# Varicose veins in the legs NICE quality standard

# **Draft for consultation**

March 2014

# Introduction

This quality standard covers the diagnosis and management of varicose veins in the legs and associated venous leg ulcers in adults (aged 18 and over). These statements are not applicable to the needs of pregnant women. For more information about the scope of this quality standard see the <u>topic overview</u>.

# Why this quality standard is needed

Varicose veins are dilated, often visible and palpable subcutaneous veins with reversed blood flow. They are most commonly found in the legs and 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.

In some people varicose veins are asymptomatic or cause only mild symptoms, but in others they cause pain, aching or itching and can have an adverse impact on their quality of life. Varicose veins may become more severe over time and can lead to complications such as skin damage (eczema and pigmentation changes), bleeding and venous ulceration. It is not known which people will develop more severe disease but it is estimated that 3–6% of people who have varicose veins in their lifetime will develop venous ulcers.

Until the publication of the NICE clinical guideline there was no definitive system for identifying which people will benefit the most from interventional treatment and no established framework within the NHS for the diagnosis and management of varicose veins. This has resulted in wide regional variations in the management of varicose veins in the UK.

The quality standard is expected to contribute to improvements in the following outcomes:

- · quality of life for people with varicose veins
- progression of venous leg disease
- complications from varicose veins (skin changes including pigmentation and eczema, venous ulcers, superficial and deep vein thrombosis and venous leg ulcers)
- varicose vein recurrence.

# How this quality standard supports delivery of outcome frameworks

NICE quality standards are a concise set of prioritised statements designed to drive measureable quality improvements within a particular area of health or care. They are derived from high-quality guidance, such as that from NICE or other sources accredited by NICE. This quality standard, in conjunction with the guidance on which it is based, should contribute to the improvements outlined in the following 2 outcomes frameworks published by the Department of Health:

- NHS Outcomes Framework 2014–15
- Improving outcomes and supporting transparency: a public health outcomes framework for England 2013–2016, Part 1 and Part 1A.

Tables 1 and 2 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Table 1 NHS Outcomes Framework 2014–15

Domain	Overarching indicators and improvement areas
3 Helping people to recover from episodes of ill health or following injury	Overarching indicator
	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 indicator	
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)		

Table 2 Public health outcomes framework for England, 2013–2016

Domain	Objectives and indicators
4 Healthcare public health and preventing premature mortality	Objective  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 (NHSOF)	

# Coordinated services

The quality standard for varicose veins in the legs specifies that services should be commissioned from and coordinated across all relevant agencies encompassing the whole varicose veins care pathway. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care to people with varicose veins in their legs.

The Health and Social Care Act 2012 sets out a clear expectation that the care system should consider NICE quality standards in planning and delivering services, as part of a general duty to secure continuous improvement in quality.

Commissioners and providers of health and social care should refer to the library of NICE quality standards when designing high-quality services. Other quality standards that should also be considered when choosing, commissioning or providing a high-quality varicose vein service are listed in 'Related quality standards'.

# **Training and competencies**

The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals involved in assessing, caring for and treating people with varicose veins in their legs should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard.

#### Role of families and carers

Quality standards recognise the important role families and carers have in supporting people with varicose veins in their legs. If appropriate, healthcare professionals should ensure that family members and carers are involved in the decision-making process about investigations, treatment and care.

# List of quality statements

<u>Statement 1</u>. People with varicose veins that are causing symptoms or complications are referred to a vascular service.

<u>Statement 2</u>. People with varicose veins who are referred to a vascular service have their diagnosis confirmed by duplex ultrasound.

<u>Statement 3</u>. People with confirmed varicose veins and truncal reflux are offered suitable treatment in this order: endothermal ablation, ultrasound-guided foam sclerotherapy, surgery or compression hosiery.

# Questions for consultation

**Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement?

**Question 2** If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

**Question 3** The population covered in this quality standard includes people with venous leg ulcers coexisting with varicose veins. Are there any quality improvement areas specific to this population?

Quality statement 1: Referral to a vascular service

Quality statement

People with varicose veins that are causing symptoms or complications are referred

to a vascular service.

Rationale

If left untreated, varicose veins will continue to cause symptoms and can lead to

bleeding, skin damage and ulceration. Interventional treatment for varicose veins

relieves symptoms and slows disease progression, improving people's quality of life.

In some localities interventions for varicose veins have been wrongly identified as

being of low clinical value and this has resulted in constrained and highly variable

local referral criteria. These commissioning constraints along with an absence of

national evidence-based guidance have led to variation in referral patterns across

the country.

Quality measures

Structure

Evidence of local arrangements and written referral criteria to ensure that people

with varicose veins that are causing symptoms or complications are referred to a

vascular service.

Data source: Local data collection.

**Process** 

Proportion of people with varicose veins that are causing symptoms or complications

who are referred to a vascular service.

Numerator – the number of people in the denominator who are referred to a vascular

service.

Denominator – the number of people who present with varicose veins that are

causing symptoms or complications.

Data source: Local data collection.

#### **Outcome**

a) Progression of venous leg disease

Data source: Local data collection.

b) Quality of life for people with venous leg disease.

**Data source:** Local data collection. For people who have had interventional treatment, patient-reported outcome measure data is collected for the NHS Outcomes Framework 2014–15 improvement area 3.1: Total health gain as assessed by patients for elective procedures iv varicose veins.

# What the quality statement means for service providers, healthcare professionals and commissioners

**Service providers** ensure that local referral pathways into vascular services are consistent with the evidence-based referral criteria in <u>NICE clinical guideline 168</u>, which include varicose veins that are causing symptoms or complications.

**Healthcare professionals** follow local referral pathways into vascular services to ensure that people with varicose veins that are causing symptoms or complications are referred to a vascular service.

**Commissioners** monitor activity across local referral pathways to ensure that the evidence-based referral criteria in NICE clinical guideline 168 are being followed.

# What the quality statement means for patients and carers

People with varicose veins that are causing symptoms or problems such as eczema or leg ulcers are referred to a vascular service.

# Source guidance

Varicose veins in the legs (NICE clinical guideline 168), recommendation <u>1.2.2</u>
 (key priority for implementation).

# Definitions of terms used in this quality statement

# Symptomatic varicose veins

Symptomatic varicose veins are those found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching). The symptoms may be associated with primary or recurrent varicose veins. [Adapted from NICE clinical guideline 168, recommendation 1.2.2]

# **Complications of varicose veins**

Complications of varicose veins are:

- 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) or a healed venous leg ulcer.

[Adapted from NICE clinical guideline 168, recommendation 1.2.2]

# Vascular service

A vascular service is a team of healthcare professionals who have the skills to undertake a full clinical and duplex ultrasound assessment and provide a full range of treatment. [NICE clinical guideline 168, recommendation 1.2.1]

**Quality statement 2: Duplex ultrasound** 

Quality statement

People with varicose veins who are referred to a vascular service have their

diagnosis confirmed by duplex ultrasound.

Rationale

Duplex ultrasound is a non-invasive scan used to image the blood vessels of the

body. It provides detailed information that helps to confirm the diagnosis and type of

venous disease and determine which treatment option will be most clinically and cost

effective (see statement 3). The handheld doppler is still used in some services but it

does not provide the detailed, accurate information produced by duplex ultrasound.

Quality measures

**Structure** 

Evidence of local arrangements to ensure that people with varicose veins referred to

a vascular service have their diagnosis confirmed by duplex ultrasound.

**Data source:** Local data collection.

**Process** 

Proportion of people with varicose veins referred to a vascular service who have

their diagnosis confirmed by duplex ultrasound.

Numerator – the number of people in the denominator who have their diagnosis

confirmed by duplex ultrasound.

Denominator – the number of people with varicose veins referred to a vascular

service.

Data source: Local data collection. NICE clinical guideline 168 clinical audit tool,

standard 1.

# What the quality statement means for service providers, healthcare professionals and commissioners

**Service providers** ensure that vascular services have adequate numbers of duplex ultrasound machines and that staff have undergone appropriate training, so that all people with varicose veins referred to a vascular service have their diagnosis confirmed by duplex ultrasound.

**Healthcare professionals** working in a vascular service ensure that people with varicose veins have their diagnosis confirmed by duplex ultrasound.

**Commissioners** ensure that they commission vascular services that have sufficient capacity, equipment and skilled staff to confirm diagnosis of varicose veins by duplex ultrasound for people with varicose veins who are referred to a vascular service.

# What the quality statement means for patients and carers

**People with varicose veins referred to a vascular service** have a duplex ultrasound scan (a scan that uses high-frequency sound waves to produce a picture of the veins) to check the diagnosis.

# Source guidance

Varicose veins in the legs (NICE clinical guideline 168) recommendation <u>1.3.1</u>
 (key priority for implementation).

# Definitions of terms used in this quality statement

### Vascular service

A vascular service is a team of healthcare professionals who have the skills to undertake a full clinical and duplex ultrasound assessment and provide a full range of treatment. [NICE clinical guideline 168, recommendation 1.2.1].

# **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. It can also be used to image blood flow in arteries. [Full guideline on varicose veins in the legs, glossary]

**Quality statement 3: Treatment of varicose veins** 

Quality statement

People with confirmed varicose veins and truncal reflux are offered a suitable

treatment in this order: endothermal ablation, ultrasound-guided foam sclerotherapy,

surgery or compression hosiery.

Rationale

Historically surgery and compression therapy were the only treatments available to

people with varicose veins, but in recent years other treatments including

endothermal ablation and ultrasound-guided foam sclerotherapy have been

developed. These newer therapies are less invasive than surgery, promote faster

recovery and need shorter hospital stays. Not all treatments are suitable for all

people and therefore it is important that the person's needs are considered when

deciding which is the most suitable treatment.

Quality measures

Structure

Evidence of local arrangements that the full range of treatments for varicose veins is

commissioned in accordance with NICE clinical guideline 168.

Data source: Local data collection.

**Process** 

a) Proportion of people with confirmed varicose veins and truncal reflux suitable for

endothermal ablation who are offered endothermal ablation.

Numerator – Number of people in the denominator offered endothermal ablation.

Denominator – Number of people with confirmed varicose veins and truncal reflux

suitable for endothermal ablation.

Data source: Local data collection. NICE clinical guideline 168 clinical audit tool,

standard 2.

b) Proportion of people with confirmed varicose veins and truncal reflux unsuitable for endothermal ablation who are offered ultrasound-guided foam sclerotherapy.

Numerator – Number of people in the denominator offered ultrasound-guided foam sclerotherapy.

Denominator – Number of people with confirmed varicose veins and truncal reflux who are unsuitable for endothermal ablation.

**Data source:** Local data collection. <u>NICE clinical guideline 168 clinical audit tool</u>, standard 3.

c) Proportion of people with confirmed varicose veins and truncal reflux unsuitable for endothermal ablation and ultrasound-guided foam sclerotherapy who are offered surgery.

Numerator – Number of people in the denominator offered surgery.

Denominator – Number of people with confirmed varicose veins and truncal reflux who are unsuitable for endothermal ablation and ultrasound-guided foam sclerotherapy.

**Data source:** Local data collection. <u>NICE clinical guideline 168 clinical audit tool</u>, standard 4.

d) Proportion of people with confirmed varicose veins and truncal reflux unsuitable for endothermal ablation, ultrasound-guided foam sclerotherapy and surgery who are offered compression hosiery.

Numerator – Number of people in the denominator offered compression hosiery.

Denominator – Number of people with confirmed varicose veins and truncal reflux who are unsuitable for endothermal ablation, ultrasound-guided foam sclerotherapy and surgery.

**Data source:** Local data collection. <u>NICE clinical guideline 168 clinical audit tool</u>, standard 6.

#### **Outcome**

Rates of endothermal ablation, ultrasound-guided foam sclerotherapy, surgery and compression hosiery treatments for varicose veins.

Data source: Local data collection.

# What the quality statement means for service providers, healthcare professionals and commissioners

**Service providers** ensure that the local treatment pathway is consistent with the evidence-based treatment order in NICE clinical guideline 168.

**Healthcare professionals** ensure that they follow the local treatment pathway to offer people a treatment that is consistent with the evidence-based treatment order in NICE clinical guideline 168.

**Commissioners** ensure that the full range of treatments for varicose veins is commissioned in accordance with <a href="NICE clinical guideline 168">NICE clinical guideline 168</a>.

# What the quality statement means for patients and carers

People with confirmed varicose veins and truncal reflux are offered treatment with endothermal ablation (in which the veins are closed off using heat), or if endothermal ablation is unsuitable, a treatment called ultrasound-guided foam sclerotherapy (in which the veins are closed off using a chemical foam), or surgery to remove the varicose veins. Only if the first 3 treatments are unsuitable, will compression hosiery (stockings designed to improve blood flow by squeezing the legs) be offered as a permanent treatment.

# Source guidance

Varicose veins in the legs (NICE clinical guideline 168) recommendations <u>1.3.2</u>
 and <u>1.3.4</u> (key priorities for implementation).

# Definitions of terms used in this quality statement

#### Truncal reflux

Truncal reflux is the backflow of blood through a venous valve in 1 or more of the 3 truncal veins – the great saphenous vein, the small saphenous vein and the anterior accessory saphenous vein. [Adapted from <u>Full guideline on varicose veins in the legs</u>, page 122 and glossary definition of reflux]

#### **Endothermal ablation**

There are 2 types of endothermal ablation: radiofrequency ablation (see Radiofrequency ablation of varicose veins [NICE interventional procedure guidance 8]) and laser ablation (see Endovenous laser treatment of the long saphenous vein [NICE interventional procedure guidance 52]). Radiofrequency ablation uses radio wave electromagnetic energy to cause venous ablation and closure by raising the temperature of the inner lumen of the vein. Laser ablation uses laser energy to cause venous ablation and closure by raising the temperature of the inner lumen of the vein. [Adapted from Full guideline on varicose veins in the legs, glossary definitions of radiofrequency ablation and laser ablation]

# **Ultrasound-guided foam sclerotherapy**

The injection of a sclerosing agent into a vein guided by real-time ultrasound imaging (see <u>Ultrasound-guided foam sclerotherapy for varicose veins</u> [NICE interventional procedure guidance 440]). [<u>Full guideline on varicose veins in the legs</u>, glossary definition of ultrasound-guided foam sclerotherapy]

# Surgery

A surgical technique of truncal vein removal, in which the vein is stripped from surrounding tissues and removed. [Full guideline on varicose veins in the legs, glossary definition of stripping]

### **Compression hosiery**

Elastic stockings to increase venous return, which can be made to measure and are available in different pressures. [Adapted from <u>Full guideline on varicose veins in the legs</u>, glossary definition of compression hosiery]

# Status of this quality standard

This is the draft quality standard released for consultation from 13 March to 10 April 2014. It is not NICE's final quality standard on varicose veins in the legs. The statements and measures presented in this document are provisional and may change after consultation with stakeholders.

Comments on the content of the draft standard must be submitted by 5pm on 10 April 2014. All eligible comments received during consultation will be reviewed by the Quality Standards Advisory Committee and the quality statements and measures will be refined in line with the Quality Standards Advisory Committee's considerations. The final quality standard will be available on the <a href="NICE website">NICE website</a> from August 2014.

# Using the quality standard

# **Quality measures**

The quality measures accompanying the quality statements aim to improve the structure, process and outcomes of care in areas identified as needing quality improvement. They are not a new set of targets or mandatory indicators for performance management.

We have indicated if current national indicators exist that could be used to measure the quality statements. These include indicators developed by the Health and Social Care Information Centre through its <u>Indicators for Quality Improvement Programme</u>. If there is no national indicator that could be used to measure a quality statement, the quality measure should form the basis for audit criteria developed and used locally.

See NICE's <u>What makes up a NICE quality standard?</u> for further information, including advice on using quality measures.

### Levels of achievement

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of

100% should be aspired to (or 0% if the quality statement states that something should not be done). However, NICE recognises that this may not always be appropriate in practice, taking account of safety, choice and professional judgement, and therefore desired levels of achievement should be defined locally.

# Using other national guidance and policy documents

Other national guidance and current policy documents have been referenced during the development of this quality standard. It is important that the quality standard is considered alongside the documents listed in 'Development sources'

# Diversity, equality and language

During the development of this quality standard, equality issues have been considered and equality assessments are available.

Good communication between healthcare professionals and people with varicose veins is essential. Treatment, care and support, and the information given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. People with varicose veins should have access to an interpreter or advocate if needed.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.

# **Development sources**

Further explanation of the methodology used can be found in the quality standards Process guide on the NICE website.

# Evidence sources

The documents below contain recommendations from NICE guidance or other NICE-accredited recommendations that were used by the Quality Standards Advisory Committee to develop the quality standard statements and measures.

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

# Policy context

It is important that the quality standard is considered alongside current policy documents, including:

- Health and Social Care Information Centre (2013) PROMs special topic –
   satisfaction with and success of surgery 2010–2011.
- Department of Health (2012) <u>Patient reported outcome measures (PROMs) in England: the case-mix adjustment methodology.</u>
- Health and Social Care Information Centre (2012) <u>Finalised patient reported</u>
   outcome measures (PROMs) in <u>England April 2010 to March 2011</u>, <u>pre- and post-operative data</u>.
- Health and Social Care Information Centre (2012) PROMs special topic EQ-5D descriptive system 2009–2010.
- Health and Social Care Information Centre (2012) PROMs special topic patient-level data 2009–2012.
- Health and Social Care Information Centre (2011) PROMs special topic equality
   2009–2011.

# Definitions and data sources for the quality measures

- Department of Health (2013) <u>NHS Outcomes Framework 2014 to 2015</u>
   Improvement area 3.1: Total health gain as assessed by patients for elective procedures iv varicose veins.
- National Clinical Guideline Centre (2013) <u>Full guideline on varicose veins in the</u> legs. NICE clinical guideline 168.

National Institute for Health and Care Excellence (2013) <u>Varicose veins in the legs</u>. NICE clinical guideline 168.

# **Related NICE quality standards**

### **Published**

- Antenatal care. NICE quality standard 22 (2012).
- Patient experience in adult NHS services. NICE quality standard 15 (2012).

# Future quality standards

This quality standard has been developed in the context of all quality standards referred to NICE, including the following topics scheduled for future development:

- · Obesity in adults.
- · Physical activity.

# Quality Standards Advisory Committee and NICE project team

# **Quality Standards Advisory Committee**

This quality standard has been developed by Quality Standards Advisory Committee 2.

Membership of this committee is as follows:

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# About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

The methods and processes for developing NICE quality standards are described in the <u>quality standards process guide</u>.

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countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

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