



Heart Valve
VOICE



*The more we
listen, the
more lives
we save*

HEART VALVE VOICE:
TOWARDS A HEART HEALTHY FUTURE:
A 2020 VISION FOR HEART VALVE DISEASE

NOVEMBER 2016



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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, comprising heart valve disease patients and those that treat the disease, including cardiologists, cardiac surgeons, GPs and patients.

As the Chief Executive of Heart Valve Voice, I am lucky enough to work on a daily basis with patients who have been diagnosed with, and effectively treated for the condition. Sadly, many people with heart valve disease 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.

Through our work with patients, clinicians, policy makers and the general public we have made great progress over the past 12 months. However, much more needs to be done to ensure people living with heart valve disease receive a timely diagnosis and can access effective and appropriate treatment for the condition.

We believe that the recommendations in this report can help to achieve this and that the early diagnosis of heart valve disease, rather than increasing the burden on the NHS, can actually help to save costs in the longer term, by keeping patients out of hospital and living independent lives. Given the burden of heart valve disease, which is only set to increase in line with the UK's aging population, it is critical that action is taken now to address these issues.

I would like to thank everyone who has contributed towards the production of this report, including our Chair, Mr Chris Young, Professor Bernard Prendergast and those involved in the ground-breaking OxVALVE Study, as well as our colleagues at the British Heart Valve Society. Their continued support ensures Heart Valve Voice is able to continue to make a real difference to the lives of heart valve disease patients across the UK.



Wil Woan, Chief Executive,
Heart Valve Voice

A handwritten signature in dark ink that reads "Wil Woan".



INTRODUCTION

The NHS is currently facing significant economic, efficiency and productivity challenges. As a result, difficult decisions around priorities, services and disease areas need to be made. The implementation of the Five Year Forward View (FYFV) is likely to impact on many areas of the NHS, with providers being challenged to reduce costs and ease pressure on overburdened services such as general practice and secondary care.ⁱ

Having revealed "inexplicable variation" in spending across the NHS, Lord Carter's recent productivity review also found that the NHS could save £5 billion every year by making better use of staff, using medicines more effectively and getting better value from the huge number of products it buys.ⁱⁱ Initiatives and challenges such as those outlined above are set to have a significant impact on all services, including in the treatment of heart valve disease.

While significant improvement has been achieved in the treatment and management of cardiovascular disease, the same cannot be said for heart valve disease, which has found itself excluded from key NHS policies such as the Department of Health's 2013 Cardiovascular Disease Outcomes Strategy. Despite its severity, there are also currently no National Institute for Health and Care Excellence (NICE) guidelines setting out recommendations on the diagnosis and treatment of heart valve disease or the care of patients, which would help to secure the best possible outcomes for those affected.

Building on our 2014 White Paper, this report brings together a range of new evidence and data on heart valve disease services in the UK, which we believe demonstrates the need for change. It sets out a number of recommendations which Heart Valve Voice believe are crucial if we are to improve the diagnosis, treatment and care of heart valve disease in the face of significant challenges for the NHS and with an aging population.

KEY RECOMMENDATIONS

RECOMMENDATION

Awareness of the signs and symptoms of heart valve disease amongst primary care healthcare professionals and the public must be improved through effective and targeted education and awareness raising campaigns.

RECOMMENDATION

All over 65s should have their hearts routinely checked with a stethoscope by a trained primary care healthcare professional.

RECOMMENDATION

NICE should develop guidelines on the diagnosis, management and treatment of heart valve disease as a priority.

RECOMMENDATION

GPs should have improved access to echocardiography (*ultrasound of the heart*) for all patients with a heart murmur or suspected heart valve disease.

RECOMMENDATION

Heart valve disease patients must have access to appropriate and effective treatments;

- Across the UK; and
- When compared to other leading European countries.



HEART VALVE DISEASE IN THE UK

Heart valve disease is a condition caused by the malfunctioning or abnormality of one or more of the heart's four valves, which affects the flow of blood through the organ. If left untreated the damage to the heart can lead to heart failure and ultimately death.

The heart, which is responsible for pumping blood through the blood vessels of the circulatory system, has four chambers. When working properly, the four valves in the heart ensure blood is flowing through these chambers in the right direction. If the heart valves become diseased or defective the valves may not open or close properly, meaning the flow of blood may be obstructed. The primary types of heart valve disease are:

- **Valve Stenosis or Obstruction:** As a result of certain medical conditions or anatomical abnormalities, a valve can either be exceptionally narrow (therefore having a "stenosis") or have a blockage or obstruction. Either of these conditions can limit the blood flow through the valve, which may result in a "back-up" of blood behind the valve - as if behind a dam - causing the heart to pump inefficiently or for blood pressure to build up in the lungs.
- **Valve Regurgitation or Insufficiency:** When a valve's leaflets fail to close completely, the valve itself can become "leaky," allowing blood to backwash through the valve (called "regurgitation"). In addition, the valve may not ever completely move the volume of blood to the next appropriate chamber.

People diagnosed with heart valve disease often report feeling tired, dizzy, breathless, having pain in the chest and swelling of the ankles and feet. Unfortunately, many people put these symptoms down to the ageing process and do not seek medical advice, so ultimately remain undiagnosed.



RECOMMENDATION

NICE should develop guidelines on the diagnosis, management and treatment of heart valve disease as a priority.

Causes of Heart Valve Disease

Whilst the chances of developing heart valve disease increase with age, it is not directly linked to factors such as gender or leading a particular lifestyle. However, it is seen to be linked to other conditions, in particular atrial fibrillation (AF). In a study of 2,500 patients in Oxford, the OxVALVE Study found that, of those who showed clinically significant (moderate or severe) heart valve disease, 21% were found to have AF, compared to just 5.7% with sinus rhythm (normal functioning of the heart).ⁱⁱⁱ

Despite the evident risk of heart valve disease patients developing AF, the latest NICE guideline on AF (CG180) does not include recommendations for those diagnosed with the condition to have an echocardiogram to check for heart valve disease. Heart Valve Voice believe that a specific recommendation in the NICE guidelines on AF would help to improve the diagnosis of heart valve disease amongst this high risk group of patients.

PREVALENCE OF HEART VALVE DISEASE IN THE UK

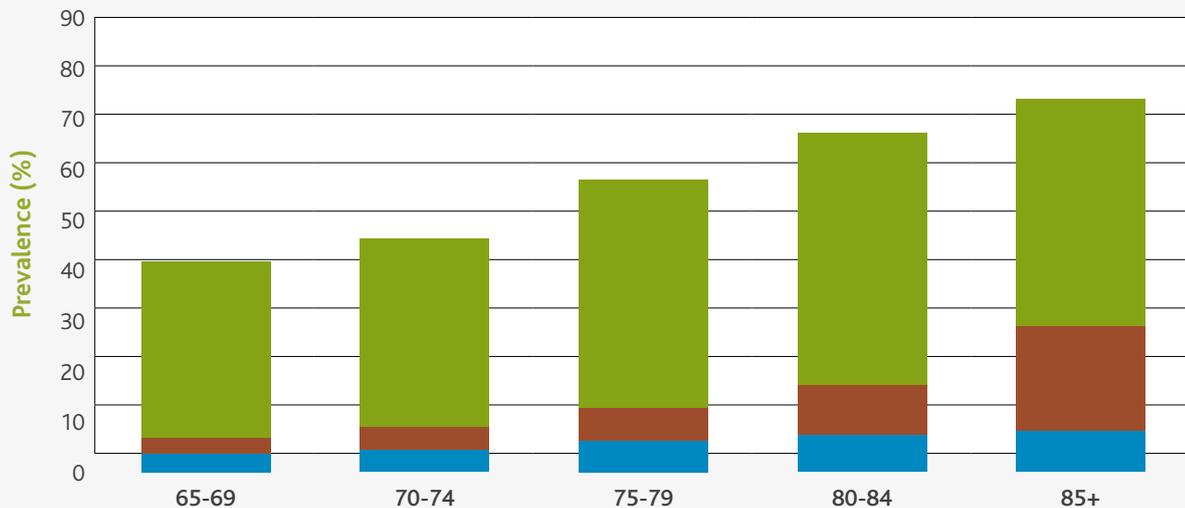
The chances of developing heart valve disease increase with age. Across the UK approximately 1.5 million people over the age of 65 are currently affected by heart valve disease. With the number of people in this age bracket set to double to 19 million by 2050, there is likely to be a major increase in the prevalence of the condition.^{iv}

The findings of the OxVALVE study demonstrate a significant correlation between the prevalence of heart valve disease and age. The bar graph below shows how the number of patients identified with both newly diagnosed moderate or severe heart valve disease and previously diagnosed heart valve disease increases with age.

The study found that:^v

- 11.3% of participants suffered from clinically significant (moderate or severe) heart valve disease; and
- Of these, 6.4% were newly diagnosed, with 4.9% having been previously diagnosed.

Population Prevalence of Heart Valve Disease According to Age^{vi}



Age (years) Figure 1. Population prevalence of valvular hearts disease according to age.

■ Newly diagnosed mild VHD ■ Newly diagnosed moderate/severe VHD ■ Previously diagnosed VHD

The study also found that, for many, the condition is complicated by the fact that more than one of their heart valves is damaged or worn. Of the 1,256 participants that were identified as having heart valve disease, over one third (38.5%) were diagnosed as having multiple valve lesions. This is demonstrated in the Venn diagram on the following page.^{vii}

Distribution of Single and Multiple Left-Sided Valve Abnormalities^{viii}

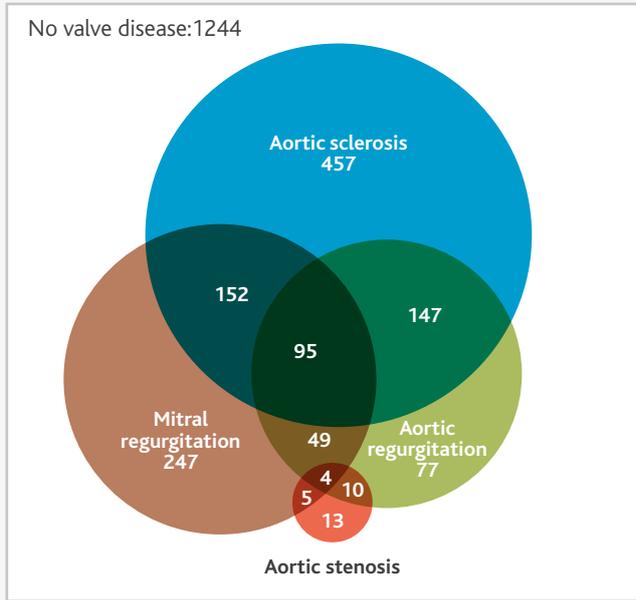


Figure 2. Venn diagram demonstrating the distribution of single and multiple left-sided valve abnormalities in OxVALVE participants with newly diagnosis valvular heart disease. The outer rectangle represents the full cohort (n=2500) and the area of each circle is proportionate to the number of participants with different manifestations of left-sided valvular heart disease. Numbers denote the number of participants in each group.

RECOMMENDATION

- Heart valve disease patients must have access to appropriate and effective treatments;
- Across the UK; and
 - When compared to other leading European countries.

Total cohort: 2500 (rectangle)

Using data obtained as part of the OxVALVE Study it is anticipated the number of people over the age of 65 with the condition will increase from 1.5 million in 2015 to 3.3 million by 2056, representing a 122% increase, with a doubling of prevalence by 2046. As such, it will be important that policy makers and clinicians plan and deliver the necessary provisions to provide the essential health services for the treatment and management of the rapidly increasing numbers of heart valve disease patients.^{ix}

UK Population Projections of Diagnosed and Undiagnosed Significant Heart Valve Disease^x

■ Undiagnosed
■ Diagnosed

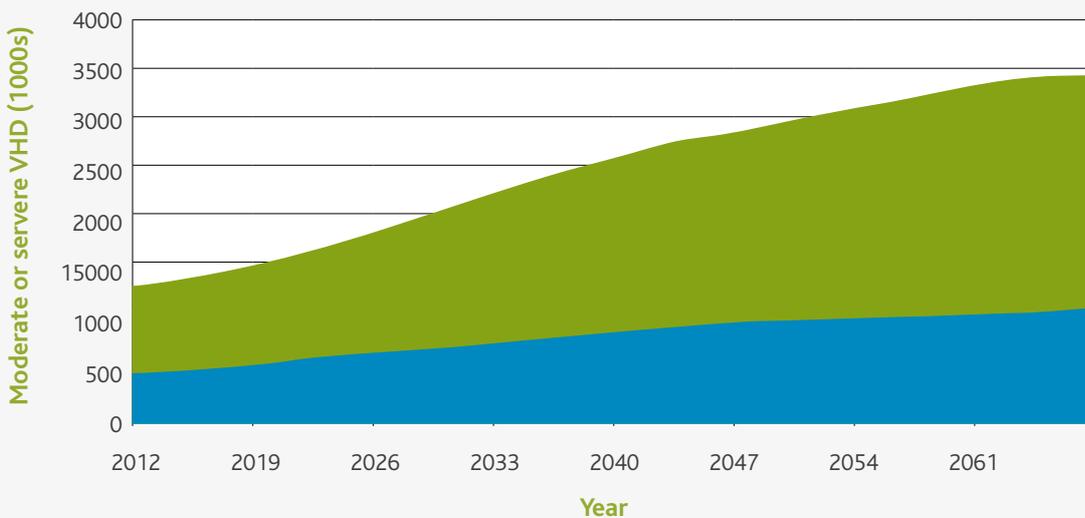


Figure 4. UK population projections of diagnosed and undiagnosed significant valvular heart disease. Diagnosed estimates are based on the number excluded from participation in the present study due to a prior diagnosis of valvular heart disease. Undiagnosed estimates are based on the number with newly diagnosed significant valvular heart disease in OxVALVE PCS.

AWARENESS AND DIAGNOSIS OF HEART VALVE DISEASE

Outcomes for patients with heart valve disease whose condition is left untreated are poor. Studies show that people with serious aortic stenosis have around a 50% chance of living two years if they are not in receipt of effective treatment.^{xi} As such, it is vital that people are diagnosed at the earliest opportunity to ensure they can be appropriately treated as quickly as possible.

This under-diagnosis may be in part due to a lack of public awareness of the signs and symptoms of heart valve disease and the severity of the condition. Heart Valve Voice feel this is putting the health of over one million over 65s at risk.

A recent survey of 1,411 people aged over 60 in the UK found that:^{xii}

- 94% of respondents did not know what aortic stenosis was;
- Under 3% were concerned about heart valve disease compared to other illnesses, including heart conditions; and
- Only 7% of respondents said they were most familiar with heart valve disease when compared to other types of cardiovascular disease. This is just ahead of congestive heart failure and rheumatic heart disease.

In order for heart valve disease to be diagnosed as early as possible a trained health care professional can take the simple step of using a stethoscope to listen for the characteristic heart "murmur", which is often the first sign of a heart valve disorder.^{xiii} Heart Valve Voice is concerned that heart valve disease patients are not being effectively diagnosed and, as a result, are not being offered appropriate treatment for the condition because of the underuse of the stethoscopes within the NHS.

The recent Heart Health Survey also found that:^{xiv}

- 50% of respondents rarely had their heart checked with a stethoscope when they visited their GP; and
- 22% said they had never had a stethoscope check performed on them by their GP.

Heart Valve Voice recognise there is an ever-increasing demand on primary care practitioners in the UK, not just in terms of heavy workload, but also in the intensity of work being carried out.

GPs are seeing 70 million more patients a year than they were just seven years ago, with fewer GPs per head of population. Over 200 surgeries closed last year, with many more on a 'cliff edge' and unfilled GP vacancies are at their highest number ever.^{xv}

Given the correlation between age and developing heart valve disease, Heart Valve Voice believe alternatives must be looked at to ensure that over 65s are being regularly checked for the signs and symptoms of heart valve disease. Given the pressure on GPs, we believe this check could be provided by other appropriately trained health care professionals in the primary care setting, for example by a practice nurse or, if the surgery or CCG has one, a resident community cardiac nurse.

A primary care stethoscope check could, for example, become a routine element of the NHS Health Check, which is a free and sophisticated check of the health of adults aged between 40 and 74.^{xvi} This service only operates in England although Scotland, Wales and Northern Ireland all have similar schemes. It is worth noting that these checks are not compulsory and depend on the willingness of members of the public to attend and their awareness of the existence and benefits of the checks.^{xvii}

RECOMMENDATION

Awareness of the signs and symptoms of heart valve disease amongst primary care healthcare professionals and the public must be improved through effective and targeted education and awareness raising campaigns.

RECOMMENDATION

All over 65s should have their hearts routinely checked with a stethoscope by a trained primary care healthcare professional.

Access to Echocardiography

If a heart murmur is detected following a stethoscope check, further tests are needed in order for a full diagnosis to be made. The most common test in this situation is an echocardiogram,^{xviii} which uses sound waves to build up a detailed picture of the heart – similar to an ultrasound scan used in pregnancy. An echocardiogram looks at the structure of the heart and valves, as well as providing information on the function and pumping action of the heart.^{xix} A recent study found that of 18,591 echocardiograms performed between two specialist centres, 377 (2%) were diagnosed as new cases of severe aortic stenosis.^{xx}

Heart Valve Voice has been made aware of concerns that there is currently significant variation across the UK in terms of access to echocardiogram tests for primary care healthcare professionals. As a result, many primary care practitioners are unable to refer patients on for further tests in a timely fashion, and therefore a diagnosis cannot be made. This is further contributing to the under diagnosis of the condition in areas of the UK with limited access to echocardiography services. Heart Valve Voice believes that in order to improve the diagnosis of heart valve disease, primary care practitioners who suspect heart valve disease or detect a heart murmur in a patient should be able to refer them on for an echocardiogram in a timely manner, no matter whereabouts in the country they are being treated.

RECOMMENDATION

GPs should have improved access to echocardiography (*ultrasound of the heart*) for all patients with a heart murmur or suspected heart valve disease.

PATIENT ACCESS TO OPTIMAL TREATMENT

If diagnosed in a timely manner, heart valve disease is an entirely treatable condition, particularly as a result of recent innovations in treatment options. Effective treatment can allow many patients to return to living normal, active lifestyles. The appropriate treatment for each patient depends on the severity of the disease.

Surgical treatment

Once a patient has been diagnosed with severe heart valve disease the only way to treat the condition is by repairing or replacing the damaged valve(s). Heart Valve Voice believe these treatments can be considered curative.

Below are the procedures currently available to advanced heart valve disease patients.^{xxi}

- **Valve repair** – Often used for mitral valves that are leaking but are not seriously damaged, but can also be used with the aortic valve. During the procedure the damaged valve is repaired, whilst maintaining the patient's tissue.
- **Valve replacement** – There are two types of valve replacement procedures: aortic valve replacement (AVR) and mitral valve replacement (MVR). These procedures replace the diseased aortic or mitral valve with a new valve during surgery. The valve replacement is often carried out via open heart surgery. However, it is possible for minimally invasive techniques to be used in order to reduce recovery times and the impact on the patient's quality of life.

- **Transcatheter aortic valve replacement (TAVI)** – A less invasive option, TAVI is often used in adults who are not considered well enough to undergo traditional heart surgery. The procedure involves inserting a new artificial heart valve inside the old valve using a balloon catheter. The procedure can be carried out under light sedation (without general anaesthetic) and does not require open heart surgery, meaning that patients require less time in hospital and are able to return to normal life much quicker than with other procedures.

A recent study by Northwestern Medicine found that there is a significant risk of mortality while waiting for AVR or TAVI and that longer waiting times may be associated with poorer outcomes in those patients that survive to intervention.

The cost of suboptimal treatment

With the economic, efficiency and productivity challenges facing the NHS it is vital that patients, including those with heart valve disease, receive optimal and timely treatment. A recent study comparing the cost effectiveness of TAVI with AVR found that, despite the higher procedural costs of TAVI, over a ten year model horizon TAVI proved much more cost effective. This was due, in part, to increased costs associated with AVR post-procedure when compared to TAVI, in particular in terms of the patients' hospital

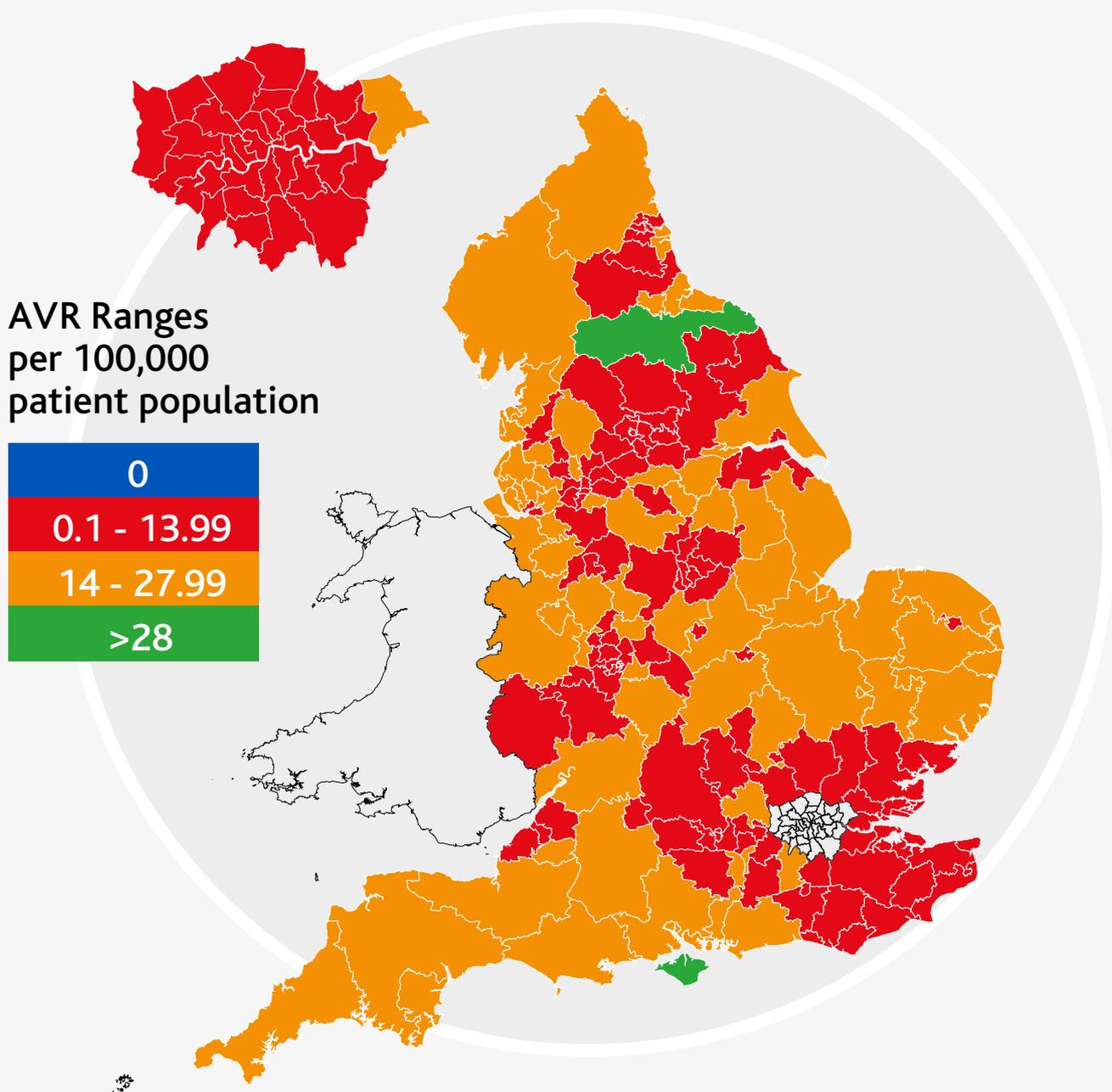
stay and other additional care costs.^{xxii} It is also worth noting the benefit to the wider economy of the non-invasive nature of TAVI. The shorter hospitalisation times mean patients of working age are able to return to employment far quicker than those who receive AVR. This could help further reduce the cost of any out of work benefits claimed by heart valve disease patients, as well as additional benefits to the economy from earlier returns to work and wider societal contributions.

Gap in treatment

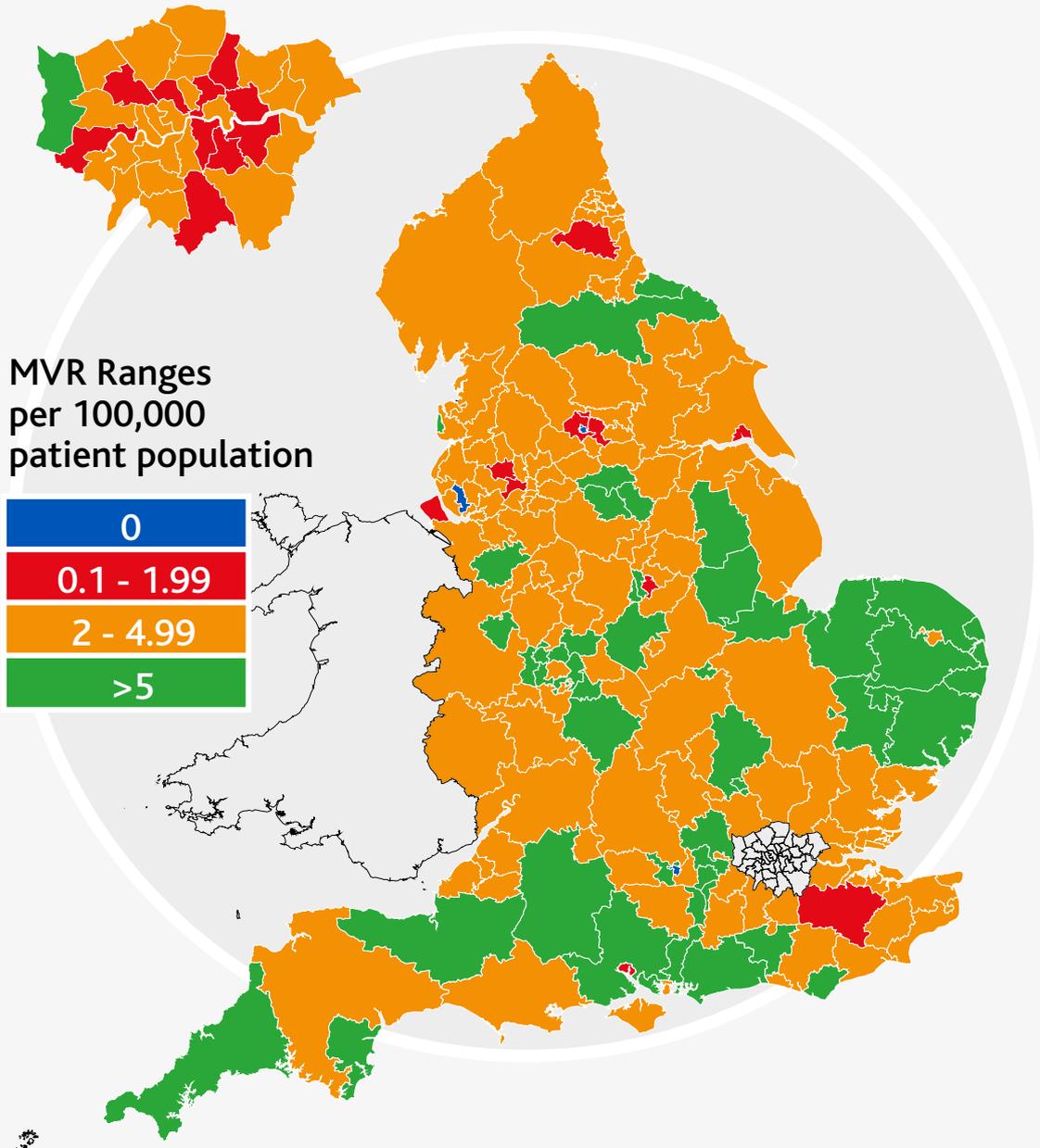
Despite the clear benefits for patients, the NHS and the wider economy of the optimal treatment of heart valve disease, there is significant variation in patient access to the different treatments currently available across the UK. This means that whilst some patients are able to access the best possible treatment for their condition, many others are missing out. The three heat maps below demonstrate the disparity in patient access to TAVI, AVR and MVR across CCGs in England.

Aortic Valve Replacement (AVR) rates across Clinical Commissioning Groups (CCGs)

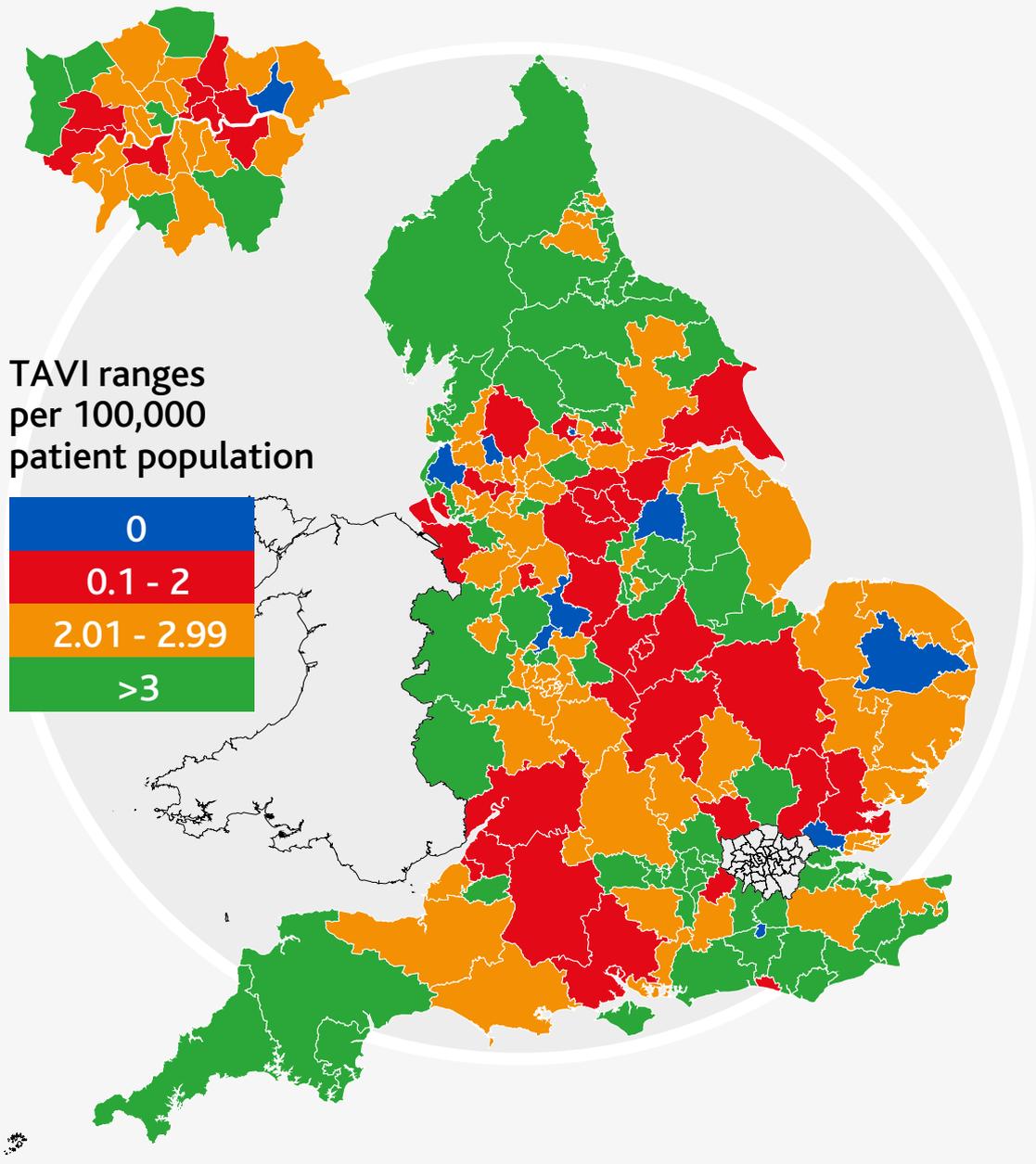
April 2014 – March 2015.



Mitral Valve Repair (MVR) rates across Clinical Commissioning Groups (CCGs) April 2014 – March 2015.



Transcatheter Aortic Valve Implantation (TAVI) rates across Clinical Commissioning Groups (CCGs) April 2014 – March 2015.



The figures show that some CCG's, such as Crawley and Cannock Chase CCGs performed no TAVI procedures at all between April 2014 and March 2015, whereas East and North Hertfordshire performed 21. Similarly, Greenwich CCG performed just 5 AVR procedures during the same period, whilst North Eastern and Western Devon performed 155.

Given heart valve disease is associated with ageing, it would be expected that areas with older populations would have higher rates of TAVI. However, the latest NHS Atlas of Variation, which has been adjusted to standardise age, shows that other factors are responsible for the variation.

These include:^{xxiii}

- The start date for different TAVI programmes;
- The volume of procedures commissioned (*particularly before the introduction of specialised commissioning in 2013*);
- The level of risk considered safe for conventional surgery to be undertaken;
- The lack of a clinical pathway for TAVI; and
- Centres with the capability to perform TAVI procedures.

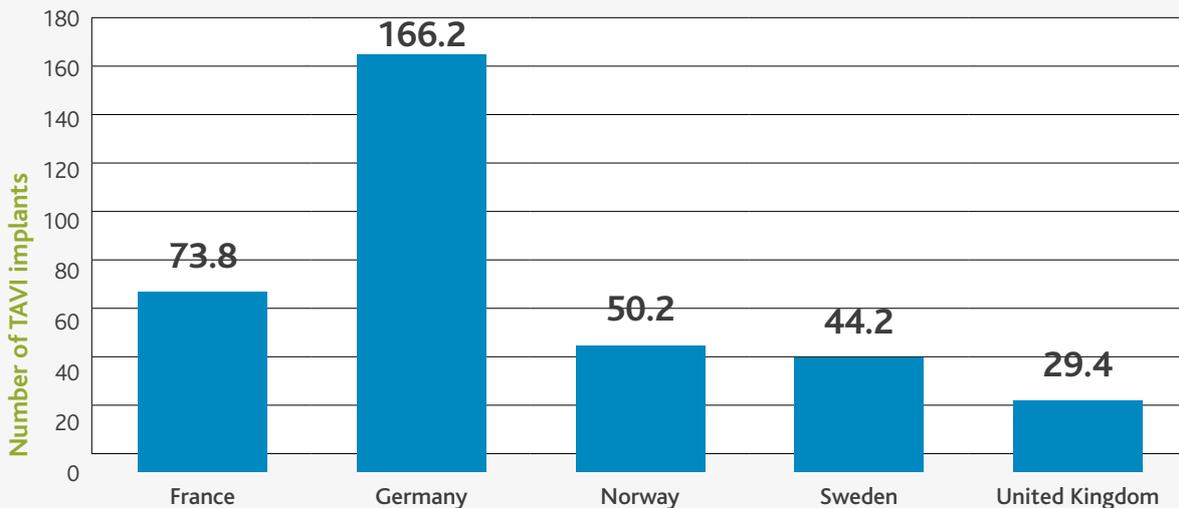
A recent study on the outcomes of treatment decisions in patients with severe aortic stenosis found that less than 50% of patients diagnosed with aortic stenosis were referred for surgery by cardiologists. The most common reason given for not doing so was that the patient was not showing symptoms of aortic stenosis, or the condition was not severe enough to merit

surgery. It is concerning therefore that the study also found that outcomes for the patients who did not receive any treatment were significantly worse than those who had some sort of surgical intervention.^{xxiv}

The report concluded that one way of ensuring that heart valve disease patients receive the most appropriate treatment and, therefore, experience the best possible outcomes would be to implement a team-based, patient-centred approach including guidelines outlining all the treatment options available to patients.^{xxv}

As well as variation across the UK, the country as a whole persistently lags behind its European counterparts in the treatment of aortic stenosis. For example, in 2011 the conventional aortic valve surgery and TAVI rates in the UK were lower than in comparable European countries and by 2013 the UK TAVI intervention rate was less than half the European average. In 2014, Germany performed the largest number of TAVI procedures (166.2 per million), followed by France (73.8), Norway (50.2) and Sweden (44.2) with the lowest number found to be in the UK (29.4).^{xxvi}

TAVI implants in 2014 per million population in five European countries



Patient access to effective treatment for heart valve disease should not be determined because of where someone lives, be that in different parts of the UK or different countries. Heart Valve Voice believe that this variation in access must be addressed through the development of mandatory national guidelines produced by NICE, which outline clear pathways for the treatment and management of heart valve disease.

CONCLUSION

Whilst significant progress has been made in the management of cardiovascular disease in the UK in recent years, this has not been true of heart valve disease. Heart Valve Voice believe more must be done to ensure people living with the condition are diagnosed in a timely manner and have access to the most effective treatment.

The findings of this report demonstrate that, given the UK's aging population and the subsequent increasing burden of heart valve disease, resolving the challenges faced in the diagnosis and treatment of heart valve disease is critical. It is also clear that not only would addressing the under-diagnosis and under-treatment of the condition improve outcomes for patients with this entirely treatable condition, but it would also save costs in the long term for a struggling NHS. We believe that the five key recommendations based on the findings of this report would

ensure significant steps are taken towards addressing these challenges and, most importantly, improving patient outcomes.

Heart Valve Voice look forward to continuing to work with patients, clinicians, policy makers and Parliamentarians to improve the diagnosis, treatment and management of heart valve disease in the UK, by highlighting the findings of this report, raising awareness of the condition and through the implementation of the key recommendations.

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| <p>ii. Operational productivity and performance in England NHS acute hospitals: Unwarranted variations. An independent report for the Department of Health by Lord Carter of Coles. February 2016. Available: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf</p> | <p>x. Large-Scale Community Echocardiographic Screening Reveals a Major Burden of Undiagnosed Valvular Heart Disease in Older People: The OxVALVE Population Cohort Study. Available: https://www.phc.ox.ac.uk/publications/634128</p> | <p>xx. Outcome of treatment decisions in patients with severe aortic stenosis, Clinton Lloyd Et al</p> |
| <p>iii. Large-Scale Community Echocardiographic Screening Reveals a Major Burden of Undiagnosed Valvular Heart Disease in Older People: The OxVALVE Population Cohort Study. Available: https://www.phc.ox.ac.uk/publications/634128</p> | <p>xi. Valvular Heart Disease & Heart Failure, Rising Awareness & Improving Treatment (slide deck)</p> | <p>xxi. British Heart Foundation, Heart Valve Disease, What are the Treatments. Available: https://www.bhf.org.uk/heart-health/treatments/valve-heart-surgery</p> |
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| <p>v. Large-Scale Community Echocardiographic Screening Reveals a Major Burden of Undiagnosed Valvular Heart Disease in Older People: The OxVALVE Population Cohort Study. Available: https://www.phc.ox.ac.uk/publications/634128</p> | <p>xiii. British Heart Foundation, Heart Valve Disease. Available: https://www.bhf.org.uk/heart-health/conditions/heart-valve-disease</p> | <p>xxiii. Public Health England and NHS England, The NHS Atlas of Variation in Healthcare. Reducing unwarranted variation to increase value and improve quality. September 2015. P122. Available at: http://www.rightcare.nhs.uk/atlas/Rc_nhsAtlas3_HIGH_150915.pdf</p> |
| <p>vi. Large-Scale Community Echocardiographic Screening Reveals a Major Burden of Undiagnosed Valvular Heart Disease in Older People: The OxVALVE Population Cohort Study. Available: https://www.phc.ox.ac.uk/publications/634128</p> | <p>xiv. UK Heart Health Survey, Research for Tonic Life Communications on behalf of Edwards Lifesciences. Carried out between 28/09/15 and 12/10/15. Sample: 1,411 people ages 60+ in the UK.</p> | <p>xxiv. Outcome of treatment decisions in patients with severe aortic stenosis, Clinton Lloyd Et al</p> |
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| <p>viii. Large-Scale Community Echocardiographic Screening Reveals a Major Burden of Undiagnosed Valvular Heart Disease in Older</p> | <p>xvi. NHS Choices, Your NHS Health Check. Available: http://www.nhs.uk/conditions/nhs-health-check/pages/what-is-an-nhs-health-check.aspx</p> | <p>xxvi. Data obtained from: 1. The British Cardiovascular Intervention Society (BCIS) (United Kingdom); 2. DESTATIS Statistische Bundesamt (Germany); 3. L'Agence technique de l'information sur l'hospitalisation (ATI) (France); 4. The National Board of Health and Welfare (Socialstyrelsen) (Sweden); 5. Nasjonalt Servicemiljø for medisinske kvalitetsregistre SKDE (Norway).</p> |
| <p>ix. Large-Scale Community Echocardiographic Screening Reveals a Major Burden of Undiagnosed Valvular Heart Disease in Older People: The OxVALVE Population Cohort Study. Available: https://www.phc.ox.ac.uk/publications/634128</p> | <p>xvii. British Heart Foundation, What's your heart age. Available: https://www.bhf.org.uk/heart-health/risk-factors/check-your-heart-age</p> | <p>xxviii. British Heart Foundation, Heart Valve Disease. Available: https://www.bhf.org.uk/heart-health/conditions/heart-valve-disease</p> |



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