1348

Final Decision Analytical Protocol (DAP) to guide the assessment of transcatheter closure of ventricular septal defects

August 2013

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MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Australian Government Health Minister to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

Purpose of this document

This document is intended to provide a consultation decision analytic protocol that will be used to guide the assessment of an intervention for a particular population of patients. The consultation protocol will be finalised after inviting relevant stakeholders to provide input to the protocol. The final protocol will provide the basis for the assessment of the intervention.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted "PICO" approach. The PICO approach involves a clear articulation of the following aspects of the research question that the assessment is intended to answer:

Patients – specification of the characteristics of the patients in whom the intervention is to be considered for use;

Intervention – specification of the proposed intervention

Comparator – specification of the therapy most likely to be replaced by the proposed intervention

Outcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention

Purpose of application

A proposal for 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 of Health and Ageing in December 2012. The proposal relates to transcatheter closure of a VSD (perimembranous and muscular) that the CSANZ claims has become a well-established alternative therapy for treatment of VSDs. However, there are no MBS items available for the proposed medical procedure.

Background

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 (MI), trauma or iatrogenic following aortic valve replacement or myomyectomy (Spies 2010). While the proposal relates to transcatheter closure of VSDs, clinical advice indicates that hybrid closure is also an option for occlusion of VSDs and will therefore be included in the assessment.

This assessment will focus on the main patient population those with congenital defects. There is a small adult patient population with VSDs acquired following MIs (less than 0.2%) or other cardiac surgery. The majority of these patients are likely to present in emergency situations and may be more suited to open surgery. For these reasons, and following clinical advice that in Australia these patients are more likely to be treated via open surgery, the patient group with acquired VSDs will not be considered as part of this assessment.

Congenital VSDs

The most common form of congenital heart defects in children are VSDs. They may occur alone or with other congenital diseases. Before a baby is born, the right and left ventricles of its heart are not separate. As the foetus grows, a wall forms to separate these two ventricles; if the wall does not completely form, one or more holes remain. The most common type of VSD is the perimembranous type that account for approximately 80% of all cases. The remaining 20% are muscular VSDs, which can be further subdivided into inlet, trabecular and infundibular defects depending on location.

VSDs are usually diagnosed early in life due to detectable levels of heart murmur. There is also a good chance that both perimembranous and muscular VSDs may close spontaneously in the first few years of life. Large, unrestricted VSDs lead to congestive heart failure, which, if left untreated will eventually lead to pulmonary arterial hypertension. Patients with smaller or restrictive VSDs may not have symptoms and are usually monitored medically. If the defect closes spontaneously no further intervention is warranted. Closure of symptomatic non-restrictive VSD is indicated in infancy.

Patients commonly present with signs and symptoms of heart failure. These symptoms include poor growth, tachypnoea, tachycardia and diaphoresis (Spies 2010).

Large unrestricted VSDs are rarely diagnosed in adulthood. If a small VSD persists into adulthood, closure is necessary for the following indications: left ventricular and/or left atrial volume overload, history of infective endocarditis or development of aortic insufficiency caused by the VSD. Measurement of cardiac shunting by calculation of Qp/Qs ratio can be an indication for VSD repair. However, there are discrepancies in the literature in the value of relying on the calculation of the Qp/Qs ratio. Thoracic echocardiography (TEE) is the best diagnostic tool to assess the size of the left atrium and ventricle (Spies 2010).

Acquired VSDs

The second form of VSD may be acquired as a complication of myocardial infarction or, rarely, cardiac surgery (e.g., septal myomectomy, aortic valve replacemet).) Post MI VSDs occur in less than 0.2% of cases (Spies 2010). The mortality and morbidity of this condition left untreated is estimated to be greater than 90%. Patient selection and timing of the procedure appear to be critical to a successful outcome. The decision to proceed to percutaneous or surgical intervention in any particular institution is made with consideration to the clinical state of the patient, urgency of treatment, experience of the cardiology team in performing the procedure, and after discussion between the surgical and cardiology teams. However, clinical advice is that in Australia these patients are most likely to be treated via open surgery rather than transcatheter approach, and acquired VSDs will not be considered further in this DAP.

Options for closure

The method and timing of closure are dependent on the type of VSD and symptoms presenting in the patient. All defects should be assessed for location, size and multiplicity. The relationship of the defect to atrioventricular valves, infundibular septum and great artery should be noted.

Surgical VSD closure remains the gold standard for the treatment of most VSDs (Spies 2010). As surgery remains the treatment of choice for inlet and sub arterial VSDs, these subgroups will not be included in the assessment.

Transcatheter closure, as opposed to surgical closure, is likely to be considered in patients with muscular defects especially if the VSD is remote for the tricuspid and aortic valves. It may be an option for patients with residual defects after surgical closure of VSD or patients with iatrogenic defects after aortic valve replacement surgery or myomyectomy. Transcatheter closure of perimembranous VSD is possible; however the risk of complete heart block is high at approximately

5% to 6% (Spies 2010). Clinical advice is that for this reason in Australia at present, perimembranous VSDs are being closed surgically.

New devices are currently being designed and trialled which may prove suitable for closure of the perimembranous VSD.

At present a subgroup of patients may undergo hybrid surgery. Hybrid techniques are especially useful when open surgical intervention alone is not achieving a satisfactory outcome and/or when the combination of two fields results in less invasive trauma to the patient. The hybrid technique allows the occlusion of VSDs by a device, with the use of a minimally invasive techniques, during an otherwise open procedure. Hybrid surgery may be performed in paediatric patients, patients with poor vascular access or the presence of other cardiac defects requiring simultaneous repair (Emile 2005). It may also be an option for patients after unsuccessful surgical or transcatheter closure.

Incidence

According to the applicant, the prevalence of congenital heart disease in Australia is about 1 in 100 and VSDs would represent 10% of the disease burden (incidence 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.

With current technologies the number of VSDs that would be closed by transcatheter technique in Australia would be low. The applicant suggests that the number currently closed by this technique would be less than 100 per year. However, based on AIHW figures this may significantly over estimate the demand for this service in the private setting. In any case, with improvement in technologies it is likely that the frequency of this intervention will gradually increase and more will be closed in this way replacing surgical treatment. However, the total number of VSDs which require closure either by surgical, hybrid or transcatheter technique should remain constant and it is anticipated that the majority of these procedures will continue to be provided in the public sector.

According to the Australian Institute of Health and Welfare (AIHW), among babies born in 2003, VSD was the most commonly reported congenital heart condition, with 630 cases recorded, followed by patent ductus arteriosus (406), atrial septal defect (402) and pulmonary stenosis (134).

At present, the therapeutic options in Australia for VSD are medication, surgery by open approach or transcatheter closure and hybrid closures.

Current arrangements for public reimbursement

The majority of procedures for closure of VSD are performed in the public sector. AIHW separation statistics for 2010-11 indicate that 93.3% (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 indicate that only 2.3% (11) of the procedures performed for closure of VSD were by percutaneous approach. Children under 5 years of age accounted for 87.4% of the surgical procedures and 27.3% of the percutaneous procedures (see Table 1). It is not possible to determine the number of hybrid closures performed from this data.

Table 1: AIHW procedures data for closure of VSD

	2008/09	2009/10
Percutaneous closure		
Under 5 years	0	3
5 years and over	8	8
Total	8	11
Surgical closure		
Under 5 years	405	417
5 years and over	85	60
Total	490	477
Total procedures	498	488

Medical devices used to close the VSD have been listed on the Prostheses List for over eight years (Table 2). Data for the five year period from 2006/07 indicate that benefits have been paid 14 times for VSD occluder devices reimbursed under private health insurance. However, there are no MBS items provide for transcatheter closure of VSD and the procedure has not been previously assessed by MSAC. Clinical advice is that other devices may be used for closure of a VSD, including devices designated for closure of patent ductus arteriosus and coils.

Table 2: VSD occluder devices - Prostheses List as at February 2013

Code	Date	Product	Sponsor	Benefit
SJ262	Bef 2005	Amplatzer Muscular VSD Occluder	St Jude Medical Australia Pty Ltd	$10,200
SJ264	Bef 2005	Amplatzer Membranous VSD Occluder	St Jude Medical Australia Pty Ltd	$10,200

The AMPLATZER Muscular VSD Occluder is a self-expandable, double disc device made from a nitinol wire mesh. The two discs are linked together by a short cylindrical waist corresponding to the size of the VSD. The waist diameter determines the maximum size of the VSD to be treated. The largest available device for congenital defects is 18 mm in diameter. In order to increase its closing ability,

the discs and waist are filled with polyester fabric. The polyester fabric is securely sewn to the device by polyester thread.

The design of the perimembranous device is slightly different from the Muscular VSD occluder. However, similar to the Amplatzer family devices, is made of nitinol wire which is self-expandable. The waist length is shorter, accommodating the defect located in the thin walled membranous septum. It is asymmetric with the shorter aortic end of the left ventricular disc for stable positioning.

The AMPLATZER TorqVue Delivery System is intended to facilitate the attachment, loading, delivery and deployment of AMPLATZER VSD Occluders. The AMPLATZER TorqVue Exchange System is intended for removal of an AMPLATZER TorqVue Delivery Sheath and subsequent exchange for an AMPLATZER Delivery Sheath of equal or larger diameter.
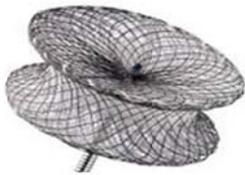
Figure 1   AMPLATZER Muscular VSD occluder

Regulatory status

The devices required for transcatheter closure of VSD have been registered with the Therapeutic Goods Administration on the Australian Register of Therapeutic Goods (ARTG) (see Table 3). It should be noted that there are a couple of devices for VSD closure currently not listed on the ARTG but which are referred to in the international literature. These include the Shanghai Shape Memory Alloy (SHSMA) occluder and the STARFlex Septal Occlusion System.

Table 3: VSD Occluder Devices Listed on the ARTG

Identifier	Sponsor	Start date	Description	Intended purpose
134071	St Jude Medical Australia Pty Ltd	20/12/2006	AMPLATZER Muscular VSD Occluder - Cardiac occluder	For the non-surgical closure of muscular VSDs
134072	St Jude Medical Australia Pty Ltd	20/12/2006	AMPLATZER Muscular VSD Occluder Post Myocardial Infarct (VSDMUSCPI) - Cardiac occluder	For primary closure of muscular VSDs in patients with acute post MI and for closure of post-surgical residual shunts.
134073	St Jude Medical Australia Pty Ltd	20/12/2006	AMPLATZER Membranous VSD Occluder - Cardiac occluder	For occlusion of haemodynamically significant perimembranous VSD in the membranous ventricular septum
191136	St Jude Medical Australia Pty Ltd	27/10/2011	AMPLATZER TorqVue LP Catheter - Cardiac occluder delivery kit	The AMPLATZER TorqVue LP Catheter is intended to facilitate the loading, delivery, and deployment of AMPLATZER devices.
162140	St Jude Medical Australia Pty Ltd	1/06/2009	AMPLATZER TorqVue 45 X 45 degree Delivery Sheath - Cardiac occluder delivery kit	To provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

Patient population

Indications for closure of a VSD are related to the size, type and location of defect and the presence of signs and symptoms of cardiac failure. In infancy, closure is recommended if the patient presents with poor growth, tachypnoea, tachycardia and diaphoresis. If a congenital VSD persists into adulthood, closure is required for the following indications: Left ventricular and/or left atrial volume overload, history of infective endocarditis or development of aortic insufficiency caused by the VSD (Spies 2010).

While this intervention may be performed on both paediatric and adult patients, transcatheter closure of a VSD using an occlusion device will be limited by factors including the size of the patient, the diameter of the VSD and the anatomical type of the VSD.

This assessment focuses on patients eligible for primary closure of congenital muscular and perimembranous VSD's by transcatheter and/or hybrid techniques. Surgery will remain the treatment of choice for doubly committed sub-arterial VSDs, inlet VSDs and acquired VSDs treated in an emergency situation.

Intervention

Most patients with congenital VSDs would attend a preadmission clinic, where the patient is assessed and consent obtained before this procedure. Patients would be admitted on the morning of the

procedure and discharged home the following day. The duration of this procedure ranges from two to four hours.

The transcatheter procedure is performed in a cardiac catheterisation laboratory. The staff required to run the laboratory and monitor the patient during the procedure would include a cardiologist, radiographer, anaesthetist, and at least two nursing staff (nurse assistant, nurse scout). The interventional cardiologist performs the procedure often with the assistance of anassistant. Hybrid surgery would be performed by a cardiac surgeon, under general anaesthetic in an operating theatre.

Initial left ventriculography will delineate the anatomy of a VSD and determine suitability for device closure. TEE may be used to determine the approach and type of procedure. Clinical advice is that the surgeon may shift between transcatheter and hybrid approaches. Left ventriculography is performed prior to release of the device and is repeated once the device is released.

Delivery of the intervention

Transcatheter closure of a VSD is performed under general anaesthesia in the paediatric population. It may be performed with sedation in the adult population. Prior to the procedure, angiography is performed to define in detail the anatomy and size of the defect which allows planning for the intervention.

Hybrid surgery is an emerging field in which patients are treated at the same time by interventional paediatric cardiologist and a cardiac surgeon. The advantages of this technique over standard surgical techniques include the real-time feedback obtained by continuous TEE monitoring during device closure. Further advantages include avoidance of cardiopulmonary bypass (CPB) in patients with isolated VSDs or, if associated cardiac lesions are present, marked reduction in CBP and myocardial ischemia time (Emile 2005).

For transcatheter procedures, access is commonly via the femoral route but can be via the neck depending on the position of the defect. A small incision is made to introduce a guide wire into the femoral artery and also into the femoral vein in order to establish an arteriovenous wire loop. For hybrid surgery, access is gained via median sternotomy or subxiphoid minimally invasive incision. With the hybrid procedure, a purse string suture is placed and the right ventricle is punctured using an 18 gauge needle and a 0.035 inch short guide wire is passed through the VSD from the right side.

In both techniques, once the wire tip is positioned in the left ventricular cavity, the needle is removed and a short, proper size, introducer sheath with the dilator is fed over the wire and advanced into the left ventricular cavity. The dilator is removed, sheath is de-aired and proper sized device is chosen.

The device is pre-soaked in non-heparinised blood, screwed on to the cable, and pulled inside the loader. This is then advanced inside the short delivery sheath until the left ventricular disc opens up in the left ventricular cavity by retraction of the sheath over the cable. The entire assembly is withdrawn until the left ventricular disc abuts the septum. Further retraction of the sheath over the cable deploys the waist and then the right ventricular disc. At this stage, the device can still be recaptured into the delivery sheath if the position is unsatisfactory. If the position is satisfactory, the devices released by counter clockwise rotation of the cable using a pin vice. A complete TEE study in multiple planes is done to confirm the position and to assess for residual shunting in any obstruction regurgitation induced by the device.

Complications such as device embolisation can occur with an incidence of 1-2%. The device may require percutaneous retrieval and a larger device implanted during the percutaneous procedure or while if this is unsuccessful, surgery may be required to close the defect.

Transcatheter closure of a VSD is usually a single procedure. Clinical advice is that it is not always possible to totally occlude the defect due to the age of the patient, severity of the symptoms and haemodynamic compromise. A significant reduction of haemodynamic compromise, resulting in a reduction of the shunt and pulmonary hypertension, may be sufficient to prevent irreversible pulmonary vascular damage for which the only option is a heart-lung transplant.

Patients will require life-long follow up as is the case for patients who are treated surgically at present. Monitoring will initially be quite frequent with follow up every two to three years once the defect has been significantly reduced or closed.

Who will perform the procedure

The applicant indicates that the percutaneous service would be provided by interventional cardiologists. The biggest provider of the service is likely to be paediatric interventional cardiologists although adult interventional cardiologists would be expected to perform this procedure to treat patients in this age group. The hybrid procedure would be performed with collaboration between congenital heart surgeons and interventional cardiologists.

The applicant indicates that, as this service is performed exclusively in large tertiary hospitals; patients diagnosed with this condition in regions will need to travel to a tertiary centre for treatment. There may be a requirement for this travel to be supported by a patient travel scheme.

Co-administered and associated interventions

Once it is established that the VSD is suitable for closure by transcatheter approach, the patient will be referred to an interventional cardiologist (paediatric or adult). A pre-surgical consultation will

occur. During this consultation the cardiologist will consider the patient's symptoms and perform a physical examination and a range of diagnostic tests.

Left ventriculography will be performed immediately before, during and after the procedure. Trans-oesophageal echocardiography may also be used to determine the best approach and type of procedure.

Most patients undergoing percutaneous occlusion will stay overnight and be discharged from hospital the following day, following investigations including echocardiography and chest x-ray.

Patients undergoing the hybrid technique may require a longer hospital stay, dependent on their comorbidities. This would be considerably less than that expected for patients undergoing a formal surgical repair with cardiopulmonary bypass.

Listing proposed and options for MSAC consideration

Proposed MBS listing

Transcatheter closure of a VSD would be rendered in-hospital with surgical assistance. The proposed MBS item descriptor is shown in Table 4.

Table 4: Proposed MBS item descriptor

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

The applicant indicates that the technique where the technology is most closely aligned to the proposed services is transcatheter closure of an atrial septal defect (ASD) and transcatheter closure of patent ductus arteriosus. However, clinical advice is that the technique of transcatheter closure of VSD involves a much higher degree of complexity and is a significantly longer procedure. This increased level of difficulty will need to be quantified in the assessment. MBS item 38272 for transcatheter closure of ASD has a schedule fee of $912.30 as of 1 November 2012.

Table 5: 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 |

Clinical place for proposed intervention

Transcatheter closure of VSD is proposed as a substitute procedure for the currently funded surgical intervention. However, not all VSD patients are suitable for device closure. This decision will be determined by the factors including the type and size of the VSD, the size of the patient and the severity of the patient's symptoms.

Closure of a VSD may also be performed using a hybrid approach. Hybrid surgery is usually pre-planned and most commonly performed for muscular defects. The decision is often based on patient size and whether additional procedures need to be performed.

The current management algorithm is illustrated in Figure 2.

Given transcatheter closure of VSD has been established for some time in the Australian health care setting, only one management algorithm is presented. It should be noted that the clinical assessment in which patients are selected for transcatheter, hybrid or surgical closure of their VSD may be occurring during their initial presentation. The diagram below illustrates this as sequential but in clinical reality clinicians may 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.

Figure 2: Broad representation of the clinical management algorithm for diagnosis and treatment of VSD currently in Australia
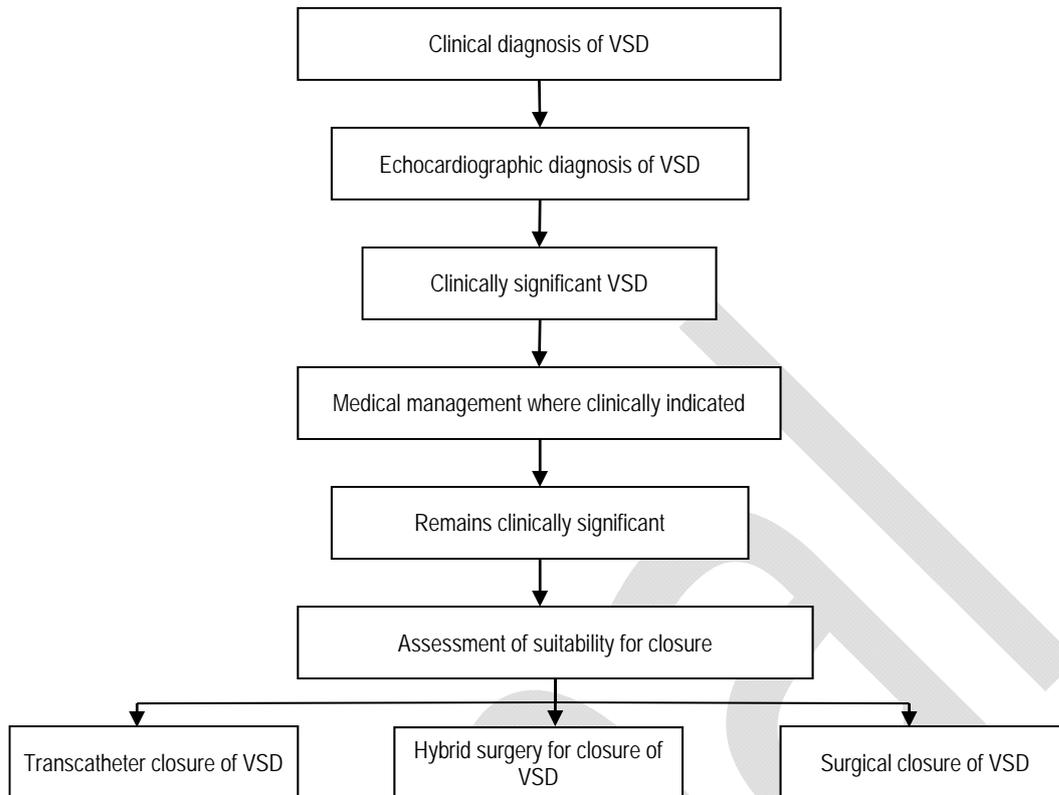
The applicant claims transcatheter closure is a direct substitute (i.e. provides patients with a new treatment alternative) for the currently subsidised intervention of surgical closure of VSD. However, it should be noted that there are some patients for whom transcatheter closure is not an option, such as patients with inlet or sub-arterial VSDs.

Comparator

According to the applicant, the standard therapy for treatment of a VSD is surgical closure utilising cardiopulmonary bypass (item 38751). Therefore surgical closure item 38751 is suggested as the appropriate comparator for the proposed service. However, the comparator item 38751 is restricted to patients with "congenital heart disease" (i.e. it is not reimbursable for closure of an acquired VSD). The Schedule fee for MBS item 38751 (Table 6), which excludes transcatheter techniques, is $2,134.50.

Surgical closure item 38751 is also the most appropriate comparator for transcatheter closure of acquired VSD.

Table 6: MBS item 38751 – item descriptor as at 1 November 2012

	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 T.8.70. CARDIAC AND THORACIC SURGICAL ITEMS - (ITEMS 38470 TO 38766) Items 38470 to 38766 must be performed using open exposure or minimally invasive surgery which excludes percutaneous and transcatheter techniques unless otherwise stated in the item.	

Currently the majority of patients with VSDs are undergoing surgical closure. The applicant estimates that surgery accounts for over 90 per cent of the treatment for VSDs. With improved technology this may change to some extent. However, the indications for closure of a VSD will not change. Additionally, transcatheter closure of a VSD will only be performed in a cardiac catheter laboratory within a large tertiary hospital.

The utilisation rate for MBS item 38751 (VSD closure by direct suture or patch, for congenital heart disease) is low. In 2012-13 there were only 107 services claimed under this MBS item. During the period 2008-09 to 2012-13, MBS data indicate that the surgical closure of VSD (item 38751) has not been bulk-billed. Table 7 shows total services and MBS benefits paid for this period. However, Medicare statistics do not include data relating to supplementary payments to patients from private health insurance funds..

Table 7: MBS Item 38751: Total Services and Benefits Paid

Item 38751	Services	Benefits Paid
2008-09	78	$82,353
2009-10	64	$66,847
2010-11	114	$117,817
2011-12	107	$122,058
2012-13	107	$116,474

Total services by gender for MBS item 38751 over the past five years indicate that surgical procedures for the closure of VSD are performed more frequently for male patients (Table 8). AIHW data for closure of VSD indicate that of the 488 total procedures for 2009-10, 57 per cent were performed for male patients.

Table 8: MBS Item 38751: 2008-09 to 2012-13 Total Services by Gender

	2008/09	2009/10	2010/11	2011/12	2012-13
Female	31	28	48	40	58
Male	47	36	66	67	49

Transcatheter closure of VSD is identified by the applicant as a direct substitute for MBS item 38751, surgical closure of VSD. Table 9 provides an age breakdown of the provision of services for the period 2008-09 to 2012-13 for MBS item 38751. Over the past five years, 75 per cent of services have been provided to children under 5 years of age.

Table 9: MBS Item 38751: 2008-09 to 2012-13 Total Services by Age

	2008/09	2009/10	2010/11	2011/12	2012-13	Total
Under 5 years	45	54	87	84	83	353
5 years and over	33	10	27	23	24	117
Total	78	64	114	107	107	470

Clinical claim

The introduction of Medicare funding for the proposed service (transcatheter occlusion of a VSD) will not change the clinical indications for closure of a VSD. The provision of this service will not result in a net improvement in health care as the primary group of patients, those with congenital muscular and perimembranous VSDs, have been well served by surgical closure. The advantages of transcatheter or hybrid closure are that this procedure may avoid cardiopulmonary bypass and the associated complications. Patients may also experience less discomfort and shorter hospital stays. Clinical advice is that transcatheter closure of a VSD is safe and allows for easier access to the defect.

Table 10: Classification of an intervention for determination of economic evaluation to be presented

		Comparative effectiveness versus comparator				
		Superior		Non-inferior		Inferior
Comparative safety versus comparator	Superior	CEA/CUA		CEA/CUA		Net clinical benefit	CEA/CUA
						Neutral benefit	CEA/CUA*
						Net harms	None^
	Non-inferior	CEA/CUA		**CEA/CUA***		None^	
	Inferior	Net clinical benefit	CEA/CUA	None^		None^	
		Neutral benefit	CEA/CUA*				
		Net harms	None^				

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

^ No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention

Outcomes and health care resources

Outcomes

Potential outcomes for the comparison of relative clinical effectiveness include, but are not limited to:

- Closure of the VSD
- reduction of the shunt and pulmonary arterial pressure or
- Avoidance of cardiopulmonary bypass with its associated neurological risk

Potential major adverse events that are of interest for the comparison of relative safety of transcatheter and surgical closure of VSD include but are not limited to:

- Patient mortality
- Haemorrhage
- Cardiac tamponade
- Infection
- Failure of significant occlusion
- Heart block
- Device embolisation, displacement or misplacement
- Interference with the mitral or aortic valve

Health care resources

Details on the health care resources required should transcatheter closure of VSD be made available are listed in Table 11.

Table 11: List of resources to be considered in the economic analysis

	Provider of resource	Units	MBS item	MBS Schedule fee	75% benefit	Government / Private / Patient
Consultation and diagnostic						
Initial consultation	Cardiologist	1	104	$85.55	$64.20	
Followup consultation	Cardiologist	ongoing	105	$43.00	$36.55 (85% benefit)	
ECG	Cardiologist	TBD	11700	$31.25	$23.45	
Chest x-ray	Radiographer	TBD	58503	$47.15	$35.40	
Transthoracic echocardiography	Cardiologist	TBD	55113 55114 55115	$230.65	$173.00	
Anaesthesia for echocardiography	Cardiologist	TBD	21936	$118.80	$89.10	
Both transcatheter and surgery						
General Anaesthesia	Anaesthetist	1	TBD			
Surgical assistant	Surgical trainee	1	51303	derived fee		
Ward stay	Hospital	TBD				TBD
Transcatheter closure						
Catheterisation laboratory	Hospital	1				TBD
Occlusion device*	Private health insurer	1				$10,200
Transcatheter Procedure	Cardiologist	1	New item	TBD		
Anaesthesia	Anaesthetist	1	TBD	TBD		
Ventriculography	Cardiologist	TBD	38218	$532.25		
Transoesophageal echography	Cardiologist	TBD	55130	$170.00	$127.50	
Surgical / hybrid closure						
Surgery	Surgeon	1	38751	$2,134.50	$1,600.90	
Cardiac bypass	Anaesthetist	TBD	22060	$396.00	$297.00	
ICU initial management	Specialist	1	13870	$362.10	$271.60	
ICU subsequent management	Specialist	TBD	13873	$268.60	$201.45	

MBS Schedule Fee as at 1 November 2012. *also used in hybrid surgery for closure of VSD

Proposed structure of economic evaluation (decision-analytic)

The PICO criteria for the evaluation are provided in Tables 12 and 13.

Table 12: Summary of extended PICO for congenital VSD to define research question that assessment will investigate

Patients	Intervention	Comparator	Outcomes to be assessed
Patients with a congenital VSD	Transcatheter closure of a VSD	Surgical closure of a VSD	Closure of the VSD. Avoid cardiopulmonary bypass. Less patient discomfort. Shorter hospital stay. Equivalent long term outcome to surgical closure.

# Clinical research questions for public funding

1. In the treatment of patients with a congenital VSD, what is the safety, effectiveness and cost effectiveness of transcatheter closure of VSD compared to surgical closure?

2. In the treatment of patients with a congenital VSD, with limited vascular access or with other cardiac defects requiring simultaneous repair, what is the safety, effectiveness and cost effectiveness of hybrid closure of VSD compared to surgical closure?

Decision analytic diagram

The decision analytic for the current treatment pathway is presented in Figure 2. Given transcatheter closure of VSD has been established for some time in the Australian health care setting, only one decision analytic pathway is presented.

Figure 2: Decision analytic pathway for current VSD treatment
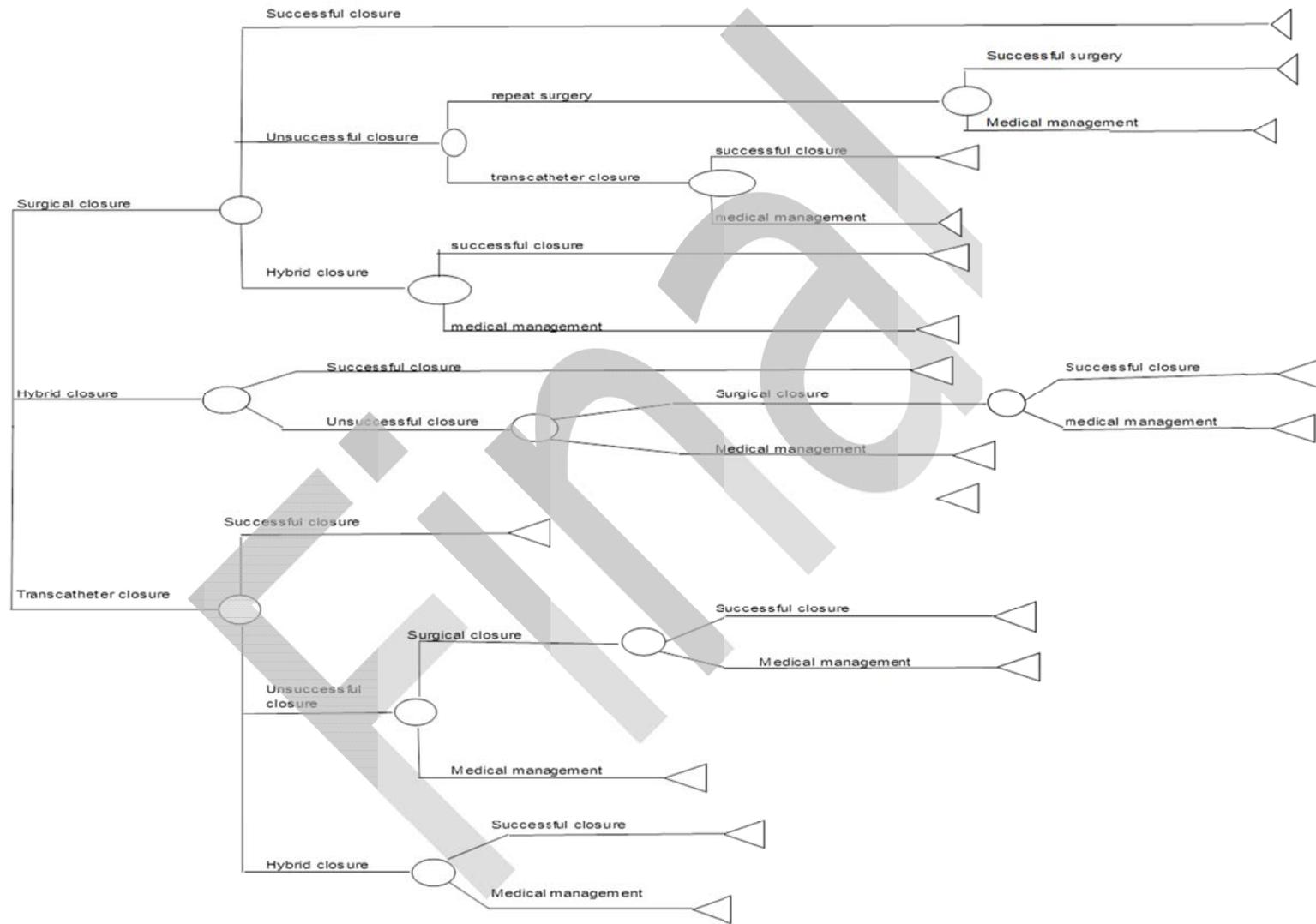
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