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Instrument cleanliness and protein misfolding disorders

Sir,

My commentary seeks to reflect, for a more general audience, the debate on the desirable standards for protein decontamination of instruments and the best ways of measuring residual protein, whilst setting this debate in the wider context of the risks and burden of Creutzfeldt—Jakob Disease and other protein misfolding disorders [1].

Simmons and Holmes question two statements [2]. First, that 5 μg/side represents a more exacting standard than the 6.4 μg/cm^2 proposed by the International Organization for Standardisation (ISO). Of course, it is possible to conceive of instruments where this would not be the case, but since many instruments would have sides larger than 0.78 cm^2 (i.e. 5 μg/6.4 μg × 1 cm^2) which is equivalent to 8.8 mm by 8.8 mm) then 5 μg/side can reasonably be characterized as a more exacting standard. Furthermore, as a standard, 5 μg/side better reflects that transmissibility depends on the total amount of transmissible protein in contact with recipient tissue. Neither standard refers to contact time and Simmons and Holmes helpfully remind us of the importance of this [2].

Second, Simmons and Holmes ask how I can state that 'in-situ measurement techniques are the safest option for instruments to be used on tissues at high risk of transmitting disease', a statement that I do not reference [2]. However, they omit the earlier part of my sentence, 'most generally agree that'. This sentence is, therefore, a statement of my opinion as to the more commonly held view of the safest measurement technique. Simmons and Holmes, of course, are perfectly at liberty to challenge this view [2]. To repeat what I say in the commentary, 'ultimately, resolving this question would require a comparison of techniques using tissue containing PrPSc that would either show, or not, a consistent relationship between the protein measured on elution and that remaining on the instrument' [1].

Simmons and Holmes remind us that this debate remains live [2]. However, until further experimental evidence is obtained to resolve it, I believe decontamination services can best base their practices on the existing guidance [3]. Whilst allowing flexibility based on local risk assessment, this guidance was the product of a solid corpus of specifically funded scientific work and of a structured process of consultation.

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