

## Statistical Design Considerations in Animal Studies Published Recently in *Cancer Research*

Kenneth R. Hess

Good statistical design is one hallmark of meritorious research. Elements such as replication, randomization, and blinding are widely recognized as being fundamental to producing valid research results (1). Although widely used in clinical research, these practices seem to be less often utilized in animal research (2). To assess the frequency of these practices in animal studies in cancer research, I reviewed the first 100 articles published in *Cancer Research* in 2010 that included comparisons between groups of animals. I reviewed each article carefully to assess which statistical design considerations were reported. In some cases, it may be that good statistical practice was followed, but that due to space constraints or emphasis on results, these were not reported.

In 14 of the 100 articles, the number of animals used per group was not reported. In none of the 100 articles was the method used to determine the number of animals used per group reported. These are important omissions because adequate replication is perhaps the key element of statistical design which helps ensure robust and reliable conclusions. Choosing the appropriate number of animals is best done by assessing the within-group variation and computing the smallest number of subjects that achieves adequate statistical power to detect scientifically interesting differences between groups (1).

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### References

1. Festing MFW, Altman DG. Guidelines for the design and statistical analysis of experiments using laboratory animals. *ILAR J* 2002; 43:244–58.
2. Kilkenny C, Parsons N, Kadyszewski E, Festing MFW, Cuthill IC, Fry D, et al. Survey of the quality of experimental design, statistical

analysis and reporting of research using animals. *PLoS One* 2009;4:1–11.

Among the 74 articles in which randomization seemed feasible, only 21 (28%) reported that they had randomly allocated animals to treatment groups. None of these articles described how the randomization was carried out. Randomization is a fundamental element of good statistical design that acts to reduce potential bias during treatment allocation (1).

Only 2 articles reported that observers (i.e., outcome evaluators) were blinded to treatment group. Blinding is another fundamental element of good statistical design and it acts to reduce bias during outcome assessment (1). This is particularly important because many of the endpoints used in cancer research are subjective in nature. Blinding may not be feasible in all experiments, but where it is feasible it should be implemented.

In conclusion, clearly, the use of essential statistical design features in animal studies as illustrated by those recently published in *Cancer Research* has room for improvement. Failure to randomly allocate animals to treatments and failure to blind observers to treatment assignment during outcome assessments are key deficiencies. Perhaps, the most important deficiency is the failure to calculate the statistically appropriate number of animals to use. These deficiencies could be easily remedied by including appropriate editorial guidelines for publication of animal research (such as the recently proposed ARRIVE guidelines; ref. 3), by more rigorous peer review with respect to these elements, and finally by more careful design on the part of animal researchers perhaps in collaboration with biostatisticians.

### Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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3. Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG. Improving bioscience research reporting: the ARRIVE guidelines for reporting animal research. *PLoS Biol* 2010;8:1–5.

## **Correction: Online Publication Dates for *Cancer Research* January 15, 2011 Articles**

The two articles noted below, which were published in the January 15, 2011 issue of *Cancer Research*, were published with incorrect online publication dates. Corrected versions of these articles have been published online.

Hess KR. Statistical design considerations in animal studies published recently in *Cancer Research*. *Cancer Res* 2011;71:625.

Correction: Surface-immobilized aptamers for cancer cell isolation and microscopic cytology. *Cancer Res* 2011;71:626.

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# Cancer Research

The Journal of Cancer Research (1916–1930) | The American Journal of Cancer (1931–1940)

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*Cancer Res* 2011;71:625.

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