

# 2018 EHRA Practical Guide, Rationale, History and Experience

An Expert Interview with Hein Heidbuchel

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## Hein Heidbuchel

Professor Heidbuchel is Chair of Cardiology at Antwerp University, Belgium. He is an all-round arrhythmologist and has a passion for improving education in cardiology. He is the current President of the European Heart Rhythm Association (EHRA). Between 2010 and 2012, he was Board Member of the European Association for Preventive Cardiology as Chair of the section of Sports Cardiology. He has published more than 270 publications and contributed to the 2010 and 2016 European Society of Cardiology (ESC) guidelines for the treatment of atrial fibrillation, was the lead author of the 'European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist anticoagulants in patients with non-valvular atrial fibrillation' (both in 2013 and 2015) and of the EHRA practical guide on radioprotection in electrophysiology. Given his election as EHRA President, Professor Heidbuchel handed the lead authorship of the 2018 update of the EHRA practical guide on non-vitamin K antagonist anticoagulants in atrial fibrillation to Dr Jan Steffel, while taking the senior authorship position.

## Keywords

Atrial fibrillation, non-vitamin K antagonist anticoagulants

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Over the past decade, there has been a marked increase in the use of non-vitamin K antagonist oral anticoagulants (NOACs) in the treatment of patients with venous thrombosis and atrial fibrillation.<sup>1</sup> There is compelling evidence of improved patient outcomes with NOACs versus vitamin-K antagonists.<sup>2,3</sup> Accurate prescription, appropriate initiation and confident use are essential in management strategies employing NOACs; however, these considerations are complicated by a treatment landscape with few head-to-head comparisons, a lack of practical interpretation of key clinical trial data and outstanding concerns around drug–drug interactions and patient comorbidities.<sup>4–7</sup> 'The 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation' seeks to provide practical and applicable insight into the optimised use of NOACs.<sup>8</sup> In this expert interview, Hein Heidbuchel of Antwerp University Hospital, Belgium discusses the rationale, history and elements of the 2018 European Heart Rhythm Association (EHRA) practical guide.

## Q. In brief, what is the rationale and the history behind the EHRA practical guide on using NOACs to treat patients with atrial fibrillation/pulmonary embolism/venous thromboembolism/deep vein thrombosis? What are the main issues with these treatments and the shortcomings of previous guidelines?

Guidelines spell out the indications for treatments but not necessarily how to use these treatments optimally in routine practice. In the case of non-vitamin K antagonist oral anticoagulants (NOACs), guidelines have expressed equivalence or even a preference to treat patients with these conditions in need of anticoagulation therapy with NOACs rather than vitamin K antagonists (VKAs).<sup>9</sup> The use of NOACs however requires the confidence of practitioners during their daily clinical work in the appropriate use of these drugs. Although the manufacturers provide documentation summarising product characteristics, these often leave many practical questions unanswered. Since the EHRA felt the need to provide such guidance, it set out to publish the first version of this practical guide in 2013.<sup>10</sup> It proved to be immensely popular all over the world, which has kept us motivated to provide updates in 2015 and 2018, integrating novel insights from many new scientific papers.<sup>1,8,11</sup>

### Q. Does the 2018 EHRA practical guide help to better identify patients who are suitable for NOAC treatment?

As mentioned, the practical guide does not address so much which patients are suitable candidates. That is guideline territory. The practical guide, however, describes best practices on how to deliver NOAC therapy most effectively and safely. By doing so, the confidence of both physicians and patients increases, which definitely helps to bring this innovative anticoagulation option to more complex patients. As an example: by setting out clear instructions on when to reduce the dose of any given NOAC (and when not to reduce!), the choice of NOAC therapy becomes less ambiguous.

### Q. Does the 2018 practical guide help with events such as bleeding/post bleeding, whilst a patient is receiving NOAC treatment?

The practical guide contains an extensive section on the management of bleeding on a NOAC, distinguishing between nuisance and minor bleeds, non-life-threatening major bleeding or life-threatening bleeding. The recent market introduction of idarucizumab – a specific reversal agent for dabigatran – is discussed and its practical use described, while the guide also hints towards the imminent release of andexanet-alfa, a direct reversal agent for the activated factor Xa inhibitors. More important than treating bleeding is the attention, throughout the full guide, to measures on how bleeding can be prevented. This ranges from appropriate dosing depending on patient characteristics (most importantly renal function) but also on concomitant other therapy. The interaction section has been largely expanded, now also including anti-cancer and anti-epileptic drugs. Finally, we introduced new guidance on whether and when to restart

NOAC therapy after bleeding, more specifically after gastrointestinal and intracranial bleeding.

### Q. What other key tools or procedures in NOAC treatment are new or have been updated in the 2018 EHRA Practical Guide? Does it advise on dosing regimens, drug interactions, comorbidities? Are there good clinical trial data available to back up all of the recommendations?

As mentioned before, drug interactions and co-morbidities get a lot of attention throughout the guide. In its 2018 iteration, we also added a section on plasma level measuring of NOACs. Although such practice is not always necessary in routine practice for the vast majority of patients, there may be specific instances where such measurements may guide clinical decisions. Such situations include emergencies, some situations with elective interventions or complex patient characteristics making assumptions about appropriate dosing highly unreliable (e.g. patients at the very low or very high extremes of body weight, and/or in combination with other factors). Unfortunately, we do not have robust scientific data backing up all clinical scenarios, but the guide points these out and calls for more definitive answers in the future.

### Q. Would using the new EHRA 2018 Practical Guide increase the potential to improve patient outcomes?

That definitely is what we, as authors, hope for. Honestly, we are confident that the guide achieves that goal, and that it contributes to more effective and safer NOAC therapy for patients all over the world. □

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