

# Genesis of improved quality in imaging through a national Australian echocardiography registry

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## ABSTRACT

**Background** Despite rapid technological advances and growth, quality in imaging has not received the focus seen elsewhere in cardiovascular medicine, resulting in significant gaps between guidelines and practice. Contemporary echocardiography practice requires comprehensive real-time data collection to allow dynamic auditing and benchmarking of key performance indices. The American College of Cardiology (ACC) proposed additional data standardisation, structured reporting identifying key data elements and imaging registries. In the absence of an Australian echocardiography registry, we developed a national clinical quality registry (GenesisCare Cardiovascular Outcomes Echo Registry). We hypothesised that measurement and local reporting of data would improve compliance of echo studies with quality guidelines and hence their clinical value.

**Methods and results** We prospectively collected data on 4099 281 echocardiographic studies entered directly into a central electronic database from 63 laboratories across four Australian states between 2010 and 2021. Real-time auditing of key data elements and introduction of quality improvement pathways were performed to maximise completeness and uniformity of data acquisition and reporting. We compared completeness of key data element acquisition (AV peak velocity, left ventricular ejection fraction, E/e', LA area, rhythm, RVSP) by time and state using de-identified data. Key performance outcomes benchmarked against the aggregated study cohort and international standards were reported to individual sites to drive quality improvement. Between 2010 and 2014 there were significant improvements in data completeness (72.0%±26.8% vs 86.8%±13.5%, p=0.02), which were maintained to 2020. In addition, interstate variability fell for both EF and E/e' (p<0.002).

**Conclusions** This large-scale collaboration provides a platform for the development of major quality improvement initiatives in echocardiography. Introduction of local quality assurance programmes via a unified national data set significantly improved the completeness of reporting of key echo quality measures. This in turn significantly improved the quality of, and reduced the interstate variability of, echo data. Developing a centralised database allowed rapid adoption nationally of local quality improvements.

## Key questions

### What is already known about this subject?

- ⇒ Establishing a definition of quality in cardiovascular imaging has been challenging, with limited agreement on quality standards for imaging.
- ⇒ The American Society of Echocardiography set guidelines for echocardiographic quality assessment and improvement, including regular auditing of studies performed in aggregate and by individual sonographers and reporting physicians, and a process of continuous quality improvement.
- ⇒ Documentation of a measured left ventricular ejection fraction should be included on at least 90% of transthoracic echocardiogram reports.
- ⇒ The translation of these guidelines into clinical practice is uncertain.

### What does this study add?

- ⇒ This study documents how establishment of a data registry for echocardiography across a national cardiology group, in parallel with establishment of a continuous process improvement and education network for sonographers and reporting physicians, can lead to clinically important and significant improvements in the quality of echocardiography reporting and thereby facilitate access to reliable clinical data, which may lead to improved patient care.

### How might this impact on clinical practice?

- ⇒ This study provides real-world data regarding one of the most common investigations in cardiology, a snapshot of issues inherent in providing optimal information to inform physician diagnosis and management, and a structure for improving the quality and accuracy of imaging data that could be translated more widely into clinical practice to improve patient care.

## INTRODUCTION

Despite rapid technological advances and sustained growth, less attention has been focused on quality in imaging than in other areas of cardiovascular medicine. To address this deficit, the American College of

Cardiology (ACC) proposed additional areas of effort, such as data standardisation, structured reporting identifying key data elements and imaging registries.<sup>1</sup> A European study exploring issues of quality reported, for example, that lack of a written referral was common, occurring in over a quarter of cases.<sup>2</sup> Public reporting of patient outcomes following hospitalisation in Australia is limited compared with other countries.<sup>1</sup>

Further, despite increasing echo volumes, there are no contemporary national data regarding echo volumes or quality in Australia.<sup>3</sup> Although an Australian cardiac procedures database has been proposed since 2001, progress towards establishing a unified, systematic approach to data collection, with a common minimum data set pertinent to the Australian context, and quality control measures to ensure integrity and privacy of data has been limited.<sup>4,5</sup>

Cardiovascular registries characterise patients and describe the manner and use of diagnostic and therapeutic strategies.<sup>6,7</sup> They facilitate analyses on the quality of care among participating institutions and document variations in clinical practice that can be benchmarked against best practice recommendations.<sup>7,8</sup>

### GenesisCare Cardiovascular Outcomes Echo Registry

The GenesisCare Cardiovascular Outcomes Echo Registry (GCOR-Echo) is a prospective Australian clinical quality registry established in 2009 that describes contemporary management, in-hospital and long-term outcomes of patients undergoing percutaneous coronary intervention (PCI) and cardiac implantable electronic device implantation, as well as echocardiography data element completeness and quality measures. GCOR provides performance and outcome measure feedback to participating hospitals, technologists and cardiologists. GCOR-Echo consecutively enrolls and records study data on all patients undergoing echocardiography by

GenesisCare-affiliated cardiologists in outpatient clinics as well as private hospitals, including ward, intensive care and emergency department settings, across Australia (table 1). It has developed and implemented a national approach, developing a system for monitoring and improving performance.<sup>9</sup>

### Aims of the GCOR-Echo Registry

The goal of the GCOR-Echo Registry is to provide a collaborative, national, centralised clinical quality register that continuously reports compliance with an agreed minimum data set based on the American Society of Echocardiography (ASE) guidelines for improving quality in imaging. The objectives are to benchmark local practice against international standards, providing data to group and individual healthcare providers to inform appropriate use of echo and drive improvement in study quality and clinical value.

To explore whether echo quality had changed following publication and introduction of the ACC recommendations, we hypothesised that the implementation of a national quality database programme, GCOR-Echo, could drive significantly improved data acquisition and completeness and reproducibility of results with independent auditing of 5% of all studies as major components of data quality in clinical echocardiography laboratories across Australia. This paper reports the effect on the outcomes of completeness of data acquisition following the introduction of the national quality database programme GCOR-Echo.

### METHODS/DESIGN

From 2010 to 2014 we introduced direct online entry of echocardiographic studies into an electronic database, selection and auditing of key data elements, and developed quality improvement pathways to maximise

**Table 1** Clinical characteristics of echocardiography patients

Clinical characteristics	2010 (n=74 400), %	2014 (n=71 467), %	P value
Age (years)	67.8±12.1	67.5±11.0	0.47
Male	72.3	76.5	<0.001
BMI >30	33.2	28.2±5.5	0.63
Hypertension	65.9	63.2	0.11
Hypercholesterolaemia	78.5	61.5	<0.001
Diabetes mellitus	22.9	24.1	0.40
Current smoker	10.3	9.39	<0.001
Previous myocardial infarction	21.7	23.1	0.33
Previous CABG	8.7	11.6	0.007
Previous PCI	18.7	31.8	<0.001
Cerebrovascular disease	8.2	7.0	0.21
Renal failure (Cr >0.20 mmol/L)	4.9	4.1	0.25

BMI, body mass index; CABG, coronary artery bypass grafting; Cr, creatinine; PCI, percutaneous coronary intervention.

completeness of data acquisition and reporting across four states. We compared completeness of key data elements (aortic valve (AV) peak velocity, left ventricular ejection fraction (LVEF), E/e', left atrial (LA) area, rhythm, right ventricular systolic pressure (RVSP) by time and state practices using de-identified data during the initial establishment of the registry and quality improvement pathways from 2010 to 2014 and the maintenance and ongoing development phase of these programmes between 2014 and 2020.

### Methodological approach

GCOR was designed within a comparative effectiveness research structure to collect and report data from hospitals and clinics located in geographically diverse regions of Australia.<sup>1 10 11</sup> Information is entered into a web-based database using an electronic clinical record form. Key performance outcomes benchmarked against the aggregated study cohort and international standards are reported to individual sites to drive quality improvement. Governance rules ensure data security and protect patient and clinician confidentiality.

Consistent with this framework, additional characteristics of the registry include (1) the capacity to evaluate associations between interlaboratory and intralaboratory systems and the provision of evidence-based care and outcomes; (2) ongoing data collection from representative centres that allow spatial and temporal analyses of change in practice and the application of treatment modalities in real-world setting; and (3) provision of a data spine for quality improvement strategies and practical clinical trials.

### Establishing data elements

A common set of elements for echocardiography studies was developed from Australian working groups (National Health Data Dictionary) and the American College of Cardiology and American Society of Echocardiography Task Force on Clinical Data Standards detailing imaging practice.<sup>8 9</sup> Data set design referred to established data sets including the American College of Cardiology National Cardiovascular Data Registry-Practice Innovation and Clinical Excellence (PINNACLE) Network.<sup>5 7</sup>

Data detail patient demographics, study indication and completeness of recording and reporting of key data elements (AV peak velocity, LVEF, Ee', LA area, rhythm, RVSP) by time and centre using de-identified data (online supplemental file 1).

### Operational framework

#### Data collection

Consecutive patients undergoing echocardiography at all Genesis HeartCare centres are enrolled in the registry. Enrolling consecutive patients and maintaining an extremely high level of data completeness support internal validity. External validity is also maximised by including studies from across the breadth of Australia and from a wide range of imaging centres in both urban

and regional areas, as well as patients with both acute and elective presentations. Data entry is automatically performed as part of routine daily practice of recording echo studies digitally by experienced technologists at each site. Data are de-identified and stored in a central electronic database with built-in error-checking features.

#### Data management and security

The registry is coordinated by a steering committee of experienced imaging cardiologists. GCOR-Echo meets the standards relating to the use of paperless records under the Good Clinical Practice regulations and complies with the National E-Health Transition Authority standard of reporting and storing data. The systems and processes with respect to privacy and data protection comply with relevant Health Records and Information Privacy Act and Information Privacy Principles.

#### Data quality assurance

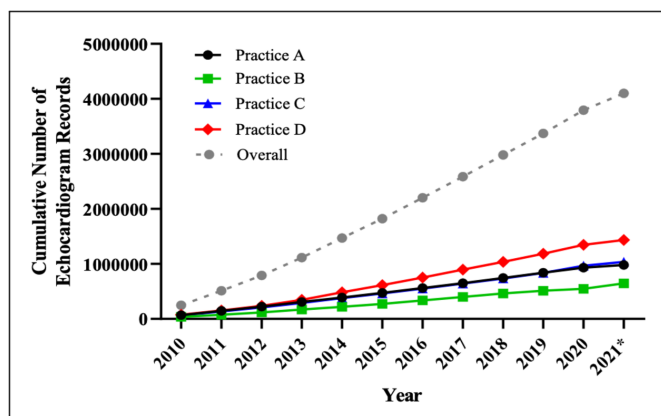
Strategies to ensure accuracy (validity) of the data include initial and ongoing training for all staff involved in data collection, automated database functions including mandatory fields, real-time data querying and error-checking, for example, out of range and logic checks, and generation of data queries to enable retrieval of outstanding items. In addition, there are regular audits for internal and external validation, as well as local and national meetings between technologists, cardiologists, research and data management staff.

#### Registry governance and reporting

The registry is directed by a national steering committee comprising representatives from participating centres and physicians with expertise in clinical registries, laboratory research and public health. Regular 6-monthly descriptive analyses are reviewed by participating institutions in an electronic site report that includes key performance indicators (KPIs). The prespecified KPIs provide robust measures of the effectiveness of the system to improve completeness of quality indicator reporting (eg, LVEF). Using these reports, individual centres are benchmarked against aggregate measures, but not against other individual hospitals. Presentation and publication of de-identified aggregate information at national and international meetings ensure appropriate peer review.<sup>12</sup> The study was reported in accordance with the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines for quality improvement studies as provided by the Enhancing the QUALity and Transparency Of Health Research (EQUATOR) network.

#### Funding

GenesisCare provides funding for the GCOR-Echo Registry, with ongoing development and maintenance supported by local practices; all acknowledge that measuring outcomes is integral to driving quality to improve patient care. This avoids any potential for bias from industry or governmental funding sources.<sup>9</sup>



**Figure 1** Cumulative number of echocardiograph studies by practice and year. \*Only the first 6 months available for inclusion.

### Patient and public involvement

This paper related to strategies to improve the technical quality of echocardiography studies and reporting. We conducted a focus group of patients to identify issues of main concern to them when undergoing a diagnostic cardiology test and determined that quality of the study and speed of reporting to the referring doctor were the most frequent patient concerns. We then requested and obtained consent from all patients in the study as part of the routine practice of echocardiographic imaging to utilise de-identified patient and image data to seek improvements in the quality of reporting of studies to the referring practitioner and patients.

### Statistics

Data were collected using a standardised digital questionnaire and analysed by SPSS V.12.0 for Windows. Tests of significance between groups have been made using  $\chi^2$  test for categorical variables and t-test for continuous variables.

### Ethics and informed consent

This registry is acknowledged as a clinical quality activity through local and national governance bodies. Data entry is consecutive and stored data are de-identified. This strategy has been effective in achieving high rates of participation essential to an effective registry, minimising bias such as the 'Hawthorne' effect.

### RESULTS

The GCOR-Echo Registry prospectively captured 4099281 studies from initially 50 increasing to 63 sites across Australia between January 2010 and December 2021 (figure 1). The 45 cardiologists involved each reported on average 1650 studies per annum. Of these studies, 36% were de novo rather than follow-up or progress studies.

Consistent with previous reports, most studies (76%) were performed on outpatients; however, a large proportion (24%) were in an acute care hospital setting. Overall, 47% of the patients were female and the average age was  $66.3 \pm 17.2$  years. Patient characteristics changed over time, with increasing rates of prior coronary intervention (PCI, coronary artery bypass grafting (CABG) yet decreasing frequency of smoking between the 2010 and 2014 cohorts (table 1).

Indications for echo comprised predominantly assessment of cardiac structure and function, aortic stenosis, dyspnoea/heart failure and arrhythmias, ischaemic heart disease, valvular heart disease, and less commonly hypertension and palpitations (table 2).

Data completeness overall improved significantly from the initial period of electronic data capture in 2010 and introduction of study auditing and quality improvement programmes progressively to 2014 ( $72.0\% + 26.8\%$  vs  $86.8\% + 13.5\%$ ,  $p < 0.0001$ ) (table 3). Completeness of reporting of LVEF by formal calculation rather than just visual estimation rose significantly from 2010 to

**Table 2** Indications for echocardiography by gender

Indications	n (%)		
	Total (N=120 530)	Female (n=55 389)	Male (n=65 118)
Atrial fibrillation/arrhythmias	13 163 (10.8)	5914 (10.7)	6967 (10.7)
Aortic stenosis	12 914 (10.8)	5938 (10.6)	6994 (10.8)
Dyspnoea/heart failure	5667 (4.7)	2598 (4.6)	3068 (4.7)
Cardiac structure and function	14 591 (12.1)	6763 (12.2)	7827 (12.0)
Chest pain	5092 (4.3)	2377 (4.4)	2715 (4.3)
Left ventricular function	18 134 (15.1)	8295 (14.8)	9774 (14.9)
Mitral valve	7404 (6.1)	3461 (6.2)	3984 (6.1)
Murmur	4636 (3.9)	2076 (3.7)	2560 (4.0)
Hypertension	7345 (6.1)	3365 (6.1)	3978 (6.1)
Palpitations	5108 (4.2)	2330 (4.2)	2776 (4.3)
Others	26 476 (21.9)	12 272 (22.5)	14 511 (22.1)

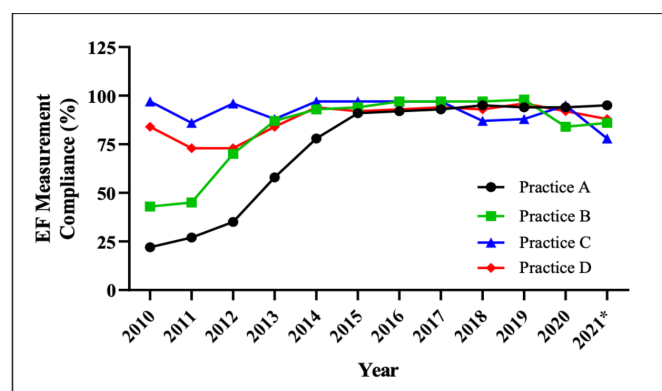


**Table 3** Completeness of data acquisition for LVEF, E/e', LA area, aortic Vmax, RVSP and rhythm of echocardiography patients

	% completeness	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)	2015 (%)	2016 (%)	2017 (%)	2018 (%)	2019 (%)	2020 (%)
A	AV peak velocity	90	98	98	98	98	72	98	98	98	98	98
	EF (all methods)	22	27	35	58	78	91	92	93	95	94	94
	Ee'	75	73	75	70	80	84	81	77	72	71	73
	LA area	89	97	97	88	95	96	95	86	93	83	82
	Rhythm	98	98	97	98	90	99	99	99	91	89	99
	RVSP	40	38	37	50	52	52	51	49	48	45	45
B	AV peak velocity	97	98	97	98	98	98	95	95	96	98	94
	EF (all methods)	43	45	70	87	93	94	97	97	97	98	86
	Ee'	76	78	83	90	91	91	92	92	93	93	87
	LA area	97	98	97	98	98	98	98	98	99	99	96
	Rhythm	89	92	89	91	93	96	98	97	98	98	85
	RVSP	67	59	79	78	75	80	70	71	76	76	53
C	AV peak velocity	12	44	72	82	76	77	87	98	98	98	98
	EF (all methods)	97	86	96	88	97	97	97	97	87	88	95
	Ee'	3	24	49	61	54	57	70	67	78	76	83
	LA area	8	43	69	84	88	80	89	93	95	94	94
	Rhythm	2	30	53	84	80	90	88	79	74	92	92
	RVSP	54	57	56	60	54	56	52	53	51	48	46
D	AV peak velocity	98	80	91	85	91	93	93	92	88	97	97
	EF (all methods)	84	73	73	84	94	92	93	94	93	96	92
	Ee'	71	56	56	79	89	84	86	85	83	87	86
	LA area	0	0	0	0	0	0	0	0	0	0	18
	Rhythm	95	65	78	89	95	89	92	89	93	93	94
	RVSP	57	50	53	55	62	61	61	61	59	59	58

AV, aortic valve; EF, ejection fraction; LA, left atrial; LVEF, left ventricular ejection fraction; RVSP, right ventricular systolic pressure; Vmax, maximum velocity.

2014 ( $63.92\% \pm 34.89\%$  vs  $90.92\% \pm 5.18\%$ ,  $p < 0.0001$ ). Completeness of ejection fraction (EF) reporting improved further from 2014 to 2020 ( $91.93\% \pm 5.18\%$  vs  $92.8\% \pm 4.08\%$ ,  $p = 0.0001$ ) (figure 2).



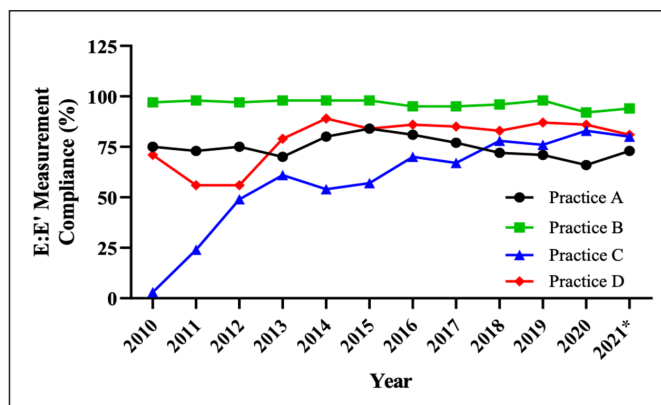
**Figure 2** EF measurement compliance by practice and year. \*Only the first 6 months available for inclusion. EF, ejection fraction.

Completeness of reporting of E/e' similarly rose significantly from 2010 to 2014 ( $55.27\% \pm 5.10\%$  vs  $78.74\% \pm 4.90\%$ ,  $p < 0.0001$ ). Reporting of E/e' improved further from 2014 to 2020 ( $78.74\% \pm 4.90\%$  vs  $82.28\% \pm 4.70\%$ ,  $p < 0.0001$ ) (figure 3).

In parallel with these changes, interpractice variability fell from 2010 to 2014 for both EF ( $68.6 \pm 11.6$  vs  $19.0 \pm 10.3$ ,  $p < 0.001$ ) and E/e' ( $61.7 \pm 5.1$  vs  $37.0 \pm 4.9$ ,  $p < 0.002$ ) (figure 4). This further declined from 2014 to 2020 for both EF ( $11.0 \pm 10.4$ ) and E ( $20.0 \pm 4.7$ ).

## DISCUSSION

This study represents the first echocardiography registry of national scope conducted within Australia. It provides not only a unique perspective on the clinical quality of imaging studies and the characteristics of Australian patients undergoing echocardiography, but also the opportunity to explore the clinical and demographic factors associated with provision of care, including appropriateness of investigations.



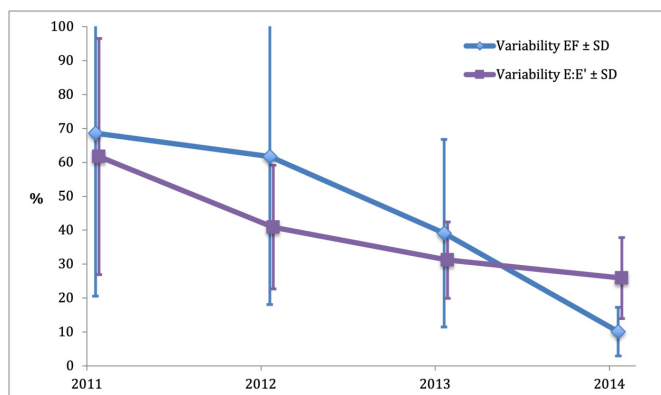
**Figure 3** E/e' measurement compliance by practice and year. \*Only the first 6 months available for inclusion.

Of these studies, 36% were de novo rather than follow-up or progress studies, a significantly larger proportion of first studies than in international series.<sup>2</sup> In some European studies there have been a high proportion of repeat studies (72%) and normal initial studies (41%), questioning appropriateness.<sup>2,3</sup> The lower proportion of repeat studies in the GCOR series may have been due to a combination of more conservative local practice patterns, societal recommendations and guidelines for reimbursement from public and private payors.

Initially, we found very high-quality studies were performed in many centres, with at first, however, wide regional variation. This improved rapidly and globally across the entire network once centralised reporting of data and feedback to local centres through a centralised quality improvement process were implemented in Australian private hospitals and outpatient clinics. Introduction of local quality initiatives via a unified national data set and database over a 2-year period significantly improved reporting of key quality echo measures.

Identification, systematic capture and auditing of key echo data elements can significantly improve the quality of and reduce the interpractice variability of echo data.

The establishment of various international and national clinical registries, including the National Heart, Lung, and Blood Institute Registry,<sup>13</sup> New York



**Figure 4** Interpractice variability for EF and E/e' by year. EF, ejection fraction.

State Percutaneous Coronary Interventions Reporting System,<sup>14</sup> US and Australasian Society of Cardiothoracic Surgeons, Society of Thoracic Surgeons (STS) registries,<sup>15,16</sup> and the Acute Coronary Syndrome Prospective Audit (ACACIA) Registry,<sup>17</sup> is testament to the need for information to be available to healthcare providers, funding bodies (government or private) and the public. Registries can help healthcare providers appreciate the effectiveness of how evidence-based guidelines are translated into real-world practice. Importantly, registries are also a key postmarketing surveillance which serves to protect patients by providing some form of accountability measure following approval by various bodies of either a drug or a therapeutic device (drug-eluting stent (DES) being a prime example), which is often based on results of randomised controlled trials with inherent limitations of size and funding independence.<sup>18,19,20</sup>

While randomised clinical trials remain an essential tool for validating the effectiveness of new devices and treatments, they cannot address low-frequency yet high-significance events, secondary prevention compliance or long-term health, quality of life, and cost-effectiveness outcomes that are critical in healthcare.

An illustration of the effectiveness of clinical quality registries in this regard was seen following public concern that arose regarding the safety and long-term outcomes, such as late and very late stent thrombosis, following DES implantation.<sup>21</sup> A long-term national database such as GCOR-Echo will go some way towards providing similar quality assurance and benchmarking opportunities against international standards to that available for PCI procedures through the Australian GCOR-PCI Registry.

Effective clinical registries describe clinical characteristics, management practices and outcomes from a broad range of patients and provide the opportunity to document, understand and potentially improve processes of care. Informed by previous local registry initiatives including ACACIA and Melbourne Interventional Group (MIG), the GCOR-Echo Registry meets the strategic and operating principles of clinical quality registries described by the Australian Commission on Safety and Quality in Health Care (ACSQHC) and includes a standardised methodological approach to data collection, quality, security, governance and output.<sup>7,18,22-24</sup>

In recent years clinical registries have become an important component of efforts to improve adherence to guideline therapies and cost-effective delivery of care.<sup>25</sup> One of the key elements is the application of a variety of research methodologies to evaluate medical interventions shown to be effective in randomised clinical trials in more diverse populations and diverse clinical contexts. This includes the real-time return of robust information on care processes and outcomes to practising clinicians. Feedback of this nature has been shown to be important in practice improvement.<sup>11,22-24</sup> Previous work has demonstrated that establishment of a national clinical quality registry with feedback of performance data to clinicians

can lead to improved patient compliance with key guideline medical therapies after PCI.<sup>25</sup>

In this paper we demonstrated that introducing a registry to document the quality of recording and reporting echo indices was associated with improvements in compliance with completing these measurements. Comprehensive standardised data elements facilitating transparency in data collection, consistency between these and other data sets, and encouragement of ongoing peer review in GCOR-Echo may explain this improvement in compliance with guideline outcomes of echocardiography.

One limitation of the registry is a feature of GCOR that is still evolving, that is, the devolution of responsibility for centres that appear to perform less effectively than their peers. This information is provided to local clinicians to implement practice change. Ongoing data collection and real-time feedback permit quasi-experimental quantification of the impact of these changes on process measures. The ACSQH recommends that clinical registries work closely with expert national clinical groups to develop governance principles to manage outlier performance of this type.<sup>26</sup> Genesis HeartCare has developed a national Clinical Leaders Forum that is integral to all aspects of advancing the quality of patient care and has an important oversight role regarding the outcomes and development of the GCOR-Echo Registry.

### Translation to other settings

Developing a national database allows rapid adoption of local quality improvements. This system has subsequently been applied to other areas of practice, including management of patients post-PCI and device implantation, as well as ambulatory ECG and blood pressure monitoring. Integrating data reporting systems with daily clinical management is essential to achieve the best quality in patient care.

### CONCLUSION

The GCOR-Echo Registry is a clinician-driven initiative describing and measuring the quality of echocardiography practice in Australian private hospitals and outpatient clinics through a centrally coordinated national network. This large-scale collaboration has provided a platform for the development of quality improvement initiatives. Introduction of local quality initiatives via a unified national data set and database significantly improved the completeness of reporting of key quality echo measures. This significantly improved the quality of data captured and reduced the interpractice variability of echo data, thereby improving these components of quality in echo studies. Developing a national database allowed rapid adoption of local quality improvements.

By recording clinical data and a process of continuous quality improvement, GCOR-Echo has significantly improved the completeness and accuracy of echo data provided to clinicians, which may facilitate improved

patient care. The GCOR-Echo Registry allows benchmarking treatment against international guidelines and practice and is an example of how developing national clinical cardiology registries may enable clinicians' efforts to improve patient care.

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**Data availability statement** No data are available. De-identified data are housed on a secure server to comply with national regulations governing privacy.

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