



FEATURE

HEALTHCARE INNOVATION

When patients innovate

Patients have unique insights to invent tools that improve outcomes and make life easier, but **Jacqui Thornton** finds that it can be a long slog getting an invention used widely

Jacqui Thornton *freelance journalist*

London, UK

This March, in Australia, a landmark passed quietly for Tal Golesworthy, a chartered engineer from Cheltenham in the UK.

He was in Melbourne with the cardiothoracic surgeon Conal Austin to speak at the Australasian Thoracic Aortic Symposium about personalised external aortic root support (PEARS), an operation in which an implant supports the patient's own aorta and aortic valve, and is designed to prevent enlargement and rupture.

While in Australia, Austin, based at Guy's and St Thomas' NHS Foundation Trust, carried out six of these life changing operations as a visiting surgeon.

Golesworthy knew exactly what those patients were going through, because he experienced the first operation of this kind, nearly 15 years ago, for aortic dilatation relating to his Marfan syndrome.

What was the difference between him and these latest patients? Golesworthy had used his engineering skills to invent the implant used in PEARs surgery after he had been told the only clinical option for him was total aortic root replacement, which offers patients the drawback of a lifetime of anticoagulant therapy. He refused and set about developing an alternative, which was successfully implanted in him in 2004.

The benefits of PEARs include a shorter operation with no need for cardiopulmonary bypass, shorter stays in intensive care, and a very low reoperation rate.

Golesworthy has been dubbed "the man who fixed his aorta." He admits, when pressed, that he's the "ultimate patient innovator."

The "ultimate patient innovator"

With the six recent Australian operations, 200 people have had the PEARs surgery in 23 specialist centres around the world, including Australia, Belgium, the Czech Republic, Ireland, Malaysia, the Netherlands, New Zealand, and the UK.

But it's been a slow and frustrating 19 year journey for Golesworthy.

He says, "For me it's a massive milestone. If I'd known it was going to be this hard, I really wouldn't have bothered: the other 200 patients are big winners, as is the NHS, which has saved a lot of money."

Golesworthy may have been a trailblazer, but patient innovation is a growing phenomenon.

The Patient Innovation website (<https://patient-innovation.com>) is a non-profit platform for patients and carers to share solutions to cope with their diseases, jointly led by Pedro Oliveira, a professor at Copenhagen Business School, and Helena Canhão, a professor at NOVA Medical School in Lisbon.

The project began in 2014 in Lisbon as an academic repository of medical innovations developed by patients, care givers, and collaborators. But the pair realised that despite patient innovation happening, it wasn't being diffused to the people who needed it.

Now the Patient Innovation website—available in Chinese, English, German, and Portuguese—encourages people from all around the world to share and evaluate solutions and adaptations that improve life for patients.

Violinist invents hand exercise device

Today there are 850 submissions on the platform from 70 countries. They include an orthopaedic hand exercise device developed by the violinist Sarah Betts. She has juvenile rheumatoid arthritis but found symptoms less pronounced in her "string" hand.¹ The device is now used at a large orthopaedics centre in the US. Another device, a thermal bra designed by Jodie Faber, who had cancer, to prevent women's breasts feeling cold after double mastectomies and reconstructive surgery,² is being sold commercially in the US.³

Previous winners at the Patient Innovation awards include Golesworthy and Michael Seres, from Radlett in the UK. Both acknowledge that the journey of a patient innovator can be tough and slow.

Seres was diagnosed with Crohn's disease aged 12, and had 20 operations before he was 40. By that stage, his only option was a small bowel transplant, and he became the 11th person in the UK to have this specialist surgery.

Afterwards, as he faced living permanently with a stoma bag, rather than for the temporary periods he had experienced earlier, he realised that he had to solve the leaking and skin problems it caused, as well as find a way to monitor when it became full rather than having to inspect it visually.

The smart bag that he developed has now been approved as a medical device by the US Food and Drug Administration and is reimbursed by US insurers. Aged 48, Seres moved to California with his family, as founder and chief executive of 11Health. The company offers a care programme for ostomy patients that combines the smart technology with coaching and is used in more than a dozen hospitals.

Its own analysis of a pilot study of 43 patients in 10 US hospitals indicated lower complication rates and adverse impact on quality of life than with standard care.⁴ Independent trials run by the Cleveland Clinic, the University of San Diego, and Stanford are currently being carried out on 200 patients.

Seres describes the journey as a "hard path." He cites NHS clinical entrepreneur programmes⁵ and Barts X Medicine⁶ as opportunities for innovative doctors. "There is no doubt that the patient is not currently treated as an equal," he says. "You have only to look at the innovation programmes available to clinicians and compare those opportunities with what patients have."

But he says that being a patient who can vividly explain the unmet need makes conversations with doctors and surgeons that much easier. "I am not simply a sales rep, I am also an end user."

In Golesworthy's case, he persuaded the UK cardiothoracic surgeon Tom Treasure⁷ of the benefits of his idea, who in turn persuaded John Pepper, a professor of cardiothoracic surgery at the National Heart and Lung Institute at Imperial College London, to carry out the first PEARS operation, on Golesworthy.

Peter Gibson, the chief executive of the company that produces the support device, says that Golesworthy was "fortunate to find a cardiac surgeon with an open and inquiring mind who was prepared to listen to his idea."

For PEARS, an independent editorial in the *Journal of the American College of Cardiology* last year,⁸ said that the data on the first 27 patients in a six year follow-up was "encouraging." There are, however, no randomised controlled trials of PEARS. The UK National Institute for Health Research worked on a trial design in 2015 but said a randomised trial was "virtually certain" to fail, partly because of the rarity of the disease.⁹ But the surgeons behind the original PEARS operations—Treasure and Pepper—make the point that other techniques were also not subject to randomised trials, probably for the same reasons.¹⁰

At the outset, both Golesworthy and Seres were attempting to introduce a physical or practical change in clinical practice. Other patient innovators are using digital technology to solve their health problems. But having a clinical supporter is still key.

Online CBT for insomnia

Peter Hames had such bad chronic insomnia 10 years ago that his GP offered him a hypnotic drug for the maximum two week period. Having studied cognitive behavioural therapy (CBT) as

part of his undergraduate degree in psychology at Oxford University, Hames asked if he could be referred. "I don't believe in talking therapies," came the reply.

By chance, Hames's sister, a clinical psychologist, recommended a CBT book by Colin Espie, now a professor of sleep medicine at the University of Oxford. Reading the book worked—and then Hames approached Espie to collaborate with him on a digital version.

From that meeting, the product Sleepio was born, an online self care programme based on CBT for insomnia, which helps people make changes to try to improve insomnia symptoms and mental wellbeing.

The original randomised controlled trial found that at eight weeks after treatment, users were, on average, falling asleep 26 minutes sooner, and sleeping for over an hour extra each night (from 5.1 to 6.3 hours).¹¹ In total, Sleepio has been studied in eight randomised controlled trials with more than 6900 people.¹²

The National Institute for Health and Care Excellence (NICE)¹³ has concluded that there was "good quality evidence" that Sleepio improves sleep, may save costs by avoiding face-to-face therapy, and showed some evidence of good user engagement and experience.

Currently, it's being used in the Thames Valley, through the Oxford Academic Health Science Network, where all 2.7 million residents can access the programme without going to a GP. It's the first large scale NHS rollout of direct access digital medicine.¹⁴

Another million people in the wider UK have access through their employer, and in March all Londoners were given free access to Sleepio through the capital's NHS digital wellbeing service Good Thinking, a collaboration between Public Health England, the NHS, London boroughs, and clinical commissioning groups.

Hames, aged 39, who has founded the digital medicine company Big Health, believes that Sleepio could relieve pressure on GP services, although currently lacks the robust evidence to prove this.

Another digital patient innovator is Stephen Bourke, aged 37, who began taking antidepressants for anxiety and panic disorder at the age of 20. He repeatedly almost ran out, accessing emergency appointments to get his prescription, because he wanted to forget his condition existed.

He has built Echo, a free to use app for chronic conditions that aims to improve adherence, by giving reminders and explaining how to take drugs. With an NHS pharmacy contract, it now has 40 000 users throughout England, of which 37% are taking antidepressants and 21% are asthma patients. Another 7% have epilepsy.

Bourke is delighted to have been made one of 13 NHS Innovation Accelerator (NIA) fellows, appointed in March, who are supported to spread their innovation throughout England, an example of a scheme that rewards patient innovators.

The NIA is an NHS England initiative delivered in partnership with England's 15 academic health science networks to encourage innovations to be disseminated faster and more systematically through the NHS.

Bourke didn't set out to be a patient innovator; it was a case of convenience. He says, "Managing my drugs became an afterthought, it became a chore that I didn't really want to think about. It became something that would creep up on me, once every two months." In the end, his wife took over his drug management.

A lightbulb moment

There was a lightbulb moment, he says, when he was applying for European Union funding for Echo, which asked what social problems the innovation tackles.

“Our clinical director said, ‘By making it easier for people to get and take their drugs, you will make them healthier. This innovation is all about solving adherence.’ At that moment, the penny dropped. We understood what our mission was,” he says.

Bourke says his work has massive implications for chronic conditions given that about half of UK adults take a repeat prescription,¹⁵ and NICE estimates that between a third and a half of all drugs for chronic conditions are not taken as directed.¹⁶

In its own study of 8481 Echo users, adherence, measured by patients ordering drugs, was more than 75%,¹⁷ although Bourke¹⁸ accepts the methodology is “far from perfect: just because patients order meds doesn’t mean they are actually taking them.”

The app collects continuous longitudinal data, which can be sent to a doctor rather than having a one off snapshot every 12 to 18 months when the patient is called in for a review. It orders and delivers repeat medications, and gives customers reminders to take them.

“Our aim is to nudge people towards better compliance,” he says. As yet he has no peer reviewed data but part of the attraction of joining the NIA is to help enable independent, robust studies of Echo.

He is also hoping to do something Bourke considers “special”—tracking voluntary non-concordance in the real world.

“If we could start tracking that, and creating a dataset, we could enable the patient to better understand what triggers adherence or not. Then they could speak to their doctor to say, ‘Hey, you know what? I don’t like taking this, because this is how it makes me feel.’”

Showing doctors how an innovation can help them, rather than cause them more work, is important. In California, Michael Seres pays tribute to two doctors in the UK, without whom he could not have achieved his success: Anil Vaidya, his transplant surgeon at Oxford pushed, helped, and supported him, and Christos Kontovounisios, the colorectal surgeon at Imperial who ran a pilot study on the smart bag. The latter “understood the impact we could have on patients and became a real clinical champion for me.”

And Seres has a message, “If you are a doctor who believes in the technology then two words are key: ‘Be brave.’ It’s so much easier not to do something—but with courage you can help technology to really scale.”

Advice for doctors from patient innovators

- Don’t assume your profession has a monopoly on medical knowledge and solutions for diseases. Open your mind
- Consider the downsides to the existing therapy that is being questioned and revised by the patient innovator, and exercise a little vision and imagination
- Work towards a logical plan that assesses the technical and medical problems in sequence: don’t try to approach and solve all the questions at once
- If there is a real unmet need for this innovation then become its champion inside your trust. Without that, it is hard to scale
- The natural instinct is to say no because it requires extra time and effort to start a project. Saying yes and then being engaged is key. Doctors have to be willing to partner patients

Provenance and peer review: Commissioned; not externally peer reviewed.

Competing interests: I have read and understood the BMJ policy on declaration of interests and have no relevant interests to declare.

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