NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and social care directorate Quality standards and indicators Briefing paper

Quality standard topic: Varicose veins in the legs

Output: Prioritised quality improvement areas for development

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1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for varicose veins in the legs. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

1.1 Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

1.2 Development source

The key development sources referenced in this briefing paper are:

- Varicose veins in the legs. NICE clinical guideline 168 (2013).
- Scottish Intercollegiate Guidelines Network (2010) <u>Management of chronic venous</u> <u>leg ulcers: a national clinical guideline</u>.

2 Overview

2.1 Focus of quality standard

This quality standard will cover the diagnosis and management of varicose veins in the legs and associated chronic venous leg ulcers in adults (aged 18 and over). The particular needs of pregnant women will be considered.

2.2 Definition

Varicose veins are dilated, often palpable subcutaneous veins with reversed blood flow, which are most commonly found in the legs. In some people varicose veins are asymptomatic or cause only mild symptoms, but in others they cause pain, aching or itching and can have a significant effect on quality of life. Varicose veins may become more severe over time and can lead to complications such as changes in skin pigmentation, bleeding or venous ulceration.

In CG168 recommendation 1.2.2 the indications for referral to a vascular service for people with varicose veins are listed. A coexisting active or healed venous leg ulcer are indications for referral, and a venous leg ulcer is defined as 'a break in the skin

below the knee which has not healed within 2 weeks'. In SIGN120 a chronic venous leg ulcer is defined as 'an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks and occurs in the presence of venous disease'.

2.3 Incidence and prevalence

Estimates of the prevalence of varicose veins vary. Visible varicose veins in the lower limbs are estimated to affect at least a third of the population. Risk factors for developing varicose veins are unclear, although prevalence rises with age and they often develop during pregnancy. It is not known which people will develop more severe disease but it is estimated that 3–6% of people who have varicose veins will develop venous ulcers in their lifetime¹.

2.4 Management

Many people with varicose veins will initially present to their GP. For people with asymptomatic varicose veins without any associated pathology, advice and reassurance may be the appropriate treatment. Interventional treatments include endothermal ablation, ultrasound-guided foam sclerotherapy and surgery. There are two main endothermal methods: radiofrequency and laser ablation. These methods heat the vein from inside causing irreversible damage to the vein and its lining, closing the vein off. In ultrasound-guided foam sclerotherapy a sclerosant foam (irritating agent) is injected into the vein to cause an inflammatory response which consequently closes it. Surgery is the traditional treatment that involves surgical removal by 'stripping' out the vein or ligation (tying off the vein). All treatments may be performed under local or general anaesthesia and are often performed on a day case basis. For people in whom interventional treatment is unsuitable, compression hosiery may be offered.

A review of the data from the trials of interventional procedures indicates that the rate of clinical recurrence of varicose veins at 3 years after treatment is likely to be between 10–30%. It is difficult to provide clear figures on retreatment rates because many of the treatments are relatively new and the long term retreatment rates have not yet been published².

¹ National Clinical Guideline Centre (July 2013) Varicose Veins Full Guideline.

² National Clinical Guideline Centre (July 2013) Varicose Veins Full Guideline.

2.5 Patient reported outcome measures (PROMS)³

Background

Since April 2009, English providers of NHS healthcare (including independent sector hospitals in England funded by the English NHS) have been inviting patients undergoing four common elective inpatient surgical procedures (hip replacement, knee replacement, groin hernia and varicose vein surgery) to complete pre-operative questionnaires on their general and condition-specific health. For varicose veins follow-up post-operative questionnaires are sent to patients 3 months after surgery.

The responses to these questionnaires have been analysed to assess the outcomes of the surgical procedures based on patients' self-reported health status. Table 1 shows the numbers of eligible hospital procedures and returned questionnaires across the years 2009-2012.

Table 1: Number of eligible varicose vein hospital procedures and returned questionnaires across 2009-2012⁴

Year	Eligible hospital procedures	Pre-operative questionnaires returned	Post-operative questionnaires returned
2009-10	34,855	15,137	9,544
2010-11	32,271	15,409	9,420
2011-12	27,102	13,278	8,133

Measures of Health

The Patient Reported Outcome Measures (PROMs) programme assesses the health gains following four clinical procedures by using validated quality of life measures that enable patients to rate their health status⁵.

All patients, irrespective of their condition, are asked to complete a common set of questions about their health status. This includes sections about the patient's circumstances, pre-existing conditions and the EQ-5D health questionnaire consisting of a five-dimensional descriptive system and a visual analogue scale (EQ-VAS) developed by the EuroQol Group.

³ The section on PROMS including the data has been adapted from HSCIC (October 2013) <u>Finalised Patient Reported Outcome Measures (PROMs) in England - April 2011 to March 2012</u>. Full tables of adjusted scores and identified outliers are available in the <u>Provider and Commissioner-level excel data files</u>.

⁴ Data taken from HSCIC (October 2013) <u>Finalised Patient Reported Outcome Measures (PROMs) in England</u> April 2011 to March 2012 page 9, table 1.

⁵ For full methodological details see the Health and Social Care Information Centre (2013) <u>Provisional Monthly Patient Reported Outcome Measures (PROMs) in England: A guide to PROMs methodology.</u>

Post-operative questionnaires also contain additional questions about the surgery, such as how the patient perceives the results of the operation and whether there were any post-operative complications, such as bleeding or wound problems.

Patients undergoing varicose vein treatment are also asked to complete a conditionspecific section called the Aberdeen Varicose Vein Questionnaire. This combines into a single score a patient's answers to a number of health questions of particular relevance to their varicose veins.

Health Gain

National scores

In table 2 the breakdown of health gains for the 3 questionnaires are presented. These figures are for improved, unchanged and worsened health gain which was calculated for completed pairs of pre and post-operative questionnaires for 2011/12.

Table 2: Number of improved, unchanged and worsened health scores across the 3 questionnaires for people with varicose veins for 2011-12⁶

	EQ-5D Index		EQ VAS		Aberdeen varicose vein	
	Number	Percentage	Number	Percentage	Number	Percentage
Improved	3,967	53.2%	3,077	42.0%	6,564	83.1%
Unchanged	2,291	30.7%	1,236	16.9%	*	*
Worsened	1,194	16.0%	3,017	41.2%	*	*

^{*}small numbers therefore figure not disclosed in the source report to protect patient confidentiality.

There has been little movement over the three years in the percentage of people reporting improved health on the various measures or in the extent of their health gain. This is reflected in table 3.

⁶ Data taken from HSCIC (October 2013) <u>Finalised Patient Reported Outcome Measures (PROMs) in England - April 2011 to March 2012</u> page 28 and 29, tables 4, 5 and 6.

Table 3: The percentage of patients with varicose veins who had improved health between pre and post-operative stages, across the years 2009/10-2011/12.⁷

Year	EQ-5D Index	EQ VAS	Aberdeen varicose vein
2009-10	52.4%	40.4%	83.4%
2010-11	51.6%	39.8%	82.5%
2011-12	53.2%	42.0%	83.1%

2.6 National Outcome Frameworks

Tables 4–5 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Table 4 NHS Outcomes Framework 2014/15

Domain	Overarching indicators and improvement areas		
3 Helping people to recover	Overarching indicator		
from episodes of ill health or following injury	3b Emergency readmissions within 30 days of discharge from hospital* (PHOF 4.11)		
	Improvement areas		
	Improving outcomes from planned treatments		
	3.1 Total health gain as assessed by patients for elective procedures iv Varicose veins		
4 Ensuring that people have	Overarching indicators		
a positive experience of care	4a Patient experience of primary care		
	i GP services		
	4b Patient experience of hospital care		
	4c Friends and family test		
Alignment across the health and social care system			
* Indicator shared with Public Health Outcomes Framework (PHOF)			

⁷ Data taken from HSCIC (October 2013) <u>Finalised Patient Reported Outcome Measures (PROMs) in England - April 2011 to March 2012</u> page 5, table in executive summary.

Table 5 Public health outcomes framework for England, 2013–2016

Domain	Objectives and indicators	
4 Healthcare public health and	Objective	
preventing premature mortality	Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities Indicators	
	4.11 Emergency readmissions within 30 days of discharge from hospital* (NHSOF 3b)	
Alignment across the health and social care system		
* Indicator shared with NHS Outcomes Framework		

3 Summary of suggestions

3.1 Responses

In total 6 stakeholders submitted comments in the 2-week engagement exercise [7/11/13-21/11/13] and a further 8 stakeholders confirmed that they had no comments to make at the topic engagement stage.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 6 for further consideration by the Committee.

Full details on the suggestions provided are given in appendix 3 for information.

Table 6 Summary of suggested quality improvement areas

Sı	uggested area for improvement	Stakeholders
Re	eferral to a vascular service	
	Currently variation in local referral patterns to vascular services and lack of awareness in primary care about the content of referral and treatment recommendations in CG168. Referral criteria specified in CG168 should be followed. Referral of people with VVs which co-exist with a healed or active venous leg ulcer emphasised.	SCM2, SCM3, SCM4, SCM5
•	Referral criteria in CG168 will significantly increase the number of people eligible for intervention and litigation costs to the NHS. There is no recognition in the risk/benefit analysis that varicose vein surgery is a major source of complaint and litigation even after perfectly competent surgery. Can the commissioners afford this new policy which will increase the case numbers?	RCSE
As	sessment and treatment in a vascular service	
•	Use duplex ultrasound to confirm the diagnosis, assess the extent of the disease and plan appropriate intervention.	SCM1, SCM2, SCM4, SCM5
In	terventional treatment – treatment hierarchy	
•	Hierarchy of intervention treatments (endothermal ablation, ultrasound-guided foam sclerotherapy and surgery) specified in CG168 should be followed. The full range of interventional treatments should be available (endothermal ablation, ultrasound-guided foam sclerotherapy and surgery).	SCM1, SCM3, SCM4, SCM5
In	erventional treatment – day case	
•	There are practices that deal with increasingly complex venous disease patients and are performing interventional treatments on more elderly unfit patients with leg ulcers. It is often not realistic to treat these patients as day cases.	RCSE
No	on-interventional treatment	
•	Compression hosiery/ therapy should only be offered when interventional treatment is not suitable.	SCM2, SCM3, SCM5
No	on-interventional treatment for high risk patients	RCSE
•	Conservative treatment (i.e. compression therapy) should be considered for high risk patients e.g. people with BMI over 30, comorbidities. There should be recognition of the technical and anaesthetic complications for obese or comorbid patients. A BMI of 30 might be a reasonable upper limit.	INOGE

Suggested area for improvement	Stakeholders	
Information for people with varicose veins		
Give people who present with varicose veins in primary care high quality information, education and nursing care. Early intervention in primary care prevents disease progression (including leg ulcers) and improves QoL.	SCM1, SCM3	
Management during pregnancy		
 Awareness that treatment of varicose veins is practicable and desirable between pregnancies. 	SCM4	
Awareness of pelvic venous congestion		
 Awareness of pelvic venous congestion and its contribution to varicose vein recurrence. 	SCM4	
SCM, Specialist Committee Member RCSE, The Royal College of Surgeons of Edinburgh		

4 Suggested improvement areas

4.1 Referral to a vascular service

4.1.1 Summary of suggestions

Referral to a vascular service

Stakeholders highlighted there is variation in local referral patterns to vascular services and a lack of awareness in primary care about the content of referral and treatment recommendations in CG168. The referral of people with varicose veins which co-exist with a healed or active venous leg ulcer was emphasised and stakeholders highlighted that people with venous leg ulcers are sometimes offered non-interventional treatment (compression bandages or hosiery) when interventional treatment may be appropriate (endothermal ablation, ultrasound-guided foam sclerotherapy or surgery). Stakeholders highlighted that timely referral and treatment prevents disease progression.

One stakeholder highlighted that the referral criteria in CG168 may significantly increase the number of people with varicose veins eligible for intervention. The stakeholder highlighted that varicose vein interventions are associated with significant risks, and consequently litigation costs to the NHS. The stakeholder feels there should be recognition that varicose vein surgery is a major source of complaint and litigation even after perfectly competent surgery and that this should be assessed in the risk/benefit analysis. This stakeholder questioned whether commissioners can afford the change in activity associated with CG168 referral and treatment criteria.

4.1.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 7 to help inform the Committee's discussion.

Table 7 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Referral to a vascular service	Referral to a vascular service NICE CG168 Recommendations 1.2.1 and 1.2.2 (key priority for implementation)

Referral to a vascular service

NICE CG168 Recommendation 1.2.1

1.2.1 Refer people with bleeding varicose veins to a vascular service [3] immediately.

NICE CG168 Recommendation 1.2.2 (key priority for implementation)

- 1.2.2 Refer people to a vascular service if they have any of the following.
- Symptomatic⁸ primary or symptomatic recurrent varicose veins.
- Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.
- Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.
- A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks).
- A healed venous leg ulcer.

4.1.3 Current UK practice

Referral to a vascular service

The NICE Costing Report (July 2013), which was published alongside NICE CG168, provides an estimate of the resource impact of the recommendations in CG168. Recommendation 1.2.2 (referral to a vascular service) and 1.3.2 (assessment and treatment in a vascular service) were considered to have the greatest resource impact nationally and the costing analysis focused on these recommendations. The cost impact of these recommendations is expected to be £600 per 100,000 population per annum. The resource impact reflects the provider costs, because at the time of writing all 3 procedures were mapped to the same HRG.

The costing analysis used the opinion of the GDG to make assumptions about the impact the recommendations will have on the numbers of treatments. The GDG estimated that recommendation 1.2.2 would result in a 25% increase in referral rates to vascular services and this would result in a corresponding increase in intervention

⁸ Defined in CG168 as 'Veins found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching).

rates. The cost of implementing recommendation 1.2.2 is estimated at £9000 per annum per 100,000 population. In relation to recommendation 1.3.2, the GDG's opinion was that surgical procedures will reduce to 5% (from 52%), endothermal ablation will increase to 70% (from 35%) and ultra-sound guided foam scleropathy will increase to 25% (from 13%). These changes in activity will produce an estimated saving of £8400 per annum per 100,000 population. Hence there is an overall resource impact of £600 per 100,000 population per annum. A further benefit is expected through the reduction in venous leg ulcers and a reduction in the number of people being prescribed compression hosiery although these savings were not accounted for in the estimated resource impact.

No information identified in relation to litigation consequences.

4.2 Assessment and treatment in a vascular service

4.2.1 Summary of suggestions

Assessment and treatment in a vascular service

Stakeholders highlighted the importance of using duplex ultrasound to confirm the diagnosis, assess the extent of the disease and plan appropriate intervention.

4.2.2 Selected recommendations from development source

Table 8 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 8 to help inform the Committee's discussion.

Table 8 Specific areas for quality improvement

Suggested quality improvement area	Suggested source guidance recommendations
Assessment and treatment in a vascular service	Assessment and treatment in a vascular service
	NICE CG168 Recommendation 1.3.1 (key priority for implementation)

Assessment and treatment in a vascular service

NICE CG168 – Recommendation 1.3.1 (key priority for implementation)

Use duplex ultrasound to confirm the diagnosis of varicose veins and the extent of truncal reflux, and to plan treatment for people with suspected primary or recurrent varicose veins.

4.2.3 Current UK practice

No current data has been identified reporting the use of duplex ultrasound to assess venous disease in the lower limb. However the full guideline⁹ provides a historical overview of diagnostic techniques and an evidence review.

Historically, veins have been investigated using venography, which is a test using X-ray, needles and contrast agents. Over the last 20-30 years, non-invasive techniques have been developed which have distinct advantages over such invasive techniques. Duplex ultrasonography (also known as duplex ultrasound or duplex imaging) is a non-invasive procedure which is used to image the blood vessels of the body. The

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⁹ National Clinical Guideline Centre (July 2013) Varicose Veins Full Guideline.

procedure provides detailed information about deep, superficial and perforating veins including the anatomical patterns of veins, vein patency, vein diameters and valve function. This detailed information may help decide the type of treatment considered most appropriate, especially when considering minimally invasive endovenous procedures. Venous duplex ultrasonography may be performed in a vascular laboratory, X-ray department or an outpatient clinic setting with a vascular scientist, radiologist or vascular surgeon performing the procedure.

The diagnostic evidence review underpinning recommendation 1.3.1 was undertaken because, despite duplex ultrasound being the gold standard, feedback suggested hand held Doppler ultrasound is still used in some clinics. Some clinicians believe it to be an adequate substitute for the more expensive and time-consuming duplex ultrasound. The hand held Doppler does not have the advantages of the grayscale ultrasound, which facilitates assessment of both the superficial and deep veins. In reviewing the evidence the GDG felt it demonstrated that the hand held Doppler is not a good substitute for duplex ultrasound, as the levels of incorrect reflux assessment were unacceptable.

A survey undertaken in 2006¹⁰ (294 respondents, 69% response rate) found that at the time 73% of surgeons routinely used a hand-held Doppler to assess varicose veins, 96% used duplex ultrasound assessment selectively and 26% used duplex ultrasound for all assessments.

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¹⁰ Edwards A, Baynham S, Lees T et al (2009) Management of varicose veins: a survey of current practice by members of the Vascular Society of Great Britain and Ireland. Annals of the Royal College of Surgeons of England. Vol 91, p77-80.

4.3 Interventional treatment

4.3.1 Summary of suggestions

Interventional treatment - treatment hierarchy

Stakeholders highlighted that the hierarchy of interventional treatments (endothermal ablation, ultrasound-guided foam sclerotherapy and surgery) specified in CG168 should be followed. The full range of interventional treatments should be available and stakeholders opinion is that the full range of interventional treatment modalities are not always made available to patients.

Interventional treatment – day case

One stakeholder highlighted that there are practices that treat more elderly unfit patients with leg ulcers who have complex venous disease. The stakeholder highlighted that undertaking interventional treatments as day case procedures is not always appropriate for this patient group.

4.3.2 Selected recommendations from development source

Table 9 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 9 to help inform the Committee's discussion.

Table 9 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Interventional treatment – treatment hierarchy	Interventional treatment 1.3.2 (key priority for implementation)
Interventional treatment – day case	No recommendations identified

Interventional treatment - treatment hierarchy

NICE CG168 Recommendation 1.3.2 (key priority for implementation)

For people with confirmed varicose veins and truncal reflux:

• Offer endothermal ablation (see <u>Radiofrequency ablation of varicose veins</u> [NICE interventional procedure guidance 8] and <u>Endovenous laser treatment of the long saphenous vein [NICE interventional procedure guidance 52]).</u>

- If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy (see <u>Ultrasound-guided foam sclerotherapy for varicose veins</u> [NICE interventional procedure guidance 440]).
- If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.

If incompetent varicose tributaries are to be treated, consider treating them at the same time.

Interventional treatment - day case

No recommendations identified.

4.3.3 Current UK practice

Variation in treatment rates at a local level

Evidence from the literature demonstrates that some local commissioning organisations have deemed varicose vein procedures to be a 'treatment of limited clinical value^{'11}, particularly if undertaken for cosmetic reasons. This approach has led to rationing of services 12,13. The Royal College of Surgeons of England have developed a commissioning guide for varicose veins¹⁴ and in this they highlight that the absence of a framework for the diagnosis and management of varicose veins has resulted in regional variations in the management of varicose veins in the UK. The NICE clinical guideline published in July 2013 now provides national criteria for the referral, assessment and treatment of varicose veins. In the commissioning guide an analysis of varicose vein and venous leg ulcer surgical and endovenous treatments recorded through Hospital Episodes Statistics at a CCG level is presented. This demonstrates that in England in 2012 there was a greater than 90fold variation (5 to 430 procedures per 100,000 population) observed between different clinical commissioning group (CCG) areas (see Figure 1). In the commissioning guide the Royal College of Surgeons of England highlight that this variation is likely to be due in part to poor quality, non-evidence-based local guidelines for the purchasing of VV treatments.

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¹¹ Audit Commission (2011). <u>Reducing spending on low clinical value treatments.</u> (accessed 3rd January 2014 http://archive.audit-

commission.gov.uk/auditcommission/sitecollectiondocuments/Downloads/20110414reducingexpendit ure.pdf)

¹² Lane T, Dharmarajah B, Kelleher D et al (2013) Short-term gain for long-term pain? Which patients should be treated and should we ration? *Phlebology*. Vol 28, Suppl 1, p148-152

¹³ Edwards A, Baynham S, Lees T et al (2009) Management of varicose veins: a survey of current practice by members of the Vascular Society of Great Britain and Ireland. *Annals of the Royal College of Surgeons of England*. Vol 91, p77-80.

¹⁴ Royal College of Surgeons of England (December 2013) <u>Commissioning guide for varicose veins</u>. (accessed 3rd January 2014 http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/varicose-veins/view?searchterm=commissioning+guide+varico)

Figure 1: Age and sex standardised rate of surgical and endovenous interventions performed in England in the NHS to treat VV or venous ulceration per 100,000 population in 2012 (each bubble represents a CCG).

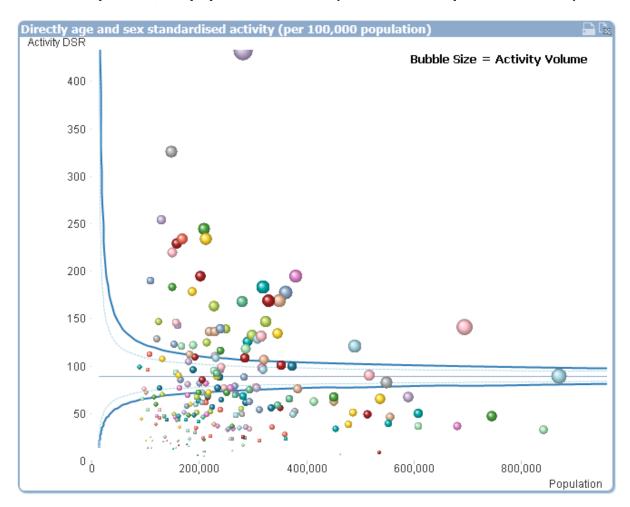


Figure 1 has been reproduced with the permission of the Royal College of Surgeons¹⁵. The data used by the Royal College of Surgeons to create Figure 1 were derived from individual patient activity. The patient's GP practices were grouped into relevant CCGs, allowing pre April 2013 data to be displayed at CCG level. The size of each bubble represents the raw count of actual activity.

Interventional treatment - day case

Analysis of the national trends in hospital episode statistics for varicose vein treatments over the period 1998-2008¹⁶ demonstrates that the proportion of procedures delivered as day case increased from 51% in1998-1999 to 75.3% 2007-2008.

¹⁵ Originally published on page 3 of Royal College of Surgeons of England (December 2013) Commissioning guide for varicose veins.

¹⁶ Kanwar A, Hansrani M, Lees T and Stansby G (2010) <u>Trends in varicose vein therapy in England:</u> radical changes in the last decade. Annals of Royal College of Surgeons of England. 94 (4) p 341–346.

4.4 Non-interventional treatment

4.4.1 Summary of suggestions

Non-interventional treatment

Stakeholders highlighted that compression hosiery/ therapy should only be offered when interventional treatment is not suitable. People with varicose veins should not be treated with compression hosiery/ therapy where they are suitable for and desire interventional treatment.

One stakeholder highlighted that conservative treatment should be considered for high risk patients e.g. people with BMI over 30, comorbidities. There should be recognition of the technical and anaesthetic complications for obese or comorbid patients. The stakeholder suggested that a BMI of 30 might be a reasonable upper limit.

4.4.2 Selected recommendations from development source

Table 10 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 10 to help inform the Committee's discussion.

Table 10 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Non-interventional treatment	Non-interventional treatment
	NICE CG168 Recommendation 1.3.4 (key priority for implementation)
	Treatment
	SIGN120
	Chapter 4 entitled 'Treatment', page 14, paragraph 4.5.4 section entitled 'recommendations for compression therapy' (key recommendation)
	Preventing leg ulcer reoccurrence
	SIGN120
	Chapter 5 entitled 'Preventing ulcer recurrence', page 19, paragraph 5.1 section entitled 'graduated compression for healed venous ulceration'
	Chapter 5 entitled 'Preventing ulcer recurrence', page 19, paragraph 5.2 section entitled 'venous surgery'

Non-interventional treatment

NICE CG168 Recommendation 1.3.4 (key priority for implementation)

Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

Treatment

SIGN120

<u>Chapter 4 entitled 'Treatment', page 14, paragraph 4.5.4 section entitled 'recommendations for compression therapy'</u>

High compression multicomponent bandaging should be routinely used for the treatment of venous leg ulcers (key recommendation).

Preventing leg ulcer reoccurrence

<u>Chapter 5 entitled 'Preventing ulcer recurrence', page 19, paragraph 5.1 section</u> entitled 'graduated compression for healed venous ulceration'

Below-knee graduated compression hosiery is recommended to prevent recurrence of venous leg ulcer in patients where leg ulcer healing has been achieved.

<u>Chapter 5 entitled 'Preventing ulcer recurrence', page 19, paragraph 5.2 section entitled 'venous surgery'</u>

Patients with chronic venous leg ulcer and superficial venous reflux should be considered for superficial venous surgery to prevent recurrence.

4.4.3 Current UK practice

4.5 Information for people with varicose veins

4.5.1 Summary of suggestions

Stakeholders highlighted the need to give people who present with varicose veins in primary care high quality information, education and nursing care. Early intervention in primary care prevents disease progression (including leg ulcers) and improves quality of life. This information needs to be accurate and some primary care practitioners require education about newer treatment options.

4.5.2 Selected recommendations from development source

Table 11 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 11 to help inform the Committee's discussion.

Table 11 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Information for people with varicose veins	Information for people with varicose veins NICE CG168 Recommendation 1.1.1
	Management during pregnancy NICE CG168 Recommendation 1.4.1

Information for people with varicose veins

NICE CG168 Recommendation 1.1.1

Give people who present with varicose veins information that includes:

- An explanation of what varicose veins are.
- Possible causes of varicose veins.
- The likelihood of progression and possible complications, including deep vein thrombosis, skin changes, leg ulcers, bleeding and thrombophlebitis. Address any misconceptions the person may have about the risks of developing complications.
- Treatment options, including symptom relief, an overview of interventional treatments and the role of compression.
- Advice on:

- weight loss (for guidance on weight management see <u>Obesity</u> [NICE clinical guideline 43])
- o light to moderate physical activity
- avoiding factors that are known to make their symptoms worse if possible
- o when and where to seek further medical help.

NICE CG168 Recommendation 1.4.1

Give pregnant women presenting with varicose veins information on the effect of pregnancy on varicose veins.

4.5.3 Current UK practice

4.6 Management during pregnancy

4.6.1 Summary of suggestions

One stakeholder highlighted the need for awareness that treatment of varicose veins is practicable and desirable between pregnancies. Waiting until a woman's family is complete delays treatment and can lead to greater damage to legs, reduced quality of life through trauma of pain and discomfort, additional days off work etc. Not treating venous insufficiency also increases the risk of pregnancy (pain, immobility and DVT).

4.6.2 Selected recommendations from development source

Table 12 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 12 to help inform the Committee's discussion.

Table 12 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Management during pregnancy	There are no recommendations which match this suggested improvement area directly however there is a recommendation about information provision for pregnant women.
	NICE CG168 recommendations 1.4.1.

Management during pregnancy

NICE CG168 recommendations 1.4.1

Give pregnant women presenting with varicose veins information on the effect of pregnancy on varicose veins.

4.6.3 Current UK practice

4.7 Awareness of pelvic venous congestion

4.7.1 Summary of suggestions

One stakeholder highlighted the need for awareness of pelvic venous congestion and its contribution to varicose veins recurrence.

4.7.2 Selected recommendations from development source

Table 13 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 13 to help inform the Committee's discussion.

Table 13 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Awareness of pelvic venous congestion	No recommendations identified. Out of scope of CG168 and SIGN120.

4.7.3 Current UK practice

Appendix 1: Key priorities for implementation (CG168)

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

Referral to a vascular service

- Refer people to a vascular service^[1] if they have any of the following.
- Symptomatic^[2] primary or symptomatic recurrent varicose veins.
- Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.
- Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.
- A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks).
- A healed venous leg ulcer.

Assessment and treatment in a vascular service

Assessment

 Use duplex ultrasound to confirm the diagnosis of varicose veins and the extent of truncal reflux, and to plan treatment for people with suspected primary or recurrent varicose veins.

Interventional treatment

- For people with confirmed varicose veins and truncal reflux:
- Offer endothermal ablation (see <u>Radiofrequency ablation of varicose veins</u>
 [NICE interventional procedure guidance 8] and <u>Endovenous laser treatment</u>
 of the long saphenous vein [NICE interventional procedure guidance 52]).
- If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy (see <u>Ultrasound-guided foam sclerotherapy for varicose veins</u> [NICE interventional procedure guidance 440]).
- If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.

If incompetent varicose tributaries are to be treated, consider treating them at the same time.

Non-interventional treatment

 Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

Appendix 2: Glossary

Glossary terms have been taken or adapted from the full guideline for varicose veins in the legs (NCGC, July 2013).

Ablation The removal of tissue. Laser and radiofrequency are types of ablation techniques. Laser ablation involves using laser energy to cause venous ablation and closure by raising the temperature of the inner lumen of the vein. Radiofrequency ablation involves using radio wave electromagnetic energy to cause venous ablation and closure by raising the temperature of the inner lumen of the vein.

Compression bandaging The application of pressure to the tissues of the lower leg via bandages to artificially increase venous return.

Compression hosiery Elastic stockings to increase venous return; these can be made to measure the patient, and come in different pressures.

Compression therapy Therapy involving the application of pressure to the tissues of the lower leg to artificially increase venous return; this includes elastic stockings or hosiery, bandages or intermittent pneumatic devices.

Duplex ultrasound A device utilising Doppler ultrasound that permits colour-coded visualisation of blood flow in the superficial, perforating and deep veins, as well as grey-scale imaging of the veins and surrounding tissue.

Endothermal A specialised form of endovenous treatment that ablates via thermal damage to the inner lumen of the vein.

Endovenous Within the vein; usually applied as a prefix to therapies such as sclerotherapy, laser ablation or radiofrequency ablation that work by ablating and sclerosing the inner lumen of the vein.

Hand held Doppler A device utilising Doppler ultrasound that permits insonation of the blood to allow assessment of flow in the superficial deep veins.

Interventional treatment In CG168 this is detailed in recommendation 1.3.2 and includes endothermal ablation, ultrasound-guided foam sclerotherapy and surgery.

Non-interventional treatment In CG168 this is detailed in recommendation 1.3.4 and includes compression hosiery.

Sclerotherapy The injection of chemical substances into a truncal or tributary vein, that causes closure of the vein. There are two types of sclerotherapy agents; liquid and foam.

Symptomatic varicose veins Veins found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching).

Varicose veins Visible distended superficial veins with venous incompetence. These are otherwise referred to as varicosity and varicosis.

Vascular service 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.

Venous ulcer A break in the skin secondary to chronic venous insufficiency.

Appendix 3: Suggestions from stakeholder engagement exercise

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
01	Specialist Committee Member	Use duplex ultrasound to confirm the diagnosis.	To ensure of the correct treatment and see the extent of the venous incompetence.	It provides effective interventional treatment and prevents diagnostic uncertainty.	
01	Specialist Committee Member	Offer endothermal ablation.	The treatment is effective. Minimally invasive. More acceptable to patients.	It is an improved longer lasting treatment.	
01	Specialist Committee Member	Give people who present with varicose veins in primary care, information, good advice and nursing care.	Well informed people can make decisions based on available evidence.	Early intervention in primary care gives improved quality of life for the patient. Ultimately prevents a venous leg ulcer.	
02	Specialist Committee Member	Referral to a specialist vascular service. Venous leg ulcer.	This is important because venous leg ulcers are often managed by practice nurses without the expertise. Community nurses often need support in management. There may be an underlying arterial problem. We know that early assessment and appropriate treatment reduces time to heal so reduces cost to patients and resources in both dressings and time.		NICE VV
02	Specialist Committee Member	Refer symptomatic primary or recurrent varicose veins.	Evidence that that timely referral and treatment can prevent disease progression.	To ensure equality of service provision	NICE VV guidance
02	Specialist Committee Member	Assessment by venous duplex.	This accurately diagnoses where reflux is evident and identifies deep venous disease but also helps to		NICE VV

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			plan treatment. Duplex assessment ensures correct intervention.		
02	Specialist Committee Member	Referral of healed leg ulcers.	The assessment and treatment of appropriate patients reduces recurrence. Recurrence comes with associated costs to the patient and resources.		ESCHAR trial.
02	Specialist Committee Member	Do not offer compression hosiery to treat varicose veins.	No evidence to say it is effective and this is often delays a definitive procedure. Many patients are not compliant and the cost of providing hosiery is wasted.		NICE VV
03	Specialist Committee Member	1 Referral of patients with symptomatic varicose veins	At present postcode lottery, 10 fold difference in referral to secondary care dependent on home address. Excellent evidence that appropriate intervention improves patient's quality of life. NICE guideline clear states that patients with symptomatic varicose veins should be referred to a vascular service.	Many people not offered optimal treatment. Large number of patients not given the opportunity to improve their QoL and also to prevent progression of their disease to a worse stage. There is evidence that varicose veins like many chronic diseases is associated with depressive symptomatology. Intervention has been shown to be very cost effective.	See NICE guideline. Hess data. Paper by Lim et al – Change in UK practise over time Michaels et al, - Cost effectiveness Gohel et al Cost effectiveness
03	Specialist Committee Member	2 Ensure timely referral of patients with suspected venous ulceration	Number of patients left with un diagnosed ulcer type and not given appropriate treatment early. NICE guideline clear states that patients with suspected venous ulceration should be referred to a vascular service.	Many patients who would benefit from vascular input are not referred early enough. Hence may get delayed healing etc. Improve patients quality of life but also potential cost saving in-terms of long term reduced healthcare costs	See NICE & SIGN guidelines. AVF/SVS guidelines.

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
03	Specialist Committee Member	3 Education of people and primary care on the management of people with venous disease	People not given appropriate information about risks of VVs and management strategies. NICE guideline highlights this.	People need accurate information about the risks of having VVs, e.g. some people have an anxiety that the presence of VVs may put them at high risk of DVT. Those in primary care need updating on knowledge of the newer modalities for treatment of varicose veins.	Nice guidelines. AVF/SVS guidelines Lane et al -paper on GP referral patterns and education
03	Specialist Committee Member	4 Availability of all treatment modalities for truncal incompetence should be offered.	At present not all modalities are available with NHS institutions. NICE guideline indicates an appropriate treatment regimen.	A treatment hierarchy of endothermal ablation then Foam sclerotherapy then surgery has been identified as being cost effective. Each patient is an individual and the ability to be able all modalities is key as venous disease is very heterogeneous.	Nice guidelines. AVF/SVS guidelines
03	Specialist Committee Member	5 Evaluation of the benefits of compression hosiery	Important as people often given support stockings rather than appropriate referral. NICE guidelines clear show that compression hosiery should only be offered to patients unsuitable for interventional treatment.	Patients often given compression stockings which are proven not be an optimal therapy if the patient's diseased veins are suitable for interventional therapy. A significant amount of money is spent on this therapy by the NHS. There is little evidence of any effect on the benefit of hosiery on preventing progression of disease and it is not cost effective. There is some evidence to support its use in patients who have had leg ulceration and the post-thrombotic syndrome.	Nice guidelines. AVF/SVS guidelines

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
04	Specialist Committee Member		Awareness of current treatment guidelines for varicose veins.	General lack of awareness amongst Healthcare professionals and public that endothermal ablation is available, what it is, and that "stripping surgery" is no longer the gold standard.	NICE guidelines 2013
04	Specialist Committee Member		Awareness that treatment of varicose veins is practicable and desirable between pregnancies	General dogma of "waiting until your child-bearing years are over". No longer applies and costly, leaving greater damage to legs, more days off work and more trauma of pain and /or ulceration by the time of treatment. Not treating venous insufficiency also increases the risk of pregnancy (pain immobility and DVT).	NICE guidelines 2013
04	Specialist Committee Member		Awareness of pelvic venous congestion and its contribution to varicose veins recurrence.	Not well recognised yet responsible for 10+% of varicose vein treatment failure (recurrence).	Various learned papers
04	Specialist Committee Member		Use of duplex assessment and endothermal ablation techniques to treat leg varicose ulceration.	Leg ulcer clinics and care in the community is very costly and treatment (cure) would improve quality of life, reduce care costs and increase independence of patients.	Evidence from literature
04	Specialist Committee Member		Improvement of local vein services to learn from best practice.	Very varied quality and cost of services provided in different areas. Best practice in quality of outcome, experience and cost should be established and	

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
				encouraged to improve standards of care and value for money across the country.	
05	The Royal College of Surgeons of Edinburgh	General	A wider panel of views may have been appropriate.		
05	The Royal College of Surgeons of Edinburgh	Complaint and litigation	Opening the intervention suite door to anyone with the mildest symptoms may significantly increase the case numbers and the litigation cost to the NHS.	There is no recognition in the risk/benefit analysis that varicose vein surgery is a major source of complaint and litigation even after perfectly competent surgery. Endovenous intervention still carries a risk of complications and as the cosmetic result is less satisfactory unless phlebotomies are performed. RCSEd think there is unlikely to be much change in this.	
05	The Royal College of Surgeons of Edinburgh	Complications with obese or comorbid patients	Some recognition of the technical and anaesthetic complications for obese or comorbid patients would assist in defending the choice of conservative treatment for these patients. A BMI of 30 might be a reasonable upper limit.		
05	The Royal College of Surgeons of Edinburgh	Target day case rates	There are practices that deal with increasingly complex venous disease patients and are performing interventional treatments on more elderly unfit patients with leg ulcers. It is often	It would be useful when defining target day case rates to take this into account, otherwise the tertiary referral centres may be penalised.	

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			not realistic to treat these patients as day cases.		
05	The Royal College of Surgeons of Edinburgh	Cost	Can the commissioners afford this new policy?		
09	Specialist Committee Member	Ensure that all people presenting with 1) symptomatic VV 2) skin changes of CVI 3) SVT 4) open CVU 5) healed CVU are referred to a vascular service for specialist assessment and consideration for interventional treatment.	There is good evidence that all these groups benefit from specialist assessment and consideration of intervention Such referral is recommended within the NICE VV CG.	Because it does not happen at the moment Individual PCTs (now CCGs) are still using a wide variety of non-evidence-based policies to "ration" treatment for lower limb venous disease in the mistaken belief that these are treatment of low clinical value.	NICE VV CG 168 http://www.nice.org.uk/ni cemedia/live/14226/645 66/64566.pdf
09	Specialist Committee Member	All people referred for specialist assessment by a vascular service should undergo duplex Doppler ultrasound to 1) confirm the presence of venous disease 2) establish the severity and extent that disease 3) plan intervention.	Clinical assessment of lower limb venous, even by 'experts', disease is highly inaccurate Hand-held Doppler is also unreliable Duplex Doppler ultrasound assessment is recommended within the NICE VV CG for all people referred with lower limb venous disease.	Because it does not happen at the moment. Failure to use duplex Doppler ultrasound leads to inaccurate diagnosis as well as inappropriate and poor quality treatment (or non-treatment).	NICE VV CG 168 http://www.nice.org.uk/nicemedia/live/14226/645 66/64566.pdf
09	Specialist Committee Member	Ensure that, where clinically appropriate, people being considered for VV intervention are offered endovenous treatments before surgery.	Endovenous treatments for VV are associated with less morbidity than surgery and are more costeffective.	Because it does not happen at the moment Many people are only being offered surgery when they could achieve the same or better outcomes with non-surgical endovenous treatments such as ETA and UGFS, more safely and at less cost to the NHS.	NICE VV CG 168 http://www.nice.org.uk/nicemedia/live/14226/645 66/64566.pdf
09	Specialist	Ensure that people are not	Conservative / compression	It is still the case that many	NICE VV CG 168

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
	Committee Member	offered just conservative / compression therapy when they are suitable for and would want to be considered for, interventional treatment.	therapy for VV is relatively ineffective when compared to interventional treatments.	(most?) people presenting with lower limb venous disease are being offered only conservative / compression therapy when they could benefit from more clinically and cost-effective interventional treatments.	http://www.nice.org.uk/nicemedia/live/14226/64566/64566.pdf
06	Royal College of Nursing	This is to inform you that there are the leg quality standard topic engage		the Royal College of Nursing to inform	n on the Varicose veins in
07	Royal College of Physicians	The RCP will not be responding to this consultation. We did not circulate via our membership for comments as we felt the issues were predominantly surgical and therefore covered by other stakeholders.			
08	Royal College of General Practitioners	Unfortunately we do not have any comments to make regarding the varicose veins topic overview. We hope to be able to submit comments when the consultation opens.			
10	Lifeblood: The Thrombosis Charity	Further to our recent telephone conversation, I can confirm that we have no comments.			
11	Vein Care Centre	Contacted via telephone and conf	Contacted via telephone and confirmed no comments at this stage.		
12	Society of Vascular Nurses	Contacted via telephone and conf	irmed no comments at this stage.		
13	Vascular Society of Great Britain and Ireland	Contacted via telephone and confirmed no comments at this stage.			
14	British Society of Interventional Radiology	Contacted via telephone and conf	irmed no comments at this stage.		