# National Institute for Health and Care Excellence

# IP1546 Percutaneous insertion of a temporary pump for left ventricular hemodynamic support in high-risk percutaneous coronary interventions

**IPAC 13/09/18**

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
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| 1 | Consultee 1<br>Specialist in Internal medicine Interventional Cardiology<br>Hamburg - Winterhude<br>Germany | **Lay description** | Dear Interventional Procedures Advisory Committee, Based on expert opinions, the National Institute for Health and Care Excellence elaborated a guidance document on the following procedure: “Percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions”.<br>While we encourage and welcome this endeavor, we do have a few comments, based on the current version of the document (July 2018):<br>• In the summarizing first box, the NICE authors describe the pump as to be inserted either in the groin or arm pit. The second is a misleading translation: In the US, the access is often described as “axillary” as its vascular point of access is the arteria axillaris (the more distal continuation of the subclavian artery). Yet the skin access is subclavian, thus under the collarbone.<br>• In the same box, the authors claim that “the aim is to help the heart pump blood round the body”. While maintaining organ perfusion surely is an important task and especially kidney protection has been clearly shown as a benefit during high-risk PCI, this statement omits the direct effects on the myocardium that are a combination of wall stress reduction by ventricular unloading and increased perfusion due to an increase in coronary flow<br>o Hemodynamic Support With a Microaxial Percutaneous Left Ventricular Assist Device (Impella) Protects Against Acute Kidney Injury in Patients Undergoing High-Risk Percutaneous Coronary | Thank you for your comments about the lay description. This is intended as a summary in lay language. It is important that it is factually correct.<br><br>**IPAC amended the lay description as follows**<br>*Some people having elective or urgent high-risk procedures to their heart arteries (percutaneous coronary interventions) may need support with circulatory blood flow support devices to reduce the risk of their heart and circulation failing during the operation. In this procedure, a catheter (small tube) integrated with a small pump is inserted into the left side of the heart through a large artery (usually in the groin or under the collar bone). The aim is to reduce the stress on the heart muscles and help the heart pump blood round the body during the interventional procedures on the heart.*<br>With reference to the studies listed:<br>Flaherty 2017 has already been added to table 2 in the overview. |

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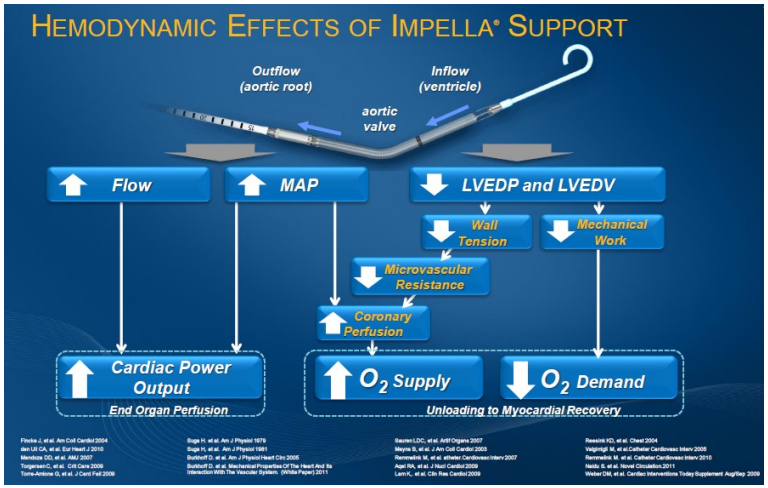
| | | | Intervention. Flaherty MP, Pant S et al;).Circulation Research. 2017; 120: 692-700<br>o Minimizing the risk of contrast-induced nephropathy and hemodynamic collapse during chronic total occlusion percutaneous coronary intervention with a percutaneous left ventricular assist device.; Regazzoli D et al; Cardiovasc. Revasc. Med. (2018)<br>  <br><br>• The term “heart operation” within the last sentence is misleading towards a surgical procedure. Instead, the term “intervention” seems more appropriate, as especially the high-risk PCI is a cardiological device indication (as compared to other indications for the devices that are surgical). | Regazzoli D 2018 (case report) was identified in the update search and has been added to appendix in the overview. |
| 2 | Consultee 7<br>Vice President, Global Market Access Cardiac Surgery Livanova | **Lay description** | LivaNova agrees with the current draft guidance that special arrangements be recommended for circulatory support utilization peri-operatively in cases of high-risk revascularization. We offer two general comments:<br>1. We suggest slight revisions in language to cover the various types of support devices, such language detailed in the table below.<br>**Location** \| **Original wording in draft guidance** \| **LivaNova proposed** | Thank you for your comments.<br><br>IPAC considered your comment but decided not to remove the word ‘pump’ from the lay guidance. |

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| | | | | **alternative wording** | |
| | | | p. 1 | In this procedure, a catheter (a thin tube) with a pump in the end is inserted into the left ventricle in the heart through a large artery (usually in the groin or arm pit) | In this procedure, a catheter (a thin tube) ~~with a pump in the end~~ is inserted into the left ventricle in the heart through a large artery (usually in the groin or arm pit) | |
| 3 | Consultee 3<br>ABIOMED Europe GmbH<br>MedImbursement | **1** | We appreciate the dedicated and comprehensive review of existing, relevant data and published evidence and overall agree with the conclusion.<br>We would like to mention the observation that although it was the overall objective to focus on Protected PCI, the recommendation seems to have been extended towards the use of Impella in urgent conditions (i.e. cardiogenic shock) within the overall scope of high risk interventions. This makes sense as long as there is awareness about the general differences regarding these indications and the clinical impact of Impella respectively. Both risk profile and mortality differ substantially between those groups. | Thank you for your comments.<br>IPAC considered your comment about the indications (elective and emergency high-risk PCI including cardiogenic shock) and amended 3.5 (bullet point 1) as follows:<br>*'Evidence of benefit for patients with cardiogenic shock is limited. In the evidence reviewed, there were only a small number of patients with cardiogenic shock who could not have percutaneous coronary intervention and the outcomes of these patients are poor'.* |
| 4 | Consultee 5<br>NHS professional | **1** | Dear Sir/Madam, I am interested observer in the consultation document prepared by NICE. I am an interventional cardiologist and have a specific interest in haemodynamic support devices in myocardial revascularization by PCI and also coronary physiology related to mechanical circulatory support. I have no conflicts of interests in regards to this topic/devices. | Thank you for your comments and comprehensive account of your clinical experience and views on the place of this procedure in clinical practice.<br>Section 1.1 (draft recommendations) of the consultation document states that |

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| | | | The consultation document has carefully outlined a number of important points about percutaneous mechanical support devices such as the Impella. I want to share my own perspective and also some insights from research that is being conducted in this field both within the UK and internationally, that I am privy to, as I have been involved with research within the field.<br><br>Currently, there are three main modes of percutaneous supporting failing hearts prior to, during and post PCI procedures which you have alluded to in the document, which are<br><br>- IABP, - ECMO, - Trans-axial devices (Impella)<br><br>Each have a number of advantages and disadvantages however I wanted to highlight the physiological differences between the three, to ensure the committee is aware of the importance of having a armamentarium of support devices to suit different patho-physiological situations, as they are each useful, but perhaps in different circumstances.<br><br>**IABP -** increases coronary flow in the presence of exhausted microvascular function/reserve (De Silva et al; PMID: 24726295), reduces after load (and therefore myocardial oxygen demand) but does not increase cardiac output significantly. There is a reduction in LV end-diastolic pressure and volume to a degree, but not by a significant amount. It is likely to be useful in selected cases in the setting of on-going ischaemia with hypotension/shock (with routine use not being beneficial - SHOCK-2 trial), but not helpful in severe pump failure, and an **acutely failing heart.**<br><br>**ECMO -** increases and maintains cardiac output (6-7L/min)' supporting the major organs, however, has deleterious effects on the heart. It increases afterload, increases myocardial oxygen demand. It subsequently increases LV diastolic pressure and volume, leading to worsening of LV function, and theoretically a worsening in infarct size, in the setting of acute myocardial | *"Current evidence on the safety of percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions shows there are serious, infrequent but well-recognised safety concerns. Evidence on efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research".*<br><br>1.3 clearly states that *"Patient selection should be done by an experienced multidisciplinary team when the urgency of the clinical situation allows".*<br><br>Although there is evidence on the use of this procedure in many clinical scenarios, IPAC recommended in 1.5 that '*further research should report details of patient selection criteria and subsequent management'*. |

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| | | | infarction. However it is invaluable in the initial stabilisation of, for example, and out-of-hospital arrest patient, to allow primary PCI to be performed and other measures introduced. The vascular complications of the 17F arterial and venous sheaths are prohibitive in its use in many patients undergoing planned revascularization outside of the emergent setting.<br><br>**Trans-axial pumps (Impella) -** allow 2.5-3.2 L/min of cardiac output. Reduce after load and oxygen demand, reduce LV wall stress and volume and pressure.The active unloading effect within the ventricle allows for a significant shift in haemodynamics (when considering pressure-volume analysis) in the correct direction. Therefore this is possibly the most physiological of devices we currently have. The data is limited in terms of mortality benefit and outcome data. However, the use of the device and patient selection is still in its infancy. More research and work is required to fine tune when it is most robust and useful.<br><br>From a clinical perspective TA devices allow the possibility of completing high-risk, complex revascularization procedures with less jeopardy. It allows more time to be taken to complete PCI procedures adequately in a more controlled fashion, which hitherto has not been possible. The degree and complexity of coronary disease being treated with PCI is increasing, as is the average age of patients being treated. This means more multi-vessel, chronic total occlusion PCI is going to be undertaken, which are often time consuming procedures, in a subset of patients with poor LV function. Devices such as Impella have the potential of ameliorating the ischaemic cascade during a procedure, to allow completion of the case, and reduce morbidity. Data to support its reduction in mortality will be difficult to obtain. The bias towards extreme ends of physiological substrate in patients it is used in (either not sick enough or too sick!) means that the device, used ‘routinely’ is unlikely to be of benefit. However, in carefully chosen cases, I have no doubt that it is of | |

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| | | | use, and offers patients and clinicians a valuable tool to reduce risk.<br><br>I look forward to reading the published document in November. | |
| 5 | Consultee 8<br>Abbott Medical UK | **1.2** | Our only comment is that there appears to be a mistake is this section where it is stated that details should be entered into the Cardiac Rhythm Management database. The PCI database would be more appropriate. | Thank you for your comment.<br>IPAC amended the details about the database in 1.2 as follows:<br>*'Details of all patients should be entered into the British Cardiovascular Intervention Society percutaneous coronary interventions database (BCIS PCI database)'.* |
| 6 | Consultee 2<br>HCD Economics Ltd on behalf of ABIOMED Europe GmbH<br><br>Consultee 3<br>ABIOMED Europe GmbH MedImbursement | **1.2** | **Comments on the Draft Recommendations:**<br><br>P3, point 1.2 "all patients should be entered into the National Audit of Cardiac Rhythm Management database at NICOR - This seems a little odd, particularly since all PCIs are routinely entered into the BCIS database, which has even had an Impella variable since 2014.<br>We politely suggest that the BCIS database is a more suitable audit in which to record these cases; units using the device would simply need to remember to code that Impella was used for the case. | Thank you for your comment. See also comment 5.<br>IPAC amended the details about the database in 1.2 as follows:<br>*'Details of all patients should be entered into the British Cardiovascular Intervention Society percutaneous coronary interventions database (BCIS PCI database)'.* |
| 7 | Consultee 1<br>Specialist in Internal medicine Interventional Cardiology<br>Hamburg - Winterhude<br>Germany | **1.2, 1.3, 1.4, 1.5** | **On draft recommendation section 1:**<br>• Concerning the safety and efficacy of the procedure, we would like to additionally mention the following recent publications on the use of the procedure:<br>o Hemodynamics and its predictors during Impella-protected PCI in high risk patients with reduced ejection fraction.<br>Russo G, Burzotta F, D'Amario D, Ribichini F, Piccoli A, Paraggio L, Previ L, Pesarini G, Porto I, Leone AM, Niccoli G, Aurigemma C, Verdirosi D, Trani C, Crea F. Int J Cardiol. 2018 Jul 17. pii: S0167-5273(18)31934-X.<br>o Indication and short-term clinical outcomes of high-risk percutaneous coronary intervention with microaxial Impella pump: | Thank you for your comments.<br>With reference to the 4 papers suggested by the consultees:<br>Russo G 2018, Baumann 2018 were identified in the update search and added to appendix in the overview.<br>Burzotta F 2015, O'Neill 2012 are already included in appendix in the overview. |

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| | | | results from the German Impella registry. Baumann S, Werner N et al Clinial Research in Cardiology (2018).<br>o Impella ventricular support in clinical practice: Collaborative viewpoint from a European expert user group. Burzotta F, Trani C et al ; International Journal of Cardiology, (2015).<br>o A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. O'Neill WW, Kleiman NS, et al; Circulation. (2012). | |
| | | | • We would recommend setting up a clear structured process and/or algorithm for the shared decision-making process mentioned in paragraphs 1.2 and 1.3. An example for such alorithms can be found in<br>o Standardization of Impella-assisted patient management. Sanna T, Battistoni I, Marini M, Valente S. Minerva Cardioangiol. 2018 Mar 28. | It is outside the remit of the IP programme to make recommendations about structured processes or algorithms for decision-making.<br>Sanna T 2018 (review) listed by the consultee has been identified in our update search and added to appendix in the overview. |
| | | | • Paragraph 1.4 refers to the required training in both the use of the device and the underlying complex percutaneous coronary intervention. Henriques et al have clearly demonstrated the effects of a learning curve and expecially when introducing the device to a new site, a clear protocol as described in (European Consensus) should be followed to start up a well-defined support program.<br>• Paragraph 1.5 states that further research is needed to report details on patient selection. With a glance to the US indications for supportive device therapy as given by the FDA, we recently observed the widening of indications towards less sick patients due to the overwhelming evidence supporting the benefit of device support during high-risk PCI: This process – which is in | Guidance on training is provided in section 1.4 and has been amended as follows: '*The procedure should only be done in specialised centres by clinicians and teams with specialised training in the use of this technology and experience in complex percutaneous coronary interventions'.*<br>IP guidance does not usually specify training protocols in more detail. Henriques 2014 listed by the consultee has already been included in table 2 in the overview. |

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| | | | itself comparable to the evolution of patient selection criteria in transfemoral aortic valve replacement – was based on a decision supported by the following evidence:<br>o The Role of Mechanical Circulatory Support During Percutaneous Coronary Intervention in Patients Without Severely Depressed Left Ventricular Function; Khaldoon Alaswad, et al;Am J Cardiol 2017. | Alaswad 2018 listed by the consultee has already been included in table 2 in the overview.<br>Although there is evidence on the use of this procedure in many clinical scenarios, IPAC recommended that '*further research is needed on patient selection criteria and subsequent management'*.<br>**I**PAC considered the comment about the widening of indications and amended 3.5 (bullet point 1) as follows: *'Evidence of benefit for patients with cardiogenic shock is limited. In the evidence reviewed, there were only a small number of patients with cardiogenic shock who could not have percutaneous coronary intervention and the outcomes of these patients are poor'.* |
| 8 | Consultee 7<br>Vice President, Global Market Access Cardiac Surgery Livanova | **2.1, 3** | LivaNova agrees with the current draft guidance that special arrangements be recommended for circulatory support utilization peri-operatively in cases of high-risk revascularization. We offer two general comments:<br>2. We suggest that consideration be given to the fact that mechanical circulatory support enables revascularizations that might not otherwise be implemented. Therefore, the comparison of mortality in revascularizations may not appropriately define acceptable evaluation criteria.<br>a. For patients who would otherwise be revascularized, mortality would certainly be appropriate as a comparator, although freedom from MACCE may also be a worthwhile intended objective.<br>b. For patients who would not otherwise be revascularized, such as patients turned down for cardiac surgery, and patients with risks of not tolerating the percutaneous //revascularization procedure, the clinical benefits of a support device would have to be intended as the improvements in quality of life due to | Thank you for your comments.<br>IPAC amended 2.1 as follows:<br>Additional support for the heart is not usually needed with angioplasty or percutaneous coronary intervention. However, a subset of high-risk patients may benefit from some form of heart support during their angioplasty procedure. This includes those with extensive or complex coronary artery disease, (unprotected left main disease, last remaining vessel or multi-vessel disease), poor left ventricular function, ongoing myocardial ischemia, cardiogenic shock and co-morbidity in whom revascularisation may not otherwise be possible. |

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| | | | improved cardiac performance that would result from the revascularization, as this would not occur without the support device. | In the evidence reviewed 'mortality' was reported as an outcome of interest along with major adverse cardiac events (MACE) and hemodynamic stability. |
| 9 | Consultee 1<br>Specialist in Internal medicine Interventional Cardiology<br>Hamburg - Winterhude<br>Germany | **2.2 & 2.3** | **On draft recommendation section 2:**<br>• In paragraph 2.2, NICE authors claim the IABP to be the most common device used. This is to our knowledge no longer in line with current standards and recommendations. IABP was downgraded to Class III (risk of stroke, no efficacy) in Europe, recently in Japan (Windecker, et al ESC Guidelines E Heart J 2014; Circulation Japan 2018). In addition, IABP support is fully dependent on myocardial activity and thus does not protect the heart sufficiently in phases of acute ischemia, e.g. during prolonged balloon inflation time.<br>• In paragraph 2.3, the recommendation states that insertion can be done "before, during or after PCI".<br>This is not in line with current data that clearly showed a benefit of early device insertion prior to PCI. Insertion in an emergency | Thank you for your comments.<br>IPAC amended 2.2 as follows:<br>*"Temporary percutaneous mechanical haemodynamic support can be used prophylactically in some elective high-risk angioplasty procedures or in urgent procedures. The aim is to support the patient's circulatory system, provide blood flow to increase cardiac output, unload the ventricle and improve blood flow to maintain haemodynamic stability. This minimises myocardial ischemia and reduces the risk of haemodynamic collapse during the procedure. Intra-aortic balloon pumps or extra-corporeal pumps may be used for temporary percutaneous mechanical haemodynamic support. Percutaneous left ventricular-assist devices for haemodynamic support are sometimes used instead of intra-aortic balloon pumps or extra corporeal pumps.*<br>Section 2.3 to 2.5 is a succinct summary of the procedure description and not a recommendation.<br>Impella devices have been used in many clinical scenarios, both emergent and elective, including high-risk coronary interventions, acute myocardial infarction complicated by cardiogenic shock, |

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<tr><td></td><td></td><td></td><td>setting with an already destabilized patient is associated with higher complication rates and a worse outcome.</td><td>decompensated left and right heart failure, high-risk ventricular tachycardia ablations, and aortic valvuloplasty.<br><br>IPAC amended 2.3 as follows:<br>Inserting a temporary percutaneous mechanical haemodynamic support device may be done before or during percutaneous coronary intervention in selected high-risk patients, and is then taken out when the patient is stable.</td></tr>
<tr><td>10</td><td>Consultee 7<br>Vice President, Global Market Access Cardiac Surgery<br>Livanova</td><td>2.4</td><td>LivaNova agrees with the current draft guidance that special arrangements be recommended for circulatory support utilization peri-operatively in cases of high-risk revascularization. We offer two general comments:<br>1. We suggest slight revisions in language to cover the various types of support devices, such language detailed in the table below.
<table>
<tr><th>Location</th><th>Original wording in draft guidance</th><th>LivaNova proposed alternative wording</th></tr>
<tr><td>2.4</td><td>The procedure is done under local anaesthesia. An introducer sheath is inserted into a large artery (usually the femoral or axillary artery) and a guidewire<br>is passed into the left ventricle. A catheter</td><td>The procedure is done under local anaesthesia. An introducer sheath is inserted into a large artery (usually the femoral or axillary artery) and a guidewire<br>is passed into the left ventricle or another</td></tr>
</table></td><td>Thank you for your comments. This IP guidance is specifically about left ventricular hemodynamic support and therefore reference to other chambers of the heart is not relevant.<br><br>IPAC amended procedure description (in 2.4) as follows:<br>The procedure is done under local anaesthesia. An introducer sheath is inserted into a large artery (usually the femoral or axillary artery) and a guidewire is passed into the left ventricle. A catheter with an integrated pump at its distal end is passed over the guidewire, into the large vessel and into the left ventricle. Fluoroscopic imaging is used during the procedure. The catheter is then attached to an automated external console which controls the pump speed and monitors its function, allowing blood to be taken from the left ventricle and pumped into the ascending aorta.</td></tr>
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| | | | | with an integrated pump at its distal end is passed over the guidewire, into the ascending aorta and across the aortic valve into the left ventricle. Fluoroscopic imaging is used during the procedure. The catheter is then attached to an automated external console which controls the pump speed and monitors its function, allowing blood to be taken from the left ventricle and pumped into the ascending aorta. | **chamber of the heart**. A catheter with an integrated pump at its distal end is passed over the guidewire, **into the artery and into the appropriate chamber of the heart depending on the specific type of support**. Fluoroscopic imaging is used during the procedure. The catheter is then attached to an automated external console which controls the pump speed and monitors its function, allowing blood to be taken from the left ventricle **or** | |

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| | | | | | **other chamber as appropriate to the specific device** and pumped into the ascending aorta |
| 11 | Consultee 4<br>NHS Professional | **3** | On vascular and bleeding complications - the rates described predate the meticulous vascular access techniques now used in (for example) TAVI: ultrasound guided puncture, the use of micro-puncture techniques and rotational angiography to check precise point of vessel entry, before upscaling sheath size (as well as simple miniaturisation of kit) have all combined to reduce vascular complications as programs have developed and increased in experience. It is to be anticipated that the same techniques utilised in placement of support devices would also reduce bleeding and other vascular complication rates to below the rates described in early trials. | | Thank you for your comments.<br>IPAC added a committee comment in section 3.5 (bullet point 3) as follows:<br>*'The risks of bleeding has reduced with improvement in the design of the technology'.* |
| 12 | Consultee 1<br>Specialist in Internal medicine Interventional Cardiology<br>Hamburg - Winterhude<br>Germany | **3.2** | **On draft recommendation section 3:**<br>• In addition to the mentioned key outcomes in section 3.2, procedural success and completeness of revascularization should also be considered of key relevance: One of the major advantages of device-protected high-risk PCI is the prolonged time of stability on balloon inflation - compare the already mentioned case report:<br>o Avoiding Hemodynamic Collapse During High-Risk Percutaneous Coronary Intervention: Advanced Hemodynamics of Impella Support. Verma, Burkhoff and O'Neill. Catheter Cardiovasc Interv. 2017 Mar 1;89(4):672-675. | | Thank you for your comments.<br>IPAC amended section 3.2 as follows:<br>*The specialist advisers and the committee considered the key efficacy outcomes to be: procedural success and completeness of revascularisation, haemodynamic stability, survival to hospital discharge, survival at 30 days, and rate of major adverse cardiac events.*<br><br>The case report (Verma 2017) mentioned by the consultee has already been added to appendix in the overview. |

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<td>Consultee 1<br>Specialist in Internal medicine Interventional Cardiology<br>Hamburg - Winterhude<br>Germany</td>
<td>3.3</td>
<td>• In their list of key safety outcomes (paragraph 3.3), the authors cite acute procedure-related mitral regurgitation as key. This is reflecting the content of a single case presented on a poster session. Details about the case are largely missing. While it is of course of relevance to report all potential issues, it seems to be misleading to define this as a key safety outcome.</td>
<td>IPAC considered your comment and removed “acute procedure related mitral regurgitation” from section 3.3 (key safety outcomes)-</td>
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<td>14</td>
<td>Consultee 7<br>Vice President, Global Market Access Cardiac Surgery<br>Livanova</td>
<td>3.3</td>
<td>LivaNova agrees with the current draft guidance that special arrangements be recommended for circulatory support utilization peri-operatively in cases of high-risk revascularization. We offer two general comments:<br>1. We suggest slight revisions in language to cover the various types of support devices, such language detailed in the table below.
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<tr><th>Location</th><th>Original wording in draft guidance</th><th>LivaNova proposed alternative wording</th></tr>
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</td>
<td>Thank you for your comments.<br><br>IPAC amended key safety outcomes (in section 3.3) as follows: ‘The specialist advisers and the committee considered the key safety outcomes to be: vascular damage, bleeding, haemolysis and left ventricle damage’.</td>
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| | | | 3.3 | The specialist advisers and the committee considered the key safety outcomes to be: vascular damage, bleeding, haemolysis, left ventricle damage and acute procedure-related mitral regurgitation. | The specialist advisers and the committee considered the key safety outcomes to be: vascular damage, bleeding, haemolysis, left ventricle damage and acute procedure-related **valve insufficiency** mitral regurgitation. | |
| 15 | Consultee 1<br>Specialist in Internal medicine Interventional Cardiology<br>Hamburg - Winterhude<br>Germany | **3.5** | • The first bullet in section 3.5 seems out of scope for a consultation on high-risk PCI. In the deep analyses provided with the consultation, it appears that in the literature review, a combination of articles on high-risk PCI and cardiogenic shock has been used. This deeply skews almost all facets of the therapeutic approach: Patients in cardiogenic shock are in a state of deteriorated hemodynamics. This does not only affect the heart but also all other systems and heavily impacts on e.g. end organ function, bleeding/hemostasis, limb perfusion. Thus, both mortality (between 40 and 60 %) and complication rates rocket in these patients, aggravated by the fact that insertion under emergency circumstances is also much more prone to errors and iatrogenic injuries.<br>Therefore, for a consultation on high-risk, yet elective PCI, only literature in line with this indication should be used to elaborate on the safety and efficacy of the procedure. | | Thank you for your comments.<br>Evidence for high-risk patients (including those in cardiogenic shock) undergoing high-risk PCI (both elective and urgent procedures) was considered by the committee in making the draft recommendations.<br>IPAC considered comments on cardiogenic shock and amended committee comment in 3.5 (bullet point 1) as follows: *"Evidence of benefit for patients with cardiogenic shock is limited. In the evidence reviewed, there were only a small number of patients with cardiogenic shock who could not have percutaneous coronary intervention and the outcomes of these patients are poor".* |

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| 16 | Consultee 2<br>HCD Economics Ltd on behalf of ABIOMED Europe GmbH<br><br>Consultee 3<br>ABIOMED Europe GmbH<br>MedImbursement | **3.5** | P6, point 3.5 -evidence of benefit for patients with cardiogenic shock is limited" - Recent studies have shown the significant value of the haemodynamic support with Impella in cardiogenic shock:<br>In treatment of acute myocardial infarction complicated by cardiogenic shock (AMICS) Basir et al. (2016) showed that Impella implantation early after shock onset, before initiation of inotropes or vasopressors and before PCI, is independently associated with improved survival in patients presenting with AMICS. Survival was found to be significantly improved if Impella implantation was initiated before PCI (survival 46% vs 35%, p = 0.04.).<br>Evaluation of their patient data Mastroianni et al. (2016) were able to show that the Impella 5.0 device surgically inserted through the axillary artery is a valuable minimally invasive short-term circulatory support in cardiogenic shock of various aetiologies" consequently using it as choice for short-term left ventricular support in cardiogenic shock managed at La PitiÃ©, France. | Thank you for your comments.<br>With reference to the 2 papers suggested:<br>Basir 2017 has already been added to appendix in the overview.<br>Mastroianni 2017 has been identified in the update search and added to appendix in the overview. |
| 17 | Consultee 2<br>HCD Economics Ltd on behalf of ABIOMED Europe GmbH<br><br>Consultee 3<br>ABIOMED Europe GmbH<br>MedImbursement | **3.1** | "**Comments on the efficacy and safety summaries:**<br>**Efficacy Summary** - Overall, considering all the sub-topics included in the efficacy summary, it appears to generally favour the Impella device over IABP. However, the recommendation states that efficacy is limited in quality, which is questionable as all the same studies are then used for the safety evidence.<br>• Mortality - All the evidence presented in the summary highlights that there are no significant differences between the two approaches in terms of mortality. However, there is a lot of evidence on this topic and deeming all of this evidence to be of limited quality is questionable.<br>• Major Adverse Cardiac Events (MACE) - Study 1 (Ontario HTA) shows Impella has superior outcomes over IABP, but most of the other studies included show no significant differences, with outcomes being very similar. | Thank you for your comments.<br>Studies on different patient groups, devices and outcomes were included in the overview evidence summary (table 2) based on a judgement about their relevance and validity.<br>The committee made draft recommendations about the procedure on the basis of the different levels of evidence relating to its efficacy and safety. Judgments about efficacy are based on an overview of the available evidence on efficacy. |

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| | | | • Major Adverse Events (MAE) - Evidence based on Study 7 (learning curve) solely, the evidence clearly shows that once the first patients (training period) had been accounted for, the MAE rates were significantly better for Impella patients than IABP.<br>• Haemodynamic Stability - Evidence consistently showed improved haemodynamic stability from using the Impella compared to IABP, including in Cardiogenic Shock.<br>• Acute Kidney Injury (AKI) - The evidence shows that the Impella device has a significant reduction in AKI compared to IABP. Moreover IABP was downgraded to Class III (risk of stroke, no efficacy) in Europe, recently in Japan (Windecker, et al ESC Guidelines E Heart J 2014; Circulation Japan 2018).<br><br>**Safety Summary:**<br>The safety evidence is not as clear cut as the recommendation may suggest; most of the evidence shows similar outcomes to the current approach and begs the question: Why is the quality of this evidence considered superior for safety when it is simultaneously deemed to be of limited quality for efficacy - the conclusions are drawn from the same sources?<br>• Bleeding Complications - Evidence that Impella can increase bleeding complications as seen with significant difference between Impella and IABP for patients needing blood transfusion after a major bleed, however must be noted the quality of evidence is rated as Low for this particular case.<br>• Vascular Complications - The evidence shows there is no significant differences between the two approaches.<br>• Fever or Sepsis - The evidence shows there is no significant differences between the two approaches.<br>• Mitral Regurgitation - Evidence for this is solely based on a case report; not representative. | The committee considered that enough evidence is known about the safety and their frequency and therefore has made the draft recommendation in 1.1, and that optimal study designs for assessing safety and for assessing efficacy can differ.<br><br>As safety is a key feature of IP guidance, the 'case report reporting mitral regurgitation' has been included.<br><br>With regard to comments on frequency of vascular and bleeding complications, IPAC added a committee comment in section 3.5 (bullet point 3) as follows: *'The risks of bleeding has reduced with improvement in the design of the technology'.*<br><br>IP guidance routinely reports both anecdotal and theoretical safety concerns. This is standard practice to ensure that potential safety issues are not overlooked. Specialist advisors refer to specific theoretical effects as a matter of concern (and even cite anecdotal complications known to them) but there |

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| | | | • Anecdotal and theoretical adverse events - Concerns this is solely hypothetical and not enough physicians were consulted.<br><br>**Additional Comments:**<br>• <u>P34. Validity and Generalisability of the Studies</u> - Impella CP is the next generation™ of Impella 2.5 - the advance is a higher flow rate of 3.5l/min versus the 2.5l/min of the 2.5. Therefore, we suggest that the evidence around Impella 2.5 is generalisable to Impella CP. Please note, Impella 2.5 and CP have a common IFU, due to the fact that Impella 2.5 and CP are a very similar device and data for 2.5 reflecting outcomes for CP as well. | are no reports of these complications in the literature.<br>The committee is aware that there are different devices and technology is evolving. Therefore in section 3.5 (bullet point 4) the committee noted that *'More than 1 device is available for use in this procedure and the technology is evolving'.*<br>Evidence for high-risk patients (including those in cardiogenic shock) undergoing high-risk PCI (both elective and urgent procedures) was considered to make the draft recommendations.<br>IPAC considered the comments on cardiogenic shock and amended committee comment in 3.5 (bullet point 1) as follows: *"Evidence of benefit for patients with cardiogenic shock is limited. In the evidence reviewed, there were only a small number of patients with cardiogenic shock who could not have percutaneous coronary intervention and the outcomes of these patients are poor".* |

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| | | | Impella CP (CE marked 04/2012) is the model used most widely in the UK and has the combination of fully percutaneous access and higher flow rate, which is important for patients with high BMI and other comorbidities that increase their procedural risk.<br>• Concerns over merging High Risk-PCI and Cardiogenic shock - The patient groups for each indication are very different usually the HR-PCI are elective cases whereas the CGS group are emergent, the risks and outcomes for each indication are very different, as, we expect, arephysician expectations. | |
| 18 | Consultee 2<br>HCD Economics Ltd on behalf of ABIOMED Europe GmbH<br><br>Consultee 3<br>ABIOMED Europe GmbH MedImbursement | **3.1** | **Comments on the studies/ scientific papers (Part I):**<br>**Study 1 Health Quality Ontario (2017)**<br>http://www.hqontario.ca/Portals/0/Documents/evidence/reports/htaimpella-1701-en.pdf<br><br>Conclusion from the paper states: Percutaneous ventricular support with Impella does not lower death rates; nor is it safer or cheaper than usual treatment with balloon pumps. On the basis of evidence of low to very low quality, Impella 2.5 devices were associated with improved hemodynamic stability, but had mortality rates and safety profile similar to IABPs in high-risk PCI and cardiogenic shock.<br>Only RCT in the study was the PROTECT II study (ONeil 2012).<br>From the Study paper the GRADE Evidence always appears to be very low or low in most cases.<br>30-Day Mortality rates are similar, with identical results for the Seyfarth (2008) of 46% but Impella has lower mortality in the Manzo-Silberman (2013) with 23% vs 29.5% on Table Page 16 (concern that this is not significant).<br>The patient groups for the two indications included HR-PCI and CGS are very different: HR-PCI are elective cases whereas the CGS group are emergent, the risks and outcomes for each indication are very different.<br><br>Concerns about the quality of the publication:<br>o Not a peer-reviewed publication | Thank you for your comments.<br>IPAC understands that the outcomes for the two indications high-risk PCI and cardiogenic shock are different and therefore provided recommendations for high-risk PCI in 1.1 and a committee comment in 3.5 (bullet point 1) for cardiogenic shock.<br><br>IPAC agrees that there is an overlap of studies in all the systematic reviews and this has been clearly stated in the overview on page 10.<br>As this is a rapid assessment, the most valid and relevant studies are presented in table 2 evidence summary in the overview to provide a balanced view of the evidence. Well-designed studies with large number of patients, those with long follow-up and any reports of additional important safety outcomes were included. The remaining studies are listed in the appendix, which presents the overall picture of the evidence on the procedure. Other potential studies may not be |

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| | | | o The method of review was not according to scientific standards<br>o Inclusion and exclusion criteria for literature was unclear and inconsistent<br>o Interpretation of the results superficial.<br><br>**Study 2 Cheng JM (2017)**<br>https://academic.oup.com/eurheartj/article/30/17/2102/50650<br>Conclusion from the paper states LVAD provides superior haemodynamic support in patients with cardiogenic shock compared with IABP, the use of these more powerful devices did not improve early survival. These results do not yet support percutaneous LVAD as first-choice approach in the mechanical management of cardiogenic shock.<br><br>From Table on Page 19:<br>o 30-day mortality identical across the two devices in two studies, with only a slight difference in one study (not significant when pooled)<br>o Bleeding significant when pooled however the two studies have opposite outcomes? This pooled result should be questioned? Studies in the paper are dated 2005, 2006 and 2008 which is relatively old data and methods/practices with the device may have been different or lack of training.<br><br>**Study 3 Briasoulis A (2016)** https://www.ajconline.org/article/S0002-9149(16)30857-8/fulltext<br>From figure 3 on page 374, Impella versus TandemHeart:<br>o Incidence rates for mortality, MI, Vascular complications, Major Bleeding were numerically superior for all but major bleeds. However, there were limited concerns over increased safety and efficacy in this high-risk population.<br><br>**Study 4 Ichou JA (2017)**<br>https://onlinelibrary.wiley.com/doi/pdf/10.1002/ccd.27316<br>Similar studies were identified that are in other systematic reviews.<br>From abstract: The Impella device was found to improve | included in the appendix because they were not identified in the search. Relevant studies highlighted by consultees have been incorporated in relevant sections in the overview.<br>This approach has been considered for effective use of programme resources and committee time and usefulness of the guidance to the NHS. The committee understands that almost all studies it considers (both primary studies and evidence syntheses) have some limitations and takes these into account when interpreting findings.<br><br>The committee notes the comments made about individual papers.<br>Regarding the Health Quality Ontario review, Health Quality Ontario stated that all analyses in the Ontario Health Technology Assessment Series are subject to external expert peer review.<br><br>Regarding the Alaswad 2018 study, the mean age in this paper is stated as 69.57 ± 11.29 years. The 96.57 is a typo and this has been amended in the overview.<br><br>Regarding the Bhatia 2016 abstract. Posters and abstracts are included if they report safety issues. The committee does not take non-peer-reviewed abstracts into account in the consideration of efficacy. |

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| | | | procedural and hemodynamic parameters. Doesnt present any significance tests in the tables on page 23 some outcomes for Impella in comparative studies against IABP:<br>o 30-day Strokes, MACE, repeat revascularisation more common from IABP (ONeil 2012)<br>o 3-month outcomes Stroke, MACE, MI, repeat revascularisation more common from IABP (ONeil 2012)<br>12 month follow up mortality greater (proportion) for IABP (Boudoulas 2012).<br><br>**Study 5 Alaswas K (2018)** https://www.ajconline.org/article/S0002-9149(17)31923-9/abstract<br>Mean age of 96.57 years? Seems extremely old when study size is n=891. Study compares Severe LVEF <35% and non-severe LVEF >35% who received MCS support in high risk PCI.<br><br>From Table Page 26 from severe vs non-severe:<br>o Significant difference for Acute Renal Dysfunction<br>o Significant difference for bleeding needing transfusion<br>o Significant difference for Hematoma<br>o Most outcomes are not significant between the groups.<br><br>From abstract: The major adverse cardiovascular and cerebral event rates were favourable overall, with no differences between the 2 groups (3.48% vs 4.54%; p=0.574).<br>What can be the message of this study? Not many safety and efficacy concerns (or differences) from using the device on severe and non-severe patients?<br><br>**Study 6 Flaherty MP (2017):**<br>https://www.ahajournals.org/doi/pdf/10.1161/CIRCRESAHA.116.309738<br><br>Conclusion from the report is supportive: Impella 2.5 (pLVAD) support protected against AKI during high-risk PCI. This renal protective effect persisted despite the presence of underlying CKD and decreasing ejection fraction.<br>Page 7 of NICE document: Positive paragraph on AKI | IPAC discussed specific issues raised by the consultee in relation to included studies and amended where required. |

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| | | | highlighting more efficacy evidence that seems to be overlooked.<br>Statistics from Page 28 Impella vs Controls:<br>o Length of Stay significantly different<br>o Need for haemodialysis significantly different<br>o Death significantly different.<br><br>**Study 7 Henriques J PS (2014):** https://www.ahjonline.com/article/S0002-8703(14)00011-8/pdf<br>Subgroup analysis to assess the learning curve of the device on outcomes.<br>From the conclusion of the paper: Significantly lower 90-day MAE (major adverse event) rates were observed with the use of Impella 2.5 compared to the use of IABP after excluding the first patient per group at each site. This prespecified analysis suggests a learning curve associated with initial introduction of the Impella 2.5. Clinical trials should better address the training aspect of new devices, especially when compared with more established devices.<br>I havent seen mention of the conclusions that can be drawn in the NICE documents maybe there has been an oversight.<br><br>From the Table on page 31 can see that if you adjust for training period the results show a clear benefit of the Impella device over IABP.<br>o MAE significant at 90 days (very close to significant at 30 days)<br>o Strokes/TIA significant at 30 days<br>o Severe Hypertension significant at 30 days and 90 days.<br><br>Case that safety & efficacy concerns should be less if appropriate training has taken place and significant evidence for efficacy that doesnt seem to be addressed in the report.<br><br>**Study 8 Bhatia N (2016):**<br>http://www.onlinejacc.org/content/67/13_Supplement/1085<br>Poster Presentation: Grey Literature? Was published in the American College of Cardiology so there is an argument for inclusion<br>Case Report: One of the lowest forms of evidence (not | |

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| | | | representative). No information on how experienced the interventional cardiologist was in using the device (level of training).<br>Setting where the device was used: en-route to hospital, is this typical? Could this be impacting the case report?<br><br>Age of the patient (52) is lower than the average/median age of the other studies (Representative argument).<br>In the Appendix, in the table the column Reason for non-inclusion states reasons why potential evidence is not included as one of the main sources;<br>o Interestingly one of these reasons used on a couple of potential evidence is that they are case reports<br>o The question is how are they any different to this case report? If the reason for non-inclusion is because they are case reports they should apply the same methodology and remove this evidence out of the consideration.<br><br>Furthermore there is a long history (https://www.mc.vanderbilt.edu/news/releases.php?release=218) and ongoing (http://www.medtronic.com/us-en/c/neuro-healthcare-webinar-series.html) cooperation between the Vanderbilt University, Nashville, TN, USA (where the report comes from) and Medtronic (Tandem HeartÂ®, solution device in this single center case experience). Also it is missed in the report from Bhatia N et al. 2016 that Tandem Heart requires a complex implantation procedure, implanting the Tandem Heart device results in difficult ICU maintenance, transseptal puncture and full anticoagulation and last but not least a septal defect is created upon explant of the Tandem Heart. Following adverse events associated with Tandem Heart: Stroke, limb ischemia and complex implant and closure of the septum. | |
| 19 | Consultee 3<br>ABIOMED Europe GmbH<br>MedImbursement | **3** | **Recommendation and Summary of key efficacy and safety findings** on percutaneous insertion of a temporary heart pump for left ventricular hemodynamic support in high risk percutaneous coronary interventions: | Thank you for your comments.<br>There is an overlap of studies in all the systematic reviews and this has been clearly stated in the overview on page 10. |

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| | | | **Study 1 Health Quality Ontario (2017)**<br>Although the Publication is recent (2017), the references are relatively old (2009-2013 for protected PCI and 2008-2015 for cardiogenic shock). Technology and best practice recommendations have evolved over time. This data does not completely address current standards.<br><br>**Study 2 Cheng JM (2017)**<br>This meta-analysis refers to percutaneous mechanical support (pMCS) in Cardiogenic Shock. References are 3 Studies, published between 2005 and 2008.<br>Technology and best practice recommendations have evolved over time. This data does not completely address current standards.<br><br>**Study 3 Briasoulis A (2016)**<br>This data refers to the use of Impella (and Tandem Heart) in Protected PCI. It includes the results of PROTECT II (2012), which is currently the most relevant RCT referring to this indication.<br><br>**Study 4 Ichou JA (2017)**<br>Systematic review, mixed indications and mixed levels of high risk within these patient populations.<br>**Conclusion 1-4:** Relevant reviews with reference to data (RCTs, cohort analysis and other reviews). However, several reference studies are included multiple times. More recent best practice publications and findings are not included.<br><br>**Study 5 Alaswad K (2018)**<br>This study refers to the use of Impella in protected PCI. The study addresses the finding that even patients with moderately compromised EF may benefit from hemodynamic protection/stabilization in the context of protected PCI.<br><br>**Study 6 Flaherty MP (2017)** | As this is a rapid assessment, the most valid and relevant studies are presented in table 2 evidence summary in the overview to provide a balanced view of the evidence. Well-designed studies with large number of patients, those with long follow-up and any reports of additional important safety outcomes were included. The remaining studies are listed in the appendix, which presents the overall picture of the evidence on the procedure. Other potential studies may not be included in the appendix because they were not identified in the search. Relevant studies highlighted by consultees have been incorporated in relevant sections in the overview.<br>This approach has been considered for effective use of programme resources and committee time and usefulness of the guidance to the NHS.<br><br>The committee noted your comments on how technology and recommendations have evolved over time. |

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| | | | This study refers to the use of Impella in protected PCI. The study addresses the observation that the hemodynamic protection of the PCI with Impella including the maintenance of coronary and peripheral perfusion also provides a kidney protective effect.<br><br>**Study 7 Henriques J PS (2014)**<br>This study refers to the use of Impella in protected PCI. This is a substudy related to PROTECT II. It addresses the learning curve with regards to the use of Impella (and IABP) within this trial which was shown to result in optimization with regards to Impella (rather than with IABP), considering that the use of Impella was new by the time of the study " the use of IABP has been more established. The Impella technology used by the time of the study (PROTECT II) has been optimized to date.<br><br>**Study 8 Bhatia N 2016 (2017)**<br>Impella in AMI, case report " addressing the safety of Impella. Mitral regurgitation (MR) after ImpellaÂ® placement (rare catastrophic complication).<br><br>**Conclusion 5-8:** Study 5-7 are addressing the use of Impella in Protected PCI and describe / confirm its efficacy. Study 8 above is a case report addressing a rare but critical complication which is fortunately an exceptional event. | |
| 20 | Consultee 2<br>HCD Economics Ltd on behalf of ABIOMED Europe GmbH | **3** | **Criticism of the use of GRADE**<br>While GRADE is one of the most widely used quality assessment tools the measure may not be the most appropriate for assessing medical devices. The tool struggles to distinguish between levels of evidence and the levels are subjective. It is suggested that the Newcastle-Ottawa tool would be more appropriate in determining the differences in quality of the evidence. | Thank you for your comment.<br>GRADE -a systematic approach to rate the quality of evidence was used in a systematic review (Heath Quality Ontario 2017) included in table 2 in the overview. Selection of this tool is the judgement of the authors. IPAC has reviewed all the evidence to make a decision about the overall quality of the evidence and does not routinely apply GRADE in producing guidance. |
| 21 | Consultee 2 | **3** | **Criticism of Comparator**<br>Concerns about the comparators for Impella: | Thank you for your comment. |

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| | HCD Economics Ltd on behalf of ABIOMED Europe GmbH | | o There is no clear alternative for the Impella device in HR-PCI or cardiogenic shock<br>o IABP is often used but the mechanism behind it is very different, evidence around its lack of efficacy has not been highlighted, and it is associated with adverse events which haven't been captured in the evidence from NICE.<br><br>1) Lee et al. 2015. The efficacy and safety of mechanical hemodynamic support in patients undergoing high-risk percutaneous coronary intervention with or without cardiogenic shock: Bayesian approach network meta-analysis of 13 randomized controlled trials. https://doi.org/10.1016/j.ijcard.2015.01.081 .<br>□□The meta-analysis highlights that IABP & pVAD both increase bleeding compared to MT in HR-PCI however pVAD high bleed rate was mainly driven by higher incidence of bleeds in the ECMO and TandemHeart.<br>□□Can see that the comparators IABP and TandemHeart both have higher adverse events of bleeding from this meta-analysis.<br>□□These adverse events with the comparators have not been highlighted in the safety evidence which seems to focus solely on evidence against the Impella device<br><br>2) Curtis et al. 2012. Use and Effectiveness of Intra-Aortic Balloon Pumps Among Patients Undergoing High Risk Percutaneous Coronary Intervention: Insights from the NCDR®. 10.1161/CIRCOUTCOMES.110.960385 .<br>□□'In randomized trials that enrolled patients with AMI undergoing primary PCI, routine IABP use was not associated with differences in procedural success or clinical outcomes. Collectively, these studies do not support the routine use of IABP for patients at high risk of adverse outcomes'<br>□□Highlights there is no evidence to support the use of IABP and focuses on the fact that there needs to be more evidence to define the setting of this procedure. | The remit of this IP guidance is to assess the efficacy and safety of percutaneous insertion of a temporary heart pump for LV hemodynamic support in high-risk PCIs and provide recommendations to the NHS on this procedure. Comparisons with any other procedures/ temporary percutaneous mechanical haemodynamic support devices to treat the same condition were potentially included.<br><br>IABP is one option for temporary percutaneous mechanical haemodynamic support and is used as a comparator in some studies.<br>IABP is not the intervention under assessment, therefore a comprehensive summary of the evidence on its efficacy and safety is not captured in the NICE assessment.<br><br>3 studies (Ho 2002, Curtis 2012, Fitzmaurice 2012) listed are all related to IABP only and therefore have not been included in this assessment of evidence.<br>One study (Lee JM 2015) listed is a systematic review and Bayesian network meta-analysis of RCTs comparing mechanical hemodynamic support devices (IABP [n=1410], pVAD [n=279]) versus medical therapy [n=1154] in high risk PCI populations. (pVADs included ECMO, Impella 2.5, TandemHeart). |

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| | | | 3) Ho et al. 2002. Stroke after Intraaortic Balloon Counterpulsation Associated with Mobile Atheroma in Thoracic Aorta Diagnosed Using Transesophageal Echocardiography. ttp://memo.cgu.edu.tw/cgmj/2509/250907.pdf<br>In the case report it highlights that for certain groups of patients (aged >65 or previous history of strokes) are at high risk of an IABP related embolism.<br>Highlights another adverse event associated with IABP, which hasn't been highlighted in the safety evidence, which seems to focus solely on evidence against the Impella device.<br><br>4) Fitzmaurice et al. 2012. Management of Intra-Aortic Balloon Pump Entrapment. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3461655/ .<br>Case report of an associated risk of a balloon rupture with an associated entrapment even though this risk is uncommon it is something that hasn't been mentioned in comparison to the Impella device. | This study has already been added to appendix in the overview. |
| 22 | Consultee 1<br>Specialist in Internal medicine Interventional Cardiology<br>Hamburg - Winterhude<br>Germany<br><br>Consultee 2<br>HCD Economics Ltd on behalf of ABIOMED Europe GmbH<br><br>Consultee 3<br>ABIOMED Europe GmbH | **3** | **Additional studies to consider**<br>It was noted that searches were completed to 29/01/2018, however since this date several other studies of high quality have emerged.<br>1. Shavelle et al. (2018) Comparison of Outcomes of Percutaneous Coronary Intervention on Native Coronary Arteries Versus on Saphenous Venous Aorta Coronary Conduits in Patients With Low Left Ventricular Ejection Fraction and Impella Device Implantation Achieved or Attempted (from the PROTECT II Randomized Trial and the cVAD Registry). AJC https://doi.org/10.1016/j.amjcard.2018.06.013.<br>2. Riley et al. (2018) Impella-assisted chronic total occlusion percutaneous coronary interventions: A multicenter retrospective analysis. Catheterization Cardiovascular Interventions. https://doi.org/10.1002/ccd.27679.<br>3. Shah et al. (2018) Hospital mortality and thirty day readmission among patients with non-acute myocardial infarction | Thank you all for your comments.<br>The Committee is grateful for this comprehensive list of additional papers suggested by the consultees.<br>With reference to the papers: some of the studies listed (Shavelle 2018, Shah 2018, Ogunbayo 2018,Karatolios 2018, Sieweke 2018 and Jensen 2018) have not been identified in our update searches as they are very recent publications. The team checked these papers and added Shavelle 2018 to table 2 and the remaining studies to appendix in the overview.<br><br>Some of the studies listed (Riley 2018, O'Neil 2018, Vetrovec 2018, Virk Hafeez |

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| | MedImbursement | | related cardiogenic shock. Int J Cardiol. https://10.1016/j.ijcard.2018.06.036.<br>4. O'Neill et al. (2018). Analysis of outcomes for 15,259 US patients with acute myocardial infarction cardiogenic shock (AMICS) supported with the Impella device. Am Heart J. https://10.1016/j.ahj.2018.03.024.<br>5. Vetrovec et al. (2018). The cVAD registry for percutaneous temporary hemodynamic support: A prospective registry of Impella mechanical circulatory support use in high-risk PCI, cardiogenic shock, and decompensated heart failure. Am Heart J. https://10.1016/j.ahj.2017.09.007.<br>6. Huh et al. (2018). Trends, etiologies, and predictors of 90-day readmission after percutaneous ventricular assist device implantation: A national population-based cohort study. Clin Cardiol https://10.1002/clc.22929.<br>7. Etiologies and predictors of 30-day readmissions in patients undergoing percutaneous mechanical circulatory support-assisted percutaneous coronary intervention in the United States: Insights from the Nationwide Readmissions Database. Clin Cardiol. https://10.1002/clc.22893<br>8. Ogunbayo GO et al. (2018). In-hospital outcomes of percutaneous ventricular assist devices versus intra-aortic balloon pumps in non-ischemia related cardiogenic shock. Heart Lung. https://10.1016/j.hrtlng.2018.02.002.<br>9. Karatolios et al. (2018) Impella support compared to medical treatment for post-cardiac arrest shock after out of hospital cardiac arrest. Resuscitation. https://10.1016/j.resuscitation.2018.03.008<br>10. Baumann et al. (2018) Indication and short-term clinical outcomes of high-risk percutaneous coronary intervention with microaxial Impella® pump: results from the German Impella® registry. Clin Res Cardiol. https://10.1007/s00392-018-1230-6.<br>11. Sieweke et al. (2018) Mortality in patients with cardiogenic shock treated with the Impella CP microaxial pump for isolated | Ul Hassan 2018, and Bavishi 2018) have been identified in our update searches and added to appendix in the overview.<br><br>Baumann 2018 has already been added to appendix in the overview. |

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| | | | left ventricular failure. Eur Heart J Acute Cardiovasc Care. https://10.1177/2048872618757393<br>12. Jensen et al. 2018. Single-centre experience with the Impella CP, 5.0 and RP in 109 consecutive patients with profound cardiogenic shock. Eur Heart J Acute Cardiovasc Care. https://10.1177/2048872617743194 .<br>Please consider our comments in the final version of the guideline. Furthermore feel free to contact me/ us for any further matters. | |
| 23 | Consultee 3<br>ABIOMED Europe GmbH<br>MedImbursement | **3** | We agree with most of the additional study suggestions presented by [redacted] HCD Economics; The Innovation Centre, Keckwick Lane, Daresbury, Cheshire, WA4 4FS). However, we would like to clearly differentiate by indication (protected PCI vs Impella being used in urgent Cardiogenic Shock).<br><br>**The following studies are related to the use of Impella in Protected PCI:**<br><br>- Shavelle et al. (2018) Comparison of Outcomes of Percutaneous Coronary Intervention on Native Coronary Arteries Versus on Saphenous Venous Aorta Coronary Conduits in Patients With Low Left Ventricular Ejection Fraction and Impella Device Implantation Achieved or Attempted (from the PROTECT II Randomized Trial and the cVAD Registry). AJC<br><br>- Riley et al. (2018) Impellaâ€• assisted chronic total occlusion percutaneous coronary interventions: A multicenter retrospective analysis. Catheterization Cardiovascular Interventions. https://doi.org/10.1002/ccd.27679<br><br>**The following studies are related to the use of Impella in Cardiogenic Shock**<br><br>- Shah et al. (2018) Hospital mortality and thirty day readmission among patients with non-acute myocardial infarction related cardiogenic shock. Int J Cardiol. | Thank you all for your comments.<br>The Committee is grateful for this comprehensive list of additional papers suggested.<br>IPAC considered your comment about the differentiation of indications (elective and emergency high-risk PCI including cardiogenic shock) and amended 3.5 (bullet point 1) as follows:<br>*'Evidence of benefit for patients with cardiogenic shock is limited. In the evidence reviewed, there were only a small number of patients with cardiogenic shock who could not have percutaneous coronary intervention and the outcomes of these patients are poor'.*<br><br>With reference to the papers: some of the studies listed (Shavelle 2018, Shah 2018, Ogunbayo 2018,Karatolios 2018, Sieweke 2018 and Jensen 2018) have not been identified in our update searches. The team checked these papers and added Shavelle 2018 to table |

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| | | | https://10.1016/j.ijcard.2018.06.036<br><br>- ONeill et al. (2018). Analysis of outcomes for 15,259 US patients with acute myocardial infarction cardiogenic shock (AMICS) supported with the Impella device. Am Heart J. https://10.1016/j.ahj.2018.03.024<br><br>- Ogunbayo GO et al. (2018). In-hospital outcomes of percutaneous ventricular assist devices versus intra-aortic balloon pumps in non-ischemia related cardiogenic shock. Heart Lung. https://10.1016/j.hrtlng.2018.02.002.<br><br>- Karatolios et al. (2018) Impella support compared to medical treatment for post-cardiac arrest shock after out of hospital cardiac arrest. Resuscitation. https://10.1016/j.resuscitation.2018.03.008<br><br>- Sieweke et al. (2018) Mortality in patients with cardiogenic shock treated with the Impella CP microaxial pump for isolated left ventricular failure. Eur Heart J Acute Cardiovasc Care. https://10.1177/2048872618757393<br><br>- Jensen et al. 2018. Single-centre experience with the Impella CP, 5.0 and RP in 109 consecutive patients with profound cardiogenic shock. Eur Heart J Acute Cardiovasc Care. https://10.1177/2048872617743194. | 2 and the remaining studies to appendix in the overview.<br><br>Some of the studies listed (Riley 2018, O'Neil 2018) have been identified in our update searches and added to appendix in the overview. |
| 24 | Consultee 3<br>ABIOMED Europe GmbH<br>MedImbursement | | In addition to all of the above, we would like to suggest additional 9 studies (comment 5-6):<br>1) Real-World Supported Unprotected Left Main Percutaneous Coronary Intervention With Impella Device; Data From the USpella Registry. Theodore Schreiber, Wah Wah Htun, Nimrod Blank,Tesfaye Telila, Nestor Mercado, Alexandros Briasoulis, Amir Kaki, Ashok Kondur. Ahmad Munir, MD, and Cindy Grines, MD. Catheterization and Cardiovascular Interventions 00:00â€“00 (2017)<br>Number of patients/follow-up: n=126 patients from single center data base within the USPella Registry. | Thank you all for your comments.<br>The Committee is grateful for this comprehensive list of additional papers suggested and the commentary provided.<br><br>With reference to the papers:<br>some of the studies listed (De Marzo 2018, Montone N 2018, Sanna T 2018, Pesarini G 2018) are reviews and |

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| | | | Direction of conclusions: This large single center retrospective evaluation substantiates and strongly supports the feasibility, safety and hemodynamic usefulness of Impella device for ULMI with acceptable inhospital and 30-day MACE rates (1.4% and 2.1% respectively).<br><br>ABIOMED comment: PCI on LM lesions is known to be associated with the potential for high risk conditions during the intervention. Especially in a population with additional comorbidities, the protection with Impella is leading to very low MACE rates.<br>This confirms the potential of Impella to protect interventions even in very high risk conditions.<br><br>2) High risk PCI: How to define it today?; De Marzo et al; Minerva Cardioangiol 2018.<br>Number of patients/follow-up: Review. No particular patent number addressed.<br>This review aims at describing, according to the most recent clinical and physio-pathological evidence the features of high-risk PCI focusing on different definition balancing benefits with morbidity and mortality outcomes.<br><br>Direction of conclusions: Growing number of high-risk complex PCI patients (new PCI population), prevalence of high-risk patients within the PCI population is expected to reach 20-24% (2019) treating these patients requires a dedicated highly skilled interdisciplinary team approach. The most critical patients often benefit most.<br>ABIOMED comment: The growing population of high-risk patients requires an adjustment of therapeutic options. Increasing complexity of procedures and therapeutic options is associated with the need for highly skilled interdisciplinary teams. An example of this effective option is the hemodynamic protection with Impella.<br><br>3) Percutaneous coronary intervention in patients refused from | therefore have been added to appendix in the overview.<br>Some studies listed have already been added to the overview (Ichou A, 2017 in table 2 and Verma S 2017 in appendix).<br>Two studies (small case series) listed (Alqarqaz M 2018, Russo G, 2018) have been identified in our update search and added to appendix in the overview.<br><br>One study (Schreiber T 2017- retrospective analysis) not been identified in our update search has been checked and added to appendix in the overview. |

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| | | | surgery: a different entity? Montone, Niccoli; Minerva Cardioangiol 2018.<br>Number of patients/follow-up: Review - no particular patient number addressed.<br>Looking at conditions for surgical ineligibility and the clinical outcome of PCI in these patients considering the evidence supporting the use of Impella in high risk patients ineligible for surgery.<br>Direction of conclusions: Patients ineligible for surgery represent a very high-risk population for any therapy. Existing clinical evidence derived from subgroups of PROTECT II suggest that a revascularization strategy using Impella to protect hemodynamics appear safe and feasible and may result in better outcomes.<br>ABIOMED comment: Patients ineligible for surgery but requiring revascularization are high risk candidates for any conventional therapy. Hemodynamic protection with Impella facilitates the PCI in these patients which provide a safe and effective treatment option.<br><br>4) Standardization of ImpellaÂ®-assisted patient management. Sanna T, Battistoni I, Marini M, Valente S. Minerva Cardioangiol. 2018 Mar 28.<br>Number of patients/follow-up: Review. No particular patent number addressed.<br>Direction of conclusions: Impella protected Procedures (IAPs) are safe and effective procedures that require managing a degree of complexity. Standardization of IAP related activities is expected to reduce intra operator variability, to increase safety and improve outcome.<br>ABIOMED comment: A proposal for the standardization of ordinary medical activities required outside the Cath-Lab for the management of patients before and after Impella-assisted procedures.<br><br>5) Impella-protected PCI: the clinical results achieved so far. Pesarini G, Gratta A, Dolci G, Lunardi M, Ribichini FL. Minerva Cardioangiol. 2018 Apr 11. | |

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| | | | Number of patients/follow-up: Review of the largest and most informative studies available.<br>PROTECT I - n=20<br>PROTECT II- N=452<br>ISAR Shock - n= 26<br>IMPRESS in STEMI - n=21<br>IMPRESS in severe shock - n=48<br>DanShock - enrolling<br>Direction of conclusions: Review on the achievements in Impella-protected PCI, mainly based on the existing RCT data.<br>ABIOMED comment: The hemodynamic performance of Impella protection have been proven superior compared to IABP in high risk settings. The available evidence includes RCTs, several observational studies and reports.<br><br>6) Effects of Impella on Coronary Perfusion in Patients With Critical Coronary Artery Stenosis; Alqarqaz M, Basir M, Alaswad K, O'Neill W. ; Circ Cardiovasc Interv. 2018 Apr;11(4):e005870.<br>Number of patients/follow-up: n=11<br>Direction of conclusions: Mechanical circulatory support with Impella can improve distal coronary pressure and coronary perfusion pressures in the presence of critical coronary stenosis.<br>ABIOMED comment: Single-center prospective cohort of 11 HRPCI treated with Impella. Impella may improve coronary hemodynamics in patients with critical coronary stenosis.<br><br>7) The effectiveness and safety of the Impella ventricular assist device for high-risk percutaneous coronary interventions: A systematic review. Ait Ichou J, LarivÃ©e N, Eisenberg MJ, Suissa K, Filion KB. Catheter Cardiovasc Interv. 2018 Jun;91(7):1250-1260. (Epublished in 2017)<br>Number of patients/follow-up: Systematic Review; 20 studies (4 RCTs, 2 controlled observational studies, and 14 uncontrolled observational studies); n=1,287 patients<br>Direction of conclusions: The Impella device was found to improve procedural and hemodynamic parameters, but only limited randomized data are available regarding clinical outcomes | |

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| | | | associated with its use.<br>ABIOMED comment: Systematic review of Impella in HR-PCI (included both emergent and elective setting).<br><br>8) Avoiding hemodynamic collapse during high-risk percutaneous coronary intervention: Advanced hemodynamics of impella support. Verma S, Burkhoff D, O'Neill WW Catheter Cardiovasc Interv. 2017 Mar 1;89(4):672-675<br>Number of patients/follow-up: 1 case report<br>Direction of conclusions: This case demonstrates an example where occlusion of the left main coronary artery during PCI balloon inflation results in rapid loss of arterial pressure. Additional insights into the underlying physiology of pMCS during HR-PCI presence of an Impella pMCS device, aortic pressure pulsatility also declines and eventually is completely lost, despite maintenance of a nearly normal mean arterial pressure value and almost no change in PAPs.<br>ABIOMED comment: Simulation of this case in a previously described and validated cardiovascular model [2,3] provides additional insights into the underlying physiology of pMCS during HR-PCI.<br><br>9) Hemodynamics and its predictors during Impella-protected PCI in high risk patients with reduced ejection fraction. Russo G, Burzotta F, D'Amario D, Ribichini F, Piccoli A, Paraggio L, Previ L, Pesarini G, Porto I, Leone AM, Niccoli G, Aurigemma C, Verdirosi D, Trani C, Crea F. Int J Cardiol. 2018 Jul 17. pii: S0167-5273(18)31934<br>Number of patients/follow-up: n=37<br>Direction of conclusions: In patients with reduced EF undergoing IMP-protected PCI, a significant pressure decrease occurs during PCI but pressure is systematically maintained at levels warranting vital organ perfusion. Critical pressure drops during PCI occur in some patients with higher jeopardized myocardium and left ventricular diastolic volumes.<br>ABIOMED comment: Protected PCI Key article from Gemelli, | |

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| | | | Roma, on the hemodynamic support by Impella during protected PCI. | |
| 25 | Consultee 3<br>ABIOMED Europe GmbH MedImbursement | **3** | After review of the entire list of studies/publications that were presented we would suggest to also consider the following studies from that list:<br><br>1) Basir MB, Schreiber T et al (2018). Feasibility of early mechanical circulatory support in acute myocardial infarction complicated by cardiogenic shock: The Detroit cardiogenic shock initiative. Catheterization and cardiovascular interventions: official journal of the Society for Cardiac Angiography & Interventions.<br>-This publication refers to the use of Impella in Cardiogenic Shock.<br>-The Detroit Cardiogenic Shock Initiative (CSI Detroit) is the first example of the prospective adoption of best practice recommendations derived from retrospective observations and leading to improved outcome.<br><br>2) Basir MB, Schreiber TL et al (2017). Effect of Early Initiation of Mechanical Circulatory Support on Survival in Cardiogenic Shock. Am J Cardiol;119:845e851.<br>-This publication refers to the use of Impella in Cardiogenic Shock.<br>- N=287.<br>-This is currently the largest published cohort describing the benefit of early (pre PCI) as compared with late (post PCI) initiation of Impella support in patients presenting with cardiogenic shock.<br><br>3) Dangas GD, Kini AS et al (2014). Impact of Hemodynamic Support With Impella 2.5 Versus Intra- Aortic Balloon Pump on Prognostically Important Clinical Outcomes in Patients Undergoing High-Risk Percutaneous Coronary Intervention (from the PROTECT II Randomized Trial)Am J Cardiol 2014;113:222e228.<br>-This publication refers to the use of Impella in Protected PCI.<br>-Sub study of PROTECT II study, re-examined the outcomes of | Thank you all for your comments.<br>The Committee is grateful for this comprehensive list of additional papers suggested.<br>With reference to the papers:<br>some studies listed (Basir 2018, Basir 2017, Dangas GD 2014, Goldstein 2017, Kovacic 2015, Pershad 2014) have already been added to appendix in the overview and reasons for this are provided. |

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| | | | PROTECT II using a prognostically relevant definition of myocardial infarction (MI) and broadened the strength of analyses by including multivariable testing for predictors of cardiovascular adverse events.<br><br>4) Goldstein JA, Dixon SR et al (2017). Maintenance of valvular integrity with Impella left heart support. Results from the multicenter PROECT II randomized study. Catheterization and Cardiovascular Interventions 1-5.<br>-This publication refers to the use of Impella in Protected PCI.<br>-During Impella support there was no appreciable change in the degree of baseline valvular regurgitation. There were no cases of structural derangement of the mitral or aortic valve after use of the Impella device. At 90-day follow-up, there was an average 22% relative increase in LVEF from baseline (27% Â± 9 vs. 33% Â± 11, P < 0.001).<br>-Addressing the complication described in the case report above.<br><br>5) Kovacic JC, Kini A et al (2015). Patients with 3-vessel coronary artery disease and impaired Ventricular Function Undergoing PCI with Impella 2.5 Hemodynamic Support Have of The PROTECT II Trial. J Interventional Cardiology 28:32-40.<br>-This publication refers to the use of Impella in Protected PCI.<br>-Subgroup study of PROECT II study- assessing in 3-vessel disease and reduced LVEF patients presenting the particular benefit of Impella Protection vs IABP in more complex procedures (multivessel intervention compared with single vessel PCI) with beneficial results related to the use of Impella.<br><br>6) Pershad A, Fraij G et al (2014). Comparison of the Use of Hemodynamic Support in Patients â€¡80 Years Versus Patients <80 Years During High-Risk Percutaneous Coronary Interventions (from the Multicenter PROTECT II Randomized Study Am J Cardiol;114:657-664.<br>-This publication refers to the use of Impella in Protected PCI.<br>-Comparative case series , N=427<br>-Outcomes were compared between patients >80 years (n=59) | |

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| | | | versus patients <80 (n=368) years enrolled in the PROTECT II trial (IABP versus Impella 2.5). Follow-up: 90 days<br>-Showing the benefit of protected PCI for patients >80Y, which is an important populations within the patients eligible for protected PCI and usually considered to be at higher risk compared with younger patients. | |
| 26 | Consultee 2<br>HCD Economics Ltd on behalf of ABIOMED Europe GmbH<br><br>Consultee 3<br>ABIOMED Europe GmbH<br>MedImbursement | **Specialist advice** | "General Comments:<br>The questionnaires are dated January 2016:<br>o Is it standard practice for the questionnaires to be done so far in advance? Or is this just an error with the date?<br>o Maybe an updated questionnaire would provide key insights after two years of physicians working with the medical device, gathering evidence and experience.<br><br>Selection of the specialist advisers:<br>o The questionnaire was only actually completed by 2 of the three specialist advisers and only 1 of these 2 had ever had experience using the device<br>o Therefore, we only have feedback from one physician that has performed procedures using the medical device.<br>o The two specialist advisors were both from the same institutions, when there are 11 institutions using the device that Abiomed had previously provided.<br>o From the quality of feedback on the medical device between the two questionnaire respondents, one has more knowledge of the device (likely down to experience)<br>o The clinical experience of Cardiothoracic Surgeons, Interventional Cardiologists, and Heart Failure Specialists who frequently use the technology to treat high-risk patients in their centres is critical in evaluating the true benefit for this patient group and the safety and efficacy profiles.<br>o There is clearly a case to find one or two more specialist advisers to fill out the questionnaire that have had experience | Thank you for your comments.<br>Specialist adviser questionnaires were done in advance (November to December 2017) for IPAC meeting in May 2018. So the IP team considers it as an administrative error and does not think that an updated questionnaire is needed. This administrative error has been corrected on the documents.<br><br>With regard to selection of specialist advisers, NICE IPAC seeks advice of at least 2 advisers who are nominated or ratified by their professional organisations to complement findings from published evidence. IPAC also seeks advice from those who have and have not done the procedure. Please see section 6.7 in the interventional procedures programme manual for further information. **https://www.nice.org.uk/process/pmg28/chapter/teams-involved-in-developing-interventional-procedures-guidance#specialist-advisers**<br>In this instance, advice was sought from 3 specialists of which 1 have and 2 have not done the procedure (one of these have not completed the questionnaire). |

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| | | | with the medical device and can provide clear and first-hand information on safety and efficacy<br><br>Specialist Adviser 1:<br>• Highlights there is a learning curve to use of the device, this has been shown in the PROTECT II study to significantly impact outcomes when adjusted for<br>• Not just for the physician undertaking the procedure but also for the supportive team<br>• Suggests using the medical device on patients in cardiogenic shock rather than starting with high risk PCI cases as it will allow more time for training<br>• Highlights this procedure will only have a minor impact on the NHS in terms of resources used<br>• States PCI is generally withheld from high risk patients who would get the greatest benefit<br>• In his experienced opinion of using the device states the Impella device makes the procedure safer and more feasible with high risk patients<br><br>Specialist Adviser 2:<br>This specialist adviser has never actually performed the procedure he is advising on and has only done bibliographic research on it<br>• From his research he mentions that the device is FDA approved and there is substantial body of evidence to support that it is safe and efficacious for carefully selected patients<br><br>Specialist Adviser 3:<br>• Didn't complete the questionnaire because the procedure is not relevant to his speciality | All of them have been nominated/ratified by their professional bodies.<br><br>IPAC thinks that specialist advice has been sought in accordance with IP programme methods and process as described above and the judgement of the committee is based on both the published evidence and expert opinion.<br><br>IPAC considered your comment and removed the advice from specialist adviser 3 from the overview. |

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| | | | Questions the relevance of this individual as a specialist adviser for this medical device " | |
| 27 | Consultee 6<br>International Center for Cardiovascular Interventions (ICCI)<br>Heart Centre Bonn<br>Medical Clinic and Polyclinic II<br>University Hospital Bonn<br>Germany | **General** | With reference to the IP 1546, Percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions I appreciate the opportunity to comment on the current recommendation and on this comprehensive summary and would like to share some observations and suggestions.<br><br>The term “high risk PCI” may likely lead to confusion between two significantly different indications for the use of pMCS:<br><br>- “protected PCI” defines a short term hemodynamic support during coronary intervention in complex anatomies with depressed LV function and<br><br>- therapeutic use in cardiogenic shock where ventricular unloading is the primary goal.<br><br>I think it is important to clearly differentiate between these two indications regarding patient selection and patient management. However, in general it was found to be important that the interdisciplinary collaboration including interventional cardiologist, cardiovascular surgery and intensive care as well and a dedicated algorithm to define patient selection and patient management in the different conditions (elective, urgent vs emergent) is well establish in order to optimize outcome.<br><br>Due to these reasons a German Working Group has been established to review and describe the respective details in regards to protected PCI. A German expert consensus (German language; Expertenkonsensus zum praktischen Einsatz von Herzkreislaufunterstützungssystemen bei Hochrisiko-Koronarinterventionen; N.Werner, I. Akin, F. Al-Rashid, T. Bauer, K. Ibrahim, K. Karatolios, F. Mellert, A. Schäfer, J.-M. Sinning, G. S Werner, R. Westenfeld, D.Westermann , A. Elsässer; Der | Thank you for your comments.<br>IPAC considered your comment on the use of the phrase ‘high risk PCI’ and agrees that the term is widely used and likely to lead to confusion between the different indications for the use of temporary percutaneous mechanical haemodynamic support devices.<br>In section 1.5 of the guidance the committee recommended that ‘further research should report details of patient selection and subsequent management’ in different conditions. |

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| | | | Kardiologe 2017) has been the current result and it is planned to extend a respective collaboration throughout Europe.<br><br>In parallel to the German Working Group, a European Working Group is addressing a harmonized consensus for the use of MCS in the setting of cardiogenic shock.<br><br>**In conclusion:** Considering two main indications (hemodynamic stabilization in the setting of “Protected PCI”) and therapy as well as recovery in case of cardiogenic shock it is recommended to address these separately in terms of patient selection, patient management, and expected outcome. In general efficient interdisciplinary collaboration (Heart Team including Intensive Care) and standardized procedures are required to establish best practices and to ensure best possible outcomes. | It is outside the remit of the IP Programme to make recommendations about specific patient selection criteria, patient management and expected outcomes for an intervention. |
| 28 | Consultee 9<br>NHS Professional | **General** | "We have adopted Impella here at the BHI and have used in cases to support elective and semi-elective complex high risk PCI. We have examples of cases where appropriate and life-transforming intervention would not have been performed if access to impella was not available due to the high jeopardy of the procedure. We are using Impella CP. The interventional community is taking on higher risk cases who have been declined revascularization by surgical colleagues. We need the tools to support this work." | Thank you for your comment.<br>The Committee is pleased to receive your views and notes your experience of it. |

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*