NICE National Institute for Health and Care Excellence

IP2042 Percutaneous insertion of a catheter-based intravascular microaxial flow pump for cardiogenic shock

IPAC date: 22/01/2026

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1.	Consultee 1 Newcastle upon Tyne Hospitals Foundation Trust	1.1	No comments but I agree with the recommendations	Thank you for your comment. Consultee agrees with main recommendation.
2.	Consultee 5 British Cardiovascular Intervention Society (BCIS)	1.1	The British Cardiovascular Intervention Society supports the recommendation.	Thank you for your comment. Consultee agrees with main recommendation.
3.	Consultee 13	1.1 Why the committee made this recommendation	I think this is a fair recommendation - but would add that it would be helpful to ensure that every patient who receives such a device should either be in a RCT and/or registry/database to ensure there is data to drive change	Thank you for your comment. The guidance recommends that further evidence should be generated but does not stipulate that this needs to be in the form of randomised controlled trials.
4.	Consultee 7	Not reported	The DANGERSHOCK trial offers high quality RCT data that Impella is an effective therapy that reduces mortality	Thank you for your comment. The committee discussed if the recommendation should be more

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			within a clearly defined cohort of shocked patients following myocardial infarction. Whilst it is fair to say that more data is required to support the use of Impella in undifferentiated cardiogenic shock, the Dangershock trial is quite clear on their inclusion criteria and the survival benefit for that particular cohort. Following that DANGERSHOCK trial, it will be ethically challenging to repeat that study, as there is no longer equipoise on on the therapy in shock after MI. The available data would suggest the following recommendations: 1. There is good RCT data to support the use of Impella to improve survival in appropriately selected patients with cardiogenic shock with MI. 2. There is inconclusive data to support the use of Impella in undifferentiated cardiogenic shock outside of MI, further evidence generation is required in this area of cardiogenic shock.	permissive for the subgroup of people who meet the criteria of the DanGer Shock trial. They noted that the trial used specific and extensive inclusion criteria, which would be difficult to implement in practice. They concluded that more evidence is needed to know if the observed benefit will apply in a broader population.

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5.	Consultee 3	Not specified	The document recognises the high quality data from the Danger Shock trial. It is unlikely further data will become available for this patient group and consideration should be given to supporting the use of the device in patients fitting the study entry criteria.	Thank you for your comment. Please see response to comment number 4.
6.	Consultee 8	Not reported	Due to inconsistent provision of care, inpatient mortality and morbidity associated with Cardiogenic shock remains high in the UK patients. In contrast, the current target of survival to discharge in the same cohort of patients in US is as high as 75%. Along-with shock team based care, US has achieved this by following evidence produced by DanGer Shock trial. Use of percutaneous mechanical support in Cardiogenic shock is endorsed by up-gradation of both European Society of Cardiology (ESC) and American College of Cardiology guidelines to Class IIA whereas Intra-aortic balloon pump has been downgraded to Class III. I have observed that this NICE guideline has looked at the heterogenous group of patients presenting with Cardiogenic shock with similar lense, despite clear benefits seen in a subset of patients with cardiogenic shock in the DanGer Shock trial. There is also now outcomes data available for the 10-year follow-up for this trial which was not included in the guidance. This	Thank you for your comment. The 10-year follow-up data has been published in a letter to the editor and has been added to the key evidence. Cost-effectiveness is not within the remit of IP guidance, so studies on cost-effectiveness are not included in the overview. Please see response to comment number 4.

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			longterm data further highlights the impact of treatment with Impella had on this patient population. Two observational studies (Padberg et al., 2024, Movahed et al., 2024) cited in NICE documentation may be misleading due to confounding indications, as they rely on claims data lacking shock severity. Additionally, several key publications related to long-term outcomes and cost effectiveness of Impella have been omitted in the production of this guidance document. In my opinion, NICE has the responsibility to produce a guidance which should support use of Impella in the subset of patients who meet eligiblilty criteria for the DanGer shock trial due to clear benefits seen in this subgroup of patients in a robust trial. This will also fulfil the NICE threshold for cost/QALY as shown in cost effectiveness studies from French and US population. Similar precedence of guidance to treat a a specific subset of patients is there across various other NICE guidelines. I fear that if left unchanged, this NICE guidance would remain misaligned with European and International guidelines. Effectively, the new IPG would already be outdated and ultimately UK population will	

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			continue to be deprived of this potentially life saving treatment.	
7.	Consultee 9	1.1	My view is that there should be two indications here. For patients with AMI-CS, who meet DANGER-SHOCK criteria (preserved RV function and favourable for good neurological outcome), routine use should be permitted. This is because it only the second RCT-proven therapy for AMI-CS, after revascularisation in the SHOCK trial 25 years ago. And the benefit in the RCT is a reduction in all-cause mortality with a favourable NNT. For all other indications, special arrangements for consent and auditing are appropriate. However, it is worth noting that enhanced informed consent is very rarely possible in patients with cardiogenic shock, given the emergent nature of the presentation. This leaves the only significant difference being a requirement for enhanced audit. Overall, I am pessimistic that there will be more impactful evidence generated than the DANGER-SHOCK results (see further comments below) and therefore feel that this should guide decisions at present.	Thank you for your comment. Please see response to comment number 4.
8.	Consultee 12	Not specified	Please note 3 points:	Thank you for your comment.

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			1) DanGer phenotype. DanGer patients represent a distinct, high-risk phenotype with robust evidence supporting Impella use. The DanGer Shock RCT demonstrated a 12.7% absolute and 26% relative reduction in mortality at 180 days in patients with STEMI-related cardiogenic shock treated with Impella CP, compared to conventional therapy, with a Number Needed to Treat (NNT) of 8. Long-term data recently published confirmed the survival benefit at 10 years (30% relative reduction in mortality and approximately 600 additional days alive per patient), despite early concerns about statistical fragility. The trial's impact led to the early termination of the J&J RECOVER IV study, as it was deemed unethical to withhold Impella therapy due to the survival benefit seen in DanGer. Moreover, International guidelines have been upgrading percutaneous mAFP (Impella) to Class I and Class IIa, prioritising survival despite increased adverse events such as bleeding, while other device classes (e.g. IABP and VA-ECMO) are being downgraded in Europe and the US to class III	The validity and generalisability section of the overview states 'Registry studies use data that has been collected for other purposes and may not include baseline characteristics such as the degree of cardiogenic shock.' The 10-year follow-up data has been published as a letter to the editor and is included in the post consultation literature table (Møller, 2025), to be added to the key evidence. Freer (2025) was identified in the update search and has been added to the key evidence. Terauchi (2025) was identified in the update search and is included in the post consultation literature table. It has not been prioritised but will be added to table 5 because the key evidence already includes a larger study from the same registry. Thiele (2024) is included in the key evidence.

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			If left unchanged, the NICE IPG would remain misaligned with European and International guidelines. Effectively, the new IPG would already be outdated. Two observational studies (Padberg et al., 2024, Movahed et al., 2024) cited in NICE documentation may be misleading due to confounding by indication, as they rely on claims data lacking shock severity. Additionally, several key publications related to long-term outcomes and cost effectiveness have been omitted. (Attached a list of supporting evidence not considered by NICE in point 2). 2) Some missing publications, misinterpretations and misuse of identified data. Several key publications supporting the clinical and economic value of Impella are missing from the current NICE documentation. These include the DanGer Long term outcomes study (Møller et al., 2025) showing a sustained 30% mortality reduction at 10 years, and a network meta-analysis (Freer et al., 2025) confirming long-term survival benefits using only RCT data.	The 2025 ACC/AHA guidelines are included in the 'Existing assessments' section of the overview. Cost-effectiveness is not within the remit of IP guidance, so economic studies are not included in the overview. Please see response to comment number 4.

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			Additional evidence from the Japanese registry (Terauchi et al., 2025) highlights improved outcomes in non-ACS cardiogenic shock, especially myocarditis. Meta-analyses by Thiele et al., 2024 confirm that unloading devices like Impella offer survival benefits in selected STEMI shock patients, unlike VA-ECMO. Recent international guidelines (JCS, EACTS/STS/AATS) and the French HAS appraisal also support Impella use. 3) The 2025 ACC/AHA guidelines upgraded Impella to Class IIa, while downgrading IABP and VA-ECMO to Class III. Meta-analyses show early Impella use before revascularisation improves short- and long-term survival. Its adaptability supports integration into regional shock networks, making it a practical and impactful solution for wider UK implementation.	
9.	Consultee 10	Not specified	Impella CP is the first device to show meaningful clinical benefit in patients presenting with cardiogenic shock secondary to acute myocardial infarction. Previous data on IABP and ECMO have failed to show similar outcomes. The number needed to treat is very small and as low as 1 in 4 for young patients. Whilst this device is	Thank you for your comment. Please see response to comment number 4.

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			associated with increased complication rate, it is important to highlight that refining its use should be the way forward. Importantly, the benefits in mortality was evident despite these complications. The long term outcome data from DanGer shock supports its use in patients that meet criteria for the study. Routine use should not be advocated given the bleeding and vascular complication rate.	
10	Consultee 15 Company JnJ Heart Recovery	Not specified	We welcome NICE's draft guidance and the opportunity to contribute to this important evaluation. While we acknowledge the committee's concerns about remaining uncertainties across the broader cardiogenic shock (CS) population, we believe that the evidence for a specific and well-defined subgroup — the "DanGer" phenotype (derived from the inclusion criteria of the DanGer SHOCK RCT: patients with STEMI-related cardiogenic shock without out-of-hospital cardiac arrest and with Glasgow Coma Scale < 8) — warrants a stronger recommendation. In this subgroup, robust randomised data demonstrate a consistent survival benefit with Impella CP™, confirmed in long-term follow-up (Møller JE et al. Long-Term Outcomes of the DanGer Shock Trial. N Engl J Med. 2025 Sep	Thank you for your comment. Murugiah (2025) was not identified in the search. It will not be included in the overview because it is a commentary and not suitable for inclusion as per the Interventional procedures programme manual. Please see response to comment number 4.

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			11;393(10):1037-1038). We therefore propose that NICE should consider normal arrangements for Impella™ in this subgroup, whilst allowing the use together with continuing evidence generation in other contexts. Cardiogenic shock (CS) is a life-threatening condition, presenting in multiple distinct phenotypes. This draft guidance outlines the varied clinical pathologies that can lead to the syndrome, with cardiogenic shock following acute myocardial infarction (AMI-CS) being the better studied in relation to Impella™ use. The technical team has performed admirably in capturing the variety within CS. Specifically for AMI-CS, several recent clinical guideline updates — particularly from the United States, but European recommendations will also follow shortly (e.g. an update of the Austrian-German S3 guideline nearing its publication) — have increasingly upgraded the strength of recommendations for Impella™ use, especially in AMI-CS, while downgrading to Class III other mechanical circulatory support (MCS) devices such as VA-ECMO and intra-aortic balloon pump (IABP). A concise and up-to-date overview of this shift is provided in Murugiah K, McDonagh T, Cohen D, et al. 2025 (Mechanical Circulatory Support in Acute	

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			Myocardial Infarction–Cardiogenic Shock: 2025 Acute Coronary Syndrome Guideline in Context. JACC. 2025 Jun;85(22):2103–2106). J&J believes European guidelines will follow, in line with their fixed update schedule.	
11	Consultee 15 Company JnJ Heart Recovery	1.1	J&J welcomes the endorsement of this procedure for use in the NHS as an option for the management of cardiogenic shock. The independent, investigator-initiated pivotal RCT DanGer SHOCK (Møller et al., 2024) showed a significant absolute reduction in all-cause mortality at 180 days (12.7%) in patients with STEMI-related cardiogenic shock treated with Impella CP, compared with conventional therapy. The relative reduction in mortality was 26% (HR 0.74; p = 0.04), and the Number Needed to Treat (NNT) to prevent one death at 180 days was 8. Despite initial concerns about robustness and fragility — the upper bound of the 95% CI reached 0.99, meaning relatively small differences in patient outcomes could	Thank you for your comment. The 10-year follow-up data has been published as a letter to the editor and has been added to the key evidence (Møller, 2025). Rao (2025) is included in the existing assessments section of the overview. Murugiah (2025) is a commentary paper and is not included in the overview. Sørensen et al. is a conference presentation and is not included in the overview. Zweck (2024) was identified in the literature search but was not prioritised as key evidence. It is included in table 5 of the overview.

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			potentially shift the results toward neutrality — longer-term results published in August 2025 (Møller et al., 2025) confirmed the survival benefit. This follow-up showed a 30% relative reduction in mortality and around 600 extra days alive per patient in the restricted mean survival time analysis at 10 years. Issues raised regarding the “As-Treated” 6-month results, which did not reach statistical significance in the original publication, were addressed in an analysis presented in the Supplementary Appendix of the 10-year follow-up paper. Here, the “As-Treated” group achieved HR 0.72 (95% CI 0.54–0.94), equating to p = 0.02, a statistically significant result. DanGer SHOCK patients represent a substantial, well-defined phenotype within the cardiogenic shock population. While variation in aetiology often complicates safety and efficacy conclusions across sub-types, for patients developing cardiogenic shock due to STEMI — without out-of-hospital cardiac arrest and with Glasgow Coma Scale < 8 — the risk-benefit evidence appears conclusive.	Please see response to comment number 4.

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			Our own J&J study in AMI-CS, RECOVER IV (NCT05506449), has been permanently discontinued following the positive results from DanGer SHOCK. The trial's independent Data Safety and Monitoring Board (DSMB) recommended discontinuation, as it was deemed unethical to potentially deny patients Impella by randomising them to the non-Impella™ arm. National principal investigators, the study chair, and the U.S. FDA agreed (see further details via TCTMD: https://www.tctmd.com/news/recover-iv-impella-trial-halted-wake-danger-shock). Consequently, no further RCTs in this phenotype are planned without Impella as integral part of control arm therapy, nor are we aware of any forthcoming (noting ULYSS NCT05366452 covers a wider cohort and is substantially delayed). In response to DanGer SHOCK results, international guidelines have upgraded percutaneous micro-axial flow pump (Impella™) use to Class I I and Class IIa, while for the first time differentiating between device classes (Rao SV et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College	

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			of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2025 Jun 10;85(22):2135-2237. Erratum in: J Am Coll Cardiol. 2025 May 13;85(18):1800). Other devices, notably IABP and VA-ECMO, have been downgraded to Class III, in part due to DanGer SHOCK, and in part due to their inability to produce positive trials of their own (IABP-SHOCK II and ECLS-SHOCK remaining neutral even with extended follow-up). The positive view of Impella™ holds despite higher adverse events — particularly bleeding — because survival gains are seen to outweigh these risks. As mentioned, a concise and up to date overview of this shift is provided in Murugiah K, McDonagh T, Cohen D, et al. (Murugiah K et al. Mechanical Circulatory Support in Acute Myocardial Infarction–Cardiogenic Shock: 2025 Acute Coronary Syndrome Guideline in Context. JACC. 2025 Jun;85(22):2103–2106). Regarding bleeding, post-hoc DanGer SHOCK analysis found no difference in all-cause mortality between patients with major bleeds (BARC 3–5) and those without or with minor bleeds (HR 0.96; 95% CI 0.67–1.39; p = 0.86). Few events occurred in the	

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			catheterisation laboratory (2.7%); more than half (50.3%) occurred after device removal (Sørensen R et al. Bleedings related to use of micro-axial flow pump in Cardiogenic Shock: A Secondary Analysis of the DanGer SHOCK Trial. Available On-Line at: https://www.tctmd.com/slide/tct-265-bleedings-related-use-microaxial-flow-pump-cardiogenic-shock-secondary-analysis). On renal injury, DanGer investigators reported all cases were self-resolving by six months (Zweck & Møller, 2025). Applicability across healthcare systems was also addressed; time from symptom onset to randomisation did not differ significantly between sites, and Denmark's cohort included sicker patients than Germany or the UK. Adjusted hazard ratios for Germany and the UK compared with Denmark were 1.06 (95% CI 0.76–1.49), indicating consistent results across regions. This was mentioned in the response to several "Letters to the Editor" received by NEJM and addressed by Jacob Møller personally (Møller JE, Hassager C; DanGer Shock Investigators. Microaxial Flow Pump in Infarct-Related Cardiogenic Shock. Reply. N Engl J Med. 2024 Jun 27;390(24):2328-2330).	

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			Therefore, J&J believes that, notwithstanding the uncertainties surrounding other phenotypes of cardiogenic shock, there is a well-defined subpopulation of patients presenting with AMI-CS for whom the evidence supports a higher level of patient access than is offered by the current recommendation.	
12	Consultee 16	1.1	I think this is truly misleading the cardiologists of the UK. Based on the SHOCK trial from 1999 we are all performing primary PCI on all acute MI patients presenting with cardiogenic shock. That trial back then did not meet its primary endpoint and only showed survival benefit at 6 months (12.8% reduction in absolute mortality), equaling a NNT of 8. The DANGER shock trial had exactly the same NNT and same reduction in absolute mortality at 6 months (12.7%). In the subanalyses of DANGER, it was shown that if this device was used in patients under 77 years of age the NNT is 5. (Klein A, Beske RP, Hassager C, Jensen LO, Eiskjær H, Mangner N, Linke A, Polzin A, Schulze PC, Skurk C, Nordbeck P, Clemmensen P, Panoulas V, Zimmer S,	Thank you for your comment. The key evidence was considered for this procedure in its own right and not in comparison to evidence for other interventions. Klein (2025) is included in table 5 of the overview. It was not prioritised for inclusion in the key evidence because it is a secondary analysis of a trial that is already included (DanGer Shock). Møller (2025) has been added to the key evidence. Thiele (2024) is included in the key evidence.

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			Schäfer A, Werner N, Engstøm T, Holmvang L, Junker A, Schmidt H, Terkelsen CJ, Møller JE; DanGer Shock Investigators. Treating Older Patients in Cardiogenic Shock With a Microaxial Flow Pump: Is it DANGERous? J Am Coll Cardiol. 2025 Feb 18;85(6):595-603. doi: 10.1016/j.jacc.2024.11.003. Epub 2024 Nov 15. PMID: 39551167.) That is a huge reduction of mortality in working people. Furthermore the long term data of DANGER shock have been presented in the ESC showing ongoing survival benefit and further widening of the KM curves up to 10 years (Møller JE, Beske RP, Engstrøm T, Jensen LO, Eiskjær H, Mangner N, Polzin A, Schulze PC, Skurk C, Nordbeck P, Clemmensen P, Panoulas V, Zimmer S, Schäfer A, Werner N, Frydland M, Holmvang L, Kjærgaard J, Sørensen R, Lønborg J, Lindholm MG, Udesen NLJ, Junker A, Schmidt H, Terkelsen CJ, Christensen S, Christiansen EH, Linke A, Woitek FJ, Westenfeld R, Moebius-Winkler S, Wachtell K, Ravn HB, Lassen JF, Boesgaard S, Gerke O, Hassager C; DanGer Shock Investigators; DanShock Investigators. Long-Term Outcomes of the DanGer Shock Trial. N Engl J Med. 2025 Sep 11;393(10):1037-1038. doi: 10.1056/NEJMc2508284. Epub 2025 Aug 31. PMID: 40888722.)	Please see response to comment number 4.

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			In my opinion there is no question that this approach saves lives. I agree there should be best practices implemented for centres who want to be shock centres. However, it cannot be stated that there are uncertainties around safety and efficacy of a procedure with a NNT of 5 despite the associated complications. What NICE could recommend is the need for appropriate discussion for shock networks that can be established between centres (hub and spoke models). It should be added that the benefit of MCS in non comatose STEMI patients was also shown in a recent meta-analysis of randomised controlled trials. (Thiele H, Møller JE, Henriques JPS, Bogerd M, Seyfarth M, Burkhoff D, Ostadal P, Rokyta R, Belohlavek J, Massberg S, Flather M, Hochadel M, Schneider S, Desch S, Freund A, Eiskjær H, Mangner N, Pöss J, Polzin A, Schulze PC, Skurk C, Zeymer U, Hassager C; MCS Collaborator Scientific Group. Temporary mechanical circulatory support in infarct-related cardiogenic shock: an individual patient data meta-analysis of randomised trials with 6-month follow-up. Lancet. 2024 Sep 14;404(10457):1019-1028. doi: 10.1016/S0140-6736(24)01448-X. Epub 2024 Sep 2.	

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			Erratum in: Lancet. 2024 Sep 28;404(10459):1198. doi: 10.1016/S0140-6736(24)02088-9. PMID: 39236726.) In summary I would agree that more evidence generation is needed in the cardiogenic shock patients that do not have "DANGER shock" like criteria. But for those STEMI patients presenting exactly with DANGER like picture, we are doing them a disservice if we do not offer them a MAFP. Of course DANGER SHOCK was not just a trial of a device vs no device. It was a protocolled approach versus current standard of care. And teams in the UK need to get up to speed with protocolled care and not only learn how to insert a percutaneous MAFP. Furthermore there are several US national database registries that lack granularity (eg echo, or lactate data) and therefore are by no means informative and are prone to significant selection bias. In my view the recommendation should change to "recommend MAFP in non comatose STEMI patients in cardiogenic shock defined as (SBP<100, LVEF<45% and lactate >=2.5) without significant RV impairment or	

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			AMI complications (VSD, mitral valve rupture, free wall rupture). In all other cardiogenic shock cases the device should be used as per current draft NICE recommendation were more data should be collected to guide practice.	
13	Consultee 17	Not specified	Patients who present with ST elevation myocardial infarction complicated by cardiogenic shock continue to experience extremely poor outcomes, and there remain only two therapeutic strategies with demonstrable survival benefit. The long established primary percutaneous coronary intervention pathway has substantially improved access to emergency coronary intervention for our population, although important inequities in access persist. The Impella device represents the first substantive advance in supportive therapy for this cohort in decades and has shown a meaningful improvement in survival. While additional randomised controlled trials would be welcome and consistent with good clinical governance, the reality is that this patient group faces exceptionally high mortality and has no other evidence based therapeutic alternatives. When centres apply the selection criteria used in the existing trials this device	Thank you for your comment. The 10-year follow-up data has been published as a letter to the editor and has been added to the key evidence. Please see response to comment number 4.

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			should be made available as part of routine care for those patients within the National Health Service. The current recommendation, however, would continue to restrict access largely to teaching hospitals and research centres. This would undermine equitable provision of care and limit the ability of the wider population to benefit from this intervention. This restricted approach is also not aligned with international professional society guidance and the current review did not include recently published long term outcome data showing sustained benefit. A national approach that does not take these developments into account risks placing patients in the United Kingdom at a disadvantage compared with those in other healthcare systems.	
14	Consultee 14	Not specified	I am an interventional cardiology consultant at St George's Hospital, London. I am also the lead for Governance and the cardiology lead for the acute shock service. Following the results of the DANGER-SHOCK trial, including the NNT=5 to save a life for patients aged <78 years included in the trial, we have integrated the use of IMPELLA CP in patients presenting with AMI-CS as per the trial criteria. I firmly believe the device saves	Thank you for your comment. Please see response to comment number 4.

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			lives and should be made available to all hospitals with the necessary infrastructure. My key message(s) are that deployment of the device needs to be in line with trial evidence and as part of a wider local or regional shock service. Patient selection, early deployment, and post-deployment care are essential to realise the full benefit of this device. When these criteria are met, the benefits, at least in my experience, save lives and absolutely justify the upfront cost.	
15	Consultee 2	1.1	1) There is now substantial evidence supporting mechanical circulatory support in cardiogenic shock. The DANGER-Shock trial is the first positive randomized trial ever conducted in cardiogenic shock using mechanical support, and it should be highlighted. It demonstrated a 12.7% absolute survival benefit in patients with acute myocardial-infarction–induced cardiogenic shock compared with standard care. This is highly significant and corresponds to a number needed to treat (NNT) of 8, and even as low as 5 in younger subpopulations. International guidelines have accordingly upgraded percutaneous micro-axial flow pumps (Impella) to Class I or Class IIa, prioritising survival despite a known increase in adverse events such as bleeding. In contrast, other device classes such as IABP and VA-ECMO have	Thank you for your comment. The 10-year follow-up data has been published as a letter to the editor and has been added to the key evidence. The 2025 ACC/AHA guidelines are included in the existing assessments section of the overview. Please see response to comment number 4.

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			been downgraded to Class III in both Europe and the US. The recently published 10-year follow-up of the DANGER-Shock trial should also be taken into account: the survival benefit is sustained, with a 30% mortality reduction at 10 years. 2) The 2025 ACC/AHA guidelines have further upgraded Impella to Class IIa, while downgrading IABP and VA-ECMO to Class III.	
16	Consultee 9	What evidence generation is needed	The issue here is with the likelihood of the generation of further data. As identified by the committee, there is only one ongoing RCT of mAFP use in cardiogenic shock (ULYSS). This trial is smaller than DANGER-SHOCK, and represents a less selective patient population about the population of patients (from the perspective of neurological injury, right ventricular function and acuity of AMI presentation). Given the size and design, it is at significantly higher risk of type 2 error than DANGER-SHOCK, which will remain the most robust evidence available even once ULYSS is published. Though all observational data is confounded, cardiogenic shock is a uniquely difficult population for this issue. Consequently, I believe the the committee has	Thank you for your comment. Consultee notes that it is unlikely that further evidence will be generated that is as robust as the DanGer Shock trial. The guidance recommends that further evidence should be generated but does not stipulate that this needs to be in the form of randomised controlled trials.

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			given insufficient weight to the only high-quality RCT evidence available to us, particularly in including meta-analyses of incorporating other devices and aetiologies of shock.	
17	Consultee 9	3.8 Committee comments	As previous, only one of the ongoing studies studies is a randomised trial, and that is less robust than DANGER-SHOCK. I do not believe that the current review given sufficient weight to the quality of RCT evidence over highly confounded observational studies. Therefore I do not believe that the evidence base will be meaningfully progressed from the current situation.	Thank you for your comment. The guidance recommends that further evidence should be generated but does not stipulate that this needs to be in the form of randomised controlled trials.
18	Consultee 6	Overview – validity and generalisability	The unblinded design is noted, and we agree that this may introduce bias. However, the outcomes observed in the DanGer Shock control group closely mirror those reported for control populations in other MCS studies involving non-resuscitated cardiogenic shock patients (JACC Cardiovasc Interv. 2025;18:818–819). Further patients in both groups were treated according to prespecified treatment protocol to align ICU management. These issues were also discussed in N Engl J Med. 2024 Jun 27;390(24):2328-2330. doi: 10.1056/NEJMc2406255.	Thank you for your comment.

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19	Consultee 2	1.1	While Impella management in the ICU requires specialised, centralised expertise, the implantation procedure itself is relatively straightforward, and—as noted—can be life-saving. Therefore, implantation should be widely accessible in all catheterisation centres (again, every second counts), with subsequent management and follow-up organised through a hub-and-spoke model. A robust and appropriate bleeding-management protocol is essential. This significantly reduces complications and improves outcomes. This point is crucial.	Thank you for your comment. The wording about who does the procedure has been changed to 'This procedure should only be done in primary percutaneous coronary intervention centres with on-site intensive care expertise and by healthcare professionals with specific training in this procedure'.
20	Consultee 4	1.1	We agree with this in principle but the MDT need to be better defined as do the criteria for a centre specialing in cardiogenic shock.	Thank you for your comment. The wording about who does the procedure has been changed to 'This procedure should only be done in primary percutaneous coronary intervention centres with on-site intensive care expertise and by healthcare professionals with specific training in this procedure'.
21	Consultee 15 Company	3.2 Current practice	Finally, J&J would like to react to some clinical respondents suggesting few UK centres would use this technology. While that may be true for certain CS phenotypes, Impella CP™ with SmartAssist™ is not	Thank you for your comment. Panuccio (2022) is included in the key evidence.

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	JnJ Heart Recovery		solely for transplant or tertiary centres; it is scalable, suitable for a wide range of interventional cardiology units including heart attack PCI centres. This allows broader geographic access and integration into coordinated care networks, such as shock teams, without extra infrastructure. Several meta-analyses support the use of Impella before revascularisation. For example, Iannaccone et al., 2022, Panuccio et al., 2022 show early use is associated with improved mortality at short- and longer-term follow-up. Restricting access to solely transplant centers, given the acuity of the condition, may lead to severe equity of access concerns, and could be ill-advised. With Impella CP™ with SmartAssist™ able to be implemented in PCI-capable centres without needing further facilities, following appropriate training, J&J believes this accessibility and adaptability make Impella™ a viable option to provide urgent rapid haemodynamic stabilisation for broader UK implementation.	Iannaccone (2022) was identified in the literature search but was not prioritised. It is included in table 5 of the overview. The wording in 'Who should be involved with the procedure' has been changed to 'This procedure should only be done in percutaneous coronary intervention centres with on-site intensive care expertise and by healthcare professionals with specific training in this procedure.'
22	Consultee 13	1.1	There are some significant caveats to this: a) highly selected patients have been shown to benefit b) the use must be by appropriately trained practitioners c) the	Thank you for your comment. The guidance states:

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			training does not stop at the cath lab d) not all patients will be able to consent at teh time due to the critical nature of their illness e) the decision to use/not use must be embedded within pathways/networks of care to ensure expert decision-making and equitable access	'Healthcare professionals do not have to offer this procedure and should always discuss the available options with the person with cardiogenic shock (and their family and carers as appropriate) before a joint decision is made, if possible.' The wording in 'Who should be involved with the procedure' has been changed to 'This procedure should only be done in percutaneous coronary intervention centres with on-site intensive care expertise and by healthcare professionals with specific training in this procedure.'
23	Consultee 2	Why the committee made this recommendation	A robust and appropriate bleeding-management protocol is essential. This significantly reduces complications and improves outcomes. This point is crucial (vandenbriele et al., JACC 2022 - doi: 10.1016/j.jacc.2022.02.052).	Thank you for your comment. A committee comment has been added about the need for a bleeding-management protocol.
24	Consultee 2	3.1 The condition	It is essential to recognise that cardiogenic shock is not a single entity. The current document refers only to "cardiogenic shock," but according to the recent SHARC classification, cardiogenic shock should be divided into four major subtypes. We should therefore refer, for	Thank you for your comment. The 'Condition' section of the draft guidance states 'It has multiple causes, including heart attack, chronic heart failure, sudden heart valve failure, cardiac arrhythmias, inflammation of the heart

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			example, to myocarditis-induced cardiogenic shock where appropriate. Management must be tailored to the specific cardiogenic shock subtype, as prognosis, treatment strategies, and overall approach differ substantially between them. Although prospective randomised trials are extremely challenging in non-AMICS populations, the evidence base is growing. Data from the Japanese registry (Terauchi et al., 2025) demonstrates improved outcomes in non-ACS cardiogenic shock, particularly in myocarditis.	muscle, blood clots in the lungs, drug overdoses and poisoning. It can also happen after open heart surgery (postcardiotomy cardiogenic shock).' Terauchi T (2025) was identified in the update search. It was not prioritised as key evidence and has been added to table 5 of the overview.
25	Consultee 13	3.10 Equality considerations	The greatest benefit in randomised data was seen in younger patients.	Thank you for your comment. Klein (2025) is a secondary analysis of the DanGer Shock trial, which is included in table 5 of the overview. It reported that in people younger than 77 years, a reduced 180-day mortality was seen in people randomised to the microaxial flow pump (OR 0.45; 95% CI 0.28 to 0.73; p=0.001), compared to people aged 77 or above (OR 1.52; 95% CI 0.57 to 4.08; p=0.40).

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26	Consultee 2	3.6 The evidence	Haemolysis should indeed be listed as a potential complication, but it is generally manageable with appropriate device management. This again underscores the importance of implementing a hub-and-spoke model.	Thank you for your comment. Haemolysis has been added to the list of key safety outcomes.
27	Consultee 11	Not specified	In the complication section it would be helpful to include haemolysis as a specific source of harm. This is at least in part the mechanism for worsening kidney injury and microvascular injury whilst on microaxial flow pumps. As a marker of harm it is easy to measure either directly (plasma free haemoglobin) or indirectly through routinely collected blood samples	Thank you for your comment. Haemolysis has been added to the list of key safety outcomes.
28	Consultee 4	What evidence generation is needed	Long term complications such as stroke, vascular injury, renal injury/haemolysis and implications for the limb beyond the access site, embolic complications from catheter shaft thrombus, LV rupture or mital valve damage might have long lasting implications for the patient.	Thank you for your comment. The draft guidance includes long-term complication rates in the evidence generation section.
29	Consultee 4	What evidence generation is needed	Long term survival is important as these devices come with a cost and resource implications that would be more justified if not only short but long term survival was judged both clinical and economically beneficial.	Thank you for your comment. The draft guidance includes long-term survival in the evidence generation section.

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			Interventions such as implantable LVADS and heart transplantation to achieve this would need recoporting.	
30	Consultee 4	What evidence generation is needed	Short and long term complications and survival and quality of life after rescue and recovery from cardiogenic shock is important as patients left with severe chronic heart failure symptoms will be at risk of future events and need for more definitive procedures	Thank you for your comment. The draft guidance includes short and long-term complication and survival in the evidence generation section.
31	Consultee 13	3.6 The evidence	Stroke?	Thank you for your comment. Stroke is included in the key safety outcomes. It was reported as an outcome in 5 studies included in the key evidence.
32	Consultee 13	3.5 The evidence	I am not sure what is meant by recovery here - is it recovery to normal cardiac function? And is there any consideration regarding LOS?	Thank you for your comment. The key efficacy outcomes have been changed. They are now: short-term survival, bridge to heart transplant or durable left ventricular device and longer term outcomes including survival and health-related quality of life.
33	Consultee 13	1.1 What evidence generation is needed	Agree - one might look at the key components of DanGer-Shock and suggest that at a minimum these data must be collected. And when used outside this, then variance and the reason for it is clearly documented.	Thank you for your comment.

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34	Consultee 2	1.1	It is important to emphasise that this therapy is life-saving, and every second often matters. As a result, there is not always enough time to fully brief family members about the different treatment options. The intervention frequently must be initiated rapidly at the clinician's discretion.	Thank you for your comment. The draft guidance states in the 'what this means in practice' section 'Healthcare professionals do not have to offer this procedure and should always discuss the available options with the person with cardiogenic shock (and their family and carers as appropriate) before a joint decision is made, if possible.'
35	Consultee 2	3.2 Unmet need	It is also important to state that Impella unloading (micro-axial flow pump unloading) not only maintains forward flow to the systemic circulation but should be viewed as a therapeutic intervention in its own right. Unloading reduces myocardial oxygen consumption and ventricular size, thereby increasing the chances of cardiac recovery—in contrast to ECMO therapy. For this reason, I cannot fully agree with the statement in section 3.3 ("unmet need"): "The procedure is used to provide temporary short-term cardiac support to people with cardiogenic shock when symptoms have not responded to other forms of treatment." This therapy should not be considered a bailout measure but rather an up-front therapy. The earlier the device is	Thank you for your comment. The committee discussed this comment but decided it was appropriate to state that the procedure is used when symptoms have not responded to other forms of treatment.

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			implanted, the greater the likelihood of myocardial recovery.	
36	Consultee 6	Overview – efficacy outcomes (longer term survival)	Thank you for this very comprehensive review of Impella treatment in AMI-related cardiogenic shock. As the principal investigator of the DanGer Shock trial, I would like to offer a few additional comments. Please note the longterm results of the DanGer shock trial has recently been published demonstrating a sustained survival benefit up to 10 years. N Engl J Med. 2025 Sep 11;393(10):1037-1038. doi: 10.1056/NEJMc2508284.	Thank you for your comment. The 10-year follow-up data has been published as a letter to the editor and has been added to the key evidence.
37	Consultee 9	3.2 Current practice	It is important to recognise in the consultation that inotropic agents, intra-aortic balloon pumps and VA-ECMO have all had neutral or negative results when tested in randomised trials. The only interventions shown to improve outcomes in cardiogenic shock are primary percutaneous coronary intervention and mAFP insertion, both in AMI-shock.	Thank you for your comment. Section 3.2 of the draft guidance describes the current practice used to manage cardiogenic shock. The guidance is not intended to be a guideline and the committee did not consider evidence for other interventions.
38	Consultee 9	3.3 Unmet need	As above, I feel it is important to be clear that none of the "other forms of treatment" have shown benefit in RCTs, other than primary percutaneous coronary intervention".	Thank you for your comment. The guidance is not intended to be a guideline and the committee did not consider evidence for other interventions.

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39	Consultee 15 Company JnJ Heart Recovery	Not specified	Thiele et al., 2024 (Thiele H, Møller JE et al. Temporary mechanical circulatory support in infarct-related cardiogenic shock: an individual patient data meta-analysis of randomised trials with 6-month follow-up. Lancet. 2024 Sep 14;404(10457):1019-1028. Erratum in: Lancet. 2024 Sep 28;404(10459) presented an individual patient data meta-analysis of nine randomized controlled trials (n = 1,114) comparing temporary mechanical circulatory support (MCS) with standard care in acute myocardial infarction–related cardiogenic shock (AMI-CS). It included both loading devices (veno-arterial ECMO) and unloading devices (micro-axial pumps such as Impella™). In this study, MCS (in a cohort consisting mainly of unloading devices) did reduce 6-month mortality (HR 0.77; p = 0.024) in the selected patients with ST-elevation AMI-CS and no risk of hypoxic brain injury (i.e. the “DanGer SHOCK” phenotype mentioned above. The authors found no overall survival benefit from early routine MCS use at 6 months (HR 0.87, p = 0.10), and generally unloading devices showed a trend toward lower 6-month mortality vs. control (HR 0.80 [0.62–1.02]; p = 0.075). On the other hand, loading devices (VA-ECMO) had no mortality impact (HR 0.93; p = 0.55).	Thank you for your comment. Thiele (2024) is included in the key evidence in the overview. Zeymer (2024) is not included in the key evidence because it assesses VA ECMO. This guidance is not intended to be a guideline and does not assess interventions other than percutaneous insertion of a catheter-based intravascular microaxial flow pump.

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			The publication is complemented by the publication of another individual patient data meta-analysis by the same team (Zeymer U et al. Do DanGer-SHOCK-like patients benefit from VA-ECMO treatment in infarct-related cardiogenic shock? Results of an individual patient data meta-analysis. Eur Heart J Acute Cardiovasc Care. 2024 Sep 25;13(9):658-661) that applied the DanGer shock selection criteria (i.e. the "DanGer" phenotype of patients with CS, STEMI, and a low likelihood of brain injury) to patients treated with VA-ECMO. The study showed no mortality benefit with the routine use of VA-ECMO leaving this cohort with only mAFP (i.e. Impella CP™) as the device class with high level evidence of clinical benefit. Separately, some of the main authors of both publications published a review (Thiele H, Desch S, Freund A, Zeymer U. Why VA-ECMO should not be used routinely in AMI-Cardiogenic Shock. J Heart Lung Transplant. 2024 May;43(5):695-699) strongly doubting the routine use of VA-ECMO in AMI-CS. Overall, both publications confirm that unloading devices offer survival benefit in carefully selected STEMI shock	

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			patients enrolled in the DanGer SHOCK RCT, further supporting use of Impella in the well-defined DanGer SHOCK phenotype. VA-ECMO and IABP, are currently both seen as Class III recommendations, limiting the available management options of this condition.	
40	Consultee 4	Why the committee made this recommendation	The morbidity and mortality from cardiogenic shock unresponsive to standard treatments (IVI inotropes etc) is high and timely skilled intervention may reduce complications from these advanced temporary mechanical circulatory support procedures, especially the impella which may have less complications than VA ECMO. There is no strong evidence for inotropes either.	Thank you for your comment. The guidance is not intended to be a guideline, and the committee did not consider evidence for other interventions.
41	Consultee 11	Not specified	Overall the recommendation and document is balanced and appropriate. There are some additional elements which could be considered in specific areas by the committee. The first is the use of microaxial flow pumps as intraprocedural support during coronary angiography and coronary interventional procedures in patients in shock or where the procedure has a predictable outcome of	Thank you for your comment. There is separate NICE interventional procedures guidance on percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions. This is stated in section 2.4 of the draft guidance. For this assessment, evidence was excluded from studies that primarily used

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			shock. There is a growing evidence base around this and it is an area where clinical use is expanding. The second is more niche with the use of microaxial flow pumps as a tool for unloading the left ventricle in patients on ECMO for cardiogenic shock. This is the subject of ongoing research at present. It would be helpful to clarify in the guidance whether the focus is on left ventricular support (majority of evidence and devices) or right ventricular support (devices exist, research is ongoing), or both as this will be helpful for clinicians when considering the document	microaxial flow pumps as support during high-risk PCI, or for left ventricular unloading during VA-ECMO support. This is stated in the overview. Evidence on right ventricular support was also excluded. This has been clarified in the overview.
42	Consultee 13	2.1 2 Information about the procedure	I think we should be more specific - this relates to left-sided support. There is right-sided support - includign with micro-axial pumps, but I don't believe this is covered in this consultation?	Thank you for your comment. Right sided support is not covered by this assessment. The title has been changed to clarify that it refers to implantation of a left ventricular microaxial flow pump.
43	Consultee 13	2.2 2 Information about the procedure	Reduce ventricular work and/or provide circulatory support. In addition, the device is used in unloading the LV. Are we including this in this consultation?	Thank you for your comment. It is unclear what the consultee is asking. The aim of the procedure is described as

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				“ to reduce ventricular work and provide the circulatory support needed to allow the heart time to recover from an acute injury” For this assessment, evidence on left ventricular unloading during VA-ECMO support was excluded. This is stated in the overview.
44	Consultee 13	2.4 2 Information about the procedure	what about high-risk valve intervention?	Thank you for your comment. For this assessment, evidence was excluded from studies that primarily used microaxial flow pumps as support during high-risk PCI. This is stated in the overview. Because of the large evidence base, non-randomised studies with fewer than 100 people were excluded. This is stated in the overview.
45	Consultee 15 Company JnJ Heart Recovery	Not specified	J&J believes two studies referenced in IP2042 may be inappropriate for causal interpretation of effectiveness. Specifically:	Thank you for your comment. The committee are used to considering different kinds of data and they are aware of limitations associated with different study designs. The ‘validity and

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			• Padberg et al evaluated outcomes of patients with AMI-CS using the health claims data from AOK, the German Health Insurance. • Movahed et al conducted a similar analysis using the Nationwide Inpatient Sample (NIS), a database of hospital inpatient stays that is derived from billing data submitted by hospitals to statewide data organizations. These data sources are not fit for purpose for cardiogenic shock research because shock severity is not identifiable in the databases, thus resulting in significant confounding by indication. The limitations of these data sources for cardiogenic shock research has been described in a seminal paper by Almarzooq et al in the Journal of the American Medical Association (JAMA Cardiology) in 2023 (Almarzooq ZI, Song Y, Dahabreh IJ, Kochar A, Ferro EG, Secemsky EA, et al. Comparative Effectiveness of Percutaneous Microaxial Left Ventricular Assist Device vs Intra-Aortic Balloon Pump or No Mechanical Circulatory Support in Patients With Cardiogenic Shock. JAMA Cardiol. 2023 Aug 1;8(8):744–54). Almarzooq et al conducted extensive epidemiological analyses to evaluate residual	generalisability' section of the overview noted that registry studies use data that has been collected for other purposes and may not include baseline characteristics such as the degree of cardiogenic shock. Almarzooq (2023) was identified in the literature search but was not included because it describes people admitted with AMICS having percutaneous coronary intervention. The use of this procedure to support percutaneous coronary intervention is covered by a separate piece of NICE IP guidance. The committee discussed this comment but decided that the 2 registry papers should remain in the key evidence. Removing the papers would not affect their decision on the main recommendation.

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			confounding in studies of AMI-CS using observational databases and concluded that these data could not support any causal interpretation in cardiogenic shock research, due to residual confounding. Randomized control trials would be required to help resolve controversies. Confounding by indication in the context of AMI-CS can be explained as follows: • Chronic comorbidities by themselves are not predictors of shock severity and mortality (Harjola VP, Lassus J, Sionis A, Kober L, Tarvasmaki T, Spinar J, et al. Clinical picture and risk prediction of short-term mortality in cardiogenic shock. Eur J Heart Fail. 2015 May;17(5):501–9; Zweck E, Ton VK, Kanwar M, Li S, Li B, Sinha SS, et al. CSWG-SCAI Stages Combined With Machine Learning-Based Phenotypes for Serial Risk Stratification in Cardiogenic Shock. JACC Heart Fail. 2025 Oct;13(10):102611; Saito Y, Shiko Y, Tateishi K, Toda K, Matsumiya G, Kobayashi Y. Combined Risk Stratification With Patient Characteristics and Biomarkers in Patients Treated With the Impella for Cardiogenic Shock. J Am Heart Assoc. 2025 May	

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			6;14(9):e040487; Yang C, Lee T, Kochan A, Barker M, Roston TM, Cairns JA, et al. Prehospital Prediction of Cardiogenic Shock Among Patients With ST- Segment-Elevation Myocardial Infarction: The EARLY SHOCK Score. J Am Heart Assoc. 2025 Oct 7;14(19):e040681; Sundermeyer J, Li S, Ton VK, Kataria R, Zweck E, Kanwar MK, et al. Impact of Comorbidities on In-Hospital Mortality Across SCAI Shock Stages. J Am Coll Cardiol. 2025 Oct 13;S0735-1097(25)07693-4.) Adjusting for existing ICD-10 diagnoses does not allow for adequate controlling of shock severity. Movahed and Padberg analysed outcomes as a function of patient comorbidities but could not evaluate outcomes as a function of shock severity as this variable is not available in claims and hospital billing data. • The most severe shock patients, regardless of comorbidities, are likely treated with percutaneous micro-axial flow pump or veno-axial extracorporeal membrane oxygenation (VA ECMO), whereas least severe patients are more likely to undergoing medical management or treatment with balloon pumps. • As a result, survival in medically managed patients and patients treated with balloon pumps is likely greater than that of patients treated with either	

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			percutaneous micro-axial flow pumps, or veno-axial extracorporeal membrane oxygenation (VA ECMO). This is not because medical management or balloon pumps are more effective, but simply because patients receiving these therapies are less likely to have experienced severe cardiogenic shock, and adequate risk adjustment between cohorts could not be performed.	
46	Consultee 15 Company JnJ Heart Recovery	3.4 The evidence	J&J applauds the technical team for the thorough review and wishes to highlight additional publications that add further clarification and have so far not been considered due to them becoming available outside the literature review window. Studies: • DanGer Long-Term Outcomes (Møller et al., 2025): 10-year follow-up confirms sustained survival benefit — 30% relative reduction in mortality and ~600 more days alive cumulatively. • Freer et al., 2025: network meta-analysis of 18 RCTs (n=1,907) finds long-term survival benefit for Impella.	Thank you for your comment. Møller (2025) has been added to the key evidence. Freer (2025) was identified in the update search and has been added to the key evidence. Terauchi (2025) was identified in the update search and but was not prioritised as key evidence and has been added to table 5 because the key evidence already includes a larger study from the same registry. Potapov (2025) was published after the update search. It has been added to the 'existing assessments' section of the overview.

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			• Terauchi et al., 2025: Japanese registry (n=731) of non-ACS CS shows early Impella introduction reduced in-hospital mortality, especially in myocarditis. Guidelines/HTAs: • 2023 JCS/JSCVS/JCC/CVIT guidelines (Nishimura et al. 2023): JPVAD with 81% survivorship. • 2025 EACTS/STS/AATS Temporary MCS guidelines (Potapov et al. 2025): Class I recommendation for tMCS in adult cardiac surgery. • French HAS Appraisal: Positive recommendation for Impella CP with SmartAssist in DanGer SHOCK patients.	
47	Consultee 9	Why the committee made this recommendation	Observational study populations should not be referred to as "trial populations". It is my view that this term should refer only to RCTs.	Thank you for your comment. The sentence has been amended: 'There is evidence from several large retrospective observational studies, but the ~~trial~~ populations in these varied and the results on efficacy are inconsistent.'
48	Consultee 13	3.2 Current practice	It should really read - intervention to reverse the underlying cause, not just revascularisation using bypass surgery or PCI - in particular as the changing	Thank you for your comment. Section 3.2 has been amended to:

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			epidemiological face of cardiogenic shock suggests as such.	'Depending on the aetiology of the acute heart failure, once the initial symptoms of cardiogenic shock have been stabilised, **interventions to reverse the underlying cause may be used, including** revascularisation using bypass surgery or percutaneous coronary intervention ~~may be used to improve the heart's function~~.'
49	Consultee 13	3.4 The evidence	There is also one head-to-head small RCT comparing IABP vs Impella in AMI-CS. There is non-randomised data regarding other aetiologies...	Thank you for your comment. Section 3.4 of the draft guidance describes the evidence that was prioritised to be included as the key evidence in the overview. The wording has been amended to make this clear: 'The **prioritised** evidence included 1 randomised controlled trial, 1 individual patient data meta-analysis, 5 systematic reviews and meta-analyses and 3 registry studies.' Bochaton (2020) is a small randomised controlled trial including 12 people. It was not prioritised because of its small sample

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				size. It is included in table 5 of the overview.

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