

20 Nov 2016 | Analysis

Medtechs Bemoan Circuitous Journey To Access UK NHS

by Ashley Yeo

Clinical medical device companies can have a hard time before securing any meaningful income from an innovative product they wish to make available to NHS buyers. That has been the experience of Forte Medical, a UK-based SME that has come up against considerable challenges in trying to engage with the NHS regarding its non-touch urine collection system.

Forte Medical Ltd.'s story is an example of how SME innovators can be pushed to the edge of existence if their genuine approaches are rebuffed by any one of the many decision-making bodies in the NHS.

Giovanna Forte, chief executive of Forte Medical, has several times this year alone stood on podiums and recounted the tortuous path that her company has had to follow, and her experiences stand as a salutary tale for similar companies and wannabes – those making efforts to get a proven innovation adopted and into UK NHS circulation.

Forte Medical is over 10 years old, but only recently scored a meaningful success in getting the message about its technology, a non-touch urine collection system called *Peezy Midstream*, understood. That was at Pitch@Palace, in October 2016, a competition that offers selected technology businesses the chance to pitch to a global audience of influencers who can catapult them to the next level.

That breakthrough notwithstanding, Forte Medical's experiences of recent years show that taking on the UK NHS is not for the faint-hearted.

Giovanna's GP brother, Vincente Forte, MD, invented the device, which secured its first funding in 2006. Forte Medical released the product in 2009, and it reached the UK market in 2010. The rationale of Peezy Midstream is that, of the 65 million urine samples delivered to the NHS every year, up to – and often over – 30% are unreliable due to contamination.

In spite of this, there is no single NHS protocol to allow urine to be accurately collected, Giovanna notes. As a consequence, patients with UTIs are not being diagnosed, and/or are being given broad-spectrum antibiotics that are failing. "It was, and is, an unmet need," says the CEO, who points out that urine can be used to diagnose any number of conditions including cancer. "In a non-touch world, our very simple device gives a first-time diagnosis," she claims.

But the company had to establish evidence for the device. Trials to prove reduced contaminations are hard to secure and can be costly – Forte Medical was quoted £135,000 (\$165,000) by one UK trust to run a trial (the true cost of which the company later found to be less than a fifth of this total). The firm finally scored successes in trials at the UCL Medical School (a three-year trial) and Barts Health (The Royal London Hospital), which showed contamination rates being reduced from 17% to 1.5%.

Results from a two-year study of urine collection methods across 1,100 patients at [*Stanford University School of Medicine*](#) are due to be released imminently.

These money-saving outcomes in theory should have allowed Forte Medical to go to procurement in the UK, but the company came up against a brick wall of inaction. The UK NHS' QIPP (Quality, Innovation, Productivity and Prevention) pathway failed to acknowledge its approaches, for example.

It took four years to get the product onto the DHL-run NHS Supply Chain, Giovanna recounts. "That's a struggle for SMEs that have to keep generating funding." Forte did get onto "e-direct," one part of the Supply Chain, and generated some income, but found that it was losing on every order because fulfilling orders directly removed any profit; the Supply Chain will not stock a product until it has achieved a certain volume. "It's a vicious circle," she says.

Keeping up with Supply Chain's tendering schedules and monitoring the NHS framework require time and attention. Frustrated by events, the company contacted NHS England chief executive Simon Stevens as well as NHS England's national medical director, among many others, to complain about its difficulties with the Supply Chain.

NHS England recommended that Forte seek out the Test Beds route. "But how much time does this take and how much money does it take for a small company to keep going for months and years while trying to work with the NHS, offering solutions that will save in our case £30 million on reducing retests and much more by way of efficiency savings?" asks Giovanna.

Forte Medical has actually kept itself going with LDA funding, angel funding and match funding. It has explored but rejected the idea of private equity funding. It has applied for grants, "a very time-consuming activity," and entered innovation awards competitions, albeit with no guarantee of winning. "It has cost us £3 million to keep going over 10 years – and over three iterations of

the product."

It has also, meantime, uncovered the need for new specimen collection systems to assist with novel early-stage cancer urine tests; work has commenced on these designs, with acceleration planned once the Peezy Midstream is generating revenue for the company.

With some laboratories – NHS and private – being remunerated on volume rather than quality, the incentive to reduce retesting is not always compelling. But Giovanna stresses that accuracy and right-first-time testing needs to be the benchmark for specimens used for laboratory investigations in order for this product to be more readily welcomed by those that mastermind urine screening.

The NHS is evidently a hard market in which to launch clinical innovations, but after much work over many years, Forte Medical at last seems to be making some headway. Giovanna's advice to budding device companies with ideas like hers is as follows:

- Make sure you're well-funded.
- Look out for first tenders and timings.
- Generate evidence, even if you're going to have a hard time with the NHS. ("It's worth it – if we had done that several years ago things might have happened faster, but we didn't have the money then.")
- Establish your cost benefits.
- Gather champions and advocates and get the support of users.
- Engage clinicians. Go to nurses. Talk to patients.
- Find good sales executives.
- Participate in industry bodies, like SEHTA (the South East Health Technologies Alliance), which support health technology businesses and foster collaborations between academia, business and clinicians. SEHTA has been a useful networking body for Forte Medical, as has the ABHI.