National Institute for Health and Clinical Excellence

Varicose Veins
Guideline Consultation Comments Table
12 February 2013 - 26 March 2013

Type (NB this is for internal purposes – remove before posting on web)

SH = Registered Stakeholders. These comments and responses will be posted on the NICE website when the guideline is published.
PR = Peer Reviewers or Experts. These comments and responses will be posted on the NICE website when the guideline is published.
GRP = Guidelines Review Panel member. These are added to this table for convenience but will not be posted on the web.
NICE = Comments from NICE. These are added to this table for convenience but will not be posted on the web.
Non Reg = These are no longer accepted and should not be added to the table

Comment	Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
1	SH	Department of Health	1	Full	General	general	Thank you for the opportunity to comment on the draft for the above clinical guideline. **I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.**	Thank you for your comment.
2	SH	Frimley Park Hospital NHS Foundation Trust	1	Full	General	general	Referral to Vascular Surgery Symptomatic primary or recurrent varicose veins - The term "Symptomatic" varicose veins is too vague and deserves more clarification. There are many types of lower limb symptoms in patients with	Thank you for your comment. **Symptomatic Varicose veins** The GDG acknowledge the difficulties of defining and clarifying the term symptomatic varicose veins. After discussion the GDG defined symptomatic varicose veins as 'those found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness, and itching) that are thought to be due to the effects of superficial venous reflux and for which no other more likely cause is apparent' (see section 1 and 6.3),

							varicose veins ranging from pins and needels to numbness to heaviness to aching and pain. The Abderdeen Vein study by Bradbury has shown that many of these symptoms may not be related to Varicose Veins whatsover. We recommend that the NICE guideline sticks to the treatment eligibility threshold of CEAP class 4 skin changes secondary to venous insufficiency which will provide a reliable and equitable guide for patients to access varicose vein treatment via their GPs and local vascular surgeons across the UK**.**	This definition is based on definitions in the literature, for example Darvall et al. Patients' expectations before and satisfaction after ultrasound guided foam sclerotherapy for varicose veins. European Journal of Vascular and Endovascular Surgery. 2009; 38(5):642-647 and NICE. Referral guidance; Varicose Veins 2001. The definition includes 'troublesome lower limb symptoms' acknowledging there are other types of lower limb symptoms other than those given as typical examples. This recommendation refers only to the referral of people to a vascular service and does not indicate everyone should be treated. When planning treatment a duplex ultrasound is recommended to confirm the diagnosis of varicose veins and assess the extent of truncal reflux. **CEAP classification** The GDG have not used the CEAP classification to provide referral criteria. In particular they noted that the CEAP classification was not designed as a measure of clinical change or to provide referral criteria. The GDG agreed that it was more important for those referring to a vascular service to use clear, key clinical indicators and listen to the person presenting rather than trying to categorise people using CEAP (section 1.1 and 6.3)
3	SH	Frimley Park Hospital NHS Foundation Trust	2	Full	General	general	Endothermal techniques as first choice for the treatment of varicose veins. The committee should go even further to make the recommendation of "endothermal techniques performed under a local anaesthetic as a day case".	Thank you for your comment. The GDG agree that the majority of endothermal techniques will be performed under local anaesthetic as a day case and they discussed the benefit of stating specifically whether endothermal techniques should be performed under a local anaesthetic and this is outlined in section 9.7.1. The health economic analysis was based on the use of local anaesthesia for endothermal ablation in an outpatient setting. The results of the sensitivity analyses on costs of the procedure showed the conclusions were robust for increases of up to £681 in the cost of endothermal ablation, and there is no

							This is to avoid patients being treated under a GA with laser or radiofrequency ablation which will lose all the cost effectiveness of this treatment strategy	reason to assume that general anaesthesia would adversely affect efficacy. The GDG estimated the costs of endothermal techniques under local anaesthetic as £623.33 and endothermal techniques under general anaesthetic as £930.33. This is an increase of £307 well below the increase of £681. Therefore, it is expected that even if endothermal treatment must be conducted under general anaesthetic it will still be the cost-effective treatment strategy. After considering this evidence and with the acknowledgement that the majority of endothermal techniques are already performed under local anaesthetic the GDG considered this addition would be unnecessary.
4	SH	Frimley Park Hospital NHS Foundation Trust	3	Full	General	general	Just for clarification, I believe that patients should be allowed to access referral to a vascular surgeon if they have CEAP class 4 skin changes irrespective of whether they have primary or recurrent varicose veins. Recurrent varicose veins should not be one of the qualifying criteria as some patients treated in a different, more accommodating NHS era may represent with recurrent veins with only CEAP class 2-3 skin changes.	Thank you for your comment. The GDG agree that patients should be allowed to access referral to a vascular surgeon if they have skin changes irrespective of whether they have primary or recurrent varicose veins. This is outlined in recommendation 4. The GDG considered it important to include people with recurrent varicose veins in the referral criteria.
5	SH	Royal College	1	Full	General	general	This is just to let you know	Thank you for your comment.

		of Nursing					that the feedback I have received from nurses working in this area of health suggest that there are no comments to submit to inform on the above draft guidelines consultation. Thank you for the opportunity to review this document.	
6	SH	Royal Society of Medicine (Venous forum)	8	Full	general	general	It may also be helpful to deliver some recommendations on how foam sclerotherapy is delivered – it is likely to be dependent on technique – and many patients may need a second treatment to be effective – perhaps more than the 20% estimated by the GDG	The GDG agree that the delivery of the techniques is an important consideration and outline this in section 9.7.1. However the delivery of the interventions was not part of the scope. The areas covered by the guideline were defined by the scope. This was informed by stakeholder comments at a workshop held on 6th May 2011 open to public consultation between 9th June until 7th July 2011 and amended accordingly. The guideline references the following NICE interventional procedures: • Ultrasound-guided foam sclerotherapy for varicose veins. NICE interventional procedure guidance 440 (2013). • Endovenous laser treatment of the long saphenous vein. NICE interventional procedure guidance 52 (2004). Available from www.nice.org.uk/guidance/IPG52 • Transilluminated powered phlebectomy for varicose veins. NICE interventional procedure guidance 37 (2004). Available from www.nice.org.uk/guidance/IPG37 • Radiofrequency ablation of varicose veins. NICE interventional procedure guidance 8 (2003). Available from www.nice.org.uk/guidance/IPG8 (see sections 2.6 and 9.7.1)

7	SH	Royal Society of Medicine (Venous forum)	1	Full	general	General	We welcome this guideline and agree with the majority of its recommendations.	Thank you for your comment.
8	SH	Royal Society of Medicine (Venous forum)	4	Full	general	General	"Vascular service" is a unclear term despite your definition. Please clarify here and elsewhere this term is used. In general we feel a "vascular surgeon" is best placed to provide the appropriate NHS treatments and assessments either in the vascular unit or a spoke hospital attached to it. For emergency referral on call arrangements are also required and are not mentioned in your definition of Vascular service.	Thank you for your comment. The GDG defined, 'vascular service' as a team of healthcare professionals who have the skills to undertake a full clinical and duplex Doppler ultrasound assessment and provide a full range of treatment (this should include endothermal abalation, sclerotherapy and surgical treatments).(See section 1 and 6.3). The details of emergency referral on call arrangements are a service delivery specification and not within the remit of this guideline.
9	SH	Royal Society of Medicine (Venous forum)	7	Full	General	General	The model is based on a number of assumptions generated by the GDG and the results of the Network meta-analysis. It is stated that many sensitivity analyses were carried out but it is not clear exactly what these were. Did this include looking at variation of recurrence rates derived from the NMA? and considering if the top up	Thank you for your comment. Full details of the sensitivity analyses are provided in Appendix L. Uncertainty in the treatment effect was accounted for through probabilistic analysis. The method of top-up treatment (assumed to be foam sclerotherapy) only impacted costs; costs were subject to extensive deterministic sensitivity analyses. The clinical inputs for the model were based on a network meta-analysis (NMA). A key benefit of conducting an NMA is the inclusion of evidence from all relevant trials – not just the direct evidence. The NMA included 8 RCTs including the 3 arm trial mentioned; these were reviewed in Chapter 9 of the main guideline. The NMA demonstrated that endothermal treatment was

							treatment was not always foam? Again how strong can the conclusions be for such a specific and hierarchical “offer” recommendation? The only trial which looked at 3 treatments found a lower recurrence rate for surgery.	associated with the lowest probability of recurrence per month. These estimates were used to parameterise treatment effects in the decision model. The model found endothermal to be the cost-effective treatment strategy. The probability that endothermal treatment is the cost-effective treatment (at a threshold of £20,000 per QALY gained) is 71%. Foam sclerotherapy only had a probability of being cost-effective of 23%, and surgery only 3%. The hierarchy allows for less cost-effective treatments to be provided when the preferred treatments are deemed unsuitable or declined. On the basis of this evidence the GDG were confidant to have an offer recommendation with a hierarchy of treatments.
10	SH	Royal College of Obstetricians and Gynaecologists	1	Full	General	General	Pleased to see that pregnancy is considered in it’s own section and that research recommendations are made	Thank you for your comment.
11	SH	Sheffield Teaching Hospitals Foundation Trust	1	Full	General	General	Vascular Surgeons at STH are very supportive of the clear guidance to primary care to refer patients with symptomatic varicose veins for treatment. We feel that the directive to refer should remain very clear, so that current post-code variation ceases.	Thank you for your comment.
12	SH	Sheffield Teaching Hospitals Foundation Trust	2	Full	General	General	The hierarchy of treatment advocated is too prescriptive, given that the comparisons of cost-efficacy are based on	Thank you for your comment. The economic model was based on a network meta-analysis of 8 RCTs and included estimates of uncertainty of treatment effect. Taking this uncertainty into account in probabilistic sensitivity analysis, the model found endothermal

							relatively limited evidence and are heavily influenced by the model derived by the GDG. This is particularly so, as the CLASS Trial results are likely to add significantly to the evidence base in this regards, but are not yet available. We would suggest instead that the 3 categories of intervention for treatment of truncal reflux should be available at all providers who receive varicose veins referrals, but that the selection of technique for individual patients should be determined by a combination of patient choice, with advice from the treating doctor when appropriate. The relative clinical efficacy should be borne in mind by medical staff when advising patients on treatment, and clearly outlined in written information made available to patients prior to decisions being made.	treatment to be the cost-effective strategy at a threshold of £20,000 per QALY gained. Probabilistic sensitivity analysis found that the probability that endothermal treatment is the cost-effective treatment (at a threshold of £20,000 per QALY gained) to be 71%. Foam sclerotherapy only had a probability of being cost-effective of 23%, and surgery only 3%. The hierarchy allows for less cost-effective treatments to be provided when the preferred treatments are deemed unsuitable or declined. On the basis of this evidence the GDG were confidant to have an offer recommendation with a hierarchy of treatments. The GDG are aware of the CLASS trial (see section 9.7.1) and the estimated reporting date of mid 2014. Clinical guidelines are based on the best available evidence. Guidelines support healthcare professionals in identifying the best treatments for their patients, but they do not replace the clinician's knowledge and skills The GDG agree it is important that anyone considering treatment for varicose veins should be given information on the treatments that are available and the expected outcomes and possible adverse events of the treatment options and have outlined this in recommendations 1 and 2.
13	SH	Vascular Society of Great Britain	3	Full	General	General	We agree with the proposed sequence of treatment (thermal, foam,	Thank you. The recommendation about interventional treatment refers to people that have confirmed varicose veins and truncal reflux. The recommendation on people

		and Ireland					surgery). The suggestion though that all symptomatic patients should be offered treatment would swamp our service locally. We suspect this would also be case in many other areas given the number of regions which have strict criteria for treatment. In an ideal world, it would be great to be able to offer treatment to all these patients, but it would need significant resource.	with symptomatic varicose veins is about referral to a vascular service for confirmation of the diagnosis and planning for treatment (which may include ' no interventional treatment'). The recommendation does not suggest that all symptomatic patients should be offered treatment.
14	SH	Vascular Society of Great Britain and Ireland	5	Full	General	General	This is a typically academic approach from a number of well-respected academic vascular surgeons and is a development of the guidelines recently published from mostly the same authors on behalf of the Venous Forum of the Royal Society of Medicine. Although this is as thorough an analysis as could be imagined - or even more so - and one appreciates what a huge amount of work has been down there is a fundamental flaw.	**GDG membership** The membership of the GDG and their professional roles are outlined at the beginning of the guideline. All the clinical members of the GDG work within the NHS. **Analysis** NICE guidelines are based on the best available research evidence and expert consensus and are developed using a standard process and standard ways of analysing the evidence. Details of the standard processes for reviewing literature are explained in the 'guidelines manual' 2012. See http://www.nice.org.uk/aboutnice /howwework/developingniceclinical guidelines/clinicalguidelinedevelop mentmethodsclinical_guideline_development_methods.jsp **Length of the guideline** One of the key principles underlying NICE clinical guidelines is that it is clear how each recommendation was decided on. The full guideline does include this depth of detail (for example; protocols, search strategies, systematic reviews, health economic analysis, evidence

							By doing such an extensive analysis the authors have tried to include almost everything that has been published on the subject in the English language literature. Because of this it is a very lengthy document, which we suspect will be read in its entirety by very few people. What they will read is the conclusions. These are derived from this mass of mainly low and very low quality evidence. If as analysed evidence is deemed to be of such poor quality surely it should be discounted and only the few items of high quality evidence given any weight? Otherwise all the low quality evidence is given pseudo-scientific credibility.	statements and the evidence to recommendation section) in order to ensure this clarity and transparency. The main points and recommendations of the guideline are available in other formats other than the full guideline to facilitate accessibility and ease of use. Please see the NICE guideline, NICE pathways and Guidance written for patients and public **Quality of the evidence and decision making** The evidence to recommendation section in each chapter details the decision making that underpins the recommendation. Each of these sections describes the quality of the evidence and how this has been taken into consideration alongside other information. The wording of the recommendation reflects the strength of the evidence. The process underlying the decision making and how the GDG use all the evidence and their expertise and experience is described in the NICE guidelines manual 2009; chapter 9. The recommendations are based on the GDG's consideration of the best available clinical evidence, the health economic evidence and their experience and expertise. The quality of the evidence from all outcomes contributing to the evidence base is one of the considerations when the GDG balance the clinical benefits and harms of a treatment. The GDG has acknowledged the paucity of high quality evidence in this area and has made several research recommendations addressing this need.
15	SH	Vascular Society of Great Britain and Ireland	12	Full	General	General	As an academic document it is interesting. As an analysis of where	Thank you for your comments **Lengthy set of guidelines** One of the key principles underlying NICE clinical

							future research is needed it is excellent As a set of guidelines for health professionals they are lengthy, confusing and subjective.- - and therefore not really fit for purpose. We have not seen the summary recommendations as yet but suspect they will be the unevidenced subjective recommendations plucked from this document. From the perspective of practising vascular surgeons, working both in the modern 'managed' NHS, or in the increasingly insurance company 'managed' private sector, there are considerable dangers and the Vascular Society will only consider endorsing it after some significant changes.	guidelines is that it is clear how each recommendation was decided on. The full guideline does include this depth of detail (for example; protocols, search strategies, systematic reviews, health economic analysis, evidence statements and the evidence to recommendation section) in order to ensure this clarity and transparency. The main points and recommendations of the guideline are available in other formats other than the full guideline. The other formats aid comprehension, facilitate accessibility and promote ease of use. Please see the NICE guideline, NICE pathways and Guidance written for patients and public **Subjective and unevidenced recommendations** NICE guidelines are based on the best available research evidence and expert consensus and are developed using a standard process and standard ways of analysing the evidence. Details of the robust standard processes for developing the guidelines are explained in the 'guidelines manual' 2009. See http://www.nice.org.uk/aboutnice /howwework/developingniceclinical guidelines/clinicalguidelinedevelop mentmethodsclinical_guideline_development_methods.jsp The GDG are confident that this guideline has been developed according to NICE processes; that it is based on the best available evidence and reflects their consensus view.
16	SH	Vascular Society of Great Britain and Ireland	13	Full	General	General	They have collected an enormous amount of data. Much of this data we are familiar with and in many cases was present	Thank you for your comments. **Quality of the data** The quality of the evidence for the outcomes and how the rating is calculated is described in detail in the GRADE

							when it was originally presented. There is enormous amount of variability about the quality of the data not only relating to the surgeons, the techniques, the equipment used and the follow up. Mosses expressed his opinion on a single tablet of stone, under ten headings (ten commandments) here we have a document running for 250 pages which is almost incomprehensible. If this document is to be published and enter the general arena it will cause massive confusion within individuals taking single paragraphs and quoting them out of context. If we are going to have guidelines lets have simple guidelines which are clearly understood and to a point. We could summarize these guidelines in a single page. We are genuinely concerned about the indications for treatment which will be seized on by the private insurance	tables for each evidence review. This is summarised in the evidence to recommendation section of each chapter, this also includes the GDG's deliberations of the evidence and the impact on the decision making. The GDG has acknowledged the paucity of high quality evidence in this clinical area in the evidence to recommendation sections and has made several research recommendations addressing this need. **Lengthy and incomprehensible** One of the key principles underlying NICE clinical guidelines is that it is clear how each recommendation was decided on. The full guideline does include this depth of detail (for example; protocols, search strategies, systematic reviews, health economic analysis, evidence statements and the evidence to recommendation section) in order to ensure this clarity and transparency. The main points and recommendations of the guideline are available in other formats other than the full guideline. The other formats aid comprehension, facilitate accessibility and promote ease of use. Please see the NICE guideline, NICE pathways and Guidance written for patients and public. The NICE guideline summarises all the recommendations on page 9 . **Endothermal techniques** The GDG agree there is there is variability in this technique and note that the two techniques have developed side by side with incremental technical improvements over the past decade. The basic principle of ultrasound guided endovenous thermal ablation is shared between the techniques and the results are very similar. Many surgeons use both systems favouring one

							companies. There are clearly four principle methods of treating varicose veins and we still do not have good data relating to recurrence rates of endovenous ablation techniques as this report clearly states the techniques have changed over the last ten years, they are using different devices and the results do not collate to the size of vein treated. Our concerns are they are during conclusions on extremely flakey data (acknowledged in report) and the guidelines as expressed are not clear to the practicing clinician. Finally there is very little in these guidelines relating to the problems and potential medico-legal claims arising from them.	over the other as wavelengths or catheter designs change. A patient who is suitable for treatment with one can usually also be treated by the other. The GDG noted that in order to compare the two techniques a stringent examination of exact technique used was required. The majority of the GDG felt that there were too many variables within the trials to be able to make meaningful distinctions between the techniques. In contrast, some of the group felt that although both techniques used heat to destroy the veins, they have different methods of generating power and different side effects. However, on balance, the GDG decided to consider the two techniques together. The clinical evidence for these techniques has been combined, although subgrouping by technique was carried out when heterogeneity of effect sizes within meta-analyses has been serious (I squared > 0.5). This rationale for combining the techniques is outlined in the introduction of chapter 9. **Quality of the evidence and decision making** The evidence to recommendation section in each chapter details the decision making that underpins the recommendation. Each of these sections describes the quality of the evidence and how this has been taken into consideration alongside other information. The wording of the recommendation reflects the strength of the evidence. The process underlying the decision making and how the GDG use all the evidence and their expertise and experience is described in the NICE guidelines manual 2012; chapter 9. The recommendations are based on the GDGs consideration of the best available clinical evidence, the health economic evidence and their experience and expertise. The quality of the evidence from all the

								outcomes contributing to the evidence base is only one of the considerations when the GDG balance the clinical benefits and harms of a treatment..
17	SH	Vascular Society of Great Britain and Ireland	15	Full	General	General	This document on varicose veins is substantial. A couple of points I noted were; Para 3.1.1 Has 2 headings 1) Pregnant women with varicose veins and 2) recurrent varicose veins. It then describes these in the wrong order ie 2 before 1. The abbreviation GDG is not included in the list of abbreviations at the end	Thank you for your comment. We have changed the order of the paragraphs. Thank you for pointing out the lack of an explanation for the GDG abbreviation. This has now been amended in the abbreviations list at the end of the guideline (p233).
18	SH	Guy's & St Thomas' NHS Foundation Trust	1	Full	General	General	More than any other guideline I have read, this one has the most disappointing lack of good quality evidence in many areas which has led the GDG to make many recommendations on expert advice. The advice seems very sensible on the whole.	Thank you for your comment.
19	SH	Guy's & St Thomas' NHS Foundation Trust	3	Full	general	general	The GDG have been prescriptive in their recommendations which is very helpful. Can NICE &/or the GDG consider writing to the NIHR about	Thank you for your comment. The NIHR do receive research recommendations from NICE, and there is a formal process in which applications for funding are made.

							the awful dearth of evidence in this field so so they allocate funding&/or put out a call for research in this field?	
20	SH	Royal Society of Medicine (Venous forum)	2	Full	1.1.2	General	1.1.2. We agree that patients should be told what treatment options are available but suggest that it is also required to explain which ones can be offered to them on the NHS and which would require private referral so that the patient is not given unrealistic expectations of the NHS at the outset**.**	Thank you for your comment. Clinical guidelines are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS.
21	SH	Royal Society of Medicine (Venous forum)	5	Full	1.3.1	general	1.3.1. We are surprised the document recommendations regarding venous duplex scanning prior to treatment should only be "considered" rather than "offered". There is simply no place in the 21st Century for venous disorders of any kind to be managed without appropriate imaging. Many of the medicolegal problems after venous surgery relate to inadequate imaging. Although not something that could be easily	Thank you for your comment. The GDG agree and the recommendation has been changed to,' use duplex ultrasound to confirm the diagnosis of varicose veins, the extent of truncal reflux and to plan treatment for people with suspected primary or recurrent varicose veins.'

							looked at by a clinical trial this should be an “offer” recommendation rather than “consider”. Additionally it is illogical since thermoablation is being recommended as first line and this requires a Duplex scan to assess for suitability! Failure to strongly “offer” Duplex will hold back the development of modern varicose vein practice and recommendation 1.3.2.	
22	SH	Royal Society of Medicine (Venous forum)	6	Full	1.3.2	general	1.3.2 . We are in general pleased to see that thermoablation appears to be the recommended treatment of first choice for venous reflux followed by foam sclerotherapy. However we note that most of the evidence and model relates mainly to long saphenous varicose veins. Is this recommendation intended for short saphenous also? If so we would question whether the evidence is really strong enough for an “offer” rather than “consider” recommendation, and ask for clarification if it is being extended to short	Thank you for your comment. **Extrapolation to short saphenous vein** The GDG acknowledge this in the evidence to recommendation section of chapter 9. The GDG noted that the same treatments would be offered to a person with either great or short saphenous varicose veins. The GDG agreed there are not any physiological or clinical reasons to indicate that extrapolation from the great saphenous vein to the short saphenous vein is inappropriate. The statement in appendix L, ' *overall, the GDG did not deem the existing literature to be sufficient on which to base recommendations. Interventional treatments were therefore identified as a priority for original economic analysis'* refers to the decision to prioritise the interventional treatments for economic modelling to further support the GDG in making a decision in this area. The model was used in conjunction with the clinical evidence

							saphenous veins. We note in appendix 11 the statement “Overall, the GDG did not deem the existing literature to be sufficient on which to base recommendations” and so presumably used the model to make recommendations**.**	and the GDG's experience and expertise to balance the benefits and harms of the treatments to make a decision. The process underlying the decision making and how the GDG use all the evidence and their expertise and experience is described in the NICE guidelines manual 2009; chapter 9.
23	SH	Vascular Society of Great Britain and Ireland	14	Full	4.2	General	The Recommendations (4.2) look reasonable apart from the following three: 1. Third bullet: “Give the patient information … that includes …. the likelihood of progression, including deep vein thrombosis, skin changes, leg ulcers. etc”. The likelihood of developing the complications cited, for people with uncomplicated varicose vein, is unknown. Information can really only state that they are very unlikely, with the aim of reassuring people who may be worried about them. The second sentence addresses this but surely the first should be along the lines “…. the fact that … possible complications … are	**The likelihood of developing complications** The wording of this recommendation to convey a sense of low risk was discussed at great length by the GDG and is outlined in the evidence to recommendation for chapter 5 (see section 5.5.1). As you have noted the GDG have included the clarifying sentence, 'Address any misconceptions the person may have about the risks of developing complications' and are happy this addresses the concern. **The hierarchy of treatments** NICE clinical guidelines set out the clinical care that is suitable for most patients with a specific condition using the NHS in England and Wales. However, there will be times when the recommendations are not appropriate for a particular patient. Healthcare and other professionals are expected to take clinical guidelines fully into account when exercising their professional judgement. However, the guidance does not override the responsibility of healthcare professionals and others to make decisions appropriate to the circumstances of each patient. These decisions should be made in consultation with, and with the agreement of, the patient and/or their guardian or carer. The GDG are happy 'unsuitable' or 'declined' reflect that there is a wide variation of patients seen in clinical

							unlikely" rather than implying (as could be inferred from the present text) that these complications are "likely". 9. " If endothermal ablation is not suitable or declined, offer UGFS …. if UGFS is unsuitable or is declined, offer surgery." Perhaps the choice of words is misleading(see my comments about "unsuitable" and "declined" re-compression below) but this suggests that surgery should be the third choice for all patients. The published clinical and economic evidence does not address the wide variation of patients seen in clinical practice – from those who are slim and fit (who may prefer surgery and make a very rapid recovery) to those with very big and extensive veins (who may require a number of treatment sessions if endothermal ablation of UGFS are used, but only one if surgery is chosen). Of course patients should be offered choice, but the strict ranking of interventions currently	practice. The GDG agree that some people may not be suitable or decline to have a specific treatment and then they should be offered the next cost effective treatment until a suitable treatment is identified. However if it is the case that someone is suitable for all of the treatments and does not decline any of then they should be offered endothermal ablation as the most cost effective option for the NHS. **Offer compression hosiery** The GDG agree that analysis demonstrated that providing compression is not cost effective compared to interventional treatment. Compression hosiery is not recommended unless it is the only treatment option left. The first recommendation in Section 4.2 (pages 34 and 35) has been amended to reflect this and now recommends,' Give information that includes ....Treatment options, including symptom relief, an overview of interventional treatments and the role of compression'. The GDG are happy that the wording of the recommendation, 'compression hosiery only if interventional treatment is not suitable or is declined.' allows for the situation where compression may still be best for some patients after specialist consultation.

							suggested by this recommendation is not how good individual clinical decisions are made for patients with varicose veins. 10. “Offer compression hosiery only if interventional treatment is not suitable or is declined”. • This is seems inconsistent with the recommendation in 4.2 (1) second bullet: “Give information… that includes ….treatment options, including symptom relief, compression and a relief overview of interventional treatments”. The latter suggests that compression hosiery is an option that people should try before considering interventional treatment. • Compression may still be best for some patients after specialist consultation, when specialists may be able to explain matters, to allay fears, and to make a shared decision that compression is the preference of the patient, with the possibility of	

							intervention in the future, if required. That is not quite the same as compression being "unsuitable" or patients "declining". ➢ "not suitable" – what does that mean? There are very few patients for whom some kind of intervention could not reasonably be done for varicose veins. I recognise this a favoured phrase of the editorial team at NICE but I am not at all sure that the Clinical Guideline Group have been served well by its use. I sense that it is not quite what they mean to say suggest that they should reconsider ➢ "declined" – suggests that the patient is offered an intervention and has refused it. This does not sit well with the spirit of shared decision making that NICE guidance should promote and I suggest that the Guideline Group reconsider this, too.	
24	SH	Vascular Society of	6	Full	5	General	Obesity is obviously to be discouraged and may well	Thank you for your comments. **Obesity**

		Great Britain and Ireland					be a factor in ulceration - but this is probably gravitational rather than specifically venous which is why neither compression nor venous interventions are especially helpful in the morbidly obese. Other than this is there really a clear link between BMI and varicose veins. They seem to occur just as frequently in those of thin and medium build. Exercise is also probably irrelevant as a recommendation. Patients with gross truncal reflux will build up higher pressures with exercise that can make their symptoms worse. Having an opinion that patients might avoid hot baths - 'because some patients find it makes their symptoms worse' (sic) is hardly appropriate in a supposedly academic document. Overall this section should be dramatically reduced or discarded.	The recommendation was based on longitudinal studies that showed BMI was independently associated with later progression after adjusting for potential confounders (see section 5.5.1). **Light to moderate activity** The reviews exploring prognostic factors for the progression of varicose veins were inconclusive (see chapter 6). In the light of this, the GDG discussed the absence of evidence and the wording of the recommendation and agreed this wording was misleading with reference to varicose veins but that generally activity was a good advice and not harmful. The GDG have changed the wording in the recommendation to ' from 'lifestyle changes may help' to 'advice on ' to avoid implying that exercise may help with symptoms or the progression of varicose veins. **Examples that might make symptoms worse** The GDG agree with your comment on hot baths and will remove this reference. We have amended the section to state that people should attend to any factors that they, as individuals, perceive to affect their condition. With the amendments the GDG are happy that this section provides valuable advice for people with varicose veins.

25	SH	Vascular Society of Great Britain and Ireland	7	Full	6	General	Sadly again this is a detailed analysis of largely 'junk data. The recommendations just do not stack up. take this paragraph as an example The GDG noted that there were many problems with the evidence including: • - many of the potential risk factors which could aid a GP have not been measured in studies • - the body of evidence was poor quality, patchy and contradictory • - the evidence was not based on rigorous multivariate analysis which considered all potential confounders was excluded thereby reducing the evidence base If this is what they found that are not in a position to give any evidence	Thank you for your comments **Quality of the evidence and decision making** The evidence to recommendation section in each chapter details the decision making that underpins the recommendation. Each of these sections describes the quality of the evidence and how this has been taken into consideration alongside other information. The wording of the recommendation reflects the strength of the evidence. The paragraph referred to is a good example of the 'quality of evidence' section. Here we have summarised clearly the quality of the evidence for prognostic factors that may influence the progression of varicose veins (section 6.3). All recommendations are based on the GDGs consideration of the best available clinical evidence, the health economic evidence and their experience and expertise. The quality of the evidence from all outcomes contributing to the evidence base is one of the considerations when the GDG balance the clinical benefits and harms of a treatment. There are many reasons why it can be difficult for a GDG to reach a decision about a recommendation. The evidence base is always imperfect, and so there is always a degree of judgement by the GDG. As in the case here there may be very little good-quality evidence that directly addresses the review question the GDG has posed. In this situation the GDG have to use other considerations (such as current practice and their expertise) to inform their decision. The process underlying the decision making and how the GDG use all the evidence and their expertise and

							based advice - they therefore fall back on joint opinion from personal experience and conjecture. We cannot fault the recommendation that patients with symptoms should be referred to a vascular service with all the appropriate diagnostic and treatment options - even if there is no clear evidence for this. The problem with the description, 'symptomatic varicose veins', is that it encompasses such a wide range. Patients are not stupid and well know that many GPs and commissioners have decided not to treat what are regarded as 'cosmetic; veins therefore they rapidly learn to develop appropriate symptoms. Patents who have cosmetic concerns which are corrected by intervention are often extremely satisfied as is recognised by most	experience is described in the NICE guidelines manual 2009; chapter 9 (see section 9.1.6 Challenges in formulating recommendations). **Symptomatic Varicose veins** The GDG acknowledge the difficulties of defining and clarifying the term symptomatic varicose veins. After discussion the GDG defined symptomatic varicose veins as 'those found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness, and itching) that are thought to be due to the effects of superficial venous reflux and for which no other more likely cause is apparent' (see section 1 and 6.3), This definition is based on definitions in the literature, for example Darvall et al. Patients' expectations before and satisfaction after ultrasound guided foam sclerotherapy for varicose veins. European Journal of Vascular and Endovascular Surgery. 2009; 38(5):642-647 and NICE. Referral guidance; Varicose Veins 2001. **Patients learn to develop appropriate symptoms** While healthcare professionals are expected to take clinical guidelines fully into account when exercising their clinical judgement the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer. This includes appropriate decision making for people presenting with cosmetic veins and cosmetic concerns. This recommendation refers only to the referral of people to a vascular service and does not indicate everyone should be treated. When planning treatment a duplex ultrasound is recommended to confirm the diagnosis of varicose veins and assess the extent of truncal reflux and plan appropriate treatment (this may or may not include

							experienced venous surgeons. . The problem with using QoL and symptom scales in these patients is that there will not be much change as their QoL was fine apart from the cosmesis. This does not mean the treatment is inappropriate or ineffective but may be measured as such.	an interventional treatment).
26	SH	Vascular Society of Great Britain and Ireland	8	Full	7	General	We cannot see the point of the exhaustive analysis of a lot of low quality studies to show whether duplex ultrasound might be better than hand held Doppler. Surely this is now pointless. 7.1 If as later suggested the primary treatments are going to be endogenous ablation or ultrasound guided foam sclerotherapy neither of these treatments are going to be considered without prior duplex scanning. 7.2 Again it is irrelevant to know whether pre-op duplex makes a difference here as the interventions recommended require it!	Thank you for your comment. The GDG agree and the recommendation has been changed to,' use duplex ultrasound to confirm the diagnosis of varicose veins, the extent of truncal reflux and to plan treatment for people with suspected primary or recurrent varicose veins.'

							7.3 You can't suggest just 'considering' use of duplex when it is a fundamental part of the treatment being proposed.	
27	SH	Vascular Society of Great Britain and Ireland	9	Full	8	General	Patients will only go on wearing stockings if they feel beneficial - compliance is pretty poor which is probably as an good indicator of their inefficacy than anything else. Pruritus is consistently misspelt - (also in the definitions section) this paragraph is of no conceivable value - there are others but this is a good example: 1 study comprising 132 participants found that compression led to a relative reduction in the level of night cramps, but the uncertainty of this effect is far too large from which to draw clear conclusions regarding benefits or harms [LOW QUALITY]. then why bother to include it?	Thank you for your comments. **Compliance of wearing stockings** The GDG agree and have noted this in the introduction of chapter 8 on conservative management, and in the evidence to recommendation section 9.7.2. **Pruritus** This typo has been amended. **Evidence statements** This is an example of an evidence statement. Evidence statements for outcomes are presented after the GRADE profiles, summarising the key features of the evidence on clinical effectiveness (including adverse events as appropriate) and cost effectiveness. Evidence statements give a transparent explanation of the link between the evidence and our recommendations, and are important in providing a summary of the evidence. It is important not to automatically exclude or ignore evidence that is of low quality and where considerable uncertainty exists. This is helpful in identifying if there is absence of evidence or there is evidence that identifies no effect. This knowledge assists the GDG in making decisions about the recommendations and also identifies where future research is needed.

28	SH	Vascular Society of Great Britain and Ireland	10	Full	9	General	This section is rather more realistic and useful We are puzzled by the exclusion early on of sequential treatment of truncal veins and then varicose. In a large experience we have found that dealing with the truncal veins results in relief of symptoms as cosmoses such that many patients need no further treatment. This has considerable cost and efficiency implications as the initial treatment is office-based whereas phlebotomies are time consuming and should probably usually be performed in a more strike environment. We would strongly contest the Carradice study which suggests that the majority of patients need further treatment on two specific counts. There are only 50 patients The assessment was a 6 weeks post procedure whereas improvement occurs symptomatically	Thank you for your comments **Sequential treatment** Given the lack of clear evidence that concurrent tributary treatments were beneficial or not beneficial, it was felt that this should be decided on an individual patient basis level and is as such reflected by the word consider in the strength of the recommendation,' If incompetent varicose tributaries are to be treated, *consid*er treating them at the same time.' The GDG discussed the limitations of the evidence from Carridice (2009). Carradice (2009) was the only RCT that dealt with the question of whether truncal treatments combined with tributary treatments were more effective than truncal treatments applied alone. Your points are valuable and were considered by the GDG. The GDG acknowledged the very short follow up period when forming the recommendation (see section 9.5.1 and 9.7.1). Thank you for example of a research recommendation and comments on the difficulties of comparisons that are solely between U/S guided foam to truncal veins and other forms of endovenous truncal therapy. The GDG agreed a study asking virtually any patient who has had open surgery on one leg and endovenous on the other which they prefer would be an interesting research study. The CLASS study is a randomised controlled trial comparing foam sclerotherapy, alone or in combination with endovenous laser therapy, with conventional surgery as a treatment for varicose veins.

							and cosmetically over 3 months or more Unfortunately this type of guideline production depends on academic rigour. Therefore my opinion below cannot be used! The study that might be useful would be to ask virtually any patient who has had open surgery on one leg and endovenous on the other which they prefer? Apart from having more discomfort during the procedure due to the administration of tumescent local anaesthesia the vast majority prefer endogenous and recover much more quickly. There is an analysis comparing complications of foam sclerotherapy versus other treatments. The problem here is that if the comparison was solely between U/S guided foam to truncal veins and other forms of endovenous truncal therapy it might be valid. In fax many	**Doubts on how the recommendations were derived.** NICE guidelines are based on the best available research and health economic evidence and expert consensus and are developed using a standard process and standard ways of analysing the evidence. Details of the robust standard processes for developing the guidelines are explained in the 'guidelines manual' 2009. See http://www.nice.org.uk/aboutnice /howwework/developingniceclinical guidelines/clinicalguidelinedevelop mentmethodsclinical_guideline_development_methods.jsp The recommendations have been based on the GDG's consideration of the best available clinical evidence, the health economic evidence and their experience and expertise. The evidence to recommendation section in each chapter details the decision making that underpins the recommendation. Each of these sections describes the quality of the evidence and how this has been taken into consideration alongside other information. The wording of the recommendation reflects the strength of the evidence. The GDG are confident that this guideline has been developed according to NICE processes and reflects their consensus, consequently this is a robust evidence based guideline fit for use in the NHS. **Compression hosiery** Thank you for your comment.

							practitioners will use foam in tortuous varicose not accessible to laser or RFA. In more superficial veins there will be an even higher rate of phlebitis and pigmentation. This may be acceptable but should only be compared against avulsion phlebotomies which are likely to produce less problems of this type - but may be more prone to produce nerve damage. Ultimately we agree with most of the recommendations - even if I have doubts as to how they were derived. We do not agree with If incompetent varicose tributaries are to be treated, consider treating them at the same time. as explained above also then contradicted in the same document on page 200 in this paragraph!:	

							Given the lack of clear evidence that concurrent tributary treatments were beneficial, it was felt that this should be decided on an individual patient basis level. Either avulsions or foam sclerotherapy could be used for tributary treatment given the absence of efficacy evidence. we do note that this topic is regarded as a research priority on page 202. We are glad that compression hosiery is now being recommend as a last resort. At present it is often used by GPs and surgeons as a rather unrealistic 'fobbing off' option	
29	SH	Vascular Society of Great Britain and Ireland	11	Full	10	General	From the point of view of achieving a seal of truncal veins compression may be necessary for less than 7 days. We have used 48hr bandaging for foam with success. To control bruising and discomfort following stripping or the early lasers then longer use of stockings is beneficial. We are not	Thank you for your comment. The recommendation does not suggest that compression should be rigidly used for 7 days post interventional treatment, but instead suggests that it is not used for more than 7 days. It could be used, as you say, for 48 hours, and the decision will be made with the patient.

							sure that the rigid recommendation of 7 days is appropriate or evidence based. If patients are more or less comfortable they will tend to pick their own length of use.	
30	SH	Royal College of Obstetricians and Gynaecologists	2	Full	2.5	14	It should be made clear that thromboprophylaxis and thromboembolic risk are outside of the scope of this guideline	Thank you. Appendix A sets out the scope for the guideline and details what topics are included in the guideline. These areas were not identified in the stakeholder consultation.
31	SH	Covidien (UK) Commercial Ltd	4	Full	9.7	19	Whilst we agree with joining EVRFA and EVLA under Endothermal Ablation in the review of the evidence and formulation of the interventional procedure recommendation. There should be a statement on the safety of EVLA. Both EVRFA and Foam Sclerotherapy are the subject of interventional procedure guidance ie. IPG8 and IPG440 respectively and had their safety reviewed and stated. EVLA has not been reviewed as an interventional procedure and thus clinicians will not be aware of the safety of this procedure if it is related to EVRFA.	Thank you for your comment. NICE Interventional Procedure Guidance 52 Endovenous laser treatment of the long saphenous vein addresses this (http://guidance.nice.org.uk/IPG52 This is included in section 2.6 listing the NICE interventional procedures incorporated into the guideline.

							Rasmussen et al (2011) concluded in their RCT comparing the four procedures: "**All treatments were efficacious. The technical failure rate was highest after foam sclerotherapy, but both radiofrequency ablation and foam were associated with a faster recovery and less postoperative pain than endovenous laser ablation and stripping".**	
32	SH	Vascular Society of Great Britain and Ireland	2	Full	4.1	34 -36	The evidence is not there to support the use of foam sclerotherapy over and above surgery for varicose veins. The use of surgery as a 3rd line option for treatment is not borne out by the evidence available. Certain situations favour surgery over foam (and vice versa) and so this blanket recommendation seems unreasonable**.**	Thank you for your comment. The evidence to recommendation section 9.7.1 details how the GDG made this decision. After consideration of the clinical benefits and harms in each of the three pairwise truncal treatment comparisons, endothermal ablation was the only treatment judged to have any clinical advantage over the others. In addition the clinical inputs for the economic model were based on a network meta-analysis (NMA).The NMA demonstrated that endothermal treatment was associated with the lowest probability of recurrence per month. These estimates were used to parameterise treatment effects in the decision model. The model found endothermal treatment to be the most cost-effective. The probability that endothermal treatment is the cost-effective treatment (at a threshold of £20,000 per QALY gained) to be 71%. Foam sclerotherapy only had a probability of being cost-effective of 23%, and surgery only 3%. On the basis of this evidence the GDG were confidant to have an offer recommendation with a hierarchy of

								treatments. The hierarchy allows for less cost-effective treatments to be provided when the preferred treatments are deemed unsuitable or declined.
33	SH	Vascular Society of Great Britain and Ireland	4	Full	4.1	34 -36	We are concerned that the relative newness of foam sclerotherapy means less published evidence and thus a potential source of bias when comparing it to older techniques. It may therefore be better or worse than we currently know but local practice and anecdote in the Venous Forum and Vascular Society suggest better. Given that it is also much the cheapest intervention currently available, we would prefer to see it given at least equal status to endovenous thermal ablation or offered as the first preference rather than as prescribed in 4.1, 4.2, and 9.7 as the second choice. Whatever the nature of commissioning in its regularly changing organisation, we have never been able locally to	Thank you for your comment. The limitations of the evidence and comparing different techniques were considered by the GDG (see chapter 9). After consideration of the clinical benefits and harms in each of the three pairwise truncal treatment comparisons, endothermal ablation was the only treatment judged to have any clinical advantage over the others. In addition the clinical inputs for the economic model were based on a network meta-analysis (NMA).The NMA demonstrated that endothermal treatment was associated with the lowest probability of recurrence per month. These estimates were used to parameterise treatment effects in the decision model. The model found endothermal treatment to be the cost effective strategy at a threshold of £20,000 per QALY gained. The probability that endothermal treatment is the cost-effective treatment (at a threshold of £20,000 per QALY gained) to be 71%. Foam sclerotherapy only had a probability of being cost-effective of 23%, and surgery only 3%. On the basis of this evidence the GDG were confidant to have an offer recommendation with a hierarchy of treatments. NICE's role is to improve outcomes for people using the NHS by producing systematically developed evidence-based guidance for health, public health and social care practitioners. Clinical guidelines set out the clinical care that is suitable for most patients with a specific condition using the NHS in England and Wales. A costing report and support materials for local commissioners to help them commission the topic are produced by NICE for

							win support for more expensive (ie. thermal ablation) interventions though traditional surgery and now foam have been purchased in our locality (subject to the common restriction to CEAP ≥ 3/4 patients). We am absolutely certain that we will not persuade our new cash-strapped commissioners to revert to allowing funding for CEAP 2 patients and especially not if for a not-the-cheapest intervention. We accept that this represents a pragmatic view rather than one based on current (biased?) evidence but it arguably is more likely to be achievable at present. We know also that many will say in response that we should argue for the best for our patients, but the evidence favouring thermal over foam ablation is not to us compelling and local experience with foam has been most encouraging.	each guideline.
34	SH	Covidien (UK) Commercial Ltd	1	Full	4.1 4.2	34	Venous reflux is the cause of chronic venous insufficiency, and is defined as reflux >2-	Thank you for your comment. The GDG agree and the recommendation has been changed to,' use duplex ultrasound to confirm the diagnosis of varicose veins, the extent of truncal reflux and to plan treatment for people

							seconds. Such diagnosis CAN ONLY be confirmed by measuring reflux time via duplex ultrasound. The GDG should reword this recommendation from 'consider' to 'mandatory assessment via duplex ultrasound'. If this is not stated patients can only be left to a visual inspection/diagnosis of anyone in the patient treatment pathway, which could deny patients much needed treatment.	with suspected primary or recurrent varicose veins.'
35	SH	Covidien (UK) Commercial Ltd	2	Full	4.1 4.2	34	We agree with the recommendation on interventional treatment. However we believe that the safety of EVLA should be stated (see Comment 4.).	Thank you for your comment. NICE Interventional Procedure Guidance 52 Endovenous laser treatment of the long saphenous vein addresses this (http://guidance.nice.org.uk/IPG52 This is included in section 2.6 listing the NICE interventional procedures incorporated into the guideline.
36	SH	Vascular Society of Great Britain and Ireland	1	Full	4.1	34	The guidelines say "consider using duplex….." Evidence, and what most would consider from clinical practice, indicate that duplex is more accurate than hand held Doppler or clinical assessment, therefore use of the word "consider" does not seem appropriate in this context. Certainly in the area of recurrent varicose veins I	Thank you for your comment. The GDG agree and the recommendation has been changed to,' use duplex ultrasound to confirm the diagnosis of varicose veins, the extent of truncal reflux and to plan treatment for people with suspected primary or recurrent varicose veins.'

							don't think the majority, if not all, vascular surgeons would plan treatment without a duplex scan	
37	SH	Stockport CCG	1	Full	6.3	74	I am concerned that the definition of symptomatic varicose veins 'those found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and/or and itching) that are thought to be due to the effects of superficial venous reflux and for which no other more likely cause is apparent.' effectively opens the flood gates to surgery for cosmetic reasons. Reducing srgery has been a better care better value indicator for some while but this guidance will inevitable see access rising. From an effective use of resources point of view, we would wish to see a disease-specific validated tool such as the Aberdeen Varicose Vein Symptom Severity Score used to define a minimum threshold of severity	Thank you for your comment. While healthcare professionals are expected to take clinical guidelines fully into account when exercising their clinical judgement the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer. This recommendation refers only to the referral of people to a vascular service and does not indicate everyone should be treated. When planning treatment a duplex ultrasound is recommended to confirm the diagnosis of varicose veins and assess the extent of truncal reflux and plan appropriate treatment (this may or may not include an interventional treatment). The GDG discussed at length the use of a tool to categorise patients for referral and or treatment. The AVVQ is a 13-question survey addressing multiple elements of varicose vein disease. Physical symptoms and social issues, including pain, ankle edema, ulcers, compression therapy use, and limitations on daily activities are examined, as well as the cosmetic effect of varicose veins. The questionnaire is scored from 0 (no effect) to 100 (severe effect). However there is no evidence linking scores on the AVVQ with later progression or response to treatment. The AVVQ does not have a proposed cut off point for when people should be referred or treated. For the GDG to recommend such a tool they would have had to specify a consensus based

								cut off threshold, and the GDG felt unable to make a decision with the evidence available to them. Similarly the GDG have not used the CEAP classification to provide referral criteria. In particular they noted that the CEAP classification was not designed as a measure of clinical change or to provide referral criteria. The GDG agreed that it was more important for those referring to a vascular service to use clear, key clinical indicators and listen to the person presenting rather than trying to categorise people using CEAP (section 1.1 and 6.3)
38	SH	Covidien (UK) Commercial Ltd	3	Full	7	96	Venous reflux is the cause of chronic venous insufficiency, and is defined as reflux >2-seconds. Such diagnosis CAN ONLY be confirmed by measuring reflux time via duplex ultrasound. The GDG should reword this recommendation from 'consider' to 'mandatory assessment via duplex ultrasound'. If this is not stated patients can only be left to a visual inspection/diagnosis of anyone in the patient treatment pathway, which could deny patients much needed treatment.	Thank you for your comment. The GDG agree and the recommendation has been changed to,' use duplex ultrasound to confirm the diagnosis of varicose veins, the extent of truncal reflux and to plan treatment for people with suspected primary or recurrent varicose veins.'
39	SH	British Medical Association	2	NICE	General	General	We are concerned about the lack of evidence for many varicose vein treatments. Whilst we recognise that the document recommends	Our research recommendations will cover this need. The NIHR do receive research recommendations from NICE, and there is a formal process in which applications for funding are made. The NIHR do receive research recommendations from NICE, and there is a formal process in which applications for funding are made. We

							further research in a number of areas, we would prefer that a greater emphasis was placed on the need for new and comparative trial data, possibly through the inclusion of a time-line for the commissioning of the data**.**	do not normally provide time lines for the commissioning of research recommendations as it is not within our scope of practice to arrange such research – instead we make research recommendations so that external researchers can consider the GDG's suggestions.
40	SH	Covidien (UK) Commercial Ltd	5	NICE		7	Venous reflux is the cause of chronic venous insufficiency, and is defined as reflux >2-seconds. Such diagnosis CAN ONLY be confirmed by measuring reflux time via duplex ultrasound. The GDG should reword this recommendation from 'consider' to 'mandatory assessment via duplex ultrasound'. If this is not stated patients can only be left to a visual inspection/diagnosis of anyone in the patient treatment pathway, which could deny patients much needed treatment.	Thank you for your comment. The GDG agree and the recommendation has been changed to,' use duplex ultrasound to confirm the diagnosis of varicose veins, the extent of truncal reflux and to plan treatment for people with suspected primary or recurrent varicose veins.'
41	SH	Covidien (UK) Commercial Ltd	6	NICE		7	We agree with the recommendation on interventional treatment. However we believe that the safety of EVLA should be stated (see Comment 4.).	Thank you for your comment. NICE Interventional Procedure Guidance 52 Endovenous laser treatment of the long saphenous vein addresses this (http://guidance.nice.org.uk/IPG52 This is included in section 3.2 listing the NICE interventional procedures incorporated into the guideline.

42	SH	British Society of Interventional Radiology / The Royal College of Radiologists	1	NICE	6.7.8	7	Many vascular services focus on the provision of treatment for arterial disease and surgery but don't necessarily have the range skills for endothermal ablation in venous disease. We would recommend that the GP should refer to a specialist with and interest in venous treatment. We agree with NICE that surgery is the least preferred option but if necessary the patient can be referred on by either the GP or the vein service .	Thank you for your comment. The referral recommendation makes it clear that people should be referred to a vascular service. A vascular service is defined as,' a team of healthcare professionals who can undertake a full clinical and duplex Doppler ultrasound assessment and provide a full range of treatment for vascular problems.**'** This implies that all assessments and treatments should be an option for all patients so the most suitable and cost effective can be offered.
43	SH	British Society of Interventional Radiology / The Royal College of Radiologists	2	NICE	22.23	7	From the recommendation linked to evidence (7.3) it is clear the GDG group were unanimous in that duplex ultrasound should be completed prior to treatment. We would ask that the recommendation therefore should state Duplex ultrasound should be used to confirm the diagnosis and plan optimal treatment.	Thank you for your comment. The GDG agree and the recommendation has been changed to,' use duplex ultrasound to confirm the diagnosis of varicose veins, the extent of truncal reflux and to plan treatment for people with suspected primary or recurrent varicose veins.'
44	SH	British Society of Interventional Radiology /	3	NICE	26	7	We agree that Endothermal ablation should be the first choice treatment for patients.	Thank you for your comment.

		The Royal College of Radiologists						
45	SH	British Society of Interventional Radiology / The Royal College of Radiologists	4	NICE	3.4	8 11	We agree with the recommendation that endothermal ablation should be the first choice treatment or foam sclerotherapy as shown by the evidence. Where this can't be performed locally patients should be referred for a second opinion to a venous centre. Surgery should not be offered only as a last resort.	Thank you for your comment. The referral recommendation makes it clear that people should be referred to a vascular service. A vascular service is defined as,' a team of healthcare professionals who can undertake a full clinical and duplex Doppler ultrasound assessment and provide a full range of treatment for vascular problems.' This implies that all treatments should be an option for all patients so the most suitable and cost effective can be offered. The hierarchy allows for less cost-effective treatments to be provided when the preferred treatments are deemed unsuitable or declined but not as a last resort.
46	SH	British Society of Interventional Radiology / The Royal College of Radiologists	7	NICE		9	We cannot see the evidence for this recommendation. If evidence is lacking then this should be left to specialist's judgement.	The evidence for the advice recommendations is outlined in chapter 5 of the full guideline and the rationale for the recommendation in the evidence to recommendation section. The GDG are happy that this section provides valuable advice for people with varicose veins.
47	SH	Royal Society of Medicine (Venous forum)	3	NICE	1.2.1 and 1.2.2	9	1.2.1 and 1.2.2 We agree bleeding varicose veins are in general urgent but would ask for clarification if this means "actively bleeding" and how minor bleeding (as opposed to major bleeding) which is to be seen in 2 weeks is	Thank you for your comment. These recommendations have now been combined to clarify that anyone with bleeding varicose veins should be referred immediately. The recommendation states that people with bleeding varicose veins should be referred to a vascular service immediately, it does not indicate were someone should be sent. If the attending clinician judges the most appropriate place for a person to be sent is A&E they should go to A&E and can still be referred immediately to the local vascular service.

							differently defined. Additionally depending on local geography such cases of bleeding varicose veins might be best sent to the nearest A&E department rather than a “vascular service” initially bearing in mind the fact that vascular units are to be nationally commissioned but will also act often with a hub and spoke arrangements to other local hospitals. Varicose vein treatments are to be locally commissioned by CCGs and may not be always commissioned at the vascular units.	
48	SH	British Medical Association	1	NICE	1.2.3	10	This guidance is helpful for GPs commissioning bodies will not always fund treatment for vascular referral in these circumstances.	Thank you for your comment. A costing report and support materials for local commissioners to help them commission the topic are produced by NICE for each guideline**.**
49	SH	British Society of Interventional Radiology / The Royal	6	NICE	22.23.24	10	We believe as per 1 that Duplex ultrasound should be used	Thank you for your comment. The GDG agree and the recommendation has been changed to,' use duplex ultrasound to confirm the diagnosis of varicose veins, the extent of truncal reflux and to plan treatment for people with suspected primary or recurrent varicose veins.'

		College of Radiologists						
50	SH	British Society of Interventional Radiology / The Royal College of Radiologists	5	NICE		11	There are no clear definitions of what symptoms should require treatment and therefore referral. We assume that those patients with varicose veins and who desire treatment for psychological/ cosmetic reasons are excluded from these recommendations. Utilization of a scoring system such as the Aberdeen Varicose vein severity score might allow clinicians to objectively assess patients for treatment. In the absence of these , the current recommendation to refer all patients with symptoms to a vascular service will likely overwhelm those services. Garratt AM, Macdonald LM, Ruta DA, Russell IT, Buckingham JK, Krukowski ZH. Towards the measurement of outcome for patients with varicose veins. Quality in Health Care, 2, 5-10, 1993. Garratt AM, Ruta DA,	Thank you for your comments. Symptomatic varicose veins are defined on page 10 of the NICE guideline. The GDG acknowledge the difficulties of defining and clarifying the term symptomatic varicose veins. After discussion the GDG defined symptomatic varicose veins as 'those found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness, and itching) that are thought to be due to the effects of superficial venous reflux and for which no other more likely cause is apparent' (see section 1 and 6.3 of the full guideline), This definition is based on definitions in the literature, for example Darvall et al. Patients' expectations before and satisfaction after ultrasound guided foam sclerotherapy for varicose veins. European Journal of Vascular and Endovascular Surgery. 2009; 38(5):642-647 and NICE. Referral guidance; Varicose Veins 2001. The definition includes 'troublesome lower limb symptoms' acknowledging there are other types of lower limb symptoms other than those given as typical examples. Healthcare professionals are expected to take clinical guidelines fully into account when exercising their clinical judgement but the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer. In this case who to refer appropriately. The GDG do not foresee vascular services being overwhelmed and estimate an increase in referrals of

							Abdalla MI, Russell IT. Responsiveness of the SF-36 and a condition-specific measure for varicose veins. Quality of Life Research, 5, 223-34, 1996. T.M.A.L. Klem , J.E.M. Sybrandy , C.H.A. Wittens Measurement of Health-related Quality of Life with the Dutch Translated Aberdeen Varicose Vein Questionnaire before and after Treatment Eur J Vasc Endovasc Surg (2009) 37, 470e476	round 25%. This figure may be an over-estimate, as prior to referral rates may have been inflated by a larger number of people with recurrent varicose veins secondary to less effective historic interventions. The GDG discussed at length the use of a tool to categorise patients for referral and or treatment. The AVVQ is a 13-question survey addressing multiple elements of varicose vein disease. Physical symptoms and social issues, including pain, ankle edema, ulcers, compression therapy use, and limitations on daily activities are examined, as well as the cosmetic effect of varicose veins. The questionnaire is scored from 0 (no effect) to 100 (severe effect). However there is no evidence linking scores on the AVVQ with later progression or response to treament. The AVVQ does not have a proposed cut off point for when people should be referred or treated. For the GDG to recommend such a tool they would have had to specify a consensus based cut off threshold, the GDG felt very uncomfortable in making such a decision with evidence available to them. Similarly the GDG have not used the CEAP classification to provide referral criteria. In particular they noted that the CEAP classification was not designed as a measure of clinical change or to provide referral criteria. The GDG agreed that it was more important for those referring to a vascular service to use clear, key clinical indicators and listen to the person presenting rather than trying to categorise people using CEAP (section 1.1 and 6.3). Thank you also for the references you cited. These were not included in the guideline as, although they did relate to issues discussed by the GDG in forming recommendations, they did not relate to any of the specific review questions and did not meet the inclusion criteria for

								any of the reviews.'
51	SH	Guy's & St Thomas' NHS Foundation Trust	2	NICE		17	VVs affect 40% of pregnant women?!!! That is a very high frequency- where does this figure come from? It is not my experience- I take many women with previous DVT through pregnancy and less than 40% have VVs and I would expect "normal " women to have a lower frequency. Please check this figure.	The following article summarises previous evidence, suggesting the prevalence is higher than 40%. But the article below is not from the UK, and, as highlighted, other estimates are lower and the GDG agreed that 40% was a reasonable estimate. Newton de Barros Junior; Maria Del Carmen Janeiro Perez, Jorge Eduardo de Amorim, Fausto Miranda Junior.Pregnancy and lower limb varicose veins: prevalence and risk factors. J. Vasc. Bras. Vol.9 no.2 Porto Alegre June 2010.

These stakeholders were approached but did not comment:

3M Health Care UK
Abertawe Bro Morgannwg University NHS Trust
Aintree University Hospital NHS Foundation Trust
All Wales Tissue Viability Nurse Forum
Allocate Software PLC
AngioDynamics
Association of Anaesthetists of Great Britain and Ireland
Association of British Healthcare Industries
Association of British Insurers
Barnsley Hospital NHS Foundation Trust
Basildon and Thurrock University Hospitals NHS Foundation Trust
Bedfordshire and Hertfordshire Tissue Viability Nurses Forum
Bradford District Care Trust
British Association of Day Surgery
British Association of Prosthetists & Orthotists
British Geriatrics Society
British Heart Foundation
British Medical Association
British Medical Journal
British Medical Ultrasound Society
British National Formulary
British Nuclear Cardiology Society

British Orthopaedic Association
British Psychological Society
British Society of Interventional Radiology
British Society of Interventional Radiology
BSN Medical
BUPA Foundation
Calderstones Partnerships NHS Foundation Trust
Cambridge University Hospitals NHS Foundation Trust
Camden Link
Capsulation PPS
Capsulation PPS
Care Quality Commission (CQC)
Central Manchester University Hospitals
Clarity Informatics Ltd
Commission for Social Care Inspection
Community District Nurses Association
Cook Medical Inc.
Croydon Health Services NHS Trust
Department for Communities and Local Government
Department of Health, Social Services and Public Safety - Northern Ireland
DJO UK Ltd
Dorset Healthcare University NHS Foundation Trust
Dorset Primary Care Trust
East and North Hertfordshire NHS Trust
Equalities National Council
Five Boroughs Partnership NHS Trust
Frimley Park NHS Foundation Trust
George Eliot Hospital NHS Trust
Gloucestershire Hospitals NHS Foundation Trust
Gloucestershire LINk
Gravitas
Great Western Hospitals NHS Foundation Trust
Hammersmith and Fulham Primary Care Trust
Health Protection Agency
Health Quality Improvement Partnership
Healthcare Improvement Scotland
Hindu Council UK
Hockley Medical Practice
Humber NHS Foundation Trust
Huntleigh Healthcare Ltd
Independent Healthcare Advisory Services
Integrity Care Services Ltd.
Lambeth Community Health
Lancashire Care NHS Foundation Trust
Lancashire LINk
Leeds Community Healthcare NHS Trust

Leeds Teaching Hospitals NHS Trust
Lifeblood: The Thrombosis Charity
Liverpool Community Health
Liverpool Primary Care Trust
Lothian University Hospitals Trust
Luton and Dunstable Hospital NHS Trust
Maquet UK Ltd
Medi UK
Medicines and Healthcare products Regulatory Agency
Ministry of Defence
Modern Aesthetic Solutions Ltd
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Institute for Health Research Health Technology Assessment Programme
National Patient Safety Agency
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
NHS Clinical Knowledge Summaries
NHS Commissioning Board
NHS Connecting for Health
NHS County Durham and Darlington
NHS Direct
NHS Halton CCG
NHS Hertfordshire
NHS Plus
NHS Sheffield
NHS Warwickshire Primary Care Trust
NHS Worcestershire
NICE technical lead
North and East London Commissioning Support Unit
Northern Ireland Vascular Surgeons
Nottingham City Council
Oxford Health NHS Foundation Trust
Oxford Radcliffe Trust
Patient Assembly
Peninsula Community Health Services
PERIGON Healthcare Ltd
Pfizer
Pharmacosmos
Pharmametrics GmbH
Public Health Wales NHS Trust
Royal Berkshire NHS Foundation Trust
Royal College of Anaesthetists
Royal College of General Practitioners

Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Paediatrics and Child Health
Royal College of Paediatrics and Child Health , Gastroenetrology, Hepatology and Nutrition
Royal College of Pathologists
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Surgeons of England
Royal Pharmaceutical Society
Sacyl
Scottish Intercollegiate Guidelines Network
Servier Laboratories Ltd
Social Care Institute for Excellence
Social Exclusion Task Force
Society of British Neurological Surgeons
Society Of Vascular Nurses
South Asian Health Foundation
South London & Maudsley NHS Trust
South London Cardiac and Stroke Network
South Tyneside NHS Foundation Trust
South West Yorkshire Partnership NHS Foundation Trust
Southend Hospitals NHS Foundation Trust
Southport and Ormskirk Hospital NHS Trust
St Georges Healthcare NHS Trust
St John Ambulance
St Mary's Hospital
Teva UK
The British Society for Haematology
The Rotherham NHS Foundation Trust
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
The Vein Care Centre
Trafford NHS Provider Services
United Lincolnshire Hospitals NHS
University Hospitals Birmingham
University of Sheffield
Urgo Medical Ltd
Vascular Society of Great Britain and Ireland
Vein Clinics of America
Veincare
Walsall Local Involvement Network
Welsh Government
West Midlands Ambulance Service NHS Trust
Western Cheshire Primary Care Trust
Western Health and Social Care Trust
Western Sussex Hospitals NHS Trust
Westminster Local Involvement Network

Wirral University Teaching Hospital NHS Foundation Trust
York Hospitals NHS Foundation Trust