

## SUCCESS FOR DOCTOR ENTREPRENEUR

# 'Necessity' was the mother of invention

Independent practitioners as entrepreneurs often get big ideas for adapting techniques and inventing new equipment. But taking your little piggy to market is not so easy – as **Dr Vincent Forte** found out. Here he shares how he overcame the difficulties to take his invention to become an award-winning global healthcare product

AFTER A BUSY surgery ten years ago, I mused with my sister about the number of women patients who had berated me that day. And all because I requested a urine sample and gave them the standard universal container to deliver it in.

Somewhat accusingly, each one said that asking a woman to deliver urine into such a narrow bottle was a typically male expectation.

Giovanna, busy with her own PR business, hadn't time for my problems. 'Just solve it,' she said. 'They are right. It's a horrible process. Make something. You always made things when we were children.'

Accepting the challenge, I designed the Female Freedom Funnel, in which incarnation (and under patent protection) it won the inaugural Medical Futures Awards, Medical Category in 2001.

The original concept was for a flushable device that would safely deliver a mid-stream urine sample (MSU) into a standard universal container, disposing of both the first-burst and the excess into the toilet. As readers of *Independent Practitioner Today* know only too well, MSU is the gold standard of urine sampling, as it represents bladder urine, not contaminated first-burst.

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#### What happened next?

Giovanna shares my love for a challenge and believed in the Female Freedom Funnel from the start. She increasingly devoted more time to 'our project' which was renamed the somewhat snappier 'Peezy'. She then embarked upon the business of product research and development, financing, manufacture, and ultimately market profile, position and sales.

During the first long years we approached existing manufacturers of medical products, especially

disposables, but not one was interested in taking on the concept of Peezy, either as a new project or under license – the common response was 'we have our own ideas'.

The flushable Female Freedom Funnel called for the services of a paper engineer to improve on the self-opening original design but with secure connection between the universal container and funnel. Before long, however, we stumbled across a cornstarch polymer, which would facilitate

flushability while allowing a more sophisticated product and manufacturing process, giving a perfect fit with the universal container and accommodating a cellulose sponge, a crucial component involved in capturing the mid-stream.

Giovanna found a food-packaging manufacturer that was interested enough in what we were doing to help with product development and implementation. They, in turn, used their contacts

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Collector's item: Dr Vincent Forte with his Peezy device to help women provide urine samples



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to work with the cornstarch polymer, which had never before been complex injection-moulded.

Together we experimented, learned how to die-cut and print the cornstarch sheet and researched appropriate coatings to prevent the product from dissolving before the crucial act had taken place. We then applied an assembly process that negated the use of adhesives.

But, by Spring 2006, the invoices were piling up, a steady drain on our personal resources; patent fees, designers, raw materials, engineers, consultants...we were not running out of enthusiasm or passion, but money.

Exploring financing on the internet one afternoon, Giovanna came across a funding workshop held by g2i (Gateway to Investment), a London Development Association body. She attended, and the very next day received a call from one of the hosts, with an

**WHAT TO DO IF YOU HAVE AN IDEA?**

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invitation to explore funding requirements.

She was duly enrolled upon the g2i Investment Readiness Course, where she learned how to construct a business plan, cash-flow forecast and talk to potential investors in their own language. At the start of the course, Peezy was voted second most investable product by others in the course.



Giovanna Forte, who runs her own PR business, gave a lot of her time to help her brother realise his invention

By the end, it came first. In September, we secured the funding we thought we needed to take us to market.

The first £150,000 didn't last long, although it helped develop, trial and test prototypes until the perfect product was achieved. But when we reached manufacturing capability by late 2007, with our organic, biodegradable, flushable Peezy, we were shocked to find that in spite of our safety data, our first customers rejected the flushable version, not wishing to take any risks with sewer blockage.

Overnight and using our existing tooling and processes, we switched to polypropylene, one of the most common among healthcare devices, but one which has to be incinerated as clinical waste. This blind alley cost us most of our funding, leading ultimately to second, third and even a fourth round to help take us to sales, which commenced during 2009.

**So why did we do it?**

We stuck with our project because, quite simply, we believed in it. Peezy improves life for women, hospitals, pathologists and nurses on the 'shop floor'.

It enhances the patient pathway, reduces contamination and retests, saves time for clinicians and patients, and improves efficiency, hygiene and infection control. And it saves money. As far as leading-edge healthcare goes, there aren't many more boxes to tick.

The NHS Centre for Evidence Based Purchasing reports that use of a mid-stream collection device yields an average saving per sample of £2, over and above the cost of the device. Peezy can save the NHS millions of pounds.

**Why does the world need it?**

Urinary tract infection affects 10-20% of women at some time in their life. The MSU and clean-

**SIX TOP TIPS FOR BUDDING HEALTHCARE ENTREPRENEURS: WHAT WE LEARNED**

- Protect your idea or design and always use a non-disclosure agreement (NDA)
- Research your marketplace, prove an unequivocal need for your idea
- Identify your competitors and make sure your offer is better
- Identify your route to market and customer base – sales are king
- Keep your overheads low and profile high
- If you part with shares to raise funding, make sure it is to people who can add value

catch samples are the most commonly collected specimens.

The MSU involves bacteriological analysis of the middle part of the urinary void. Discarding the initial flow reduces the possibility of contaminating the sample with skin or urethral organisms. Producing an MSU is often performed incorrectly.

There is no standardised method of taking an MSU sample (HPA 2004). MSU collection devices

reduce contamination rates and may also reduce spillage of urine; they also improve patient care by reducing the number of repeat samples and thereby improving access to treatment and reduce costs by minimising the need to repeat MSU samples.

Methods we have come across include passing urine directly into a 21mm necked universal container – difficult at the best of

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times, messy and disastrous at worst – or using an intermediate container such as a jug, which is often reused by different individuals – unbelievable but true. Contamination of the sample by bacteria washed off the skin leads to inaccurate results in up to 30% of samples. Contamination rates are important because little clinical significance can be attached to such a sample, which therefore may need to be repeated with additional inconvenience to the patient, additional cost to the healthcare provider and a possible delay in commencing treatment.

#### How many urine samples are collected each day in the UK?

There is no reliable estimate for the numbers of urine samples for which Peezy would be a relevant tool. The data simply does not exist. Our estimates of 100m samples a year in the UK, between primary and secondary care are considered conservative, and are ratified by all clinicians that we have asked.

#### Is Peezy safe to use?

We commissioned an independent microbiology specialist laboratory to extensively test Peezy to establish that there is no contamination of urine collected through it that might affect laboratory and near-patient tests. We have established it does not contaminate sterile fluid or surfaces it might contact during normal use, such as toilet seats and floors.

The first pass of 20-25ml of urine exits via the bottom outlet. The cellulose sponge in the outlet expands, allowing the urine to back up and fill the universal container. A dye test (shown on our website) demonstrates this is a pure mid-stream sample. The

excess leaves through an exhaust beneath the attached universal container. Within a few seconds the urine drains away and stops dripping. Peezy is detached from the container and disposed of, leaving the patient, the environment and the sample bottle clean and dry.

Peezy has been registered with the Medicines and Healthcare Regulatory Authority, which has approved all stages of clinical research, and is satisfied with our patient safety data.

Peezy is CE-marked and Funnelly Enough, our company, has ISO13485:2003 certification and quality standards assurance covering clean-room manufacture and traceability.

#### What's user feedback like?

Interviews with users show them expressing in wonderful everyday language the sheer relief and joy experienced when they use it and realise they have been liberated from the mess and indignity of traditional methods.

Our pilot trial data reveals a high acceptability of Peezy even though this was a prototype testing stage. Subsequent acceptability testing of the final product in clinical settings confirms it is preferred to existing methods of urine collection by a vast majority of users, and the acceptability reaches near-100% levels on second and subsequent uses.

Crucially – and for a clinician-inventor giving additional satisfaction – benefits for the elderly, the very young and patients with learning difficulties or visual impairment are tangible, as not only is there no pressure to start-stop-start the urine flow to achieve mid-stream, but it is also very easy for a carer to hold the device in

### FINANCE AND DEVELOPMENT HELP

■ **Gateway to Investment (g2i.org):** maximises the success of London-based companies raising private investment. Delivered by a consortium of private-sector specialists, g2i offers advice, support and assistance to help companies develop their teams, propositions and pitches

■ **London Technology Fund (londontechnologyfund.com):** targets the gap in funding for technology companies at the earliest stages of development

■ **Exomedica (exomedica.com):** for medical technology and innovation finance and development

■ **Medical Research Council (mrc.ac.uk):** funds research through a range of grants, calls, highlight notices, studentships and fellowships

■ **The Wellcome Trust (wellcome.ac.uk):** helps to bridge the gap between fundamental research and commercial application by funding applied research and development projects to a stage where they are attractive to a follow-on funding, such as venture capital, industry and public-private partnerships

■ **Health Tech and Medicines Knowledge Transfer Network (healthtech.globalwatchonline.com):** accelerates innovation and technology exploitation in the broad health industries sector

■ **NHS National Innovation Centre (nic.nhs.uk):** supports innovators, commissioners and clinicians to speed up the development and use of innovations that will benefit the NHS

■ **NHS Innovation Hubs (innovations.nhs.uk):** regional centres set up to champion the cause of healthcare innovation and to identify, develop and commercialise innovations and intellectual property created by NHS staff

place without being obtrusive, or make unwelcome contact with the patient. Urine sampling has just got a whole lot easier and more dignified for those less able to help themselves.

One private hospital customer told us 'you have virtually eliminated our false-positive results'. Some NHS trusts are starting to order Peezy, which has strong attractions for antenatal, outpatients, GUM and sexual health clinics.

#### What works wins ... and where we are now

Peezy has finally started to build sales, reaching nearly 100,000 in 2009. It has become popular in Scandinavia, Belgium and Denmark where hygiene and dignity for female patients is a priority and where, interestingly, healthcare-acquired infection is not an issue. With inquiries from other European countries including Romania, our European agents are now expanding the customer base across all 23 European countries.

Earlier this year, Peezy was honoured at the British Design Week Awards earlier with 'Best Industrial Product' and 'Best of Show', beat-

ing technology giant Apple into second place with the sleek MacBook Air.

Last year, it went on to win the Technology Category award at the NHS East of England Health and Social Care Awards and was a finalist in the nationals. ■

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*Dr Vincent Forte is a GP in Gorleston, Norfolk, and has worked as a forensic physician to two police forces. He co-wrote the best-selling GP textbook Symptom Sorter*

### USEFUL AGENCIES FOR ADVICE

■ **Medical Futures (medicalfutures.co.uk):** a site for medical professionals wishing to develop their ideas

■ **The Intellectual Property Office (ipo.gov.uk):** advice and guidance on patents, trademark, design and copyright matters

■ **Medicines and Healthcare products Regulatory Agency (mhra.gov.uk):** the government body responsible for ensuring that medical devices work and are safe. This is where to gain approval to market your invention

■ **Business Link (businesslink.gov.uk):** a valuable port of call for anyone considering a start-up. The website also provides templates for legal documents such as the all-important non-disclosure agreement



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