National Institute for Health and Clinical Excellence

Clinical guideline: Venous thromboembolic diseases

PRE-PUBLICATION CHECK FORM

Organisation	Order number	Section number in FULL guideline	Page number	ERROR REPORT	NCGC response
National Patient Safety Agency	1		131	**Appropriate dose:** Dosing errors in administering LMWH to patients have been the subject of a National Patient Safety Agency alert (NPSA Rapid response 14170); Should read: **Appropriate dose:** Dosing errors in administering LMWH to patients have been the subject of a National Patient Safety Agency alert (NPSA Rapid Response Report 14170);	Thank you for your comment. We agree and have updated this.
LEO Pharma	1	4.2	36	LEO Pharma does not believe the recommendation regarding length of treatment with a LMWH accurately reflects the considerations of the GDG as highlighted in the 'Guideline Consultation Comments Table'. The recommendation currently states "Start the LMWH, fondaparinux or UFH as soon as possible and continue it for 5 days or until the international normalised ratio (INR) (adjusted by a vitamin K antagonist [VKA]; see recommendation 17) is 2 or above for at least 24 hours, whichever is longer." Within the 'Guideline Consultation Comments Table' however, it is stated "we had recommended 5 days of anticoagulation with LMWH as the minimum". In order to reflect the GDG's considerations and recommendation, LEO Pharma suggest that the recommendation should read as follows: ""Start the LMWH, fondaparinux or UFH as soon as possible and continue it for a minimum of 5 days or until the international normalised ratio (INR) (adjusted by a vitamin K antagonist [VKA]; see recommendation 17) is 2 or above for at least 24 hours, whichever is longer." We would also suggest adding a footnote recommending users to refer to the individual SmPC for further information.	Thank you for your comment. We have amended the response to our consultation comment and recommendation for clarity to include 'at least' 5 days: Start the LMWH, fondaparinux or UFH as soon as possible and continue it for at least 5 days or until the international normalised ratio (INR) (adjusted by a vitamin K antagonist [VKA]; see recommendation 17) is 2 or above for at least 24 hours, whichever is longer.
	2	4.3	39	As above	Thank you for your comment. The recommendation in the full

					guideline which states that: Start the LMWH, fondaparinux or UFH as soon as possible and continue it for 5 days or until the international normalised ratio (INR) (adjusted by a vitamin K antagonist [VKA]; see recommendation 17) is 2 or above for at least 24 hours, whichever is longer. The GDG noted in the linking evidence section that 'it is important to continue the initial parenteral treatment with heparins for fondaparinux until the INR is 2 or above for at least 24 hours, or 5 days, whichever is longer'. The GDG have not recommended a minimum of 5 days, as the majority of LMWH's are licensed for 5 days and therefore such a change in recommendation would suggest an extension beyond the licence.
	3	7.5	127 – 132 incl	As above	Thank you for your comment. The recommendation in the full guideline which states that: Start the LMWH, fondaparinux or UFH as soon as possible and continue it for 5 days or until the international normalised ratio (INR) (adjusted by a vitamin K antagonist [VKA]; see recommendation 17) is 2 or above for at least 24 hours, whichever is longer. The GDG noted in the linking evidence section that 'it is important to continue the initial parenteral treatment with heparins

					for fondaparinux until the INR is 2 or above for at least 24 hours, or 5 days, whichever is longer'. The GDG have not recommended a minimum of 5 days, as the majority of LMWH's are licensed for 5 days and therefore such a change in recommendation would suggest an extension beyond the licence.
Bayer plc	1	2.6	16	**Relationships between the guideline and other NICE guidance** Rivaroxaban is also currently undergoing a single technology appraisal (STA) for venous thromboembolism (treatment and long term secondary prevention). http://guidance.nice.org.uk/TA/Wave22/17. The 2nd appraisal committee meeting is due to be held on 17 April 2012 with the FAD available in May 2012. Reference to this STA has not been included in this list of other NICE guidance, and as it relates to the same clinical area as this guideline it should therefore be referenced. The NICE guidelines manual (2009) states that "If technology appraisal recommendations have not been finalised at the time of guideline consultation, the guideline should cross-refer to the appraisal consultation document" (Section 8.1.3.3).	Thank you for your comment. We agree and have added this into the list of other NICE guidance.
Bayer plc	2	7.3	109	Lines 277 to 279 inaccurately state that oral factor Xa antagonists are "yet to be licensed in the UK" Rivaroxaban, an oral direct factor Xa inhibitor, was licensed for the "treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults" in December 2011.	Thank you for your comment. Lines 277 to 279 were referring to which agents were considered in the evidence review for treatment of VTE. We were only able to consider agents which were already licensed during when the reviews were conducted. We have amended the sentence to enhance the clarity"…at the time the evidence review were conducted,, these agents were not licensed in the UK for the treatment of VTE and therefore not considered in this review." We are waiting for any additional wording from the NICE editor.

Bayer plc	3	General		As the rivaroxaban FAD will be available before the publication of this clinical guideline, it is disappointing that the development of these related guidance have not been coordinated so that the published appraisal recommendations for rivaroxaban could be incorporated into the clinical guideline. This process is recommended in the NICE guidelines manual 2009 (section 8.1.3.1). The publication of a national clinical guideline which does not incorporate recommendations regarding all available treatment alternatives, including rivaroxaban, will be rendered immediately outdated and therefore be of limited value to the NHS.	NICE to respond.

Please add extra rows as needed

Please email this form to: VTE3@nice.org.uk
Closing date: 5.00pm on 16 April 2012