

When the Science Outruns the System

Heart technology now moves at the speed of consumer electronics — yet we still assess and fund it with a process built for pills. It is time New Zealand gave cardiac devices a pathway of their own.

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CARDIOLOGY IS THE fastest-moving frontier in medical device innovation. Every 12 to 24 months, a new generation of structural, interventional or electrophysiology technology reaches clinical use: transcatheter edge-to-edge repair (TEER) for leaking mitral and tricuspid valves, Impella percutaneous heart pumps for high-risk procedures and cardiogenic shock, specialised guidewires and microcatheters that open chronically blocked arteries, transcatheter aortic valves (TAVR), leadless pacemakers, and AI-enabled heart monitors that patients wear home.

Yet in New Zealand, these technologies are still assessed and funded through processes designed for pharmaceuticals. That is a fundamental mismatch — one that delays access for patients and inflates costs downstream.

A model built for molecules

A pharmaceutical molecule is static: the pill approved today is

chemically identical to the one dispensed in a decade. Cardiac devices are the opposite. An Impella heart pump, or a heart valve goes through several meaningful design generations within a single health technology assessment cycle. By the time the appraisal concludes, the product it examined has often been superseded.

The differences run deeper than iteration speed. A statin works the same in any hand; a device does not. Success rates for opening chronic total occlusions climb sharply with operator volume and training. Case numbers explicitly credential TAVR and TEER programmes internationally. An Impella pump only delivers its potential inside a coordinated shock team. Appraisals that ignore operator learning curves and centre volumes will systematically misjudge what a device is actually worth in steady-state practice.

Trial timelines compound the problem. Pivotal studies for

cardiac devices often read out after the next generation is already CE-marked or FDA-approved, leaving funders perpetually reimbursing yesterday's technology. And the economics are different in kind: a device earns its keep through avoided open-heart surgery, shorter intensive-care stays and fewer readmissions — value that per-tablet cost-effectiveness logic simply cannot see.

Why devices deserve their own lane

Consider the pace. Interventional devices in cardiology require simultaneous updates on hardware-and-software cycles closer to consumer electronics than to drugs, with meaningful clinical gains between each generation.

Consider the stakes. Cardiovascular disease remains the leading cause of death globally and one of the largest single drivers of hospital, surgical and long-term care spending.

And consider the evidence we already have. Device registries — TVT, IMPELLA Quality, and PCI datasets linked to risk scores — already generate regulator-grade, real-world outcomes data that could support earlier, evidence-based reimbursement decisions. Meanwhile the procedures themselves keep shifting:

TEER now replaces open mitral surgery for selected patients, TAVR replaces surgical valve replacement, and a successful catheter-based opening of a blocked artery can avert bypass surgery altogether — dramatically compressing hospital stays, intensive-care use and recovery times.

The economics of moving early

Independent analyses across multiple jurisdictions consistently reach the same conclusion: early adoption of next-generation cardiac devices reduces the total cost of care. TEER for secondary mitral regurgitation has been shown in the landmark COAPT trial to cut heart-failure hospitalisations by roughly half. Impella-supported high-risk procedures give selected patients an alternative to surgical revascularisation. Successfully opening a chronically blocked artery reduces angina admissions and repeat procedures.

Even where a device carries a higher unit price, the system-level savings — fewer open-heart operations, shorter stays in intensive care and on the ward, lower thirty-day readmissions, and reduced downstream heart-failure care — frequently appear within two to three years.

Nothing about the operators without the operators

Because outcomes with cardiac devices depend on the operator and the centre, the clinicians who actually implant TAVR valves, deliver TEER, run shock teams and cross blocked arteries must be embedded in the system that approves and funds those devices.

They alone hold the procedural data, the patient-selection judgement and the centre-volume insight that determine whether a device delivers — or wastes — its potential value.

That means interventional and structural cardiologists sitting on every appraisal committee as full members, not merely consulted witnesses, to define the right patient population, the right comparator and realistic learning-curve assumptions. It means clinician-led credentialing and volume standards attached to funding, so reimbursement is tied to centres and operators meeting evidence-based case thresholds — as already applied to TAVR and TEER internationally. And it means registries co-designed and jointly owned by clinicians and funders, so real-world evidence reflects procedural reality rather than only trial-eligible cases.

A five-point prescription

The Cardiac and Respiratory Foundation NZ recommends a dedicated cardiac device approval and funding pilot programme — distinct from the pharmaceutical process — built around five principles:

- Conditional, time-limited approval tied to mandatory real-world evidence collection through device registries.
- Iterative review for incremental hardware and software updates, avoiding full resubmission for minor generational changes.
- Coupled assessment of clinical and economic value in a single, accelerated process — not sequential reviews that add years.
- Ring-fenced innovation funding

so adoption is not blocked by short-term hospital budget cycles when long-term system savings are clear.

- Clinician co-governance, with formal seats for practising interventional, structural and electrophysiology cardiologists at the appraisal, commissioning and post-market review stages.

Cardiac devices are the clearest example of medical technology that can save lives and save money at the same time — but only if our approval and funding systems can keep pace with the science. A dedicated pathway is a low-risk, high-return reform. The technology is ready. The evidence is ready. The question is whether the system is.

Letitia Harding is Chief Executive/ Tumū Whakarae of the Cardiac and Respiratory Foundation NZ, the national heart and lung health charity formed in July 2026 through the amalgamation of the Asthma and Respiratory Foundation NZ, Lung Foundation NZ, Bronchiectasis Foundation and Kia Manawanui Trust – The Heart of Aotearoa. Letitia has been the Chief Executive of the Asthma and Respiratory Foundation NZ since 2017, she sits on the 2025 World Health Organisation's Asthma Guideline Development Group, has held co-chair positions with the Global Alliance Against Respiratory Disease, and sat on numerous international advisory boards looking at the assessment of new health technologies.