FINAL REPORT OF THE TAVI REVIEW GROUP:

NATIONAL PLANNING FORUM SUBGROUP

NOVEMBER 2010
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EXECUTIVE SUMMARY

1. Introduction
Severe symptomatic aortic stenosis is the most common valvular heart disease in the western world affecting 3% of those aged over 75. Without treatment mortality rates are as high as 50% at one year. The most effective treatment is to replace the valve through open heart surgery.

Transcatheter aortic valve implantation (TAVI) is an alternative treatment to conventional aortic valve replacement (AVR). It is less invasive and can be carried out without opening the chest cavity.

TAVI was introduced in 2002 and is widely available in the USA, Europe and the UK. In the UK around 1000 TAVI procedures have now been performed. There are two main valve systems available provided by different manufacturers. Both are currently used in centres across the UK.

2. Evidence Base
UK and European guidance states that TAVI should only be considered for those who are considered ‘inoperable’ or at ‘high mortality risk’ for conventional AVR, due to limited evidence of clinical efficacy and lack of evidence on cost-effectiveness. There is a lack of standardisation of the definitions of ‘inoperable’ and ‘high risk’ as they are primarily based on clinical judgement.

There are no published randomised controlled trials (RCT) comparing TAVI with AVR. There is one published RCT, the PARTNER trial, which compares TAVI with standard treatment in patients considered ‘inoperable’ for AVR. TAVI was shown to significantly reduce mortality at one year compared to standard treatment (31% versus 51%). However, with regard to safety TAVI was associated with a significantly higher incidence of major strokes and vascular complications. In terms of outcomes there is a lack of RCT data beyond one year. Provisional data from the PARTNER trial on quality of life suggests improvements in TAVI patients compared to controls.

3. Needs Assessment
The exact population need for TAVI is unknown and there is variation in opinion on the need for TAVI. The UK TAVI consensus meetings have estimated a population need of 16/million. Data from the UK TAVI registry show that in 2009 the mean population demand in England was 9.9/million, although this demand is restricted in some areas, for example by capping. The group thought that a current population demand for Scotland might be around 10/million, bearing in mind the practicalities of establishing a new service. This equates to 50 TAVI procedures per year.

Data from the UK TAVI registry show that there is huge variation in the numbers of patients defined as ‘inoperable’, reflecting the lack of standardisation in the definition. Therefore it is very difficult to make a clear distinction between inoperable and high risk patients and accurately quantify their numbers. However, expert opinion suggests a 50:50 split.
The prevalence of aortic stenosis and need for valve replacement will increase over time due to the ageing population. The need for TAVI is also likely to change as additional clinical and cost effectiveness data become available.

Capping of TAVI numbers has been applied in some English centres and should be considered in Scotland. Capping ensures that numbers and costs are controlled where need and demand are uncertain.

4. **Principles and Requirements of TAVI Service**

A minimum interventional cardiology infrastructure and arrangements to manage complications are required for any TAVI Centre. There should be proctorship by an established centre initially. Audit, collection of cost data and research participation should be undertaken.

Larger volume surgical centres are recommended and a minimum number of cases per year is thought to be between 25 and 50.

Consistency in patient selection is essential for TAVI. The multidisciplinary team has a key role in ensuring consistency of patient selection for TAVI, based on need and capacity to benefit. A Scotland wide multidisciplinary team would be expected to improve equity of access to TAVI across Scotland and provide country wide consistency in patient selection.

The majority of TAVI centres have insufficient numbers to be able to provide more than one valve type. There is differing opinion as to whether having access to more than one valve type is advisable. Developments in technology are likely to reduce the need for more than one valve type.

5. **Costs of Providing TAVI for Scottish patients**

There is a lack of robust cost data. Evidence from a sample of patients sent to England for TAVI from Scotland suggest a higher cost per case than that estimated by TAVI service business cases.

The cost of providing a service does depend on whether a TAVI procedure is deemed a ‘replacement’ for open surgery or an ‘additional’ treatment for previously inoperable patients. This is because the costs of TAVI can be offset against the costs of surgery in ‘high risk’ patients who would have been operated on. The costs cannot readily be offset against patients who were previously judged inoperable. Although hospital admission may be reduced.

- There is very limited cost data available for TAVI and all cost estimates have major limitations.
- The estimated minimum cost per patient for TAVI is £21,059 as a new procedure. As a replacement for AVR in ‘high risk’ patients a minimum additional cost of £2,582 is expected. However, actual costs may be nearer £44,000 as a new procedure and £26,000 as a
replacement. Over time though this is expected to reduce as clinical experience grows.

- For a population need of 10/million the cost of a TAVI service in Scotland is likely to range from £64,550 to £2,210,650 dependent on the accuracy of cost estimates, arrangements for TAVI provision and the population chosen to be eligible. The current costs of TAVI procedures for Scottish patients treated in England could be offset against this.

6. Summary of Options

Options for a TAVI Service in Scotland

OPTION 1
A TAVI service should not be made available. Any requests for TAVI should be assessed on an individual patient basis by health board exceptions panels.

OPTION 2
A TAVI service should be made available as a new treatment for patients considered ‘inoperable’ for conventional AVR, who otherwise have a reasonable life expectancy and capacity to benefit.

OPTION 3
A TAVI service should be made available for patients identified as having ‘high mortality risk’ with conventional AVR, as a replacement procedure.

OPTION 4
A TAVI service should be made available for ‘inoperable’ patients and for ‘high risk’ conventional AVR patients, as a replacement procedure.

Potential TAVI Service Delivery Options

OPTION A
Patients referred to an English TAVI service for treatment.

OPTION B 1
1 TAVI service in Scotland providing treatment at 1 site with 1 staff team.

OPTION B 2
1 TAVI service in Scotland providing treatment at 2 sites with 1 staff team.

OPTION B 3
1 TAVI service in Scotland providing treatment at 2 sites, each with its own staff team. Initially with one overarching MDT to ensure equity.

OPTION B 4
2 TAVI services in Scotland providing treatment at 2 sites, each with its own staff team.
Conclusion

The NPF is invited to review the above options and consider which is most appropriate for patients in Scotland.
CHAPTER 1: Introduction

Background

1. The TAVI Review Group was established in August 2010 at the request of the National Planning Forum to consider the provision of Transcatheter Aortic Valve Implantation (TAVI) in Scotland.

2. This report aims to enable the NPF to make an assessment of the options for the future provision of TAVI based upon the technology’s efficacy and safety; its cost and service design requirements, and potential future demand for the service in Scotland.

Remit

3. The remit of the TAVI Review Group, as approved by the NPF, was to:
   • Consider the extent and the quality of the evidence surrounding the use of TAVI;
   • Take evidence from leading experts regarding the efficacy, safety and cost effectiveness of TAVI relative to alternative treatments (conventional valve replacement or medical management); and
   • Provide a range of options for the NPF to consider as the basis for making a recommendation on the use of TAVI in respect of meeting the current and future health needs of the Scottish population.

4. Membership of the Group is contained in Appendix 1.

Working Methods and Methodology

5. The Group fulfilled its remit by:
   • Commissioning SHTG working group to produce an Evidence Note reviewing published evidence on TAVI. As there was a lack of published evidence NHS QIS also produced a more detailed report which included unpublished data and grey literature;
   • Developing a standardised questionnaire for experts to complete;
   • Interviewing clinicians and experts with an interest in and/or experience of TAVI or health service planning within Scotland and in the UK;
   • Undertaking a full needs assessment for TAVI using Scottish, UK and European data. Including:
     • Epidemiology – literature review
     • Comparative – TAVI provision in UK
     • Evidence gathering from experts
     • Projections for future need
   • Collating and reviewing Scottish, English and Welsh cost data; and
   • Reviewing and discussing the evidence at a series of meetings.

6. The Group utilised a Decision Tree approach.

7. In recognition of the similarities between the issues surrounding both TAVI and Extra Corporeal Membrane Oxygenation (ECMO), the Group adopted the working methodology used in the production of the Final Report.
of the Scottish ECMO Expert Group. This facilitated the rigorous evidence gathering process and report’s production within the timescale allowed for by the NPF.

8. This report is a summary of all the evidence collated by the TAVI Review group. Full details of the methods used and evidence gathered can be obtained from the Scottish Government on request.

Evidence Gathering
9. Following the ECMO review model all NHS Boards were invited, through their Board Chief Executive/Medical Director, to nominate experts in cardiology and service planning to contribute toward the evidence gathering process. Additionally any individual that wished to contribute towards the review through the evidence gathering process was invited to do so.

10. Experts were invited to complete a standard template and provide oral evidence to the Review Group at a series of evidence gathering sessions. This evidence was collated and summarised.

11. This approach enabled the TAVI Review Group to consider local and national experts’ views on the practical issues surrounding TAVI in addition to the latest published clinical evidence.

Aortic Stenosis, TAVI Definition and Development

Aortic Stenosis
12. Aortic stenosis is the most common symptomatic valvular heart disease in the western world and it represents a narrowing of the aortic valve in the heart. The most common cause is degenerative and the prevalence of aortic stenosis is increasing with an ageing population. The condition worsens as people get older.

13. The prevalence of severe aortic stenosis is around 3% in those aged over 75 years and rises steeply with increasing age. The standard definitions for severe aortic stenosis are an aortic valve area of less than 0.8 cm², a mean aortic valve gradient of 40 mmHg or more, or a peak aortic-jet velocity of 4.0 m per second or more.

14. Symptoms of aortic stenosis include heart failure with breathlessness, chest pain, palpitations and dizziness. Without intervention patients with severe symptomatic aortic stenosis have a poor prognosis and a mortality rate of around 50% at three-years, although rates as high as 50% at one-year and 65% at two-years have been reported in elderly patients.

15. Treatment options include stretching the valve with a balloon (valvuloplasty) or replacing the valve by open heart surgery or TAVI. The most effective treatment is replacing the valve by open heart surgery which requires a general anaesthetic, opening the chest and a cardiopulmonary bypass machine. Conventional Aortic Valve Replacement (AVR) can restore life expectancy to something close to the usual age, sex adjusted life expectancy.
**Transcatheter Aortic Valve Implantation (TAVI) Description**

16. TAVI (formerly described as Percutaneous Aortic Valve Replacement – PAVR) represents an alternative to a conventional open heart procedure. Use of the treatment to date has focused on the very high risk or inoperable patients with severe symptomatic aortic stenosis (SSAS).

17. TAVI is designed as a less invasive alternative where the aortic valve is replaced without opening the chest cavity. The device is delivered either transfemorally (via the femoral artery) or transapically (through the left ventricle). Whichever approach is used, a balloon catheter is advanced to the aortic valve over a guide wire, the aortic valve is stretched and the new one inserted. TAVI can be carried out under local (with sedation) or general anaesthesia.

**TAVI Technology**

18. There are two manufacturers leading the development of TAVI implantation technology. These are Edwards Life Sciences (Edwards SAPIEN Transcatheter Heart Valve; second generation) and CoreValve Corporation (CoreValve Percutaneous Revalving System; second generation). Both valve systems are currently in use in centres in the UK. These two technologies differ in their design, construction and method of implantation. The Edwards Valve can be implanted by both a transapical and transfemoral route. The CoreValve is undertaken by the transfemoral route only, although a transapical approach is in development and is likely to be available in the near future. Significant improvements in valve technology have already occurred in the last few years and these are expected to continue.

**Current UK Provision of TAVI**

19. Since the introduction of TAVI in 2002 around 10,000 TAVI procedures have been carried out worldwide. The first TAVI procedure was performed in the UK in 2007 and by 2009, 877 TAVIs had been performed in the UK.

- In England most regions now commission a TAVI service. There are now 25 centres performing TAVI in England with numbers of procedures undertaken per centre ranging from 5 to 114.

- In Wales, the health service had been providing TAVI on an individual patient basis but has recently chosen to commission a local TAVI service following a major review. They expect to eventually carry out up to 45-50 procedures a year.

- In Scotland, NHS Boards have been approving TAVI on an individual patient basis only with referral to England. In 2009, 12 Scottish patients underwent TAVI following referral to centres in England.

20. While provision of TAVI in England and Wales has grown steadily there is currently inconsistency in the approach adopted by Scottish NHS Boards to the provision of TAVI. While a number of Boards have established
mechanisms (ECPs) to consider patients eligible for TAVI, the level of provision between these Boards varies.
CHAPTER 2 – TAVI Evidence Base

Methods
21. A number of guidance documents were used to provide evidence for this report. These include:
   • NICE guidance on TAVI produced in 2008;
   • The British Cardiovascular Intervention Society (BCIS) and the Society of Cardiothoracic Surgeons (SCTS) position statement on TAVI;
   • The English commissioning framework for TAVI for severe symptomatic aortic stenosis; and
   • The European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI) position statement on TAVI.4-7

22. A systematic literature search was undertaken by NHS QIS on behalf of the SHTG working group to identify relevant secondary and primary research evidence on the clinical and cost-effectiveness of TAVI. The NHS QIS evidence note summarises the available published secondary evidence and RCT data and the full report summarises subsequent published primary research, unpublished data, and grey literature. The additional full report was requested because there is so little published secondary evidence on TAVI.

23. Finally, expert evidence was taken from clinicians, public health professionals and planners from Scotland and the UK to supplement the very limited evidence base.

Patient Selection
24. Patient selection is of critical importance in the use of TAVI. The European position statement advises that TAVI should currently be restricted to patients with severe symptomatic aortic stenosis, who have been rigorously assessed by the specialist valve MDT to be at high risk for surgery or with absolute contraindications for surgery. TAVI is not recommended for patients who simply refuse surgery on the basis of personal preference, it is currently premature to consider TAVI in patients who are good surgical candidates (moderate/low risk), and TAVI should not be performed in patients with life expectancy of less than one year.

25. The UK Commissioning Framework states that patient selection for TAVI should be based on surgical clinical judgement as well as risk scoring and the ideal arrangement to achieve this is a triage and assessment process carried out by a multidisciplinary, multiconsultant-based specialist valve team. One reason for this is that the threshold for offering surgical AVR to patients assessed to be at high risk, and willingness to operate, varies between surgical centres.

26. There is no consensus on what constitutes high surgical risk, no reliable method to identify which elderly patients are most likely to benefit from AVR, and no standard criteria by which to select patients for TAVI. Two main scoring systems are used to assess cardiac surgical risk; the European
System for Cardiac Operative Risk Evaluation (log EuroSCORE) and the Society of Thoracic Surgeons (STS). However, these were not designed for aortic stenosis patients, their discriminatory powers are poor, and their reliability is uncertain. The usual ‘high risk’ patient will have a logistic Euroscore of >20 or an STS score of >10. In addition expert opinion is that patients with a log Euroscore of > 40 are usually not suitable for TAVI and palliative care is more appropriate. However expert opinion is that clinical judgment, rather than scoring systems, is most important in assessing operative risk and decisions should always be based on this.

27. In the UK there is variation in patient selection for TAVI. In England most centres undertake TAVI for ‘high risk’ and ‘inoperable’ patients but a couple of regions have chosen to commission TAVI only for ‘high risk’ or only for ‘inoperable’ patients. Wales has chosen to commission TAVI for ‘high risk’ patients only, as a replacement to conventional AVR, primarily for cost reasons.

Clinical Effectiveness, Outcomes, Safety and Quality of Life Evidence

PARTNER IDE Randomised Controlled Trial

28. There has only been one published RCT of TAVI, the multicentre PARTNER IDE (Placement of Aortic Transcatheter valve) trial, sponsored by Edwards Lifesciences.8,9 Patients were randomised in two separate cohorts: ‘high risk’ patients eligible for surgery were randomized to undergo TAVI or surgical AVR (cohort A); while those who were considered not to be suitable candidates for surgery were randomized to TAVI or standard treatment: medical management and/or balloon aortic valvuloplasty (cohort B). It is of note that this is standard treatment in the USA, whereas in the UK valvuloplasty is very rarely performed. Only results for cohort B have been published.

29. In cohort B, 358 patients considered ‘inoperable’ using conventional AVR, but with a life expectancy greater than 1 year and no other major medical conditions, were randomized and 179 were allocated to transfemoral TAVI. All-cause mortality at one-year was significantly lower in the TAVI group (30.7%) compared with the standard treatment group (50.7%). Therefore in the first year five patients needed to be treated with TAVI to prevent one death. At one-year a significantly higher proportion of survivors in the TAVI group (74.8%) compared with the standard treatment group (42.0%) were asymptomatic or had mild symptoms defined as NYHA functional class I or II (p<0.001).

30. Mortality at 30 days was not significantly different to controls. Major strokes were more common in the TAVI group compared with the control group at 30-days (5.0% versus 1.1%) and one-year (7.8% versus 3.9%), but only the former was borderline statistically significant (p=0.06). Major vascular complications and major bleeding events were significantly more frequent in the TAVI group at both time points: 16.2% versus 1.1% at 30-days, 16.8% versus 2.2% at one-year (p<0.001); and 16.8% versus 3.9% at 30-days (p<0.001), 22.3 versus 11.2% at one-year (p=0.007), respectively. Minor
vascular complications were significantly more frequent in the TAVI group at both time points 30.7% versus 5.0% at 30-days (p<0.001) and 32.4% versus 7.3% (p<0.001) at one year. There was no statistically significant difference in rates of myocardial infarction (MI) or acute kidney injury. No patient required urgent cardiac surgery to manage complications. Valve embolisation occurred in one patient (0.6%) and 2 (1.1%) underwent two or more valve implantations.

31. Moderate or severe paravalvular aortic regurgitation was present in 11.8% of patients in the TAVI group at 30-days and in 10.5% at one-year. Moderate or severe transvalvular aortic regurgitation was present in 1.3% of patients in the TAVI group compared with 16.9% in the control group at 30-days and in 4.2% and 15.2%, respectively, at one-year. Three patients in the TAVI group (1.7%) underwent a repeat TAVI procedure to treat clinically significant paravalvular (n=2) or transvalvular (n=1) aortic regurgitation. New pacemaker implantation rates were not statistically significantly different between the two groups.

32. Quality of life was assessed but these outcomes have not yet been published. However, the results were presented at an American Heart Association special report session. As these data are unpublished they must be interpreted with caution. Quality of life was measured using three self administered questionnaires. The Kansas City Cardiomyopathy Questionnaire (KCCQ) was used as the primary end point and the two others as secondary endpoints. Only the KCCQ results have been presented. For KCCQ scores overall TAVI patients had an almost 21-point improvement in scores at 6 months and 24.5 point improvement by 12 months compared to controls, a statistically significant difference. Significant differences were also seen for KCCQ symptoms, physical limitations, social limitations, and quality of life.

33. Limitations of this study are that it was industry sponsored, patient numbers were relatively small; median duration of follow up was only 1.6 years; the mean log EuroSCORE was lower in the TAVI group than in controls; and in the control group 12 patients underwent surgical AVR despite their 'inoperable status', 5 received a left ventricular apical-aortic conduit and 4 underwent TAVI at non-participating sites. In addition TAVI was compared to standard treatment in the USA which is not the same as standard treatment in the UK, where very little valvuloplasty is undertaken.

Non Randomised Controlled Trials
34. Procedural success rates of between 75 and 100% for TAVI have been shown in evidence from published and unpublished case series and TAVI registry data. Short term clinical efficacy appears to be good based on echocardiographic measurements of valvular function and improvements in heart failure symptoms, as measured by the NYHA score. However, there is little published data on survival at 6 months or more and no directly comparable data on long term outcomes of TAVI compared with alternative interventions. One year mortality rates ranged from 20-45%. There was a lack of data on quality of life.9
35. From all sources 30-day mortality rates range from 6.4% to 25% with higher mortality rates in TAVI by the transapical route than with the transfemoral approach, probably reflecting differences in patient risk. Complication rates observed in TAVI patient series vary widely. These include: vascular complications, especially with the TF approach; stroke; valve migration, malpositioning and embolisation; renal failure requiring dialysis. Expert opinion was that the risk of stroke was reducing over time due to improvements in technology.

36. Information on the durability of implanted valves was limited, but studies found no significant deterioration in Edwards valves at one-year. Expert opinion was that valve durability had been consistent to over 3 years.

37. Quality of life measures were used in four uncontrolled case series and did show some improvements in quality of life secondary to TAVI. However, the limitations are that the numbers in all the studies were very small, there were no control groups and overall this data is insufficient to draw conclusions.

UK TAVI Registry
38. Data from the UK TAVI registry show procedural success for TAVI in 99% of cases. The median age of patients was 83. In-hospital mortality was 6.2%, mortality at one year was 20% and mortality at two years was 25%. In terms of major complications 4% of patients had a stroke and 1.3% of patients had an MI following TAVI. 26% of patients treated with the Medtronic CoreValve and 7% with the EdwardsSAPIEN valve required a pacemaker.

Cost effectiveness
39. Experts consistently reported that there is very little cost effectiveness data available for TAVI.

40. There is no published peer reviewed evidence regarding the cost effectiveness of TAVI compared with surgical AVR or medical management. Unpublished and grey literature report wide-ranging estimates that suggest that TAVI is generally cost-effective compared with medical management (ICER range £2000 to £27,000/QALY) and either cost-effective (ICER range £200 to £10,000/QALY) or not at all cost-effective (£86 to £208,000/QALY) compared with surgical AVR. These results must be interpreted with caution as they are largely based on manufacturer models which were not derived from randomised controlled trials and the broad range of results indicates the unreliability of the estimates.9

Health Economics Appraisal Team Report
41. The SHTG commissioned the Health Economics Appraisal Team at Glasgow University to produce a report, on the cost-effectiveness of TAVI compared with conventional surgical AVR and medical management for the treatment of Aortic Stenosis in Scotland. Their report found that:

- For high risk (inoperable) patients, TAVI was more expensive and more effective than medical management with an ICER of approximately
£18,000 per QALY. There was considerable uncertainty around these estimates as the clinical effectiveness evidence was immature; and

- For low and medium risk patients eligible for conventional valve replacement the cost effectiveness of TAVI is unclear.

42. The key drivers of cost-effectiveness were the reduction in operative mortality; and the cost of the device and the degree to which this is offset by length of stay, particularly in high-dependency units.

43. Expert opinion was that TAVI may be close to cost neutral or potentially cost minimising for the ‘high risk’ surgical group, as a replacement for AVR through reductions in hospital length of stay.

44. It is clear from the evidence gathering sessions that TAVI has been commissioned in the UK as a replacement for AVR, on the basis that this option has the potential for being cost effective. It has also been noted that there are fewer costs to potentially offset for inoperable patients, where palliative care is the main treatment. However, there is no good evidence of clinical effectiveness to support TAVI as a replacement procedure.

Conclusions

- **Patient Selection:** TAVI should only be considered for those who are ‘inoperable’ and/or at ‘high risk’ with conventional surgery. There is a lack of standardisation of the definitions of ‘inoperable’ and ‘high risk’ as they are primarily based on clinical judgement.

- **Clinical Efficacy:** Evidence is limited and there are no published RCTs comparing TAVI with conventional AVR. In the one RCT comparing TAVI with standard treatment in patients who were considered ‘inoperable,’ TAVI significantly reduced mortality at one year with a number needed to treat of 5.

- **Safety:** TAVI is associated with a significantly higher incidence of major strokes and vascular complications.

- **Outcomes:** There is a lack of data on long-term outcomes beyond one year.

- **Quality of Life:** There is a lack of RCT data on quality of life. However, unpublished results from the PARTNER RCT do suggest TAVI improves quality of life at 6 and 12 months, compared to standard therapy in the USA.

- **Cost Effectiveness:** There is insufficient information to reliably estimate the cost-effectiveness of TAVI. However, TAVI has been commissioned in some centres in the UK as a replacement for AVR on the basis it has potential for cost offsetting.
• **Availability:** TAVI is widely available in the USA, Europe and the UK.
CHAPTER 3: Needs Assessment

Methods
45. A health needs assessment is a systematic method for reviewing the health needs of a specific population. Its purpose is to assist in decision-making regarding priorities and resource allocation in order to improve health and reduce inequalities. In order to provide the most accurate assessment of need for TAVI several different analyses were undertaken. These were a literature review to identify any epidemiologically based measures of need; a demand based comparison of TAVI provision in the UK; evidence gathering from experts in the field from Scotland and England including clinicians, planners and public health experts; and a projection of future need.

Literature review to identify the need for TAVI in Scotland
46. There are currently no published data on the absolute population need for TAVI as it is a new procedure. The UK TAVI consensus meetings in 2008 and 2009 estimated the need for TAVI at around 16/million. This represents around 800 procedures per year in England and 80 per year in Scotland. Given the current lack of epidemiological data these estimates are based largely on assumptions and extrapolation. This estimate of 16/million includes 10-20% of conventional AVR patients where TAVI is a replacement for surgery in those at high risk for conventional surgery. The UK national commissioning framework for TAVI suggested that TAVI is appropriate for those where the anticipated operative mortality with conventional AVR is considered prohibitive, that is the top 10% of predicted risk. If TAVI were to replace 10% of AVRs in Scotland, this equates to 87 TAVIs per year based on 2009 AVR figures.

Demand based assessment of need
47. Data were obtained from the TAVI registry and from Information Services Division, Scotland. The TAVI registry records information on all TAVI procedures undertaken in the UK. In order to estimate need for Scotland, population rates for TAVI procedures in the UK were calculated. Dr David Cunningham, senior manager of the central cardiac audit database, was asked to provide information on the number of TAVI procedures in the UK in 2009 and advise how these related to the local population. Scotland and Wales were excluded from the calculations as they only had ad-hoc provision of TAVI at this time (see table I).
Table I: UK TAVI Registry Data 2009

<table>
<thead>
<tr>
<th>Region</th>
<th>Population</th>
<th>TAVI procedures</th>
<th>Rate per million population</th>
</tr>
</thead>
<tbody>
<tr>
<td>North East</td>
<td>2,565,500</td>
<td>20</td>
<td>7.9</td>
</tr>
<tr>
<td>North West</td>
<td>6,864,300</td>
<td>73</td>
<td>10.6</td>
</tr>
<tr>
<td>Yorkshire &amp; Humber</td>
<td>5,177,300</td>
<td>38</td>
<td>7.3</td>
</tr>
<tr>
<td>East Midlands</td>
<td>4,399,600</td>
<td>29</td>
<td>6.6</td>
</tr>
<tr>
<td>West Midlands</td>
<td>5,381,900</td>
<td>41</td>
<td>7.6</td>
</tr>
<tr>
<td>East of England</td>
<td>5,661,000</td>
<td>41</td>
<td>7.2</td>
</tr>
<tr>
<td>London</td>
<td>7,556,900</td>
<td>90</td>
<td>11.9</td>
</tr>
<tr>
<td>South East Coast</td>
<td>4,283,200</td>
<td>94</td>
<td>21.9</td>
</tr>
<tr>
<td>South Central</td>
<td>4,025,400</td>
<td>35</td>
<td>8.7</td>
</tr>
<tr>
<td>South West</td>
<td>5,177,900</td>
<td>43</td>
<td>8.3</td>
</tr>
<tr>
<td>ENGLAND TOTAL</td>
<td>51,092,000</td>
<td>504</td>
<td>9.9</td>
</tr>
</tbody>
</table>

48. These figures indicate the mean number of TAVI procedures undertaken in England in 2009 to be 9.9 cases per million population per year. The English TAVI steering group stated that this figure does not represent population need or demand, as commissioning constraints determined that the number of procedures was far below estimated population need. It has been estimated by Dr Cunningham that in England there will be a 25% rise in TAVI procedures undertaken in 2010, compared to 2009.

49. In terms of patient selection the TAVI registry records the primary reason for a TAVI being performed. Those who were ‘turned down for surgery’ are the group classified as ‘inoperable’. Those at ‘high risk for surgery’ are the group who were eligible for a conventional AVR but where a TAVI was chosen as a replacement procedure. The data show an enormous variation (2-98%) between centres in the percentage of patients classified as having TAVI because they were ‘turned down for surgery’, rather than ‘high surgical risk’. This reflects the lack of standardisation in the definition. It was recommended by the English TAVI steering group that although reasons for performing TAVI are recorded by the TAVI registry conclusions should not be drawn from this aspect of the dataset as they are likely to be misleading.

Caveats of TAVI data
50. There are marked variations in commissioning TAVI in England. Most areas commission a TAVI service although a few provide TAVI on an individual patient basis. Some regions only commission TAVI for ‘inoperable’ patients and some only commission TAVI as a replacement procedure in ‘high risk’ patients, any other requests in these regions are on an individual patient basis. Some regions cap their TAVI numbers e.g. 70 for East and West Midlands, reflecting available resources.

Expert opinion on need for TAVI in Scotland
51. In our evidence gathering sessions there was consensus that a precise figure for need was unknown, though a reasonable estimate of need might be around 16/million. Some with a special interest in TAVI felt the need might be 20/million or possibly even higher. The opinion from the English TAVI
steering group was that the latest estimates from Europe suggest a true population need of nearer 50 per million.

52. The variation in opinion on need related mainly to differing views on the extent that TAVI should be a replacement for conventional AVR. Currently RCT evidence is not available to support TAVI as a replacement therapy. However, the opinion of surgeons and TAVI specialists was that TAVI is a treatment that they wish to use for patients at very high risk for conventional AVR. There are no other effective treatments for this population and clinical experience is that they have poor outcomes from AVR.

53. Expert opinion was that TAVI is approximately 50% a replacement for high risk patients and 50% a new procedure for inoperable patients. However, this is dependent on classification between ‘inoperable’ and ‘high risk’ which is highly subjective. Expert opinion was also that there were very few genuinely inoperable patients.

54. TAVI is a new procedure and expert opinion was that the need and demand for TAVI were likely to change over time as further research evidence becomes available. Some experts felt that there may be an increase over time in the numbers of ‘high risk’ patients where TAVI was considered the most suitable treatment. This would be due to increasing confidence in TAVI, leading to the risks of AVR being judged to be higher than risks of TAVI.

55. Expert opinion also suggested that due to practicalities associated with establishing a new TAVI service the demand for TAVI is likely to be somewhat lower than actual need in the first one to two years.

56. There is the potential for a backlog in demand for TAVI, as it has not been routinely available in Scotland. English experience is that this has not been a particular issue as life expectancy for this population is only around one to two years.

Estimated need for TAVI in Scotland

57. Based on this needs assessment the need for a Scottish TAVI service is likely to be between 5 and 20 cases per million population. The group agreed that the most reasonable estimate of demand for TAVI currently in Scotland was 10/million. This estimate was based primarily on the UK registry data and bearing in mind practicalities associated with establishing a new TAVI service. For Scotland these population estimates equate to the following numbers of TAVI procedures:

- 5/million = 25 TAVI procedures per year
- 10/million = 50 TAVI procedures per year
- 16/million = 80 TAVI procedures per year
- 20/million = 100 TAVI procedures per year

58. Limitations of the estimate of 10/million are that registry data may not accurately reflect need or demand and may be more reflective of cost restrictions. This estimate incorporates an expectation that in the first couple of years of setting up a service the demand may be lower than when a service is
well established. A further limitation is that need will depend on patient selection for TAVI. For example if TAVI is only recommended for ‘inoperable’ patients or only for ‘high risk’ patients the demand per year may be less. Finally the significant limitations of this estimate must be recognised and it is therefore advised that population need is reviewed at regular intervals.

Projected future need for TAVI in Scotland

59. In order to estimate future need for TAVI the incidence of aortic stenosis was investigated, since it is known to be increasing. In addition figures for the number of AVRs performed over the last 10 years were obtained as a gauge of increasing need for aortic valve replacement. It is of note that the UK need estimate for TAVI of 16/million included an assumption that TAVI may replace 10-20% of conventional AVRs in the UK.

60. To investigate the incidence of aortic stenosis in Scotland, hospital admissions data were obtained from ISD by Dr Colin Berry, Glasgow Cardiovascular Research Centre, for a paper currently submitted for publication. The data show that the number of patients admitted with a first report of aortic valve disease has increased from 935 in 1989 to 2,692 in 2005.

61. Since 2001 there has been a twofold increase in the annual number of patients undergoing aortic valve replacement in the UK and the patients having AVR are becoming more elderly and more high risk. In 2009 in the UK approximately 8750 conventional aortic valve replacements were performed and almost 40% were in patients aged over 75 years.

62. In Scotland ISD data show that the number of aortic valve replacements has increased from 635 in 2000 to 867 in 2009. This equates to an increase of just over 3% per year over the last 10 years. Limitations of this figure are that it is unknown if AVRs are increasing due to increased need or due to increased availability of AVR. However incidence figures suggest that SSAS is increasing over time. Therefore the need for aortic valve replacement whether by AVR or TAVI is likely to increase related to the ageing population.

Conclusions

• TAVI is a new procedure and exact population need is unknown.

• There is variation in opinion as to which patients should undergo TAVI.

• The UK estimate of need for TAVI is 16/million.

• The group thought that a current population demand for TAVI in Scotland might be around 10/million based on UK registry figures and practicalities associated with establishing a new TAVI service. This equates to 50 procedures per year. Population need may be higher than this.

• The prevalence of aortic stenosis and need for valve replacement will increase over time due to the ageing population.
• The need for TAVI is likely to change over time and therefore population need should be reviewed and actively managed at regular intervals, for example every two years.

• Capping has been applied to TAVI in England and this should be considered for Scotland.
CHAPTER 4: Principles & Requirements of a TAVI service

Methods
63. A number of guidance documents were used to produce this report. These included:
   - NHS QIS Evidence Note and Full Report;
   - The British Cardiovascular Intervention Society (BCIS) and the Society of Cardiothoracic Surgeons (SCTS) position statement on TAVI;
   - The European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI) position statement; and
   - The UK Commissioning Framework for TAVI for severe symptomatic aortic stenosis.5-7,9

Standards and Performance Management
64. NHS Boards need to be convinced of the quality of a service in order to refer patients outwith their area and establish service level agreements. However, quality standards that would allow performance management of TAVI services have not yet been developed. Expert opinion was that there have not yet been sufficient numbers of TAVI performed in the UK to permit an accurate judgement of individual centre’s performance.

65. Expert opinion agreed that as a starting point any cardiac centre wishing to provide TAVI would require:
   - a minimum interventional cardiology infrastructure, including immediate access to vascular surgeons and interventional radiologists to deal with major peripheral vascular complications, as detailed in the BCIS position statement and UK Commissioning Framework document; and
   - significant involvement of cardiologists with TAVI experience.

66. The UK Commissioning Framework advises that any new TAVI centre setting up will require a careful process of proctorship and phased roll out supervised by an established centre.

Volume
67. The English National Consensus meeting on TAVI in 2009 recommended that TAVI should be delivered by a regional service model with activity concentrated in high volume surgical centres. Clinicians need to undertake volumes that maintain their skills and allow them to accrue experience in patient selection through their MDT. The British Cardiovascular Intervention Society (BCIS) and Society of Cardiothoracic Surgeons (SCT) have also emphasised the importance of discouraging occasional practice and small volume units.

68. The optimum number of cases for a TAVI centre to perform is uncertain. BCIS and SCT have suggested that an appropriate minimum number of cases might be around 25 per year but given the learning curve and infrastructure needed somewhere in the order of > 50 cases per year would be optimal.
69. This view was echoed in expert evidence where it was also suggested that in the long term an optimal service would require around 35-50 cases/year. Currently the majority of centres in the UK have performed between 10 and 50 cases up to December 2009. However five centres had performed between 63 and 114 TAVI. The Department of Health update on TAVI commissioning in England states that commissioners are seeking to develop TAVI on a regional basis in a small number of established high volume centres rather than wider proliferation to a larger number of small volume units. Clinicians need to undertake volumes that maintain their skills and allow them to accrue experience on patient selection through their MDT.

70. In terms of a learning curve, immature TAVI centres were found to be able to offset the risk to the patient through the use of proctoring and optimum patient selection. These centres were able to quickly amass the necessary experience to deliver patient outcomes comparable with those from longer running centres.

Consistency of Patient Assessment
71. In terms of determining patient eligibility there is as yet no reliable method to identify which patients are most likely to benefit from AVR, no consensus on what constitutes high surgical risk, and no standard criteria by which to select patients for TAVI.

72. This was understood to be a significant issue in England where it is accepted there is considerable variation between regions in the commissioning of TAVI. All experts from England and Wales advised that a single MDT for Scotland was desirable as it would help ensure consistency in patient selection and equity of access to TAVI. Expert opinion was that there is the potential for indication creep for TAVI outwith the recommended patient population and a robust MDT is the best means to prevent this.

73. Clinicians from Edinburgh and Glasgow indicated a preference for a regional MDT over a national one as they currently have well functioning regional cardiac MDTs. Concern was also expressed about the feasibility of running a national MDT. A limitation of a national MDT might be that it would be harder for clinicians to be involved in the decisions on patients they will treat. There was agreement that clinicians should always have the final say on whether they are happy to treat a particular patient.

74. A Scotland wide MDT, that met with sufficient regularity and involved the treating TAVI practitioner, could be expected to help mitigate against variation in the determination of patient risk and eligibility.

Staffing
75. The UK Commissioning Framework states that a TAVI multidisciplinary team should consist of: cardiac surgeons, interventional cardiologists, an imaging specialist, cardiothoracic anaesthetists and experienced nurses. Patient selection should be based on consideration of the risk/benefit ratio of open heart surgery to TAVI.
76. English expert opinion recommended, from experience, that a care of the elderly physician was essential for the MDT. In addition a co-ordinator (much like a transplant co-ordinator) has also proved very valuable. Expert opinion advised that of the interventional cardiologists, one should not be involved with TAVI. A palliative care specialist was also recommended.

Co-location and Access to Services
77. The UK Commissioning Framework recommends that TAVI units should be sited where there is a cardiac surgery department experienced in valve surgery and the management of high risk and complex cases. There should also be a cardiology department with expertise in structural heart disease (interventional and echocardiographic) skills including the management of great vessels.

78. The literature suggests that TAVI patients are at increased risk of stroke and vascular complications. In order to manage vascular risks the European position statement advises that close collaboration with surgeons skilled in vascular access repair and endo-vascular procedures are necessary. The UK Commissioning Framework states that immediate on-site access to vascular surgeons and interventional radiologists to deal with major peripheral vascular complications is required. Expert opinion was that this could be obtained from an on-site vascular team or from cardiac surgeons/interventionists with vascular expertise.

79. Guidelines do not give any recommendations on co-location of stroke services. The Leicester centre’s experience is that stroke risk is very small and has reduced since the PARTNER trial due to changes in the technology.

80. Any prospective TAVI centre should be able to demonstrate that appropriate arrangements are in place to manage any additional risk of stroke or vascular complication associated with TAVI.

Research and Audit
81. All UK TAVI activity is currently commissioned on the basis of participation in the UK TAVI Registry as per the UK Commissioning Framework. Experts consistently advised that audit is essential given the current immaturity of the evidence base. It was also recommended that TAVI units should be involved in UK trials if possible. It was hoped that audit and research activity would help further refine patient selection and improve patient outcomes. It was also recommended that cost data should be collected from the outset.

Valve selection
82. Evidence from Leicester recommended that both types of TAVI valve should be available as they are different sizes and suit different patients. 65-70% of patients are anatomically suitable if only 1 type of valve is available, which increases to 85% if the 2 types of valve are available. Nearly all centres in the UK use only 1 type of valve, as it requires a centre with very large numbers to be able to develop and sustain the expertise in using 2 valve
types. The UK Commissioning Framework advises that new centres should restrict themselves to one device. Evidence from Wales suggested that patient selection was key and choice of valve was unimportant in comparison. Expert opinion was that as valve technology improves there may no longer be differences between valves in terms of patient suitability.

Conclusions

- A minimum interventional cardiology infrastructure and arrangements for access to appropriate services to manage complications are required for any TAVI Centre, as per the BCIS Statement.

- Any new TAVI centre setting up will require a careful process of proctorship and phased roll out supervised by an established centre.

- The optimum number of cases for a TAVI centre to perform is uncertain, however large volume surgical centres are recommended. An appropriate minimum number of cases might be around 25 - 50 per year.

- Consistency in patient selection is essential to ensure access to treatment is based on need and capacity to benefit. A Scotland wide MDT could be expected to help mitigate against variation in patient selection and eligibility and ensure equity of access across Scotland.

- TAVI centres should participate in the UK TAVI registry, collect cost data and take part in clinical trials where possible.

- The majority of centres have insufficient numbers to be able to provide more than one valve type. There is differing opinion as to whether having access to more than one valve type is advisable. Developments in technology are likely to reduce the need for more than one valve type.
CHAPTER 5: Projected costs of a new TAVI service in Scotland

Background
83. There is an economic burden to the NHS due to severe symptomatic aortic stenosis in elderly patients not deemed suitable for conventional open chest surgery. Such patients can be repeatedly hospitalised, often with prolonged lengths of in-hospital stay and even when returned to the community, can consume additional resources from primary care and social services.

84. There is a lack of robust cost data for TAVI and there is insufficient information to reliably estimate cost-effectiveness. Centres undertaking TAVI in the UK are only now starting to collect long term cost data related to implementing this new technology. Much of the cost data currently available has rested on cost assumptions supplied by the manufacturers of the valves. These assumptions need to be robustly challenged and analysed to ensure that they are as cost effective as the conclusions in the reports produced to date.

Estimated costs for provision of a TAVI service within Scotland
85. Costs for the provision of a TAVI service within Scotland have been obtained from papers submitted to National Services Advisory Group in 2008 by Royal Infirmary, Edinburgh and Golden Jubilee Hospital, Glasgow (GJH) (see appendix 2). The GJH also submitted papers to the West of Scotland Regional Planning Group following a horizon scanning exercise in 2008.

86. Revenue costs are estimated by Edinburgh to be of the order of £22,000 to £23,000 per procedure based upon 2008/09 costs. The Glasgow costs are in the order of £20,800 to £23,429 per procedure based upon 2009/10 costs, the variation depending upon which TAVI valve is used.

87. The summary costs of TAVI shown in Table II below relate to the following two patient groups:
   i) as a new procedure,
   ii) as a direct replacement for AVR.

Table II TAVI costs for TAVI as a new procedure and as a replacement for AVR

<table>
<thead>
<tr>
<th>Patient Pathway</th>
<th>Resources/Details</th>
<th>Cost per Case £</th>
<th>New Patients</th>
<th>AVR to TAVI</th>
<th>Marginal Cost Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre - Admission</td>
<td>2 -3 weeks prior to admission</td>
<td>956</td>
<td>289</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Admission</td>
<td></td>
<td>436</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td></td>
<td>19,494</td>
<td>14,491</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Discharge</td>
<td></td>
<td>58</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Follow up</td>
<td></td>
<td>115</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Total Cost</td>
<td></td>
<td>21,059</td>
<td>14,780</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
88. Figures developed by GJH were used to calculate potential costs for a TAVI service in Scotland. The four potential TAVI service options detailed in chapter 6 have been used to estimate numbers of TAVI patients. Total cost estimates have been provided for population needs of 5, 10, 16 and 20 per million (see table III).

89. The GJH figures were used to populate this cost model as they give both the full cost and the marginal cost of replacing AVR with TAVI in ‘high risk’ patients. In this model it has been assumed that the cost per procedure in a Scottish centre would be £21,059 per patient for TAVI based on a fixed tariff. A major caveat is that there is a lack of substantive audit data available to verify the business case that these costs are based on. Data on treatment costs for patients undergoing TAVI in England indicate that costs may be higher due to longer ITU stays. A further limitation is that the division of patients into ‘high risk’ or ‘inoperable’ is based on a clinical judgement and is therefore variable. Finally the current costs to NHS Scotland of TAVI have not been included in this table. If TAVI is not provided in Scotland there will still be a cost for TAVI from referrals to England.

90. Full cost profiles are detailed in Appendix 2. The cost estimates provided by Edinburgh and Glasgow are comparable with other centres within the UK who are charging a fixed tariff of between £22K and £27K per procedure. However, these estimates need to be compared with the actual costs incurred by patients sent to England in financial year 2009/10, where the final charges were much greater. The reason for the difference is due to longer ITU stays. To allow for these variations in cost estimates for TAVI two estimates of cost have been provided. One is based on a fixed tariff for the cost of the procedure and standard expected lengths of stay. The other cost estimate is based on actual costs incurred by Scottish patients undergoing TAVI in England, where longer stays in ITU incurred additional costs (see tables III and IV). It is thought that the cost of TAVI will be nearer the higher estimate. However, costs should reduce over time as clinical experience grows. A national procurement exercise would also reduce costs.
### Table III  Estimated cost of TAVI based on fixed tariff for 4 TAVI service options for needs of 5, 10, 16 and 20 per million

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<thead>
<tr>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. No Tavi Scotland (patients sent to England)</td>
<td>25</td>
<td>£1,105,325</td>
<td>50</td>
<td>£2,210,650</td>
<td>80</td>
<td>£3,537,040</td>
<td>100</td>
<td>£4,421,300</td>
</tr>
<tr>
<td>Potential offset savings (2)</td>
<td>-£158,574</td>
<td>-£304,950</td>
<td>-£487,920</td>
<td>-£609,900</td>
<td></td>
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<tr>
<td>Net additional total cost</td>
<td>£946,751</td>
<td>£1,440,710</td>
<td>£2,305,810</td>
<td>£2,970,900</td>
<td></td>
<td></td>
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<tr>
<td>Net additional cost per case</td>
<td>£37,870</td>
<td>£38,114</td>
<td>£38,114</td>
<td>£38,114</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Inoperable only</td>
<td>12</td>
<td>£252,708</td>
<td>25</td>
<td>£526,475</td>
<td>40</td>
<td>£842,360</td>
<td>50</td>
<td>£1,052,950</td>
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<tr>
<td>Potential offset savings(2)</td>
<td>-£158,574</td>
<td>-£304,950</td>
<td>-£487,920</td>
<td>-£609,900</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net additional total cost</td>
<td>£94,134</td>
<td>£180,525</td>
<td>£278,040</td>
<td>£324,050</td>
<td></td>
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<tr>
<td>Net additional cost per case</td>
<td>£0</td>
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<td>£0</td>
<td>£0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Replacement for high risk only</td>
<td>13</td>
<td>£192,140</td>
<td>25</td>
<td>£369,500</td>
<td>40</td>
<td>£591,200</td>
<td>50</td>
<td>£739,000</td>
</tr>
<tr>
<td>Potential offset savings(2)</td>
<td>-£158,574</td>
<td>-£304,950</td>
<td>-£487,920</td>
<td>-£609,900</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Net additional total cost</td>
<td>£33,566</td>
<td>£64,550</td>
<td>£103,380</td>
<td>£129,100</td>
<td></td>
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<tr>
<td>Net additional cost per case</td>
<td>£2,582</td>
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<td>£2,582</td>
<td>£2,582</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4. Inoperable and high risk</td>
<td>25</td>
<td>£444,848</td>
<td>50</td>
<td>£895,975</td>
<td>80</td>
<td>£1,433,560</td>
<td>100</td>
<td>£1,791,950</td>
</tr>
<tr>
<td>Potential offset savings(2)</td>
<td>-£158,574</td>
<td>-£304,950</td>
<td>-£487,920</td>
<td>-£609,900</td>
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<td></td>
</tr>
<tr>
<td>Net additional total cost</td>
<td>£286,274</td>
<td>£591,025</td>
<td>£945,640</td>
<td>£1,182,050</td>
<td></td>
<td></td>
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<tr>
<td>Net additional cost per case</td>
<td>£11,451</td>
<td>£11,821</td>
<td>£11,821</td>
<td>£11,821</td>
<td></td>
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</tbody>
</table>

### Table IV  Estimated cost of TAVI based on actual costs for 4 TAVI service options for needs of 5, 10, 16 and 20 per million

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<tbody>
<tr>
<td>1. No Tavi Scotland (patients sent to England)</td>
<td>25</td>
<td>£1,105,325</td>
<td>50</td>
<td>£2,210,650</td>
<td>80</td>
<td>£3,537,040</td>
<td>100</td>
<td>£4,421,300</td>
</tr>
<tr>
<td>Estimated additional ITU stay over standard</td>
<td>£0</td>
<td>£0</td>
<td>£0</td>
<td>£0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential offset savings (2)</td>
<td>-£158,574</td>
<td>-£304,950</td>
<td>-£487,920</td>
<td>-£609,900</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net additional total cost</td>
<td>£846,751</td>
<td>£1,440,710</td>
<td>£2,305,810</td>
<td>£2,970,900</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net additional cost per case</td>
<td>£33,870</td>
<td>£34,114</td>
<td>£34,114</td>
<td>£34,114</td>
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<td></td>
</tr>
<tr>
<td>2. Inoperable only</td>
<td>12</td>
<td>£252,708</td>
<td>25</td>
<td>£526,475</td>
<td>40</td>
<td>£842,360</td>
<td>50</td>
<td>£1,052,950</td>
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<tr>
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<td>£0</td>
<td>£0</td>
<td>£0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential offset savings(2)</td>
<td>-£158,574</td>
<td>-£304,950</td>
<td>-£487,920</td>
<td>-£609,900</td>
<td></td>
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<tr>
<td>Net additional total cost</td>
<td>£94,134</td>
<td>£180,525</td>
<td>£278,040</td>
<td>£324,050</td>
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<tr>
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<td>£0</td>
<td>£0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Replacement for high risk only</td>
<td>13</td>
<td>£192,140</td>
<td>25</td>
<td>£369,500</td>
<td>40</td>
<td>£591,200</td>
<td>50</td>
<td>£739,000</td>
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<td>£0</td>
<td>£0</td>
<td>£0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential offset savings(2)</td>
<td>-£158,574</td>
<td>-£304,950</td>
<td>-£487,920</td>
<td>-£609,900</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Net additional total cost</td>
<td>£33,566</td>
<td>£64,550</td>
<td>£103,380</td>
<td>£129,100</td>
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<tr>
<td>Net additional cost per case</td>
<td>£2,582</td>
<td>£2,582</td>
<td>£2,582</td>
<td>£2,582</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Inoperable and high risk</td>
<td>25</td>
<td>£444,848</td>
<td>50</td>
<td>£895,975</td>
<td>80</td>
<td>£1,433,560</td>
<td>100</td>
<td>£1,791,950</td>
</tr>
<tr>
<td>Estimated additional ITU stay over standard</td>
<td>£0</td>
<td>£0</td>
<td>£0</td>
<td>£0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential offset savings(2)</td>
<td>-£158,574</td>
<td>-£304,950</td>
<td>-£487,920</td>
<td>-£609,900</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net additional total cost</td>
<td>£286,274</td>
<td>£591,025</td>
<td>£945,640</td>
<td>£1,182,050</td>
<td></td>
<td></td>
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<tr>
<td>Net additional cost per case</td>
<td>£11,451</td>
<td>£11,821</td>
<td>£11,821</td>
<td>£11,821</td>
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</tbody>
</table>
92. As a new procedure TAVI has been estimated to cost £21,059 based on a fixed tariff or £44,213 based on actual costs, where a mean additional ITU stay has been included (see table V). As a replacement for AVR, TAVI is estimated to incur an additional cost of £2,582 based on a fixed tariff. This includes a marginal cost for TAVI of £14,780 and potential savings on bed days of TAVI compared to AVR of £12,198, as estimated by GJH. This figure is similar to equivalent calculations undertaken in other areas of the UK. Based on actual costs this figure increases to £25,736 as a replacement for AVR, including a mean additional ITU stay over standard.

93. No assumption has been made regarding any potential resource transfer from primary care or general medicine in these figures.

Costs of Patients sent to England

94. In 2009, 12 patients were referred by NHS Scotland Boards to centres within England and underwent TAVI. In order to estimate costs for providing TAVI at an English centre, rather than in Scotland, cost data was obtained for a convenience sample of 6 patients sent to the Royal Brompton Hospital in England over a 12 month period in 2009 (see table V). This illustrates that whilst the standard charge was £25,009 per patient for the procedure, the mean overall cost per patient was £44,213 (see table V). These additional costs are due to extended ITU stays in England. The main limitation of these figures is that it is not known if these are typical patients receiving TAVI.

95. Based on these figures this gives a total estimated cost for TAVI in Scotland in 2009 of £530,558. These costs of TAVI have not been included in the potential savings in the costs analysis for TAVI in Table III. However, there would be potential savings to NHS Scotland from these costs if a TAVI service were available in Scotland.

Table V Costs of TAVI for Scottish patients at English centre

<table>
<thead>
<tr>
<th></th>
<th>£</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cost for 6 patients</td>
<td>265,279</td>
</tr>
<tr>
<td>Average cost per patient</td>
<td>44,213</td>
</tr>
<tr>
<td>Lowest cost per patient (1 ITU/HDU stay)</td>
<td>25,009</td>
</tr>
<tr>
<td>Highest cost per patient (23 ITU/HDU stay)</td>
<td>70,778</td>
</tr>
<tr>
<td>Estimated cost of 12 patients at average cost</td>
<td>530,558</td>
</tr>
</tbody>
</table>

Conclusions

- There is very little cost data available for TAVI and all cost estimates have major limitations.
- The estimated minimum cost per patient for TAVI is £21,059 as a new procedure. As a replacement for AVR in 'high risk' patients a
minimum additional cost of £2,582 is expected. However, actual costs may be nearer £44,000 as a new procedure and £26,000 as a replacement. Over time though costs are expected to reduce.

- For a population need of 10/million the cost of a TAVI service in Scotland is likely to range from £64,550 to £2,210,650 dependent on the accuracy of the cost estimates, arrangements for TAVI provision and the population chosen to be eligible. The current costs of TAVI procedures for Scottish patients in England could be offset against this.
CHAPTER 6: Options for a TAVI service in Scotland

96. The following are the options in considering provision of a TAVI service to the population of Scotland. In all the options for a TAVI service a cap on numbers has been assumed. This is essential for accurate estimation of costs and for the reasons set out on page 34. The costs included below are for one year. They are based on a population need of 10/million and an assumption that 50% of TAVI will be a new treatment for ‘inoperable’ and 50% will be a replacement procedure for ‘high risk’ patients. A limitation is that it cannot be assumed that these are what the actual numbers would be for option 2 or option 3 as judgements about which patients are ‘inoperable’ and which are ‘high risk’ vary considerably.

97. Two costs have been included. Option A assumes a fixed tariff for TAVI of £21,059, whereas option B is based on actual costs of TAVI, which includes an additional ITU stay, giving a cost of £44,213. Where TAVI is a replacement for AVR the marginal cost has been used and potential savings on bed days from AVR to TAVI have been included in the final figures. A limitation is that it is unknown whether these potential savings on bed days will be realised. Overall it is thought costs are likely to be nearer the higher estimate.

OPTION 1

A TAVI service should not be made available. Any requests for TAVI should be assessed on an individual patient basis by health board exceptions panels.

Cost:

a) Not applicable.

b) £1,905,700 based on 50 patients at an average cost of £38,114 per patient.

Pros

• Long term outcomes of TAVI are unknown, there is only limited evidence of clinical efficacy and no evidence of cost effectiveness.

Cons

• This is likely to perpetuate inequity in access to TAVI across Scotland
• It would be impossible to ensure consistency in patient selection as is recommended for TAVI.
• TAVI is an increasingly common procedure in the UK, Europe and the USA and clinicians wish to have it as an option in Scotland.

Costs

• Cost per patient is likely to be higher if TAVI is delivered on an ad hoc basis.
• It would not be possible to cap TAVI numbers.
OPTION 2

A TAVI service should be made available as a new treatment for patients considered ‘inoperable’ for conventional AVR, who otherwise have a reasonable life expectancy and capacity to benefit.

Cost:
   a) £526,475 based on 25 patients at a cost of £21,059 per patient
   b) £1,105,325 based on 25 patients at a cost of £44,213 per patient

Pros
   • There is evidence of clinical effectiveness in this group.

Cons
   • There is a lack of cost effectiveness data to support TAVI.
   • Long term outcomes of TAVI are unknown.

Costs
   • As this is a new procedure/intervention there are additional costs of a minimum of £21,000 per patient.

OPTION 3

A TAVI service should be made available for patients identified as having a ‘high mortality risk’ with conventional AVR, as a replacement procedure.

Cost:
   a) £64,550 based on 25 patients at an additional cost of £2,582 per patient.
   b) £643,400 based on 25 patients at an additional cost of £25,736 per patient.

Pros
   • Clinicians wish to use TAVI for ‘high risk’ patients as this group often have poor outcomes with conventional AVR.

Cons
   • There is no high quality evidence of clinical or cost effectiveness in this population.

Costs
   • This is a replacement for AVR and is expected to incur additional costs of around £14,780 per patient, however savings may be made from reduced ITU stays.
OPTION 4

A TAVI service should be made available for ‘inoperable’ patients and for ‘high risk’ conventional AVR patients, as a replacement procedure.

Cost:

a) £591,025 based on 50 patients at an average additional cost of £11,821 per patient.

b) £1,748,725 based on 50 patients at an average additional cost of £34,975 per patient.

Pros
- This is the option preferred by clinicians.
- There is evidence of clinical effectiveness in the ‘inoperable’ group.
- Clinicians wish to use TAVI for ‘high risk’ patients as this group has poor outcomes with conventional AVR.

Cons
- There is no high quality evidence of clinical effectiveness in the ‘high risk’ population.
- Long term outcomes of TAVI are unknown.
- There is no evidence of cost effectiveness for either group.

Costs
- As a new procedure/intervention for the ‘inoperable’ group there are additional costs of a minimum of £21,000 per patient.
- As a replacement for AVR in the ‘high risk’ group TAVI is expected to incur additional costs of around £14,000 per patient, however savings may be made from reduced ITU stays.
Potential TAVI Service Delivery Options

If a TAVI service is to be made available to the population of Scotland these are the options for service delivery:

OPTION A
Patients referred to an English TAVI service for treatment.

Pros
• Significant expertise in TAVI has been built up in some English centres.

Cons
• Scotland may be left behind other European countries in clinical practice in the area of TAVI.
• This is an elderly population where long distance travel for treatment may not be appropriate.

Costs
• Cost per patient is higher than it would be for a Scottish TAVI service.

OPTION B 1
1 TAVI service in Scotland providing treatment at 1 site, with 1 staff team.

Pros
• One service is essential to ensure consistency in patient selection and equity of access to treatment across Scotland, particularly for a capped service.
• One site ensures greater patient numbers, which is likely to improve outcomes.

Cons
• One site might only give access to one valve within Scotland, however this is expected to be a short term limitation due to advances in technology.

OPTION B 2
1 TAVI service in Scotland providing treatment at 2 sites, with 1 staff team.

Pros
• One service is essential to ensure consistency in patient selection and equity of access to treatment across Scotland, particularly for a capped service.
• Only one team ensures greater patient numbers for clinicians, improving outcomes.
Two regions will gain expertise in TAVI.
Any burden on NHS facilities eg ITU, will be split between two sites.

Cons
Two sites will increase overall numbers of staff involved, which may reduce some of the benefits in outcome expected from one team.
Potential practical difficulties associated with one team working across two sites.
One team would only give access to one valve within Scotland, however this is expected to be a short term limitation due to advances in technology.

OPTION B 3

1 TAVI service in Scotland providing treatment at 2 sites, each with its own staff team. Initially with one overarchin g MDT to ensure equity.

Pros
- One service is essential to ensure consistency in patient selection and equity of access to treatment across Scotland, particularly for a capped service.
- A single service gives greater control over managing future developments and potential expansion of a TAVI service.
- Any burden on NHS facilities eg ITU, will be split between two sites.
- Both valve types could be provided in Scotland, one by each team. However this may only be a short term benefit due to advances in technology.
- Clinicians preferred a two team option.

Cons
- Larger TAVI centres are recommended due to benefits on outcomes.

OPTION B 4

2 TAVI services in Scotland providing treatment at 2 sites, each with its own staff team.

Pros
- Clinicians thought it might be easier to work within regional teams.
- Both valve types could be provided in Scotland, one by each team. However, this may only be a short term benefit due to advances in technology.

Cons
- Two services would make it very difficult to ensure consistency in patient selection and equity of access to treatment across Scotland, particularly for a capped service.
- Two services would make it harder to control future developments and potential expansion of TAVI.
• Two services would treat smaller numbers, than one large service limiting ability to build up expertise in patient selection and treatment, which adversely affects outcomes.

• Patient numbers build up gradually in new TAVI services supporting sequential development for more than one service. If two new services set up simultaneously numbers would be small for longer, prolonging the learning curve and potentially adversely affecting outcomes.

**Additional Factors for Consideration**

**National MDT versus regional MDT**

The definitions of ‘inoperable’ and ‘high risk’ are made on clinical judgement. The threshold for considering TAVI is likely to reduce over time, as fewer conventional AVRs are performed on ‘high risk’ patients. Evidence from England indicates that the main learning curve for TAVI is in patient selection. A national MDT would ensure consistency in patient selection which is crucial for a service with a limited evidence base to support it. In practice patients would be assessed by their local cardiology service and then referred to the national MDT if they were considered suitable for TAVI. Clinicians should always have the final say on whether they are happy to treat a particular patient.

Once a Scottish TAVI service had been functioning well for a couple of years a regional MDT may be sufficient. Regional MDTs are easier to facilitate and were preferred by most Scottish clinicians.

**Capping of TAVI numbers**

Capping has been used in a number of TAVI services in England. The group were not uncomfortable with the idea of capping numbers for a Scottish TAVI service. Capping ensures that numbers and costs are controlled where need and demand are uncertain. Capping may also help ensure patient selection does not expand outwith the target population. A limitation of capping is that it could create a waiting list.

The MDT would play a key role in managing a cap and ensuring that access to TAVI is based on need and ability to benefit. In order to ensure equity across Scotland, a Scotland wide MDT would be essential. This is particularly important during the first couple of years as expertise and experience in patient selection is gained.
APPENDIX 1

MEMBERSHIP

Membership of the group is listed below and includes representatives from cardiology and planning, nominated by the 3 regions of NHS Scotland. The work of the Group was supplemented by the Scottish Government Health Directorates and the Scottish Health Technologies Group, as under:

Chair: Dr Ross Cameron, Medical Director, NHS Borders
  o Dr Jennifer Armstrong, Scottish Government Health Directorates, (Deputy Chair)
  o Dr Annie Ingram, Director of Regional Planning and Workforce Development, NoSPG
  o Heather Knox, Director of Regional Planning, WoS
  o Dr Malcolm Metcalfe, NoS Clinical Lead for Cardiac Services
  o Dr Brian Montgomery, Medical Director NHS Fife, Chair of SEAT Cardiac Planning Group
  o Dr David Murdoch, Consultant Cardiologist and Lead Clinician, NHS Greater Glasgow & Clyde Cardiology MCN
  o Jacqui Simpson, Interim Regional Director of Planning, SEAT
  o Dr Barry Vallance, Lead Clinician for Heart Disease and Chair of the National Advisory Committee on Heart Disease
  o Dr Neil Dewhurst, President of the Royal College of Physicians of Edinburgh
  o Dr Jane Bray, Specialist Registrar Public Health, Scottish Government
  o Peter Croan, Head of Finance & Operations, NSD

SGHD Support
  o Robbie Pearson
  o Tom Plichcer
  o Tammy Nicol

NHS QIS - Scottish Health Technology Group Support
  o Heather McIntosh
  o Susan Myles
## Patient Pathway: Inpatient

<table>
<thead>
<tr>
<th>Patient Pathway</th>
<th>Time Resource/Details</th>
<th>WTE</th>
<th>Cost per Case (£)</th>
<th>Marginal Cost only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre - Admission</td>
<td>2-3 weeks prior to admission</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MDT</td>
<td>1 hour of 2*Cardiologist/Surgeon</td>
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<td>0</td>
<td>0</td>
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<tr>
<td>New Outpatient Clinic</td>
<td>1 hour</td>
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<td>0</td>
</tr>
<tr>
<td>Bloods</td>
<td>FBC, U&amp;A</td>
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<td>15</td>
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<tr>
<td>ECG</td>
<td>old HCI 2003 price 3%/annum</td>
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<td>48</td>
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<tr>
<td>ECHO</td>
<td>84</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
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<td>196</td>
<td>196</td>
<td>196</td>
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<tr>
<td>Chest X-ray</td>
<td>Used cost book avg. plus inflate</td>
<td>65</td>
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<td>0</td>
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<tr>
<td>PFT</td>
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<td>30</td>
<td>30</td>
<td></td>
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<tr>
<td>Booking Office - letters/contracts to pa</td>
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<td>0.003</td>
<td>1.82</td>
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<td>150</td>
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<td>0</td>
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<td>50% of cases</td>
<td>16.50</td>
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<tr>
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<td>50% of cases - 1 night</td>
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<td>0</td>
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<tr>
<td>Admission</td>
<td>1 day - Level 3</td>
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## Procedure

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<tr>
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<th>Cost per Case (£)</th>
<th>Marginal Cost only</th>
</tr>
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<td>Cath Lab Team</td>
<td>2 hrs</td>
<td>512</td>
<td>512</td>
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<tr>
<td>Theatre Team - Standby</td>
<td>2 hrs</td>
<td>232</td>
<td>158</td>
<td>158</td>
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<tr>
<td>Tavi valve</td>
<td>cv £11,750 90% - ELS £14,394 10%</td>
<td>12,014</td>
<td>12,014</td>
<td>12,014</td>
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<tr>
<td>Cath lab disposables</td>
<td>based on Angio + add on</td>
<td>1541</td>
<td>1541</td>
<td>1266</td>
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<tr>
<td>Pacemaker</td>
<td>01.10</td>
<td>484</td>
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<td></td>
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<tr>
<td>TOE-*1 Cardiologist</td>
<td>0.5 PA</td>
<td>266</td>
<td>266</td>
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<tr>
<td>Drugs - Theatre</td>
<td></td>
<td>43</td>
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</tr>
<tr>
<td>Drugs - ICU</td>
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<td>10</td>
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<td>CICU stay</td>
<td>1 day</td>
<td>1,017</td>
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<tr>
<td>HDU - N2B ratio</td>
<td>4 days - Cardiology CCU</td>
<td>1322</td>
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<tr>
<td>Ward stay</td>
<td>2 days - Level 3</td>
<td>873</td>
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<tr>
<td>Cardiologist</td>
<td>0.25 PA</td>
<td>84</td>
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<tr>
<td>Catering</td>
<td></td>
<td>96</td>
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</tr>
<tr>
<td>Overheads</td>
<td>(assumed 5% of total cost)</td>
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## Discharge

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<th>Marginal Cost only</th>
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<td>Drugs prescription</td>
<td>clopidrogel, paracetamol</td>
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<tr>
<td>Letter to GP re discharge follow up</td>
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<td>0.0015</td>
<td>0.02</td>
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<tr>
<td>Transport</td>
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## Follow up

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<tr>
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<th>Time Resource/Details</th>
<th>WTE</th>
<th>Cost per Case (£)</th>
<th>Marginal Cost only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beardmore (50% of cases) - 1night</td>
<td></td>
<td>22.50</td>
<td></td>
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<tr>
<td>Outpatient return visit</td>
<td>30 mins</td>
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<tr>
<td>Cardiologist</td>
<td>0.25 PA</td>
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## Total Cost

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<th>WTE</th>
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<tr>
<td>New Patients</td>
<td>21,061</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAVR to TAVI</td>
<td>14,780</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### COST OF SERVICE

The estimated breakdown of costs for the procedure are as follows:

<table>
<thead>
<tr>
<th></th>
<th>COSTS</th>
<th>SUBTOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative Assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>magnetic resonance angiogram</td>
<td>£500</td>
<td></td>
</tr>
<tr>
<td>multi-slice computed tomogram</td>
<td>£500</td>
<td></td>
</tr>
<tr>
<td>coronary angiogram/aortography</td>
<td>£800</td>
<td></td>
</tr>
<tr>
<td>percutaneous coronary intervention in 50%</td>
<td>£1,500</td>
<td>£3,300</td>
</tr>
<tr>
<td>Edwards-SAPIEN™ valve</td>
<td>£12,000</td>
<td>£12,000</td>
</tr>
</tbody>
</table>

**TRANSFEMORAL**

**Catheter laboratory consumables**
- catheters, wires, dilatation balloon, pacing wire | £1,000 |
- cath lab staffing (1 nurse/technician/radiographer) | £1,200 |
- transoesophageal probe maintenance | £100 |
- sterile disposables | £100 |
- anaesthetic equipment, disposables & maintenance | £200 | £2,900 |

**Post-operative care**
- 1 day ITU | £1,500 |
- 1 day cardiothoracic high dependency unit | £800 |
- 5 (1+4) days in-patient stay with physio. support | £500 | £2,800 |

**TRANSAPICAL**

**Surgical Costs**
- operating room costs, equipment, staffing | £2,000 |
- 1 day cardiothoracic high dependency unit | £800 |
- transoesophageal probe maintenance | £100 |
- operation equipment | £100 |
- anaesthetic equipment, disposables & maintenance | £500 | £3,700 |

**Post-operative care**
- 1 day ITU | £1,500 |
- 2 days cardiothoracic high dependency unit | £1,600 |
- 5 (1+4) days in-patient stay with physio. support | £500 | £2,800 |

**Post-discharge care**
- sequential 2D echocardiography (x4) | £400 |
- pacemaker (30% of £2000) | £600 | £1,000 |

**TOTAL**
- Transfemoral = £22,000
- Transapical = £22,800
REFERENCES


