UNIVERSITY OF CAMBRIDGE
Winton Centre for
Risk and Evidence Communication

Decision Aid Supporting Document

Varicose Veins v9.1 (Sept 2023) planned review (3 years)

This document is designed to give further information about how we made the Decision Support Tool (Decision Aid).

This supporting document and the decision aid were written and researched by Leila Finikarides and Dr Alexandra Freeman.

Each tool had an expert advisory group nominated by NHS England, who commissioned the tools, the involvement of relevant charities or support groups, and was designed through rounds of redesign and feedback from clinicians, patients and members of the public who might use it. These were one-on-one interviews, and the feedback was collated and acted on in multiple rounds.

EasyRead versions were then made through a similar process of iterative testing with experts and users.

Users (patients and the general public) are our focus, we include them from the beginning of the process and their views and feedback throughout are at the very heart of what we aim to do. The decision aids are for them.

Each tool is made to comply with the guidelines or criteria on decision aid development by IPDAS and NICE. Very often they go beyond what many might consider as a 'decision aid' because our work with patients and clinicians has emphasised how much patients want 'everything in one place' and clinicians find it helpful to have 'the perfect consultation' laid out to support them.

Patients particularly appreciated the help that the documents gave them in preparing for an appointment (knowing what might happen in advance, and helping prompt questions they might want to ask), pages that help them when they talk to their doctor, and those that remind them what's going on, what might happen, and what did just happen (what did the doctor tell me in the room). The extra information can make the documents seem long, but patients preferred this extra length, as long as the sections were easily navigable.

In this document you can find out more about who helped design the tool, some of the reasoning behind key decisions, and what reference sources were used. You can also see the answers to some of the questions we posed to the people we tested it with about how they might use the tool, which led to key decisions about its design. These are only examples designed to give you a sense of how they were made – the full process is too detailed to document.

In designing the graphical representations of the numbers, we use a large body of research into risk communication done over many years (some by us), plus the testing we do during the production of the tools.

Graphic design was by the company Luna9.

Who was involved?

	number	
Expert Advisory Group (Clinicians & Patient Representatives) & their Declarations of Conflicts of Interest (COI)	**X 10**	**Expert advisory group:** **Mr Andrew Garnham** (Consultant Vascular Surgeon, Head of School of Surgery West Midland, Vice President Vascular Society Great Britain and Ireland) No COI to declare. **Mr Dan Carradice** (Consultant Vascular and Endovascular Surgeon, Vascular Surgery Specialty Lead for Research: Royal College of Surgeons of England, Chair of the Special Interest Group for Venous Disease Research: Vascular Society of Great Britain and Ireland, Executive Council of the Venous Forum: Royal Society of Medicine No COI to declare. **Dr Sam Finnikin** (GP and NHSE National Clinical Specialist Advisor in Personalised Care) No COI to declare. **Dr Sarah Onida** (Consultant in Vascular Surgery and Honorary Senior Lecturer, Lead for the Venous platform trials) No COI to declare. **Mr Michael Wall (***Consultant Vascular and Endovascular Surgeon, Black Country Vascular Network,* Training Programme Director for Central CT training (West Midlands) Deputy Director R&I Dudley Group of hospitals NHS Foundation Trust No COI to declare **Vanessa Davis** (Expert by experience (patient advisor)) No COI to declare **Dr Vicki Carradice** (GP with a special interest in Varicose Veins) No COI to declare **Leanne Atkin** (Vascular Nurse Consultant, Society of Vascular Nursing Exec and Legs Matter Exec) No COI to declare

		Prof Ellie Lindsay OBE (Life President The Lindsay Leg Club Foundation) No COI declared **Andy Richards** (Expert by experience (patient advisor)) No COI to declare
Other clinicians (not part of the expert advisory group) who were interviewed or provided input or feedback	**X 11**	**Other clinicians:** Vascular surgeons x3 Specialist vascular nurses x4 Community nurses x4 **Prof Gerry Stansby** (Chair of North of England Cardiovascular network group for Vascular Surgery. Previous Chair NICE Quality Standards group for Venous thromboembolism) – Feedback on v 1.0 **Prof Alun Davies** (Professor of vascular surgery and consultant surgeon) Feedback on v2.3 **Professor Bruce Campbell** (Honorary Vascular Consultant) Feedback on v2.3 & v5.0 & v9.1
Patients and public involved in 4 rounds of testing and feedback	X 17	Including people of a range of ages, ethnicities, education levels Out of the 17: 10 had had varicose veins 7 had not had varicose veins 2 were autistic 1 had English not as their first language
Organisations		Legs Matter The Lindsay Leg Club
Who are the Winton Centre for Risk & Evidence Communication?		The Winton Centre was funded by a philanthropic donation from the David & Claudia Harding Foundation to help communicate evidence 'to inform, not persuade'. The team carried out research in how best to communicate numbers and uncertainty, created training courses to help professions who needed to communicate evidence in a balanced way, and produced tools to communicate evidence on different topics. They were commissioned, and funded, by NHS England to produce a series of printable decision support tools in 2022 and 2023. The funding for this work came from NHS England and the Winton Centre's own core funding.

What questions do we ask of our expert group and user testers and why?

We interviewed the expert advisory group, regular patients and potential users of the decision aid and regular clinicians who might use the decision aid. We interviewed each tester (regular patients or users, and regular clinicians) via video call, usually for about an hour.

We need to understand which information to include and to what level of detail.

For users (patients):
We always first asked about their experience of the condition or the decision to be made. We asked them what did they want to know at the time and what would they have liked to have known. We asked them what they would tell someone now who was making the decision.

We then asked for their feedback on the decision aid.
We ask if they would like a clinician to go through the document with them.

Then we ask them:

- Whether they understood the purpose of the document (that it is a decision aid, not an information sheet).
- Whether they would read it, if they would find it useful, would it help them make a decision?
- Whether, if they were handed the document by a clinician, they would read it.
- Whether, if they saw this document on a table, for example in a clinic waiting room, they pick it up, and *want* to read it.

The aim of these decision aids is to help people make a decision. But in order to be useful and used, they need to be read. And in order to be read, they need to be picked up. We therefore amend and refine the documents and retest them (with a mix of the same and different testers) until the answers to these questions are “yes”.

If people want a clinician to go through the document with them, we make sure it’s clear in the document that this is what they can do and, on the front page, which pages are (most) useful to be used in a consultation with a healthcare professional.

For clinicians (both our expert group and regular clinicians):
We ask:

- What is the decision being made? (what are the treatment options that are available)
- At which point in a patient’s pathway/disease progression are they making the decision, and therefore what is the background knowledge of the potential user

(what do they already know), and when and how would they physically receive this leaflet?
- Are there inclusion / exclusion criteria around the decision aid?
- How would the decision aid be used, e.g. by users ‘on their own’ before a consultation with a clinician, or always first with a clinician

The answers to these questions help us to understand which information to include in the leaflet, at what level of detail and language to use.

What is the decision? **And / or** **What are the treatment options available?**	**<u>What is the decision? And / or What are the treatment options available?</u>** Whether to have treatment for varicose veins and which treatment to choose. Treatment (closing or removing veins) for varicose veins is usually specific to the pattern of veins and the individual (“the right treatment for the right vein”). It is also sometimes offered according to the usual practice of the surgeon. Treatment (closing or removing the veins) is the only way to remove varicose veins. There are, though, things that people can do to alleviate symptoms. We describe: • Do nothing - you can always choose not to have treatment. • Things I can do myself, to help symptoms (pain, aching etc.), including compression stockings. • Treatment - this is usually endothermal ablation (heat treatment) plus removing the prominent veins. Glue, foam or other treatments are also sometimes used. We decided to include all of these under the description of “treatment” and not split out the individual methods because, as a patient, you are offered the treatment modality that is most suitable for your veins following a mapping scan and which your surgeon is experienced in. We did, however, make it clear that patients have a right to ask about other treatments available in other centres, by other surgeons. We had split out the risks and benefits of the different kinds of treatment in v2.0, but changed this in v3.0 because the risks & benefits from the different treatments are broadly similar and often specific to the individual. These are discussed in detail by the operating surgeon before any procedure.
When in the pathway will it be used? (clinician answer)	The expert group and other clinicians advised that the decision aid is made available to patients as early as possible: • It should be easy to find online when patients first start to research their condition • In primary care when varicose veins are first diagnosed • If not, then in secondary care when patients have been referred It is useful for patients to know the likelihood of progression to (for example) leg ulcer, and what to look out for, and to understand symptoms where varicose veins could be the cause.

	Waiting times can be long, and this time could usefully be filled with information about what people can do to help themselves, and ensuring that treatment is the right thing for them. A specialist nurse, during testing, added: *“Start in primary care, especially community based care. At the GP, most people present with aching legs and skin changes. It would be useful for them to already have an awareness that varicose veins might be the cause.”*
When would it be useful? (patient answer)	**Q: When would a document like this be useful?** **Answers** *“Straight after diagnosis, when exploring treatment options”* *“When I was told I have varicose veins, then keep it, to weigh up options best for me at all points moving forwards”* *“When I was told I have varicose veins and to keep for reference”* *“As soon as possible when finding out I had varicose veins”* *“Could it be in a wating room?... Could GP have it in their room to hand out?”*
How would it be used?	Varicose vein diagnosis, progression and treatment can happen over time (a number of weeks or months) and by more than one specialist. Care for ulcers, for example, is often by a team of clinicians, e.g. GP, community nurse, wound care nurse, podiatrist, physiotherapists, and others. Clinicians want patients to have access to the document so patients can be prepared for their next appointment and prepared for signs of progression and problems. *Clinicians/Healthcare professionals:* *“Good for patient preparation [for appointment]”* *“Good as a takeaway for patient to review after visits and return prepared for next session”* *“Next appts prep pages - I like these pages, these can be helpful for us (community) nurses to talk through next steps with patients too if they have appointments coming up.”* *Patients:* *“I wish I would have been given something like this in one of my appointments. May even go back to GP and see what my options are now.”*

	"I have read through the document and was very impressed I wish I was given this at the beginning of my problem. *…I wanted to know if the treatment would work or not. I had ulcers and they were affecting my life terribly, I even considered amputation at one point… I don't think a lot of people understand the pain."*
Are there any exclusion / inclusion criteria ?	Varicose veins are not treated for cosmetic reasons on the NHS. This decision aid is for symptomatic varicose veins.
Would you prefer a printed version, online electronic version or both? (Patient answer)	We know from testing previous decision aids that most clinicians would prefer these were electronic online tools. NHS clinicians typically do say they have facilities to print (black and white only). Most of the community nurses said it should be patient choice, but noted that not everyone has online access or access to a printer. They would like hard copies to give out to patients. Of the 15 patients who answered this question: - 6 wanted it printed - 9 wanted it both printed and online - None wanted it online only
Any other comments?	One of the expert group had undertaken a questionnaire of clinicians in Jan 2023 asking them about risks they talked about to patients. There were 33 different risks in the long list. We discussed which risks to include in the decision aid. In testing with patients and clinicians it was decided that patients do not need to know all the 'consent risks' at the point they're making a decision about treatment, but they do want to know some risks. We decided to reduce the number of risks we list for treatment to those that patients wanted to know and that clinicians felt important to tell them at this stage of the decision making process. There was not a lot of high quality evidence around treatment options – particularly around non-surgical treatments (like compression stockings). There is a risk of DVT from treatments, but there's also a risk of varicose veins if you have a DVT, adding a confounder.

	One person pointed out that varicose veins are “*not terribly life threatening but can cause a lot of misery…depression, low mood anxiety that is better after intervention [treatment]*”
Were there any key decisions made when designing the document, and what was the reasoning behind them?	The expert group made a decision early on to include glue as one of the treatment modalities, and there was a lot of discussion about foam – whether it was effective. A decision was made later on not to show the benefit statistics for each individually because patients are usually offered treatments specific to the diseased veins they have, the evidence available on efficacy and based upon the training and experience of the surgeon. They are not normally asked to choose between treatment modalities and the risks and benefits are very similar at a population level. The expert group wanted to make it clear the varicose veins do not just occur in old people, young people get them too. There was some concern within the group about overemphasising ‘do things yourself’ because there is little evidence of the effectiveness of anything other than the treatment procedures/surgeries. Use of compression, for example, is the best studied non-invasive treatment, but it is uncomfortable, difficult to use consistently and well, and so compliance is poor. If you need treatment, getting it earlier is better, and giving ‘do it yourself’ alternatives might delay that for some people. We were, however, keen to ensure that people had a genuine choice and so provided all the options, with quantitative evidence where it was available (e.g. for compression). Patients were very keen to know how to prevent varicose veins coming back, but we did not have evidence on methods of prevention. There is no evidence on any measures that prevent veins. How much to include about ulcers was an ongoing conversation. They’re not *that* common but common enough and serious enough that patients wanted more information about them that might be imagined. We worked hard on how to do this without being persuasive (i.e. making it sound as though the information about ulcers was there to make treatment of varicose veins reducing the likelihood of ulcers seem more important). We tried to make sure that we kept the absolute risks of ulcers with and without treatment close to the information about ulcers. The expert group also had a discussion about how quickly those presenting with ulcers should be seen. There is a NICE recommendation that patients are referred for urgent vascular treatment within 2 weeks from primary care, but being realistic and managing patients’ expectations, we phrased it as “your GP will make an urgent referral” (although clinicians pointed out that there is no such thing as an urgent referral in most cases, the urgency comes

	from the receiver end on clinical triage. The only universal urgent referrals are for suspected cancer.) Dec 2023 There was a discussion among the expert group about how to convey to patients the reason why it is impossible for some GPs to refer patients for treatment, even if they have symptoms. A GP had raised with NHS E that under some ICBs it is not possible to refer patients for all symptoms as recommended by NICE. This results in an unsatisfactory situation whereby patients may choose treatment according to the decision aid, evidence, and NICE guidance, but the GP will be unable to allow them to access that treatment due to the local ICB rules. This may lead to conflict between patient and GP. After much discussion it was decided that the following wording would be included in the document *NICE is the body which makes healthcare recommendations to the NHS (page 10).* *NICE say if you have any of these symptoms or complications you can choose to have the treatments on page 6.* *Some areas have restrictions on who can have treatment depending on their symptoms or other factors.* *Your GP will be able to tell you if treatments are available to you in your area.* .

Some example answers from our patient and regular clinician testers and actions we took on the basis of them (organised by testing round)	
Round 1	*PATIENTS* *"It's long, maybe change order. I would like to know more before reading about treatments. Seems like text has been shortened too much in places so that text has lost meaning."* **In previous decision aids we put 'more information about the condition' towards the end of the document. After testing in round 1 and 2 we moved this 'more about' page to earlier in the leaflet. People wanted to know more about varicose veins, what they are and how they got them, before they made a decision about treatment.** *"I have read through the document and was very impressed I wish I was given this at the beginning of my problem. It explains and helps understand."* *"Easy to read and follow, colours and contrast is good. Like the side by side comparisons."*

	We implement learning from testing other decision aids (we had published 11 and tested 6 others when we created this one). We have learned which colours were good to use, how to use them so that they are useful and acceptable to people with visual issues. This tester was autistic with extra visual needs. *"Will it be a booklet in A4 or A5? A4 is better for my eyes at my age. I like the picture diagrams. Could you add more to show what the procedures and tools look like?"* 'fill in before appointment' pages: *"I like this - good for you to remember what was said and what to ask"* *"These pages look really helpful. You get lots of info and referrals etc… so having a place to put your details and thoughts is very helpful and you can then take thee along."* **We made sure there was enough room to write down the contact details of different members of the care team as well as multiple spaces for appointments. This was different so some other decision aids where repeat visits were not as commonplace.** Clinician: *"Could you have multiple copies of this page to be filled in as people progress through their treatment? Questions at the start may change as decisions are made, contacts may change as people move from GP, to consultant to community care, and next steps will change after each appointment."* **Unfortunately space didn't allow us to have multiple versions of the page, though people can print extra, and if people print the documents single-sided there will be more room on the backs of pages for writing.** *Patient* *"I really like the format and design. I looked through some of the examples that you said you made last year and can see that they belong together, same style, etc... may be good if people start to recognise these documents across different disorders/medical issues."* *Clinician* *"Will those coloured boxes match the pages? That is very helpful e.g blue for treatment options, Purple for more info…….."*

Round 2	*CLINICIANS* *“Would it be A4 size or leaflet/booklet size? Bigger may be better for older or visually impaired patients”* *“REWORD the description of phlebitis”* *“‘next appts’ pages - Maybe more space for contacts - GP, Surgeon, Vascular Nurses, Community & district nurse, wound nurse, compression nurse……….”* *NURSE* *“Pictures and diagrams are helpful too, I feel like I have even learned a few things about the procedures.”* *“ I don’t feel like the decision aid helped me to make a decision - none of the options seemed to outweigh the others enough to sway my opinion if I were to need the treatment - which one is actually best?”* *CLINICIAN* *“I’d argue that we see a lot "younger" people too - 30-40+, but it’s always seen as an ‘old person problem’”* **We removed reference to prevalence of varicose veins by age. Clinicians told us that younger people get varicose veins and it’s not an ‘old person’ condition.** *PATIENT* *“Clear, helpful to understand what varicose veins are if you did not have awareness before. Images clear, to understand what the damage looks like.”* *CLINICIAN* *“Who to talk to - what is going to happen to them? These are what are most important to patients.”* *“I talk about mental health and preparation for treatment. Not being mentally prepared can be a stumbling block that prevents treatment from happening or being completed. Mental health is big issue, especially for people with tired, achy legs who have been dealing with symptoms for some time.”* **We included reflective questions about mental health on the ‘what’s important to you’ page. The Leg Club and other links on the ‘more information page’ has emotional and peer support for people.**

	PATIENT *“Colours were confusing”* **We changed the colour scheme to be clearer** *PATIENT* *“I like to have lots of info. Some don’t. It’s up to you how much research you want … and to know this has had input from lots of different experts takes some of that effort away.”* *CLINICIAN* *“I’m worried that people who have symptoms might not be treated. Worried about the emphasis. Worried the saying not all varicose veins need to be treated is putting emphasis such that people might not seek help when they should. There’s three groups – asymptomatic don't need treatment; bleeding and discoloured – need treatment; plus a group in the middle whose symptoms could be made better if they have treatment”* **We addressed this issue by stating clearly (and checked through testing with patients) the likelihood of symptoms, symptom progression and asymptomatic varicose veins. Treatment or not is always a patient choice when offered (i.e. not for the asymptomatic group).**
Round 3	PATIENTS *“This has me thinking that I need to visit a doctor about current symptoms. It looks like a good and helpful document. Info is good – just needs more images and tarting up and will be an amazing tool and asset to those who have no knowledge/experience of varicose veins.”* *“Maybe make clear that you have lot of veins so the treatment will not affect your circulation after.”* **We included a sentence about this** *“‘damaged to skin’ makes a lot of sense - mine was not red but hot & tender”* *“‘How did I get VV’ - none of this applies to me?? Still a mystery? Change to "These are the most common reasons…….."”* **We changed the wording** *“Stocking - make prescription more clear. Do you have to pay?”*

	We changed the wording *"The second option you showed me looks best: text on left and options to compare side by side - less text, clear comparison"* v2.3 page 8 (final version page 7) this referred to the symptom improvement and ulcer recurrence. "'How often do you get …' section: maybe fill out their own scale as these are too vague/spaced out. "Daily" may be too often but "once a week" not often enough." **We replaced the scale with tick boxes for if you do or don't have each item.** *"I have naively thought that I am done after surgery - make it clear that this can return and might not be obvious on the surface e.g visible varicose veins not always the case. Does there need to be post surgery follow up - once you have varicose veins you have follow up screenings? Every x years?"* **We ensured that we included numbers for the number of people whose varicose veins came back after surgery.** *(community nurse)* *"I like that it encourages them to make a decision then discuss what they think is right with the Doctors, rather than just being told 'this is treatment'."*
Round 4	Clinician input - discussion about ulcers, recurrence, prevalence - discussion around symptomatic / asymptomatic prevalence and treatment and that VV are not treated cosmetically on NHS. - Queries around inclusion of stockings as a treatment option. NICE does not recommend stockings unless you are not suitable for surgical treatments, or while you're waiting for a procedure or you don't want any of the procedures. **We changed the wording slightly to make this clearer, but wanted to keep them as an option for those who choose not to have a procedure, in accordance with the guidance.**

	Final version: - *Thanks - this looks fantastic* - *Well done - I am sure it wasn't easy and took a lot of work - I couldn't see anything that needed changing - it looks great and I'd like to start using it here as soon as it is officially available*

Reading age range	V8.1	Using https://readabilityformulas.com/readability-scoring-system.php Average Reading Age Consensus Calculator Average reading age 10-11 (v6.2)

Where did we get our numbers from?

This section explains what sources we used, and why.

How many people have the condition?

Where possible we try to use the most recent UK registry/audit data for the prevalence of a condition, or (if many who have the condition may not be diagnosed and hence recorded as having it), survey or other relevant methods of determining prevalence.

For the prevalence of varicose veins and associated symptoms, we used:

Bradbury 1999 - Edinburgh Vein Study https://doi.org/10.1136/bmj.318.7180.353
(1566 people: questionnnaire & examination, Scotland)

Carpentier 2004 https://doi.org/10.1016/j.jvs.2004.07.025
(2000 people, questionnaire and examination, France. Table 1)

Maurins 2008 - Bonn Vein Study https://doi.org/10.1016/j.jvs.2008.04.029
(3072 people surveyed and examined in Germany (Table II for vvs, Table I for skin changes - C4 classification))

For the prevalence of skin ulcers, we used:
Maurins 2008 - Bonn Vein Study https://doi.org/10.1016/j.jvs.2008.04.029

Nelson 2014
https://doi.org/10.1002/14651858.CD002303.pub3
Cochrane Collaboration review on compression for leg ulcer recurrence

Carvalho 2016
https://doi.org/10.1002/14651858.CD009432.pub2.

Cochrane Collaboration review on aspirin for leg ulcers

And the NICE guidance (2013) https://nice.org.uk/guidance/cg168
For the prevalence of ulcers in those with varicose veins.

Potential benefits & harms of different treatment options
For this section of each decision aid, we try to find the absolute risks (the number out of every 100 people who would have experienced the outcome) for each of the things that patients and clinicians tell us is important. Numbers can come from observational studies (where people choose their treatment and the outcomes are recorded), or from clinical trials (where people are assigned to a treatment at random). Which is more useful depends on the circumstances, but in some clinical trials some people assigned to one treatment ends up taking another (for different reasons). Some academic studies report the outcomes as if they had taken the treatment they were originally assigned (called 'intention to treat' data), and some studies report the outcomes depending on the treatment that they actually took (called 'per protocol' or 'per treatment' data). We always try to find 'per protocol' data as this is more useful for an individual wanting to know what might happen if they have one treatment or another.

We usually start by looking at trustworthy summaries of evidence, such as those done by NICE or by the Cochrane collaboration.

If these summaries give us all the numbers that we need, and are considered up to date by the expert group, we would use those. If not, we would look for any large trial in a population that is relevant to the UK and use the findings of that. If there are many trials, we would collate them all and tend to cite a range based on the lowest and highest number for each outcome found across those studies (rounding the numbers to give an appropriate sense of the degree of certainty). Where there is consensus that there is 'no significant difference' between different outcomes, we will ensure this is reflected in the ranges we give.

The expert group will agree all the numbers, and suggest better sources for them, throughout the development process.

We started with the NICE clinical guideline for varicose veins in the legs (2013), and the interventional procedures guidance for radiofrequency ablation (www.nice.org.uk/guidance/ipg8), ultrasound guided foam sclerotherapy (www.nice.org.uk/guidance/ipg440), endovenous laser treatment (www.nice.org.uk/guidance/ipg52) and endovenous mechanochemical ablation (www.nice.org.uk/guidance/ipg557), plus the Cochrane reviews by Whing (2021), Shingler (2021), Paravastu (2016), Oliveira (2021). Carvalho (2016) and Nelson (2014).

We then sought specific papers to provide data to answer the questions that patients wanted.

For the recurrence of skin ulcers, we used:

For ‘do nothing’:
Nelson 2014
https://doi.org/10.1002/14651858.CD002303.pub3
Cochrane on compression for leg ulcer recurrence

For compression stockings:
Gohel 2007 - ESCHAR trial
https://doi.org/10.1136/bmj.39216.542442.BE
500 patients in UK
(we couldn’t use Gohel’s EVRA trial because they used ablation of healed ulcers)

For treatments (lumping all together):
Gohel 2018 – EVRA
https://doi.org/10.1056/NEJMoa1801214
450 patients in RCT, UK. Numbers from text

For symptom improvement it was difficult to find evidence of how many patients record an improvements in symptoms – most trials record a mean improvement in rating on a scale.

However, we were able to find and agree on approximate figures based on:

For ‘do nothing’:
Krijnen 1997
https://www.jstor.org/stable/44994981
114 people randomised to placebo or stockings

Although not a good trial, the findings were also in line with the placebo arm of:
King 2015
https://doi.org/10.1016/j.ejvs.2015.06.111
279 patients
(in which patients wore stocking for 12 days at the start, after a placebo injection).

We rejected the data from
Kakkos 2018
https://doi.org/10.1016/j.ejvs.2017.10.004
A small study in only 30 patients, as they were wearing non-compression stockings

For compression stockings:
Michaels 2006 – REACTIV
https://doi.org/10.3310/hta10130
1000 or so patients, but split into different groups
This reported patients with ‘severe’ and ‘moderate’ vvs separately. We used both figures to form the complete range.

For ‘treatment’ we used:
King 2015

https://doi.org/10.1016/j.ejvs.2015.06.111
279 patients

Todd 2014 – VANISH2 trial
https://doi.org/10.1177/0268355513497709
235 patients (table 2)

We rejected data from the Michaels 2006 – REACTIV trial because the surgical techniques used in that trial are out of date (non-guided).

For the risks of treatment, we used data from:

For pins and needles/numbness:
NICE CG168 https://www.nice.org.uk/guidance/cg168/evidence/full-guideline-pdf-191485261

For short-term pain:
Gibson 2016
https://doi.org/10.1177/0268355516635386
King 2015
https://doi.org/10.1016/j.ejvs.2015.06.111
Todd 2014
https://doi.org/10.1177/0268355513497709

For contusion:
Gibson 2016
https://doi.org/10.1177/0268355516635386

For recurrence of varicose veins:
Whing 2021 Cochrane
https://doi.org/10.1002/14651858.CD005624.pub4
(4% per year – study under review by one of the experts)

This figure was also in line with the Bonn Vein Study and REACTIV.

For DVT:
Heit 2015 for baseline (general population
https://doi.org/10.1038/nrcardio.2015.83

For those taking treatment, we started with Turner 2023
https://doi.org/10.1097/SLA.0000000000005709
but it had mixed trials with different lengths of time before follow-up, and some of the data they cited didn't seem to match the data in the original papers themselves. So, we turned to the review article by Testroote 2013 (https://doi.org/10.1177/0268355512475121) which gave figures from the literature for those diagnosed by ultrasound (much higher) compared

to those with symptomatic thrombosis. Since our baseline figure, and what patients were interested in, was symptomatic thrombosis, we decided to use that.

Testroote’s figures of ‘around 0.5%’ from the literature again did not give an explicit time period, but Barker 2017 gave UK Hospital Episodes Data from 261,169 people, and gave figures for DVTs at different timepoints. This allowed us to give a figure for 1 year. It was also reassuring that at this timepoint, the rate was not significantly different between different treatment options.