Recommendations for factor VIII product source to treat patients with haemophilia A

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Dear Sir,

We appreciate that Coppola, together with the whole Executive Committee of the Italian Association of Haemophilia Centres (AICE)1, agreed with us2 on the reasons underlying the increased consumption of plasma-derived factor VIII products recorded in Italy between 2011 and 2014. We also agree with them that previously-untreated patients with severe haemophilia A are unlikely to have contributed to the observed increase, not only because very few of them are born in Italy each year (15-20 cases) but also because being infants of small body weight they cannot be large consumers of factor VIII in absolute terms. Even though being a previously-untreated patient is by definition a short-lasting condition, these are the people with haemophilia who are at the highest risk of developing inhibitors. Thus, it is to be hoped that the forthcoming new Principles of Treatment from AICE will provide meaningful, specific recommendations on how to choose factor VIII products for this critical category of patients. We also agree with Coppola et al. 1 that the forthcoming AICE recommendations should emphasise once more and forever that the choice of the source of factor VIII products by haemophilia doctors should be based upon shared decision-making involving patients and their families. This principle of shared decision-making was illustrated by Mannucci et al.3 in an article published in 2012 with one of Coppola's co-authors (ES). In that article on how to choose factor VIII products, the authors stated that the informed choice should take into account the perception that recombinant factor VIII products are safer from the point of view of the theoretical risk of transmission of infections. The perception that plasma factor VIII products are safer from the point of view of inhibitor risk was also mentioned in the frame of shared decision-making³. The striking current novelty is that the results of SIPPET (Survey of Inhibitors in Plasma-Products Exposed Toddlers), a study with a randomised design4 (thus providing the highest level of clinical evidence), have transformed the aforementioned perception into evidence, and that this new information should be now conveyed without ambiguity to patients during the decision-making process.

Disclaimer of conflicts of interest

The Authors declare no conflicts of interest, with the exception of PMM who declares having received in the past 12 months honoraria for lectures as a speaker or for chairing symposia organised by Alexion, Bayer, Baxalta-Shire, Grifols, Kedrion, LFB, and Novo Nordisk. He has also acted as a scientific consultant for Bayer and Kedrion.

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Arrived: 30 January 2017 - Accepted: 7 February 2017 Correspondence: Pier Mannuccio Mannucci Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico Via Pace 9 20122 Milan, Italy e-mail: piermannuccio.mannucci@policlinico.mi.it