MED DEVICE ONLINE

Guest Column | September 19, 2018

5 Reasons Your Medtech Market Likely Is Smaller Than You Think

By Mike Fix, Navigant

Across all the medical technologies and disease areas I've analyzed, I've found that true market opportunity size rarely is well understood. When we meet with clients to kick off a new strategic market assessment, we're provided with an overview of the new

technology or potential acquisition. Most times, the client leadership team cites a hefty figure for the anticipated market opportunity.

Unfortunately, there are many reasons your market may be smaller — perhaps much smaller — than you think. From the hundreds of technologies and therapeutic areas our team has worked on, here are the five most common reasons:

1. **Incidence, Not Prevalence**

   It's almost never enough to simply look at how many people exist with a given condition. A host of critical questions must be addressed to drill down to the true market potential of a given technology, including the distinction between prevalence and incidence.

   The dynamics of prevalence and incidence can wreak havoc on how the market opportunity is defined. In most cases, incidence should be the primary view of the technology's annual, ongoing revenue potential. This is especially true when the subset of patients expected to get the biggest clinical benefit (aka, "perfect patients") is a relatively small portion of the overall opportunity, making the market opportunity even more reliant on incidence as the current pool of highly attractive patients are converted to therapy.

   For example, at a glance, the opportunity for a new obesity treatment seemed huge, because the condition affects 80 million people in the United States and millions more

globally. That's the prevalence number the client team focused on. But, while obesity had grown 20 percent over the past 20 years, it was now slowing as Baby Boomers aged out and the overall pool of surgical candidates declined. In the end, fact-based analysis, factoring for several disease- and technology-related factors, dropped the *prevalence* pool to less than five million, with an annual *incidence* rate below 200,000 candidates/year, and thus lowered the achievable revenue potential considerably.

2. **Gross Vs. Net**

Every technology experiences a translation from its technical Indications for Use (IFU) to the practical group of patients who will actually be considered by physicians for a therapy or procedure. These factors range from clinical considerations — such as limited life expectancy or inability to comply with required behavior/medicine changes — to economic considerations, such as patients without insurance or those unable to afford the out-of-pocket costs.

This is how you get from the "gross" total (IFU criteria) to the "net" addressable patient population, meaning those who are realistic candidates for treatment. The difference between gross and net can result in anywhere from five percent to 95 percent of patients being excluded from the net opportunity.

Medtech companies usually underestimate the gross-to-net exclusions, resulting in an overstatement of opportunity size. For more mature technologies, this also impacts the ability to accurately understand market penetration and growth potential.

3. **Diagnosed Vs. Undiagnosed Patients**

One of the most difficult barriers to overcome is a low diagnosis rate for the target disease area. The patients are out there, but cannot be identified as good candidates for treatment.

Without accounting for diagnosis rate, your market opportunity may be missing a critical point: treatment comes with diagnosis only. Unless patients are aware of their conditions and talking to physicians, they will not be candidates for your technology.

Some patients may already be fully diagnosed, or existing diagnostic tools can be used to identify patients. But, for many novel therapies, investment is required to develop new diagnostic tools, tie them to clinical outcomes, and make them easy and cost-effective for physicians to use.

Also, in some cases, a technology is ahead of the diagnosis curve, meaning it is capable of treating something that isn't yet being diagnosed effectively or consistently.

For example, when drug therapy was initially launched to treat osteoporosis, the disease was under-diagnosed because it was usually only spotted as a result of broken bone trauma from falling. Only after the medical industry adopted a low-cost bone-density scan as a standard of preventive care did the diagnosis rate increase and, along with it, the adoption of drug therapy to treat osteoporosis.

4. **Patient Bother**

Even if a patient has been diagnosed, their condition may not bother them enough to make them a realistic candidate for your technology.

This can manifest itself in a number of ways. They may not seek care for their condition, meaning it will never be discussed with their physician, where new forms of treatment may come up. Or, they may not perceive their level of symptoms to be significant enough to warrant undergoing a procedure.

Often, this dynamic is related to their perceived level of risk for the technology or procedure, where the "bother threshold" will vary depending on the patient's perceived risk vs. benefit tradeoff.

For example, this can be seen again with obesity. Self-reported health and exercise data show that 68 percent of severely obese patients report being in good or excellent health, despite only 15 percent reporting that they exercise. If

few obese patients believe they have a health issue, that translates to many candidates who will not be motivated to undergo a procedure.

5. **Unmet Need**

It seems like a no-brainer, but it's often a brain puzzler: genius medical technologies fail to gain adoption, because literally there is not enough market need.

Even effective, novel technologies need to be critically evaluated to determine the incremental value they provide compared to the existing standard of care. In many cases, physicians are highly satisfied with how they are providing care, so getting them to change their current behaviors will be extremely challenging.

In the current healthcare environment, technologies that offer economic or time savings to the healthcare system must demonstrate equivalent or improved clinical outcomes to achieve adoption. Outcomes remain the primary driver when evaluating new solutions, especially among payers. An example of this is the many digital health technologies struggling to gain traction with payers and providers without sufficient — and extensive — clinical evidence.

Additionally, the situation impacted by a new technology needs to be meaningful to clinicians, or they will not be engaged. For example, if the procedure being impacted is rarely performed, or the target patient is rarely encountered,

the new technology will not be a high priority for the healthcare system, and clinicians will not be motivated to change their approach.

Thinking through all the real-world reasons why a clinician wouldn't or couldn't treat someone with your technology is critical to an accurate understanding of the market opportunity. Sadly, some organizations don't prioritize rigorous opportunity analysis until they start to feel the stress of early commercialization not meeting expectations.

But, true market potential is knowable long before you're in the red. We've uncovered cases in which the disease comprised a tiny fraction of a large, well-known condition, making it nearly impossible to show clinical significance — in which drug therapies rendered surgical options fruitless; in which the industry itself lacked a standardized definition of the condition or how to best treat it; and many other "preventable" scenarios.

In each of these cases, with advance knowledge of their product's true potential, the companies could have shifted course to invest and plan strategically, nurturing the technology's *market* development in parallel with *product* development to harness a higher return on investment (ROI).

Based on the results of the hundreds of strategic market assessments our team has performed collectively, it's best to be sure you understand the defensible, fact-based market need for your

great idea before investing significantly in an intuitive belief of its potential.

Any of these five reasons, among others, could derail your business. The key is knowing the realities of the market ahead of time, and carefully planning out your pathway to becoming a new standard of care. As we like to say, knowing is everything.

About The Author

Mike Fix is Director of Life Sciences at Navigant. He has more than 15 years of experience across the pharmaceutical and medical device industries, with additional experience in retail. His work focuses on leading engagements assessing market landscapes for startups, mid-size, and multinational medical device manufacturers. He also manages and develops the firm's market development software application. Most recently, he has worked on projects in therapeutic areas including chronic venous insufficiency (CVI), coronary artery disease, emphysema, heart failure, hospital acquired infection, migraine, and obesity.