

NEED CRITERIA AS GUIDING LIGHT: SANDSTONE DIAGNOSTICS

“We originally approached the opportunity from a scientific standpoint of ‘how could we do this better?’ Through research, the place we got to was ‘what does our market need?’ Sometimes those are the same thing, but often times they’re different.”
– Greg Sommer, CSO, Sandstone Diagnostics

After helping to develop a powerful cell-counting technology for biodefense applications, Sandstone Diagnostics founders Greg Sommer and Ulrich Schaff recognized that the technology could be adapted to address diagnostic needs in healthcare. Male fertility testing rose quickly to the top of their list when their research validated the need for a better way to test men’s fertility that was private, convenient, cost effective, and actionable. The end result was Trak, a robust device, mobile app, and web platform that can not only count sperm, but is poised to change the paradigm around men’s health and family planning.

Background

Sometimes great solutions are born backwards, with the development of a core technology preceding a deep understanding of the need it will solve. This was the case with Sandstone Diagnostics. Company founders Greg Sommer and Ulrich Schaff were employed by Sandia Labs when they helped develop SpinDX, a “lab-on-a-disk” diagnostic technology that rapidly performed immunoassays and cell counts using tiny blood samples. Although SpinDx was created for bio-defense applications, Sommer and Schaff recognized its potential in healthcare diagnostics. Along with a third founder, Sara Naab, they licensed the technology and launched Sandstone Diagnostics.

Once the new company was formed, the team’s first challenge was to delay further technology development until they determined specifically where the most compelling unmet need existed in the health field that could potentially be addressed by their solution. After performing a broad landscaping and comparative assessment of different possibilities, the founders became enthusiastic about opportunities in the area of male infertility. “From a technological perspective, building a home spin device to count sperm cells was definitely something we could do,” recalled Sommer. “And it appeared that the field was ripe for innovation.”¹

Need Research

With this target need area in mind, Sommer explained, “We did a deep dive into researching male infertility to make sure we really understood the critical problems in the space and what criteria a solution would have to meet to be accepted.” Defining a set of must-have and nice-to-have need criteria was essential because these factors would directly guide the company’s future technology development and help ensure that Sandstone effectively adapted its solution from bio-defense to male fertility.

The team initiated its investigation by reviewing the literature, interviewing doctors, and talking with couples. “Infertility is kind of an interesting space that isn’t widely discussed—it’s quiet and a little bit taboo,” Sommer said. “At the same time, everybody either knows somebody who has been through

fertility challenges, or they have experienced it themselves, so once we started asking questions we ended up talking to a lot of people.”

Through these conversations, Sommer and his team learned that fertility treatment tended to be driven more by women than men. “Generally, when a couple starts trying to conceive, if the woman doesn’t get pregnant after several months, she is the one who will go in to see her OB/GYN,” said Karen Drexler, who became the CEO of Sandstone Diagnostics in 2016. “And OB/GYNs treat women, so often the male partner isn’t even part of these initial conversations.”

The founding team observed that the couple had to be trying to conceive for 12 months or longer to be considered infertile, and only then was the woman referred to a reproductive endocrinologist or fertility clinic. “There’s an early waiting period where the woman can do very little, and that’s stressful,” said Sommer. “One of our first thoughts was that testing the male partner could be done in this time period.”

Male testing is essential because male fertility is a sole or contributing factor in 43 percent of infertility cases.² Despite this, Sommer noted, most men aren’t tested until a couple is 18 months into the fertility process. “That’s a really long time when they’ve experienced month after month of not getting pregnant.” Even then, Drexler added, “Only about 15 percent of men seek treatment.”

While there are several explanations for this, the primary reason was simply that most men find it awkward and embarrassing to talk about fertility and to go in for testing. “For men to get tested, they have to visit either a urologist or a fertility specialist for a semen analysis, which involves going into the clinic, stepping into the backroom, producing a semen sample, handing it to a technician, and then waiting while the sperm are examined under a microscope. It’s an uncomfortable experience and so men avoid it,” said Sommer. Other barriers to testing include distance to the fertility clinic (sometimes three hours or more) and cost because, more often than not, couples pay for fertility treatment out of pocket.

Through their conversations with physicians, the Sandstone team also learned that information and assistance related to men’s reproductive health is lacking. “There’s a fairly small set of urologists who are interested in not only helping a man improve his fertility status, but also looking at his overall health. Meanwhile, infertility is tied to higher rates of chronic disease,” Sommer described. “We saw that there was a possibility of helping men improve their overall health as part of their fertility journey.”

A survey of the competitive landscape revealed that while the female side of the equation was rife with ovulation tracking apps and connected thermometers, there was, at the time, only a single product designed for men. “This is a simple yes/no test that tells men if they are above or below a certain threshold, 20 million sperm cells per milliliter of semen,” Drexler said. “Not only does it provide very limited information (Is he just above the threshold? Just below? Significantly below?), the test also doesn’t acknowledge that male fertility is a changeable condition, influenced by health and habits. A yes/no test doesn’t allow men to see changes over time.”

Need Criteria

Based on this research, the Sandstone team was able to define meaningful need criteria that would guide them in customizing their technology to meet the requirements of men seeking to assess their fertility. Most importantly, they confirmed that developing a home testing option would remove one of the most significant barriers to fertility testing by protecting men’s privacy and increasing their comfort level. Additionally, the test had to be easy-to-use, provide (at minimum) an accurate reading of a man’s sperm count, and be more informative than a simple yes/no response so that users gained a clearer understanding of their count relative to the optimal level. Additionally, the test had to provide personalized, actionable information that would allow men to make necessary lifestyle changes to

optimize fertility and overall health. “While female infertility treatment often involves medical procedures like hormone therapy or in vitro fertilization, sperm count can often be improved through simple lifestyle changes like achieving a healthy weight, exercising, reducing alcohol intake, and avoiding excess heat,” noted Sommer. Finally, it would have to be less expensive on a per-test basis than a clinic visit since most couples would continue to pay for it themselves.

The founders also defined a handful of nice-to-have need criteria that they ideally would like their test to address. These nice-to-haves would help drive adoption but were not identified by the target audience as essential. One such criterion was having the test also analyze sperm motility. Motility refers to the sperm's ability to move through a woman's reproductive system to reach the egg. Sperm with abnormal movement will have difficulty reaching and penetrating the egg. While not quite as essential as measuring sperm count, the team thought it would be ideal to have its test measure motility, as well, since both are important indicators of male fertility.

Need Research

When the team described their need criteria and technology development plans to physicians and prospective users, the response was overwhelmingly positive. “When we brought up the idea of easily and effectively obtaining an initial sperm count at home, both physicians and couples were very enthusiastic,” Sommer said. “Several doctors became advisors, helping us further define the product needed to do.”

As the team began to build out the diagnostic test and plan its path to market, Sandstone made progress in addressing its must-have criteria, but ran into challenges with the nice-to-have criterion for motility as they explored their regulatory pathway. The founders felt that getting their technology approved by the FDA was important. “There were scenarios where we could take it to market without FDA clearance, but we wanted this to be a validated and accepted medical tool,” said Sommer. As a side benefit, obtaining FDA clearance would also give the team some protection from future competitors because of the amount of work and financial investment involved in getting a product through the regulatory process.

However, assessing motility is a more complicated process than counting sperm and after several preliminary meetings with the FDA, the Sandstone team realized that the cost of gathering the extensive clinical trial data required by the FDA to clear this feature was simply out of reach for the young company. Accordingly, the Sandstone team revised their design parameters to focus solely on developing a best-in-class sperm count product. “We decided to take a very solid but streamlined product through FDA clinical trials and clearance and then build upon that over time,” said Sommer. Even then, getting clearance for the initial product, focused on sperm counting, required a three-site, 240-person clinical study and several years of interacting closely with the agency.

In preparation for launch, the Sandstone team enhanced its first product by increasing their focus on education and awareness building within the target audience of potential users. “When a man takes a test, our message, especially if he comes out on the low end, is that it's okay, this is a pretty common condition, but there's a lot you can do about it and we want to help you improve your overall health and see changes in sperm quantity. That's probably the biggest evolution—that the test evolved from a diagnostic into more of a tracking and improvement tool,” said Sommer.

Ultimately, Sandstone released Trak in January of 2017 as a direct-to-consumer medical device. The technology functions as a battery-powered centrifuge that spins a disposable cartridge containing the semen sample. Gradations in the cartridge allow users to determine whether the number of sperm cells collected is considered low, moderate, or optimal, and how close their count is to those demarcation

points. The accompanying app tracks sperm count over time, and helps men monitor and improve their reproductive and overall health with a health and habits questionnaire. It also provides personalized lifestyle recommendations and extensive web-based educational support.

According to Drexler, even though Sandstone set aside one of its nice-to-have need criteria in the first version of the technology, “the way the product turned out is better than what we had originally envisioned. Our value proposition now is around helping couples plan for the fertility journey. We expect that early users will be couples already trying to conceive and we’re also hearing that couples are doing things to prepare to have a family. We see ourselves as being an important part of that planning process.”

“There’s so much misinformation out there around men’s fertility and men’s sexual health,” Drexler said. “We’re really excited about our product, app, and website becoming trusted resources in an area that’s difficult for a lot of guys to talk about by providing high quality information, grounded in science.”

Key Insights

- **Even when you start with a technology, getting the need right still matters**
Good technologies sometime start with an interesting scientific discovery. But in order to be successful, it’s imperative to identify and deeply understand what unmet need(s) that can best be addressed by the technology before you get too far into product development.
- **Think of need criteria as a guiding light**
“Every Deep need research and user interviews help you become an expert in the problem that needs to be solved. Establishing need criteria makes critical insights actionable. By defining a set of requirements that are most essential to address in order to displace the current standard of care, you have a roadmap for designing and developing your solution.
- **Stay flexible**
During product development, you will undoubtedly hit roadblocks and issues that threaten your solution’s ability to deliver on all of your need criteria. Recognize that such trade-offs sometimes must be made, and your need criteria may need to be revised. Just be sure not to eliminate must-haves without validating the shift in priorities with a representative sample of your target users.
- **Focus on outcomes**
“Work on solving a real problem. Focus on outcomes....what you can change, how you can help people change behavior, how you can help impact decisions. Look for something that is meaningful where the information can be used for decision-making and not just for the sake of collecting data.”
– Karen Drexler

¹ All quotations are from interviews conducted by the authors, unless otherwise noted.

² “Infertility FAQs,” Center of Disease Control and Prevention, <https://www.cdc.gov/reproductivehealth/infertility/> (July 12, 2022).