Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1348 – Transcatheter closure of ventricular septal defect

Sponsor/Applicant/s: **Cardiac Society of Australia and New Zealand (CSANZ)**

Date of MSAC Meeting: **28 November 2013**

1. Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of transcatheter closure of ventricular septal defect (VSD) was received from the Cardiac Society of Australia and New Zealand (CSANZ) by the Department in December 2012.

Transcatheter closure of a VSD is performed under general anaesthesia in the paediatric population. It may be performed with sedation in the adult population. Access is commonly via the femoral route but can be via the neck. Prior to deployment of the device, angiography is performed to define in detail the anatomy and size of the defect which allows planning for the intervention. The VSD is crossed using a catheter from the left ventricular side and a device is deployed which aims to completely occlude the VSD.

Transcatheter techniques would replace standard surgical closure of VSDs for those defects suitable for use of these devices. Patients with acquired VSDs requiring urgent or emergency treatment are likely to undergo surgical rather than transcatheter closure. The current devices available are muscular and membranous VSD occluders.

Transcatheter closure techniques may be suitable for membranous VSDs and muscular VSDs. The application indicates that transcatheter closure is appropriate treatment for patients with a muscular VSD. Currently perimembranous VSDs are being closed surgically in Australia because of an associated high incidence of complete heart block when transcatheter devices are utilised. New devices are currently being designed and trialled which are likely to prove suitable for closure of the perimembranous VSD. Surgery will remain the treatment of choice for doubly committed subarterial VSDs, inlet VSDs and acquired VSDs treated in an emergency situation.

Transcatheter closure of a VSD would be performed in-hospital with surgical assistance.

A VSD is a hole in the ventricular septum between the left ventricle and the right ventricle. It can occur as a congenital defect or can be acquired in the setting of an acute myocardial infarction, trauma or iatrogenic following aortic valve replacement or myomyectomy surgeries. VSD is one of the most common congenital heart defects.

The two types of VSD suitable for transcatheter closure are the membranous (or perimembranous) VSD and the muscular VSD.

The prevalence of congenital heart disease is about 1 in 100 and VSDs would represent 10% of the disease burden (1 in 1000). The natural history of a VSD is that 80-90% of these defects will close spontaneously. Many of the residual defects are small and do not require intervention.

2. Background

There are no MBS items for transcatheter closure of VSD and the procedure has not been previously assessed by MSAC.

3. Prerequisites to implementation of any funding advice

The VSD occluder devices have been registered with the Therapeutic Goods Administration on the Australian Register of Therapeutic Goods (ARTG).

There are a couple of devices for VSD closure currently not listed on the ARTG but which are referred to in international literature.

As at February 2013, the VSD occluder devices listed on the Prostheses List were:

- AMPLATZER Muscular VSD Occluder; and
- AMPLATZER Membranous VSD Occluder.

4. Proposal for public funding

Applicant Proposed MBS item descriptor

VENTRICULAR SEPTAL DEFECT, transcatheter closure of (Anaes.) (Assist.) Fee: to be determined Benefit: 75% =

The application indicated that the technique which uses similar technology would be transcatheter closure of an atrial septal defect (ASD) and transcatheter closure of patent ductus arteriosus (PDA).

MBS item 38272 for transcatheter closure of ASD has a schedule fee of $912.30 as of 1 November 2012.

Applicant MBS item descriptor for 38272 as at 1 November 2012

Category 3 – Cardio-Thoracic ATRIAL SEPTAL DEFECT closure, with septal occluder or other similar device, by transcatheter approach (Anaes.) (Assist.) Fee: $912.30 Benefit: 75% = $684.25 85% = $837.80

The majority of the services would be provided by paediatric interventional cardiologists.

5. Consumer Impact Statement

Feedback noted that as this service is performed exclusively in large tertiary hospitals, patients diagnosed with this condition in regional areas will need to travel to a tertiary centre

for treatment. Therefore, there may be a requirement for this travel to be supported by a state based patient travel scheme.

6. Proposed intervention's place in clinical management

At present, the therapeutic options in Australia for VSD are medication, surgery by open approach or transcatheter closure (technically available only in the public system). Hybrid surgery is also performed where clinically appropriate.

Transcatheter closure of VSD is proposed as a substitute procedure for the currently funded surgical intervention. However, not all VSDs will be suitable for device closure. This decision will be determined by factors including the type and size of the VSD, the size of the patient and the severity of the patient's symptoms. Clinical input was that closure of a VSD can also be performed by a hybrid approach. Hybrid surgery is usually planned and most commonly performed for muscular defects. The decision is often based on patient size and whether additional procedures need to be performed.

Given transcatheter closure of VSD has been established for some time in the Australian health care setting, only one management algorithm was presented. The clinical assessment in which patients are selected for either transcatheter or surgical closure of their VSD may occur during their initial presentation. The clinical management algorithm illustrated this as sequential but in clinical reality many clinicians would ascertain the characteristics of the VSD immediately on referral. Additionally, the surgeon can shift between transcatheter and hybrid approaches with the decision made after a ventriculogram. Therefore, hybrid surgery for closure of a VSD has been separated from the transcatheter approach in the algorithm.

The application claimed that transcatheter closure is a direct substitute (i.e. provides patients with a new treatment alternative) for the currently subsidised intervention of surgical closure of VSD. However, it should be noted that there are some patients for whom transcatheter closure is not an option. Surgery will remain the treatment of choice for doubly committed sub-arterial VSDs, inlet VSDs and acquired VSDs treated in an emergency situation.

7. Other options for MSAC consideration

Nil.

8. Comparator to the proposed intervention

The submission stated that standard therapy for treatment of a VSD is surgical closure utilising cardiopulmonary bypass (item 38751). Therefore, the surgical closure MBS item 38751 was suggested as the appropriate comparator for the proposed service.

MSAC noted that the comparator item 38751 is restricted to patients with "congenital heart disease" (i.e. it is not reimbursable for closure of an acquired VSD). MSAC did not consider the comparator valid in the Australian context as the majority of surgical VSD closures are performed on neonates and infants who would not be considered candidates for transcatheter closure due to the increased risk of morbidity.

Surgical closure of VSD is performed as in-hospital procedure only, with data indicating that approximately a quarter of patients are treated as private patients in the public system.

MBS funding for open heart surgery for congenital heart disease can be found on the 1974 Schedule. A specific MBS item for closure of VSD for congenital heart disease was introduced on the Schedule on 1 November 1992. The Health Insurance Regulations *1973*

exclude transcatheter techniques from MBS item 38751. The current MBS item descriptor for surgical closure of VSD is presented in the following table.

Current MBS item descriptor for 38751 as at 1 November 2012

Category 3 – Cardio-Thoracic 38751 VENTRICULAR SEPTAL DEFECT, closure by direct suture or patch, for congenital heart disease (Anaes.) (Assist.) Fee: $2,134.50 Benefit: 75% = $1,600.90

9. Comparative safety

Two comparative studies for transcatheter versus surgical closure of congenital VSD were identified by the literature search for inclusion (Liu 2012 and Xunmin 2007). Three further articles on transcatheter versus surgical closure of congenital VSD were also included (Pawelec-Wojtalik 2005, Zheng 2009 and Oses 2010).

All five studies were non-randomised. In all the studies only certain subjects were considered eligible for transcatheter closure. Generally, younger or smaller children and those with large VSDs were considered ineligible. Subjects that did not meet the criteria for transcatheter closure were treated surgically.

As a result of these criteria there were imbalances between treatment groups in patient characteristics in the studies, with patients allocated to transcatheter closure being older, larger/heavier and having smaller VSDs.

The size of the studies varied significantly with one very large study (Zheng 2009) and four smaller studies. As might be expected with non-randomised studies, the treatment arms in the larger studies were not numerically balanced.

In Liu (2012) a different device was used compared to the other four studies which used the same VSD occluder devices.

The Zheng (2009) study included subjects with both perimembranous and muscular VSDs. However, outcomes were only presented for the whole group and were not broken down by VSD type. All the other studies enrolled subjects with perimembranous defects only.

One comparative study for intraoperative device closure (hybrid surgery) versus surgical repair of congenital VSD (Xu 2012) was identified by the literature search.

1. Mortality rates

Only one subject died in the comparative studies. This was a 4-year-old boy who had significant left ventricular dysfunction and myocardial stunning on weaning from cardiopulmonary bypass following surgical VSD repair. The child appears to have died fairly soon after surgery.

2. Overall complications

Four of the studies reported the incidence of important complications. The descriptor used for inclusion of such complications varied across studies, and the incidence figures obtained varied significantly. However, in all four studies there did not appear to be a significant difference in the incidence of such events between closure methods.

Two studies also reported on the incidence of minor complications. In both studies the incidence of such complications was higher with surgical closure.

The same two studies reported on the total complications rate (i.e. important plus minor complications).

Significant haemorrhage was reported only with surgical closure in the submitted studies. One patient in Xunmin (2007), and six patients in Zheng (2009) required re-operation for bleeding. The percentage of patients requiring blood products was notably less frequent with catheter closure.

Pericardial effusion occurred only in patients receiving surgical closure. In Xunmin (2007) (n=1) and Oses (2010) (n=2) the patients who developed a pericardial effusion required drainage. In Zheng (2009), six patients developed effusions but no further information was provided.

The infections identified in the five studies were generally pneumonia or wound infection. These were only reported in patients treated with surgical closure.

In a number of the cases in the transcatheter group, subjects developed complete atrioventricular block (AVB) during the procedure. In these cases the catheterisation procedure was aborted and surgical VSD closure undertaken. In only one study (Oses 2010) was there a suggestion of an increased incidence of pacemaker insertion (5.4% vs. 2.9%). However, the difference in terms of numbers of patients was small (2 vs. 1 patient).

Left bundle branch block occurred with a slightly higher incidence with transcatheter closure, whereas right bundle branch block was notably increased with surgical closure. One study (Oses 2010) reported on PR and QRS intervals. Transcatheter closure was associated with significant prolongation of mean PR interval at long-term follow-up. There were no significant differences in mean QRS interval.

Device embolisation was reported in only one of the five studies (Oses 2010). The device embolised into the left ventricle during the catheterization procedure in one subject. The patient underwent emergency surgery including VSD repair.

The studies did not suggest that percutaneous closure was associated with an increased incidence of cardiac valve incompetence.

In one of the studies (Liu 2012), there was a statistically significant difference in mean LVEF in favour of surgery. However the difference was not clinically significant and was not found in the other two studies.

Transcatheter closure appeared to be associated with a small increased risk of blood vessel injury and transient device thrombus. Transcatheter closure did not appear to be associated with an increased incidence of any other specific adverse event.

Hybrid closure
There were no deaths in either group in the study.

The incidence of overall complications was higher in the surgery group, however there was no significant difference in the incidence of major complications.

There were no cases of haemorrhage reported for the study. Blood products were required in 9% of subjects in the hybrid surgery group and 100% of patients in the surgery group (p-value not reported).

Pericardial effusion was only reported in the surgery group. In three patients the pericardial effusion was considered a major complication, requiring surgical drainage, with 250mLs draining in the first 24 hours. In the other two subjects the pericardial effusions were considered minor.

Infective complications were also only reported in the surgery group. All seven infections in the surgery group were cases of pneumonia, and all were considered minor complications. The incidence of complete AVB was higher in the hybrid surgery group. There was one case of grade II AVB in the conventional surgery group. In the hybrid surgery group, one subject developed transient complete AVB during the procedure and reverted to sinus rhythm when the device was withdrawn. The patient then underwent conventional surgical closure. The other subject developed complete AVB on the fifth day after surgery and reverted to sinus rhythm after a three-day course of corticosteroids. Neither patient required pacemaker insertion.

In the conventional surgery group, the subject with grade II AVB reverted to sinus rhythm after a two-day course of corticosteroids.

As with transcatheter closure, cases of left bundle branch block were more common after device placement and cases of right bundle branch block were more common following conventional surgery.

No cases of device embolisation, displacement or misplacement were reported.
In Xu (2012), there was an increased incidence of new tricuspid incompetence following hybrid surgery. The three cases were described as ‘trivial or mild’. With long-term follow up the degree of regurgitation decreased in one subject and remained stable in the other two. There were no reports of new onset aortic or mitral valve incompetence.

The only other adverse event reported was atrial premature beats, with an incidence of 2/89 (2.2%) in the hybrid surgery group and 2/97 (2.1%) in the conventional surgery group.

In terms of safety, transcatheter closure is associated with a comparable incidence of major complications, and a lower incidence of minor complications compared to surgical closure.

Concern has been expressed in the literature regarding a potentially increased risk of complete atrioventricular block with transcatheter closure (Penny 2011). However, this was not a consistent finding in the comparative studies, and the incidence of permanent pacemaker insertion was comparable for the two treatment modalities. As might be expected, the comparative studies suggested that transcatheter closure is associated with some increased risk of blood vessel injury and transient thrombosis on the device. There was no suggestion of an increased incidence of any other adverse event.

The safety data from the single comparative study of intraoperative device closure (hybrid surgery) for congenital VSD demonstrated a lower incidence of minor complications compared to surgical closure. However there was a suggestion of an increased risk of complete atrioventricular block (2.2% vs. 0.0%).

MSAC noted the safety issues associated with closure and that data on long-term safety, e.g., the increased risk of complete heart block, are not available. MSAC considered that overall, transcatheter closure and surgical closure have similar safety with different risk profiles.

10. Comparative effectiveness

1. Closure of the VSD

Results for successful closure of VSD are summarised in the following table.

VSD closure rates (%)

	Pawelec 2005	Xunmin 2007	Zheng 2009	Oses 2010	Liu 2012
Catheter	100.0%	97.3%	99.8%	97.3%	99.4%
Surgery	100.0%	100.0%	100.0%	100.0%	98.9%
p-value	NR	ns	ns	NR	0.671

NR=not reported; ns= 'not significant'.

The reasons for unsuccessful *catheter* closure were:

- Transient complete atrioventricular block (AVB) during the procedure in 2 subjects (Xunmin 2007);
- Complete AVB (n=1) and severe tricuspid regurgitation (n=1) (Zheng 2009);
- Device embolisation into the left ventricle during the procedure (n=1) (Oses 2010); and
- Severe tricuspid regurgitation during the procedure (n=1) (Liu 2012).

All these subjects required subsequent surgical closure of their VSD.

The reasons for unsuccessful *surgical* closure were:

- Complete AVB requiring a permanent pacemaker (n=1); and
- Fatal left ventricular dysfunction after cardiopulmonary bypass (n=1) (Liu 2012).

2. Residual shunt

The proportion of patients with a residual shunt was as follows.

Residual shunt rates (%)

	Pawelec 2005	Xunmin 2007	Zheng 2009	Oses 2010	Liu 2012
Catheter	9.1%	2.7%	0.5%	5.4%	3.8%
Surgery	8.3%	4.2%	0.6%	8.8%	6.4%
p-value	NR	NR	ns	0.92	0.287

NR=not reported; ns= 'not significant'.

The residual shunts were generally described as 'trivial' or 'small' and many closed spontaneously with longer follow-up. There were two subjects with 'moderate' residual shunts (n=1 in both Oses (2010) and Liu (2012)) and both had been treated with surgical repair.

3. Avoidance of cardiopulmonary bypass

The proportion of patients assigned to transcatheter closure who avoided cardiopulmonary bypass was as follows.

Avoidance of cardiopulmonary bypass (%)

Pawelec 2005	Xunmin 2007	Zheng 2009	Oses 2010	Liu 2012
100.0%	97.3%	99.8%	97.3%	99.4%

4. Reduction in pulmonary artery pressure

Measures of pulmonary artery pressure were not reported in any of the five comparative studies. One case of pulmonary hypertensive crisis with cardiorespiratory arrest (with subsequent recovery) was reported in Oses (2010), the patient had had surgical VSD closure.

5. Patient discomfort

Direct measures of patient discomfort were not reported in any of the five comparative studies. Two studies reported on time to resumption of normal activities, an endpoint that may reflect the level of patient discomfort. In both studies there was a statistically significant benefit with transcatheter closure.

6. Hospital stay

Four of the studies measured length of hospital stay. In all these studies transcatheter closure was associated with a shorter average hospital stay. In three of the studies the difference reached statistical significance.

7. Long term effectiveness outcomes

The effectiveness outcomes described above are all outcomes obtained at long-term follow-up. However, duration of follow-up varied across studies. In Liu (2012), average duration of follow-up was approximately 5 months. In Oses et al (2010), the average duration of long-term follow-up was approximately 42 months (3.5 years). Duration of follow-up in the other three studies was approximately 12 months.

Oses (2010) reported on the incidence of residual shunts both at hospital discharge and at long-term follow-up.

Incidence of residual shunt (%)

	At discharge	At long-term follow-up
Catheter	11.1%	5.4%
Surgery	23.5%	8.8%
p-value	0.26	0.92

Hybrid closure

The hybrid approach failed in 2/89 patients (2.2%). One subject developed transient complete AVB during the procedure. The other subject was considered a failure because of a residual shunt after deployment of the device. Both subjects underwent surgical correction of their VSD.

In the hybrid surgery group ‘tiny’ residual shunts were detected in 25.3% of subjects immediately after the procedure. However, these all resolved within the first three months of follow-up.

In the conventional surgery group a residual shunt was detected in one subject (1.0%) one week after surgery. This was subsequently closed with a hybrid procedure.

Cardiopulmonary bypass was avoided by 97.8% of subjects assigned to the hybrid surgery procedure.

The reduction in pulmonary artery pressure at 12 months was comparable in the two groups. The study did not report any measures of patient discomfort.

The length of inpatient stay was significantly shorter in the hybrid surgery group.

Mean ± SD duration of follow-up in this study was 20.5 ± 3.2 months, with a range of 13-32 months. Other long-term effectiveness outcomes reported in the study are summarised in the following table.

Long-term effectiveness outcomes (Xu 2012)

RVSP at 1 month (mmHg) – mean ± SD	
Hybrid surgery	11.8 ± 3.6
Surgery	11.2 ± 3.2
p-value	1.000
Percent decrease in LVEDD at 12 months – mean ± SD	
Hybrid surgery	10.4 ± 5.7
Surgery	9.5 ± 4.4
p-value	0.762
Percent decrease in cardiothoracic ratio at 12 months – mean ± SD	
Hybrid surgery	7.2 ± 2.3
Surgery	7.8 ± 1.9
p-value	0.894

RVSP=right ventricular systolic pressure; LVEDD = left ventricular end diastolic diameter

The studies of transcatheter closure of congenital VSD indicated that the procedure has comparable effectiveness to surgical closure when used in an appropriately selected patient population. In such a population, the procedure is associated with a high rate of successful closure and a low incidence of significant residual shunt. In addition, transcatheter closure is associated with some advantages over surgical closure, such as:

- Avoidance of the need for cardiopulmonary bypass;
- A more rapid return to normal activities; and
- A shorter hospital stay.

The single comparative study of intraoperative device closure (hybrid surgery) for congenital VSD also indicated effectiveness comparable to surgical closure, with the advantages of avoidance of cardiopulmonary bypass and a shorter hospital stay.

Based on the studies presented, MSAC noted that transcatheter closure is associated with a high rate of successful closure (99.8%, Zheng *et al* 2009; 99.4%, Liu *et al* 2012) and a low incidence (0.5% Zheng *et al* 2009; 3.8%, Liu *et al* 2012) of significant residual shunt. In addition, transcatheter closure is associated with some advantages over surgical closure.

Overall, MSAC agreed that transcatheter closure of VSD is likely to be non-inferior in terms of comparative safety and effectiveness despite issues with the limited evidence base.

11. Economic evaluation

A cost-minimisation analysis was presented for the service relative to that of surgical closure of congenital VSD.

The analysis did not restrict the service by the age of the patient or the type of the defect. The analysis also took into account that the service is currently provided for small numbers of patients, and therefore the total government expenditure on the service is likely to be small. The potential for use of the service in a wider population or setting than the target population and setting was considered unlikely.

After repair of a VSD, long-term follow-up is necessary. However, for the purposes of the analysis, the assumption was made that the follow-up would be of a similar nature for both transcatheter and surgical closure of VSD. Therefore, the follow-up period was not factored in to the cost-minimisation analysis.

The costs and benefits of transcatheter or surgical closure of VSD were assumed to be similar post discharge from hospital. Therefore, discounting was not applied to the cost-minimisation analysis. Variables used in the economic evaluation included MBS items, the prosthetic item and health care resources. Specialist consultation and diagnostic services were included in the analysis for all patients undergoing closure of VSD by either surgical or transcatheter technique. The health care resource items for which there would be a change in use associated with providing transcatheter closure of VSD include diagnostic and hospital services and the cost of providing the device itself.

Transcatheter closure of VSD aims to successfully deliver the device with no residual shunt and complete regression of signs of volume overload. The outcomes generated by the economic evaluation represent the final outcomes of treatment.

Transcatheter closure of VSD was proposed to be non-inferior to surgical closure of VSD. The comparison of the cost per patient for transcatheter versus surgical closure of VSD is summarised below. The comparison indicated that transcatheter closure of VSD is less expensive compared to surgical closure ($17,011 and $18,638 respectively for 2012-13).

The cost of the ADO device significantly adds to the overall cost of the procedure. However, in terms of cost-effectiveness of health resources (excluding the device cost), transcatheter closure of VSD provides relative benefit, for example shorter recovery time with a significantly decreased length of hospital stay, at lower costs.

Comparison of cost per patient

	Transcatheter		Surgery	
	Units	**Total**	**Units**	**Total**
Consultation and diagnostic				
Specialist initial consultation	1	$64.20	1	$64.20
Electrocardiography (ECG)	2	$46.90	2	$46.90
Chest x-ray	2	$70.80	2	$70.80
Transthoracic echocardiography	2	$346.00	2	$346.00
Both surgery and transcatheter				
Operating theatre / Catheter lab	1	$1,790.00	1	$1,790.00
Ward stay	3	$2,322.00	8	$6,192.00
Transcatheter closure of VSD				
Device	1	$10,200.00		
Anaesthesia (cardiac catheterisation)	1	$103.95		
Anaesthesia time (3:01 to 3:10 hrs)	1	$237.60		
Surgical assistant (20% of fee)	1	$136.85		
Cardiac catheterisation	1	$482.00		
Transcatheter closure of VSD	1	$684.25		
Ventriculography	1	$399.20		
Transoesophageal echography	1	$127.50		
Surgical closure of VSD				
Initiation anaesthesia (open heart)			1	$297.00
Anaesthesia time (4:01 to 4:10 hrs)			1	$311.85
Assistant			1	$320.18
Surgical closure of VSD			1	$1,600.90
Cardiac bypass			1	$297.00
ICU stay			3	$6,627.00
ICU initial attendance			1	$271.60
ICU followup attendance			2	$402.90
TOTAL		**$17,011.25**		**$18,638.33**

The proposed fee for transcatheter closure of ASD was used for the financial evaluation of transcatheter closure of VSD. However, it should be noted that the proposed MBS item descriptor for transcatheter closure of VSD did not refer to any associated imaging and cardiac catheterisation that may be performed at the time of the procedure.

If imaging were included, the proposed MBS item descriptor would be as presented in the following table. This proposed descriptor would include the transcatheter closure of VSD plus cardiac catheterisation (item 38206: Schedule fee - $642.65); ventriculography (item 38218: Schedule fee - $532.25); and Transoesophageal echography (item 55130: Schedule fee - $170.00).

Applicant Proposed MBS item descriptor with imaging and cardiac catheterisation

VENTRICULAR SEPTAL DEFECT, transcatheter closure of, with imaging and cardiac catheterisation (Anaes.) (Assist.) Fee: to be determined Benefit: 75% =

MSAC agreed that associated imaging and cardiac catheterisation should be included in the MBS descriptor and associated fee when performed by the same operator. MSAC considered that the MBS fee should be modelled on the current MBS fee of $912.30 for item 38272 – transcatheter closure of atrial septal defect.

12. Financial/budgetary impacts

The estimated number of procedures for transcatheter closure of VSD is outlined in the following table. The percentage of procedures treated percutaneously is 2%, in line with AIHW procedures data for closure of VSD. As this procedure is already performed in the public setting, only private percutaneous treatment of VSD was relevant for the purposes of the financial analysis.

Estimated number of procedures

	2012-13	2013-14	2014-15	2015-16
Patients (increase 4.7% pa)				
Surgical	528	552	578	605
Percutaneous	12	13	14	14
Total	540	565	592	619
Private hospital patients (26%)				
Surgical	135	141	148	155
Percutaneous	3	3	3	4
Total	138	144	151	158

For the purposes of the financial analysis, transcatheter closure of VSD was treated as a once-only procedure, i.e. successful insertion of the device will result in a resolution of the disease process.

With current technologies, the numbers of VSDs that would be closed by transcatheter technique in Australia would be low. The submission suggested that the numbers currently closed by this technique would be less than 100 per year. With improvement in technologies it is likely that the frequency of this intervention would increase and more would be closed in this way replacing surgical treatment. However, the total number of VSDs which require closure either by surgical or transcatheter technique should remain constant.

The majority of procedures for closure of VSD are performed in the public sector. AIHW separation statistics for 2010-11 indicate that 93% (460) of a total of 493 patients were treated in public hospitals. However, hospital data does not provide a breakdown of the surgical approach used.

AIHW procedure data for 2009-10 indicated that only 2% (11) of the procedures performed for closure of VSD were by percutaneous approach. Children under 5 years of age accounted for 87% of the surgical procedures and 27% of the percutaneous procedures.

The MBS cost was based on the 75% benefit of the MBS items. The total cost of the proposed intervention to the MBS is $2,699.

A large proportion of the cost of transcatheter closure of VSD is the cost of the device. Devices currently listed on the Prostheses List have a list price of $10,200.

Overall, the cost of transcatheter closure of VSD (with device cost included) compared to that of open surgery was estimated to be $17,011 and $18,638 respectively.

In summary, for an estimated three patients treated in the private healthcare setting in 2013-14, transcatheter closure of VSD was estimated to provide a small saving to the MBS of $4,516 over surgical closure of VSD.

13. Other significant factors

Currently, MBS item 38751 may only be claimed in association with the closure of congenital VSDs. However, clinical advice received was that surgery will remain the treatment of choice for acquired VSDs treated in an emergency situation. Based on clinical advice that item 38751 does not reflect current practice it was suggested to amend as below by removing the words "for congenital heart disease" so as not to inhibit access to patient rebates.

MBS item 38751 – item descriptor as at 1 July2013 Category 3 – Cardio-Thoracic
VENTRICULAR SEPTAL DEFECT, closure by direct suture or patch~~, for congenital heart disease~~ (Anaes.) (Assist.) (See para T8.70 of explanatory notes to this Category) Fee: $2,134.50 Benefit: 75% = $1,600.90

MSAC supported amending the current MBS item 38751 for surgical closure of VSD to reflect current clinical practice (that includes post infarct and other types of VSD) by removing the words 'for congenital heart disease'.

14. Key issues for MSAC from ESC

ESC raised concerns regarding the comparator, noting that surgical patients are often sicker and have larger VSDs. ESC also noted that there was potential for "creep" in procedural numbers related to transcatheter closure of VSD for smaller defects that would currently be observed and managed medically.

ESC suggested that identification of overseas registries, if available, may provide further information on clinical effectiveness.

ESC considered that credentialing for the VSD technique would need to be robust given the low usage numbers and the necessity of maintaining the skill level to ensure the safety of the procedure.

15. Summary of consideration and rationale for MSAC's advice

The applicant proposed Medicare Benefits Schedule (MBS) listing of transcatheter closure of ventricular septal defect (VSD). MSAC noted that a VSD can occur as a common congenital abnormality, or it can be acquired in the setting of acute myocardial infarction or trauma.

MSAC noted that the majority of VSD transcatheter interventions will be provided by paediatric interventional cardiologists.

The comparator nominated in the application and the current practice for treatment of a VSD is open surgical closure on cardiopulmonary bypass. However, MSAC noted that the comparator item is restricted to patients with congenital heart disease (i.e., it is not reimbursable for closure of an acquired VSD) and did not consider the comparator valid in the Australian context. The majority of surgical VSD closures are performed on neonates and infants who would not be considered candidates for transcatheter closure due to the increased risk of morbidity.

MSAC noted safety issues associated with closure included complications of transvascular access, heart block and the need for a pacemaker (low rate in "experienced hands"), and the need for cardiopulmonary bypass (low risk) to address incomplete closure or device

embolisation. Data on long-term safety, e.g., the increased risk of complete heart block, are not available. MSAC considered that overall, transcatheter closure and surgical closure have similar safety with different risk profiles.

MSAC agreed that this device should be entered into the cardiac devices registry (if this new registry takes place).

Clinical effectiveness of transcatheter closure versus surgical intervention was based on five non-randomised studies. MSAC noted that the majority of these studies were undertaken overseas in older and heavier children, and the applicability of the results to the Australian population is uncertain, particularly as the patients in the studies would generally not be routinely considered candidates for transvascular approaches in Australia. However, MSAC noted that there is unlikely to be a randomised trial conducted for transcatheter versus surgical closure of VSD due to the small number of patients and that transcatheter closure is now an established treatment in selected patients.

Based on the studies presented, MSAC noted that transcatheter closure is associated with a high rate of successful closure (99.8%, Zheng *et al* 2009; 99.4%, Liu *et al* 2012) and a low incidence (0.5% Zheng *et al* 2009; 3.8%, Liu *et al* 2012) of significant residual shunt. In addition, transcatheter closure is associated with some advantages over surgical closure, such as:

- Avoidance of the need for cardiopulmonary bypass;
- A potentially more rapid return to normal activities; and
- A shorter hospital stay.

MSAC also noted that transcatheter closure does not require a stay in a paediatric intensive care unit. Overall, MSAC agreed that transcatheter closure of VSD is likely to be non-inferior in terms of comparative safety and effectiveness despite issues with the limited evidence base.

MSAC noted that the estimated utilisation is 10–20 devices per year. This may potentially increase over time in line with practice in China, where transcatheter closure is more readily considered. However, MSAC noted that in Australia the risk of surgery is low and the standard of perioperative care is consistently high therefore any increase would likely be small.

A cost minimisation analysis was undertaken for transcatheter closure relative to that of surgical closure of congenital VSD. MSAC noted that the cost of the device significantly adds to the overall cost of the transvascular procedure. However, the cost per patient comparison (with device cost included) indicates that there may be a small cost saving of approximately $1,000 for transcatheter closure compared with surgical closure. MSAC agreed that both surgery and device interventions may occur in scenarios where there is diagnostic uncertainty, and additional costs may be incurred as a result of further intervention.

MSAC agreed that associated imaging and cardiac catheterisation should be included in the MBS descriptor and associated fee when performed by the same operator. MSAC considered that the MBS fee should be modelled on the current MBS fee of $912.30 for item 38272 – transcatheter closure of atrial septal defect.

Lay summary

Transcatheter closure of VSD is an alternative to heart surgery for patients with this condition. A transcatheter closure device is placed in the heart through a tube (catheter) to permanently close the defective opening in the heart.

MSAC acknowledged limitations with the evidence base. Overall, MSAC accepted that transcatheter closure of VSD is similar to surgery in relation to safety, clinical effectiveness and cost-effectiveness and supported public funding for the procedure.

16. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of transcatheter closure of VSD, MSAC advises that it supports public funding of a new MBS item, with an item descriptor of:

VENTRICULAR SEPTAL DEFECT, transcatheter closure of, with imaging and cardiac catheterisation (Anaes.) (Assist.)
Fee: $912.30

MSAC also supports amending the current MBS item 38751 for surgical closure of VSD to reflect current clinical practice (that includes post infarct and other types of VSD) by removing the words 'for congenital heart disease'.

17. Applicant's comments on MSAC's Public Summary Document

No comment.

18. Context for decision

This advice was made under the MSAC Terms of Reference.

MSAC is to:

Advise the Minister for Health on medical services that involve new or emerging technologies and procedures and, where relevant, amendment to existing MBS items, in relation to:

- the strength of evidence in relation to the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
- whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported;
- the proposed Medicare Benefits Schedule (MBS) item descriptor and fee for the service where funding through the MBS is supported;
- the circumstances, where there is uncertainty in relation to the clinical or cost-effectiveness of a service, under which interim public funding of a service should be supported for a specified period, during which defined data collections under agreed clinical protocols would be collected to inform a re-assessment of the service by MSAC at the conclusion of that period; other matters related to the public funding of health services referred by the Minister.

Advise the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.

MSAC may also establish sub-committees to assist MSAC to effectively undertake its role. MSAC may delegate some of its functions to its Executive sub-committee.

19. Linkages to other documents

MSAC's processes are detailed on the MSAC Website at: www.msac.gov.au.