GIG CYMRU
NHS WALES

Bwrdd Iechyd Prifysgol
Bae Abertawe
Swansea Bay University
Health Board

Meeting/Date	**Health Board** **19 August 2021**		**Agenda Item**	**2.1**
Report Title	Transcutaneous aortic valve insertion (TAVI) – Update			
Report Author	Dr Richard Evans, Executive Medical Director			
Report Sponsor	Dr Richard Evans, Executive Medical Director			
Presented by	Dr Richard Evans, Executive Medical Director			
Freedom of Information	Open			
Purpose of the Report	To update the Health Board on the current position in relation the progress made in treating the patients on the TAVI waiting list and the Royal College of Physicians' (RCP) review of the service.			
Key Issues	• The Royal College of Physicians' (RCP) conducted a review of the TAVI service in 2019/20, including casenote reviews of two groups of patients and a site visit to the service in 2019. • This paper provides assurance regarding the actions taken to demonstrate improvement in the governance of the service. • A detailed communication plan has been developed to share the report's findings with patients' families/next of kin and key stakeholders.			
Specific Action Required ***(please ✓ one only)***	**Information**	**Discussion**	**Assurance**	**Approval**
			✓	
Recommendations	The Health Board is asked to approve future reports being received through Management Board via the Quality and Safety Governance Group every six months, providing evidence that it has reviewed its performance against national quality and outcome standards.			

TRANSCUTANEOUS AORTIC VALVE INSERTION UPDATE

1. INTRODUCTION

This paper provides an update on progress on transcutaneous aortic valve insertion (TAVI) focussing on the progress made in treating the patients on the waiting list and the external review of the service by the Royal College of Physicians (RCP).

2. BACKGROUND

TAVI is a procedure used in people who have severe aortic stenosis as an alternative to conventional ‘open’ surgery for replacing the aortic valve. TAVI may be the procedure of choice for patients in whom conventional surgery is precluded due to the clinical risk associated with multiple co-morbidities or frailty.

In 2018 it became apparent that a number of patients had died while on the waiting list for TAVI. Given the mortality associated with severe aortic stenosis, there was concern that failure to address a growing waiting list was material in causing harm to patients. In response, the Health Board convened an executive-led ‘Gold Command’ group to oversee improvement actions.

3. EXTERNAL EXPERT REVIEW BY THE ROYAL COLLEGE OF PHYSICIANS

The Royal College of Physicians (RCP) has been commissioned to undertake a review of the service, comprising three separate elements:

i. A retrospective casenote review of 32 patients who died while on the waiting list for TAVI between 2015 and 2018

ii. A site review by an expert panel convened by the RCP to provide assurance regarding the improvements made to date, and to advise on any further service changes required. The RCP review team visited the UHB for two days on 22-23 July 2019.

iii. A further casenote review by the RCP of the remaining 51 patients who died on the TAVI waiting list.

    The review of this cohort of patients found:

    - Only 10 of the 51 patients had a documented clear decision to proceed with TAVI
    - 31 patients were never actually on the waiting list for TAVI but had begun the TAVI pathway. These patients had been referred to the TAVI team and were awaiting an appointment, or investigations had begun and were incomplete at the time of the patient’s death. In three such cases, TAVI was deemed unsuitable for the patient, treatment was deferred due to other clinical conditions, or local surveillance was decided upon.

- The review team was unable to reach judgements on ten cases. Nine cases were outside the scope of this review as the patient had not met with the TAVI team, had not been selected for TAVI or added to the waiting list for TAVI, and therefore could not be said to have been on the TAVI pathway. A further case was excluded because insufficient information was provided to the review team to support judgements on the care provided to the patient.

The themes arising from the final clinical record review echo those identified by the previous RCP case record review in 2019 and have been addressed through the detailed improvement plans.

Five recommendations were made, and have formed the basis of an improvement plan (Appendix 1)

4. ASSURANCE MEASURES

Improvement plans have been put in place for all three aspects of the RCP's reports. Assurance on progress has been provided through the Quality and Safety Committee and monitored through a Quality Dashboard, benchmarking clinical outcomes with national best practice. The Quality Dashboard for July 2021 is appended (Appendix 2).

5. GOVERNANCE AND RISK ISSUES

There remain challenges to maintaining the waiting list position given the component waiting times and the potential for patients to be referred in to the service at a late stage in their pathway. However, the team have maintained the service exceptionally well.

The COVID pandemic has had an impact on the service: the demand for TAVI has rose during the first and second waves due to the transfer of patients from the surgical aortic valve replacement list.

There is now robust management of the waiting list and strong clinical leadership in the service. The service aims to treat patients within 18 weeks of referral for TAVI; the data or July 2021 shows 96% achievement of this goal:

Waiting time (whole pathway)	**Number of patients waiting**
0-17 Weeks	44
18-26 Weeks	1
27-35 Weeks	1
36-45 Weeks	0
46-52 Weeks	0
Total	**46**

This contrasts with the position at the beginning of November 2018, when 63 patients had been waiting over 26 weeks for a TAVI and 21 patients had died during the preceding 12 months while waiting for a TAVI.

No patients have died while waiting for a TAVI since May 2019.

6. COMMUNICATION

A core objective when commissioning the review was to be open and transparent with the families of those affected and to communicate and engage, where possible, with family members sensitively and in a way that allowed opportunities for feedback and comment.

The RCP has now provided detailed commentary on the clinical management of individuals reviewed. The next of kin of deceased patients whose care was reviewed by the RCP have been contacted and given the opportunity to discuss the circumstances and raise any issues. The full feedback will be shared with relevant families, who have been written to and invited to discuss the feedback with senior clinicians.

7. FINANCIAL IMPLICATIONS

Funding has been secured for the projected level of activity for 2021/22. The contract with WHSSC has been increased to 121 cases. The forecast performance is for the year is 160 cases. In normal circumstances there is a contractual mechanism to secure additional funding for over-performance, however as all contractual funding flows have been blocked for the duration of the pandemic, the additional activity above the contract baseline will this year be funded by Welsh Government recovery funding.

8. RECOMMENDATION

The Health Board is asked to approve future reports being received through Management Board via the Quality and Safety Governance Group every six months, providing evidence that it has reviewed its performance against national quality and outcome standards.

Governance and Assurance

Link to corporate objectives *(please ✓)*

Promoting and enabling healthier communities	Delivering excellent patient outcomes, experience and access	Demonstrating value and sustainability	Securing a fully engaged skilled workforce	Embedding effective governance and partnerships
	✓		✓	✓

Link to Health and Care Standards *(please ✓)*

Staying Healthy	Safe Care	Effective Care	Dignified Care	Timely Care	Individual Care	Staff and Resources
	✓	✓		✓	✓	✓

Quality, Safety and Patient Experience

This paper describes how the Health Board is ensuring that there is expert external review of TAVI deaths so that lessons can be learned to drive improvement in quality, safety and patient experience.

Financial Implications

The Health Board will need to consider redress for any breach of duty of care.

Legal Implications (including equality and diversity assessment)

The Health Board will need to consider redress for any breach of duty of care.

Staffing Implications

None

Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015 - https://futuregenerations.wales/about-us/future-generations-act/)

Report History	
Appendices	Appendix 1: TAVI Assurance Framework for Cohort 2, August 2021 Appendix 2: TAVI Quality Dashboard, July 2021