NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE guidelines

Equality impact assessment

Venous thromboembolic diseases: diagnosis, management and thrombophilia testing (update)

The impact on equality has been assessed during guidance development according to the principles of the NICE equality policy.

1.0 Checking for updates and scope: before scope consultation (to be completed by the Developer and submitted with the draft scope for consultation)

1.1 Have any potential equality issues been identified during the check for an update or during development of the draft scope, and, if so, what are they? (Please specify if the issue has been highlighted by a stakeholder)
During development of the draft scope the following potential equality issues were identified: • Disability: It has been highlighted that people with a learning disability may need specific consideration when looking at pharmacological treatment for VTE, especially with regard to self- management of longer term medication. People with frailty or people who have restricted movement, need to be considered, as people who are less mobile can have poorer outcomes after having a VTE. Settings where there is less opportunity for mobilisation, such as nursing homes, need to be considered. • Gender reassignment: Hormone treatment given to people undergoing male to female transition includes high dose oestrogen which is a risk factor for VTE. • Religion/ beliefs: Heparin is one of the pharmacological treatments for VTE and is derived from porcine origin. People with beliefs about animal derived products need to be given consideration when discussing different antithrombotic pharmacotherapy. Religion and beliefs were considered by the original guideline and specific recommendations were made. These

recommendations are not included in this update of the guideline.

- Age: there is an increasing incidence of VTE with increasing age. Younger men have the highest risk of recurrent VTE.

- Other definable characteristics:

    - Whilst intravenous drug users are at higher risk of having a VTE, there are issues with treatment of this population group (for example, poor venous access and non-compliance). This leads to poorer outcomes in this group.
    - Migrant workers and Gypsies, Roma and travellers, and any group of people for whom establishing long-term follow-up for VTE treatment could be challenging. Lack of follow up could lead to poorer outcomes.
    - People who have a BMI classification of obese III (a BMI of 40kg/m^2 or more): People who are obese may have reduced mobility and therefore be at increased risk of DVT or PE. There is also added complexity in calculating an accurate dose of pharmacological anticoagulant in obese people.
    - People who have stage 3 to 5 chronic kidney disease: People with renal impairment are at a higher risk from contrast with certain pharmacological anticoagulant medications due to their impaired kidney function[1]. Therefore people with impaired kidney function are not able to have certain investigations (CTPA) or receive certain anticoagulant pharmacotherapy.

1.2 What is the preliminary view on the extent to which these potential equality issues need addressing by the Committee? For example, if population groups, treatments or settings are excluded from the scope, are these exclusions justified – that is, are the reasons legitimate and the exclusion proportionate?

Positive outcomes are known to be more difficult to achieve in these population groups, and therefore specific recommendation in these groups may need to be

[1] Please note a factual error was noted following initial publication of this scope and this sentence was amended 29/03/2018 to acknowledge that people with impaired kidney function are at a higher risk from contrast with certain medications.

1.2 What is the preliminary view on the extent to which these potential equality issues need addressing by the Committee? For example, if population groups, treatments or settings are excluded from the scope, are these exclusions justified – that is, are the reasons legitimate and the exclusion proportionate?
made to address this. Pregnant women are excluded from this guideline because there is separate guidance on managing DVT and PE in this population group, published by the Royal College of Gynaecologists (RCOG), (RCOG, 2015). NICE has produced guidance on risk assessment of VTE in pregnant women (Venous thromboembolism: reducing the risk for patients in hospital, NICE Clinical Guideline 92) and for recognising the signs and symptoms of potentially life-threatening conditions, including VTE, during the postnatal period (Postnatal care up to 8 weeks after birth, NICE Clinical Guideline 37).

Completed by Developer ___Sara Buckner

Date_____24.01.2018

Approved by NICE quality assurance lead ___Simon Ellis

Date_____26.01.2018

2.0 Checking for updates and scope: after consultation (to be completed by the Developer and submitted with the revised scope)

2.1 Have any potential equality issues been identified during consultation, and, if so, what are they?
Two stakeholders queried that pregnant women have been excluded from the scope of the guideline. One stakeholder queried if the scope should specifically mention mental health trusts as an included setting. One stakeholder queried if people with liver impairment should be given specific consideration in the guideline.

2.2 Have any changes to the scope been made as a result of consultation to highlight potential equality issues?
No changes have been made to the scope as a results of equalities issues identified during scope consultation, the reasons for this are: Pregnant women are excluded from this guideline because there is separate guidance on managing DVT and PE in this population group, published by the Royal College of Gynaecologists (RCOG), (RCOG, 2015). NICE has produced guidance on risk assessment of VTE in pregnant women (Venous thromboembolism: reducing the risk for patients in hospital. The guideline will cover all settings where NHS-funded care is provided which includes mental health trusts. People with liver impairment are included in the guideline. If evidence in this population is identified during the update of this guideline the evidence will be considered and a subgroup analysis may be performed.

2.3 Is the primary focus of the guideline a population with a specific disability-related communication need? If so, do the key messages for the public need to be produced in an alternative version? If so, which alternative version is recommended? The alternative versions available are: • large font or audio versions for a population with sight loss • British Sign Language videos for a population deaf from birth • 'Easy read' versions for people with learning disabilities or cognitive impairment. Does an alternative version(s) of the consultation documents also need to be produced?
The primary focus of the guideline is not a population with a specific disability-related communication need, therefore there is not a need for an alternative version of the guideline.

Updated by Developer _____Katrina Penman

Date__29.03.2018

Approved by NICE quality assurance lead _____ Simon Ellis

Date _____ 20.04.2018

3.0 Guideline development: before consultation (to be completed by the Developer before consultation on the draft guideline)

3.1 Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how?

The scoping process identified a number of potential equality issues: Age, IV drug users, people with learning disabilities, people undergoing male to female gender reassignment, religious beliefs, migrant workers and Gypsies, Roma and travellers, people who have a BMI classification of obese III, people who have stage 3 to 5 chronic kidney disease.

The Guideline Committee has addressed these areas as follows:

Age

The scoping process identified that there is an increasing incidence of VTE with increasing age and that younger men have the highest risk of recurrent VTE. To enable the committee to make separate recommendations for these people where necessary and possible, subgroup analyses for age were carried out for the following reviews if data was available: IVC filters, the pharmacological treatment and duration of treatment. In addition, there were 2 review questions that specifically looked at the use of an age-adjusted D-dimer test in people aged over 50 years.

For the optimum duration of treatment for VTE review, subgroup analyses were performed for several different prognostic tools. The committee made recommendations to use DASH to predict VTE-recurrence specifically in those people aged under 65 years as the DASH tool was found to have good classification accuracy in this age group; comparably, the DASH tool had poor classification accuracy in people 65 years of age or older.

For the pharmacological treatment of VTE, analyses were performed for the elderly (65 years of age or older) and those under 65 years of age. The committee agreed

3.1 Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how?
that they could not make specific recommendations for this group due to uncertainty around some of the outcomes. In addition, the committee also recommended that comorbidities, contraindications and the person's preferences are also taken into account during the decision-making process. The committee agreed that, taken together, these recommendations should ensure that a suitable treatment regimen is chosen for older people, who often have comorbidities and may be taking other medications. In addition, the committee made a recommendation for a review (at last once yearly) of general health, risk of VTE recurrence, bleeding risk and treatment preferences for people having long-term anticoagulation treatment. This should add an extra level of protection for older people who may have, or develop, cognitive impairment or dementia or be increasingly prone to falls and ensure that their treatment continues to meet their needs. The IVC filter review identified evidence for people aged 80 years and over, but they were unable to make separate recommendations for this group due to the poor quality of the evidence. **Learning disabilities** The committee discussed the impact learning disabilities may have on each of their recommendations. The committee noted that in particular, there is a need to consider learning disabilities when prescribing pharmacological treatment for VTE, due to the potential impact this disability may have on drug adherence. However, the committee agreed that specific recommendations for this group do not need to be made as poor drug adherence is not specific to the treatment of VTE. Instead, the recommendations for the pharmacological treatment of VTE included a cross reference to the NICE guideline for medicines adherence. The committee also noted that the guideline on patient experience in adult NHS services addresses factors such as disabilities and effective communication and this is referred to in the discussion section. In addition to recommending specific treatment options the committee also recommended that comorbidities, contraindications and the person's preferences are also taken into account during the decision-making process. The committee agreed that taken together these recommendations would enable the issue of adherence for those with learning disabilities to be taken into consideration to ensure that a suitable treatment regimen is chosen. **Gender reassignment, migrant workers and Gypsies, Roma and travellers** People undergoing gender reassignment, migrant workers and Gypsies, Roma and travellers were all considered during the guideline development process. The committee did not make any specific recommendations for any of these groups due to a lack of evidence. However, the committee agreed that their recommendations did not need to be adapted for use in these groups because many of the issues

3.1 Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how?
concerning these groups were around access to treatment which was not in the scope of this update. They agreed that the pharmacological treatment recommendations offer a range of treatment options in most cases and the clinician and person with VTE can select the most appropriate one for them given their clinical needs, preferences and circumstances. **Obesity** The committee included obesity as a subgroup analysis in a number of reviews: IVC filters, pharmacological treatment, D-dimer testing, outpatient treatment and the pulmonary embolism rule out criteria (PERC) reviews. No evidence was found for people with obesity III (BMI of 40kg/m^2 or more) in the pharmacological treatment review, however the committee discussed evidence from subgroup analyses for people with obesity assessed as a BMI of 30kg/m^2 or more. The evidence was poor due to limited sample sizes and numbers of events and the committee made consensus recommendations for the pharmacological treatment in people with obesity. They also included obesity as a subgroup analysis in the pharmacological treatment research recommendations. **IV drug users** No evidence was found for this group in the any of the reviews, but the committee made a research recommendation to identify the optimal pharmacological treatment strategy for DVT or PE in people who use intravenous drugs. **Religious groups** The committee discussed the issue surrounding animal products in the pharmacological treatment of VTE and the religious implications this could have. The committee were concerned that most of the anticoagulants were of heparin origin and that apixaban and rivaroxaban contain lactose from cow's milk. The committee amended an existing recommendation in the information section to include the animal origin of the above direct oral anticoagulants (DOACs). This section was otherwise out of scope of the update. **Chronic kidney disease** There was limited evidence for the people with chronic kidney disease (also known as renal impairment). The committee made consensus recommendations for the pharmacological treatment of these people based on their level of renal impairment or failure. This highlighted the importance of taking note of the requirements for caution, dose adjustment and monitoring in the medicine's summary of product characteristics and following locally agreed protocols or advice from a specialist or multidisciplinary team to ensure that a person with VTE and renal impairment

3.1 Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how?
receives the best possible treatment. In addition, the committee also recommended that comorbidities, contraindications and the person's preferences are also taken into account during the decision-making process. The committee agreed that, taken together, these recommendations should ensure that a suitable treatment regimen is chosen for people with renal impairment, who may have additional comorbidities and are likely to be taking other medications.

3.2 Have any **other** potential equality issues (in addition to those identified during the scoping process) been identified, and, if so, how has the Committee addressed them?
In addition to discussions for learning disability, the committee discussed general cognitive impairment (such as cognitive impairment due to dementia) and the concerns they had with adherence in these populations, which would be an increasing issue as practice moves increasingly towards treatment with the DOACs which require less monitoring than VKA. However, similar to those people with learning disabilities, the committee agreed that specific recommendations do not need to be made as the problem of drug adherence is not specific to the treatment of VTE. Instead, the recommendations for the pharmacological treatment of VTE included a cross reference to the NICE guideline for on medicines adherence. In addition, the committee made a recommendation for a review (at last once yearly) of general health, risk of VTE recurrence, bleeding risk and treatment preferences for people having long-term anticoagulation treatment. This should add an extra level of protection for people with cognitive impairment and ensure that their treatment continues to meet their needs. The committee also noted that people with VTE often carry anticoagulation alert cards or information to alert people should they fall ill and that these are increasingly contained within the lock screen or apps in smart phones. However, they agreed that the increasing use of such technology could be problematic for older people or those who lacked the technical ability to use such features (or access to smart phones). These issues were out of scope of the update so the committee did not make any recommendations.

3.3 Have the Committee's considerations of equality issues been described in the guideline for consultation, and, if so, where?
The Committee's considerations of equality issues are described in the evidence reviews for each question, in particular in the benefits and harms, and other considerations sections of the discussion sections associated with the relevant review questions.

3.4 Do the preliminary recommendations make it more difficult in practice for a specific group to access services compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
The committee agreed that none of the recommendations should make it more difficult for any of the groups identified above to access services.

3.5 Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
Provided the NICE guideline on medicines adherence is referred to and the recommendations about taking comorbidities, contraindications and the person's preferences into account when offering anticoagulation treatment are followed then no groups should be disadvantaged by the recommendations the committee made.

3.6 Are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access to services identified in box 3.4, or otherwise fulfil NICE's obligation to advance equality?
No.

Completed by Developer: Marie Harrisingh

Date: 4/10/2019

Approved by NICE quality assurance lead: Simon Ellis

Date: 26/11/2019

4.0 Final guideline (to be completed by the Developer before GE consideration of final guideline)

4.1 Have any additional potential equality issues been raised during the consultation, and, if so, how has the Committee addressed them?
The stakeholders raised the issue that people with low body weight (less than 50kg) may also need different treatment options to people with more normal body weight. They also asked for a section on the pharmacological treatment of people with triple positive antiphospholipid syndrome (APS) to be added to the guideline to reflect treatment options following the recent MHRA safety alert about the use of DOACs in these people.

4.2 If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access services compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
The recommendations on pharmacological treatment for people with obesity III (BMI of 40kg/m^2 or more) have been amended as follows: • they have been expanded to include people with low body weight (less than 50kg) • the use of BMI for high body weight has been replaced by the use of absolute weight (greater than 120kg) to better reflect the information provided in the summary of product characteristics for the anticoagulants. Other relevant changes are as follows: • A section on the pharmacological treatment of people with triple positive APS to be added to the guideline to reflect treatment options following the MHRA safety alert. These changes and the other amendments made in response to stakeholder

4.2 If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access services compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
comments are not expected to disadvantage any particular groups of people.

4.3 If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
The changes to the recommendations are not expected to have this effect.

4.4 If the recommendations have changed after consultation, are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access to services identified in question 4.2, or otherwise fulfil NICE's obligations to advance equality?
The changed recommendations are not expected to introduce any barriers to, or difficulties with, access to services.

4.5 Have the Committee's considerations of equality issues been described in the final guideline, and, if so, where?
The Committee's considerations of equality issues are described in the evidence reviews for each question, in particular in the benefits and harms, and other considerations sections of the discussion sections associated with the relevant review questions. They are also covered in the relevant rationale sections in the guideline where they relate to specific recommendations.

Updated by Developer ___Susan Speirs_____

Date_____03.03.20_____

Approved by NICE quality assurance lead _____

Date_____

5.0 After Guidance Executive amendments – if applicable (to be completed by appropriate NICE staff member after Guidance Executive)

5.1 Outline amendments agreed by Guidance Executive below, if applicable:
The changes requested by GE are outlined below; • To add text to the guideline rationale for initial and long-term anticoagulation treatment to state that sensitivity analyses were carried out varying the drug prices but these analyses did not change any of the conclusions from the economic model. • To add text to clarify that the 'concerns' in recommendation 1.5.3 refers to both ethical concerns and allergies. These changes are not expected to have adverse impacts on any of the groups defined above.

Approved by Developer: Susan Spiers

Date: 11.03.20

Approved by NICE quality assurance lead: Simon Ellis

Date: 20.03.20