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Response to Anastasio et al. – Severe imported falciparum malaria – Clinical and drug supply challenges

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Dear Editor,

We read with interest the letter by Anastasio and colleagues, "Severe imported falciparum malaria — Clinical and drug supply challenges." [1] We appreciate their calling to attention the critical issue of the limited availability of intravenous antimalarials in the United States. However, we would also like to add some clarification regarding the availability of parenteral artesunate, and the prospects for its approval from the U.S. Food and Drug Administration (FDA) in particular.

The authors correctly point out that parenteral artesunate is not FDA approved, but is available through the Centers for Disease Control and Prevention (CDC) under an investigational new drug (IND) protocol. In partnership with Walter Reed Army Institute of Research, CDC has made limited quantities of artesunate available through this IND since 2007. Anastasio et al. assert that FDA's lengthy approval process is the reason why artesunate is not yet available for widespread use. However, the reality is that to date, no pharmaceutical company has sought to make artesunate commercially available in the United States through the submission of a new drug application to FDA.

Adding to the intravenous (IV) antimalarial supply problem is the discontinuation of production of IV quinidine since December 2017. For now, quinidine is available until the existing stock expires at the end of March 2019. In situations where IV quinidine is not available or not tolerated, IV artesunate continues to be available from CDC. FDA and CDC are jointly working on ensuring an alternative supply of IV antimalarials for the U.S.

The authors presented a case of severe malaria treated initially with quinidine, then switched to IV artesunate because of adverse effects of the quinidine. They suggest that the fatal outcome might have been prevented with more timely access to artesunate since it is a more effective drug. While the Twomey article that was cited [2] was not a comparative study, other studies have indeed shown a superiority of artesunate over quinine [3,4]. However,

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tmaid.2018.11.003.

it is likely that the key opportunities for prevention, and a better outcome, occurred a bit more upstream [5]. Most cases of malaria like this one could have been prevented through the proper use of malaria chemoprophylactic drugs. Furthermore, prolonged delays in seeking care can result in progression from uncomplicated malaria to very severe cases with increased likelihood of fatal outcomes regardless of which antimalarial medicine is used. While this case calls to attention the current state of the intravenous antimalarial supply in the U.S., it also highlights the importance of malaria chemoprophylaxis as a life-saving intervention, and the importance of seeking care immediately when ill after returning from a malaria-endemic area.

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