

# Cardiology Practice Review™

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Issue 34 - 2024

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## Abbreviations used in this issue:

**ACC** = American College of Cardiology; **ACHD** = adult congenital heart disease; **ACRA** = Australian Cardiovascular Health and Rehabilitation Association; **AF** = atrial fibrillation; **AHA** = American Heart Association; **ANZSVS** = Australian and New Zealand Society for Vascular Surgery; **ATAGI** = Australian Technical Advisory Group on Immunisation; **AusPAR** = Australian Public Assessment Reports; **CARE-BMT** = Cardiovascular Registry in Bone Marrow Transplantation; **CHD** = congenital heart disease; **CPD** = Continuing Professional Development; **CSANZ** = Cardiac Society of Australia and New Zealand; **CTA** = computed tomography angiography; **CV** = cardiovascular; **CVD** = cardiovascular disease; **ESC** = European Society of Cardiology; **HSCT** = haematopoietic stem cell transplantation; **MRI** = magnetic resonance imaging; **PAD** = peripheral artery disease; **PBS** = Pharmaceutical Benefits Scheme; **PI** = Product Information; **TAVI** = transcatheter aortic valve implantation; **TGA** = Therapeutic Goods Administration.

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## Welcome to the 34<sup>th</sup> issue of Cardiology Practice Review.

This Review covers news and issues relevant to clinical practice in cardiology. It will bring you the latest updates, both locally and from around the globe, about topics such as new and updated treatment guidelines, changes to medicines reimbursement and licensing, educational, professional body news and more. Finally, on the back cover, you will find our COVID-19 resources for Cardiologists and a summary of upcoming local and international educational opportunities, including workshops, webinars, and conferences.

We hope you enjoy this Research Review publication and look forward to hearing your comments and feedback.

Kind Regards,

**Dr Janette Tenne**  
Editor

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## Clinical Practice

### AHA Scientific Statement: Cardiovascular management of patients undergoing haematopoietic stem cell transplantation

The American Heart Association (AHA) has released a scientific statement on the cardiovascular (CV) management of patients undergoing haematopoietic stem cell transplantation (HSCT). It summarises data on HSCT-related CV complications and provides guidance for managing patients throughout the transplantation process.

The statement outlines the various phases of HSCT, from the pre-transplantation workup to long-term survivorship. It notes that CV complications can occur during each phase, with acute issues like arrhythmias and heart failure being most common in the immediate post-transplantation period. Long-term survivors face increased risks of CVD, secondary malignancies, and endocrinopathies.

A key finding is the high incidence of arrhythmias, particularly atrial fibrillation (AF) and flutter, which occur in 2-10% of adult HSCT recipients. Heart failure is also a significant concern, with an incidence ranging from 0.4-2.2%. In paediatric patients, left ventricular dysfunction and pericardial effusions are the most common CV complications.

The statement emphasises the importance of a comprehensive pre-HSCT CV evaluation, which should include risk stratification, exclusion of high-risk disease, cardiac reserve assessment, and CV status optimisation. The CARE-BMT risk score is highlighted as a valuable tool for predicting CV events in adult HSCT recipients. During the transplantation process, close monitoring and management of acute issues like fluid balance and arrhythmias are crucial.

The statement recommends ongoing monitoring and management of CV risk factors for long-term survivors, with a low threshold for evaluating CV causes of symptoms. Future research should focus on refining risk stratification and developing evidence-based guidelines to optimise outcomes in this high-risk patient population.

<https://tinyurl.com/5eyf4pij>

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GP members of the **Royal Australian College of General Practitioners (RACGP)** are able to include Research Reviews as part of the self-record unaccredited category 2 QI&CPD points by logging onto the [RACGP](#) website.

## Clinical performance and quality measures for adults with valvular and structural heart disease

The 2024 ACC/AHA Clinical Performance and Quality Measures for Adults with Valvular and Structural Heart Disease outline a comprehensive set of eleven measures, i.e., five performance measures and six quality measures, to evaluate and improve care for patients with valvular and structural heart disease.

The performance measures are based on Class 1 guideline recommendations and target high-impact areas, such as anticoagulation for mechanical heart valves, appropriate valve interventions for severe symptomatic aortic stenosis and chronic severe aortic/mitral regurgitation, and regular echocardiographic monitoring for severe primary mitral regurgitation. These measures are suitable for public reporting and pay-for-performance programs.

In contrast, while clinically meaningful, the quality measures may not yet have sufficient evidence to support their use in public reporting. They include documentation of procedural risk and heart team discussion prior to valve intervention, appropriate use of transcatheter aortic valve implantation (TAVI) in the elderly, and post-procedural echocardiography. These quality measures can be used for internal quality improvement efforts.

A key highlight is the emphasis on shared decision-making with patients, accounting for individual risks and preferences when considering valve interventions. The guidelines also stress the importance of a multidisciplinary heart valve team approach to optimise patient evaluation and management.

Overall, this comprehensive measure set provides healthcare providers and institutions with tools to assess and improve the quality of valvular and structural heart disease care. Implementing these measures can help drive adherence to guideline-recommended therapies, enhance patient outcomes, and reduce unwarranted variation in care. Ongoing evaluation of these measures in real-world practice will be crucial to refine and update them as needed.

<https://tinyurl.com/muzbac9a>

## AHA Science Advisory: Advancing wearable biosensors for congenital heart disease

Wearable biosensors offer significant potential to transform the management of congenital heart disease (CHD) by enabling continuous, remote monitoring of patient physiology and behaviour. However, several challenges must be addressed before these technologies can be effectively integrated into routine clinical care. A recent science advisory from the AHA reviews the use of wearables in patients with CHD, how to improve these technologies for clinicians and patients, and ethical and regulatory considerations.

One key challenge is the need for better validation and analytical accuracy of wearable devices in the CHD population. Patients with CHD often have physiologic measures outside the typical ranges used to validate commercial wearables, such as low oxygen saturation or high heart rates. Further research is needed to evaluate the accuracy of wearable data in this patient population.

Another critical barrier is integrating wearable data into the clinical workflow and electronic health records. Clinicians require efficient tools to screen large volumes of continuous wearable data and identify clinically relevant changes, as well as methods to incorporate these data into patient management decisions seamlessly. Advances in artificial intelligence and machine learning may help address this challenge by automating data analysis and flagging concerning trends.

Looking ahead, wearables have the potential to significantly enhance existing home monitoring programs for high-risk CHD populations, such as infants with single-ventricle physiology. Continuous monitoring of physiologic variables could enable earlier detection of clinical deterioration and prompt intervention. However, ensuring wearability and adherence, addressing health equity concerns, and navigating regulatory considerations will be crucial to realising the full potential of these technologies in CHD care.

In conclusion, while wearable biosensors hold great promise, substantial work remains to overcome technical, clinical, and regulatory hurdles and integrate these technologies effectively into the management of CHD. Multidisciplinary collaboration will be essential to driving progress in this rapidly evolving field.

<https://tinyurl.com/srsrjw9d>

## Exercise therapy for chronic symptomatic peripheral artery disease

A clinical consensus on the use of exercise therapy for patients with chronic symptomatic peripheral artery disease (PAD) is now available. It was produced by the European Society of Cardiology (ESC) Working Group on Aorta and Peripheral Vascular Diseases in collaboration with the European Society of Vascular Medicine and the European Society for Vascular Surgery.

The clinical consensus emphasises that supervised exercise programs should be the first-line treatment for patients with PAD who present with exercise-induced limb symptoms. These programs should be coordinated by vascular physicians and overseen by exercise professionals.

Before starting an exercise program, patients should undergo comprehensive medical screening to assess for any contraindications. Walking ability, functional status, and quality of life should be evaluated before and after the program to determine the patient's response. The consensus recommends walking training as the primary exercise modality, with alternative training like resistance or cycling used when walking is not feasible.

The optimal exercise program should have a frequency of at least three sessions per week, lasting at least 30 minutes, and a total program duration of at least three months. Although moderate-to-high claudication pain during exercise has been the standard, the consensus notes emerging evidence that low or no-pain exercise may also be effective and improve adherence.

For patients without access to supervised programs, structured home-based exercise with behaviour change techniques is recommended as an alternative. Home-based programs have shown benefits, though supervised programs tend to produce greater improvements in walking distance and quality of life.

This consensus highlights the strong evidence supporting exercise therapy as a cornerstone of PAD management. It guides the critical components of effective exercise programs to help clinicians optimise care for patients with symptomatic PAD. Increasing access to these programs, mainly supervised options, remains a significant challenge.

<https://tinyurl.com/5n7k9cbk>

## Quality indicators for the care and outcomes of adults undergoing transcatheter aortic valve implantation

The ESC has published quality indicators for the care and outcomes of adults undergoing TAVI. These quality indicators were developed following a standardised methodology involving the identification of key domains of TAVI care, a systematic review of the literature, and a modified Delphi process to select the final set.

Twenty-two main and five secondary quality indicators were identified across eight domains. These include structural measures, patient selection, risk stratification, patient-reported outcome measures, pre-procedural assessments, procedural considerations, post-procedural care, and clinical outcomes.

The quality indicators cover essential aspects of TAVI care, such as the availability of on-site cardiac surgery, the establishment of a multidisciplinary Heart Team, the proportion of patients aged  $\geq 80$  years receiving TAVI, the use of risk prediction models and frailty assessment, the utilisation of pre-procedural cardiac imaging, the preference for transfemoral access and local anaesthesia, the use of appropriate antithrombotic regimens, and key clinical outcomes like mortality, stroke, and paravalvular leak.

These quality indicators are designed to be used for quality improvement initiatives and benchmarking of TAVI care. Notably, the authors found that 70% of the quality indicators can be directly measured using the EuroHeart TAVI registry, an ESC initiative that captures patient information for continuous quality improvement. This highlights the feasibility of implementing these quality indicators in clinical practice and using the data to drive quality improvement efforts. As TAVI continues to expand, adopting these ESC quality indicators can help ensure the delivery of high-quality, evidence-based care for patients with severe aortic stenosis.

<https://tinyurl.com/2jtkvzkb>



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<sup>o</sup>Pooled patient-level analysis of ORION-9, -10 and -11 phase 3 trials of LEQVIO vs placebo in 3,660 adult patients (3,655 in safety population) with HeFH, ASCVD or ASCVD risk equivalents (T2DM, FH and 10-year risk of a CV event >20% as assessed by Framingham risk score) and LDL-C above target of 1.8 mmol/L, on a background of maximally tolerated statin (unless intolerant or contraindicated) ± ezetimibe. Co-primary endpoints: placebo-corrected reduction from baseline in LDL-C at Day 510 (17 months) of 50.7% (95% CI -52.9, -48.4; p<0.0001); placebo-corrected time-adjusted reduction in LDL-C from baseline between Day 90 (3 months) and Day 540 (18 months) of 50.5% (95% CI -52.1, -48.9; p<0.0001).<sup>1</sup>

ASCVD, atherosclerotic cardiovascular disease; CI, confidence interval; CV, cardiovascular; FH, familial hypercholesterolaemia; HCP, healthcare professional; HeFH, heterozygous familial hypercholesterolaemia; LDL-C, low-density lipoprotein cholesterol; PCSK9, proprotein convertase subtilisin-kexin type 9; siRNA, small interfering RNA; T2DM, type two diabetes mellitus; TEAE, treatment-emergent adverse event.

**References:** 1. Wright RS et al. J Am Coll Cardiol 2021; 77: 1182–1193. 2. LEQVIO (inclisiran) Australian approved Product Information. 3. Stoekenbroek RM et al. Future Cardiol 2018; 14: 433–442.

**PBS Information:** Authority Required (telephone/online) for patients with hypercholesterolaemia. Refer to PBS Schedule for full Authority information.



PLEQ1021

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

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## Clinical genetic testing for atrial fibrillation

A trailblazing White Paper published in the *Canadian Journal of Cardiology* reviews the current state of genetic testing for AF, a common and complex cardiac arrhythmia. It outlines the growing evidence linking genetic factors to AF risk and explores the potential clinical applications of genetic testing in this context.

Epidemiological studies have firmly established that genetics play a significant role in AF susceptibility. In addition to rare, highly penetrant genetic variants, common, low-impact genetic variants contribute to an individual's overall genetic vulnerability to developing AF. Rare variants have been identified in genes like *KCNQ1*, *NPPA*, and *MYL4* through family-based studies, while larger case-control analyses have implicated genes like *TTN* that are also associated with cardiomyopathies.

The White Paper highlights that AF can sometimes be the initial manifestation of an underlying genetic cardiomyopathy or channelopathy, such as dilated cardiomyopathy, hypertrophic cardiomyopathy, or Brugada syndrome. In these cases, identifying the genetic cause can have significant clinical implications for monitoring, treatment, and cascade screening of family members. Studies have shown that the presence of a pathogenic genetic variant in patients with early-onset AF is associated with an increased risk of mortality.

While the current yield of genetic testing in isolated, early-onset AF may be modest, the authors argue that screening these patients for potentially more malignant genetic conditions is still warranted. They provide a framework for incorporating genetic testing into the clinical management of AF, focusing first on ruling out coexisting cardiogenetic diseases. Further research is needed to define the optimal genetic testing approach and evaluate the cost-effectiveness and clinical utility of genetic testing in the broader AF population.

<https://tinyurl.com/36476vzx>



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## Regulatory News

### PBS update: Familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia

Inclisiran (Leqvio®) (284 mg/1.5 mL injection, 1.5 mL syringe) is now listed on the PBS for treating familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia. Authority applications for initial and grandfather treatments can be made in real-time using the Online PBS Authorities system or by telephone. Prescriptions for continuing treatment are Authority-Required (STREAMLINED).

Evolocumab (Repatha®) (140 mg/mL injection, 1 mL pen device; 420 mg/3.5 mL injection, 3.5 mL cartridge) has had an amendment to remove the grandfather restriction. Authority applications for initial treatment can be made in real-time using the Online PBS Authorities system or by telephone. Prescriptions for continuing treatment are Authority-Required (STREAMLINED).

<https://tinyurl.com/34zdepxt>

### PI updates: Diltiazem hydrochloride (Cardizem CD)

Diltiazem hydrochloride (Cardizem CD) is indicated in the treatment of hypertension and the management of chronic stable angina (effort-associated angina) where there is no evidence of vasospastic or unstable angina. The Australian PI was revised on February 05, 2024, to include lichenoid drug eruption as an adverse event.

<https://tinyurl.com/34n87juz>

### PI updates: Gadobutrol (Gadovist)

Gadobutrol is indicated for contrast enhancement in cardiac MRI in adults and children, including full-term newborns. This includes assessing rest and pharmacological stress perfusion and delayed enhancement. The Australian PI was revised on February 07, 2024, to include acute respiratory distress syndrome as an adverse event.

<https://tinyurl.com/ypkprhj2>

### New AusPAR: Enoxaparin sodium

The new AusPAR for enoxaparin sodium (Exarane/Exarane Forte) is approved for the prevention of thromboembolic disorders and thrombosis, the prophylaxis of venous thromboembolism, and the treatment of deep vein thrombosis, unstable angina, non-Q-wave myocardial infarction, and acute ST-segment elevation myocardial infarction.

<https://tinyurl.com/y6r4pzxc>

### TGA safety advisory: Medicines containing *Withania somnifera* (Withania, Ashwagandha)

*Withania somnifera*, commonly known as ashwagandha, is readily available without a prescription and over-the-counter in various outlets such as supermarkets, health food stores, and pharmacies. Some studies cite the cardioprotective effect of *Withania somnifera*, which is used to prevent and treat various conditions, including atherosclerosis and hypertension.

The Therapeutic Goods Administration (TGA) has issued a safety advisory to alert healthcare professionals that medications and herbal supplements containing *Withania somnifera* have been associated with significant adverse events in certain individuals. Both consumers and healthcare providers must recognise the potential risks associated with its use.

Symptoms such as yellowing of the skin or eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and loss of appetite should raise immediate concern and prompt discontinuation of *Withania somnifera*, followed by seeking medical advice. Individuals with a history of liver problems should exercise caution and avoid products containing this herb altogether.

Reports indicate that gastrointestinal issues, including severe nausea, vomiting, and diarrhoea, have been observed shortly after ingestion of *Withania somnifera* products. In some cases, these symptoms were severe enough to necessitate hospitalisation. Additionally, there have been very rare instances of liver injury associated with the use of *Withania somnifera*, with some cases requiring medical intervention and hospitalisation.

Healthcare professionals should remain vigilant when assessing patients presenting with symptoms suggestive of liver injury, considering the potential involvement of complementary medicines containing *Withania somnifera*. It is paramount to report any adverse events associated with these products to facilitate ongoing monitoring and regulatory actions if necessary.

<https://tinyurl.com/mrxk37v9>

## News in Brief

### Heart Foundation's food and nutrition position statements

The Heart Foundation's food and nutrition position statements offer evidence-based guidance on heart health-related nutrition topics. They cover heart-healthy eating patterns, meat, eggs, dairy, dietary fat, salt intake, fish, phytosterols, and alcohol consumption. These resources aim to inform healthcare professionals and the public about heart-healthy nutritional choices.

<https://tinyurl.com/4bu3wssw>

### ATAGI advice on seasonal influenza vaccines in 2024

The Australian Technical Advisory Group on Immunisation (ATAGI) has released advice regarding the administration of 2024 seasonal influenza vaccines. It covers available vaccines by age, virus strains included, vaccination timing, immunisation for pregnant women, National Immunisation Program-funded eligibility, and medical conditions increasing influenza complication risks for immunisation providers in Australia.

<https://tinyurl.com/akdwe97j>

### ACHD Workforce Global Survey

A global survey has been launched to explore factors influencing cardiologists' and trainees' decisions to pursue a career in adult congenital heart disease (ACHD). It aims to understand motivations and deterrents comprehensively. The questionnaire covers demographics and training and takes 5–7 minutes to complete.

<https://tinyurl.com/8u7mmt79>



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## COVID-19 Resources for Cardiologists

CSANZ <https://tinyurl.com/y3xp2729>

ACC <https://tinyurl.com/y68aud3a>

ESC <https://tinyurl.com/wn3fst>

## Conferences, Workshops, and CPD

Please click on the links below for upcoming local and international cardiology meetings, workshops, and CPD.

ACRA <https://tinyurl.com/y4yj8xb5>

CSANZ <https://tinyurl.com/3mwt5tr>

Cardiac Skills Australia <https://tinyurl.com/7hx6zmdt>

Heart Foundation <https://tinyurl.com/2wfm3f3>

Australian Centre for Heart Health <https://tinyurl.com/e2yjcreu>

ACC <https://tinyurl.com/y2khytpz>

AHA <https://tinyurl.com/zajc9a7>

ESC Congresses and Events <https://tinyurl.com/y6ko68yf>

ESC Education <https://tinyurl.com/y3zkjp3o>

## Research Review Publications

[Dapagliflozin treatment effect in patients with chronic kidney disease, heart failure](#)

[Dapagliflozin across the range of ejection fraction in heart failure and type 2 diabetes](#)

[Acute Coronary Syndrome Research Review](#) with Professor John French

[Atrial Fibrillation Research Review](#) with Dr Andre Catanchin

[Cardiology Research Review](#) with Associate Professor John Amerena

[Heart Failure Research Review](#) with Professor Andrew Coats, and Dr Mark Nolan

[Interventional Cardiology Research Review](#) with Conjoint Professor Craig Juergens



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