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National Institute for Health and Care Excellence

IP1700 Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg

IPAC date: 13 December 2018 and 14 March 2019

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
First consultation				
1	Consultee 1 Consultant Radiologist	General	I would like to comment on the above draft guideline. We currently perform mechanical thrombectomy at our centre for acute iliofemoral deep vein thrombosis with the Angiojet system. The vast majority of cases involve patients with significant clot burden in the iliac veins, in line with NICE guidelines. A small number of patients with only femoropopliteal thrombus have had mechanical thrombectomy when there were severe symptoms despite anticoagulation. Even though the overall proportion of patients with post-thrombotic syndrome was similar in the pharmacomechanical thrombolysis (PMT) vs anticoagulation group in the ATTRACT trial, the proportion of patients with moderate to severe post-thrombotic syndrome was lower in the PMT group. I believe his correlates with our current practice of treating patients with significant iliac vein thrombus and severe presenting symptoms despite conservative treatment. All out cases are performed as a day case basis and have facilitated the discharge of patients with large DVTs who would otherwise have to be managed in hospital due to severity of symptoms. I believe the Angiojet thrombectomy is clinically effective and cost efficient treatment option for acute DVT in suitable patients.	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed. Cost effectiveness is not within the remit of the IP programme.

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2	Consultee 2 Consultant Interventional and Diagnostic Radiologist	General	Dear Sir/Madam, I am writing with regard to the above Draft nice recommendations. Our institution uses the angiojet mechanical thrombectomy device for patients with symptomatic ileofemoral DVT, and we are able to perform this as a day case procedure, leading to significant improvement in quality of life for these patients. All patients have a rigorous follow up and cases are selected where there is significant impact from the acute DVT. I strongly feel that this is a good treatment, with good outcomes, and delivers a better quality of life to these patients than oral anticoagulation alone. I am happy to be contacted more about this if needs be.	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed.
3	Consultee 3 Consultant Radiologist	General	I would like to comment on the above draft guidance. The guidance is based on the ATTRACT trial, which does does not reflect current UK practice. In common with other UK centres, we follow current NICE guidance and only intervene in symptomatic ilio-femoral DVT. The ATTRACT trial had a large proportion of cases where DVT that did not extend above the inguinal ligament were treated, this is outside current NICE guidelines and not our current practice. We use the Angiojet device rather than catheter thrombolysis. We perform all our procedures as day cases – the use of the Angiojet allows us to do this, and saves significant costs in terms of inpatient bed stay. Therefore I feel that use of the Angiojet allows us to treat patients in accordance with current NICE guidlelines in an effective and very cost effective way.	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed. Cost-effectiveness is not within the remit of the IP programme.

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4	Consultee 4 NHS Professional	General	I am pleased to hear that NICE have decided to review the role of Mechanical Thrombectomy in treating acute Ilio-Femoral DVT. However, I am disappointed that the document suggested no potential role in long term benefit. I wanted to clarify few points about the use of Mechanical thrombectomy in our institution. We have first acquired Angio-Jet in 2006 and was used successfully for arterial thrombectomy. We were providing CDT for acute and recent onset Ilio-femoral DVT. We knew then that CDT may take 3-4 days to clear venous thrombus with all the risks associated with Bleeding, stroke, long HDU stay etc. . Therefore and considering our success in using angiojet for arterial thrombectomy we have decided in 2009 to started Mechanical thrombectomy for DVT. We have restricted its use for recent onset (less than 2 weeks) DVT with symptoms such as massive swelling or debilitating pain. We have performed nearly 400 treatment for Ilio-femoral DVT eversince. And a recent review of the last 100 patients treated over the last 5 years were prospectively reviewed using Vilalta score and QOL showed more than 50% good response with no PTS and 25% had mild PTS. All those cases were treated using angio-jet and on average 12hrs CDT. They were all discharged home within 48hrs of the procedure. We have had no complications using angio Jet whether for DVT or arterial Thrombectomy. Our review has been written up and in process of submission for a peer reviewed Journal. I quite understand that some people have no faith in mechanical thrombectomy and its benefit on the long term. However, the procedure has great advantage in minimising hospital stay and in some superselective post long haul or pregnancy DVT we have successfully cleared the clot in one	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed. Procedures with a ‘research only’ recommendation may be reassessed when relevant new research is published.

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			session and patients were sent home within 24hrs. The majority of our patients go back to work within a day or two of the procedure. We believe that a national registry is the best way forward rather than a Research. Registry can be easily followed up for a period of 5 years and we can use BSIR platform. It is unfortunate that ATTRACT trial results have mixed peripheral and Iliofemoral DVT together hence the outcome of the trial were not encouraging. Another research is difficult to justify if it is going to be prospective. I hope my comments will help the reviewer to give further consideration to the use of Mechanical thrombectomy and encourage a national registry. Best wishes	
5	Consultee 5 Company BTG PLC	General	A point for clarification is that physicians and budget holders may assume this guidance covers other non-mechanical technologies for DVT, such as Catheter Directed Thrombolysis (IPG-523), especially as IPG-523 was not referred to until page 30 of the consultation document- should this be clarified earlier?	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
6	Consultee 6 Private Sector Professional	Lay box	The brief boxed introduction states, â€œThe aim is to prevent long-term problems such as swelling of the leg and ulceration.â€ Indeed the best rationale to support routine use of percutaneous mechanical thrombectomy (PMT), or any other endovascular DVT treatment strategy, would be if the treatment is shown to prevent the long-term occurrence of the post-thrombotic syndrome (PTS). However, it is important to remember that in actual clinical practice, these procedures are	Thank you for your comment. The lay description has been changed. This comment was discussed by the committee, along with other comments received during consultation, and the

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			often used to achieve reduction of severe, activity-limiting symptoms (pain and/or swelling) in patients with extensive thrombosis, either as part of initial therapy or after an initial course of anticoagulation has failed. Many affected patients are bed-bound because of these symptoms. In addition, reduction in PTS severity is also an important long-term aim of therapy â€“ although this outcome is mentioned in the document, the data on this outcome does not appear to have been factored into the recommendations.	main recommendation was subsequently changed.
7	Consultee 6 Private Sector Professional	General	Regarding the ATTRACT Trial, the NICE evidence review has included the published article describing the main study outcomes (Vedantham S, et al. N Engl J Med 2017). However, it is important for the NICE Committee to be aware that we have completed three important secondary analyses that enable greater insight into when pharmacomechanical catheter-directed thrombolysis (PCDT, which blends catheter-directed thrombolysis and PMT) may offer relevant patient benefits: A. An analysis focused on the 391-patient subgroup who presented with acute iliofemoral DVT (defined as DVT involving the iliac and/or common femoral vein, with or without other involved veins, defined per reporting guidelines of the Society of Interventional Radiology and American Heart Association) was accepted for publication in Circulation on October 25, 2018, and is due to go online any day now. This analysis found that in patients with acute iliofemoral DVT, the use of PCDT did not influence the occurrence of PTS or recurrent venous thromboembolism over 2 years, but that it did significantly reduce early leg symptoms and 2-year PTS severity (findings that were also suggested by the analysis of the overall ATTRACT cohort), and also provided greater improvement in venous disease-specific quality of life (QOL)	Thank you for your comment. Procedures with a ‘research only’ recommendation may be reassessed when relevant new research is published. For A: The subgroup analysis has been added to table 2 of the overview (Comerota AJ et al., 2018). For B and C: The committee does not consider efficacy findings from papers that have not yet been accepted for publication. Once these papers have been accepted and/or published, their findings can be used by the committee.

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			over 2 years. B. An analysis focused on the 300-patient subgroup who presented with acute femoral-popliteal DVT (i.e. that did not extend to the common femoral or iliac vein) is currently under journal review. This analysis found no benefits to the use of PCDT in femoral-popliteal DVT patients. C. Our detailed analysis of health-related QOL is also currently under journal review. We found that: 1) for the entire cohort of patients in ATTRACT, PCDT resulted in greater improvement in health-related QOL during the first 6 months after randomization, but not afterwards, compared with No-PCDT; 2) considering only patients with iliofemoral DVT, PCDT resulted in greater improvement in health-related QOL at all times through 24 months, compared with No-PCDT, with the largest difference being within 6 months after randomization; and 3) considering only patients with femoral-popliteal DVT, PCDT did not improve QOL at any time point.	
8	Consultee 6 Private Sector Professional	1.1	In Section 1.1 of the Draft Recommendations, the Committee acknowledges the suggestion that some people may benefit from PMT, but the wording evinces concern for the level of certainty in understanding which patients may benefit. Please note that: A) in the main ATTRACT paper (entire cohort), patients > 65 years of age appeared to fare worse both for efficacy (for PTS prevention, p-interaction =0.04) and safety (5 of the 6 major bleeds occurred in patients > 65 years old, which is consistent with the age distribution of bleeding in thrombolytic studies of other disease states); and B) in the iliofemoral DVT subgroup paper, we also found a suggestion that any benefits of PCDT upon the occurrence of moderate-to-severe PTS may be less apparent in patients > 65 years old.	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed.

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9	Consultee 6 Private Sector Professional	General	It should be noted that a number of studies suggest that the addition of PMT to catheter-directed thrombolysis shortens treatment time, reduces the needed thrombolytic dose, and may thereby improve safety. Although PCDT in ATTRACT caused more bleeding than anticoagulation alone, the 1.7% major bleeding rate for PCDT recipients (with no fatal or intracranial bleeds) compares favorably to other studies. For example, major bleeding in the CAVENT Trial (Enden T et al, Lancet 2011) evaluating catheter-directed thrombolysis (with no PMT) was 3.2%. As such, while I acknowledge that there is no head-to-head randomized comparison of methods, it seems logical and possible that the addition of PMT can reduce bleeding when catheter-directed thrombolysis is used, which should argue for caution in denying providers the ability to use it for specific patients.	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed.
10	Consultee 6 Private Sector Professional	General	The document acknowledges, but does not consistently clarify, the distinction between using PMT alone, versus using PMT along with a thrombolytic drug. I agree that there is very little published evidence to demonstrate the clinical benefits of using PMT alone (with percutaneous devices) for lower extremity DVT.	Thank you for your comment. The guidance is intended to cover the use of PMT with or without a thrombolytic drug.
11	Consultee 6 Private Sector Professional	General	Collectively, the ATTRACT secondary analyses (when published in the peer-reviewed literature) will offer excellent opportunities to appropriately tailor the use of PMT to patient groups for whom there is no evidence of benefit, while preserving access for the patients who may benefit. Specifically, they point to the strong likelihood of there being substantial benefit to the use of PCDT (a blend of CDT and PMT) in highly symptomatic patients with acute iliofemoral DVT who are less than 65 years of age. It should also be borne in mind that ATTRACT evaluated the first line use of PCDT in initially presenting DVT patients. But the NICE guidelines appear to encompass any use of PMT â€“ including	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed.

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			patients who are continuing to experience severe activity-limiting pain and swelling after initial anticoagulation. This is of major concern â€“ the Committeeâ€™s determination that PMT â€œshould only be used in the context of researchâ€ would leave anticoagulation â€œsymptom non-respondersâ€ without any way to alleviate their pain and swelling to enable them to resume their normal daily activities; but PCDT has now been shown in a high-quality randomized trial to reduce these very symptoms. Considering all the available evidence from our trial and others, a blanket designation of PMT as being â€œfor research only â€ does not seem to serve the best interests of patient care. I commend NICE for, and concur with, its desire to reduce patient harm and costs by avoiding the use of PMT where it does not provide benefit. But I believe NICE can do better in tailoring its recommendations. I suggest that if any hard limitation needs to be applied, that PMT could be considered â€œresearch only â€ for the following patient groups: a) patients with lower extremity DVT that does not involve the common femoral vein, iliac vein, or inferior vena cava; and b) patients who do not have DVT symptoms or activity limitation of at least moderate severity. For patients who do not exhibit signs of acute limb-threatening circulatory compromise, requiring a minimum period of anticoagulation first (e.g. 3-7 days) and discouraging use in patients > 65 years of age could also keep utilization at levels that are justified by the patient need. I urge the Committee to re-consider its position. At a minimum, I respectfully suggest that the Committee may wish to await publication of the above data before finalizing its	

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			recommendations. If I can be of help, I would be happy to engage the Committee further.	
12	Consultee 6 Private Sector Professional	General	I am the National Principal Investigator for the multidisciplinary investigator team that completed the Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis (ATTRACT) Trial (registered at www.clinicaltrials.gov - NCT 00790335). I am speaking on behalf of myself alone - these comments do not reflect the views of the NIH, NHLBI, or others.	Thank you for your comment.
13	Consultee 7 Company Penumbra, Inc	1	DATE: November 21, 2018 RE: IPG10086 - Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg Dear Dr. Clutton-Brock and members of the advisory committee: We thank you for your time and effort spent in reviewing the data regarding mechanical thrombecotmy (MT) in DVT. We also appreciate the opportunity to comment on the current draft recommendations and participate in the upcoming discussion in December. Draft Recommendations Regarding the draft recommendations in section 1, we agree that further research can improve patient selection criteria, and help identify those patients who may benefit most from this procedure. Sub-group analysis of the Attract trial are ongoing and may bring further clarification. We do not agree, though, with the statement that â€œEvidence on efficacy does not show benefit for most peopleâ€□. The largest RCT trial on 692 patients (Attract) with a follow-up of 2 years did for	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed.

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			instance demonstrate that moderate to severe postthrombotic syndrome (PTS), so long term DVT disability, was significantly reduced in those patients receiveing MT. Moderate-to-severe postthrombotic symptoms cause pain, discomfort, diminished quality of life, disabilities, and incapacities and reducing this syndrome represents an important benefit for the patients. The question of safety and efficacy of mechanical thrombectomy appears to have been answered in the literature, as it has been shown that MT for acute deep vein thrombosis, when initiated timely, is safe, allows quick thrombus removal and pain reduction and allows in the long term to reduce moderate to severe PTS. Seen the good safety profile of the mechanical thrombectomy procedures with well recognised but infrequent complications, prospective observational studies, such as a real life registry may be the most appropriate method to answer the remaining questions regarding patient selection. Limiting mechanical thrombectomy for the treatment of DVT to be performed only in â€œresearchâ€ may potentially hinder the development of patient selection criteria and patient benefit. Furthermore, we would expect significant difficulty approving a RCT as the ethics may be questionable because pain relief and restoration of blood flow must be initiated quickly and anticoagulant therapy is not always a good answer for these suffering patients. Patient inclusion in a RCT may in addition be hindered by loss of equipoise following the already published trials. Therefore, we suggest changing the recommendation to â€œSpecial Arrangementsâ€ and propose that a DVT registry be set up with the cooperation of the NHS, professional societies and industry.	
14	Consultee 7 Company	2.4	The Procedure	Thank you for your comment.

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	Penumbra, Inc		In section 2.4 the overall procedure description is adequate; however, MT can also be performed prior to thrombolysis in order to reduce clot burden with the goal of reducing thrombolytic infusion times.	Section 2.4 of the guidance has been changed.
15	Consultee 7 Company Penumbra, Inc	General	Committee Considerations The Evidence We appreciate the extent of the review and criteria for data inclusion. We believe these studies mentioned below, though not considered within the current â€œinterventional procedure overviewâ€ fit within those criteria and should be reviewed: 1.Â Â Â Â Â Â Â Â Cakir, V., Gulcu, A., Akay, E., Capar, A. E., Gencpinar, T., Kucuk, B., Karabay, O. & Goktay, A. Y. Use of Percutaneous Aspiration Thrombectomy vs. Anticoagulation Therapy to Treat Acute Iliofemoral Venous Thrombosis: 1-year Follow-up Results of a Randomised, Clinical Trial.Â Cardiovasc. Intervent. Radiol.Â 37, 969â€“976 (2014). This is a randomized study on 42 patients,comparing percutaneaous aspiration thrombectomy (PAT) (n=21) vs anticoagulation therapy (n=21), published in 2014. It showed better venous patency rates at 12 months for PAT group vs medical treatment group, and significant improvement in clinical symptom scores. In this study, deep venous systems became totally cleared of thrombi in 12 patients treated with PAT. The venous patency rates in month 12 were 57.1 and 4.76% in the interventional and medical treatment groups, respectively. A statistically significant improvement was observed in clinical symptom scores of the interventional group (PAT) with or without stenting (4.23Â Â±Â 0.51 before treatment; 0.81Â Â±Â 0.92 at	Thank you for your comment. Evidence on percutaneous aspiration thrombectomy alone was excluded from the analysis – this is noted in the ‘Issues for consideration by IPAC’ section of the overview.

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			month 12) compared with the medical treatment group (4.00Â Â±Â 0.63 before treatment; 2.43Â Â±Â 0.67 at month 12). During follow-up, four patients in the medical treatment and one in the interventional group developed pulmonary embolisms. Conclusions: For treatment of acute deep vein thrombosis, PAT with or without stenting is superior to anticoagulant therapy alone in terms of both ensuring venous patency and improving clinical symptoms. PAT is a safe, inexpensive, and easily performed method of endovascular treatment Â with a low rate of major complications. Our present findings and literature data suggest that PAT can be used as first-line treatment in proximal deep vein thrombosis patients, especially when thrombolytic treatment is contraindicated.	
16	Consultee 7 Company Penumbra, Inc	General	2.Â Â Â Â Â Â Â Â Wang W,Â Sun R,Â Chen Y,Â Liu C. Meta-analysis and systematic review of percutaneous mechanical thrombectomy for lower extremity deep vein thrombosis.Â J Vasc Surg Venous Lymphat Disord.Â 2018 Nov;6(6):788-800. doi: 10.1016/j.jvsv.2018.08.002. Objective: The objective of this review was to evaluate the efficacy and safety of percutaneous mechanical thrombectomy (PMT) with or without catheter-directed thrombolysis (CDT) in the treatment of lower extremity deep venous thrombosis (DVT). Methods: We searched PubMed for clinical trials and prospective or retrospective case series (comparative or single-arm studies) that focused on PMT +/- CDT in the treatment of DVT, published before March 2, 2017. We meta-analyzed perioperative outcomes and complications and long-term outcomes of this procedure. We also compared the results between PMT +/- CDT and CDT alone, using the data	Thank you for your comment. This article was identified in the updated literature search and has been added to table 2 of the overview and was considered by the committee.

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			from comparative studies. Results: Overall, 1323 PMT +/- CDT patients from 35 studies were included in our study. The rate of patients experiencing successful thrombolysis with a partial or complete lysis rate was 93.4% (95% confidence interval [CI], 90.1%-95.6%) or 67.0% (95% CI, 59.1%-76.4%), respectively. The pooled proportion of 30-day rethrombosis rate was 11.9% (95% CI, 6.7%-20.3%). The 30-day DVT-related mortality was 2.4% (95% CI, 1.6%-3.7%). The perioperative incidence of major bleeding and pulmonary embolism was 4.6% (95% CI, 2.9%-7.3%) and 3.8% (95% CI, 2.5%-6.7%), respectively. During the follow-up, the late rethrombosis rate was 10.7% (95% CI, 8.7%-13.0%; the average follow-up period ranged from 2.8 to 32.1 months). About 15.1% (95% CI, 9.6%-22.9%) of patients developed post-thrombotic syndrome during follow-up (the average followup period varied from 3.8 to 29.6 months). In comparing the results of PMT +/- CDT with CDT alone, six studies were included (195 patients in the PMT +/- CDT group and 193 patients in the CDT group). The partial thrombolysis rate was higher in the PMT +/- CDT group (odds ratio [OR], 2.64; 95% CI, 1.34-5.21; P=.005), whereas the complete lysis rate was not (OR, 1.38; 95% CI, 0.87-2.18; P=.17). The difference between the Villalta scores of the two groups during follow-up had no statistical significance (OR, 0.50; 95% CI, 1.34 to 0.34; P=.24). The thrombolytic drug dose in the PMT +/- CDT group was much lower than that in the CDT group (standard mean difference, 0.98; 95% CI, 1.59 to 0.38; P=.001), and the procedural time was shorter in the PMT +/- CDT group (mean difference, 16.94; 95% CI, 22.38 to 11.50; P < .00,001). There was no significant difference in major bleeding (OR, 1.20; 95% CI, 0.50-2.90; P=.24) or pulmonary embolism (OR, 1.18; 95% CI, 0.16-8.73; P=.87) between the two groups.	

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			Conclusions: PMT with or without CDT is a relatively effective and safe approach for lower extremity DVT patients because of the acceptable incidence of perioperative complications and satisfying short- or long-term outcomes. (J Vasc Surg: Venous and Lym Dis 2018;6:788-800.)	
17	Consultee 7 Company Penumbra, Inc	General	We have also included a discussion by Oâ€™Sullivan, et. al. regarding the issues around the ATTRACT trial referenced in the overview document. The trial has several limitations that are well documented and Drs. Oâ€™Sullivan, de Graf and Black mentioned the following: â€œDespite employing the most experienced physicians and statisticians in the design and execution of this trial, with the benefit of 10â€“15 years of further venous experience, it does suffer from several major methodological issues. This increased experience means that it is imperative that the results of ATTRACT are placed in context of current treatment regimens to ensure that patients who would benefit, continue to receive appropriate treatment, and are not prejudiced by the outcome of this study.â€□ As a manufacturer of thrombectomy devices, we have the unique privilege of interacting with both providers and patients. In so doing, we are often able to see the benefits of our research and work in action for individuals and their families. We have included a brief document discussing individual cases and illustrating the benefits of treating appropriate DVT patients with mechanical thrombectomy. While not a proof source, these case discussions are illustrative of the type of benefits that patients may experience from allowing continued performance of the procedure with current treatment regimens outside the strict setting of â€œresearchâ€□.	Thank you for your comment. Evidence is only included in the overview if it reports clinical outcomes. Editorials and commentaries are not included.

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			Again, thank you for your time and attention and we look forward to continued collaboration regarding this important therapy option for those suffering from this disease. Warm Regards, [redacted]	
18	Consultee 8 Charity Thrombosis UK	General	We thank you for contacting us and inviting us to participate. The consultation document has been circulated to our medical Trustees and also looked over by lay members. At this point we think the item is important, but have no further comment to add.	Thank you for your comment.
19	Consultee 9 Health Professional (NHS)	General	I think that there is a subset of patients who would benefit from the procedure but that we don't really know yet who they are and therefore more research is required here. As with a number of IR procedures the evidence base is thin. In addition the consultation is not broad enough as purely performing mechanical thrombectomy is rarely done, I always perform thrombolysis both during and after the procedure to get an optimum result. In addition venoplasty and stenting is also required or else the long term results are suboptimal and the patient returns with similar symptoms even if vein is 'clear'. I think this is a procedure that can be safely provided in any large DGH as long as you have clinicians with an interest and a team of appropriately trained staff performing the procedure. Timing is important to time of symptom onset ie as quoted <14 days, but at this later time success usually limited. Otherwise can be done once clot organised after 6 months - but that is a different procedure!	Thank you for your comment. The guidance is intended to cover the use of PMT with or without a thrombolytic drug.

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			I have experience in using the Angiojet device and Cragg-Mcnamara infusion catheters. Have tried using other devices with limited success.	
20	Consultee 10 Specialist society BSIR	General	BSIR RESPONSE TO NICE GUIDELINES IN DEVELOPMENT FOR Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg. The British Society of Interventional Radiologists represents interventional radiologists/image guided surgeons throughout the UK. We have asked our members to submit comments to us on your proposed guidance and would like to make the following points. Mechanical thrombectomy for DVT has been performed in this country for many years and is considered standard care in many centres for patients with limb threat as a result of DVT. We are alarmed that it may be considered only for use in the context of research. The guidance states that there are well recognised but infrequent complications and that the evidence of efficacy does not show benefit in most people. This is not true in our experience and certainly not true in the context of iliac or arm DVT. Having discussed the options, and the limitations, many patients choose thrombectomy over anticoagulation or catheter directed lysis only. Mechanical thrombectomy offers advantages over CDT: 1. Quicker mode of action, CDT may be too slow in a severely threatened limb 2. Minimised and very low risk of haemorrhage 3. More rapid mobilisation and therefore recovery	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed. The IP guidance only covers acute DVT of the leg.

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			4. Less drain on resources in particular less need for critical care facilities. We accept that more data needs to be gathered on the safety and efficacy of this technique and we would strongly urge NICE to consider proceeding in this manner with a national registry with recording of all cases and outcome data. The BSIR has made initial enquiries with our industry partners who would be able to provide financial support to set up and run this registry. The data would be owned by and interrogated by BSIR independent of outside influence, and we would welcome engagement with NICE as to the relevant dataset. BSIR would be happy to share outcome measures and patient experiences with NICE. Mechanical thrombectomy is a valuable treatment for patients with acute DVT and threatened limbs and should continue to be available to clinicians. The entry of cases into a registry will allow gathering of valuable data on outcome and complications. The procedure could continue to be performed under the â€˜special arrangementsâ€™ designation. Yours sincerely	
21	Consultee 11 Consultant Interventional Radiologist	General	Dear NICE advisory board, I am writing to you as a vascular specialist. I have been involved in the vascular arena since 1993. I trained as a Radiologist in Derriford Hospital, Plymouth, followed by St. George's Hospital, London. I obtained my CCST-UK in 1998; I	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the

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			then did a year as fellow in Vascular and Interventional Radiology in Stanford University, California; followed by 3.5 years as a consultant in Rush-Presbyterian St. Lukes Medical Centre, Chicago, IL. I performed a locum in IR in Lewisham Hospital for 6 months in 2002, before returning to Galway, Ireland where I have been a Consultant in Interventional Radiology since 2002. It is fair to say that I have a broad experience of different healthcare systems, and extensive experience in vascular disease. While in Stanford I was exposed to the concept of thrombus removal for acute deep vein thrombosis. Up until then my experience had been almost exclusively arterial. I learned that certain patients with DVT suffered greatly in the acute phase, and equally many did not. I soon realised that the more proximal the DVT, typically the more serious the outcome. It also rapidly became apparent that this was an undertreated problem as people would attend Stanford from all over the world with serious post thrombotic syndrome. Many of these people were highly intelligent, and had been assiduous not only in taking their anticoagulation but also in wearing their compression stockings. Despite adhering to “best medical practice” they had developed venous leg ulceration and their lives were hugely affected by this. I was impressed by the Stanford attitude to attempt to do something to help. Prior to my arrival they had published their experience with catheter directed thrombolysis for acute deep vein thrombosis and while in Stanford, the results of the venous registry came out, showing clearly superior results in terms of venous patency in those patients with ilio-femoral DVT than those with infra-inguinal DVT. Since then I have spent more and more time performing deep venous intervention; Galway is one the “reference sites” for	main recommendation was subsequently changed. Cost-effectiveness is not within the remit of the IP programme. Evidence is only included in the overview if it reports clinical outcomes. Editorials and commentaries are not included. Because of the large evidence base, case series with fewer than 30 patients and case reports were excluded from the overview, unless they reported a unique safety event. This is noted in the appendix of the overview. Reference 1 refers to the use of catheter-directed thrombolysis, which is not within the remit of this guidance. Reference 2 was not included in the overview because it is a case series of 19 patients. Reference 3 is a review, which has been added to the appendix of the overview.

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			deep venous work in Europe. I have learned a great deal in the last 20 years. Most physicians still think that thrombolysis is given systemically as per the GUSTO trial for acute myocardial infarction. They only vaguely grasp that catheter directed thrombolysis concentrates the thrombolytic agent to the thrombosed area, and has much higher rates of success in terms of thrombus removal, with much lower rates of significant bleeding. And if there is some missing knowledge surrounding thrombolysis, there is profound ignorance concerning percutaneous mechanical thrombectomy for acute deep vein thrombosis. My personal deep venous experience initially was based on the Stanford practice employing catheter directed thrombolysis for acute deep vein thrombosis. We published this in 2000 - Endovascular management of Iliac Vein Compression Syndrome (1). We learnt that the combination of catheter directed thrombolysis followed by stent placement worked well in patients with acute ilio-femoral DVT. One case made a significant impression on me. A 45 year old nurse working in Stanford developed an acute massive left leg DVT and presented to us; she underwent standard catheter directed thrombolysis over 48 hours. Her leg improved markedly, but her fibrinogen fell to an almost undetectable level on the second morning- it was pure luck that she did not have a major bleed. Ultimately, she did well. This impressed upon me that Catheter Directed Thrombolysis did work very well, but did have significant risks. Over the next few years we searched for a device which could remove the thrombus but not expose the patient to the risks of catheter directed thrombolysis- hence percutaneous mechanical thrombectomy. Ultimately, we published this in	Reference 4 was not included because it is a case series of 4 patients. Reference 5 refers to the use of thrombolysis and stent insertion.

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			2007 (2) using the Trellis catheter (sadly no longer commercially available). We continued to detail our experience in 2011 publishing a "how to" review in CVIR (3); a description of percutaneous mechanical thrombectomy in superior vena cava syndrome in the same year (4), and later elaborated on the successful treatment of cancer patients who also develop DVT (5) (2015), The purpose of listing these publications is not intended as some sort of ego trip, but merely to underline the fact that we have been performing percutaneous mechanical venous thrombectomy with increasing precision for well over 10 years. It is absolutely NOT a research project- it is what we use on a daily basis as our go to method for treatment of venous thrombosis- and we have a high rate of success. Currently we perform perhaps 3 deep venous interventions per week, and percutaneous mechanical thrombectomy forms the mainstay of our work for acute deep vein thrombosis. It has been fairly well demonstrated that PMT works as well as CDT, but at a much lower rate of bleeding. There are also considerable savings in terms of the need for HDU beds, blood tests, recurrent venograms and overall length of stay in hospital (2). We embarrassingly never got around to publishing our economic analysis of the cost benefit of PMT but I have included the file in this submission. Nowadays, with the array of devices available, it is rare for our unit to actually perform CDT; we achieve success in acute ilio-femoral deep vein thrombosis (which we define as confirmed open vein with rapid in line flow up to the IVC) using PMT alone in over 90% of cases, and there is a very low risk of bleeding. In our experience the advantages of PMT over CDT include:	

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			1-Speed of action: particularly when the leg is threatened in acute phlegmasia dolens; I have had several cases where amputation was unequivocally averted with PMT; CDT would have simply been too slow. 2-more efficient use of resources- less trips to the vascular suite for check venography; less blood tests, no need of HDU beds- this latter is critical when assessing the true costs of a PMT device- typically the cost of the device is less than one day in HDU, and typically a CDT case takes two to three days in HDU- so usually the "real" cost of a PMT procedure is less than a CDT case. This was the case when we measured it in 2007- PMT costs about half what CDT costs. 3_ more rapid recovery- thrombus removal followed by balloon dilatation and stent formation means the patient can mobilise within hours and not days. Patients are discharged more quickly, easing pressure on beds 4_ increasingly we perform this a a scheduled day case procedure using similar resources to many surgical procedures such as varicose vein treatment Finally, I am attaching a critique of the recently published ATTRACT trial- we published this review just a few months ago and I have modified it slightly but the end message is the same- the ATTRACT trial does not reflect current best practise in Europe and should not be used as a measure of what successful thrombus removal means in 2018. Sincerely, References: 1. Endovascular Management of Iliac Vein (May Thurner) Compression Syndrome. O'Sullivan et al. JVIR 2000, 11:823-836	

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			2. Pharmaco-Mechanical Thrombectomy of Acute Deep Vein Thrombosis using the Trellis-8 Isolated Thrombolysis Catheter. O'Sullivan et al. JVIR 2007, 18, 715-724 3. The Role of Interventional Radiology in the Management of Deep Vein Thrombosis. O'Sullivan et al. **Cardiovasc Intervent Radiol.** 2011 Jun;34(3):445-61 4. Isolated Pharmacomechanical Thrombolysis Plus Primary Stenting in a Single Procedure to Treat Acute Thrombotic Superior Vena Cava Syndrome. O'Sullivan et al. **J Endovasc Ther.** 2010 Feb;17(1):115-23. 5. Thrombolysis and iliofemoral vein stent placement in cancer patients with lower extremity swelling attributed to lymphedema. O'Sullivan et al. J Vasc Interv Radiol. 2015 Jan;26(1):39-45.	
22	Consultee 12 Professor of Radiology & Consultant in Interventional Radiology	General	Please find enclosed my comments on the are NICE documentation. I think it is premature at the minute to make this a research only intervention. The attract trial included too many of the wrong patients i.e. Infrainguinal DVT. The Cavent trail included only Iliofemoral Dvt and was positive out to 5 years. The Dutch CAVA trial us due to report this year or early next year. WE perform PMT routinely on Iliofem DVT patients.	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed. The CAVA trial is 'Ultrasound Accelerated Catheter-directed Thrombolysis for Primary Iliofemoral Deep Vein Thrombosis (IFDVT) Compared to Non-invasive Conventional Anticoagulant Therapy Alone: a Dutch Randomized Controlled Multicenter Clinical Trial.'

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				Ultrasound accelerated catheter-directed thrombolysis is not within the remit of this guidance.
23	Consultee 13 Company Boston Scientific	General	The overview document of IP1700 highlighted that the committee's decision was primarily driven by the ATTRACT trial results. We would like to highlight some key evidence and shared clinical observations, why this study should not be the key driver of your decision as a whole but you should focus instead on the ATTRACT Iliofemoral DVT subgroup analysis presented in our comments under new evidence to support iliofemoral DVT.	Thank you for your comment. The committee considered detailed review of the evidence from 14 sources, which included 2 randomised controlled trials (1 of which also had a subgroup analysis), 1 systematic review, 2 registries, 3 non-randomised comparative studies, 4 case reports and a review on acute kidney injury that was reported as a conference abstract only. They also considered additional evidence that was included in the overview and advice from specialists.
24	Consultee 13 Company Boston Scientific	General	Inconsistency of the NICE process We would like to highlight that the IPG committee has been inconsistent in the decision to apply 'research only' to this draft guidance, compared to previous decisions in this specific area of care and based on the level of evidence available. Currently in the NICE guidance on Deep Venous Thrombosis there are two approved interventional treatment options for iliofemoral DVT (IFDVT). In the Thrombolytic therapy section of the main guideline (CG144) 1. Catheter-Directed Thrombolytic therapy (CDT) can be considered for patients with symptomatic iliofemoral DVT who have: • symptoms of less than 14 days' duration and • good functional status and • a life expectancy of 1 year or more and	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed. The guidance is intended to cover the use of PMT with or without a thrombolytic drug. Jenkins at al. 2014 Deep Venous Thrombosis: An Interventionalist Approach. Ochsner Journal Winter

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			• a low risk of bleeding. CDT refers to - intra-thrombus delivery of a thrombolytic drug via slow infusion through a traditional multi-sidehole infusion catheter (Vedantham 2016) 2. Ultrasound‑enhanced, catheter‑directed thrombolysis (UE -CDT) • A second treatment option in the form of Ultrasound‑enhanced, catheter‑directed thrombolysis for deep vein thrombosis was approved with special arrangement in Interventional procedures guidance [IPG523] in 2015 UE-CDT refers to intra-thrombus delivery of a thrombolytic drug via an ultrasound-emitting infusion catheter. Mechanical and drug component (Vedantham 2016) A third category which is currently not reflected in NICE guidance is Pharmacomechanical Catheter Directed thrombolysis/Thrombectomy (PCDT/PMT). PCDT/PMT is capable of intra-thrombus delivery of a thrombolytic drug by bolus drug delivery and dispersion through a catheter-based drug delivery device, along with thrombus fragmentation and removal. PCDT/PMT features a Mechanical and a drug component (Jaff 2011, Khan 2014, Vedantham 2016). Both UE-CDT and PCDT/PMT have been described by different NICE committee as variants of CDT. Please note that the acronyms PCDT/PMT are often used interchangeably in the literature and are used together in this document for clarity. PCDT/PMT is a well-represented and accepted in the international society guidelines in the treatment of iliofemoral DVT which we have summarised below: PCDT/PMT is preferred over CDT	14(4):633-640 – this article is a review that has been added to the appendix of the overview. Kahn SR, et al. Circulation. 2014 130(18):1636-61 – this is a scientific statement from the American Heart Association. It recommends ‘CDT and PCDT, in experienced centers, may be considered in select patients with acute (≤14 days) symptomatic, extensive proximal DVT who have good functional capacity, ≥1-year life expectancy, and low expected bleeding risk (Class IIb; Level of Evidence B).’ Jaff MR, et al. Circulation. 2011;123:1788–1830 – this is a scientific statement from the American Heart Association. More recent guidelines from the Society for Vascular Surgery and the American Venous Forum are included in the overview. Vedantham S, et al. J Thromb Thrombolysis (2016) 41:68–80 – this is a review. A more recent review by the same author is included in the appendix of the overview.

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			- (International Union of Angiology [IUA], Society for Vascular Surgery/, American Venous Forum, [SVS/AVF]) In acute iliofemoral DVT CDT/PCDT/PMT – no preference - Society of Interventional Radiology (SIR) in Symptomatic iliofemoral DVT, select patients with femoral DVT - European Society of Cardiology (ESC) in Selected patients with iliofemoral DVT, symptoms <14 d, life expectancy >1 year Society for Vascular Surgery/, American Venous Forum – no preference - Society of Interventional Radiology (SVS/AVF, SIR) in Limb-threatening venous ischemia due to iliofemoral deep venous thrombosis - American Heart Association (AHA) in Select patients with acute, symptomatic, extensive proximal DVT and low expected bleeding risk Stand-alone Percutaneous Mechanical Thrombectomy (MT) without utilizing thrombolytic drugs is not recommended by the International Union of Angiology (IUA), the European Society of Cardiology (ESC). We are aware that addressing clinical pathways is outside the scope of the IPAC, but in August 2018 an exceptional review of the main guideline was undertaken. The stimulus for the review was cited as the publication of the ATTRACT study. The review concluded that no new evidence was found that affected the recommendations of this guideline. As a result, the guideline remains unchanged for CDT. In light of this highlighted evidence we would respectfully ask NICE to highlight PCDT/PMT as a distinct category with proven advantages for the iliofemoral sub-population. We are highlighting the IF DVT sub-population, since proximal DVT	ESC- Mazzolai L, et al. Eur Heart J. 2017 Feb 17 is a joint consensus document from the European society of cardiology working groups of aorta and peripheral vascular diseases and pulmonary circulation and right ventricular function. It states that 'Primary acute DVT stenting or mechanical thrombus removal alone are not recommended.' Nicolaides AN, et al. International Union of Angiology (IUA). Volume 32, No 2. CDER Trust, London, UK. April 2013 states 'Early thrombus removal using CDT (level of evidence: low) or pharmacomechanical thrombolysis (level of evidence: low) may be used in expert centers in selected patients with iliofemoral DVT.' Vedantham S, et al. J Vasc Interv Radiol. 2014;25(9):1317-25 is included in the appendix of the overview. Meissner MH, et al. J Vasc Surg. 2012;55(5):1449-62 is included in the 'Existing assessments of the procedure' section of the overview.

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			involving the common femoral and/or iliac veins, referred to as iliofemoral DVT (IFDVT), represents a disease process with a worse prognosis and higher risk for poor clinical outcomes compared to DVT not involving the common femoral or iliac draining veins. Data available for this sub-population shows that early intervention with these technologies improves clinical outcomes and quality of life. Jenkins at al. 2014 Deep Venous Thrombosis: An Interventionalist Approach. Ochsner J. 2014 Winter 14(4):633-640 We would respectfully ask the committee to consider the above inconsistencies in the comparison with regard to the ileo-femoral subpopulation treated with PCDT/PMT and ask that it be moved out of research only arrangement to an improved category. References - Kahn SR, et al. Circulation. 2014 130(18):1636-61 - Jaff MR, et al. Circulation. 2011;123:1788–1830. - Vedantham S, et al. J Thromb Thrombolysis (2016) 41:68–80 AHA- Kahn SR, et al. Circulation. 2014 130(18):1636-61. ESC- Mazzolai L, et al. Eur Heart J. 2017 Feb 17. IUA- Nicolaides AN, et al. International Union of Angiology (IUA). Volume 32, No 2. CDER Trust, London, UK. April 2013. SIR- Vedantham S, et al. J Vasc Interv Radiol. 2014;25(9):1317-25. SVS/AVF- Meissner MH, et al. J Vasc Surg. 2012;55(5):1449-62. Societal acronyms: AHA, American Heart Association; AVF, American Venous Forum; ESC, European Society of Cardiology; IUA,	

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			International Union of Angiology; SIR, Society of Interventional Radiology; SVS, Society for Vascular Surgery	
25	Consultee 13 Company Boston Scientific	General	New evidence to support IFDVT The sub-group analysis for the ATTRACT trial is due for publication in Circulation. (Comerota et al 2018, Endovascular Thrombus Removal for Acute Iliofemoral Deep Vein Thrombosis: Analysis from a stratified multicentre randomised trial, Circulation). We would respectfully ask NICE to include this latest data set that will demonstrate benefits to the IFDVT and strengthens the case for the request for an improved level of guidance for the ilio-femoral sub-population treated with PCDT/PMT. In light of the committee's request for further evidence in this highlighted population, we respectfully request that NICE delays the process for the 2-3 weeks that will see the publication of this study, to ensure that patients in the sub-population that this treatment benefits are not disadvantaged. This subgroup analysis of the ATTRACT study incorporates 391 iliofemoral DVT patients randomised to PCDT/PMT or anticoagulation alone showed that PCDT/PMT resulted in significant • Reduction of any PTS at 2 years using VCSS • Reduction of moderate/severe PTS at 2 years • Reduction of severe PTS at 2 years • Reduction of pain and swelling at 10 and 30 days • Improvement in disease specific quality of life at 2 years The primary endpoint of ATTRACT was reduction of PTS at 2 years. The secondary and safety endpoints were: • the resolution of acute DVT symptoms; rates of major bleeding, symptomatic PE, recurrent venous	Thank you for your comment. The subgroup analysis has now been published and has been included in table 2 of the overview. Lin et al. (2006) is included in table 2 of the overview. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed.

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			thromboembolism, and death; venous disease-specific and general QOL; and cost-effectiveness; • To identify pre-treatment predictors of heightened therapeutic response to PCDT/PMT via correlation of PTS scores and QOL change scores with demographic variables, DVT risk factors, symptom duration, and anatomic thrombus extent; and to determine the anatomic/physiologic conditions needed to prevent PTS via correlation of PTS scores and QOL change scores with post-treatment thrombus burden, recurrent DVT, and valvular reflux As previously mentioned in point 1 above, NICE Guideline CG144 distinguishes the patient population with symptomatic ilio-femoral DVT and recommends CDT for these patients. The 5-year follow up data for the CAVENT study further solidifies the fact that the ilio-femoral population benefits from such endovascular procedures. It demonstrated that additional catheter-directed thrombolysis resulted in a persistent and increased clinical benefit during follow-up for up to 5 years. The option that is left for these patients is anticoagulation that makes them worse off. The TORPEDO trial included in your review demonstrated this. (Sharifi et al Catheter Cardiovasc Interv. 2010). In addition PCDT/PMT has superior outcomes when compared directly to CDT as highlighted in Lin 2006, Catheter-direct thrombolysis versus pharmacomechanical thrombectomy for treatment of symptomatic lower extremity deep venous thrombosis (Peter H. Lin, M.D, et al The American Journal of Surgery 192 (2006) 782–788 https://doi.org/10.1016/j.amjsurg.2006.08.045)	
26	Consultee 13 Company Boston Scientific	General	Excluded sub-population Evidence Three studies that demonstrated relevant clinical outcomes in IFDVT, were excluded from your review because of the	Thank you for your comment.

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			inclusion of ATTRACT, that had a larger patient number. To the committee's own account ATTRACT had significant failings, that should not be used to determine clinical practice. • the ATTRACT study treatment arm was not randomised or powered to differentiate between CDT and PCDT/PMT, so any drawn conclusions should apply equally to CDT and to PCDT/PMT. • 42 patients were screened for every one patient enrolled, indicating potentially significant selection bias • The study randomised 692 patients at 56 sites over a period of 10 years, resulting in an average randomisation rate of 1.2 pts per site per year, with many of the sites randomising significantly fewer than 1 patient per year. • The stenting rate was far lower than current practice that would be seen in the iliofemoral population. • The devices used were older generation technology no longer on the market. • Vessel patency status was not established. We would like to highlight the review of the following article, that clearly concludes that the ATTRACT study was designed to fail and should not be used to disadvantage the iliofemoral DVT patient sub-population which currently benefit from this treatment, as does the healthcare system. • Black et al, How Attractive is ATTRACT, Cardiovasc Intervent Radiol 2018 doi: 10.1007/s00270-018-2016-y These 3 studies demonstrated that Angiojet PCDT/PMT was comparable or better than CDT in treating the IFDVT. The first two studies are non-randomized comparative studies, comparing Angiojet PCDT/PMT vs CDT, that include more than 30 patients, and show less severe PTS and lower risk of PTS at 1 and 2 years. The third is a very recent series of 68 pts followed to 1 year.	The committee considered detailed review of the evidence from 14 sources, which included 2 randomised controlled trials (1 of which also had a subgroup analysis), 1 systematic review, 2 registries, 3 non-randomised comparative studies, 4 case reports and a review on acute kidney injury that was reported as a conference abstract only. They also considered additional evidence that was included in the overview and advice from specialists. Opinion articles are not usually selected for inclusion in the overview. The evidence base varies between procedures and different limits may be used for inclusion criteria, to keep the number of papers manageable. The 3 studies cited were not excluded; they are included in the appendix of the overview. The aim of the appendix is to present the overall picture of evidence on the procedure and to allow all relevant studies to be listed without making the overview excessively large.

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			As in IPG523, the BERNUTIFUL trial of only 48 patients was deemed relevant to be included in the study selections and the guidance allocated was special arrangements. In this randomized controlled clinical trial of patients with acute iliofemoral deep vein thrombosis treated with a fixed-dose catheter thrombolysis regimen, the addition of intravascular ultrasound did not facilitate thrombus resolution. 5 out of 7 patients in the treatment group and 9 out of 11 patients in the control group that required a bailout procedure received Angiojet (PCDT/PMT) to achieve resolution. This further highlight that Angiojet (PCDT/PMT) in the ilio-femoral sub-population, should receive an improved level of guidance above research only. Further we would respectfully ask you to re-consider the evidence from the 3 mentioned studies in the table below, since they examined similar patient numbers, device and population, when allocating the level of guidance to be considered for the ilio-femoral population.	
27	Consultee 13 Company Boston Scientific	General	Kuo TT, Huang CY, Hsu C P et al. (2017) Catheter-directed thrombolysis and pharmacomechanical thrombectomy improve midterm outcome in acute iliofemoral deep vein thrombosis. Journal of the Chinese Medical Association: JCMA 80: 72–9 — Non-randomised comparative study, n=61, FU=2 years — CDT and PMT have similar venous outcomes in patients with acute iliofemoral DVT, although post-thrombotic syndrome is less severe following PMT than after CDT. Huang CY, Hsu HL, Kuo TT et al. (2015) Percutaneous pharmacomechanical thrombectomy offers lower risk of post-thrombotic syndrome than catheter-directed thrombolysis in patients with acute deep vein thrombosis of the lower limb. Annals of Vascular Surgery 29: 995-1002 — Non-randomised comparative study, n=39, FU=1 year — Both PMT and CDT are effective treatment modalities in patients with acute proximal DVT. Compared with CDT, PMT provides similar treatment success, but with lower risk of PTS at 1-year follow-up. Mert Dumantepe, Ibrahim Uyar, Phlebology 2018, The effect of Angiojet rheolytic thrombectomy in the endovascular treatment of lower extremity deep venous thrombosis. Vol. 33(6) 388–396 — Case series, n=68, FU=1 year — PMT with or without stenting is superior to anticoagulant therapy alone in terms of both ensuring venous patency and improving clinical symptoms. This technique is a safe, effective and easily performed method of endovascular treatment with a low rate of major treatment complications and shows promising clinical midterm results..	Thank you for your comment. These 3 studies are included in the appendix of the overview.
28	Consultee 13 Company Boston Scientific	General	This recommendation will be a challenging change in practice because PCDT/PMT is routinely used in UK clinical practice for the ileo-femoral DVT. In fact, UK clinicians use PCDT/PMT as 1st line treatment over CDT in this population due to the improved outcomes and immediate symptomatic relief they have observed in their practice. In comparison to patients	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the

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			treated with CDT, patients do not go to HDU or ITU post procedure, treatment time and recovery time is faster. CDT was introduced to overcome the limitations of systemic thrombolysis and the invasiveness of surgical thrombectomy (Khan 2014). PCDT/PMT is an evolution of CDT. It is widely used in clinical practice as it likely to reduce treatment time and thrombolytic dose. Dopheide and his colleagues from Bern describe the advantages of PCDT/PMT using the AJ Zelante cathether perform thrombus removal and provisional stent placement in a single session, without the need for prolonged CDT, admission to the intermediate care unit or second look venography. In contrast, CDT always requires a staged intervention with catheter placement, prolonged CDT in a monitored unit, and second or third look venography with provisional stent placement. Dopheide JF, et al.Vasa. 2018 Jan;47(1):56-62. Research only will put patients at a disadvantage for this sub-population.	main recommendation was subsequently changed. Dopheide JF, et al.Vasa. 2018 Jan;47(1):56-62 is included in the appendix of the overview.
29	Consultee 13 Company Boston Scientific	General	New evidence We would like to respectfully ask NICE to review a recent meta-analysis that was published in J Vasc Surg in November 2018: “Venous and Lym Disease: Wang et al 2018, Meta-analysis and systematic review of percutaneous mechanical thrombectomy (MT) for lower extremity DVT”. This study is the first meta-analysis to report the results of Percutaneous MT for the management of lower extremity DVT, including with or without CDT. Percutaneous MT (with or without CDT) was demonstrated to be an effective and safe alternative therapy for DVT: satisfactory lysis rates, low thrombosis recurrence rates, rare severe perioperative complications, and good long-term result with low incidence of PTS. It also shows the results for comparison between the treatment by Percutaneous MT +/-	Thank you for your comment. This article was identified in the updated literature search and has been added to table 2 of the overview and was considered by the committee.

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			CDT and CDT alone. Percutaneous MT +/- CDT presents better efficacy of thrombus removal with a much lower dosage of thrombolytic drugs and shorter procedural time, and the treatment could prevent PTS just as CDT does. doi: 10.1016/j.jvsv.2018.08.002	
30	Consultee 14 Interventional Radiology Department, Guys & St Thomas' NHS Foundation Trust	General	I am a Consultant Interventional Radiologist and member of the multidisciplinary (Vascular Surgery, IR, Haematology) venous team at St Thomasâ€™ Hospital. As a team, we perform a large proportion of all the deep venous interventional procedures carried out in the UK, including thrombectomy of acute iliofemoral deep venous thrombosis (DVT) and treatment of chronic iliac/caval occlusions in patients with post-thrombotic syndrome (PTS). The majority of the acute iliofemoral DVT treatment is performed in the IR department, and we therefore feel well-placed to comment on this draft guidance and raise our concerns regarding its potential effect on individual patient experiences and outcomes as well as the health economics of thrombotic disease in this country. Our first concern regards the scope of this guidance and how this may have brought bias into the analysis of the published evidence. Although section 3.4 states that the mechanical thrombectomy procedure is used to remove clots from leg veins that are above the knee, the title of the guidance simply states â€œâ€¦for acute deep vein thrombosis of the legâ€□, and the primary RCT referenced (the ATTRACT study) recruited patients with both iliofemoral and femoropopliteal DVT. This goes against currently accepted practice of only offering thrombolysis for iliofemoral DVT (as stated in the American Venous Forum guidelines), and therefore the pooled outcomes from this trial cannot be taken as representative for treatment of iliofemoral DVT alone. As NICE guidance CG144	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed.

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			clearly states, catheter-directed thrombolytic therapy should be reserved for patients with iliofemoral DVT, and we believe this indication alone should also be specified in the draft mechanical thrombectomy guidance, thus altering the prism through which the ATTRACT data is examined.	
31	Consultee 14 Interventional Radiology Department, Guys & St Thomas' NHS Foundation Trust	General	We would also like to point out that the long-term success of any treatment incorporating mechanical thrombectomy depends not only on the characteristics of the device employed, but also on the way in which any vein compression syndrome and/or thrombophilia underlying the presenting DVT is managed (with stenting and effective anticoagulation respectively). To take ATTRACT as an example, only 28% of patients in the pharmacomechanical thrombectomy group received a stent. Whilst the inclusion of femoropopliteal DVT (43% of the ATTRACT cohort) will have somewhat reduced the number of ATTRACT patients requiring stenting (as there is currently no durable stent solution for diseased veins below the common femoral vein), in our experience we have found that the vast majority (>90%) of patients with iliofemoral DVT have an underlying compression syndrome (usually May-Thurner) and therefore will require a stent to secure the long-term patency of their iliac veins following mechanical thrombectomy. Therefore, a large portion of the ATTRACT cohort were sub-optimally treated, and their outcome data again thus cannot be considered representative of more modern treatment protocols.	Thank you for your comment. This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed.
32	Consultee 14 Interventional Radiology Department, Guys & St Thomas' NHS Foundation Trust	General	As regards modern treatment protocols, we have developed our method for management of acute iliofemoral DVT at St Thomasâ€™ over several years by rigorously analysing our data to find areas where we can improve on both clinical outcomes and patient experience. At the British Society of Interventional Radiology (BSIR) 2018 annual scientific meeting we presented a comparison of our patients treated with catheter-directed thrombolysis (CDT) alone with those treated	Thank you for your comment. Cost-effectiveness is not within the remit of the IP programme.

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			with mechanical thrombectomy using AngioJet devices with or without adjunctive CDT. As expected, use of AngioJet devices resulted in significant reductions in the mean time that patients remained on CDT (from 53 hours in those who had CDT alone down to 26.6 hours in those who had AngioJet treatment on the first day) and dose of lytic drug they received (from 56.7 mg of rtPA down to 42.1 mg â€“ 20 mg of which is mostly re-aspirated during mechanical thrombectomy with the AngioJet devices). This has obvious financial benefits, as most institutions in the UK require patients to be monitored in a high-dependency unit whilst on thrombolytic infusion (costing upwards of Â£1000 per day), and with a 20 mg vial of rtPA costing around Â£180 (referencing current pricing in the British National Formulary). Furthermore, being on a thrombolytic infusion is an unpleasant experience for many patients (due to common symptoms such as pain in the limb being lysed, contact bleeding/bruising, haematuria/per-vaginal bleeding â€“ which get worse the longer they remain on CDT). Interestingly however, we also noticed an improvement in patency of patients' iliac stents following AngioJet mechanical thrombectomy on day 1, to the extent that this cohort of our series have a primary-assisted patency of 100% out to 2 years following treatment of their iliofemoral DVT. Therefore, we believe that early mechanical thrombectomy in iliofemoral DVT not only affords a reduction in cost and improvement in patient experience over CDT, but also results in at least a medium-term gain in patency of stents placed to treat iliac vein compression syndromes, thus reducing incidence of PTS in these patients, which is the eventual goal of all acute DVT treatment.	
33	Consultee 14 Interventional Radiology Department,	General	Whilst we agree that there needs to be further research in this area to produce more refined data on iliofemoral DVT outcomes with mechanical thrombectomy (and there are indeed a number of trials currently ongoing worldwide to	Thank you for your comment.

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	Guys & St Thomas' NHS Foundation Trust		demonstrate the outcomes achievable with modern thrombectomy protocols similar to the St Thomasâ€™ method of early AngioJet with the option of 1 day of adjunctive CDT described above) the exclusion of mechanical thrombectomy from UK physiciansâ€™ armoury at this early stage will directly impact the care of hundreds of patients every year, both in patient experience, cost to the health service and long-term socioeconomic effects of increased number of patients who go on to develop PTS after iliofemoral DVT. Accepting that interventional treatment of DVT is still in its relative infancy, we would be delighted to meet with the panel to share data from our extensive experience of using mechanical thrombectomy in the treatment of iliofemoral DVT, as we believe we have a responsibility to our patients not to be guided by data from inadequately-designed studies using techniques approaching obsolescence, which would prevent us from offering them the most modern and effective treatment for their condition available today.	This comment was discussed by the committee, along with other comments received during consultation, and the main recommendation was subsequently changed. Procedures with a 'research only' recommendation may be reassessed when relevant new research is published. Cost-effectiveness is not within the remit of the IP programme.
Second consultation				
1	Consultee 1 Company Straub Medical	2.3	The treatment with unfractionated or low molecular weight heparin, followed by oral anticoagulants (usually warfarin) should be regarded rather as prevention of DVT proliferation instead of a clot removal.	Thank you for your comment. Section 2.3 of the draft guidance states: 'A DVT is usually treated with unfractionated or low molecular weight heparin, followed by oral anticoagulants (usually warfarin).' It does not state that this is for clot removal.
2	Consultee 1 Company Straub Medical	**2.4**	Percutaneous mechanical thrombectomy for acute DVT of the leg can be done together with direct infusion of a thrombolytic drug into the thrombus. However, It can be done by itself, too,	Thank you for your comment.

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			if purely mechanical thrombectomy devices are used. Pure mechanical thrombectomy avoids the risks of complications of thrombolytic drug therapy hence it should be considered as an treatment option on case by case basis if a clinical rationale exist. Following references can be evoked in that respect: 1. Berkan Ozpak, Gokhan Ilhan, Barcin Ozcem, Hakan Kara. Our Short-Term Results with Percutaneous Mechanical Thrombectomy for Treatment of Acute Deep Vein Thrombosis. Thoracic Cardiovasc Surg 2016;64:316-322. 2.https://linc2019.cncptdlx.com/media/1050_Michael_Lichtenberg_24_01_2019_Room_1_-_Main_Arena_1.pdf	Section 2.4 of the draft guidance states: 'Percutaneous mechanical thrombectomy for acute DVT of the leg is usually done together with direct infusion of a thrombolytic drug into the thrombus. However, it can be done by itself if thrombolytic drugs are contraindicated.' Ozpak B et al. (2016) was identified in the literature search, but it was not included in the overview because it is a retrospective case series with only 21 patients. Because of the large evidence base for this procedure, non-comparative studies with fewer than 30 patients were excluded. This is noted in the appendix of the overview. The second cited study is a conference presentation. Conference abstracts and presentations are not normally considered adequate to support decisions on efficacy and are not generally selected for presentation in the overview, unless they contain important safety data.
3	Consultee 2 Company Boston Scientific	**1.1**	We are pleased that NICE has further considered through the consultation process the new evidence and clinician feedback that demonstrates clear clinical benefits in the iliofemoral (IL) subgroup, and has moved the level of guidance to special arrangements. This will help reduce some of the barriers patients have in accessing such life-changing technologies, in	Thank you for your comment.

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			a population known to have the poorest clinical and quality of life outcomes.â€□	
4	Consultee 2 Company Boston Scientific	**General**	Boston Scientific are committed to investing in further research to improve patient selection criteria for pharmaco-mechanical thrombectomy.	Thank you for your comment.
5	Consultee 3 Professor of Radiology and Surgery (US)	**1.1**	I am the National Principal Investigator for the multidisciplinary investigator team that completed the Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis (ATTRACT) Trial (registered at www.clinicaltrials.gov - NCT 00790335). This study was primarily funded by the National Heart Lung and Blood Institute (NHLBI) of the United States National Institutes of Health (NIH), with supplemental funding and in-kind support provided by four companies: Boston Scientific Corporation, Covidien (now Medtronic), Genentech (a Roche Company), and BSN Medical. **I am writing to provide a few additional comments for the Committee's consideration on the updated (January 2019) draft of the interventional procedures consultation document entitled, "Percutaneous Mechanical Thrombetomy for Acute Deep Vein Thrombosis of the Leg", issued for public comment by NICE. Please note that I also submitted comments on the earlier draft.** Disclosures: I speak on behalf of myself alone. The comments here do not reflect the views of the NIH, NHLBI, or others. Grant support from Cook Medical goes to my institution (Washington University) for site participation in a clinical study, as did the above-mentioned support for the ATTRACT Trial's conduct. Neither me nor my family receive anything personally from these or other companies. **Specific Comments**	Thank you for your comment. Section 1.1 of the guidance has been changed.

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			1. I appreciate the responsiveness of the Committee to previous comments submitted by myself and (presumably many) others, and I believe that the current draft of the document is much improved. 2. Section 1.1, second bulleted point states, “For distal DVT that does not extend proximal to the common femoral vein the evidence on efficacy is inconclusive, therefore this procedure should only be used in the context of research.” However, DVT that extends ***into but not above*** the common femoral vein is considered “iliofemoral DVT”, which is known as a high-risk condition for which percutaneous mechanical thrombectomy has an important role to play, for the following reasons: A. The accepted definition of “iliofemoral DVT” that is endorsed by the Society of Interventional Radiology and the American Heart Association is “DVT involving the iliac and/or common femoral vein, with or without other involved veins”. This is logical, because there is no major deep tributary that separates the common femoral vein and external iliac vein – physiologically, the common femoral vein is basically the caudal extension of the iliac vein. Obstruction of one or the other, or both, represents obstruction of the common venous outflow tract from the limb. B. ***Using the above definition of iliofemoral DVT***, studies found it to be associated with: 1) more recurrent VTE; 2) a higher frequency of post-thrombotic syndrome (PTS); and 3) more severe PTS. Patients with DVT in the common femoral vein are at high risk for late complications. C. ***Using the above definition of iliofemoral DVT***, the randomized ATTRACT Trial’s subgroup analysis found the use of pharmacomechanical catheter-directed thrombolysis (which includes percutaneous mechanical thrombectomy) to be associated with improved resolution of leg pain and swelling	

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			(within 30 days), reduced PTS severity including reduced occurrence of moderate-or-severe PTS (over 2 years), and improved venous disease-specific quality of life (over 2 years). Hence, the data suggests that percutaneous mechanical thrombectomy is reasonable to perform as long as the DVT extends ***into*** the common femoral vein, even if it does not extend ***above*** it. Therefore, I propose that the above sentence in Section 1.1 can be re-worded in one of two ways: "For distal DVT that does not extend into the common femoral vein or iliac vein the evidence on efficacy is inconclusive, therefore this procedure should only be used in the context of research." **or** "For distal DVT that does not extend proximal to the femoral vein the evidence on efficacy is inconclusive, therefore this procedure should only be used in the context of research." **I respectfully urge the Committee to make the suggested change to Item #2 above – the common femoral vein is simply the caudal segment of the common venous outflow tract of the limb. The available data shows that correctly delineating its involvement is important in characterizing the long-term risk posed by the DVT and the utility of using percutaneous mechanical thrombectomy.**	
6	Consultee 3 Professor of Radiology and Surgery (US)	**2.7**	Section 2.7: I suggest adding a phrase to the end of the sentence as follows: "Adjuvant angioplasty or stenting of the vein may be needed if thrombus removal reveals an anatomical lesion that contributed to the formation of the DVT or that increases the risk of recurrence."	Thank you for your comment. Section 2.7 of the guidance has been changed.
7	Consultee 4	**General**	Re: Public Consultation NICE Guidance IP1700 – Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg	Thank you for your comments.

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	Vascular Society of Great Britain and Ireland		We welcome the opportunity to comment on the updated draft guidance IP1700 and are very much in support of the guidance suggesting Special Arrangements for ilio-femoral DVT and research only for femoral DVT. As you may be aware the European Society of Vascular Surgery is currently developing guidance to cover the treatment of VTE. This covers the provision of clot removal strategies and we trust this guidance, when published, will be congruent with these recommendations. The Dutch CAVA trial which will present at the end of this month as well as additional trials (CLEAR- DVT – in submission for ethics approval in the UK) should improve the quality and quantity of data available for analysis. We note with interest the comment with respect to Audit and that relevant audit criteria have been identified by NICE and an audit tool will be made available when the guidance is published. We are in total support of robust national audit and as you may be aware the National Vascular Registry is in the advanced stage of incorporation of acute DVT treatments into the NVR. The ideal form of audit would be a national registry. To be successful and informative a registry needs to be: 1) Inclusive and involve all stake holders in the design and implementation - i.e. BSIR, VS, British Society of Haematology and Patients 2) Be regularly audited and robust - i.e. linked to HES and have independent data assurance 3) Been underpinned by strong research governance and ethics for evolving therapies - for example adoption on the NIHR portfolio as with the ROPE registry	NICE can only recommend submission of data to registers which are currently in existence at the time of publication and which meet the criteria set out in our programme manual. A national registry will be recommended in section 1 of the guidance if it is available when the guidance is published. We would be pleased to receive more information about any register that is able to collect data on patients undergoing percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg. If no national register is available then NICE will develop an audit tool which will be made available to be used locally by clinicians should they wish. The audit tool developed by NICE is not subject to consultation.

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			4) Have broad support from industry to ensure funding and enrolment. Thus far we are not aware of broad consultation on the 'audit tool' and are anxious to ensure success of any data collection to ensure appropriate development of these technologies. We look forward to collaboration across the groups involved in delivering care to these patients.	
8	Consultee 5 Anticoagulation UK	**Overview**	Some observations. Overview document In the overview document on page 3, it refers to patients typically being given warfarin. To our knowledge, patients are now being offered one of the DOACS licenced for this purpose unless otherwise indicated. This needs to be addressed in this document.	Thank you for your comment. The wording in the overview has been changed.
9	Consultee 5 Anticoagulation UK	**2.3**	IP consultation Document Current treatments 2.3 as above – referral to (usually warfarin) This needs clarification and reference to DOACS too.	Thank you for your comment. Section 2.3 of the guidance has been changed.
10	Consultee 5 Anticoagulation UK	**General**	General • Post Thrombotic Syndrome is a serious condition which can impact on the quality of life of patients and this is acknowledged in the document. This is a common problem for people who have had a DVT and even when the DVT is treated successfully and there is no recurrence, the damage to the vascular system impairs circulation and symptoms can appear many years thereafter. I have personal experience of PTS which has worsened over the years, having only had one DVT in my teens and with a family history of DVT, have seen at first hand the debilitating impact on family members, both physically and psychologically. We are aware of patients who cannot wear compression stockings due to the fragility of the	Thank you for your comment.

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			skin and skin disorders and therefore struggle to manage this condition effectively.	

"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."