

## LETTER

### There is no baby in the bath water

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### To the Editor

Dr. Berger makes many good points in his letter and I am grateful to him for his response [1].

He is, of course, correct when he states that all statisticians should not be condemned. I fully acknowledge that there are many with justifiably high reputations and who, like him, have contributed a great deal to this academic discipline.

However, the target of my criticism is statistics-based research. In other words, epidemiological studies and large-scale randomised trials (RCTs) that seek to detect small differences in outcome between the treatment groups and draw causal inferences when the differences are statistically significant. It is my contention that such studies are flawed and that their product is all but worthless [2].

Despite all the checks and balances that are put in place in large RCTs, we cannot be sure that the conditions for internal validity have been satisfied. Thus, the groups may differ in factors other than the treatment. Nor can we be sure that the statistical analysis is reliable, not only because of faults in use of statistical techniques, but also because of the increasingly recognised uncertainties regarding frequentist statistics. Yet, perhaps of greatest concern is the belief that the demonstration of a very small, statistically significant difference in outcome justifies causal inference. The more this is examined, the less convincing it is found to be [2].

But even if, for the sake of argument, we set aside these problems, there remains the question as to the value of the findings of large RCTs. The benefits on offer are, by the nature of these studies, trivial. The results have little external validity and the size of the treatment effects are, to all intents and purposes, of no relevance or meaning to individual patients.

On the surface, dispensing with all statistics-based research may appear to be a particularly extreme proposal. But this depends on the assumption that there is really something worthwhile that would be lost by this action. Given the above, I do not see any evidence that this is the case. There is no baby in the bathwater.

Were the attack directed at statisticians, I would agree with much of Dr. Berger's letter. But it isn't. It is aimed at the methodology of statistics-based research. And it is this that is seriously flawed.

### References

- [1] Berger, V.W. (2011). Trials: The worst possible design (except for all the rest). *International Journal of Person Centered Medicine* 1 (3), 630-631.
- [2] Penston, J. (2010). *Stats.con – How we've been fooled by statistics-based research in medicine*. London: The London Press.