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## Australian Government
### Department of Health and Ageing

# Review of the Medicare Benefits Schedule (MBS) items for Pulmonary Artery Catheterisation (PAC)

# MBS Quality Framework

## Final Review Protocol

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Project Team:  Joe Scuteri          HealthConsult      Project Director
               Lisa Fodero         HealthConsult      Project Manager
               Diana Traves        HealthConsult      Project Consultant
               Samara Lewis        NHMRC CTC          Project Consultant
               Merel Kimman        NHMRC CTC          Project Consultant
               Luke Marinovich     NHMRC CTC          Project Consultant


HealthConsult Pty Ltd
Head Office: 4409/93 Liverpool Street, Sydney, New South Wales, 2000
Phone (02) 9261 3707: Fax (02) 9261 3705: Email: admin@healthconsult.com.au

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## APPENDIX

# 1
# Introduction

This Chapter introduces the review by describing the background, the general principles under which it will be carried out and the objectives.

## 1.1    BACKGROUND

In the 2009-10 Budget, the Australian Government agreed to put in place a new evidence-based framework for managing the MBS into the future through the measure *Medicare Benefits Schedule – A quality framework for reviewing services* (MBS Quality Framework). A key component of the MBS Quality Framework is implementing a systematic approach to reviewing existing MBS items to ensure they reflect contemporary evidence, offer improved health outcomes for patients and represent value for money. The primary focus of the process is quality-related issues with the key objective of identifying and evaluating MBS services that present potential safety and quality issues to encourage more appropriate clinical use.

HealthConsult Pty Ltd, as part of its contract with the Department of Health and Ageing, will undertake a review of the evidence relating to Pulmonary Artery Catheterisation (MBS items 13818, 13876, 11600, 22012, 22014, 22015, 38200 and 38206). It should be noted that a number of these item numbers are not exclusive to Pulmonary Artery Catheterisation (PAC), but it is possible for a service provided using a pulmonary artery catheter to be billed under any of the listed MBS items.

## 1.2    PRINCIPLES TO GUIDE MBS REVIEWS

MBS Quality Framework reviews are underpinned by the following key principles:

- reviews have a primary focus on improving health outcomes and the financial sustainability of the MBS, through consideration of areas potentially representing:
  - ➢ patient safety risk;
  - ➢ limited health benefit; and/or
  - ➢ inappropriate use (under or over use).
- reviews are evidence-based, fit-for-purpose and consider all relevant data sources;
- reviews are conducted in consultation with key stakeholders including, but not limited to, the medical profession and consumers;
- review topics are made public, with identified opportunities for public submission and outcomes of reviews published;
- reviews are independent of Government financing decisions and may result in recommendations representing costs or savings to the MBS, as appropriate, based on the evidence;
- secondary investment strategies to facilitate evidence-based changes in clinical practice are considered; and
- review activity represents efficient use of Government resources.

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## 1.3 PURPOSE OF THIS DOCUMENT

This document is intended to outline the methodology that will be used to generate an evidence based analysis to support the review of Pulmonary Artery Catheterisation (PAC). The objectives of the review protocol are to:

- define the relevant clinical questions that the review will focus on;
- clarify the role of PAC in current clinical practice;
- clarify the mechanisms for identifying evidence and provide an opportunity for discussion of clinical and methodological issues;
- clarify timelines associated with this project; and
- clarify roles and responsibilities of key stakeholders.

## 1.4 OBJECTIVES OF THE REVIEW

The objective of the review is to carry out an evidence-based assessment of PAC that will inform ongoing Government decisions in relation to Medicare support for these services (MBS items 13818, 13876, 11600, 22012, 22014, 22015, 38200 and 38206).

Two of the relevant MBS item numbers (13818 and 22015) are only used for the insertion of a pulmonary artery catheter. The item numbers 13876, 11600, 22012 and 22014 relate to the monitoring of various cardiac pressures using an indwelling catheter[1], which may or may not be a pulmonary artery catheter. These MBS items are therefore not exclusive to cardiac pressure measurement and monitoring using a pulmonary artery catheter. However, it is important to note that these items are only being reviewed in circumstances that involve PAC.

The MBS item numbers 38200 and 38206 relate to the insertion of a pulmonary artery catheter under fluroscopic guidance in an angiography suite or catheterisation laboratory by a cardiologist for the purposes of diagnosing pulmonary hypertension. These MBS item numbers may also be claimed without the specific use of a pulmonary artery catheter (e.g. cardiac output measurements obtained by another method). Again, these MBS items are only being reviewed in circumstances that involve PAC.

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[1] An indwelling catheter is a catheter left inside the body either temporarily or permanently. This term is not restricted to describing the use of the pulmonary artery catheter.

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# Key stakeholders

This Chapter sets out the key stakeholders that will be involved in the review of PAC MBS items which include the members of the Clinical Working Group, the Consumers Health Forum and the general public.

## 2.1    CLINICAL WORKING GROUP

A Clinical Working Group (CWG) has been established for the duration of the review to ensure the review reflects an understanding of current Australian clinical practice and draws valid conclusions from the available evidence.  While the CWG has commented on the draft Review Protocol and will be given the opportunity to comment on the draft final Review Report in their individual capacity, the CWG will not be able to make recommendations on future financing arrangements.  The members are experts in PAC and have been identified by, although they do not formally represent, the following clinical craft groups:

- Australasian Society of Cardiac and Thoracic Surgeons
- Cardiac Society of Australia and New Zealand
- College of Intensive Care Medicine of Australia and New Zealand
- Australian and New Zealand Intensive Care Society
- Australian and New Zealand College of Anaesthetists
- Australian Society of Anaesthetists
- Australasian College of Emergency Medicine

The CWG is chaired by a representative of the Department of Health and Ageing, includes a Medical Advisor from the Department, and the chair of a previous MSAC Advisory Panel (that reviewed continuous wave Doppler).

## 2.2    CLINICAL CRAFT GROUPS

The key clinical craft groups listed above have been invited to identify members of their group that have expertise in PAC to be members of the CWG.  As stated above the identified experts do not formally represent the craft groups.  The clinical craft groups will be formally consulted through being invited to make submissions on the draft Review Protocol and the draft Review Report as part of the public submissions process.  In addition, HealthConsult will seek to consult personally with clinicians (including CWG members) to fully understand the Australian context for claiming the MBS items under review when a pulmonary artery catheter is use, and to discuss the findings of the draft Review Report.

## 2.3    CONSUMERS AND THE GENERAL PUBLIC

The general public has the opportunity to comment on both the draft Review Protocol and the draft Review Report.  The public consultation period in respect of both documents will be at

least two weeks. Also, representatives of the Consumers Health Forum will be personally consulted to provide comment on the draft Review Protocol and the draft Review Report. To obtain additional consumer input, HealthConsult will also search relevant online discussion forums that may include material relating to the consumer experience with PAC.

## 2.4 CONSULTANTS

HealthConsult Pty Ltd, working in conjunction with the NHMRC Clinical Trials Centre (CTC) at the University of Sydney, is responsible for drafting the Review Protocol (this document); and for identifying, analysing and synthesising the evidence related to PAC (MBS items 13818, 13876, 11600, 22012, 22014, 22015, 38200 and 38206) using the methodology set out in Chapter 5 to produce the Review Report. HealthConsult will provide a Review Report at the completion of the project that will help inform the Government's consideration of MBS benefits for PAC services into the future.

HealthConsult (www.healthconsult.com.au) and the NHMRC CTC (www.ctc.usyd.edu.au) both have wide experience in undertaking systematic reviews. HealthConsult has recently completed a review of the demand for, and supply and use of cord blood in Australia; a horizon scan of new radiation technologies and treatments in the context of possible impact on the MBS; and is in the process of assessing the islet transplantation procedure for Nationally Funded Centre (NFC) status. The NHMRC CTC has completed many systematic reviews including for Medical Services Advisory Committee (MSAC) dating back to 1999, most recently, an assessment for NFC Status of Peritionectomy with Hyperthermic Intraperitoneal Chemotherapy.

## 2.5 THE DEPARTMENT OF HEALTH AND AGEING

The Department of Health and Ageing (the Department) has contracted HealthConsult Pty Ltd to undertake the review of PAC (MBS items 13818, 13876, 11600, 22012, 22014, 22015, 38200 and 38206) and is responsible for the ongoing management of this contract.

During the review, the Department is also responsible for:

- provide comment on and approve the draft Review Protocol prior to the Protocol being made available online for public comment;
- provide comment on and approve the draft Review Report, including recommendations, prior to the report being made available on-line for public comment; and
- approve the final Review Report should any significant changes be made following the public consultation period.

Following the finalisation of the Review Report, the Department will be responsible for providing advice to the Minister for Health and Ageing on future subsidy arrangement for the MBS items 13818, 13876, 11600, 22012, 22014, 22015, 38200 and 38206. This advice will be informed by the Review Report but will also draw on other information such as budgetary considerations.

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# 3

# Background on PAC

This Chapter describes PAC, the context in which it is used, and the justification for a review under the MBS Quality Framework.
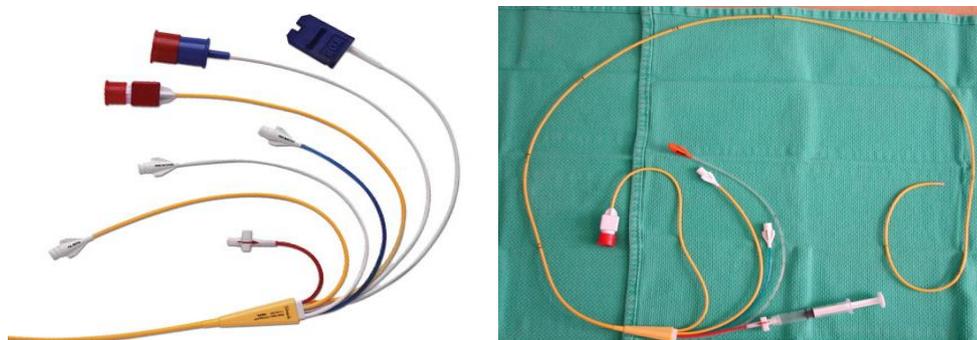
## 3.1 DESCRIPTION OF PAC AND ITS USE

This section describes PAC covering the equipment used to perform the procedure and how it is used; the patient conditions in which it is used; the diagnostic and monitoring data that are generated; the settings where it is used; the relevant MBS item numbers; the professionals involved; and the history of its listing on the MBS.

### 3.1.1 What is a pulmonary artery catheter?

PAC is performed using a long balloon tipped catheter that is positioned in the pulmonary artery[1]. Often referred to as a Swan-Ganz catheter in honour of its inventors Jeremy Swan and William Ganz, from Cedars-Sinai Medical Center (Los Angeles)[2], the pulmonary artery catheter is a multi lumen catheter that is typically around 110 cm long with extra connecting tubes for attachment to the pressure transducer and monitoring equipment (see Figure 3.1).

**Figure 3.1: Views of a pulmonary artery catheter**



Source: http://www.edwards.com/products/pacatheters/ccombo.htm          Source: http://emedicine.medscape.com/article/1824547-treatment

There are a wide variety of catheters used internationally[3], modern catheters consist of up to five lumens[4] and typically contain:

- A distal lumen with a 1.5 cc balloon located just proximal to the tip of the catheter that attaches to the transducer. The balloon is used to float the catheter into position so that pressure measurements can be obtained[5]. The distal lumen contains the balloon inflation valve, which is only used to inflate the balloon[5]. This lumen may also be used for injecting medications, aspirating mixed venous blood samples, or some catheters contain a fibre optic filament at the tip of the catheter for continuous measurement of mixed venous oxygen saturation (i.e. % of haemoglobin saturated with oxygen in mixed venous blood, $SvO_2$)[5].

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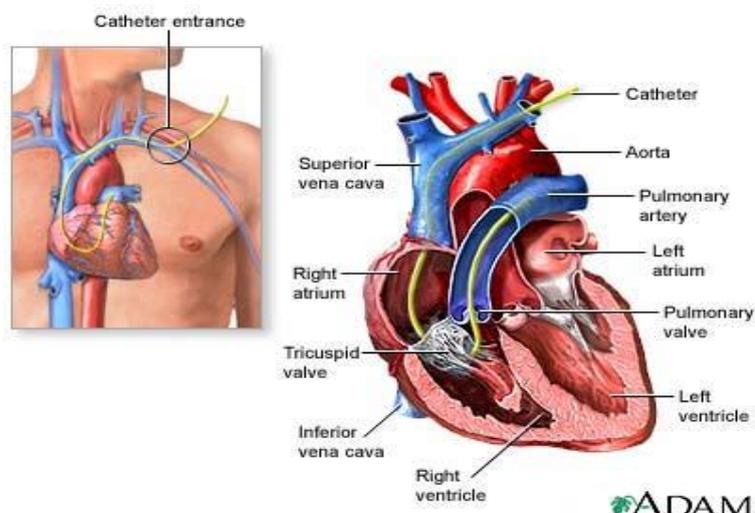Final Review Protocol

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- Approximately four cm proximal to the balloon is the thermistor that connects to the transducer. The thermistor is used to measure temperature changes for the calculation of cardiac output.
- The ventricular lumen is approximately 20 cm from the tip. Once the catheter is inserted this lumen resides in the right ventricle[5]. This lumen may contain pacing leads that are connected directly to a pacemaker[5]. If cardiac pacing is not required the lumen can be used for infusions and blood sampling[5].
- The proximal lumen is approximately 30 cm from the tip. Once the catheter is inserted it resides in the right atrium. This lumen is used for measuring central venous pressure (CVP) and may also be used for aspirating blood samples, injecting drugs or injecting the thermal bolus used for thermodilution cardiac output measurements[5]. Some catheters have two lumens ending in the right atrium; one for routine infusion of drugs or continuous pressure monitoring and the other for infusion of thermodilution materials and other periodic injections.

The transducer is an instrument that is used to sense physiological changes; pressure, flow and temperate and transform them into electronic signals[6]. The monitor connects to the transducer and amplifies electronic signals from the transducer and filters out interfering signals[6]. The monitor displays the electronic signals in waveform and also provides a digital readout of the pressure values[6]. A flush device, which is connected to an IV pressure bag, controls the flow of normal saline solution that may also contain heparin, to keep the catheter free of blood clots[6].

### 3.1.2 How is pulmonary artery catheterisation performed?

The balloon is floated through the right atrium, across the tricuspid valve, through the right ventricle and the pulmonary valve and into the pulmonary artery. Waveforms are obtained on a monitor which includes pressure waveforms and on which an ECG is displayed. The anaesthetist or intensivist monitors the patient's pressures to ensure the catheter is properly placed, and the ECG provides the specialist with information about any arrhythmias which has been triggered and requires immediate attention. Figure 3.2 shows the positioning of the pulmonary artery catheter in the heart.

**Figure 3.2: Position of pulmonary artery catheter in the heart**



Source: http://instruct.tri-c.edu/dlucas/resp1320/Content/hemodynamics.htm

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When a pulmonary artery catheter floats to the wedge position, the inflated balloon at its tip isolates the distal pressure monitoring from upstream pulmonary artery pressure (PAP). Blood flow ceases between the catheter tip and a junction point where pulmonary veins draining the occluded pulmonary vascular region join other veins in which blood still flows towards the left atrium. A continuous static column of blood now connects the wedged pulmonary artery catheter tip to this junction point in the pulmonary veins near the left atrium. Thus wedging the pulmonary artery catheter functionally extends the catheter tip to measure the pressure at the point at which blood flow resumes on the venous side of the pulmonary circuit (see Figure 3.3)[7].

**Figure 3.3: Inflated balloon of PAC in position in the pulmonary artery**
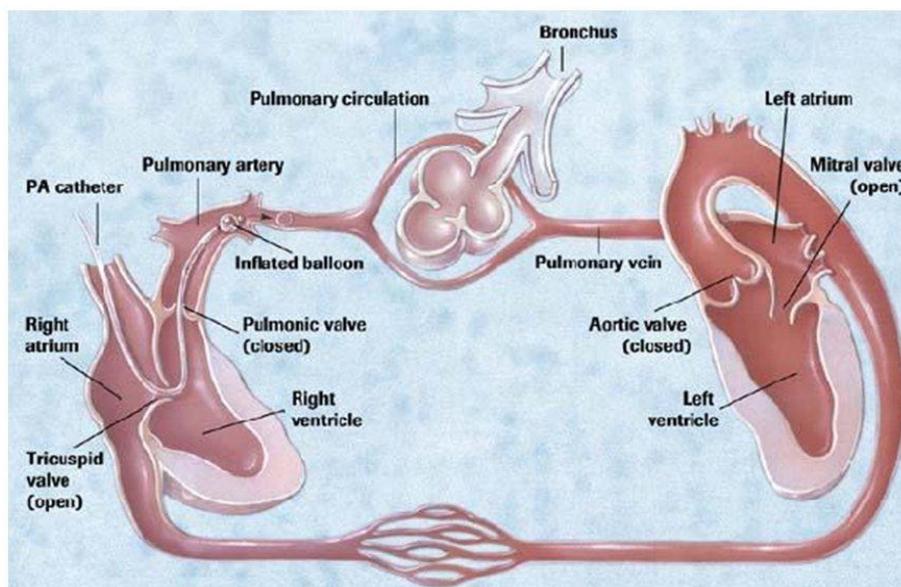


Source: http://www.ispub.com/journal/the_internet_journal_of_anesthesiology/volume_11_number_2_1/article/

Because resistance to flow in the large pulmonary veins is negligible, pulmonary artery wedge pressure (PAWP) provides an accurate, indirect measurement of both pulmonary venous pressure and left atrial pressure (LAP)[8,9,10].

### 3.1.3   The conditions/diseases that PAC is used to monitor/diagnose

Initially developed for the management of acute myocardial infarction (AMI), PAC has gained widespread use in the management of a variety of critical illnesses and surgical procedures. A brief review of the literature suggests that PACs use in measuring important haemodynamic indices (e.g. pulmonary artery occlusion pressure, cardiac output, mixed venous oxygen saturation) allows more accurate determination of the haemodynamic status of critically ill patients than is possible by clinical assessment alone. The additional information can be important in caring for patients with confusing clinical pictures, in whom errors in fluid management and drug therapy can have important consequences. In surgical patients, PAC data often help to evaluate haemodynamic changes that may lead to serious peri-operative complications. Pre-operative PAC data are purported to be helpful in determining whether it is safe for high-risk patients to proceed with surgery.

PAC can be used as a diagnostic tool. In addition to initial assessment of haemodynamic function, the pulmonary artery catheter can be kept in place for several days allowing

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evaluation of serial measurements to monitor haemodynamic status. This feature confers several advantages over tools, where the procedure needs to be repeated each time to obtain a measurement, for example trans-oesophageal echo-cardiography. General indications for use of PAC are shown in Table 3.1.

**Table 3.1: General indications for use of PAC**

| Diagnosis and Evaluation: | Therapeutic Management: |
|---|---|
| <ul><li>Differential diagnosis of shock:<ul><li>Cardiogenic shock;</li><li>Septic shock; or</li><li>Hypovolaemic shock.</li></ul></li><li>Evaluation of pulmonary oedema:<ul><li>Cardiogenic pulmonary oedema; or</li><li>Non-cardiogenic pulmonary oedema.</li></ul></li><li>Etiology of cardiac failure<ul><li>Restrictive pericarditis;</li><li>Constrictive pericarditis; or</li><li>Cardiac tamponade.</li></ul></li><li>Evaluation of cardiac structures:<ul><li>Valvular diseases/dysfunction;</li><li>Intracardiac shunts; or</li><li>Ventricular septal defect.</li></ul></li><li>Evaluation of pulmonary hypertension:<ul><li>Primary pulmonary hypertension; or</li><li>Secondary pulmonary hypertension.</li></ul></li><li>Evaluation in renal failure to assess volume status</li></ul> | <ul><li>Management of advanced heart failure</li><li>Management of complicated myocardial infarction:<ul><li>Hypovolemia vs cardiogenic shock;</li><li>Ventricular septal rupture vs acute mitral regurgitation;</li><li>Severe left ventricular failure;</li><li>Right ventricular infarction;</li><li>Unstable angina; or</li><li>Refractory ventricular tachycardia.</li></ul></li><li>Treatment of primary pulmonary hypertension</li><li>Management of preoperative, perioperative and postoperative cardiac or major surgical patients</li><li>Management of patients with multi-organ failure</li><li>Ventilator management</li><li>Assessment of therapy:<ul><li>Afterload reduction;</li><li>Intra-aortic balloon counter-pulsation;</li><li>Beta blockers;</li><li>Vasopressors;</li><li>Inotropes; or</li><li>Vasodilators.</li></ul></li><li>Assessment of fluid requirement in critically ill patients:<ul><li>Haemorrhage;</li><li>Sepsis;</li><li>Acute renal failure;</li><li>Burns; or</li></ul></li><li>Multitrauma requiring fluid resuscitation.</li></ul> |

### 3.1.4  What does pulmonary artery catheterisation measure?

PAC provides haemodynamic information (i.e. information on the continuous movement of blood; its pressures and volumes). Table 3.2 describes the key haemodynamic measures produced using PAC.

**Table 3.2: Key measures produced using PAC**

| Parameters | Definition | Normal Range |
|---|---|---|
| Cardiac output (CO) | CO is the amount of blood pumped by each ventricle per minute and is a product of the heart rate (HR) and stroke volume (SV)[11]. | 5-8 L/min |
| Stroke volume (SV) | SV is the volume of blood pumped from one ventricle of the heart with each beat. SV is calculated using measurements of ventricle volumes and subtracting the volume of the blood in the ventricle at the end of a beat (called end-systolic volume) from the volume of blood just prior to the beat (called end-diastolic volume). The term *stroke volume* can apply to each of the two ventricles of the heart, although it usually refers to the left ventricle. | 55-100 mL |
| Heart Rate (HR) | HR is the number of heartbeats per unit of time (bpm). | 60-80 bpm |
| End-diastolic volume (EDV) | The volume of blood in a ventricle at the end of filling (diastole)[12] EDV is often used synonymously with preload. | 120–130 mL |

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| Parameters | Definition | Normal Range |
|---|---|---|
| End-systolic volume (ESV) | The volume of blood remaining in a ventricle at the end of contraction, or systole, and the beginning of filling, or diastole[12]. ESV is the lowest volume of blood in the ventricle at any point in the cardiac cycle. The main factors that affect the ESV are afterload and the contractility of the heart. | 50–60 mL |
| Central venous pressure (CVP) or right arterial pressure | CVP describes the pressure of blood in the thoracic vena cava, near the right atrium of the heart. Specifically CVP is an estimate of the preload on the right side of the heart and reflects blood volume that is returned from the systemic circulation[13]. CVP is an approximation of right atrial pressure, which is a major determinant of right ventricular end diastolic volume. | 2-8 mm Hg |
| Pulmonary vascular resistance (PVR) | PVR is afterload on the right side of the heart; the back pressure exerted by blood in the large arteries leaving the heart, the heart must pump against this pressure to eject blood[11] PVR measures the resistance that the right ventricle must pump or work against. This is called afterload. | 150-250 dynes/sec//cm$^5$ |
| Systemic vascular resistance (SVR) | SVR is afterload on the left side of the heart; the resistance in the arterial vasculature as the left ventricle pumps against pressure in the aorta and the arterial vasculature[13]. SVR measures the resistance that the left ventricle must pump or work against. This is called afterload. | 800-1200 dynes/sec/cm$^5$ |
| Pulmonary artery wedge pressure (PAWP) | PAWP also known as pulmonary capillary wedge pressure (PCWP), or pulmonary artery occlusion pressure (PAOP). PAWP is an estimate of the preload on the left side of the heart. It reflects the volume returning to the left atrium after circulating through the pulmonary system[13] and is an indirect estimate of pulmonary venous pressure and left atrial pressure[14]. | 8-10 mm Hg |
| Left ventricular end diastolic pressure (LVEDP) | LVEDP determines, in part, the amount of 'stretch' or 'preload' on the ventricular myocardial fibres before systole commences[15]. This is an important determinant of cardiac performance because as preload rises, the contractile force of the heart increases. | 5-12 mm Hg[16] |
| Mixed venous oxygen saturation (SvO$_2$) | SvO$_2$ measures the percentage of haemoglobin saturated with oxygen in mixed venous blood. This measure reflects the global balance between oxygen delivery and oxygen consumption (i.e. an indicator of tissue oxygenation). | 60-80% |
| Cardiac index (CI) | CI is a parameter that relates the cardiac output (CO) to body surface area (BSA), thus relating heart performance to the size of the individual. The unit of measurement is litres per minute per square metre (l/min/m$^2$). | 2.6 - 4.2 L/min/meter$^2$ |

PAC directly measures right atrial pressure, right ventricular and pulmonary artery systolic and diastolic pressures. Through the inflation of a balloon at the catheter tip and resultant occlusion of a pulmonary artery branch, pulmonary artery wedge pressure (PAWP) can be measured. This indirectly measures left ventricular end-diastolic pressure (LVEDP) and therefore reflects the functioning of the left side of the heart. PAC also directly measures mixed venous oxygen saturation (SvO$_2$) which is an indicator of tissue oxygenation levels.

The clinical significance of measuring PAWP is because it allows an assessment of the compliance of the pulmonary circulation by providing an indirect measure of the left atrial pressure (LAP). The clinicians consulted to date advised that PAC is the only device capable of measuring PAWP. They considered that it is important to measure PAWP to diagnose the severity of left ventricular failure and to quantify the degree of mitral valve stenosis. Both of these conditions elevate LAP and therefore PAWP (these pressures are normally 8-10 mm Hg). Aortic valve stenosis and regurgitation, and mitral regurgitation also elevate LAP. When these pressures are above 20 mm Hg, pulmonary oedema is likely to be present, which is a life-threatening condition. By measuring PAWP, the physician can titrate the dose of diuretic drugs and other drugs that are used to reduce pulmonary venous and capillary pressure, and thereby reduce the pulmonary oedema. Measurement of PAWP can therefore help to guide therapeutic efficacy.

It is also considered necessary to measure PAWP when evaluating pulmonary hypertension. Pulmonary hypertension is often caused by increased pulmonary vascular resistance (PVR). To calculate this, pulmonary blood flow (usually measured by the thermodilution technique), pulmonary artery pressure and pulmonary venous pressure (i.e. PAWP) measurements are required. Pulmonary hypertension can also result from increases in pulmonary venous pressure and pulmonary blood volume secondary to left ventricular failure or mitral or aortic valve disease. PAWP is also considered useful in evaluating blood volume status when fluids

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are administered during hypotensive shock. Finally, calculating PAWP is also thought to be important in the diagnosis of acute respiratory distress syndrome (ARDS).

### 3.1.5 Service delivery setting

Pulmonary artery catheterisation is provided in public and private hospitals in Australia. Insertion of the pulmonary artery catheter is most often done in theatre in association with the administration of anaesthesia but it may also be done in ICU without the administration of anaesthesia. The insertion of a pulmonary artery catheter also occurs in an angiography suite and/or cardiac catheterisation laboratory for the purpose of measuring PAWP as an aid in the diagnosis of pulmonary hypertension. In fact, the PAWP measurement is required as a perquisite to prescribing certain medications listed on the Highly Specialised Drug (HSD) program under the Pharmaceutical Benefits Scheme (PBS).

### 3.1.6 The MBS item numbers relevant to pulmonary artery catheterisation

There are eight MBS item numbers which relate to PAC services as shown in Table 3.3. Four item numbers (13818, 22015, 38200 and 38206) are for the insertion of a pulmonary artery catheter. Item number 13818 is for the insertion of pulmonary artery catheter and item number 22015 is for the insertion of pulmonary artery catheter in association with the administration of anaesthesia. Item numbers 38200 and 38206 can be claimed if a pulmonary artery catheter is inserted (and pressure measurements made) under fluroscopic guidance in an angiography suite or catheterisation laboratory.

**Table 3.3: Description of PAC services funded under the MBS**

| Item Number | MBS Item Number description |
|---|---|
| 13818 | RIGHT HEART BALLOON CATHETER, insertion of, including pulmonary wedge pressure and cardiac output measurement (Anaes.)<br>**Fee:** $107.45 **Benefit:** 75% = 80.60 85% = $91.35 |
| 13876 | CENTRAL VENOUS PRESSURE, pulmonary arterial pressure, systemic arterial pressure or cardiac intracavity pressure, continuous monitoring by indwelling catheter in an intensive care unit and managed by a specialist or consultant physician who is immediately available and exclusively rostered for intensive care – once only for each type of pressure on any calendar day (up to a maximum of 4 pressures)<br>**Fee:** $72.65 **Benefits:** 75% = $54.50 85% = $61.80 |
| 11600 | BLOOD PRESSURE MONITORING (central venous, pulmonary arterial, systemic arterial or cardiac intracavity), by indwelling catheter – once only for each type of pressure on any calendar day, up to a maximum of 4 pressures (not being a service to which item 13876 applies and where not performed in association with the administration of general anaesthesia)<br>**Fee:** $ 65.45 **Benefit:** 75% = $49.10 85% = $ 55.65 |
| 22012 | BLOOD PRESSURE MONITORING (central venous, pulmonary arterial, systemic arterial or cardiac intracavity), by indwelling catheter – once only for each type of pressure on any calendar day, up to a maximum of 4 pressures (not being a service to which item 13876 applies) when performed in association with the administration of anaesthesia (3 basic units)<br>**Fee:** $56.10 **Benefit:** 75% = $42.10 85% = $47.70 |
| 22014 | BLOOD PRESSURE MONITORING central venous, pulmonary arterial, systemic arterial or cardiac intracavity), by indwelling catheter – once only for each type of pressure on any calendar day, up to a maximum of 4 pressures (not being a service to which item 13876 applies) when performed in association with the administration of anaesthesia relating to another discrete operation on the same day (3 basic units)<br>**Fee:** $56.10 **Benefit:** 75% = $42.10 85% =$47.70 |
| 22015 | RIGHT HEART BALLOON CATHETER, insertion of, including pulmonary wedge pressure and cardiac output measurement, when performed in association with the administration of anaesthesia (6 basic units)<br>**Fee:** $112.2 **Benefit:** 75% = 84.15 85% = $ 95.40 |
| 38200 | RIGHT HEART CATHETERISATION, with any one or more of the following: fluoroscopy, oximetry, dye dilution curves, cardiac output measurement by any method, shunt detection or exercise stress test.<br>**Fee:** $428.55 **Benefit:** 75% = $321.45 85% = $364.30 |
| 38206 | RIGHT HEART CATHETERISATION WITH LEFT HEART CATHETERISATION via the right heart or by any other procedure with any one or more of the following: fluoroscopy, oximetry, dye dilution curves, cardiac output measurements by any method, shunt detection or exercise stress test.<br>**Fee:** $618.30 **Benefit:** 75% = $463.75 85% = $547.10 |

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Benefits for monitoring of pressures using an indwelling catheter[2], which may or may not be a pulmonary artery catheter, are payable under four MBS item numbers including 11600, 13876, 22012 and 22014. Item numbers 11600 and 13876 relate to, and are claimable in addition to, item 13818 (i.e. insertion of a pulmonary artery catheter). Item 11600 is for pressures measured by an indwelling catheter when not performed in association with the administration of general anaesthesia. Item number 13876 is for pressures measured by an indwelling catheter in an intensive care unit that is managed by a specialist or consultant physician who is immediately available and exclusively rostered for intensive care. Item numbers 22012 and 22014 relate to, and are claimable in addition to, item 22015 (i.e. the insertion of pulmonary artery catheter in association with the administration of anaesthesia). Item number 22012 is for pressures measured in association with the administration of anaesthesia. Item 22014 is for pressures measured in association with the administration of anaesthesia relating to another discrete operation on the same day.

Item numbers 38200 and 38206 cover the insertion of the pulmonary artery catheter and the taking of pressure measurements in an angiography suite or cardiac catheterisation laboratory. Advice provided by clinicians consulted to date suggests that these MBS item numbers are being claimed by cardiologists performing the PAC in the outpatient setting in association with other investigations such as oximetry and exercise stress test to confirm a diagnosis of pulmonary hypertension.

### 3.1.7 Service providers claiming MBS benefits for PAC

The main specialty group claiming MBS item number 13818 are intensivists, with item number 22015 almost exclusively claimed by anaesthetists. This pattern reflects the understanding derived from preliminary consultations with clinicians that the pulmonary artery catheters are inserted mainly in theatre by anaesthetists pre-surgery with the insertion undertaken in ICU by an intensivist (i.e. benefits claimed as 13818). This situation will be further investigated through consultation with practising clinicians.

The pressure monitoring MBS item numbers (13876, 11600, 22012 and 22014) can be claimed for measuring a number of pressures (e.g. central venous pressure, right atrial pressure, pulmonary artery pressure etc) by an indwelling catheter (i.e. not just a pulmonary artery catheter). Data analysis will be undertaken in order to determine what monitoring item numbers are claimed in association with the use of a pulmonary artery catheter.

Based on a review of some hospital procedure manuals, PAC pressures can be obtained by appropriately experienced and accredited medical staff of the intensive care service. This includes intensivists, cardiologists, cardiac anaesthetists, accredited registrars and accredited critical care nurses. Preliminary consultations with clinicians suggest that anaesthetists are the most common users of PAC for private patients. The details of the service model for public and private patients will be determined through MBS data review and further consultations with clinicians.

The main specialty group claiming MBS item number 38200 and 38206 are cardiologists. This pattern reflects our understanding derived from consultations with clinicians that the pulmonary artery catheters are inserted in angiography suite or cardiac catheterisation laboratories for the purposes of diagnosing pulmonary hypertension and prescribing one of

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[2] An indwelling catheter is a catheter left inside the body either temporarily or permanently. This is not restricted to describing the use of the pulmonary artery catheter.

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five medications listed on the HSD program under the PBS. This situation will be further investigated through consultation with practising clinicians.

### 3.1.8   Year of adoption in health system

PAC has been in clinical use for almost more than 40 years. In terms of when the related MBS item numbers were included on the MBS, the item start date and description start date for each MBS item number is shown in Table 3.4.

**Table 3.4: Item, description and schedule fee start dates for MBS item numbers**

| MBS Item number | Type of date | Date |
|---|---|---|
| 13818 | Item Start Date | 01-Jul-1993 |
| | Description Start Date | 01-May-1994 |
| 13876 | Item Start Date | 01-May-1994 |
| | Description Start Date | 01-Nov-2008 |
| 11600 | Item Start Date | 01-Dec-1991 |
| | Description Start Date | 01-Nov-2008 |
| 22012 | Item Start Date | 01-Nov-2001 |
| | Description Start Date | 01-Nov-2008 |
| 22014 | Item Start Date | 01-Nov-2001 |
| | Description Start Date | 01-Nov-2008 |
| 22015 | Item Start Date | 01-Nov-2001 |
| | Description Start Date | 01-Nov-2001 |
| 38200 | Item Start Date | 01-Dec-1991 |
| | Description Start Date | 01-May-2007 |
| 38206 | Item Start Date | 01-Dec-1991 |
| | Description Start Date | 01-May-2007 |

## 3.2   CONTEXT FOR THE PAC REVIEW

This section examines the context for the review of PAC under the MBS Quality Framework, including the circumstances in which PAC is used, the MBS usage and associated expenditure, alternative monitoring tools to PAC, the impact of PAC on related services, concerns about the use of PAC and a brief discussion of previous technology assessments.

### 3.2.1   Incidence and prevalence of diseases or conditions for which PAC is used

As already described, the literature suggests that there are numerous conditions/diseases that PAC can be used to monitor/diagnose. Information gathered by consulting with clinicians to date suggests that in Australia PAC is mainly inserted prior to cardiac surgery (e.g. bypass surgery, valvular procedures etc), in patients in ICU that have unstable haemodynamic function (although this is significantly less common than use in major cardiac surgery) and in patients in an angiography suite or catheterisation laboratory for the purpose of diagnosing pulmonary hypertension and in turn prescribing one of five medications listed on the HSD program under the PBS.

In order to gain an understanding of the incidence of cardiac surgery procedures in Australia, MBS data was reviewed for cardiac surgery procedures and is shown in Table 3.5 over the last five years.

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**Table 3.5: Benefits claimed under MBS for cardiac surgery, 2004-2009**

| MBS item numbers under | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|---|
| Surgery for ischaemic heart disease* | 9,046 | 8,371 | 7,990 | 8,202 | 7,938 | 7,515 |
| Valvular procedures$^{\alpha}$ | 5,714 | 5,864 | 6,065 | 6,470 | 6,432 | 6,760 |
| Arrhythmia surgery$^{\beta}$ | 143 | 221 | 280 | 339 | 374 | 414 |
| Procedures of thoracic aorta$^{\gamma}$ | 643 | 627 | 706 | 788 | 715 | 876 |

Source: Medicare Australia – Medicare Benefits Schedule data.
* MBS item numbers 38496, 38497 to 38504. $^{\alpha}$ include MBS item numbers 38475 to 38493 $^{\beta}$ includes MBS item numbers 38512 to 38518. $^{\gamma}$ includes MBS item numbers 38550 to 38577.

The data in Table 3.5 shows that surgery for ischemic heart disease (e.g. coronary artery bypass surgery) has declined from 2004 to 2009 by approximately 20% whereas there has been an increase in the number of claims for valvular procedures in the same period. Further work is required to understand the extent to which PAC is performed in association with cardiac surgery (see Chapter 5 for some suggested further analyses of MBS data).

Further investigation into the potential population in ICU is also required. Some preliminary data on diagnosis which clinicians have advised that patients may have in ICU that may result in PAC being performed include shock (e.g. cardiogenic, hypovolaemic etc) and acute respiratory failure. Data on these diagnoses have been extracted from the Australian hospital statistics compiled by the Australian Institute of Health and Welfare, as shown in Table 3.6.

**Table 3.6: Separations from Australian hospitals, 2001-02 to 2007-08**

| ICD code | Principal Diagnosis | 2001-02 | 2002-03 | 2003-04 | 2004-05 | 2005-06 | 2006-07 | 2007-08 |
|---|---|---|---|---|---|---|---|---|
| R57.0 | Cardiogenic shock | 175 | 167 | 152 | 147 | 128 | 112 | 148 |
| R57.1 | Hypovolaemic shock | 27 | 29 | 37 | 35 | 34 | 28 | 32 |
| R57.8 | Other shock | 9 | 7 | 4 | 7 | 6 | 2 | 3 |
| R57.9 | Shock, unspecified | 34 | 17 | 30 | 24 | 21 | 28 | 26 |
| J96.0 | Acute respiratory failure | 1,386 | 1,463 | 1,280 | 1,425 | 1,385 | 1,559 | 1,530 |
| J96.9 | Respiratory failure, unspecified | 820 | 826 | 846 | 862 | 864 | 872 | 879 |

Source: Australian Institute of Health and Welfare. National Hospital Morbidity Data

Review of Table 3.6 shows that separations for cardiogenic shock and hypovolaemic shock have been quite stable in the period from 2002/03 to 2007/08. Further data analysis will be required to clearly establish the potential target population for PAC, however based on initial clinical input the ICU component of the population is largely dependent on clinician preference and the availability of other devices (e.g. echocardiography etc), rather than specific diagnosis of patients.

The outpatient component of the population (i.e. PAC performed in angiography suite or catheterisation laboratory) is patients with suspected pulmonary hypertension. In order to estimate the number of patients with primary pulmonary hypertension in Australia that are prescribed a HSD on the PBS, a PBS data extract will be required. The number of patients admitted to hospital with a diagnosis of pulmonary hypertension will also be examined. These data will be obtained as part of the process of preparing the Review Report.

### 3.2.2 MBS usage and expenditure

Figure 3.4 shows that once item number 22015 was introduced in 2001 (as a result Relative Value Guide (RVG) for Anaesthesia), most of the services that were previously claimed using item 13818 were claimed using 22015. The essential difference is that item 22015 is claimed when the pulmonary artery catheter is inserted in association with the administration of anaesthesia (i.e. in theatre) and 13818 is now only used when it is inserted without the

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administration of anaesthesia (i.e. in ICU). Overall, Figure 3.4 shows that there has been a reduction of 11% in the number of claims for MBS item 22015 since 2002 and a reduction of 58% in claims for 13818, demonstrating a reduction in the use of PAC across all settings. These data are consistent with the decline in use of PAC that is inferred from Table 3.7 (i.e. reduction in cardiac bypass surgery).

**Figure 3.4: Number of claims for MBS items 13818 and 22015 since 1994**
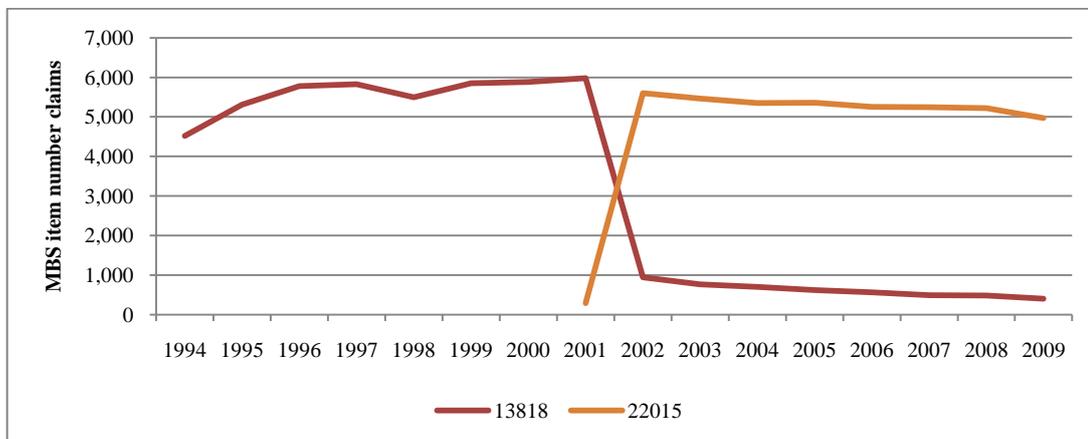


Source: Medicare Australia. Medicare Benefits Schedule data

Figure 3.5 shows that there has been an increase of 71% in the number of claims for MBS item 38200 and an increase of 66% in claims for 38206 since 1994. However, care needs to be taken in the interpretation of these data as PAC is not always performed when a service is claimed under items 38200 or 38206. This issue will be further investigated in the process of preparing the Review Report.

**Figure 3.5: Number of claims for MBS items 38200 and 38206 since 1994**
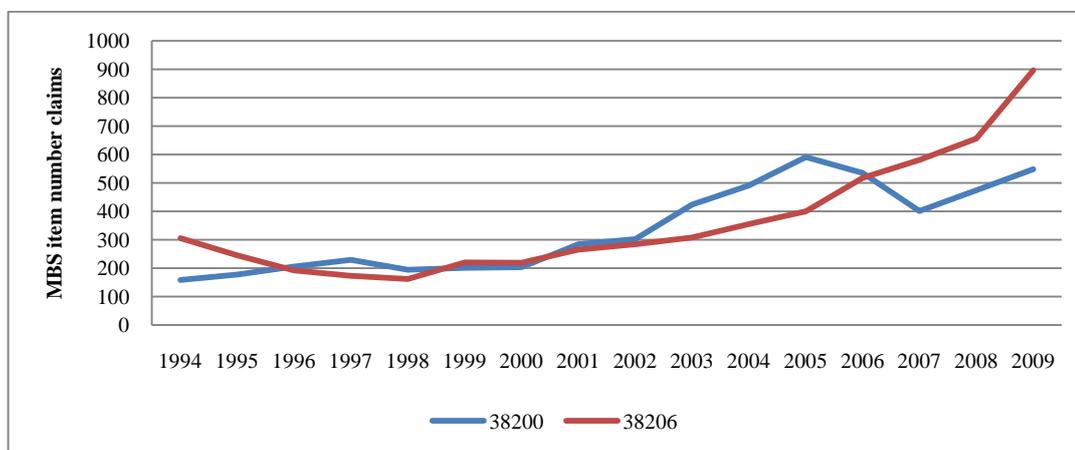


Source: Medicare Australia. Medicare Benefits Schedule data

Table 3.7 examines the expenditure on the insertion of pulmonary artery catheters (MBS item numbers 13818 and 22015 only) since 1994. Consistent with the utilisation data, it shows that expenditure on the insertion of pulmonary artery catheters outside of theatres has decreased every year since the item numbers were split (i.e. 2001). Expenditure on the insertion of pulmonary artery catheters in theatres has remained relatively static in absolute terms at around $430,000, meaning that it has fallen in real terms.

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**Table 3.7: Expenditure on PAC related services since 1994**

| Year | Benefits paid by MBS Item numbers (benefit) | |
|---|---|---|
| | 13818 | 22015 |
| 1994 | $405,540 | |
| 1995 | $327,470 | |
| 1996 | $362,422 | |
| 1997 | $365,619 | |
| 1998 | $350,521 | |
| 1999 | $378,424 | |
| 2000 | $386,724 | |
| 2001 | $396,902 | $22,440 |
| 2002 | $63,643 | $434,591 |
| 2003 | $53,145 | $410,943 |
| 2004 | $49,871 | $404,330 |
| 2005 | $44,875 | $415,933 |
| 2006 | $41,694 | $413,153 |
| 2007 | $39,808 | $422,565 |
| 2008 | $37,321 | $430,504 |
| 2009 | $31,629 | $418,296 |

Source: Medicare Australia. Medicare Benefits Schedule data

These data do not represent the total picture for three reasons. First, MBS only provides benefits for services provided to patients in private hospitals and to private patients in public hospitals. Second, the data on the number of pressure measurements need to be obtained, when used in association with the PAC item numbers. Third, data on the number of pulmonary artery catheters inserted in an angiography suite and cardiac catheterisation laboratory need to be estimated as there are no data available to determine when a PAC is inserted with an MBS claim of 38200 or 38206 (these items cover both the insertion and the taking of a single measurement). These issues will be pursued when the review is carried out in accordance with this protocol.

### 3.2.3 Alternative MBS funded services/comparator services

Measurement of the cardiac output is an essential part of any haemodynamic study. It is still argued that regardless of other cardiac monitoring techniques, the pulmonary artery catheter remains unique in providing pulmonary artery pressure (PAP), pulmonary wedge pressures (PAWP) as well as venous oxygen saturation, in addition to cardiac output. A review of alternative cardiac output monitoring devices, as shown in Table 3.8, confirms this position.

**Table 3.8: Examples of alternative services/comparator services for measuring cardiac output**

| Parameters | PAC | Central venous pressure catheter | PiCCO® Transpulmonary Thermodilution Technique | Transesophageal echocardiograph | FloTrac ® Pulse Contour Devices | CW Doppler Ultrasonic cardiac output measurement | Impedance cardiography (ICG) | LiDCO (R) Lithium Dilution to measure CO | NICO ® Non-Invasive Cardiac Output |
|---|---|---|---|---|---|---|---|---|---|
| Cardiac output (CO) | Yes | No | Yes[17] | Yes[17] | Yes[17] | Yes | Yes[18] | Yes[17] | Yes[17] |
| Systemic vascular resistance (SVR) | Yes | No | No | No | Yes[19] | Yes[20] | Yes[18] | No | No |
| Central venous pressure (CVP) | Yes | Yes[21] | No | No | No | No | No | No | No |
| Pulmonary vascular resistance (PVR) | Yes | No | No | No | No | No | No | No | No |
| Pulmonary artery wedge pressure (PAWP) | Yes | No | No | No | No | No | No | No | No |
| Mixed venous oxygen saturation (SvO$_2$) | Yes | No | No | No | No | No | No | No | No |

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A number of the devices shown in Table 3.8 have been developed to minimise the invasiveness of obtaining cardiac output measurements. The reliability studies of these devices often use PAC, the 'gold' standard in cardiac output monitoring as a comparator and have shown variable results[17]. The unreliability of the results obtained from these other devices as well as the associated mathematical assumptions, calibration requirements, difficult set up and the need for training has limited their uptake.

There are MBS item numbers for trans-oesophageal echocardiography (TOE; Item number 55118) and echocardiography using both pulse wave (PW) and continuous wave (CW) Doppler ultrasound technology (Item number 55113, 55114 and 55115). There are limitations in the use of both these devices. Specifically TOE requires the patient to be unconscious, well sedated, or anaesthetised and is therefore not always practical in the ICU setting. However, clinicians advised that TOE is often used during cardiac surgery in addition to PAC in order to provide the anaesthetist with a visual aid. The use of echocardiography is limited in that it does not provide continuous measurement of the required haemodynamic parameters and it requires a clinician with skills in echocardiography to be present.

There are also MBS item numbers for central vein catheterisation (item numbers 13318, 13319, 13815 and 22020) which can be used in association with the blood pressure monitoring MBS item numbers under review (e.g. 13876, 11600, 22012 and 22014). There are no MBS items specifically for the use of Pulse Contour Cardiac Output (PiCCO) however in practice clinicians claim the central vein catheterisation MBS item numbers in association with the blood pressure monitoring MBS item numbers under review.

### 3.2.4 Concerns about the use of PAC

As an invasive procedure, PAC is associated with potentially catastrophic adverse events. Broadly, the adverse events can be categorised into those due to the invasive procedure, including haemorrhage, organ rupture, and loss of the guide-wire; due to the pressure measurement techniques, including valvular and vascular damage, arrhythmias, and pulmonary injury; and due to the loss of skin integrity, including bleeding and infection[22,23,24,25,26,27,28]. Death, major morbidity (medical complications), and need for emergency major surgery are known risks.

Complications related to PAC use were reported soon after its introduction[29,30,31]. However PAC safety was not clearly questioned until near the end of the 1980s and into the 1990s when the mortality rate was reported to be greater in those patients who received PAC after acute myocardial infarction[32,33]. However, a majority of scientists and clinicians discounted these concerns. Studies that suggested PAC use was associated with greater morbidity and mortality were criticised for poor study design, and study samples were considered biased because patients who received PACs purportedly had greater severity of illness, so would naturally have greater morbidity and mortality[34].

In 1996, a large-scale, multisite, case-matched prospective cohort study of critically ill medical and surgical patients (n = 5,735) by Connors and colleagues indicated that PAC use was associated with greater morbidity and mortality[35]. Adverse effects of pulmonary artery catheter insertion included arterial injury, pneumothorax, and arrhythmias. The catheter can be associated with potentially fatal pulmonary artery haemorrhage, thromboembolism, sepsis, and endocardial damage. Serious questions about the safety and efficacy of PAC were soon expressed by both clinicians and the general public.

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In response, the National Institutes of Health; and the National Heart, Lung and Blood Institute in conjunction with the Federal Drug Administration, convened the Pulmonary Artery Catheterisation and Clinical Outcomes Workshop in 1997[36]. This group was charged with developing recommendations to improve the utility and safety of the PAC. Four recommendations arose from a consensus process. These included the:

- standardisation of education for physicians and nurses with regular measurement and monitoring of knowledge to improve the quality and use of data obtained and ensure safety;
- conduct of randomised clinical trials in specific patient populations (refractory heart failure, low-risk coronary artery bypass surgery, hypoxic pulmonary disease, and sepsis) to determine the safety and efficacy of PAC use;
- systematic evaluation of any new technology developed for use with critically ill populations to ensure safety and efficacy; and
- the use of international collaborative efforts in this research.

Another concern in the available literature relating to PAC is that adequately measuring hemodynamic data is fraught with difficulties. Examples include errors in positioning the PAC such that alveolar rather than pulmonary venous pressure is measured, confounding of readings from positive pressure ventilation, and failure of PAWP to accurately measure left ventricular preload and other measures[37].

### 3.2.5  Previous assessment of PAC

The Center for Medicare and Medicaid Services (CMS) requested a technology assessment report on pulmonary artery catheter monitoring in patients hospitalised in critical care settings. The report was published in March 2008. The primary goal of the report was to describe the utility of PAC monitoring with relevance to the relative effectiveness and safety, and how it affects outcomes in the Medicare population in the USA (i.e. people at least 65 years old) hospitalised in critical care settings.

The CMS requested a description of PAC and related devices, their indications, and a systematic review of the evidence supporting their use. Specifically, they posed four questions for review, as follows.

- **Question 1:** What types of devices and techniques are currently used to assess cardiac output and manage volume status in critical care settings (including operating and recovery rooms)?
- **Question 2:** What are the specific indications for pulmonary artery catheter placement in critical care settings?
- **Question 3:** Does therapeutic management of cardiac output and volume status based on pulmonary artery catheter monitoring in critical care settings lead to improved patient outcomes compared to non-invasive and less invasive techniques?
- **Question 4:** What complications and adverse events associated with pulmonary artery catheter monitoring have been reported?

The information and findings in the CMS technology assessment report will be updated by conducting this review.

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## 3.3 JUSTIFICATION FOR REVIEW

A recent MSAC application for 'Real-time measurement of cardiac output and other cardiac flow parameters (without concurrent cardiac imaging) using continuous wave Doppler techniques' (June 2009, MSAC application 117) brought the risks of using PAC to the attention of the MSAC Committee. The concern raised in MSAC application 117 was that for patients where PAC is used, there are indications of lack of improvement in patient outcomes. Additionally, serious PAC-related complications have been reported to occur in 0.1% to 0.5% of surgical patients[38,39].

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# 4

# Clinical/Research Questions

This Chapter develops the clinical/research questions to be answered through the review and presents the associated clinical flowcharts.

## 4.1 THE CLINICAL/RESEARCH QUESTIONS USING PPICO

Through preliminary discussion with stakeholders, it has been established that the nature of the PAC review should be different from the typical Medical Services Advisory Committee process. Nonetheless the PPICO (target Population, Prior tests, the Intervention (i.e. index test), Comparator, Outcomes) criteria have been used to develop well-defined clinical/research questions for the review. Some adjustments to the usual format have been made as shown in Table 4.1.

**Table 4.1: Development of the research questions for the PAC review**

| Population | Prior Tests | Index test | Comparator | Outcomes |
|---|---|---|---|---|
| 1. Patients scheduled for major surgery (open heart surgery, heart transplant surgery and other procedures to be determined) | None | PAC used to monitor and treat changes in cardiac function during recovery period from surgery | No PAC | **Impact on Patient Management** <br> Treatment instigated <br> Treatment avoided <br> Investigations avoided <br> **Effectiveness** <br> Morbidity <br> Mortality <br> Quality of life <br> **Safety** <br> Pulmonary artery rupture (Fatal/non-fatal) <br> Other complications (pneumothorax, bleeding, arrhythmia, infection, insertion complications, surgery) <br> **Secondary outcomes** <br> Length of hospital stay <br> Length of intensive care stay |

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| 2. Patients with unstable haemodynamic measures in ICU | Range of haemodynamic tests including blood pressure, cardiac output, central venous pressure | PAC used to further evaluate diagnosis and determine any required interventions and measure the effectiveness or treatment | No PAC | **Impact on Patient Management** Treatment instigated Treatment avoided Investigations avoided **Effectiveness** Morbidity Mortality Quality of life **Safety** Pulmonary artery rupture (Fatal/non-fatal) Other complications (pneumothorax, bleeding, arrhythmia, infection, insertion complications, surgery) **Secondary outcomes** Length of hospital stay Length of intensive care stay |
| --- | --- | --- | --- | --- |
| 3. Patients with suspected pulmonary hypertension | Echocardiography, Computerised Tomography and blood tests | PAC used to diagnose pulmonary hypertension and hence prescribing one of five drugs on the Highly Specialised Drugs Program (the results of a right heart catheter composite assessment are required for authorising PBS benefits). | No PAC | **Impact on Patient Management** Treatment instigated Treatment avoided Investigations avoided **Effectiveness** Morbidity Mortality Quality of life **Safety** Pulmonary artery rupture (Fatal/non-fatal) Other complications (pneumothorax, bleeding, arrhythmia, infection, insertion complications, surgery) |

**Clinical/Research Questions**

1. What is the additional value of PAC for patients undergoing major surgery? Of specific interest is
   - What are the risks associated with using PAC? What is their incidence? Specifically, what is the risk of pulmonary artery rupture and the likelihood that this is a fatal complication?
   - What is the benefit of PAC? Does the use of PAC (in respect to what is measured uniquely by PAC) change patient management and alter patient outcomes?
   - Is there a sub-group of pre-surgical patients for which PAC should be used?
2. What is the additional value of PAC for patients with unstable haemodynamic measures in ICU? Of specific interest is
   - What are the risks associated with using PAC? What is their incidence? Specifically, what is the risk of pulmonary artery rupture and the likelihood that this is a fatal complication?
   - What is the benefit of PAC? Does the use of PAC (in respect to what is measured uniquely by PAC) change patient management and alter patient outcomes?
   - Is there a sub-group of ICU patients for which PAC should be used?
3. What is the additional value of PAC for patients with suspected pulmonary hypertension? Of specific interest is
   - Is it essential to measure pulmonary artery wedge pressure in the assessment of patients with pulmonary hypertension?
   - What are the risks associated with using PAC? What is their incidence? Specifically, what is the risk of pulmonary artery rupture and the likelihood that this is a fatal complication?
   - What is the benefit of PAC? Does the use of PAC (in respect to what is measured uniquely by PAC) change patient management and alter patient outcomes?
   - Is there a sub-group of patients with suspected pulmonary hypertension for which PAC should be used?

## 4.2 THE CLINICAL FLOWCHARTS

As shown in Table 4.1 there are three populations where PAC is performed. The first being patients scheduled for major surgery, mainly open heart surgery. The clinical decision pathway which determines the use of PAC is provided in Figure 4.1.

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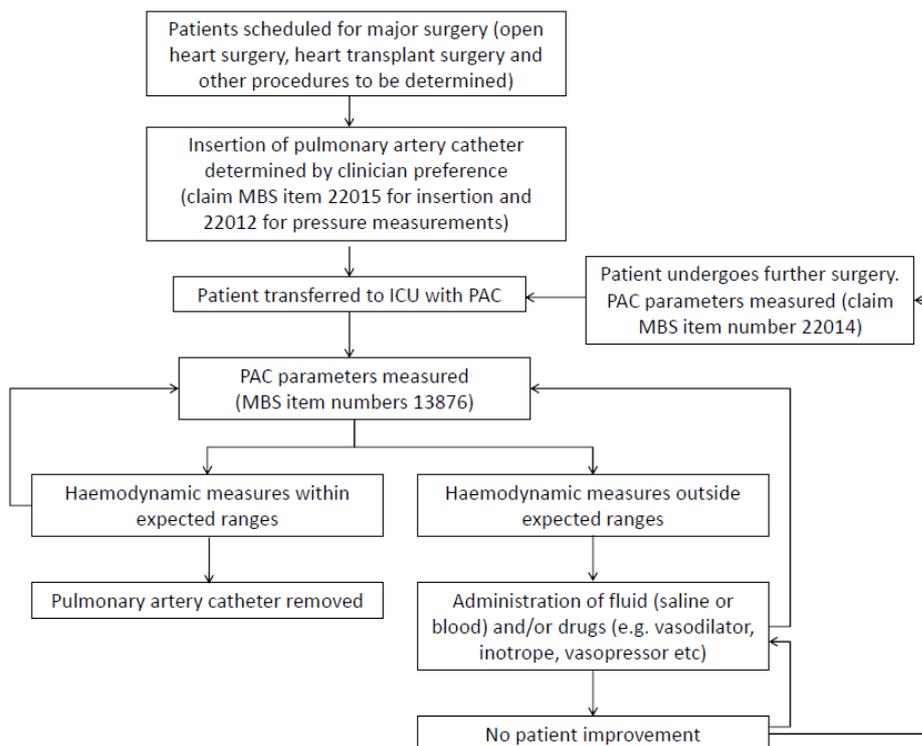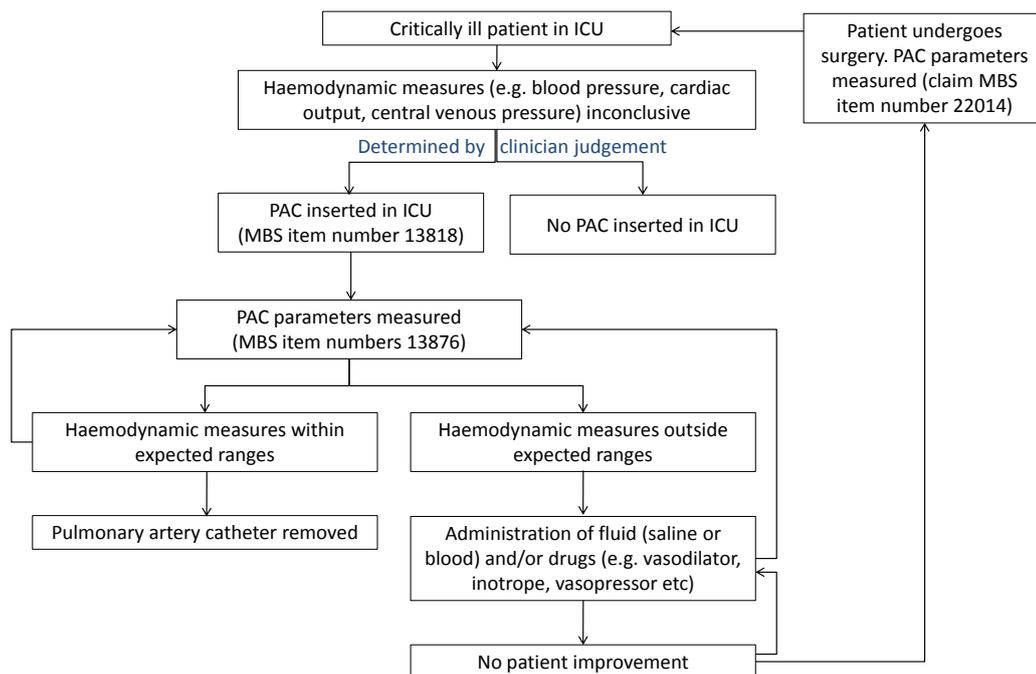**Figure 4.1: Clinical decision pathway for PAC with major surgery**



Figure 4.1 shows that the decision to perform PAC prior to major surgery, particularly open heart surgery, is largely due to the preference of the surgeon and/or anaesthetist. Post surgery, the PAC is used for the continuous monitoring of haemodynamic parameters which provides the surgeon and/or anaesthetist and/or intensivist with indicators about patient recovery.

For the second population of patients, patients in ICU, the decision to perform PAC is due to either inconclusive results or the limited ability of other haemodynamic monitoring devices to provide the required parameters (e.g. PAWP) for clinicians to diagnose their patient or to monitor the chosen therapeutic intervention. The clinical decision pathway which determines the use of PAC in the ICU setting is provided in Figure 4.2.
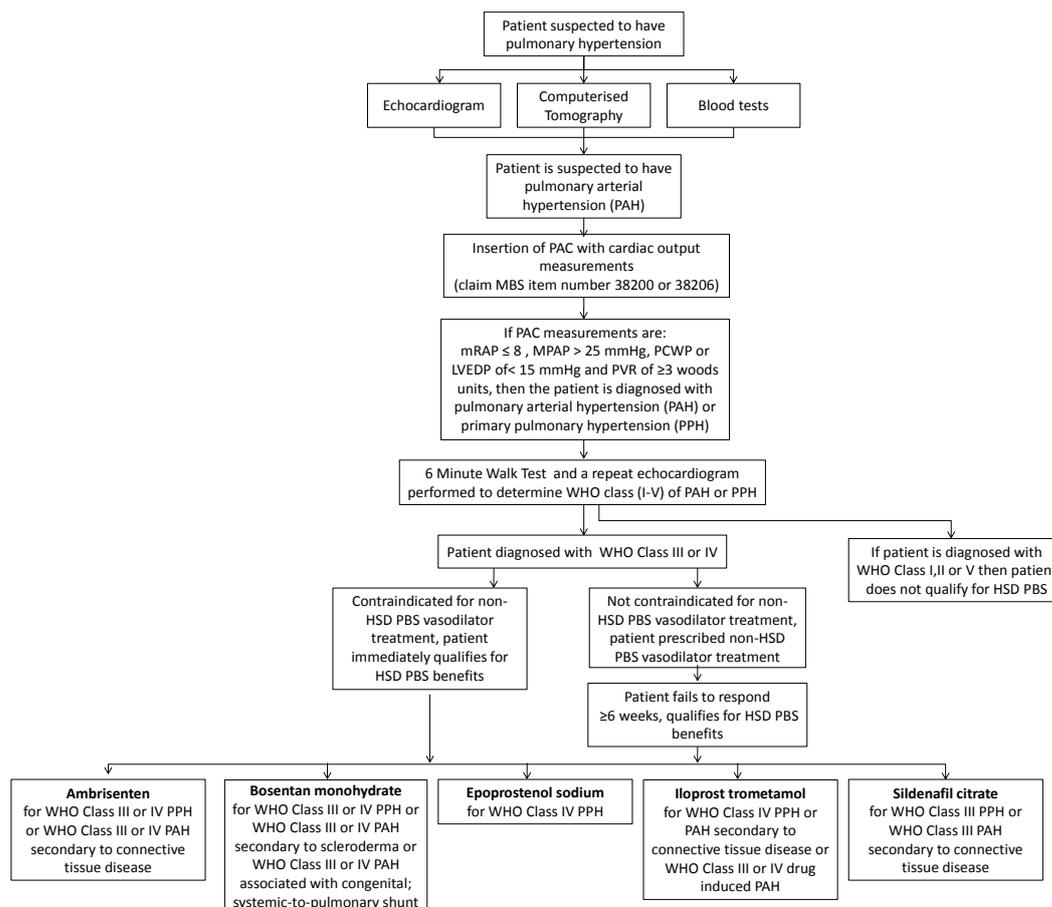
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**Figure 4.2: Clinical decision pathway for PAC in ICU**



For the third population, pulmonary artery catheters are also inserted, as part of an ambulatory care service provided in an angiography suite or cardiac catheterisation laboratory, for patients with suspected pulmonary arterial hypertension (PAH) or primary pulmonary hypertension (PPH). The decision to perform PAC is made after consideration of the results of a series of prior tests used to distinguish between five major types of pulmonary hypertension including pulmonary arterial hypertension from venous, hypoxic, thromboembolic, or miscellaneous varieties.

PAC is performed in order to confirm PAH or PPH, and as a prerequisite to prescribing one of five drugs on the Highly Specialised Drugs Program (the results of a right heart catheter composite assessment are required for authorising PBS benefits). When PAC is performed in an angiography suite or cardiac catheterisation laboratory for this purpose (i.e. PAC is inserted, pulmonary wedge pressure and cardiac output is measured, and then the PAC is immediately withdrawn) MBS item number 38200 (i.e. right heart catheterisation only) or 38206 (if done in association with left heart catheterisation) is claimed. The clinical decision pathway which determines the use of PAC in the angiography suite or catheterisation laboratory setting is provided in Figure 4.3.

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**Figure 4.3: Clinical pathway for the use of PAC in the diagnosis of pulmonary hypertension**



The first written application for PBS subsidised treatment with the first PAH or PPH agent needs to be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all three tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted.

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# 5

# Review methodology

This Chapter outlines the proposed methodology for reviewing PAC against the clinical/research questions developed above. It includes the literature review; MBS and hospital data analysis, stakeholder consultation, and economic evaluation approaches.

## 5.1 LITERATURE REVIEW

A comprehensive search of the scientific literature will be conducted to identify relevant studies addressing the key questions. The databases to be included in the search are: MEDLINE® (from 1966 to present), MEDLINE® In-Process & Other Non-Indexed Citations, EMBASE (Excerpta Medica published by Elsevier) and Cochrane databases (3rd quarter 2006). The search will be restricted to English language studies of humans. In electronic searches we will use various terms for pulmonary artery catheters (including Swan-Ganz), limited to humans, and relevant research designs.

We will also review reference lists of related systematic reviews and selected narrative reviews and primary articles. We will review databases maintained by health technology assessment (HTA) agencies to identify existing assessments of pulmonary artery catheters. We do not plan to systematically search for unpublished data. In terms of supplementary search strategies, as part of consultations with clinicians, clinicians will be asked if they are aware of any clinical guidelines, unpublished studies, reviews relevant to this review of PAC.

The selection criteria in Table 5.1 will be applied to all publications identified by the literature search to identify studies eligible for inclusion in the systematic review. Study eligibility will be assessed by at least two reviewers.

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**Table 5.1: Inclusion/exclusion criteria for identification of relevant studies**

| Characteristic | Criteria |
|---|---|
| Publication type | Clinical studies included. Non-systematic reviews, letters, editorials, animal, in vitro and laboratory studies excluded. **Systematic reviews** Systematic reviews that have been superseded will be excluded **Primary studies** Primary studies published during the search period of included systematic reviews excluded **Change in patient management studies** excluded if: • change in therapeutic impact is not determined by comparison to a clearly defined non-PAC or pre-PAC management plan • reported outcomes are a subjective rating of physician's perceived usefulness of the test without actual change in management plan **Effectiveness studies** included if: • prospective, comparative trial • >20 patients **Safety studies** included if: • >500 patients included |
| Patient | >70% of patients as defined in Table 4.1 |
| Intervention/Test | PAC plus prior tests |
| Comparator | No PAC |
| Outcome | Studies must report on at least one of the following outcomes: • Impact of PAC on clinical management: treatment avoided, treatment instigated, investigations avoided • Patient outcomes: (length of hospital stay, length of intensive care stay, morbidity, mortality, Quality of life • Safety: pulmonary artery rupture (fatal/non-fatal), other complications (pneumothorax, bleeding, arrhythmia, infection, insertion complications, surgery) |
| Language | Non-English language articles excluded |

All eligible studies will be assessed according to the NHMRC Dimensions of Evidence, which are described in Table 5.2. There are three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified for a particular intervention. The last two require expert clinical input as part of their determination.

**Table 5.2: Dimensions of Evidence**

| Type of evidence | Definition |
|---|---|
| Strength of the evidence ➢ Level | The study design used, as an indicator of the degree to which bias has been eliminated by design. |
| ➢ Quality | The methods used by investigators to minimise bias within a study design. |
| ➢ Statistical precision | The p-value or, alternatively, the precision of the estimate of the effect (as indicated by the confidence interval). It reflects the degree of certainty about the existence of a true effect. |
| Size of effect | The distance of the study estimate from the "null" value and the inclusion of only clinically important effects in the confidence interval. |
| Relevance of evidence | The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used. |

One aspect of the 'strength of the evidence' domain is the level of evidence, which will be assigned using the NHMRC levels of evidence outlined in Merlin et al 2009[40]. Study quality will be evaluated and reported using the NHMRC Quality Criteria (shown in Table 5.3) for randomised controlled trials, cohort studies, case control studies and systematic reviews.

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**Table 5.3: Quality criteria for RCTs, cohort studies, case-control studies and systemic reviews**

| Study type | Quality criteria |
|---|---|
| Randomised controlled trials[a] | Was the study double blinded? <br> Was allocation to treatment groups concealed from those responsible for recruiting the subjects? <br> Were all randomised participants included in the analysis? |
| Cohort studies[b] | How were subjects selected for the 'new intervention'? <br> How were subjects selected for the comparison or control group? <br> Does the study adequately control for demographic characteristics, clinical features and other potential confounding variables in the design or analysis? <br> Was the measurement of outcomes unbiased (ie blinded to treatment group and comparable across groups)? <br> Was follow-up long enough for outcomes to occur? <br> Was follow-up complete and were there exclusions from the analysis? |
| Case-control studies[b] | How were cases defined and selected? <br> How were controls defined and selected? <br> Does the study adequately control for demographic characteristics and important potential confounders in the design or analysis? <br> Was measurement of exposure to the factor of interest (eg the new intervention) adequate and kept blinded to case/control status? <br> Were all selected subjects included in the analysis? |
| Systematic reviews[c] | Was an adequate search strategy used? <br> Were the inclusion criteria appropriate and applied in an unbiased way? <br> Was a quality assessment of included studies undertaken? <br> Were the characteristics and results of the individual studies appropriately summarised? <br> Were the methods for pooling the data appropriate? <br> Were sources of heterogeneity explored? |

[a]Based on work of Schulz et al (1995) and Jadad et al (1996) [b]Based on quality assessment instruments developed and being tested in Australia and Canada [c]Based on articles by Greenhalgh (1997) and Hunt and McKibbon (1997)
Source: National Health and Medical Research Council (NHMRC), 2000. How to review the evidence: systematic identification and review of the scientific literature, NHMRC, Commonwealth of Australia, Canberra.

Data will be extracted from individual studies using a standardised data extraction form designed specifically for this review. Data extraction will be performed by one reviewer and checked by a second reviewer.

## 5.2 MBS DATA ANALYSIS

MBS data are available for MBS item numbers 13818, 13876, 11600, 38200 and 38206 since the early 1990's and for MBS item numbers 22012, 22014 and 22015 since 2001. A brief review of MBS data over the last 10 years for the purposes of drafting the review protocol identified that after the introduction of 22015 in 2001, there was a dramatic decrease in the claiming of MBS item 13818.

Further data analysis will be undertaken to inform the review of PAC, with examination of the patterns of use of PAC for haemodynamic monitoring in the period since the new items have been introduced. The aim is to detect changes in the number of measurements that may be taken each time a pulmonary artery catheter is inserted.

The second issue is to examine the age range of patients, to determine whether or not the target population should include children. The data to be investigated are shown in Table 5.4.

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**Table 5.4: PAC claims by patient age, 2009**

| MBS Item Number | Age profile of patients | | | | | |
|---|---|---|---|---|---|---|
| | 0-17 | 18-39 | 40-54 | 55-64 | 65+ | Total |
| 13818 | | | | | | |
| 22015 | | | | | | |
| 38200 | | | | | | |
| 38206 | | | | | | |
| All PAC patients | | | | | | |

The third issue is to establish what sub-group of patients have a major surgical procedure on the same day as, and within one to three days (before or after) of, the insertion of a PAC. From the clinical consultations, it is expected that many patients will have a cardiac surgical procedure on the same day as PAC. The other major surgical procedure groups will be defined following further consultation with clinicians. The aim is to clearly establish what proportion of PAC is performed around surgery.

The fourth issue to be examined is the extent to which PAC is used in conjunction with other procedures to make haemodynamic measurements. The diagnostic procedure categories will be defined through further consultation with clinicians. The aim is to establish the extent to which PAC is used together with other procedures that produce haemodynamic measures.

## 5.3   HOSPITAL DATA ANALYSIS

From clinical consultations, it is known that PAC is almost exclusively performed in hospital theatres or ICUs or angiography suites (including cardiac catheterisation laboratories). Accordingly, hospital data will be examined at a number of levels in order to establish the types of patients on which PAC is used. MBS data relates only to private hospitals and private patients in public hospitals. The national hospital morbidity data, which covers public and private hospitals, will be examined to determine:

- the number of separations where PAC is performed by year back to 2001;
- the principal diagnosis profile of patients for whom PAC is performed;
- the surgical procedure profile of patients for whom PAC is performed;
- the age profile of patients for whom PAC is performed; and
- the discharge disposition profile of patients for whom PAC is performed.

In addition to national hospital data the possibility of identifying hospital level datasets that can provide data on:

- the frequency of incidents arising from the use of PAC; and
- the profile of outcomes for patients who had a PAC related incident.

The review team will liaise with data custodians to determine the extent to which the specified data are available to arrange transfer of data extracts for analysis.

## 5.4   STAKEHOLDER CONSULTATION

The key features of the proposed consultation processes are:

- initial consultations with key staff of DoHA to discuss the issues to be addressed and to identify stakeholder expectations;

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- initial consultations with members of the CWG to discuss the issues to be addressed and to identify stakeholder expectations; to gather clinical interpretations and opinions of the material identified in the preliminary literature analysis; and to gather information to input into the development of the draft Review Protocol;
- review of the draft Review Protocol by the CWG and subsequent release for public comment;
- consultations with representatives of the Consumer Health Forum in respect of the draft Review Protocol;
- consultations (if required) with members of the CWG to discuss issues raised in the public submissions in response to the draft Review Protocol;
- consultations with other stakeholders (submission authors) to follow up issues raised in submissions (as appropriate) in response to the draft Review Protocol;
- further consultations with members of the CWG as necessary to discuss the material identified in the literature review and data analysis;
- review of the draft Review Report by the CWG and subsequent release for public comment;
- consultations with representatives of the Consumer Health Forum in respect of the draft Review Report;
- search of relevant online discussion forums that may include material relating to the consumer experience with PAC;
- consultations (if required) with members of the CWG to discuss issues raised in the public submissions in response to the draft Review Report (as appropriate); and
- consultations with other stakeholders (submission authors) to follow up issues raised in submissions (as appropriate) in response to the draft Review Report (as appropriate).

The consultation strategy is designed to engage all key stakeholders as well as to ensure that all of the issues raised through the public submission process are understood and addressed.

## 5.5    ECONOMIC EVALUATION

Only a preliminary economic evaluation of PAC will be conducted as part of this review, relying on studies identified through the systematic literature review.  A formal modelled economic evaluation of PAC will not be conducted as part of this review.

In the literature searches, acceptable evidence would include trial-based costing studies, cost analyses and economic modelling studies.  Acceptable outcomes would include: cost, incremental cost-effectiveness ratio e.g. cost per event avoided, cost per life year gained, cost per quality adjusted life year or disability adjusted life year.  The applicability of any identified economic analyses to the Australian health system will be assessed.

## 5.6    REVIEW OUTCOMES

The conclusions regarding PAC services that are assessed will be provided in a draft report. This report will be presented in chapters according to each service being reviewed.  The results of the MBS item data analysis, guideline concordance activity, mini-HTA and consumer engagement will be synthesised for each service under review.  A summary statement and conclusion will be developed for each "service" chapter.  Following public consultation and feedback from the MQFEAC the report will be finalised.

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Reviews are expected to result in primary and supplementary review outcomes:

- **Primary review outcomes:** where an evaluation suggests that an item under review is supported by the evidence, the likely recommendation will be that the MBS listing will be retained in its current form. However, should an evaluation suggest that the listed MBS items or services are inconsistent with contemporary evidence in relation to its clinical use or effectiveness, direct amendments to the MBS may be recommended. These may include one or more of the following changes:

  ➢ addition or removal of MBS items;
  ➢ changes to the Schedule fee;
  ➢ refinement of MBS item descriptors to better target patient groups, clinical indicators and/or promote the use of optimal clinical pathways; and/or
  ➢ potential for interim-listing pending the collection of item-specific data.

  Potential amendments to the MBS arising from reviews will be undertaken through consultation with the relevant stakeholder groups.

- **Supplementary review outcomes:** initiatives to facilitate evidence-based changes in clinical practice. In addition to primary review outcomes relating to MBS reimbursement, reviews may indicate the need for secondary investment strategies aimed at bridging the divide between current evidence, including clinical guidelines and current clinical practice. To achieve this, a number of strategies may be implemented following the evaluation of individual items or services. These strategies may include, but are not limited to, the following:

  ➢ development or revision of clinical practice guidelines for evaluated services where there is an identified need;
  ➢ strengthening or targeting of auditing/compliance activities;
  ➢ education and training initiatives for practitioners and/or consumers;
  ➢ exploring incentive-based initiatives to promote improved clinical practices or linking education and training programs to access incentives; and
  ➢ the development of research opportunities where gaps in effective service provision are evident.

  The identification of mechanisms to support evidence-based best practice will complement and reinforce any primary outcome MBS amendments to help improve health outcomes for patients, whilst ensuring the most efficient use of limited resources.

In addition to the primary and supplementary review outcomes relating to PAC, the evaluation method being tested for this review will be assessed and critiqued as part of the project, with suggestions for modification/revision provided, along with the final report.

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# 6
# Review timeframe

This Chapter outlines the expected timeframes of the review process (see Table 6.1).

**Table 6.1: Expected time frames for review process**

| Deliverable | Anticipated dates |
|---|---|
| Final draft protocol submitted to Department | 3 November 2010 |
| Public consultation on protocol | 5 to 28 November 2010 |
| Evaluator considers comments and amends protocol | End January 2011 |
| Final protocol submitted and agreed by Department | Early February 2011 |
| Review | December to February 2011 |
| Draft review report due | End February 2011 |
| Public consultation on draft review report | March 2011 |
| Final report | April 2011 |

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