Mitral and tricuspid valve replacement and repair

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4 Executive summary

This report aims to understand the diagnosis and treatment rates for patients with mitral and tricuspid valve (MTV) disease, which are the most common forms[1] of heart valve disease (HVD), to give an insight into the potential transcatheter treatment field in 2021 and beyond.

The data analysis undertaken as part of this report, although an approximation, highlights how woefully inadequate diagnosis and treatment is for this patient population. The number of patients left untreated is alarming. There is also an unacceptable variation in provision of services, and part of the reason for this is that the true prevalence of MTV disease is unknown. Currently the severity of disease is not coded within the Hospital Episode Statistics (HES) data, so it is impossible to know whether patients have mild, moderate or severe disease. It is essential that disease severity is coded explicitly and to compare who is providing good service.

Currently the number of percutaneous mitral valve leaflet repair (PMVLR) procedures commissioned is assumed to be 400 per year, rising to 450 over five years[2]. NHS England appreciate that this may be a low estimate but there is no current demand documented for increasing these numbers. The figures presented in this report suggest otherwise. Specialised Commissioning needs to provide enough funding and commissioning resources to meet the current demand of patients requiring intervention and to also devolve the commissioning responsibility down to Integrated Care Systems (ISCs).

The recently published GIRFT cardiology report[3] gives clear recommendations for HVD care. GIRFT is calling for a network approach to HVD, and with the imminent announcement of the cardiac clinical networks which have HVD as a priority, alongside new technologies coming onto the market, there is a real opportunity for transformation.

Cardiology is one of the 14 high-volume elective care specialities that form part of the Elective Care Transformation Programme[4] (ECTP); changes required include optimising outpatient pathways through triage, and initial diagnostic activity in the community through diagnostic hubs. It is vital that there are explicit referral pathways at a regional level for PMVLR and percutaneous tricuspid valve repair to address this low-volume highly-specialised intervention. GIRFT recommends that each tertiary centre should have a single point of entry into a pathway for the assessment and consideration for intervention, with rapid triage protocol and specialist heart valve multidisciplinary team (MDT) for consideration of patients for surgery or percutaneous interventions.

Action points

1. **Ensure explicit prevalence data on population likely to need intervention**
2. **Increase awareness and diagnosis rate**
3. **Highlight inequality and the 'treatment gap'**
4. **Make the case for the benefits of non-invasive intervention for the overall patient care pathway**
5. **Code HVD severity explicitly**
6. **Support COVID-19 recovery**
7. **Understand implications of system integration**
8. **Develop a formal integrated HVD care pathway**
9. **Workforce and capacity mapping**
10. **Lobbying for services**
11. **Technology procurement**

5 Background

There are four valves within the heart, mitral, tricuspid, aortic and pulmonic valves, which ensure that blood flows in only one direction. This report focuses on the mitral and tricuspid valves, referred to collectively as MTV, that sit between the atria and ventricles of the heart. Mitral and tricuspid regurgitation are the most common valve abnormalities on echocardiographic screening[1].

5.1 Mitral valve disease

The mitral valve allows blood to flow from the left atrium to the left ventricle. Mitral regurgitation (MR), sometimes called insufficiency, is the most common form of heart valve disease (HVD) and happens when the valve does not close properly and blood flows back into the atrium from the ventricle. The heart has to work harder to pump blood from the left ventricle to the aorta, resulting in an enlarged left ventricle. If not treated, this can lead to further problems including heart failure.

MR can be degenerative (primary or structural) or functional (secondary). Degenerative MR (DMR) is caused by 'wear and tear' to the chords and leaflets in the valve. In functional MR (FMR) the chords and leaflets are structurally normal but there is geometrical distortion of the sub-valvular apparatus caused by idiopathic cardiomyopathy or weakening of the cardiac walls caused by coronary artery disease (ischaemic MR). DMR is treated by surgery to repair or replace the mitral valve. FMR can be conservatively managed using drugs for treating heart failure but this is not curative, and surgical options such as undersized annuloplasty may be an option. However, people with MR of either cause are usually older (typically over 70 years) and frail, with multiple comorbidities. This increases the perioperative risks of morbidity and mortality for open heart surgery. For these patients, PMVLR may be an appropriate management option.

5.2 Tricuspid valve disease

Tricuspid regurgitation (TR) is a heart condition in which the valve between the two right heart chambers (right ventricle and right atrium) doesn't close properly and blood flows backward into the right atrium. Tricuspid valve disease often occurs with other heart valve problems, such as an enlarged right ventricle, infective endocarditis, and less commonly, Marfan syndrome, rheumatoid arthritis, rheumatic fever, injury, carcinoid tumours, and myxomatous degeneration.

TR may not have symptoms, or the symptoms may be vague, such as weakness and fatigue. These symptoms develop because the heart is not pumping enough blood to allow the body to receive the needed oxygen.

Treatment may not be required if the symptoms are not problematic; however, where treatment is needed, surgical valve repair or valve replacement usually corrects the condition. Those with untreated, severe TR may face a poor prognosis, either from the valve disease itself or because of the complications from the underlying condition causing the valve problem.

6 Prevalence and treatment data for mitral and tricuspid valve disease

MTV disease diagnosis rates are low, therefore analysis was undertaken using prevalence estimates to give an indication of the population size in England affected by these valve conditions. These patients will need either regular monitoring or treatment intervention of some kind so it is important that services are aware of the local population requiring care.

Without the availability of a prevalence estimate for MTV disease overall, the analysis has been performed using the estimated prevalence of MR and TR. Although this is not ideal, MR and TR represent the majority of MTV disease and therefore serve as a useful starting point to get a sense of the scale of MTV disease. This highlights that going forward it is important that there is a prevalence estimate available for all MTV disease so that services can get a true picture of the population requiring care.

It is already known that MTV treatment rates are very low, however the analysis quantified those patients undergoing MTV replacement or repair procedures to clarify the true picture, and also to highlight variation around the country. Using the estimated population prevalence of moderate-severe disease the analysis also sought to indicate the treatment gap between those receiving treatment and the number of people with a diagnosis.

6.1 Methodology

Data analysis was undertaken to estimate the prevalence of MR and TR among the population aged 65 years and over. This was estimated using the adjusted prevalence benchmarks from the Heart article by Cahill TJ, Prothero A, Wilson J, et al (2021)[5]. The benchmarks are as follows:

- Community prevalence of moderate or greater MR within adults aged ≥65 years is 3.5%
- Community prevalence of moderate or greater TR within adults aged ≥65 years is 2.6%

These benchmarks have been applied to ONS Mid-2019 Population Estimates[6] for CCGs and aggregated to ICS level.

Data was collated showing a count of the number of patients admitted to hospital as an inpatient with a diagnosis of either mitral valve (MV) or tricuspid valve (TV) disease over the three-year period 2018 to 2020 (inclusive). See Figure 20 in the appendix for the list of ICD-10 codes used. Also shown in Figure 1 is the number of patients diagnosed with MV or TV disease as a percentage of the estimated population with moderate-severe MR or TR. Note that this is an approximation, since there is no available estimate for the prevalence of MTV disease overall; MR and TR prevalence has been used instead.

The number of patients was analysed who had an inpatient diagnosis of MV or TV disease between 2018 and 2020 (inclusive) and who subsequently had a procedure of MTV replacement or repair (either within the same inpatient spell or in a subsequent spell). See Figure 20 in the appendix for the list of OPCS codes used. Patients treated with MV or TV replacement or repair was also shown as a percentage of the estimated incidence of moderate-severe MR or TR. Incidence has been calculated using the community prevalence of moderate-severe MR (3.5%) and the community prevalence of moderate-severe TR (2.6%) combined with ONS Mid-Year Population Estimates[6] for CCGs in mid-2017, mid-2018 and mid-2019.

The key data has been presented in maps alongside the four key treatment centres performing non-invasive MitraClip:

- Oxford University Hospital
- Royal Brompton Hospital
- University Hospitals Bristol
- Wythenshawe Hospital

The analysis highlights the treatment gap, i.e. the number of patients with a diagnosis yet currently going untreated. Part of the analysis includes treatment costs and clinical coding classifications for MV repair.

6.2 Summary

Our data analysis estimates that overall in mid-2019 there was a total of 631,577 people aged ≥65 years with moderate-severe regurgitation[7], compared to just 81,875 who received a diagnosis (annual average).

Figure 1: Summary of data analysis

	MV	TV
Prevalence estimate (population aged ≥65 years in mid-2019)		
Moderate-severe regurgitation[7]	362,380	269,197
Severe regurgitation[6]	141,328	78,336
Diagnosis (patients aged ≥65 years)		
MTV disease (2018-20)	171,200	74,425
Annual average (moderate-severe MTV disease)	57,070	24,810
% patients diagnosed MTV disease / estimated population moderate-severe MTV regurgitation	15.7%	9.2%
Treatment (patients aged ≥65 years)		
Valve replacement (2018-20)	2,925	230
Valve repair (2018-20)	4,705	1,230
Annual average	2,543	487
Treatment rate (patients aged ≥65 years)		
% patients treated with replacement or repair / estimated incidence moderate-severe MR or TR	44%	12%

6.3 Prevalence of valve disease

By applying Cahill et al's prevalence estimates[5] for moderate-severe MR and TR, the analysis found that in mid-2019 there were 10,353,716 people[6] in England aged ≥65 years, of which an estimated total of 362,380 had moderate-severe MR and 269,197 had moderate-severe TR[7].

Figures 2 and 3 show the data at ICS level. ICS populations aged ≥65 years range from 110,849 to 607,687, with between 3,880 and 21,269 people with moderate-severe MR (see Figure 2), and 2,882 to 15,800 with moderate-severe TR (see Figure 3).

This data gives an estimate of the population with moderate-severe MR and TR disease. However, severity of disease is not coded, so the extent of disease for these population estimates is not clear. However, by applying the prevalence for severe disease found in the study by Cahill et al (2021)[5], which was 39.0% for MR and 29.1% for TR, it is therefore estimated that there are 141,328 people with severe MR and 78,336 people with severe TR (see Figure 1). These are the patients who most urgently require diagnosis and treatment.

Figure 2: Estimated population with MR among people aged ≥65 years (mid-2019)[7]

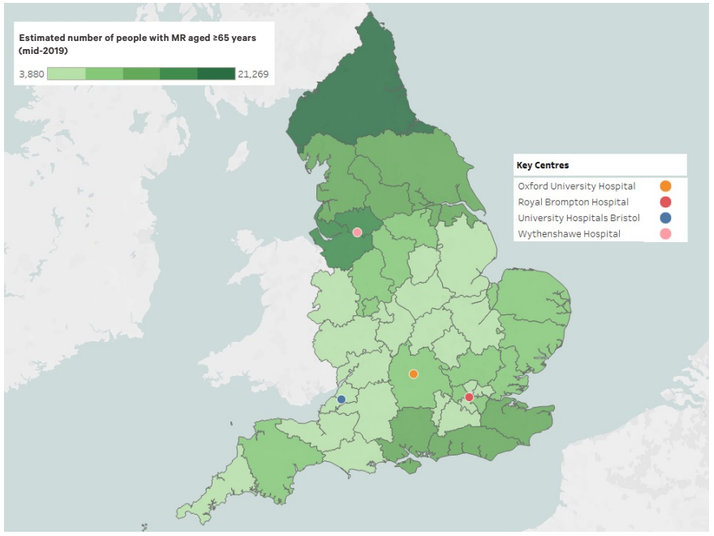
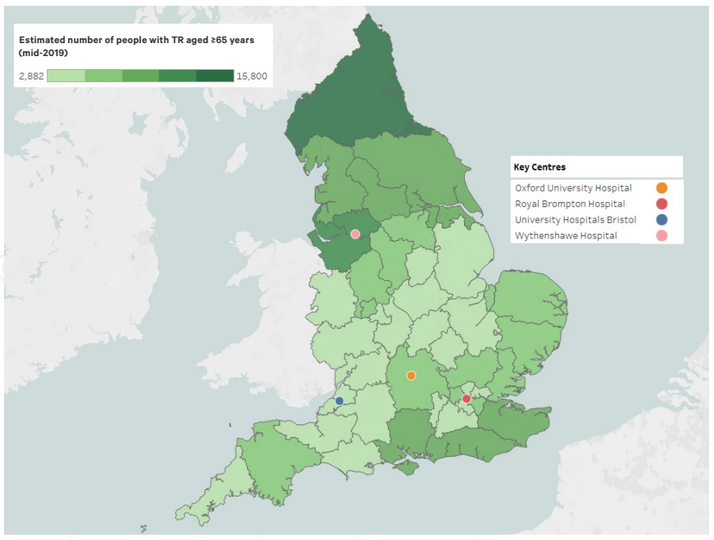


Figure 3: Estimated population with TR among people aged ≥65 years (mid-2019)[7]



1

Ensure explicit prevalence data on population likely to require intervention

Currently there is very poor understanding of the number of patients affected by MTV disease. For those with moderate-severe disease, it is essential that they are identified by services to receive the appropriate monitoring and intervention to achieve the best outcomes. The alternatives are conservative treatment or death. Integrated systems must understand the size of the patient population requiring care.

6.4 Diagnosis of MTV disease

This section on diagnosis refers more broadly to all forms of MTV disease, not just MR and TR (although the majority of these patients will have MR or TR). From 2018 to 2020 inclusive, a total of 171,200 people aged ≥65 years received a diagnosis of MV disease and 74,425 had a diagnosis of TV disease. At ICS level this ranged from 1,440 to 12,710 for MV (Figure 4), and 565 to 5,775 for TV (Figure 5).

These diagnosis figures for MTV disease are concerning, because an estimated 141,328 people alone have severe MV disease, and even more worryingly 78,336 are estimated to have severe TV disease which suggests that not all people with severe disease are receiving a diagnosis. There is also a huge geographical variation across England in terms of diagnosis rates for both MV and TV disease; this could be due to some areas having clear referral guidance and valve clinic MDTs; however, the variation is not centred around the NHS England designated treatment centres. It is unclear why some ICSs are diagnosing more patients than others, it could be down to interested clinicians.

Figure 4: Patients diagnosed with MV disease (2018 to 2020 inclusive)

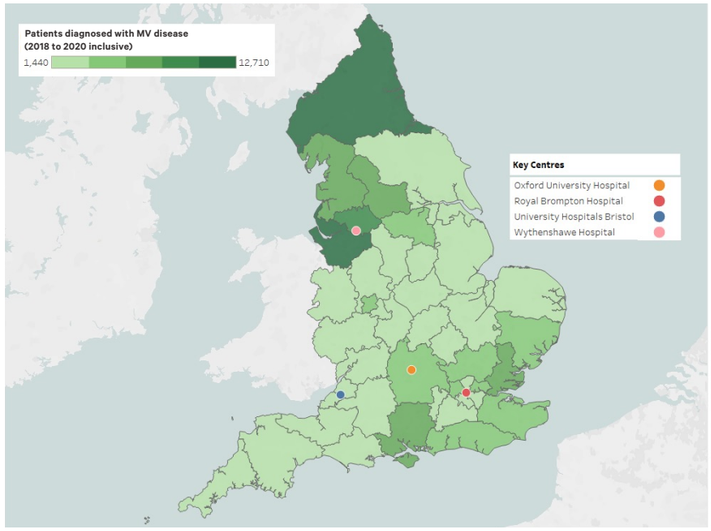
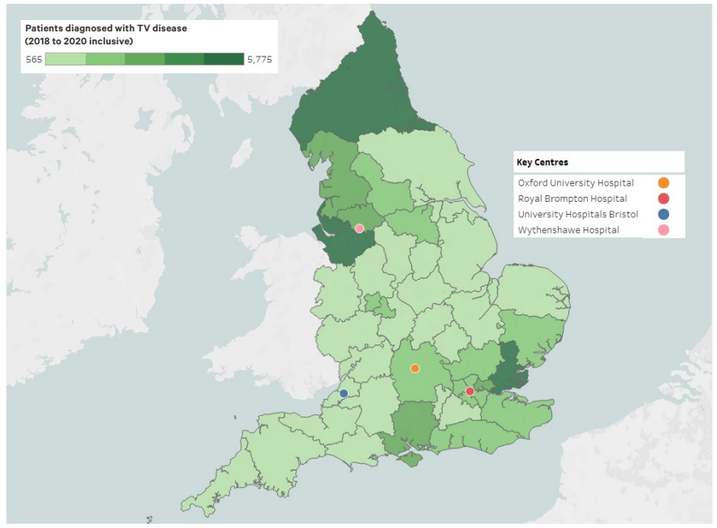


Figure 5: Patients diagnosed with TV disease (2018 to 2020 inclusive)



6.5 Relative diagnosis rate (as % of estimated population)

The proportion of patients aged ≥65 diagnosed with MV disease from 2018 to 2020 in England as a percentage of the estimated total population with MR in mid-2019 was only 47%; however, this varied widely by ICS from 26% to 82% (see Figure 6). For TV disease as a percentage of the estimated TR population, the diagnosis rate in England was just 28%, ranging enormously from a low of 11% right up to 95% at ICS level (Figure 7). Diagnosis rates and levels of variation are alarming, although bear in mind that the diagnosis rates presented here are an approximation (since there is no available estimate for the prevalence of MTV disease overall so MR and TR prevalence has been used instead) which is likely a significant overestimate of the rate of diagnosis. The true picture is likely to be even worse, although highlights the need for a prevalence estimate for all MTV disease so that services can accurately understand the population requiring care. The high level of variation in diagnosis rate could be related to an interested clinician based at a specialist centre.

Figure 6: Patients diagnosed with MV disease (2018 to 2020 inclusive) as a percentage of estimated population with MR (mid-2019)

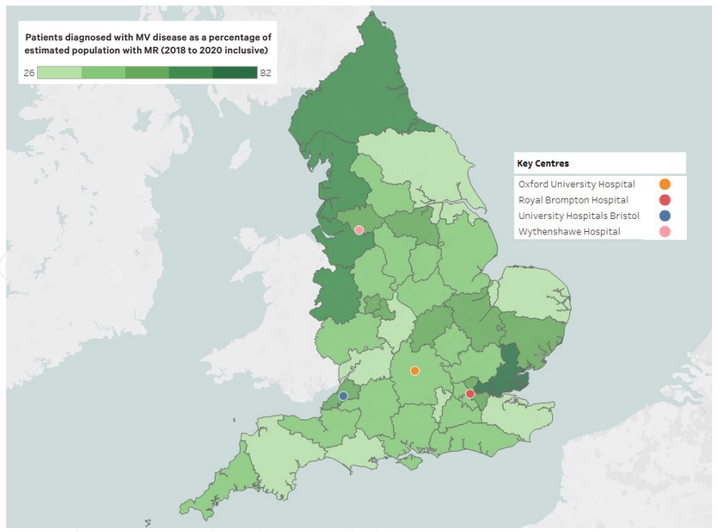
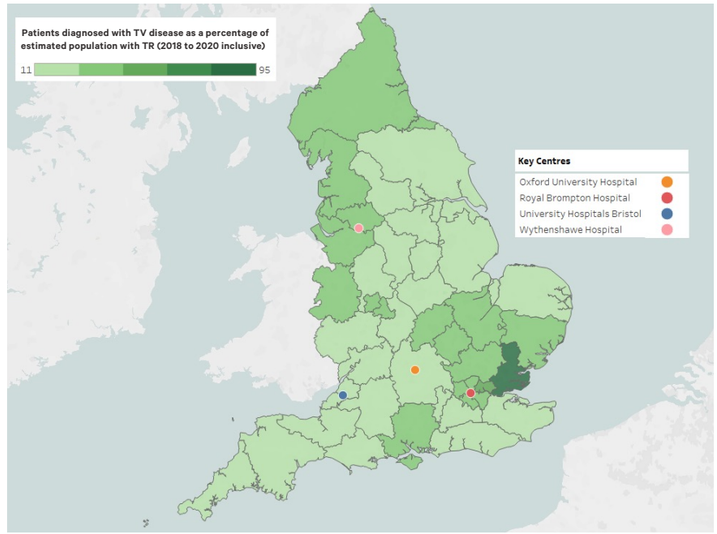


Figure 7: Patients diagnosed with TV disease (2018 to 2020 inclusive) as a percentage of estimated population with TR (mid-2019)



Improve awareness to increase the number of patients receiving diagnosis

2

Both public and primary care awareness of MTV disease needs to improve to ensure that patients are referred for diagnostics and identified sooner. Currently diagnosis of MTV disease is extremely low, with an unacceptable level of variation around the country causing concerning healthcare inequality. Without diagnosis patients cannot access the treatment they need. Services need to implement proactive measures to identify patients and must ensure that HCPs are aware of MTV disease and know how to refer patients effectively for specialist assessment. Since MTV disease requires specialist diagnostics, referral guidance would be at a regional or supra-regional level, rather than cardiac clinical network level.

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6.6 Mitral valve treatment

The analysis examined patients undergoing both MV replacement and repair treatments. Patients in England who were treated with MV replacement from 2018 to 2020 totalled 2,925 ranging from 25 to 205 by ICS (see Figure 8). For MV repair, a total of 4,705 patients received this treatment, ranging from 40 to 245 by ICS (see Figure 9).

Figure 8: Patients treated with MV replacement (2018 to 2020 inclusive)

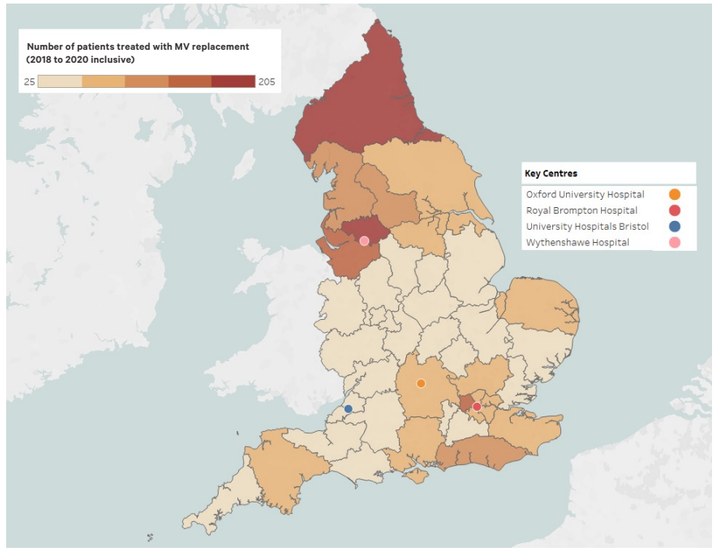
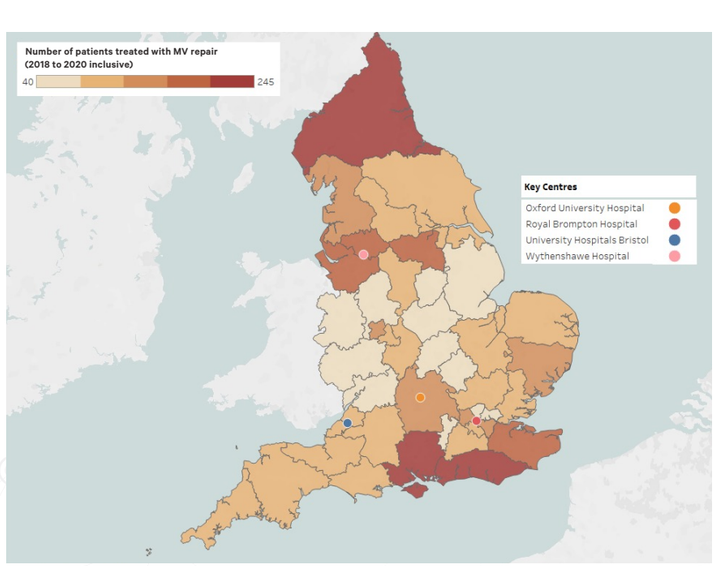


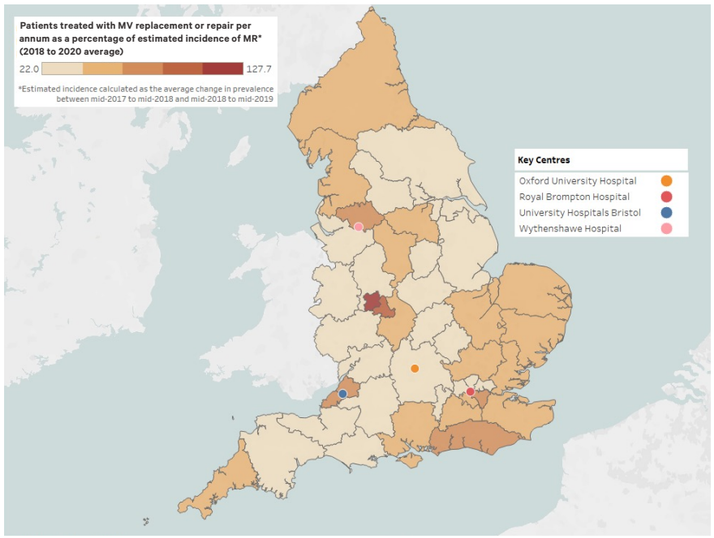
Figure 9: Patients treated with MV repair (2018 to 2020 inclusive)



6.7 Mitral valve treatment rate (as % of estimated incidence of MR)

Figures 8 and 9 show total numbers of patients who received MV treatment, whereas Figure 10 shows the MV treatment rate (replacement or repair) relative to the estimated incidence of severe-moderate MR. This helps to give a better idea of how ICSs are performing in terms of the proportion of patients being treated. The national average rate of treatment is very low – just 44% – although with wide variation, ranging from 22.0% (Shropshire, Telford and Wrekin ICS) to 127.7% (The Black Country and West Birmingham ICS). The reason the latter figure is very high may relate to the incidence rates only being an estimate (see methodology above) and also that this treatment rate is based on three years' data; there may have been a backlog from previous years causing an overload in this particular time period.

Figure 10: Patients treated with MV replacement or repair per annum as a percentage of estimated incidence of MR (2018 to 2020 average)



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6.8 Tricuspid valve treatment

Patients treated with TV replacement from 2018 to 2020 totalled 230, ranging from -1[9] to 20 by ICS (see Figure 11). For TV repair, a total of 1,230 patients received this treatment, ranging from 10 to 80 by ICS (see Figure 12).

Figure 11: Patients treated with TV replacement (2018 to 2020 inclusive)

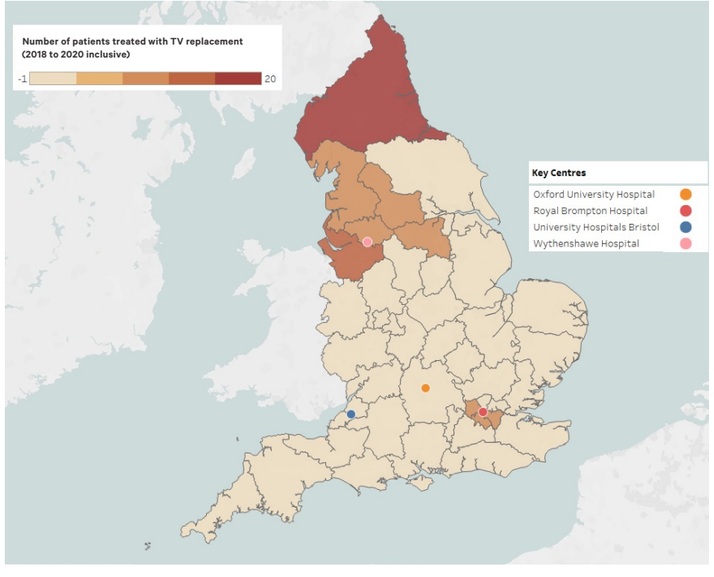
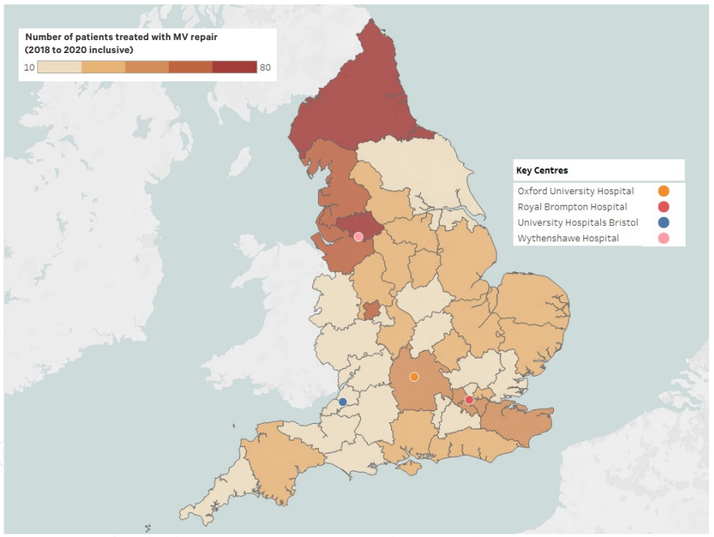


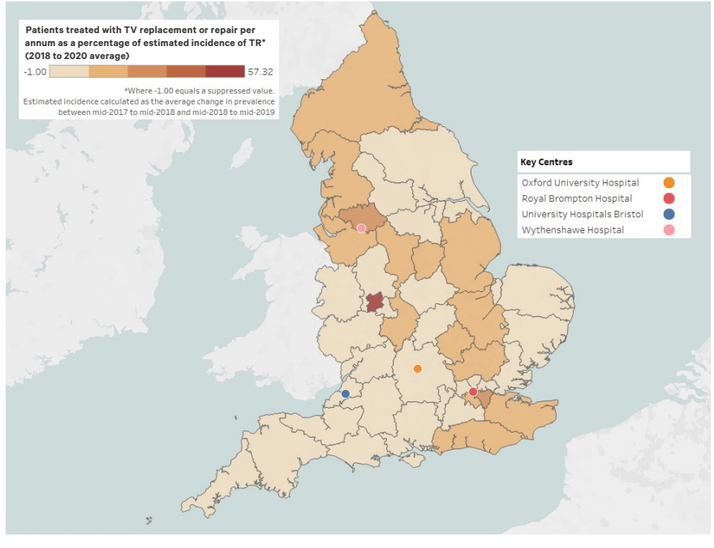
Figure 12: Patients treated with TV repair (2018 to 2020 inclusive)



6.9 Tricuspid valve treatment rate (as % of estimated incidence of TR)

Figure 13 illustrates the TV treatment rate (replacement or repair) relative to the estimated incidence of moderate-severe TR. The national average rate of treatment is extremely low at 12% but with relatively wide variation, ranging from -1.0%[10] (various ICSs) to 57.3% (The Black Country and West Birmingham ICS).

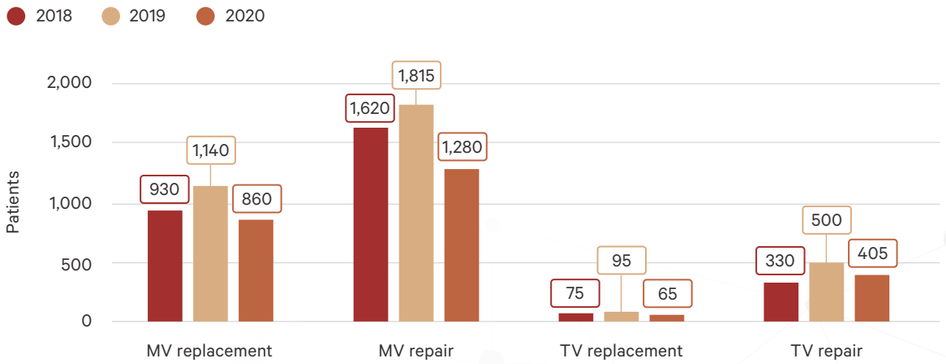
Figure 13: Patients treated with TV replacement or repair per annum as a percentage of estimated incidence of TR (2018 to 2020 average)



6.10 MTV treatment trend

Figure 14 shows a consistent increase across all interventions for patients treated with MTV replacement or repair between 2018 and 2019. These figures decreased noticeably in 2020, although this is to be expected since many procedures were postponed as a result of COVID-19.

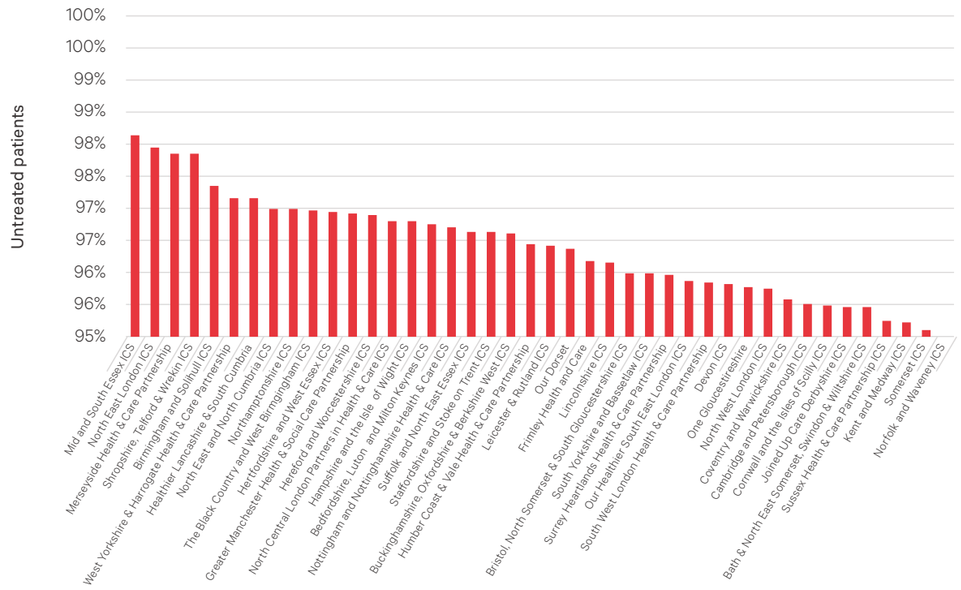
Figure 14: Patients treated with MTV replacement or repair by year, England (2018 to 2020 inclusive)



6.11 The treatment gap

The 'treatment gap' was calculated to show the percentage of patients who had an inpatient diagnosis of either MTV disease between 2018 and 2020 but did not receive valve repair or replacement at any time in the three-year period. On average, 97% of people in England diagnosed with MTV disease are left untreated – only 3% are treated with either MV or TV replacement or repair. This treatment gap is consistently high across ICSs, ranging from 95% to 98% of patients (see Figure 15). Given how underdiagnosed MTV disease is, it is reasonable to assume that this is a conservative estimate and that the true treatment gap is even wider. These results are supported by the findings of Cahill et al (2021) who found the rate of surgical intervention in subjects with MR or TR was extremely low[5]. Although in reality not everybody with moderate-severe disease would meet criteria for treatment, we can assume that a significant proportion should be receiving treatment with an intervention of some kind, especially those with severe disease who need urgent treatment. The stark undertreatment of this population does not bode well for patient mortality and quality of life.

Figure 15: Untreated patients - diagnosed with MTV disease but not treated with MTV replacement or repair as a percentage of all diagnosed patients (2018 to 2020 inclusive)



3 Highlight inequality and the 'treatment gap'

The alarming level of patients who go untreated must be highlighted. This creates a serious healthcare inequality between those few patients who get access to treatment, and the large majority who do not.

6.12 Treatment costs

Figure 16 shows the cost and hospital duration details for patients undergoing treatment. Cost per patient is fairly similar (£13,140 to £16,245) and mean length of stay (MLOS) ranges from 12 to 19 days.

Figure 16: Patients treated with MTV replacement or repair, England (2018 to 2020 inclusive)

Procedure	Patient count	MLOS	Mean pre-op duration	Mean post-op duration	Total cost	Cost per patient	Average elective waiting time (days)	Average time elapsed between initial diagnosis of insufficiency and treatment
MV replacement	2,925	18	2	12	£43,170,520	£14,760	63	146
MV repair	4,705	12	1	8	£61,825,100	£13,140	70	150
TV replacement	230	19	2	10	£3,444,330	£14,975	52	141
TV repair	1,230	18	1	12	£19,979,530	£16,245	65	169

MLOS is very high currently, if new procedures are brought to market that are less invasive and can reduce MLOS dramatically. This could be seen as very beneficial to systems as they try to recover from the pandemic and deal with the elective backlog as well as new patients presenting.

4 Make the case for the benefits of non-invasive intervention for the overall patient care pathway

It is important to underline the value that non-invasive intervention brings to the total care pathway compared with invasive surgery. This can make a significant difference in healthcare resource use: cost, MLOS, hospital throughput (how many patients can be treated in a day) and staff demand. This needs to be included in any value proposition for new technology coming to market. It is worth noting that due to the pandemic, many hospital trusts are increasing their critical care bed capacity going forward. This will allow more elective surgery to take place and presents an opportunity for more non-invasive procedures with the capability for patients to recover quickly.

Secondary care data is taken from the English Hospital Episode Statistics (HES) database produced by NHS Digital. Copyright © 2021, NHS Digital. Re-used with the permission of NHS Digital. All rights reserved.

6.13 Clinical coding for MV repair

Figure 17 gives patient number and cost data for MV repair based on three different coding classifications[11]. There is a marked difference in the patient count and cost per patient between code categories. This level of variation indicates a lack of consistent coding in HES which needs addressing with a standardised approach.

Figure 17: Clinical coding classification of MV repair, England (2018 to 2020 inclusive)

	Patients			Cost			Cost per patient		
Coding	**2018**	**2019**	**2020**	**2018**	**2019**	**2020**	**2018**	**2019**	**2020**
NHS Digital coding	30	45	45	£344,460	£549,785	£554,310	£12,300	£12,785	£12,595
GIRFT coding	35	50	50	£414,705	£624,375	£616,720	£12,565	£13,005	£12,335
HRG coding	325	300	195	£2,858,740	£2,807,675	£1,846,370	£8,825	£9,420	£9,515

Clearer coding is important for understanding disease burden and treatment needs of patients. Currently there is no coding category for the severity of HVD which is problematic because it limits our understanding of how many patients have mild disease and require active surveillance but not necessarily treatment for their condition. Without clear coding of the severity of disease, it cannot be deduced from the Hospital Episode Statistics (HES) data exactly how many people are eligible for treatment. Nonetheless, an extremely small percentage of patients diagnosed with MTV disease are subsequently undergoing valve replacement or repair. Even if a lot of patients have mild or moderate disease, a significant proportion will have severe disease and need urgent treatment before the window of opportunity is missed. GIRFT could assist with developing a uniform coding recommendation around HVD including a severity classification for valve disease patients.

5

Code HVD severity explicitly

Coding of disease severity needs to be explicit and it is important clinicians ensure documentation is accurate. It may be useful for clinicians to engage with their local coders to facilitate appropriate coding. Data flows should be addressed so that accurate numbers of these procedures can be provided to cardiac registries. Currently there is no requirement for data submission to the national registry (NICOR) – there could be a discrepancy between the national picture and reality due to the variation in coding and as such payments are not reflected.

7 Commissioning for MTV treatment

This section looks at commissioning of PMVLR and percutaneous tricuspid valve repair treatment. NHS England's Commissioning through Evaluation (CtE) programme has been the access route to PMVLR treatment; however, to date there has been no progress towards formal funding of this within the NHS. The best way to deliver services is to match demand with capacity and make the best use of resources through a network model. The shape and function of services should be dictated by local need. As we head towards 2022 it will be important to get a sense of how NHS system integration will affect service delivery for MTV patients.

7.1 Access to treatment through Commissioning Through Evaluation

Until now treatment for PMVLR has been enabled in England through the NHS England CtE programme, and it might be expected that a similar scheme would be set out for other technologies coming to market (e.g. for tricuspid valves). This programme enabled a limited number of patients to access treatments that showed significant promise for the future but were not funded by the NHS, and allowed the collection of new clinical and patient experience data within a formal evaluation programme.

There were two main phases to the PMVLR programme:

- **Phase 1:** an agreed number of patients were recruited to the CtE programme within a few selected centres across England. NICE identified the total number of patients required to support data analysis.
- **Phase 2:** the analysis phase tested the expected benefits of the treatment.

NHS England commissions CtE projects from NICE, and NICE manages the projects to a timescale, process and methods devised by NHS England.

In June 2017, NHS England published a policy document[12] governing these projects but the majority of the MitraClip scheme was developed, conducted and concluded before this document was published. The process followed is below:

- A cardiology CtE Steering Group was established by NHS England to oversee the project involving clinical leads and other stakeholders.
- NICE and the external assessment centre (EAC) worked closely with the steering group and with the MitraClip Individual Technology Group in the design of the MitraClip registry and to ensure data collection requirements and to reinforce clinical ownership of the project.
- NICE was accountable to Ann Jarvis, Programme Director (Clinical Strategy) for Specialised Commissioning at NHS England, for delivery of the CtE programme. For this scheme, NICE reported on a quarterly basis via standard reports and monitoring meetings with NHS England.
- The National Institute for Cardiovascular Outcomes Research (NICOR) was contracted by Newcastle and York EAC to design and host the online registry for MitraClip procedures, to provide a project management function and to promote data entry quality and completeness by commissioned CtE centres.
- NICE published the evaluation report[13] in March 2019.
- The CtE programme evaluated MitraClip; the 'Clinical Commissioning Policy: Percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation in adults' was published in July 2019[2].

There has been no progress following the pandemic. The technology has not been launched and therefore minimal evaluation has taken place. This raises the question of why access to PMVLR treatment goes through the route of CtE, and with such a restrictive cap on numbers, when the data analysis in this report highlights the large burden of unmet need for MTV disease. Far too many patients go undiagnosed and do not receive treatment, which results in very poor mortality and quality of life outcomes. New valve technologies that come to market need to be adequately funded so as to meet the clinical demand without any arbitrary capacity capping and ensuring sufficient funds are provided to treat patients with severe disease.

The criteria for commissioning PMVLR needs to be explicit for patients with symptomatic severe MR. These individuals must have access to assessment by a specialist heart valve team, which may be at a regional level, who have the capability to undertake valve repairs. However, these patients should not be assessed as inoperable or very high risk, and teams should opt for minimally invasive treatment which should be lobbied for as a priority. It seems that a very high bar is set for non-invasive treatment, which is perhaps due to teams in the UK having limited clinical experience, although once trained in these procedures it should become more the norm, especially following the pandemic. Given the new technology coming to market is it important to gain consensus on the appropriate eligibility criteria. Patients should be assessed as having a high likelihood of procedural and medium-term successful outcomes with respect to effective and durable reduction in mitral regurgitation. Individual improvement in symptoms, quality-of-life, and functional status as well as survival must be considered.

Patients will be classified as having a very high or inoperable surgical risk using the Society of Thoracic Surgeons' calculator or logistic EuroSCORE surgical risk scores, assessment of frailty, significant organ dysfunction

and co-morbidities. Additional factors that may preclude surgery include severe mitral annular calcification, the presence of a 'hostile chest', e.g. prior mediastinal radiation or chest malformation, patent left internal mammary artery bypass graft crossing the midline or prior tracheostomy.

7.2 Recent updates

Following publication of commissioning policy there was a hiatus before procedures were undertaken. Initially three sites were chosen to be providers of PMVLR so that England was covered in the North, South and London. These were:

- Royal Brompton Hospital, London
- University Hospital Bristol, South West
- Wythenshawe Hospital, North

In 2020, clinicians felt the only service that was working well is the Royal Brompton Hospital; Bristol has done very few procedures and so too has Oxford University Hospitals NHS Trust (not specifically commissioned).[14]

To expand the overall provider base NHS England asked for expressions of interest so that each of the seven regions would have a provider. The market testing for expressions of interest has been completed but due to the COVID-19 second wave the national/regional work programme was reprioritised. Regions have said that PMVLR was not a high priority so it is on hold right now but may resume in April 2021 (post wave 2 surge). It will be interesting to see if this will change as we emerge from the pandemic. The COVID-19 pandemic has highlighted the fragility in the system and provides justification for service change. Maximal use should be made of virtual clinics where possible, to avoid the need for patients to travel on multiple occasions to specialist centres.

6

Support COVID-19 recovery

The pandemic has brought challenges for the delivery of services but undertaking this percutaneous procedure is less invasive and can rapidly treat patients at a time when reduction in hospital stay and contact, and increase of hospital throughput to reduce the backlog, is essential. This point needs to be reinforced for NHS reset.

Now that the GIRFT cardiology report[3] has been published, and details of the cardiac clinical networks are expected to be announced shortly, HVD will be made a priority and therefore MTV disease will be getting more focus, and there should be at least seven regional centres for care. It is clear that the way cardiology services are commissioned, planned and delivered needs to change. The current service is focussed around hospitals rather than pathways which is detrimental to patients and risks inappropriate duplication of service provision and inadequate and variable access to care. The hope is that the momentum from GIRFT and the cardiac clinical networks will help drive these changes.

Clear referral pathways need to be established across these clinical networks to enable patients timely access to diagnosis and treatment. The best way to deliver cardiology services is to match demand with capacity and make the best use of resources through a network model. The British Heart Valve Society published its framework for network-based care of heart valve disease[15] in 2020. Each network should have a formal pathway agreed for the assessment, surveillance and referral of patients with HVD, with the shape and function of services dictated by function and local need.

Heart valve centres should provide replacement of valves in all four positions, mitral or tricuspid repair, aortic root and ascending aortic surgery, surgical atrial fibrillation ablation, and transcatheter aortic valve implantation (TAVI). The heart valve centre should ensure an adequate volume of procedures per centre and operator to maintain the competency level and optimal outcomes (see Figure 18[15]). This would mean that treatment would need to be provided in fewer centres, probably at a regional level as the GIRFT report suggests, but this would be an evolving picture as more centres become able to treat patients in the future. Where appropriate, patients should be informed of techniques not available at their centre of care and should be offered referral elsewhere. Examples include the Ross procedure, aortic valve repair, and the transcatheter mitral procedures.

Figure 18: Types of procedures and minimum volume of procedures[15]

Procedure	Heart valve centre	Individual operator
Mitral procedures (repair and replacement)	100	50
Percutaneous mitral edge-to-edge repair	25	NA
Aortic valve replacement	100	25
Aortic root replacement	40	NA
TAVI	75	40

These figures are based on expert consensus or retrospective analyses. Excellent results confirmed by external audit are more important than volume targets. However, excellent results are more likely with high volume operators in high volume centres.

NA, no consensus available

7.3 System integration and Specialised Commissioning

Cardiology operates through both local commissioning (primary and secondary care) and specialised commissioning (tertiary and quaternary care). Currently Specialised Commissioning covers: transcatheter therapies for heart valve disease, such as transcatheter aortic valve implantation (TAVI), cardiac surgery including provision of surgical interventions for coronary revascularisation, and valve disease requiring surgical valve repair or replacement.

Since publication of The NHS Long Term Plan[16] (2019) NHS England and NHS Improvement, the Department of Health and Social Care have published their legislative proposals for the NHS[17] (2021). This sets out plans on how they will give ICSs greater say in the way the Specialised Commissioning budget is spent in their area. Whilst NHS England will remain directly responsible for the funding and commissioning of specialised services at a national level, new arrangements will be developed giving ICSs an advisory role in the planning and prioritisation of specialised services and allocation of resources, and ICSs could seek delegated powers to commission specialised services. One of these arrangements involves the establishment of new NHS England-led Specialised Services Planning Boards in each ICS. Full details are awaited about which specialised commissioning services will be delegated to ICSs.

It is now known that from April 2023 a large part of Specialised Commissioning will be devolved to the ICSs to manage. However, the budget details are yet to be announced. It may be that ICSs are designated the funds allowing them to commission appropriately for their population.

Provider organisations will play an active and strong leadership role in systems and will help to set system priorities and allocate resources. Clinical networks at system, regional and national level will also have important roles in decisions about clinical pathways and clinically-led service change; however, how they interact with and geographically align with ICSs is not clear yet and could create a layer of complexity in the system. What is clear is that the new system-led approach will focus care on the overall patient journey, with end-to-end cost a major factor. It will be worthwhile to map out the ideal gold standard care pathway as there is generally a lack of awareness within commissioning around the true impact of the type of intervention selected.

7

Understand implications of system integration

There needs to be greater understanding of the implications of system integration within the NHS and relationships between the ICSs and Specialised Commissioning in terms of service delivery for PMVLR. At a regional level, services will still require the cardiac networks to lead the agenda with ICSs – it will be interesting to see to what extent the boundaries of the cardiac networks align with those of the ICSs. There is confusion in the system around funding from April 2022; COVID-19 has impacted budget planning in 2020 and there is difficulty in predicting service need for the future year. While this report presents some of the data, a detailed pack for each ICS will need to be produced containing in-depth coding that allows systems to establish their local need and enable them to commission appropriately.

8 Formal integrated care pathways for MTV disease

The GIRFT cardiology report[3] advises that all networks must have pathways in place for the diagnosis and management of patients with heart valve disease, including referral to specialist teams at a tertiary centre. However, currently there are no explicit pathways for PMVLR. Most procedures are undertaken at the Royal Brompton Hospital but other clinicians, in Oxford for example, have undertaken the procedures both locally and in the USA and have good expertise and vision for development of services.

Pathway development needs to be a priority:

1. Single point of entry into a pathway for the assessment and consideration for intervention in tertiary services.
2. Rapid triage protocol for direction of obvious cases.
3. Referrals to be made to the relevant heart team and not to an individual cardiologist.
4. Each network should have a mitral/tricuspid MDT for consideration of patients for surgery or percutaneous interventions.
5. Formal referral pathways need to be in place and may be to another network for low-volume highly specialised interventions like PMVLR.

The COVID-19 pandemic has brought challenges for the delivery of services but undertaking this percutaneous procedure is less invasive and can rapidly treat patients at a time when reduction in hospital stay and contact is essential. This point needs to be reinforced for NHS reset. Digital tools are an important part of service transformation, especially following COVID-19. Services should make full use of virtual clinics and results of all investigations, irrespective of where they are performed, should form part of a continuous NHS record of care so they are accessible anywhere.

Develop a formal integrated HVD care pathway

8

A formal integrated pathway needs to be developed and agreed and centres undertaking the procedure be made explicit. This would enable a clear referral pathway from the community diagnostic hubs into the multidisciplinary team for specialist management of mitral and tricuspid valve disease and would raise the profile of the role of HCPs in the community around HVD.

Central to the care pathway for MTV patients is the specialist MDT, which includes cardiac physiologists, pharmacists, and radiologists. All networks must provide a specialist heart valve MDT that can review and rapidly triage MTV patients, and that can meet at least weekly to discuss complex cases.

The national shortfall of cardiac physiologists is a concern, as is the shortfall of echocardiographers which is another important aspect of workforce planning for the diagnosis of MTV disease. Echocardiography services should be provided seven days per week to facilitate patient flows and to maximise throughput; however, currently, only just over half (51%) of trusts are doing so[3]. To achieve this there will need to be regional-level workforce planning.

Figure 19: Good practice recommendations for mitral valve MDT meetings[15]

Objective	Frequency	Documentation	Participants
• Review clinical data and imaging of all patients considered for mitral valve surgery. • Determine indication for intervention. • Determine appropriateness of intervention and frailty (especially in multi-morbid or elderly patients). • Determine risk of intervention. • Determine likelihood of repair in primary MV disease. • Assign repairable primary MV disease to a mitral repair surgeon with volumes and results meeting quality targets. • Consider trans-catheter interventions. • Clinico-pathological feedback. • Discussion of all adverse events in order to share learning and minimise risk of recurrence.	At least weekly, or more frequently depending on hospital case volumes.	Documentation should include: • Date of MDT • participants • outcome • communication with patient, GP, referrer. MDT outcome database maintained to audit against actual intervention.	• **Key member** Mitral valve surgeon. • **Key member** Cardiologist with expertise in HVD ± imaging. • **Key member** Physiologist/scientist with expertise in imaging. • **Key member** Valve nurse. • **Key member** MDT administrator. • **Key member** Structural interventionist. • **Desirable member** Heart failure specialist (especially for patients with secondary mitral regurgitation or decompensated HVD). • **Other members can include:** Electrophysiologist, Microbiologist, Care of the Elderly physician, etc., depending on the case.

Workforce and capacity mapping

9

Identification of competent workforce and detail of the required team for MTV interventions and capacity mapping:

- Structural heart disease coordinator
- Cardiologist with expertise in valve disease/imaging
- Interventional cardiologist
- Cardiac surgeon
- Care of the elderly consultant as required
- Cardiac anaesthetist.

9 Commissioning and procurement

The current state of play for treatment commissioning is woeful. Lobbying is needed to prompt an overhaul of the services provided to MTV patients. Following the publication of the GIRFT cardiology report and the introduction of the new cardiac clinical networks, there is a significant opportunity to put HVD on the map – however, this must include MTV disease. This needs to be adequately funded and supported by clear referral guidelines so that symptomatic severe patients can access treatment.

There was overwhelming agreement[14] from clinicians that they should be involved in the commissioning and procurement of services such as PMVLR. Opinion is that this should be removed from central commissioning with organisations such as the British Cardiovascular Intervention Society (BCIS) used to lobby for retention of the clinical voice. This should now come from the cardiac clinical networks.

10

Lobbying for services

It is essential that there is expansion of the number of MTV patients that can be treated. Therefore the NHS England cap would have to be scrapped to allow for a 10- or 20-fold increase of the current level per year. Even at network level, patients are travelling long distances for treatment which would be addressed by making treatment available in more centres.

Currently the Department of Health and Social Care Procurement Transformation Programme[5] (PTP) articulates a similar national procurement approach in the new NHS Supply Chain Operating Model. The Specialised Commissioning High-Cost Tariff-Excluded Devices programme aims to reduce pricing variation and drive transparency, while providing value for money, accelerating the adoption of effective new technologies and delivering savings for the NHS from procurement opportunities via NHS Supply Chain partners.

NHS England Specialised Commissioning and NHS Supply Chain are working with NHS providers to support migration to the new model and to proactively resolve any issues during implementation. The system should see improved clinical practice and device optimisation, as clinicians will be able to choose the best device for the patient from a clinically-evaluated, evidence-based catalogue, although there is concern that devices on offer will be the cheapest rather than best quality option.

The new national Expert Reference Group on devices is going to pilot cardiac devices and work with Specialised Commissioning's existing Device Working Groups. New valve technologies will go through this route; the Device Working Group will be the key decision maker on clinical value of new products.

The Structural Heart Framework is anticipated to go live in June 2021; a separate framework for PMVLR and replacement devices is expected in September 2021.

11

Technology procurement

GIRFT's cardiology report should carry weight for enabling the appropriate procurement. The technology should be available for both degenerative and functional mitral valve regurgitation (MR) but prevalence needs to be explicit. Introduction of specific coding for degenerative and functional regurgitation would be valuable.

10 Conclusion

There is an opportunity now, following the publication of The NHS Long Term Plan[16] which made cardiac disease a priority and GIRFT's clear recommendations for a network approach to HVD, and with the imminent announcement of the cardiac clinical networks which have HVD as a priority, alongside new technologies coming onto the market. We could be on the cusp of a treatment revolution. However, this will need to be resourced appropriately in order to meet the demand, as the data analysis in this report indicates that current provision is woefully inadequate. Our analysis also highlights the need for prevalence estimates for MTV disease so that services can more accurately understand the local population in need of MTV care. Action to improve care and outcomes for people with MTV disease, around the points below, should ultimately be centred around patients.

Action points:

1. **Ensure explicit prevalence data on population likely to need intervention**
2. **Increase awareness and diagnosis rate**
3. **Highlight inequality and the 'treatment gap'**
4. **Make the case for the benefits of non-invasive intervention for the overall patient care pathway**
5. **Code HVD severity explicitly**
6. **Support COVID-19 recovery**
7. **Understand implications of system integration**
8. **Develop a formal integrated HVD care pathway**
9. **Workforce and capacity mapping**
10. **Lobbying for services**
11. **Technology procurement**

11 Abbreviations

CtE	Commissioning Through Evaluation (NHS England programme)
DMR	Degenerative mitral regurgitation
DWG	Device Working Groups
EAC	External Assessment Centre
ECTP	Elective Care Transformation Programme
FMR	Functional mitral regurgitation
FRP	Financial Reconciliation Process
GIRFT	Getting It Right First Time
HES	Hospital Episode Statistics
HRG	Healthcare Resource Group
HST	Health Solutions Team
HVD	Heart valve disease
ICS	Integrated care system
IDI	In depth interview
MDT	Multidisciplinary team
MLOS	Mean length of stay
MR	Mitral valve regurgitation
MV	Mitral valve
NICE	National Institute for Health and Care Excellence
NICOR	National Institute for Cardiovascular Outcomes Research
NOM	New operating model
OPCS	Office of Population Censuses and Surveys (Classification of Interventions and Procedures)
PbR	Payment by results
PMVLR	Percutaneous mitral valve leaflet repair
PRIS	Papworth Referral Information System
PTP	Procurement Transformation Programme
MTV	Mitral and tricuspid valve
TR	Tricuspid valve regurgitation
TV	Tricuspid valve
VCM	Visible Cost Model

12 Appendix

Figure 20: Diagnosis and procedure codes

ICD-10 code	Diagnosis description
Mitral valve disease	
I050	Mitral stenosis
I051	Rheumatic mitral insufficiency
I052	Mitral stenosis with insufficiency
I058	Other mitral valve diseases
I059	Mitral valve disease, unspecified
I340	Mitral (valve) insufficiency
I342	Nonrheumatic mitral (valve) stenosis
I348	Other nonrheumatic mitral valve disorders
I349	Nonrheumatic mitral valve disorder, unspecified
Tricuspid valve diseases	
I070	Tricuspid stenosis
I071	Tricuspid insufficiency
I072	Tricuspid stenosis with insufficiency
I078	Other tricuspid valve diseases
I079	Tricuspid valve disease, unspecified
I360	Nonrheumatic tricuspid (valve) stenosis
I361	Nonrheumatic tricuspid (valve) insufficiency
I362	Nonrheumatic tricuspid (valve) stenosis with insufficiency
I368	Other nonrheumatic tricuspid valve disorders
I369	Nonrheumatic tricuspid valve disorder, unspecified

OPCS code	Procedure description
Mitral valve replacement	
K251	Allograft replacement of mitral valve
K252	Xenograft replacement of mitral valve
K253	Prosthetic replacement of mitral valve
K254	Replacement of mitral valve NEC
Mitral valve repair	
K255	Mitral valve repair NEC
K258	Other specified plastic repair of mitral valve
K259	Unspecified plastic repair of mitral valve
Tricuspid valve replacement	
K271	Allograft replacement of tricuspid valve
K272	Xenograft replacement of tricuspid valve
K273	Prosthetic replacement of tricuspid valve
K274	Replacement of tricuspid valve NEC
Tricuspid valve repair	
K275	Repositioning of tricuspid valve
K276	Tricuspid valve repair NEC
K278	Other specified plastic repair of tricuspid valve
K279	Unspecified plastic repair of tricuspid valve

13 References and notes

1. Singh JP, Evans JC, Levy D, et al. Prevalence and clinical determinants of mitral, tricuspid, and aortic regurgitation (the Framingham heart study). Am J Cardiol 1999;83:897–902.
2. NHS England (2019) Clinical Commissioning Policy: Percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation in adults. Available at: **https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2019/07/Clinical-Commissioning-Policy_Percutaneous-mitral-valve-leaflet-repair-for-primary-degenerative-mitral-regurgi.pdf** (accessed September 2021).
3. GIRFT (2021) Cardiology: GIRFT Programme National Specialty Report. Available at: **https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2021/08/Cardiology-Jul21k-NEW.pdf** (accessed September 2021).
4. NHS England, Elective Care Essentials Programme. Available at: **https://www.england.nhs.uk/elective-care-transformation/elective-care-essentials-programme/** (accessed September 2021).
5. Cahill TJ, Prothero A, Wilson J, et al. Community prevalence, mechanisms and outcome of mitral or tricuspid regurgitation. Heart. 2021 Mar 4;heartjnl-2020-318482.
6. ONS Mid-2019 Population Estimates for Clinical Commissioning Groups (CCGs) in England by Single Year of Age and Sex. Available at: **https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/datasets/clinicalcommissioninggroupmidyearpopulationestimates** (accessed September 2021).
7. Estimated using the adjusted prevalence benchmarks from the Heart article by Cahill TJ, Prothero A, Wilson J, et al (2021)[5]. The benchmarks are as follows: community prevalence of moderate or greater MR within adults aged ≥65 is 3.5%; community prevalence of moderate or greater TR within adults aged ≥65 is 2.6%. These benchmarks have been applied to ONS Mid-2019 Population Estimates for CCGs and aggregated to ICS level.
8. Estimated using the prevalence of severe regurgitation clinical and echocardiographic characteristics of patients in Cahill TJ, Prothero A, Wilson J, et al (2021)[5]. Severe MR 39.0% and severe TR 29.1%.
9. Represents low number suppression.
10. Represents low number suppression.
11. **NHS Digital Coding:** Using the clinical coding classifications provided by NHS Digital, these counts are based on each of the following OPCS codes being present within the same spell:
    - K25.5: Mitral Valve Repair Nec
    - Y07.2: Clipping of organ Noc
    - Y53.4: Approach to organ under fluoroscopic control
    - U20.2: Transoesophageal echocardiography.

    GIRFT Coding: These counts are based on the recommendations of an GIRFT expert coder and require the following OPCS codes being present within the same spell:
    - K25.5: Mitral Valve Repair Nec
    - Y07.2: Clipping of organ Noc
    - Either Y53.4: Approach to organ under fluoroscopic control or Y78.1: Arteriotomy approach to organ using image guidance fluoroscopy.

    HRG Coding: The final classification is based on an OPCS code of K25.5: Mitral Valve Repair Nec being present in a spell alongside a HRG code of ED25C - Standard, Single Heart Valve Replacement or Repair.
12. NHS England (2017) Methods: Commissioning through Evaluation. Available at: **www.england.nhs.uk/wp-content/uploads/2017/06/methods-commissioning-through-evaluation.pdf** (accessed September 2021)
13. NICE (2019) Interventional procedures guidance [IPG649]. Percutaneous mitral valve leaflet repair for mitral regurgitation. Available at: **https://www.nice.org.uk/guidance/ipg649** (accessed September 2021).
14. Wilmington Healthcare (2020) Edwards Pascal Mitral Valve Repair System: Market Research.
15. British Heart Valve Society (2020) Network based care for heart valve disease. Available at: **https://www.bhvs.org.uk/wp-content/uploads/2020/05/BHVS-Blueprint_2020.pdf** (accessed September 2021).
16. NHS (2019) The NHS Long Term Plan. Available at: **www.longtermplan.nhs.uk** (accessed September 2021).
17. Department of Health and Social Care (2021) Integration and innovation: working together to improve health and social care for all. Available at: **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/960549/integration-and-innovation-working-together-to-improve-health-and-social-care-for-all-print-version.pdf** (accessed September 2021).

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