

SCOPING AND FINALIZING YOUR NEED STATEMENT

Learning Objectives

After reading this brief, you will be able to...

- I. Understand the key components of a need statement and how to experiment with different variations
- II. Recognize and overcome common pitfalls in need statement development
- III. Leverage your need research to arrive at a final need statement that will serve as an effective mission statement for your project

Getting Started

The need statement is the cornerstone of the whole biodesign process. It's your hypothesis about what the real need is that you're trying to solve. It provides a powerful way of clarifying and communicating what's most important about your project – and later helps you assess which of the solutions you create will best address it.

In the toolkit called Choosing a Need Area and Drafting Your First Need Statement, we recommend starting with a preliminary draft of your need statement as a rough prototype to get the process going. Now, with more rigorous research, you'll have the information you require to make your need statement more precise and insightful. By the time you decide on the final need statement, each word will be supported by data and validated by key stakeholders in the field.

Why bother? This is much more than just wordsmithing. Taking the time to get to a strong, well-validated need statement forces you to dig deeply enough that you won't miss hidden problems that can wreck your project at a later stage. The need statement is an antidote to the kind of "Ready-Fire-Aim" innovation that happens because of our tendency to jump too quickly to solutions. Done well, the need statement serves as the foundation of your project and the guiding light for all subsequent steps in the innovation process.

The Basics

The need statement follows a common format:

"A way to [address the problem] in [a specific population] in order to [achieve a desired outcome]."

In other words:

- **WHAT change is required?** Usually this is a clinical challenge that currently isn't being adequately addressed.
- **WHO is most affected?** Most often this is patients, but another stakeholder (e.g., care providers) could be the ones most negatively affected by current care paradigms.

- **HOW** will you measure how good your solution is? The point here is to select which outcome the key decision-makers in your need area would value most from a new solution.

See Figure 1 for a few examples of how these three components come together. These particular examples are actual need statements, generated by trainees, that led to technologies now helping patients.

Figure 1 – Commercially Available Technologies ... and the Need Statements They're Based On

	The Need: A way to treat dry eye in patients with moderate to severe disease that is more effective than topical cyclosporine. The Solution: Oculeve True Tear™ device, when placed in the nasal cavity, emits tiny pulses of energy that send nerve signals to the brain and then back to the tear glands to stimulate natural tear production.
The Need: A way to reduce hand tremors in patients with essential tremor in order to restore their ability to eat, drink, and write. The Solution: The Cala Health Trio™ is a non-invasive device that relieves hand tremors. Surface stimulation is delivered via the wrist and carried to the brain, disrupting pathological tremor frequency signals.	
	The Need: A way to dilate heavily calcified vascular lesions in patients with ischemia in order to safely restore blood flow. The Solution: The Shockwave™ lithotripsy catheter contains emitters within the balloon to generate pressure waves. The energy creates micro-fractures in calcified plaque so the vessel can be safely dilated to restore blood flow.

Photos courtesy of the Oculeve, Cala, and Shockwave teams

One effective mechanism to help you get your need statement right is **need scoping**, where you try out different variations of the problem, population, and outcome in order to come up with the optimal combination. The goal of need scoping is to land on a final version of the need statement that's broad enough to be significant and compelling, but focused enough to be actionable.

We provide more detailed information about scoping each component of the need statement in the sections below, using a running example focused on night terrors (see Box 1). This information works well with the Need Scoping Worksheet that you can use on your project. You also can watch

the video called Bringing Problem, Population, and Outcome into Alignment with an Iterative Approach for a recent student team example.

BOX 1

Understanding the Real Need with Night Terrors

A team of students identified an interesting need when one of its members was staying with his sister. On the first night of the visit, he learned that his nephew suffered from night terrors. Seeing first-hand what the family experienced as a result of the condition convinced the student that this was an important unmet need to pursue. When he returned to campus and described the incidents to his teammates, they were intrigued. Their need research provided an orientation and further convinced them of the need for a better solution.

Night terrors are episodes of inconsolable screaming, flailing, and intense fear that affect up to 40 percent of children during sleep. They sometimes occur in combination with sleepwalking, increasing the risk of injury from falling or other mishaps since the child is not completely aware of their surroundings. Night terrors differ from nightmares in that the child remains asleep – even if they look wide-eyed and awake. Most often, the child cannot be aroused from the night terror for the several minutes that it lasts. This alien behavior can be a terrifying experience for the parents. After a string of these episodes, which can be nightly, parents end up exhausted and emotionally depleted. Children frequently don't remember the night terrors in the morning, but suffer from poor sleep quality. When families seek treatment, they're commonly told not to worry and that the child will outgrow the night terrors within a few years.

As the team conducted increasingly in-depth research and interviews, they went through multiple variations of their need statement – ultimately ending with “a way to **prevent night terrors** in **children** in order to **increase nights without sleep disturbance**.” Read more about their journey in the sections that follow.



Photo purchased from iStock Photo

Problem

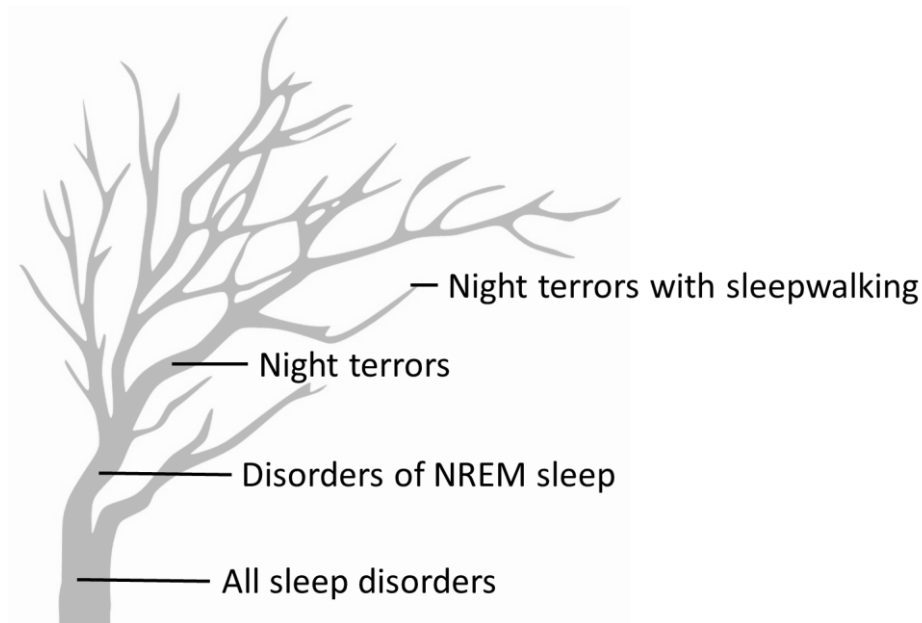
As the first component of the need statement, the problem is meant to clearly describe a health issue that current solutions do not adequately address.

In any health-related scenario – whether it comes from a clinical observation, a vignette provided in class, or your personal experience – there are almost always multiple potential problems to consider. The key is to use your need research to determine which problem represents the most compelling opportunity.

In most cases, you have a core problem that you can use as a starting point. For example, with the night terror need described in Box 1, the core problem is the fact that the child experiences a disruptive night terror. However, you can scope the problem in two different ways.

First, you can experiment with the size of the problem, making it smaller or larger. In order to do this, you need to look deeply into the mechanism of action for the condition – the underlying physiological, biological, chemical, mechanical, or electrical abnormality that causes the condition. Health conditions are categorized in a branching chain of increasing specificity. In the sleep terrors example, as shown in Figure 2, this ranges from all sleep disorders (broadest) to the combined condition of night terrors plus sleepwalking (narrowest). For this project, the team’s research suggested that they were unlikely to solve all sleep disorders, or even all disorders that occur during non-rapid eye movement (NREM) sleep, with a single invention since there was no common mechanism across these conditions that they could address. At the narrow end of the scale, the team realized that focusing all the way down to the combined condition of sleep terrors plus sleepwalking was unnecessarily limited. Most sleep terrors have a uniform neurophysiological cause. So, if that problem could be remedied, it would take care of the smaller subgroup with sleepwalking caused by the terrors.

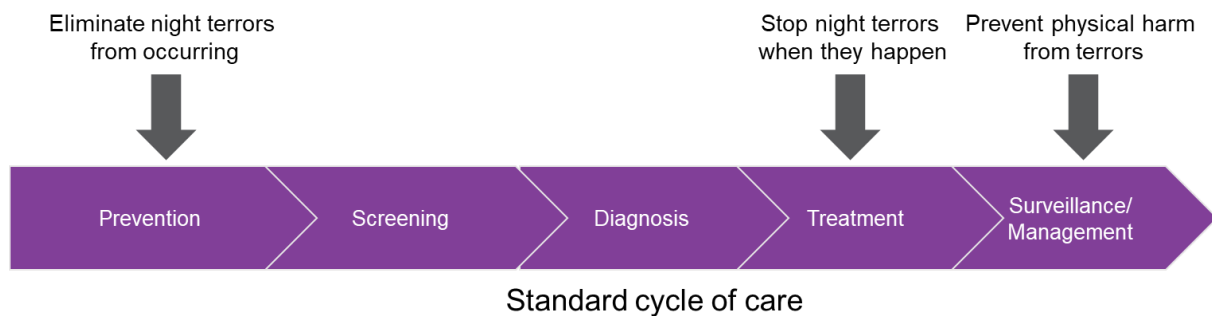
Figure 2 – Scoping by Size and Priority of the Problem



Generally speaking, the more specific and focused the problem, the greater the chance you’ll have of focusing on a single mechanism of action and resolving the issue. But, with increased focus, you run the risk of overlooking a broader or **superseding need** – a need that, if solved, would make your problem and its solution irrelevant. The whole point of the scoping exercise is to find the broadest focus that has a coherent mechanism behind the problem. This makes the ultimate market as big as possible to justify the time and expense of development.

A second way to scope your need from the standpoint of the problem is to think about the cycle of care and consider issues that are temporally upstream (to the left in Figure 3) or downstream (to the right) from your initial take on the core problem. In the night terrors example, one problem you could focus on is stopping night terrors when they occur. But could there be a way of preventing them in the first place? Or perhaps there's something that can be done after the night terror begins that will keep the child safe during the incident?

Figure 3 – Scoping by Cycle of Care



What you learn about the disease state will help you answer these important questions. In our example, you would go back to the clinical literature to determine how well we understand night terrors. Has there been interesting research on what causes them...how to interrupt them...or how to prevent them that you could leverage to advance the project? Pay special attention to “late-breaking” research from the last year or two, since this may provide an important new perspective on the need. And, again, keep the idea of superseding needs in mind. If you decide to tackle the challenge of treating night terrors and someone else finds a way to prevent them, that project will render yours obsolete. There's a balance to be had, though, in not going too broad—and winding up with a need that is not well enough understood or sufficiently homogenous in its mechanism of action to be addressed with a single solution. Usually this balance becomes clear once you understand your need area well enough. The proof that you have landed with a right-sized need will come when you begin to brainstorm solutions: if your need is too broad, you will find that solutions do not flow easily. No problem-- this is just a signal to loop back in the process and tighten up your need statement.

This part of the scoping exercise is a good place to look for a unique insight into the need itself, which can set you up for a truly innovative project. Where you begin as a starting point in thinking about your problem is likely the same place where other groups have focused. Experimenting with moving upstream and downstream may give you a unique take on the real problem that others have not recognized. See more about insights in the toolkit called *Becoming an Expert in Your Need Area through Research*. And watch the video called *Leveraging the Cycle of Care to Iterate a Need Statement* for a team example.

One other point about the scoping process: Refining the need statement can be frustrating at times because you're dealing with incomplete data. You should be relying on validated clinical information as much as possible, but there will inevitably be gaps. You should be able to address at least some of these through data gathered through primary sources (see the toolkits on *Clinical Observation*, *Interviews*, and *User Surveys*).

COMMON PITFALLS**Problems with Embedded Solutions**

One common challenge that students wrestle with is a tendency to embed a solution within the problem component of the need statement. Remember: a need statement should describe *what* change is required, not *how* it will be addressed.

The biodesign method of beginning the need statement with “A way to...” is intended to head off the tendency to sneak a solution into the need statement. This way of constructing the statement helps to keep you open to any way of achieving the outcome.

It can still be tricky, though, to keep solutions out of the need statement. Sometimes this happens because students – or their clinical advisors – jump too quickly to ideas for solving the problem. Other times, it’s because they view the problem in a way that’s too closely linked to the current standard of care.

Why is this such a problem? Embedding a solution into a need statement constrains the creativity of the team too early by focusing on only one direction for a solution. It also can short-circuit the process of fully characterizing the need. Seizing on a solution trajectory can prevent you from discovering some critically important aspect of the need that no one else has appreciated and that later could provide the key to a novel solution.

An example of a solution-constrained need statement

A way to coat a prosthetic implant that decreases the rate of infection in hip implant patients in order to reduce the rate of revision surgery.

An example of a solution-independent need statement

A way to decrease infection in patients with prosthetic hip implants in order to reduce the rate of revision surgery.¹

Population

The population in the need statement identifies who is most directly affected by the problem.

Most of the time, health-related problems have an impact on multiple stakeholders – patients, their family members or caregivers, physicians, nurses, and other care providers, hospitals or other facility administrators, insurance payers, the healthcare system at large, etc. In fact, brainstorming a list can be a good way to get started in thinking about your population. For the night terror example, the top entries on the list of stakeholders were:

- Children experiencing night terrors
- Parents or caregivers
- Primary care physicians

- Sleep experts

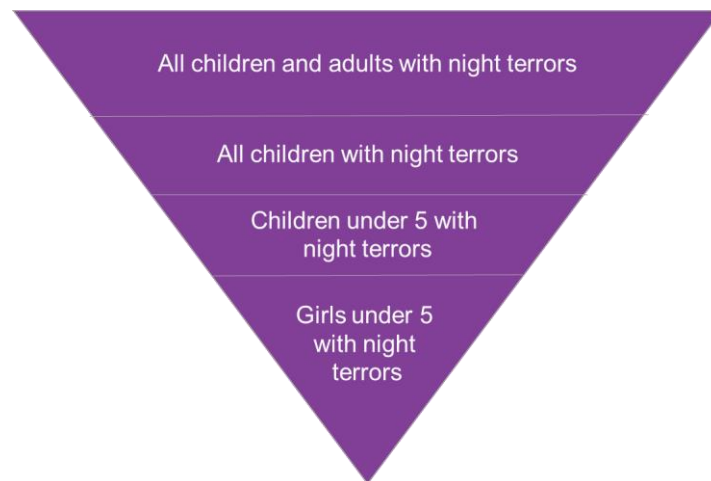
In this case, healthcare facilities and insurance payers did not make the top tier because the solutions that existed were not usually administered in a healthcare facility and there was no widely available reimbursement for treatment. However, they would typically be included on your list for most needs, since hospitals and insurance companies are very often essential decision makers.

Your next challenge is to determine which stakeholder group is most negatively affected by the problem. More often than not, this will be patients, but it's worth thinking critically about this.

With your preliminary population in mind, it's time to perform a check on the scoping of your need from the standpoint of the population (see Figure 4). The strategy is to scope both up and down to try to find a right-sized group for your project. For instance, if you start by thinking about all children with night terrors, you would:

- **Scope up (broadening the population)**
What about children with any sleep disorder? Or children with sleep disorders that occur at other points in the sleep cycle? Expanding another way, what about all patients with night terrors – including adults?
- **Scope down (narrowing the population)**
What about children in different age brackets – for example, children under 5 years old? Or perhaps, getting still narrower, girls under 5 years?

Figure 4 – Scoping by Size of Population



Just as with the first approach to problem scoping, your goal is to find the largest possible segment of the population that is uniform or homogeneous with respect to the basic mechanism behind the condition, such that a single solution can potentially address the whole group.

Population scoping overlaps with the problem scoping approach described above. The reason to re-scope from the perspective of population is that it serves as a second check that you have correctly sized your need statement. Depending on your need, you may get more traction with one or the other approach (problem or population scoping), but it is important to experiment with both.

The team working on the night terrors need discovered important differences in how night terrors affect children and adults, so trying to address both of these populations with a single solution wouldn't make sense. However, there was little variation across different ages or genders of children, so the team settled on all children with night terrors as the appropriate population for the need statement.

COMMON PITFALLS

Overestimating the Population

Overestimating the population in a need statement is another common mistake. This is the result of a natural bias that can creep in to the scoping exercise – namely, the tendency to inflate the population so that the need appears to be really important.

Consider the need example “a way to decrease infection in patients with prosthetic hip implants to reduce the rate of revision surgery.” While all patients would generally appreciate a lower infection risk, hospitals will likely not be motivated to pay a premium to reduce infection rates for all implant patients if the rates are fairly low overall. However, for certain patients – like people with comorbidities such as immune deficiencies or diabetes – the risk of infection is significantly higher. As a result, hospitals could be more receptive to a higher cost technology if it substantially reduced the likelihood of infection in this subgroup. Insurance companies, which pay for revision surgeries, would also be likely to adopt a solution that reduces infection and, therefore, reduces the need for repeat operations. We'll come back to this concept in the Outcomes section.

As a general rule, teams tend to underestimate how difficult it is to change the standard of care. Starting with a slightly smaller initial population where there's a more compelling case for change (a “beachhead”) can be an effective way to gain initial entry into the market.

Outcome

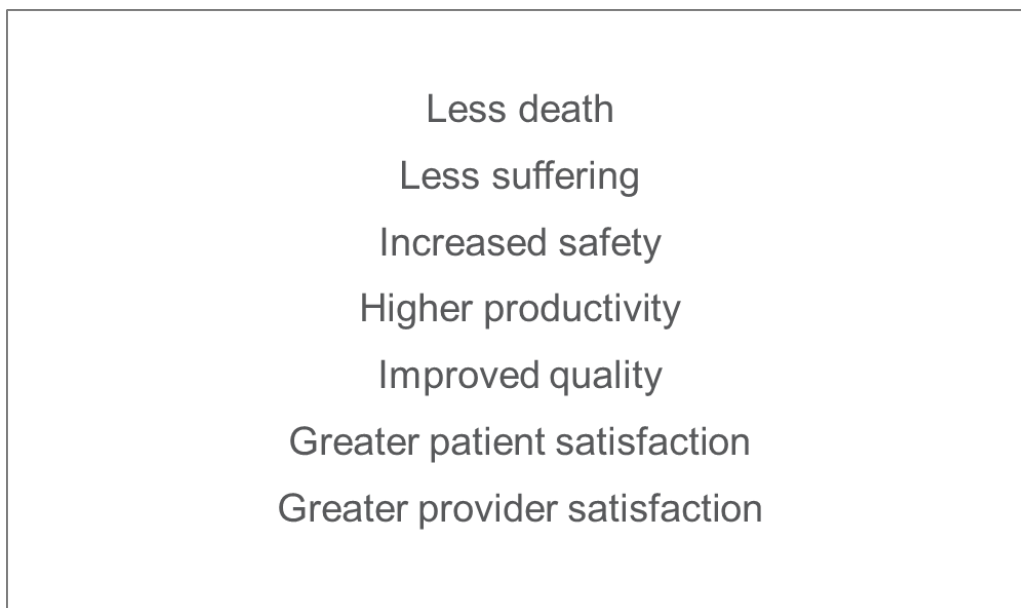
The outcome in your need statement should clearly define what benefit the key **decision maker** in the need area would value most from any new solution that successfully addresses the problem. Decision makers are those who act as the gatekeepers for whether or not a new solution is widely adopted. Your chosen outcome should be meaningful to the decision maker in your need area and ideally should be measurable using a strong, widely accepted metric. This will help you demonstrate the success of your new solution and ultimately drive adoption.

It's best to focus on a single outcome in your need statement. It can be tempting to think about more than one – for example, if you're working in an area where improved outcome and lower cost are needed, why wouldn't you want to highlight both? The reason for focusing on one outcome is that it forces you to prioritize the single thing the key decision maker wants most. It gives you a clear focus for the project and is less confusing when communicating your goals to others. This doesn't mean that secondary outcomes are not important, but these can be included as part of the need criteria (see the toolkit called Making Need Research Actionable via Need Criteria).

As a first step in choosing an outcome, go back to the list of stakeholders you made when thinking about your population and use interviews and research to determine which one represents the key decision maker. In the night terrors example, the team determined that parents were the real decision makers since they manage their children's health and are the main purchasers of solutions.

The next step is to consider what's most important to your decision maker. Target outcomes exist in a rough hierarchy, as shown in Figure 5. At the top of the hierarchy is reduced mortality. At the bottom is provider satisfaction, or improving the user experience for the person delivering care.

Figure 5 – Hierarchy for Scoping Your Outcome



All of these outcomes are potentially worthy targets, but solutions that deliver outcomes higher on the pyramid typically take more time and money to develop, test, and bring into patient care. Those at the bottom tend to be more incremental and, therefore, faster and less expensive to move into practice. So in choosing your outcome, you need to keep in mind the scale of the project (in terms of time, expense and human capital) that you're willing to launch.

As you consider what your decision maker cares most about, try to scope up and down within this construct, recognizing that not all outcomes may apply to your particular need area. Night terrors are not a matter of life and death. The nuance about outcomes for this need is how to weigh safety versus quality of life. In this case, the team learned that parents were, in fact, most concerned about the severe negative impact that night terrors have on the family's quality of life (patient and family satisfaction). Through surveys, they heard that parents and their children both felt negative emotional consequences from strings of nightly incidents. This helped the team realize that parents would be excited about a new solution that would enable children and parents to get better sleep and feel less emotionally drained.

Once you understand what your decision maker cares most about, you have to think about how you would measure that outcome. Fundamentally, in order to drive adoption of the solution you invent, you'll need to prove that it results in a significant improvement relative to your outcome

metric. Go back to the literature to determine what measures are widely used and accepted in the space. Be sure to consider whether the time and cost required to run a study to get the desired results is consistent with the size of the opportunity you're pursuing.

In the night terrors example, one potential metric for measuring rest would be a sleep study – an overnight exam conducted in a specialized laboratory that monitors EEG and other parameters. This outcome measure would have the advantage of being well-validated and highly quantitative. But, what parents really cared about – quality of life – could be much more easily measured simply by having parents keep a log of the number of nights without sleep disturbance over a few weeks. The team recognized that this was a much less expensive and more directly useful outcome measure. As a result, they decided that increasing the nights of undisturbed sleep should be the primary outcome measure in their need statement.

COMMON PITFALLS

Confusing Problem and Outcome

It's not unusual for teams to wrestle with the relationship between the problem and the outcome in their need statement. As a guiding principle, think about solving the problem as an action you can take, and the outcome as the result you hope to achieve. There's a temporal relationship between these two concepts – the action comes first and is then followed by the result.

There are still situations where it can be challenging to decide what to designate as the problem and what to put as the outcome. In some cases the most important problem and the desired outcome can seem like the same thing – for example, reducing infection rates associated with hip implants [problem] in order to reduce the number of patients who experience infections [outcome]. This situation usually occurs when the problem is so apparent that it's obvious why eliminating it would be valuable. In these cases, it can be helpful to dig deeper into the problem to try to find an outcome that focuses on what the decision maker cares about most. For example, if one of the major complications (and costs) from hip implant infections is the need for revision surgery, this provides an objective and measurable result that would be compelling for the facilities and/or insurance companies that bear the cost of these repeat procedures.

Confusion about which is the problem and which is the outcome also happens with need areas that are focused on reducing adverse events. For instance, osteoporosis patients with hip fractures face multiple challenges, including a higher-than-average need for revision surgeries. If you're uncertain about how to organize the need statement, create a draft and then experiment with swapping the problem and outcome. The first draft might be "a way to repair hip fractures in osteoporosis patients in order to decrease the rate of revision surgery." When you flip this and try out decreasing the rate of revision surgery as the problem ("a way to decrease the rate of revision surgery in order to..."), it becomes clear that this does not make as much sense: multiple factors can contribute to the rate of revision surgery and there's not a singular mechanism of action that you can affect.²

Finalizing Your Need Statement

Once you think you've landed on your near-final need statement, be sure to share it with a variety of stakeholders – especially decision makers in your need area – to see if it resonates. This is another critically important way in which the need statement acts like a prototype. Having something specific that stakeholders can react to leads to a richer and more focused response in your interviews – and can coax out further insights into the true nature of the need.

As you do this, be careful not to look only for confirmatory input. Just as you would try to pressure test a scientific hypothesis, you should be consciously looking for something that might “kill” your need statement before you take it forward. Although this might seem painful in the short term, it's actually a wonderful chance to save yourself a lot of wasted time and regret later in your project. If you get feedback that the need statement does not reflect a compelling opportunity, go back to your need research and continue to iterate. If, on the other hand, your need statement passes this pressure test,³ you can feel confident that you've hit on something important that justifies the continued investment of your time and energy.

BOX 2

What Happened with the Night Terrors Project?

After brainstorming a number of approaches, the team invented a system that uses a smart phone app and an under-the-mattress sensor and vibration pod to detect and intervene when the child is about to move into the night terror cycle.

The system gathers data from the parents about when the night terrors are happening, their severity, and how many night terrors the child is having. This information is processed through an algorithm to predict when to turn on the vibrations to interrupt the unhealthy sleep patterns that result in night terrors. When activated, the vibration pod brings the child out of the disordered sleep cycle but turns off before actually waking them. In one clinical study, the technology stopped 8 out of 10 night terror attacks within 4 weeks of use.

The project went on to become a start-up called Lully.

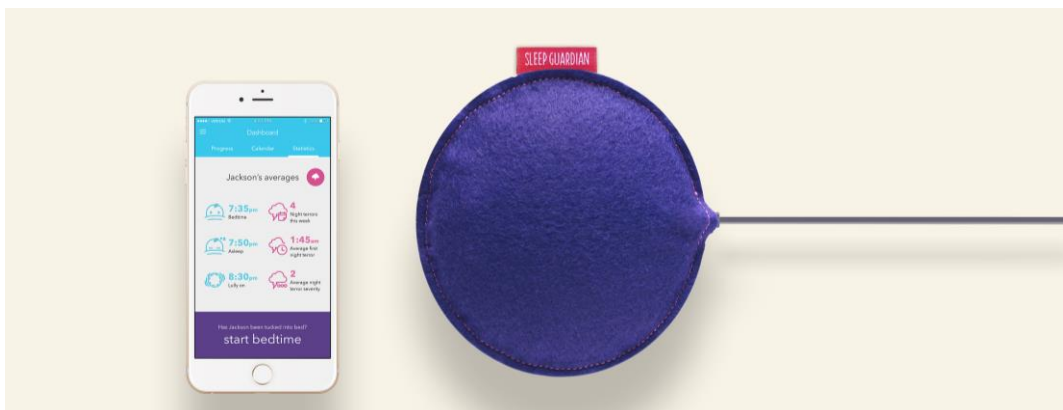


Photo courtesy of the Lully team

Credits

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Notes

¹ Nassir Mokarram, Lyn Denend, Jonathan Lyon, Douglas Rait, Todd Brinton, Josh Makower, Paul Yock, "Need Statements in Healthcare Innovation," *Annals of Biomedical Engineering*, June 2021, <https://link.springer.com/article/10.1007/s10439-021-02782-3> (June 15, 2021).

² Ibid.

³ Ibid.