CHAPTER 1

# Identifying an Unmet Need

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## ABOUT THE AUTHORS

**Steven Bokshan, MD**, is an orthopedic surgery resident at Brown University and a serial med-tech entrepreneur. His previous companies utilized *Google Glass* to enhance surgical teaching in the United States. With a strong background in statistics, he has also utilized time-based costing models and complex clinical simulations to perform economic analyses for various early stage companies. He has successfully fundraised as CEO of multiple companies. His current company, SmartOR, Inc., is working to disrupt the technological landscape of the modern operating room.

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## Introduction: Embracing Innovation

Here, we discuss the process of identifying an unmet orthopedic need. Although entrepreneurship represents a separate discipline, a surgeon's unique skillset gives them significant potential for entrepreneurial innovation and identifying an unmet need. To better understand this, we must first consider the strengths of a surgeon. Dr. Arlen Meyers, otolaryngologist and president of the Society of Physician Entrepreneurs, discusses the unique skills that ultimately prepare physicians for entrepreneurship (Table 1.1).[1] Among the most crucial are pattern recognition, familiarity with research, and ability to collect real-time feedback. To identify an unmet need, an orthopedist must learn to utilize and leverage these strengths in an

**Table 1.1 Components of a Physician's Medical Training That Are Crucial for Identifying an Unmet Need**[1]

| Common physician strengths essential for identifying an unmet need |
|---|
| Utilizing pattern recognition |
| Familiarity with research allows for proposing a hypothesis and systematically testing that hypothesis |
| Utilizing real-time feedback to adjust or pivot |
| Building judgment based on a series of previous experiences, successes, and failures |
| Performing internal risk and cost-benefit analyses |
| Having a bias toward taking action |

entrepreneurial manner. Having passion for identifying gaps and inefficiencies in clinical treatment or operations required to deliver care is requisite to the forward thinking nature of true clinician-innovators.

## PATTERN RECOGNITION

As we will discuss later in the chapter, the first step in identifying an unmet need is to **observe** a phenomenon that requires clinical improvement. In order to translate these observations into a defined **clinical problem**, the successful innovator must utilize **pattern recognition** in order to identify the common thread that is causing the clinical problem.[2] As notable endocrine surgeon Atul Gawande discusses at length in his novel *Better*, surgeons have a profound affinity toward pattern recognition.[3] Consider a recent orthopedic example. TMZF (titanium, molybdenum, zirconium, iron) femoral stems for total hip arthroplasty became available in the early 2000s and were touted by engineers and device vendors for their improved biomechanical profile. Shortly thereafter, arthroplasty surgeons began observing an uptick in the number of catastrophic stem failures. The resulting metal on metal corrosion ultimately caused dramatic metallosis, leaving patients with significant systemic side effects.[4] Although there were less than 100 cases of this catastrophic failure ultimately reported at the time of identification, arthroplasty surgeons quickly recognized this subtle association between TMZF alloy and stem failure.

Although the catastrophic failure of TMZF alloy represents a rather dramatic example of pattern recognition, orthopedists rely on less dramatic forms of pattern recognition to carry out their daily clinical duties. As part of their surgical training, orthopedists utilize pattern recognition to classify and distinguish injury types to form a treatment plan.

For example, which types of fracture patterns are anatomically stable versus unstable? Which types of meniscus tears are amenable to repair versus meniscectomy? Do patient characteristics or comorbidities affect which treatment is required? All of these questions require a complex series of pattern recognition in which an orthopedist considers prior experience and evidence-based literature to formulate a treatment strategy. Therefore, when utilizing pattern recognition to identify an unmet need, the orthopedist must simply learn to repurpose the skill as opposed to learning it de novo.

## RESEARCH

Regardless of the setting an orthopedist works, they possess the ability to use research in order to build a successful practice. Through their medical training, physicians are taught to develop hypotheses based on their observations and to rigorously test those hypotheses. Consider that in 2017 alone, a total of 334 orthopedic clinical trials were under active status.[5] This ability to propose novel hypotheses and challenge dogma is one of the orthopedist's greatest potential strengths in innovating. Leveraging these skills, the innovator challenges **confirmation bias**, or the tendency to become rigidly attached to an innovation because it holds personal value or has remained dogma, a common issue with surgical specialties.

Consider a recent example. When *Google Glass* was first announced in 2012, author S.B. became one of the first surgeons to use it in the operating room. This futuristic prism sat in the surgeon's peripheral vision and allowed for real-time control of any digital media with a simple voice command of "OK Google, …." Prior to the device being released, *Glass* had made headlines and national news. A large following of surgeons believed that the device would revolutionize the surgical field, with applications ranging from real-time video conferencing to targeted tumor resections. Admittedly, when it was first released, confirmation bias played a large role in setting high expectations for the device. Many surgeons wanted the device to usher in a wave of real-time digital media processing in the operating room. Unfortunately, few surgeons had anticipated that, in an operating room environment where noise levels can exceed 100 decibels, *Glass* could recognize fewer than half of the commands it was given.

As *Glass* slowly faded away from the OR, it taught us an important lesson. With any innovation or new idea, inventors must first challenge themselves; in other words, the innovator must test their hypothesis that a need is unmet (i.e., avoiding a **type 1 error**). When a need is truly unmet, there is a tendency for the innovator to frequently and even spontaneously revisit the issue.

### COLLECTING REAL-TIME FEEDBACK

Orthopedic surgeons use real-time feedback to enhance patient care. This is, perhaps, the most important innovation-related skill that orthopedists possess. To cite several examples: we use dynamic stress x-rays to determine the need for acute surgical intervention, we assess our patients' responses after administering medical therapies, and we modify surgical techniques based on intraoperative success and patient outcomes. This ability to modify behavior based on real-time feedback is essential to identifying an unmet need.

For example, consider a surgeon who wished to develop a novel device for internal fixation of a meniscal tear. Prior to product development, the surgeon must collect feedback from colleagues regarding the device. An optimal device would incorporate the most successful components of a competing device but exclude its disadvantages. Pilot testing is required, during which a small sample of surgeons utilize the device and make suggestions influencing further product development (this is often referred to as **focus grouping**). Through the use of real-time feedback, the innovator is able to modify the device in order to more successfully fulfill an unmet need. Product development must remain a fluid process incorporating feedback from surgeons, engineers, device companies, and patients. This fluidity, also known as **pivoting**, is a crucial part of the innovation process.

## The Process of Identifying an Unmet Need

Although there is no exact formula for identifying an unmet need, the process generally follows a series of steps. These include performing mindful **observations**, translating a series of observations into a **clinical problem**, and ultimately addressing this problem with a novel **innovation**.

### OBSERVATION

Orthopedists are at a unique advantage in identifying unmet clinical needs. Aside from the patient, they are the only individual to observe the entire course of a patient's care (see Figure 1.1 for description of the care process). This process begins when the patient seeks treatment for a musculoskeletal complaint and ends with the resolution of the problem. The process of delivering orthopedic care is extremely complex and involves many ancillary staff members across different environments (e.g., office, operating room). It is important to realize that an innovation can be made in any or all of these aspects of care, with the first step being careful observation.

In order to identify an unmet need, an orthopedist must make unbiased and mindful observations about the success of the orthopedic care

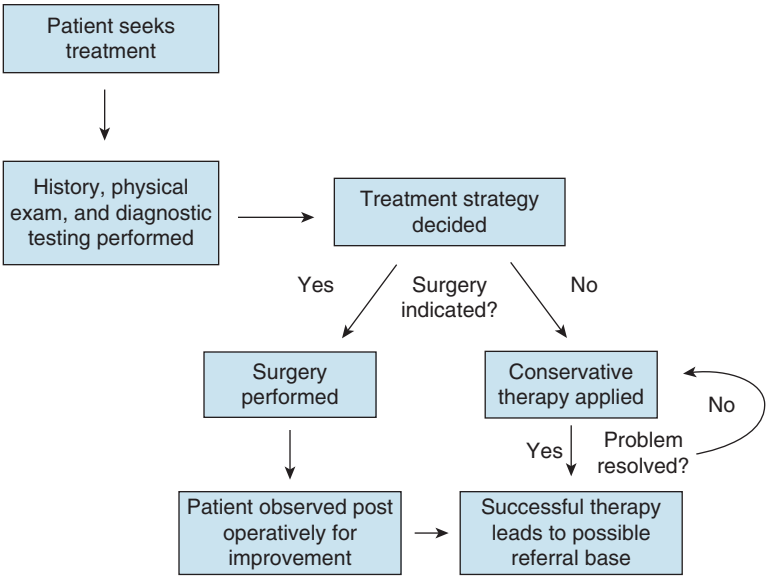


**Figure 1.1** A simplified flow diagram of the orthopedic care process.

they are providing. Collecting real-time feedback is essential, with a particular emphasis on experiences that do not occur as desired or that tend to recur in a suboptimal manner. For example, a common observation in an outpatient orthopedic practice may be that patients are being seen inefficiently, with office days lasting beyond the desired expectation. Although it is entirely possible to outsource this problem to an outside consulting service, the orthopedist may be in the strongest position to translate these mindful observations into a solution.

Returning to the previous example of an inefficient office day, consider author SB's experience with using mindful observation to identify the problem. This particular practice consisted of nearly 30 different orthopedists seeing patients in the same office building, some with upwards of 60 patients in a day. By 3 PM, there was a recurring theme. Despite average surgeon-patient interaction times of approximately 8 to 10 minutes (most patients were slotted for a 15-minute visit), patient wait times began to increase. But how could this happen if the actual patient encounter was nearly half the time allotted for each encounter? On further analysis of the wait times, we found that the largest wait times occurred on days consisting of primarily postoperative visits. These wait times seemed counterintuitive, as most postoperative visits only required a brief physical exam and suture

removal. Through a series of mindful observations, we ultimately found that largest factor leading to delayed wait times was not the clinical encounter, but rather a delay from the oversaturated x-ray facility. With upwards of 90% of postoperative patients requiring x-rays, we identified the source of patient delay.

After observing aforementioned the clinical problem, we utilized an office modeling program to determine the most efficient solution: deploying digital radiography in the x-ray suites. By reducing x-ray cassette reloading requirements, digital radiography allows for smaller doses of radiation and shorter patient wait times. This solution ultimately translated to higher patient satisfaction and a greater number of patients seen per day.[6]

Patient satisfaction, however, is not the only endpoint for which mindful observation can be utilized. An orthopedist can use mindful observation to identify areas of unmet needs in many different facets of patient care, such as operating room efficiency and success of resident education. In the above example, there were actually multiple suboptimal outcomes including longer patient wait times (which has been directly tied to patient satisfaction), overburdened x-ray technicians, dissatisfied ancillary staff members from a prolonged office day, and a decreased number of overall patients seen by the orthopedist.[6] It is also important to realize that, because of the complex relationships among different resources in the care setting, a proposed innovation for an unmet need may simultaneously improve one endpoint and negatively affect another, i.e., the large cost of retrofitting x-ray facilities with digital technology. Ideally, when proposing a solution for an unmet need, the innovation should positively affect all those involved.

## IDENTIFYING A CLINICAL PROBLEM

As stated before, identifying a **clinical problem** is the second step in the process of identifying an unmet need. Although observations are a series of unbiased data points used to identify a suboptimal clinical endpoint, they alone do not represent a clinical problem. In order to truly represent a problem or an unmet need, there must be sufficient **scope** surrounding the observation. Sufficient scope refers to a significant clinical or economic burden that is a direct result of the suboptimal observation. It is true that scope of a clinical problem may first be measured informally through real-time patient feedback or focus grouping with colleagues. Prior to fundraising, however, it is imperative to quantify the economic burden of the problem. If the economic burden is not significant enough to offset the potential cost of a proposed innovation, it becomes very difficult to justify the scope of the innovation.

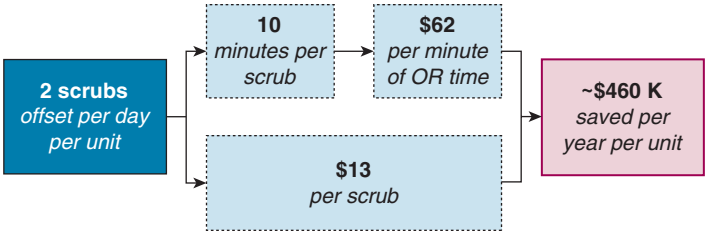


**Figure 1.2** Economic burden analysis for a device that reduces breaches of surgical sterility.

For example, consider that you are developing a product that reduces breaches of sterility in the operating room. In an effort to reduce this burden, you devise a new low-footprint and ergonomic miniature fluoroscopy unit that prevents at least two accidental contaminations at a surgical center daily (based on small pilot data). As shown in Figure 1.2, the economic scope of this clinical problem must first be calculated.[7] Knowing the baseline economic scope helps to objectively value the economic advantages of the proposed innovation.

## INNOVATION

Once a clinical problem of significant scope has been identified, the orthopedist may begin the process of **innovation**, or creating a solution to an unmet need. First and foremost, this process must begin with appropriate documentation. It is imperative that an innovator has a notebook for written documentation of their ideas. This written record serves a twofold utility. First, as more feedback is collected, documenting previous iterations of the product aids in telling the timeline and story of the product: a step that is crucial during initial pitch meetings. The second advantage of written documentation is to have a written record (signed, dated, and timed by the creator) of which you initially conceived the idea. This information can serve as a source of legal documentation.

Once you have begun the process of innovation, it is essential to have a complete understanding of the technological landscape surrounding the concept. Despite existence of an unmet need, it is possible that the current state of technology precludes a reasonable solution. Consider the previous example of *Google Glass* in the operating room. Upon its initial release, the state of voice recognition was very different from the present.[8] With noise levels in the operating room exceeding 100 decibels, previous voice recognition was unable to achieve command recognition rates above 50%. Recent advances in artificial intelligence algorithms allow for complex noise

cancellation and vocal tracking, and it has only recently become possible to perform vocal recognition in the operating room. An understanding of what is technologically possible is crucial when evaluating the attractiveness of innovation around an unmet need; the need will remain unmet without a technical solution.

As a second example, consider a spine surgeon who would like to develop a device that wirelessly detects fine finger motions to track the rehabilitation process for a cervical cord spinal injury. Over the course of the last decade, wireless motion technology has advanced dramatically from recognizing only gross motion at larger joints to now measuring millimeter-level finger movements. Such technology would be appropriate to measure the small improvement seen in cervical cord rehabilitation.[9] Specifically, Project Soli from Google X utilizes radar waves to detect finger movements at a higher resolution than previously reported. These recent advances have made the creation of wireless finger movement detection technologically possible, a feat that was not possible in the early 2000s.

Although innovating can often be the most rewarding step in the process, successful innovation is best supported by the observation and problem identification phases; skipping these earlier, foundational phases is a common pitfall. This is particularly true as advances in technology facilitate rapid movement from idea generation to product development. This lack of **due diligence** frequently yields difficulty during the fundraising process and can be a fatal flaw in the early business lifecycle. As an example of poor due diligence, consider an orthopedist who seeks to develop a novel device to more accurately measure blood loss during surgery. With recent advances in biosensor development, one potential solution would be to outfit a suction device with an infrared sensor to measure the volume of blood passing through the suction tubing per unit of time. Although this device represents a novel solution to an important problem, it does not add any value to the current surgical landscape, as postoperative blood counts are often checked routinely following surgery. Here, it is unlikely that a clinical problem was identified prior to the device development, as the clinical and economic scope of this potential innovation would not justify the cost of product development.

## Conclusion

Orthopedists are uniquely situated to identify areas of unmet needs. With a training that fosters many of the core strengths of entrepreneurship, orthopedists can translate these abilities to identify unmet clinical

needs. An innovation is best received when an unmet need has sufficient scope and the technological landscape provides a cost-effective solution. Although there any many pitfalls that may occur during the innovation process, a disciplined approach supported by due diligence is much more likely to result in a successful outcome. Perseverance is essential, as the vast majority of innovations will require significant evaluation, modification, and reevaluation to achieve a successful result.

## KEY TAKEAWAY POINTS

- Orthopedists' training provides them with many strengths that should be utilized when identifying an unmet need. These include pattern recognition, familiarity with research, and the ability to collect real-time feedback.
- The process of identifying an unmet need includes observation, defining a clinical problem, and innovating.
- An observation is the process of mentally or physically recording an aspect of the patient care process, frequently one that occurs in a suboptimal manner.
- A clinical problem has been observed multiple times and represents an inefficient or suboptimal delivery of care.
- It is essential to avoid bias and common pitfalls during the process of innovation.

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