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A Problem Well Defined is Nearly Solved

An approach toward understanding problems worth solving

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by

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Abstract

Contemporary design methodologies tend to focus on problem solving rather than problem understanding. As such, many medical device design projects begin with a search for solutions rather than a clear appraisal of needs. Understanding clinical needs, user needs, unmet needs and the differences between them is crucial. Through a process of filtering research into an array of needs the author prescribes a method to help designers find the essential value of a design effort. This process concludes with the creation of design requirements, a list of which will be among the first documents submitted to the FDA as part of regulatory compliance for a given device. For medical device startups, design consulting firms and corporate manufacturers, a clear understanding of needs can mark the difference between designing a product and solving a problem.

Keywords: design process, medical device design, problem understanding, needs assessment, FDA design control guidelines
Medical device designers tout sophisticated processes to assure stakeholders of a robust approach toward creating safe, reliable and profitable products. A process that exposes needs and unmet needs can aid in determining whether a project is suitable for further development. But even if a device performs adequately and safely, there can still be no guarantee that the product will be considered useful by intended users. The issue of usefulness can be viewed as a matter of value. If a design team can first identify the practical value in solving a problem, the solution may become nearly self-evident.

If the product fails to succeed once on the market, it could remain a mystery whether the failure is due to inaccurate information from stakeholders, deficiencies in the process, or a myriad of commercial or clinical oversights.[1] Failure can also come through a product development team’s decisions or disinclination to make decisions. These afflictions point to either a lack of information or a lack of planning. Both can be mitigated by adopting an appropriate design process. Yet even the most effective process cannot uncover value if it is not implemented.

Through the author’s experience in industry, including corporate manufacturers and consulting firms, as well as experience with academic design teams through the University of Cincinnati’s Medical Device Innovation and Entrepreneurship Program, a number of instances occurred in which some design teams consistently made successful inroads with the client, not necessarily by proposing innovative solutions, but by identifying important problems that needed to be addressed. Conversely, some design teams seemed to invest tremendous energy and effort in attempting to validate multiple iterations of a solution without success.
It was speculated that the lack of success by the latter teams stemmed from an inadequate understanding of the problem.

The goal of this thesis is not to revolutionize the design process. Instead, the aim is to articulate a methodology that draws from the habits of successful designers in order to create a roadmap that will keep a design team focused on the problem. This should help the team avoid prejudices toward particular solutions in the early stages of the design process.

A further aim is to confront misconceptions about the nature of needs in the context of medical device design. What are needs exactly? Are these user needs? Clinical needs? Market needs? The fact that some needs may already be met by existing products has proved disorienting for some design teams. It is hoped that this methodology will enable development teams to understand the landscape of needs so that they can be analyzed and applied toward the advancement of design requirements. A list of these requirements will serve as one of the first documents of record to be submitted to the FDA in fulfillment of regulatory requirements for a medical device.

A clear grasp of procedure-based needs may serve as a filter through which to evaluate potential solutions. Understanding the problem will help the team move past unrealistic or ill-advised concepts so that more time can be spent on evaluating concepts that are appropriate for a robust solution.

The front end of the process is of tremendous consequence, as the initial phases culminate in the formulation of design requirements - the input for the establishment of design specifications. Design requirements cannot be adequately addressed without a solid
understanding of the problem; and the problem cannot be understood apart from a survey of all
the needs associated with a medical procedure.

Two primary tenets emerge to aid the construction of a design methodology:

• Effective design teams follow a process to create devices that have value. This process
  must be documented for regulatory compliance.

• Identifying problems begins with understanding needs. The problem can only be
  recognized after assessing all the needs that fall within a medical procedure.

A medical device solution must be derived from a clinical problem

The purpose of a medical device is to treat or assist in the treatment of a clinical problem.

Acute conditions, chronic illness, disease and injury are problems exhibited by patients and
addressed by a medical professional. Clinical problems may be identified from:

• Pain - determine what prevents a procedure from being delivered in a less painful manner

• Death - evaluate events leading to death for preventable issues and complications.

• Stress - ascertain the physical, mental, or emotional strain or tension on the part of the
  physician, patient or other stakeholder.

• Risk - understand what problems have influenced an approach involving greater risk.

• Malfunction - establish what caused the problem in a device or piece of equipment.

• Uncertainty - watch for instances where a provider is unsure or indecisive about how to
  proceed.

• Dogma - determine what assumptions and behaviors persist among providers without
  critical assessment of those areas
- Cost - identify what aspects of a procedure incur significant costs.
- Inefficiency - evaluate the treatment process from the perspectives of the patient, the provider, and the system. [2]

**Design teams are required to follow a process**

In the realm of consumer and commercial product design, to get from an idea to a product it is wise to follow a process. In the realm of medical device design, to get from an idea to a regulated product, a regulated process must be followed.

It is not only the products that are subject to FDA approval; the very process by which a device is designed is subject to regulation. FDA design control guidelines are provided by the institution and are intended to serve as a framework for medical device manufacturers. The burden is thus on the manufacturer to implement design controls and create an effective means of documenting the expectations of the design, as well as specifications, inputs, and outputs. [3] Their purpose is to incorporate a system of checks and balances in order to expose deficiencies and discrepancies between a design concept and the design requirements. [4]

![Fig. 1 The FDA design control process map; also known informally as the “FDA Waterfall”](image)
The FDA has set design controls in place requiring documentation of the design process. The purpose of this documentation is simply to indicate that the device actually does what the designer says it’s going to do - and does it safely. It is up to the design team to determine whether there is value in creating a new device.

An inevitable truth that ought to be acknowledged is that many design projects begin with a solution. The process sometimes begins with a physician who has an idea for a device. The physician may engage a manufacturer or design firm to validate the solution, create prototypes & go through the testing and regulatory phases. Ultimately, a product is released to the marketplace where the true value of the device will be tested.

Asking the right questions from the beginning can streamline development efforts and help teams avoid spending effort that is not aligned with the goals of the project or the company.[5] A clear understanding of the components leading up to design control will make the regulated process not just a mandated undertaking but a worthwhile effort.

**Applied Investigation**

This thesis will explore the front end design process through the application of the proposed principles to a medical device design project. The author joined a design team in the University of Cincinnati’s Medical Device Innovation and Entrepreneurship Program. The team was charged with exploring the feasibility of a new endoscopic device to be used in the treatment of chronic sinusitis. In order to better understand the procedure and the devices involved, the student design team interviewed physicians, observed clinical procedures, created procedure maps and reviewed the current Intellectual Property. These actions served to help the team understand the patient’s condition, treatment options, and the clinical environment. Front-end methodology was applied to see how problem understanding through needs assessment would affect the formulation of design requirements.

Fig. 2 A design project is introduced to evaluate the efficacy of a needs-finding process.
Keeping in mind that the design control process map is a framework, design consulting firms and manufacturers may elaborate within the spaces between steps of the guideline. Figure 3 illustrates the process followed in UC’s Medical Device Innovation & Entrepreneurship Program. Using the FDA waterfall as a base, actions that ought to take place have been identified as well as where those actions take place in the process. The process begins with investigation and then leads to the development of design requirements. These requirements create parameters for the development of possible design solutions. The student design teams are required to build prototypes throughout the process and verify their solutions from the standpoints of usability, material selection and clinical efficacy.

The FDA design control waterfall provides a structure to organize design documentation, but does not provide explicit direction. This is intentional. The FDA does not mandate a particular process, but since design documentation will follow this framework, it reasons that the process should fit within this framework as well. It is the designer’s job to decide what steps work for each application - for every design project there may be a unique design methodology.

Each step of the waterfall includes inputs, outputs or a combination of activities. This tool promotes project advancement by prescribing activities that should take place during each phase of the process. The process is likely to vary among different segments of industry and even among distinct manufacturers and design agencies.

However, all of this points toward problem solving, not necessarily problem understanding.
Expanding on the process map - the front-end process in a nutshell

Somewhere between investigation and design requirements (the first two columns of the waterfall map,) there is an opportunity to drill down to the most fundamental conditions that lead to a new design.

A brief preview of the Front End Process Roadmap (see figure 4) reveals that problem definition begins with investigation such as ethnography, procedure observations and benchmarking. Root Cause analysis is then used to help uncover the underlying cause of the problem; from there a comprehensive list of needs is developed, and then those needs are assessed based on whether they are met needs or unmet needs. All this becomes input so that the
team can begin to develop solutions to each need. These conceptual solutions are then converted to design requirements.

Using this flow of inputs and outputs, each step of the process becomes a filter from the previous step and the input for the following step. In the diagram it seems to take on a particularly linear flow - in real life there will be many return paths and unpredictable connections, especially among the final steps of the front end process. There is also a lot of document creation and brainstorming taking place. This is intentional, but it is not busy work; one of the main goals of all of these steps is to get members of the design team talking and interacting. The team may consist of mechanical engineers, electrical engineers, human factors researchers, industrial designers and marketing. It is important to have contributions from everyone on the team to capitalize on the strengths that each discipline brings to the table.

Fig. 4 Expanded process map detailing the front-end steps leading to design requirements.

**The process begins with inquiry**

The first step toward understanding the clinical problem is to identify and analyze known elements about a procedure. The initial inquiry phase immerses the design team in the
A PROBLEM WELL DEFINED IS NEARLY SOLVED

An environment of clinical, technical, ethnographic and business elements. These elements are distilled and documented to become useful tools in the development of devices.

Investigation and inquiry is an ambitious process demanding numerous resources. Failing to comprehend research is costly, even if the product never makes it to market. The danger is having invested in research only to misunderstand the essence of the problem. There must be a method in place to objectively examine the research and see that it is applied in an appropriate manner. The creation of a needs document based on root cause analysis is an effective way to animate that research toward conceptual solutions and ultimately the formation of design requirements. According to the FDA, “development of a solid foundation of requirements is the single most important design control activity.” [4]
Inquiry becomes the input that should be directed through the filter of Root Cause Analysis (RCA) to uncover a comprehensive list of needs. The Five Whys are a common and useful tool for RCA. (See figure 6.) This is a method of asking questions where each Why leads to another Why until the core issue is uncovered. All of the prior investigation (procedure observations, physician interviews and benchmarking) is meant to educate the team, enabling them to ask intelligent questions about the procedure and why it is performed in its current fashion. The intent is to keep an open-ended question going, usually taking 4 or 5 questions to work down through the layers of presumed problems to arrive at the core issue. The exchange usually begins with an assumption. Each question that follows challenges the assumption. This method takes persistence as well as a nuanced understanding of the circumstances surrounding the procedure. It forces a constant clarification of objectives until an essence is reached that can be considered satisfactory.

The purpose of inquiry is to understand needs

Assessment of needs is one of the most enigmatic concepts in the product development process. The FDA Design Control Waterfall includes “User Needs” in the illustrated chart, but little information is available to promote understanding of needs as they relate to medical devices. What should be classified as a need? Should a need be included in the document if another product is meeting one of more of the discovered needs? Designers get a lot of mileage out of the phrase unmet needs - but are these the only problems left to solve? Should the team ignore any needs that are currently being met by other devices? The short answer is no.
Root Cause Analysis

Root Cause Analysis was one of the methods used to identify underlying issues surrounding the current endoscopic sinus procedure. The following is an example of RCA being used to help identify procedural needs. In this example a physician states a perceived design requirement. The interviewer follows up with questions to uncover layers of insight into the clinical problem.

*I need a device with a rigid shaft.*
Why do you need a rigid shaft?

*So that I can control placement of the balloon.*
Why is it hard to control placement?

*You can’t always get the wire where you want it to go.*
Why is the wire difficult to navigate?

*The wire is floppy, so it has trouble going into an obstructed or partially obstructed opening. Also, the anatomy is highly variable, especially in patients who have had prior procedures; the wire gets hung up on projections [resulting from prior procedures.]*
Why is the wire so flexible?

*The wire is similar to that used in vascular interventions, so it’s a holdover from another kind of procedure.*

Here the physician states that he simply needs a device with a rigid component as opposed to a floppy wire. We learned that some of the real problems lie in navigation of the components as well as the irregular anatomy in which he is working. These responses reveal more insight into the overarching problem. Here are some of the needs uncovered in this exchange:

The procedure needs to:

Accurately deliver treatment to desired locations within the sinus
Treat sinusitis in patients who have had prior surgeries
Treat sinusitis in patients of varying anatomy
Fit in with existing ENT technology and surgical techniques

Fig. 6 Application of root cause analysis
When discussing needs, it is imperative to get a comprehensive picture of everything that must happen to achieve clinical success. The design team needs to know not just what is happening with one device or the physician; the team must understand the entire landscape surrounding the clinical procedure.

**The procedure is the focus of needs**

The procedure is the point at which all stakeholders are engaged. To focus on the patient, the device or the physician is to ignore another feature or stakeholder. But when the focus is on the procedure there is a much better chance of understanding the relationships between the stakeholders and picking up on subtleties that can affect clinical outcomes.

![Stakeholder/Procedure Relationship](image)

**Fig. 7 stakeholder/procedure relationship**

In the context of a medical device development process, needs should be defined as *all the things that are necessary to create a successful clinical outcome*. First and foremost a need is a *problem* that must be solved.
By this point in the development process, a significant investment of time and resources has been devoted to inquiry. In order to extract value from that inquiry, root cause analysis must distill findings into a needs document. As noted earlier, the focus of this document must be upon the clinical procedure. If one looks first at the user, technology, or even anatomy, solutions will inevitably be devised and masquerade as a self-fulfilling need. This is difficult to recognize and is exacerbated by the tendency of users to articulate their own design requirements as needs. [6]

By starting with the procedure rather than the user or technology, the design team may more effectively maintain objectivity and openness to possible solutions later in the process. Designers need to retain an unbiased perspective as they immerse themselves in the activities, language and habits surrounding clinical practice. [7] Needs cannot always be assessed simply by what users say, they must also be gauged in light of what they do. [6] Physicians and healthcare workers are often accustomed to working in less than ideal conditions and develop compensatory behaviors...
that are unnoticed by the user. This will continue until the behavior is pointed out or a solution is presented that mitigates the condition engendering compensation. The physician’s perspective is often given top priority [2]; but when exploring needs, it is important to consider the procedure from the standpoints of various personnel. A clinical procedure is primarily a systemic endeavor.

Creating a needs document

All of this careful consideration should lead to a list of needs. This list is a document that will be used to stimulate discussion for the formulation of design requirements. A needs document will need to remain flexible since nuances and details will emerge throughout a device’s development. The needs document should divide all needs into a minimum of three categories:

- **Must-haves**: These address needs that justify the creation of a product
- **Wants**: These will detail the value that a new device can offer.
- **Nice-to-haves**: These can express a new product’s differentiation from other products on the market and any advantages that come with that territory.

These categories and the context of need statements may be more easily distinguished if considered as an open-ended statement:

- The procedure must ____________.
- We want the procedure to ____________.
- It would be nice if the procedure would ____________.

Creating a needs document in this manner offers the team a way to distill research so it is usable. The creation of the document is also intended to stimulate communication between disciplines. Various disciplines often represent different stakeholders in the design of a device. Design teams
comprised of industrial designers, engineers, and marketing professionals need a way to integrate their sometimes disparate interests. By focusing on the clinical procedure and its associated needs, teams will address the most concentrated convergence of all stakeholders of the device.

In summary, the method of drawing up a needs document consists of the following essential components (in order): Inquiry & Investigation, Root Cause Analysis, Creation of prioritized needs statements with a focus on the medical procedure. This document will evolve over the life of the project. The team’s understanding of the procedure will grow, and new

### Endoscopic Dilator Team Needs Document

#### Specific Needs for the Procedure

**Must-Haves:**
- The procedure must treat chronic sinusitis
- The procedure must enhance drainage from sinuses
- The procedure must Permanently alter anatomy within the sinus
- The procedure must Accurately deliver treatment to desired locations within the sinus
- The procedure must Minimize scarring from treatment
- The procedure must Prevent damage to the skull base
- The procedure must Prevent damage to the orbit

**Wants:**
- We want the procedure to Treat Sinusitis in patients who have had prior surgeries
- We want the procedure to Treat Sinusitis in patients who have coexisting conditions
- We want the procedure to Treat sinusitis in patients of varying anatomy
- We want the procedure to Create an opening in obstructed sinus tissue
- We want the procedure to Expand an opening in partially obstructed sinus tissue
- We want the procedure to Minimize the need for post-operative healing
- We want the procedure to fit in with existing technology and surgical techniques
- We want the procedure to afford visual evidence of successful treatment
- We want the procedure to be performable by surgeons with varying levels of expertise
- We want the procedure to be available to patients at a low cost

**Nice-to-Haves:**
- It would be nice if the procedure would Clean the site of treatment
- It would be nice if the procedure would accommodate non-surgical revisions

Fig. 9 Example of a needs document
information can appear at any stage of the process. The document should change to reflect the
 cultivation of new insights.

Next steps

To make effective use of the needs document, a few steps remain to apply needs
assessment towards design requirements. Namely gap analysis to reveal unmet needs, then
concept solution generation.

Gap analysis

Procedures for diagnosis and treatment may range from simple to complex and could
require no devices at all or a suite full of equipment and instrumentation. If a procedure is
offered, existing products are obviously meeting at least some of needs inherent in that procedure
with some degree of success. In order to understand the opportunity gap, the team must
understand the landscape of devices and how they contribute to a successful clinical outcome.

Gap Analysis utilizes Comparative Product Analysis to help sift through the needs of a
procedure and understand which needs are currently met and which are unmet. The needs
document provides a list of all the things necessary to achieve a successful clinical outcome.
Products that compete in the arena of a given procedure will meet some of these needs.

When procedural needs are listed by priority, they may be compared against existing
devices. From here it is easy to see where devices fall short and where they succeed. The needs
left unanswered are exposed as unmet needs. Unmet needs will help identify the market
opportunity. A new device will presumably address more than just unmet needs, as medical
device design usually seeks to build efficiencies, combining technologies to reduce time or steps
required in a procedure. The collection of needs unveiled through inquiry, root cause analysis and gap analysis represents a picture of the problem that the design team is going to address.

Fig. 10 Example of Gap analysis. In this example, procedural needs are compared against the devices used in a procedure. The chart indicates which needs are being met by which devices. The remaining gaps indicate needs that are not met.

**Conceptual solutions**

By consulting the needs document, the design team is now free to devise solutions. These solutions should remain conceptual. They do not need to be full system solutions, nor do they need to be accompanied by drawings or diagrams. A dialog and brainstorming session should be opened to get as many ideas down as possible. This brainstorming process is a filter to identify all the possible ways that existing needs and unmet needs can be solved. Each concept answers the question: What must the device do to solve the problem? These concepts should then be judged against needs and unmet needs to identify the highest value solutions. Each
potential solution may or may not be feasible if combined with other solutions, and each may not solve the problem to the same degree.

Fig. 11 Conceptual solutions to a need. In this example the design team is addressing a need related to accuracy of deployment for the ENT surgical device.

**Design Requirements**

If a need is a problem to be solved, a design requirement is an action that solves that problem. Developing design requirements is arguably the most important step in the process. It is these requirements by which the device will ultimately be judged. It would be easy to create a solution, and then phrase requirements that are embodied in the solution. But as previously noted, a design team cannot confidently address solutions without first understanding clinical needs.
### Endoscopic Dilator Team
**Design Requirements**

<table>
<thead>
<tr>
<th>design requirement</th>
<th>need addressed</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device can expand tissue in the sinus region</td>
<td>Expand an opening in partially obstructed sinus tissue</td>
</tr>
<tr>
<td>The device expands tissue with minimal movement or slippage of dilating component so that the desired site is expanded</td>
<td>Accurately deliver treatment to desired locations within the sinus</td>
</tr>
<tr>
<td>The device can access the frontal sinus</td>
<td>Permanently alter anatomy within the sinus</td>
</tr>
<tr>
<td>The device can access inflamed, diseased, or obstructed openings</td>
<td>Create an opening in obstructed sinus tissue</td>
</tr>
<tr>
<td>The device flattens the agger nasi cell to open the frontal sinus</td>
<td>Treat chronic sinusitis</td>
</tr>
<tr>
<td>The device enables the user to control navigation of the device so that the user can arrive at the site of treatment easily and quickly</td>
<td>Enhance drainage from sinuses</td>
</tr>
<tr>
<td>The device enables the user to ascertain the exact location of the expanding tip during navigation and deployment so the user can deploy the device with confidence</td>
<td>Permanently alter anatomy within the sinus</td>
</tr>
<tr>
<td>The device allows direct visualization of a dilating component for visual confirmation of deployment at the desired location</td>
<td>Expand an opening in partially obstructed sinus tissue</td>
</tr>
<tr>
<td>The device promotes clarity in the field of visualization when blood and pus are present by introducing suction so that the user can clearly see the site of treatment</td>
<td>Minimize scarring from treatment</td>
</tr>
<tr>
<td></td>
<td>Minimize the need for post-operative healing</td>
</tr>
<tr>
<td></td>
<td>Fit in with existing technology and surgical techniques</td>
</tr>
<tr>
<td></td>
<td>Treat Sinusitis in patients who have had prior surgeries</td>
</tr>
<tr>
<td></td>
<td>Treat sinusitis in patients of varying anatomy</td>
</tr>
</tbody>
</table>

Fig. 12 Application of needs toward confirmation of design requirements
At this stage the task is to evaluate all the potential solutions and evaluate them according to how well they actually solve the problem. Any number of evaluation tools could be called into play from Quality Function Deployment to a Pugh matrix; whatever seems most appropriate for the team and the project. The point is to decide what design requirements will most effectively solve the problem and produce a successful clinical procedure.

Design teams should be able to trace design requirements back to their roots in the needs that they fulfill. This can be a way to implement a system of checks to avoid relying on intuition over whether a requirement will actually bring value to the design. The result is a prioritized list of design requirements, just as the FDA is asking for as part of the team’s design controls documentation.

Conclusions

Once clinical needs and requirements are understood, the design team should have a clear roadmap leading toward a final design. Having started with a rational grasp of the problem definition, conceptual solutions should be easy to select. Ultimately the path to product launch through verification and validation is served, assuring that the best possible design requirements are documented based on problem definition in the comprehensive environment addressing clinical, user and market needs.

Additionally, the feasibility assessment methodology can complement and enhance the FDA regulated process. This process is utilized to define measurable criteria that confirm that the device will perform as intended by design. By engaging in rigorous investigation, the design team can better determine the most appropriate and efficient development path for subsequent
development stages. That is, the method proposed not only helps a team end up with a better product; it helps determine the best way to verify and validate the solution.

By starting with a more comprehensive grasp of the problem, a clear pathway emerges to direct development efforts toward the things that will bring value to a new device. Procedure-centric design requirements address the comprehensive environment including clinical, user and market needs. By focusing on the procedure rather than on the user, the device or the patient, a team can better understand the landscape of needs as they pertain to the user, the device and the patient.

An objective evaluation method can help designers to avoid prejudices and remain impartial when evaluating multiple possible solutions. By dissecting a design project down to the fundamental needs of the procedure, it may be easier to remain objective and avoid getting attached to a solution too early in the process.

Clearly identified needs and unmet needs provide design teams with a targeted goal. Solutions have more realistic aspirations of being adopted as a standard of care. By understanding needs and unmet needs, we can better understand where the opportunities are for a new device and how the device would best fit in to the procedure given the products that are available.

Finally, once the design team understands where the value lies, then a solution will become nearly self-evident.
Proviso

It should be noted that the process proposed as well as the method by which it was developed works under a few assumptions. The first is that the product development process is collaborative. This cooperation not only extends to participation toward a common goal, but presupposes commitment to this front-end process by all members of the design team. It is understood that under actual conditions team members may vary in their responsibilities and in the time that they devote to a given project.

Also, this process is intended for use as a product development tool. The methods described should enhance communication and collaboration between team members. Neither the process nor its resulting documents are suggested as ways to engage clients or enhance marketing of a device.

These methods should help a medical device design team understand the overarching problem that needs to be addressed within a clinical procedure. As such, the process proposed here extends only through the creation of design requirements. These requirements will serve as the basis for product specifications, leading to product design and testing. Numerous established methodologies can be employed as part of subsequent development steps progressing from design verification through product validation.
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