

“Don’t shoot the messengers.....”: The new NICE Guidance for the prevention of venous thromboembolism in adults – fake news or a real opportunity?

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The latest guidance (NG8) from the National Institute for Health and Care Excellence (NICE) for the prevention of venous thromboembolism (VTE) for patients in hospital aged 16 years and older has just been published¹. The authors have had the opportunity to represent the Trauma and Orthopaedic community on the subgroup advising the general committee. This has been two years of committee work – as ever a mixture of education, debate, sometimes frustration and compromise. The new guideline was generated in accordance with the published NICE methodology², it is rigorously evidence-based and we have had been able to have some influence. The recommendations are considerably more comprehensive than previously but as ever the process has exposed more questions than answers. We would like to highlight to the community some of the wider issues around the development of the guidance and the committee’s aspirations for the use of the guidance for the benefit of our patients.

We have sought to bring balance to the guideline which many of us felt was lacking in the previous iteration. For example, we are agreed that there is very good evidence that we can reduce the incidence of VTE. It follows therefore that we should be able to reduce the risk of death from VTE. Unfortunately, there is presently little, if any, contemporary scientific evidence that fatal VTE can be prevented. The introductory paragraph to the guideline stating that fatal pulmonary embolism was the most common cause of preventable in hospital death has been revised to remove the word ‘preventable’.

NICE guidelines make evidence-based recommendations on a wide range of topics, with an aim to promote individualised and integrated care. Recommendations are for individual healthcare practitioners, who should use them in their work in conjunction with their judgement and in discussion with patients. As such they are not rules to which we should slavishly adhere. Throughout the guideline the phrase “the risk of VTE outweighs the risk of bleeding”, or vice versa, is incorporated within the Recommendations. This requires a clinical assessment of risks and should be documented by all following discussions with patients. The present Department of Health Risk Assessment tool is not validated and many of us have issue with it when

applied to our patients. The requirement to use this tool has now, therefore, been removed. The National Institute for Health Research has already responded to this pressing need for urgent further research and has commissioned studies to improve our risk assessment processes.³ Our community should take this on.

Quite appropriately, where such studies exist, NICE will *only* consider Level 1 evidence – that is evidence from randomised controlled trials (RCTs) – to make judgements about the *relative* effectiveness of different treatments. Evidence from prospective audits such as the National Joint Registry (NJR), regional or local registries could not be considered. However, RCTs are not epidemiological studies designed to determine the incidence of VTE. We successfully argued to use data from the NJR in the development of the models for hip and knee arthroplasty which led to very different estimates of the cost-effectiveness of the different treatments and this is reflected in the updated Recommendations. The use of aspirin, for instance, appears for the first time in NICE guidance for the prevention of VTE in total knee replacement. The late addition of some treatments to the Recommendations, based upon technology appraisals that lay outside of the scope of the committee, was not based upon the findings from these comprehensive models.

NICE appraises the quality of the available evidence using the GRADE⁴ system. It was very quickly apparent to us during this process that the evidence is almost all of low quality. This limitation poses important research questions, and we considered over 130 of these, of which five are selected by the main committee as the priority questions. The five priority research recommendations are all directly relevant to our patients – the development of a validated risk assessment tool, dose strategies in the “obese”, the use of direct oral anti-coagulants (DOACs) in lower limb immobilisation, the use of aspirin in fragility fractures of the lower limb, and the duration of prophylaxis after total hip replacement.

Many of us will be disappointed that the Recommendations have not gone far enough in our opinion. The guideline includes all level 1 evidence published up to March 2018; in our opinion the most clinically and cost-effective treatments are indeed those suggested. The breadth of some of the recommendations reflects the uncertainty within the evidence-base. The core issue is the poor quality of the evidence that presently exists, despite all the recent observational studies extolling virtues of drugs like aspirin. It is incumbent on our community to plan, conduct and

deliver the RCTs we need to inform future guidance. We would urge the British Orthopaedic Association, the British Hip Society, British Association for Surgery of the Knee, the British Orthopaedic Foot and Ankle Society and Orthopaedic Trauma Society (OTS), and their memberships, to participate actively in large scale, multi-centre RCTs in an attempt to answer these questions so that any further guideline may incorporate practices reported in national, regional and local audits.

Each of us in our own units needs to review and consider this *guidance* carefully, participate in developing our own unit policies, and strive to help deliver the next generation of evidence to inform future iterations of the guideline.

References:

1. <https://www.nice.org.uk/guidance/ng89>
2. <https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview#information-about-this-manual>
3. <https://www.nihr.ac.uk/funding-and-support/funding-opportunities/1819-the-cost-effectiveness-of-venous-thromboembolism-risk-assessment-tools-for-hospital-inpatients/8167>
4. <http://www.gradeworkinggroup.org>