# National Institute for Health and Care Excellence

# IP1929 percutaneous thrombectomy for intermediate-risk or high-risk pulmonary embolism

**IPAC date: 14th September 2023**

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| 1 | Consultee 1<br>NHS professional | 1 | I am a Consultant Interventional Radiologist working in a tertiary vascular unit and currently treat PE patients with endovascular techniques. I have concerns about these draft guidelines being implemented and the potential negative impact on this patient cohort with mortality rates between 25-50%.<br><br>Current guidelines recommend systemic thrombolysis as the primary therapy for high risk PE. However a significant number of the patients we currently treat have contra-indications to lytic therapy, and have no other viable treatment options. Another group to consider is those patients who fail to respond to lytic therapy and continue to deteriorate. Mechanical thrombectomy is a potentially life-saving treatment in these patients with limited other options.<br><br>On a practical level enrolling the aforementioned patient groups, with no other viable treatment option, in an RCT would be extremely challenging. High risk / massive PE patients are inherently unstable with rapid decision making required again making recruitment into an RCT very challenging.<br><br>With regard to available data on technique / device safety and efficacy in high risk patients:<br>-The recently published results of the FLASH registry (Inari FlowTriever device 800 patients) have demonstrated a | Thank you for your comment.<br>Published evidence on mechanical thrombectomy until July 2023 was considered by the committee.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br>The team also identified another publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'. This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. So therefore this study has not been included in the overview. . |

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| | | | favourable safety profile and short term efficacy of the device in both intermediate and high risk PE.<br>-The recently presented (American College of Cardiology 2023) FLAME study (Inari FlowTriever device) (prospective, non-randomised) demonstrated a mortality rate of 1.9% in mechanical thrombectomy arm vs 29.5 in a context arm.<br><br>Long term data is potentially lacking for this technique, but the majority of published PE data on all treatment modalities focuses on mortality outcomes.<br><br>In summary I think the most appropriate classification for this technique would be special arrangements to enable ongoing data collection and monitoring of outcomes. Placing the technique in the research only category would severely limit treatment options for a significant proportion of high risk / massive PE with potential negative outcomes.<br><br>I would be happy to be involved in any further discussions / consultations regarding this draft guidance. | *Morrow, D.A.; Bergmark, B.A. Outcomes In High-risk Pulmonary Embolism Patients Undergoing FlowTriever Mechanical Thrombectomy: The FLAME Study in Perspective. European heart journal. Acute cardiovascular care; 2023.*<br><br>IPAC considered the comments and additional new evidence and amended the guidance to support the use of this procedure under 'special arrangements' in people with high-risk pulmonary embolism who have limited treatment options (those who are unable to have thrombolysis, and for whom there are no other treatment options or alternative treatments have failed). For all other people with high-risk or intermediate-risk pulmonary embolism, the procedure should be used only in research. See section 1 in the guidance.<br><br>IPAC considered the comments and concerns about conducting trials in this critically ill population in their deliberations. They noted that it is challenging but not impossible to conduct RCTs in this group of patients. They also noted an ongoing trial, the PEERLESS study NCT05111613, in this population.<br><br>The guidance has recommended either research in formal clinical studies or routine data collection through registries. |
| 2 | Consultee 2 Thrombosis UK | 1 | Thank you for inviting Thrombosis UK to comment on this important piece of work. | Thank you for your comment and agreeing with the recommendations. |

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| | | | As previously noted in our patient representative submission, this practice is an important option or addition to thrombolysis in massive and intermediate risk PE, and particularly so with the current global shortage of thrombolytic agents.<br><br>We agree with the conclusions of the interventional procedures guidance and would urge Centres to set up registries to allow us to learn more about this procedure. We need more data to fully understand the risks and benefits. | Section 1.2 of the draft guidance states that further research should be in the form of RCTs and registries. 1.3 states the data that needs to be collected.<br>NICE received 1 submissions from patient organisations about percutaneous thrombectomy for high-risk and intermediate-risk pulmonary embolism.<br>Patients' views on the procedure were consistent with the published evidence and the opinions of the professional experts. |
| 3 | Consultee 3<br>Inari Medical | 1 | In our opinion, the draft, in its current form, fails to recognize the lack of therapeutical options of patients with high levels of mortality. The draft does not fully appraise the evidence supporting the safety and effectiveness profile of the FlowTriever and sets unachievable standards of evidence for the therapy. And finally, it does not note the difference in the mechanism of treatment of the FlowTriever compared to other mechanical thrombectomy therapies.<br><br>We believe that if the draft of the IPG came to pass as it is, it would seriously limit the possibilities of treatment of high risk pulmonary embolism patients. | Thank you for your comment.<br>IPAC considered the comments and additional new evidence and amended the guidance to support the use of this procedure under 'special arrangements' in people with high-risk pulmonary embolism who have limited treatment options (those who are unable to have thrombolysis, and for whom there are no other treatment options or alternative treatments have failed). For all other people with high-risk or intermediate-risk pulmonary embolism, the procedure should be used only in research. See section 1 in the guidance.<br>Published evidence on mechanical thrombectomy was considered by the committee when making their draft recommendations. See section 1 in the guidance. |

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| | | | | In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br>IPAC considered comments about the mechanism of action of the FlowTriever system. Section 3.5 clearly states that<br>*'The committee noted that more than 1 device can be used for this procedure. Devices vary in the size of the introducer and their mechanism and are at different stages of development'.*<br>The committee made recommendations based on the available evidence. Please note that it evaluated the procedure rather than a specific device. |
| 4 | Consultee 4<br>NHS professional | 1.1 | The reason is inappropriate is that it removes a life saving treatment as option in patients with high risk PE who have failed systemic thrombolysis or have thrombolysis contraindications. To suggest surgical pulmonary embolectomy as a reasonable alternative is almost laughable, it is completely inappropriate in the vast majority of patients and essentially not available in the UK due to lack of expertise. I work in a tertiary centre with | Thank you for your comments and sharing your experiences.<br>IPAC considered the comments and additional new evidence and amended the guidance to support the use of this procedure under 'special arrangements' in people with high-risk pulmonary embolism |

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| | | | cardiothoracic surgery on site and I have never heard of cardiothoracic surgeons agreeing to perform one.<br><br>I have performed this technique in high risk patients in patients who have contraindications to thrombolysis or one patient who had had systemic thromboylsis, without this procedure each of these patients would have died.<br><br>Now I know that guidelines should not be based on anecdotes but this demonstrates the harm caused by insisting it only be used in research. Essentially removing it as a treatment option is extremely dangerous will lead to harm.<br><br>I completely agree with the sentiment that it has not been demonstrated through the research that it should replace thrombolysis as first line treatment for high risk PE (although the FLAME study has presented results which are favourable on this). But this (and the current NICE guideline on VTE) ignores patients who have either failed thrombolysis or have contraindications. | who have limited treatment options (those who are unable to have thrombolysis, and for whom there are no other treatment options or alternative treatments have failed). For all other people with high-risk or intermediate-risk pulmonary embolism, the procedure should be used only in research. See section 1 in the guidance.<br><br>IPAC considered your comments and amended section 2.3.<br><br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br><br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br><br>The team also identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'. This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |

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| 5 | Consultee 5<br>NHS professional | 1.1 | This is overly restrictive and will prevent the UK from part-taking in randomised controlled trials. These are complex procedures with a significant learning curve. | Thank you for your comment.<br>IPAC considered the comments and additional new evidence and amended the guidance to support the use of this procedure under 'special arrangements' in people with high-risk pulmonary embolism who have limited treatment options (those who are unable to have thrombolysis, and for whom there are no other treatment options or alternative treatments have failed). For all other people with high-risk or intermediate-risk pulmonary embolism, the procedure should be used only in research. See section 1 in the guidance.<br>The research and ethics governance framework will oversee safe introduction of the procedure. Section 1.2 states that *Further research should be in the form of randomised controlled trials or registries.* |
| 6 | Consultee 7<br>NHS professional | 1 | In my opinion I respectfully ask NICE to reconsider the statement that "Percutaneous thrombectomy for massive pulmonary embolism (PE) should be used only in research". I believe thromboaspiration should be considered as the primary treatment for intermediate high risk PE that require intervention (after a pulmonary embolism multidisciplinary team decision) and for high risk 'massive' PE thromboaspiration should be performed as part of registry (after a pulmonary embolism multidisciplinary team decision) pending review in 12 months.<br>Performing a randomised control trial for high risk PE I believe would be extremely challenging both practically and | Thank you for your comment.<br>IPAC considered the comments and additional new evidence and amended the guidance to support the use of this procedure under 'special arrangements' in people with high-risk pulmonary embolism who have limited treatment options (those who are unable to have thrombolysis, and for whom there are no other treatment options or alternative treatments have failed). For all other people with high-risk or intermediate-risk pulmonary embolism, the |

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| | | | ethically given the high acuity and mortality associated with high risk PE (around 50%). | procedure should be used only in research. See section 1 in the guidance.<br>IPAC considered your comments and concerns about conducting trials in this critically ill population in their deliberations. They noted that it is challenging but not impossible to conduct RCTs in this group of patients. They also noted an ongoing trial, the PEERLESS study NCT05111613, in this population.<br>The guidance has recommended either research in formal clinical studies or routine data collection through registries. |
| 7 | Consultee 9<br>British Society of Interventional Radiology (BSIR) | 1.1 | The British Society of Interventional Radiology (BSIR) would like to express its concerns with the suggested guideline on percutaneous thrombectomy for massive pulmonary embolus due to the following reasons:<br>*1.1 Percutaneous thrombectomy for massive pulmonary embolism (PE) should be used only in research.*<br>It is a practice in many hospitals in the UK to offer percutaneous thrombectomy to patients in whom thrombolysis is contraindicated or failed. At national conferences and webinars conducted by BSIR, the practice of catheter directed thrombectomy has shown to be of value in this patient group. The decision to provide catheter directed thrombectomy is undertaken by a group of consultants including intensivists, respiratory physicians, cardiologists, and interventional radiologists. Our recommendation is that this procedures is allowed to be used after a multidisciplinary team decides that it is appropriate. | Thank you for your comments.<br>IPAC considered the comments and additional new evidence and amended the guidance to support the use of this procedure under 'special arrangements' in people with high-risk pulmonary embolism who have limited treatment options (those who are unable to have thrombolysis, and for whom there are no other treatment options or alternative treatments have failed). For all other people with high-risk or intermediate-risk pulmonary embolism, the procedure should be used only in research. See section 1 in the guidance.<br>Most of the evidence was for intermediate-risk pulmonary embolism, and patient selection was not clear. |

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| 8 | Consultee 10<br>NHS professional | 1 | I would be grateful for your positive consideration of thrombo-aspiration for massive and sub massive pulmonary emboli.<br>I am professor of haemostasis and thrombosis at UCLH/UCL, and as such am involved in a daily capacity with thrombosis/thromboembolism.<br>The treatment of such situations with systemic thrombolysis should only be reserved, in my opinion, to those centres which cannot provide localised interventions, given the associated morbidity (and mortality).<br>CDT is an excellent standard of therapy. However, in the current era, thrombolysis even via CDT, is becoming increasing contra indicated, especially in larger units, where there are a number of disease complexities such as oncology, benign and malignant haematology, obstetrics, intensive care or post surgery.<br>Our own experience of thrombo aspiration, unquestionably, saved the life of our patient. He could not have CDT and would have died without this procedure.<br>The is evidence for the benefit of thrombectomy in PE-(FLAME study)-which achieved a late breaking abstract at ACC in 2023.<br>I appreciate that further data would be beneficial and a UK registry would be optimal, perhaps allowing roll out in designated centres in the first instance.<br>Not supporting this techniques will have a negative impact on specific patient groups and I would be grateful for your consideration and support in allowing availability of this procedure. | Thank you for your comments and sharing your experiences.<br>IPAC considered the comments and additional new evidence and amended the guidance to support the use of this procedure under 'special arrangements' in people with high-risk pulmonary embolism who have limited treatment options (those who are unable to have thrombolysis, and for whom there are no other treatment options or alternative treatments have failed). For all other people with high-risk or intermediate-risk pulmonary embolism, the procedure should be used only in research. See section 1 in the guidance.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br>The team identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study' (abstract presented at American College of |

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| | | | | Cardiology). This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |
| 9 | Consultee 3<br>Inari Medical | 1.2 | Massive pulmonary embolism has a high in-hospital mortality over 30%. About 40% of the patients are contraindicated to lytics and of those surviving and being treated, 8% experience treatment failure. The FLAME study shows a significant and clinically meaningful reduction in mortality (1.9% vs. 28.8%) for this type of patients. There is, therefore, a clear concern for a lack of the principle of equipoise in an RCT for such a grave patient population. Plus, the logistic concerns of doing an RCT in a small patient population (approximately 5% of all pulmonary embolisms) that need to be treated quickly, is considerable.<br><br>AHA to generate high quality evidence in high-risk PE:<br>_"Nonrandomized prospective studies of endovascular devices with prespecified performance goals for clinical effectiveness are reasonable for high-risk PE.<br>-The best primary measure of clinical effectiveness is short-term mortality.<br>-Prospective studies of high-risk PE should examine all patients with high-risk PE at participating institutions regardless of treatment strategy (anticoagulation alone, systemic lysis, interventional device, surgical embolectomy, mechanical support, or any combination of these). This can be accomplished by concurrent registries for high-risk | Thank you for your comment.<br>IPAC considered your comments and concerns about conducting trials in this critically ill population in their deliberations. They noted that it is challenging but not impossible to conduct RCTs in this group of people. They also noted an ongoing trial, the PEERLESS study NCT05111613, in this population.<br>The guidance has recommended either research in formal clinical studies or routine data collection through registries.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the |

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| | | | patients not treated with a PE device under evaluation."<br><br>These recommendations from the AHA regarding the development of clinical evidence for high risk PE patients are followed in our FLAME study. | FLASH registry) were added to the overview.<br>The team also identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'.is This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. NICE may update the guidance on publication of this study. |
| 10 | Consultee 5<br>NHS professional | 1.2 | Registries are necessary to power and design RCTs appropriately. In case of FLowTriever with the completion the FLAME study (presented ACC this month) there is sufficient data to design and power a trial of that device. others need further data. | Thank you for your comment and agreeing with section 1.2.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br>The team identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'(presented at American College of |

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| | | | | Cardiology). This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |
| 11 | Consultee 8<br>NHS professional | 1.1, 1.2 | Secondly, the draft guideline suggests that "Percutaneous thrombectomy for massive pulmonary embolism (PE) should be used only in research". Whilst I agree that further research in this field is essential, restricting use in this way denies critically ill patients access to potentially life-saving treatment. The current guidelines recommend systemic thrombolysis for treatment of massive PE. This is based on a small number of studies, with the only randomized-control study being in 8 patients. There are already more patients than this in the FLAME study of high-risk patients treated with FlowTriever. It is also known that more than half of patients with massive PE do not actually receive systemic thrombolysis with bleeding risk being a common reason not to administer treatment. In this regard, percutaneous thrombectomy provides a potentially life-saving alternative. Additionally, it is known that recruitment of critically ill patients into randomized studies is extremely challenging. In my opinion, percutaneous thrombectomy should be recommended as a treatment option for massive PE where the procedure is available in a timely manner. I believe these cases should only be performed in experienced centres and inclusion in research should be encouraged. | Thank you for your comments.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br>IPAC considered the comments and additional new evidence and amended the guidance to support the use of this procedure under 'special arrangements' in people with high-risk pulmonary embolism who have limited treatment options (those who are unable to have thrombolysis, and for whom there are no other treatment options or alternative treatments have failed). For all other people with high-risk or intermediate-risk pulmonary embolism, the procedure should be used only in research. See section 1 in the guidance. |

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| | | | | IPAC considered your comments and concerns about conducting trials in this critically ill population in their deliberations. They noted that it is challenging but not impossible to conduct RCTs in this group of patients. They also noted an ongoing trial, the PEERLESS study NCT05111613, in this population.<br>The guidance has recommended either research in formal clinical studies or routine data collection through registries. |
| 12 | Consultee 9<br>British Society of Interventional Radiology (BSIR) | 1.2 | *1.2 Further research should be in the form of randomized controlled trials or registries*<br>The current guidelines suggest IV thrombolysis which is contraindicated in around 40% of patients in a patient group which has a mortality between 30-50%. Getting a significant amount of patients in this category into a randomized trial especially based on size and position of clot as suggested in the draft guideline is practically difficult. The BSIR will consider setting up a national registry to collect data prospectively. | Thank you for your comment.<br>IPAC considered your comments and concerns about conducting trials in this critically ill population in their deliberations. They noted that it is challenging but not impossible to conduct RCTs in this group of people. They also noted an ongoing trial, the PEERLESS study NCT05111613, in this population.<br>The guidance has recommended either research in formal clinical studies or routine data collection through registries. IPAC is pleased to know that BSIR will consider setting up a national registry for this procedure. |
| 13 | Consultee 3<br>Inari Medical | 1.3 | Six months follow up are already available from the FLASH registry data on 800 US patients. While both massive and sub-massive PEs are included, the results of the 63 patients with a massive PE have just been published, confirming the excellent results in terms of safety and | Thank you for your comment.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the |

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| | | | effectiveness. We keep collecting patients into the FLASH registry study from Europe.<br><br>The FLAME study is a prospective, multicenter, non-randomized, parallel group, observational study of high-risk PE. FLAME was designed following principles outlined by the AHA to generate high quality evidence in high-risk PE (see comment in subsection 1.2).<br><br>The Context Arm (patients treated with other non-FlowTriever treatments) provided context and helped capture all high-risk PE patients in the study to assess outcomes. The Context Arm outcomes looked similar to the historical data, giving us confidence that it's representative of the high-risk PE population.<br><br>The Historic Arm was established to provide the performance goal. This performance goal was derived from a recent 2023 published meta-analysis of 18 prior studies in high-risk PE (https://www.jscai.org/article/S2772-9303(22)00588-9/fulltext), consisting of a composite of:<br>1. In-hospital all-cause mortality<br>2. Bailout to an alternate thrombus removal strategy<br>3. Clinical deterioration<br>4. Major bleeding<br><br>The FLAME study had to be stopped after the interim analysis due to the high difference in outcomes in favour of the FlowTriever therapy, including mortality (1.9% vs. 28.8%), bailout strategy (4.0% vs. 16.9%), clinical deterioration (16.0% vs.16.9%), and major bleeding (12.0% vs. 18.6%).<br><br>In the sickest group, patients in the SCAI-SHOCK D/E | overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br><br>The team also identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'. This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |

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| | | | stage, 0 out of 11 of the patients treated with FlowTriever died, while 15 out of 32 died in the Context arm. | |
| 14 | Consultee 5<br>NHS professional | 1.3 | Define long-term. Given the data from PEITHO one does not expect to influence the incidence of chronic thromboembolic disease. | Thank you for your comment.<br>A high-risk pulmonary embolism can quickly cause death. The majority of published studies on all treatment modalities focus on 30 or 90 day mortality outcomes. Long term clinical follow-up was not available for percutaneous thrombectomy.<br>The committee was informed by the experts that suffering a large pulmonary embolism does not influence the development of chronic thromboembolic pulmonary hypertension. |
| 15 | Consultee 3<br>Inari Medical | | Massive pulmonary embolism has a high in-hospital mortality over 28.3% and 30-day mortality is 30.2%. About 40% of the patients are contraindicated to lytics and of those surviving and being treated, 8% experience treatment failure. In-hospital major bleeding is 13.8% and ICH is 3.6%. | Thank you for your comment. |
| 16 | Consultee 4<br>NHS professional | 2.2 | The terms massive and submissive are outdated and misleading. They should not used as many people confuse thrombus burden and the "massisvness". | Thank you for your comment.<br>IPAC considered your comment and they agreed that these terms are commonly used in clinical practice. These terms have been amended and defined clearly in section 2.2. |

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| 17 | Consultee 5<br>NHS professional | 2.3 | Agree that thrombolysis is the accepted first line therapy in shock (based on 16 patient study), but where there is a failure of lysis to resolve shock or absolute contraindications - thrombectomy is a guideline (ESC) supported option, CDT does not make sense in the immediate post systemic lysis period, since most patients have a depressed fibrinogen level. | Thank you for your comment.<br>A clinical consensus statement by the European Society of Cardiology and the European Association of Percutaneous Cardiovascular Interventions (Pruszczyk 2022) suggests that *'patients with high-risk PE and a contraindication to systemic full-dose thrombolysis may be considered for surgical embolectomy or CDT should be considered'.* This existing assessment was considered by the committee in their deliberations and also included in the overview of evidence.<br>Section 2.3 is intended to be a simple summary of current treatments. The text has been amended in light of comments received. |
| 18 | Consultee 3<br>Inari Medical | 2.3 | The recommendations from the current guidelines are based on a meta-analysis with 4 studies of intermediate-high and high PE patients (Marti et al. 2014). Of the four studies, 3 (UPET 1970, Ly 1978 and Dotter 1979) did not observe a difference in mortality. Only one study, Jerjez-Sanchez 1995, saw a significant difference: an RCT with 8 patients in total. The study was interrupted because the first 4 patients in the control group died, and no patients died in the thrombolytic group. The overall estimate effect of thrombolytic therapy in all-cause mortality for high-risk PE is: (OR: 0.48; 95% CI: 0.2–1.15), that is, a non-significant statistically speaking effect. In PE related mortality, the results were statistically significant, but again, limited to a very small number of studies with a small number of patients, decades old and problematic designs, and | Thank you for your comment about evidence for recommendations on thrombolysis for patients with intermediate-risk and high-risk pulmonary embolism. It provides some context about the poor level of evidence from thrombolysis which has been adopted as first line therapy.<br>Section 2.3 is intended to be a simple summary of current treatments. |

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| | | | excluding negative outcomes that might be related to the treatment such as bleeding. | |
| 19 | Consultee 5<br>NHS professional | 2.3 | Lysis for submassive PE is not superior to anticoagulation - PEITHO study | Thank you for your comment.<br>The Pulmonary Embolism Thrombolysis (PEITHO) trial is out of the scope of this guidance. |
| 20 | Consultee 6<br>Penumbra Europe GmbH | 2.3 | As suggested in the NICE draft recommendation, we would like to provide additional relevant evidence including references to be taken into consideration in the procedure overview:<br><br>1. Pruszcyk P et al. (2022) EuroIntervention. 18e623-e638. Percutaneous-treatment-options-for-acute-pulmonary-embolism-a-clinical-consensus by the ESC Working Group It is suggested to add this reference to section 2.3 “Current Treatments” in draft guidance as the authors denote in section “INDICATIONS FOR CATHETER-DIRECTED THERAPY” (“CDT”) supporting statement “Percutaneous thrombectomy is usually used if someone has had a massive PE and they cannot have surgery, and when thrombolysis is contraindicated or has failed”. [please note that the acronym CDT in this statement is making references to catheter-directed THERAPIES -explicitly including mechanical thrombectomy devices- and not thrombolysis].<br><br>The authors of the consensus statement include Penumbra’s INDIGO System in their list of catheter-directed therapies as RESCUE TREATMENT. | Thank you for your comment.<br>Section 2.3 in the guidance is about current treatments is intended to be a simple summary and no references are added.<br><br>We added the clinical consensus statement (Pruszczyk 2022) to the overview under the ‘existing assessments’ section.<br>Please note the guidance is focused on the procedure ‘percutaneous thrombectomy for intermediate-risk or high-risk PE’ and considers current devices which includes Penumbra’s Indigo system. |

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| 21 | Consultee 9<br>British Society of Interventional Radiology (BSIR) | 2.3 | This is an evolving technology which has shown good results when used in the appropriate setting which is why the BSIR would like to see the procedure being classed as an alternative to patients who have a contraindication for thrombolysis when discussed in a multidisciplinary setting. This would be in line with other guidelines from the | Thank you for your comment.<br>Section 2.3 states that 'catheter directed therapies are usually used if someone has had a high-risk PE and they cannot have surgery, and when systemic thrombolysis is contraindicated or has failed'. |
| 22 | Consultee 3<br>Inari Medical | 2.5, 3.1 | While the committee acknowledges that there is more than 1 device and different mechanisms, the draft lumps all devices together. Out of 6 publications, 4 belong to the FlowTriever, and that is not taking into account the new FLAME study results, or the FLASH study with the high risk PE population.<br>The FlowTriever is also the only therapy with a mechanism of true large bore aspiration. It is the only therapy that combines aspiration with mechanical thrombectomy. And it is also the only therapy that is lytics free. One can only conclude, therefore, that the mechanism of action is fundamentally different for the FlowTriever and has been recognized as such by both the German G-BA and the French HAS in their evaluations to grant it innovation funding (NUB and PECT respectively). | Thank you for your comment.<br>IPAC considered comments about the mechanism of action of the FlowTriever system and grouping of devices together.<br>The committee made recommendations based on the available evidence, while bearing in mind that it is evaluating the procedure rather than a specific device. The guidance referred to technological developments in section 3.5 as described by the specialist advisers, companies or other sources.<br>Thank you for bringing to our attention 2 key studies.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the |

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| | | | | FLASH registry) were added to the overview.<br>The team also identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'. This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |
| 23 | Consultee 3<br>Inari Medical | 2.5 | The variations are important. For example, the FlowTriever is a lytics free therapy and a bloodless thrombectomy. It is also the only device with a large bore catheter, and the only device that offers both aspiration and mechanical thrombectomy combined to fully extract the clot. Mechanisms of action are fundamentally different and this is important when evaluating safety and efficacy outcomes. | Thank you for your comment.<br>IPAC considered comments about the mechanism of action of the FlowTriever system, variations to consider when evaluating and grouping devices together.<br>The committee made recommendations based on the available evidence, while bearing in mind that it is evaluating the procedure rather than a specific device. The guidance referred to technological developments in section 3.5 as described by the specialist advisers, companies or other sources. |
| 24 | Consultee 8<br>NHS professional | 2.5 | The draft guidelines acknowledge that there are now a number of devices available. Whilst each device is designed to extract clot, they vary in their bore size and therefore are unlikely to be directly comparable. The largest bore device is the FlowTriever system, which is also the one with the largest volume of research data including outcome and safety data. | Thank you for comments. IPAC considered comments about the mechanism of action of the FlowTriever system with large volume of data, and variations to consider when evaluating and grouping devices together. |

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| | | | | The committee made recommendations based on the available evidence, while bearing in mind that it is evaluating the procedure rather than a specific device. The guidance referred to technological developments in section 3.5 as described by the specialist advisers, companies or other sources. |
| 25 | Consultee 3<br>Inari Medical | 3.1 | Since the publication of the draft, two abstracts have been presented for high risk PE patients treated with the FlowTriever therapy. A subgroup analysis of the FLASH registry and the FLAME study. The FLAME study is a prospective, multicenter, non-randomized, parallel group, observational study of high-risk PE. High-risk PE patients are very difficult to study in randomized trials. FLAME was designed following principles outlined by the AHA to generate high quality evidence in high-risk PE. The FLAME study had to be stopped after the interim analysis due to the high difference in outcomes in favour of the FlowTriever therapy, with 17% of patients reaching a primary composite endpoint compared to a performance goal of 32% ($p<0.01$). Most strikingly, the mortality was low in the FT arm (1.9% vs. 28.8% historical control).<br><br>Both studies have been presented as abstracts in international congresses and we expect the publication in a peer reviewed journal in the coming months. | Thank you for your comment.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br>The team also identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'. This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |

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| 26 | Consultee 3<br>Inari Medical | 3.1 | More than 40.000 patients with Pulmonary Embolism have been treated worldwide with the FlowTriever. Real world patient outcomes have been published in the 800-patient US cohort of the FLASH registry, with additional patients being currently enrolled in Europe. This, coupled with the recently presented FLAME study, the largest interventional study in high-risk pulmonary embolism show that the FlowTriever has an excellent safety profile. | Thank you for your comment.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br>.<br>The team also identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'. This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |
| 27 | Consultee 4<br>NHS professional | 3.1 | The new FLAME study is not included (understandable as it was not complete at time of start of the consultation) | Thank you for your comment.<br>See response to comment 26. |
| 28 | Consultee 5<br>NHS professional | 3.1 | Appreciate FLAME not yet published, but given the strength of evidence from this trial, conclusions will be out of date in a few months | Thank you for your comment.<br>See response to comment 26. |
| 29 | Consultee 5 | 3.1 | As previously indicated. Flame study does change the landscape | Thank you for your comment. |

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| | NHS professional | | | See response to comment 26. |
| 30 | Consultee 6<br>Penumbra Europe GmbH | 3.1 | As suggested in the NICE draft recommendation, we would like to provide additional relevant evidence including references to be taken into consideration in the procedure overview:<br><br>1. M.A. De Gregorio et al. / International Journal of Cardiology 287 (2019) 106–110; a prospective study that includes 54 patients with unstable PE (aka massive PE) treated with Indigo CAT8.<br>Results should be added to section “Evidence Summary - Pulmonary Arterial Pressure” (https://www.nice.org.uk/consultations/1735/2/evidence-summary ) stating “De Gregorio (2019) reported of the 54 patients with acute unstable PE, mean systolic pulmonary artery pressure decreased from 60.2mm Hg to 55.2 mm Hg (p = 0.01) after thrombectomy, and to 40.5mm Hg after catheter thrombolysis (p = 0.0001).”<br><br>Results should be added to section “Evidence Summary - Mortality” (https://www.nice.org.uk/consultations/1735/2/evidence-summary ) stating: “De Gregorio (2019) reported in-hospital PE-related death occurred in six patients (11%; 95% confidence interval [CI], 4.2–23%) at a mean follow-up of 1.1 days.”<br><br>2. Hennemeyer C et al. The American Journal of Medicine (2019) 132:240−246; a retrospective study including 36 patients (9 massive, 27 submassive) treated with CDT, consisting of aspiration thrombectomy (18), ultrasound-assisted thrombolysis (8), or both (10). | Thank you for your comment and providing additional evidence.<br>The team added a recent systematic review and meta-analysis (*Chandra 2022 Mechanical aspiration thrombectomy for the treatment of pulmonary embolism: A systematic review and meta-analysis. Vascular Medicine 2022, Vol. 27(6) 574–584*) which includes (De Gregorio 2019) to the overview of evidence.<br>Hennemeyer 2019 is not included in the overview of evidence as the study compared CDT plus anticoagulation with anticoagulation alone. Also, CDT consisted of thrombectomy, thrombolysis or both. |

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| | | | Results should be added to section “Evidence Summary - Pulmonary Arterial Pressure” (https://www.nice.org.uk/consultations/1735/2/evidence-summary ) stating “Hennemeyer (2019) reported an absolute reduction in RV/LV ratio for patients with massive pulmonary embolism who underwent CDT that was – 0.67 +- 0.85 (p = 0.04) compared to an absolute reduction in RV/LV ratio for patients with massive pulmonary embolism who were treated with anticoagulation was -0.16 +- 0.31 (P = 0.17). The mean reduction in RV/LV ratio in patients with massive pulmonary embolism treated with CDT was 24% vs 9% in patients treated with anticoagulation alone (P = 0.17).<br>*Hennemeyer C, Khan A, McGregor H, et al. Outcomes of catheter-directed therapy plus anticoagulation versus anticoagulation alone for submassive and massive pulmonary embolism. Am J Med. 2019;132(2):240–246.* | |
| 31 | Consultee 7<br>NHS professional | 3.1 | I am writing in response to the NICE’s IPG draft for “Percutaneous thrombectomy for massive pulmonary embolus” [GID-IPG10243].<br>I am aware that the device companies that make catheters for thromboaspiration for PE have been in contact regarding the results of recent published data (e.g. FLAME study that was presented at ACC Congress the 5th of March 2023).<br>I do not have any conflict of interest with regards to the devices used for this procedure (I have received an honorarium from penumbra for teaching about embolisation).<br><br>As an Interventional Radiologist who performs thromboaspiration and catheter directed thrombolysis for intermediate high risk PE I wanted to draw your attention to | Thank you for your comment.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview. |

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| | | | the results of the FLAME study which is a subset analysis of the FLASH registry.<br>The FLAME data has demonstrated a huge improvement in mortality and clinical outcome in patients with high risk aka Massive PE.<br>Although small number of patients (63) were treated with thromboaspiration for high risk PE the interim analysis demonstrated a significant difference in outcomes in favour of the thromboaspiration therapy, with a 90% reduction in mortality rate compared to other therapies (1.9% vs 29.5%).<br><br>These results I believe should be considered by NICE in their review of all the available data for PE intervention in high risk 'massive' PE. | The also team identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'. This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |
| 32 | Consultee 8<br>NHS professional | 3.1 | I am writing in response to the NICE's IPG draft for "Percutaneous thrombectomy for massive pulmonary embolus" [GID-IPG10243]. I am an interventional cardiologist with experience in interventional management of acute pulmonary embolism with both catheter-directed thrombolysis (EKOS) and percutaneous thrombectomy (FlowTriever). I do not have any conflict of interest with regards to the devices used for these procedures.<br><br>I have a number of comments regarding this draft guideline. Firstly, there are two important recent studies of percutaneous thrombectomy. The FLAME study was recently presented at the ACC congress on 5th March 2023). This showed an impressive reduction in in-hospital mortality with FlowTriever in patients with massive PE compared to a context arm of patients treated with alternative treatments including thrombolytic, catheter-directed thrombolysis or anticoagulants (in-hospital mortality 1.9% vs 29.5%). The FLASH registry of 800 | Thank you for your comment.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br>The team also identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'. This is an opinion article on the principal findings of the study presented at |

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| | | | patients (predominantly intermediate-high risk) treated with FlowTriever showed a low in-hospital mortality (0.3% at 48 hours) and low complication rates. I believe this data should be considered by NICE in their review of all available data. | a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |
| 33 | Consultee 8<br>NHS professional | 3.1 | In my opinion, the draft guideline in its current form fails to recognise that many patients with massive PE do not actually receive guideline-based therapy with systemic thrombolysis and does not fully include the latest evidence that demonstrates excellent outcomes and a favourable safety profile with large bore aspiration | Thank you for your comment.<br>Recent update searches have identified new publications (Toma 2022, Chandra 2022) and these have been considered by IPAC and included in the overview summary of evidence.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview. |
| 34 | Consultee 9<br>British Society of Interventional Radiology (BSIR) | 3.1 | **Why the committee made these recommendations**<br><br>*'There is enough evidence that the procedure reduces clot burden but not enough evidence of improvement in short- and long-term outcomes. There is also not enough good quality evidence on safety. There is no data from randomised controlled trials and very little evidence of long-term follow up, particularly patient-reported outcomes. Although this procedure is being assessed for massive PE, most of the data is for sub-massive PE'.*<br><br>The Flame study which was presented at the recent American College of Cardiology did show some encouraging results that the committee might want to consider. FLAME was designed to evaluate outcomes in high-risk PE patients treated with large-bore mechanical | Thank you for your comment.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the FLASH registry) were added to the overview.<br>The team also identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME |

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| | | | thrombectomy or other contemporary treatments. This was a prospective, multicenter, non-randomized, parallel group, observational study of high-risk PE. | study'. This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |
| 35 | Consultee 3<br>Inari Medical | 3.4 | While the committee acknowledges that there is more than 1 device and different mechanisms, the draft lumps all devices together. Out of 6 publications, 4 belong to the FlowTriever, and that is not taking into account the new FLAME study results.<br>The FlowTriever is also the only therapy with a mechanism of true large bore aspiration. It is the only therapy that combines aspiration with mechanical thrombectomy. And it is also the only therapy that is lytics free and bloodless.<br>One can only conclude, therefore, that the mechanism of action is fundamentally different for the FlowTriever and has been recognized as such by both the German G-BA and the French HAS in their evaluations to grant it innovation funding (NUB and PECT respectively). | Thank you for your comment.<br>IPAC considered comments about the mechanism of action of the FlowTriever system, variations to consider when evaluating and grouping devices together.<br>The committee made recommendations based on the available evidence, while bearing in mind that it is evaluating the procedure rather than a specific device. The guidance referred to technological developments in section 3.5 as described by the specialist advisers, companies or other sources.<br>In our recent update searches we identified 2 publications: Toma 2022 (the full US cohort of the FLASH registry) and Inci 2023. These studies were added to the overview of evidence, presented to the committee and considered as part of IPAC discussion.<br>Also 2 recent publications related to high-risk PE patients (Silver 2023- FLAME study, Horowitz 2023- sub-study of the |

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| | | | | FLASH registry) were added to the overview.<br>The team also identified a publication (Morrow D 2023) related to the sub-group analysis of the FLASH registry 'the FLAME study'. This is an opinion article on the principal findings of the study presented at a scientific session and not a peer reviewed publication of the study. Therefore, this study is not included in the overview. |
| 36 | Consultee 4<br>NHS professional | General | The current draft guidelines is incompatible with the final paragraph. It also fails to acknowledge than <30% patients with high risk receive systemic thrombolysis (references can be provided) | Thank you for your comment.<br>The committee is aware of this and considered this in their deliberations. |
| 37 | Consultee 5<br>NHS professional | General | Percutaneous thrombectomy is most often performed in large volume PE in intermediate high risk or moderately haemodynamically compromised patients. Shock (ie massive is less common).<br>I think the main worry is large numbers of centers performing low numbers of procedures - rather than a blanket prohibition of registry or clinically driven procedures. Only centres, undertaking interventional research in acute PE, with an established PERT team, undertaking a sufficient number of any given procedure (say 20+ per year), supported by a safety committee review of outcomes and root cause analysis of any serious incident should perform thrombectomy. This would prevent a mushroom effect, but allow the development of expertise, and avoid biasing subsequent RCTs through poor quality interventional expertise. | Thank you for your comment.<br>IPAC considered the comments and additional new evidence and amended the guidance to support the use of this procedure under 'special arrangements' in people with high-risk pulmonary embolism who have limited treatment options (those who are unable to have thrombolysis, and for whom there are no other treatment options or alternative treatments have failed). For all other people with high-risk or intermediate-risk pulmonary embolism, the procedure should be used only in research. See section 1 in the guidance.<br>It is not within the remit of IP programme to make recommendations on the number of |

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| | | | | procedures that should be carried out. It is the role of commissioners of health services to set these types of standards for the hospitals that provide their services. It is recognised that some units will be starting to use a procedure de novo, and that they may not initially be able to do the procedure in substantial numbers. The research and ethics governance framework will oversee safe introduction of the procedure. |
| 38 | Consultee 11<br>NHS patient | | I am writing in relation to a procedure which I understand is currently noted as IPG10243.<br>I had a bowel obstruction removed in March which was found to be cancerous. Four weeks after that operation I suddenly had extreme difficulty breathing and went to A&E at Barnet Hospital where it was discovered blood clots had formed across both my lungs.<br>Following internal consultation with the team at the Royal Free Hospital I was transferred immediately in order to undergo this procedure IPG10243.<br>Whilst my situation was incredibly serious and I understand there were other options for removing the clots, this particular procedure meant my breathing and overall recovery was back to normal within hours rather than days or weeks. I am now back home within 72 hours of arriving in A&E.<br>As such I would ask that this procedure be considered for others so that they too can benefit from the incredible results just as I have. | Thank you for your comment and sharing your experience. IPAC considered your views in their deliberations. |

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| | | | I also have to add that the team at the Royal Free who dealt with me on this procedure should be commended for their excellence throughout the process from consultation to aftercare.<br>By all means please feel free to contact me should you wish to discuss any further details. | |

*"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."*