

Focused Ultrasound Market Study

Essential Tremor



Clinical trials for focused ultrasound, FUS, treatment of essential tremor, ET, began in 2011. As a result, we have a decade of information that is worthy of analysis. Below, we take a closer look at what drives the adoption of this technology.

Timelines of the factors that drive adoption

When we compare the relative number of treatment sites that have adopted FUS to the relative number of patients treated with the technology, it is clear that the increase in treatment sites precedes the increase in number of patient treatments.

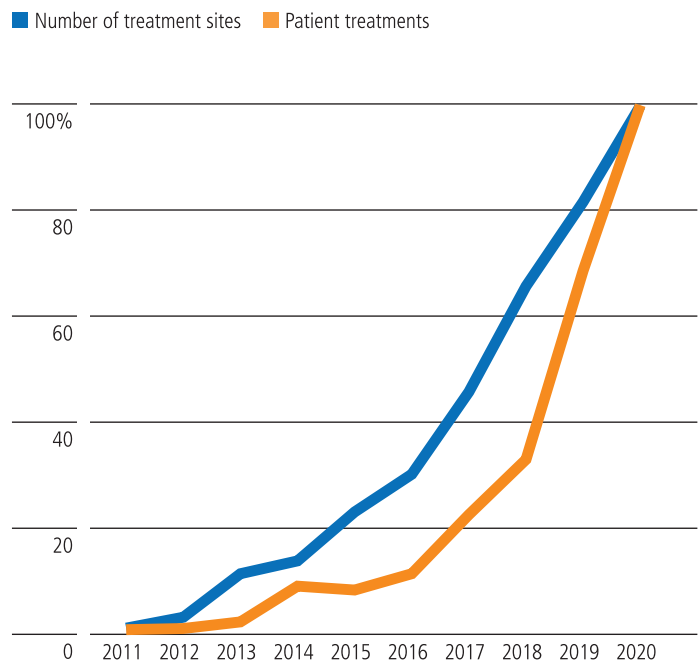
In 2016, when reimbursement—also referred to as insurance coverage—for the procedure was first granted, there were one-third the number of sites that there are today. In contrast, only one-tenth the number of patients were being treated in 2016, as compared to current treatment volumes.

There are two main factors that potentially drive site adoption and patient treatment volume. Regulatory approval is critical, since physicians cannot utilize a technology unless it is approved in their country. Reimbursement by government health agencies or private insurers is also a vital factor, since patients often cannot—or will not—pay out-of-pocket for medical treatment.

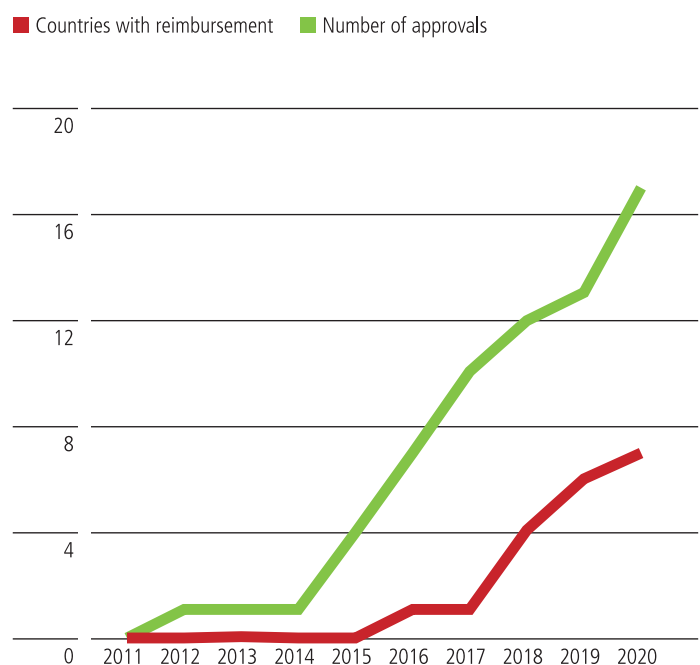
When the number of global regulatory approvals is compared to the number of countries granting insurance coverage, we see that approvals lead reimbursement, in the later years by a healthy margin.

This is not surprising, since regulatory approval is a prerequisite of reimbursement. Although regulatory approval and insurance coverage both require data about patient safety and efficacy, those for reimbursement are of greater rigor than these required for approval. Reimbursement also requires information on utilization (how many cases are being performed) and cost-effectiveness. Data for the last two factors can only be obtained after the device has been in commercial use for a certain period of time, creating a lag in reimbursement relative to approvals.

Treatment Sites vs. Patient Treatments



Approvals vs. Reimbursement



Correlating the factors

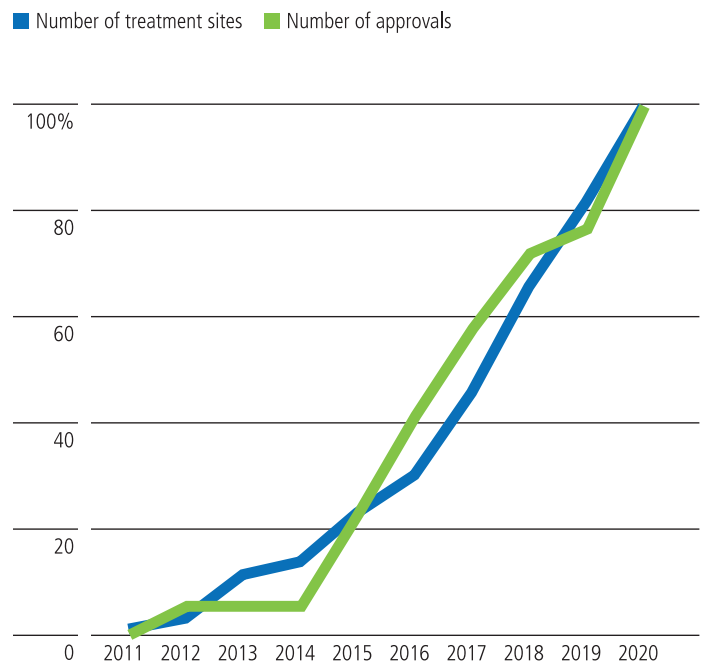
So which factor drives site adoption, and which drives patient treatments? The graph to the right demonstrates that the relative rate of site adoption tracks very closely with that of regulatory approvals. In fact, the correlation coefficient between the two (the degree to which the number of approvals predicts the number of sites adopting FUS, and vice-versa) is 0.96. In other words, using one to predict the other will be accurate 96 percent of the time.

In addition, the relative number of patient treatments tracks most closely with the relative number of countries that reimburse the procedure, although reimbursement does lead patient treatments to an extent. The correlation coefficient in this case is 0.94.

Interpreting the correlations

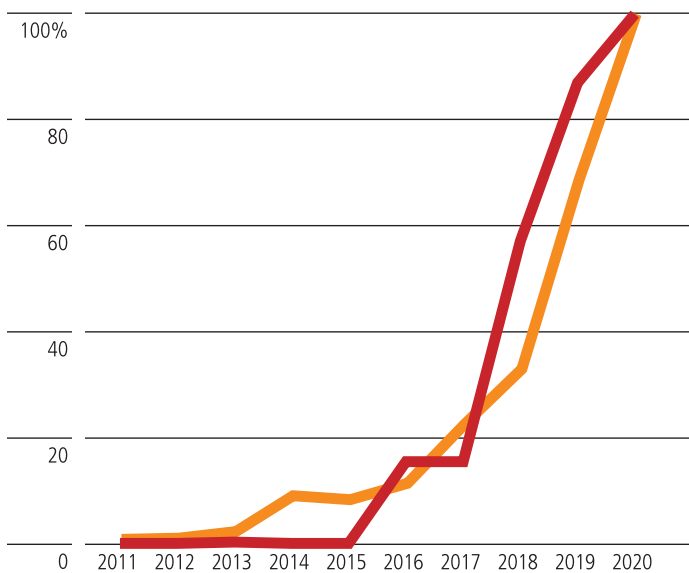
The close alignment between reimbursement and patient treatments was not unexpected. As mentioned above, patients are often unable or unwilling to pay for a medical procedure out-of-pocket. This is especially true in the many countries with socialized medicine, where the concept of a patient paying directly for a procedure is largely unheard of. Essential tremor is a debilitating, but not a life-threatening, disease. In addition, there are alternative ET treatment procedures that are covered by insurance in most countries. Because of this, patients who wish to have their ET treated specifically with FUS, in countries that don't currently offer insurance coverage are likely to assume a wait-and-see position, with the anticipation that their country will soon offer reimbursement.

Treatment Sites vs. Approvals



Patient Treatments vs. Reimbursement

■ Patient treatment ■ Countries with reimbursement



The graph above shows reimbursement somewhat leading patient treatments. This likely results from two factors.

- Most essential tremor patients are not aware of new insurance coverage immediately after the decision is announced, often finding out about this only after consultation with their neurologist or neurosurgeon.
- There is almost always more demand for the procedure than there are treatment times available to perform it. As a result, it takes some time for patient treatments to catch up with new coverage.

Both of these factors cause a lag between coverage being granted and the patient treatment numbers reflecting this fact.

The one remaining question is: why does site adoption track most closely with regulatory approvals and not reimbursement? Reimbursement of FUS-based ET treatments began in 2016, with the number of countries reimbursing the procedure increasing rapidly since then. Even though the rate of treatment sites adopting the technology increased after 2016, we have certainly not seen the exponential growth that you would expect if reimbursement drove site adoption. We propose two theories to explain this close relationship between site adoption and regulatory approvals.

It is not uncommon for medical centers to choose to purchase the equipment “on spec” after approval is granted, with the expectation that coverage will soon be forthcoming. In the US, 80 percent of new medical technologies that obtain FDA approval are later granted Medicare coverage. Because of this, future prospects for insurance coverage likely offset the financial risk of purchasing the equipment.

A less economic rationale we’ve heard while in discussion with many ET treatment sites—academic and for-profit institutions alike—is based on the medical industry concept of “compassionate care.” Medical centers are willing to purchase medical equipment, regardless of potential profitability, as long as it provides a clear improvement in patient outcomes.

Based on this information, we view the consistently robust growth in the number of treatment sites as evidence that FUS for the treatment of ET is seen as an attractive alternative to competing technologies, and one that may be worth acquiring, even if the odds of future insurance coverage are not absolute.

2021 State of the Field

This case study appears in the *2021 State of the Field Report* which is available on the Foundation's website.

The report documents the progress that is only possible through the hard work, time, and resources of everyone in our community.

New this year: an in-depth analysis of all research areas; the cumulative number of mechanisms of action by indication and stage of research; and a detailed look at industry trends, regulatory approvals, and investments in the field.

