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The Authors' Reply

The response of Dr Aronson to the recommendations put forward by a common International Society of Pharmacovigilance (ISOP) and International Society of Pharmacoepidemiology (ISPE) working group[1] is interesting. His main concern seems to be the fact that we mostly duplicate material presented in a previous set of guidelines that we did not cite.

These absent guidelines are not easy to find. Indeed, the title of the editorial "anecdotes as evidence"[2] does not hint that there may be a set of recommendations for the publication or reporting of adverse drug reactions. These guidelines were annexed as an electronic supplement to the cited editorial. They were not labelled as "guidelines for publication of reports," but as "extra tables and a suggested protocol," thus they were not really obvious. The recommendations themselves are not indexed in MEDLINE; finding them does require a certain degree of observation and intuition, or precognition, possibly. None of the very cognizant persons who worked on our guidelines were aware of this "protocol." It is not certain if this protocol can be cited, as there is no clear reference.

Our guidelines, and those of Dr Aronson, are but two in a long series with similar intent, such as those included in the French Good Pharmacovigilance Practices[3] or the definitions of data elements for transmission of adverse drug reaction reports, that are freely available on a variety of websites, such as the European Medicines Agency, the European Federation of Pharmaceutical Industries Associations or the International Federation of Pharmaceutical Manufacturers and Association and the US FDA, and derive from a previous European project;[4] both came out long before Dr Aronson's protocol, but he cited neither. There are many others, since Venulet's initial collaborative paper in 1985[5] following earlier comments on poor published reports quality.[6] The desire to define ideal data content for the reporting of adverse drug reaction reports will certainly continue, and we expect further guidelines to appear. We just hope they build on ours and others' and reach the goals we may have missed. Ours are tailored to a paper medium, but will that still be relevant in a few years?

To comment on substance rather than form, some of Dr Aronson's recommendations are not really practical. For example, most adverse drug reaction reports or anecdotes are published as letters to the editor, and are not offered space for a summary: the word count taken by the summary alone would usually account for that allowed for the whole of the report. Actually the summaries of all case reports are published, and accessible electronically, in *Reactions Weekly*. We did not invent anything new, nor did Dr Aronson; we just thought it was useful to try to improve the quality of reporting of adverse drug reactions in the medical literature, a key element in alert generation,[7] by again proposing guidelines, but this time as a collective effort, through professional societies and their journals. Previous efforts obviously failed, we hope that this one may fare a little better.

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