



Kath Giles has
worked in the
operating theatre
and the boardroom.
Photo: David Henry

Female focus leading research

Female researchers and entrepreneurs have powered many of WA's health care advancements.

Story: Matt Mckenzie

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-Kath Giles

KATH Giles is excited about a decision taken by US medical regulators in early May.

OncoRes Medical, the business Dr Giles leads as chief executive, secured a special approval from the US Food and Drug Administration for a device designed to help fight breast cancer.

The FDA's designation of OncoRes's QME Imaging System as a breakthrough device will speed the process to market, although about four years of work remain.

It is hoped the system can help reduce the recurrence of breast cancers after surgery.

About 2.3 million breast cancers were diagnosed worldwide in 2020, Dr Giles said, with about 331,000 in the US.

"That number is expected to increase to 440,000 women by 2030, which is really not that far away," she said.

Treatment is either through a

lumpectomy, targeting the tumour, or a mastectomy, which removes the whole breast.

While the lumpectomy is the preferred option, there's a chance small amounts of cancer can be missed, risking relapse.

"Surgeons are still reliant on sight and touch to [detect] if they've removed the tumour," Dr Giles told *Business News*.

"It's like looking for a grain of sand in a bowl of jelly, with a glove.

"If they miss it, this puts the woman at a significant risk, at least double if not more, of the breast cancer coming back at the same location.

"Surgeons don't know that they've missed any until it gets taken to the lab ... a week after surgery is complete."

That often means a need for a second surgery, increasing risk of complications and leading some women to choose a mastectomy, because they are

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not confident the whole cancer will be removed.

"It has a massive psychological impact on patients and families," Dr Giles said.

OncoRes's QME Imaging System is intended to bring together two techniques to help surgeons know immediately if they have excised all of the tumour: optical coherence tomography and micro-elastography.

The system will use an imaging probe within the surgical cavity, using light waves to pick out differences between fatty, dense, and cancerous tissue.

The micro-elastography then measures tissue thickness as a heat map to overlay on top of the optical coherence tomography image.

US win

The FDA's designation of QME as a breakthrough device puts it in a group of about 400 such devices, all of which it is hoped will enable earlier access for patients needing treatment for irreversibly debilitating or life-threatening conditions.

"To get the designation, not only do you have to be treating a disease [or] a problem they think is incredibly important to solve; the device has to have the potential to make a significant difference to these patients," Dr Giles said.

"The approval is absolutely awesome.

"What it means for us is we get expedited access through the FDA ... and [will be] approved for marketing as quickly as possible."

The rules in the US for these devices are also changing, including insurance and Medicare coverage of breakthrough devices.

There's still a lot of work to do before QME could receive the go-ahead for full-scale use, however.

The next steps will be producing clinical evidence, data collection and, most immediately, a capital raising.

OncoRes previously secured \$6 million from Australia's Medical Research Commercialisation Fund, which is managed by Brandon Capital Partners.

Dr Giles has been involved in Bran-

don as an investment manager since 2012.

"For me, this tech was love at first sight," she said.

"Having worked with surgeons in theatre, I could see this was exactly what they were looking for."

Leading lights

Medical innovation has a long history of leadership from women in Western Australia.

Two of the state's best known medical minds are Fiona Wood and Fiona Stanley, but there are many who have made an impact.

Spray-on skin for burns patients was developed by Professor Wood, with the technology commercialised by Avita Medical.

Professor Stanley, an expert in children's health, led development of the WA Maternal and Child Health Research Database and was later founding director of the Telethon Kids Institute.

Her research targeted causes and



2.3m

Breast cancer diagnoses worldwide 2020

prevention of birth defects and major neurological disorders.

Research included work with Carol Bower, who was inducted into the WA Science Hall of Fame in 2019, with the two joining forces on efforts to mandate fortification of flour with folate.

That was after WA research identified a link between folate and spina bifida in babies.

The move helped reduce the prevalence of neural tube defects in Aboriginal children by 68 per cent between 2011 and 2016, it has been reported.

Professor Bower was a founding researcher at Telethon Kids Institute and director at the Fetal Alcohol Spectrum Disorder (FASD) Centre for Research Excellence.

She established Australia's first birth defects registry and uncovered the link between low folate and neural tube defects.

Former chief scientist Lyn Beazley was inducted to the science hall of fame in 2013 for work on recovery from brain damage and changes to

treatment of infants at risk of pre-term delivery.

There are others who made an impact outside of research roles.

Mary Raine bequeathed nearly \$1 million in 1960 to what became the Raine Medical Research Foundation, which contributed to medical research including the Raine Study of pregnant WA women.

At OncoRes, Dr Giles is backed by chief medical officer Christobel Saunders.

Dr Giles said there was a growing group of talented WA women in the industry.

"The listed biotechs [have a] strong bunch of women chief executives on WA companies," she said.

"The community is really open and inclusive, and I personally have been given a huge amount of opportunity."

Brandon Capital had been supportive of her earlier in her career despite family commitments.

"It's awesome," Dr Giles said.

"Long may WA continue to lead the way." ■