



## Authorship—More than just writing, but how much more?

by Liz Wager

Defining scientific authorship is damn difficult. (If you are shocked by my use of strong language, be assured that I am simply following the advice of Mark Twain who wrote: “Substitute ‘damn’ every time you’re inclined to write ‘very’; your editor will delete it and the writing will be just as it should be”. However, I am hoping that the editor will not delete the expletive in this case, as I reckon the emphasis is justified.)

### Applying the ICMJE authorship criteria

EMWA members should be familiar with the authorship guidelines of the International Committee of Medical Journal Editors (ICMJE) [1]. These are widely quoted, yet even the *BMJ*'s instructions to authors note that the ICMJE criteria “have serious flaws” [2], so I know that I am not alone in my struggles with these well-intentioned but often unhelpful guidelines. Professional medical writers are well aware that drafting a publication does not make the writer an author in the way that, say, writing a poem makes the writer an author—although one or two journals (notably *Neurology* [3]) seem to think that it does (see Box). In this respect the ICMJE criteria are quite helpful, since they state that authors must be involved in the design, analysis or interpretation of a study as well as in developing the manuscript.

*Neurology* defines an author as a person who has made a substantive intellectual contribution to the submitted manuscript. A substantive contribution includes one or more of the following:

Design or conceptualization of the study  
OR analysis or interpretation of the data  
OR drafting or revising the manuscript for intellectual content

Professional writers employed by pharmaceutical companies or other academic, governmental, or commercial entities who have drafted or revised the intellectual content of the paper must be included as authors.

<http://www.neurology.org/misc/auth2.dtl#AUTHORSHIPDEFINTION>

For clinical trials, it is therefore clear that, as we noted in the EMWA guidelines [4], writers rarely qualify as authors. Especially when working from protocols and trial reports

(prepared by other writers) and in close cooperation with the investigators, the person who drafts the manuscript does only a minimal amount of interpretation and therefore does not meet the first ICMJE authorship criterion.

The situation is more complex when we consider review articles (see article by Elizabeth Crane in this issue of *TWS* [5]). If a writer is involved in refining the question, searching the literature and collating the findings, it is hard to argue that these activities do not constitute design, data collection and analysis / interpretation. The latest version of Good Publication Practice (GPP2) therefore advises that “if [a medical writer] ... is willing to ‘take public responsibility for relevant portions of the content’ then he or she may be in a position to meet the remaining ICMJE criteria for authorship” [6]. The phrase about taking public responsibility is, of course, a direct quotation from the ICMJE criteria. In fact, I find the ICMJE statements linking authorship to responsibility are often more helpful than the more detailed criteria that follow. I have often argued that, as a writer, I cannot take responsibility for the research, even though I might take responsibility for the way in which it is reported. If I cannot explain why a particular trial design, drug dose, endpoint or statistical method was used then I cannot be an author.

But this otherwise helpful advice about authorship and accountability is not without problems. What does ICMJE mean by “relevant portions of the content”? Until recently, when training writers or junior researchers about authorship, I used to explain that this means that editors do not expect pathologists to be able to justify the statistical analysis, and likewise, that it would be unreasonable to expect statisticians to understand the choice of histological staining techniques. But several major journals that endorse the ICMJE authorship criteria now require authors to state whether they had access to the study data implying that all authors should somehow take responsibility for the analysis.

### Access to data

The *BMJ* asks authors to state “whether all authors had full access to and can take responsibility for the data and analyses”, although it does not appear to demand that they always can [2]. *The Lancet* requires that “The corresponding

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- > author should confirm that he or she had full access to all the data in the study” [7]. *JAMA* insists that “at least 1 named author (e.g. the principal investigator) who is independent of any commercial funder or sponsor must indicate that she or he ‘had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.’” [8].

A recent case in the UK has highlighted this issue. Professor Richard Eastell was charged with negligence by the General Medical Council (which licences UK doctors) because he was the lead author on a paper which stated that all authors had access to the data and analyses when, in fact, this was not the case [9]. He had originally been charged with professional misconduct for publishing an untruthful statement, but the charge was reduced to negligence after Professor Eastell explained that the statement about data access had been added to the paper by a medical writer working for the sponsor and he therefore had not lied but rather had failed to notice and correct the statement. The case probably came before the GMC because it is part of a long-standing dispute between a former member of Professor Eastell’s department, Dr Aubrey Blumsohn, and the sponsor, Proctor & Gamble over the interpretation of, and indeed access to, the raw data [10].

Whatever one thinks of Eastell’s defence that he had simply failed to remove a statement rather than actually lied, many investigator-authors will probably be thinking ‘that

could have been me’. Most authors do not have the statistical expertise or even the software or computer capabilities to analyse the results of big studies. So, while it might be commendable for all authors to have access to the data, I am tempted to wonder what many of them would do with it if they had it.

The original version of GPP recommended that “All authors, external and internal, should have access to the statistical reports and tables supporting each publication” [11]. In other words, we recommended that authors should see the analysed (rather than the raw) data. This requirement has been strengthened in GPP2 which states that “Sponsors have a responsibility to share the data and the analyses with the investigators who participated in the study. Sponsors must provide authors and other contributors (for example, members of a publication steering committee or professional medical writers) with full access to study data [...] Information provided to the authors should include study protocols, statistical analysis plans, statistical reports, data tables, clinical study reports, and results intended for posting on clinical trial results websites.” [6]. While avoiding use of the term ‘raw data’, by specifying “the data and the analyses” separately, and then going on to mention “data tables” as well as other documents, GPP2 strongly implies that authors having access to the analysed data is not enough.

### Data collection

Until 1999, the ICMJE authorship criteria did not mention data collection. According to the original guidelines, only people who had been involved in the design of a study and the analysis and interpretation of its findings could qualify as authors. This meant that most investigators usually did not qualify as authors under a strict interpretation of the criteria even if they were actively involved in developing the publication. Including data collection as one of the research activities that may, in addition to contributing to the publication, qualify for authorship was in some ways helpful. However, it also created problems because it meant that anybody who collected even a single item of data could qualify for authorship if they were involved with writing the paper and approved the final version. Sponsors therefore escaped from a situation in which hardly anybody met the ICMJE criteria into one in which all investigators potentially could be authors so somebody had to decide who would develop the paper and be listed. In order to determine authorship and communicate this clearly to all potential contributors, it is therefore not enough for companies to state that they will abide by the ICMJE criteria. GPP2 therefore now recommends that publication agreements

## Drug prices

A short article in the *Economist* compared the price of brand and generic versions of ciprofloxacin. The comparison was based on information from Health Action International. It found that a course of the branded versions sold in the UK at half the price at which it sold in the US and while a course of branded pills sold for an average of \$101 in the US the generic version is \$9.25. A chart of the prices of Ciprofloxacin showed that the product was most expensive in the US and Brazil and least expensive in Switzerland, Pakistan, India and Nepal. Online comments from readers pointed out the greater bargaining powers with drug companies commanded by countries with national health systems. On the other hand citizens of those countries paid more in taxes to pay for the health systems. A few comments criticised the sloppiness of the chart that presented the comparison and one comment proved that the Americans do have a sense of humour: “We (the US) have to pay the most for drugs because to pay less would be godless socialism and we can’t have that.”

[http://www.economist.com/daily/news/displaystory.cfm?story\\_id=15320793&fsrc=nwl](http://www.economist.com/daily/news/displaystory.cfm?story_id=15320793&fsrc=nwl)

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should define “the criteria that will be used to determine authorship” [5]. Establishing a writing group or publication steering committee at the start of a trial now seems not just helpful for developing publications but essential to manage expectations about authorship and avoid disputes when the study has finished and investigators clamour to be listed as authors. Interestingly, GPP2 also recommends that the authors (rather than the sponsor) should be responsible for ensuring “authorship is attributed appropriately” [5]. It will be interesting to see whether editors agree about who is to blame if inappropriate authorship practices (such as guest and ghost authorship) are discovered.

If all investigators meet the first ICMJE criterion (because they were involved in collecting data), decisions about membership of the writing group become the key factor in determining authorship. So who should decide who is on the writing group and therefore, in effect, who the authors will be? In my experience, this has usually been the sponsor, although I know of one drug company that appoints study steering committees, consisting entirely of external (i.e. non-company) people, which decide on authorship (which may include company personnel). This system may be a reaction to journals, such as *The Lancet*, that require authors to state that they “had final responsibility for the decision to submit for publication” [6]. To be honest, I have never quite understood the purpose of such statements or what editors were trying to achieve by them. I suspect the wording comes from a paper by several ICMJE members which stated “As editors, we strongly oppose contractual agreements that deny investigators the right to examine the data independently or to submit a manuscript for publication without first obtaining the consent of the sponsor [...] Many of us will ask the responsible author to sign a statement indicating that he or she accepts full responsibility for the conduct of the trial, had access to the data, and controlled the decision to publish.” [12] While I have always opposed sponsors being able to veto publications (and we stated this in the GPP guidelines [11]), I have never seen the point of journal editors asking authors to say that they were not prevented from publishing their findings because the fact that a manuscript has been submitted to a journal shows that this was not the case. It reminds me of an irascible conductor of a student choir, who used to spend the first 5 minutes of every rehearsal berating the latecomers who had not yet arrived, which always seemed pointless to me, as the only people who heard his tirade were the innocent ones who had arrived on time.

If statements about decisions to publish do not relate to determining whether or not results will ever see the light of day, perhaps editors want to know who decided when or where they should be published. If so, they are in line with GPP2, which states that authors should be responsible for making “decisions about practical issues concerning presentation and publication (for example, choice of congress

or journal)” [6] and that this responsibility should be confirmed in a written agreement. However, (slightly oddly to my mind) GPP2 does not mention any role for the publication steering committee in such decisions.

### What should medical writers do?

What do medical writers need to do to comply with all these guidelines and journal requirements on authorship? My first advice is to ensure that the target journal for any publication is identified early in the writing process and to check that journal’s requirements carefully. There are a number of different interpretations of the ICMJE criteria and some journals appear to have adopted their own criteria for authorship and acknowledgements. Professional writers should be aware of these and should advise their customers and all potential publication contributors about them and try to ensure that they will be followed. If journals do not impose specific requirements (and, in fact, most do not [13]), then writers should check the ICMJE criteria and company policies. If companies start to follow GPP2, then publication agreements signed at the start of a study or before writing begins should become increasingly common but, in the meantime, we’ll have to struggle on without them.

Having started with some slightly blasphemous words from one of my favourite writers I shall finish with some more of his excellent advice, namely “Always do right. This will gratify some people and astonish the rest.” Mark Twain would have made a great medical writer.

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