Commentary Article

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Authors' response

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We welcome the critique from Dr Wellek and Dr Jennen-Steinmetz. In particular, we share their concerns that a reference range (RR) should not be unnecessarily wide, leading to an avoidable low sensitivity of the RR. When a P-content and γ-confidence tolerance range (TR) is used as RR, this concern can be addressed by simply increasing the sample size n to improve its sensitivity since 'as the sample size increases, the computed tolerance interval will approach the probability interval that actually contains the specified population proportion'.[1(p.150)] To be more precise, it has been proposed[2] to choose the sample size n to control the sensitivity of a (P, γ) TR in terms of

$$\Pr\{\text{ TR contains at least } 100P^*\% \text{ of the population }\} \leq \delta_0$$

where $P < P^* < 1$ is pre-specified for a sufficiently small value of $\delta_0 > 0$. This sample size formula guarantees that there is no more than a small chance δ_0 that the TR includes a proportion of $100P^*\%$ or more of the population. Tabulation of the sample sizes for the normal distribution can be found in Faulkenberry and Daly[3] and Hahn and Meeker[1(Ch.9)] or easily computed by using the `R` package `tolerance`.[4]

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References

1. Hahn G and Meeker WQ. *Statistical Intervals: A Guide to Practitioners*. 2nd ed. New York, NY: Wiley, 1991.
2. Faulkenberry GD and Weeks D. Sample size determination for tolerance limits. *Technometrics* 1968; **10**: 343–348.
3. Faulkenberry GD and Daly JC. Sample size for tolerance limits on a normal distribution. *Technometrics* 1970; **12**: 813–821.
4. Young DS. `tolerance`: An R package for estimating tolerance intervals. *J Stat Softw* 2010; **36**: 1–39.

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