does not convincingly elucidate the need - Sufficient facts and/or citations are not presented to characterize how the disease is seen from the clinical/epidemiological perspective, experienced from the patient perspective, and encountered from the clinicians' perspective - The wound healing and problem pathways are not described, and it is unclear what our future product could elute - Vocabulary demonstrates a general lack of comfort with the relevant terminology - Citations lacking or in inappropriate format	Missing key information and/or substantial issues in categories such as the below: - Disease state is lacking in detail and/or does not convincingly elucidate the need - Sufficient facts and/or citations are not presented to characterize how the disease is seen from the clinical/epidemiological perspective, experienced from the patient perspective, and encountered from the clinicians' perspective - The wound healing and problem pathways are not described, and it is unclear what our future product could elute - Vocabulary demonstrates a general lack of comfort with the relevant terminology - Citations lacking or in inappropriate format
Existing Solutions & Regulation (20%)				
Content: - Description of product(s) which are either currently used or fulfill a similar function in another field - Visuals of the products - Explanation of the products' shortcomings - Analysis of the gaps and opportunities for an innovation - Discussion of the suitability of any product as substantially equivalent (ie. predicate device or not) - Discussion of regulatory path, including device classification	- Products highlighted capture the spectrum of products / approaches available - Existing products / approaches are well described including what they are, how they work, their strengths/weaknesses - Connections are established between existing products and need statement via the identification of shortcomings - Visuals of the products effectively illustrate important aspects of said products - Products highlighted are accurately described as a predicate or not a predicate device. - Categorization of your future design (biologic, drug, device, or combination), device classification (I, II, or III) and regulatory path (510K, exempt, de novo, or PMA) are correct, clear, and thorough. - Citations are ample and appropriate	A few minor issues in categories such as the below: - Clarity and/or a few missing details of the product(s), how they work, their strengths, and/or shortcomings - Connection to the problem statement is a little unclear - Products don't fully represent the most relevant solutions in and/or outside of the field - Analysis of the gaps/opportunities are not fully convincing and/or evidence-based - Incorrect conclusions on substantial equivalence or lack of details in regulatory pathways - Citations lacking or in inappropriate format	Several significant issues in categories such as the below: - Clarity and/or a few missing details of the product(s), how they work, their strengths, and/or shortcomings - Connection to the problem statement is a little unclear - Products don't fully represent the most relevant solutions in and/or outside of the field - Analysis of the gaps/opportunities are not fully convincing and/or evidence-based - Incorrect conclusions on substantial equivalence or lack of details in regulatory pathways - Citations lacking or in inappropriate format	Missing key information and/or substantial issues in categories such as the below: - Clarity and/or a few missing details of the product(s), how they work, their strengths, and/or shortcomings - Connection to the problem statement is a little unclear - Products don't fully represent the most relevant solutions in and/or outside of the field - Analysis of the gaps/opportunities are not fully convincing and/or evidence-based - Incorrect conclusions on substantial equivalence or lack of details in regulatory pathways - Citations lacking or in inappropriate format

Stakeholder Analysis (20%)				
<p>Content:</p> <ul style="list-style-type: none"> - Written summaries of positive and negative impact for each stakeholder identified, using both cycle of care and the flow of money analysis - Graphical representation of your findings (e.g. flowchart with stakeholders as nodes and indicators of positive/negative effects.) 	<ul style="list-style-type: none"> - Stakeholders from both cycle of care and flow of money analyses are presented are well-considered, leaving no major gaps - Analysis is balanced, conveying accurately how parties would benefit or not from the meeting of the communicated need - Chart(s) is presented which clearly indicates the connections between stakeholders and provides a visualization of their effect (e.g. by arrows, with + or -) - Citations are ample and appropriate 	<p>A few minor issues in categories such as the below:</p> <ul style="list-style-type: none"> - Diagram either missing entirely or insufficient in extent - Claims about stakeholders present without sufficient justification/rationale - Analysis indicates overwhelming negative reaction to need being addressed without ample discussion - Analysis oversimplifies (e.g. takes "too rosy of a view") the reactions of stakeholders - Citations lacking or in inappropriate format 	<p>Several significant issues in categories such as the below:</p>	<p>Missing key information and/or substantial issues in categories such as the below:</p>
Market Analysis (20%)				
<p>Content:</p> <ul style="list-style-type: none"> - Analyze the properties (size, growth, and dynamics) of the market (TAM) --- Include a graphic of the market dynamics - Identify the target market (Population), separating into Total Available Market, Serviceable Available Market, and Serviceable Obtainable Market (TAM, SAM, SOM) --- Include a graphic of TAM, SAM, and SOM - Describe who you expect to compete with for market share, as justification for your SOM from the identified SAM 	<ul style="list-style-type: none"> - TAM/SAM/SOM are justified with written rationale for their calculations - Graphics are appropriately presented which highlight both the general dynamics of the TAM and also the breakdown of the TAM/SAM/SOM - Major players are identified along with example offerings (linked to existing solution analysis above) and a breakdown of the relative dominance/parity in the market - Justifications for split from Total to Available to Obtainable are reasonable and based on team's choice of selling to or competing with major players - Citations are ample and appropriate 	<p>A few minor issues in categories such as the below:</p> <ul style="list-style-type: none"> - Graphics missing entirely or do not effectively communicate market dynamics - Approach to TAM/SAM/SOM lacking in justification or quantification - Missing market players and/or lacking information about their relative share of the market - Errors or missing expansion on the suitability of the market for a product with relation to the key players and future dynamics - Citations lacking or in inappropriate format 	<p>Several significant issues in categories such as the below:</p>	<p>Missing key information and/or substantial issues in categories such as the below:</p>

Summary (20%)				
Content: - Who is impacted, magnitude of the problem (Population) - Description of the current situation and difficulties (Problem) - Summary of existing solutions and their limitations (Outcome) - Need statement - Scope/constraints imposed by VMO	- An overall summary that supports the Problem, Population, and Outcome to be seen in the Need Statement, which effectively establishes the design space --- summary quickly states the Problem, who is impacted/stakes of the Problem, and is backed by appropriate statistics, pulled from earlier sections of the report - Need statement is concise, well-scoped, and actionable --- Superseding needs, if present, are noted along with a discussion of the likelihood that they will be addressed by other parties - After the initial needs are defined, the scope is defined considering the constraints from VMO (bypass graft or hip implant)	A few minor issues in categories such as the below:	Several significant issues in categories such as the below:	Missing key information and/or substantial issues in categories such as the below:
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REMINDER: Logistics (up to 10% deduction if not correct)				
Font, font size, spacing, margins, page numbers, and word limits	See assignment description	A few minor issues	Several significant issues	Missing and/or substantial issues

Time to start researching!



Clinical Needs Finding

- VMO executives have handled this for you!
- Your projects have been narrowed to two design spaces!
 - Hip Implant + growth factors for osseointegration
 - Drug eluting bypass

HOWEVER, we need to **back up a step** and define the
PROBLEM to understand the NEED

Problem vs. Need

Problem – Current situation, who is involved, and the associated doubt, difficulty, or uncertainty

Need – CHANGE in outcome required to address a problem and who would benefit

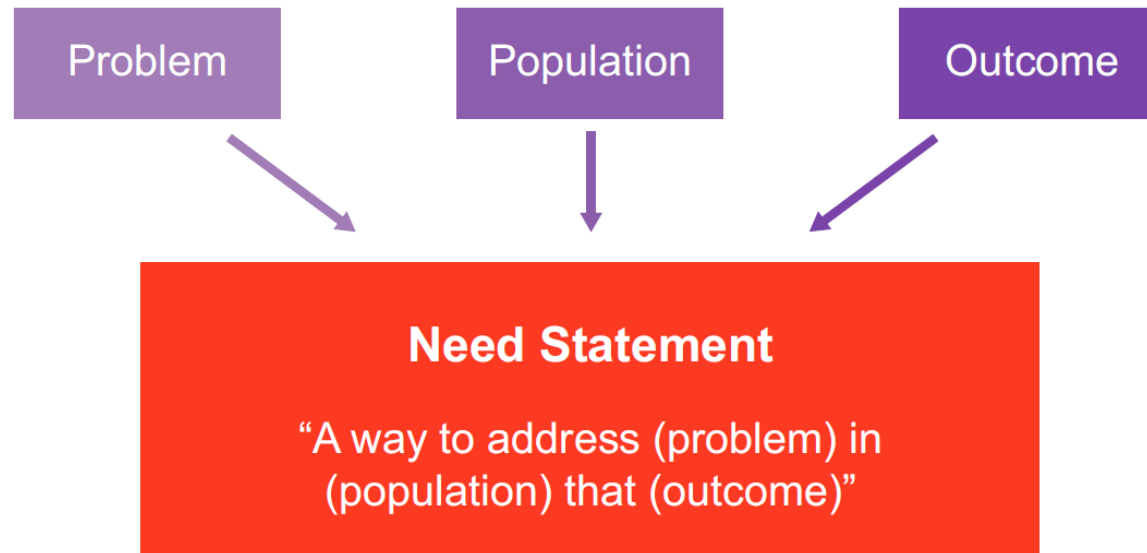


FIGURE 1.3.1

An effective need statement typically includes three essential components.

Problems

Dr. Mays'
vs.

Needs

Hungry
No parking
Lactose intolerant



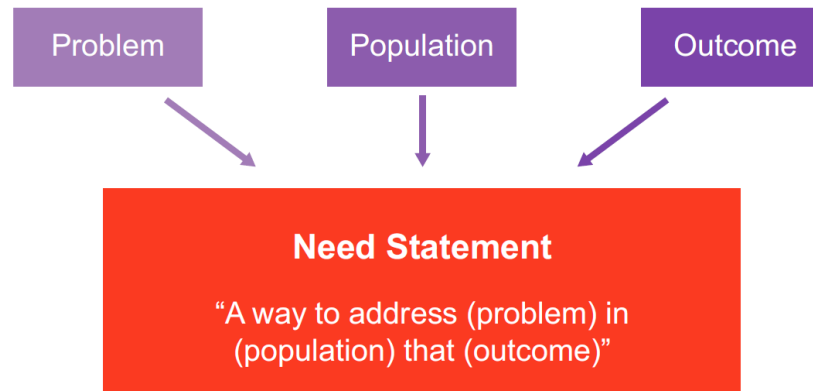
To not be hangry
To be on time for Lecture
My mocha latte

A way to address the **hunger** of **Dr. Mays** so that **no one is subjected to hanger**

A way to address the **no parking** situation of **Dr. Mays** so that they are **on time for Lecture**

A way to allow a **lactose intolerant individual** to **consume a mocha latte** without **adverse effect**

Do you know
exactly what the
solution is to
these problems?







Pitfall	 Problematic Example	 Improved Example
NEED IS TOO GENERAL	<p><i>A way to improve outcome of spine surgery</i></p> <ul style="list-style-type: none">● Not clear which surgery, initial diagnosis, or how to improve	<p><i>A way to reduce risk of re-herniation after lumbar discectomy for sciatica to reduce re-operation</i></p> <ul style="list-style-type: none">● Clear about procedure, diagnosis, and complication
NEED IS TOO SPECIFIC	<p><i>A way to treat bifurcation lesions in the left main coronary artery to reduce recurrence rates</i></p> <ul style="list-style-type: none">● No reason to limit to this population—many patients have bifurcation lesions in other main coronary vessels	<p><i>A way to treat coronary bifurcation lesions to reduce recurrence rates</i></p> <ul style="list-style-type: none">● Increases the patient population at least several-fold● Likely that same solution will work across all types/patients

FIGURE 1.3.3
Potential pitfalls in writing needs statements.



Pitfall



Problematic Example



Improved Example

NEED IS STUCK IN
CURRENT PRACTICE

A way to close sternotomy without risk of sternal-wire breaking

- Focuses on sternal-wire; closes out other approaches
- Focuses on part of procedure that doesn't deliver result

A way to close a sternotomy following CABG quickly and securely that reduces wound dehiscence

- No reference to current solution, targets procedure goal

NEED HAS AN EMBEDDED
SOLUTION

A way to ultrasonically weld suture in surgery

- Completely limits to one approach

A way to secure an aortic valve prosthesis with minimal or no on-pump time to reduce cognitive dysfunction after surgery

- Identifies specific procedure and problem while leaving solution open

NEED IS BUILT ON A NEGATIVE

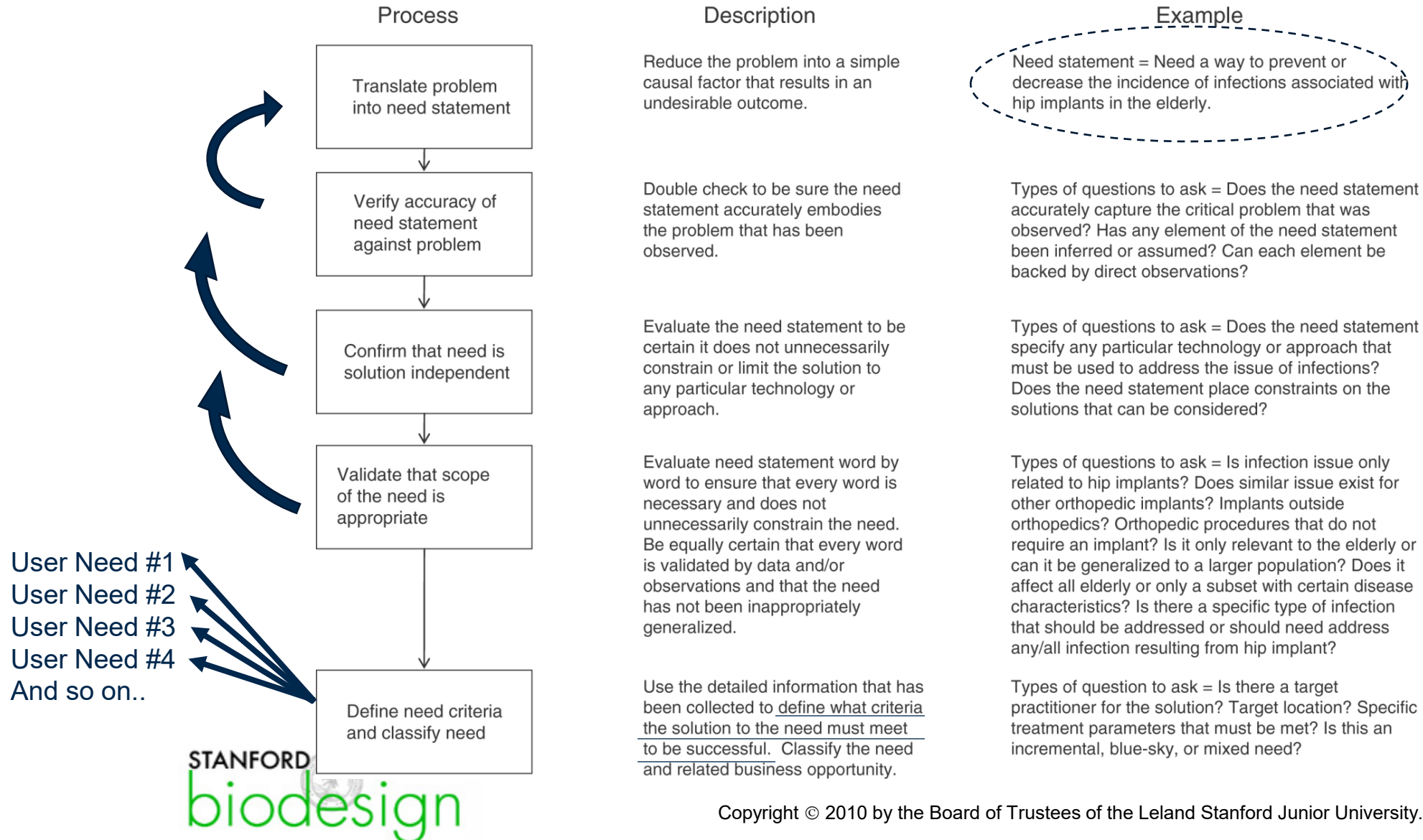
A way to not have infections related to dialysis catheters

- Focuses negatively on one specific issue of one solution

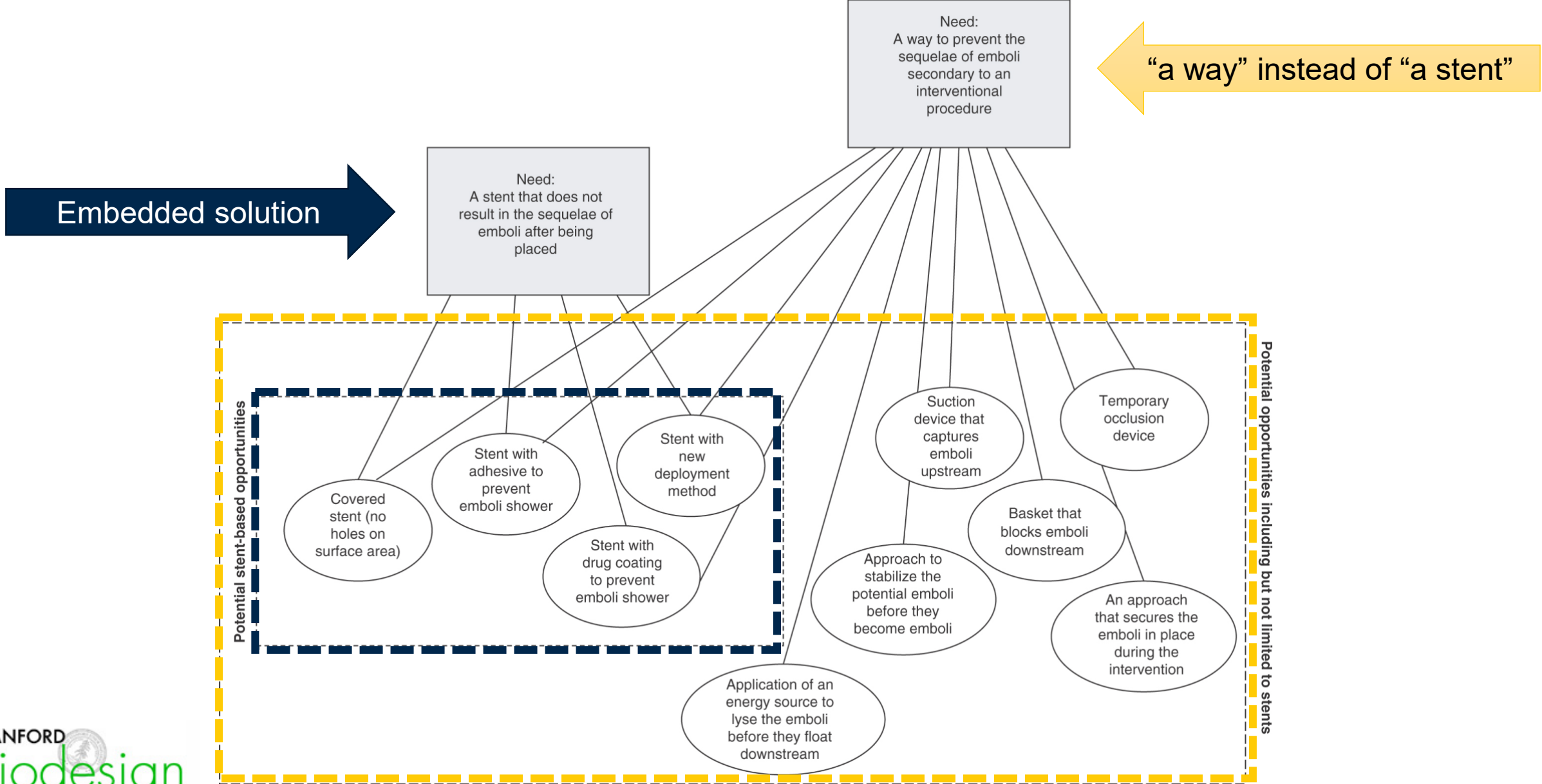
A way to provide long-term, high-flow vascular access for hemodialysis with reduced risk of infection

- Not so negative; focuses on the goal of dialysis catheters rather than the specific solution and is therefore less limited

Creating a Needs statement is an iterative process



Embedded solutions close out potential solutions!



Superseding Needs, if addressed, solve your downstream Need

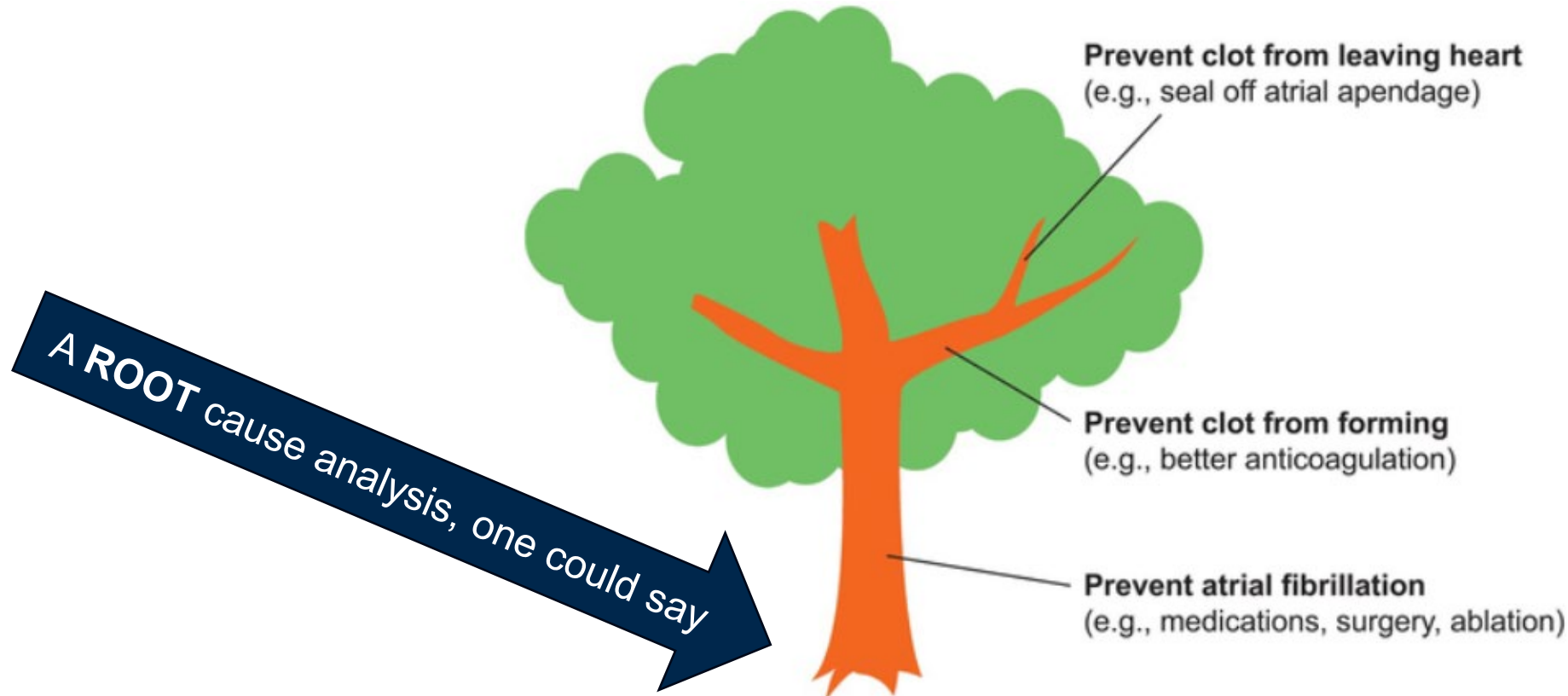


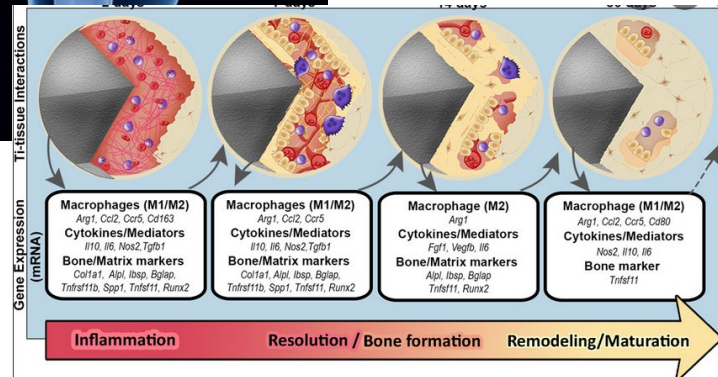
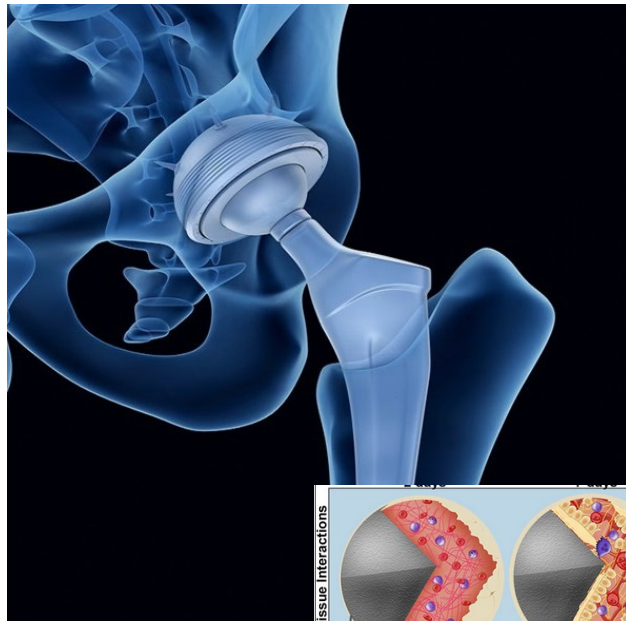
Figure 1.3.2 An example of superseding needs and related solutions.

The closer the need is to the underlying mechanism, the less likely you'll have a superseding need

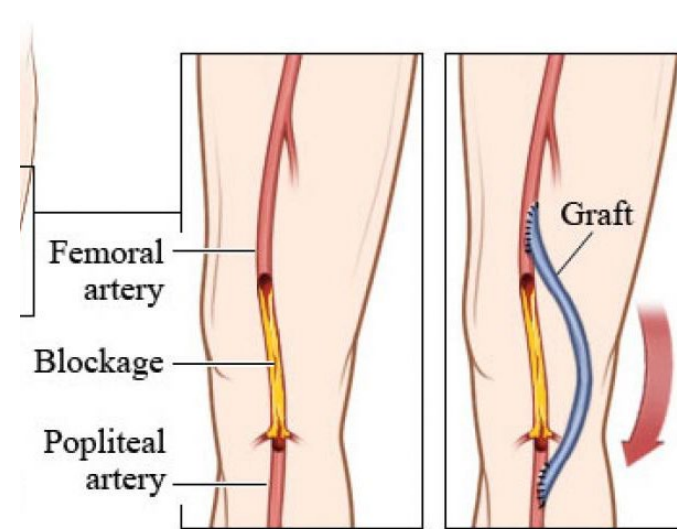


Even if you know your endgoal, still write a needs statement without solution bias

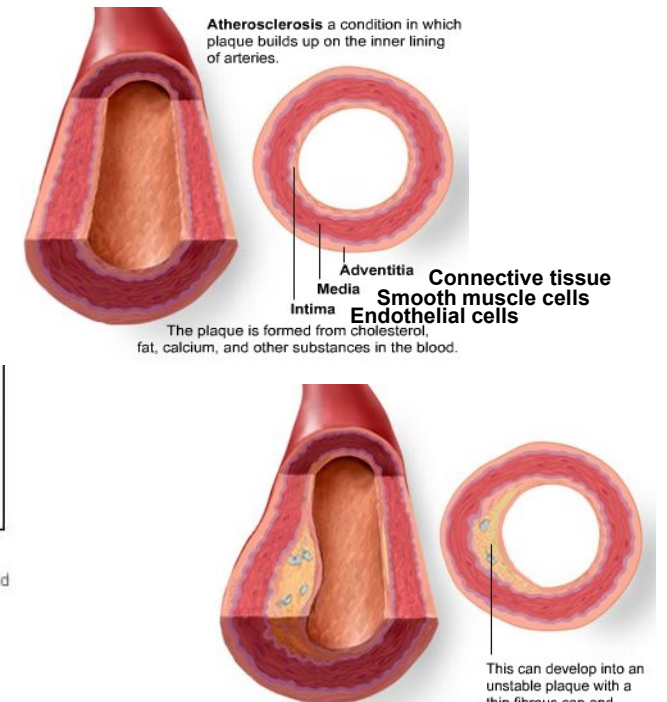
Hip Implant with Growth Factors



Drug Eluting Bypass Graft

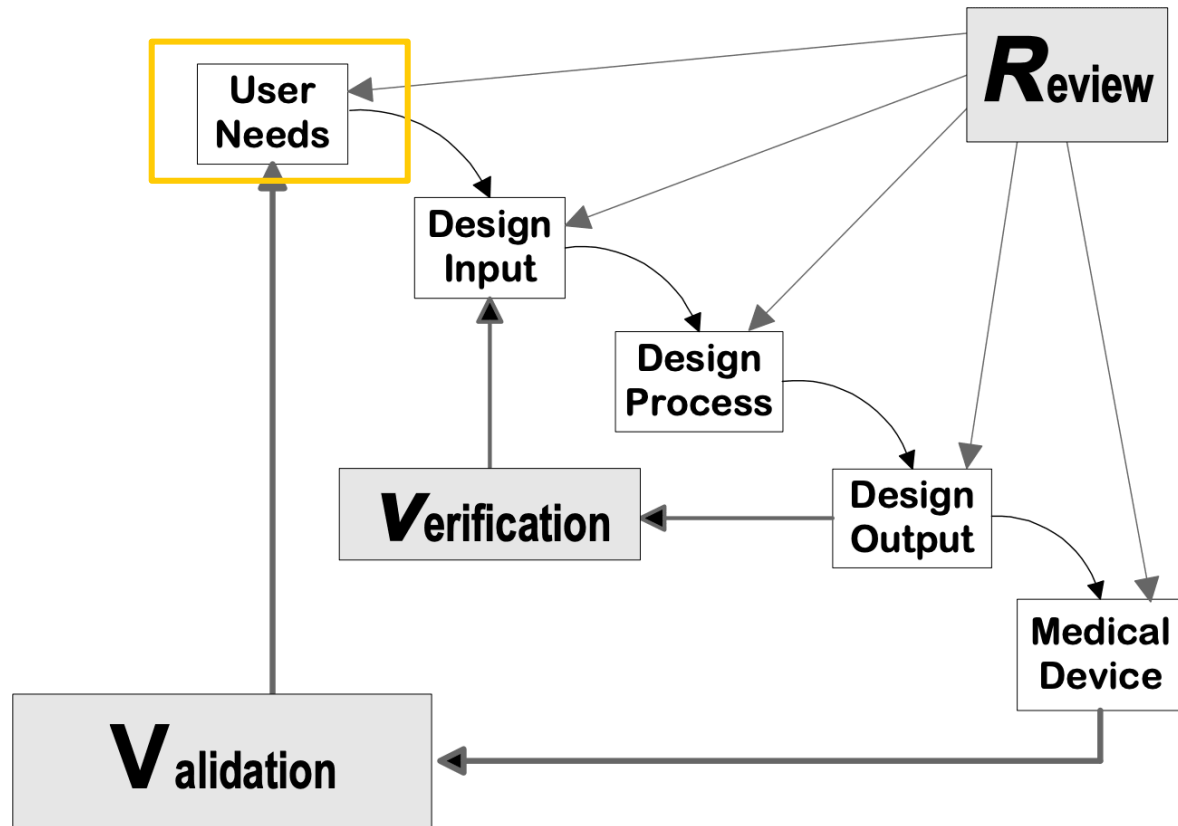


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Mayo Clinic Staff -
<https://www.mayoclinic.org/tests-procedures/coronary-bypass-surgery/about/pac-20384589>

Defining the **P**roblem to get the **U**ser **N**eeds



- **Population:** *Who* is affected by *what*?
 - How many people annually in the US?
 - How much money is spent annually on the problem?
- What are the current devices/approaches?
 - How much market share does each option own?
- Are there **problems** with the current options?
 - Do all options do functionally the same thing?
 - Are there any unique functions that only one option has?
 - *What desired **outcome** isn't happening?*
 - And ***what needs to occur** to get **that outcome***

How do YOU get to the Needs statement?

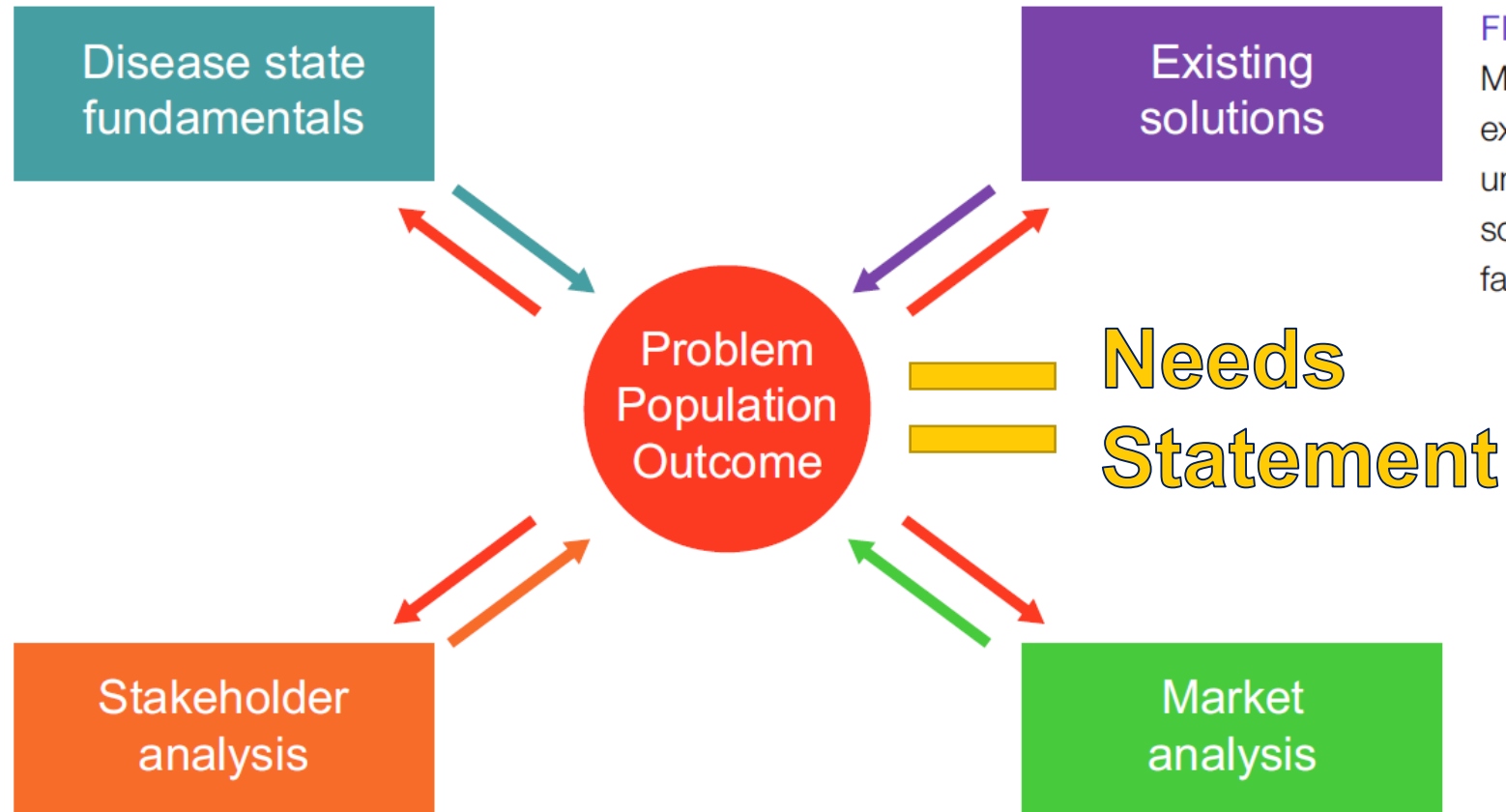


FIGURE 1.2.2

Maximizing the value of needs exploration requires a fundamental understanding of disease, existing solutions, stakeholder, and market factors.

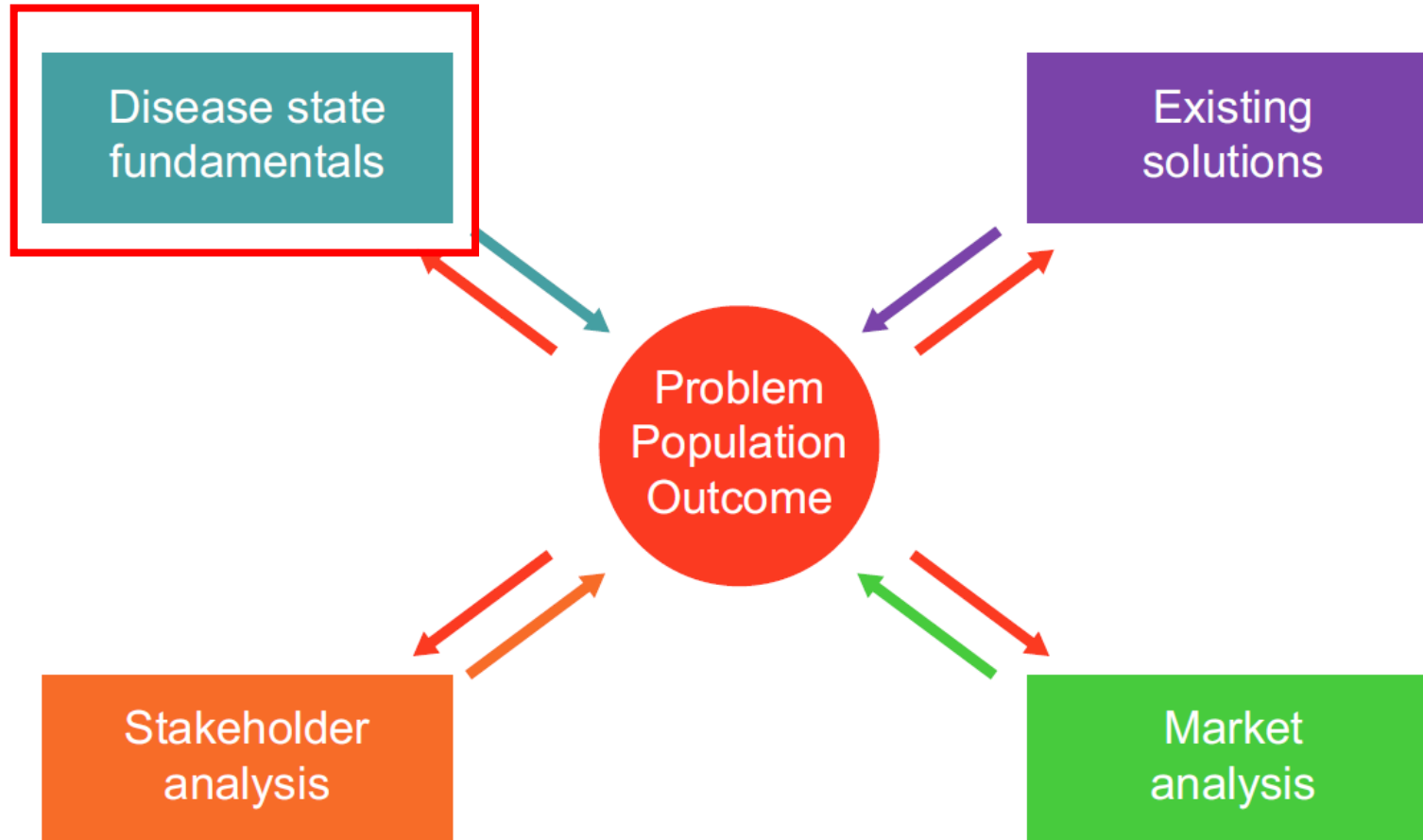


FIGURE 1.2.2

Maximizing the value of needs exploration requires a fundamental understanding of disease, existing solutions, stakeholder, and market factors.

Start your Literature search BIG!

Broad terms / Biological fundamentals

Mayo Clinic, Wikipedia, Textbooks

Hip and bone? Immune systems? Arteries and veins?

Atherosclerosis? Aseptic Loosening?

(find better keywords and papers)

Use Review Papers to narrow in on finer details

Broad terms / Biological fundamentals

Mayo Clinic, Wikipedia, Textbooks

Hip and bone? Immune systems? Arteries and veins?

Atherosclerosis? Aseptic Loosening?

(find better keywords and papers)

Deeper dive on biological details

PubMed, Scopus, Web of Science

Current treatment? Therapeutics?

REVIEW PAPERS

Some general key words for broad learning

Broad terms / Biological fundamentals

Mayo Clinic, Wikipedia, Textbooks

Hip and bone? Immune systems? Arteries and veins?

Atherosclerosis? Aseptic Loosening?

(find better keywords and papers)

Table 2.1.1 *Six key areas of disease state analysis.*

Focus area	Description
Epidemiology	Describes the causes, distribution, and control of disease in the population. ⁹
Anatomy and physiology	Describes the normal anatomy and/or function of the organ system, which may include various organs or areas of the body affected by the need.
Pathophysiology	Describes the disturbance of normal anatomy and physiology caused by a disease or other underlying physical, mechanical, electrical, or biochemical abnormality.
Clinical presentation	Profiles the patient state and clinical status associated with a disease. These include the symptoms (what the patient feels and experiences) and signs of the disease (what one might find on a clinical exam or with lab testing).
Clinical outcomes	Profiles the most common outcomes experienced by patients as a result of having the disease.
Economic impact	Outlines the cost of the disease to the healthcare system.

Project Specific Keywords for broad learning

Broad terms / Biological fundamentals

Mayo Clinic, Wikipedia, Textbooks

Hip and bone? Immune systems? Arteries and veins?

Atherosclerosis? Aseptic Loosening?

(find better keywords and papers)

Hip Keywords

Osteoarthritis
Growth Factors
Hip Implant
Osseointegration
Aseptic Loosening
Bone healing
Wound healing

Bypass Keywords

PAD	Vascular grafts
Grafts	Stenosis
Restenosis	Angioplasty
Thrombosis	Atherosclerosis
Infection	
Atherosclerosis	
Autografts	

Review papers for what you could be eluting

Broad terms / Biological fundamentals

Mayo Clinic, Wikipedia, Textbooks

Hip and bone? Immune systems? Arteries and veins?

Atherosclerosis? Aseptic Loosening?

(find better keywords and papers)

Deeper dive on biological details

PubMed, Scopus, Web of Science

Current treatment? Therapeutics?

REVIEW PAPERS

More Hip Keywords

Bone growth hormones

Bone growth factors

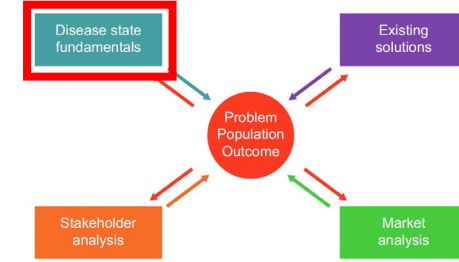
Anti-inflammatory factors

More Bypass Keywords

Hormones

Cytokines

Anti-restenosis Drugs



How to “read” a scientific paper**

1. Title
2. Abstract
 - a) If looks promising → MGetIt
3. Figures (Results)
 - a) If need background info – Intro instead
4. Conclusion
5. If paper looks good, go back for:
 - a) Introduction
 - b) Methods
 - c) Results text
 - d) Conclusion

Skim paper for importance

Dive down only as far as you need to
(and take notes!)

Once importance is determined,
THEN

Deep dive of paper!
Confirm your understanding
Be ready to summarize and combine with
other sources for your writing

** This is the order and method that works for me, you may find another way works better for you. HOWEVER, being able to skim for importance is a worthwhile skill!

Which specific growth factors or drugs is most promising

Broad terms / Biological fundamentals

Mayo Clinic, Wikipedia, Textbooks

Hip and bone? Immune systems? Arteries and veins?

Atherosclerosis? Aseptic Loosening?

(find better keywords and papers)

Deeper dive on biological details

PubMed, Scopus, Web of Science

Current treatment? Therapeutics?

REVIEW PAPERS

Specifics!

Which proteins? Which growth factors?

Which anti inflammatory drugs?

Successes in literature?

Primary Sources are best!!!!
Avoid the reference game of telephone!!!

How to actually *DO* a literature search?

After the break



Using the U-M Library Resources

August 27, 2025

BME 350 - Introduction to Biomedical Engineering Design
Luesoni Kuck / Biomedical Engineering Librarian

 LIBRARY

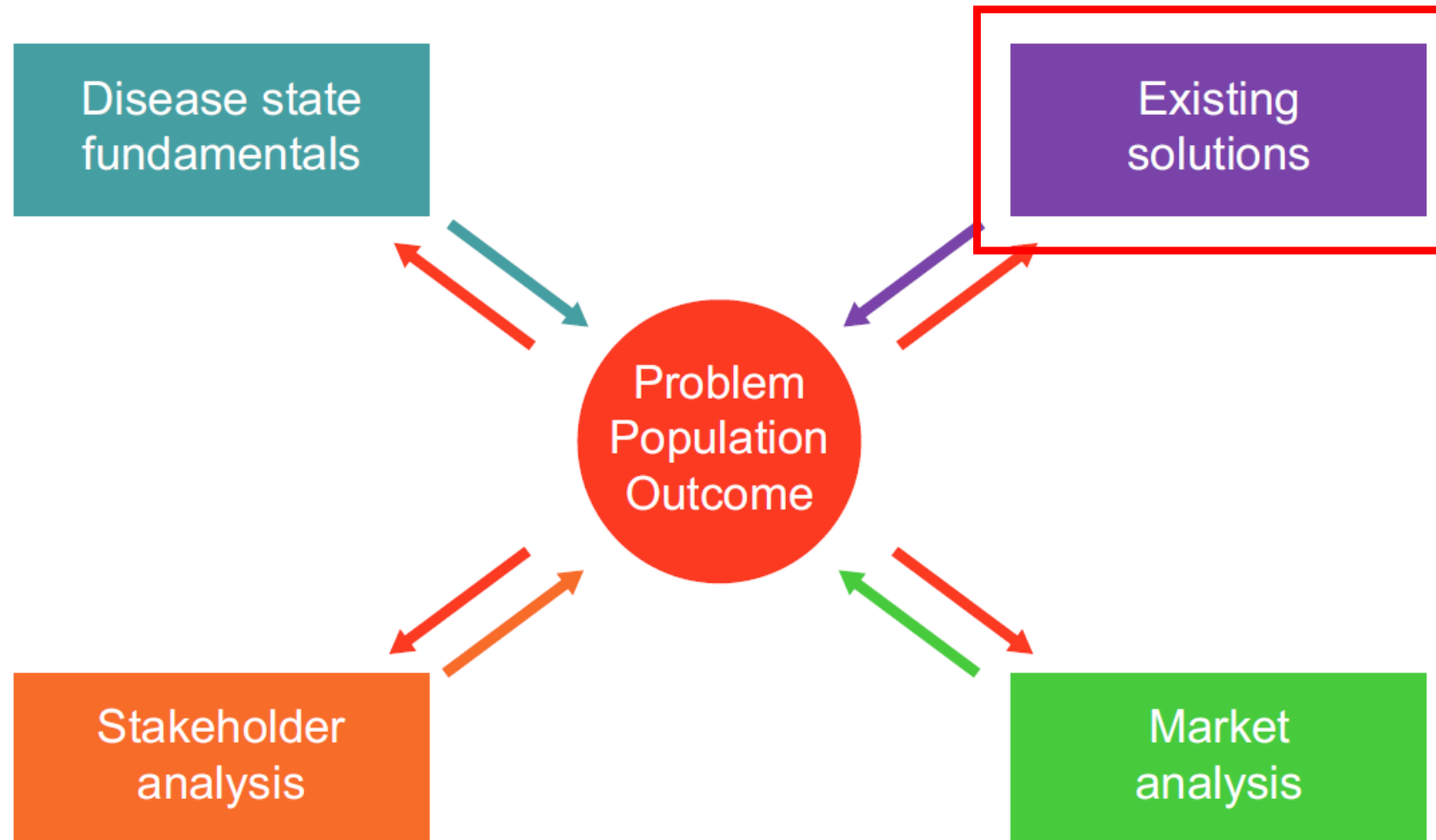


FIGURE 1.2.2

Maximizing the value of needs exploration requires a fundamental understanding of disease, existing solutions, stakeholder, and market factors.

Existing Solutions

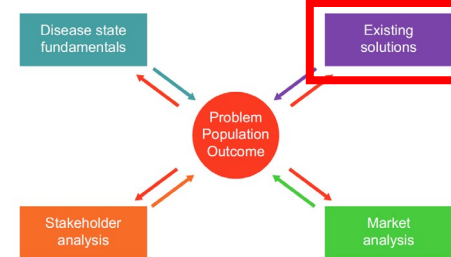
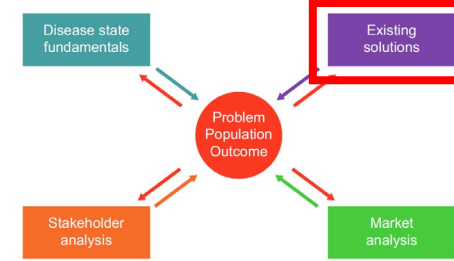


Table 2.2.1 *Be careful not to overlook any solution types when researching existing solutions.*

Type of solution	Description
Diagnostics	Determination of whether (and to what extent) patients are affected by a given condition.
Behavioral and lifestyle treatments	Patient-driven solutions such as modifying one's diet and exercise.
Pharmacologic or biologic treatments	Chemical or biologic agents; usually injected or orally delivered.
Percutaneous treatments	Therapies administered via a catheter.
Minimally invasive treatments	Procedures performed using small incisions (e.g., laparoscopic procedures to access the abdomen or a joint; pacemaker placement).
Open surgery	Procedures that require the surgeon to cut larger areas of skin and tissues to gain direct access to the structures or organs involved.
Services	Human-centered interventions such as physical therapy and respiratory therapy.
Disease management	Products or services to monitor a patient's condition and guide therapy.



FDA Database

- [Product Classification](#)
- [510\(k\) Premarket not](#)
- [Premarket Approval](#)
- Search, pick a device

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the subject Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology MR Labeling 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

Contact Person: Caleb Barylski
Specialist, Regulatory Affairs
Telephone: (574-371-0250)
Caleb.Barylski@zimmerbiomet.com

Date: 08-Nov-2018

Subject Device: **Trade Name:** Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology MR Labeling
Common Name: Hip Prosthesis

Classification Name:

- LPH - Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)
- LWJ - Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (21 CFR 888.3360)
- LZO - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented (21 CFR 888.3353)
- MEH - Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate (21 CFR 888.3353)

Predicate Device(s):

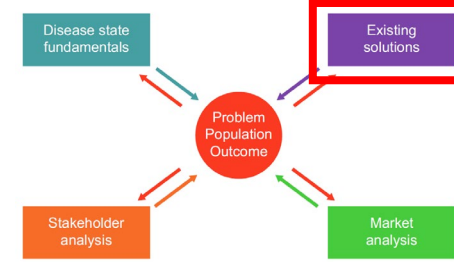
	Zimmer, Inc.
K063251	Zimmer M/L Taper Hip Prosthesis With Modular Neck Technology
K071856	Zimmer M/L Taper Hip Prosthesis With Kinectiv Technology System, Model(S) 7848 Series(Modular Necks), 7713 Series
K081007	Zimmer M/L Taper Hip Prosthesis With Kinectiv Technology System

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

iritis, polyarthritis, collagen
ie femur; congenital hip dysplasia,
he affected extremity and acute

nt is contraindicated; irreducible
res and comminuted femoral neck
is of the femoral head; pathological
y affected.

Datasheets and Patents



- Product Websites
 - Ie. Depuy
 - More sensationalized
 - Dig past sales brochures
 - Might find:
 - Specification sheet
 - Technical Datasheet
 - User Manual
- FDA databases
 - Summaries!

Strategies for Searching for Patents

- Patent searching is **complex and time consuming**. Plan on spending a few hours learning the search process and additional hours searching and evaluating results.
- You will need to **document your search**. Keep careful records of which patent databases you search, what keywords and classification numbers you search in the databases, document numbers of the patent and application documents that you retrieve and examine, and the date and time of your search.
- **Keyword searching alone is never enough**. A comprehensive patent search requires that you search by classification and sub-classification numbers.

Databases to Search for Patents

TOP PATENT DATABASE

- [European Patent Office \(Espacenet database\)](#)
Search for European, US, Japanese and other worldwide patents.

OTHER PATENT DATABASES

- [Derwent Innovations Index](#) [↗](#)
Facilitates rapid, precise patent searching and merges the value-added patent information from Derwent World Patents Index with the patent citation information from Derwent Patent Citation Index.
- [InnovationQ Plus](#) [↗](#)
An intellectual property analytics tool used for researching patents, patent applications, and prior art.
- [Patent Public Search](#)
United States Patent & Trademark Office database that covers U.S. patents issued from 1790 to the most recent weekly issue date.
- [Google Patents](#)
Covers patents and applications from USPTO, EPO, WIPO, DPMA, CIPO and SIPO.



Document Library
Technical Data Sheet 16400;
16396; 16398; 16399

Public

Rev:1

Effective: 07/21/2006

Status: Active

3M™ PPS™ SUN GUN (Color Matching Light)

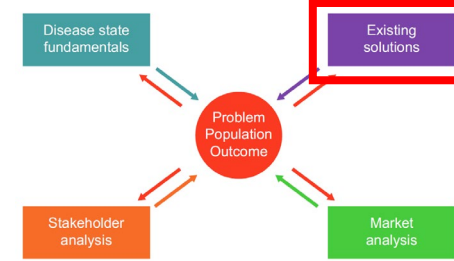
Data Sheet

3M Part No.(s)	3M Part Descriptor(s)
16400	3M™PPS™ SUN GUN (Color Matching Light) - Kit
16396	3M™PPS™ SUN GUN (Color Matching Light) Battery Charger & Power
16398	Supply
16399	3M™PPS™ SUN GUN (Color Matching Light) NiCD Battery
	3M™PPS™ SUN GUN (Color Matching Light) Coor Correction Bulb

3M Fax on Demand Identification Number : 16400

Description

3M™PPS™ SUN GUN (Color Matching Light) with NiCD Battery , Charger & Power Supply.



Features, Advantages, Benefits

Features

Light source that replicates natural sunlight.
Compliant with the European RoHS directive and WEEE global environmental regulations.

Advantages

Choosing the correct variant or alternate color chip (Begin with the correct paint formula)

Benefits

Reduces the chance of costly re-work or comebacks related to color mismatch, lack of coverage, metallic layout, pre-paint and post paint imperfections due to inadequate shop lighting.

Typical Physical Properties

Light Intensity, Lux (Normal Mode)	1300 - 2100 lux	12 volt
Light Intensity, Lux (Turbo Mode)	> 2100 Lux	14.4 volt
Spectral Output of Bulb (Percentage of light vs. Natrual Daylight)	99.35% CRI (Color Rendering Index)	
Bulb Color Temperature Rating	4700 Kelvin	
Beam Angle	36 degrees	

Example datasheet with specifications

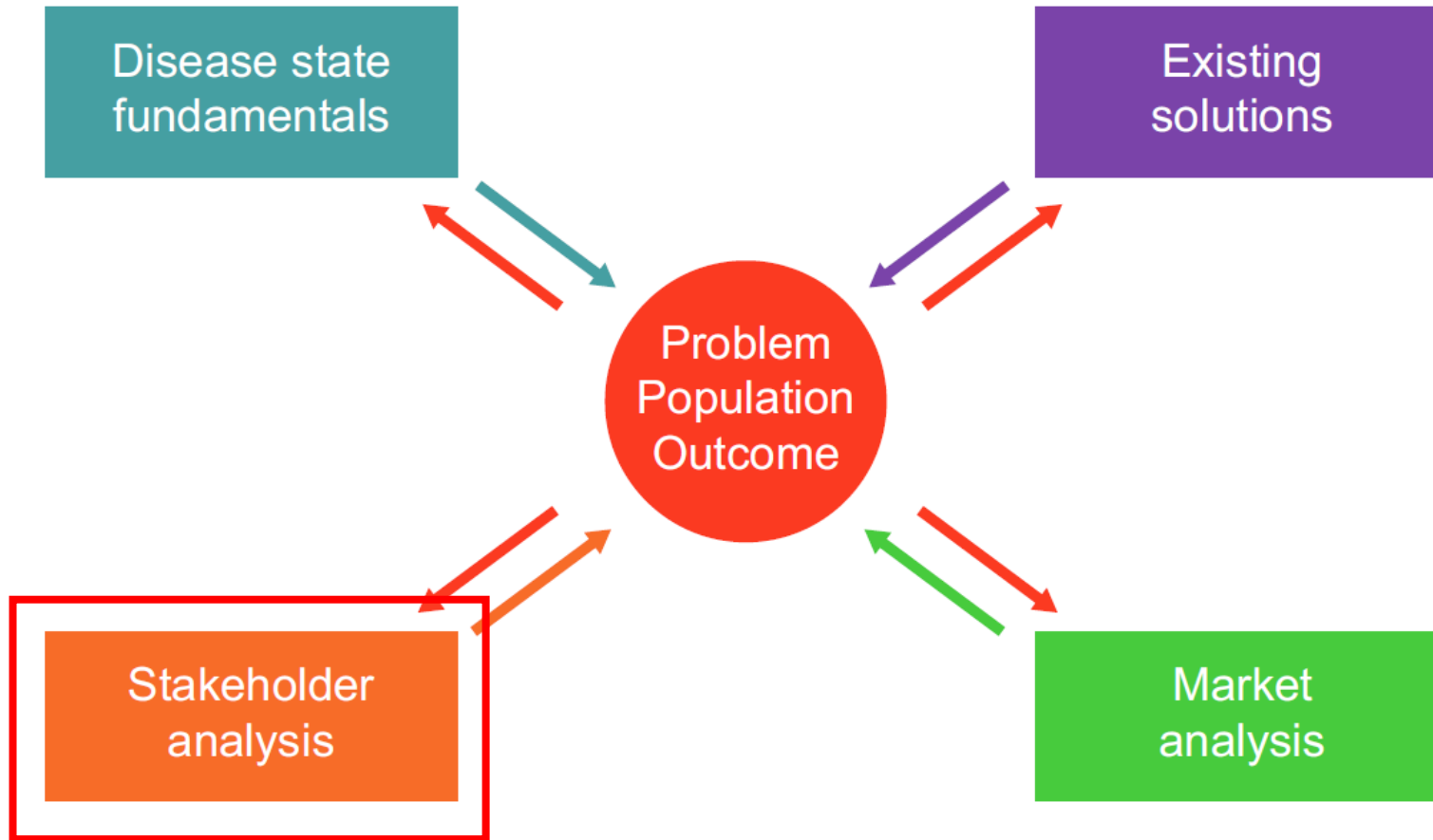
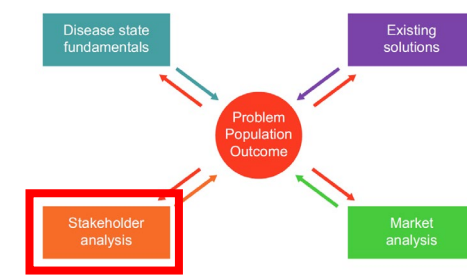


FIGURE 1.2.2

Maximizing the value of needs exploration requires a fundamental understanding of disease, existing solutions, stakeholder, and market factors.

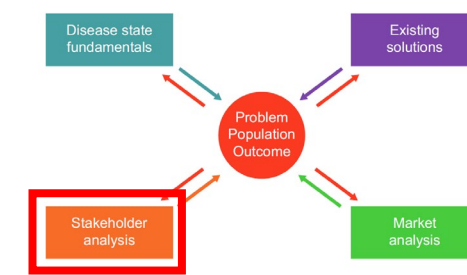
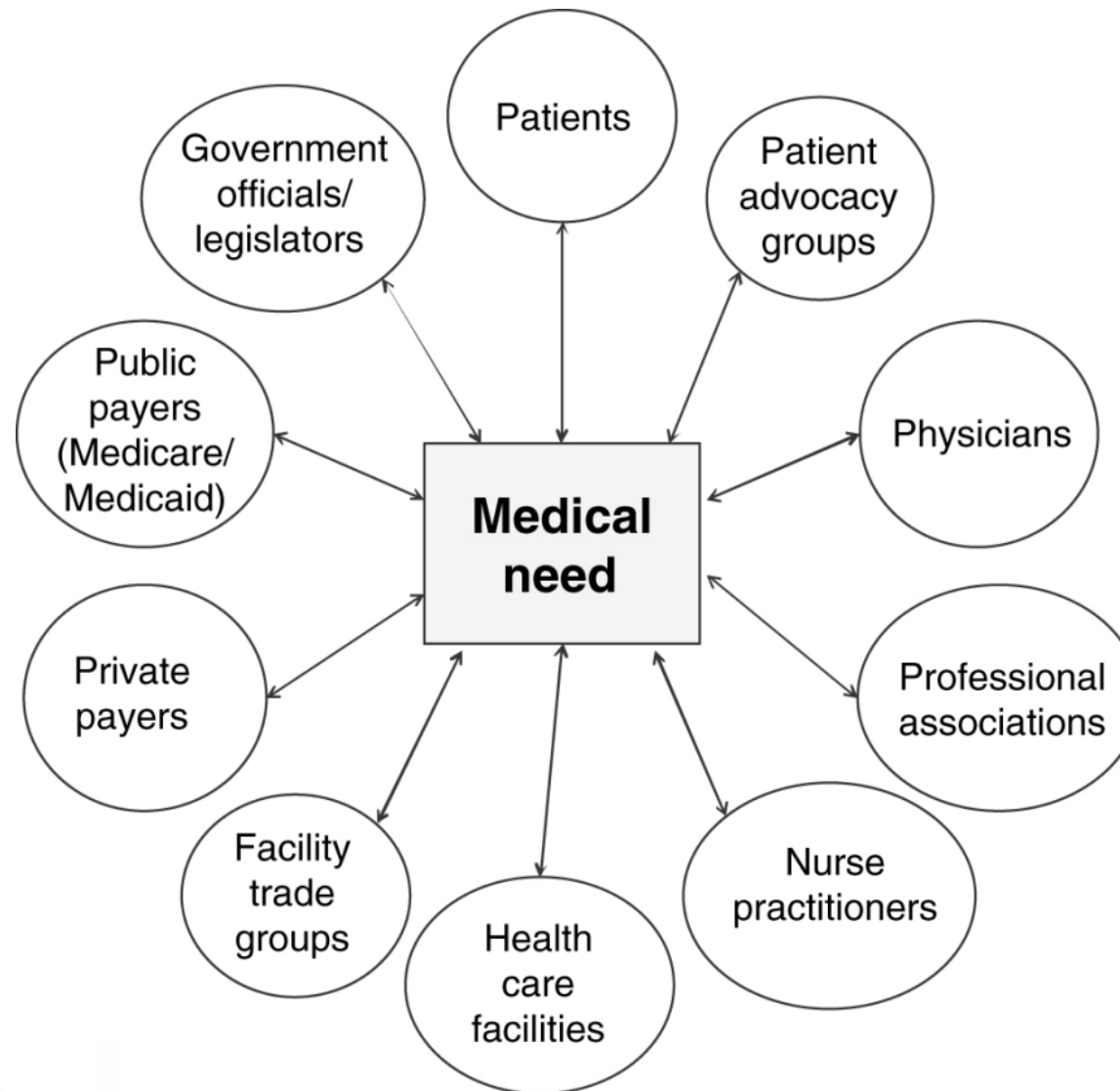


Users, End-Users, Stakeholders

- Stakeholder¹
 - 1: a person entrusted with the stakes of bettors
 - 2: one that has a stake in an enterprise
 - 3: one who is involved in or affected by a course of action
- Engineering Terminology
 - one who is involved in or affected by **what you are designing.**

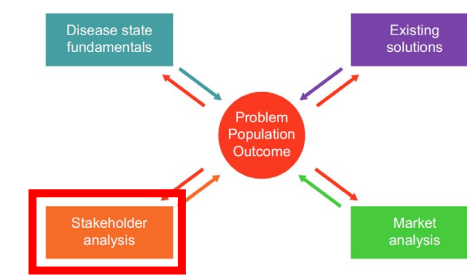
1) "Stakeholder" *Merriam-Webster.com*. 2021. <https://www.merriam-webster.com/dictionary/stakeholder> (May 18, 2021)

Examples of Medical Stakeholders

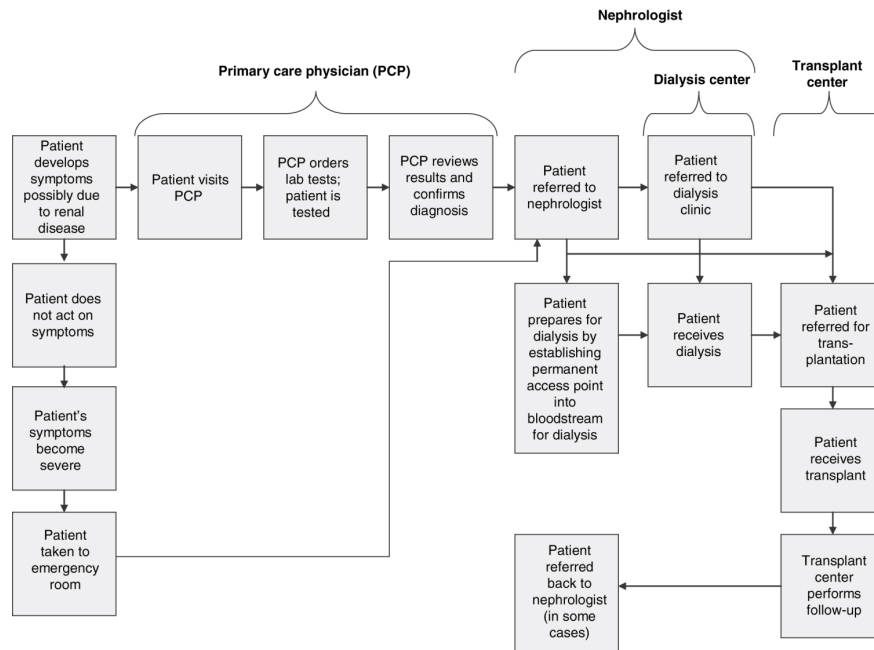




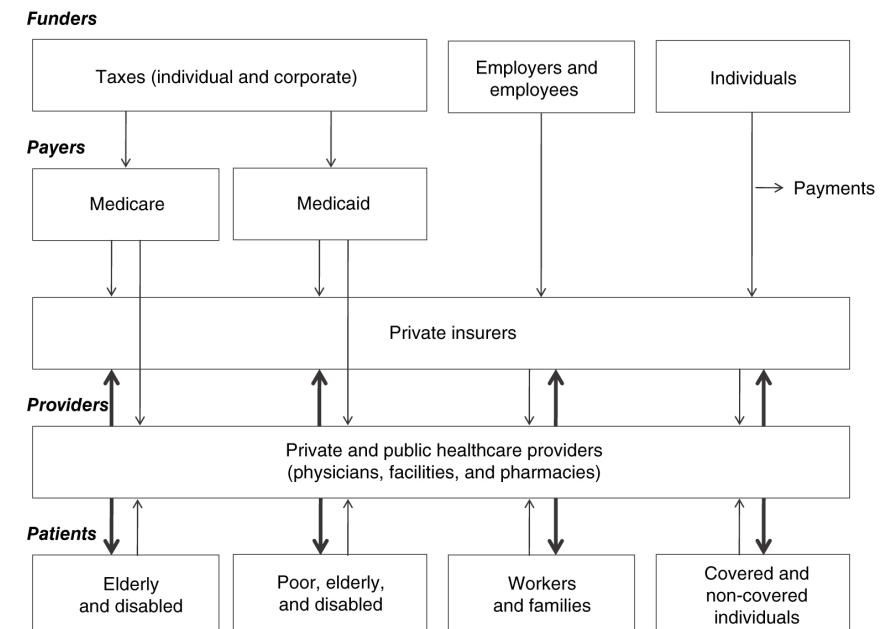
Support your Needs statement with a *Stakeholder Analysis*



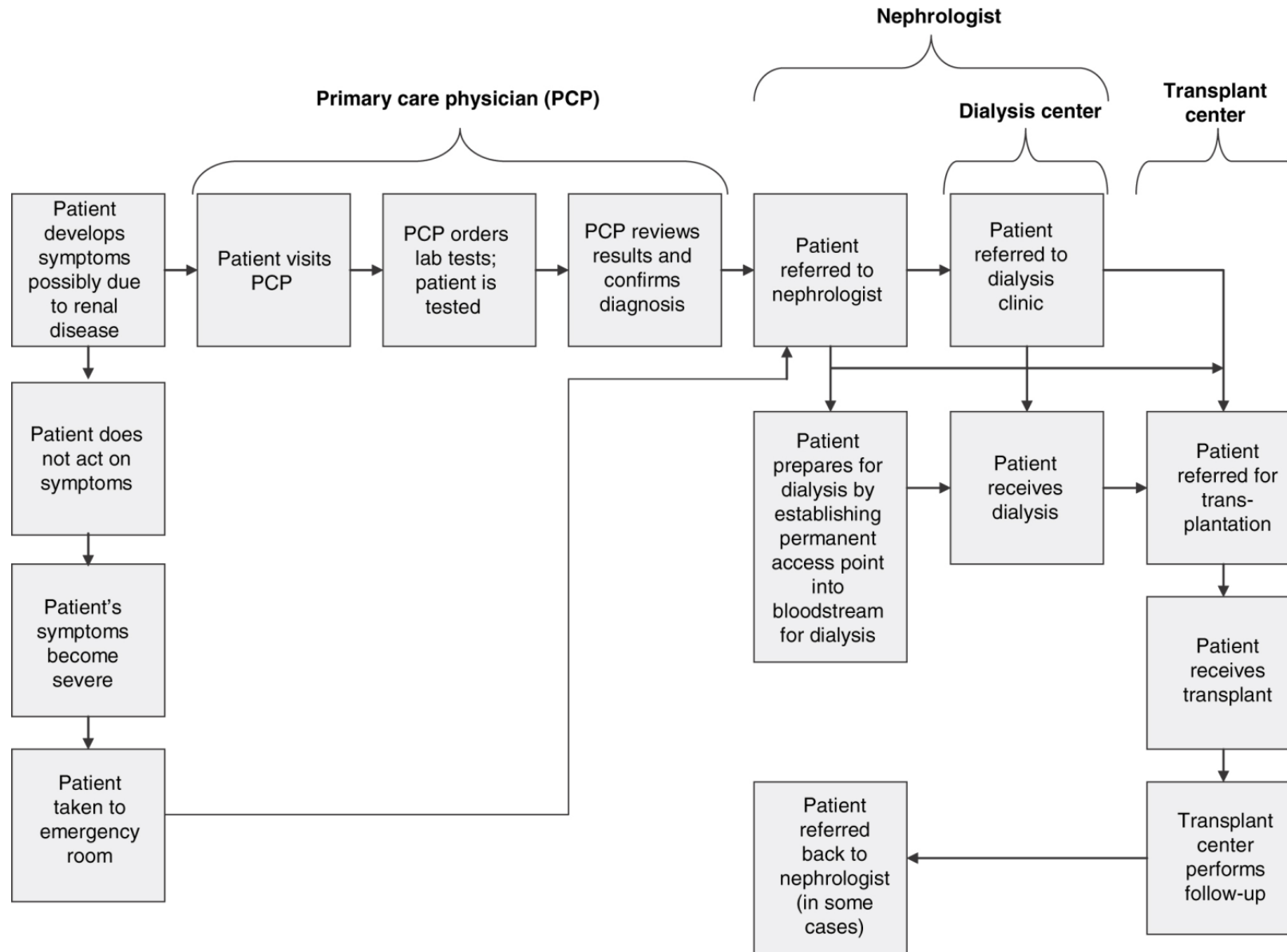
Cycle of Care



Flow of Money

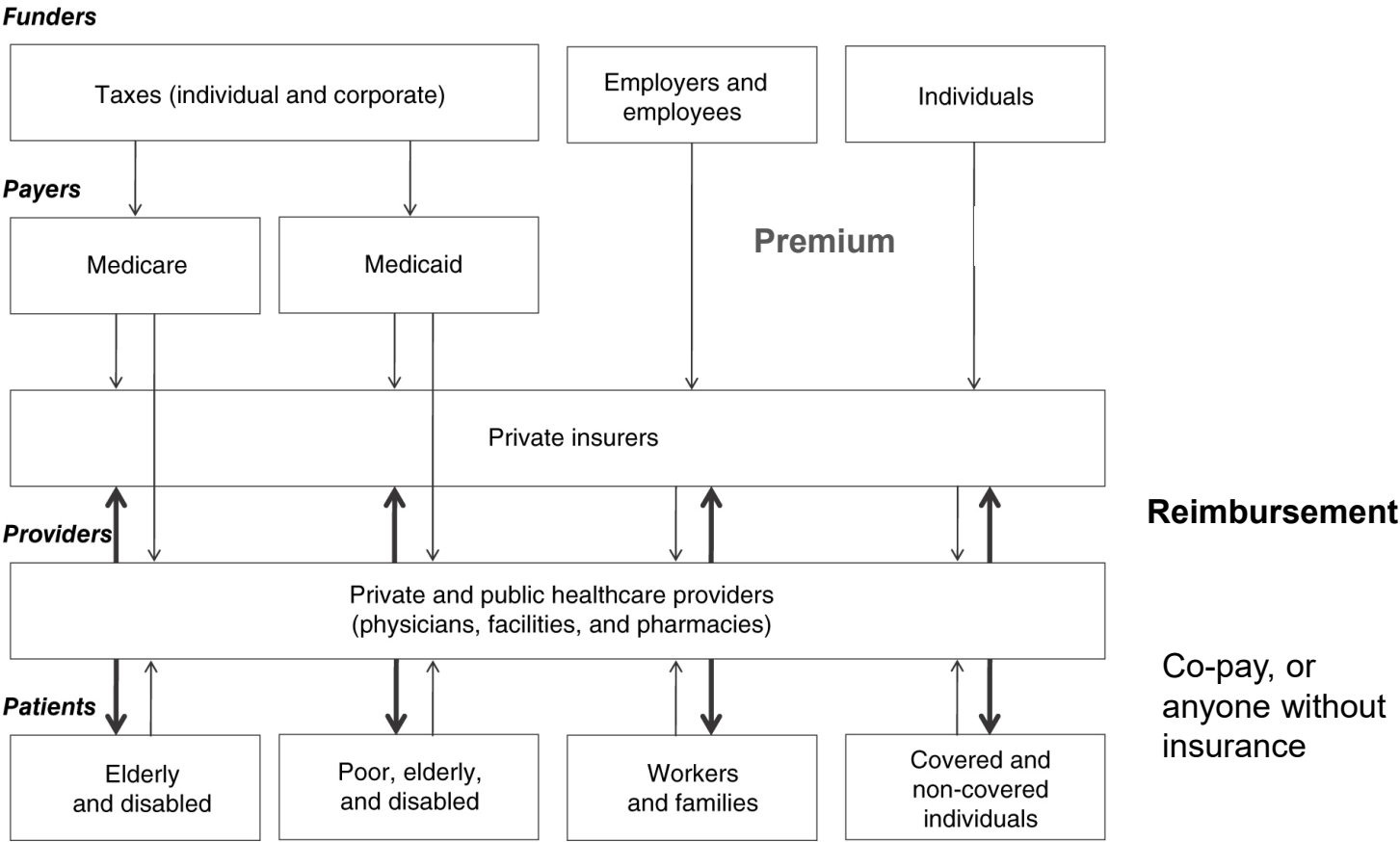
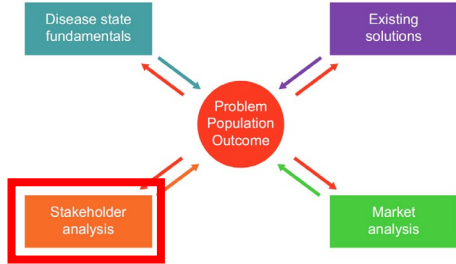


What stakeholders are involved in the problem?
Impact of future product? (Positive or negative)





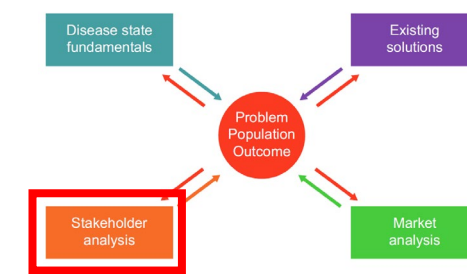
Flow of Money Analysis (U.S. Healthcare Financing System)



Based on N. Sekhri, Bulletin of World Health Organization, 2000, 78 (6) pp. 832.



Published Stakeholder Analyses



MGet It Your pathway to electronic resources

Exploring User Requirements for an Exoskeleton Arm Insights from a User-Centered Study with People Living with Severe Paralysis

By: Kobbelgaard, Frederik Victor

Publication Date: 2021-08-26

Book: Human-Computer Interaction – INTERACT 2021: 18th IFIP TC 13 International Conference, Bari, Italy, August 30 – September 3, 2021, Proceedings, Part I

Page: 312 - 320

ISSN: 0302-9743

ISBN: 3030856224

Resource: Book Chapter

DOI: 10.1007/978-3-030-85623-6_19

[Go To Item](#)

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If there's a paywall or a broken link, email a librarian!

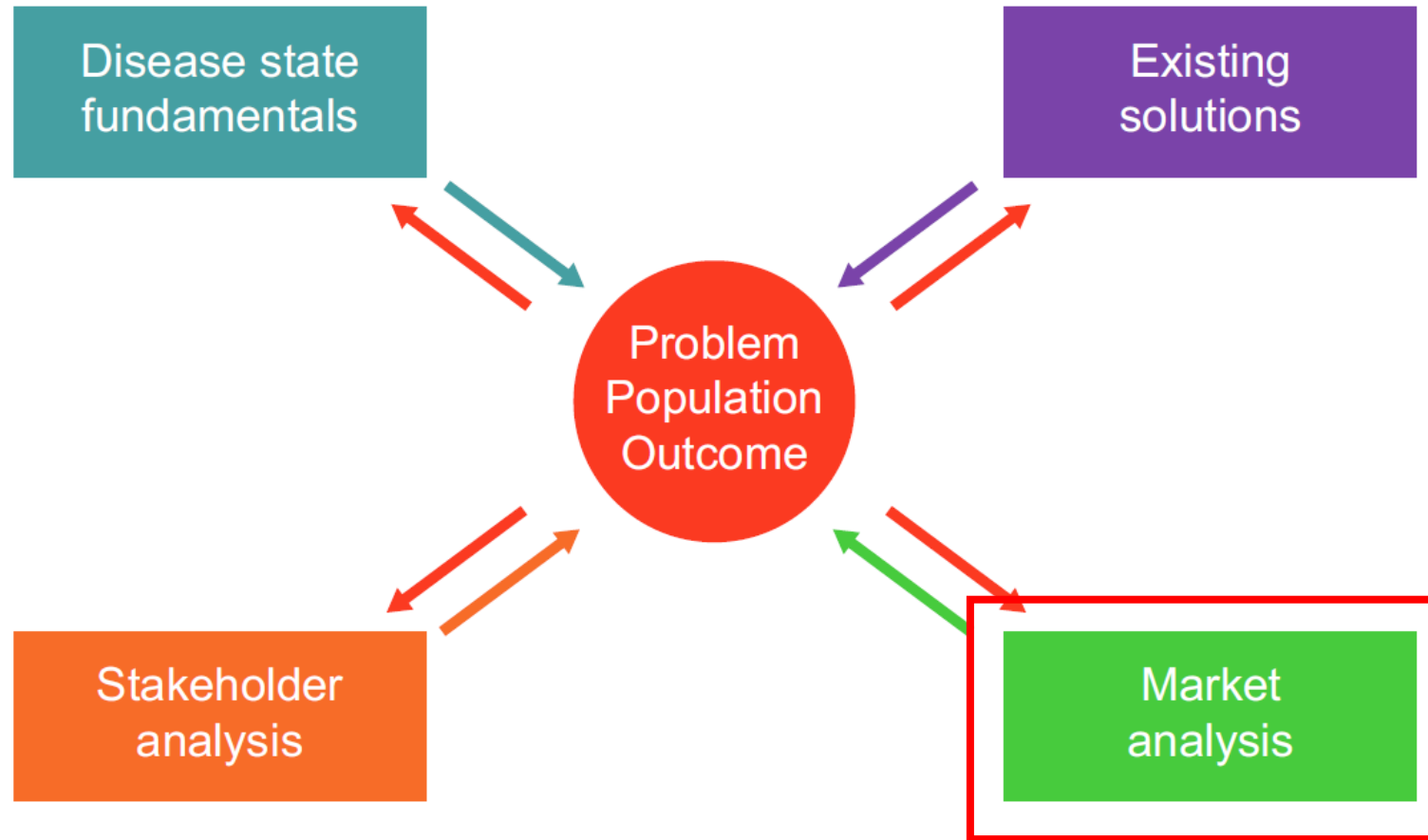


FIGURE 1.2.2

Maximizing the value of needs exploration requires a fundamental understanding of disease, existing solutions, stakeholder, and market factors.

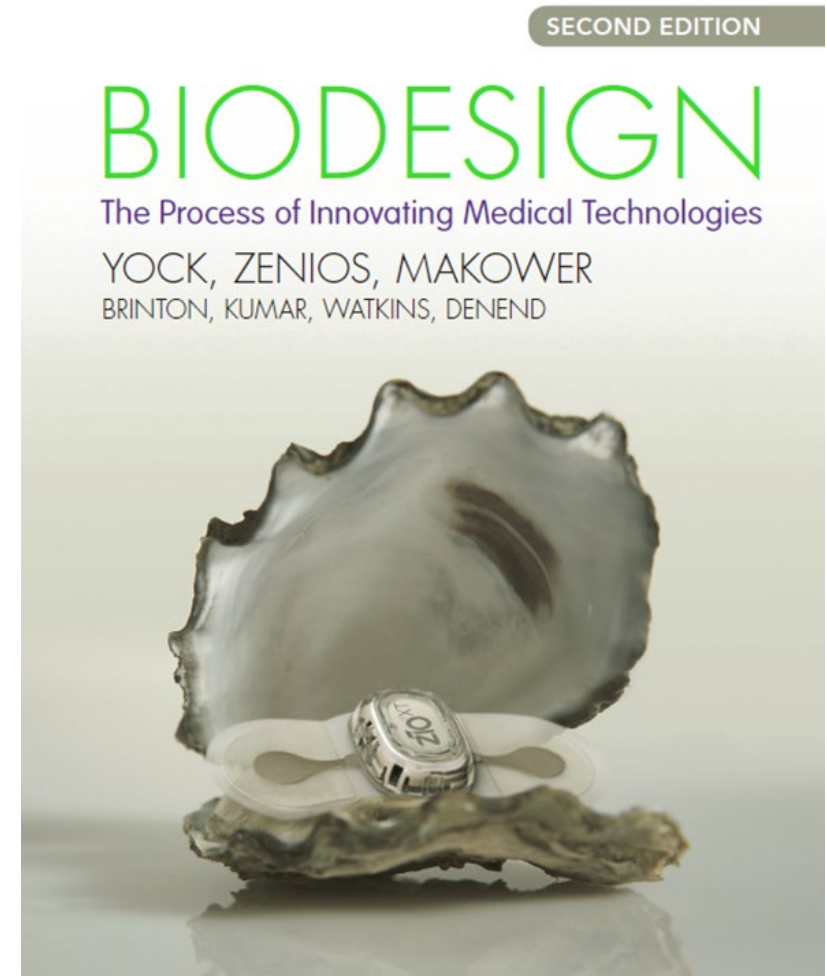


Take a 5-minute Break!

Versailles, France – August 2025

Plan for today

- Problems & Needs
- The Needs Statement
 - Disease State Fundamentals
 - Existing Solutions
 - Stakeholder Analysis
- *Break*
 - Market Analysis
 - Guest: Luesoni Kuck, BME librarian
- In-Class Activity: Resource Hunt



Companion reading for today's lecture topics:
Yock et al Sections 1.1-1.3 p. 50-109

<https://search.lib.umich.edu/catalog/record/99187447397606381>

Market Analysis

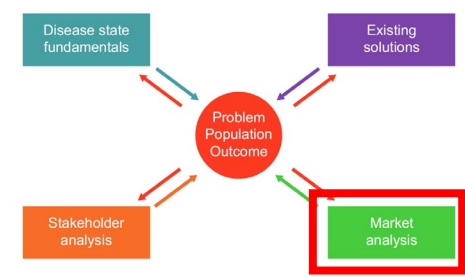
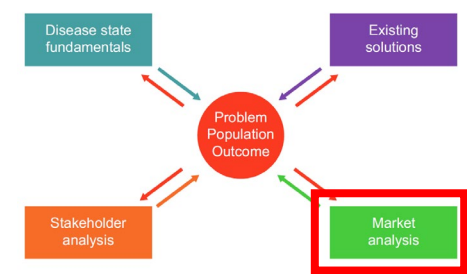


Table 2.4.1 *There are six key steps for performing a market analysis.*

Step	Topic	Questions to investigate
1	Market segmentation	What are the key factors that can be used to divide potential customers into distinct market segments in which the population shares common needs and perceptions (e.g., patient characteristics, treatment options, provider attributes, and payer mix)?
2	Market size	What is the size of the market opportunity in each market segment and its potential for growth and expansion?
3	Market dynamics	What are the competitive dynamics in each market segment that a new entrant would face? Are new companies created and are they successful? What is the nature of their competitive relationship with existing companies? Are companies acquired in this space?
4	Market needs	How well are the needs of customers within each segment addressed by existing solutions? How closely aligned are they with the need the innovator is seeking to address?
5	Willingness to pay	How willing is each market segment to pay for a new solution and, if applicable, what do customers pay for existing solutions?
6	Target market	Which market segment(s) is (are) most likely to embrace a solution?



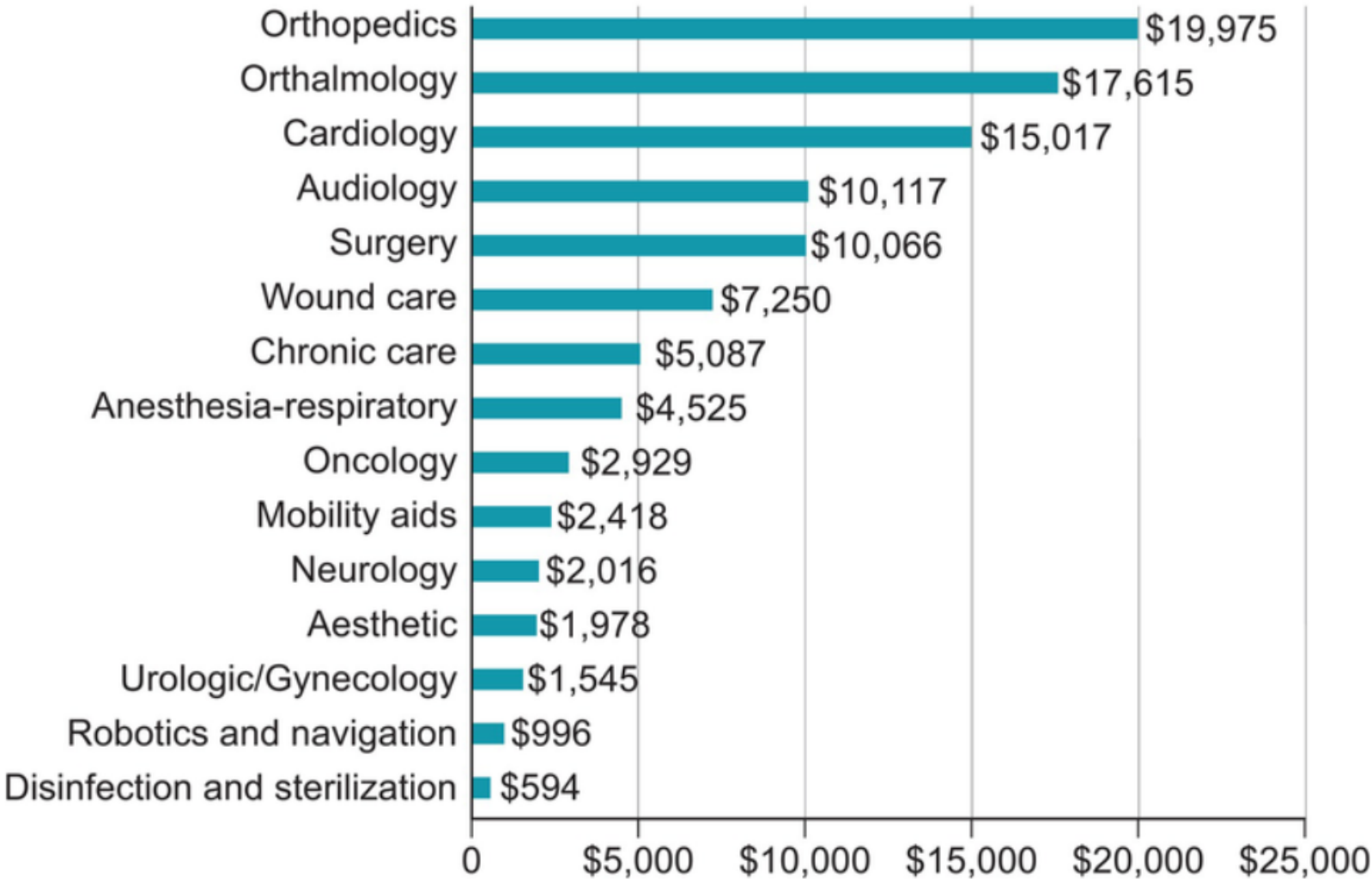
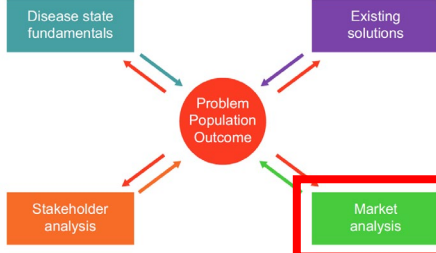
Market Analysis

Table 2.4.1 *There are six key steps for performing a market analysis.*

Step	Topic	Questions to investigate
<div>Careful! What population of people are you reaching? “Prevalence” and “Incidence” Annual cost ^^Always tied to a location – relate to your target population!</div>		
5	Willingness to pay	How willing is each market segment to pay for a new solution and, if applicable, what do customers pay for existing solutions?
6	Target market	Which market segment(s) is (are) most likely to embrace a solution?



Medical Device Revenues by Major Treatment Area



Note Revenue is NOT the same as profit

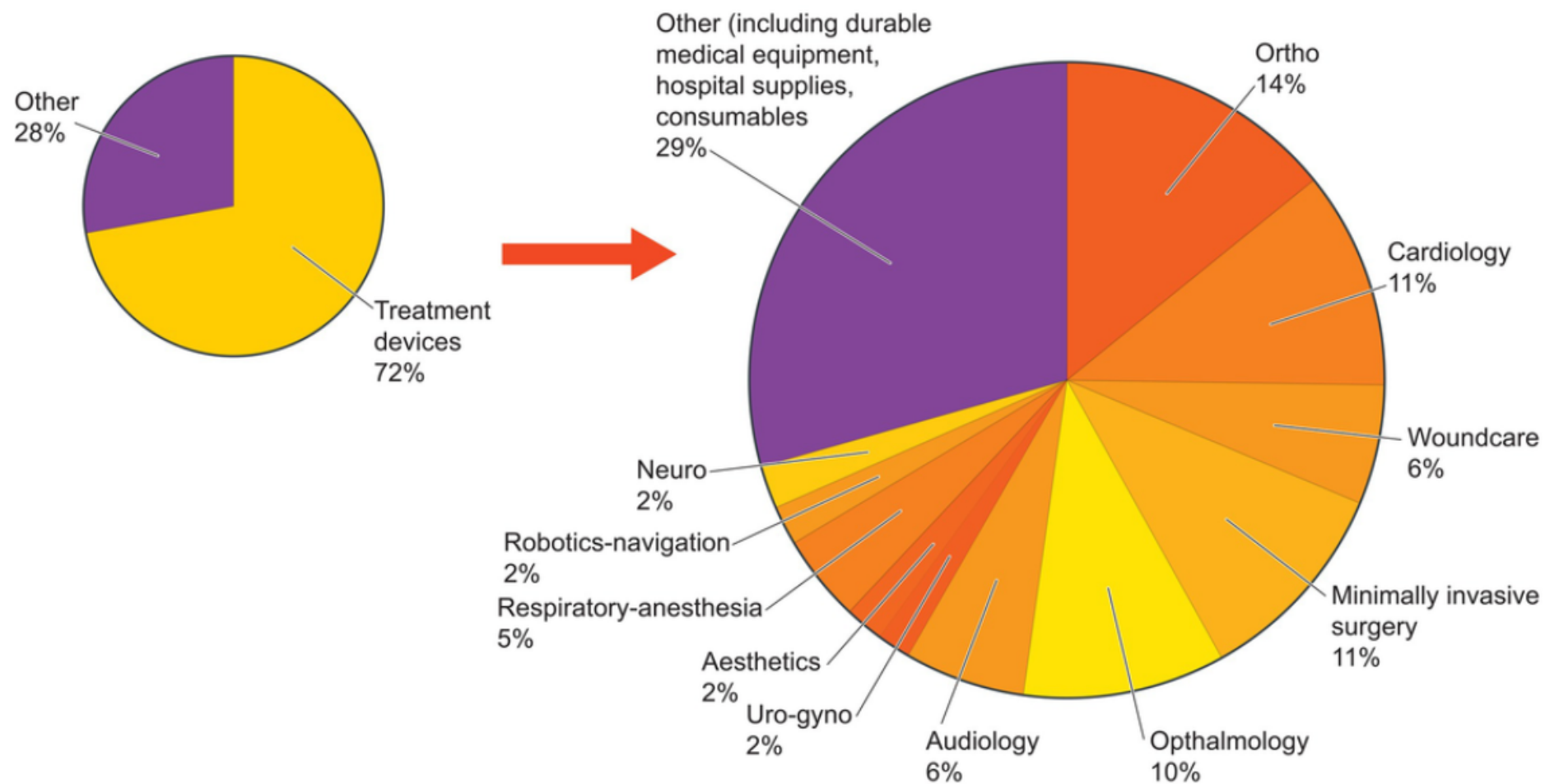
Numbers in \$US Millions

Not just the market size but also the market growth and the market dynamics will affect the decision making for your design.

“U.S. Medical Devices Market Outlook,” Frost & Sullivan, 2012

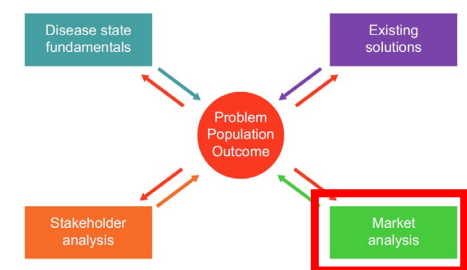
Figure 1.1.4 Information about medical device revenues by major medical segment can be helpful in choosing a strategic focus (from “U.S. Medical Devices Market Outlook,” Frost & Sullivan, 2012; reprinted with permission).

Global Medical Devices Market: Segmentation by Product Class, 2012



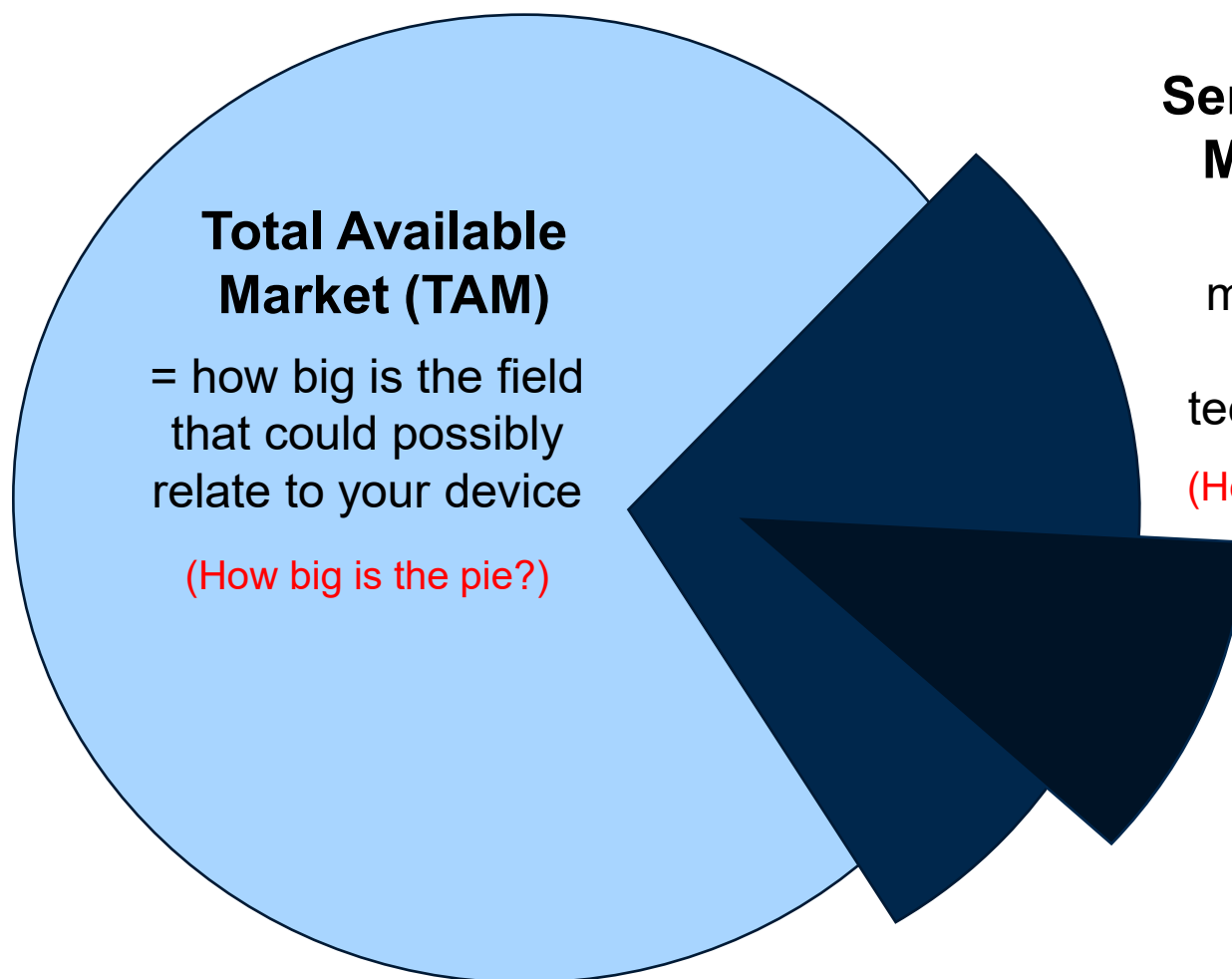
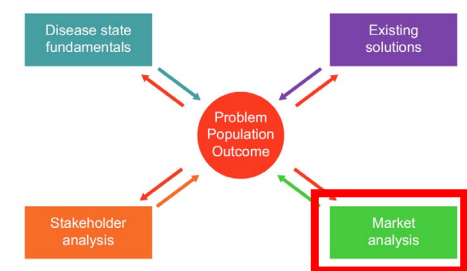
Note: All figures are rounded. The base year is 2012. Source: Frost & Sullivan analysis.

Figure 1.1.5 Market segmentation by product class can vary by geography, so innovators may wish to consider data for different locations. Note: all figures are rounded; the base year is 2012 (from “Global Medical Devices Market Outlook,” Frost & Sullivan, 2013; reprinted with permission).





TAM vs. SAM vs. SOM



Total Available Market (TAM)

= how big is the field that could possibly relate to your device

(How big is the pie?)

Served Available Market (SAM)

= how big is the market that can be reached by your technology/services.

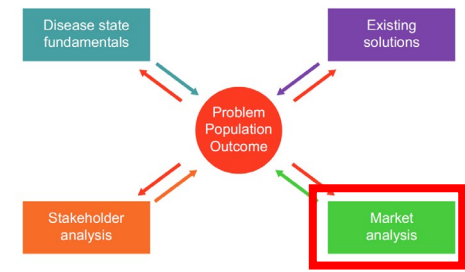
(How much could I eat?)

Serviceable Obtainable Market (SOM)

How big is the market that your technology / services could *realistically* reach?

(How big is my slice?)

BME librarian – Luesoni Kuck



How do YOU get to the Needs statement?

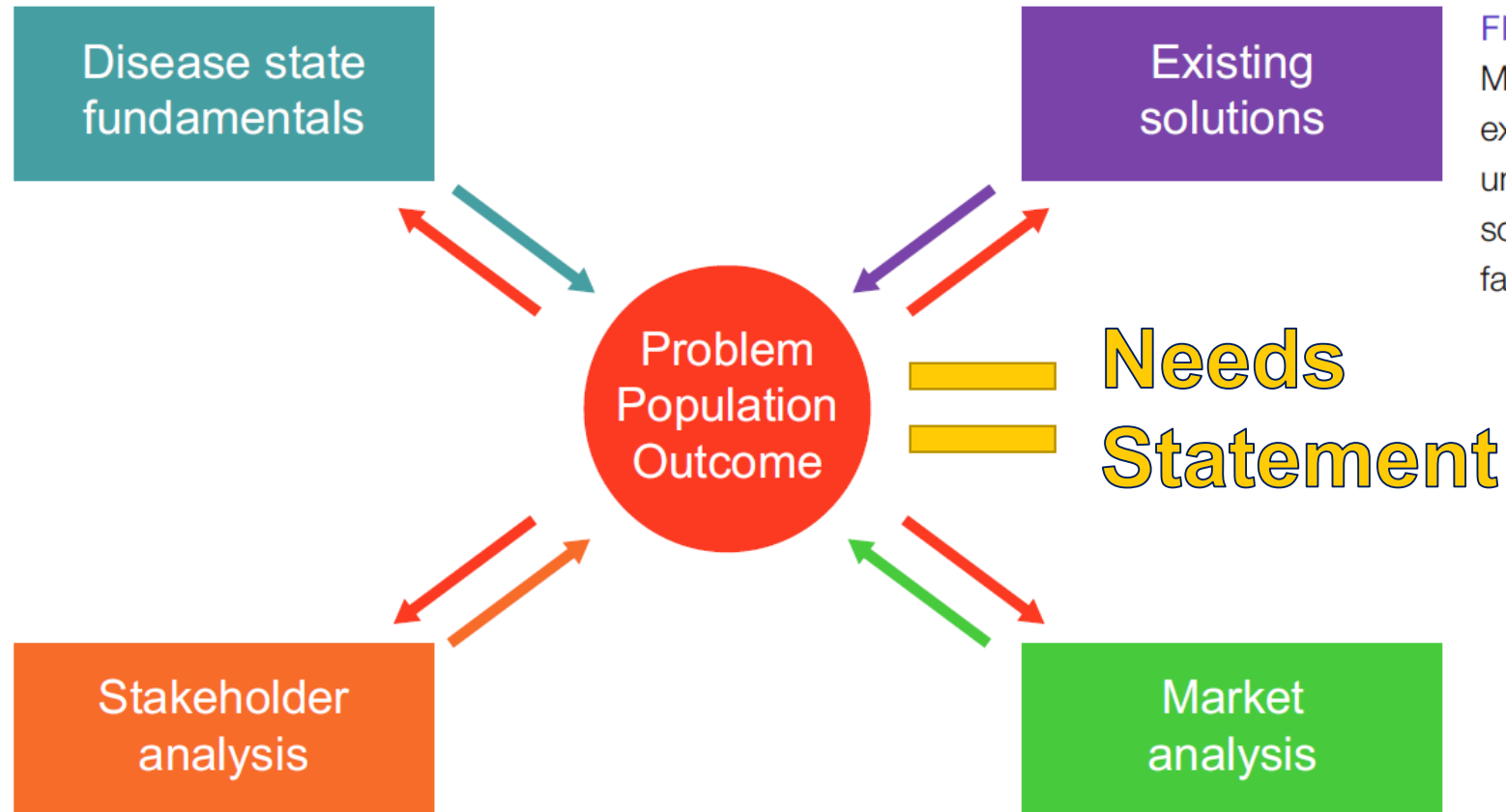


FIGURE 1.2.2

Maximizing the value of needs exploration requires a fundamental understanding of disease, existing solutions, stakeholder, and market factors.

In-Class Assignment: Reference Hunt!

Individual assignment, **5pts**, **Due:** “End of Class” or 11:59pm in two calendar days

Submit to Canvas notes related to the project that most interests you at this moment. Notes should contain:

- **WHO:** Authors, Company, Inventors, or Database name
- **WHEN:** Year that information was published or created
- **WHAT:** Title of paper/patent, name of device, or other identifying label
- **WHY:** Why you think this reference/resource is credible
- **HOW** did the deep dive go?
 - Short summary of what you learned and whether this paper should be read more closely or not.
- **WHERE** does it fit in the User Needs draft?

****This type of note scaffolding is sometimes helpful, but not always #SBNA**
After this assignment, feel free to note-take however you want!

Next time!

- Team Charter and Project Management
 - Version controls suggestions
 - In-Class: Team Charter