EMWA European Medical Writers Association

The Write Stuff

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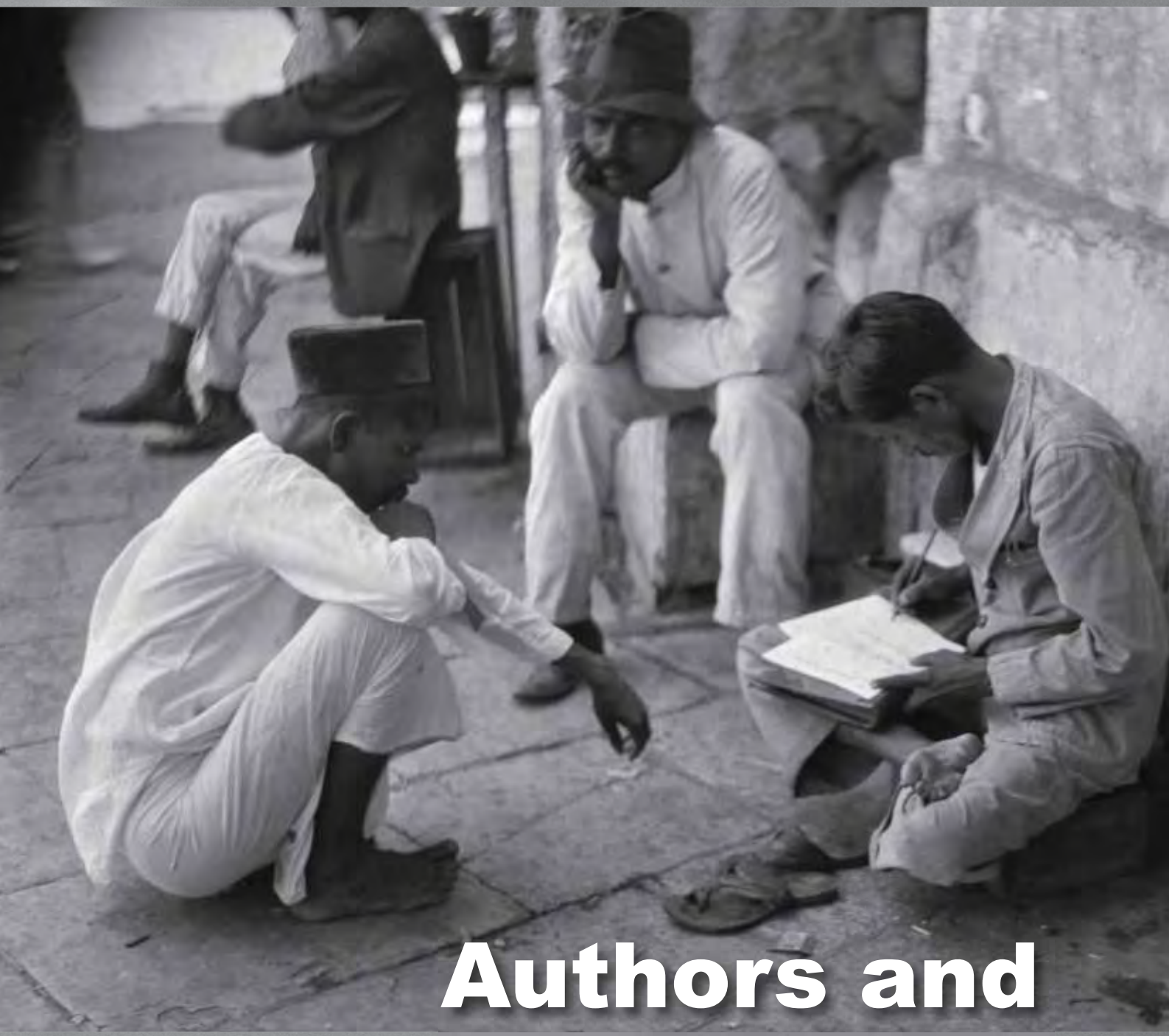

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Journal insights

The *Write Stuff* is the official publication of the European Medical Writers Association. It is issued 4 times a year and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims, but opinions expressed in individual articles are those of the authors and are not necessarily those held by EMWA as an association.

Articles or ideas should be submitted to the Journal Editor (see below) or another member of the Editorial Board.

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Subscriptions are included in EMWA membership fees. By writing to emwatws@associationhq.com non-members can subscribe at an annual rate of:

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- The *Write Stuff* typically publishes articles of 800–2500 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and e-mail address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted by e-mail as an MS Word file using Times New Roman (or equivalent), 10 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style, min. 360 x 510 pixels).

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From the Guest Editor's desk:

Not *who* but *how*...

by Iain Patten

Ghost authorship, *Guest authorship*, *Gift authorship*..... Gosh, what a pickle this authorship game is in! Authorship in the biomedical sciences has evolved from humble beginnings as an apparently simple and rarely questioned concept to a complex and highly problematic term almost guaranteed to generate confusion, argument and even accusation. You need look no further than the recently publicised Vioxx scandal for a glimpse of how medical writers are affected by the ethical concerns surrounding ghost and guest authorship [1].

While it is certainly true that the involvement of medical writers in the development of manuscripts for peer-reviewed journals has raised a number of serious concerns, the climate of mistrust and the assumptions that go with that may be out of step with the reality of how many professionals work [2]. By virtue of their position in the manuscript development process, medical writers and editors may in fact be ideally placed to monitor and uphold the very ethical standards they are assumed by many to be responsible for violating. For some this may seem a case of the poacher turned gamekeeper, but it is worth considering for a moment that many medical publications professionals have worked hard to establish and strengthen ethical standards, while others have only recently gained sufficient confidence to demand that their legitimate contribution to medical and scientific communication be recognised.

Responsibility where responsibility is due

In her article in this issue of *TWS*, Liz Wager [3] notes that "drafting a publication does not make the writer an author in the way that, say, writing a poem makes the writer an author", stating upfront that this is something "professional medical writers are well aware [of]". This is a key distinction in the work that many of us do, but just how clear are we about the nature of the difference? When is the act of writing synonymous with authorship and when is it separable? According to Mario Biagiolo [4], Professor of the History of Science at Harvard University, literary authorship, as in the poem Liz refers to, involves an act of creation in which the author's self is communicated through writing. Thus, the right to authorial ownership stems from the work being produced by something already belonging to the author—his or her own self. The *content* and the *writing* are indivisible in as much as creativity and composition are one and the same. According to Biagiolo, however, the same logic cannot apply to scientific authorship. Here, the content is not the author's personal expression but rather a "statement about nature". A scientific claim only becomes associated with an author once it has been subjected to the scrutiny of the scientific community (hence the race for publication common to 'competing' researchers—no such race for primacy would be relevant in the case of literary authorship, since public scrutiny is of no relevance to the right of ownership in personal creative expression). Thus, Biagiolo argues, scientific authorship is not a question of rights but rather of rewards. But of course, the flip side of that particular coin must also be responsibility.

Like any reward system, scientific authorship is culturally defined. In other words, each scientific community determines the criteria to be applied when deciding who qualifies for authorship. An example that may surprise some readers of *TWS* for instance is found in the authorship criteria applied in high-energy physics. Here, it is not uncommon for all members of a large research collaboration to sign all papers arising from that collaboration, in some cases even if the work reported was done before that 'author' joined [5]! In the biomedical community this would be seen as gift authorship (note the language of reward systems) and if brought to light could be highly detrimental to an author's reputation. Although various organisations offer guidance on the authorship criteria to be applied in biomedical science, in most situations the reference guidelines continue to be those established by the International Committee of Medical Journal Editors (ICMJE) [6]. These criteria have been steadily updated (see article from Ana and Matko Marušić in this issue of *TWS* for a history of the ICMJE authorship criteria) and attempts have been made to reflect the multiple contributions that bring an article to the point of publication. Nevertheless, authors and other contributors continue to struggle with their interpretation—either through ignorance or deliberate transgression (see articles from Ana and Matko Marušić, Joselita Salita and Diarmuid De Faoite in this issue of *TWS*). What sort of contribution merits recognition as an author and what is only worthy of acknowledgment in our particular reward system? If the writing process and the material described are separable in science, does writing represent a contribution worthy of authorship? Prevailing thought among medical communications professionals suggests not. But there are numerous voices of dissent.

If a writer can be a contributor without being an author, we must be able to judge carefully where the boundary between writing and authorship lies and negotiate it appropriately (see article from Elizabeth Crane in this issue of *TWS* for a discussion of this tricky distinction in relation

to review articles). Currently, the ICMJE criteria draw the line between the presence and absence of "substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data". In most situations, it is argued [3,7], a medical writer would not meet this criterion and would not, therefore, qualify as an author. While this is logically consistent with the guidelines, it still raises concerns. GPP2, citing the ICMJE Uniform Requirements, talks of a writer's *willingness* to "take public responsibility for relevant portions of the content" [8]. Perhaps understandably, this suggestion that responsibility is optional has been called into question [9]. In her commentary on Liz Wager's article, Elise Langdon-Neuner [10] argues that choice should not come into it. According to Elise, writers must take public responsibility for the way an article is written. The implications of this argument are significant. As Liz Wager points out, authors cannot be expected to take responsibility for all elements of a study or its presentation—a clinician, for instance, might not be expected to understand the statistical analysis sufficiently to take full responsibility for it, or by the same logic, a statistician might not be in a position to recognise the clinical implications of the findings (see the article from Steven Julious et al in this issue of *TWS* for insights into where statisticians fit in the authorship debate). According to Elise, by this logic writers should take responsibility for their element, namely "the way the research is reported". The fact that statistical analysis is an "appropriate [portion] of the content", as required by the ICMJE [6], however, hinges on the definition of content. Just like clinical investigators, statisticians are likely to have been involved in analysis and interpretation (and in many cases, study design) and are therefore in a position to take responsibility for an aspect of *what* is reported rather than *how* it is reported. This distinction may be reasonable, but if only authors carry responsibility, the outcome seems to be that those only involved in the writing process are in a position to be conveniently absolved of responsibility for anything. Authors must acknowledge the fact that they have received writing support [7,8], yes, but they are also the ones who take responsibility for it. This seems unsatisfactory. Whether or not you believe, like Elise [10] and others [11], that responsibility for drafting a manuscript should be considered an authorship contribution, if the role of medical writers and other professionals involved in facilitating manuscript development is to be seen as legitimate, full responsibility must be taken for the nature of their involvement rather than devolving that responsibility to byline authors. Few medical publications professionals are likely to seek the reward offered by appearing in the byline, since their career development is not dependent upon it. But the long-term future of their profession is increasingly dependent upon public acceptance of their legitimate and ethically acceptable role in medical and scientific publications, and this will not come without accountability.

The question in the end is not *who* was involved in the development of a manuscript but rather *how*. Take an apparently simple question: Who does the writer work for? Guidelines such as those developed by EMWA [7] and the recently published GPP2 guidelines [8] focus on providing support for named authors, with an emphasis on the authors taking final responsibility. Yet the assumption is more likely to be that the writer was working *for* the sponsor, certainly when the sponsor is paying the writer's salary. It may not be enough to say that a writer abides by current guidelines [8]. Perhaps it is time to look carefully at the process of manuscript development. Take, for instance, the question of manuscript review. Acknowledging the involvement of a medical writer in most situations may technically avoid ghostwriting, but it says little about the actual nature of the involvement. There are many areas in which questionable influence can be exerted. GPP2 asserts the legitimate right of industry sponsors "to review [...] articles and abstracts before they are submitted, *and to share scientific comments with the authors*" (my italics) [8]. This echoes the EMWA guidelines [7], where it is made clear that although it is reasonable for sponsors to make contributions or comments, this "should not prevent the involvement of authors at the early stages". By naming the process—i.e. sharing of comments with the authors—we can begin to define a transparent process for manuscript development. There is no doubt that sponsors will review manuscripts developed by medical writers and communications agencies, but in the absence of clear guidelines on how, authors may not always know who has been involved or whether, while the manuscript was out of their hands, changes have been suggested in wording, emphasis, citation, etc.—all elements that could affect how an article is understood and the subtle messages that it conveys. Yes, guidelines already indicate that authors are responsible for approving content, but if the writing process is not fully transparent, passing the final responsibility to the authors is surely inappropriate. In just the same way that academics in most fields seek critical input from their peers, it is illogical to prohibit advice and guidance from highly experienced professionals simply because they are employed by the sponsoring company [although it may be reasonable to question their role—many companies now prohibit any involvement of marketing personnel in publications activities (see Box on page 35)]. The important point is that authors should be privy to those comments and therefore in a position to discuss whether and how they affect the final wording of the manuscript. This is a clear example of where medical publications professionals can, and I would argue should, take more not less responsibility for the writing process. A medical writer, for instance, is in a position to know whether comments were made by, say, members of a publications steering committee, whether they were clearly communicated to the authors, and whether any and all such critical input was acknowledged. So, why not stand up and take responsibility for it rather than seek refuge in the final approval of the content by authors? By virtue of their position at the centre of this process, between byline authors and industry sponsors, medical writers and other publications professionals are arguably better placed than corresponding authors to attest to the nature of the manuscript development process. >

From the Guest Editor's desk:

> Facilitating writing and supporting authorship

Elise's argument that drafting an article should be considered an authorial contribution may be based on a particular view of the drafting process. Here, drafting is seen as an isolated process in which one individual produces a 'preliminary version' of an article for subsequent approval (further highlighting the crucial importance of transparency in the 'internal' review process). According to this logic, whoever *drafts* an article must be an author. There is no doubt that this approach has been and may continue to be used by many medical writers. But are there other ways to consider how a draft is produced? Skilled writers can work according to the instructions of those responsible for determining *content*, namely the authors, helping them to communicate their thoughts effectively, acting as a critical consultant to help identify those areas in which interpretations may not be clear or forms of presentation need to be changed to follow reporting guidelines or meet the specific publication requirements of a journal. This is the realm of the facilitator—for me, there can be no better term to describe what all medical publications professionals can and should aspire to.

The concept of facilitation can be applied across the spectrum of writing support provided to authors. In this issue of *TWS*, Mary Ellen Kerans [12] describes her way of working as an author's editor and translator. The approach, which stems from a larger body of research into the nature of the writing process, places the responsibility for content entirely with the authors. The facilitator guides the author through areas of the text that cause problems for the reader, offering sensitive feedback that provides an opportunity for reflection and revision. Only once the content has been agreed with the author does more traditional editing occur to prepare the text for submission. I would argue that such an approach is highly applicable to a medical writing context during manuscript drafting. In the examples described by Mary Ellen, she elicits revision by the authors, who are responsible for the writing at this stage. However, it is perfectly conceivable that a writer could instead elicit *instruction* while helping to write a draft. This is quite different from the idea of drafting as an isolated process. Here, the writer must use skills similar to those described by Mary Ellen to facilitate authors' thought processes while deciding on the content of a manuscript. Although the polish may be provided by the medical writer's skill as a wordsmith and expert in scientific communication, the content is developed collaboratively, the writer acting as advisor and scribe rather than provider of content for approval. One of the arguments against the use of medical writers is that scientists will no longer learn how to communicate their ideas. However, the approach described by Mary Ellen highlights a role for modelling good writing practice. Perhaps, then, the experience of working with a medical writer could even be educational for less-experienced authors.

Facilitating writing and supporting authorship is something that should be common to many of the professional activities that encompass the work of *TWS* readers. In addition to Mary Ellen's description of her approach to working with authors as an editor and writing mentor, this issue of *TWS* contains an article from Karen Shashok [13] on helping authors to become active participants in the international scientific knowledge community. She describes work at Shiraz University of Medical Sciences in Iran as part of the AuthorAID in the Eastern Mediterranean project, which, like other AuthorAID initiatives, supports academics who face linguistic, social and economic barriers to publication. AuthorAID in the Eastern Mediterranean is just one example of how the community of language professionals represented among EMWA members and readers of *TWS* helps to provide many authors with a more effective voice in their professional communities. In the translation section of this issue of *TWS*, Susan DiGiacomo [14] offers a different perspective on this role. According to Susan, "The risk of a bad translation is that it can all too easily cast doubt on the quality of the research and the analysis, damaging a neophyte author's credibility ..." If we substitute "bad translation" with "poorly written article", one might argue that Susan's statement describes the reasoning behind the work most of us do. In our own different ways, we are facilitators all.

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EMWA's 3-year strategic plan

by Helen Baldwin

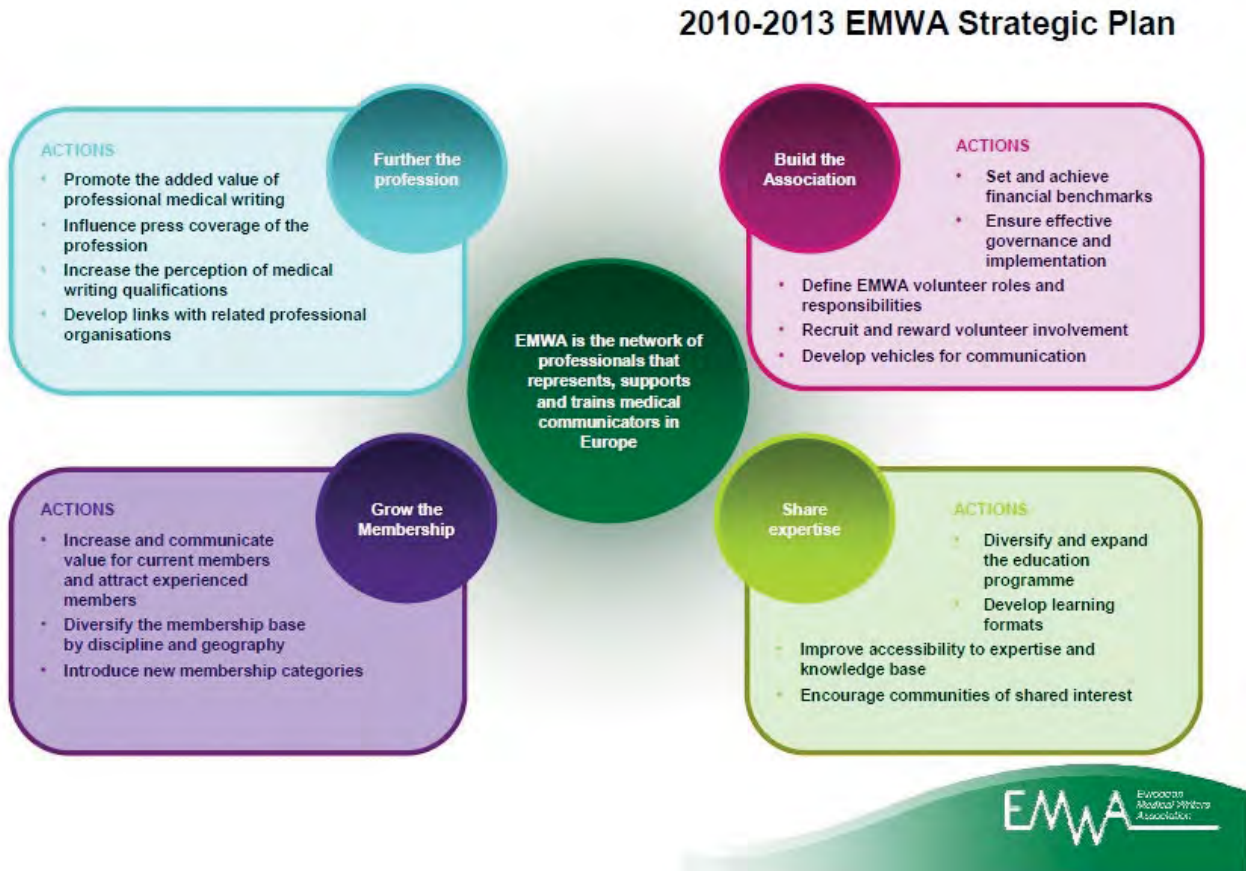
EMWA has clearly come a long way in the last 18 years since its early beginnings when a handful of medical writers met at the pub for a few beers and exchanged tips on how to do their jobs better. Our association now boasts 930 members from 33 countries worldwide, an education programme of 95 approved workshops, and we are holding our 30th conference which 350 delegates are expected to attend in Lisbon in May. As we continue to grow, we need to ensure that EMWA is constantly improving in order to fulfil the expectations of the expanding and diversifying membership and that our association is truly achieving its goals and fulfilling its potential.

Of course, to achieve our goals, we need to start by defining them! With this aim in mind, EMWA's Executive Committee (EC) recently held three one-day strategy planning meetings in Frankfurt and London. At these meetings the EC considered EMWA's strengths and weaknesses, defined the association's mission and positioning, and identified the areas which we considered most important to develop in the next 3 years. This initiative led to the production of EMWA's strategic plan for 2010-2013 (see figure) which I would like to tell you about in this article.

EMWA's mission statement

EMWA is the network of professionals that represents, supports and trains medical communicators in Europe.

Yes, I know, it sounds rather serious and boring compared with the Star Trek mission statement ("to explore strange new worlds, seek out new life, and new civilisations, and to boldly go where no man has gone before"), but sadly medical writing and exploring space just don't seem to overlap much. Although I can think of a couple of 'spaced-out' members who would probably disagree! >



Message from the President

> EMWA's positioning

EMWA is an established European network of medical communicators (including medical writers, editors, translators and related professions) which champions professional standards, offers a wide range of certified training by experienced leaders, and provides diverse platforms and knowledge-sharing opportunities, through:

- *bi-annual conferences held throughout Europe,*
- *foundation and advanced certificate professional development programmes,*
- *a quarterly speciality journal providing topical, academic and thought-provoking articles in print and online,*
- *and a website offering online resources, services and networking opportunities.*

The above may seem obvious if you have been a member for a while, but potential EMWA members may not realise everything we have to offer and it is important to state these benefits clearly on our website and in our other communications.

EMWA's four strategic pillars

Once we had defined EMWA's mission and the positioning, we agreed upon the four main strategic areas which would require action over the next 3 years. These four strategic pillars are: further the profession, grow the membership, build the association, and share expertise.

We believe that one of EMWA's main missions should be to promote the added value of the medical writing profession. We all agree that medical writers bring enormous benefits–but what exactly is this 'added value' and how can we raise awareness of it outside of our sphere?

Here is a list of just a few of the many qualities that a professional medical writer generally has: scientific/medical training, excellent grammar and spelling, effective communication skills, accuracy, consistency and clarity, ability to summarise large volumes of data, effective data presentation and interpretation, professional integrity, and knowledge of guidelines and ethical principles. Does your boss realise that you bring all these benefits to your company? Probably not!

So our aim over the next few years is to increase awareness and respect for the medical writing profession in as wide an audience as possible including our customers and employers, the media and the general public, medical journals, academic institutions, students, peer professions, and the public sector (e.g. government agencies).

Influencing the press coverage of the profession is especially important in the face of the public criticisms often levied at us by newspaper journalists. Medical writers are commonly portrayed by the press as evil, corrupt 'ghosts' who are paid large amounts of money to write lies for pharmaceutical companies. We plan to promote EMWA's anti-ghost-writing guidelines more strongly (http://www.emwa.org/MembersDocs/GuidelinesCMRO.pdf) and to send regular press releases putting the story straight whenever relevant articles appear in the news. We already started to put this plan into action at the end of last year when we sent a press release from EMWA to a long list of medical journalists and editors (http://www.emwa.org/Home/Ghostbusting.html) in response to the publication of the GPP2 guidelines (http://www.bmj.com/cgi/content/full/339/nov27_1/b4330).

We also plan to continue to develop links with other related professional organisations. A couple of years ago we joined forces with the Institute of Clinical Research (ICR) to hold two successful joint symposia; the next event is in preparation and will take place in September 2010 in London. This type of collaboration is beneficial for members of both associations as it broadens their choice of events and increases their network of contacts. Furthermore it promotes EMWA and medical writing as a profession. We are currently in the process of building similar collaborations with various other organisations including the European Forum for Good Clinical Practice (EFCGP) and The Organisation for Professionals in Regulatory Affairs (TOPRA).

Another strategic priority is to increase the perception of medical writing qualifications. With this aim, our Education Officer and his committee are currently investigating the possibility of developing a partnership with a university or other academic institution. It would be excellent if our foundation and advanced certificates were to be formally accredited by such an institution. Alternatively, our workshops could perhaps be integrated into a university Masters of Science (MSc) degree course. These initiatives and others will be the subject of discussions and negotiations over the next few months.

One of the points we agreed upon during our strategy discussions is that we would like to see EMWA continue to grow. Why? Because medical writing is a rapidly growing

profession, new medical writers need training, and EMWA offers the best medical writing training courses in Europe. In addition, there are many untapped sources of potential members within certain European countries (especially Eastern Europe) and within related disciplines (e.g. medical education writers, clinical research personnel, medical translators etc.) By expanding EMWA to encompass these geographical and professional areas, and by encouraging new members to attend our conferences and workshops, we will continue to increase the quality of medical writing in Europe as a whole.

It is also important to increase the value of EMWA membership for you–the current members. As a starting point, we sat down and listed all of the benefits of being an EMWA member today:

- Membership of an organisation representing a recognised profession
- CV enhancement
- Opportunity to join subcommittees, working groups and other volunteer roles
- Journal:
  - Receipt of the printed journal and immediate online access
  - Opportunity to write articles for publication in the journal
  - Source of up-to-date information on new guidelines, techniques etc.
- Website:
  - Access to the members-only section of the website
  - Opportunity to have a freelance listing or reduced rates on a company listing
  - Opportunity to participate in member-led forums
- Opportunity to attend the biannual conferences
  - Foundation and advanced workshops on all aspects of medical writing
  - Plenary sessions, seminars, and discussion panels on different themes
  - Ability to enrol for foundation and/or advanced EPDP
  - Networking opportunities and social programme

I'm sure you agree that this is already an impressive list of benefits. Nevertheless, we plan to consider ways to increase this list in order to make EMWA membership even more attractive for current and potential members.

When an organisation grows quickly it is sometimes difficult to keep up to date with administrative issues such as writing Standard Operating Procedures (oh no, the dreaded SOPs!) This has happened to some extent with EMWA, so one of our aims is to properly document our procedures in order to facilitate head office and EC activities and ensure that information is not lost when EC officers step down. Head office will also be helping EMWA's treasurer to set and achieve financial benchmarks in order to ensure that our finances remain healthy and that we don't spend more than we earn (something else that can easily happen when you grow too fast).

We also plan to clearly define EMWA volunteers' roles and responsibilities (EC officers, subcommittee members etc.) as this will help to organise the tasks of our volunteers and hopefully assist in finding more helping hands in the future. With this in mind, we also plan to find new ways to recruit and reward volunteer involvement. It is so important to remember to say "thank you". For example, if you look in the Lisbon conference brochure and on the website, you will see that we have listed the names of all of the volunteer members who were part of the conference steering committee. We are very grateful for their help in putting together this conference and felt it was important to mention them by name so that all the other members are aware of their input. Wouldn't you be pleased to see your name printed in there next time?

We also plan to develop vehicles for communication both within EMWA and externally. For example we recently sent all members an e-newsletter with all the latest information about what's going on in EMWA. This is more fun and reader-friendly than a plain e-mail and can include links to more detailed information on our website. We have also started EMWA groups on Linked-In (http://www.linkedin.com), FaceBook (http://www.facebook.com) and Twitter (http://twitter.com/OfficialEMWA). I have to admit I don't understand much about this sort of 'new-fangled' way of communicating–but we need to do it if we are to stay ahead of the game and attract new younger medical writers who were born with a laptop in their crib!

The last of our four strategic pillars concerns the sharing of expertise–and this has in fact always been EMWA's primary goal. Our education programme is a wonderful system in which experienced members generously share their knowledge and expertise, on a purely voluntary basis, with less-experienced members. We plan to continue to diversify and expand our education programme in order to attract >

Message from the President

> new members from other disciplines, as well as to satisfy the needs of more senior members. We have also started to investigate the possibility of other learning formats, such as e-learning. We are also exploring how we can facilitate knowledge-sharing through other channels, such as our journal and website. The journal has long been an invaluable point of reference for those in our profession. Plans are underway to revamp our online journal, improving accessibility to its content and making our current archive fully searchable. Furthermore, recently, thanks to the help of Ingrid Edsman and Neil Fisher, we now have an online Freelancer Resource Centre that brings together resources relevant to our freelance members. This is the first of a number of new website features designed to provide novel ways of sharing expertise online.

Next steps

I have really enjoyed my time as EMWA Vice President and President, but during my 3 years of office, I was sometimes concerned that the EC had so many tasks and details to deal with that we never seemed to have time to look at the big picture and ask ourselves questions like "Why does EMWA exist?", "What do our members hope to gain from being a member–and are they getting it?", "How can we convince the outside world that medical writers are highly professional individuals who bring enormous added value to their projects?".

I am therefore very proud to say that, despite my initial concerns that we were so bogged down with work that we would never 'see the wood for the trees', we did manage to make time to step away from our busy workloads and to succeed in defining EMWA's strategic plan for the next 3 years. This plan will be an enormous help to head office, as well as to present and future EC members and subcommittee members, in guiding the direction of their efforts and activities.

I would like to thank my Vice President, Laurence, for her support over the last year and wish her every success in her position of President starting at the Lisbon AGM in May. Laurence has played a key role in our strategy discussions and it was a pleasure to work beside her. I would also like to thank the other members of the EC: Andrea, Elise, Gillian, Laura, Shanida and Stephen. All of them agreed to take 3 full days out of their busy schedules (in some cases on their own holiday time) in order to spend time thinking about how EMWA could best serve its members. Finally, my thanks go to our head office team, particularly Jennifer, Carolyn and Melanie, who gently guided us through this process.

I will be sad to step down in Lisbon, but I am entirely confident that Laurence will do a great job as our next President, and I believe that this 3-year strategy plan will be an enormous help to everyone involved and will ensure that EMWA continues to flourish and to fulfil its potential in every way.

Helen Baldwin
President
helen.baldwin@scinopsis.com

EMWA European Medical Writers Association

We are delighted to announce that the venue for EMWA's 31st conference will be Nice, France.

This beautiful city on the French Mediterranean coast is easily accessible from most major European cities, and the conference hotel, which overlooks the sea, is a perfect location for a our 2-day autumn conference, to be held from Thursday 11th to Saturday 13th November 2010.

Many workshops will be on offer covering a wide range of medical writing topics for those wishing to obtain credits towards their foundation or advanced EMWA professional development programme certificates or simply to update their knowledge and skills.

In addition there will be a chance to meet old friends and make new ones at the welcome buffet on the Thursday evening and the conference dinner on the Friday evening. These social events are excellent opportunities for networking with other medical writers from Europe and beyond.

Further details will be posted on the website at **www.emwa.org**.

A snowy start to the year at EMWA's Head Office

During early January 2010, the UK experienced some unusually severe weather which called for a temporary rebrand at EMWA's Head Office. We wish to apologise for any inconvenience if you experienced a delay in our normal response times during this period.

The EMWA ski lodge

As you can see, the roads were impassable for several days

During the second week we managed access on foot and closed early to make sure our colleagues could get home before dark

Thankfully we are now back to normal

Call for Workshop Leaders

Since the EPDP brochure was last updated in October 2009, I am delighted to have received a number of new workshop proposals on a range of topics including publication ethics, medical devices and advanced statistics, all of which have been suggested by members in EMWA's recent surveys and conference evaluations. I hope that some of these workshops will be available to members for the Nice conference or in spring 2011. If you are interested in becoming an EMWA workshop leader, a good place to start is to study the EPDP Brochure and the Workshop Leaders Handbook, both available from the EMWA website. Even though the EPDP has been expanding rapidly over the last three years (doubling in size and now comprising about 100 workshops), there are still areas that are under-represented in the programme, and there are many topics of interest to medical writers that are not covered at all.

Prospective workshop leaders are welcome to propose a topic of their own choice for consideration by the EPDC. Workshops in the options Medical Communication and Medical Science, and in all options at advanced level, would be especially welcome. Specific topics that have been mentioned in responses to the surveys include:

- The risk management plan
- Clinical trial registries
- Appendices to clinical study reports
- Investigational medicinal product dossiers
- Health economics
- Non-clinical writing
- Management and training of medical writers
- Medical marketing and promotional material
- Medical journalism
- Medical writing for the media

If you would like to join the EPDC, or become a workshop leader, or would like more information, please contact me and the EPDC at epdc@emwa.org.

Stephen de Looze
Education Officer

How many 'F's are there in the following text?

FINISHED FILES ARE THE RE
SULT OF YEARS OF SCIENTI
FIC STUDY COMBINED WITH
THE EXPERIENCE OF YEARS...

Answer on page 27

What's news at EMWA

Call for Applicants for the EMWA Professional Development Committee

Vacancies have arisen on the EMWA Professional Development Committee (EPDC). I invite applications from EMWA members for this position. Ideally you will be an experienced EMWA workshop leader, or have other experience that will be of benefit to the EPDC. As an EPDC member, you will be involved in all aspects of developing and maintaining the EMWA Professional Development Programme (EPDP), ensuring quality of the workshops in the programme and supporting the development of new workshops through mentoring of new workshop leaders. By serving on the EPDC you can help shape the future of this vital programme at the heart of EMWA's activities. Furthermore, candidates for the post of EMWA Education Officer must have served on the EPDC.

Stephen de Looze
Education Officer

TWS call for Regulatory Section Editor

TWS is looking for a volunteer to write a quarterly column on developments such as changes in FDA and EMEA regulations that affect regulatory writing. A column format similar to the current 'Biomedical publishing shorts' and 'Words, Grammar & Co.' columns is envisaged but alternative formats are also possible if preferred by the prospective section editor.

This is a chance to 'get into writing', extend your CV, and keep yourself as well as your colleagues up to date. If this might interest you, please contact me, Elise, by e-mail to editor@emwa.org.

Meet the EMWA Executive Committee candidates... 2010

EMWA's Executive Committee will be elected based on voting by members present at the Annual General Meeting in Lisbon on 12th May 2010. If you will not be present you may also vote by proxy in advance by sending your vote to EMWA's Head Office (info@emwa.org) before 15.14 hours on Monday 10th May or appoint another EMWA member as your proxy and provide that member with your voting form to take to the AGM. You will receive your voting form in the post as part of your AGM pack.

For the position of Conference Director: Sunethra Wimalasundera

I would like to apply for the position of Conference Director as I believe that I have the ideal combination of skills and personality to conduct this role.

I have experience of organising meetings from my time as a CRA where I was involved in setting up site initiation meetings for study investigators. This required liaising with venues, caterers and delegates to ensure their availability. I have also had the opportunity to organise several weddings including my own and am aware of the many aspects of ensuring a successful social event.

I believe, I have very good interpersonal skills as I am very communicative, approachable, persuasive and enjoy being part of a team.

Finally, I would like to apply for this position as it would be a great honour to assist EMWA as an organisation which has been an integral part of my professional development for over 5 years.

For the position of Vice President: Rita Wellans

I am honoured by the invitation of several EMWA colleagues to forward my candidacy for the position of EMWA Vice President. My involvement with EMWA started in the late 1990s when I returned to Europe, after an academic career in the USA, to pursue a professional career in the pharmaceutical industry. A workshop on 'Basics of epidemiology for medical communicators' already developed for the core curriculum of the American Medical Writers Association was soon adapted for EMWA. Motivated by the generous feedback from workshop participants and fellow workshop leaders, a second workshop was rolled out for the advanced curriculum. As a member of the EMWA Professional Development Committee since 2008, I continue to enjoy being actively involved in supporting the development of new workshops by mentoring of new workshop leaders. I hope to contribute further to the booming bright future of EMWA as Vice President.

Plagiarism hurts

Recently at an EMWA conference workshop I was surprised when a set of slides appeared on the screen at the front of the class that I recognised. Two of the slides were identical to slides that I had produced for my own workshop. Four of the other slides were not identical. The format and wording were slightly different but the order of the slides and the ideas expressed were the same as those on my slides. All six slides were plagiarised from my work.

I approached the workshop leaders after the conference and they apologised and have removed the offending slides from their presentation. However, I have been prompted to write this article because the experience was painful to me for a number of reasons. One reason was that I had put a considerable amount of time and effort into researching the material in the slides including conducting an online questionnaire. In general the material was developed from knowledge I had gained through my experiences over the years and my ideas of how to deal with specific situations. The full power of Professor Blass's words on discovering that his work had been plagiarised by the famous (now infamous) British TV psychiatrist, Dr Persaud, hit me "He had taken paragraphs from my work…which I have spent more than 10 years researching. I felt outrage, disbelief and incredulity this could happen, that a person who is himself a writer could do this [1]." Plagiarism hurts.

Another reason was that it was EMWA. Often we are reluctant to complain but my experience is not an isolated incidence at EMWA. Adam Jacobs wrote a short piece in *TWS* less than a year ago about his experience of having entire paragraphs of text from his website copied verbatim on other companies' websites [2]. Two of those other websites were run by fellow EMWA members. He is not the only EMWA member to have had promotional material plagarised and I am not the only workshop leader to have had material plagiarized by other EMWA members.

One of the arguments often put forward for using a medical writer, one of our raison d'être so to speak, is that we help authors to comply with guidelines and write ethically. It's more than ironic therefore if we plagiarise one another. EMWA members should be aware of what constitutes plagiarism, not least because articles have been written in *TWS* about plagiarism in recent years [3-5], but obviously some memories need refreshing.

To quote from Jak Gladney "Plagiarism is the deliberate or careless representation of another's work as your own", and he adds, "it is essentially a lazy man's crime"[6]. Indeed a plagiarist is very lazy because it is easy to avoid either by using the same words as used by the original author and placing them between quotation marks or by paraphrasing the original work. But providing the exact reference is always, always necessary, even if you paraphrase.

The following statement in EMWA's EPDP brochure (page 8) does <u>not</u> mean that workshop leaders can use one another's material without first seeking permission:

"In some cases, the same or similar topics are covered from different perspectives by different workshop leaders. Participants should read the workshop abstract (see section 3) if they are not sure which choice to make between similar workshops."

If you do want to use any material produced by a colleague at EMWA, or by anyone else, you should

1. contact the colleague and ask for permission to use the material *and*
2. acknowledge the source of your this material, e.g. state that this material originates from Xyz's presentation abc (title of that presentation) and is being presented with her/his permission or this material is republished with permission from xyz (and give a reference).

Elise Langdon-Neuner
editor@emwa.org

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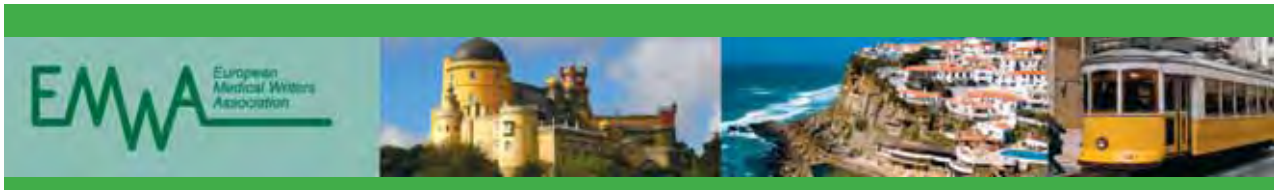

Register for the 30th EMWA Conference in Lisbon on http://www.emwa.org/Lisbon-2010.html

A contribution to the authorship debate: Can we trust definitions and declarations?

by Ana and Matko Marušić

The trade of authorship is a violent, and indestructible obsession.
George Sand (French writer, 1804-1876)

In biomedicine, authorship may not be a violent obsession but it continues to attract heated debates. The 30-year history of the definition of authorship in the Uniform Requirements for Manuscripts submitted to Biomedical Journals (URM) of the International Committee of Medical Journal Editors (ICMJE) demonstrates how the definition of authorship in biomedicine has evolved over time and how it has solved some problems but created others.

The history of authorship definitions in biomedicine

It is difficult to follow the history of authorship definitions before the electronic age: the ICMJE website only archives the full text of URM revisions from 2004 (http://www.icmje.org/archive.html) and provides a list of selected publications from 1979 (http://www.icmje.org/selected_citations.pdf), when the URM was first published by the International Steering Committee (ICMJE came into existence in 1982) [1]. An overview of the changes in the definition of authorship is presented in Table 1, and is based on the search for URM revisions published in individual member journals. The first two URMs, from 1972 and 1982, did not define authorship at all. The only mention made of the roles of different individuals in the publication was the following instruction relating to the Acknowledgment section of a submitted manuscript: "Acknowledge only persons who have made substantive contributions to the study" [1,2].

The first definition of authorship was put forward in the 1988 revision [3], with 3 main sets of criteria which are still in use today: substantial contribution to a) the research leading to the manuscript, b) preparation of the manuscript and c) final approval of the manuscript to be published. Authors were required to take public responsibility for the whole content of the manuscript, and at least one of them had to be responsible for "any part of an article critical to its main conclusions". There were no changes relating to authorship in the 1991 URM revision [4], but the 1994 URM revision [5] introduced the recommendation that the order of authors in the byline should be the joint responsibility of the authors and could be explained in writing in the manuscript. The 1995 revision [6] took out these instructions on the order of authors and expanded those on corporate (collective) authorship, requiring that all members of the group named as authors, regardless of their position in the byline or a footnote, should fully meet the authorship criteria. The 1997 revision of the URM [7] brought back the instructions on the order of authors and replaced the option for editors to require justification for the assignment of authorship with the possibility that they could request and publish information on the contribution of individual authors.

An important change to the definition of authorship occurred in 2000. There is no print version of this revision and the electronic version is not available any more. The only document referring to this change is an editorial by John Hoey from the *Canadian Association Medical Journal* [8]. The first important change was that more contributions were considered eligible to meet the first criterion for authorship, as the requirement for authors to have been involved in "conception and design, or analysis and interpretation of data" was replaced by "substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data". Thus, data acquisition became a legitimate authorship contribution. The second change was in the requirement for public responsibility of individual authors, which was reduced from the whole content to "appropriate portions of the content". It was, however, expected that "one or more authors should take responsibility for the integrity of the work as a whole, from inception to published article". These definitions have remained mostly unchanged until today (Table 1).

Contributors vs. authors

The changes to the URM in 1997, which introduced the option for editors to ask for and publish information on the contributions of individual authors, were prompted by the call for responsible authorship by Drummond Rennie and his colleagues [9]. They proposed "dropping the outmoded notion of author in favor of the more useful and realistic one of contributor". The notion of contributorship was accepted by the ICMJE journals, as reflected in the yearly URM revisions since 2004, which are available in full text from the ICMJE web-site (http://www.icmje.org/archive.html). The former section on authorship is now called "Authorship and Contributorship" and strongly encourages editors to "develop and implement a contributorship policy, as well as a policy on identifying who is responsible for

the integrity of the work as a whole". However, the notion of contributors instead of authors never prevailed. Today's journals still publish the author byline under the title on the front page, and the contributions of the authors are published in small print at the end of the article.

To accommodate the contributorship policy, journals developed various different formats through which contributions relevant for authorship could be declared, and this introduced the problem of the validity of such a declaration. When we started collecting information on authors' contributions in our journal, the *Croatian Medical Journal*, we were surprised to discover that many authors did not satisfy the criteria for authorship [10]. We thought that one of the reasons for a high number of undeserving authors might have been the way we asked for information on their contributions, as research from psychology shows that self-reported surveys (such as contribution declaration forms) have significant limitations. To test this possibility, we performed a number of studies related to the reliability and other psychometric characteristics of contribution disclosure forms.

We first tested the association between authorship eligibility and the format of contribution declaration forms used by 3 major general medical journals. We showed that the journal with the lowest proportion of authors who did not meet the ICMJE criteria had an instructive declaration format, telling the respondent how many contributions are needed to satisfy the ICMJE authorship criteria. In >

Table 1 History of the definition of authorship in the Uniform Requirements for Manuscripts submitted to biomedical journals (URM) by the International Committee of Medical Journal Editors

URM	
1988, 1991	All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is also not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author. A paper with corporate (collective) authorship must specify the key persons responsible for the article; others contributing to the work should be recognised separately (see "Acknowledgments"). Editors may require authors to justify the assignment of authorship.
1994	*The following statement was added:* The order of authorship should be a joint decision of the coauthors. All authors should meet the previously mentioned basic criteria. Because the order of authorship is assigned in different ways its meaning cannot be inferred accurately unless it is stated by the authors. Authors may wish to add an explanation of the order of authorship in a footnote. In deciding on order authors should be aware that many journals limit the number of authors listed in the table of contents and that the National Library of Medicine lists only the first 10 authors in MEDLINE.
1995	All persons designated as authors should qualify for authorship. The order of authorship should be a joint decision of the coauthors. Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to (a) either conception and design or else analysis and interpretation of data and to (b) drafting the article or revising it critically for important intellectual content and on (c) final approval of the version to be published. All three conditions must be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is also not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author. Editors may require authors to justify the assignment of authorship. Increasingly, multicentre trials are attributed to a corporate author. All members of the group who are named as authors, either in the authorship position below the title or in a footnote, should fully meet the criteria for authorship as defined in the "Uniform requirements." Group members who do not meet these criteria should be listed, with their permission, under Acknowledgements or in an appendix (see Acknowledgements).
1997	All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author. Editors may ask authors to describe what each contributed; this information may be published. Increasingly, multicenter trials are attributed to a corporate author. All members of the group who are named as authors, either in the authorship position below the title or in a footnote, should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the Acknowledgments or in an appendix (see Acknowledgments). The order of authorship should be a joint decision of the coauthors. Because the order is assigned in different ways, its meaning cannot be inferred accurately unless it is stated by the authors. Authors may wish to explain the order of authorship in a footnote. In deciding on the order, authors should be aware that many journals limit the number of authors listed in the table of contents and that the National Library of Medicine lists in MEDLINE only the first 24 plus the last author when there are more than 25 authors.

Can we trust definitions and declarations?

2004 – 2006	Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgements. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship. All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Some journals now also request that one or more authors, referred to as "guarantors," be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information. Increasingly, authorship of multi-center trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship. The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed.
2007	*The section on the order of authorship changes to:* The group should jointly make decisions about contributors/authors before submitting the manuscript for publication. The corresponding author/guarantor should be prepared to explain the presence and order of these individuals. It is not the role of editors to make authorship/contributorship decisions or to arbitrate conflicts related to authorship.
2008 – 2009	*The section on large, multicentre groups changes to:* When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributorship defined above and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. The NLM indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.

> contrast, a higher proportion of authors not meeting the ICMJE criteria was found in the journals that had either an open-ended answering format or a list of contribution categories to choose from [11]. We then demonstrated a causal relationship between the structure of the contribution disclosure form and the likelihood that authors met ICMJE criteria for authorship in a randomized study in our own journal [12], confirming that the cognitive task of mapping the answer to the response format influenced the answers on the forms and, consequently, the attribution of authorship. The instructional format of the contribution declaration was again associated with the lowest proportion of authors not meeting the ICMJE criteria, because such a format leads the respondent to give socially (editorially) desirable answers, as has been shown in psychology research [13].

In the next study, we assessed the reliability of contribution declaration forms, defined as the extent to which a test is dependable, stable and consistent when administered to the same people on different occasions. When the same corresponding authors were asked about their contributions to the same manuscript at two different time points, more than two-thirds differed in at least one contribution choice between the two disclosure statements [14], demonstrating poor reliability of the contribution declaration forms as an accurate way of assessing authorship of a manuscript.

In another randomized study, we tested whether offering a range of response alternatives for declaring contributions would influence the respondent's answer by providing a reference range to assess the behaviour to be reported [15]. When authors could choose the extent of their contribution on a scale from 0 (none) to 4 (full), they reported more contributions eligible to meet ICMJE authorship criteria than those who were offered only a binary (yes-no) format for declaring a contribution. This study also showed that the authors perceived all ICMJE-eligible contributions as at least ordinal variables, except for the "Final approval of the article", which was perceived as a dichotomous variable.

Our research demonstrated that contribution declaration policy and authorship criteria themselves have been introduced into the scientific publication process without adequate evidence for all aspects of their validity. Also, a number of reports show that researchers in biomedicine differ from journal editors in their views on what constitutes authorship [16-18]. Obviously, there is much confusion and misunderstanding in the arena of biomedical authorship, and perhaps journal editors should not have taken on the responsibilities of the research community to define when one deserves to be considered an author of the published research. This may have been the reason for the introduction of a disclaimer into the 2007 URM revision (http://www.icmje.org/2007_urm.pdf): "It is not the role of editors to make authorship/contributorship decisions or to arbitrate conflicts related to authorship".

Conclusions

The history of authorship definition and research into current authorship practices in biomedicine demonstrates that there is still much confusion and misunderstanding about authorship among stakeholders in the research enterprise. The existing contribution disclosure and authorship forms do not seem to be the best format for making judgments on authorship, and more research is needed on the cognitive aspects of their construction and evaluation. Until there is enough evidence to propose reliable guidelines for authorship, perhaps it would be best to ask each manuscript author a single open-ended question: "Why do you think you deserve to be the author of this manuscript?"

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Reasons to doubt Shakespeare's authorship

DoubtAboutWill.org[1], a site dedicated to legitimising the Shakespeare authorship issue, makes fascinating reading. Shakespeare is the only presumed writer of his time for whom there is no contemporary evidence of a writing career. Although the reigns of Queen Elizabeth and King James I were well-documented times there is no evidence for Shakespeare having written his works from the time he lived. The main reason to believe he was the author dates from 7 years after he died and primarily rests on testimony in the First Folio collection of the plays published in 1623. The site details grounds for rejecting each piece of prima facie evidence for Shakespeare's authorship including the different spellings of his name, doubts surrounding the testimony in the First Folio, which reads like a sales pitch, and that even the monument effigy of Shakespeare has been 'repaired', i.e. altered to depict a writer, since it was erected in the early 1600s.

There are also numerous incongruities between Shakespeare's life and his reputation as a famous writer. For instance, he left no handwritten documents behind—unusual for a writer—and there is no trace of how he acquired the requisite knowledge to write works demonstrating a wide knowledge of law, philosophy, classical literature, history astronomy etc.—books were expensive and difficult to obtain except at universities and private libraries.

Having read the account you may well be tempted to add your signature to the declaration of reasonable doubt.

1 http://doubtaboutwill.org/declaration

Authorship: Definitions and declarations—A perspective from the *BMJ*

Commentary on: A contribution to the authorship debate: Can we trust definitions and declarations?

by Sally Carter

Ana and Matko Marušić's article raises some interesting questions about guidelines for authorship. At the *BMJ*, we attempted to follow Rennie et al's [1] suggestion of replacing authors with contributors and guarantors [2]. The initial intention was to have an interim period of authors plus contributors, but more than 10 years later we've still not made that final step. Our notes on authorship and contributorship explain how we list contributors in two ways [3].

Value of contributorship details as well as authorship

"Firstly, we publish a list of authors' names at the beginning of the paper and, secondly, we list contributors (some of whom may not be included as authors) at the end of the paper, giving details of who did what in planning, conducting, and reporting the work. … One or more of these contributors are listed as guarantors of the paper" [3, 4].

The concepts of contributorship and guarantorship are important because they clarify the International Committee of Medical Journal Editors' (ICMJE) criteria for authorship. They help ensure several things. Firstly, that the right people get credit for the work and take responsibility for it, and, perhaps, get the intellectual property rights. They also allow the researchers to work out themselves how each person contributed, and it allows credit to be given to others who helped but didn't meet the ICMJE criteria—for example, an assistant who collected the data from patients but didn't design or analyse the study or write the paper. Another reason for having contributors is that gift and guest and ghost 'authors' can be credited there rather than appearing inappropriately in the authors' byline [5].

Attempts at methods for determining authorship and contributorship

Ana and Matko Marušić assessed various formats of declaration forms and found that none seemed wholly satisfactory. The *BMJ* does not use a form, but editors repeat the advice given in the writing instructions in their correspondence with the authors throughout the process during which the article is revised and then accepted. As the guidelines explain, "Researchers must determine among themselves the precise nature of each person's contribution, and we encourage open discussion among all participants"[3]. The *BMJ* does not insist that researchers are listed in order of size of contribution. The Vancouver guidelines point out that readers should infer nothing from the order of authors since conventions differ [2].

Difficulty in defining authorship, how to proceed

A further point worth mentioning is that authorship and contributorship get much more woolly when people collaborate to produce an article that is not original research—for example an editorial, or a review article. In these cases, we ask authors to, "state who had the idea for the article, who performed the literature search, who wrote the article, and who is the guarantor…"[3].

The Marušićs conclude, "that until there is enough evidence to propose reliable guidelines for authorship, perhaps it would be best to ask …'Why do you think you deserve to be the author of this manuscript?'" Richard Smith ended his1997 editorial [2] by saying, "In moving from authors to contributors and guarantors we are entering a new era, and it seems wise not to be too prescriptive. We need to learn from experience and adapt the new system."

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TWS

TWS welcomes articles on any topics of interest to medical writers. Authors do not need to be members of EMWA to contribute to the journal. Articles should be submitted to editor@emwa.org. Enquires about subscriptions to the journal should be sent to info@emwa.org.

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 >

> 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

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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Responsibility of medical writers who draft articles reporting clinical trials

Commentary on: Authorship–More than just writing, but how much more?

by Elise Langdon-Neuner

We cannot dismiss the work of a medical writer as being of little importance, can we? Writing is more than mechanically setting words onto paper. The tremendous emphasis on the writing itself is what has given rise to the booming medical writer industry. Medical writers have not clamoured to be named as authors on biomedical papers. Unlike scientists their career progress does not depend on publications. The secrecy generally implicit in ghostwriting, which for centuries had not been viewed as a problem, only became an issue of public concern in the biomedical sciences when cases came to light where the writing did not genuinely interpret the study data, but rather was influenced by a marketing agenda which could cause harm to patients.

Liz Wager [1] and the *BMJ* are certainly not alone in their view that authorship criteria laid down by the ICMJE guidelines have serious flaws. In the main these flaws arise in their interpretation, where authors do not agree with or wish to follow the spirit of the guidelines—although they will sometimes declare compliance to nominally satisfy the requirements for publication. Only 24% of authors surveyed in a large study of pathologists and physicists agreed with the guidelines [2], which were decided and are regularly updated by the Vancouver group comprising 12 editors of general medical journals. While the ICMJE are a standard point of reference for defining authorship in the biomedical sciences, in practice authorship is governed by the rules and customs of authors' institutions and governing bodies. These rules and customs often reflect the ICMJE guidelines but override them where tradition is stronger. The naming of the head of a department as an author on every paper is one such example. Another flaw in the guidelines is that while they have concentrated on criteria for allocating credit within a traditional concept of scientific authorship, responsibility for today's papers, especially those reporting clinical trials or which are part of a pharmaceutical company's planning policy extends to employees of such companies—including statisticians and medical writers—who fit uneasily into the ICMJE's authorship criteria. Nevertheless, even within the current flawed criteria I believe that there is an argument for including medical writers on the byline of reports of clinical trials published in biomedical journals.

Liz's and I part company on her sentence "Professional medical writers are well aware that drafting a publication does not make the writer an author in the same way that, say, writing a poem makes the writer an author." I think that it can. Let's first take a step back. Medical writers tend to claim that they only provide writing assistance. 'Writing assistance' is different from drafting an article. The first is only worthy of acknowledgement according to the ICMJE guidelines. It's the second that is worthy of authorship: "All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a departmental chair who provided only general support" [3]. Note that 'purely *draft* the article' or 'not who only *drafted* the article' is **not** the wording. So what does drafting mean? According to the *Oxford Dictionary* a draft is a preliminary version of a piece of writing. Who produced the draft? If it was the researcher the medical writer is providing writing assistance but if it was the medical writer we are looking at authorship. A recent report provides a vivid illustration of the importance of the first draft and control of the manuscript (see Box on page 24). It has been contended that in any event at present an acknowledgement of writing assistance by a medical writer is taken to mean that the medical writer wrote and contolled the paper [4] as set out in Figure 1.

But wait, you say. According to the ICMJE, to qualify as an author a medical writer also has to analyse or interpret the data. I have two arguments here. One is that if the medical writer is preparing a manuscript from clinical trial data he[1] (personally or under instruction from his employers) may well be selecting which data to present and selecting how it is presented, drawing up tables or graphs. My other argument is that choosing the words and structure that transfer thoughts onto paper is also an interpretation. I subscribe to the notion that writing whether it be a report or a poem invariably involves interpretation and influences readers, "Language is not neutral. It is not merely a vehicle which carries ideas. It is itself a shaper of ideas" (Dale Spender).

This leads to my main quarrel with the GPP2 guidelines. Liz points out that they advise that if a medical writer is willing to take responsibility for relevant portions of the content he may be in a position to meet the remaining ICMJE criteria for authorship. The contention here is that authorship depends on 'willingness'. Surely if a researcher publishes his research he cannot choose, he must accept

1 As a counterbalance to Adam Jacob's use of 'she' in his commentary see footnote on page 28

Figure 1. Acknowledging ghostwriters does not accurately reflect their authorship role. This figure is a reprint of Figure 1 in [4], which was modified from Fugh-Berman A, Dodgson S. Ethical considerations of publication planning in the pharmaceutical industry. *Open Medicine* 2008. Available: http://www.openmedicine.ca/article/view/118/215. Used under a Creative Commons license which permits the modification and re-use of intellectual content as long as it is properly acknowledged.

responsibility for it. If a writer drafts a paper from material produced in a clinical trial he must take responsibility for the integrity of his presentation. So, although Liz says she might take responsibility for the way the research is reported, I say, I'm afraid she has to if she drafted the manuscript. She might not be able to explain why a particular trial design, statistical method etc. was used but here she would most likely be in good company with the other researcher authors who were only au fait with their part of the trial. Is the statistician responsible for the work done collecting the data in the lab? To be fair Liz does question what the ICMJE guidelines mean by authors taking responsibility for 'relevant portions of the content'. The main purpose of the guidelines as I have already mentioned seems to be to lay down criteria for awarding credit to qualify for authorship but here the guidelines venture into imposing responsibility on the author for the integrity of the paper. However, the logical concept that not all the authors can be responsible for all aspects of the paper is gaining acceptance (See Box about *Science*'s policy below). Instead someone needs to be responsible for each portion, one of which is the interpretation involved in drafting if the medical writer is selecting what to present, making decisions on graphic representations as well as choosing the words and structure of the paper.

There is also a circular argument which highlights the inadequacy of the ICMJE guidelines. 'Authors' have to be involved with the study. Yes, but they also have to be involved with the drafting of the manuscript. If we argue that medical writers cannot be authors because they are not involved with interpretation of the study then those who did interpret the study cannot be authors if they were not involved with the drafting. Ah, you say, but they only need to have approved the drafts. Not quite. The guidelines actually say to be an author the researcher should be involved in "drafting the article or revising it critically for important intellectual content." Do all the academic authors make this contribution when a medical writer drafts the manuscript or a statistician makes an analysis? According to the ICMJE they should, but can they and do they? Here I can do no better than to quote from a recent paper on industry-sponsored ghostwriting "Physicians may rationalize their participation in the publication of ghostwritten articles because they read and agreed with the manuscript, or even because they made a number of editorial changes they believed qualified the authorship. However, this fails to address the main problem that key marketing messages have already been incorporated into the manuscript [by the medical writer]" [5]. The article goes on to consider that more seriously the author might not have analysed the raw study data, which is another requirement of the ICMJE guidelines.

Liz deals with access to data. It's very important and the Eastell case is a good illustration. Eastell has since been cleared of misconduct by the GMC but the very fact that the GMC saw fit to investigate the matter shows how seriously they view authors' claims of having access to data [6]. Eastell did not >

Guarantors per data set to discourage 'honorary authorship'

Science now requires senior authors to certify that they have personally reviewed the original data generated by their group and the figures and tables are appropriately presented. As most papers result from co-operations between groups this is a move away from one author as guarantor for the paper. *Science* does not accept provision of laboratory space or supplying samples as adequate for authorship, for which the intellectual contribution is of prime importance. The idea that mentoring should be acknowledged is also aired in Bruce Albert's editorial, Promoting Scientific Standards. *Science* 2010;327:12.

Responsibility of medical writers

> have access to all the data—only one author, the sponsor's statistician, had this access—but the GMC found that he never said he did, the medical writer is believed to have added this statement and it would appear Eastell did not critically revise the statement but, remember, he was cleared of misconduct. Liz omits to mention that this paper did contain errors, e.g. one graph had been trimmed to exclude some of the more extreme values. Who drew the graph? It might have been a coauthor, the statistician or the medical writer.

The ICMJE's 'decision to publish' and 'final approval' provisions also fail to reflect the real life situation. Quite apart from the finding that 'final approval' is the ICMJE authorship criteria where authors are least compliant [7], if an article is part of a publication planning policy, who is making the decision to publish and who gives the final approval? One person at least is probably the manager of the publication planning department or the medical writer's boss. Does the name of this individual appear in the byline?

At the end of the day my question is this: if each of the researcher authors and the statistician is taking responsibility for his part of the work what is it that is stopping medical writers from taking responsibility for their part, i.e. the drafting, if they have done this? If it is solely that they do not feel they deserve the credit of authorship according to the ICMJE's criteria, the Vancouver group should make provision for a declaration that a paper has been produced as part of a company's publication planning policy. If individuals employed by the company selected and analysed the data to be presented, drafted the article, or approved the paper they could then be named in the declaration and accept responsibility for their contribution. In this way transparency would be achieved and any fear that medical writers might have of carrying the whole weight of the sponsor's internal decisions solely on their shoulders would be avoided—a fear that possibly plays a greater role in their shying away from authorship than the debates on meeting authorship criteria laid down by the ICMJE reveal.

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Who produced the draft and controlled its revision?

McHenry and Jureidini examined documents produced in court proceedings against SmithKline Beecham (SKB) relating to their antidepressant drug paroxetine (Paxil/Seroxat)[1]. The 3 studies conducted by SKB to obtain regulatory approval for the paroxetine for adolescents had failed to show superiority of the drug over placebo on the primary outcomes. Prescription of Paxil to adolescents therefore was only possible off-label. SKB contracted Scientific Therapeutics Information (STI) to prepare a based on one of the studies, Study 329. STI was to be paid $17,250 for production of the paper. Sally Laden, the medical writer at STI, testified that she prepared the first draft without input from any of the authors. She relied on the final clinical report of study 329 provided by SKB. Although her writing assistance was acknowledged in the paper her role in writing the first draft and guiding the process as well as her relationship with the sponsor was not revealed.

When questioned why her first draft failed to distinguish between primary and secondary efficacy variables, Laden replied "this may have been my interpretation of the data" but she did not know why there were 8 primary efficacy variables in the draft whereas there had only been 2 in the report. McHenry and Jureidini found that in contrast to the clinical report Laden's draft gave a systematic misleading impression of efficacy and safety. The published paper's claim that paroxetine is "generally well-tolerated and effective for major depression in adolescents" was not supported by the data. The substance of the published paper did not differ from the first draft. From McHenry and Jureidini's analysis of the documents they concluded that at least 10 of the 22 named authors made no contribution to the article content and those who did mostly provided only minor text editing. Several undeclared SKB employees made greater contributions. One of the authors submitted an amendment to correct the inaccurate account of serious adverse events but his amendment was tempered, apparently from the SKB/STI side, prior to publication. McHenry and Jureidini found difficulty in deciphering who was responsible for the distortions in the final paper but concluded that the sponsor retained control of the manuscript and "the fact that the article was ghostwritten meant that individuals unknown, presumably from within SKB, could intervene without the named authors being encouraged to step in to correct any manipulation of the data."

1 McHenry LB, Jureidini JN. Industry-sponsored ghostwriting in clinical trial reporting: A case study. Accountability in Research 2008;15(3):152-167

Authorship and review articles: Multiple shades of grey...

by Elizabeth Crane

The current environment

As evidenced by recent headlines in major newspapers, review articles have been of particular interest to the media and United States Congress [1-3]. Review articles relating to clinical trials and pharmaceutical products seem to possess an aura of mystery to the general public because their origins often lie within a 'strategic publication plan', thereby amplifying the potential for bias and product promotion. In particular, the roles of the authors and the sponsoring company are central to the public's suspicion. A leading perception is that the content of review articles is largely dictated by the sponsoring company rather than by the authors. The term 'guest authorship' is used to describe cases in which an individual listed in the byline did not actually contribute to the article and merely approved a draft manuscript prior to submission. The content of such a paper may have been written with assistance from a professional medical writer whose role is undisclosed, also referred to as 'ghostwriting'. Finally, 'ghost authorship' describes cases where someone's, perhaps a medical writer's, contributions to the paper are substantial and intellectual enough to qualify for authorship, though the individual is absent from the byline.

While it is very clear how *not* to determine authorship of review articles, identifying individuals who do qualify as authors is not always easy. Existing guidance published by editorial [4, 5] and professional writing organizations [6-8] are an essential reference to provide clear expectations and requirements for ethical publication practices. While these guidance documents quite clearly apply to publication of original research papers, there is significantly less instruction regarding publication and determining authorship of review articles. Additionally, lessons can be learned from cases and resulting media coverage on how to interpret and apply current guidelines to formulate, or update, ethical policies and practices.

As the vast majority of authors, medical writers and publication planners have no aspirations of achieving public infamy, this paper will review the current guidelines for determining authorship and how they do, or do not, apply to review articles, and discuss the implications for publication policies and practices.

Guidelines for authorship

The International Committee of Medical Journal Editors (ICMJE) Uniform Requirements [4] is the standard by which many journals and industry-related entities set their authorship policies. ICMJE states that authorship criteria are met when an individual fulfils all three of the following requirements:

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content
- Final approval of the version to be published

While these criteria do not directly refer to review articles, they can be stretched and extrapolated to fit reviews and other types of non-research publications. The third condition—approval of the final version—is straightforward and applies to any type of publication. The second condition—drafting the article or providing intellectual contributions—is also clear and applicable, though the question of what qualifies as an important intellectual contribution could be the basis of its own supplement. Nonetheless, the vagueness applies equally to research and non-research publications.

In systematic reviews, publications in which there is a methodology by which searches were conducted and literature included for evaluation, the first condition could translate to conception of the review article, determination of search parameters and inclusion criteria, execution of literature searches, or evaluation and interpretation of qualifying literature. Non-systematic or narrative reviews, those that describe a topic and have softer methodology and criteria for article inclusion, are more difficult to apply to current authorship criteria. The initial, broad idea for a review article may originate from numerous sources: an individual, discussions during a sponsored advisory board, a hallway conversation, or frequently received questions to a sponsor's Medical Information Call Centre, to name a few. Additional research and discussion are needed to transform a very general idea (for example, a review of nighttime heartburn) into a concept that can be developed into a review manuscript (for example, a review of the physiology and available pharmacological and non-pharmacological treatments for nighttime heartburn in adults). In the cases where a scientific expert formulates the initial concept and continues forward to develop the concept into a full-fledged publication, the qualification for potential authorship is clear. In the other cases where an agency, a team or a committee identifies the initial, general idea and brings it forth to one or more scientific experts for further discussion, the experts need to be accountable for >

Authorship and review articles

> transforming the rough concept to a point where an outline can be developed. Then they should be able to confidently demonstrate their contribution, assume responsibility for the work and fulfil the first criterion for authorship.

Some journals are addressing the unique authorship requirements of non-research papers. The *Annals of Internal Medicine* has modified the first ICMJE criterion by stating that the author must have "conceived and planned the work that led to the article or played an important role in interpreting the results, or both" [9]. Additionally, the *British Medical Journal* specifically approaches the roles of those contributing to non-research articles, as author or otherwise, by requiring transparency in declaring which individuals conceived of the paper, performed literature searches and wrote the paper [10]. However, the *BMJ* model for contributorship does not further stipulate any specific criteria for distinguishing byline authors of non-research articles.

It is also worth noting that the ICMJE Uniform Requirements [4], and other guidelines that reference it, state that authors listed in the byline must be able to take public responsibility for the work. This includes being able to explain and defend the work to peers in the scientific and publication fields. However, in an environment where authors are not only criticised in print by journal editors, but can be subpoenaed to testify about their knowledge of study data and contributions to a manuscript, public responsibility takes on deeper significance. While sorting out specific roles and significant contributions, those involved in creation of review articles must remember that their inclusion in the paper, regardless of whether this be in the byline or the acknowledgements, is a public endorsement of the work.

With a lack of specific authorship criteria for review articles, editors, authors and publication professionals are left to their own devices in interpreting the current guidelines, and interpretation is notoriously variable when done on a case-by-case basis. Inconsistent interpretation can also lead to a spectrum of strict-to-lenient application of authorship criteria, which will further confuse and frustrate all stakeholders.

Considerations for applying authorship criteria

Authorship qualifications are generally not an issue when the individual who conceived of the review topic also drafts, revises and approves the manuscript, as all criteria are elegantly met. However, the more prevalent, and complicated, scenario is when a scientific expert agrees to develop a concept to publication and have writing or editing assistance provided by a medical writer and funded by an industry sponsor, as discussed earlier. This scenario becomes further complicated when the medical writer possesses the credentials and scientific expertise to lend important intellectual contributions to the concept, design of literature searches, and evaluation and interpretation of the literature. In this complex scenario, a number of effects and implications should be considered.

First, if one agrees with the extrapolation of the first ICMJE condition for authorship—contribution to manuscript concept development, design and execution of literature searches, and literature evaluation—it is then very important to ensure that the scientific experts invited as potential authors are actually engaged in designing the literature searches and evaluating the literature for inclusion/exclusion, as well as interpreting the research. On occasion, the author actively or passively (through lack of responsiveness) delegates to the medical writer the lead in designing and executing the searches. The medical writer may also conduct the preliminary sorting and prioritization of results. The result can be two-fold: the author is excluded from the process, thereby missing an opportunity to qualify, and the writer is potentially meeting the first criterion for authorship. As described in the EMWA guidelines [6], conduct of an extensive literature search could qualify a medical writer for authorship. Non-responsive authors should be reminded of the responsibilities of authorship and importance of their contributions. If they fail to seize the opportunity and provide significant input, then they should be removed as an author. Conversely, medical writers should remember to solicit direction from potential authors and refrain from filling in the gaps on behalf of the non-responders. In fact, during the project initiation phase, it may be worthwhile for the medical writer and sponsor to discuss expectations of authors (e.g. does an e-mail stating that a draft "looks good" constitute acceptable input?) and a plan of action for whom will contact non-responsive authors at what time points. All stakeholders, including authors, benefit from having clear expectations at the onset of the project.

The role of a medical writer as potential author has been controversial. If an individual, professional medical writer or not, fulfils the conditions for authorship, then guidelines [4-8] agree that the individual must be included in the author byline. Additionally, if the writer or his/her employing agency received funding from the manuscript's sponsor, this fact should be clearly disclosed. This case becomes complex for those sponsoring companies with written, or unwritten, policies explicitly prohibiting compensation (e.g. honoraria, consulting fees) for authorship activities. If a professional medical writer, who is paid a fee for service under such a policy, becomes an author, the sponsor is left in a quandary—violate their policy or request that the writer return payment or decline authorship. None of these options are attractive, and declining authorship when one qualifies only perpetuates the unacceptable practice of ghost authorship. For companies with strict payment policies, all stakeholders need to discuss roles and expectations during the project planning stage. It must be very clear as to whether a medical writer possessing appropriate scientific qualifications will have an opportunity to qualify as an author, or whether the expectation is for the writer to act in a purely supportive role. Writers and agencies should, in turn, determine if they are comfortable entering

into business agreements with stipulations that the medical writer will remain in a disclosed contributorship role.

Another aspect of review article authorship is the role of the sponsor's employees. Many industry medical directors and scientists are recognised for their academic research achievements made prior to embarking on a career in the pharmaceutical industry. Some industry scientists are well-known for their notable research achievements made during their industry tenure. As a result, these individuals are often invited, or solicited, to author reviews on a topic or product in their area of expertise. Clearly, there is a potential conflict of interest that requires detailed disclosure, particularly if the sponsor had a role in funding or reviewing the publication. However, someone with relevant expertise should not be prevented from accepting an invitation to author a review paper solely on the basis of being employed by industry. An employer's internal policies may further detail the steps necessary to review and approve such projects, as well as disclosures and disclaimers needed for the resulting publication. Medical writers should solicit details of the scope of the internal review (e.g. limited to legal and intellectual property, or were content and the decision to publish directly influenced?) and gain agreement on a brief and accurate disclosure of such activity in an effort to provide transparency to the journal and public.

Due to their credentials and expertise with a product or therapeutic area, industry employees may be able to make important contributions to an unsolicited review manuscript and potentially serve as authors. In fact, these individuals are likely part of the sponsor's internal publication review process, even if they are not authors. Therefore, the definition of roles and expectations at the initiation of the publication is very important. Some product teams prefer employees *not* to author sponsored non-research papers. This practice may be an effort to reduce potential bias and, hopefully, increase likelihood of acceptance of the review. Aside from anecdotes of rejections, the true efficacy of this approach is not known because sponsorship of the paper is already a potential source of bias, regardless of the presence of a sponsor-author. For sponsors who do allow employees to qualify for authorship of sponsored review papers, it is essential to offer a complete, detailed disclosure statement describing the pertinent financial and personal relationships, as well as if the sponsor provided other means of support, reviewed the article or participated in the decision of whether or not to publish.

As authors, writers, editors and publication planners continue to share and debate current review article policies and practice, establishment of best practices grows closer on the horizon. In lieu of a defined best practice, those involved in development of review articles should document their current procedures so that, if questioned by editors or attorneys, they are prepared to explain and defend the selection and roles of authors and contributors.

Conclusion

In the absence of guidelines that specifically address authorship of review articles, transparency in disclosing the roles and potential conflicts of interests of authors and contributors is an ethical and appropriate course of action. Additional consultation with journal editors to confirm which individuals meet authorship requirements can also be helpful to ensure that criteria are applied in a manner that is compliant with the journal's policies. Professional organisations and journal editors should consider developing authorship criteria for non-research papers.

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Answer to quiz on page 11

There are 6 'F's. You counted 4? Usually people can only count 4 'F's in the text because most brains cannot process 'OF'.

The trouble with narrative reviews

Commentary on authorship of review articles

by Adam Jacobs

Multiple shades of grey indeed. The role of medical writers in primary research publications is reasonably well defined, and a wide variety of guidelines show a remarkable consistency in what is expected, generally echoing the EMWA guidelines [1] in saying that the medical writer's contribution must be transparently acknowledged. However, things become considerably more complicated when medical writers contribute to review articles. Elizabeth Crane steers a sensible course through what are undoubtedly some very turbulent waters.

So why are reviews so much more complex than primary manuscripts? In a primary manuscript, it is unlikely that a medical writer would qualify for authorship. To do so, according to the ICMJE criteria, would require that the writer had not only written the paper, but also been appropriately involved in the study itself. There may be times when this would be true, perhaps if the medical writer had also taken a leading role in writing the protocol, although even then it is unlikely that the writer would have had sufficient decision-making responsibility in the study design. So primary manuscripts are easy. The medical writer must be acknowledged for her[1] contribution, but does not qualify for authorship. To use a word that has officially entered the English language during 2009 [2]: simples!

In systematic reviews, the situation may well also be straightforward. If a medical writer is involved in a systematic review, it is likely she is contributing substantially to the work of the review (searching the literature, checking papers against inclusion criteria, extracting data for meta-analysis etc), and would often qualify for authorship. For the systematic reviews we write at Dianthus Medical, our medical writers are routinely listed as authors, and this does not appear to be at all controversial.

The problem arises in narrative reviews. When we wrote the EMWA guidelines, we were rather vague about whether medical writers should be authors in such cases. This is mainly because we realised that the situation is complex, and it is unlikely that a prescriptive one-size-fits-all approach would be successful. Instead, the important thing is to keep in mind some general principles, which Elizabeth describes admirably in her article. In my opinion, the important question is the extent to which the medical writer is determining the content of the article. For example, is the medical writer making important decisions about which papers are included in the review, and the conclusions that can be drawn from them? Such tasks should only be undertaken, of course, if the medical writer is suitably qualified to do so. If she is not, then all such decisions must be made by the authors of the review, and the medical writer should be mentioned only in the acknowledgements. However, if the medical writer is making properly informed decisions about the content of the article, then that certainly qualifies her for authorship.

Whatever the decision about authorship status, it is of course always important that the role of the medical writer be disclosed to the journal in a spirit of full transparency. Sometimes, it may be appropriate simply to let the journal know what roles the medical writer has undertaken, and leave it up to the journal editor whether those roles merit authorship.

To end on a somewhat controversial note, perhaps I could suggest that the best answer to this conundrum is that we should not be writing narrative reviews at all. If a review of a topic is needed, why not make the default position to write a systematic review?

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1 I have referred to medical writers throughout as 'she'. This was deliberate. I am mostly referring to situations in which there would only be one medical writer, so it would seem unnatural to write 'they'. I also find it extremely clumsy to write 'he or she'. I have therefore decided to play the odds, given that the overwhelming majority of medical writers seem to be 'she'.

Headline howlers

The following are apparently genuine newspaper headlines:

Red Tape Holds Up New Bridges
New Study of Obesity Looks for Larger Test Group
Kids make Nutritious Snacks
Local High School Dropouts Cut in Half
Miners Refuse to Work after Death
Typhoon Rips Through Cemetery; Hundreds Dead
Something Went Wrong in Jet Crash, Expert Says

Highlighting recent proposed best practice for statisticians in the reporting and publication of pharmaceutical industry sponsored clinical trials

by Steven Julious, James Matcham, Stephen Pyke, Michael O'Kelly, Susan Todd, Jorgen Seldrup and Simon Day

Abstract

In this paper we highlight recent recommendations for statisticians as to best practice for the reporting of clinical trials sponsored by the pharmaceutical industry. Recommendations are made covering: independent review; author responsibilities and recognition; publication timing; freedom to act; conflicts of interest; full author access to data and trial registration. Although the recommendations are made from a statistical perspective we hope that their applicability can be recognised in the wider pharmaceutical trials community, which is the purpose for writing this article.

Introduction

Motivated by an article in *Journal of the American Medical Association* (*JAMA*) on the reporting of industry sponsored clinical trials written by the journal's editors [1] we have made proposals for best practice for statisticians in the reporting and publication of pharmaceutical industry sponsored clinical trials. The initial impetus for writing these proposals was an invited paper session at the 2009 Statisticians in the Pharmaceutical Industry (PSI) Conference in Brighton, which we were invited to organise. The title of the session was 'Reporting of industry trials: JAMA, its impact, and the way forward'. We soon realised, however, that the topic was considerably broader than the session title encompassed and we believed that, while the JAMA editors may have been writing with respect to some genuine concerns, the situation had moved on since the original 2005 article.

Therefore, as part of the conference session we also evaluated the current situation with respect to the potential for bias in the reporting of industry sponsored trials, as well as the current level of public disclosure of industry sponsored trials [2,3]. From the start of our collaboration we were of the opinion that the best approach to addressing concerns with the reporting of industry sponsored trials was to be proactive in addressing any potential issues. We therefore worked together to form proposals for best practice for statisticians in the reporting of trials. The proposals themselves only represent the views of the authors, but it is our hope that the publication of these proposals will ignite a more general debate amongst trial statisticians from pharmaceutical companies and other sponsoring groups. These proposals were published first in *Pharmaceutical Statistics* [4] and we would encourage the reader to access this article along with accompanying commentaries.

Best practice for statisticians in the reporting and publication of industry sponsored clinical trials

Recommendations for best practice should promote the role of all authors in taking responsibility for the planning, design, conduct, analysis and reporting of a trial even if, in most instances, the trial statistician principally takes responsibility for the full and accurate reporting of the results and the statistical interpretation. It is in this context that we make the following recommendations. These are taken directly from reference [4].

1. The statistical author should be responsible for the statistical aspects of the paper

The authoring statistician should take responsibility for the statistical content of the paper. This should include but is not restricted to the correct statement of the trial objective and endpoints, the sample size justification, patient flow, analysis data set definition (e.g. Intent to Treat, per Protocol), presentation of the results and statistical interpretation of the results. It is also important that the paper appropriately identifies the methods that were planned in the original protocol and justifies any deviations from this in the final analysis results that appear in the paper.

2. The person responsible for statistical aspects of the trial should be recognised as an author

Subject to the framework for authorship established by the International Committee of Medical Journal Editors (ICMJE)[5] the statistician who is responsible for the design, conduct, analysis and reporting of a clinical trial should be identified and named as an author of the publication. They should be appropriately qualified and experienced. Where papers are submitted with no statistician declared as an author this should be noted and justified. If the trial has included a Data Monitoring Committee (DMC), the trial statistician should ensure that any statistician member of the DMC and any statisticians supporting the work of the DMC are identified and their role in the trial should be summarised. This should include the specific duties of the DMC statistician and the recommendations that they contributed to.

3. Protocols should be published and/or made publicly available in a timely manner

There should be a clear means for journal reviewers and editors to confirm the pre-defined study objectives, endpoints >

Best practice for statisticians

> and methods of analysis through having access to a publicly available protocol. This would enable them to confirm whether the published record of the trial adds, changes or omits important elements of the trial as conceived and set out in the protocol. It would also make clear where any results have been held back or retrospectively added. Publishing these details on a publicly accessible trial registry goes some way to addressing this and it is recommended that it be routine practice to include the pre-defined statistical methods of analysis for key trial outcome measures. The trial statistician should ensure that the protocol materials published include all the relevant details so that a subsequent reviewer can readily identify the trial objective, endpoints, design, sample size and proposed method of analysis for the primary endpoint.

4. Financial and other conflicts of interest should be disclosed

There should be a clear statement identifying who sponsored the trial. The trial statistician could be a sponsor company employee and/or employee of a contract research organisation who has been contracted by the sponsor to take the role of the trial statistician. They could also be an employee of an academic organisation who is running the trial with an industrial sponsor. Along with the other co-authors, the trial statistician should declare any financial interest and conflict of interest in terms of their employment status together with any direct and indirect financial interests in the sponsor and/or other relevant companies.

5. The authors should have freedom to act

The primary investigator and other co-authors should not be pressured by any sponsor company, either contractually or otherwise, to suppress the publication of trial results, or present the trial in a manner that they feel to be inappropriate. Freedom to act is particularly relevant to the trial statistician. There should be no impediment to the trial statistician in their role as author to appropriately presenting trial results. The trial statistician should understand that by being an author they are taking professional responsibility for the accurate reporting of the trial and the results as presented are a true and fair reflection of the outcome of the trial.

6. All authors should have full access to trial data

The authors of the trial manuscript should have appropriate access to the data collected during the trial and should have played full part in the interpretation of the results from the trial. In particular they should have access to the data set used for the analysis and they should have access to the results of all of the analyses that have been conducted. An important duty for the trial statistician is to ensure that the data and results of the trial are presented to each of the authors in a timely manner. They should also ensure that the authors can access and understand the results and should facilitate communication between all authors to satisfactorily address any questions.

7. The trial results should be published

All trials should have their results published in publicly accessible registries designed for the purpose. This should also be done in a timely fashion after the completion of the trial (no more than one year after last subject last visit is good practice). As appropriate it is recommended that the trials are also published in peer review journals. Any publication should be identified and linked to the previously published trial protocol. The trial statistician should ensure that the results are made publicly available in a manner that is understandable to the wider medical community and is complete such that all results are disclosed and others are able to use the results in further research (e.g. meta analyses).

8. Independent statistical review should be highlighted

Many industry sponsored clinical trials undergo some form of statistical review by independent experts and / or regulators (e.g. available from published FDA Advisory Panel materials and European Public Assessment Reports) both in the design and in the review of the results. Where this takes place, the nature and scope of independent review should be described in the published manuscript. Where the review has been paid for, a statement should be made clarifying the nature of the relationship between sponsor and expert.

The above proposals were written with industry sponsored trials in mind, but it is clear that they are relevant to all trials, both industry and public sector sponsored. Many of the recommendations are generic and their intention is to improve the quality of reporting of studies and reduce bias.

Conclusions

When we wrote the proposals set out in [4] and described above we did so with the intention of encouraging debate. We hope also that the recommendations will form a basis for good publication practice for statistical authors, particularly those in the pharmaceutical industry, as well as for disciplines outside of statistics.

All URLs in *TWS* are active in the online version

TWS is published online before print in the Members Only section of the EMWA website (www.emwa.org). All URLs in the online version of the journal are live and provide a direct link to the respective websites.

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Medical writers, statisticians, and authorship

The medical writing community has long been aware of the important ethical issues surrounding authorship of clinical trial publications. However, as medical writers, we are often watching this debate from the sidelines, as we do not usually qualify for authorship of the papers we write (although we sometimes do). The main focus of medical writers' efforts in this area has been to promote awareness of the importance of properly attributing authorship of papers and to ensure that medical writers' contributions are made in an ethical and transparent manner, as recommended in EMWA's guidelines on publications [1].

The article by Steven Julious and coauthors explains some of the steps that industry statisticians (through their professional association, PSI) have recently been taking to ensure that statisticians also fulfil their role in publications in an ethical manner. PSI are to be congratulated on this initiative, which is described in more detail in the series of 3 papers published in *Pharmaceutical Statistics* cited in Steven's article. Statisticians are extremely important contributors to clinical trial publications, and the best practice recommendations are a welcome step towards ensuring that their contributions improve the quality of publications.

I hope all EMWA members will be aware of these guidelines when writing publications of clinical trial results and will do their best to ensure that the project statistician is named as an author of the paper. Medical writers may not often be authors of papers, but they still have a vital role to play in supporting statisticians and other authors and promoting ethical practices.

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Reference:

1. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin* 2005;21(2):317–321.

'Ough'

'Ough' can be pronounced in eight different ways all of which feature in the following sentence: A tough, dough-faced ploughman strode through the streets of Scarborough, coughing and hiccoughing thoughtfully.

Guest authorship—How common is it and what are the reasons behind it?

by Diarmuid De Faoite

As this issue of *The Write Stuff* shows, the problems of authorship—and more particularly the correct attribution of work done—have taxed writers for a long time and will most likely continue to do so for the foreseeable future.

The practice known as guest, honorary, gift or unjustified authorship [1] remains an issue in many disciplines. While there are some small variations in what is understood by each name for it, they all nevertheless result in people being listed as authors whose contribution to the piece is unclear and perhaps even non-existent. For this reason I will use the term 'guest' throughout this article. Before I explore possible reasons as to why guest authorship happens, let us quickly examine just how prevalent it is.

Levels of guest authorship in the literature

In 1996, Flanagin et al. [2] examined 6 medical journals and found that a total of 156 (19.3%) of 809 articles met the criteria for guest authorship. In 2008, a group at the *Journal of the American Medical Association* repeated the 1996 study using an anonymous online survey of authors published in six leading general medical journals [3]. Preliminary results showed that 20.6% of articles had evidence of guest authors, similar to the figure of 19.3% reported by Flanagin et al. Other recent studies indicate that the problem of guest authorship has not gone away [4, 5].

Obviously, the group members behind a paper are generally aware of the contribution made by each listed author. However, this arrangement is imperceptible to both journal editors and readers alike, making the identification of guest authors almost impossible.

What are the repercussions of guest authorship?

A study by O'Brien et al [6] of 127 corresponding authors noted that the majority believed there were potential detrimental effects of guest coauthorship for the authors themselves (73%) and for their coauthors (83%). These negative consequences included personal liability for guest authors (29%) and the diminishment of the relative contribution of their coauthors (54%). More worrying was the finding that 62% of respondents thought that guest authorship may have a negative effect on patient care but only 2% had experienced this in reality. Another study [7] that surveyed promotion and tenure committee chairpersons found that the contribution made by individual authors was perceived to be less with each increase in the total number of authors in the byline. The only exception to this rule was when the last author was also the corresponding author.

Perhaps one answer as to why people are unjustifiably listed as authors can be attributed to some extent to unfamiliarity with inclusion/exclusion criteria. A Dutch study which relied upon the feedback of 352 authors of 115 original articles published in 1995, showed that approximately 36% of them did not fulfil the ICMJE criteria for inclusion as an author [8]. Almost 60% of the authors were unfamiliar with the ICMJE guidelines while many authors considered them to be too strict. These issues appear to be quite widespread [1, 9].

The influence of others

Of course, not every case of guest authorship can be attributed to misunderstanding inclusion criteria. Normal human interactions and relationships have an impact upon the practice. Baethge [10] noted that in addition to letting someone appear as an author as a way of saying thanks for a minor contribution to the study, other motives included "a friendly service to a well-liked colleague, respect for one's academic mentor, or the use of a prominent name to acquire a putative advantage in the peer-review process." Indeed, Bhopal et al [9] found that 32% of the 66 faculty members surveyed at a British university had had the strange experience of being listed as an author of a paper they knew nothing about! (see Box on page 33 for an example of this phenomenon.) However, it is not always the case that including guest authors is done out of collegiality or to impress a journal's editorial staff.

Other grounds put forward reflect the increasing pressures academics are under and include the politics of securing funding [11] as well as the need for publications to progress in their career [12]. The usefulness of publications for a person's self-esteem, reputation, and career has been well documented [7]. Lorimer, as quoted in Fluxgold [13], notes that some professors will publish as many as 10 articles based on one experiment in order to fatten their curriculum vitae.

I have no doubt that the constant pressure to build up an impressive body of work is also a factor in guest authorship. Kwok [14] notes that academic bullying can take many forms and might influence authorship. For example, a senior member of the academic staff pressures a junior collaborator to surrender the important first author position because the senior staff member wants the accolades and career benefits of being listed first. As a junior (business)

researcher I saw this very thing happen to one of my first papers. My lower status ensured that I was too reticent to complain. Interestingly, Kwok's paper ends by noting that research on the personality traits of such people is required if appropriate steps are to be taken to negate their actions.

Is behaving badly in academia an innate trait in people or a learned behaviour? At what point in their careers do some medical professionals begin to bend the rules? One study solicited the opinions of medical students at different stages of their studies at Dundee University Medical School across a range of ethical topics [15]. Significant differences in the responses were found for some of the scenarios, including forging signatures, resubmitting work already completed for another part of the course, and falsifying patient information. In these, a larger proportion of year one students regarded the scenario as wrong and would not engage in the behaviour compared to students in other years. The authors speculate that these results may be explained by increasing academic pressure as well as more opportunities for students to engage in such behaviour as they progress through university.

A recent survey of 499 newly qualified doctors of medical science in Sweden found that 47% of medical dissertations included authors who did not meet the ICMJE authorship criteria and 41% of co-authors had not written or critically reviewed their 'co-authored' work [16]. The questionnaire showed that doctoral students were not aware of any unacceptability associated with guest authorship and had not been instructed in the principles of authorship, which was considered a failure on the part of the supervisors. The readiness of some students to engage in unethical practices and the impact of this later in their career has also been observed in other studies [17, 18].

The effectiveness of preventative measures

Are medical practitioners therefore entering the world of academic research already steeped in a culture of unethical conduct? Ainsworth and Szauter [17] note that while behaviour at medical school is not a perfect predictor of future difficulties, it does represent an opportunity for intervention in a relatively supervised setting. However, Kalichman and Friedman [18] call into question the benefit of current programmes, reporting that exposure to ethics training was not associated with a difference in past or potential unethical behaviour among the 549 biomedical trainees in their study. A meta-analysis by Antes et al [19] found that ethics instruction is moderately effective. Their results offer some pointers on how to improve the impact of such training. Separate seminars achieved better results than when ethics is an integral part of a curriculum. The authors recommend using interactive case-based formats which replicate the real-life thought and decision-making processes people go through when faced with an ethical dilemma. In addition, social interaction (as opposed to the use of online courses) appears to be an important element of successful delivery.

An intractable problem?

To summarize, it appears that at times the medical world can cultivate the opportunity for some dishonest practices, and in some cases bad behaviour appears to be deeply ingrained [14, 17, 20–22]. The evidence at hand suggests >

Unwanted coauthorship

A question was raised for discussion on Principal Investigator.org[1] by an 'up and coming' researcher who had had rambling discussions with a colleague at the institute lunch table during which they shared thoughts and ideas. The colleague subsequently published a paper in a major journal and listed the researcher as a coauthor—without his permission. The researcher thought his colleague might be trying to ride on his 'coattails' and asked for advice.

The general response from the discussion group was that the researcher could not let the situation go as the action was unethical. The colleague would have declared to the journal that the researcher had seen and approved the paper and consented to its submission, whereas this had not been the case. Possibly the colleague implicitly expected in return that his name would be included on the researcher's papers. Problems could also arise through being held publicly responsible for work conducted by another. Suggestions included approaching the colleague, the institution and writing to the journal to publish an erratum.

One respondent pointed out that *The Journal of Physical Chemistry* prevents this situation by e-mailing each author to confirm approval of the submission. This would seem an obvious solution and it is surprising that journals do not do this as a matter of course. Another respondent wrote that he had sent a paper for approval to a coauthor who had provided some funding for the project but was otherwise uninvolved. He did not hear from the coauthor and wrote to the editor to tell him that he did not have the coauthor's approval. The editor published the article with that author's name anyway. Not only is the editor's action here open to question but it also illustrates that at least one respondent considered that the mere provision of funding is sufficient for authorship, contrary to the specific exclusion of funding as an authorship criteria in the ICMJE guidelines.

A legal expert who responded thought that the colleague could have violated the researcher's legal right to publicity and was seeking to use the researcher's name for the 'commercial purpose' of enhancing his own paper for acceptance by the journal. Laws concerning the right to publicity appear to vary between states in the US.

1 http://www.principalinvestigators.org/newsDetail.php?No.-15-Intellectual-Property-Unwanted-Inclusion-as-Co-Author-of-Paper-19

Guest authorship

> that changing this culture is not something that can be done simply through the introduction of codes of practice which are often ignored or not known [1, 8, 24]. In the interests of balance, it should also be kept in mind that there is room for improvement in reducing unethical practices not only by authors, but also by the reviewers and editors of scientific journals [11, 25].

A root and branch reform is required to eliminate the sense of entitlement to authorship that certain people further up the hierarchy feel they have as a result of their position, and not as a result of their contribution. However, my personal feeling is that such a paradigm shift will likely take generations to come about—if ever!

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What is this terrible infatuation?

That is the question Donald M. Murray, correspondent with *The Boston Globe*, asks at the age of 83 years because he has never got it right but the joy of trying keeps him young. It's writing, of course. Murray relates that during his career he was often offered promotion, an opportunity to earn more money as an editor and relax in meetings rather than graft at the writer's desk. But he was never tempted by the offers because he was captivated by writing. The flow of writing was always a surprise to him and a challenge, wanting to write and not knowing if he could. Murray quotes E.B. White "a blank sheet of paper holds the greatest excitement there is for me…it holds all the hope there is, all fears…I have moments when I wish I could either take a sheet of paper or leave it alone, and sometimes, in despair and vengeance, I just fold them into airplanes and sail them out of a high window, hoping to get rid of them that way… only to have an updraft bring them back up again." Murray concludes that writing is an obsession by which he tries to capture a fragment of life and reveal its wonder.

Source: http://www.boston.com/news/globe/living/articles/2006/12/26/finding_pleasure_in_the_challenge_of_a_blank_sheet/

If you want to know how to fold and fly airplanes go to http://www.aviationexplorer.com/paper_airplanes.html

Fostering transparency in Pfizer supported publications

Public trust in pharmaceutical company supported publications requires that authorship is correctly attributed, medical writers if involved in a publication are recognised, and all sources of potential bias are disclosed including pharmaceutical industry funding.

To facilitate adherence to the standards mentioned above it is important that pharmaceutical companies develop a publication policy detailing the company's authorship criteria and disclosure requirements.

Pfizer's publication policy, which is available publicly, supports the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for all Pfizer supported publications. It further states that all individuals who deserve authorship based on the criteria should be named in the byline and those who do not should be acknowledged elsewhere. The ICMJE guidelines are applied to both Pfizer employees and external authors.

The policy also stipulates that medical writers must work under the direction of the authors and be recognized in the resulting publication; either as an author if they meet the authorship criteria or as a contributor in the acknowledgement section.

Pfizer's policy also addresses the role of marketing in publications. Commercial colleague involvement in peer reviewed publications, either medical journals or congresses, is not allowed. Marketing colleagues cannot author, comment on and/or influence the development of peer reviewed publications.

Developing a policy is only the first step; creating awareness of the policy and training are essential components of implementation. In Pfizer US over the last few years, in an effort to ensure external authors are aware of the ICMJE guidelines on authorship and the requirement to acknowledge medical writing assistance and disclose financial support, Pfizer sends out a standard letter to each external author of a Pfizer-supported manuscript at the start of the manuscript. The letter explicitly states the ICMJE criteria for authorship and Pfizer's policy on disclosure of support. Each author is requested to sign a form acknowledging that they will adhere to the authorship guidelines and disclosure policy.

Pfizer's medical colleagues as well as publication vendors contracted to provide medical writing support receive computer-based training including a short test on Pfizer's publication policy.

Ongoing oversight of adherence to the policy is achieved via a checklist that is completed prior to journal submission for every Pfizer-supported manuscript. The checklist requires members of the Pfizer publication team to sign off on adherence to the authorship criteria and that all Pfizer support has been disclosed in the manuscript. To facilitate appropriate disclosure of Pfizer support, standard acknowledgement language has been developed, e.g. "The study was sponsored by Pfizer" and "Editorial support was provided by <name> at <company/affiliation> and was funded by Pfizer Inc".

The checklist also requires members of the team to check that the manuscript is consistent with the information registered on clinicaltrials.gov and that the data are consistent with the data tables and that the data support the interpretation.

By instituting a publication policy, educating/training authors and medical writers and providing oversight Pfizer has demonstrated its commitment to integrity and transparency in publications.

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TWS Editorial Meeting

EMWA's 30th Conference

If you would like to become involved with article writing, copyediting, proof reading, or have suggestions or questions, or just want to know what is going on at your journal, you are very welcome to come to an informal *TWS* editorial meeting to be held during EMWA's 30th Conference in Lisbon.

Please make a note in your conference diary:

17.30 Friday, 14 May 2010, in room Obidos B on floor 0 at Hotel Tiara Park Atlantic, Lisbon

So many questions in a sentence with just 79 characters!

The postdilution volume was either 500, 1000 or 1500 mL/h, and rarely 2000 mL/h.

The author asked me: '(1) Do I need to use *either*, and (2) should the *and* before *rarely* be an *or*, and (3) do I need commas around *rarely*?

Check out your answers with mine on page 68

Alistair Reeves
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Authorship practices in Asian cultures

by Joselita T. Salita

Introduction

I believe my experience of authorship practices in the marine biology field may also be relevant to the biomedical sciences. The 'publish or perish' phenomenon is so widespread in academia that issues of authorship and related malpractices seem likely to be universal.

Who deserves authorship?

During my time as a research assistant in a Philippine university, any 'substantial intellectual contribution' justified authorship, despite the vagueness of the phrase. The International Council of Medical Journal Editors (ICMJE) began drafting their 1985 authorship guidelines in 1978, and they were adopted by the Council of Scientific Editors (CSE) in 1999 [1]. However, these guidelines were not discussed in our research group, and Bhopal and co-workers (1997) reported that the vast majority of British medical scientists remained unaware of them [2].

The current (2008) ICMJE guidelines give three authorship criteria, all of which must be met: 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published [3]. The guidelines are very strict and many believe that researchers should work with editors to redefine authorship criteria [2]. Some journals have therefore developed systems to increase transparency of contributorship. In practice, authorship is still usually based on a common understanding among co-authors. Although the ICMJE guidelines state that acquiring funds, collecting data and generally supervising research are not enough to merit authorship [3], the fact that the criteria are not measurable is the weakness of these guidelines. This also leads to problems with ordering authors' names on the byline. Laboratory heads are usually responsible for the conception and design of big research schemes so they almost always meet criterion number one. They also revise the paper critically for *important* intellectual content and approve the final version of the manuscript. As a result, authorship practices in the Philippines have not changed compared with 15 years ago.

Authorship malpractices

Laflin and co-workers summarise the categories of authorship malpractices defined by ICMJE [4]. Gift and guest authorships fall under the category of honorary authorship, which are not honourable at all. If an author does not meet the ICMJE criteria, then authorship is misattributed and therefore, 'honorary'. The difference between gift and guest authorship has more to do with the position of the receiving author. Guest authors are usually experts in the field whose names increase the chances that the paper will be published in a prestigious journal. Gift authors do not contribute to the writing or research itself but for numerous reasons are given the 'gift'. Ghost authors are those whose names do not appear on the byline. In the medical field, they are typically thought of as medical writers and statisticians who are often funded by pharmaceutical companies as detailed in other articles in this issue. For this article, I refer to students or research assistants, who have been involved in major stages of the research but are denied authorship.

Shapiro and co-workers showed that gift authorship is widely practised so that 20 to 50% of authors do not meet the criteria set by ICMJE [5]. A survey in the *Lancet* also showed that 32% of scientists are willing to gift authorship to increase their paper's chances of publication or boost their careers [4]. Authorship may also be gifted for reasons of mutual support or friendship [6], reciprocities in the case of collaborative investigations [4, 7], coercion by senior investigators (otherwise known as 'White Bull' effect [8]), prevention of conflicts [9] and motivating students in research [7, 10].

Scenarios of authorship in Asia

Ganatra (1996) reported that authorship rules in India follow the convention of the institute and had not changed in 40 years [11]. According to him, the person who wrote the paper and did most of the work (usually the research assistant) may be the first author and may present the paper at local conferences. At national conferences, the laboratory head is first author and presents the work, and at international conferences, the institute head becomes first author and presenter. Kakkar (2004) mentioned the strong practice of gift authorship in India and ignorance of the ICMJE guidelines [12].

A Japanese scientist told me that in Japan, the laboratory head gets automatic senior authorship as the 'source of research ideas'. We subsequently realised that our definitions of a 'senior author' differed. For me, the 'senior author' makes a major contribution to the paper and is therefore listed first, which is the conventional definition [13]. For the Japanese scientist, however, the senior author is always the laboratory head and his name appears last on

the list. It was not clear whether the last position is a special position such as in other societies [4].

An ex-colleague from Indonesia related that laboratory heads also get automatic co-authorship. Sometimes, institute heads get authorships just for their titles. The amount contributed by each author is not necessarily reflected in their order on the byline but the person who prepares the paper is always the senior author and the laboratory head follows automatically.

In the Philippine institute, where I started my career, laboratory technicians never manage to become authors, by virtue of 'substantial intellectual contribution', but laboratory heads or thesis advisors always do. If the laboratory head writes the paper, he gets sole authorship although the research assistant runs the experiments (and may have independently modified the experiments), does and interprets the statistical tests and researches the literature. These contributions may not be substantial enough for co-authorship and may not even be mentioned in the acknowledgments. However, if the research assistant writes the whole paper, the laboratory head is always automatically a co-author. The laboratory head, as the *source* of the main project ideas is always considered to make a *substantial* contribution to the paper's theme no matter how specific the paper's topic is. In established research groups, where research assistants also contribute to formulating new project goals, it is often difficult to trace the source of the original idea. And in spite of increased participation of research assistants at the conception stage, and consequent decreased intellectual contribution of the laboratory head, the latter is still recognised as a co-author. When graduate and post-graduate students have their theses published, they also co-author their papers with their advisors even if the advisor's contribution is mainly editing the draft. Although theses are independently conceived, done and written by students, the fact that the experiments are performed within the frame of the advisor's project, and that the advisor provides guidance, which may entail an intellectual contribution, this ends up in co-authorship in the resulting publication.

After discussions with eight Asian scientists, I realised that gifting authorship to laboratory heads is not a condemned practice in Asia. Givers find it normal, and this attitude may be difficult to change because it is imbedded in the four Asian values discussed below.

Courtesy to or respect for authority. Courtesy is a deeply rooted Asian value. Laboratory heads are seen as having worked their way into a position to be respected, and there is general acceptance of authority figures. Bhatia and co-workers relate gift authorship in India to 'guru-shishya parampara', a teacher–disciple relationship [14].

Gratitude or indebtedness. Students or research assistants feel indebted to their superiors for choosing them, rather than believing that they achieved their position through their own merits. Humility is a virtue in Buddhist Japan, Catholic Philippines and Muslim Indonesia. Moreover, in the Philippines, the value of indebtedness ('utang na loob') goes beyond gratitude [15], and cannot be reciprocated, necessitating lifelong efforts to return the favour [15].

Diplomatic gesture or bribery. Even those whose careers have started to progress gift authorship to their immediate boss, as a diplomatic gesture or bribe, to ensure that they maintain their position, or to gain support for future activities or strong recommendation letters. If collaboration with other institutes or countries is involved the gifting is called a *diplomatic* act. Although collaborative research is likely to be limited to perhaps 4 people, papers may end up with more than 10 authors including immediate bosses and sometimes institute directors from both countries. This ensures that there are 'real products' from such undertakings and encourages future activities. It is also done in the West as it 'encourages sharing of ideas' [10].

Social pressure and harmonious relationships. In Asia, it is plainly difficult not to practice gift authorship because of social pressures. Superiors can make academic life difficult or impossible. Bhatia and co-workers mention possible academic penalties and team conflicts in India if traditional authorship practices are not followed [14]. Further, Asians act collectively. In many Asian cultures, the value system favours the group: for example, the family, neighbourhood, or community. Laboratory heads gain financial support for their laboratories based on numbers of publications but teaching and administrative tasks often make it difficult for them to publish. The support of the laboratory team enhances their research reputation. The research assistant follows this trend, contributing to the common goal and becoming a valued group member. Filipinos call this 'pakikisama' [16], and many gift authorship even when working in the West.

What is unethical about gifting authorship?

For those receiving it, the question is easily answered. It is accepting undeserved reward and, as Bagioli pointed out, it could be seen as 'libel to nature' [1]. For those giving it, it may depend on the reasons. If it is done to get something in return, it is a clear act of corruption but if the reason is to give due respect and gratitude to your superior or for attainment of the common good, is it still unethical? I believe it is because, as McKneally says, the values at the root of science and its publications are truthfulness, trustworthiness and fairness [13]. If these values are not maintained, science is corrupted. In science, everyone is a student, for science is the continuous pursuit of knowledge. The usual student–professor, assistant–laboratory head relationships must be challenged and the practice of bowing to authority must be ended. Like all exercises for the pursuit of truth, authority is recognised only if fairness is practised. Gifting authorship can lead to abuse such as parasitism and misconduct in the scientific world [8].

>

Authorship practices in Asian cultures

> Consequences of non-deserving authorship

Authorship criteria must be adhered to so that editors can find appropriate peer reviewers. 'Frequent gift authorship can make someone with little knowledge of a subject appear to be an expert, and lead to them being inappropriately invited to review' [17]. We rely on scientific publications to maintain the integrity of the peer-review process, and this demands an honest merit-based system of authorship.

Authorship brings responsibility as well as intellectual credit. Inappropriate authorship can be embarrassing and have potentially detrimental career consequences. Well-known examples include the case of John Darsee, who in the 80s falsified data and had department heads from Harvard and Emory universities as co-authors [6, 7]. Similarly, Slutsky from the University of California in San Diego and Hwang of the University of Pittsburgh fabricated data and took with them unknowing co-authors [7].

The 'generosity' of gifting authorship can also be disadvantageous for young scientists. A Filipino friend of mine kept practising this even in his post-doctoral days, until he was wrongly assessed as not being independent enough to carry out a research project.

Denial of authorship

More serious is the practice of denying credits to those who really generated the papers. Bagioli considers this a type of plagiarism [1]. Although ICMJE put much effort into protecting the integrity of authorship to make it easier for editors to find reviewers, abuse of students and assistants through denial of authorship continues.

In the West the names of deserving assistants and post-doctoral fellows are often omitted from papers [18]. Some countries have agencies that handle complaints on such authorship malpractices [8]. Some universities, such as Stanford and Johns Hopkins, have offices of postdoctoral affairs and some institutions have an ombudsman to handle such grievances [18]. In many institutions, however, the victims move to 'a better job', rather than go through this process [18]. This type of ghost authorship is most likely to continue in Asia, where disputes are more often avoided than settled.

The future

Authorship malpractices can be a vicious cycle. Younger scientists may in turn practise authorship abuse when their time comes; the abused becoming abusers. For example, Laflin and co-workers cited a study showing that 75% of scientists who had experienced authorship abuse were willing to list undeserving authors [4].

Systems of transparency are being worked out and implemented in order to lessen if not eradicate abuses in authorship practices [1, 3, 4, 6, 19]. Perhaps these will be successful and will also reach Asia. It may not be easy to change the value systems but an increased maturity and understanding of the responsibilities of a scientist to society may be an initial step. Bhatia and co-workers suggest that training and continued education in ethical concerns should be part of science programs at the undergraduate level [14].

Acknowledgments

I thank the scientists who responded to my e-mail queries, especially Shizue Izumi, who mediated between me and her Japanese friend.

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Eliciting revision: An approach for non-authors participating at the boundaries of scientific writing, editing and advising

by Mary Ellen Kerans

We expect young scientists to learn to write and publish from fellow scientists: our expectations are based on either first-hand experience or published accounts by observers of the process (e.g., [1,2]). With luck a junior scientist will be guided by a wise senior and surrounded by fellows with varying degrees of experience to give feedback at all stages of research from conception to reporting and defending. A scientist's readers are all candidate role models and a novice author's first contact with distant readers comes through journal peer review. When researchers study this social system they apply various terms. Anthropologists say that activities (like scientific enquiry and communication) are learned contextually through *situated learning* and *legitimate peripheral participation* [3]. Applied linguists say the end result is initiation into a *discourse community* [4]. Most of us simply call incidental teaching in context *mentoring*.

Outsiders often enter the picture, however. They might be translators, medical writers or author's editors—whether professionals or someone's cousin or friend. Conventional wisdom has it that an ideal writing facilitator would be as similar as possible to an author. Doctors, we think, should be assisted by other medical or biomedical scientists. This is why many online editing services promise authors whose native language is not English (E2 authors) that their papers will be handled by English speakers who studied or are graduate students in an appropriate field.

Although I share these notions, I work in a non-Anglophone setting where writing facilitators are needed but ideal discipline-specific matches will only occasionally be possible. I therefore take an alternative approach. Before I fully edit a manuscript, I elicit revision from an author—who remains the source of scientific expertise and the defender of the manuscript. In this system, the paper emerges incrementally through cycles of substantive revision. I edit some sections as we go along but focus with the author on content in early drafts. Final editing to prepare the paper for external peer review comes only when the text seems complete and the overall structure well conceived—a sequence much like the natural writing process of proficient writers in their native language. I will describe the sources and main features of this approach.

"The editor says I have to do 'substantive revision' before he'll send the paper for peer review. I don't know what that means."

The unusual statement of this section's subtitle was spoken by my first author-client, who arrived about 25 years ago. I'm not a scientist, but I did happen to know what substantive revision would mean, even in the absence of a peer reviewer's report. I trained to teach English as a second language in the 1970s, at a time when new lines of research into writing, the socio-cognitive nature of academic communication, and the 'functional grammar' of texts were emerging. One line—which produced the 'writing process literature' of the mid-1970s through the early 1990s—turned out to be very relevant to my task of eliciting revision of the medical research paper this author wished to resubmit. This literature clarified how writers develop ideas into all manner of texts. The researchers looked at how proficient writers see what needs to be revised. They also contrasted the practices and attitudes of more and less proficient writers, leading to a sense that there were 'promising practices' novices needed to learn in addition to the attributes of admirable finished papers.

The findings encouraged recursive writing (multiple drafts as ideas emerge and are refined) and implied ways to resolve the tension between a writer's purpose and the needs or expectations of real readers (in other words, with a view to publication). In educational settings, developing authors being guided according to 'process-oriented' principles are helped to focus on their ideas and insights first, look critically, interpret the implications of criticism, and gradually produce a manuscript that will be effective with readers. Short conversations (called 'conferences') about a manuscript help an author see how to move the text closer to publishable quality.

Brief, focused conferences with an alert, responsive reader

Brevity of talk—relative to writing—is a principle that underlies conversations leading to revision. A story that illustrates the power of brevity comes from an early writing process researcher who worked with well-known workshop leader, Donald Murray. In her foreword to a small book on adopting the emerging approach in a children's classroom [5], the teacher-researcher mentioned driving six hours for only a half-hour meeting with Murray. "Whatever happened during those conferences, it not only made the trip worthwhile, it also transformed my writing and teaching of writing, she reflected" [p. vi].

My conferences with scientists are longer, at an hour to an hour and a half, but they share the goal of transforming writing, nudging the author back to authoring as soon as possible. Each conference is unique because it is a >

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> conversation about one manuscript, but the literature on the attitudes and behaviours of writers and what they say to themselves and each other hints at what an author's editor can helpfully say. The structure and content of my conferences are synthesised in the table. The research that underpins the table comes from videotapes I made of two conferences toward the late 1990s, when I was curious to know if my practice had drifted from its original conceptions as I'd gained experience with medical texts. The data from the tapes served to supplement a case report of a third author's revision of a paper after similar conversations [6]. The tapes revealed how very similar, and hence replicable, such meetings are. For this article, I've constructed a new table organised according to the underlying principles for anyone who might like to try the approach.

The principles, actions and techniques grounded in theory together share the purpose of reinforcing the author's engagement with ideas and the manuscript. Putting into practice principles 3, 4 and 5 (the main part of a conference) is the least formulaic: this is the most challenging part for the author's editor who is not a writer. The messages I bring to the table are similar to those of any medical

Table 1 Principles that guide a process-oriented writing conference and how they unfold with scientists*

Principles	Actions	Reasons and notes on technique
1. Set a realistic goal for the conference.	Brief conversation to agree on what should be accomplished at the meeting.	• It's not necessary to go over an entire manuscript. Few authors have the time to have long meetings or the budget to pay for them. Attention span may also be an issue. • An author needs time alone with the manuscript. Use conference time to give guidance (principles 3 through 5) and provide an E2 author with a sense of being supported. Leave the responsibility for developing and explaining the content to co-authors.
2. Focus on the writer's experience.	Ask the author to comment on • how the writing went, and • what concerns he or she has about the manuscript.	Since authors seem to enjoy this and sometimes say too much for a brief conference, it's best to just listen for insights that will be useful during the rest of the conference.
3. Focus on the manuscript as it is and the reader's response to it. **4. Model re-reading to detect dissonance† in a manuscript.**	• Ask questions about main messages, why certain concepts are mentioned, about information that seems missing or incongruous, about citing. • Read particularly problematic or key sections aloud. • Mention what works well and why. • Authors also ask questions and express concerns.	• An author often benefits most from simply knowing how a reader responds to specific portions—in detail and overall. • Reading a section aloud is especially useful when working with E2 authors, though native-language writers also benefit. Readability problems stand out. Also, both editor and author will need to re-experience a problematic section before it can be worked on effectively. Additionally, novice authors may not realise that constant re-reading is a natural part of writing, especially after substantive changes are made. A conference allows this behaviour to be modelled naturally. • Mentioning positive points isn't a mere face-saving move. The aim is to reinforce an author's feel for what works.
5. Model the writing process.	• Real-time editing or more substantive rewriting • Drafting of new material by the author	• Writing and note-taking emerge naturally from reading aloud. If authors think the 'expert' should lead, they may need to be encouraged to take the most active role. Authors may introduce new material that wasn't present in the submitted manuscript (a reason why even highly interventionist editing is not authoring, as the editor does not know the author's full research and reading experience). • Sometimes the editor might write (revising) with the author watching. Novice authors may need to see that it's not always easy for 'the expert' to find the right wording and E2 authors are more likely to confidently retain their active role if they see that nothing is written in stone (yet). • On other occasions it might be best to leave the author alone to concentrate and write for a few minutes. (Make an excuse to withdraw—such as going to print forgotten tables.) • Remember the conference should be brief. Working this way on one paragraph, or even part of one, is usually plenty for an intelligent author to get the point. The overall goal is to facilitate the author's autonomous revision back home.
6. Focus on what the writer will do after the conference.	• Based on what's been worked on during the conference and the stages reached, outline revision steps, 'negotiating' with the author. Ask the author when he or she will take up the manuscript again and how much time will be available. Ask what will be done first, second, etc. • Make tentative process recommendations based on what you think will best suit the author's style, personality, and ability to organise time. • Set a timetable.	• Having a plan of action and visualising the process will make the complex task seem less overwhelming. • Don't hesitate to ask for a partial draft to be returned. Help the author establish achievable goals. • If the timetable isn't met (as it often isn't), you may need to call to find out why. It may be that the author needs a 10-minute phone conference to re-set goals. Or there may be interesting new developments you need to know about.

*The principles in the table are derived from my reading of the writing process literature of the 1970s-1990s, partly under the guidance of my own mentor, Gay Brookes. The actions are a synthesis of those observed in videotaped conferences, included in Kerans [5].

† Sommers [7] defines dissonance as incongruities between intention and execution. She found that proficient writers attended to dissonance and were revising at all stages of composing. Less proficient (student) writers revised superficially, at the word or sentence level of text.

writer, instructor or editor, but the manner of delivering them can be different. Instead of saying, "Further discussion of [a certain point] is needed," or "This is unclear," or "There is little discussion of [...]," I've trained myself to be more specific, saying, "You raise the point of [...] and note your findings are similar to those of [...], but *I'm not sure how you see the relation between their findings and yours or what you want me to remember most at the end of the paragraph. Could you explain now?*" I listen and take notes of phrases. Once the E2 author's explanation is in full swing, I may interrupt and say the message is now clearer, showing some of the noted phrases that were helpful to me. I may suggest the author redirect the energy that has gone into explaining conversationally and instead take a few minutes to start editing the paragraph, putting the new ideas I've jotted down (or others) at the head. I promise to re-edit to correct the English (or translate and incorporate) before e-mailing a new file later that day. This small change in manner of speaking and working keeps the focus on the author's work. My contribution as a reader is reactive. My contribution as an editor follows the author's.

A few more examples might help to bring principles 3 through 5 into sharper focus. I don't ask rhetorically, "Is this the most appropriate reference?" but rather I reveal my response when reading by saying something along these lines: "*These references surprise me* because you say they demonstrate efficacy, *yet I see* one is a general review and the other a case report. Do we need to change the references or the wording?" Then I listen and act in response, modelling revision of phrasing or noting the author's intention to obtain new references. Likewise, it's not threatening to my position or the author's if I say something like, "*I'm confused when I read* [...] because you've just written about [...] and *I was expecting* you to discuss [...] next. *Can you explain why* you've introduced this point now?" I phrase my response that way rather than saying "This statement contradicts [...]" or "This point seems irrelevant (or 'doesn't flow')."

Finally, the traditional ways of starting and closing a conference are also shown in the table beside principles 1, 2 and 6. Authors usually have much to say and I gain insight from hearing how the draft was produced (processes) as well as noting how they express attitudes and uncertainties. Understanding the author well helps me reinforce effective practices, fill in gaps by suggesting heuristics and correct questionable practices such as copy-paste 'patch writing' in a firm but unthreatening, natural way at opportune moments. Similarly, ending the conference by discussing a realistic plan that feels right and corresponds to a timetable helps the author visualise solitary revising. This is especially important for novices or anyone who might have had frustrating publishing experiences. Writer's block occurs during revision as well as during early composing. (Even proficient writers become blocked, but they have a repertoire of ways to get past it.)

Practical issues

Though conferences are always too short to address all the problems a manuscript might have, they're long enough for an author to decide on useful directions to take to bring the paper closer to completion. Novices might require several meetings, whereas a proficient author might need only one or two or might be able to work with me at a distance. Briefer virtual conferences with experienced revisers are an option I use often: the author and I might have a half-hour phone conversation once I've sent a partially edited manuscript we can both view on screen. Fluent writers might even work with me on a portion of text by e-mail or chat. Videoconferences have also sometimes been possible. I still insist on face-to-face meetings with new clients who live nearby, however, and occasionally meet with experienced ones—if they're taking on a new text type, for example. A reason face-to-face conferences can accelerate revision is that I can monitor how an author is responding to feedback more easily and change approach quickly if necessary. Authors are also more likely to express their uncertainties spontaneously in person.

In preparing, I take into account other knowledge fields and writing approaches that will be more familiar to EMWA members. Like most of my colleagues I check whether an author has chosen a journal and heeded its instructions before sending me the manuscript. (E2 authors are mostly on a tight budget and my clients pay for editing by the hour, so I try to have them do everything they can on their own.) I also look at the abstract and provide pertinent reporting guidelines (CONSORT, STROBE, etc.) to those unfamiliar with them. I look into the social context of their writing. This means I find out who, besides the contact author, is most involved with drafting and revising, because some of my work might include helping a novice drafter plan strategic interaction with co-authors. All of these early steps are compatible with the approach because they are normal components of the scientific writing process.

If authors express difficulties, I may suggest we work with a partial manuscript. This helps with early correction of problems such as a tendency of some E2 authors to fail to make their contribution to the field explicit [8] or to give insufficient or unconvincing reasons for performing a study in the introduction [9]. A methods section might also be drafted in an incomplete or confusing way by even experienced authors whose co-authors have given insufficient support. Some may benefit from a phone conference at this point.

When a complete manuscript is available, I prepare for a conference by reading and, if portions seem fairly clear, I edit them lightly (incomplete editing being possible because I know I'll see the manuscript again). Portions of text, especially in the discussion, may remain unedited because they are in need of much substantive revision. >

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> We'll talk about the author's intentions in chosen portions and possibly analyse pertinent examples of writing from papers in the author's reference list (genre analysis, [4]). Any portions that are unclear or even simply uninteresting might be candidates for such treatment in the main part of the conference (principles 3 to 5 in the table).

Successive authoring and editing cycles follow. The main goal is straightforward enough to be clear at all times: to provide whatever support a non-author can give an E2 author so that a manuscript receives a respectful review and is finally published in an appropriate journal. The E2 author is supported in terms of language, reporting practices, writing processes, and international journal procedures in an individualised way. I take care not to over teach concepts an author already understands.

Constraints, advantages and generalisability

Eliciting revision is a strategy I use as an author's editor with no desire to be a writer. I cannot be certain that the principles are readily generalisable to medical writing situations, though I suspect some may be of use to those who wish authors to engage fully with the manuscript.

An objection that is often raised is that recursive writing takes time, especially for novices, who are always surprised that authoring is more complicated than they thought. (Proficient authors also need time, but they take it in stride instead of complaining!) Social pressures to publish fast and in abundance do work against encouraging authors to do the revising themselves and those with higher budgets may well expect not to have to work on writing. They may prefer to get on with planning the next study. However, as author's editors share with medical writers the purpose of alleviating the frustrations writing can bring, authors should save time overall, certainly not waste it, by working in this way rather than alone.

An advantage of this admittedly advisory, even 'educational', approach is that more E2 authors with tight budgets may be able to obtain help in their own communities, where language service providers may be available even though English-speaking field-specific experts may be lacking. The approach can be implemented by a literate, attentive, empathetic reader familiar with the features of the author's literature (through personal experience or genre analysis) and equipped with an understanding of the social and cognitive processes of writing.

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Physical demands of medical writing

What does it take to be a medical writer? Physically, I mean. I found this description as part of a job ad[1] for a senior medical writer in the US, right between Work Environment and Competency

"Physical Demands: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions."

So far so good. However, the description went on to describe the specifics of these physical demands, as follows:

"While performing the duties of this Job, the employee is regularly required to sit and talk or hear. The employee is frequently required to stand; walk; use hands to finger, handle, or feel and reach with hands and arms. The employee is occasionally required to climb or balance and stoop, kneel, crouch, or crawl. The employee must frequently lift and/or move up to 10 pounds."

Now, isn't the writer ever required to write or type at all?

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1 HittList 20 Nov 2009. Job list at Emma Hitt Medical Writing, LLC.

How AuthorAID in the Eastern Mediterranean helps researchers become authors

by Karen Shashok

The publication playing field is not level for non-native users of English or for researchers in developing countries, and this problem has been discussed from many angles [1]. What can be done? Hooman Momen, director of Knowledge Management and Sharing at WHO Press (World Health Organization), has noted the recent growth in efforts to help developing-country researchers become authors, while recognising that the current capacity of these initiatives is far from sufficient:

> …an array of editors (language editors, author's editors, copy editors, technical editors and manuscript editors) is valiantly bridging the gap by trying to harness the output of scientist, whose mother tongue is often not English, within the syntax and grammar of the English language. They often succeed brilliantly, but the demand is so great and is increasing so quickly for the small and stagnating number of editors, that change needs to occur [2].

In most developing countries, access to high-quality on-site editorial mentoring is limited. AuthorAID projects (http://en.wikipedia.org/wiki/AuthorAID) are designed to overcome this inequity and thus improve researchers' chances of becoming successful authors. These projects facilitate contacts between aspiring research authors and volunteer advisors who can help scientists get published, e.g., scientific experts, journal gatekeepers (editors and peer reviewers), professional language editors and author's editors. By putting researchers (often in the East and South) in contact with mentors (often from the West and North), AuthorAID projects help ensure that developing-country researchers are as well equipped as their peers in better-endowed research environments to participate in the international scientific knowledge community. Below I describe how AuthorAID in the Eastern Mediterranean equips researchers with two types of skills needed to become an author: practical (manuscript preparation) and social (identifying the community of peers and joining the community).

Authorship skills: Writing and revising manuscripts

AuthorAID in the Eastern Mediterranean (AAEM) [3] began in January 2009 as an on-site project hosted by Shiraz University of Medical Sciences in Shiraz, Iran (www.sums.ac.ir/english/ shiraz/university.html), an institution known for its high academic standards and innovative teaching methods. Researchers and I worked face-to-face while I edited their manuscript on a PC, explaining the reason for each change. Live editing, interrupted frequently by explanations and responses to the author's questions, meant that it took many more hours to edit a manuscript than if I had simply worked on it alone, but also enabled researchers (as well as author's editors-in-training who observed the sessions) to learn first-hand how to identify problems in the text and decide on the best solution.

Gatekeepers may have "low tolerance for ways of defending an argument or emphasising a point that depart from how the reviewer expects these elements of scientific writing to be handled", and unfortunately, text that 'sounds unusual' to reviewers may bias their judgment of the scientific content even when the content itself is understandable [4]. Language professionals, I feel, are often more knowledgeable about good research writing than gatekeepers are, and more sensitive to researchers' efforts to write as well as possible. Burrough-Boenisch recommended that, "language professionals could refrain from 'correcting' unambiguous, non-standard English" and instead "could empower the author to make the final decision, by explaining our 'native speaker' reactions to the original and suggesting an alternative" [5].

To provide authors with written feedback they could use to revise their texts, I typed notes in the text on specific problems and possible ways to solve them. In accordance with Burrough-Boenisch's author-empowering approach, I usually framed these notes as a warning about negative reactions by gatekeepers, an explanation of why the negative reaction was likely and a recommended solution (e.g., to add, delete or move something or to rethink and rewrite part of the text). Although authors sometimes asked me to write or rewrite text for them, I declined politely and reminded them that as researchers, they needed to become self-sufficient authors. More than once I feared authors would struggle with large numbers of suggestions for substantial changes, yet invariably I was impressed by how quickly they learned to implement the feedback and produce a greatly improved manuscript.

Researchers whose first language is not English sometimes use published research articles as models and imitate text features that author's editors consider vices rather than virtues. This write-by-imitation strategy can result in overuse of the passive voice, very long sentences and too much hedging. Although hedging is a useful rhetorical strategy in the right circumstances, excessive hedging >

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> often lengthens sentences and makes them hard to read. In terms of the reader's reactions, overhedging has the further undesirable effect of suggesting that the researchers lack confidence in their results. If the researchers themselves sound uncertain about the value of their findings, readers may suspect that their uncertainty stems from insecurity about the quality of the work rather than from the difficulties of writing in a second language.

To avoid the chance that the researchers would be victims of their own modesty, I explained that too much hedging might lead readers to question the validity of their findings. I reminded them that it is acceptable, and more persuasive, to sound confident about claims that are based on solid data and evidence, and advisable to reserve hedging for when they proposed novel interpretations and suggested new research directions.

Linguistic bias is manifested when reviewers ask authors to have a native-English speaker revise the manuscript even when there are no errors in English usage. Gatekeepers' criteria for good scientific English style vary widely and are not always trustworthy [6]. Kourilova noted that, "[i]n some instances, [reviewers] may be biased against non-native speakers and feel compelled to criticize the language". By way of example, she described the case of a manuscript by a Slovak doctor in which the English was "thoroughly subedited by his friend, a British scientist, whose name however did not appear in the paper. One reviewer acknowledged the high level of language and style, while the other one asked for complete language revision by a native speaker" [7]. As many *TWS* readers may know from experience, some reviewers criticise the English even when a native-English-speaking coauthor has checked the manuscript or when a native-English-speaking editor or medical writer is thanked in the Acknowledgments.

Fear of negative reactions because of poor English leads some researchers to copy chunks of text from published articles or textbooks. Authors I worked with explained that the reasons for resorting to copy-and-paste writing were to speed the writing process and avoid complaints by reviewers and editors about the language. In other words, they copied text not to steal ideas or words, but for convenience to save time and avoid rejection [8,9].

Gatekeepers, however, have little sympathy for the motives that lead non-native English authors to copy and paste, so it is important to educate researchers about the risks of copying and inaccurate citation (the latter a frequent though probably unintended result of copy-and-paste maneuvers). First, correct usage and readability are not guaranteed by copying from previous publications. English is not the first language for an increasing proportion of published authors, and the current trend to skimp on good copy-editing has led to a decline in the quality of the editing in much of what gets into print [6,10]. As a result, published articles in English—even in high-impact-factor journals—may not be gold-standard models of good scientific English style. Second, inexact citation breaks the chain of accurate attribution and due credit, and is considered a serious ethical issue [11]. Third, if reviewers and editors detect segments of copied text, they will be biased against the authors because gatekeepers perceive copying to be a violation of professional ethics, not a practical solution for limited English proficiency. Fourth, because awareness of the problems of plagiarism and lax citation has increased in recent years, editors are increasingly likely to take measures against authors who are caught. So copy-and-paste writing may not only prevent acceptance of a manuscript, but may have serious consequences for the first or corresponding author's career, their coauthors' reputations and their institution's prestige.

At the heart of the writing process is the writer's identification with his or her words. To give researchers confidence in their own words, I explained the importance of engaging readers by offering not only new information, but a new interpretation of what their findings might mean. Researchers have no time for rehashes of other writers' words, and expect something new from each article they read—something that will inspire readers to think about their own research in a new way. Inspiration can only happen if the authors use new words—their own authorial voice—to reflect their insights. Helping researchers to understand that their readers care more about what *they* have to say than about what others have already said contributed, I feel, to the increased confidence in their work researchers reported after they received AAEM help with their manuscripts.

Social skills: Joining the international knowledge-sharing community

A better understanding of the expectations for courteous, respectful behaviour within the research culture helps researchers from 'the periphery' avoid rejection and ostracism when they inadvertently break the rules of etiquette. During AAEM author-editing sessions, researchers and I spent much time discussing these expectations and what they mean for authors.

For example, some researchers are unaware of the taboos against multiple simultaneous manuscript submittal and duplicate publication [12,13], and argue that it is unfair for journals to make them wait months for a rejection before they are allowed to resubmit their work elsewhere. Peer reviewers do not always detect duplicated material in a manuscript, so the literature already contains many instances of inappropriately copied material. Confusingly, there is no consensus among gatekeepers as to whether reviewers should be expected to check for and flag plagiarism, and many editors say they do not have the resources for this task. When aspiring authors point to examples of duplicate publication and plagiarism by prestigious colleagues in their research field, they may wonder why predecessors have got away with it whereas less well known authors are criticised or punished when caught [14]. As pressure to

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publish goes global, it propagates the motivation to cheat by reproducing the same research environment and evaluation criteria that have led to widespread ethical abuses in English-speaking and industrialised countries.

Educating authors about the long-term advantages of not cheating is a challenge in the current research environment. During AAEM author-editing sessions I explained the reasoning behind current editorial policies and tried to motivate authors to accept them—if for no other reason than to avoid potentially damaging retribution from editors for infractions. Moreover, authors who don't waste reviewing resources or bore their readers by overloading the system with papers that contribute little or nothing to the knowledge pool are more likely to earn the respect of their peers in the long run.

For research to have an impact, it needs to be seen by readers who will use the new information. Many researchers I've worked with found their readers by trial (submitting initially to the highest-impact-factor journal) and error (being rejected and submitting to the next-highest-impact-factor journal until the manuscript was eventually accepted). But an article may be overlooked or ignored even if it appears in a high-impact-factor journal. Choosing the 'right' journal—ideally, a decision made before or while the manuscript is being written, not after it has been drafted—takes time and some thought.

I encouraged researchers to think about ways to expose their research to the greatest number of most interested readers. Who needs to know what you have found in order to become a better practitioner or researcher? This question helped researchers identify their audience. The next step was to find out which journals were read by the intended audience. If there was little overlap between readers' preferred journals and the journals cited in the manuscript, this usually meant that either substantial editing was needed before the article could meet readers' expectations for relevance and interest, or the intended audience and target journal needed to be reconsidered.

Once candidate journals had been identified, it was time to research their editorial board, recent publications, geographical coverage and citation patterns. Editorial board members and recent publications from the writers' own country or region were a positive sign that the journal would be prepared to review the manuscript. At this stage the impact factor and average time between manuscript submittal and publication might be checked as 'tie-breakers' between equally appropriate journals.

One of the most important outcomes of the AAEM project according to authors was increased confidence in the value of their research. This was a surprise for me because researchers at Shiraz University of Medical Sciences have an admirable publication record. But it may be a reflection of the insecurity many Eastern Mediterranean researchers feel in the context of problematic East-West relations. The issue of non-science-related biases [7,15-21] was frequently mentioned as a barrier to manuscript acceptance. Confidence-building is one of a publication mentor's most important roles, and motivating researchers to be persistent is one useful way to prepare them for the challenges that new authors inevitably face as they learn how to gain the attention and respect of international readers.

The Catch-22 of writing for an international readership

Social, cultural and political factors unrelated to scientific quality can influence how readers react to articles [15,16,21-26]. In addition to these biases, unknown authors face the hurdle of readers' reluctance to 'make friends' with new colleagues whom they haven't yet 'met'. Curry and Lillis [17] described researchers' reticence to accept publications from unfamiliar authors as "the relegation of periphery scholars to roles in which they consume and confirm center-based research but are not allowed access to platforms from which to contribute different perspectives and findings". When non-native English-speaking researchers seek help from those more familiar with the priorities and preferences of the main journals in their field, they hope this help will make their contributions more acceptable to gatekeepers. But in response to this guidance authors may sacrifice information about potentially interesting research questions in favour of "the preferences of center-based journals" [17]. Moreover, feedback from native-English-speaking peers—usually perceived by aspiring authors as more powerful members of their scientific community—can contribute to the 'creative destruction' of a text by obliging authors to make changes in the content and writing that satisfy gatekeepers' personal preferences without actually improving the article [6,27].

The dilemma for authors from emerging research communities is therefore how much to 'sacrifice' to gain acceptance by international readers, and which novel ideas to publish in national or regional journals that may have more tolerance for novelty. Unfortunately, novel ideas published in 'small' journals are often overlooked by researchers in the 'centre', who then proceed to make the same discovery, publish it in a 'more international' journal and claim priority for it [20]. Although acceptance by an international audience necessarily means investigating questions >

> with global implications, this acceptance often comes at the price of deleting more original aspects of the discussion and emphasising issues that interest key gatekeepers. The need to follow current research fashions to join the international knowledge community can thus influence choices about what to include in a particular manuscript. As a result, scientific self-censorship can limit the variety of viewpoints and insights relatively unknown authors can contribute—a situation that represents one of the most frustrating paradoxes of international research publication.

Obstacles to publication faced by non-native users of English from developing regions are barriers to authorship and knowledge-sharing [21]. AuthorAID in the Eastern Mediterranean improves writing and publication skills, and empowers authors to feel confident in their data, their own words and their right to be a respected member of their international scientific community. By helping researchers become authors, AuthorAID in the Eastern Mediterranean, like other AuthorAID projects, helps to level the playing field for researchers in emerging scientific communities who wish to be contributors to as well as consumers of scientific knowledge.

Revisit the EMWA website www.emwa.org

The EMWA website is continuously being developed to provide more resources, information and networking opportunities for the medical writing community. Check it out if you have not looked it up in the past few months. You will find:

- general and specialist discussion forums, the freelance support centre, member blogs, EMWA's WikiEncyclopaedia
- a monthly webeditorial, useful reading and useful links for medical writers
- job advertisements
- freelancer and company listings
- information about the upcoming EMWA conference, including the conference brochure, an online conference planner, online registration for EMWA members and important travel and accommodation information
- details of past EMWA conferences, including a photo gallery of pictures from some of the more recent conferences
- Information about the benefits of EMWA membership and easy membership application through an online application form
- EMWA news and other news relevant to our profession, including a newsdesk for latest news items, press releases and an events calendar

And coming up shortly **fully searchable** access to all *TWS* past issues.

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Whose citations are they?

by John Rodgers

Citations play a critical role in scientific communication, but authors, readers and reviewers seem to discern their functions poorly. I propose a theoretical framework for discussing these functions and address the question of how authors can take responsibility for their own citations.

Confronting the frequent occurrence of plagiarism in graduate student writing in the biological sciences, I began, about a decade ago, to think that teaching graduate students not to plagiarise was not the critical issue. In my experience, almost all cases of plagiarism by students and post-doctoral fellows occurred in the Introduction or Discussion sections and were due to lack of training in the arts and skills of writing. My students had a poorly developed sense of how to cite. They had learned that citation is a means of 'giving credit' to avoid plagiary. Students related to their citations awkwardly, often 'borrowing' them from their source text. Citations were dragged into the text in much the same way that words, phrasing and ideas in the source text were loosely paraphrased or patch-written into their own texts. The students had little sense of what citations might do for them as elements of writing itself. I wanted to teach them how to cite skilfully. It was time for them to take ownership of the citations. It was time to ask of them, and of myself, "Whose citations are they?"

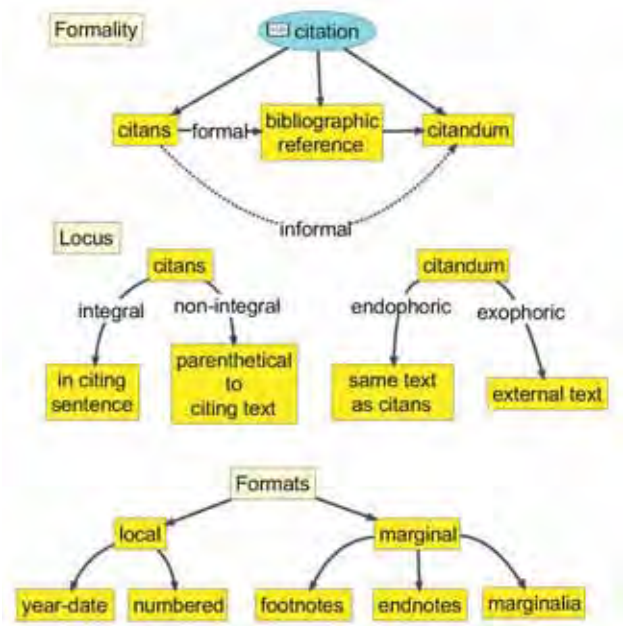

Figure 1 **Citation forms. An unconventional nomenclature differentiates the appearance of the citation as a metatextual element in the citing text (the 'citans', plural 'citantia') and in the cited text (the 'citandum', plural 'citanda'). In conventional usage the terms 'citation', 'reference' and often 'footnote' are interchangeable. 'Citation' refers to the non-textual conceptual relationship that is manifested by the textual elements citans, reference and citandum, but also the set of textual elements that manifest the citation. The reference is missing or allusory in informal citations. 'Locus' refers to the textual positions of citantia and citanda, 'format' to the stylistic conventions used to express them.**

Citations

In analyzing this question with respect to texts, I consider the nature of three types of citation function and several meanings of ownership. Let me first set out some terminology, chosen to avoid the imprecision of the common terms in English. By 'citation' I mean a functional relationship between a referring text and a source text (Figure 1). The citation is a thread with two termini: the citans (commonly referred to as a reference, a citation, a cite, an in-text reference and a variety of other terms) in the text and the citandum (often referred to as the referent) in the source. The citation helps weave together (plexis) texts and their sources. Skilful citation produces a seamless and effective text (euplexis), but failure to cite skilfully produces a fabric of patches, crude mends and plagiarisms (dysplexis).

The citation may be formal, such as one using the Vancouver citation styles, or informal, such an allusion. Formal citations have as intermediary text elements the bibliographic references found in footnotes, endnotes or reference lists. Informal citations lack (formal) references; allusive citantia fail to connect with their citanda for readers >

Figure 2. **Typology of citation functions. Most citation functions can be classified in one of three broad groups; a particular citation might exert more than one function. Authorising functions handle the authority and credibility of and credit due to authors; they authorise the text as trustworthy in the commons. Evidentiary functions handle the relationship of citations to particular arguments. Mapping functions orient the writer and reader within the commons.**

Whose citations are they?

> outside the 'intellectual commons' or 'disciplinary community' assumed by the author.

Citations can be characterised in terms of their form (format, formality, locus) (Figure 1) and function (Figure 2). Format refers to the stylistic structures used to render textually the citans and its reference. In print media the citans is meta-textual; it is itself a text participating in the physical structure of the text [1]. Formality refers to whether the citation uses an explicit reference or relies on the reader's familiarity with the field to identify the citandum. In electronic media, citantia or references may be replaced with hypertext links directly to the citanda, bypassing both the need for and the value of the reference. With respect to locus, the citandum may be endophoric, found elsewhere in the citing text, (e.g. "see below"), or exophoric, found in an external source. The following three sentences illustrate formality and locus, as well as other features discussed below:

a. *Within a sentence, a citans may be integral or non-integral.*
b. *Swales classified the citans as integral or non-integral [2].*
c. *A citans may be classified as integral or non-integral [2].*

In sentence (a) the citation to John Swales is both informal (lacking a reference) and allusive (opaque to most biomedical scientists but perhaps not to many readers of *TWS*). The same citans is integral in (b) in that it forms a syntactic (parsable) part of the sentence itself. In this case, 'Swales', an element retained from the citandum, becomes the subject of the citing sentence. In contrast, the citans is non-integral in (c) because it is merely parenthetical to the sentence. This sentence would have the same content with or without the citans.

The typology of citation functions shown in Figure 2 draws from a rich literature that cannot adequately be cited here. The analysis of citations draws on three main sources: the tradition of rhetoric and English composition studies exemplified in the United States by Kenneth Burke [3] and focused recently on citation functions by Shirley Rose [4]. Swales comes from this tradition. From social science come the other two major tributaries. In the literary constructivist movement the names of Foucault [5], Gilbert [6], Wollgar and Latour [7] figure prominently. The Mertonian school [8] led directly to theories of social credit and Garfield's aggressive deployment of information science to the numerical analysis of citations [9]. The confluence of these tributaries was first described by Swales [2] and reviewed more recently by White [10]. (See also Cozzens [11].)

The functions of citations are authorising, evidentiary and mapping. Through their authorising functions, citations legitimise the text and establish the author as trustworthy in the discourse community. Evidentiary functions mediate the logical role of source texts. They may justify claims of causality, explain terms or experimental operations, or provide evidence in an argument. Logical citation functions are confirmatory, oppositional, evolutionary [12] or hedging [13]. Finally, mapping functions orient readers and writers within the constantly shifting commons, which must be constructed on the fly by the reader in order to decode the text. Mapping functions may be informational (e.g. 'as reviewed by…'), axiological, conceptual or community-defining functions. An expert's choice not to cite may indicate that the author considers the idea to be in the commons; a novitiate may inappropriately follow the rule-of-thumb, 'When in doubt, cite!', thereby proving his naivité. In the sample sentences exhibited above, sentence (a) assumes the reader is familiar with Swales already, or will not be interested. In sentence (b), Swales is an authorising figure only to those in a community familiar with the literature of English composition. Swales is relegated to a minimalist position in sentence (c). The mapping functions are critical to the demarcation of private and 'common' knowledge within a discourse community. Moreover, certain well-known citations can be symbols for larger bodies of ideas [14]. Thus, the names of Burke, Merton, Foucault, Garfield and Latour I dropped in the previous paragraph symbolically evoke several rich intellectual traditions.

Note that the citation in (b) is clearly attributive; we don't know whether Swales provides 'evidence' for this claim, but we know that it is Swales' claim. In contrast, the citation in (c) is profoundly unclear; we are tempted to think that the claim is supported by evidence in the citandum; that the citandum contains the source of the concept of an integral citation is obscured. The authorising functions can be further divided into authoring, tasking and attributive, all of which explain the role of authorities in the text. For example, the authoring function establishes the bona fides of the named authors. Acknowledgments and author descriptions assign specific tasks to different named authors and non-authorial contributors. The attributive citation identifies the source of an idea, work or text. It mediates the exchange of Mertonian credit, discharging the intellectual debt of authors owed to their sources. This is the sole citation function taught to most students, bringing them to grief when they fail to exert it appropriately.

The writing and citation traditions of the humanities allow their writers to wield the full diversity of citation forms and functions. A cultural trend spanning more than a century within the sciences has reduced the repertoire of citation functions available to the scientist [15, 16]. The scientific report uses attributive citations very little. Integral citations, which facilitate attribution, are nearly extinct. The conditions which make relevant the use of paraphrases and summaries are nearly as rare as those calling for quotations. An informal analysis of papers in my own field (immunology) suggests that evidentiary citations outnumber attributive citations at least twenty-fold. Many student writers in the sciences, trained in the colleges to cite attributively, are hard-pressed to make the transition smoothly.

Ownership of citations

The junior scientist has little skill using evidentiary citations. Moreover, the novice has a tenuous command of the field, does not really know what is in the commons and what is not. Indeed, only an expert can command the domain of 'common knowledge'. My experience with student writers is that most citations are either 'borrowed' from a source or downloaded from a search engine based on a brief read of the abstract. (A correspondent suggests instead that novice writers are wed to a poverty of citanda and are resistant to incorporating new ones.) Thus is born the initial reference list. To this list a senior author may add a few references; under pressure from the publishing house, they may have to trim a few out. A reviewer may request a citation or two on the grounds it is important to the field. Whose citations are these?

In legal theory, there are three kinds of rights, separably attached to ownership: possession, use and disposal. Thus, I might own a book but have no right to copy it; someone might own a famous painting but have no right to alter it. To this list, add a fourth: a 'right of origination'. A creator has the right to remain associated by name with the created work (work for hire is an important exception).

Consider citations in the light of these four rights of ownership. Who originates citations? Who possesses them? Who uses them? Who can alter or destroy them?

Who originates a citation? If one accepts that a citation is a relation, it doesn't belong quite to text or source text. With legs standing on two continents, the citation originates in both, belongs to neither. The citation separates itself as a countable entity; in Garfield's citation maps, the nodes (citantia and citanda) are dwarfed by the swarms of citation links standing on their shoulders. Surely, Foucault is the author of the famous sentence asserting that the author is the principle of thrift limiting the proliferation of meaning, found in the Harari translation [5]; isn't Foucault partly the author of any citation to him? Isn't that the meaning of Mertonian credit? We give Foucault credit, we give him his due, because the citation, in the guise of a citandum, is his. But without an authorial choice there is no citation of Foucault, so the credit for the citation, under the veil of a citans, belongs to the author, not to Foucault. In this case, there are two and even three citanda from which to choose. Many citers mistakenly cite Bouchard's translation [17]. This in an example where the citation should place the citandum with Harari, not with Bouchard. Or, if we consider citations from Garfield's viewpoint, the citation of Foucault appears to stand alone, its termini being of minor import. In this view, the citation belongs to the commons in which it operates.

According to historians of the footnote, citantia in the tradition of British philosophy and the humanities tended to use integral citantia and commentative footnotes [1, 11], so that in some circles the terms 'citation' and 'footnote' are nearly synonymous (e.g., [18]). Under the influence especially of German chemists, the sciences have discarded footnotes and integral citantia. This fits the positivist conceit of hard science, in which arguments are established through the unveiling of evidence, not human authority. In many styles (as in *TWS*) citantia are reduced to a number, often no more than a superscript. This tidy style obscures the identity of source authors, reducing their visibility to writer, reader and reviewer. Coupled with the ease of using reference-managing software, the contemporary writer risks losing both the kinaesthetic and literary experiences of handling source texts and notecards. Originary 'ownership' of citations by authors is limited to a few keystrokes.

The rights of possession have little relevance here. Source-authors are not possessive; they rise up when they are *not* cited. It used to puzzle me that most of my colleagues do not see the recycling of source-text citations as plagiarism, but the present analysis makes sense of this. The non-integral evidentiary citans is so terse that it barely registers as belonging to an author. So little scholarly effort goes into selecting and using a citation that it appears hardly to represent scholarly effort. Moreover, it is possible that within the positivist ethic of scientists, citation of evidence, like evidence itself, appears to be in the public domain. Because of its inherently relational construction, which we have seen already destabilises the right of origination, and its increasingly minimalist presence as a meta-textual element, authors feel less possessive of their citations than of their words. Likewise, the rights of disposal and alteration are rarely invoked. Most authors care little if, for example, when reformatting a text for a different journal, they must convert citations from a name-year to a numbering system, even though this considerably changes the functional landscape of citation.

The rights of use are potentially important but severely limited due to the impoverished repertoire of citation techniques available to the scientist. The deft writer can use linking words to express logical development with evidentiary citations in the Introduction and Discussion sections of a paper; occasionally a nuanced phrase will reveal an attributive usage. The ideal author of written science is nearly voiceless, and only the most careful writing can differentiate between an attributive and evidentiary citans indicated by a number.

This is a conundrum for those of us concerned with the appearance of dysplexis in science writing. It appears to me that the majority of dysplectic transgressors are writers unskilled in citation or scientists not yet expert in their own commons. We can blame the colleges for the simplistic view that euplexis is achieved by paraphrasing and attributing one's sources. But it is not enough to blame those who might have trained our students. We can also observe that graduate, medical and post-doctoral training programs provide little training in the art of skilful citation. This will not surprise the readers of *TWS*, who are well aware that scientists rarely have the inclination or time to invest themselves in the skills of literary and educational scholarship. The apprentice model for training biomedical researchers is flawed in this aspect; mentors rarely have the skills needed to train the next generation of writers. >

Whose citations are they?

> Mertonians assume that citations deliberately reflect the relative influence of texts on a scientist's thinking. The anthropological study by Latour and Woolgar [7] of a future Nobel laureate's laboratory seems to me to support that model. I suggest, however, that this is not the general case. Instead, I suggest a different model, a 'null' token model in which formal citations are little more than whispers in a game of Rumour, in which the (unskilled) writer has tenuous knowledge of sources but provides the citation merely as a 'token' needed for publication. This model could be seen as cynical but might play a role in citation analysis parallel to the role played by Kimura's neutral mutation theory [19] in population and evolutionary genetics. This was the null hypothesis that most mutations have little (positive) effect on fitness. In this neutral model, citations are null tokens; they serve no particular function but are carried along to satisfy the minimalist needs of reviewers. In this model, citations belong to no-one except the commons, where they are blown about by winds and gusts of scientific fashions, or where some might serve as selfish memes. The entry of citations into the commons must be deliberate, but once there, how can we know that they are maintained through deliberation rather than fashion? Are there statistical properties that could distinguish null token networks from Mertonian networks? This is a question for the social scientists.

The task for educators is to teach skilful, reflective citation. I suggest that undergraduate students, and graduate students in their dissertations, be encouraged to use commentative footnotes deliberately to reflect on the functional role of citations in their texts. This practice will not extend into the print journals, but writers well versed in the manifold uses of citations will handle themselves better when breathing the cold thin air of scientific writing.

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Informed consent or overwhelming paperwork?

The Food and Drug Administration (FDA) is proposing to add a new item to the list of required elements of informed consent[1]. The proposal is that Patient Information Leaflets (PILs) for clinical trials that are conducted under Investigational New Drug (IND) regulations include a statement that the data collected during the trial has been or will be submitted to the National Institutes of Health/National Library of Medicine (NIH/NLM) for inclusion in the clinical trial registry databank (www.ClinicalTrials.gov). The proposed requirements apply both to drug and device trials.

The FDA argues that the informed consent regulations protect subjects who participate in clinical trials. Amongst other benefits, the regulations educate participants so that they can make autonomous decisions, and protect them from unethical practices. These are admirable aims. However, the FDA proposes that in addition to the factual statement about the registry databank, the statement should include a descriptive explanation of its nature and purposes. Investigators and Institutional Review Boards (IRBs) may require even more information to be added.

The FDA is currently inviting comments; the deadline is 1st March 2010. If the proposal is accepted, medical writers will need to use their best summarising skills to include all of the required elements of informed consent, plus the additional elements requested by the IRBs and Independent Ethics Committees (IECs) in as few pages as possible. Despite common agreement that PILs are too long, the number of details that must be included continues to grow.

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1 Federal Register. Proposed Rules. 29 December 2009, Vol 74, No. 248

Relationship counselling for medical texts

Commentary on: Whose citations are they?

by Iain Patten

With the possible exception of Dawn Barker (see article on page 52), I would imagine few medical writers listing relationship counsellor as one of their usual professional roles. Careful reading of John Rodgers' article on the nature and function of citation suggests we might do well to reconsider. In fact, look closely and you will realise that, for those of us working with articles destined for publication in peer reviewed journals, an enormous amount of our work is directed towards ensuring healthy relationships—between the text and the material it makes reference to.

Nothing that is written in an academic article stands alone—it is inevitably embedded in a wider framework of meaning that is informed by other texts. This is the basic premise of intertextuality. Citations represent the individual expression of these interactions, the links between text and surrounding information that make up the framework of meaning. As in human relationships, citation encompasses a whole host of different interactions. Yet for something so central to how a text is understood, citation is too often a mere afterthought in the scientific writing process. John Rodgers presents us with an erudite challenge to face up to the dysfunctional relationships that pass for citation in so many articles.

Citation is not just about reference lists. In fact, formal references need not even come into it. Providing a reference to Watson and Crick's 1953 letter to *Nature* would hardly be needed to support a general statement on the structure of DNA in a biomedical research article, but the allusion to their work would nevertheless be understood by most readers without the need for a formal citation. An applied linguist who wanted to use their famous understatement "It has not escaped our notice..." [1] in a paper on scientific discourse would instead have to consider that the target audience is less likely to be familiar with the writing of Watson and Crick. This is what makes the informal citation allusory when provided in a biomedical research article. Thus, the careful interweaving of information is dependent not only on the writer but also on the reader. Skilled writers, aware of their intended audience, will adapt the citation relationships to their purpose. The important point is that the relationships between text and source (between citans and citandum in the terminology proposed by John) inevitably exist—the question is whether they are healthy or dysfunctional.

As in human relationships, the source of citational dysfunction may often be developmental in origin. Like John, I have believed for some time that the emphasis placed on acknowledgement of sources in student writing is itself the cause of many of the citation problems found in academic articles. Inexperienced authors are often taught to paraphrase, use quotations and 'cite' their sources, but that only provides symptomatic relief for the problem of plagiarism. The references may all be present, but how they relate to the material discussed may be completely obscure. In many situations, readers can only make assumptions about the true content of the cited material or the reason it is provided. As a consequence, the information conveyed in the text may only be partially understood. Of even more concern is the possibility that the writing may suggest something inaccurate about the cited material and that misinterpretation may be perpetuated by other authors who themselves have limited skill in the art of citation.

John ends his article with a challenging hypothesis, that most citations are simply 'tokens' provided to meet a formal expectation but indicative of no meaningful relationship between the author and the cited material. Consider for a moment the last text you worked on. What informed the decision to cite certain studies? Was there a conscious relationship between the writing and the cited material or were some studies cited because they were referred to in a recent paper or perhaps because someone else provided them in an outline or draft? Did the purpose of the citation influence how the text was written (where in the text the reference was provided, whether the author's name was mentioned, etc.)? In sum, how actively involved are you in developing the citation relationships that will determine how the texts you work with are understood? Don't imagine for a moment that this does not have consequences beyond good writing style. When citation becomes a game of whispers, meaning can be lost and inaccuracy is introduced [2].

John points out that "mentors rarely have the skills needed to train the next generation of writers". If the peers and supervisors of publishing scientists have not been adequately trained in nurturing healthy citation relationships, then those of us who support their writing must take care to ensure that we are. Taking the time to carefully read and digest John's excellent article is one way in which we can do just that.

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Medical writing: A marriage made in heaven or an affair of the heart?

by Dawn Barker

I am a practicing child and adolescent psychiatrist, and I also love to write. I can relate to Anton Chekov, who once said "medicine is my lawful wife and literature my mistress", although in my case medicine is my 'lawful husband' and literature my 'paramour'. There are many similarities: I hide the books I have bought and the receipts for my creative writing classes from my real life husband; there is always a novel hidden in my bag in case we have time for a quick liaison; I spend hours thinking about my writing projects rather than doing work for my real job. Medicine has been my stable, dependable but rather mundane partner; writing my exciting, thrilling passion. I had never considered that both relationships could be compatible. Traditionally, medicine is considered to be a science, while writing is a creative art.

The phrase 'medical writer' has always misled me. When I joined the Australian Medical Writers' Association, I was surprised to find that most of the members were professional writers who wrote about medicine, rather than doctors who also wrote. Of course, the clinical work of a doctor involves a huge amount of writing. For every hour I spend with a new patient, I have approximately two hours of paperwork to complete: I must write the case history; a formulation and management plan; and letters to colleagues. I also write clinical guidelines, academic papers, and lectures. But I have never classified that type of scientific medical writing as creative or artistic.

The phrase 'medical writer' has always misled me

When I became interested in what I thought was 'proper' writing, I began with book reviews and brief articles for online psychiatric sites, which I could justify as work. Then I progressed to short stories, a feature article for a magazine, and a newspaper article. I am now working on a novel, and I have a blog (http://psychiatristparent.wordpress.com). With experience, I have come to realise that medicine and writing are not mutually exclusive, but in fact are very complimentary.

In the practice of medicine, there is no doubt that we depend on evidence, fact, and logic: the hallmarks of science. For some clinicians, such as pathologists or surgeons, this may be enough to be successful. However, for many specialities, the art of medicine is a significant part of the treatment. Most people would agree that when choosing a doctor, their communication, empathy, and 'bedside manner' are as important as their clinical expertise. Of all the medical specialities, my own—psychiatry—has arguably the most need for artistry. While we always aim to use evidence-based psychiatric treatment, a significant amount of what we do cannot be measured or proven, but works. I believe that a vital part of treatment is the art of communication.

However, the jokes about the poor state of doctors' handwriting imply that our written communication is not as successful as our verbal skills. When we do get it right, it is wonderful: there is nothing more interesting than reading a well thought out case history. As a medical student, I remember my fascination when I started to read patients' files. This was particularly true of patients with mental health problems, in whom a life history is an essential part of diagnosis. I came to realise that doctors are very privileged to be given access to a patient's unique story.

Unfortunately, we often get it wrong, and our clinical writing fails to capture the richness and depth of our patients' deeply personal tales. Part of the blame lies with hospital procedure and bureaucracy, which has created our own dialect of Orwellian doublespeak. Patients have become 'clients' and 'consumers'; families have become 'carers' (whether or not they care); and bedside manner has become a 'therapeutic alliance'. Instead of being encouraged to write the narrative of a patient's story, we are mandated to fill in forms full of specific headings and tick boxes. While this is meant to aid communication, our writing is akin to a questionnaire rather than a summary of our understanding of a unique individual. Young doctors are being trained to fill in forms rather than wait for a patient to tell a story.

Clinical writing fails to capture the richness and depth of our patients' deeply personal tales

As a result, words have been lost in favour of acronyms, and medical notes are a secret code, decipherable only to those in the clandestine club. Our written sentences lack structure and grammar, but instead look like a printed alphabet: *'HPC: 49 YO man PW RUQ PAIN, D&V and SOB for 4/52, uses ETOH daily'*. This type of writing tells us nothing. It doesn't tell us why this patient drinks alcohol (ETOH) daily: how does it make him feel? What does he drink? How does he feel leading up to the first sip, and how does he feel the next day when the empty bottles crash into the bin and clang through his pounding head?

Medical writing: A marriage made in heaven

Why has he waited four weeks to see a doctor? What is his greatest fear about his pain? Is it the same pain his father had before he died?

Fear of litigation also affects our clinical writing, as we are very aware that anything we write may be evidence in court one day. My own reaction to a recent subpoena to appear as a witness was panic. My first thought was, "what have I written in the notes?" I find myself writing clichéd management plans and summaries so that I know that I have written down what managers and lawyers want to hear. In their view, if it's not written in the file, it wasn't done.

Writing, on the other hand, has always been considered to be an art—which undoubtedly good writing is. However, some would argue that the art is being stripped away, with writing becoming more formulaic. A good example of this is academic writing. While there is still an art to writing a readable research paper, most people can simply follow the submission guidelines in the back of any journal and present a passable journal article. To be published, one must write in exactly the way in which creative writers are taught not to: write in the third person point of view, in passive language, under set headings with an expectation of heavy jargon. A well written paper is undeniably more readable and informative, but is not a necessity for being published, as a look in any journal will reveal. Medical writing can easily fall into this trap.

Our sentences are like a printed alphabet

This split between art and science in medical writing is unnecessary. Many doctors have been successful in resisting the degradation of our artistic skills by turning to writing creatively outside of their clinical work. Over the years, some doctors who have done this successfully include Sir Arthur Conan Doyle, Anton Chekhov, Michael Crichton and Khaled Hosseini. There are many reasons why doctors can make good creative writers. First, they spend hours hearing the most unique and bizarre life stories, which they have to piece together. Second, they are used to working hard with success being a long-term goal. Third, their writing can be fuelled by the cathartic experience and the escape from the stress of their work.

Creative writing is also used in medicine to enhance clinical work. In the USA, literature is used in some medical schools (e.g. at Harvard University) to help medical students understand the effects of illness on people. Human illness has been a theme in literature throughout history, with some of the greatest works having medicine—including psychiatric illness—as a central theme: Tolstoy's *Anna Karenina;* Flaubert's *Madame Bovary*; and Shakespeare's *Macbeth* and *Hamlet*. In my clinical work, I use both writing and reading to help children and adults therapeutically: literature can provide externalisation, normalisation of problems, and a creative outlet. In psychiatry, there is a technique called narrative therapy which uses the principals of telling stories to help patients to process psychological issues. I believe that my own voracious fiction reading helps me to be a better clinician by giving me access to different people and different worlds, as well as helping me to escape from the pressures of my job.

So, can we marry the science of medicine with the art of writing? Can Chekov's wife and mistress live harmoniously? Times have changed since Chekov wrote his words over 100 years ago. We are much more comfortable with relationships now that would have previously been unconventional. Medicine and writing are growing closer than ever, and this relationship should be nurtured and allowed to mature. Encouraging the partnership to grow will benefit both parties, and medical writing can be a wonderful example of a modern marriage.

There are many reasons why doctors can make good creative writers

Disclosure

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Beyond STROBE: Registration of observational studies

While the STROBE statement (http://www.strobe-statement.org/) improves clarity in the way observational studies are reported they come too late to influence the study design, according to an editorial in the *BMJ* which proposes that all observational studies should have protocols and that these should be registered. Observation studies include cohort and case-control studies. Around 14000 observational studies are already registered at clincialtrials.gov and it is suggested that the results should also be registered. The editorial points out that observational studies are vulnerable to bias and selective reporting. Furthermore consumers cannot easily distinguish hypothesis-driven studies from exploratory, post hoc analyses. Changes from the statistical analysis originally planned are usually not apparent from reports of the studies and there is little deterrent against data dredging and selective reporting. The editorial also details the arguments against compulsory registration and outlines the *BMJ*'s policy of asking authors who submit observational studies to explain the origins, motivations and data interrogation methods of their work.

Source: Loder E, Groves T, MacAuley D. Registration of observational studies. *BMJ* 2010;340:375-376

Series on medical writing: Reaching beyond the obvious

High performance medical writing Step two: People

by Richard Watson

My last article [1] focussed on the need to step out from behind our computers and interact with those around us, but clearly there is more to that simple intent than may initially be thought. Stepping out from behind our computers is the vital first step in engaging our customers and colleagues, but equally critical is the manner in which we conduct ourselves when we emerge. But is choosing the correct approach always as simple as it may seem?

Spanning the murky waters of the River Thames from the buzzing commuter hubs of the south to the financial power houses of the north, London Bridge is an internationally recognised name in the rich architectural heritage of the United Kingdom's capital city. Captured in the reality of history and the fantasy of nursery rhyme, it is a vital link on the route between home and workplace for the countless thousands who stream into the city everyday. It is an essential piece of working architecture: solid, reliable, always there, but, in my opinion at least, also very boring. Amongst London's rich and complex mix of ornate, grand, and sometimes challenging buildings, there is very little about this particular structure that makes it stand above the many other bridges that serve the same purpose across this stretch of river. Its low, sleek design renders it almost invisible against Tower Bridge, its more architecturally intricate and chocolate box adorning neighbour. Nevertheless, it is there to do a job and it does that job well; in the many years that I regularly crossed that part of the Thames not once did I have to get my feet wet.

How we engage our customers and colleagues is critical.

Unfortunately, crossing London Bridge is not without hazard because it is both a bridge and a wonderfully effective giant funnel, channelling the stream of commuters from the nearby railway station into two pedestrian walkways on either side of the road. The seemingly endless compression of human beings that it generates forms a wave of life that is powered by a common goal of reaching work on time or securing a rare seat on the 5:35 train to Plumstead. Despite the physical discomfort that this twice daily crush generates, being part of the crowd brings a reassuringly odd sense of purpose and community; security in numbers perhaps. Unfortunately, I was never part of that crowd. It is a two-way crossing and I was always going in the wrong direction.

It's hard to describe how difficult it is to march against the flow of such a crowd. Faith in the warmth of human kindness would suggest that even the most hardened of commuters would relinquish a small piece of pavement for those heading the other way, maybe even offer a friendly good morning as the fleeting moment is shared. Instead, it is more like encountering the organised ranks of the Roman Army, each pin-stripe clad or high-heeled legionnaire linking into an impenetrable attack formation, all flanks bristling with a vicious array of golf umbrellas that are wielded with a degree of eye-gouging irresponsibility that can bear no defence. The options available to those facing such a situation are limited: give up and go home (not really an option no matter how tempting); stand back and wait for the flow to subside (or, more accurately, stand back and let your life ebb away because the flow of commuters never subsides); put your head down and charge. I do not recommend the third option; it is reckless, foolhardy, and comes with a substantial risk of embarrassment. But I would be lying if I didn't admit that in the pressure of the moment I was that reckless, foolhardy, and frequently embarrassed individual. I would grasp the third option with all the desperation of a man with a train to catch. These were, without doubt, head down and charge situations.

I learned very quickly that this strategy had two serious flaws. Firstly, the collective forces exerted by a crowd moving with a common aim are undoubtedly much greater than the sum that could be exerted by each of the component parts. Secondly, and of equal importance, is the fact that I have never possessed snake hips capable of endlessly weaving through the tiniest of gaps. So the head down and charge strategy was actually the bounce off the first layer and appear very, very silly strategy. Head down and charge was very one-dimensional and prone to failure as a result. I had to vary my approach. Fortunately, the solution was relatively easy, a case of understanding my opponents a little better. Through careful observation, mostly when looking up from the gutter due the failure of the third option, I realised that the oncoming crowd could be placed into three very broad but useful categories. Category One was the hardened commuters, the vast majority who crossed that bridge every day, at exactly the same time, with the same number of footsteps and via a route that was fixed with the precision of satellite location. They knew every inch of the bridge better than the designers themselves and they had adjusted and minimised the path

The volume of our daily interactions is unparalleled in human history.

they followed with such care and attention that they would rather die than deviate even a millimetre to let someone pass. Category Two was the heavily laden. We've all been part of this group at some point—individuals who have overestimated their capacity to carry extra items on top of their usual burden. Dragging an overweight suitcase or balancing an oddly shaped display stand, these were veritable oases in the commuting desert. The erratic carriage of these virtual weapons under such tightly spaced conditions would create isolated but not insignificant pockets of confusion and space as fellow commuters jostled to escape the inevitable bash on the head from a swinging item. Category Three was the tourists. Tourists have no concept of the rules of commuting. They wander. They dawdle. They stop to look at things and take photographs. And, just like a rock in a fast flowing stream, they create yet more pockets of confusion and space.

It's people, not words, that are at the heart of a medical writer's world.

Armed with this knowledge I somehow made that daily crossing. No longer was brute force and raw courage applied, but a careful, thought out approach based on a swift observation of the advancing crowd. Like a lion seeking the weakest antelope in the herd I would identify the over laden businessman and dart into the space he was creating or weave around the tourists as they froze in a fixed pre-photo pose, graciously accepting every metre or two that was gained. It wasn't direct, it wasn't easy, but some focused consideration of the situation followed by a twist here, a turn there, and a shimmy when required would get me safely to the other side. A basic understanding of the people with whom I was interacting made all the difference.

And there's a lesson for us all in this.

The huge benefits delivered by modern information technology are accompanied by a potential for an intensity, volume, and diversity of daily interactions that is unparalleled in human history. No matter where or how we work, be that as a one person operation or part of a complex multinational team, all of us experience the weight of an oncoming crowd on a regular basis. How often has navigating an avalanche of e-mails felt like an exercise in crowd control? How often have you felt your heart sink when your voicemail indicator is flashing like a disco light on Saturday night? How often does the queue outside your office door or the list of people to meet seem to stretch to the moon and back? In the midst of this pressure how tempting is it to take a deep breath and charge in, hoping with all your might that you'll get to the end of the day in one piece through a combination of luck, momentum, and a tried and tested one-dimensional approach? But is the convenience of such an approach worth the risk of resembling a soulless, rambling, poorly informed and insincere customer helpline during each of these interactions?

Regardless of our level of experience or how much confidence we have in our own ability, we must never forget that we operate on a two-way street, and equal importance must be given to the needs and aims of those with whom we are interacting as to what we intend to get from those exchanges. A one-dimensional strategy can never be acceptable. A clear and structured approach that may be welcomed by an inexperienced colleague or client may be the exact opposite of the collaborative and explorative needs of others. See each and every communication as a unique opportunity. Take whatever time you have to learn, to understand, and offer a genuine interest in the situation at hand. Customise your approach for your customer.

As we open messages, take calls, and shake hands, we need to look beyond the crowd and understand the individual who is capturing this moment of your time: their needs, their styles, their preferences, their motivation. This is crucial in the quality-driven but often subjective or opinion-led arena in which we operate. Only when we achieve this understanding can we hope to offer the level of personal service our customers seek and to deliver documents of the highest possible quality. Believe it or not, it's people, not words, that are at the heart of a medical writer's world. The painstaking care and attention that a writer gives to placing the correct word in the correct place must always be matched by the provision of an equal amount of care and attention to the interactions that surround the writing process.

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The intriguing story of a highly unsystematic Cochrane review

by Adam Jacobs

A strange story hit the mainstream news in early December about a systematic review of the role of neuraminidase inhibitors (such as oseltamivir [Tamiflu]) in treating flu [1]. This made the lead story on 8 December on Britain's prestigious TV news programme Channel 4 News [2]. The story involved the Cochrane Collaboration, the *British Medical Journal*, and Roche (makers of Tamiflu), and I don't believe any of them emerged from the story with much credit.

A previous Cochrane review [3] had concluded that oseltamivir was effective in preventing the complications of flu, based on a meta-analysis of 10 studies [4] that found a 59% reduction in hospitalisations. However, that meta-analysis, despite having been published in the prestigious *Archives of Internal Medicine*, contained a schoolboy error in its statistical analysis. This is surprising, given that Roche has some very smart statisticians and that one would hope that a journal such as the *Archives* would have some good peer-reviewers. However, it's not earth-shatteringly astonishing. Mistakes like that get through more often than we'd like to think.

So what was the error? What they had done was to add up all the hospitalisations in the oseltamivir and placebo groups in all 10 trials, and to treat the totals as if they had come from a single trial. That is not a statistically valid method, because it means that the analysis is not based on a randomised comparison. The trials had different inclusion criteria and therefore different risks of hospitalisation, and not all trials had equal numbers of oseltamivir and placebo patients. The effect of the drug was therefore confounded by the type of trial[1]. A correct way to do the analysis would either be by logistic regression[2], controlling for the trial, or by a meta-analysis of the results of all trials. Pooling the data and ignoring which trial they came from, however, which is what was actually done, is seriously flawed.

When the Cochrane reviewers came to update their meta-analysis, they realised that the review on which their previous conclusions had been based was flawed, so they needed more details on the 10 trials included in the meta-analysis. Sadly, only 2 of them had been published. Although that is disappointing by today's standards of clinical trial transparency and reporting, it would be wrong to be too hard on Roche for that: the trials completed about 10 years ago, and at the time it was quite common for many trials to remain unpublished. So the sensible thing for the Cochrane reviewers to do would be to ask Roche to supply the data.

However, rather than asking Roche directly for the data, they discussed the problem with Channel 4 News, who then approached Roche to ask for the data. It is unclear why they chose to approach Roche through an intermediary from the media rather than doing so directly. As Roche said in their response on the *BMJ* website [5], this was "a move that questioned whether the motives for inquiries were truly for clarity and scientific validation". Indeed.

However, although Roche had a great opportunity at that point to occupy the moral high ground, they spectacularly missed that opportunity by not making the data available in full. They were prepared to supply the data to the Cochrane reviewers if they signed a confidentiality agreement, but the reviewers were not prepared to sign such an agreement. This makes both sides look pretty bad to me. I don't see why Roche can't make the data available in full, and I don't see why the Cochrane reviewers should refuse to sign a confidentiality agreement. Maybe Roche believed that there were some valid reasons to keep the data confidential, although personally I struggle to imagine what those reasons could be, let alone how they could trump the absolutely pressing public relations reasons for making all the data available. It's also hard to imagine why the Cochrane reviewers felt unable to sign the agreement, even if they did have every right to feel a bit miffed at being asked to do so. Their failure to sign the agreement looks like they were simply trying to make a point, and is totally inconsistent with a desire for honest scientific enquiry.

Nonetheless, some data were supplied, and although they were not sufficiently detailed to answer all the Cochrane reviewers' questions, progress was being made, dialogue had been established, and it might be reasonable to think that ongoing dialogue would result in the necessary data being supplied before too long. However, the Cochrane reviewers were too impatient for this. They decided to go ahead and publish their review anyway.

1 Shameless plug: anyone who has trouble following this statistical argument about confounding is highly recommended to attend the EMWA workshop "Critical appraisal of medical literature" (unfortunately not on offer in Lisbon), where confounding is explained in detail.

2 Further shameless plug: anyone who is not familiar with logistic regression is highly recommended to attend the EMWA workshop "Statistical analysis of binary data" (available in Lisbon: book early to avoid disappointment), where logistic regression is explained in detail.

This seems extraordinary to me. The whole point of Cochrane reviews is that they are supposed to be systematic, in other words to include all the available data. To knowingly publish a review that excludes 8 relevant studies because they weren't willing to wait until they had got hold of the data seems irresponsible.

The Cochrane reviewers could easily have waited until they got the data before publishing their review. Roche could easily have published the study reports, in full, on their website. However, as it is, neither side did the things that they could easily have done to give us a reliable answer to the question of whether oseltamivir prevents complications of flu. So the rest of us still don't know whether or not it does.

All in all, a bad day for science.

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This article is an edited version of a blog that was previously published on my website.

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Word macros: A free resource

Macros are a useful aid for editing files in Word. After spending 20-odd years writing, editing and publishing using Macs and Acorns, **Paul Beverley** (paul@archivepub.co.uk) thought that other writers and editors might like to benefit from his development work. He has written a book about using Word macros which is downloadable without charge from his (advert-free) website at: http://www.archivepub.co.uk/TheBook. The book is an invaluable resource even if you are not a technical whiz kid. It explains the basics under the headings: What is a (Word) macro? Why use a macro? How do I run a macro? What jobs can macros do? Installing a macro.

But if you are a technical whiz kid he suggests that you skip these sections and go straight to "My Ten Best Macros".

Definitions box

Potency

The term potency is one of the most misunderstood and misused words in medicine. It clearly has something to do with the power of a drug, and the International Union of Pharmacology (IUPHAR) defines potency as: 'An expression of the activity of a drug, either in terms of the concentration or amount needed to produce a defined effect, or, less acceptably, with regard to the maximal effect attainable. An imprecise term that should always be further defined.'[1] A potent drug is therefore a drug that is effective at a low dose or low concentration (high dilution).

There are a number of ways of expressing potency numerically. The commonest is as the reciprocal of the dose (or concentration) that produces a defined effect, usually half the maximal effect. The dose (concentration) that produces half the maximal effect is the ED_{50} (EC_{50}), so that the potency is $1/ED_{50}$ (or $1/EC_{50}$). The units are those of a dilution (mol^{-1} for a dose or $L..mol^{-1}$ for a concentration). A more precise term is the pD_2—an exponent system (like pH) defined as the negative logarithm (to the base 10) of the dissociation equilibrium constant or K_A. (The K_A is defined as the molar concentration of the drug that causes 50% of the receptors to be occupied at equilibrium). For example, if the K_A of a drug is 10^{-9} $mol.L^{-1}$ (i.e. 1 $nmol.L^{-1}$), its pD_2 is 9.0. The more potent a drug is, therefore, the higher will its pD_2 be.

Interestingly, in homeopathy, the term potency is used to define how dilute a particular preparation is. Starting from the Mother Tincture (an alcoholic solution or extract of the original material), serial 100-fold dilutions are made with distilled water. Each of these dilutions is referred to as a potency. Thus, a preparation at the tenth potency has been diluted 1 in 100 ten times. For example, starting from a Mother Tincture at a concentration of (say) 1 $g.mL^{-1}$, our preparation at the tenth potency would have a concentration of 10^{-20} $g.mL^{-1}$. Homeopathic remedies are commonly used at the thirtieth potency, which, starting from our 1 $g.mL^{-1}$ Mother Tincture, would be 10^{-60} $g.mL^{-1}$. Homeopathic remedies are therefore the safest medicines available as they are, by their very nature, completely incapable of producing any adverse effects.

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1 *Pharmacol Rev* 995;47:255–266

Lisbon—The 3-D city

by Geoff Hall

When I heard that the venue for EMWA's 30th conference was Lisbon. I was confused. No, that can't be right. Lisbon was 2003. Where are we really going? Lisbon confirmed, I was frankly delighted. The 2003 conference took place in the modern outskirts of Lisbon. The 2009 spring conference really is closer to the heart of my favourite city. Favourite city? What about Paris? Rome? Swindon? Terrific cities, with great charm and history, but Lisbon edges it for me. (OK, so I wasn't serious about Swindon.)

Lisbon has a lot going for it; European capital with an Atlantic coastline and beaches within a few minutes of the city centre. A visitor to Lisbon can enjoy the history of one of the great centres of former European power in the morning and a visit to a charming resort in the afternoon. So let me introduce you to the city.

I visited Lisbon for the first time on my honeymoon in 1971. (Those who know my wife will deduce that this must have been a different one as Pat is too young to have been married for 39 years—and who could put up with me for more than 40?) In those days, the dictator Salazar ruled Portugal. The impressive 25th April suspension bridge across the Tagus was the Salazar Bridge and life was lived at a gentler pace. A new Mercedes was a rare sight. Today, Lisbon is the capital of an important EU state and, thanks in part to EU development cash, the traffic barely moves on Friday evenings.

Hotel Tiara Park Atlantic hosts the 2010 EMWA spring conference and so this is probably the best place to start this quick guide to the city. Step outside the door of the hotel and you will find the *Eduardo VII* (Edward VII) Park—named after the British king (1901-1910) to mark a visit and as a reminder of the long and friendly association between these two countries. Look south from the park and you will get an instant picture of the topography of the city centre; a broad, steep-sided valley.

Eduardo VII Park is located on the north side of Marquis Pombal Square at the head of the impressive Avenida da Liberdade.

A little history here. Marquis de Pombal is regarded as one of Portugal's greatest statesmen. A statue to him stands in the square. He is so highly regarded because of his response to one of the blackest days in Portugal's story—1st November 1755. Out in the Atlantic, one of the most powerful earthquakes in European history caused instant devastation in the capital and throughout southern Portugal. Occurring on the Christian feast of All Saints' Day meant that thousands perished in church as ancient buildings collapsed on their heads. A while later, survivors were mesmerised to find that the sea retreated leaving the wide Tagus River empty, revealing centuries-worth of lost shipping and cargoes. Today, we would recognise this as the precursor of a tsunami. The parts of the city that avoided devastation by the ensuing flood were soon ablaze. Lisbon was destroyed. The man who masterminded its reconstruction was the prime minister Sebastião de Melo, later the Marquis of Pombal. Readers with an interest in architecture might enjoy researching 'Pombaline style'.

Back to our view. To the east (the left in the view from the park) rises the rock on which you will find the Castle of St George and the most historic part of the city, Alfama. The western side of the valley is steeper, the districts Chiado and Bairro Alto—the upper town. In between, the valley floor, and towards the river, the Baixa, is the main commercial centre. A leisurely stroll south down the *Avenida da Liberdade* will take you to some of the main squares of the city.

The Squares

First, the *The Praça dos Restauradores* (Restorer's Square) dedicated to the restoration of the independence of Portugal in 1640 after 60 years of Spanish domination, is home to the architecturally distinguished Rossio railway station. (This is where you can catch a train to Sintra, a world heritage site with its royal park and palaces Sintra is about 45 minutes from Rossio Station.) Close by you can find the *Elevador da Glória* (Glória Funicular) that will take you to the high town, Bairro Alto. Next, wander into the *Praça Dom Joao da Cámar* where you will find the original facade of Rossio Station.

Next, *Praça de Dom Pedro IV*, commemorates Portugal's first liberal king. The square is known simply as Rossio. The 'Heart of Lisbon' is the centre of the city and home to cafés, bars and a hubbub of commercial activity. To the east, is the smaller *Praça da Figueira*, a more comfortable size for sitting at a pavement café than Rossio it is also an important focal point for travel round the city with bus, metro and tram stops.

Baixa

Pronounced *by-sha*, Baixa is the Pombaline grid of streets between Rossio and the *Praça do Comércio* on the waterfront. The buildings are both delightful and, for their era, remarkably advanced in resistance to the effects of earthquake. Someone, perhaps Pombal himself, thought it a good idea to dedicate some of the north-south streets to particular trades. I know of at least one EMWA member who will be hoping that the tradition still holds true for *Rua dos Sapateiros*. Not so, sadly, but this street, spanned at its Rossio entrance by the decorative arch *Arco do Bandeiro*, is a good choice for a route south to the river—traditional cafes, cheap restaurants, Art Nouveau and an Indian tandoori restaurant for when you've had enough of Portuguese food.

However, my route of choice would always be the *Rua Augusta*. Pedestrianised and with a wealth of shops and boutiques. You will know you've found it as you look to its far end past pavement cafes to the dramatic triumphal *Arco da Rua Augusta*. I recommend that visitors make at least three stops during their walk down the street—in addition to the open-air cafes. (Incidentally, I have discovered that Portuguese waiters don't understand the English expression 'small brandy' when ordered with coffee as a morning livener. Fortunately, I've never troubled to learn the pronunciation of the Portuguese expression '*conhaque pequeno*'.)

First stop, a crossing road *Rua de Santa Justa*. Turn right, to the west, and you have a great view of the structure that guides often call Lisbon's Eiffel tower—the *Elevador de Santa Justa*, which takes passengers up a level to the charming *Largo do Carmo* in the lower part of Bairro Alto.

Turn around to face the east, and you'll be rewarded by a glimpse of the city's guardian, the *Castelo de Sao Jorg*.

To the right and beyond the castle is the most ancient part of the city Alfama. Walk on down *Rua Augusta* and another key crossing is *Rua da Vitoria*. Turn to your right here to look west and you will see what looks like the mouth of an enormous concrete cave. It is in fact one of the two entrances to the Baixa-Chiado metro station that links the blue and green lines of the system, making it one of the most important transfer stations. Wait a minute, you might think. If Baixa and Chiado are two distinct districts, how can they share a metro station? The answer is simple in

Elevador de Santa Justa

St George's castle from the top of the Elevador de Santa Justa. (Taken on my visit 25 January 2010—and the weather really was as good as it looks)

>

> this 3-D city. The two entrances are not far apart on a map but they are at quite difference altitudes. The station's impressive cascade of escalators provides an energy-saving, speedy and free way of travelling between the levels.

The next point at which to stop on the stroll down *Rua Augusta* is *Rua da Conceiçao*. This is an important point in the city, as it is one of the most convenient places to board the 28 tram. The 28 tram (*electrico*) runs from here to the west, up into Chaido and then down to the waterfront close to the *Cais do Sodré* railway station.

The cascade of elevators linking the Baixa and Chiado entrances of this important metro station provide a free ride between the districts

In the opposite direction the 28 tram visits some of the most picturesque sights and interesting locations in the city. These small classic yellow trams are old and quirky; and the few of the old style that remain, go up and down through the narrowest streets. A cheap travel card allows passengers to hop on and off tram No. 28, other trams and underground metro all day. (See Getting about.)

Ask the driver to let you know when to get off for Castilo. *Largo da Santa Luzia* is best. Then it is but a short uphill walk to enjoy the stunning views from the *Castelo de São Jorge* and a historical treat. A few stops further on, brings the 28 to the edge of Alfama and close to Lisbon's best known street market—The *Feira da Ladra* (Thieves' Market) beneath the National Pantheon on Tuesdays and Saturdays. Flee market sums it up, but it's worth a visit and is open conveniently for those arriving for the conference early or adding the weekend to the trip.

Alfama

Alfama is Lisbon's most emblematic quarter and one of the most rewarding for walkers and photographers thanks to its medieval alleys and outstanding views. Its foundation of dense rock sheltered the area from the 1755 earthquake and the ensuing tsunami. Despite this and the frequent description of a walk through Alfama as a step back in time few, if any, of its delightful buildings predate the Christian re-conquest—although the Moorish influence is everywhere. With its narrow streets, tiny squares with sometimes surprisingly large churches, Alfama is a delight.

Chiado

Probably the most desirable residential area of the city, Chiado is an elegant shopping area with a delightful square and famous theatres, bars and cafes and the museum of contemporary art. There is also a museum of pharmacy. It is close to the *Elevador da Bica* that connects the area with the *Cais do Sodra* and its railway station. And it's all on the route of the 28 tram.

Getting about Lisbon

In this brief article, there simply is not room for a full description of Lisbon's potentially confusing transport system, and so I will make just one recommendation–the Sete Colinas card–and a mention. A ride on a bus, tram, lift or funicular costs €1.40. A single metro ticket costs €0.75. The Sete (7) Colinas (Seven Hills) card sold in the ticket kiosks of Carris and the Metro for €0.50, is a rechargeable electronic ticket that can be charged with a simple ticket, or with a combined ticket for the Carris (bus, tram and funiculars) and Metro networks. This costs €3.70 for one day. I bought mine in January 2010 in the lottery shop in the south-east corner of Rossio Square. €0.50 for the card and 3 days unlimited travel on the listed modes of transport—total €11.60. There is a dearer alternative that might suit some—the Lisboa card. This permits the use of all public transport facilities in the city and trains between Lisbon and Sintra or Cascais and also offers free entrance or discounts in monuments, museums or tourism circuits. The prices are €15 for 24 hours, €26 for 48 hours and €32 for 36 hours.

Cais do Sodré railway station

Trains from here connect Lisbon along the sophisticated Estoril coast to the fishing village turned popular resort, Cascais, passing tourist favourites at Belém, the Jerónimos Monastery, and the the *Torre de Belém* its defender. Without leaving the train, you get a nice view too of the Monument to the Discoveries, erected in 1960 on the 500th anniversary of the death of Henry the Navigator, the instigator of the Portuguese adventures into the unknown.

The bronze statue sitting at a table in front of Lisbon's most famous coffee shop Café A Brasileira in Chiado is the poet Fernando Pessoa: born June 13, 1888—died of cirrhosis 30th November 1935. The service must have been better then. Pessoa is the one on the left.

Bairro Alto

The upper town, to the north and west of *Chiado*, is the place to find many of the best restaurants, several of which feature traditional *fado* singing in the evenings, bars and clubs.

Praça do Comércio

We end our stroll down the spine of the city. Passing through the impressive 19th-century triumphal arch we reach its historic entrance—Commerce Square—once the main maritime portal to Lisbon. Normally one of the most majestic sites of Lisbon, when I visited at the end of January 2010 it was a bit of a building site. Let's hope they've finished by May. The old marble steps leading up to Commerce Square from the River Tagus are a reminder of countless merchant sailors would have come to pay duties and trade. Its other name, Palace Square, comes from the palace that was located here for 400 years, until the 1755 earthquake.

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Special rates at Lisbon hotels for conference delegates

EMWA has secured a special rate at three hotels for conference delegates:

Tiara Park Atlantic Hotel

A special rate of €150 per room, per night for a deluxe single occupancy bedroom, has been secured at the conference hotel. This rate includes a buffet breakfast, taxes and service. In order to book a room, please download the booking form using the link below. Once you have completed the form, please return the form to the Tiara Park Atlantic, either by fax + 351 21 389 05 00 or e-mail sofia.fecha@tiara-hotels.com.

Sana Lisboa Park Hotel

The Sana Lisboa is located within 15 minutes walking distance, of the conference hotel. EMWA has secured a rate of €125 for a single room and €135 for a double room. This rate is per room, per night, and includes a buffet breakfast, taxes and service. To proceed with a booking, please complete the booking form, using the link below. Once you have completed the form, please return the form directly to the hotel by fax +351 21 00 64 345 or e-mail rebqt.lisboa@sanahotels.com.

Hotel Sofitel Lisbon Liberdade

The Hotel Sofitel, is located within 15 minutes walk of the conference hotel. EMWA has secured a rate of €135 for a single room, or €150 for a double room. This rate is per room, per night, which includes a buffet breakfast, taxes and service. To proceed with a booking, please contact, Ms. Rita Afonso using the following e-mail address: h1319-sl@sofitel.com and quote EMWA to secure a room under this special rate.

These details can also be found on the booking form available on the EMWA website: www.emwa.org

Share a room: Would you like to cut expenses and share a room at the conference hotel with another delegate? To find out more log in at http://www.emwa.org/component/option,com_facileforms/Itemid,105/

'News'

The word 'news' came from the first letters of the words North, East, West, South. This is because information was being gathered from all different directions.

Register for the 30th EMWA Conference in Lisbon on http://www.emwa.org/Lisbon-2010.html

In the bookstores ...

Holiday reading for medical writers

Victoria Hislop: The Island. Headline Review, 2006. ISBN 978-0755309511. *7.99 GBP. 496 pages.*

Leprosy is caused by a bacillus, *Mycobacterium leprae* and is treated today using a multidrug approach which includes dapsone, rifampin, and clofazimine taken for many months (http://www.who.int). However, until the mid 20th Century there was no cure or treatment. Historically, people were frightened to associate with lepers as the disease was considered extremely contagious and incurable. For this reason, leper colonies were founded and placed in isolated and remote locations.

Spinalonga, a now deserted small island off the island of Crete, and the site of a Greek leper colony from 1903 to 1957, was one of the last leper colonies in Europe. Today it is a tourist attraction and holidaymakers to this part of Greece can take a 10-minute boat trip to visit and explore the abandoned colony.

In this book we are introduced to the Petrakis family who lived in Plaka, a small village opposite Spinalonga, from which the boat serving the leper colony departed. Through the personal tragedy of the Petrakis family and their association with Spinalonga we are given an insight into what it was like to be a leper in Europe in recent times. The extreme measures people took to keep their disease hidden are described, and the consequences if they or a member of their family was identified as having leprosy are explored in the fictional story of the family. The feelings of shame associated with the disease, and as described in the book, are unimaginable today.

Identification of those with leprosy meant the almost immediate isolation of the person from family and friends. A description of a child with leprosy being forcefully removed from family and placed in the care of the Spinalonga leper community, with family contact only allowed by correspondence, is heart wrenching.

The community built their own houses, as well as administering their own infrastructure and shops including a bakery and café. Provision was made to teach children on the island school which the leper community had constructed. The day-to-day lives of people on the island are brought vividly to life by the author, and descriptions of characters conducting life as normal whilst never being allowed to leave the island are emotional.

The Spinalonga community had its own system of government and the struggles they had to undertake to receive adequate food, water, medical attention and financial support from the government are well documented through characters introduced by the author.

Although a work of fiction and a jolly good holiday read, you will learn something new about a disease area that, for many, is unfamiliar. I would recommend that you pack this book for your holidays along with some hankies if you are apt to weep while reading a moving and touching story.

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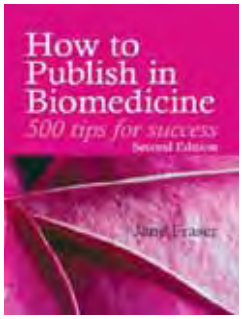
Leprosy today

Leprosy is believed to have originated in India and to have been brought to Europe in the fourth century BC by Greet soldiers returning to Europe from their wars in Asia. The disease persisted in Europe until the fifteenth century and then declined for reasons unknown. The number of cases in the world was subsequently dramatically reduced by the implementation of multiple drug therapy as recommended by the WHO's Action Programme for the Elimination of Leprosy established in 1994.

Although leprosy still exists, its treatment is an example of a drug industry success story in treating a disease that is related to poor socio-economic conditions. This is demonstrated by a leper colony set up in an isolated place in the Egyptian desert in the 1930s, similar to that on the island described in the book reviewed here. That colony, Abu Zaalbal, is now the largest leper colony in Egypt with 5,000 inhabitants. It is a thriving community with a bakery, mosque and even a prison. There is a school but none of the children who attend the school have leprosy, to the credit of the medical control service run by Caritas. In the 1930s people with leprosy were forcibly brought to the colony. But now people who come to the colony as lepers are reluctant to leave once cured not only because of the stigma that is still attached to the disease but also because of the excellent services provided at the colony. These, together with the job prospects in the colony, have attracted healthy individuals to move into the community. People with leprosy can now be treated as outpatients throughout Egypt. Accordingly Abu Zaalbal has been threaten with closure, a proposal that is met with strong resistance from the ex-lepers living in the colony.

Source: Knell Y. Egypt leper colony grows into successful community. Available at http://news.bbc.co.uk/2/hi/middle_east/8521577.stm

500 writing tips from an expert



Jane Fraser: How to Publish in Biomedicine: 500 Tips for Success (2nd edition). Radcliffe Publishing, 2008. ISBN 978-1846192630 (paperback). 20.00 GBP, 25.00 euro, 191 pages.

I bought Jane Fraser's *How to Publish in Biomedicine: 500 Tips for Success* (2nd edition) sight unseen and thought that I was buying another book on preparing scientific manuscripts. And I did but I also got much, much more. Ever wish that you could follow a senior medical writer around for a week to glean jewels of knowledge that only the experienced can impart? If your answer is yes, then this is the book for you.

Jane Fraser is a research scientist who moved out of the lab and into writing when she realised that she enjoyed writing about science more than doing it. She has decades of experience in publishing, and since 1991 has been training other scientists to be better and more effective writers. Reading her book, you feel her mentoring personality reaching out to you: she wants to tell you every titbit. Jane holds nothing back, but I guess that's obvious from the title—after all 500 tips are a lot.

The book itself is a slim 200 pages or so, organised in 33 chapters. It might be more correct to call them topics because each is about five pages with none running longer than eight pages. This system of many short topics makes it easy to find the information you want when you are in a hurry. Each topic includes a brief introduction followed by several bullet points in declarative form that address the reader. For example, a tip on tables: do not leave cells blank. Jane goes on, in three to five sentences, to explain why and tells you what you should do. Short, succinct and effective.

About half of the topics cover research papers, from planning to dealing with reviewers' comments. The book then moves on to other types of writing, including theses, books and informal science writing. Jane's advice that writing for informal newsletters and magazines can be "great fun" inspired me to submit a short piece for an internal company newsletter. It was indeed fun to write, and I never had so many colleagues interested in my work before. The final topics are on clear and correct writing, the mechanics of writing and useful tools for writers. Practical word lists suggest simpler terms for more complicated ones. Jane takes a positive and light-hearted approach to writer's block and time management with her tip on breaking your work down into manageable chunks: an elephant is easier to eat if you slice it first.

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Industry vs patient perspective

Dear TWS

Juliet Roberts' article on patient compliance published in the last issue of *TWS* [1] is very relevant to the world of diabetes as 'compliance' is such a cornerstone of treatment. However, the article is written from an industry perspective. For example the term 'patient compliance' is very much based on the bio-medical model and paints a picture of a passive patient doing as he/she is told. Currently there is movement towards self-care with the patient taking control of his/her treatment. Even the term 'patient' is frowned on in diabetes, it's 'person with diabetes', i.e. the disease does not define the person. Although the article does not focus on this area it would have been good to see an acknowledgment.

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Reference:
1. Roberts J. Patient compliance: New media tools to help patients take their medications. *TWS* 2009;18(4):218-220.

Note from the editor: Big brother pills are on their way. Government requirements that pharma companies prove their medications are effective in practice looks set to push forward technology that ensures compliance. One company, Vitality, has developed a cap for pill bottles that telephones patients who forget to take their pills. Novartis is reported to be negotiating a deal with the start-up Proteus Biomedical to acquire rights to their 'smart-pill' technology. The pill swallowed by the patient contains an edible device which is activated by stomach fluids to send wireless signals to a chip in a patch on the patent's skin or implanted under the skin. This chip in turn sends a message via the Internet to the doctor. The doctor thus receives information as to whether the patient is taking pills as prescribed and if drugs are causing any adverse reactions with other medications taken by the patient. The big brother pill spying on the patient from within might not go down too well with some patients.

Write a book review for *TWS*

If you would like to start writing articles for journals but you do not know how and where to begin, I can recommend getting started with a book review. The first articles I ever wrote were book reviews. *TWS* not only accepts reviews of books relevant to medical writing but, as you will see from one of the excellent reviews in this issue, also books that medical writers might like to read in their leisure time. If you have read a book that you would like to review or you have spotted a new book that *TWS* could obtain for you to review, please contact me, Elise, at editor@emwa.org.

Journal watch

GPP2 guidelines: Recommendations for good publication practice in biomedical research

by Nancy Milligan and Adam Jacobs

This edition of journal watch focuses on the new good publication practice guidelines (GPP2), which were published by the International Society for Medical Publication Professionals (ISMPP) in the *British Medical Journal* in November last year [1]. GPP2 updates the earlier guidelines [2] and makes recommendations that aim to "help individuals and organisations maintain ethical practices and comply with current requirements when they contribute to the communication of medical research sponsored by companies". The guidelines apply to peer reviewed journal articles and presentations at scientific congresses.

Methods used to develop GPP2

Briefly, the ISMPP recruited a steering committee from ISMPP members with more than 10 years experience in biomedical publishing. The 14 volunteers considered the original guidelines and reviewed new literature on the subject before drafting the new guidelines after discussion. The steering committee recruited (by invitation and open requests for volunteers) an international consultation panel of 193 people, who reviewed the draft guidelines and submitted comments on them. Members of the steering committee assessed and ranked the comments based on their frequency, their critical or beneficial rating, and their importance. The comments were then used to create the final guidelines.

Role of medical writers

We were pleased to read that the new GPP2 guidelines support the valid role that professional medical writers can play in the communication of medical research, and we were especially pleased to see the declaration that medical writers, if they are properly acknowledged, should not be considered ghostwriters. The guidelines go on to give advice to medical writers when working with authors; in essence, writers should ensure:

- Close collaboration with authors (for example, all authors should be aware of medical writer involvement; there should be direction from the lead author from an early stage of the project; authors should ultimately control and direct the writing; authors should review and comment on the outline and the subsequent drafts and approve the final version and any versions after peer review)
- Funding and potential conflicts of interest are declared
- Appropriate acknowledgment of medical writing contributions are made
- Authorship is attributed if appropriate (for example, if the medical writer has contributed extensively to literature searches and helped define the scope of the article)

The position of GPP2 reflects EMWA's own published guidelines on the legitimate role of medical writers in the development of ethical publications [3]; the EMWA guidelines are also referred to in the article.

Authorship and contributorship

GPP2 suggests that "particular care should be taken to attribute authorship and to acknowledge contributions appropriately". The guidelines recommend assignment of a lead author (to take the lead for writing and managing the work) and a guarantor (to take overall responsibility for the integrity of a study and its report); the lead author and guarantor can be the same person. They also recommend using the International Committee of Medical Journal Editors criteria for authorship [4] to attribute appropriate authorship for a piece of work. Briefly, to be considered an author, each individual "should have participated sufficiently in the work to take public responsibility for appropriate portions of the content" and have made "substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data"; been involved in "drafting the article or revising it critically for important intellectual content"; and have given their "final approval of the version to be published" [4]. GPP2 states that all listed authors should fulfil these authorship criteria (if not, they would be considered a "guest author") and all those who fulfil the criteria should be listed as authors (if not, they would be considered a "ghost author").

GPP2 goes on to support the use of a contributorship model to describe exactly who did what during a project, and therefore hopefully help to avoid any ambiguity. It is suggested that clear, concise descriptions of the role of each individual contributor (including but not limited to the authors) are made in an acknowledgement within the article or presentation. Individual contributions could include study conception or design, conceiving the idea for an article, conducting or managing a study, data collection, statistical analysis, data interpretation, analysis of published literature, drafting a manuscript, critically reviewing a manuscript, and manuscript approval. We would normally expect the contributions a medical writer makes to be acknowledged in this way. It is also important that each individual gives their permission to be acknowledged.

Acknowledgements and conflicts of interest

GPP2 recommends that all articles and presentations include an acknowledgements section, which should fully recognise author contributions and contributions of all individuals not listed as authors, such as medical writers (as discussed

more fully in the section above); the involvement of the sponsor in the study and its reporting; and the funding sources for the research and reporting (which would include funding of any medical writing services).

It is also recommended that authors disclose all potential financial and non-financial conflicts of interest that could inappropriately influence or seem to influence professional judgement.

Other features of the guidelines

The updated guidelines also make some other specific recommendations on:

- Roles and responsibilities: companies should produce at the earliest opportunity written agreements that describe their obligations for good publication practice and clearly layout the responsibilities of sponsors, authors, and other relevant contributors
- Access to data: sponsors should provide authors and other contributors with full access to study materials including protocols, statistical analysis plans, statistical reports, data tables and listings, and clinical study reports
- Publication steering committee: it might be useful to form a steering committee of authors, investigators, and other contributors to oversee the publications and presentations from a study; they also suggest that steering committee members may become authors, but membership does not automatically confer authorship
- Specific types of projects: authors should be explicit about whether articles or presentations are primary or secondary and care should be taken to avoid duplicate publications; journal or congress guidelines should be followed; review articles should be comprehensive and clearly describe the methods used for searching, selecting, and summarising the information; established reporting standards such as CONSORT, STARD, STROBE, PRISMA, and MOOSE [5] should be followed
- Publication planning, registering, posting, and documenting: using a publication plan can help ensure appropriate, efficient, and complete communication of study results; sponsors should follow relevant legislation and guidelines on registering and posting clinical trials; companies should implement policies detailing the types of documentation to produce and retain during a study and reporting

Finally, GPP2 provided a checklist that they recommend following to ensure good publication practice for articles and presentations. The checklist included five areas for consideration: integrity, completeness, transparency, accountability, and responsibility.

Response from EMWA

In a rapid response to the article, Adam Jacobs (EMWA Press Officer) and Helen Baldwin (EMWA President) applaud the updated guidelines and the advice they give for promoting ethical publication standards. They do however bring up two areas of concern. Firstly, they noticed that the recommendation published in the original GPP guidelines that "companies should endeavour to publish the results from all of their clinical trials of marketed products" appears to be missing in GPP2. They argued that to avoid publication bias that it is important that both positive and negative results are published. Secondly, they were concerned that the role of the publication steering committee described in GPP2 was ambiguous, suggesting that they appear to allow for the possibility that employees of the sponsor company could be members of the steering committee without being authors of the publication. This seems to be dangerously close to ghost authorship and therefore Jacobs and Baldwin suggest that it is important to ensure that sponsor employees should either be named authors or, if not, they should have no input into the content of the publication.

In response to these concerns, the GPP2 authors agreed that ghost authorship is unacceptable and point out that contributorship statements should be used to describe exactly who did what.

Was it worth it?

The GPP2 guidelines were developed following an extensive consultation process involving a great many people and considerable effort. It might be reasonable to ask what this effort has achieved in improving on the original GPP guidelines. In truth, the answer is probably "not very much". Yes, some things are new, for example the recommendation that authors are not paid an honorarium for being authors. However, none of the new items is really earth-shattering, and not all the items listed in a "what's new?" box within the guidelines are even new anyway (for example "contributorship guidance recommends describing the role of the sponsor", which was already recommended in the original GPP). However, one thing that is new is that the guidelines were written under the auspices of ISMPP, so even if the GPP2 guidelines have not moved the cause of publication ethics greatly forward (although of course it is always helpful to restate ethical principles and make it more likely that they will be widely known), they have certainly succeeded in generating publicity for ISMPP.

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4. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. www.icmje.org.
5. EQUATOR Network. Library for health research reporting. www.equator-network.org/resoruce-centre/library-of-health-research-reporting/.

Out on our own

This section is very brief in this edition. We received no articles for publication and have not yet prepared a report on the Freelance Business Forum in Frankfurt.

Freelance Support Centre

We would like to thank Neil Fisher, Ingrid Edsman and Shanida Nataraja very much for all the work they put into the Freelance Support Centre, which was recently launched on the website. We hope this will form the basis for a continually growing resource for new and experienced freelancers, and are looking forward to receiving suggestions as to how it can be expanded.

Freelance Business Survey 2010

The Freelance Business survey was launched in the second week of February by an email to all members and an announcement on the website. If you are a freelancer or do freelance work, please take the time to respond to the survey by following the link on the website. The survey is open until 31 March 2010.

Discussion Forum on website

All members were also informed by Shanida and Head Office that the discussion forum on the website now has an RSS feed facility, which means that once you have set up this facility, you are informed when new messages and answers to messages are posted. Freelance members have often asked for this type of discussion forum before and the RSS feed facility is easy to set up, so now it is your chance to make full use of this opportunity of fielding questions and discussing them with an audience of almost 1,000 colleagues (if all members sign up, that is)!

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How old is the word 'freelance'?

Although 'freelance' was originally used to mean a 'medieval mercenary warrior' the word does not date back to the Middle Ages but was coined by Sir Walter Scott in the nineteenth-century. He first used 'free lance' (as two words) in his medieval novel *Ivanhoe* (1820) to describe a man who did not serve any particular lord, and whose services could be rented by anybody.

The word was first used figuratively in the 1860s to mean 'a person (as a politician) who contends in various causes without being attached to a particular group'. The use of 'freelance' referring to a writer arose by the 1880s, and the verb 'to freelance' by around 1900.

Source: http://www.randomhouse.com/wotd/index.pperl?date=19960617

TWS call for articles about women

The cover of the first 2010 issue of *The Economist* sported the question "What happens when women are over half of the workforce?" The question was prompted by the imminent event of women crossing the 50% threshold to become the majority in the American workforce. As the medical writing profession has long been in this happy situation *TWS* is calling for articles about women and medical writing.

Please send articles, letters to the editor and suggestions for individual articles or future issue themes to me, Elise, at langdoe@baxter.com.

Anybody there?

The Radisson Blu Scandinavia Hotel in Copenhagen exhorts visitors to their website to do the following: *Need help? Call our toll-free number and speak with a live person*!

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Useful websites for regulatory writers

http://www.ema.europa.eu/
For information on Guidance documents, EPARs, Orphan Drugs, Paediatric Investigation Plans, Centralised Procedures and EMA News (EMA is the new name for EMEA by the way). There are links to the homepages of all EU competent authorities from this page.

http://www.hma.eu/
For information on European Regulatory Procedures (DCP and MRP). CHMP Good Practice Guidance, Q&A documents.

http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/index_en.htm
For EudraLex—Notice to Applicants with links to relevant legislative documents in all EU languages.

http://www.mhra.gov.uk/index.htm
For MHRA Guidance, Q&A documents, and now has a special industry page.

With thanks to **Susan Bhatti** (Susan.Bhatti@premier-research.com) for providing this list.

Phytotherapy—An introduction

by Karin Eichele

Phytotherapy is defined as the use of plants or plant extracts for medicinal purposes. Herbal medicines usually refer to plants that are not part of the normal diet.

Herbal medicines have a tradition of thousands of years. Just think of Hippocrates and Galen. Ancient Greek and Roman medicinal practices made use of plants. The ancient medical knowledge was preserved in the monasteries of the Middle Ages. These were once the centres of medical expertise and with their herb gardens provided the source for medicinal preparations. In the centuries following the Middle Ages, university scholars dealt with the topic of herbal medicines. Herbal medicines always played an important role in traditional medicine. However, chemical entities replaced more and more the traditional herbal medicines system and they became the standard practice of the twentieth century.

But even in modern medicine, phytotherapy plays a role. Nowadays, the importance of phytotherapy is again increasing. Many patients prefer herbal medicines and especially value the good tolerability. Furthermore, herbal medicines are now approached far more scientifically. Results from clinical and preclinical studies are meanwhile available for some traditionally used remedies. Modern herbal medicinal products fulfil high standards and are subject to clinical development plans establishing their efficacy and safety. Organisations like the European Scientific Cooperative On Phytotherapy (ESCOP: www.escop.com) aim at advancing the scientific status of phytotherapy. The herbal monographs published by ESCOP are established sources and are accepted by European regulatory authorities.

I have put together a selection of websites and databases of plants used for herbal medicines where you can find useful information on their historical use, indications, safety and chemical composition.

www.herbalgram.org
The homepage of the American Botanical Council is one of the most reliable sources on the Internet regarding herbal medicines. The monographs published by the council are produced by an expert committee formed by the German government to evaluate the safety and efficacy of more than 300 herbs and herb combinations. Most of the content is freely accessible. For full access, e.g. the English translation of the German Commission E monographs, you need to subscribe.

www.pfaf.org
"Plants For A Future" is a source centre for rare and unusual plants. It includes a large database of 7000 plants which are not all rare and unusual. Many are rather quite common and well-known. The database is not only limited to the medicinal use of plants, a useful summary of edible plants is also provided.

www.phytotherapies.org
This site was developed as a source for herbal practitioners. You can browse herbal drug monographs which summarize the historical use, current indications and dosing instructions, pharmacological actions, the major constituents, and reference to clinical or pharmacological studies. The database also allows a search by indication, pharmacological action or constituent. You have to register to access this information, however, this is free of charge.

www.ars-grin.gov/duke
Dr. Duke's Phytochemical and Ethnobotanical Databases focus on chemicals. Herbal medicinal products contain hundreds of potentially biologically active compounds. Surely it is not valid to extrapolate in vitro effects without further evaluation. However, these compounds, either individually or synergistically, exert physiologic roles and various pharmacologic actions contributing to the overall effect. The database allows the search for chemical constituents of a plant and provides cross-links to the pharmacological action known for the specific substance.

http://plants.usda.gov/gallery.html
The PLANTS Gallery is a US database with over 40,000 photos and drawings of plants. The gallery is not restricted to medicinal plants.

If you find a web site that should be mentioned in the next issue, or if you have any other comments or suggestions, please e-mail me at: karin.eichele@bionorica.de.

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'Rule of thumb'

'Rule of thumb' originates from an old English law which stated that you could not beat your wife with anything wider than a thumb.

Linguistics corner

Current medical discourse research

The Linguistic corner aims to publish abstracts of papers related to oral or written medical discourse of interest to the *TWS* readership. Abstracts are numbered consecutively to build into a series that can be saved as a collection. Contributions should be in English but can relate to papers published in other languages. Francoise Salager-Meyer invites you to send abstracts to her at: francoise.sm@gmail.com.

Medical research articles in the comparative perspectives of discipline and language

The traditional conception of scientific discourse as objective and neutral has been refuted in many and different analyses of academic discourse over the last decades. Even medical researchers, often described as the most 'objective' authors, produce articles that are both argumentative and rhetorical.

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Abstract 5

In: Gotti, Maurizio & Salager-Meyer, Françoise (eds.) 2006, Advances in Medical Discourse Analysis: Written and Oral Contexts.Bern: Peter Lang

The main focus of this paper is personal and polyphonic expressions as manifested in academic discourse. It is shown in which ways and to what extent medical research articles may differ linguistically and rhetorically from research articles taken from the disciplines of economics and linguistics. As regards the nature of medical articles, isolated from the discipline perspective, the paper also looks at similarities and differences between articles written in three different languages: English, French and Norwegian.

The reported observations stem from the KIAP project (short for *Cultural Identities in Academic Prose: language versus discipline-specific*) where the key research issue is whether cultural identities may be identified in academic prose, and, if so, whether these identities are language or discipline-specific in nature (www.uib.no/kiap). Studies of various linguistic and rhetorical features have been undertaken, with a point of departure in the hypothesis that discipline is more important than language as regards cultural identities.

In very general terms, the theoretical framework consists of the following orientations (from macro- to micro-level): Our point of departure is the rhetorical perspective on scientific discourse (Prelli 1989); at a more specific level, we take the genre perspective into consideration (Swales 1990; Hyland 2000). However, the main analyses are undertaken at the utterance level, to some extent inspired by the French enunciative approaches (Ducrot 1984); at this micro-level, one of our theoretical perspectives is the theory of linguistic polyphony, as developed in ScaPoLine (Nølke / Fløttum / Norén 2004).

The results show that there is not much direct personal presence and argumentation of the type *we argue* or *in this article we have shown* in medical articles. This does not mean that medical researchers do not argue. There are more subtle formulations which clearly indicate argumentation, for example expressions of polemic negation and concession. However, the quantitative findings reported in this paper leave no doubt that medical discourse in all the three languages studied here is less rhetorically explicit than economics and especially linguistics discourses are. Both personal presence and interaction with the readers are weaker in medical articles. This general observation is supported by the various qualitative studies undertaken.

Answers from 79-character sentence on page 35

1) No. *Either* is not wrong, but is not needed.

2) Has to be *or*.

3) Difficult. Those with *commatitis* (and their number is not small) would say that *rarely* should have a comma before and after. If the commas were there, I don't think I would 'edit them out' of a text, but if they weren't there, I wouldn't 'edit them in'. In other words: both are OK. This is OK for a single adverb, but if the modifier were longer, e.g. *in an unexpected 12% of cases*, then you need to separate this adverbial phrase off from the text with something. The choice is with brackets, commas or dashes. Since the 12% were unexpected, you would probably choose dashes here to highlight this. Or you could say *or 2000 mL/h in an unexpected 12% of cases*.

Citing Wikipedia and encyclopedias

A member of the World Association of Medical Editors (WAME) recently asked on the association's listserver [1] whether any journals allowed citations to Wikipedia. There were no replies from medical editors who said they did allow such citations in their journals. Matt Hodgkinson from BioMed Central pointed to articles in Wikipedia which explain that citation to Wikipedia in research papers is not acceptable because Wikipedia is not considered to be a credible source [2-4]. Researchers should instead read and refer to the original sources cited in the Wikipedia article. One article in Wikipedia about researching with Wikipedia [2] advises that you should be "wary of any one single source (in any medium—web, print, television or radio), or of multiple works that derive from a single source" and that "Wikipedia, along with most encyclopedias, is unacceptable as a major source for a research paper. Other encyclopedias, such as *Encyclopædia Britannica*, have notable authors working for them and may be cited as a secondary source in most cases. For example, Cornell University has a guide [5] on how to cite encyclopedias." This website also has a useful section titled "Citing materials from online sources".

TWS allows citation to Wikipedia in opinion pieces for general lay definitions but citation of original sources is preferable.

References:

1. http://www.wame.org
2. http://en.wikipedia.org/wiki/Wikipedia:Academic_use
3. http://en.wikipedia.org/wiki/Wikipedia:Researching_with_Wikipedia
4. http://en.wikipedia.org/wiki/Wikipedia:Citing_Wikipedia
5. http://www.library.cornell.edu/newhelp/res_strategy/citing/apa.html

Article metrics: The death knell of the impact factor and journals?

The impact factor of a journal is driven by a few highly cited articles [1]. One of the problems therefore with assessing a scientist for job promotion based on the number of articles he has published in high impact factor journals is that what is being assessed is the citation rates of certain articles in the journal rather than the quality of the scientist's paper itself.

The Public Library of Science recently developed a system of 'article level metrics' which are attached to individual articles. Juliet Walker, one of its board members, explains [2] the system by reference to the metrics attached to the most popular article ever published in *PLoS Medicine*: 'Why most published research findings are false' by John Ioannidis. A tab, 'metrics', at the top of the article shows not only how many times the article has been cited and in which databases and even blogs but also how many times the article has been viewed, and how many times it has been downloaded. Thus the interest a paper has created among readers who might not be writing papers and citing is also measured. This is a step closer to measuring the influence a piece of research has on the community. *PLoS* is keen to extend the system to mentions of papers in parliament and official reports. Juliet believes that because articles can be published quickly on databases, the metrics will dispense with the need for journals as a tool in assessing scientists, heralding the death knell of journals.

References:

6. Callaham M, Wears RL, Weber E. Journal Prestige, Publication Bias, and Other Characteristics Associated With Citation of Published Studies in Peer-Reviewed Journals.*JAMA.* 2002;287:2847-2850.
7. http://blogs.bmj.com/bmj/2009/11/02/

richard-smith-the-beginning-of-the-end-for-impact-factors-and-journals/

Peer review: Pressure to publish reviews

A group of 14 stem cell researchers have written an open letter to the major scientific journals complaining that important research in their field is not being published whereas papers that hardly advance knowledge in the field are being published. They say that this is because a clique of rival researchers review the papers and either reject them or delay publication by asking for unnecessary experiments to be done so that they can publish their work first. A vast amount of public funding is channelled into stem cell research and continued funding depends on researches publishing their findings in scientific journals. It is suggested that competition between rival groups for grants engenders unscrupulous behavior. Competition between journals is another element which the group believes leaves editors depending on favoured reviewers who in turn submit their own papers to the journal. Accordingly editors dare not offend these reviewers for fear of losing their papers to a rival journal.

The solution proposed by the open letter is that the reviews leading to a paper's publication should be published as supplementary material online along with the paper. Spokespeople for both *Nature* and *Science* deny the allegations but do not appear inclined to publish reviews.

Source: Ghosh P. Journal stem cell work 'blocked'. Available at: http://news.bbc.co.uk/2/hi/science/nature/8490291.stm

Words, Grammar & Co

Too much plural

The event had no sequelaes. This is not surprising because events may have only 'sequelae' (Latin plural of 'sequela'). This is one Latin term in common use in our field where I make an exception to my (still personal and disputed) 'rule' that well-established Latin and Greek terms may just take an 's' or 'es' in the plural (viz. 'memorandums' or 'maximums').

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Un... or in... ? That is often the question

Languages teem with inconsistencies, and you only have to look as far as the negative prefix in English for a good example. We have a panoply of possibilities: *un.*.. (untouched), *in.*..(inept), *im.*.. (impervious), *ir.*.. (irreplaceable), *non.*.. (nonserious), and *a.*.. (asexual)—and I have probably missed a couple of other possibilities (such as *de.*.. and *dis.*.. in their wider senses). Even considering just *un.*.. and *in.*.., often only one is possible, sometimes both, and sometimes language shows a distinct preference for one or the other—even when using the same root word in a noun or an adjective. And sometimes the different prefix results in a (very) different meaning.

I was reminded of this recently when I edited a text which referred to *instable compounds*, which doesn't sound right (to me, anyway!), and automatically changed it to *unstable compounds*. Then vacillated a little. If we say *unstable* rather than *instable*, why do we say *instability* and not *unstability*? There is no answer to that. It is just a matter of usage. *The Shorter Oxford English Dictionary* lists *instable*, first recorded in 1483, as 'now rare', so it has almost become a dictionary word[1], but nobody can tell you why. *Instable* predated *unstable* (1549) by 66 years, but *unstable* has a much larger entry. So despite being a later arrival, in the subsequent 5 centuries, *unstable* won over *instable*. So much for adjectives.

For the nouns *instability* and *unstability*, we have the reverse situation. *Unstability* is in the dictionary but is definitely more of a dictionary word than *instable*, and does not sound right. Here, *instability* won the day and is definitely here to stay.

Nowadays, we can use computer searches, albeit unvalidated[2], to point us in the right direction in cases of doubt. And sure enough, Google broadly confirmed what *The Shorter Oxford Dictionary* says: 5.8 million hits for *unstable* and 0.5 million for *instable* (plus the question: Do you mean unstable?) and 4.8 million hits for *instability* and only 85,000 for *unstability* (plus the question: Do you mean instability?). *Unstability* therefore still has some users, but, in proportion, far fewer than those who use *instable*.

This is further complicated because the dictionary also gives *unstableness* and *instableness* as possibilities, but as far as I am concerned (and, I hope, all users of English) these are definitely dictionary words and have had their day (if they ever had one).

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New words and old feelings

So now we know. And all we medical writers have been waiting on tender hooks haven't we? The word of the year 2009 is 'unfriend'! This at least is according to those who took part in the vote held under the guise of the *New Oxford American Dictionary*. With this word and some others social networking websites made their impact on last year's words of the year list commissioned by Oxford University Press. 'Unfriend' means to remove someone as a friend from Facebook or a similar site. But for the meaning of 'tweetups', 'Zombie Bank', 'snollygoster', 'staycations' and more please look elsewhere [1]. I will just tell you about bossnapping because this might be useful to you. This is the action taken by employees to protest against redundancies and cutbacks by which they prevent senior managers from leaving company premises.

While we all excitedly await the announcement of word of the year lists—so that we can impress colleagues, bosses, pals at the pub, clients or whoever with our grip of the here-and-now—David Mitchell finds these new words dispiriting [2]. They remind him of his school days when teachers frowned on words like 'nice' and 'good' saying they were boring. Rather rich says Mitchell when he considers how boring school was. And he adds that "Slagging people off for saying "nice" and "good" is what leads to their resorting to "awesome"." (He seems a bit out-of-date here because I have not not heard 'awesome' once from my kids once recently. It seems to have been usurped by 'random.'') Mitchell's problem is that although we are usually told to use language correctly to avoid ambiguity there is little substance to this argument. For instance, he says

> "No one ever accidentally bought more potatoes than planned because they were told to buy less rather than fewer. Of all the times I've typed: "Hopefully see you then" in an e-mail, no one has ever subsequently complained that, when they saw me, I didn't seem hopeful."

He concludes that the rules do matter—it's just obeying them that doesn't. And the truth of the matter is when slang becomes correct, mispunctuation is overlooked and American spelling is adopted, he feels a mug for having learnt the rules. He could have been doing more exciting things at school.

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Reference:
1. Savill R. 'Tweetups' and 'unfriend' among Oxford English Dictionary's 'words of the year'. The Telegraph, 30 December 2009. Available at: http://www.telegraph.co.uk/news/newstopics/howaboutthat/6905776/Tweetups-and-unfriend-among-Oxford-English-Dictionarys-words-of-the-year.html
2. Mitchell D. Only a poltroon despises pedantry. *The Observer,* 3 January 2010. Available at: http://www.guardian.co.uk/commentisfree/2010/jan/03/david-mitchell-english-language-grammar

1 Dictionary word: in all languages, a word found in the dictionary which is obsolete, but which is retained in the dictionary so that its meaning can still be described.

2 This is a good example of the difference *in*... and *un.*.. can make. Something *unvalidated* has simply not been validated, but something *invalidated* has been validated and declared invalid (*unvalid* does not exist)

Do you really know the meaning of English's foreign words?

English has borrowed a vast number of foreign words but how well do you know them? Here are just a few common examples:

'Déjà vu' (French) was first used in a French translation of Sigmund Freud's *Psychopathology of Everyday Life* published in 1901 to describe a feeling that Freud suggested corresponded to the memory of a subconscious daydream. Now the term is also used to mean when an event feels similar to something that happened in the past.

'**Via**' is one Latin word for three English words (by way of). It implies more strongly than 'through' that a solution or destination has been arrived at by dint of a little detour.

'**Lingua franca**' (Italian) literally means Frankish language. Arabic speakers in the Middle East in medieval times referred to Europeans as Franks. The Frankish language was predominantly Italian with some Persian, French, Greek and Arabic words by which people of different native tongues could communicate with one another. The term lingua franca is now used for any common language spoken by speakers of different languages.

'**Kudos**' (Greek) means glory or renown. It's a singular noun in Greek and was first used in British English at the end of the eighteenth century. The Americans, however, assumed the 's' at the end meant it was a plural noun so they use the word 'kudo' unless someone has received more than one accolade in which case it's kudos.

A '**a prior**' (Latin) idea or argument is one based on inherent knowledge rather than fact. 'A posterior' is the opposite, knowledge gleaned through experiment or experience.

Finally be careful when you ask for an '**alfresco**' (Italian) meal in Italy. It might mean 'in the fresh air' in English but in Italian it is slang for 'in prison'.

Source: Rhodes C. A Certain Je Ne Sais Quoi. London, Michael O'Mara Books Limited, 2009; ISBN: 978-1-84317-364-9

An excellent article on manuscript writing— For what it's worth

'Right your writing. How to sharpen your writing and make your manuscripts more engaging' has to be read (fortunately it is Open Access)[1]. The reason it has to be read is because it gives some excellent examples of paragraphs as originally written and edits them to show how to introduce concepts gently, ensure each sentence is a consequence of the preceding one, avoid long strings of modifiers, avoid lazy verbs and ensure each idea has its own sentence. The improvement wrought by the editing epitomises the difference between good and poor science writing.

The article also sets outs some writing rituals suggested by Margaret Cargill (see book review in *TWS*'s volume 18 (4) page 245) and Tara Gray: build your paper around the results, rather than setting aside chunks of time write daily for 15 to 30 minutes, log your time to motivate you to keep up your writing, post your thesis on a wall to keep it in your face and make it easier to change and edit your thesis, use topic sentences to concentrate the mind, send early drafts to non-experts and read out loud to improve the tone, flow and logic of an argument.

However, on a disheartening note, William Penrose wrote an online comment on the article: "it's always seemed to me that the standards they [language experts] deplore are actively enforced by the science community. By the time co-authors, associates, internal editors, department managers, institutional editors, and journal reviewers were done with my writing, the same old polysyllabic words, passive voice, overly cautious conditionals, and dead words were all put back in. I think the notion that turgid prose is somehow more intellectual and intimidating is woven right into our scientific culture."

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Hoping for a hyphen

The following sentence was spotted in the *BMJ* [2009;339:b5448 (19 Dec, p 1385)] by **Neville Goodman** (nevwgoodman@mac.com) who had to stop at 'dependent' and re-read the sentence. It needed a hyphen.

"We have developed a list of 25 technique dependent physical diagnostic manoeuvres that we teach to our trainees."

Alzheimer's disease or Alzheimer disease?

An eponym is a name of a disease derived from the person who discovered the disease. Alois Alzheimer, a German physician, is credited with the discovery of this debilitating disease in 1904 when he present the case of a 51-year-old woman who had shown severe memory loss and whose brain was found on autopsy to be shrunken and to have abnormalities.

A recent debate about whether eponyms should be abandoned is outline by Narayan and colleagues in their paper reporting their research on the frequency of use of the words 'Down's syndrome' and 'Down syndrome' [1]. Those in favour of abandoning eponyms argued that they >

1 Grant B. Right your writing. How to sharpen your writing and make your manuscripts more engaging. *The Scientist* 2009;23(11):65-69. Available at: http://www.the-scientist.com/article/display/56104/

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> "lack accuracy, lead to confusion, and hamper discussion in a globalised world". The motion's opponents argued that eponyms are "often practical and form a medical shorthand" and "they bring colour to medicine and they embed medical traditions and culture in our history". The researchers' concern was not however the dropping of eponyms but whether they should be written in the possessive or nonpossessive form. They conducted their study of medical books and journals in 1998 and again in 2008. A gradual shift from 'Down's syndrome' to 'Down syndrome' was seen over this period with the frequency of the possessive form more predominant in publications in European countries and that of the nonpossessive form more common in American publications. The researchers recommended the nonpossessive form should be used as the standard to avoid problems in literature searches created by inconsistency.

Reference:

1. Narayan J, Sukumar B, Nalini A. Current use of medical eponyms –a need for global uniformity in scientific publications. *BCM Medical Research Methodology* 2009;9:18. Available at: http://www.biomedcentral.com/1471-2288/9/18

Which is the world's hardest language? (or: How many 'we's' are there?)

Before coming to an answer to this question, an article in the *Economist* traces the elements that make a language difficult [1]. English is quickly dismissed as a relatively simple language which is just absurdly spelt.

On difficulty can be the diversity of sounds in a language. For example the sound 'ma' in English has four distinct sounds and meanings in Mandarin, which is relatively simple compared with other Chinese languages. Click languages such as Xhosa, a South African language, and the unusual sounds of !Xóõ spoken by around 1000 people in Botswana are probably the most difficult to speak. When it comes to grammar, Estonian has 14 cases including incessive, inclusive, elative, adessive, absessive. Then there are noun classes in some languages which go beyond male, female and neuter. The Peruvian language Bora has 350 classes of noun. Sometimes the logic that gathers nouns together in a particular class is not clear. For example the linguist George Lakoff described one class of the Dyirbal language (spoken in Australia) to include women, fire and dangerous things. Agglutination is another complication. The English 'antidisestablishmentarian' is nothing against the possibilities in Turkish. But there is more. In Kwaio, spoken in the Solomon Islands, 'we' is different depending on whether it is 'we two', 'we few' or 'we many' and each of these forms has further forms that are inclusive 'we including you' or exclusive. Verbs in some languages have endings that indicate the time something happened, the size of the object or position of the speaker.

The article concludes that Tuyuca of eastern Amazon is the world's hardest language, perhaps because in addition to a long list of the sort of complications already mentioned, verb-endings give information on how the speaker knows something, e.g. *diga ape-wi* means 'the boy played soccer (I know because I saw him)' whereas *diga apehiyi* means 'the boy played soccer (I assume)' and this, as the author points out, could be a journalist's nightmare.

As for the 'we's', John Page took the article to task in his letter to the editor [2] for suggesting that 'we' only has one form in English. He pointed out that 'we' has three meanings in English: we meaning you and I, as in 'we had dinner together'; the royal we meaning I, as in 'we are not amused'; and the marital we, as in 'we need to take the garbage out.'

Reference:

1. Tongue Twisters. *The Economist*, 19 December 2009 page 128-129.
2. Page J. Tongue bashing (letter to the editor). *The Economist*, 9 January 2010 page 13.

Appropriate hanging hyphen?

I think most of us now agree that the following use of the hanging hyphen has become acceptable in our types of text, in this case avoiding the repetition of *-based*: [1] *Drug X is available in an oil- or water-based cream vehicle*.

But what about the following: [2] *Up- and down-stream changes in processing have been made …* . My usual advice is that the hanging hyphen should be used only if the term is a hyphenated term, as with *oil-based* in example [1]. Because *upstream* and *downstream* are not hyphenated, I would prefer *Upstream and downstream changes …* in example [2]. But what about [3] *Up- and down-regulation were both observed*? I do not hyphenate upregulation or downregulation because the hyphen does not help the reader to understand the term or phrase (my major criterion for using hyphens; wherever possible I avoid them). But many authors prefer to hyphenate these two terms. Does this mean that example [3] would be acceptable in a text where both were hyphenated?

Any thoughts, *TWS* readers?

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Saying 'No'

Jan Freeman of the Boston Globe [1] tells us that it is 'nutty' to claim that you cannot say *I ate no bananas*. Proponents of this say that you should always say *I did not eat any bananas* because you can't eat *no bananas*. How complicated do prescriptivists want to make our lives? I agree with Jan Freeman. Of course you can eat *no bananas* because *no* is used here as an adjective meaning *not any*. Any

fool can tell you that! (Or can they?) But can any fool reading this answer this one: which is ***better***, [1] *No adverse events associated with the nervous system were observed* or [2] *Adverse events associated with the nervous system were not observed* (recent question in a training session). I have played around with these two in all sorts of contexts, and there may be extreme situations where one is preferable to the other because you can always find exceptions. However, I spontaneously go for [1] because I think it is good for the reader to see the negation up front, and this is just how we usually express this idea. But as for which is ***better*—**I don't know. Any thoughts on this?

Whatever—if you opt for starting with *No*, your subject is always in the plural in English—*No adverse eventS WERE observed*, and not *No adverse event was observed*, as in many other languages.

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Reference:

1. Freeman J. Rule by Whim. The Boston Globe. 21 December 2008.

How to sneer with inverted commas

When was the last time you saw *paperback* written with a hyphen? Our copy of *Norton's Star Atlas*, published in Edinburgh in 1966, tells us that "it was also intended to be used as a companion to Webb's invaluable 'Celestial Objects for Common Telescopes' (recently reprinted in America as a '*paper-back*') …".

In the meantime, the hyphen has disappeared uncontroversially from the word paperback on this side of the Atlantic. But the inverted commas around the word *paper-back* tell a different story. They are from the author and not from me, and are great evidence of how to sneer with punctuation marks. The author either meant "Look at the way those silly Americans write paperback—with a hyphen indeed!", or "This is a new-fangled American word which will never establish itself on our side of the Atlantic", or even "The Americans may use this adjective as a noun, but I disapprove, and it should be 'paper-backed' anyway".

Whatever, the author is suggesting that you should distance yourself from the expression. Fortunately, *Norton's Star Atlas* did not have a very wide circulation. We now all agree that paperback is a noun and an adjective without a second thought. This does, however, illustrate that you should be careful with inverted commas around terms, as they often—sometimes unjustifiedly—call the term they surround into question without the reason being clear to the reader.

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Business: Preview of *TWS*'s June issue and call for articles

It's been a long hard winter in Europe but spring is coming, a time to spring clean, grab new opportunities, and start initiatives. By popular demand, the theme of the upcoming June issue of *TWS* is 'Business'. A wide spectrum of topics relevant to medical writers whether working in large pharmaceutical companies, small medical writing businesses, CROs, medical communications or as freelancers will be covered by this theme.

Articles are lined up on methods of managing and developing businesses and projects, including innovative ideas on how bring in expertise in related areas and how to manage projects outside the traditional medical writing area. There will also be articles on harnessing the business potential of social networking through Twitter, Facebook, LinkedIn etc., important aspects of patents and technology transfer/business development, codes of compliance, and working in a CRO as well as coping with social isolation as a freelancer.

Do medical writers add value? One question of particular interest to every medical writer is whether our work in writing and processing documents actually adds value to the process. According to Art Gertel, intuitively we know that there are gains in quality, efficiency, and compliance with industry/journal standards when professional medical writers are deployed. But do we have evidence? You will be able to read Karen Woolley's article in the June issue to find out.

You are also welcome to submit an article on any other topic which you feel fits into the business concept. As always we are pleased to accept articles or short reports on subjects of interest to medical writers which are **outside** the theme of the issue. Remember not only is writing an opportunity for you to share your expertise with other medical writing professionals but an article published is a new addition to your CV. And *TWS* is happy to provide you with a pdf to post on your website.

Please submit articles (up to 2500 words) and short reports/boxes (up to 100 words) for the June issue to editor@emwa.org by 15th April.

Gained in translation

Science at the multilingual crossroads

"No two languages are ever sufficiently similar to be considered as representing the same social reality. The worlds in which different societies live are distinct worlds, not merely the same world with different labels attached."

Edward Sapir (1884–1939)

The article by Susan DiGiacomo in this issue of *TWS* highlights in many ways what translation is essentially about. Perhaps most important, translation is not a matter of language. Rather, translation takes place at the level of culture, with culture being whatever it is we know, perceive, or believe, how we behave, and what rules and conventions we adhere (or choose not to adhere) to.

The concept of culture was given a firm place in translation theory in the early 1990s [1]. The idea that there is an intricate connection between language and culture, language and thought, language and behaviour dates back to the widely travelled German diplomat and philosopher Wilhelm von Humboldt. His observations later gave rise to two rather conflicting philosophical perspectives—one maintaining that thought is conditioned by language, as stated by Sapir and Whorf, and the other postulating that language is based on universal principles shared by all humans, as brought forth by one of Whorf's most adamant critics, Noam Chomsky.

Taken to their extreme, Sapir and Whorf's theory of linguistic relativism would mean that translation is essentially impossible, whereas Chomsky's theory of linguistic universality would imply that everything is perfectly translatable. The translator does not have to choose between these extremes. However, he does have to determine "the point on the scale between them which is valid for the case in question. In other words, the extent to which a text is translatable varies with the degree to which it is embedded in its own specific culture, also with the distance that separates the cultural background of source text and target audience in terms of time and place" [2].

Susan highlights two text genres that are located on rather different points on this 'scale of translatability' [2]. A biomedical article, striving for objectivity, is likely to be characterized by highly conventional speech, making reference to concepts that have their direct, or a near-direct, equivalence in the target language. At the other end of the spectrum are writings that are strongly marked by the author's creative individuality and subjectivity, at times stretching the confines of language norms and requiring the translator not merely to look up a term in a dictionary but to search deeper in whatever it is the author knows, perceives, or believes, how he behaves, and what rules and conventions he adheres (or chooses not to adhere) to.

Why would this be relevant for a community of European science writers? First, these fundamentals of translation are true, to varying degrees, for every text genre—no matter how conventionally standardized or individually creative a text may be. Whichever text, text segment, or unit of thought we read, write, or translate, it will be located on some point of the scale of translatability. Second, with Europe encompassing some 50 countries and an almost uncountable number of different languages, translation takes place wherever people from different countries or regions come together in one place. As we take a radiographic look at what happens in translation, we learn much about how our partner in speech learns, knows, perceives, believes, feels, and behaves. As Susan's text convincingly shows, this can be a rewarding experience.

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Translating patient education materials

Chest's medical writing tip of the month for February 2010 considers translation.

In their article 'Translating patient education materials' Jett and Ivnik conclude that providing patients with educational materials written in their own language with culturally appropriate translation is crucial to meeting patients' needs. It considers whether or not existing materials should be translated and what to consider before deciding to translate any patient education materials into a specific language.

Available at: http://chestjournal.chestpubs.org/content/137/2/488.full.pdf+html

'Insider' translation: An anthropologist as translator of anthropology

by Susan M. DiGiacomo

"For me this is the essential challenge in translation: hearing, in the most profound way I can, the text in Spanish and discovering the voice to say (I mean, to write) the text again in English."

Edith Grossman, Translator's Note to the Reader, *Don Quixote* [1]

As a result of a series of nonreproducible biographical contingencies (a story detailed elsewhere; see [2]), I am both an anthropologist and a translator of anthropology. The first author I translated, 20 years ago, is now my colleague in the anthropology department of the Catalan university where we both teach. I run a departmental publication support service for my colleagues and our graduate students that includes translation into English from Catalan and Spanish. Because I write in Catalan as well as in English, I have also translated Anglophone anthropology into Catalan. What enables me to do this is the linguistic and cultural fluency I have acquired over the course of three decades, beginning with my dissertation fieldwork in Barcelona, the Catalan capital, in the late 1970s and early 1980s.

Because I count medical anthropology among my specialties, my familiarity with medical discourse and the structure of medical writing allowed me to become a translator of biomedicine as well. For two years I ran an in-house translation service at a foundation connected to a Barcelona children's hospital. I still retain a few faithful clients from that period, and I also work as part of a group that translates all 10 yearly issues of a Spanish dermatology journal into English.

While good translation in any discipline is faithful to the original in terms of meaning, linguistic register, usage, technical vocabulary, and voice, translating texts in my own field of research and teaching allows me to blur the boundaries of translation to a considerably greater extent than I would attempt in translating biomedicine, crossing over into author's editing, acting as a peer reviewer, and rewriting. I do this carefully, because my aim is not to substitute my voice for the voices of my clients but to represent their voices in English. This kind of effort has its parallel in ethnography, where the aim is not to speak for mute cultural Others, but to allow them to emerge through an ethnographic text that, in addition to disciplinary conventions of representation, is strongly marked by the ethnographer's subjectivity. This is quite distinct from biomedical writing, in which 'voice,' as an anthropologist would understand it, is notably absent because the instrument of knowledge production is an experimental protocol, a statistical programme, or a diagnostic test; hence the heavy use of passive verbs that obscure agency, suggesting that any similarly expert objective observer would 'see' the same results. What is valorized is objectivity, constructed rhetorically through narrative structure and syntax. Subjectivity is to be avoided at all costs because it threatens the generalisability of the work.

My job, then, in translating biomedicine is to help my physician clients achieve something approximating the objective and impersonal biomedical voice of the articles published in the English-language journals they cite. By contrast, in translating anthropology my point of departure is one I share with all writers of ethnography: the starting assumption that the instrument of knowledge production is the person of the ethnographer. Biography and experience position us in the world, situating us in ways that both facilitate and inhibit our understanding of the phenomena we propose to study. Voice is one of the ways in which subjectivity is embodied in ethnographic writing. This is a point to which I will return later.

A not insignificant portion of the work I do involves correcting or, more often, retranslating texts incompetently translated by someone else. These tend to be clumsily literal renderings that reveal ignorance of basic concepts in anthropology and a view of translation as the substitution of words in one language for words in another language. They are tone-deaf on three levels simultaneously: English syntax and usage (even when the translator is a native English speaker), anthropological discourse, and the author's voice. Following is an example, an abstract:

> I hereby present a case-study of a Brazilian *frequent flyer* I met during my field work at *Clinica Psichiatrica* in Genoa. Her account put forth a meaningful duality: she was living in a perfect state of syncretism and pluralism both causal and treatment wise. On one hand, she was employing rituals of white magic and Candomblé in order to be cured, she defined her disorder as a *"spiritual disease"*, and she declared the cause of her suffering to be the presence of "two *exus"* – two demon spirits. On the other hand, she situated her disorder in a biomedical context and correctly followed the pharmacological treatment prescribed by the local psychiatrist. She defined her illness as "depression" and voluntarily >

An anthropologist as translator of anthropology

> went to the clinic when she felt "anxious and self-harmful". In her eyes, both systems were effective and operative. Unlike other informers for whom the folkloric system granted healing whereas the biomedical only provided a cure, Silvia considered both as a remedy, a temporary relief to her condition of being "different".

The original Spanish (written by a native Italian speaker) is competent, though not perfect, and reads as follows:

> Presento un estudio sobre una *frequent flyers* brasileña conocida durante el trabajo de campo en la *Clinica Psichiatrica* de Génova. Su narración presentó una sugestiva dualidad: vivía en un perfecto sincretismo y pluralismo causal y asistencial. Por una parte utilizaba los rituales de magia blanca y Candomblé para curarse, ubicaba su trastorno entre las *«enfermedades espirituales»* y reconoce en la presencia de «*dos exus*» – espíritus demonio – la principal causa de su sufrimiento. Por la otra, coloca su enfermedad en el contexto biomédico y utiliza adecuadamente una terapia farmacológica proporcionada del psiquiatra territorial. Define su mal «*depresión*» y voluntariamente acude en la clínica cuando si percibe *«agitada y con comportamientos autolesivos»*. Para ella ambos los sistemas son eficaces y efectivos. A diferencia de otros informantes donde el sistema tradicional garantiza una sanación, mientras que el biomédico sólo una cura, para Silvia ambos son un remedio, un alivio temporal a su condición de «*diversa*».

My re-translation reads:

> This article presents a case study of a Brazilian "frequent flyer" (a psychiatric euphemism for relapsing patients) I came to know during my fieldwork at a psychiatric treatment center in Genoa. Her narrative reveals a syncretic explanatory model and a pluralistic approach to treatment. Defining her disorder as a "spiritual disease," she traced her suffering to the presence of two *exus* or demon spirits from which she sought relief through white magic and Candomblé rituals. Simultaneously, she situated her disorder in a biomedical context, defining it as "depression," voluntarily going to the clinic when she felt "anxious" and inclined to harm herself, and adhering assiduously to the pharmacological treatment prescribed by the local psychiatrist. In her eyes, both systems were useful and effective. Unlike other informants for whom traditional forms of therapy held out the promise of true healing while biomedicine merely offered a cure, Silvia regarded both as remedies, sources of temporary relief from an affliction she experienced as being "different."

"*Una sugestiva dualidad*" is not really "a meaningful duality;" the author is taking note of a paradox, the starting point in many ethnographic texts. The original Spanish text contains a number of minor grammatical mistakes: "*flyers*" is plural, but the author is referring to a single individual; the verb tenses shift from past to present; some verbs have missing or incorrect prepositions. The first translation corrects most of these, but misses the syntactic problem in "*vivía en un perfecto sincretismo y pluralismo causal y asistencial*." Which adjectives modify which nouns? The solution is awkward and the linguistic register, at the end, inappropriate: "she was living in a perfect state of syncretism and pluralism both causal and treatment wise." "Causal wise" is ungrammatical, and "treatment wise," something one might hear in casual speech, sorts badly with the pomposity of the opening: "I hereby present" and "her account put forth," both of which sound legalistic rather than academic. People do not "correctly follow" treatment regimens, they "adhere" to them. "*Informantes*" is translated as "informers," which places the text in the domain of police investigation rather than ethnography; the correct translation is "informants." People may engage in acts of self-harm ("*comportamientos autolesivos*"), but they are not "self-harmful." "*El sistema tradicional*" is not, in anthropological discourse, "folkloric" but simply the traditional medical system. "Relief to," incorrect in English, is a literal translation of "*alivio a*." The original contains two footnotes (not reproduced here because of space constraints), inappropriate in an abstract; the first translator simply translated them. My translation eliminates the long footnote entirely, since it introduces an unnecessary level of detail, and reduces the short footnote to an explanatory parenthesis.

In this case, my task was to resituate the text in ethnographic discourse and standard English usage. This situates the author as one conversant with the relevant concepts and theoretical approaches in her discipline, and knowledgeable about the abstract as a literary form. The risk of a bad translation is that it can all too easily cast doubt on the quality of the research and the analysis, damaging a neophyte author's credibility as an anthropologist.

At the other end of the spectrum, I have both retranslated and translated directly from the original writing by mature professionals in my field. There are three authors with whom I have worked frequently enough over periods as long as two decades so that I have a sense not just of their research, but of their style as ethnographic writers. In these cases, my task is not to improve their writing through the translation process, as is often the case with less experienced writers, but to allow their voices to speak through me.

The texts the Catalan authors write do not necessarily correspond rhetorically and structurally in every way to an American model of anthropological writing, and when I translate, I try to preserve difference on this level of the text. There are different national traditions of writing

ethnography, and within those traditions considerable individual variation. Lawrence Venuti [3] defined translation as "the forcible replacement of the linguistic and cultural difference of the foreign text with a text that will be intelligible to the target-language reader." If I believed that this is what translation really is, I don't think I could do it. Framed in this way, it is an act of violence and cultural imperialism. The translated text should be one that does not erase difference, but transposes it, and in this translation resembles the ethnographic enterprise itself. An anthropological text does not eliminate cultural difference by assimilating Others to ourselves, but instead makes their otherness accessible. In the same way, in translation 'intelligibility' is always relative, never absolute, and the translator's aim is to reduce the opacity of the foreign text, not to do away with its foreignness. While this obliges the American reader to work a little harder, I try to facilitate this task, making an unfamiliar kind of text as accessible as possible by holding myself to a high standard of fidelity to the value of language as a way of knowing, not merely a code.

For some time I have been tracing parallels between translation practice and ethnographic practice, and until recently I thought I had located most of the important ones (see [4]). All ethnographers know that their very presence alters the context they observe and write about. Until I chanced last year upon an essay posted on my oldest client's blog [5], however, I had not imagined the extent to which the translator's increasing familiarity with the author's voice and style not only allows the translator to 'embody' it [5], but the extent to which the author's voice and style may, in response, develop in ways he or she did not initially anticipate. Comelles analyzes the passage from the first text on which we collaborated as author and translator, to a second text at a remove of ten years. During that decade, Comelles' style and ethnographic voice in Catalan had evolved and matured, and both of us had had occasion to experiment in our own work with an ethnographic genre known as autoethnography, the use of personal experience as an analytic category. Comelles writes of the first text as a co-production, an implicit recognition of the translator's authorship. This is rare enough in a world in which translation is generally viewed not as productive but as reproductive, lacking in creativity and originality, a copy in another language. His insight, I think, is grounded in another nonreproducible biographical contingency: the experience of growing up trilingual, using Catalan, Spanish and French in different contexts and for different purposes. What he has to say about the second text, however, took my breath away. While the translated text is, he says, fully "his," the boundary between Self and Other has shifted (an effect also produced by the best ethnographies). "It is," he writes,

> as if Susan had stepped into my skin, and the emotional force of my ethnographic experience, originally written in Castilian, has been transferred entire into the English version with the same delicacy as if I/she had written it. …I can only understand this degree of shared sensitivity as a result of common experience in relation to severe illness, but I would also say that Susan's work over ten years as my editor and English translator seemed to allow her to become me, or perhaps it is that I too, conscious of her sensitivity and ability to embody my narrative style, feel liberated when I write in Castilian a text she will translate, because I know that her English version will capture precisely the narrative tone I used, a tone whose music is fundamental in turning an academic text into a fully personal one (my translation).

At this point we are well beyond what we can easily recognise as the objective advantages of an author/translator partnership in which both share the same technical vocabulary and professional discourse. The double pronoun "I/she" points toward a double transformation: over time and successive collaborations, the translator has become not only an interlocutor but a kind of alter-ego, and the author's voice, in response, is liberated to become more authentically his. The possibilities of transformation and even transgression inherent in ethnographic practice, then, are also present in translation practice. Anthropologists and translators not only facilitate the movement of ideas across boundaries; they themselves are boundary crossers, shape changers, and thus subversives, challenging the commonsense notion that identities are fixed and unitary (see [4]).

Anthropologists commonly have recourse to translation as a metaphor to explain what the interpretation of cultures consists in. My experience as an anthropologist translating anthropology suggests to me that translation may be more than a metaphor, something closer to a metonymy of the ethnographic encounter. This would help to explain its potentially transforming power for both translator and translated author.

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