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## Prophylaxis Guidelines – A Plea to NICE

Sir

Dr. Alderson and Professor Baker wrote(1, 2) criticising our opinion piece(3) and preceding Lancet paper(4) concerning antibiotic prophylaxis (AP) for infective endocarditis (IE) but failed to disclose that they work for NICE and were involved in the recent review of guideline CG64.

We remain concerned that the strict review criteria used by NICE exclude animal data and contemporary observational studies as providing sufficient evidence to influence guideline change. Despite our exhaustive efforts (and those of others), a definitive randomised controlled trial seems highly unlikely due to cost, complexity, and ethical issues.(5) As a consequence, the current criteria dictate that NICE guidance addressing this controversial question can never change. In this context, the original 2008 decision to withdraw antibiotic prophylaxis (even for high-risk patients) in the absence of a randomised controlled trial (and when less observational evidence was available) seems questionable.

Our observational study demonstrated cause for concern and there was a clinical and moral duty to report our findings. In our manuscript, we highlighted the limitations of our data and explored alternative explanations for our findings.(4)

Dr. Alderson and Professor Baker remarked that NICE had the Lancet data reviewed by an independent statistician who criticized our analysis, but failed to point out that he was commissioned by NICE to provide this critique or that the Lancet paper was reviewed by 9 independent experts (including 3 statisticians), none of whom raised similar criticisms. In fact, even the NICE statistician concluded that he could find “no factual error with the modelling approach used in the [Lancet] paper”.(6) However, by adding 2 extra change-points to the analysis (June 2004, June 2011), he could reduce the significance of the IE increase that we detected in March 2008. It should be highlighted that the aim of the study was to determine if the fall in AP prescribing caused by the March 2008 NICE guidelines was associated with an increase in IE incidence and that was the change-point we therefore pre-specified. None of the Lancet reviewers questioned the use of this single change-point. Furthermore, NICE gave no reason for choosing these extra two change-points. Nevertheless, adding extra change-points inevitably reduces the power to detect a significant change at any one of them.

We acknowledge that NICE responded to a letter of concern we submitted during the public consultation process, but they have failed to address the important issues it raised. Our plea is that NICE engage in open discussion with cardiologists, dentists, researchers and patients with expertise on this topic. Currently, its interpretations remain at odds with pertinent stakeholders, including international guideline committees in Europe and the USA.

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London, London, London, London, New York USA, Rochester MN USA.

References:

1. Alderson P, Baker M. Prophylaxis guidelines: Repeated points. *Br Dent J*. 2016;220(7):324.
2. Alderson P, Baker M. Prophylaxis guidelines: Repeated points. *Br Dent J*. 2016;220(9):429.
3. Thornhill MH, Dayer M, Lockhart PB, McGurk M, Shanson D, Prendergast B, et al. Guidelines on prophylaxis to prevent endocarditis. *British Dental Journal*. 2016;220(2):51-6.
4. Dayer MJ, Jones S, Prendergast B, Baddour LM, Lockhart PB, Thornhill MH. Incidence of infective endocarditis in England, 2000-13: a secular trend, interrupted time-series analysis. *Lancet*. 2015;385(9974):1219-28.
5. Thornhill MH, Lockhart PB, Prendergast B, Chambers JB, Shanson D. NICE and antibiotic prophylaxis to prevent endocarditis. *British Dental Journal*. 2015;218(11):619-21.
6. National Institute for Health and Care Excellence (NICE). Prophylaxis against infective endocarditis 2015 [NICE Clinical Guideline No 64]. Available from: <http://www.nice.org.uk/guidance/cg64/chapter/Recommendations>.