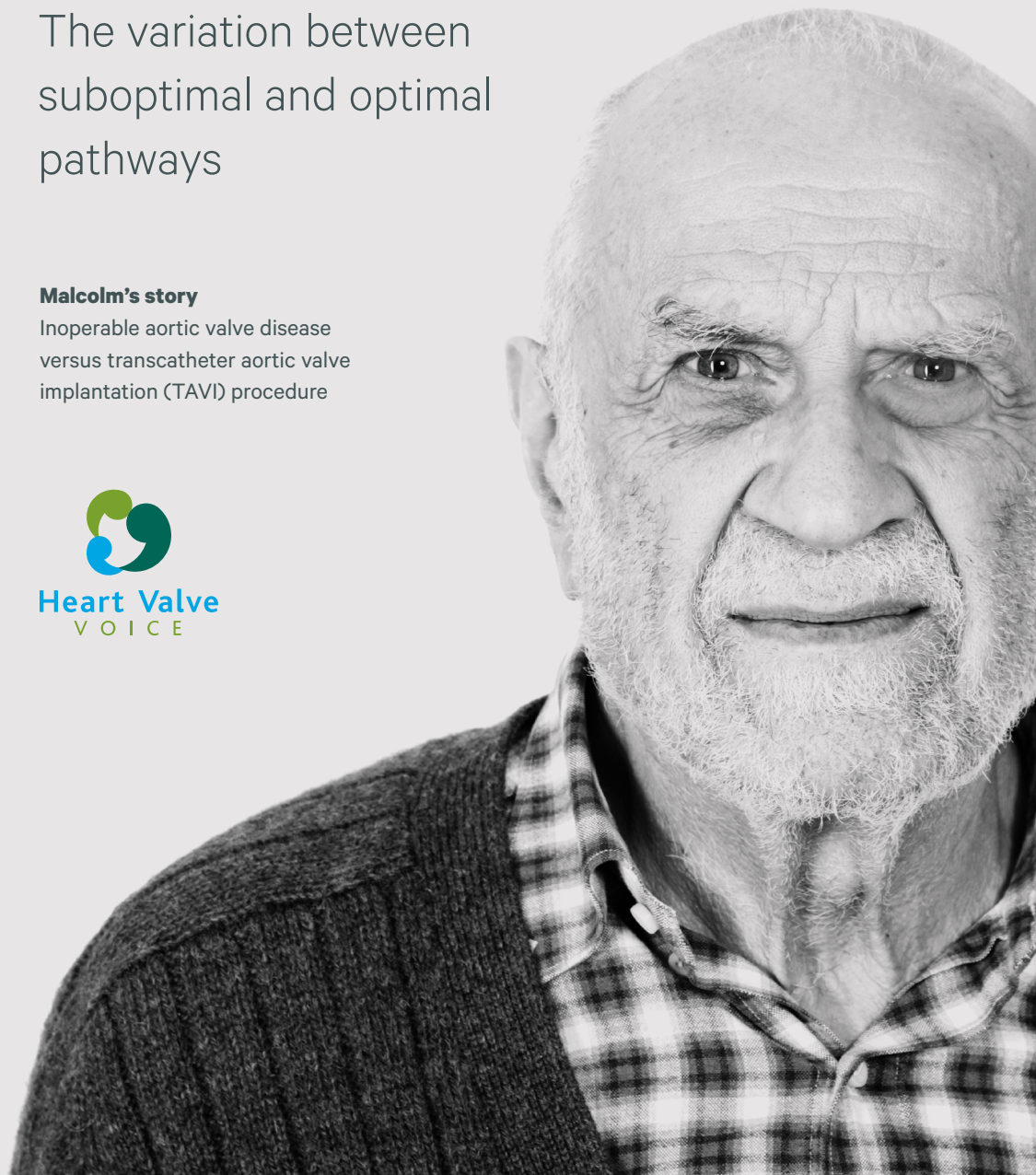


Unwarranted Variation Scenario

The variation between
suboptimal and optimal
pathways

Malcolm's story

Inoperable aortic valve disease
versus transcatheter aortic valve
implantation (TAVI) procedure



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-

4. ICD-10 codes, terms and text © World Health Organization, 1992-2018
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Foreword

Heart Valve Voice is the UK's dedicated heart valve disease charity. Formed in 2013, we are a patient-physician charity, bringing together heart valve disease patients and those that treat the disease, including cardiologists, cardiac surgeons, physiologists, GPs and nurses.

Heart valve disease is a little-known disease but highly prevalent. Across the UK approximately 1.5 million people over the age of 65 are currently affected by heart valve disease and that number is only expected to grow with the number of people in this age bracket. The OxVALVE Study reported that for people over the age of 65, the prevalence of heart valve disease will affect as many as 3.3 million people by 2056, representing a 122% increase.

As the Chief Executive of Heart Valve Voice, I am lucky enough to work with patients who have been diagnosed with, and effectively treated for heart valve disease on a daily basis. Sadly, many people with the condition in the UK go undiagnosed, and access to effective treatment is variable across the country. Our mission is to improve the diagnosis, treatment and management of the condition by raising awareness of the need for timely detection and intervention, to ensure all patients receive appropriate care and support no matter where they live.

What does the significant variation in the diagnosis, treatment and management of heart valve disease across the UK mean for patients? It means those patients who are not so fortunate to have easy access to appropriate treatments, experience delays in diagnosis and in some cases they don't receive the best treatment for their age and comorbidities or any treatment at all, which can seriously affect their long-term prospects. Unfortunately, heart valve disease is a life-threatening disease and significant delays in treatment can lead to heart failure and death. The quality of a patient's treatment should not be dependent on where they live, the services offered, or how effectively a patient pathway can be delivered.

We have seen a number of new technologies made available to valve disease patients through the NHS. The minimally invasive techniques and new technologies involved in procedures such as Aortic Valve Replacement (AVR), Mitral Valve Replacement (MVR) and Transcatheter Aortic Valve Replacement (TAVI) have significantly improved outcomes, allowing many patients to return to living normal, active and symptom-free lives. The Government's Life Sciences Industrial Strategy^b, which was published in August 2017, set out ways in which the UK can move forward to a world leading position so as to take advantage of the health technology trends of the next 20 years. This includes encouraging NHS and industry collaboration in order to improve patient care through better adoption of innovative treatments and technology.

We believe that the recommendations in this report can help to remedy the problem of treatment access by delivering optimal treatment of heart valve disease, rather than increasing the burden on the NHS. These solutions can actually help to save costs in the longer term, by keeping patients out of hospital and living independent lives. Given the prevalence of heart valve disease, which is only set to increase, it is critical that action is taken now to address these issues.

I commend this report for bringing together this group of leading clinicians from across the patient pathway, along with patients, to highlight the difference in optimal and sub-optimal treatment of the disease in the UK. Not only will this help to address the variation in the quality of heart valve disease services in the UK and improve patient outcomes, but will support the NHS in delivering these services more efficiently.

Wil Woan

Chief Executive of Heart Valve Voice



a. D'Arcy JL, Coffey S, Loudon MA, et al. Large-scale community echocardiographic screening reveals a major burden of undiagnosed valvular heart disease in older people: the OxVALVE Population Cohort Study. *Eur Heart J*. 2016;37(47):3515–3522

b. Life sciences: industrial strategy (2017) A report to government from the life sciences sector. Source: <https://www.gov.uk/government/publications/life-sciences-industrial-strategy>

Analysis Style

NHS RightCare has developed a series of long-term conditions scenarios using a style of analysis where suboptimal and optimal case studies of a fictitious, but realistic, patient are compared and contrasted. The intention is to highlight potential improvement opportunities.

The RightCare work is powerful (and often moving) and as such the goal is to inspire more stakeholders to take note and take action towards positive change.

The aim of Heart Valve Voice, like NHS RightCare, is to raise awareness through supporting local health economies – including clinical, commissioning and finance colleagues – to think strategically about designing optimal care for people, in this case, with serious heart conditions.

This scenario has been developed with experts in this specialist field and includes prompts for commissioners to consider when evaluating their local health economy requirements.

The story of Malcolm's experience of a heart failure care pathway, and how it could be so much better

In this scenario using a fictional patient, Malcolm, we examine high risk¹ heart failure caused by aortic stenosis within a comorbidities care pathway, comparing a suboptimal clinical scenario against an ideal pathway. At each stage we have modelled the costs of care, not only financially to the local health economy, but also the cost impact on the patient and their family's experience.

This document is intended to help commissioners and providers understand the implications, both in terms of quality of life and costs, of shifting the care pathway from suboptimal to optimal for relevant patients. It demonstrates how such changes can help clinicians and commissioners improve the value and outcomes of the care pathway.

A summary slide pack has also been produced as an appendix to give a summary for different audiences.

This scenario has been produced in partnership with clinical and patient stakeholders using the NHS RightCare methodology. The aim is to help clinicians and commissioners improve value and outcomes for this patient group.

High surgical risk is defined by the Society of Thoracic Surgeons as a mean Predicted Risk of Mortality at 30 days of 10 percent or greater¹

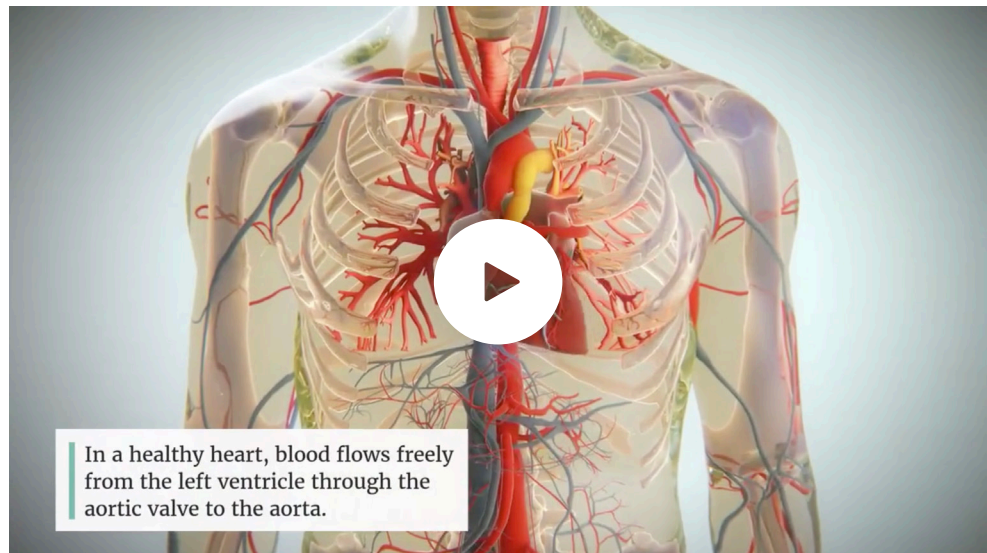
Context and introduction

Heart failure is a complex clinical syndrome of symptoms and signs that suggest the efficiency of the heart as a pump is impaired. It is caused by structural or functional abnormalities of the heart.

Around 900,000 people in the UK have heart failure. Almost as many have damaged hearts but, as yet, no symptoms of heart failure.²

Heart (cardiovascular) disease can refer to various types of conditions that can affect heart function. These types include:

- Coronary artery heart disease that affects the arteries to the heart (the most common cause of heart failure²)
- **Valvular heart disease** that affects how the valves function to regulate blood flow in and out of the heart (the focus of this case study)
- Cardiomyopathy that affects how the heart muscle squeezes
- Heart rhythm disturbances (arrhythmias) that affect the electrical conduction
- Heart structural problems³ developed before birth
- Heart infections which cause the heart muscle to be damaged



Video

AS is usually a progressive condition which results in the narrowing of the aortic valve opening and consequently causes impaired outflow of blood from the heart.

Aortic stenosis (a type of valvular heart disease)

Aortic stenosis (AS), which is the focus of this case study, is one of the most common moderate or severe heart valve diseases⁴. AS is usually a progressive condition which results in the narrowing of the aortic valve opening and consequently causes impaired outflow of blood from the heart. The video below⁵ explains this process visually.

2. Petersen S, Rayner M, Wolstenholme J (2002) Coronary heart disease statistics: heart failure supplement. London: British Heart Foundation.

3. Structural heart disease is a defect or abnormality of the heart that is non-coronary, i.e. it does not affect the blood vessels in the heart. Many structural heart conditions are congenital (present at birth), but these abnormalities can also form later in life due to wear and tear from aging, infection or result from another underlying condition. Source <http://www.uchospitals.edu/specialties/heart/services/valve-disease/structural.html>

4. D'Arcy JL, Coffey S, Loudon MA, et al. Large-scale community echocardiographic screening reveals a major burden of undiagnosed valvular heart disease in older people: the OxVALVE Population Cohort Study. Eur Heart J. 2016;37(47):3515–3522.

5. Source Edwards Lifesciences.

Surgical aortic valve replacement (SAVR) with an artificial (biological or mechanical) prosthesis is the conventional treatment for patients with severe symptomatic AS who are well enough for surgery.

Transcatheter aortic valve implantation (TAVI) is a less invasive alternative treatment that involves inserting a new valve through a catheter, usually by way of a large blood vessel at the top of the leg, into the heart and inside the existing faulty valve.

Severe symptomatic AS is the most frequent heart valve disease among the elderly and is associated with poor outcomes if left untreated⁶. SAVR is the traditional treatment and improves symptoms, quality of life, and prolongs survival⁷. However, a substantial number of patients (30–40%) are deemed unsuitable for SAVR because of their advanced age and/or multiple comorbidities that they have, which considerably raises the peri-procedural risk⁸.

More needs to be done to address the mortality risk for patients with aortic valve diseases, which has increased significantly since 2001, as depicted in Chart 1.

Mortality in the over 65-year-old population:

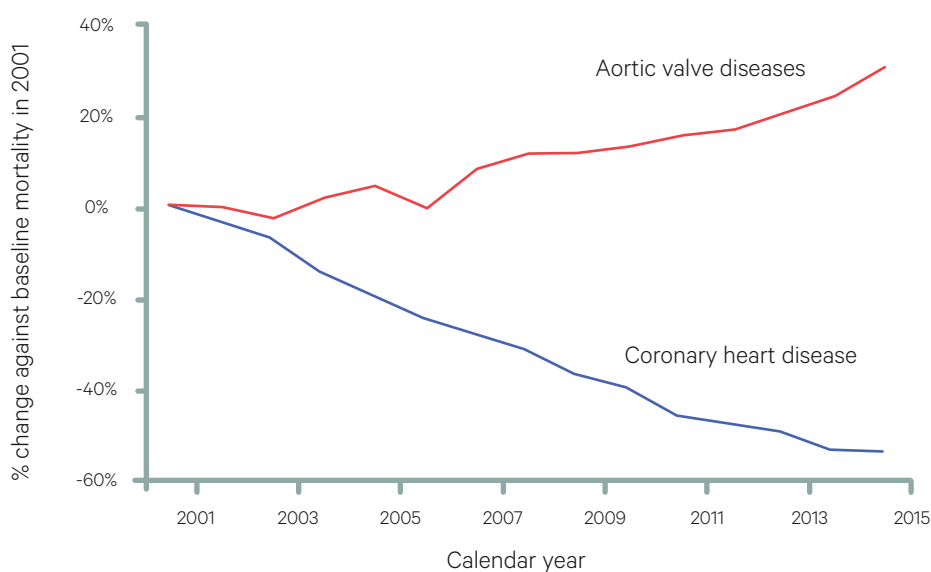


Chart 1
Comparing mortality in aortic valve disease and coronary artery disease in the over 65s

Although more people over 65 die from coronary heart disease than aortic valve diseases, the percentage of deaths due to aortic valve diseases have increased whilst those due to coronary heart disease have declined.

Source: World Health Organization Cause of Death Query online. Available at http://apps.who.int/healthinfo/statistics/mortality/causeofdeath_query/ (last accessed August 2018)

ICD-10 codes used: 135 for Aortic valve diseases and 120-125 for Coronary heart disease

6. Otto CM, Lind BK, Kitzman DW, et al. Association of aortic-valve sclerosis with cardiovascular mortality and morbidity in the elderly. *N Engl J Med.* 1999;341:142–147.
7. Kvidal P, Bergström R, Hörte LG, et al. Observed and relative survival after aortic valve replacement. *J Am Coll Cardiol.* 2000;35:747–756.
8. Iung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? *Eur Heart J.* 2005;26:2714–2720.

Introducing Malcolm

Malcolm is an 80-year-old widower and father of two who retired from work as a supervisor at Wedgwood 15 years ago. His children, grandchildren and football are his greatest passions. Strangely, he supports Arsenal despite living in Stoke!

Malcolm was enjoying a reasonably active retirement despite having been diagnosed with chronic obstructive pulmonary disease (COPD) 20 years previously. His COPD was only mild⁹ and he had been really sensible trying to control any risks that might provoke an exacerbation. He had managed to gradually stop smoking over a six-month period after diagnosis and had not had a cigarette since. After the devastating blow of losing his wife, Pat, six years ago his COPD flared up again but stabilised shortly afterwards.



He now kept himself busy watching the majority of the premiership matches with his three close friends in the council-owned retirement village where he lived and he always went to the Arsenal-Stoke games with his younger son, Rob, for a great day out.

Malcolm has two sons, three grandchildren and one great grandchild, but only his recently divorced son, Rob, lives nearby. He worried about Rob a great deal and helped out quite a lot with looking after his grandchildren.

Malcolm tried to keep physically active through walking and liked to treat Rob and the kids to a meal out at the pub as often as he could, which they all enjoyed – although Rob couldn't stand his dad's habit of looking at the underside of the plate after every meal to see where it was made.

Malcolm was also kept busy on a daily basis looking after his 75-year-old friend Eddie who lived in a neighbouring flat. Eddie had complex health problems and Malcolm was a godsend in terms of shopping, helping around the house and reminding Eddie to take his medication. They had a great laugh together and generally kept loneliness at bay!

Malcolm had always been an active “can do” character who never let anything hold him back. However, with his ailments building up, he was starting to feel his age. Seven years ago Malcolm had a stent procedure for angina but thankfully since then he had been free from those symptoms.

Since the stent he was diagnosed with type 2 diabetes¹⁰ and although this was controlled with oral medication for five years he was now using insulin. His COPD had worsened over time, currently moderate in severity,¹¹ but was well managed with inhalers.

Malcolm regularly took Eddie's spaniel, Mr Pickles, out walking so he was getting a good amount of exercise which helped keep him in reasonable shape for a man of his age with his comorbidities. Despite this exercise Malcolm was obese with a BMI of 32 (5'9" and 98kg) – it must have been all those oatcakes with bacon and cheese that he liked so much (a Stoke delicacy). This wasn't helped by the low dose of steroids (prednisolone) that he needed to take over the last four years after he developed severe muscle aches whilst walking. His GP had diagnosed him with polymyalgia rheumatica. The steroids made this much better and he had needed to take a low dose since then. The symptoms of breathlessness had progressively worsened and made doing normal things much more difficult.

9. Global Initiative for Chronic Obstructive Lung Disease Inc (2018) Global Strategy for the diagnosis, management and prevention of chronic obstructive lung disease www.goldcopd.org. GOLD grade 1 diagnosis with spirometry.

10. Managed by quarterly appointments with the practice diabetes nurse.

11. Global Initiative for Chronic Obstructive Lung Disease Inc (2018) Global Strategy for the diagnosis, management and prevention of chronic obstructive lung disease www.goldcopd.org. GOLD grade 2 at this stage.

Malcolm's suboptimal health journey

In June 2017 Malcolm noticed that he was getting more breathless walking up the steep hill to the park on the daily route with Mr Pickles. For a while he had been compensating by taking a different route to avoid the steep incline. On this occasion he felt as if he couldn't go on walking but he thought the pollen in the air might be affecting his COPD more than usual. However, by August 2017 things had got worse rather than better so he made an appointment with the GP. The GP prescribed a second inhaler (bronchodilator). Malcolm's FEV₁¹² was around 48% at this point in time.

Malcolm found that the extra inhaler did not help much at all, which was disappointing because the shortness of breath was really affecting him and he was increasingly finding that he couldn't do as much around the house for Eddie.

Malcolm then made several trips to the GP about his breathlessness, which the GP treated as a chest infection, but antibiotics didn't make him feel much better¹³.

On one occasion whilst out walking Mr Pickles he became so out of breath and dizzy that he slumped over a park bench. Looking very ill indeed, a passer-by rushed to help Malcolm and called 999 for an ambulance. This resulted in an A&E attendance, where they detected a heart murmur, followed by an overnight stay in the hospital, an echocardiogram, and a referral to cardiology. This whole experience really frightened Malcolm.

The cardiologist found that he had a severe narrowing of his aortic valve and diagnosed him with AS. He advised that this may need an operation to correct the problem and arranged for Malcolm to have an angiogram, which had a five-week waiting list. (This was needed as part of the surgical assessment, especially as Malcolm had a stent in the past.) The cardiologist then referred Malcolm to a surgeon.

A common problem can be delay to diagnosis because of COPD severity – it is assumed that worsening breathlessness is due to lung disease rather than aortic stenosis. Patients also often remodel their behaviour to compensate for their symptoms which further masks the problems (they make excuses for not doing things rather than recognising symptoms).

12. Forced expiratory volume is measured during the forced vital capacity test. The forced expiratory volume in one second (FEV₁) measurement shows the amount of air a person can forcefully exhale in one second of the FVC test. <https://lunginstitute.com/blog/fev1-and-fvc/>

13. There is increasing evidence and concern that many GPs are missing the early signs of heart failure and that patients are only being diagnosed in secondary care when they are already very ill. <https://www.telegraph.co.uk/news/2018/08/27/majority-heart-failure-cases-missed-gps-target-culture-blamed/>

In February 2018, after another six weeks' wait, Malcolm saw the surgeon who explained that taking into consideration his past medical history and current health status his clinical opinion was that he was a **high-risk**¹⁴ patient for open heart surgery. Furthermore, surgery would not be the right option for him. In general, a patient like Malcolm could have another two or three years of life if he were to look after himself well. The surgeon did not mention TAVI as an option.

TAVI can be an effective method to treat AS¹⁵ in the elderly¹⁶. As depicted in Figure 1 only 4% of patients had further AS hospital admissions after a TAVI procedure within the examined time period of five fiscal years between 2012/13 to 2016/17.

Using Euroscore II, Malcolm's estimated surgical mortality comes out at 9.5% due to comorbidities and age. Note: although a variety of risk algorithms will be used as a guide, the determination of "high risk" will always be at the discretion of the surgeon based upon the specifics of the individual patient.

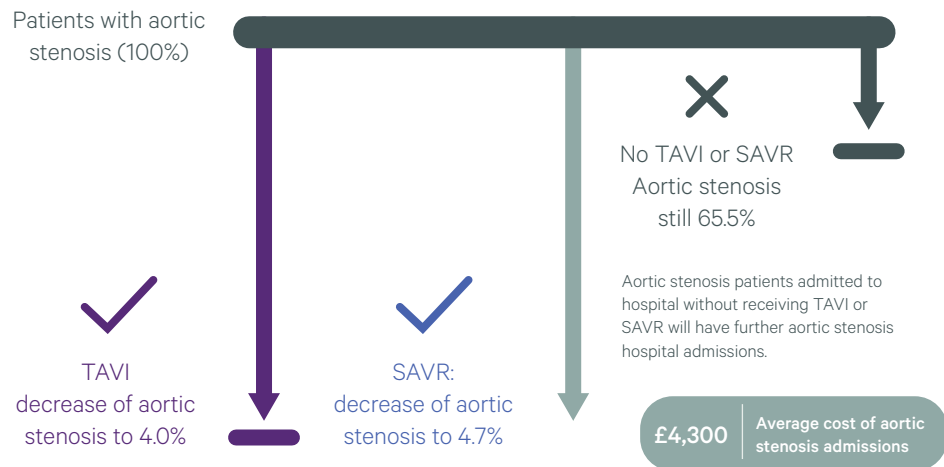


Figure 1
TAVI effectiveness (2012/13 to 2016/17)¹⁷

Although this prognosis was a real shock to Malcolm, he felt like he'd had a good life and that another three years would be time enough to have a bit more fun and to make sure all his affairs were in order. What Malcolm didn't know, and had not been explained to him, was that combined with the COPD these comorbidity issues might be distressing for the remainder of his life.

14. The Euroscore risk profiling tool can be found here: <http://www.euroscore.org/calc.html>. The vital sign and medical markers that the consultant would consider in their personal judgement for this case for risk determination are available upon request.

15. ICD-10 codes I35.0 Aortic (valve) stenosis and I35.2 Aortic (valve) stenosis with insufficiency as a primary diagnosis. NB, secondary care data is taken from the English Hospital Episode Statistics (HES) database produced by NHS Digital, the new trading name for the Health and Social Care Information Centre (HSCIC) Copyright © 2018, the Health and Social Care Information Centre. Re-used with the permission of the Health and Social Care Information Centre. All rights reserved.

16. Patients aged between 66 and 95 years.

17. Wilmington Healthcare data produced September 2018 data HES data 2012/13 to 2016/17 and average cost of admission for 66- to 95-year-olds paid to providers in 2016/17.

The decline

It did not take long for Malcolm to realise that life was never going to be the same again. Within three months, his COPD had deteriorated following a heavy cold (with more GP visits and antibiotics) and he was now so breathless that he had to completely stop helping Eddie and walking Mr Pickles. This was devastating for both men (and the dog who had to be taken to a rescue centre). From this date onwards Eddie had to have a care package of support which was ongoing for the remaining five years¹⁸ of the story.

Around this time Malcolm had to stop driving, which meant he could no longer visit his son Rob and help look after the grandchildren. Both Malcolm and Rob become increasingly isolated and unhappy.

This was also a tipping point for Rob who was signed off work with clinical depression¹⁹; the break-up of his marriage and the inability of his father to provide as much care for his children as previously (because of Malcolm's deterioration) was all too much for him to cope with.

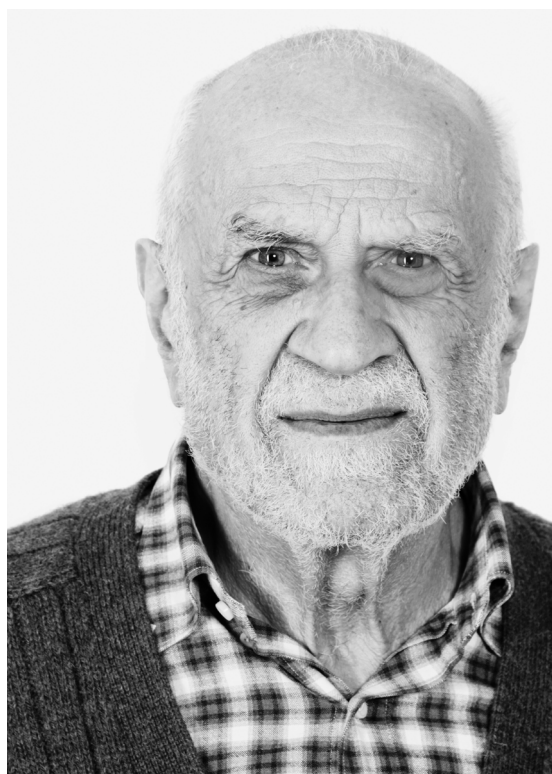
After receiving the advice, around six months later in September 2018 Malcolm was visibly deteriorating and needed nursing and social services support²⁰ at home for ten months and then nursing home care for a further eight months – until the end of his life.

As he became frailer he became more unsteady on his feet. Malcolm fell three times, getting soft tissue damage which resulted in a GP visit each time. At this point, Malcolm constantly worried about falling and so he invested in a mobility scooter – £750 was a big chunk of his savings!

The scooter definitely helped for a few months and meant that Malcolm could still go out – he hated being cooped up all day long. However, unfortunately early in the new year, Malcolm had a more serious fall in the bathroom and he had to press his panic button; an ambulance crew was dispatched to his flat. He was taken to A&E and had an overnight stay in hospital as a precaution given that he was so shaken; luckily, he had no fractures or serious injuries.

This change in his condition and the serious fall were the trigger for social services to install an array of home equipment to support Malcolm²¹ (commode, specialist bed, hand rails, etc).

By Easter 2019, Malcolm developed oedematous legs (due to his heart failure) which were constantly weeping fluid and resulted in the formation of small leg ulcers in these areas.



18. To match the timeframe of the optimal story.

19. Assumed that Rob relies upon these prescriptions until one year after his father's death.

20. First six months one weekly district nurse and then progression up to two visits per week for four more months. Plus community nurse for 10 months, and five visits per week until admitted to nursing home. Plus daily social services visits for meal support before the nursing home.

21. A social worker helped Malcolm to complete the care needs assessment.

These problem areas had to be attended to daily by a community nurse to change his wet dressings.

Malcolm's compromised oxygen intake and general inability to move around affected the integrity of his skin and he was a high risk of pressure ulcers²². His generalised deterioration meant he was no longer able to self-administer his insulin safely. Combined with the overwhelming distress he experienced due to breathlessness he was in a very sorry state.

By July 2019 the district nursing team caring for Malcolm determined that his frailty, poor health and lack of mobility were so severe that he needed more services than they could provide. A needs assessment for full-time nursing care (Continuing Health Care²³) was undertaken and he was admitted to a nursing home in August 2019.

Although Malcolm now had access to care 24/7, his deterioration was still significant. During his time in the nursing home he required six visits from his GP, and on eight occasions he was visited by specialist heart failure nurses. From October 2019, Malcolm also received long-term oxygen therapy.

In Malcolm's final three months things got so bad that he was rushed to A&E three times with syncope episodes and once with heart failure.

The tables had turned. For most of his life Malcolm had spent a lot of his time helping and supporting his friends and family. Now he was completely incapacitated and he felt completely isolated and totally fed up.

His friends and people in the community missed him too. Eddie, although not well himself, organised a giant get well soon card and managed to get almost fifty well-wishers to sign the card. It was an emotional experience for everyone involved when he delivered the card to the nursing home.

Malcolm died in March 2020, two years after his diagnosis. During this time – the last 18 months in particular – he had a very poor quality of life indeed. Much can be learned from his story.

The costs of these episodes alone (ambulance, A&E and admissions) cost the NHS £8,581. All these costs are avoided within Malcolm's optimal case – see the financial section below for more financial insights.

Suboptimal pathway learnings:

- Greater awareness of heart valve disease (HVD) is needed, amongst both primary care professionals and the public.
- All patients complaining of breathlessness should have their hearts routinely checked with a stethoscope by a trained primary care health professional.
- Symptoms of valve disease like tiredness, breathlessness and swollen ankles may be attributed to normal ageing but should be investigated.
- This scenario raises the importance of "no decision about me without me" in a significant way. These patient engagements need to be handled very carefully and decisions need to be taken over time. Patients often do not understand the impact on their quality of life and the positive and negative elements of surgery and non-surgical options for management.

22. <https://www.thecalculator.co/health/Waterlow-Score-Calculator-1116.html>

23. https://www.continuing-healthcare.co.uk/continuing-healthcare-checklist-and-process?rsrc=1&gclid=EA1aIQobChMIqav-z7Pb3QIVLLHtCh0rtAqDEAAYASADegJQkfd_BwE

- The impact on primary care from secondary care referrals is sometimes not adequately resourced or planned – as demand increases, more heart failure palliative care teams in the community are likely to be required in many areas.

Messages for commissioners

- Commissioners need to understand the implications of structural heart disease (which includes aortic stenosis) and the impact on lives.
- Between 2015 and 2025, the number of people aged 65 years and older will have increased by 19.4%.²⁴
- Approximately 1.5 million people over the age of 65 across the UK are affected by HVD.²⁵
- Evidence shows 30% of people with heart valve disease are left untreated.²⁵
- As depicted in Figure 2, there is a wide variation in access to TAVI procedures around the country for patients who need it. Commissioners should be aware of this variation and how many people in their own health economy might need treatment but lack access.²⁶
- Commissioners can be the vehicle to drive change through redesign, contractual levers like CQUIN, and use of QIPP to deliver efficiency savings for the management of HVD.

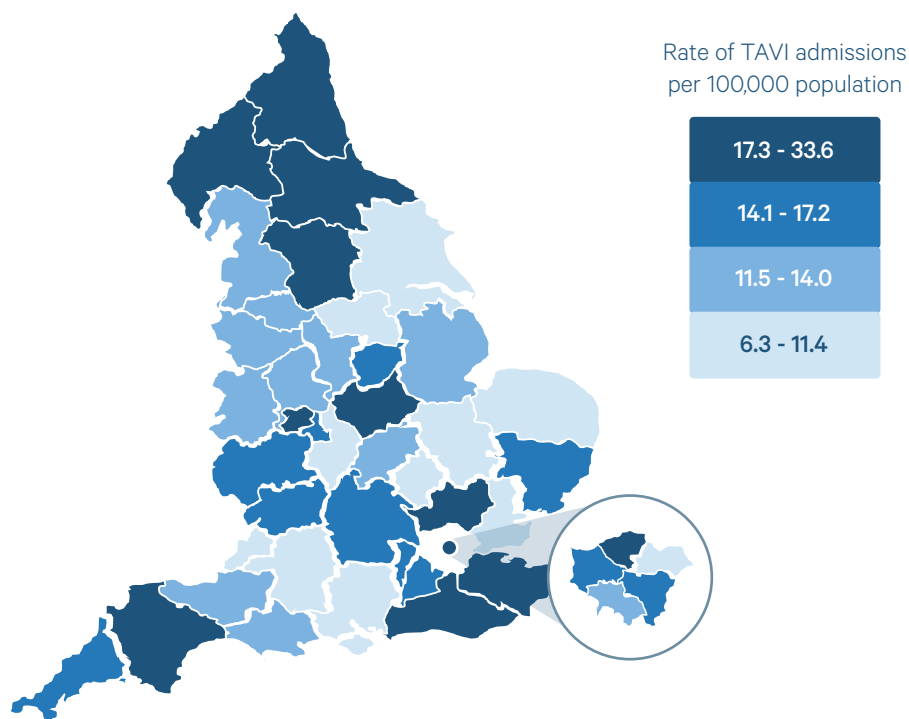


Figure 2
Rate of TAVI admissions per 100,000 population 2016/17²⁶

24. Guzman-Castillo M, Ahmadi-Abhari S, Bandosz P, et al. Forecasted trends in disability and life expectancy in England and Wales up to 2025: a modelling study. *Lancet Public Health*. 2017;2:e307-13.
 25. Heart Valve Voice (2016) The 2016 UK Heart Valve Disease Survey. Available at: https://www.heartvalvevoice.com/application/files/3614/9482/8596/Heart_Valve_Voice_UK_Survey_2016_pdf
 26. Wilmington Healthcare data produced September 2018 data HES data 2016/17.

- Five Year GP Forward View encourages GPs to develop new models of care that will better manage those groups of the population most at risk of needing support. Models exist for improving heart failure management, for example, through the joint appointment of British Heart Failure Society nurse specialists in CCGs.
- Integrated Care Services are in a prime position to implement optimal pathways for HVD and AS.
- In the near future Primary Care Homes will be another valuable means to address the needs of this potentially high-cost client group.
- Third sector partnerships can be crucial in supporting service change in this area.

Messages for the public

- Whilst commissioners, GPs and providers have a responsibility to focus on HVD, the public also has a responsibility to look after their own health, in line with the self-care agenda and prevention of illness.
- HVD can be recognised by identifying potential signs and symptoms of this condition, and understanding the health indicators that warrant making a visit to the GP. This reminder from Heart Valve Voice serves as a helpful prompt:

Feeling older than your age? Think **HEART Valve Disease**:

- **H**aving chest pain – Are you suffering from chest pain, dizziness, or experiencing palpitations?
- **E**xercise difficulties – Are you finding it difficult to exercise and move around as easily?
- **A**ge – Are you feeling older than your age?
- **R**espiratory difficulties – Are you feeling short of breath?
- **T**iredness – Are you suffering from tiredness and fatigue?
- **V**isit your **D**octor, if you are experiencing any or all of these symptoms!
- The Heart Valve Voice symptoms tracker is a useful tool which has been created to help people who develop symptoms like breathlessness, swollen ankles and tiredness to capture their symptoms ahead of visiting their healthcare professional.²⁷ These symptoms are not only just part of normal ageing.

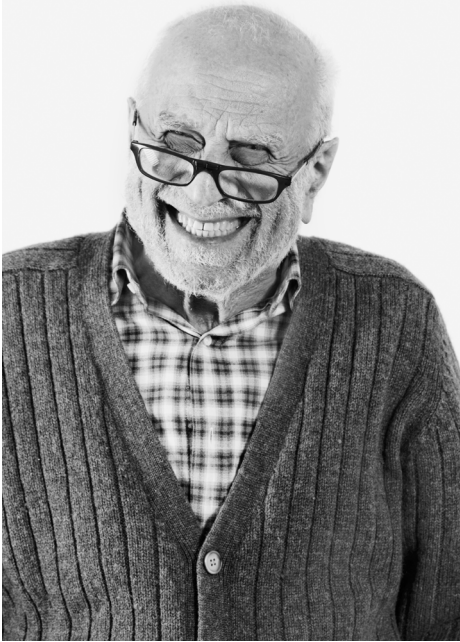
Questions for GPs and commissioners to consider

At the CCG population level there will be large numbers of people that will increasingly fall into this cohort of patients where a specialist evaluation of the most appropriate treatment for them (no surgery vs TAVI) will be required in the coming months and years ahead. Therefore, the following questions are very important for immediate consideration.

In the local population, who has overall responsibility for each of the following:

- Ensuring the public have greater understanding of the symptoms relating to heart valve disease?
- Educating, training and auditing primary care clinicians to be more aware of AS and to undertake early stethoscope examinations?
- Ensuring timely referral, communication and action throughout the pathway, including patient engagement, education and decision support?
- Identifying and targeting individuals who require specialist multidisciplinary team reviews and evaluation?
- Ensuring sufficient echocardiogram availability (including open access GP echo availability)?
- Ensuring sufficient aftercare support in primary and community settings given earlier discharge from hospital?
- Identifying and reporting on measurable positive and negative procedure associated outcomes?
- Quality assurance and value for money in aortic stenosis care?
- Understanding if your health economy already has valuable local data around patient experience and outcomes for aortic stenosis care in your area?
- Understanding how this local data could be used to identify and drive improvements?
- Evaluating any existing engagement activity that has already taken place with patients with regards to aortic stenosis?

Knowing the answer to each question above is vital in understanding who manages which components of the whole system. Most importantly, it is impossible to effect optimal improvement if key people in the system are not aware of the answers.



What could have happened differently? Malcolm's optimal pathway

Malcolm is an 80-year-old widower and father of two who retired from work as a supervisor at Wedgwood 15 years ago.

Malcolm was enjoying a reasonably active retirement despite having been diagnosed with chronic obstructive pulmonary disease (COPD) 20 years previously. His COPD was only mild²⁸ and he had been really sensible trying to control any risks that might provoke an exacerbation.

He had managed to gradually stop smoking over a six-month period after diagnosis, and had not had a cigarette since. After the devastating blow of losing his wife, Pat, six years ago his COPD flared up again but stabilised shortly afterwards.

In June 2017 Malcolm noticed that he was getting more breathless walking up the steep hill to the park on the daily route with Mr Pickles, his friend's dog. For a while he had been compensating by taking a different route to avoid the steep incline. On this occasion he felt as if he couldn't go on walking, but he thought the pollen in the air might be affecting his COPD more than usual. However, by August 2017 things had got worse rather than better, so he made an appointment with the GP. The GP listened

to Malcolm's heart with his stethoscope, heard a heart murmur and referred him directly to hospital for an echocardiogram. From there he was referred straight to a heart valve clinic.

By October 2017 Malcolm had attended the clinic and was introduced to Kevin, a TAVI nurse co-ordinator who was a linchpin in the management of the interdisciplinary system for AS patients in Stoke. Kevin made sure that Malcolm knew exactly what was going on every step of the way²⁹ – Malcolm really liked him.

Six weeks later in December 2017 Malcolm saw a surgeon and a TAVI specialist on the same day. He was referred immediately for an angiogram, and CT scan (which took several weeks). Following a multidisciplinary team meeting it was decided that Malcolm was a suitable candidate for a TAVI procedure because he had severe AS and was a high surgical risk for open heart surgery.

(Note: TAVI procedures are faster and can also reduce the number of open heart surgeries required, thereby **reducing theatre time** requirements. This results in greater productivity and greater NHS savings^{30a, 30b}. Importantly, TAVI could therefore also help support the reduction in NHS waiting lists for cardiac surgery.)

Malcolm's condition and all the implications and options were fully explained to him. See the video below³¹ for an insight into the information that would be shared in the consultation.

TAVI procedures can be much more productive for a hospital (by reducing theatre time) with 3 or 4 per day (7 per day in other parts of Europe^{30b}) compared to 2 or 3 surgical operations per day.

28. Global Initiative for Chronic Obstructive Lung Disease Inc (2018) Global Strategy for the diagnosis, management and prevention of chronic obstructive lung disease www.goldcopd.org. GOLD grade 1 Diagnosis with spirometry.

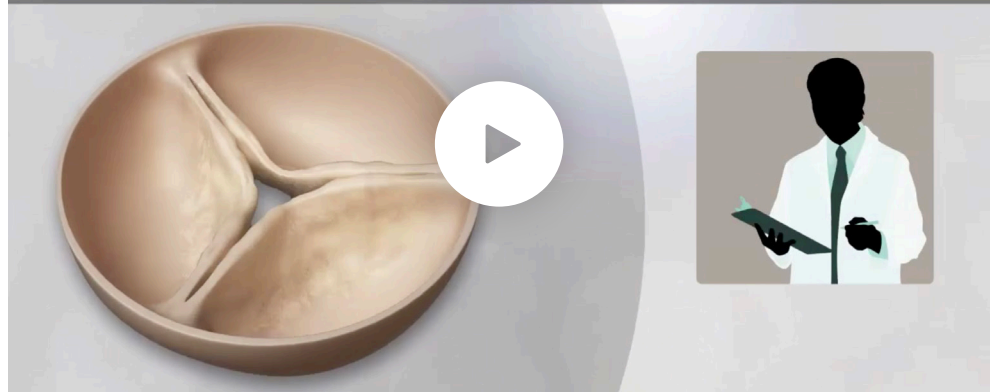
29. Appointments: once for the assessment, again on admission and post operatively, and then six weeks post operatively, and then annually.

30a. The NHS Institute for Innovation and Improvement paper "The productive operating theatre" reports that average theatre costs are £1,200 per hour (£480 per hour for non-staff costs)

30b. PCR London Valves 2017 presentation – TAVI Optimisation – "7 Cases in a day" by Leiden University Medical Centre Netherlands.

31. Source Edwards Lifesciences.

Treatment Options for Aortic Stenosis



Video
Treatment options for aortic stenosis

The procedure

Six weeks later in February 2018, Malcolm had his TAVI procedure – a transfemoral TAVI was performed in the catheter lab under local anaesthetic.

The procedure went well and within hours Malcolm was feeling better. He only required a short period on the ward for observation, to check his mobility and to confirm that he had no infections. The observations were all good and Malcolm was home within 48 hours³² of the procedure – in line with increasing numbers of patients who are discharged within two days after TAVI³³, see Chart 2.

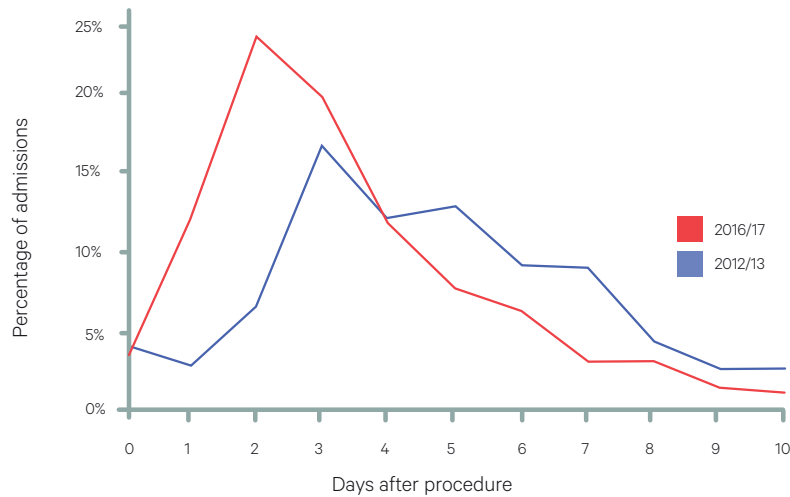


Chart 2
TAVI discharge analysis in England (2012/13 to 2016/17)³⁴

The TAVI procedures are improving – in 2012/13 13.9% of aortic stenosis patients undergoing TAVI were discharged within two days and in 2016/17 that had increased to 38.7%.



Note: It is the belief of the working group that reduced procedure times and speedier discharge times are the result of advances in technology and the upskilling of cardiologists (through training and greater experience).

The recovery

Malcolm was surprised by how quickly he was able to go home and get back to his familiar surroundings. He felt like his recovery was just unbelievable; he felt so well so quickly. Every day he noticed he could breathe a bit more easily until he didn't really notice he was breathless at all.

He had been instructed to continue to take aspirin for life to minimise the risk of blood clotting.

He went for a follow-up appointment, including a repeat echocardiogram, at the TAVI clinic six weeks later and reported that he had no untoward issues. His cardiologist was pleased with his progress, saw no abnormalities with the echocardiogram and said they would see him again in a year's time³⁵.

So now Malcolm only had his quarterly diabetes appointments with the practice nurse and his inhalers to manage his COPD which was easy to cope with.

Malcolm felt like a new man. He no longer suffered from anywhere near the same levels of fatigue and breathlessness he had before, and was back to his usual busy routine of taking care of his friend Eddie, walking the dog, and enjoying watching the football with his son Rob and his friends.

Malcolm was excited about life and even started salsa lessons with a special lady, Gill, whom he met whilst on his usual dog walking route. They did more walking than dancing, and they did not expect to be invited onto Strictly Come Dancing any time soon, but they really enjoyed the social element of these weekly events. For the first time since his wife passed away, Malcolm was enjoying the spark of connection and was enjoying life.

Malcolm visited his cardiologist one year after the TAVI procedure who was delighted with the outcome. The cardiologist could see that the TAVI had provided him with a new lease of life.

With new vigour, Malcolm had lost some weight and made sure that he kept his diabetes and COPD well controlled. He kept to his regular appointments with the practice nurse and generally did as he was told, both from the practice nurse and Gill, his new wife!

Since the TAVI operation Malcolm had been able to support his son Rob through a very difficult time. Not only had he been able to spend a lot of time with Rob, he had also been able to help with the grandchildren which has been a huge source of support for his son. Malcolm helped him to resettle into a new home close by and was frequently there in the afternoons to help the kids with their homework before Rob got home from work. It was a real joy for Malcolm to be there for his son and his grandchildren and to see him get back on his feet.

Malcolm and Gill were able to look after each other and care for Eddie and Mr Pickles for a further five years of the story. Malcolm lived a happy and contented life. The story ends in May 2023 as this is a six-year period from the very start of his symptoms. Patients with TAVI can go on to live many more years, but by analysing an extra three years of life, the case has been made in a balanced and prudent way.

Based on his positive experience with Kevin, the TAVI nurse coordinator, Malcolm felt inspired to go back to the cardiac unit as a volunteer to support patients going through a TAVI procedure. By becoming a Heart Valve Voice Ambassador³⁶ he offered to help with filling out forms, talking to patients, sharing his story, and offering support after their treatment.

Summary

1. This scenario study is consistent with the majority of RightCare studies carried out in this format, i.e. by getting things right first time (via education, prompt diagnosis, great communication, appropriate decision making with the patient etc). More often than not there are significant savings for the NHS and much improved outcomes for the patient, their families and the wider community.

This analysis is also aligned with the NHS Getting It Right First Time (GIRFT; www.gettingitrightfirsttime.co.uk) national programme which is designed to improve the quality of care within the NHS by reducing unwarranted variations.

By tackling variations in the way services are delivered across the NHS, GIRFT identifies changes that will help improve care and patient outcomes, as well as delivering efficiencies and cost savings.

Importantly, like this analysis, GIRFT is led by frontline clinicians who are expert in the areas they are reviewing. This means the data that underpins the GIRFT methodology is being reviewed by people who understand those disciplines and manage those services on a daily basis.

2. When planning for QIPP and CIP improvements, commissioners and decision makers need to consider whole pathways and not just isolated procedures.
3. Where high-risk patients are referred from secondary care back to primary and community care settings there can be a lack of appreciation of the final stages of the pathway. In this case, had the surgeon in the suboptimal case foreseen Malcolm's last two years of suffering and understood the benefits that TAVI (in this case) could have offered, he might well have had a detailed conversation with Malcolm making all the choices much clearer to him. Ongoing knowledge sharing between primary care and secondary care is recommended.
4. It is important that we raise awareness of the need to listen to patients' hearts. GPs and primary care professionals with suitable training are best placed to identify possible abnormalities through stethoscope auscultation for both heart and lung.
5. Greater awareness is required to raise the profile of heart valve disease in primary care.
6. As TAVI procedures become more common place and post-procedure hospital stays shorten, it is important that primary care can meet the needs of patients following discharge. Lack of home care support could stifle acute discharge efficiency improvements.

The ‘bills’ and how the two pathways compare

For the financial evaluation a detailed analysis was performed by mapping the lifecycle of the pathways (six years, from June 2017 until May 2023, with matching timeframes for both). Through this process it is possible to identify the cost drivers that would be incurred in primary, community, emergency and hospital care, using, where appropriate, the NHS National Tariff, NHS reference costs. The wider social and economic impacts have been considered but not the cost beyond the health remit or the social, emotional, physical and financial costs to the patient and family members.

This scenario is using a fictional patient, Malcolm. It is intended to help commissioners and providers understand the implications, both in terms of quality of life and financial costs, of diagnosing and treating high risk patients with aortic stenosis faster and more appropriately.

Note: The financial costs are indicative and calculated on a cost per patient basis on the most up to date and available prices (mainly 2017/18 prices). Local decisions to transform care pathways would need to take a population view of costs and improvement.

Summary financial analysis				
Provider	Suboptimal Pathway £s	Optimal Pathway £s	Optimal Pathway Savings £s	Optimal as a % of Suboptimal
Acute	12,328	30,668	-18,340	248.8%
Ambulance service	1,098	—	1,098	0.0%
Community teams	8,959	—	8,959	0.0%
Primary care	34,325	6,967	27,358	20.3%
Social services	473	—	473	0.0%
Grand total	57,182	37,635	19,548	65.8%

Table 1
Summary financial analysis
(Exclusively Malcolm costs)

Table 1 summarises costs in two pathways showing a net saving of £20k over the almost six-year period of analysis – the suboptimal pathway costs have been reduced by 34%.

Table 2 highlights that if you take into account the costs of the extra care for Eddie and Rob in the suboptimal case, then **the savings increase from £20k to £46k** (which could fund over 1,350 GP appointments³⁷).

Table 2
 Summary financial analysis
 (Malcolm plus Eddie and Rob
 health-related costs over the six-
 year period of analysis)

Summary financial analysis				
	Suboptimal Pathway £s	Optimal Pathway £s	Optimal Pathway Savings £s	Optimal as a % of Suboptimal
Grand total (including Eddie & Rob)	83,599	37,635	45,965	45.0%

The key difference between the suboptimal and optimal pathways is prompt detection of the heart murmur, prompt diagnosis of heart valve disease and then the prompt understanding by the multidisciplinary team that a TAVI would be an appropriate course of action for Malcolm as a high-risk patient. Good communication between the right healthcare professionals results in life-changing outcomes for patients and their families.

In this case, Malcolm has three extra years of life and almost five years of much improved quality of life (that we have modelled here – he could live considerably longer), whilst at the same time generating significant economic savings for the NHS and the tax payer in the process.

This case is a reminder to commissioners that the “whole pathway” has to be taken into consideration when undertaking value-for-money analysis. Procedure costs (and heart valves in this case) are only one component of the bigger picture.



Cost drivers – Malcolm only			
	Suboptimal £s	Optimal £s	Optimal Savings £s
111/999 call	10		10
A&E visit	672		672
Ambulance called out	1,088		1,088
Angiogram direct access	145	145	0
Antibiotics	40		40
Cardiology consultant review	158	1,103	-945
Community nurse	4,434		4,434
CT scan		196	-196
District nurse review	2,139		2,139
Echocardiogram (complex) EY50Z	176	352	-176
Fall episode	1,844		1,844
Heart failure admission	3,055		3,055
Heart failure nurses	275		275
Inhaler prescription	2,192	4,795	-2,603
Meals on wheels	473		473
Medical review – GP practice	544	204	340
Multidisciplinary assessment (MDT)		273	-273
Nursing home (CHC)	28,793		28,793
Oxygen services	1,800		1,800
Practice diabetes nurse	124	204	-79
Prescription for insulin	726	1,540	-814
Prescription issued by GP – steroids	106	224	-118
Social care equipment (specialised bed/handrails etc)	1,000		1,000
Surgical consultant review	199	199	0
Syncope admission	5,804		5,804
TAVI co-ordinator – specialist nurse		141	-141
TAVI procedure		10,060	-10,060
TAVI valve (est)		18,000	-18,000
Valve clinic (heart)		199	-199
Wound care (bandages etc)	1,386		1,386
Grand total	57,182	37,635	19,548

Table 3
A detailed breakdown of activity costs of both scenarios over the six years of analysis.³⁸

38. Nursing home costs have been applied at £837 per week (West Midlands average). The average costs per week in the UK are around £841 <https://www.which.co.uk/elderly-care/financing-care/financing-a-care-home/381597-care-home-fees> This is prudent because Continuing Health Care (CHC) (applied in this case) are more expensive – (Stoke City Council advised that CHC fees range from £750 per week up to £1500 per week).

Investment cashflow

Cashflow is an important consideration for commissioners as fast payback is always critical when managing projects where organisational budgets are fixed on an annual basis.

This analysis (including the health and social care costs for Malcolm, Eddie and Rob) shows that, as expected, the first year optimal pathway is more expensive by £26k because the medical interventions are prompt and there is surgical and device investment within this early stage.

However, the costs in the suboptimal case really start to build from year two onwards as care needs increase especially with nurse visits, multiple hospital admissions and eventually nursing home care. This means that the optimal investments have paid back just after the two-year point – this can be seen visually in Chart 3.

(Figures approximated due to roundings.)

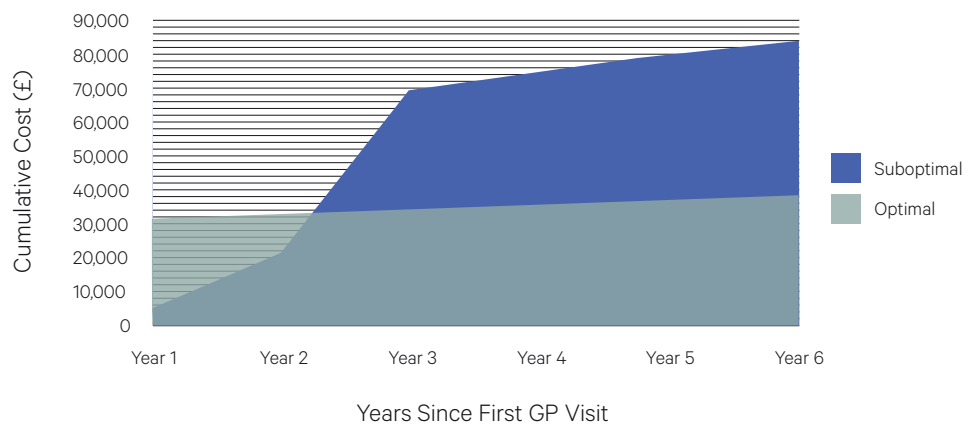


Chart 3

A visual representation of the cumulative cashflow for both scenarios: Suboptimal vs optimal cashflow analysis (Malcolm + Eddie & Rob)

Financial calculation notes

- As noted above, the financial calculation presented here represents an indicative level of efficiency potential of the case only. Firstly, as the case is an example pathway, differential pathways for other patients may increase or reduce the potential benefit. Secondly, the potential releasing of resource associated with implementing the optimal pathway across a larger cohort of patients will be subject to over-arching contractual arrangements in place between providers and commissioners, which may differ across the country. For example, some of the financial benefits identified in the case may not be fully realisable where the elements of the pathway are subject to block contracts or risk/gain shares in place between contracting parties. Equally, the release of resource may only be realised should there be a critical mass from within the targeted patient population. Each healthcare organisation and system will need to assess the potential for realising the financial benefits identified within the case.
- It should also be noted that the financial calculation is considered from a commissioner perspective. The impact on income and costs for provider organisations will also require consideration in the implementation of the optimal pathway.
- Each healthcare organisation and system will need to assess the potential for realising the financial benefits identified within the case.
- This case has been calculated at 2017/18 prices for all years of the analysis, i.e. up until 2023.
- Note the extra costs of the valve (funded by specialist services) have been included within the innovative scenario – so it is fully costed. A sum of £18,000 has been added to the innovative scenario for the valve. This is a prudent sum as it is at the upper end of market costs and can be cheaper than this depending upon the manufacturer, specification of the valve, and the commissioning arrangements (volume discounts etc.) that are in place.
- The NHS cost implications relating to Eddie and Rob have been included within the analysis (Table 2 and Chart 3), taking the total savings up to £48.2k but these savings have not been included within Tables 1, and 3 as these tables focus on the costs for Malcolm exclusively.
- The cost implications of Rob being unfit for work (tax and benefit implications) have not been included within this financial analysis, thus potential savings would be significantly greater had they been included within the optimal case, i.e. a prudent approach has been taken in this regard.

Methodology of HES analysis

NHS Digital, Wilmington 2018 methodology: Patient data was analysed utilising Hospital Episode Statistics (HES). Findings shown are therefore based on real patient outcomes rather than clinical trials.

Aortic stenosis patients were selected based on their diagnosis (ICD-10 codes I35.0 Aortic (valve) stenosis and I355.2 Aortic (valve) stenosis with insufficiency as a primary diagnosis), age (from 66 to 95 years) and treatment. Treatment types were categorised as TAVI, SAVR and other treatment. TAVI treatment was identified by the use of two operative procedure codes (OPCS-4) simultaneously: Xenograft replacement of aortic valve (K26.2) and any of the following approach codes: approach to organ through artery (Y79.1 to Y79.9) or transapical approach to heart (Y49.4). SAVR treatment was also identified by the use of two OPCS-4 codes: plastic repair of aortic valve (K26.1 to K26.9) and cardiopulmonary bypass (Y73.1). A small number of patients underwent both TAVI and SAVR (surgical aortic valve replacement); these patients were excluded from the analysis.

Links to other resources

For more information about AS, its detection, management, guidelines and policy you may want to look at the following resources:

- **Guidance**
 - National Institute for Health and Care Excellence (2017) Transcatheter aortic valve implantation for aortic stenosis. NICE, London: www.nice.org.uk/guidance/ipg586
- **Organisations**
 - Heart Valve Voice www.heartvalvevoice.com
 - Heart Valve Voice www.heartvalvevoice.com/about-us/get-involved
 - British Heart Foundation www.bhf.org.uk
- **Tools and support**
 - New York Heart Association (NYHA) heart failure classification tool <https://manual.jointcommission.org/releases/TJC2016A/DataElem0439.html>
 - Haemodynamic assessment (usually by echocardiography and Doppler): <http://pact.esicm.org/media/HaemMon%20and%20Mgt%208%20April%202013%20final.pdf>
 - Symptom tracker and consultation guide to help people if they might have concerns about heart valve disease capture symptoms ahead of visiting their GP:
 - Heart Valve Voice: Symptoms Tracker https://www.heartvalvevoice.com/application/files/9014/5882/2628/Symptoms_tracker.pdf
 - Heart Valve Voice: Consultation Guide https://www.heartvalvevoice.com/application/files/4214/5883/1158/Consultation_Guide_copy_2.pdf
 - Health Service Journal: Guide to heart valve disease <https://www.hsj.co.uk/specialist-care/an-hsj-and-edwards-supplement-heart-valve-disease/7023506.article>

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You can also contact the NHS RightCare team via email at rightcare@nhs.net

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Wilmington Healthcare

Beechwood House
2-3 Commercial Way,
Christy Close, Southfields
Basildon, Essex
SS15 6EF

T +44 (0)1268 495 600

E info@wilmingtonhealthcare.com

W www.wilmingtonhealthcare.com

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