NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Varicose veins in the legs

Date of Quality Standards Advisory Committee post-consultation meeting:
08 May 2014.

2 Introduction

The draft quality standard for varicose veins in the legs was made available on the NICE website for a 4-week public consultation period between 13 March and 10 April 2014. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 12 organisations, which included service providers, national organisations, professional bodies and others. Three stakeholders stated that they had no further comments to make.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

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

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

Stakeholders were also invited to respond to the following statement specific questions:

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?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Concerns were raised that venous ulcers is made reference to in the introduction to the quality standard, but not referred to in the statements. One stakeholder, in

response to question 1, stated that as varicose ulceration is not included the draft quality standard does not accurately reflect the key areas for quality improvement.

Consultation comments on data collection

- Concerns were raised that data would be difficult to collect for statement 1 due to a lack of recording of people presenting with varicose veins in primary care and subsequently the number referred for specialist opinion. One stakeholder stated that statement 2 is auditable.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People with varicose veins that are causing symptoms or complications are referred to a vascular service.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Stakeholders agreed that there is a need for referrals to a vascular service.
- Several stakeholders queried the practical implications. Two responses expressed concern that achievement of this statement may exceed capacity in vascular surgery departments. A further concern related to the potential difficulty in recording the number of patients with varicose veins seen in primary care and the number referred for specialist opinion.

- One comment suggested amendment to the wording of the rationale for statement 1 to indicate that not all varicose veins lead to complications. It was highlighted that NICE clinical guideline 168 indicates insufficient research on numbers of patients developing complications.

5.2 Draft statement 2

People with varicose veins who are referred to a vascular service have their diagnosis confirmed by duplex ultrasound.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- It would be achievable and audit possible in secondary care.
- Two responses suggested amendments to statement 2 to improve accuracy. One stakeholder stated that the use of duplex ultrasound is to test for venous reflux, not to confirm a diagnosis. The second response called for wording that reflected the use of duplex to establish cause or source.
- The inclusion of reference to a handheld doppler in the rationale was queried and it was suggested that this be removed, as the technology is outdated.

5.3 Draft statement 3

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.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Two responses raised the issue of patient related factors in treatment options. It was highlighted that the clinical guideline does not take into account factors, such as personal preference, medical fitness, or pain thresholds. The statement should reflect the need to discuss all options, suggest recommended treatment and allow the patient to choose.
- It was recommended that endovenous ablation and foam scleropathy should both be offered rather than surgery. Measurement would be documented evidence of reasons for treatment choices to identify rates of those having surgery first offered endovenous ablation and foam scleropathy.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

Concerns were raised that venous ulcers is made reference to in the introduction to the quality standard, but not referred to in the statements.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comments[1]
1	Frimley Park Hospital NHS Foundation Trust	Quality Statement 1	Information regarding the uptake of these guidelines by CCGs may be further enhanced by ensuring a registry is kept of patients turned down for treatment after an individual funding request is raised by their vascular specialist or GP referring them for their symptomatic varicose veins. Despite the publication of the new NICE guidelines in 2013, local CCGs in England and Wales are slow to change access for treatment for their patients. A varicose vein treatment "Turn Down" audit may allow a comparison of accessibility to treatment. Numerator: Number of patients turned down for treatment. Denominator: Number of patients receiving surgery for varicose veins.
2	Veincare	Quality Statement 1	My experience from being secondary care specialist on a CCG board has taught me that it will be almost impossible to get GPs to record the number of patients in an area who present with VVs. It will therefore be difficult to record the number of patients with VVs seen in primary care and the number referred for specialist opinion. Thus quality statement one is unachievable. It should not be used in its current form.
3	British Medical Association	Quality statement 1, page 7 - definitions	The definition of 'Symptomatic varicose veins' needs more detail; we appreciate that this is discussed in the full clinical guideline but GPs often encounter patients who are "symptomatic" simply because they do not like the cosmetic appearance of their legs and have an occasional ache in hot weather.
4	British Association of Dermatologists	Quality Statement 1	We agree that there is a lack of awareness that early referral for intervention of varicose veins is cost-effective, and that this should be addressed. We also share the concern expressed in the comments that this may exceed capacity in vascular surgery departments.
5	British Association of Dermatologists	Quality Statement 1 and 2	We agree that patients with varicose veins and venous leg ulcers should be referred to the vascular team in the first instance. It is not uncommon for patients to be referred to vascular surgery departments, therefore prolonging the appropriate treatment, especially if there is a discrepancy with Doppler's which aren't always accurate if they have been carried out at all.
6	Gloucestershire Hospitals NHS Foundation Trust	Quality Statement 2	Can we please make a plea for accuracy here? The diagnosis of varicose veins is made by seeing varicose veins, not by duplex. This tests for venous reflux, there is a difference. The statement perhaps should therefore read "People with varicose veins who are referred to a vascular service and who require treatment have their reflux pattern confirmed by duplex ultrasound".
7	Veincare	Quality	This is achievable and can be audited in secondary care.

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement No	Comments[1]
		Statement 2	
8	British Society of Interventional Radiology	Quality Statement 2	Comment about quality statement: The duplex scan should not simply be to confirm the diagnosis. It should assess the presence of a normal or abnormal deep venous system and also establish the cause/source of the varicose veins in order to guide further management. This should be reflected in the wording of the quality statement
9	Society of Vascular Technology of Great Britain and Ireland	Quality Statement 2, Page 8 - rationale	The handheld Doppler has been replaced somewhat by venous duplex, for this reason is the last sentence needed? Or are you trying to get across the point I am trying to make (which I think you are). We feel that the quality standard should not even make reference to the handheld Doppler being used in this way as it is outdated.
10	Society of Vascular Technology of Great Britain and Ireland	Quality Statement, Page 9 - service providers	Vascular work is highly demanding on the ultrasound machine and we feel there should be some recommendation of up to date machinery with high frequency probe of at least 10MHz for superficial work and lower frequency of 6Mhz for deeper structures . In addition, increasingly more and more difficult patients are being treated (in the instances of ulcers) leading to increasing difficulty of duplex imaging (obese patients) and therefore it is important to have machinery adequate enough to image deep veins in large patients as this may impact treatment.
11	Gloucestershire Hospitals NHS Foundation Trust	Quality Statement 3	We should not offer treatment in any order. We should discuss all the treatment options, allow the patient to choose, and where appropriate suggest to each patient what we recommend. All other things being equal, and subject to individual suitability the preferred treatments, in order, are endothermal ablation, ultrasound-guided foam sclerotherapy, surgery or compression hosiery.
12	Veincare	Quality Statement 3	Nice guidance 2013 does not take into account patient related factors such as personal preference, medical fitness, pain threasholds, desire to have sclerotherapy vs endothermal etc. The standard of endovenous then foam then surgery is inappropriate. NICE guidance would be improved if it expressly stated that endovenous and foam should be offered rather than surgery: saphenofemoral or saphenopopliteal ligation. The standard will be more easy to measure if it is changed to: Any patient who has a groin or popliteal fossa incision (saphenofemoral or saphenopopliteal ligation) should have been considered for and offered either endovenous thermal ablation or foam sclerotherapy. The denominator can be number of patients who have saphenofemoral or saphenopopliteal ligation and the numerator, the number who have documented evidence of being offered the alternatives and the reason why they did not have them.
13	British Association of Dermatologists	Introduction	Many patients require the expertise of a variety of professionals, including vascular surgeons, dermatologists, geriatricians, community nurses, dermatology nurses and tissue viability nurses. Optimum management requires a joined-up approach between these groups, and multi-disciplinary services involving primary and secondary care should be considered.
14	British Association of Dermatologists	Introduction	It may be ultimately cost-effective for all patients with venous ulcers and varicose veins to be assessed in the multi-disciplinary team, and then followed up according to an agreed management plan.
15	Royal College of Obstetricians and	Introduction, Page 2	Last sentence in data source 'iv varicose veins' – needs rewording in both places

ID	Stakeholder	Statement No	Comments[1]
	Gynaecologists		
16	British Medical Association	Question 1	We do not think that this draft quality standard accurately reflects the key areas for quality improvement as varicose ulceration is not included.
17	British Medical Association	Question 2	If the systems and structures were available, we do think that it would be possible to collect the data for the proposed quality measures
18	British Medical Association	Question 3	Management of varicose ulceration is an integral part of managing varicose veins and vice versa, depending on the severity of the condition when the patient presents. We therefore believe that recommendations for best practice managing these ulcers and the requirement to expedite secondary care vascular intervention within a short time scale once the ulcer has healed, should be included in a quality standard. As raised in the previous consultation on the NICE guideline, we are still concerned about the lack of evidence for many varicose vein treatments. 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.
19	Veincare	General	The quality standard (and NICE Guidance) does not take into account the economic pressures on NHS commissioners (CCGs). CCGs have finite resources and many have taken the decision to limit funding of VV treatment to patients with certain complications of VV. The statement that all VVs will lead to complications is wrong. It was admitted in the 2013 guidance that there is insufficient research to know who and how many patients progress to develop complications. It is unrealistic to expect all patients with VVs to be referred for secondary care and the NICE guidance 2013 is unlikely to be followed.
20	British Association of Dermatologists	General	A standardised proforma may be helpful to ensure all associated conditions and features are identified, as per the guidance.
21	Society of Vascular Technology of Great Britain and Ireland	General	We feel it is important for any unit offering treatment of varicose veins to have staff skilled in ABPI measurement (vascular scientist, nurse specialist, staff nurse etc) as this is often required to rule out arterial contribution to ulcers and can be important before commencing compression bandaging (ulcers or after surgery) or compression hosiery.
22	Society of Vascular Technology of Great Britain and Ireland	General	Doppler is capital D as it is a name.
23	Society of Vascular Technology of Great Britain and Ireland	General	There is not much reference to treatment in “non truncal” varicosities is this deliberate?. For example a patient with active venous ulceration may have foam sclerotherapy on calf varicosities fed exclusively by an incompetent calf perforator.
24	NHS England	General	Thank you for the opportunity to comment the draft consultation for the above Quality Standard I wish to confirm that NHS England has no substantive comments to make regarding this consultation.
25	The Royal College of Surgeons of Edinburgh	General	The Royal College of Surgeons of Edinburgh support the above Quality Standard as drafted.
26	The Royal College of	General	Some of our Fellows expressed an opinion that the Quality Standards may require to be updated when the CLASS

ID	Stakeholder	Statement No	Comments[1]
	Surgeons of Edinburgh		trial reports. There is varied debate amongst clinicians about the hierarchy of treatment and the availability of duplex scanning. Duplex scanning should be available in most hospitals.
27	Department of Health	General	Thank you for the opportunity to comment on the draft for the above quality standard. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
28	Royal College of Nursing	General	This is to inform you that there are no comments to submit on behalf of the Royal College of Nursing to inform on the draft Varicose veins in the legs quality standard

Stakeholders who submitted comments at consultation

British Association of Dermatologists

British Medical Association

British Society of Interventional Radiology

Department of Health

Frimley Park Hospital NHS Foundation Trust

Gloucestershire Hospitals NHS Foundation Trust

NHS England

Royal College of Nursing

Royal College of Obstetricians and Gynaecologists

Society of Vascular Technology of Great Britain and Ireland

The Royal College of Surgeons of Edinburgh

Veincare