NICE National Institute for Health and Care Excellence

2021 exceptional surveillance of venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism (NICE guideline NG89)

Surveillance report

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Surveillance decision

We will not update the NICE guideline on venous thromboembolism in over 16s.

However, in response to the Healthcare Safety Investigation Branch (HSIB) safety observation that the Department of Health (DH) venous thromboembolism (VTE) risk assessment tool does not provide a stratified risk for predicting a patient's likelihood of developing VTE or pulmonary embolism (PE), but instead serves as a prompt for clinicians to develop an appropriate treatment plan, we will amend recommendations 1.1.2 and 1.1.5 in the NICE guideline to clarify that the role of the DH VTE tool is to aid development of a treatment plan.

Reason for the exceptional review

This exceptional surveillance review was triggered by the HSIB report on the management of venous thromboembolism risk in patients following thrombolysis for an acute stroke (HSIB 2020).

The HSIB investigation followed an incident in which a patient who had a stroke was admitted to hospital, received an initial risk assessment for VTE during a consultation ward round and was assessed as having a high risk of bleeding and could not therefore be administered anticoagulant medication. The HSIB report says that 'An intermittent pneumatic compression (IPC) device was considered an appropriate treatment for the patient and the relevant box on the VTE risk assessment form was ticked.' They report that:

'...in order for IPC devices to be fitted, the Trust's process was for the doctor to document the order to fit the IPC device on the patient's prescription chart; this step was not completed. A subsequent VTE risk assessment, that should have been conducted 24 hours after the first, was not completed'.

The patient was not fitted with an IPC device; their condition deteriorated, and they were diagnosed with a pulmonary embolism on the seventeenth day of admission. They were then prescribed anticoagulant medication (standard treatment for PE). The patient was transferred to a medical high dependency unit and remained there for 6 days, then returned to the stroke unit and received rehabilitation for a month.

The HSIB investigation focused on 'the management of VTE risk in inpatients following thrombolysis for an acute stroke' and the 'detection of medical problems (that impact on VTE risk) occurring in inpatients following thrombolysis for an acute stroke'.

Methods

The exceptional surveillance process consisted of:

- Feedback from topic experts via a questionnaire.
- Considering the evidence used to develop the guideline in 2018.
- Examining related NICE guidance and quality standards.
- Examining the NICE event tracker for relevant ongoing and published events.
- Assessing the HSIB report findings against current recommendations to determine whether the guideline needs updating.

We decided that literature searches were not needed because the HSIB safety recommendation was made on the basis of an incident, not newly published evidence, and the information we had from the original guideline and topic experts was enough to establish whether an update to the guideline was needed.

We engaged with topic experts who were recruited to the NICE centre for guidelines expert advisers' panel to represent their specialty. Fifteen topic experts were contacted and asked to complete a questionnaire. We received feedback from 8 topic experts (4 consultants specialising in stroke, a consultant in haematology, a consultant in acute medicine pharmacology and therapeutics, a consultant in geriatric medicine, and a nurse consultant in anticoagulation and thrombosis).

For further details about the process, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Information considered in this exceptional surveillance review

Risk assessment tool as a treatment plan prompt (safety

observation O/2020/070):

This safety observation states that 'there is no validated VTE risk assessment tool in the UK that produces a stratified risk for predicting a patient's likelihood of developing a deep vein thromboembolism or pulmonary embolism. If it is not possible to produce a stratified VTE risk assessment, it may be beneficial to consider amending the title of the published VTE risk assessment tool in the NICE guideline. This would reflect its true purpose as a prompt for clinicians to develop an appropriate treatment plan rather than creating the perception that it produces an assessment of risk.'

The HSIB report says that the DH VTE tool does 'not provide a stratified risk on completion of the 'risk assessment' process. The VTE risk assessment form records the presence of the patient's individual risk factors but does not weight or score these factors. In its current form it is more suitable to aid decision making toward a treatment plan. Using the words 'risk assessment' in the title is misleading and could lead to clinicians not completing the appropriate actions required to ensure that patients receive the appropriate VTE preventative measures.'

Recommendation 1.1.2 in the NICE guideline states:

- 'Assess all medical patients to identify the risk of VTE and bleeding:
  - As soon as possible after admission to hospital or by the time of the first consultant review
  - Using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health VTE risk assessment tool.'

Recommendation 1.1.5 has the same wording, but for 'all surgical and trauma patients'.

Information considered when developing the NICE guideline

Evidence was identified for a number of VTE risk assessment tools (14 studies looking at risk tools for predicting VTE in medical patients and 4 studies on the clinical effectiveness of risk tools for reducing VTE; see volume 1 of the full guideline). However, the committee determined that none of the tools demonstrated sufficiently accurate performance for predicting VTE or bleeding risk, with none reaching the committee's pre-specified sensitivity and specificity thresholds (greater than or equal to 80% and greater than or

equal to 60% respectively) and many reporting only poor discrimination. The committee agreed that risk assessment is a critical part of the pathway for VTE prophylaxis and that risk tools are beneficial in this process. However, in the absence of clear evidence, there was disagreement about which tool to recommend.

The final decision by the guideline development group to recommend 'using a tool published by a national UK body, professional network or peer-reviewed journal' and to name the DH VTE risk assessment tool was made following a committee vote on several alternative options for recommendations on assessing VTE risk: 1) use the DH VTE risk assessment tool, 2) use the IMPROVE (International Medical Prevention Registry on Venous Thromboembolism) tool, 3) use either the National VTE Risk Assessment tool or the IMPROVE tool, 4) consider medical patients at risk if immobility was a factor and they have an additional risk factor, with individual risk factors being provided as examples in a box, or 5) use an existing derived or validated tool or checklist.

It was reported that:

'...after considerable debate a committee meeting consensus was reached to rule out the first 3 options. However, no consensus was reached on whether to recommend options number 4 or 5 ... Because of the split decision the committee voted ... The vote produced a majority favouring option 5. Following stakeholder consultation, the committee also decided to acknowledge in the recommendation that the most commonly used VTE risk assessment tool for hospital patients in the NHS is the National tool.'

The rationale for including the DH VTE tool was also based on the National VTE Prevention Programme, which mandates the use of a national VTE risk assessment in all adult patients admitted to an acute hospital, with the DH VTE tool being used as current practice for surgical, medical and trauma patients. The committee noted that there were no published studies validating the DH VTE tool's performance at predicting medical patients' risk of VTE and risk of bleeding. They also noted that the DH VTE tool 'performed more like a checklist' as it is not a weighted tool, but instead involves an in-or-out decision.

Because of the uncertainty in the evidence for 1 risk tool over another, the committee prioritised a research recommendation asking 'What is the accuracy of individual risk assessment tools in predicting the risk of VTE and risk of bleeding in people admitted to hospital?' The rationale for this research recommendation also highlights that there was 'concern that the DH VTE tool may not accurately identify those who are most likely to get VTE.'

NICE's quality standard

Statement 1 on VTE and bleeding risk assessment in the NICE quality standard on venous thromboembolism in adults requires that 'medical, surgical or trauma patients have their risk of VTE and bleeding assessed using a national tool as soon as possible after admission to hospital'. It says that 'a national tool should be published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool is the Department of Health and Social Care VTE risk assessment tool'. The exceptional surveillance review decision will be shared with the quality standards team to consider amending this statement.

Topic expert feedback

As the VTE risk assessment tool is by the DH (that is, not a NICE product), NICE cannot change the title of the tool. Therefore, topic experts were asked for views on a proposal to change the description of the DH VTE risk assessment tool as a 'risk assessment tool' to a 'tool used to develop a treatment plan'. Topic experts responded that many hospitals modify the DH VTE tool and that it is a generic VTE risk assessment tool that does not inform VTE prevention management in acute stroke. Six topic experts agreed with the proposal to change the wording within recommendations 1.1.2 and 1.1.5 of the NICE guideline. Describing the DH VTE tool as a 'tool used to develop a treatment plan' was considered a more accurate reflection of its function; although some felt it was an unnecessary change as they did not think it would impact on practice, and that the purpose of a risk assessment is to inform a treatment plan. One topic expert thought the current wording of the recommendations is clear and does not need to be changed.

Proposed action

NICE will amend the wording of recommendations 1.1.2 and 1.1.5 of the NICE guideline to highlight that the role of the DH VTE tool is to support treatment plans (see overall decision).

Stroke-specific VTE assessment tool and treatment ordering system (safety recommendation R/2020/090):

This safety recommendation states that 'The Intercollegiate Stroke Working Party with support from the Joint Stroke Medicine Committee and NHS England and NHS Improvement develop a stroke-specific VTE assessment tool and system for ordering the

associated treatment for patients who have suffered a stroke. HSIB recommend that the Intercollegiate Stroke Working Party supports development of a tool that ensures that important information is recorded and reviewed at appropriate intervals.'

As the HSIB recommendation is not aimed at NICE, we did not consider that it had an impact on the NICE guideline; however, we consulted with topic experts for their view.

Topic expert feedback

Six topic experts agreed that no changes are currently required to the NICE guideline in response to the safety recommendation that a stroke-specific VTE assessment tool and system for ordering associated treatment is developed by the Intercollegiate Stroke Working Party. Topic experts involved in the development of the NICE guideline highlighted that they were aware at the time of development of the issues raised by HSIB concerning the DH VTE tool, and that this is reflected in the guideline (see information considered when developing the NICE guideline). Some concern was also raised by a topic expert about the development of a stroke-specific tool, describing it as 'unnecessary', unlikely to offer improved benefits and that it would 'take years to develop, validate and implement'. However, another topic expert thought that a stroke-specific risk assessment tool is needed, and that NICE could highlight the generic aspects of the DH VTE tool.

Of the 2 topic experts who responded that changes should be considered, 1 said 'change is required', but did not provide further information on what these changes should be. The other topic expert responded that 'many organisations already use tools that are developed in house and it would be good to have a standardised tool for stroke patients across the system which can be audited'.

Proposed action

No action for NICE (see overall decision).

Reassessment of VTE risk (safety observation O/2020/071)

This safety observation states that 'it would be beneficial for future VTE guidelines in relation to stroke to explicitly state when further VTE assessments are required during a patient's stay in hospital.' The authors note that if recommendation 1.1.8 in the NICE guideline (which says to 'reassess all medical, surgical and trauma patients for risk of VTE and bleeding at the point of consultant review or if their clinical condition changes') was

'routinely undertaken, this might identify whether the patient is suitable to receive any appropriate thromboprophylactic (VTE preventative) measures', but they have concerns that there is no requirement 'to record or monitor IPC [intermittent pneumatic compression] device status in a patient's notes, after the initial order to fit them is made' and that 'the lack of a routine follow-up check and its record means that if the initial order to fit IPC devices is not made, it is more likely that IPC devices would never be fitted to a patient.'

Information considered when developing the NICE guideline

Recommendation 1.1.8 of the guideline, on reassessing patients for risk of VTE and bleeding at the point of consultant review or if their clinical condition changes, was decided by committee consensus. The committee considered that

'undertaking the reassessment at the point of senior review or more frequently if there is a change in clinical condition would allow tailoring the need and the frequency of reassessment to the individual clinical condition and optimise outcomes.'

The committee noted that current practice was for reassessment to be undertaken within 24 hours,

'...which requires staff time, without evidence of cost-effectiveness. Hence the committee considered that it is not possible to mandate 24 hours as the time of review. Reassessment at the time of senior review was considered to be the most convenient and least resource intensive option as the reassessment would be done as part of a scheduled review'.

NICE's quality standard

Statement 4 on reassessment in the NICE quality standard on venous thromboembolism in adults requires that 'medical, surgical and trauma patients have their risk of VTE reassessed at consultant review or if their clinical condition changes'. As such, this supports the measurement of implementing recommendation 1.1.8 as hospitals are required to provide data showing that medical, surgical and trauma patients have their risk of VTE reassessed at consultant review and/or if their clinical condition changes.

Topic expert feedback

Three topic experts thought that further changes are not required concerning when further VTE assessments are required during a hospital stay for patients with stroke. The topic experts highlighted that during development of recommendation 1.8 on reassessment, the committee were concerned that having a set time for reassessment may turn it into a tick box exercise instead of a proper clinical assessment. They also said that if a set time period for reassessment was given there may be the unintended consequence of not reassessing at appropriate clinical points (that is, when a clinical event occurs). Two topic experts thought however that there should be a daily assessment of VTE risk and that there should be daily VTE prophylaxis assessment. Other topic experts thought that clearer guidance on when to reassess and commence VTE prophylaxis in stroke patients would be useful; and that written consent from a patient for intermittent pneumatic compression should be considered. However, 1 topic expert said that additional details were unnecessary as they are about routine quality processes of medical care, which is not the remit of NICE guidance.

Proposed action

No action for NICE (see overall decision).

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

We will not update the NICE guideline on venous thromboembolism in over 16s. The HSIB report is based on an incident that would have been less likely to occur if the recommendations in the NICE guideline and the hospital's own procedures had been followed. Limitations of the DH VTE tool were recognised during the development of the NICE guideline and resulted in a research recommendation that highlighted the need for further research on the accuracy of individual risk assessment tools in predicting the risk of VTE and risk of bleeding in people admitted to hospital.

As the HSIB safety recommendation (R/2020/090) to develop a VTE risk assessment tool is not directed at NICE and the majority of topic experts thought that no changes were required in response to the HSIB recommendation, no changes to the recommendations

within the NICE guideline are being proposed concerning a stroke-specific VTE assessment tool and system for ordering associated treatment.

With regards to safety observation O/2020/070, as the VTE risk assessment tool is by the DH, NICE cannot change the title of the tool. Instead, we are amending the wording within recommendations 1.1.2 and 1.1.5 to highlight that it is used to inform treatment:

- Using a tool published by a national UK body, professional network or peer-reviewed journal.

A tool commonly used to develop a treatment plan for medical/surgical and trauma patients is the Department of Health VTE risk assessment tool.

While safety observation O/2020/071 suggests that there may be an issue with implementing recommendation 1.1.8, NICE has also produced statement 4 in the NICE quality standard on venous thromboembolism in adults, which supports the measurement of implementing recommendation 1.1.8. We received a mixed response from topic experts as to whether a time period for VTE reassessment should be made. As the timing of reassessment was considered during development of the NICE guideline, we do not think any further changes are currently needed to it.

All comments received will be considered at the next standard surveillance review, alongside any newly identified evidence.

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