The Write Stuff

The Journal of the European Medical Writers Association

The Role of the Writer

Featuring:

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EMWA European Medical Writers Association

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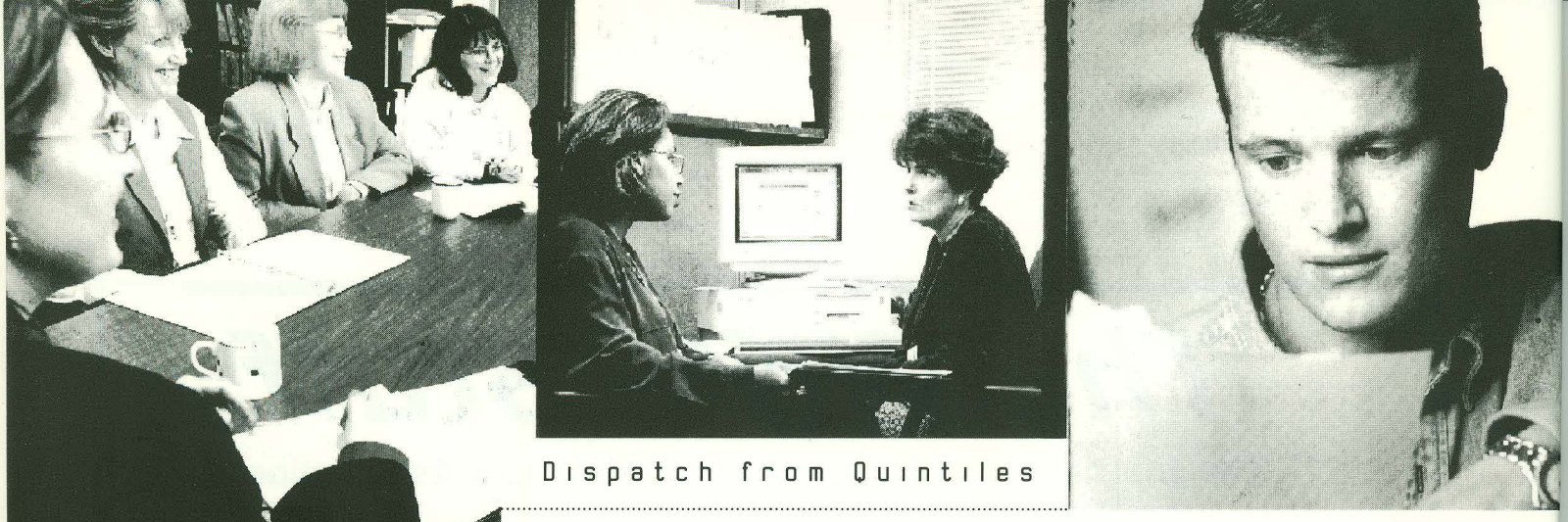

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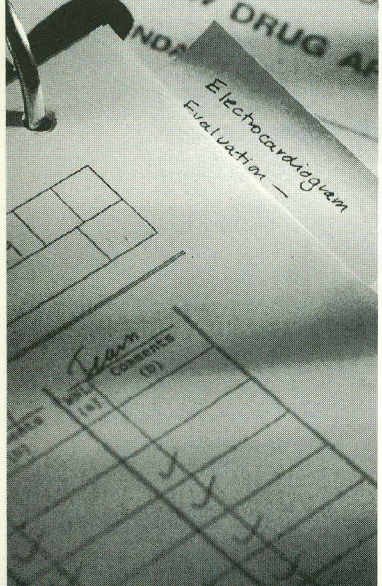

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The Role of the Writer (Autumn) . . .

[INT] - indicates that the article has also appeared at the EMWA internet site: http://www.emwa.org

Journal Insights

The Write Stuff is the official publication of the European Medical Writers Association. It is issued quarterly and aims to provide EMWA members with relevant, informative and interesting issues 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.

Subscriptions:

Subscriptions are included in EMWA memberships. Non-members can subscribe at an annual rate of:

- £20 within Europe
- £30 outside Europe

Back Issues

Subject to availability, previous issues of the EMWA newsletter can be obtained for the cost of mailing by contacting Philippa Clow at EMWA headquarters.

Behind the press...

Editor-in-Chief
Barry Drees

Artistic Director
Julia Forjanic Klapproth

Copy Editor
Chris Priestley

Meetings of Interest
Sarah Heritage

From the Literature
Liz Wager

Instructions for Contributors:

- **The Write Stuff** typically publishes articles of 500 - 1500 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 to a contribution will be cleared with the author before publication.
- Submissions should include contact and E-mail addresses as well as telephone/fax numbers. Suitable quotes for side boxes should be indicated or they can be selected by the Editorial Board.
- Material should be submitted electronically on computer disc or by e-mail according to the following specifications:
  - MS Word file
  - Arial font (or equivalent), 11point, single space
- If a submission is accepted, a recent photograph of the author (a portrait picture, CV-style) will be requested although it is not mandatory.

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The Editor's Red Pencil

By Barry Drees

Greetings fellow members,

Well, here we are already, the second issue with the new format, and I'd like to start things off by thanking all those members who helped me put together the first issue (some of whom I was able to subsequently press into service on the editorial board) and all of you who've written or called me with comments or support for the first issue. Especially noteworthy in this regard were the extensive comments and suggestions on publishing from Karen Shashok in far away Granada. I was hoping for the new format to make a big splash and, judging by the feedback I got, it succeeded.

It was not, however, without problems. Let's be honest, using chaos theory as a guiding principle for proof reading and copy editing was not a good idea. Each article was sent to the publisher separately, by different people, and a final copy edit was not possible for all sections. The result was that the entire issue was merrily sprinkled with typos (Can you find them all?). Many people wrote to me mentioning a few and it was interesting to see that almost everyone noticed something different (although, true to the spirit of Edgar Allan Poe's The Purloined Letter, no one seemed to notice that the page numbers in the table of contents were wrong!). The most obvious and straightforward thing, therefore, is that each issue from now on will be compiled in its entirety at one place where it can be proofread and copyedited before it is sent to the publisher. We will also demand a copy of the final journal for a last, comprehensive check before publishing. This should eliminate inconsistencies in format and reduce those irritating typos.

Let's be honest, using chaos theory as a guiding principle for proof reading and copy editing was not a good idea.

My main concern with the first issue was content, but it now looks like that won't be the problem it was in the past, so now we're looking to jazz up the format and presentation a bit. Thus, you'll probably be noticing further changes and refinements in the next few issues. As always, any input you'd like to offer on the new format would be more than welcome; after all, the journal belongs to all the members, and it should reflect your needs and interests.

I'd now like to introduce everyone to the first members of our new editorial board. I'm thrilled to have the pleasure of working with such highly qualified and enthusiastic colleagues (they must be enthusiastic if they volunteered for this). Please remember that they are all helping me produce a first-class journal when you get their call in the middle of the night asking you to submit a piece.
Julia Forjanic-Klapproth consulted with me extensively on the initial design of the new format and will be joining *The Write Stuff* as our Artistic Director. She hails originally

from Vancouver, Canada, did her doctoral work on the molecular genetics of neurogenesis in *Drosophila melanogaster* in Germany, and has a minor degree in Fine Arts from Simon Fraser University in Vancouver. She is a published poet as well as a medical writer and has had a lifelong interest in art and graphic design, as well as a fascination with exotic papers.

Sarah Heritage joins us from Sanofi in the UK where she is currently a senior medical writer after having done her doctorate at St. Georges Hospital Medical School in London on the effects of various vasoactive agents on the human placenta. She has volunteered to take over the "Meetings of Interest" section which was easily the section in the new format which generated the biggest response. If this were a newspaper, Sarah would be our sports editor as she lists windsurfing, badminton, cycling, and snowboarding as her hobbies.

Believe me, no one felt worse about the typographical errors in the last issue than me, so in an attempt to ensure that this doesn't happen again, I've been extremely fortunate to obtain the inestimable skills of my colleague Chris Priestley, who has an eye for detail second to none, and who will be our copy editor. Chris studied languages at the Universities of Bath (England) and Innsbruck (Austria) and worked as a translator at HMR for 5 years before becoming a medical writer. I should point out though, that his role is advisory, i.e. not all the things he points out can be fixed for reasons of printing or publishing, and that I make the final decision and thus am still responsible for any mistakes.

I am particularly pleased that I was able to add some (as they say in the sports pages) veteran experience to the board by coaxing Liz Wager out of EMWA journal editorial retirement (she was the editor in 1993-1994) to take over the "From the Literature" section. Liz also brings to the job her extremely varied professional experience. She has a degree in zoology from Oxford, was an editor with Blackwell Scientific Publications, was National Chairperson of the UK section of Amnesty International, and last but not least, is currently a medical writer at Janssen. She's a member of EASE and CBE as well as EMWA, gives courses on medical publications throughout Europe, and enjoys choral singing, B&W photography and opera in her spare time (goodness, what spare time?).

You'll notice that we are continuing to evolve with our journal in that we're adding author photos and a more standardized format. We're also attempting to give each issue a unifying theme, so it may be that what is promised in the "Next issue" segment doesn't appear right away, but don't worry, you'll see it eventually. Finally, I've been thrilled with the positive response in terms of members sending articles, but let's not get complacent. There's lots of you out there I haven't heard from yet and after all, this is your journal too!

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From the President's Desk

by Gerold Wilson

Dear Fellow EMWA members,

I hope all of you had a restful and enjoyable summer and that you had better weather than we had in Berlin. In the last issue of The Write Stuff, I outlined what I hoped the Executive Committee would accomplish in the coming year. I am happy to now report that we have attained at least one of our goals. Within the next few days, I will receive the Articles of Incorporation for signature. By the middle of October EMWA will be incorporated as a non-profit organisation. This will immeasurably add to our legitimacy and help us to gain more recognition. I am excited about this important step, and I hope you join me in this excitement.

The transfer of our bank account to the UK is now complete. I want to take this opportunity to thank Philip Cooper for the dedication and hard work he put in as our Treasurer for five years. During Philip's tenure, the Treasurer had to not only keep the books straight, but he also willingly shouldered the burden of keeping track of registrations for annual conferences and sent out homework assignments for workshops. He held one of the busiest offices in our organisation for five years and did so with professionalism and good humour. Hats off to Philip!!

In June/July 1998, in response to a brilliant suggestion from Phillipa Clow, EMWA introduced a once-a-year billing system. Under this system, all of us will pay our membership dues at the same time annually. With the implementation of this system, we hope to save administrative expenses and streamline membership management. Although I've heard that there have been a few growing pains during the switch, I'd like to ask for your patience and understanding. The future gains in efficiency and convenience should more than offset any short-term problems we have this year. If you have any questions about membership, please contact Phillipa (see back cover).

In January 1999, the AMWA Executive Committee (EC) will discuss and vote on the continuation of our affiliate status with them. Prior to that, I will attend the AMWA annual conference in Vancouver in October where I will discuss our affiliate status with Art Gertel (current AMWA president), Barbara Good (AMWA president-elect), and other members of the AMWA EC. Depending on the results of these talks, I will ask to be invited to the AMWA EC meeting to present our position. I feel that a continuation of the affiliate status is mutually beneficial and I would like to extend the agreement indefinitely. However, I also think that some adjustments need to be made in certain financial aspects of our agreement with AMWA and I would like to see less bureaucracy with regard to our subscription of the Core Curriculum Programme. If any of you have opinions regarding our affiliate status, please send me an e-mail (see below) and let me know what you think.

I call on all EMWA members to make it a goal this year to recruit one new member.

From the President's Desk

In my last letter to you, I mentioned that the EC would like to move forward this year on the corporate sponsorship concept. Unfortunately, we have not made much progress on this front. However, at the EMWA EC meeting in November this year, we will discuss this and I hope that I can put this project on the road in the first few weeks of 1999. Corporate sponsorship, depending on the extent of funds that we might receive, would enable us to put more emphasis on what I think our most important function as an organisation is: continuing education. I would like to see annual conference registration fees and workshop fees decrease and I would like for us to be able to organise an annual two-day, workshop-only session in addition to our annual conference. This can only be accomplished with more funding. The only two ways I see us gaining more funding is to increase membership or obtain regular, continuing corporate sponsorship.

Another item on the agenda for the EMWA EC meeting in November will be measures we can take to increase our membership. I have a number of ideas and I am sure that Debbie Jordan and the other members of the EC will also help us but your help is vital. I call on all EMWA members to make it a goal this year to recruit one new member. So far in our short history, word-of-mouth has been our most successful recruitment tool. Word-of-mouth should not be our method of choice in the future to increase membership, but until we have something more productive in place, it can be more effective than nothing.

The Copenhagen conference is taking form. The slate of workshops, the keynote speaker, topics for plenary sessions, and social events have been selected. Geoff Hall and Julia Cooper have done a truly fine job! I have every expectation that the 1999 conference will be our best yet and I hope that you can attend.

Finally, I want to thank Barry Drees and Marian Hodges for the excellent work they have done with our journal and website. The Write Stuff is not only the "right stuff", it is SUPER STUFF! Please show our journal to colleagues and friends. It is something that we are all proud of and goes a long way towards establishing our credibility as a professional organisation. Over and over again, people have told me that the EMWA website is great!! And, the Members Only section is a real hit. I have visited the website regularly for about 2 years. Over this time, I have seen it grow in size and quality. I truly envy Marian's web skills and flair. I encourage you to visit the website often and to make use of the Dialogue section in the Members Only page to make your views known.

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A Ghostly Reply: EMWA Member Responds to "A Ghostly Crew"

(THE LANCET 1998; 351: 1741)

(reprinted with permission of The Lancet and the author)

by Liz Wager

As a professional ghost, I want to respond to David Sharp's comments[1]. First, I agree that it is unacceptable to expect anyone to put their name to a review to which they have contributed nothing. But the remedy is simple: doctors have only to say no. However, I disagree strongly with his comments about the role of professional writers in clinical-trial publications.

His objections to ghostwriters seem to be based on the outmoded principle that whoever makes the first marks on the paper is, by definition, a study's author. I do not accept that seeking help from a professional writer "goes against the spirit of author responsibility", when it is perfectly acceptable to seek help from statisticians &c. Your two references show the failure of the current authorship system and the need for systems in which credit is not given only for writing the paper[2,3]. Richard Horton's March 7 commentary[2] and Rennie and colleagues[3] acknowledge that research usually involves many people. They propose that one or two should act as guarantors, taking responsibility for a project's overall integrity. Yet nowhere do they say that guarantors must necessarily write the first draft, just as they do not necessarily perform every power calculation or clinical measurement. The move towards contributors, as proposed by Rennie and co-workers (and adopted by some journals, including *The Lancet*), should encourage openness, and I agree that help with writing should be acknowledged. However, traditional acknowledgements to individuals for help in preparing manuscripts do not reveal whether their contribution was typing or substantial editing, nor who paid their salary or fee.

I do not accept that seeking help from a professional writer "goes against the spirit of author responsibility", when it is perfectly acceptable to seek help from statisticians &c.

You are concerned that studies' sponsors will have a chance to comment before external investigators. This approach implies that such investigators are unable to detect bias in the presentation of results and ignores the fact that the most important review is surely the final one, not the first. Therefore, I cannot accept David Sharp's distinction between "legitimacy" of authors' editors and that of professional medical writers. The only difference between them is that authors' editors rework draft manuscripts prepared by someone else, whereas ghostwriters prepare first drafts and then incorporate contributors' changes. Authors' editors may substantially rework papers and investigators may completely rewrite ghosted drafts so the net effect is exactly the same–the only difference is the order of the work.

Finally, in the era of evidence-based everything, does *The Lancet* have any evidence that the use of professional medical writers causes harm? In my experience, professional writers speed up the writing process and improve the quality of the final paper. Instead of criticising the ghosts, journal editors and sponsoring companies should work together to draw up guidelines of acceptable practice.

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Democracy and the Professional Communicator

The Vital Role that Technological Writers have in Bridging the Gap between Science and the Public

by Carrie M Nielson

Our task of communicating science, technology, and health information to the public is an important one. We might not realize just how important it is becoming in an age when science and technology are moving at breakneck speeds. When we make clear scientific information available to the public, we don't just work for the companies who hire us; we work for a more democratic society, where citizens can make informed decisions about the technology, including drugs and medical therapies, they use. Traditionally, news media have been poor communicators - because of mis-understanding or lack of interest in science - and the public has been ignorant or misinformed of many important issues in science and medical technology. Our combined skills in understanding science and medicine and communicating clearly are vital to an informed, involved public.

Communicator as Advocate of the Lay Citizen

While technology becomes increasingly important to our work and even takes up our leisure time, explanations of technology and science are getting more difficult to understand. A 1992 study of the lexical difficulty of science publications illustrates how inaccessible they have become over the years to lay audiences, including scientists outside of the field of discussion. Whereas sixty years ago journals like *Nature*, *Science*, and *Scientific American* were written at or around the level of a modern newspaper, today they are up to thirty times more difficult.[1] When text gets this difficult, not only do readers stop understanding, they stop trying to understand. "When the difficulty of the average article [in *Scientific American*] approached 15 [times the difficulty of a modern newspaper], there was a decline of over 125,000 subscribers, implying that many readers found texts written at those levels too opaque."[1] Driving this increase in difficulty is increased specialization in science and accompanying new terms and concepts. While science reaches unprecedented levels of knowledge and understanding, readers require an unprecedented amount of background and training even to read the language used to report research in many fields.

> ***Knowledge will forever govern ignorance: and a people who mean to be their own Governors must arm themselves with the power knowledge brings.***
>
> *American statesman James Madison*

Publications specializing in science increasingly fail to meet citizens' needs for simplified information, especially in recent decades, but popular mass media have long been criticized for oversimplified, sensationalist, and incomplete reporting of complex issues. Dorothy Nelkin discusses the inappropriate reporting in the 1940s of a new procedure called lobotomy. "The press welcomed the new technology . . . with uncritical enthusiasm, though prevailing opinion within the medical community

remained skeptical of the practice."[2] Between 1945 and 1952, articles in *Reader's Guide*, *New York Times*, and *Time* were overwhelmingly biased toward the use of the technique; few articles gave neutral accounts, and even fewer reported the warnings of doctors who knew the damaging side effects.[2] If we consider these two alternatives - esoteric science publications and incomplete popular media - for sources of citizens' knowledge, it becomes clear that the challenge of providing complete, clearly written communication with sufficient resource to background information is still waiting for competent, unbiased communicators.

Communicator as Agent of the Expert

To foster better communication with the public, we should also help experts distribute the scientific information they hold. Openness and the desire to be understood are attractive qualities for anyone - especially for those who are involved in controversial discussions. Good communication of the benefits and risks of research are not only essential for responsible citizenship but encourage the trust necessary to keep lines of communication open. Lack of information (or lack of *understandable* information) is often construed as secrecy or deception, even when none is intended, and can in this way damage relationships with the public. "Because secrecy can debilitate judgment and choice . . . it often affects others even when it is not intended to. This helps explain why, in the absence of clear criteria for when secrecy is and is not injurious, many people have chosen to regard all secrecy as potentially harmful."[3] Although some secrets are necessary for trade and competition, the communicator should work on behalf of experts to bring as much relevant information as possible to the public to secure the expert's image as a person of goodwill.

A popular government without popular information or the means of acquiring it, is but a prologue to a Farce or a Tragedy or perhaps both.

American statesman James Madison

The benefits of open communication were proven this June, when Swiss citizens rejected the "Gene Protection Initiative", allowing genetic research to continue. When the debate began two years ago, scientists started to leave their laboratories and communicate with the public. Columns by scientists appeared in popular newspapers. Laboratories opened their doors to the public for tours and lectures. At the University of Zurich's Institute for Experimental Immunology, co-director Hans Hengartner said the vote proves that their efforts worked: "Swiss people did not respond well to the scare tactics used by the initiative's sponsors. In the end, what counted the most was objective information".[4] Microbiologist Richard Braun chairs the Gen Suisse foundation in Bern: "We have learned through this campaign that it is best to be as open as possible about your research . . . Now, even with this decisive vote, scientists cannot withdraw back into an ivory tower. We have to keep up this dialogue with the public".[4]

Through a study that surveyed experts in the pharmaceutical industry, John Abraham and Julie Sheppard found that many experts supported more open communication with the public and bemoaned the industry's culture of secrecy. They said that not only would better communication improve public relations, it would "lead to improved regulatory decision-making" and "improve the quality of the decision-making process".[5]

The sentiment was that if they knew they would be accountable directly to potential consumers, they would have to make the decisions they knew they could defend honestly and directly. Bok also reports that scientists working under conditions of intense secrecy have testified to its stifling effect on their judgment and creativity. "It can debilitate judgment, first of all, whenever it shuts out criticism and feedback, leading people to become mired down in . . . unexamined, often erroneous beliefs and ways of thinking. Neither their perception of a problem nor their reasoning about it then receives the benefit of challenge and exposure."[3] Again, I am not proposing we divulge trade secrets or compromise competitive advantages as long as they do not present a risk to society. But when possible, communicators will help both experts and the public by making research understood and open to constructive feedback.

Technology and science will only become more prevalent in almost every aspect of our society in the future. If we are to continue to live in a democracy, we must be able to make informed decisions about that technology. As communicators, we have the ability to make such responsible decision-making possible.

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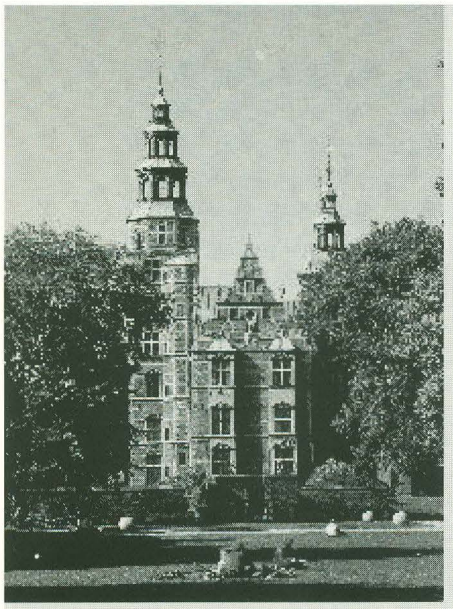

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Why Medical Writing?

by Adam Jacobs

I have always wanted to be a medical writer, ever since I was a little boy. When, at the age of five, all the other kids in the playground were saying that they wanted to be train drivers or astronauts when they grew up, I told them that I needed a career with more job satisfaction, so I wanted to be a medical writer.

OK, I lied. I had never even heard of medical writers until about 6 years ago, much less thought of becoming one. I expect my story is fairly typical: I started out as a research scientist, but after a while I started to ask myself why, after spending all those years working towards my PhD, I was doing a job with a dreadful salary and lousy career prospects. Having come to the conclusion that writing about science was at least as much fun as doing it, I found a job translating foreign scientific documents into English (an excellent training for any writer: having to ponder over the precise meaning of each sentence really teaches you what language is all about). After a couple of years of translating mostly medical documents, it was a natural enough transition to become a medical writer.

Now, in my early thirties, and in my second job as a medical writer, I have finally decided that I really do want to be a medical writer when I grow up. I have found a career that I enjoy: I get to keep in touch with the latest developments in medical research, I feel appreciated by colleagues and clients alike, and I am paid far more than ever I was as a scientist. As an added bonus, I never have to go to work in the mornings wondering if anybody is going to let anything particularly smelly or toxic out of the fume cupboard today (one of the highlights of my career as an organic chemist was a night in hospital after a little accident with some phosgene).

Do we really help to make the world a better place, or are we no better than accountants and lawyers, just muscling in on the action to grab our share of the loot?

But, until last month, there was always a little nagging doubt at the back of my mind. Is it a useful career? Scientists in laboratories are, one hopes, pushing back the frontiers of knowledge and helping to make the world a better place. Those actively involved in the clinical research that I spend much of my time writing about are helping to apply that knowledge and find better ways to fight disease. The physicians who then make use of that research to offer their patients the best available treatment are also unquestionably doing a useful job. But what about medical writers? Where do we fit into all this? Do we really help to make the world a better place, or are we no better than accountants and lawyers, just muscling in on the action to grab our share of the loot?

Last month, I attended the XXIst CINP (Collegium Internationale Neuropsychopharmacologicum) Congress in Glasgow, along with several thousand psychiatrists from around the world. I discovered two important things there. First, psychiatrists smoke a lot. I assume they hope that by encouraging smoking, they will ensure that those making use of healthcare services will be more likely to visit their colleagues in,

for example, oncology or respiratory medicine, and so be less likely to bother a psychiatrist. Second, medical writers do a job which is not only useful, but essential. One of the striking things about the talks given at the conference was the difference between those in the main sessions, where the speakers had mostly prepared their own presentations, and those in the industry-sponsored sessions, where the sponsors could afford to employ professional help in producing the talks. The latter talks were of a consistently high standard. They followed a logical sequence, data were presented clearly, and as a result, it was easy to follow what the speaker was saying.

The contrast with the talks prepared without professional help was staggering. I am not saying that all the speakers who prepared their own talks were poor communicators, and I would certainly not wish to suggest that psychiatrists are worse than members of any other branches of the medical and scientific professions. However, it made me realise that communicating medical research was a very different skill to doing it. Some of the speakers were no doubt experts in their field, but clearly had no idea how to present their research findings to an audience. One talk consisted of slide after slide of dense tables of data in a very small font. The research might have been very interesting, but I will never know because I had difficulty keeping awake during the talk, and, in common with at least half the audience, left before the end. One would have hoped that a psychiatrist, of all people, should realise that few people have the mental capacity to take in data from 15 × 20 tables at the rate of one table every couple of minutes.

However, on reflection, is it surprising that many of the talks were less than perfect? Psychiatrists, like all clinicians, must put the welfare of their patients first. The research process itself also makes considerable demands on their time, so preparing lectures cannot be given too high a priority. Moreover, few clinicians or scientists receive any training in effective communication. Scientific and clinical research is becoming ever more difficult and sophisticated, requiring increasing amounts of expertise from those involved in it. It is probably no more realistic to expect all clinicians to be expert communicators than it would be to expect someone such as myself to carry out open heart surgery.

Scientific and clinical research is necessary and important, but it is of little use if its results are presented so badly that the audience loses interest and falls asleep or walks away, so that few people ever become aware of the research. I came away from the conference happy that any increase in my risk of developing lung cancer from four days of heavy passive smoking was more than offset by the joy in my discovery that medical writers do an essential job. There is a real need for professional communicators, who do understand how to present complex research in a way which is interesting, and who are willing to devote their professional lives to that process of communication. In these days of increasing complexity in medical research, I am sure that medical writers will become an ever more essential part of the process. If I meet a five-year-old who wants to be a medical writer when he or she grows up, I shall know we are making real progress.

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Reversing the Report-Production Process When Teaching Pharmaceutical Writing

by Robert J Bonk

Medical writing provides a critical service today, with the creation and dissemination of health care information a key element in improving the well-being of society's members. Timely provision of accurate, understandable information on health care and medical topics plays a pivotal role in bringing the benefit of improved health to society. And as society's demand for health care information continues to increase, the craft of medical writing becomes more visible within the field of professional communication. Hence, teaching techniques for professional communication, as applied to health care topics, indirectly benefit society by ensuring effective provision of health care information—now and in the future.

As colleges and universities begin to recognize our profession's potential for growth, they are starting to develop courses, or entire programs, on medical writing. Instructors tailor such courses to many individuals, including medical students[1], osteopathic residents[2], and scientific researchers[3]. These students, however, differ fundamentally from those studying for a career in technical writing itself. Hence, I developed a course on writing pharmaceutical research reports for the University of Delaware's program in business and technical writing. This program, an option within the English curriculum, includes a concentration for undergraduate majors seeking a degree, as well as a certificate for continuing-education students already having an undergraduate degree.

An issue often faced in teaching any branch of professional communication is the bridge between technical knowledge and rhetorical skills. Medical writers in the pharmaceutical industry, for example, often move from earlier careers as scientists to writers who apply that scientific knowledge. But courses and programs that seek to educate students to begin a career in medical writing must grapple with the disparity expected with students majoring in a communication area who would typically lack a strong medical or life-science background. To allow the students in my course to focus on writing rather than science, I approached teaching how to write a pharmaceutical report by reversing the process that usually occurs in practice. This paper describes the design of this course and its expected benefits. Educators constructing syllabi for other courses in medical or technical writing may also benefit by applying this reverse strategy that I developed for teaching pharmaceutical writing.

This paper was presented in part at the 56th Annual Conference of AMWA in Chicago, Ill. (November, 1996). The original presentation, "Reverse Strategy for Teaching Pharmaceutical Writing to College Students in Technical Writing Programs," formed part of the plenary session on "Communicating in Medicine".

COURSE DESIGN

My course introduces students to the field of medical writing, with a focus on research reports for the pharmaceutical industry. Students receive an introduction to the drug development process that provides the necessary context for the practical writing assignments that

complement the lectures and discussion. This introduction allows all students, especially those lacking experience with the medical or pharmaceutical fields, to understand the purpose and audience for the writing assignments.

This introduction to drug development proved valuable in creating an even playing field for the different types of students expected in a technical-writing course. As assessed through an initial questionnaire, students in my first class did form two such groups:

- Advanced undergraduate writing majors with limited science education
- Post-undergraduate science majors with limited writing experience.

Overall, the course centers on preparation of a clinical research report for a study of a drug in humans; these clinical reports represent a large proportion of the documents handled by medical writers in the pharmaceutical industry. As for many technical documents, however, clinical reports require familiarity with data interpretation. For example, a medical writer usually works with a team in interpreting data from a clinical study, preparing a detailed research report, and then condensing that report into a journal article for publication.

To shift the focus back onto writing, my course applies a reverse strategy: students select a published article on a clinical trial; most students in my first class chose articles on clinical trials of drugs to treat illnesses with which they or family members had direct experience. From the published article, students prepare three principal writing assignments (see table) that together form a clinical report. This approach reverses the typical process of preparing a publication from a clinical report that, in turn, is based on interpretation of the study's data.

Table. Assignments for the reverse-strategy course on pharmaceutical writing

Assignment	Topic	Additional challenges
1	Objectives and Methods	Familiarity with aspects of trial design
2	Results and Conclusions	Data presentation and organization
3	Full Revised Report	Crafting of professional portfolio piece

The journal article provides source material from which the student crafts the research report, using a template[4] provided in class. This template represents a scaled-down report, formatted with section headings and subheadings, with parenthetical directions for information to include or not to include. Recommendations for providing tables and figures to complement text are given. Examples suggest formats for the cover page, report summary, table of contents, index of appendices, and appendices themselves. Because reports must be tailored to the type of research study (for example, short-term pharmacokinetic study or long-term oncology study), the template does not prescribe every nuance, but instead highlights issues for consideration.

The three writing assignments do not require the student to interpret original data from the research study, as they would on the job in the pharmaceutical industry. Instead, each assignment challenges the student to selectively organize the information found in the published article into the sections of a

clinical report. Incomplete sections must be identified; the student may suggest wording in such cases. For example, empty safety tables might be constructed if the source publication lacked data on rates of adverse events. A prefatory memo documents attribution of source material from the chosen publication, identifying those sections independently crafted. My evaluation includes comparing the submitted report with the source publication. Grading depends upon a checklist of format, language, accuracy, and consistency similar to that used for other writing courses.[5]

COURSE BENEFITS

This reverse-strategy course in pharmaceutical writing benefits the students in several ways. First, each student can explore a drug topic of personal interest or relevance. Second, discussions of ongoing drafts simulate group interactions integral in today's workplace.[6] Third, by obviating the need to interpret scientific data, this course created a common ground for diverse student groups, circumventing a conundrum usual even in graduate courses in technical writing.[7] Fourth, as a portfolio piece, the student's report substantiates his or her understanding of the field of pharmaceutical writing.

Secondary benefits of this course indirectly relate to the academic and pharmaceutical communities. Specifically, medical writers in the pharmaceutical industry can identify practical information to complement rhetorical theory in classroom settings; enhanced courses will better prepare students for potential employment as medical writers in a drug company. For example, practicing medical writers could recommend published articles for source information and additional document templates, such as overview regulatory documents.[8] and publication manuscripts,[9] that could then be used in other reverse-strategy courses. Shared opportunities for designing these courses, moreover, strengthen ties between practitioners and students of medical writing.

In my first offering of this course, participating students at the University of Delaware found that the reverse strategy allowed them to focus on writing while still becoming familiar with the process of drug development. Because of its initial success, I adapted this reverse strategy to an undergraduate course for physical therapy students at the Philadelphia College of Pharmacy and Science. A key objective of this second course was to familiarize second-year students with the case-report format integral to their field of study. These students, who had not yet taken their fundamental courses in physical therapy, were challenged to prepare a case report. For source information, I supplied abbreviated descriptions from a published textbook[10] on clinical cases, followed by interpretations of those cases. As in my course on pharmaceutical writing, students focused not on interpreting the underlying science but on evaluating the source information, identifying needed material, and structuring a document according to a supplied template.

Opportunities for this reverse strategy apply to other documents and courses in medical writing. Published articles could supply source material, for instance, to be repackaged as abstracts, slides, or posters that familiarize students with professional conferences that they most likely have not yet attended. Basic textbooks for medical school could supply source information for preparing continuing-education materials. In these or other representative documents, an underlying template would guide the students as they focused on writing in such reverse-strategy courses.

CALLING ALL EDUCATORS!

Are you interested in educational and training issues at the heart of the medical writing profession? If so, please heed this call to join colleagues who share your goal of furthering our profession through continuing the education of established professionals while mentoring the development of new medical writers. Initially using e-mail communication among interested AMWA members, we hope to foster dialogue on the future directions of our Educators Section. Joining our effort is simple enough: send an electronic message with your Internet address to either rjbonk@udel.edu or bart@launchpad.ca-we'll do the rest. And don't be shy about including your thoughts on education issues!

ROBERT J. BONK, Ph D.
AND BART HARVEY, MD, Ph D.

ACKNOWLEDGEMENTS

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View from the South: Medical Writing in South Africa

by Daleen Krige

Here, in the southernmost part of Africa, medical writing as a career is a largely unknown choice. To understand the present situation, you need some background knowledge about the pharmaceutical industry in South Africa. Most companies here are outposts of parent companies somewhere else on the globe (mostly Europe) and are situated in the Gauteng province (where Johannesburg is). Medical writers, albeit usually not known by that name, are mostly responsible for the package inserts and information sheets to accompany their company's products for marketing and/or information. Furthermore, these inserts were mainly written in the (previous) two official languages: English and Afrikaans (related to Dutch). Get the picture? Nothing much in terms of innovation.

Yet even before the coming of democracy and a more open policy regarding science and technology, companies in Europe found South Africa a very beneficial "testing ground". Not only was it far from rival companies in Europe (minimizing confidentiality risks), but it was and still is inexpensive: the South African Rand is much weaker than most European currencies. That is one of the reasons for CROs mushrooming all over the country. I am working in one such CRO in Bloemfontein, in the "centre" of South Africa. My main assignment is to write study reports and prepare manuscripts for publication in appropriate medical journals. There are also pharmaceutical companies of local origin, doing research work in South Africa with their own in-house writers.

To comfort: sometimes,
to acquaint: often,
to educate: always

In a nutshell, that is the background and situation of medical writing in South Africa up to now, but what new challenges await us, in the twenty-first century? Firstly, the government policy has changed, and we now have **eleven** official languages. There are many people, especially among the Black population, who do not understand Afrikaans at all and have an extremely weak knowledge of English. How are we going to accommodate medical writing in so many languages? Preparing patient information and package inserts promises to be a daunting task.

Yet another trend in the circles of the policy makers is the acknowledgement of traditional medicine and its improved status as a tool in primary health care. Especially since the WHO Alma Ata conference in 1978, there is growing support for either the **inclusive** system or the **integrated** system. In the inclusive system, allopathic and traditional medicines exist next to each other and both are considered legitimate. In the integrated system, a new system is created by the merging of allopathic and traditional medicines.

Whichever of these systems is eventually implemented doesn't change the problems and responsibility of the medical writers. Perhaps the most pressing issue is the fact that *muti* (traditional medicine) is so widely used in an almost infinite variety of forms and very little knowledge exists about ingredients, potency, toxicity, etc. To be able to report accurately on these "treatments" is going to be a mammoth task, as the whole system, in the absence of any sophisticated physiological knowledge, serves primarily to comfort and alleviate symtpoms rather than cure disease. This is not to say, however, that traditional treatments are not effective, but rather that they have different strengths and weaknesses from allopathic (Western) treatments. Should medical writing here bridge the gap and properly inform, educate and (perhaps) comfort? And if so, what are the appropriate methods for describing and presenting a system of medicine not based on double-blind clinical trials and p-values?

It may sound as if the new century is only going to confront us with problems, but this is surely not the case. It is very exciting to be here, in Africa, doing one's own bit to accurately report on matters of scientific interest and being able to break ground to benefit the larger community.

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From the Literature ... a Tale of Old Boys, Journalology and Skulduggery

By Liz Wager

When your husband complains that you read the *BMJ* in bed it is a sure sign that medical writing has taken over your life. If you not only read scientific papers but search out articles about the journals themselves you are in an advanced stage of journalitis and cure is probably impossible. I offer this column for fellow sufferers and anybody who has to deal with the medical literature. As you will see, my main interest is peer-review and issues surrounding the publication of clinical trials. If any readers suffer from the regulatory form of journalitis and would find it therapeutic to report their findings, I'd be happy to share my column space.

There has recently been a bumper crop of articles for those interested in 'journalology' and the ethics of medical publishing. Whole issues of *JAMA* and the *BMJ* are devoted to the peer review process and conflict of interest respectively (*JAMA* July 15th, **280**, No 3 and *BMJ* August 1st, **317**: 291-358). *JAMA* covers a range of papers presented at the Peer Review Congress which took place in Prague last year while the *BMJ* concentrates on research sponsorship by tobacco, alcohol and baby milk companies. For those of us working in the pharmaceutical industry it may come as a relief to discover that other industries are even more reviled by journal editors but, on a serious note, it might have been interesting to have seen a discussion about the more everyday problems of conflicting interest which arise when money changes hands between companies and doctors.

The thorny issue of authorship

Even more recently, *The Lancet* (Sept 12th, **352**: 892-9) features a series of short articles about the thorny issue of authorship in which eminent journal editors argue over whether the current guidelines (from the so-called Vancouver group) are useless or simply not enforced sufficiently. Anyone who has to negotiate authorship with colleagues or investigators should watch this debate as there are signs that many journals will change their policies soon. The *BMJ* and *Lancet* are already experimenting with lists of who did what and the concept of the contributor may soon replace our existing ideas of what constitutes an author. For an idea of what many journal editors have in mind you should look at Rennie *et al's* prophetic piece on 'When authorship fails' in *JAMA* **278**: 579-585 (Aug 20th, 1997). I welcome the move towards contributors as I find the Vancouver authorship guidelines don't work with multicentre, company-organised research and have often felt that scientists in the industry get a raw deal. If we, as professional scientists or professional writers, want others to respect our work and recognise the high quality of research performed by the pharmaceutical industry, I believe that the first step is recognition of who does what. The old system of authorship propped up the cosy, but inaccurate, view that the main intellectual contribution in company-sponsored clinical trials comes from external investigators. Companies were happy to support this myth in the

For those of us working in the pharmaceutical industry it may come as a relief to discover that other industries are even more reviled by journal editors.

mistaken belief that it made their publications appear more objective and less biased (despite the fact that most readers can spot an industry-sponsored study at a hundred paces and funding was acknowledged in the small print). Strict enforcement of the Vancouver guidelines also meant that many people involved in data collection, trial monitoring, data analysis and medical writing never got acknowledged. If the role of professional writers is acknowledged, accusations of 'ghost writing' will disappear (for my views on this see elsewhere in this issue). I am taking part in an authorship task force for the Council of Biology Editors and would love to hear from any EMWA members with strong views on this topic, or anybody with anecdotes about problems with the Vancouver guidelines or suggested solutions.

Research fraud and other dirty dealings

Another hot topic is research fraud, and this is the focus for a recent edition of the *BMJ* (June 6th, **316**:1726-33). The perspective is very UK-centric but there are commentaries from the US and Denmark. I was disappointed that the emphasis was on setting standards in academia, as though nobody had thought of the problem before, and there is virtually no mention of the pharmaceutical industry's long-standing and well-tested mechanisms for detecting and preventing fraud.

If you relish alleged skulduggery by the industry you might be interested by claims in the *BMJ* that Bristol-Myers Squibb Canada tried to prevent publication of a report (*BMJ* **317**: 618). The same journal also reports a dispute between Apotex and a hospital investigator over the right to publish controversial findings (*BMJ* **317**: 618). While it is always uncomfortable to see the industry's reputation besmirched, these cases are a sobering reminder of the importance of ethical contracts with investigators. If you are involved with, or concerned about, pharmaceutical companies' marketing activities then a report by Health Action International called *'Blurring the Boundaries: new trends in drug promotion'* makes thought-provoking reading but the tone is rather inflammatory. This group clearly enjoys knocking the industry but some of their points are, nevertheless, worth considering.

Exclusive proof that journal editors are a bunch of old amateurs!

If you have ever received a high-handed rejection from an omnipotent editor, you must surely have indulged in some speculation about their qualification for the job. *JAMA* July 15th **280**: 286-7 spills some of the secrets including the fact that most editors simply learn on the job and receive no formal training. A staggering 96% of the editors were male, 69% were 50-69 and 10% were over 69 so it appears that the 'old boy network' is very much at work here. Papers from present and former editors of the *British Journal of Psychiatry* (**173**: 110-115) provide more detail about the peer-review process and, in particular, what editors do when reviewers disagree.

Next issue I plan to review recent papers on electronic publication and anything else which catches my eye. If you spot something interesting, do let me know (my e-mail is lwager@jacgb.jnj.com).

Meetings of Interest

By Sarah Heritage

The following are listed as a service to EMWA members. EMWA does not endorse these meetings in any way. Those having the **[EMWA]** symbol include presentations from EMWA members. If you would like to have something listed here to share with other members, please contact Sarah Heritage, Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK.
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Date	Meeting/Sponsor	Location
Nov 24-25	**Understanding European Regulatory Requirements** Rostrum Personal Development Mildmay House, St Edwards Court London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1708 776 016 or (+44) 1708 735 000	London, UK
Nov 24-25	**The Common Technical Document** Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1708 776 016 or (+44) 1708 735 000	London, UK
Nov 25-27	**Pharmacokinetics in Drug Development** TPI Ltd., 32 Station Approach, West Byfleet, Surrey, KT14 6NF, UK Tel: (+44) 1932 351 733	London, UK
Nov. 30 **[EMWA]**	**Integrierte Studienberichte nach ICH** (German language) Kendle/gmi, Stefan-George-Ring 6 D-81929 München, Germany Tel: (+49) 89 993913 0	Munich, Germany
Nov. 30	**The Clinical Expert Report** Management Forum Ltd., 48 Woodbridge Rd, Guildford, Surrey, GU1 4RJ, UK Tel: (+44) 1483 570 099	London, UK
Dec 1-2	**Medical Statistics for Non-statisticians** Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1708 776 016 or (+44)1708 735 000	London, UK
Dec 12	**Scientific and Technical Writing,** Forum, Institüt for Management, GmbH Postfach 10 50 60 D-69040 Heidelberg, Germany Tel: (+49) 6221 500502	Heidelberg, Germany
Jan 27-29 (1999)	**Foundation Course in Medical Writing** PPD-Pharmaco, Maxwell Courses Ambassador House, 8 Carlton Crescent, Southampton, SO15 2EY, UK Tel: (+44) 1703 724 800	London, UK

Coming next issue . . . (Winter)

Past, Present and Future issue

Traditional Medicine and Healers in South Africa
Daleen Krige
Tired of reading about the problems of HMOs and the NHS? Then try reading about a medical system grappling with the unimaginable difficulties of integrating modern medicine with a thousand year old system of traditional healing.

Alternative Medicine in Germany
Anna Kassnel
So, you think alternative medicine is only potions and witchdoctors in Africa? Find out about the ever-expanding field of alternative medicine in a modern European nation. As alternative therapies begin to undergo rigorous clinical testing and increased acceptance among the medical establishment, will they need medical writing soon?

View from the Past
Mike Mathews
Our series of articles exploring the diversity of EMWA moves from the three dimensions of geography into the fourth dimension - time, as one of EMWA's founding fathers tells us about the birth of EMWA and describes his feelings today on discovering that the baby has grown up.

View to the Future
Stephen de Looze
Now we take a look at the other direction of time and learn that, not only will medical writing survive the current claims that templates, SOPs and electronic submissions will make it redundant, but that with the information age rapidly coming into full force, medical writers will be needed as never before.

The Changing Face of EMWA
Gerold Wilson and Barry Drees
A comparison of the results of the Madrid and Edinburgh conference questionnaires reveals whether and how member backgrounds and needs are changing.

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