Reply from the authors

We really appreciate the interest of Smith and McCarthy in our study. They raised two issues which we would like to comment on.

First, the authors’ point is well taken and they are absolutely right with their critique that we did not list normal coagulation and platelet count/function as specific inclusion criteria. Although not listed, we can guarantee that the following criteria were filled in each case: Quick (Prothrombin Time) >30%, PTT <50 seconds and platelets >50×10⁹ litre⁻¹. Coagulopathy and central venous access has been studied in a few studies, however, the results are not particularly impressive. Regarding anti-platelet strategies and central venous cannulation there are - to our knowledge - no studies available at all.

The second issue raised by the authors deals with cost, accessibility and time delays of real-time US in CV catheterisation. First, I would like to say that we are in line with Smith and McCarthy regarding these points. However, while doing research on the subject of central venous access and patient safety for more than 15 years now, I have had a lot of discussions with colleagues who have concerns about: how to deal with the refusal of hospital administrations to invest in ultrasound equipment for anaesthesia and intensive care departments (which is an issue in many German hospitals), their limited access to ultrasound machines while performing central venous access in several operating theatres simultaneously (which is reality in many larger hospitals), their own misconception that using ultrasound (US) for central venous access would represent an unnecessary time expenditure (the misperception that US is only for cowards or the unskilled is persistent and widespread).

To change the culture of not using US we guess that there is no way for directive regulations. The only way for an effective change is to get people involved and interested in this issue. Hence, we are convinced that our study is one further step forward on the road to a safer environment as far as central venous access is concerned. Finally, we would like to thank the BJA for giving us the opportunity to comment on the issues raised by Smith and McCarthy.

Declaration of interest
None declared.

References
study with adequate statistical power that justifies an indication for the use of FBC beyond the negligible group of patients with bleeding due to proven selective hypofibrinogenoemia. In conclusion they said, ‘Included trials are of low quality with high risk of bias and are underpowered to detect mortality, benefit or harm. More research is urgently needed.’ The entire group had no conflicts of interest. In response Kozek-Langenecker and colleagues published an Editorial in the British Journal of Anaesthesia (BJA), expressing their unhappiness about the cautious conclusions of the authors. We learned that Wikkelsø and co-workers were not notified by the editors of BJA let alone asked for a comment, though the title of the respective editorial, ‘Fibrinogen concentrate: Clinical reality and cautious Cochrane recommendation’ explicitly and critically address this group and this particular publication. This basically means that a highly prestigious anaesthetic journal gave a single group a forum for their personal opinion. In our mind BJA hereby let its duty of neutrality, probably unintended, by leaving the criticised group out.

The authors in question – all - correctly disclosed their conflicts of interest. The liberal use of fibrinogen concentrate (FBC) in settings without proven benefit has been repeatedly promoted by them and affiliated groups, and we are worried therapists may feel pressurised that way. We believe that the frequent and increasing application of FBC all over the world and its impressive sales figures are the consequence of ‘scientific marketing’ rather than scientific evidence. To shine a light on the impressive dimensions of the issue, we considered one of the suggested indications, open heart surgery, and a single population. Administering 2 g FBC to each of 100 000 patients undergoing cardiac surgery per year in Germany would be equivalent to a sales volume of nearly 75 million Euros (75 000 000). Against this background therapists would be wise to contemplate alternative opinions.

Attitude to benefits and indications of a drug can be characterised as either ‘reluctant’ or ‘enthusiastic’. Regarding the generous use of FBC we are reluctant. To our liking enthusiasm for a drug so expensive, whose effects are only suggested but not yet proven, is not comprehensible.

It is explicitly not our intention to impute dubious motives to the ‘enthusiastic’ authors or to question their integrity. However, we have to face that candid critics judge medical literature to be undermined with flaws and bias, saying that ‘competition and conflicts of interest distort too many medical findings’. The large amount of ‘enthusiastic’ FBC-literature, entirely sponsored by producers of the drug will further inspire this ‘negative attitude.

We are convinced our system should be challenged. Is it really enough to simply declare conflicts of interest without consequences? Is the COPE statement still effective? Langer and colleagues reviewed 297 guidelines drawn up by German specialist societies in the years 2009–2011, concluding, ‘Standards to deal with conflicts of interest are lacking and should be urgently developed.’ It is the duty of scientific bodies, universities, IRBs, journals/editors to make every effort to limit bias in scientific literature. Disclosure of authors’ research-related perks and publishing companies’ economic ties to drug companies could be an additional instrument to adhere to the path of virtue.

Declaration of interest

None declared.

References

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