

Written evidence submitted by Edwards Lifesciences (CBP0039)

About Edwards Lifesciences

Edwards Lifesciences is a leading medical devices company providing lifechanging technologies to people with structural heart conditions and providing best-in-class monitoring technology in the operating room and intensive care units. Our heart treatment technologies provide curative and restorative treatment to people suffering from heart valve disease – a progressive, severe and debilitating condition with a high risk of mortality without treatment.

Our response to this inquiry

Edwards Lifesciences welcomes this timely inquiry. In our response, we have chosen to focus on the role that smart investment in innovative technologies can and should play in addressing the rising backlog in care that has emerged due to the Covid-19 pandemic, namely for the detection, diagnosis and treatment of heart valve disease.

Summary

Minimally invasive therapies for valvular heart disease, such as transcatheter aortic valve implantation (TAVI), have a huge advantage of avoiding critical care occupancy, by shortening the convalescence period needed and allowing patients to leave after a few days, or in some cases on the same day, thereby providing a safer, more efficient, and more cost-effective treatment option.

It is a particularly effective treatment option for the elderly population who are often unable to undergo traditional surgery due to underlying frailty. An estimated 1.5 million people in the UK have heart valve disease (HVD); with demographic ageing, this figure is set to double by 2046.¹

Utilised properly, TAVI could be extremely beneficial in supporting the reduction of the backlog caused by Covid-19, due to hospital capacity and resources released through its roll-out. However, a number of changes are needed across the sector: improved diagnostic capabilities; consideration of TAVI for all patients with heart valve disease (HVD) as soon as they are diagnosed; a fully staffed workforce with relevant TAVI training; and infrastructure to allow the full utilisation of TAVI equipment and training.

Heart valve disease

Symptoms of heart valve disease are usually breathlessness or exertion. However, due to the poor use of stethoscopes in GP appointments and health checks across the UK, approximately a half of patients with heart valve disease are not diagnosed until significant valve disease has developed. Heart diseases are also currently mostly diagnosed in hospitals despite 40% of patients having symptoms which should have triggered an earlier assessment².

This means that by the time the patient presents, it is likely that the heart has become compromised (heart failure), which can cause significant problems, admissions to hospital, loss of independence etc., and it is less likely that an operative intervention would be considered at this stage.

Transcatheter Aortic Valve Implantation (TAVI)

¹ BHF (July 2018). Heart valve disease facing diagnosis crisis over next 40 years. Access: <https://www.bhf.org.uk/for-professionals/healthcare-professionals/blog/2018/heart-valve-disease-facing-diagnosis-crisis-over-next-40-years>.

² NHS Long Term Plan, p.g 62. Bottle, A., Kim, D., Aylin, P., Cowie, M., Majeed, A. & Hayhoe, B. (2018) Routes to diagnosis of heart failure: observational study using linked data in England. *Heart*. 104 (7), 600-605. Available from: <https://doi.org/10.1136/heartjnl-2017-312183>

Minimally invasive surgery refers to any surgical procedure that is performed through tiny incisions instead of a large opening. Because a smaller incision is made, patients typically have a quicker recovery time and suffer less pain than traditional open surgery but with the same benefits. A minimally invasive approach has been found to be more cost-effective as it often requires a shorter hospital stay, decreased amounts of imaging and laboratory tests and reduced numbers of required readmissions and follow-up costs. It is particularly effective for elderly patients who are often unable to undergo traditional surgery.

Transcatheter aortic valve implantation (TAVI) is a safe and cost-effective innovative treatment for heart valve disease. While recovery for open surgery patients may take several weeks, after TAVI they would have been released home typically after 48 hours.

Importance of smart investment in technology

One of the positive impacts of the Covid-19 response has been the recognition for and increased utilisation of digital and health technology in diagnosing and treating patients. This includes direct interventions, such as using Artificial Intelligence (AI) and machine learning to identify the most at-risk individuals, and improvements to address overall capacity, like delivering remote monitoring and consultations.

Of particular benefit is the greater adoption of minimally invasive surgery options for a wider range of patients, such as the TAVI. The avoidance of open heart surgery and a shorter recovery time reduces the likelihood of infection and complications, and patients can return to a more active life sooner without the need to compromise on quality of care. This then also releases capacity and resources across the sector, helping a wide range of patients.

Changes needed to support the utilisation of TAVI

The care backlog continues to rise and presents a continual growing problem for the NHS and social care services. As of end of May 2021, for NHS England alone, by referral to treatment (RTT) waiting times there were over 5.3 million patients waiting to start treatment, an increase of 15.9% compared to the end of February 2020 (pre-Covid-19). Over 230,000 patients were waiting for cardiac services, and over 20% of these had already been waiting 18+ weeks.³

The equipment for TAVI is already available in many hospitals, and could support addressing the backlog of care by decreasing waiting and recovery times for patients with HVD, and releasing much-needed capacity and resources. However, for the TAVI equipment to be utilised effectively and have maximum impact benefit, both for HVD patients and the wider health and care service, several key issues need to be addressed:

Diagnosis

The earlier HVD is detected, the sooner it can be diagnosed and treated. Poor diagnostic capabilities due to a lack of specialist echocardiographers can delay diagnosis, worsening patient outcomes and reducing the chance they will be suitable for TAVI.

The introduction of digital technology, such as digital stethoscopes, is a quick and easy way to assess those with breathlessness accurately and upfront, helping to triage as well as to diagnose, therefore supporting all patients onto the most efficient and effective pathway. Additionally, there needs to be

³ NHS, July 2021. *Statistical Press Notice NHS referral to treatment (RTT) waiting times data May 2021*. Can be viewed at [May21-RTT-SPN-publication-69343.pdf \(england.nhs.uk\)](https://www.nhs.uk/statisticalpress/publication-69343.pdf)

a greater awareness of HVD and how to detect it by primary care practitioners, particularly for patients over the age of 65 and suffering from breathlessness.

Equity of healthcare

It will be pertinent to ensure that alongside earlier diagnosis, all patients with HVD are considered for TAVI. Although TAVI will not be appropriate for all patients, through earlier detection, TAVI can be considered as a viable option for more patients than it is currently treating. By using non- and minimally invasive treatments early on in the disease progression, patients can more readily return to an active life and are less likely to need further treatment or support through wider services.

TAVI is a particularly effective treatment option for elderly patients. With clinically significant heart valve disease affecting around 13% of people aged 65+,⁴ and with the number of people aged 75+ expected to grow by almost 60% over the next 20 years,⁵ heart valve disease poses a significant threat to overall population health in the years to come. Elderly patients are often unable to undergo traditional surgery. TAVI allows them the chance to live longer and more active lives.

Workforce

Specialist training is required to utilise the existing TAVI technology, however this is often restricted to senior clinical staff, contributing to wide variation in the rate of TAVI provision across trusts, with less efficient TAVI units providing over 50% fewer TAVIs in a clinical day⁶.

Training and upskilling different professionals across the workforce is key to meeting growing demand for heart valve disease care. Training should be offered to nurses and associates to upskill the workforce in HVD management and the use of TAVI technology. Cardiac physiologists and specialist nurses should be supported in extending their skillset to fill various functions such as echocardiography and cardiac surveillance, addressing the national shortage in accredited echocardiographers⁷. To address limits in staff availability, cardiac networks could instigate rotas to ensure specialist expertise for TAVI provision and ensure 7/7 access to echocardiography services.

In primary care, professionals are often unaware of the symptomology of heart valve disease, with signs such as breathlessness put down to natural ageing, which contributes to missed diagnoses. Within primary and community care there is welcome work being undertaken on the prevention of cardiovascular diseases and complications such as heart failure, but similar training needs to be undertaken to support primary and community professionals with screening and patient monitoring to identify symptoms of treatable but unpreventable conditions such as heart valve disease. Referring teams should be equipped to refer patients to relevant specialists and lay out all treatments for heart valve disease available.

Infrastructure

Although there is already good availability for TAVI devices, the number of TAVI treatments are severely limited where the amount of cath lab time available for TAVIs is often limited to one or two days a week only.

⁴ D'Arcy, J. et al., December 2016. The OxVALVE Population Cohort Study.

⁵ DHSC, February 2021. *Integration and innovation: working together to improve health and social care for all*.

⁶ Getting it Right First Time (GIRFT) (February 2021). Cardiology. GIRFT Programme National Specialty Report. P. 52.

⁷ GIRFT, February 2021, p. 44.

The number of TAVI treatments administered daily is capped despite rapid patient throughput and convalescence demonstrated across trusts, limiting the scale at which the backlog in heart valve disease treatment can be managed. Both daily provision and weekly cath lab time for TAVI should be evaluated to expand capacity.

Conclusion

Due to its minimally invasive nature, utilising TAVI in treatment of HVD across the UK wherever possible can significantly help to address the Covid-19 backlog as it is quicker, reduces the overall cost due its reduction in need of capacity and resources through a short recovery time, and reduces the risk of infection and the attendant need for additional care and support.

However, to see its full benefits, and see equity of care, the following changes need to be implemented in all ICSs:

1. Diagnostics must be improved to ensure that diseases are detected and diagnosed as soon as possible. For HVD and treatment with the use of TAVI, this means increased use of stethoscopes and the introduction of digital stethoscopes.
2. There needs to be a greater awareness of HVD and its detection, particularly in elderly patients, by primary practitioners.
3. All patients must be considered for minimally invasive treatments. For HVD, this means assessing the use of TAVI as treatment as soon as HVD is diagnosed.
4. Effective training for increased groups of health and care staff, including nurses, to use and administer TAVI equipment, ensuring that eligible patients can receive the best and most timely treatment.
5. Infrastructure must be improved so that the already available equipment can be utilised effectively.

Thank you for your time and consideration and we hope that our recommendations will prove useful in addressing the backlog to cardiovascular disease care and wider services. We look forward to reading the Committee's report following the inquiry.

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