Heart Valve
VOICE

Giving a voice to those with HEART VALVE DISEASE

A Heart Valve Voice White Paper

5th November 2014

Acknowledgements

Heart Valve Voice combines the patient and clinical expertise needed to raise awareness of the impact of heart valve disease on patients and the NHS. Heart Valve Voice's mission is to improve the diagnosis, treatment and management of heart valve disease by raising awareness of its severity and the need for timely detection, to ensure all patients receive appropriate support and the right treatment at the right time.

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Heart Valve Voice faculty, chaired by
Professor Ben Bridgewater, *Consultant Cardiac Surgeon, University Hospital of South Manchester, Manchester, UK*

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Dr Jarir Amarin, *GP Principal, Carlton House Surgery, Enfield and CHD Clinical Lead for Enfield, UK*
Mr Malcolm Dalrymple-Hay, *Consultant Cardiothoracic Surgeon, Derriford Hospital, Plymouth, UK*
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Dr Clinton Lloyd, *Consultant Cardiac Surgeon, Derriford Hospital, Plymouth, UK*
Professor Philip MacCarthy, *Clinical Director of Cardiovascular Services, King's College Hospital, London*
Dr Bernard Prendergast, *Consultant Cardiologist and Clinical Director of Cardiothoracic Services, John Radcliffe Hospital, Oxford, UK*
Dr Dave Smith, *Consultant Cardiologist, Morriston Hospital, Swansea, Wales*
Mr Joseph Zacharias, *Consultant Cardiothoracic Surgeon, Blackpool Victoria Hospital, UK*

About Heart Valve Voice

Heart Valve Voice is a multi-disciplinary group of experts in the field of heart valve disease including patients and representatives from cardiac societies, cardio-thoracic surgery, interventional cardiology, primary care and cardiac patient groups.

More information about the group is available at:
www.heartvalvevoice.co.uk

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HEART VALVE DISEASE: AN OVERLOOKED CARDIOVASCULAR DISEASE

Heart valve disease is a heart condition where the heart valves no longer work properly. When the valves are damaged it can rapidly affect the pumping action of the heart. Heart valve disease is particularly prevalent amongst older people. It affects in excess of one million people in the UK today, and will impact more people in the future, given an ageing population.

Those with the disease can feel tired, breathless and dizzy and many people may put their symptoms down to age, not realising that they have a heart condition. Heart valve disease can progress to heart failure. If severe aortic stenosis, a particular type of heart valve disease, is left untreated, half of those patients will die within two years of developing symptoms.

Heart valve disease is an overlooked disease, despite the priority given to tackling cardiovascular disease in the UK; for example, it is not included in England's 2013 Cardiovascular Disease Outcomes Strategy. Few people in the UK (less than three per cent of people over the age of 60) are concerned about the disease. However, there are treatments which are very effective at treating symptoms and improving life expectancy.

OLDER PEOPLE ARE MISSING OUT ON TREATMENT

This White Paper highlights that older people with heart valve disease are treated unfairly; they may not receive treatment because of their age, or because of where they live, or perhaps even both. This paper includes the evidence that illustrates this inequity across the UK, and the evidence that the UK's older people miss out on treatment compared with many of their European counterparts.

Heart Valve Voice believes that people with heart valve disease deserve better, particularly older people. Heart valve disease must become a priority for the NHS. We cannot lose sight of the one million people in the UK with heart valve disease today, and the thousands more older patients and carers who will be affected in the future, as the UK population ages.

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INNOVATION MEANS THAT MOST PATIENTS WITH HEART VALVE DISEASE, REGARDLESS OF THEIR AGE, CAN BE TREATED

Doctors can take the simple step of listening to a patient's heart to explore whether a patient may have heart valve disease. Once diagnosed, repairing or replacing the damaged heart valve effectively 'cures' the underlying disease. The alternative, of managing patients using medicines alone (known as medical management), can temporarily alleviate some symptoms but does nothing to reverse or slow progression of the disease.

Treatment for heart valve disease has an impressive history of innovation; building on the breakthrough of the heart and lung machine in the 1950s. Different types of heart valves were first developed in the 1960s and this constant progress has continued up to the present day, including the 2002 breakthrough of the less invasive procedure, transcatheter aortic valve implantation (TAVI). Together these innovations mean that most patients with heart valve disease can now be treated if they are diagnosed and referred early enough.

Evidence continues to build on the benefits from heart valve repair and replacement. Mortality from conventional surgical aortic valve replacement (AVR or SAVR) has been falling over time. Treatment of valve disease by surgery may even restore the patient to typical life expectancy. Trials, such as PARTNER, show TAVI is significantly better than medical management in reducing mortality. The evidence goes beyond survival too, showing improvements for patients in terms of symptoms and quality of life.

Treatments are considered good value for money for the NHS too. Heart Valve Voice believes that aortic valve surgery is a cost effective treatment. TAVI is considered cost effective in the UK for patients who are not suitable for surgery.

Successful treatment changes lives. Ivy who is 90, a heart valve disease patient and a member of Heart Valve Voice says that,

> *I'm pleased I did have [the TAVI] done. I probably wouldn't be here! I haven't an ache in my body. I can walk up hills and I don't get out of breath…I feel absolutely good!*

Heart Valve Voice believes that treatment, whether valve repair, replacement or TAVI, can offer a new lease of life.

Executive Summary

MAKING THE NHS AN AGELESS SERVICE FOR PATIENTS WITH HEART VALVE DISEASE: A CASE FOR CHANGE

Heart Valve Voice knows that there are barriers to treatment in the UK. The barriers occur across all services in the NHS, from primary care to specialist care, but overcoming them will help the UK achieve healthy ageing, a goal that will help the UK to positively respond to the ageing population.

CHANGE IS NEEDED BECAUSE:

- Fifty-nine percent of those aged 60 years surveyed in the UK say that their doctor rarely or never checks their heart with a stethoscope. That places the UK in ninth place out of ten European countries.

- There is a **persistent treatment gap**; evidence suggests at least 30% of those with severe forms of heart valve disease are left untreated. Retrospective review of cases in Southampton supports the findings from the general research, confirming that not all patients who could have clinically benefited from aortic valve replacement were receiving this treatment between 2008 and 2010. More recent data shows that despite 29,000 admissions to hospital for aortic stenosis in England, fewer than 7,000 procedures were carried out in 2012.

- **Not all patients receive optimal treatment, with late diagnosis, low levels of referral** to specialists as part of multidisciplinary teams (MDTs), and **late treatment**. Data from Plymouth and Exeter illustrate low levels of referral; 54% of patients were not referred to the cardiac surgeon between July 2012 and July 2013, despite having heart valve disease confirmed by echocardiography. Those not referred were older (average age of 86 years) than those referred to a surgeon (average age of 76 years). Less than 20% of new admissions for aortic stenosis received an aortic valve replacement within six months of admission between 2002 and 2012. In fact, the proportion receiving a valve within six months was at its lowest since records began in 2012, at just 13%. Increasing surgery rates will not only offer improvements for patients, but also support surgeons to become even more expert and deliver better quality of care. Late treatment means patients progress to have heart failure.

- The **UK persistently lags behind other European countries**. The UK has lower conventional aortic valve surgery and TAVI rates than our European counterparts, and only had higher TAVI intervention rates than Ireland and Portugal in 2011.

- **There are persistent inequities in access to treatment across the UK; where a patient lives within the UK affects their treatment**. The most up-to-date data available in 2013 show that some Clinical Commissioning Groups (CCGs) undertook no TAVIs at all; Heart Valve Voice would expect to have seen at least some patients treated with TAVI in each CCG.

The knock-on effects of under-diagnosis, low referrals and under-treatment are missed opportunities to improve quality of life and lengthen life for many older people. Older people deserve the new lease of life that heart valve repair and replacement provides.

Heart Valve Voice calls for greater priority to be placed on heart valve disease accompanied by increased investment in providing curative valve repair and replacement for the UK's population suffering from heart valve disease. We want:

1. **Heart valve disease to be included in current strategies for cardiovascular disease**
2. **An awareness campaign for healthcare professionals and potential patients on the symptoms of heart valve disease and the importance of early diagnosis and treatment**
3. **15-minute GP consultations for the over-75s**
4. **Appropriate referral and follow-up between primary, secondary and tertiary care with a key role played by a multidisciplinary team (MDT) to inform treatment decisions in partnership with patients**
5. **The same level of surgical and transcatheter valve replacement as other leading European countries**
6. **The same access to heart valve replacement treatment wherever a patient lives within the UK**

Introduction

Heart Valve Voice is a young organisation, having started its work in 2013. Heart Valve Voice brings together patients, cardiologists, cardiac surgeons, GPs, and a cardiac patient society who know best the impact of heart valve disease on the patient and on the NHS, from primary care to specialist care.

Heart Valve Voice's mission is to **improve the diagnosis, treatment** and **management of heart valve disease** by **raising awareness** of its **severity** and the **need for timely detection** to ensure all patients receive **appropriate support** and the **right treatment** at the **right time**.

Cardiovascular disease has been a priority for the UK over many years, and there have been real improvements in the prevention and treatment of cardiovascular disease over the last decade (Department of Health's 2013 publication). Heart valve disease is a form of cardiovascular disease, particularly affecting older people. Nevertheless, it is not included in key policies such as the Department of Health's 2013 Cardiovascular Disease Outcomes Strategy. The European Heart Health Survey,[1] commissioned by Heart Valve Voice, found few people in the UK (less than three per cent of people over the age of 60 years) are concerned by heart valve disease. Nearly half don't know what aortic stenosis is. Less than five per cent correctly identify aortic stenosis as having the lowest chance of long-term survival from diseases such as cancer and Alzheimer's disease. At the same time, nearly a third (30%) of those aged over 60 years are extremely worried that poor heart valve health would infringe on their independence to undertake daily chores such as getting dressed, washing up and cooking. This White Paper is just one way to raise awareness of heart valve disease.

This White Paper is by no means a systematic review of the evidence base, it presents the facts and figures that Heart Valve Voice believes that politicians, policy makers and the wider NHS need to know in order to take informed decisions about investing in services to tackle heart valve disease. It also presents evidence of inequities in patients' access to treatment, from where they live, to how old they are. This is in line with the wider evidence base that demonstrates that older people attending hospital with heart disease are less likely to be fully investigated and less likely to receive treatment than younger people (Centre for Policy on Ageing 2009).

Heart Valve Voice recognises that the NHS is under financial pressure and understands that difficult choices need to be made about priorities, and which services to invest in. However, Heart Valve Voice believes that we must not lose sight of 1 million people in the UK with heart valve disease today, and the thousands more older patients and carers that will be affected in the future as the UK population ages. Heart Valve Voice believes that earlier treatment of heart valve disease will also avoid costly care for patients who go on to have terminal heart failure.

We make six recommendations throughout the paper and summarised again at the end, which if acted on, would demonstrate a commitment to truly making the NHS an ageless service for heart valve disease patients, in line with the NHS Constitution in England (NHS 2013),[2] and the ban on age discrimination[3] enshrined in the Equality Act 2010 and implemented across the NHS in 2012 (Department of Health 2012).

1. The survey was conducted from October to December 2013 with 9,579 respondents aged over 60 years from ten countries.
2. The NHS Constitution includes a right for patients that they will not be unlawfully discriminated against in the provision of NHS services including on grounds of age as well as other protected characteristics. See NHS 2013.
3. Age discrimination is defined as unfairly treating people differently because of their age. The ban is only intended to prevent harmful uses of age. The Act does not prevent differential treatment where this is objectively justified. See Department of Health (2012).

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Introducing heart valve disease

SUMMARY

- Heart valve disease is a progressive and serious heart condition where the heart valves no longer work properly. Heart valve disease is likely to make a person **feel tired, dizzy, breathless and suffer chest pain**. People with heart valve disease are **less able to do the things that they would normally do**. Many people may simply **put their symptoms down to 'getting old'**

- Diseases of the heart valves can affect the pumping ability of the heart muscle. If not acted upon early enough, the **damage to the heart can be irreversible**, even after the faulty valve is treated

- Heart valve disease has a very poor prognosis. **If left untreated, 50% of people with symptomatic aortic stenosis**, a particular type of heart valve disease, **die within two years**. However, valve replacement offers an effectively curative option to those with the disease

- Heart valve disease **affects one million people in the UK** and is closely linked to age

- The UK population is ageing – doubling the number of over 65s to 19 million by 2050 – that means **heart valve disease is going to increase in the UK**

- Health services across the UK **need to plan** for this **increase in the number of older patients with heart valve disease**

WHAT IS HEART VALVE DISEASE?

Heart valve disease is a condition caused by either wear or disease of the heart valve(s), affecting the flow of blood through the heart. When diseased or defective, heart valves may not open or close properly and can interfere with the flow of blood. The most common valve problems involve the mitral and aortic valves, which are located on the left side of the heart (Patient.co.uk).

The primary types of heart valve disease are (Patient.co.uk):

- **Valve stenosis:** As a result of certain medical conditions or anatomical abnormalities, a valve can be exceptionally narrow (therefore having a 'stenosis') which can limit the blood flow through the valve. This may result in a 'back-up' of blood behind the valve as if behind a dam, causing the heart to pump inefficiently

- **Valve regurgitation:** When a valve's leaflets fail to close completely, the valve itself can become 'leaky', allowing blood to backwash down through the valve (called 'regurgitation'). As a result the heart may not be able to effectively move the volume of blood to the next appropriate chamber

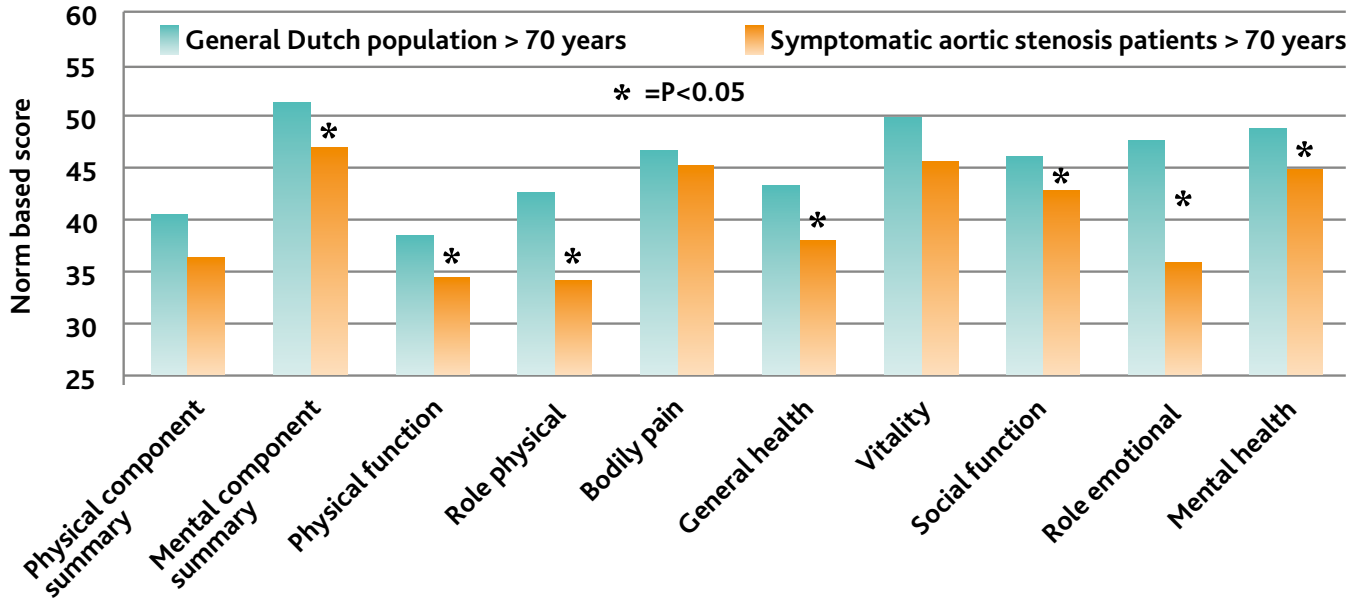
Heart valve disease can affect the muscles in the heart and their ability to pump, and the patient will then have heart failure. Heart valve disease can progress to cause irreversible damage to the heart, even after a faulty valve is treated. If a patient has very advanced heart failure, this may then require a heart transplant.

WHAT DOES IT FEEL LIKE TO HAVE HEART VALVE DISEASE?

The symptoms of heart valve disease include fatigue and shortness of breath, light-headedness, fainting, difficulty exercising, and for some a cough (Lindroos *et al* 1993, Mayo Clinic).

Research from the Netherlands, illustrated in Figure 1, has shown that people with symptomatic severe aortic stenosis experience poorer quality of life than those in the general population (van Geldorp *et al* 2013a).

Figure 1: Quality of life of symptomatic patients with severe aortic stenosis aged >70 years versus the Dutch population aged >70 years



Source: van Geldrop *et al* (2013a). Note: a higher norm based score = better quality of life.

Dario is 72 years old and his heart valve disease was diagnosed in 1993. He is currently Director of Coaching at the Academy at Crewe Alexandra football club.

> ***I have to go up all the stairs [for my work] and I became increasingly aware of the fact that by the time I got to the top, I needed to have a rest. I was out of breath. I was so breathless I had to sit down.***

Tony is 75 years old and his heart valve disease was diagnosed in 2002. At the time he didn't know he had a problem until he felt dizzy and collapsed during a circuits class at the gym.

> ***I realised later how sluggish I felt before my heart valve disease was treated.***

Ivy is 90 years old and her heart valve disease was diagnosed in 2010.

> ***I was getting out of breath if I walked up a hill. You think to yourself, well, 80-odd, bound to get these things. You put it down to your age don't you. Then I was getting an ache in my chest.***
>
> **Ivy also experienced falls that resulted in her breaking both her ankles.**

Fred is 87 years old and his heart valve disease was diagnosed in 2009.

> ***Before the diagnosis, there was a lot of work to do on the garden, a lot of work on the hillside and we really enjoyed our retirement. I thought nothing at all of going 12 to 15 trips up the hill. Then I got to the stage that I had to stop four times just to go up the hill once. I was just getting absolutely breathless.***

Not everyone will notice the symptoms of heart valve disease; hence heart valve disease can be 'asymptomatic'. Symptoms can develop gradually and people may be less able to exercise rather than automatically being aware of the symptoms of heart valve disease (Edwards 2011a).

Introducing heart valve disease

HOW MANY PEOPLE HAVE HEART VALVE DISEASE IN THE UK NOW? AND HOW MANY WILL HAVE HEART VALVE DISEASE IN THE FUTURE?

Approximately one million people over the age of 65 years across the UK are affected by heart valve disease (Malhotra 2012). Heart Valve Voice's analysis of UK Hospital Episode Statistics (HES)[4] found that 200,000 people were admitted to hospitals in England with a diagnosis of aortic stenosis between 2002 and 2012.

The prevalence of heart valve disease increases with age; in western countries, between two per cent to seven per cent of those aged over 65 years have aortic stenosis (Spaccarotella *et al* 2011) and US population-based research found that 13.3% in the over-75 age group have some form of heart valve disease (Nkomo *et al* 2006). US research also suggests that there could be undiagnosed heart valve disease in the US population (Nkomo *et al* 2006), a finding that Heart Valve Voice believes is true for the UK too.

The OxVALVE study, a four-year study based in Oxfordshire, is working to identify people with valvular disease and establish incidence in the population (OxValve.nhs.uk). Results from OxVALVE are expected soon and are anticipated to show that a large group of elderly patients were identified who had previously not been diagnosed with heart valve disease. Many of these people required further assessment and treatment for their previously undiagnosed heart valve disease.

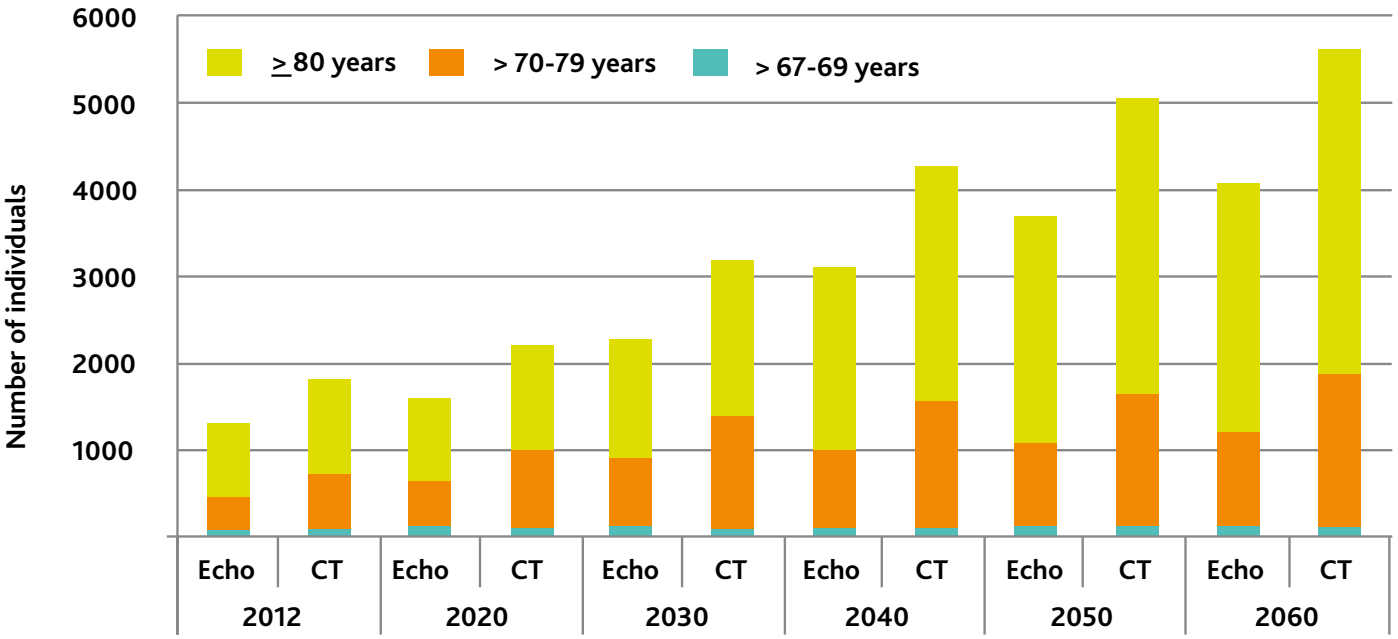
The UK population is ageing and projections suggest that there will be a doubling of the number of people aged over 65 years to around 19 million by 2050 (House of Commons Library Research 2007). The number of cases of heart valve disease increases with age; hence, an ageing population will likely increase the number of people with the disease across the UK (Malhotra 2012).

The ageing population is a result of a variety of factors, but as argued by Oliver (2014) it can be seen as *"a victory for modern medical and public health advances and for improved societal conditions"*. Heart Valve Voice believes that advances in treating diseases like heart valve disease is part of that success story.

We are not aware of UK-based projections for the future numbers of patients that will be affected by heart valve disease. However, projections available from Iceland (Figure 2) highlight that there is likely to be an increase in aortic stenosis, especially in those aged over 80 years. Heart Valve Voice believes that we will see a similar pattern in the UK, although on a much greater scale reflecting the UK's much larger population. The UK must plan for this and become 'ready for ageing' as called for by the House of Lords Select Committee on Public Service and Demographic Change in 2013 (House of Lords 2013).

4. HES is a data warehouse that contains details for all admissions, outpatient appointments and accident and emergency attendances at NHS hospitals in England (HSCIC; Hospital Episode Statistics).

Figure 2: Projected number of people with severe aortic stenosis in Iceland, 2012 to 2060



Source: Danielsen *et al* (2014)
Note: Projections are based on prevalence inferred by the rates derived from ECHO (echocardiography) and CT (computerised tomography).

Recommendation 1: Heart valve disease to be included in current strategies for cardiovascular disease

This will ensure that there is a focus on heart valve disease, and plans are made to ensure that the NHS in England, Scotland, Wales and Northern Ireland can meet the needs of the increased number of older patients with heart valve disease as the UK population ages.

Most patients with heart valve disease can be treated

SUMMARY

- Diagnosis starts with a **simple step – listening to the heart with a stethoscope**
- Heart valve disease is **a treatable condition if diagnosed in a timely way – if aortic stenosis is left untreated, half of symptomatic patients will die within two years**
- **Innovation** in treatment options means **most patients can now be treated – valve repair and replacement can be thought of as 'curative'**, medical management (using medicines to treat the symptoms) does nothing to reverse or slow the progression of heart valve disease
- **Innovative treatments** open up therapy to patients who previously had no option, potentially reduce time spent in hospital and ensure that the NHS leads the way in providing the best possible care for patients

A SIMPLE STEP TOWARDS DIAGNOSIS

Heart valve disease is a treatable condition, but first it needs to be diagnosed in a timely way. Heart Valve Voice believes that using a stethoscope to listen to the heart is one of the simplest steps that GPs can take towards diagnosis. The doctor can listen for a characteristic heart murmur that is usually the first indication of a problem with the heart valves.

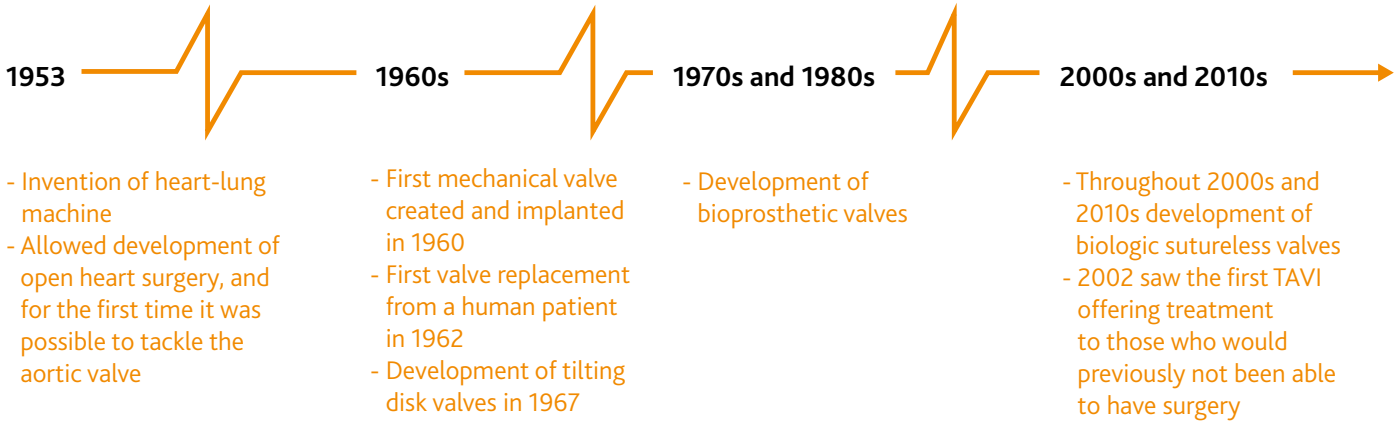
Further diagnostic tests can then be undertaken, ranging from electrocardiography (recording the heart's electrical activity) through to echocardiography (ultrasound of the heart).[5]

IMPROVING AND LENGTHENING LIVES WITH APPROPRIATE TREATMENT

Treatment for heart valve disease varies according to the severity of the disease and can range from monitoring, through to taking medicines to different types of surgery (Patient.co.uk). Once severe disease is diagnosed, repairing or replacing the damaged heart valve is the only way to effectively treat the condition and Heart Valve Voice believes that these interventions can be thought of as 'curative'. The alternative, of managing patients using medicines alone, may help manage symptoms but does not reverse or slow progression of the disease. The consequences of not treating are serious: if severe aortic stenosis – a form of heart valve disease – is left untreated, 50% of patients will die within two years (Spaccarotella *et al* 2011).

Today's options to treat heart valve disease have been the result of innovations made over many years; the heart and lung machine provided the first opportunity to tackle the aortic and mitral valve and new valves have been developed over the years (Figure 3). Advances in techniques mean that conventional surgery is safer (SCTS Blue Book Online) and newer, less invasive machines (minimal extra corporeal circulation, or MECC) are available for heart valve surgery with beneficial effects for patients (Rajakaruna *et al* 2012).

Figure 3: Innovation in heart valve disease surgery



Source: Heart Valve Voice drawing on Braunwald (2000), British Heart Foundation (2013), Carrell, Englberfger and Stalder (2013) and *Cardiovascular News* (2012).

5. For more details on heart valve disorder diagnosis see the Heart Valve Voice Fact Sheet available at: www.heartvalvevoice.co.uk

Most patients with heart valve disease can be treated

Today's procedures include:

- **Valve repair** – where the valve can be repaired during surgery and the patient's tissue maintained. This is sometimes possible with the aortic and very often possible with the mitral valve

- **Valve replacement**, i.e. either aortic valve repair (AVR) or mitral valve repair (MVR) – where the aortic or mitral valve is replaced during surgery. Minimally invasive techniques can be beneficial for patients

- **Transcatheter aortic valve replacement (TAVI)** – a less invasive option compared with surgical replacement. TAVI, at present, is for those patients who are considered too high-risk for surgical valve replacement

If a patient's heart valve disease progresses to advanced heart failure they may then need a heart transplant. If a patient is not suitable for transplant then they are untreatable.

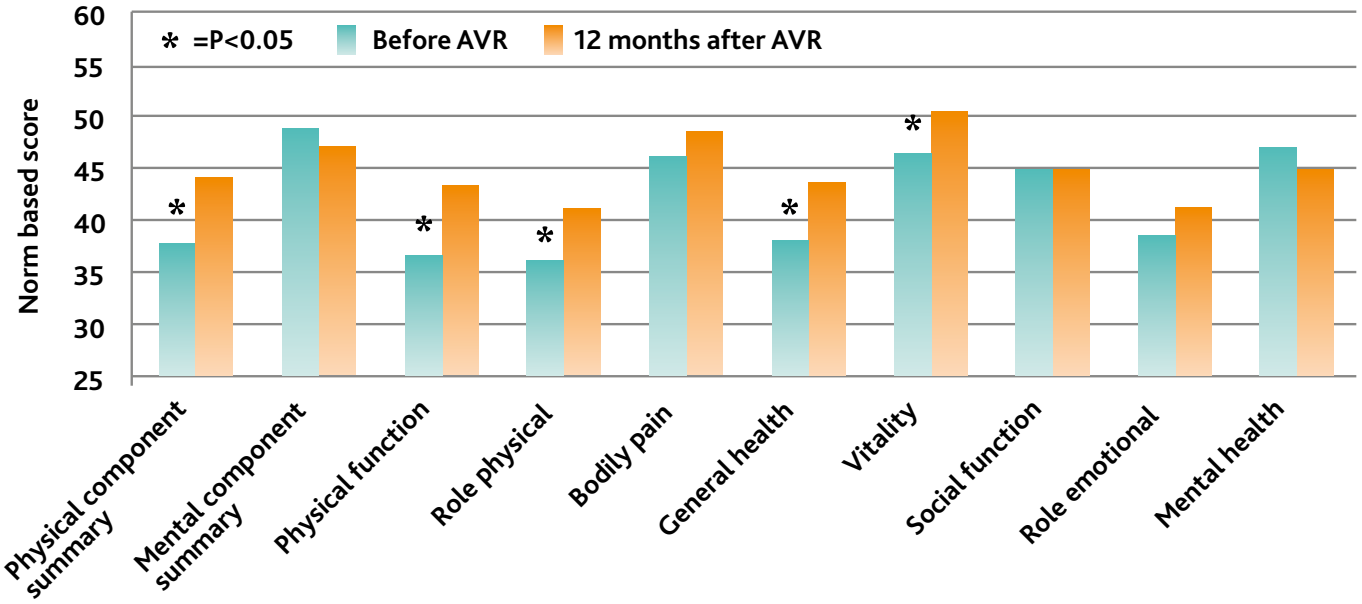
We know that successful surgery can make a real difference to patients' lives. For example, mortality rates have fallen from 2.3% in 2003 to 1.7% in 2012/13 following isolated first-time AVR for patients across the UK. For first-time isolated MVR it has fallen from 5.8% to 4.2% over the same time period (SCTS Blue Book Online).

Minimally invasive surgical AVR has also been reported to be associated with a reduction in transfusion incidence, intensive care stay, hospitalisation, and renal failure, and has a mortality rate that is comparable to conventional AVR (Phan *et al* 2014).

TAVI has been found to be significantly superior to medical management in terms of mortality after two years in the PARTNER Trial;[6] mortality curves demonstrated rates of 43.3% and 67.6%, respectively. Three-year data presented in October 2012 have demonstrated a sustained and increasing survival benefit from TAVI too (Kapadia *et al* 2012). The most recent mortality rate for TAVI in the England is 1.99% (NHS England HES database 2013).

Quality of life is also a key consideration for treatment, with evidence showing that after one year, those given a valve replacement report improvements in quality of life (Figure 4). Statistically significant improvements were seen in terms of physical function, general health and vitality. That compares with those receiving medical management who reported worsening of quality life across the general health domain (van Geldrop *et al* 2013b).

Figure 4: Quality of life of symptomatic patients with severe aortic stenosis before and 12 months after AVR



Source: van Geldrop *et al* (2013b). Note: a higher norm based score = better quality of life.

6. The PARTNER Trial (Placement of AoRtic TraNscathetER Valves) funded by Edwards was the world's first prospective, randomised, and controlled trial for TAVI. The Trial included two cohorts: In Cohort A the safety and effectiveness of the balloon-expandable Edwards SAPIEN Transcatheter Heart Valve (THV) was compared with AVR in high-risk patients with severe symptomatic aortic stenosis. In Cohort B, the safety and effectiveness of the balloon-expandable Edwards SAPIEN THV was compared with standard therapy (best medical management) in inoperable patients with severe symptomatic aortic stenosis. Edwards (2011b).

Most patients with heart valve disease can be treated

TAVI patients have experienced marked improvements in health status and quality of life after one year compared with those having standard therapy (Reynolds *et al* 2011). After two years, 83.1% of TAVI patients were asymptomatic or had mild symptoms versus 42.5% of those having standard therapy ($p<0.0001$) and TAVI also improved functional status of patients (Makkar *et al* 2012). The health and quality-of-life benefits from TAVI have been described as "comparable to a ten-year reduction in age" (Cohen 2010).

European guidelines highlight that deciding on the appropriate treatment relies on an individual risk-benefit analysis led by a multidisciplinary heart team. Risk-benefit analysis should consider the improvement of the patient's prognosis versus the natural history of heart valve disease (Vahanian *et al* 2012). Clinical judgement is considered vitally important in decisions about appropriate interventions (Al-Lamee *et al* 2011), including TAVI (Généreux *et al* 2012).

There is also a range of English guidance available from the National Institute for Health and Care Excellence (NICE) to aid decision making in using innovative treatments for heart valve disease. NICE guidance recommends use in the context of research, for percutaneous mitral valve annuloplasty (NICE 2010) and percutaneous mitral valve leaflet repair for mitral regurgitation (NICE 2009). NICE recommends that some options are used in specialist units only including percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction (NICE 2013) or by surgeons who have special expertise and specific training, as is the case for thoracoscopically assisted mitral valve surgery (NICE 2007). NICE recommends use of balloon valvuloplasty for aortic valve stenosis under normal arrangements for consent, audit and clinical governance (NICE 2004). NICE has also looked at the use of TAVI and suggests that TAVI is used for patients with aortic stenosis who are unsuitable for SAVR. NICE recommends that TAVI be used with special arrangements for patients where SAVR may be suitable but poses a high risk (NICE 2012). In September 2014, NICE issued full guidance on transcatheter valve-in-valve implantation for aortic bioprosthetic valve dysfunction (NICE 2014).

European guidelines also stress treatment decisions should be reached through the process of shared decision-making with patients (Vahanian *et al* 2012).

Much research is still ongoing to help inform treatment decisions. The OxVALVE study is not only looking at incidence as we described earlier, but is hoping to develop improved treatment strategies for valvular heart disease (OxValve.nhs.uk).

CHANGING PRACTICE, CHANGING THE IMPACT ON THE NHS

Changing treatment options not only have implications for patients, but also the approach and resources used in the health care system. Heart Valve Voice believes that missing heart valve disease leads to costly care.

New treatment options such as TAVI tend to come at an additional financial cost. Research has explored cost effectiveness of TAVI and found it to be cost effective in treating patients with severe aortic stenosis who are ineligible for SAVR (Watt *et al* 2012, Orlando *et al* 2013). TAVI has been projected to be more effective and less costly than SAVR over ten years (Fairbairn *et al* 2013). Research has also found that TAVI can reduce use of the healthcare system; for example, use of the TAVI option in a London hospital suggested that patients subsequently required fewer consultations with their GPs than those having a SAVR (Awad *et al* 2014). Research from South Wales has found lower costs overall in those having TAVI versus those being medically managed between 2006 and 2011 (Dave Smith, personal communication 25 September 2014).

Most patients with heart valve disease can be treated

WHAT SUCCESSFUL TREATMENT MEANS FOR REAL PEOPLE

Patients who have had valve replacement and TAVI have explained what it has meant for them below:

Dario is 72 years old and his heart valve disease was diagnosed in 1993. Dario has had two open-heart aortic tissue valve replacement operations. He had his first tissue aortic valve replacement when he was 62 years old. Dario was back to work within six weeks following his first operation.

Dario says that; *"the second operation was straight forward… it hasn't been too difficult".*

He says that following his second operation, *"I'm quite capable of doing everything I did. I'm back on the treadmill….. I'm active. That's the most important thing for me, is to be able to be active".* **He goes on to say that, *"I have a good quality of life now. I'm in the gym quite often, I can play tennis. I'm fine."*** **Thinking about his future he says, *"I don't think it'll be the heart that will get me!"***

Fred had a TAVI in 2009.

In his own words, Fred says *"without the TAVI I couldn't have got back to the level of life that I'd really enjoyed. I'm raring to go. Within a month of having the TAVI, I was doing three hours a day outside [in the garden] with absolutely no trouble at all".*

He says that he's *"back to almost 100% now".*

Tony is 75 years old and first became aware of his heart valve disease during a circuit class at the gym in 2002. He was rushed to hospital and after a week of testing was diagnosed with heart valve disease. A few weeks after the incident, he underwent open-heart surgery to insert his aortic valve replacement.

Tony says that; *"After my operation I felt 20 years younger. Nobody wants an operation but I don't regret it, I don't know where I'd be now if I hadn't had it. I feel much better".*

Following the procedure, Tony was training at the gym again pretty quickly.

Ivy had a TAVI in 2010.

In her own words Ivy says *"I made my own mind up [about having a TAVI]. I'm pleased I did have it done. I probably wouldn't be here!"*

She goes on to say that following the TAVI *"I haven't an ache in my body. I can walk up hills, and I don't get out of breath … I feel absolutely good".*

Her friends point out what a difference it has made, saying *"Ivy seems 20 years younger".*

Making the NHS an ageless service for patients with heart valve disease: A case for change

SUMMARY

- There are **barriers to treatment** to overcome across the NHS in order to improve the lives of those with heart valve disease in the UK
- **Inadequate use of the stethoscope leading to under-diagnosis and late diagnosis** in primary care can limit treatment options – and **limits the scope to improve patients' lives**
- **There is a persistent gap in treatment** – generally 30% of those with severe symptomatic aortic stenosis are left untreated – with evidence of a specific **UK treatment gap**. Despite 29,000 admissions for aortic stenosis in England in 2012, fewer than 7,000 procedures were carried out
- **Not all patients are getting the optimal treatment**, with **late diagnosis, low levels of referral** to specialists including multidisciplinary teams (MDTs), and **late treatment**. Less than 20% of new admissions for aortic stenosis received an aortic valve replacement within six months of admission between 2002 and 2012. Increasing treatment rates will benefit **patients and support quality improvements in the NHS** as physicians will become even more expert. Late treatment means patients progress to have heart failure
- The **UK persistently lags behind other European countries**. For example by 2013, the UK TAVI intervention rate was less than half the EU average. The UK has lower conventional aortic valve surgery and TAVI rates than our European counterparts and only had higher TAVI intervention rates than Ireland and Portugal in 2011
- **There are persistent inequities in access to treatment across the country: where a patient lives in the UK affects treatment**, for example the most up-to-date data available in 2013 even suggests that some Clinical Commissioning Groups (CCGs) had no TAVIs at all; Heart Valve Voice would expect to have seen at least some patients treated with TAVI in each CCG
- Improving heart valve disease treatment will **help the UK achieve healthy ageing**
- The knock-on effect of under-diagnosis, late diagnosis and under-treatment are **missed opportunities to improve the quality of life and lengthen life for many older people**

Heart Valve Voice believes there are many opportunities to improve the lives of patients who have heart valve disease. It is by recognising and tackling the problems in the current system across the UK that we can achieve this. We set out the case for change below.

INADEQUATE USE OF THE STETHOSCOPE

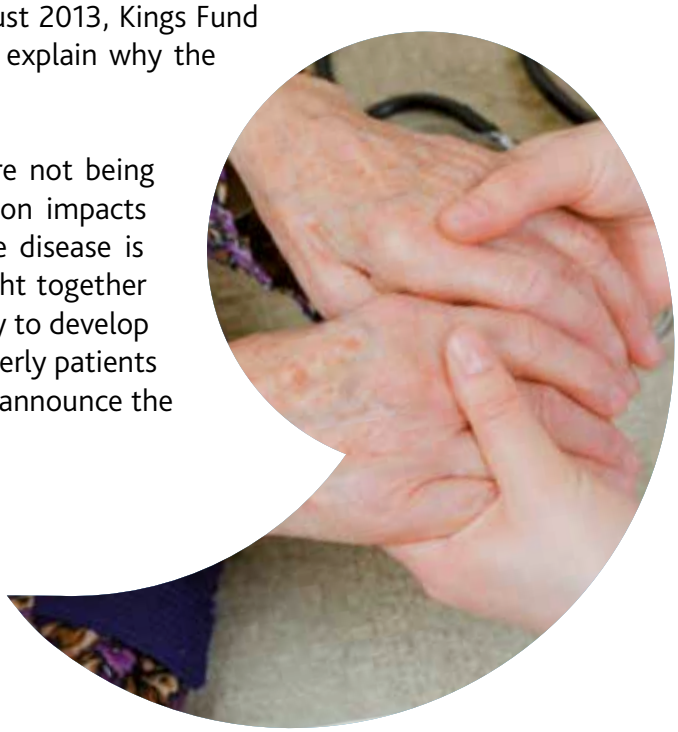
Heart Valve Voice believes that patients can sometimes put their symptoms down to the effects of ageing and we cannot expect people to know about every heart condition. However, Heart Valve Voice believes that once patients experience symptoms and seek help from their GP, their GP should consider whether heart valve disease may be behind the symptoms. Their GP can take the simple step of listening to the heart with a stethoscope.

However, the European Heart Health Survey[7] found that 59% of people in the UK over the age of 60 years said that their doctor rarely or never checks their heart with a stethoscope. On this measure, the UK compares poorly to our European neighbours: ninth out of ten from the countries included in the survey.[8] The UK had the lowest proportion reporting that their doctor checks their heart every visit out of all ten countries; just 10% of respondents said this was their experience in the UK versus over 70% for France.

Dr Jarir Amarin, a GP at Carlton House Surgery, Enfield, London told us that; *"As a GP I feel it would be beneficial to have more time with patients who are over the age of 65 and, as part of those consultations, listen to their heart with a stethoscope. However, those of us working in primary care have many competing priorities and I would welcome government or NHS guidance, and if possible provision of additional resource, to support us in allowing more time for consultations with the older patient."*

Primary care in the UK is under severe strain (Nuffield Trust 2013, Kings Fund 2014) and Heart Valve Voice believes that this helps to explain why the stethoscope is not used as often as we would like.

Heart Valve Voice fears that this means that patients are not being effectively diagnosed in primary care, which has knock-on impacts in terms of appropriate treatment options if heart valve disease is diagnosed later. As a result, Heart Valve Voice has brought together a group of leading GPs with a special interest in cardiology to develop GP guidelines for the effective diagnosis and referral of elderly patients most at risk of having heart valve disease. This group will announce the guidelines in the next few months.



7. The survey was commissioned by Heart Valve Voice and conducted from October to December 2013 with 9,579 respondents aged over 60 years from 10 countries.
8. The survey included respondents from: France, Germany, Italy, Sweden, Belgium, Spain, Switzerland, Austria and the Netherlands.

Recommendation 2: An awareness campaign for healthcare professionals and potential patients on the symptoms of heart valve disease and the importance of early diagnosis and treatment

Greater awareness will help both healthcare professionals and patients to consider whether there is a heart problem that lies behind a patient's symptoms.

Recommendation 3: 15-minute GP consultations for the over 75s

For older patients, where mobility becomes a significant problem, ten minutes is often not sufficient to allow a full examination. Longer consultations will give both patients and GPs the time and space to discuss symptoms and to explore if heart valve disease is causing them.

TREATMENT GAP

The importance of patients receiving timely and appropriate treatment of heart valve disease cannot be overstated. Just as we noted earlier in this White Paper, over half of patients with untreated severe aortic stenosis die within two years (Spaccarotella *et al* 2011).

Research has consistently found that there is a gap in treatment for patients with severe symptomatic aortic stenosis (Bouma *et al* 1999, Lung *et al* 2003, Pellikka *et al* 2005, Charleson *et al* 2006). This research shows that at least 30% of those with severe symptomatic aortic stenosis are left untreated and between 30 and 60% of patients with aortic stenosis do not receive a surgical replacement valve (Lung *et al* 2003, Bouma *et al* 1999, Charleson *et al* 2006 and Bach *et al* 2007).

Retrospective review of patient cases can provide useful insights into practice. Retrospective analysis of patient cases at Southampton General Hospital suggests that not all patients who could have clinically benefited from aortic valve replacement were receiving this treatment between 2008 and 2010 (Badran *et al* 2012). This means the general findings of a gap in treatment are also found here in the UK.

Ben Bridgewater's analysis of HES offers an insight into what is happening in practice across England up to 2012 (NHS England Hospital Episode Statistics (HES) database). Analysis of HES reveals that despite rising admissions for aortic stenosis, with close to 29,000 new admissions in 2012 versus just fewer than 13,000 in 2002, the number of procedures was just below 7,000 in 2012. Heart Valve Voice's view is that this illustrates a significant gap; whilst we would not expect all patients to undergo an aortic valve replacement, we would expect more than the 24% that appear to be receiving it based on HES data. This is in line with research from other countries that finds a significant gap (Bouma *et al* 1999, Lung *et al* 2003, Pelikka *et al* 2005, Charleson *et al* 2006).

Estimates suggest that the UK could have an eligible patient population of over 23,000 for TAVI (Osnabrugge *et al* 2013). Heart Valve Voices believes that the UK needs to plan for this.

Heart Valve Voice believes that reasons for the gap are complex, but funding may be playing a role. For example, Dr Dave Smith, Consultant Cardiologist, who practices in Swansea, Wales, says;

> In Wales, there is no direct funding for TAVI. The costs of the procedure are funded as part of the long-term agreement (LTA) for conventional surgery. Therefore reimbursement costs reflect conventional surgery costs and as a result, TAVI centres in Swansea and Cardiff incur a significant financial loss each time a TAVI procedure is performed.

NOT ALL PATIENTS ARE GETTING OPTIMAL TREATMENT: LATE DIAGNOSIS, LOW REFERRALS AND UNDER-TREATMENT

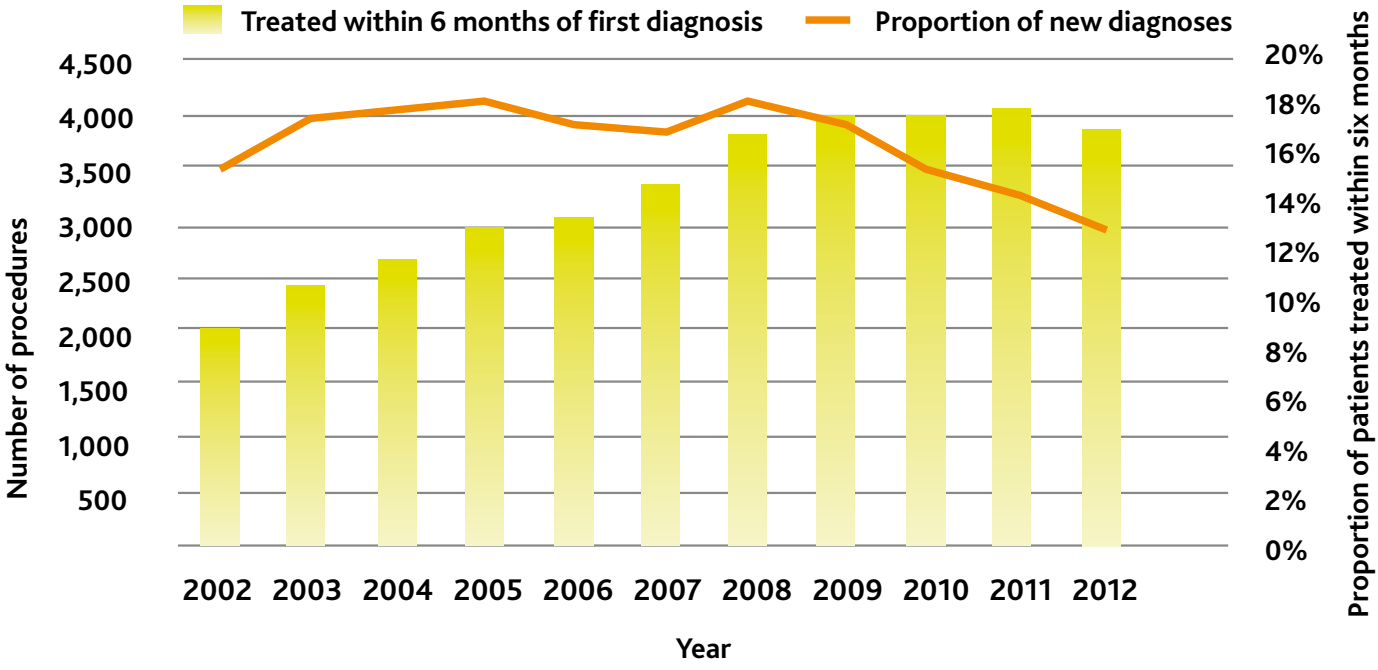
Heart Valve Voice believes that patients in the UK are not diagnosed early enough. This means that heart valve disease has progressed into conditions such as heart failure. Heart valve disease causes heart failure because a narrowed or leaking aortic valve or a leaking mitral valve causes the left ventricular (pumping chamber of the heart) to work too hard. After a period of time, the left ventricle dilates (gets bigger) and starts to weaken and pumps less vigorously, resulting in heart failure. One in four (25%) of isolated AVR surgery patients and at least one in three (36%) of isolated MVR patients show damage to the heart muscle (SCTS Blue Book). When patients deteriorate in this way, any operation on their heart becomes more risky and the benefits to be derived from surgery are less. It is therefore vital to repair or replace heart valves before the onset of heart failure.

Heart Valve Voice also believes that not all patients are receiving optimal treatment. There are some patients who are not referred to the surgical department (van Geldrop 2009). One in four patients have already deteriorated by the time they see a surgeon, which means that their surgical risk is increased and they are not able to get the full benefits of surgery (Bridgewater 2014b). Review of all patients undergoing echocardiography at the Derriford Hospital, Plymouth and the Royal Devon and Exeter Hospital, Exeter found that 10% (38 patients from 377) of those with aortic stenosis were not referred at all to a cardiologist or surgeon, and 44% were referred to the cardiologist but not the surgeon to be considered for replacement therapy (Dalrymple-Hay and Lloyd 2014).[9] Age may play a role, with those not referred being older (average age of 86 years) than those referred to a surgeon (average age of 76 years). Advanced age was the reason given for no referral for 63% of patients, second only to co-morbidities (71%). Heart Valve Voice believes that this may be due to lack of awareness about what is currently possible with conventional and newer technologies. Even when patients had reached a cardiologist, a third (33%) were felt not to have significant disease despite clear echocardiographic findings of severe aortic stenosis and were therefore not referred for a surgical opinion.

9. This data was provide via a personal communication and regards the following unpublished data: Dalrymple-Hay M, Lloyd C. A prospective study to assess patient pathway for patients with severe aortic stenosis in the South West of England. 2014 [Unpublished]

Referral to surgical departments is encouraged to allow MDT discussions to aid in patient selection for surgery, with the potential to improve survival for those with severe symptomatic aortic stenosis (van Geldrop 2009). However, Heart Valve Voice's analysis of HES shows less than 20% of new admissions for aortic stenosis receive an AVR within six months of admission (see the figure below). In 2012 the proportion receiving a valve within six months hit its lowest since records began at 13%.

Figure 5. Patients receiving AVR within six months of admission with AS



Source: Heart Valve Voice analysis of NHS England Hospital Episode Statistics (HES) database 2013 Note: Unique patients with either a primary or secondary diagnosis code for aortic stenosis with or without aortic insufficiency. Admissions are non-outpatient episodes but do not necessarily include an overnight stay in hospital.

Over 40% of patients are New York Heart Association (NYHA) class 3 or 4 [10] at the point of treatment, and are not deriving the optimal benefits from replacement (Bridgewater 2008).

We also believe that increasing surgery rates will not only bring benefits to patients, but also enable UK surgeons to become truly expert in valve interventions, and comparable with the leading centres in Europe and North America.

10. The New York Heart Association (NYHA) classification of heart failure has 4 classes: Class 1: no symptoms on ordinary physical activity. Class 2: slight limitation of physical activity by symptoms. Class 3: less than ordinary activity leads to symptoms. Class 4: inability to carry out any activity without symptoms (Patient.co.uk Heart failure diagnosis and investigation).

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Heart Valve Voice believes that patient information is clearly lacking. Mr Clinton Lloyd, Cardiac Surgeon, practicing in Plymouth says; *"In a recent review in Plymouth and Exeter we assessed patients' understanding of the disease and treatment options; 10 to 70% of patients were not informed of what their condition meant for them, and over 75% were not told of the treatment options of SAVR or TAVI."*

He goes on to say; *"patients with documented severe heart valve disease should be referred to a MDT for a range of options most of which would involve open or minimally invasive surgery but may also involve TAVI."*

Heart Valve Voice believes that referral to a MDT including a surgeon and interventional cardiologist allows full and open discussion of a patient's diagnosis, prognosis and potential treatment options. An informed consensus can therefore be reached between clinician and patient.

Recommendation 4: Appropriate referral and follow-up between primary, secondary and tertiary care with a key role played by a multidisciplinary team (MDT) to inform treatment decisions in partnership with patients

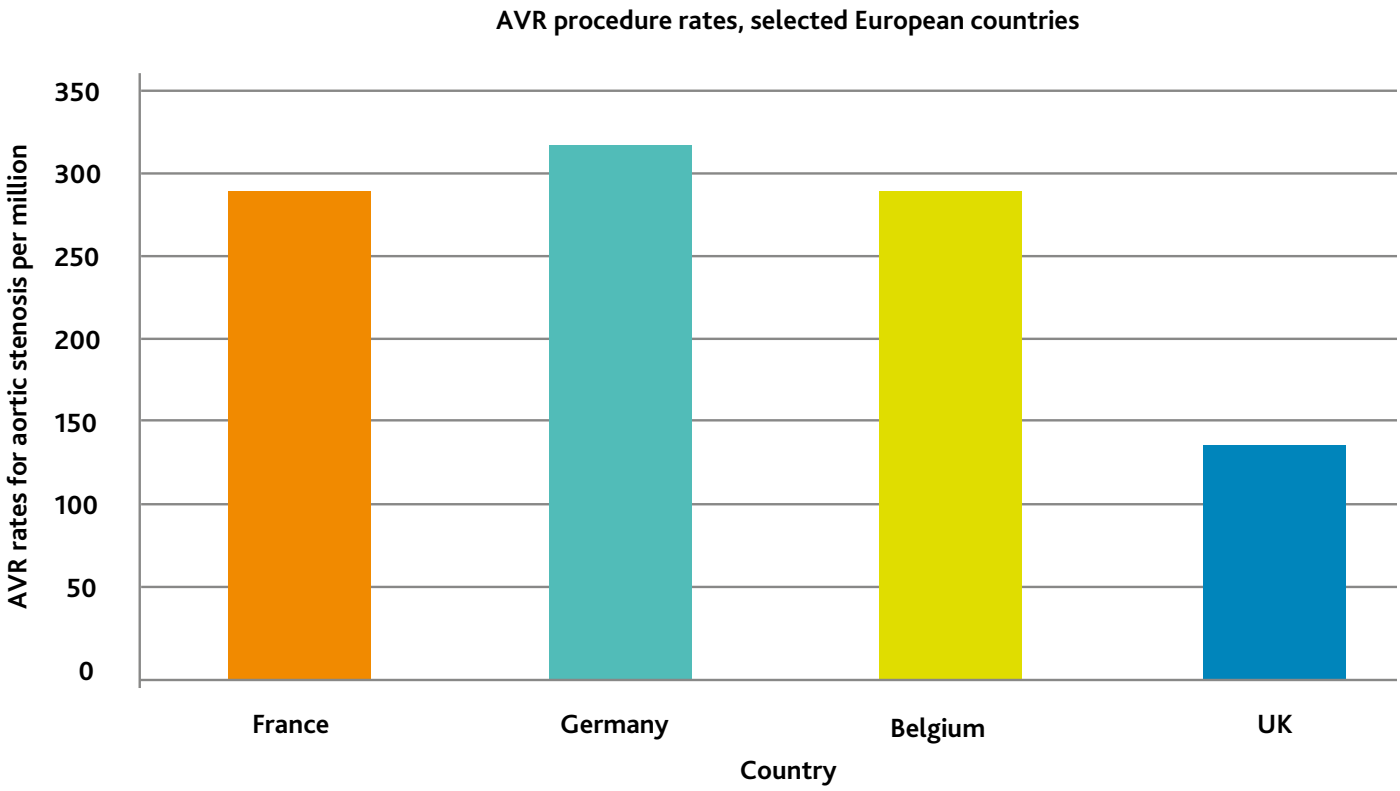
We need to move away from late diagnosis, low referrals and late treatment so that patients can benefit from the effective treatments available which improve quality of life and add years to life.

THE UK IS LAGGING BEHIND EUROPE

It is difficult to determine the appropriate treatment intervention rates and it can be unclear what constitutes a best practice rate, but international comparisons can help to explore variations and provide an insight into the gap between countries (see Nashef *et al* 2000 and Bridgewater *et al* 2010 for examples of work exploring variation in coronary surgery). Comparisons have been undertaken looking at different procedure rates for surgery for heart valve disease. They suggest that UK patients with heart valve disease may well be missing out on treatment compared with patients in other European countries.

For example, France has more than double the UK rate for AVR procedures for aortic stenosis; 283 per million versus 137 per million in the UK in 2010/2011 (Figure 6). The UK is also behind Germany (311 per million) and Belgium (283 per million) during the same period.

Figure 6: AVR procedure rates, selected European countries 2010/11



Sources:
Belgium = BACTS (2013)
Germany = Hamm CW *et al* (2014)
France = Le Programme de médicalisation des systèmes d'information (PMSI)
England = NHS England Hospital Episode Statistics (HES)

The UK's use of TAVI also lags behind those seen in other countries. In 2011, the UK rate was just below 20 TAVI implants per million, which is less than the top three countries of Germany (approximately 90 per million), Switzerland (approximately 65 per million) and Denmark (approximately 45 per million). France, with a similar population size, was almost double the UK rate in 2011 (just under 40 per million compared to under 20 per million in the UK). In fact, the UK only had better rates than Ireland (fewer than 10 per million) and Portugal (fewer than 5 per million) (Piazza 2013).

More recent data on funded procedures show that the UK is still behind France. In 2013, England's TAVI rate was at 16 per million (NHS England Hospital Episode Statistics - HES) while France was at 57 per million (Le Programme de médicalisation des systèmes d'information). According to the BIBA Medical Survey data from 2013, the European average was 53 patients per million. In England, the commissioning policy for funded TAVI procedures for 2013/14 was set at a level equivalent to 25 per million population across England (NHS Commissioning Board 2013). This anchors England at a rate far below many other countries.

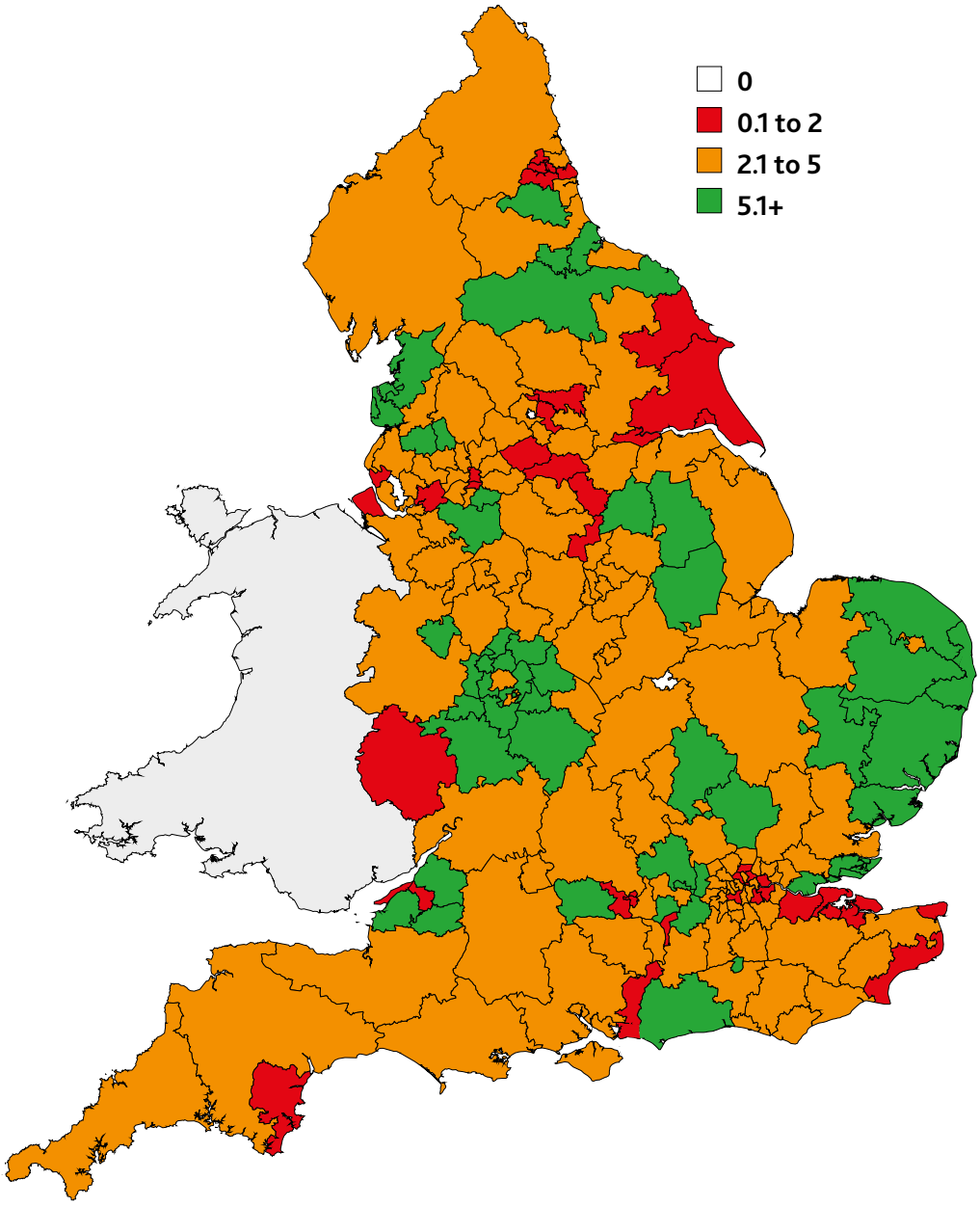
Recommendation 5: The same level of surgical and transcatheter valve replacement as other leading European countries

The UK lags well behind Europe, but Heart Valve Voice believes that heart valve disease patients in the UK deserve the same as our European neighbours.

TREATMENT DIFFERS ACCORDING TO WHERE PATIENTS LIVE WITHIN THE UK

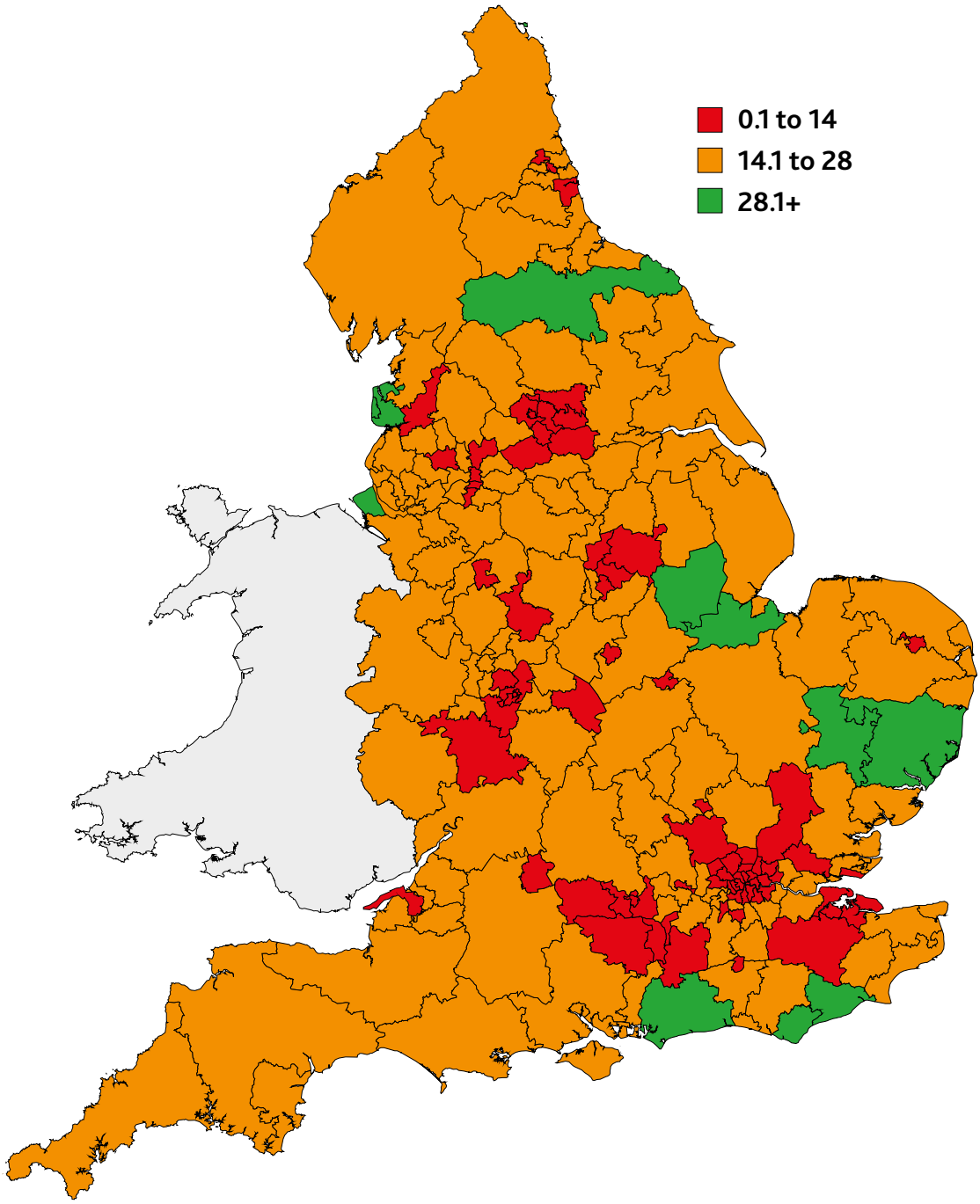
There is evidence that there are differences in treatment according to where patients live within England. Variation in MVR, AVR and TAVI is clear at the CCG level too (see Figure 7, Figure 8 and Figure 9). This illustrates that in London in particular, there were low rates of MVR and AVR in 2013, for example only approximately five per cent of CCGs had AVR rates over 28.1 per 100,000 people (see Figure 8). For TAVI, approximately 17% had rates over 2.5 per 100,000 population (the NHS Commissioning Board's recommended level), and the vast majority were at or below 1.5 per 100,000 population (see Figure 9).

Figure 7: Mitral Valve Repair rates across Clinical Commissioning Groups, Jan – Dec 2013



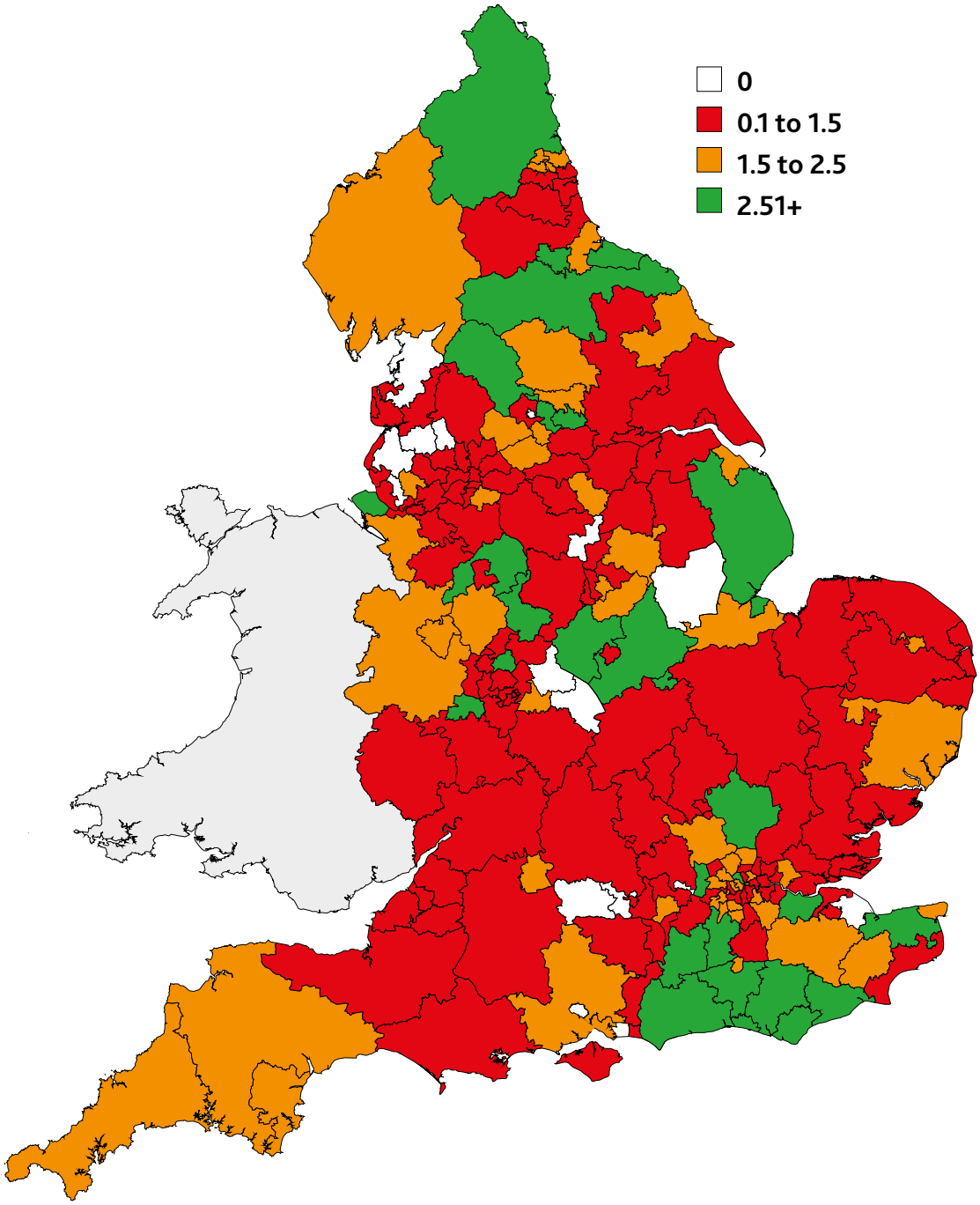
Source:
Health & Social Care Information Centre (HSCIC): Hospital Episode Statistics. 2014.

Figure 8: Aortic Valve Replacement rates across Clinical Commissioning Groups, Jan – Dec 2013



Source:
Health & Social Care Information Centre (HSCIC): Hospital Episode Statistics. 2014.

Figure 9: TAVI rates across Clinical Commissioning Groups, Jan – Dec 2013



Source:
Health & Social Care Information Centre (HSCIC): Hospital Episode Statistics. 2014.

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Heart Valve Voice undertook an analysis of HES, which reveals that 15 CCGs had no patients at all who had undergone a TAVI This, in Heart Valve Voice's view, demonstrates a gap, as we'd expect to see at least some patients treated with TAVI in every CCG.

Reasons for why patients are not receiving treatments that can offer clinical benefits are not always justified (Vahanian *et al* 2012). Some patients may be inappropriately denied surgery because of perceived risk (Thaden, Nkomo and Enriquez-Sarano 2014). Others may be denied surgery because of age alone, despite evidence that older patients (aged over 80 years) can experience survival benefits similar to those of younger patients (Charleson, Legedza and Hamel 2006). In the UK, Badran *et al* (2012) suggest that the reasons potentially eligible patients were denied AVR between 2008 and 2010 in Southampton varied but included; high operative risk, co-morbidities and advanced patient age, as well as the patient's own decision. TAVI is a procedure which would be appropriate for many of these patients.

Age, however, should not preclude SAVR. In 3,104 patients aged between 80 and 85 years who underwent uncomplicated SAVR, mortality was 3.9% and one year mortality 9.1% (iData).[11]

11. The iData app was created by a partnership of the Society for Cardiothorarcic Surgery (SCTS), National Institute for Cardiovascular Outcomes Research (NICOR) and the University of Manchester.

Recommendation 6: The same access to heart valve replacement treatment wherever a patient lives within the UK

Patients should not be disadvantaged by where they live, they should be able to access the effective procedures that are available to treat heart valve disease.

ACHIEVING HEALTHY AGEING

Heart Valve Voice believes that tackling heart valve disease will help the UK achieve healthy ageing. Healthy ageing is the process of optimising opportunities for physical, social and mental health to enable older people to take an active part in society without discrimination and to enjoy an independent and good quality of life (The Healthy Ageing Project 2007).

Heart Valve Voice also believes that tackling heart valve disease will help Europe achieve the target of increasing healthy life years (HLYs) by two years by 2020. This target has been set as part of the European Commission Innovation Union Partnership on Active and Healthy Ageing (European Commission Innovation Union Key Initiatives). HLYs indicate the number of years a person of a certain age can expect to live without disability (European Commission Public Health Indicators). The European Commission points out that; *"it is important for policy-makers to be aware of the opportunity cost of doing too little to prevent ill-health"* (European Commission Public Health Indicators, Healthy Life Years).

Healthy ageing can be achieved in a number of ways, from maintaining an active lifestyle to better care and improving treatment of the conditions that most impact upon HLYs. Heart Valve Voice believes that heart valve disease is an example of just such a condition, and one where treatment has been revolutionised over the last ten years.

Heart Valve Voice Recommendations

Heart Valve Voice believes that there are many opportunities to improve the lives of those who have heart valve disease.

Heart Valve Voice calls for greater priority to be placed on heart valve disease accompanied by increased investment in providing curative valve repair and replacement for the UK's older people suffering from heart valve disease. We want:

1. **Heart valve disease to be included in current strategies for cardiovascular disease**
2. **An awareness campaign for healthcare professionals and potential patients on the symptoms of heart valve disease and the importance of early diagnosis and treatment**
3. **15-minute GP consultations for the over 75s**
4. **Appropriate referral and follow-up between primary, secondary and tertiary care with a key role played by a MDT to inform treatment decisions in partnership with patients**
5. **The same level of surgical and transcatheter valve replacement as other leading European countries**
6. **The same access to heart valve replacement treatment wherever a patient lives within the UK**

Find out more

You can contact the Heart Valve Voice secretariat at:

Tonic Life Communications

Telephone: **+44 (0) 207 798 9900**

Email: **HeartValveVoice@toniclc.com**

Follow us on Twitter **@HeartValveVoice #HeartValveDisease #HeartValveVoice**

Visit the website **www.heartvalvevoice.co.uk**

Glossary

Aortic valve	One of the heart valves that controls blood flow from the lower heart chambers to the arteries. It is located at the outlet of the heart between the left ventricle (major pumping chamber of heart) and the aorta (major blood vessel which supplies blood around the body).
Mitral valve	One of the heart valves that controls blood flow from the upper heart chambers to the lower chambers. It sits between the left atrium (upper right chamber of heart) and the left ventricle (major pumping chamber of heart), very close to the lungs. It is effectively the valve that is situated between the lungs and the major pumping chamber of the heart.
Mechanical valve	An artificial valve, made from a mixture of metals, very smooth carbon and a cloth sewing ring which enables it to be sewn in the heart. Once a mechanical valve is inserted, lifelong blood thinning treatments are required.
Tissue valve	An artificial valve, made from animal heart components (pig or cow) and, mounted on a frame with cloth surround, enabling it to be sewn into the heart. There is no requirement for blood thinning treatment once a tissue valve is inserted, unless there is another reason for these tablets to be given. Unlike a mechanical valve, a tissue valve may wear out over time.
Mitral valve repair (MVR)	The mitral valve is a dual-flap valve. If the two flaps – or leaflets – do not meet properly when the valve closes this can result in leakage which can be repaired by restoring the meeting points of the valves. If a mitral valve repair is carried out, the presence of the patient's normal tissues is maintained and the best outcome is usually achieved.
Surgical aortic valve replacement (SAVR or AVR)	The aortic valve is replaced during open heart surgery with either a tissue valve or a mechanical valve.
Transcatheter aortic valve implantation (TAVI)	TAVI stands for Transcatheter Aortic Valve Implantation and is an alternative to conventional surgical replacement of the aortic valve for patients who are inoperable or at high risk for surgery. It involves inserting a crimped valve on a catheter into the narrowed aortic valve via a wire. Once in position, the valve is either balloon inflated or self expands within the diseased valve to alleviate the narrowed valve and improve blood flow.
Minimally invasive procedures	Unlike traditional open heart surgery, minimally invasive procedures allow a heart valve to be inserted through small incisions. This may offer quicker recovery times and, potentially avoids some of the complications associated with conventional heart surgery. However, at this stage this is not suitable for every patient and should be discussed with a healthcare professional.

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