Medical Writing

Contents

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Regular Features

Themes of upcoming issues of *Medical Writing*

The theme of the June 2013 issue is '**Medical Writing around the World**'. We are no longer accepting articles for this issue.

The theme of the September 2013 issue will be '**Health Economics and Market Access**' to coincide with the theme of the May 2013 conference in Manchester. The deadline for feature articles is June 19, 2013.

The theme of the December 2013 issue will be '**Good Pharma**'. This issue will be on efforts to improve transparency and ethics in the pharmaceutical and device industries. The deadline for feature articles is August 20, 2013.

We are currently considering themes for 2014. Suggestions are welcome.

Correspondence relating to these issues and ideas for further themes should be addressed to editor@emwa.org.

Medical writing education

Phillip Leventhal

Editor Medical Writing

Editorial

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Although medical writing as a career has been around for a few decades, medical writing education is relatively new. Many medical writers end up teaching scientific or medical writing, and have built their courses and their teaching style without any training or systematic guidance. The field of medical writing is continuing to grow and new people are being attracted to it, so accredited training and a systematic method for teaching are becoming necessary.

This issue of *Medical Writing* is intended to help give the field of medical writing education a push in the right direction with a collection of articles on the essential competencies for medical and scientific writers and how to effectively teach them. The first three articles give guidance on what to teach to publication writers. Edward Barroga details a set of modules for publication writers and a simple evaluation system for assessing their competencies. Takako Kojima and colleagues continue with an article describing a series of lectures and group-based workshops that combine writing skills with publication ethics. Finally, Elisabeth Heseltine explains how to build an effective scientific writing workshop for non-native speakers of English.

Most people teaching medical or scientific writing come from a scientific or linguistic background and have never had specific training in education. Two articles in this issue should provide basic tools for effectively teaching medical writing. Louise Fuller gives practical tips for anyone thinking of becoming a full- or part-time medical writing trainer or for established trainers looking for new ideas, and Felicity Neilson describes the powerful learner-centred approach to teaching, where learners use what they already know to better assimilate new information.

For those interested in earning a degree in medical writing as way into a medical writing career, there are few academic programmes (see page 16 for a list). However, Dan Benau, Director of Biomedical Writing Programs at the University of the Sciences, explains that formal education from an accredited programme gives a more uniform foundation of knowledge – and therefore a better foundation for a medical writing position – than experience alone or experience combined with short-term training. In the article, Dan also shares his experience at the University of the Sciences, which should be helpful for those building new academic programmes in medical writing.

Finally, Melodie Hull describes the field of clinical writing – writing health professionals use on a daily basis – and what learners and clinical writing teachers need to know.

But wait, there's more …

In addition, to these valuable articles on medical writing education, Gabriele Berghammer and Anders Holmqvist continue their series on page layout and readability, Joseph Ross and Harlan Krumholz discuss the movement to require sharing of clinical trial data and its expected effects on medical writers, and Laura Carolina Collada Ali explains how volunteering for a professional association like EMWA can expand your skills and advance your career.

Medical Writing is evolving

Medical Writing continues to evolve. We have a few exciting new additions in this issue. First, we welcome Stephen Gilliver and Margaret Gray as our new Associate Editors. Their help and excellent work are very much appreciated. We are also thrilled to have three new regular features: Lisa Chaimberlain's Medical Communication section, Diana Raffelsbauer's Medical Journalism section, and Barry Drees' humor section, The Light Stuff.

Finally, we have heard your comments and requests and will be making further improvements to *Medical Writing* in 2013.

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Message from the President

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EMWA President

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Dear Medical Writers

It is time for me to give you another brief update on the activities of the EMWA Executive Committee (EC) and our plans for 2013, as well as a short preview on the spring conference in Manchester.

The autumn conference in Berlin was a great success and was attended by over 200 members. More than 100 members responded to the post-conference survey and 99% confirmed that the conference had fulfilled their objectives with regard to training, networking, lecturing, general programme content, and obtaining credits for EMWA certification. With regard to the latter, I am sure many members will be happy to hear that the EC has now decided to extend the duration of future autumn conferences so that it will be possible to attend a maximum of four workshops at these events in future.

At the EC meeting in Berlin it was also decided to introduce an EMWA student scholarship and to dedicate this to the memory of the late Geoff Hall, a former EMWA president and one of the founder members of the organisation, who himself received the first Nick Thompson Fellowship in recognition of his outstanding contribution to the development of EMWA as a fully fledged independent organisation. The Geoff Hall Scholarship will be awarded to two students each year and will include 2 years of free membership, free conference registration for the duration of the scholarship, and one free foundation course at the first conference. The scholarship will be officially launched at the spring conference in Manchester and details on how to apply for 2014 will be published on the website and in the journal.

Following the excellent responses to both the freelance survey and the salary survey at the end of last year, we hope that the feedback from the E-learning survey will help us to determine the interest of our members in online training opportunities. Although distance learning obviously cannot (and will not) replace the EMWA conferences, the EC are aware that a large proportion of members are unable to regularly attend these events. Therefore, the possibility of online training could add to the repertoire of the organisation and enable more members to profit from their EMWA membership. So please do complete the survey and let us know your needs, so that we can investigate how to best serve your requirements!

Looking forward to the Manchester conference in May, the new style programme includes a full day's symposium on Writing for Health Economics and Market Access, which includes plenary sessions led by international experts providing insights on 'Health Economics and Medical Writing', 'The HTA perspective: a view from NICE', 'Writing for Health Technology Assessment' and 'Consolidated Health Economic Evaluation Reporting Standards', as well as 'Providing Value for Medicines in Elderly People'. There will be panel discussions and plenty of opportunity to ask questions and interact with the speakers. Of course in addition to the symposium we will be offering over 50 different workshops on a wide range of medical writing topics as well as lots of interesting and entertaining social events. We do recommend early registration for the conference, as the popular workshops tend to fill up very quickly!

So, on that note I will just add that I hope to see many of you in Manchester very soon and look forward to a lively and well-attended conference.

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EMWA's position on ghostwriting

Adam Jacobs

On behalf of EMWA

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The European Medical Writers Association would like to make it clear that, contrary to what you may have read in a recently published popular science book, it is not a 'ghostwriters' association'. EMWA is an association for professional medical writers, and deplores ghostwriting. We have published guidelines for the role of medical writers in publications, which make it clear that ghostwriting is unacceptable.[1]

EMWA notes the important distinction between ghostwriting, which is unethical, and professional medical writing assistance, which is legitimate and desirable.[2] Ghostwriting is what happens when someone writes a paper for publication in the medical literature, and neither the identity of the writer nor the funding source of the writing is disclosed to the reader. In contrast, EMWA guidelines state that the contribution of medical writers and their funding source should be made explicit. A medical writer who does not fulfil a journal's authorship criteria, and is therefore not eligible to be listed as an author, must be listed in an acknowledgements section to avoid ghostwriting.

Research evidence shows that the involvement of professional medical writers in publications is associated with fewer retractions for misconduct[3] and better compliance with reporting guidelines.[4]

EMWA is committed to continuing efforts towards the eradication of ghostwriting in the medical literature. Anyone who has any constructive suggestions for how EMWA could more effectively achieve this aim is welcome to contact us.

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Essential modules for teaching publication writers

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Abstract

Medical writers often help train researchers to compose and publish scholarly articles. Although this represents only a small portion of what medical writers do, it is important for those who train academic researchers to be knowledgeable and competent. Here, I describe 16 modules, each consisting of specific writing and editing activities, which need to be taught to *publication writers*. I also suggest a simple evaluation system for assessing *14* competencies in medical writing and editing needed by publication writers to perform their role successfully.

Keywords: Medical writing, Scientific writing, Scholarly articles, Training modules, Evaluation, Editing

One of the main functions of medical or research institutions is to advance knowledge by conducting research. Once completed, research findings are communicated either as presentations in conferences or in the form of academic publications or both. To make research findings available to a wider audience, most academic work is published in a journal article form.

For manuscripts to pass peer review, they must effectively communicate information in the most understandable and expedient fashion. A principal reason why some cutting-edge research never gets published is that it is poorly written and communicated. To overcome this problem, medical communicators who specialise in medical writing and editing should collaborate with academic researchers to help them develop their publishing careers.

Medical writers and editors who specialise in scientific writing and publishing (referred hitherto as '*publication writers*') primarily write, edit, or develop medical materials by gathering, organising, interpreting, and presenting information in a manner appropriate for the target journal. The articles they prepare include original articles, reviews, case reports, short communications, special reports, or letters to the editor, which require both specialist knowledge and communication expertise. Publication writers must possess superior writing and editing skills to be able to help researchers compose and publish their scholarly articles. This can be achieved through continuing education and appropriate training using specially developed medical writing and editing modules for academic publications.

However, there are few medical writing and editing modules to teach publication writers how to help researchers effectively communicate in scholarly publications, and modules need to be continually developed. These modules must specifically address the different aspects and components of writing, editing, and publishing of scholarly articles. Importantly, the essential modules that need to be taught to these publication writers must be carefully integrated into a well-organised curriculum.[1,2] Such modules can also be used in medical writing and editing internship programmes in academic institutions.[3]

In this article, I introduce 16 essential modules, each consisting of specific medical writing and editing activities, which can be taught to publication writers to enhance their ability to help researchers write effectively (Table 1). I also suggest a simple system for evaluating *14* competencies in medical writing and editing of scholarly articles that can be used to ensure that publication writers can perform their role successfully (Table 2).

Essential modules

Module 1. Writing, editing, and reviewing a medical paper

In this module, the publication writer comprehensively reviews a medical paper and corrects the style, format, syntax, language, science, content, logical flow, and overall impact of the study. The publication writer carefully upgrades the paper's

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Table 1: Summary of modules, critical activities, and essential skills developed

Module	Critical activities	Essential skills developed
1. Writing, editing, and reviewing a medical paper	Correcting, upgrading, improving, reviewing, and confirming text	In-depth analysis, critical appraisal, accurate assessment, attention to detail
2. Writing and editing a cover letter	Improving tone, writing declarations, suggesting reviewers	Synthesis, microediting, attention to detail, in-depth understanding
3. Clarifying journal decision letters[4]	Analysing, clarifying, and simplifying journal decisions	Critical thinking, in-depth analysis/interpretation, simplifying sentences
4. Rewriting and editing of papers conditionally accepted[4]	Reviewing, re-editing, proof checking, and providing point-by-point responses	Critical appraisal, knowledge assessment, ensuring appropriate revisions
5. Writing and editing of responses to reviewers' comments[4]	Rewriting responses, editing explanations, ensuring accurate scientific rebuttal	Careful analysis, accurate interpretation, writing concise responses
6. Rewriting and editing of papers for submission to another journal[4]	Rewriting/editing of text, providing advice on new target journal	Critical thinking and analysis, appraisal of peer-reviewed journals, text rewriting
7. Writing and editing of posters and slide presentations[4]	Streamlining/organising text, checking figure resolution, evaluating presentation/layout	Detailed preparation, microediting, attention to detail
8. Writing and editing of oral presentation script and coaching presentations[4]	Editing text that encourage audience interaction, audio recording, coaching presentations	Creation of interactive script, proficiency in audio file preparation
9. Styling papers to conform to the guidelines for authors[4]	Rewriting/editing to adhere to author guidelines, clarifying unclear points of guidelines	Attention to detail, assessment of deficiencies/unnecessary parts, journal appraisal
10. Support with online submissions[4]	Editing/preparing files and disclosures, online submission	Mastery of submission software, preparation of files, online submission proficiency
11. Annotating galleys[4]	Checking for minor errors, annotating PDF-formatted galley	Attention to detail, accuracy in making annotations in the PDF file
12. Citing different types of material found online[5]	Citing non-print materials, e-publications, post-publication peer review, and supplements	Citation of and familiarity with online materials, citing electronic materials
13. Writing and editing references[6]	Correcting citation format, checking reference accuracy, formatting references	Attention to detail, accuracy in following journal instructions, reference formatting
14. Abstract writing and editing[7]	Abstract writing, formatting, and styling; meeting word limits and structural formats	Concise study summation, mastery of rules in abstract editing, meeting requirements
15. Communicating with authors (author–editor relationship)[4]	Clarifying unclear parts with authors, writing queries to authors	Improved communication, discussion synthesis, enhanced author–editor relationship
16. Ethical issues in medical writing[8–12]	Reviewing materials on ethical issues, attending meetings on ethics, correcting ethical issue statements	Familiarity with ethical issues/legal implications in medical writing, accuracy in editing ethical statements/declarations

medical terminology, checks the validity of the methodology, reviews scientific nomenclature, improves readability, performs a structural review, gives advice on the most appropriate format, and confirms the number and format of keywords. These activities sharpen the publication writer's ability to make an in-depth analysis of the study; effectively communicate research findings; make a critical appraisal of the writing style and content of the manuscript; accurately assess the novelty, scientific knowledge, and impact of a study; macro-edit (substantive or content editing); and microedit (copy or line editing).

Module 2. Writing and editing cover letters

Here, the publication writer improves the text and tone of a cover letter by highlighting the importance of the study, writing statements to acknowledge the efforts of contributors or declare competing interest(s), and suggesting possible reviewers. By undertaking

these activities, the publication writer harnesses skills in synthesising the main study highlights, as well as in microediting, paying attention to detail, and understanding the novelty of a study.

Module 3. Clarifying journal decision letters[4]

This module allows the publication writer to carefully analyse and clarify decisions made by the journal editor following peer review. As necessary, the publication writer rewords or simplifies sentences in the decision letter for clarity and ease of understanding. These activities refine the publication writer's ability to think criticially, analyse and accurately interpret the journal editor's decision, and simplify but preserve the meaning of difficult or ambiguous sentences in decision letters.

Module 4. Rewriting and editing of conditionally accepted papers[4]

For papers that are conditionally accepted for publication, the publication writer thoroughly reviews and determines the exact decision of the journal editor, re-edits the newly added parts, proof checks the rest of the manuscript for consistency and logical flow, and assists in preparing the point-by-point responses to the comments raised. These tasks improve the publication writer's ability to make a critical appraisal of the manuscript, clearly assess the scientific knowledge and depth of the study, upgrade and clarify author responses, and ensure appropriate revisions in the paper to answer the issues raised.

Module 5. Writing and editing of responses to reviewers' comments[4]

The focus in this module is for the publication writer to edit or rewrite point-by-point responses to the comments raised, upgrade the explanations of revisions made in the text and cover letter, edit or reword scientific rebuttal by building persuasive and scientific-based arguments, and provide advice, support, and composition for designing response content. This process enhances the publication writer's ability to make a careful analysis and interpretation of journal editors' and reviewers' comments, think critically and evaluate the manuscript and author responses, assess scientific knowledge and depth of the study, and provide concise responses to all comments.

Module 6. Rewriting and editing of papers for submission to another journal following rejection by the original target journal[4]

Here, the comments of the original target journal are carefully analysed by the publication writer. The publication writer then rewrites or edits the newly added parts in the manuscript according to the salient comments raised, and provides advice on the selection of a new target journal. These activities broaden the publication writer's ability to think criticially and analyse reasons for manuscript rejection, make a precise appraisal of peer-reviewed journals, and rewrite and edit the paper to address important points raised in the original comments.

Module 7. Writing and editing of posters and slide presentations[4]

In this module, the publication writer organises and streamlines the text, checks the quality and resolution of the figures, and evaluates and edits the layout and appearance of a poster and slide presentation. By carefully doing these activities, the publication writer perfects skills in the detailed preparation of poster and slide presentations, microediting, in designing the layout, and in organising text and figures.

Module 8. Writing and editing of oral presentation scripts and coaching presentations[4]

The presentation script is edited by the publication writer to ensure a spoken tone that encourages interaction from the audience about the technical content of the presentation. Also, the publication writer records the oral presentations, coaches the speaker on delivery of the presentation, and corrects pronunciation. These activities polish the publication writer's ability to create an interactive presentation script and enhance proficiency and expertise in preparing audio files in different formats and delivery speeds.

Module 9. Styling papers to conform to the guidelines for authors[4]

The publication writer meticulously rewrites and styles a paper to adhere to the guidelines for authors of the target journal and clarifies unclear points of the guidelines for the authors. With these activities, the publication writer masters the ability to examine the details of author instructions, make a critical assessment of a manuscript's deficiencies and unnecessary parts, and appraise scholarly journals.

Module 10. Support with online submissions[4]

As most scholarly journals now require online submissions, the publication writer edits and prepares all files and disclosures needed, assists authors in submitting their papers online, and ensures successful manuscript online submission. These activities improve the publication writer's ability to use

different types of journal submission software, prepare all required files, figures, and tables in the correct format, and master all the necessary elements and steps of online submission.

Module 11. Annotating galleys[4]

The publication writer carefully checks the galley of an article for errors in formatting, punctuation, terminology, spelling, typescript, and headings. These activities hone the publication writer's skills in making concise electronic annotations in the PDF file and sharpen the publication writer's attention to detail.

Module 12. Citing different types of material found online[5]

Materials found online are a vast resource for citation in scholarly articles. For this module, the publication writer appropriately cites non-print materials associated with journals, accepted publications ahead of print, e-pages and e-publications for journals, e-letters, post-publication peer reviews, and data supplements. The publication writer thus becomes proficient in identifying and citing different types of relevant materials found only online, gains familiarity with different types of online material typically used as sources in the medical literature, and improves the ability to cite these online materials.

Module 13. Writing and editing references[6]

The reference section is one of the most neglected parts in scholarly articles and can contain careless spelling, typographical, and formatting errors. In this module, the publication writer corrects the citation format of the references in the text, checks the accuracy of all references, and formats the references in accordance with the journal's guidelines. This greatly refines the publication writer's ability to format references and follow journal instructions.

Module 14. Abstract writing and editing[7]

The abstract contains the highlights of the completed research and must follow the format required by the target journal. In this module, the publication writer rewrites an abstract to meet the standard style, word limit, and structural requirements. The publication writer therefore refines the ability to make a concise summary of the results, highlight key findings, and meet word or formatting requirements.

Module 15. Communicating with authors (author–editor relationship)[4]

With the aim of enhancing the author–editor relationship and achieving a better appraisal of the scholarly article, the publication writer builds and maintains a collaborative relationship with the author, clarifies any ambiguous parts of the article, and develops a feedback mechanism with the author. Alternatively, the publication writer writes polite queries regarding unclear parts in the text for the authors to address if they are unable to meet and discuss these parts immediately. In this process, the publication writer improves the ability to clarify issues; extract, synthesise, and summarise important points from the discussion; and build and strengthen the author–writer/editor working relationship.

Module 16. Ethical issues in medical writing[8–12]

The publication writer must ideally be familiar with ethical and legal issues in medical writing and publishing (e.g. reporting data, conflicts of interest, financial disclosures, and declarations). To achieve this, the publication writer reads and must thoroughly understand materials on conflicts of interest, financial disclosures, duplicate publications, or other declarations related to manuscript submission. Participation in meetings or conferences on ethics in medical writing and publishing can enhance the publication writer's understanding of target journal requirements regarding ethical declarations and help the publication writer correct ethical issue statements in the manuscript text.

Competency evaluation

Competency evaluation is necessary to assess the publication writer's skills and overall competency as a medical writer and editor of scholarly articles. This can be done before, after, or both before and after training. The competency evaluation can be used for setting expectations and for performance evaluation. This evaluation system described here consists of 14 competency areas. The publication writer or the publication writer's supervisor rates the level of competence for each area. I suggest using a 'PAGE' rating system, where P is poor, A is average, G is good, and E is excellent. A rating of P or A indicates a strong need to improve and master essential skills in medical writing and editing of scholarly articles. A summary of the different competency areas for evaluation is shown in Table 2.

Competency 1. Appropriately uses language and syntax

Consistently corrects language and syntax of the scholarly article. This involves a comprehensive check of grammar, punctuation, spelling, hyphens,

Table 2: Summary of competency areas of medical writers and editors of scholarly articles for evaluation

Competency areas
1. Appropriately uses language and syntax
2. Correctly eliminates ambiguities
3. Ensures correct structure and format
4. Meets the word count requirements
5. Accurately writes ethical statements and disclosures
6. Makes concise corrections and achieves brevity
7. Adheres to guidelines for authors
8. Accurately corrects the science, content, study design, and logical flow
9. Correctly identifies sources of errors
10. Highly adaptable and flexible
11. Promotes effective teamwork
12. Effectively sets priorities
13. Can work and make decisions independently
14. Interacts harmoniously with colleagues and remains open to suggestions

capitalisation, units of measure, typographical errors, terminology, sentence construction, references, structure, format, logical flow, and relevance. The publication writer also correctly explains or defends any corrections of the language and syntax made based on published rules/guidelines on scientific writing and editing.

Competency 2. Correctly eliminates ambiguities
Accurately identifies and corrects ambiguities and inconsistencies in the text, tables, figures, and references.

Competency 3. Ensures correct structure and format
Comprehensively writes or consistently edits the text to meet the structural and format requirements of the target journal in terms of manuscript sections, headings, text requirements, abbreviations, and units of measure.

Competency 4. Meets the word count requirements
Appropriately rewrites or edits the title, abstract, and main text to the required character or word count of the target journal.

Competency 5. Accurately writes ethical statements/ disclosures
Writes or edits the necessary ethical statements and disclosures relevant to the manuscript.

Competency 6. Makes concise corrections and achieves brevity
Correctly identifies the most appropriate sentences or parts that can be removed from the text for brevity.

Competency 7. Adheres to guidelines for authors
Provides correct advice on meeting content guidelines, or can edit and style a paper to the journal guidelines.

Competency 8. Accurately corrects the science, content, study design, and logical flow
Comprehensively assesses and corrects the science, content, design, and logical flow of the study; correctly evaluates the reliability of results; and can explain or defend any corrections made from a scientific point of view.

Competency 9. Correctly identifies sources of errors
Correctly identifies possible sources of mistakes that may bias the findings.

Competency 10. Highly adaptable and flexible
Can interact and carry out in-depth discussions with diverse authors of different medical fields.

Competency 11. Promotes effective teamwork
Works well as part of the editor–author team and is able to provide personalised support during the writing process and full editing assistance after peer review until acceptance.

Competency 12. Effectively sets priorities
Can set priorities when working with multiple articles.

Competency 13. Can work and make decisions independently
Can competently and quietly work independently, but is aware of personal limitations. Welcomes constructive criticisms and strives for continuous improvement of work and relationships with authors and co-workers.

Competency 14. Interacts harmoniously with colleagues and remains open to suggestions
Works well individually or with others, interacts harmoniously with colleagues, and remains polite and open to suggestions.

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Combined workshops on medical writing and publication ethics for Japanese postgraduate students and faculty members

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Abstract

Although the importance both of skills in medical writing in English and of an understanding of ethics in medical publishing is increasingly recognised, these subjects are not comprehensively taught to Japanese medical doctors and students. Limited resources, teaching staff, and time prevent most Japanese medical schools from implementing standard educational programmes on these topics. To address this, we developed two brief but intensive programmes of lectures and group-based workshops, each incorporating both medical writing skills and publication ethics; one was for Japanese postgraduate medical students, the other for faculty development. The main topics in the programme for postgraduate students were the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, and oral and poster presentation skills. The programme emphasised the importance of medical writing skills and of issues, such as authorship and conflict of interest. The faculty development programme covered handling communications with editors and reviewers after manuscript submission, as well as ethical misconduct issues. We believe these programmes provide a unique and effective means of enhancing awareness of publication ethics and improving medical writing skills among professionals in Japanese healthcare institutions.

Keywords: Medical writing, Medical publication ethics, Non-native English speakers

Since the late 1990s, significant changes have been made to medical writing guidelines, such as the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*,[1] and the *American Medical Association Manual of Style*,[2] particularly on ethical aspects of medical publishing, reflecting increased awareness of the need for transparency in publications. However, education in Japanese medical schools in such areas has not reflected this international trend, and a lack of awareness and knowledge of publication ethics has led to professional problems damaging the careers and reputations of some Japanese medical researchers.

In Japan, many medical schools lack appropriate teaching staff and resources to deliver, independently, undergraduate and postgraduate courses on medical English, medical communications and writing, or publication ethics.[3] They also lack staff who can together provide editorial support and promote international publications. Nevertheless, some Japanese medical schools, recognising the need for education in these areas, have begun to collaborate with other medical universities, that do offer such educational programmes, to conduct workshop programmes for their students and faculty. At the request of Jichi Medical University School of Medicine our institutions have together, since 2009, developed and conducted annual workshop programmes combining topics related to medical writing and ethics.

Structure of the postgraduate and faculty development programmes

Most of the workshops we delivered in 2009 and 2010 focused on medical writing skills and publishing strategies, such as common mistakes in medical

writing and how to respond to reviewers' comments, presented as lectures with handout materials. In 2011, we decided to incorporate publication ethics into the programme, although doing this effectively demanded a restructured programme involving active participation to maximise understanding of the issues. We developed a programme combining lectures and group-based workshops for the postgraduate students, and a separate programme of lectures and problem-based learning workshops for the faculty, who generally have more experience of scholarly publishing.

Postgraduate programme (2011)

The postgraduate programme consisted of two 2-hour evening sessions. Each session involved a 50-minute lecture and a 50-minute interactive group-based workshop. The topics of the main lectures were (1) fundamentals of the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, and (2) oral and poster presentation skills, topics that we considered essential for medical doctors with limited experience of writing medical papers in English, and of presenting at international conferences.

One objective of the group-based workshop was to increase active participation and discussions. After a 30-minute introductory talk on authorship and peer review, participants were divided into small groups, given several short sample case descriptions related to the topic (Box 1),[4] and asked to develop and present answers to set questions as a group. All groups were given the same questions. In addition, participants were required to answer general questions on the introductory material (Box 2).[4]

Box 1 Sample case on guest authorship[4]

A Chinese researcher, using data she obtained during a 2-year fellowship in the USA, writes a paper in Chinese on cardiac bypass. Out of respect to her US mentor, she offers to include his name among the authors of the Chinese paper, even though he reads no Chinese. The mentor understands the kindness of the gesture, and has a general idea of the work and understands the English language abstract.

Questions

- If you were the mentor, what would you do?
- Since the mentor knows that few, if any, of his colleagues will read it, and he does not plan to include it in his list of published papers, is it acceptable for him to agree?

Box 2 General questions on authorship/peer review[4]

- What is a guest author?
- If a journal asks you to peer review a paper, and you find it was written by a friend of yours, what should you do? How about if it were written by someone you intensely dislike?
- Do you agree with the definition of authorship in the Uniform Requirements? Why? Why not?

Faculty development programme (2011)

The faculty development programme was delivered in one 4-hour evening session, consisting of two 50-minute lectures and one 2-hour problem-based learning activity on publication ethics. These lectures covered more advanced topics than those of the postgraduate programme, such as how to respond to reviewers' comments and interpreting letters from editors-in-chief. Actual letters from editors and comments from peer reviewers were collected beforehand from the expected participants to increase relevance and raise interest.

The problem-based learning activity on publication ethics focused on actual cases notified to the Committee on Publication Ethics (COPE), an organisation that aims to increase the integrity of academic journals by advising editors on publication ethics.[5] This session started with a short lecture on COPE and its flowcharts, and participants were introduced to the full spectrum of publication misconduct and to the concept that some widely accepted practices may be unethical.[6]

Participants were then divided into small groups, and were asked to (1) identify the key issue or problem of the given case; (2) refer to the appropriate COPE flowchart; and (3) follow the flowchart and discuss the steps advised, with a final group presentation (Box 3).[7]

Students' responses to the programmes

Each participant filled out a questionnaire asking whether they considered the programme

Box 3 Sample case from COPE website[7]

A paper was accepted and published in journal A, which dealt with a cohort of patients with an unusual respiratory pathogen. A similar paper had been published in an US journal B by the same authors, a few months before. It dealt with more or less the same patients (a few more had been added) and provided some extra secondary outcome data but with the same conclusions.

The editor of journal A considered this to be duplication, but the authors deny this on the grounds that there are further data.

Question

Discuss the steps COPE advises in their flowchart (see COPE website).[7]

worthwhile, what they had learned, and whether the programme had altered their perceptions. Most responses were positive, indicating that these programmes provide effective training in medical writing skills and publication ethics for postgraduate students and faculty. Postgraduate programme participants indicated that their appreciation of the importance of both topics had increased, as had their knowledge of authorship policies, peer review, and conflict of interest. Faculty programme participants indicated that they had gained knowledge on handling communications with editors and reviewers after manuscript submission.

Discussion

We believe that these postgraduate and faculty programmes are unique in combining the teaching of medical writing skills and medical publication ethics in short sessions on 1 or 2 days. The use of English as an international language poses a challenge for many authors, whose native language is not English.[8] Japanese medical researchers now face the additional burden of growing international concern about publication ethics. Such researchers, with limited time, writing expertise, or English writing skills are likely to seek medical writing assistance[9] and, to avoid serious ethical misconduct, they particularly need to understand what is considered ethically acceptable.

With this in mind, postgraduate and faculty development programmes combining medical writing training and medical publication ethics education should be encouraged in Japanese medical schools. These programmes will assist medical researchers with limited time to improve their knowledge of these areas, which is essential for developing their research and publishing careers.

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Author information

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Teaching scientific writing to non-native English speakers

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Abstract

Scientists and clinicians around the world are facing the tyranny of publishing in English in journals with high-impact factors. The workshop format is not suitable for language teaching. Participants in workshops on scientific writing whose first language is not English should therefore be taught the structure of scientific manuscripts. Once a manuscript is properly organised, the English can be improved by a native-English-speaking person, preferably an author's editor. As an example, I describe the basic design of a 3-day workshop on scientific writing for non-native English speakers. Specialists in scientific writing are not necessarily language teachers; the skill should be taught as a subject in its own right, preferably as part of general training in research.

Keywords: Scientific writing, Teaching, Workshop, Non-native English speaker

Scientists and clinicians all over the world want to publish in 'international journals', which is a euphemism for English-language journals. The top 20 impact factor scores in 2012 were for journals published in Canada, the United Kingdom, or the USA.[1] Those who decide to sign up for a workshop in scientific writing (or who are sent by their superiors) want to (or are obliged to) have their papers published in high-impact-factor journals.

The institutions that express interest in a workshop on scientific communication have various expectations, but their main aim is to try to increase their rate of publication. A university, such as the University of Malaya in Kuala Lumpur, Malaysia, may have the specific aim of becoming one of the top 100 universities in the world, which depends entirely on the number of publications from the university that are published in journals with a high Thomson Reuters impact factor. Other institutions, such as the Academy of Science and Technology in Dakar, Senegal, may just wish to introduce researchers and clinicians to the idea that they should try to publish.

English is often the participants' third or fourth language. For instance, in many countries in north and west Africa, a participant will speak a local dialect, the national language, and French as their first three languages. What, therefore, is the best way to approach the teaching of scientific writing?

A common misunderstanding is that the workshop will help the participants to improve their English. Most of the workshops advertised on the Internet and elsewhere last a maximum of 3 days and are usually much shorter – half a day. The short workshop mode, in which there may be as many as 20 participants, is unsuitable for language teaching, as there is little chance for meaningful exchanges between participants and the workshop leader. A few pointers can be given for correct use of grammar and avoiding obvious grammatical errors, but it is not realistic to expect that the participants' command of English will be improved within a few days.

The participants who attend a workshop in scientific communication must be screened to ensure that they have a sufficient command of English to understand the presentations of the facilitator. In most contexts, the discussion among the participants is also held in English, although certain aspects may give rise to heated exchanges in the local language. It is important for the facilitator to insist on a summary in English of such exchanges, both for mediating the discussion and to familiarise the participants with the vocabulary associated with the topic.

The facilitator therefore should emphasise from the beginning that language is not a problem, at least not in writing a first draft of a manuscript. Participants should be told to concentrate from the beginning on the *structure* of the article, on the premise that an article that is logically organised is easier to understand than one that has no clear beginning or end. Furthermore, it will be easier for an editor to correct any problems of language if the organisation of the paper is clear. One of the main problems in most draft manuscripts is that

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the question being addressed is not stated clearly. Every form of scientific communication must start with the answer to the question 'Why did you start?' If readers are not given the context of the study, they are unable to situate its importance within the field. Also, once the author has the answer to that question clearly in mind, he or she will find writing the rest of the paper easier.

The next questions that must be answered, in order, are 'What did you do?', 'What answer did you get?' and 'What does it mean?' in the refreshingly clear outline presented by Austin Bradford Hill in the 1960s.[2] The participants are shown that the answers to these apparently simple questions are the basis for the IMRaD structure (Introduction, Materials and Methods, Results and Discussion).

Workshops are often didactic, based on presentations by the facilitator and on handouts, as in many settings the participants have little experience in writing scientific papers and cannot participate in discussions on the material being presented. One way of involving participants is to use their own draft manuscripts to illustrate each aspect of scientific communication. It might be thought that this practice, with comments and criticisms being made at every step by both participants and the facilitator, would give rise to hurt feelings and resentment. In my experience of 35 years of teaching scientific communication to a total of perhaps 2000 participants, this has happened only once. Exclamations of 'Oh, everything's wrong with my paper!' are countered with assurances that all the information is there but it must be better organized. As in any teaching situation, participants must constantly be encouraged and assured of their competence. 'You're the scientists [clinicians]. You know the subject area. You read papers in English all the time and understand this topic much better than I do.'

As an example, I describe a 3-day workshop on scientific writing for non-native English speakers. This workshop is designed to give non-native speakers of English a basic understanding of writing scientific articles for international journals. The workshop does not include English-language teaching.

A 3-day workshop on scientific writing for non-native English speakers

My 3-day workshops are based on three manuscripts offered by participants, with the understanding that they are confidential documents and that all copies must be returned to the participant at the end of the workshop. Before the workshop, all participants are sent and asked to read the three manuscripts.

Participants also receive several handouts:

- The latest version of the Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication of the International Committee of Medical Journal Editors (ICMJE).[3]
- A set of checklists for each part of the paper and for revising subsequent drafts.
- A table illustrating the basis for choosing certain types of graphs.
- The structure of a discussion as proposed by the British Medical Journal.[4]
- Lists of words and phrases that can be simplified.
- A summary of a 1-hour presentation on writing style, given at the end of the workshop.

Beginning of the workshop

At the beginning of the workshop, I ask the participants to introduce themselves, to describe their experience in writing and what they expect to gain from the workshop. Their experience may not necessarily include writing manuscripts for publication but may be in writing reports or a thesis. These introductions allow me to judge the participants' command of English. Their expectations often include improving their English, and I gently explain that this is not possible but that improving the structure of their manuscript will make it easier for the editor of the journal, the reviewers and readers to understand it.

Searching the literature and selecting a journal

Next, there is discussion among the participants on literature searching, in which they inform each other about the resources available to them at their institution and also about how to record the information they find, such as in EndNote.[5]

They are then told to choose the journal in which they wish to have their paper published. This always creates some surprise, but I make it clear that journals differ in small and large ways, and a manuscript written with a specific journal in mind will have a better chance of being considered by that journal.

Detailed discussion of a paper

The three manuscripts are then used for detailed discussions on each aspect of a paper. I describe the functions of each element, with the checklists;

then, the participants comment on the examples. Does the title accurately, clearly, and concisely describe the content of the paper? Is it informative? Does it contain the main key words?

An issue that often gives rise to a discussion is authorship. Although participants are made aware of the criteria established by the ICMJE, it is important to allow discussion about applying those criteria in the local institutional context. The facilitator must show respect for established local customs, while at the same time pointing out the advantages of applying the ICMJE criteria, which the participants almost always recognise.

Several hours are spent on improving the abstracts. Participants are reminded that this is the part of the paper that will be most widely read (perhaps the only part) and that it must faithfully reflect each section of the paper, answering each of Bradford Hill's questions. Time is spent on making sure the proportions of text used to answer each question are suitable and on refining the wording, to make every word count.

The remaining sections of the manuscript are discussed during the rest of the first day and the second. Towards the end of the second day, there is a discussion on submitting the manuscript to the journal, including the letter to the editor that accompanies it, and a short presentation on writing style. It is interesting that scientists whose first language is not English are more resistant than native speakers to the idea of simplifying language. They are quite comfortable with using a phrase like 'implementing a learning process' instead of 'teach'. The ghastly phraseology that has crept into scientific discourse[6] seems normal to them, and they are resistant to the idea that they can write the way they speak.

On the third day, participants are given an article that has no title or abstract and are asked to work in groups of four to five to write a title, an abstract and keywords and to comment on the structure of the article. The whole group reconvenes to discuss the results. This gives me a chance to see how well the principles of writing have been understood. If time permits, I edit the abstracts on screen to illustrate some of the points of writing style.

Time for questions

If there is time, the facilitator can answer any remaining questions from the group, such as showing how the structural principles apply to other forms of scientific communication, such as literature reviews, case reports, oral presentations, and posters.

Evaluation of the workshop

To evaluate the usefulness of the 3-day workshops, I invite each participant who brought a manuscript to revise it on the basis of the workshop comments and to send it to me for English-language editing before they submit it to the journal of their choice. I also ask to be kept in the loop of reactions from the editor of the journal and reviewers' comments and offer to help the author to respond and follow-up the paper until publication. Similarly, workshop participants who did not bring a manuscript are invited to send the first manuscript they write after the workshop to me for editing and follow-up to publication. When I first proposed this, I thought I would be overwhelmed with manuscripts; however, I received only one or two manuscripts from each workshop. Does this mean that the participants did not subsequently write papers or that they were too timid to send them? It is difficult to say without actually e-mailing all 2000 participants I have had over the years.

Conclusion

If scientific writing became part of teaching on scientific method and conduct, it would finally assume its proper position in a student's training. There is little training in this field, and the training that is available often centres on teaching grammar and spelling. Specialists in scientific communication are not necessarily language teachers – scientific communication should be taught as a subject in its own right, with English-language teaching as a completely separate course.

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Certificate and degree programs in Medical Writing

Program	Location	Cost	Description and comments	Website/contact
EMWA certificates in medical writing	European Medical Writers Association; requires attendance at multiple conferences in Europe	Cost varies	For professional medical writers; requires attendance at several conferences and membership in EMWA	http://www.emwa.org/training.html
MSc in Medical Writing	Medical University of Innsbruck, Austria	Approximately €15,000-18,000 for 2 years	Course currently being restructured. Will restart in Fall 2013. Expected to include 1 week/year onsite and the remainder online.	Michael Nogler michael.nogler@professor-nogler.at
PGCert in medical communications	University of Worcester, UK	€1800	Part-time on site over one year; three 20-credit modules; combination of in person on weekends and online	http://www.worcester.ac.uk/courses/medical-communications-pgcert.html
Master's in medical writing and certificates in regulatory writing and in marketing writing	University of the Sciences, Philadelphia, PA, USA	€38,000 for Masters, €13,500 for certificates	Courses online	http://www.gradschool.usciences.edu/biomedical-writing/biomedical-writing-program-overview
Certificate in medical writing & editing	University of Chicago, USA	€1150 per 3-day course, 4 courses required for certificate (€4250 total)	Taught on site in Chicago or online	https://grahamschool.uchicago.edu/content/medical-writing-and-editing
AMWA certificates in Medical Writing	American Medical Writers Association; requires attendance at multiple conferences in the US	Cost varies	For professional medical writers; certificate available, requires attendance at several conferences and membership in AMWA	http://www.amwa.org/default.asp?id=250

A field guide to medical writing training

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Abstract

Teaching medical writing is a varied, interesting, and satisfying role. You might find yourself teaching PhD students to write theses, laboratory scientists to write posters, clinicians to write papers, or professional medical writers to improve their skills. Each of these groups starts with different levels of knowledge and requires different teaching approaches. There is no single prescription for the ideal training course. In fact, to provide maximum benefit to trainee writers, each course will have to be fully tailored to their needs and designed to keep them interested and involved. This article provides ideas to help develop and run effective (and fun) writing training courses. The five main aspects covered are research, planning, developing content, assembling course materials, and managing the training day.

Keywords: Writing, Training, Research, Content, Structure, Tips

Effective dissemination of scientific data has never been more critical. Publication of clear, well-constructed papers helps to maintain the standard of the burgeoning scientific literature, and is essential for individual career advancement and building the reputation of institutions. Therefore, effective training of new medical writers (scientists, clinicians, and medical writing professionals) is becoming increasingly important.

This article provides practical tips for anyone who is thinking of becoming a full- or part-time medical writing trainer or for established trainers looking for new ideas. Most of the activities have been tried and tested by me, and some of the notes on things to remember are in here because they are things that I have at some stage managed to forget. When I am running a course on medical writing, I stress the importance of knowing your subject, doing your research, consulting the guidelines, planning your content, and taking care over details. These same principles are true for creating an effective training course.

Do your research

Like a first day at school, it can be daunting to arrive at an unfamiliar building, negotiate security and reception staff, find the right room, and then embark on a day of training with a group of people that you do not know. Make it easy on yourself – get to know the course organiser(s), keep in touch while you develop the course, ask for the facilities that you need, and then plan, plan, plan, plan, plan. You cannot plan too much. Try and picture the whole day in your head. Make sure that you know what is happening when. You do not need the stress of running round an unfamiliar building looking for an information technology (IT) technician at the moment when your trainees arrive. A training day without surprises makes for a happy trainer.

Before you begin to prepare the course content, get a full briefing from the course organisers – they are there to help you. Very often, one person is in charge of logistics and another in charge of content; in an ideal world you would visit the institution and meet the organisers. In reality this seldom happens, but do not let this put you off getting the information you need. Draft yourself a list of questions and make sure that you get the answers (Fig. 1).

It is important that that you are clear on the client's objectives for the training. Do not just take a verbal brief – write it down and send a confirmatory email. If your course is successful and you are asked to repeat it several times, there can be 'objectives creep'. Review of objectives can keep everything running smoothly.

Then find out everything that you can about the audience. What do they know? What do they not know? What level of information do they need? How experienced are they? Are they students, laboratory scientists, or medical communication

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Course objectives

- What are the areas to be covered?
- Should there be particular emphasis on one or more aspects that are important to the students or the institution?
- How long is the course?

The audience

- How many will attend?
- What is the scientific/medical/professional background of the trainee writers?
- How many do not have English as their first language?
- Do they all have the same level of experience in their field?
- What are their primary target publications (e.g. key journals and congresses)?
- What guidelines and constraints are there on the trainees (e.g. regulatory, journal, house style or industry guidelines)?

Logistics

- Who will be the course contact at the training site (you can be very delayed while reception determines that you are a bona fide trainer)? What is the name, department and extension number of your contact?
- Who will photocopy your hand-outs? What is their extension number? When do they get into work?
- How will the hand-outs get to the training room? Where can you collect them from? When?
- Will there be an IT professional on standby before your course starts? If so, what is their name and extension number?
- Is coffee and lunch provided? For you? For the trainees?
- Will there be everything that you need, such as a computer/projector/flip chart/pens/post-its/Blu-Tac?
- What computer operating system are they using? (Linux can be a nasty surprise for Windows-based mortals)
- Will you be allowed to use your own laptop or to plug in a USB stick?
- Can you have the room set up for group work?
- Will the students receive a certificate of attendance? Do you need to give it out? If so, who will provide this? When?
- If you are staying overnight before the course who will book the hotel? Does it include breakfast?
- If you are travelling overseas, who will book the flights? (Some institutions get advantageous rates and prefer to do the booking); make sure that you book early to get the best rates

The venue

- Get a map! Not just how to get to the institution, but also get instructions on what door to use where to park and how to get to reception (very important for big hospitals and research facilities)

Feedback

- Will you be given feedback? Do you need to hand out a feedback form? How will this be provided?

Fees

- Agree course fees and travel expenses in writing
- If you are developing a bespoke course, ensure that your fee covers both planning and giving the course
- If you are travelling by air or another potentially costly route and your fare is non-refundable, make sure that the organisers know that you will ask for a refund if the course is cancelled or the date is altered
- Make it clear if you will need to arrive the night before and so will have to pass on the costs of bed and breakfast

Figure 1: Important points to cover when researching your training event.

professionals? Do a bit of method acting – put yourself in their shoes. Your course will be greeted with wild adulation if you adapt it for your audience.

Logistics are the biggest source of stress – try to plan for all eventualities. I travel with all the course material on a laptop, on a USB stick, and as a printed copy. I also email everything to the organisers in advance. Most organisers say that they have a laptop and projector already set up, but it is surprising how often I have had to use my own laptop or even work from photocopies of my own printout because of IT or other issues. I also take my own water bottle and sandwiches. Some institutions cannot organise a jug of water on a table or lunch for the trainer!

Most training organisers prefer to print your hand-outs for you as it is cheaper (and it is a big burden for you to carry hand-out booklets for up to 30 trainees). However, tracking down these hand-outs and other course materials when you arrive on site can be difficult. Always arrive at the venue with enough time to deal with these logistical issues. If there are none, you might have time for a cup of tea and a break!

The biggest difficulty for most institutions seems to be organising the layout of a room between its use, the night before, and you starting your course at 9 am. Often, furniture must be rearranged before the trainees arrive. Wear clothes that allow you to move tables and chairs without becoming dishevelled. And do not rely on the trainees to help; before 9 am, many trainees appear to be sleepwalking.

Planning your course pays dividends

Have you been to one of those courses where the trainer obviously gives the same course every time? I have sat through many, often wondering about the relevance of the material to me. I have subsequently popped the course hand-out on the shelf and forgotten about it. Random information is not useful; information and examples directly relevant to my daily life – now you have my attention! Of course it is easiest and most time- and cost-effective to develop your ideas once and give the course multiple times. However, to really make a difference for the trainees, each course needs to be carefully tailored to their needs. Be aware that planning a course can take a lot more time than actually giving it – make sure that you allow yourself enough time to develop an outline, slides, hand-outs, and exercises or games. Also build in time to rehearse beforehand – luckily my friends and family are very patient and could probably give most of my courses now!

Develop a detailed outline

A detailed outline helps on many levels. And I mean a really detailed outline – with a time allocation for every element, a clear flow of ideas throughout the day and learning objectives for each activity. One of the most important uses for an outline is as a document for discussion with the client. That way you both know what to expect from the training. I generally ask the person in charge of course content (and any appropriate student bodies or line managers) to sign off on the outline before I develop the course. I find the outline is also very useful as an onsite agenda – it stops individual sessions overrunning and means you can complete the entire course on time.

Think modular structure

There are going to be elements that are common to all courses and others that are specific to the knowledge level and expertise of the trainees or the requirements of the course organisers. If you develop a series of standard elements that will suit all trainees, then you can mix and match these with bespoke elements for individual courses. This saves time on course preparation and means that on the day you have an easier training day – familiar content is easier to deliver than new material.

An approach that I have found to be successful is: *Do – Discuss – Recap*, which reinforces the training elements several times, without being boring. 'Do' is a writing exercise or a game. 'Discuss' is a group discussion designed to pull out all the key points from the trainees (a flip-chart and coloured pens are all you need for this) and 'Recap' is a PowerPoint presentation or a chat from you, the trainer. I like to use a short PowerPoint presentation so that all the relevant points are covered without too much brain-strain on my part during the day. Slides are also useful additions to a hand-out because trainees can listen to you rather than simply scribble down your slides. Avoid 'death by PowerPoint' – drawing pictures on flip-charts remains an effective though low-tech training technique…and is not susceptible to computer crashes, power cuts, and other technical problems. A modular series of *Do – Discuss – Recap* exercises is a valid way to design a training course – the trainees are involved in all stages of the course and the day is livelier and more fun than a series of lectures.

Exercises and games should be designed so that they can easily be adapted to different audiences. If you have more than two or three people in your class, aim for group exercises. The objectives and outcomes of the exercise must be clear to the trainees – if you cannot relate the activity directly to medical writing then do not use it. Exercises should be selected based on an understanding of the needs of the audience; examples of subjects for generic exercises that can be adapted to any audience are shown in Fig. 2. Both for you as the trainer and for the trainees, it is worth mixing modules of 'heavy' and 'lighter' content throughout the day. Perhaps a session on grammar and style could be followed by an hour critiquing diagrams and posters.

- Planning content for a trainee's own thesis or dissertation or a scientific paper that they will soon have to write
- Discussing the content of the various elements of a scientific paper
- Writing an abstract for a paper which has had the abstract removed and then comparing it with the actual published abstract
- Rewriting a poor paragraph
- Spotting errors that have been introduced into a congress abstract
- Criticism of published abstracts/posters/graphs and tables/papers

Figure 2: Topics for writing exercises that can easily be adapted to any audience.

Even keen students can find it hard to stay awake during a long training day. To keep their attention focused on the training, design exercises that make them move around. Use teams of different sizes, so desks and chairs have to be shuffled around or appoint spokespeople from groups who have to come up to the flip-chart to report on group findings.

Many trainees find it difficult to write on any subject other than their own specialty. If your audience is trained in health economics, use health economics examples and exercises, but do not try those examples with optical physicists. For exercises that require individuals to write or edit, try the exercise yourself and then allow them twice the amount of time taken by you. If this is too long for the time available, then think again – trainees are very slow at writing in a training situation. Also, always have backup material available – trainees will have differing speeds of working and some may need additional work to keep them quiet while slower students are concentrating.

Many people are extremely worried about being embarrassed in public, particularly those with poor spoken English. Getting trainees to discuss issues in pairs or to mark each other's work is fun for them without being stressful (and is less work for you than assessing and criticising all their work).

And finally, be cautious about using humour – this may not work with all nationalities, and humour differs greatly between cultures.

Start the day with a writing exercise

Many trainers start by going around the room and asking people their names and research topics. This does not work for me. The trainees probably know each other, but if not, unless they need to know each other to successfully complete the course, this is a slow and uninteresting way to start (especially if there are many participants). I begin by asking everyone to create a name card for their desk by folding a piece of card and then, using black felt-tip pen, to write their first name in capitals on the front and the back of the card. Once everyone in the group has finished, I ask anyone who was stressed by, or unable to carry out that writing exercise, to raise their hand. Of course no-one does and people often laugh. We then discuss why this task is easy. In this one 5-minute exercise there is everything that you need to know to be a medical writer: you have to understand the subject (most people know their own names), know what you are going to write and how you are going to do it (your name in capitals on a piece of folded card) and follow the relevant guidelines (instructions from the trainer). This activity involves all trainees immediately, starts the bonding of the group, makes a key point about writing, and sets a light-hearted tone. Stragglers who miss it will not be at a disadvantage, as all the ideas will probably be repeated several times during the day. Never start your course using material in hand-outs, just in case the photocopies are unavailable.

Grab their attention after lunch

The period immediately after lunch is difficult. Lunch has a tendency to drag trainees back into their normal daily routines. Do not schedule a presentation from you in the postprandial dip period unless you want to watch people snooze. Instead, start the afternoon with a bit of fun, ideally a short game or a fun exercise relevant to writing skills. For professional medical writers I use a game of *Chinese Whispers* to illustrate the importance of giving and taking an effective briefing. As always, the whispered message becomes more and more garbled as it passes from one person to another. The discussion point is that the final person in the chain would be unable to undertake the writing task because the brief would be insufficient. For scientists and medics, I have a team game to remind them of the basics of writing I hand each team a brown envelope containing a jigsaw puzzle in a box (I use six Disney jigsaw puzzles with 20

pieces each that I got from toy shop.) After a count-down from three, the teams race each other to complete the puzzle in the fastest time. However, I have tampered with all but one puzzle. The team with all the correct pieces and the correct picture on the box usually wins the game. The message to the students is that if you research and plan your article (assemble all the pieces) and have a picture in your head of what you are going to write and how you are going to write it (the picture on the box) AND that the pieces correspond to the picture, then writing is a relatively smooth and frustration-free process.

Take it easy at the end of the day

On a one-day course, plan the most critical content for the middle of the morning. Interactive training is very tiring for trainees and they are often running out of energy by 3 or 4 pm. At the end of the day, do something which requires them to walk and talk, such as a poster walk. To do this you can ask the course organisers to supply up to 10 posters produced by that institution. Using their newly obtained understanding of medical writing in general and of content, structure, and design of a poster in particular, the trainees can assess how well the posters work as scientific communication tools. This useful end-of-day exercise shows trainees that they have learned a lot about medical writing during the training day and are now able to write and design an effective scientific poster. It also demonstrates that many published scientific posters fail to inform the audience effectively and so fail to disseminate the hard-won research results of the author.

Top tips for trainers

Once you have written the course, do not forget to check that you have all the arrangements in place and the tools that you need (Fig. 3). Try not to leave this to the last minute or you and your computer will be working all night on the night before the course – just when you should be getting some sleep. And this is always when your printer runs out of ink.

On the day of the training course, perhaps the most important tip for success is to *Make Time for You*. Always arrive early; far better to be twiddling your thumbs or to have time to brush your hair and go to the loo than to rush flustered and sweating into a room full of trainees. And do not get so carried away with the wonders of medical writing that you forget to eat or drink. Make sure that you take a bottle of water with you and drink it while the trainees are doing group work. I also carry throat sweets in case I talk too much and my throat dries out! Keen students often ask lots of questions at coffee breaks and at lunchtime, so take care to leave enough time to drink your coffee and eat your lunch.

As you enter the building, note the locations of toilets and fire escapes near to the teaching room and try to remember the way out – you will need at least two of these important places on the day. (I have been stranded for what seemed like hours in the darkened basement of a major London hospital after teaching hours).

A first impression counts, as does day-long comfort, so plan your clothing. Wear a jacket to give a professional first impression, but make sure that you dress smartly with layers of clothing underneath – 20 focused individuals can generate a lot of heat and poor temperature control is common in training rooms. Also, wear comfortable shoes – you might not have a chance to sit down for 8 hours.

Do not forget to introduce yourself and highlight your experience to establish your credentials for the day. It is surprising to me that many trainees turn-up and spend a day or two in a writing skills course, yet have no idea of the competence of the trainer. Certainly, most institutions do not tell

- Laptop containing all slides and material
- Projector if you have one
- All slides and print items on a USB stick
- One clear colour printout of all hand-outs (in case they have to be photocopied at the last minute)
- An agenda with timings and an annotated set of slides and hand-outs for you to use
- Props for games (I often carry 4 small jigsaw puzzles and a roll of A3 poster printouts)
- Essential stationery for any activities (e.g. post-its, pens, Blu-Tac)
- Map & directions
- Travel tickets and money
- Booking confirmation for B&B or hotel if needed
- Water, snacks and any medications you might need

Figure 3: Pre-course checklist.

trainees who the trainer is and why they have been chosen.

Trainees love hand-outs and checklists – but do not be tempted to give these out until the end of the day, otherwise some may choose to leave at coffee or lunch break. Let them know at the beginning of the day that they need to stay to the end to get the hand-outs. Similarly, if the institution provides a *Certificate of Attendance*, do not hand this out until the course ends.

Good luck and good training!

I hope that these thoughts and observations prove helpful to other trainers. Although it is not possible to give comprehensive guidelines for medical writing trainers in an article such as this, you can be sure that the advice and exercises given here have been fully field-tested and definitely work well in a variety of training situations and across a range of audiences.

Author information

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Teaching scientific writing using the learner-centred approach

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Abstract

Learner-centred teaching is particularly suited to the teaching of scientific writing. The underlying premise of the learner-centred approach is simple: the learner will better assimilate new information if it is built on what they already 'know' than if it is imposed from the outside as in a teacher-centred approach. This approach goes step by step, progressively integrating new knowledge without artificially bending the course of the session to fit into preconceived content. The learner-centred approach has enormous advantages for the trainer: it is highly gratifying to stay focused on a group's needs, learn to listen to individuals, share the learning experience, and follow the trainees' progress. At the end of the session, very often groups go home with a deep, relevant training experience that 'speaks' to them, is immediately applicable, and is therefore likely to stay firmly anchored.

Keywords: Learner-centred, Training, Scientific writing

I run a small company specialised in training, writing, and translating for the pharmaceutical and medical sectors in France. Over the years our activities have developed to match changing needs. We now offer a range of training courses that respond to a specific market: professional training in English to non-native speakers. Language schools have been offering 'specialised' courses for years, but these are often delivered by general English teachers working from manuals, lists of vocabulary and particular expressions, and grammar for a given sector. The onus is on teaching the language rather than providing the necessary strategies for the professionals in a group – who are often highly trained and experienced – to become autonomous. My personal interest in medical writing, and an ever-increasing demand for editorial assistance, led my company to explore offering scientific writing training to research teams in hospitals, biotech start-ups, and pharmaceutical companies.

I have a mixed background of science, language teaching, and communication, the three skill areas which I combine to develop courses in France. One of the most defining periods in my professional life was being exposed to a pedagogical approach called *learner-centredness*. This article describes my experience with learner-centred training and how it is particularly suited to the teaching of scientific writing.

The premise of learner-centred teaching

Though learner-centred teaching came into its own in the 1980s, its beginnings are often associated with the works of John Dewey,[1,2] Carl Rogers,[3] as well as the work of Jean Piaget (1896–1980) on cognitive development.

The underlying premise of the learner-centred approach is simple: the learner will better assimilate new information if it is built on what they already 'know', that is, their own personal experience, than if it is imposed from the outside as in a teacher-centred approach. Learner-centredness means delivering courses where the learning is directly related to the learner's own experience, their own reality. It is 'brick-by-brick learning' rather learning through scaffolding erected around a structure to be built.

In most professional training courses, there is something I like to call 'The Binder'. The trainer arrives at the training session and hands out a beautiful binder containing course material, references, golden rules etc. Everyone is happy: the course organiser because they think they are getting their money's worth (the thicker The Binder the more valuable the training); and the participant who can use The Binder as a crutch to fall back on and an excuse for those moments where attention is low. The trainer may hold The Binder up as proof of how much work was put into the course and may

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use it as a shield when the going gets tough. And this 'off-the-peg' approach is typically prepared before the trainer has even met the group.

In contrast to training using The Binder, learner-centred training goes step by step, progressively integrating new knowledge, without artificially bending the course of the session to fit into preconceived content. The clear advantage is that, if guided correctly by the trainer, the trainees leave with the necessary tools to carry on the work autonomously. Rather than a training course being a question of simply getting through the material, it is about integrating the tools to become independent. As Carl Rogers put it, 'A person cannot teach another person directly; a person can only facilitate another's learning'.[4]

The learner-centred approach is an *active* approach, as opposed to the often-passive Binder approach. In The Binder approach, the trainer announces, 'We are going to learn "A"', whereas in the learner-centred approach, the trainee says, 'I don't need to learn "A", I need to learn "B"', to which the facilitator can reply, 'Fine, how can I help you?'

The trainer instils a sense of responsibility and confidence in the learner by adopting the role of a facilitator rather than that of a presenter of information. By remaining focused on the real needs of the group, setting realistic objectives, encouraging exchange and feedback, and accepting the power-shift, the outcomes are group-dependent, long-lasting, and pave the way to further learning once the course has finished.

Why the learner-centred approach is effective in teaching scientific writing to non-native English speakers

Who is the expert – or the teacher – in a scientific writing group of non-native English-speaking researchers? How can the individual and collective expertise of the participants be best put to use to optimise active, immediately applicable learning? Typically, the group will have a high level of expertise – they may be researchers, engineers, or bench scientists – but a high level of expertise generally goes hand in hand with an equally high level of frustration when it comes to writing in English. The focus in training should be on the use of English as a tool rather than on the language they have often had so much trouble learning at school. Furthermore, in writing, probably more than in most other situations where trainees need to use English, it is essential that they develop a sense of responsibility and confidence.

Michael Lombardo and Robert Eichinger's[5] 70/20/10 Learning and Development model is especially interesting to consider in this context. This model states that 'about 70% of knowledge or development comes from on-the-job experiences, tasks, and problem solving, 20% from feedback and from working around good or bad examples of the need, and about 10% from courses and reading'.

So, how does learner-centred training work?

The learner-centred approach starts from the very beginning. Often, the training manager responsible for organising training for their company, or institution, has only a vague idea of the real needs of the group and the task at hand. The trainer might need to make sure that the distinction between English training and scientific writing training in English is clear. This can be dealt with by a quick phone call and followed by a written description, where the trainer describes a typical programme and outlines the approach, stressing that the focus remains firmly anchored on the learners' needs.

The next step is for the trainer to find out about the participants' profiles and their perception of needs. This is best done through a needs analysis form which consists of a tick-box questionnaire identifying what their background is, what sort of texts they write, and includes a section for them to express what they feel their needs are. This last item can also be used to get a rough idea of how they write in English. As well as initiating contact, a needs analysis is an ideal way of getting participants to think about what they would like to work on and how they would like to work. At this stage I also ask the participants to send me examples of their writing so that I can compare them with what the institution or company considers to be 'best in class', such as reports by headquarters or published articles. I then perform a gap analysis, which means going through their documents, flagging up items that need attention, and selecting similar sentences or paragraphs from the model document for comparison. I then prepare the course work around these examples.

Depending on the group's needs, the following main points often emerge from the gap analysis:

- Differences in cultural expectations in writing
- Importance of structure: information needs to appear where the reader expects to find it
- Relevant language points per unit of structure
- Importance of the KISS principle (Keep It Short, Stupid!): a particular issue for French speakers who are taught to write in a literary style

- Grammar, vocabulary, typical expressions
- Identifying the purpose of the writing and the goals of the reader to determine expectations and style
- Exploring available resources, discussing how these can be most effectively used
- Creation of a quality check-list and learning how to assess one's own work.

A major challenge in any writing course is creating a dynamic approach and developing a sense of group. Writing is personal and individual and there often is a reluctance (or embarrassment) to have one's own work analysed and used as an example of what *not* to do. Focus on good examples and encourage good ideas from participants who are perceived as being poor English speakers. It should be stressed that the course can be run in the group's mother tongue or that participants can ask questions or participate spontaneously in their own language.

Brainstorming can encourage spontaneous participation. A buddy system, where more experienced participants are partnered with those who are less experienced, is also often effective. Discussions can take place in pairs or small groups and the findings then reported back to the group.

Above all, I highly recommend limiting the use of photocopies and exercises. I have also found that it is far more useful to set up writing tasks as intersession assignments rather than asking people to start writing during the workshop.

So, can you do it?

Confidence is key. While the learner-centred teacher requires relevant experience in scientific writing and needs to feel at ease in the environment, you do not necessarily need to consider yourself an expert writer. As Rogers pointed out, to run a learner-centred course, the facilitator should be '… sufficiently secure within herself (himself) and in her (his) relationship to others that she (he) experiences an essential trust in the capacity of others to think for themselves, to learn for themselves'.[6]

My experience has taught me that certain hurdles must be anticipated. Instilling a true learner-centred approach takes time, not always a cheap resource in our stressful, time-strapped era. Learners are very much used to a directive approach – the teacher is there to teach me – and they sometimes feel short-changed when they realise that the effort will be coming from them. They also like getting The Binder and time is needed for them to accept that the real Binder is one that they will compile themselves and that the best resources come from their day-to-day environment. And finally, it can be quite a challenge for you to stay on the sidelines and accept that the outcome, or the group's conclusions, might not be perfect or where you would have liked to get them. You may be very tempted to let the group go through the motions only to tell them in the end how it should be done (and thus to justify oneself as an expert)!

The learning-centred approach has enormous advantages for the trainer: it is highly gratifying to stay focused on a group's needs, learn to listen to individuals, share the learning experience, and follow the trainees' progress. At the end of the session, very often groups go home with a deep, relevant training experience that 'speaks' to them, is immediately applicable, and is therefore likely to stay firmly anchored. The approach is particularly suited to groups of non-native English speakers who are 'experts' and accomplished professionals in their fields.

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On educating the medical writer

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Abstract

Most medical writers received their education on the job rather than through formal education. These writers may have gaps in knowledge when compared with lists of competencies published by professional organisations in the clinical research and medical writing fields. Formal education from an accredited programme gives a more uniform foundation of knowledge than experience alone or experience combined with short-term training. This article, based on the observations of a regulatory medical writer turned academic programme director, addresses some of the differences between education and training, educational approaches and delivery methods, and potential effects on employment prospects.

Keywords: Medical writing education, Medical writing training, Core competencies, Educational approaches, Educational outcomes

Background

This article is based on my observations as the Director of Biomedical Writing Programs at the University of the Sciences in Philadelphia for the past $4\frac{1}{2}$ years. I began my career as a regulatory medical writer in 1991, at which time I had no education at all in that field. It's not that I lacked education, I had a PhD in Biology, 7 years of post-doctoral experience, and a number of publications to my name. What I had learned by the end of my first week at Wyeth-Ayerst Research was that writing clinical and regulatory documents for the pharmaceutical industry was different from writing basic research results for peer-reviewed scientific journals. Like most medical writers who started their careers in the pharmaceutical and device industries in the 20th Century, I learned 'on the job' supplemented by training that was available through a number of professional organisations. As far as I have been able to determine, no formal education specifically in the field of medical writing was available before 1998 when the University of the Sciences programme began.

Education vs. training

The reader may wonder why I say that education in the field was not available when, clearly, training was available before 1998. Although the two terms, education and training, are frequently used interchangeably, there are, to my mind at least, distinct differences between the two. In the US, academic institutions are usually accredited by regional associations of schools and colleges or by other examining bodies that are recognised by the US Department of Education. Training providers, if they are accredited, are accredited by independent agencies such as the Accreditation Council for Continuing Medical Education or professional organisations. To me, however, the main difference is that education is foundational while training is situational. To clarify further, athletes train for a sport, but if they have come up through the university ranks they will have majored in physical education or a related field. The training builds their muscles and reactions, but the education gives them the understanding of what is happening to their muscles and why certain regimens work better than others.

Other differences between education and training are the extent of exposure to the content, the depth of that exposure, and the detail of assessment of student performance and programmatic effectiveness. Most training lasts from several hours to a day or two at most; assessment is usually straightforward polling of the understanding of content. Agencies that accredit academic programmes prescribe the minimum duration of student–instructor contact that will define a 'credit hour'. A credit hour works out to 15 hours of contact plus additional student preparation and detailed assessment of student performance such as essays and

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research projects over a 15-week semester. Most courses are 2 or 3 credit hours.

Core competencies needed by medical writers

The basic competencies of all professional writers include knowledge of organisation of ideas, grammar, usage, syntax, and the physical and electronic tools of writing. These are not specific to medical writing. Educating medical writers requires teaching the foundations of clinical research including the ethical, scientific, clinical, statistical, and analytical background required for the writer to be an effective reporter of regulatory information and clinical research results. To this end, any formal education programme should provide a curriculum that covers the core competencies of clinical research as described by the Consortium of Academic Programs in Clinical Research (CoAPCR).[1,2] The CoAPCR competency list is summarised in Fig. 1. A model of specific competencies expected of medical writers in general, regulatory, non-regulatory, and management roles has been published by Woolley and Clemow[3] under the auspices of the Drug Information Association Medical Writing Special Interest Area Community. These two competency lists form the basis of the content of an educational programme for medical writers, but do not describe the possible approaches or delivery methods for the content.

Document vs. granular approaches for medical writing programmes

Several approaches are possible in a medical writing programme, but the two that were tried in ours were a document-based approach and a granular approach. A *document approach* means courses that centre on a given document, such as the investigator brochure and its components, or class of documents such as the annual safety report, periodic safety report, and other pharmacovigilance reports. A *granular approach* means courses that examine common components of many documents such as ethics statements and the ethical basis of those statements, adverse event reports and the associated documents such as patient narratives, and efficacy reporting along with the statistical basis of efficacy.

Ultimately, we have found that a blend of document and granular approaches is most successful for the core of the programme. Granules of theory are incorporated into overview courses such as drug development for medical writers, continuing medical education, promotion of medical products, and therapeutics. The central documents that incorporate these (e.g. New Drug Applications, the Common Technical Document, and scientific and clinical journal article writing within publication planning) are taught as applications of the document granules. The details of different

1. Scientific Concepts and Principles of Research Design			
Medical terminology	Descriptive statistics	Research design principles	Design validation
2. Medical Product Development			
Drug/device development cycle	Global regulatory agencies and their roles	Regulatory website familiarity	Conflicting global regulatory policies
3. Ethical Considerations and the Responsible Conduct of Clinical Research			
Evolution of ethical conduct of human research	Current ethical standards applied to human research	Controversies regarding the application of current standards	Revision of ethical standards in parallel with new research areas and results
4. Clinical Study Operation and Regulatory Compliance			
Varying roles of different clinical research personnel	Informed consent documentation	Regulatory and clinical documentation required for clinical research	Case study familiarity
5. Study and Site Management			
Selection of study sites and training of site personnel	Site initiation, monitoring, audit, and closeout. ICH GCP practices	Patient recruitment practices and health record documentation	Investigator relations and investigator meetings
6. Data Management and Informatics			
Clinical trial data collection and data flow	Review, tracking, and resolution of data errors	Data quality control and assurance planning	Database lock and frozen file techniques
7. Communication of Scientific Data			
Plans for communication between sponsor, CRO, and sites	Data presentation methods including tables, graphs, listings	IMRAD publication writing, posters, and other scientific presentations	Literature searching and literature review
8. Professionalism, Teamwork and Leadership			
Professional issues in intellectual property, ethics, plagiarism, and conflicts of interest	Meeting coordination and facilitation	Cultural competency and understanding of cultural diversity	Leadership, team processes, critical thinking, and human resource issues

Figure 1: Eight competency domains and selected competencies from the CoAPCR Domains and Competencies of the Consortium of Academic Programs in Clinical Research. The competencies displayed were selected by the author and is not comprehensive, the complete list of competencies can be found at: https://docs.google.com/file/d/0BzEWyRPWlbdBLWtmM09kUm5uRUk/edit?pli=1.

regulatory roles or marketing writing roles are fleshed out in an on-going stream of elective courses that are available on a scheduled or one-time basis.

Online vs. onsite?

Delivery of content can be online, onsite, or a combination of both. We have found that 100% online delivery of courses works best because it allows the widest possible geographic reach. Most of our students are in North America, including Canada and the United States, but we have had overseas students as well. Our online delivery includes both asynchronous classes (students do not have to be online simultaneously) and synchronous (generally webinars but also some mobile social media delivery). Because there is no requirement to be online at a specific time, asynchronous delivery is probably the most convenient form for students; synchronous delivery is useful because it is more efficient when the content is complex and requires significant question-and-answer interaction between instructor and students.

Conclusion

In the present pharmaceutical/device industry environment, medical writers who have had an education in medical writing will offer potential employers a candidate with broader understanding of the field and more flexibility in performing the tasks required than candidates with some experience but limited background. This translates to candidates who are more likely to benefit from experience and training in an on-going position when hired.

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One-day Symposium on Writing for Health Economics and Market Access at the EMWA Conference in Manchester

EMWA is pleased to invite you to a one-day symposium on Writing for Health Economics and Market Access on Thursday 9 May 2013.

Medical writers are increasingly involved in this area, whether through writing reimbursement submissions, helping companies communicate the economic value of their products, or reporting data from economic and quality of life endpoints. Writing is also a key part of the job for many health economic and market access professionals who do not think of themselves primarily as writers.

This timely event includes an overview of economic communication needs, the do's and don'ts of writing for health technology assessment (HTA) submissions, a run-through of the newly published CHEERS guidelines on reporting pharmacoeconomic evaluations, and a session on proving value in elderly populations, who account for such a large proportion of the market for drugs and devices. In addition, a representative from NICE will talk about its decision-making process and the principles of HTA.

We hope to see you there! The symposium is open to members and non-members and offers excellent value for money, so please do spread the word among your colleagues. Register via the EMWA website, under 'Conferences'.

The EMWA Conference is being held at the Manchester Central Convention Complex, Manchester, England, from 7–11 May 2013. This year, the conference opens at 18:00 with a networking event entitled *Better communication means better patient outcomes: vision or illusion?* which promises to make an exciting start to the usual top-quality programme offered.

Learning and teaching clinical writing

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Abstract

Clinical writing, a specialised type of medical writing, refers to the types of writing health professionals use on a daily basis such as medical charts and forms. It requires knowledge of both formal and informal medical language and culture. An appreciation of the intent of the writing and the target reader is essential for effective clinical writing. The intent of clinical writing is to provide safe patient care through accurate, concise, and factual documentation. This article explores key elements of clinical writing and how to learn and teach it.

Keywords: Clinical writing, Target audience, Intent, Chart, Context, Authenticity

Clinical writing

Clinical writing refers to the types of writing health professionals use on a daily basis, for example, preparing progress or treatment notes in medical records, updating patient charts, preparing letters for consultation and referral, and completing various administrative forms. Clinical writing contains factual information. It imparts essential, accurate, and specific information about patient conditions, diagnostics procedures, treatments, and prognoses. Clinical writing differs from other kinds of medical writing – it affects patient care. It also has legal implications and can be used as evidence in malpractice or negligence lawsuits.[1,2]

Following are examples of clinical writing in patient charts (medical records). These are short entries written in a style and using terms easily understood by peers. Some provide information, others provide direction.

- Failed to stamp clinical record with addressograph.
- Record apex numerically as appropriate. See flowsheet.
- Record O2 Sat numerically.
- Start IV to KVO. Maybe piggyback some antibiotics later. Vitals till then hourly.
- Wound has begun to ooze purulent discharge.
- Pt. crashed. Code called.

Clinical writers communicate not only with medical terminology but with specific words, abbreviations, acronyms, and phrases that form their professional jargon (see Fig. 1 for an example). Clinical writing is brief, written in cryptic form, and in the case of charting, rarely exhibits complete or proper sentence structure. An example of such cryptic writing is shown in Fig. 2, which is from a nurse's focus notes describing the assessment and management of a patient's post-operative pain.

Consultation reports and summaries use a mixed style of formal and informal word choices but tend to use more traditional grammar and syntax. The target audience of clinical writing, then, is other healthcare professionals who will be familiar with the style and language.[1,3] For example, it is quite acceptable for a patient chart to say: 'Resps. laboured. Placed in Semi-Fowler's for relief. Puffer given'. This means the patient was having difficulty breathing and so was placed in a semi-sitting position in bed to relieve the difficulty. The patient was given two short inhalations of a bronchodilator medication by means of an aerosol device.

The target audience of clinical writing

During the writing process, clinical writers need to be keenly aware that their writing will be read and

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Cardiovascular Status	Edema (Loc)
	CWMS
Respiratory Status	Lung Sounds
	O2 Therapy
	Chest Physio/DB&C
	Inc Spirometer

Figure 1: Examples of a section of an assessment form. This section of an assessment form describes the patient's cardiovascular and respiratory status. Abbreviations: (Loc), location; CWMS, colour, warmth, movement, sensation; O2, oxygen; physio, physical therapy; DB&C, deep breathing and coughing; Inc Spirometer, incentive spirometer.

used by a variety of health and allied healthcare professionals. The primary intent of clinical writing is to communicate with members of the healthcare team such as doctors, nurses, care aides, therapists, laboratory technicians, and unit clerks. However, under certain circumstances, the target audience of clinical writing might also include health administrators, researchers, and medico-legal professionals. For the writing to be received with the writer's intent, the material needs to be expressed in a tone that these co-professionals will easily recognise and accept.

Authenticity and linguistic choices in clinical writing

Clinical writers need an excellent command of written English. This foundation enhances their ability to master new specialised vocabulary without being side-tracked by needing to learn basic English. Swan (1997) and others assert that some styles of speech and writing have their own rules and structure.[4] Clinical writing is one of these; it uses jargon consisting of medical terminology and a wide array of specialised abbreviations and acronyms. Learners of clinical writing need exposure to this style in order to learn the jargon correctly.

Medical writers or teachers of English or medical writing may not understand this style of writing unless they have worked in healthcare. To successfully produce accurate clinical writing, the learner needs to be exposed to the source – authentic clinical writing. This is supported by the research of Svendsen and Krebs,[5] who were among the earliest researchers in the field of language and career needs, particularly in healthcare. They found that teachers often make assumptions about the language an employee needs to learn, but their assumptions are not always accurate. As a result, the employee is not taught authentic workplace language. Many educators now appreciate that both learners and non-medically trained teachers need to be familiar with authentic material to understand it and teach it effectively.

Inappropriate word and phrase choices are caused by a lack of authentic language awareness. This is particularly important for clinical writing, as clinical readers are less receptive to writing that does not conform to the healthcare culture. The use of unusual word choices or unfamiliar phrasing can be a significant communication barrier. For example, a comprehensive medical consultation report risks being seen as inappropriate if written only in highly technical terms and strewn with rarely used medical terminology. This will greatly diminish its importance and impact. On the other hand, the same report written with an appropriate use of medical language – jargon and professional, medical terminology – can achieve its goals. Therefore, with access to authentic material, learners learn to produce the appropriate language style.

Context and learning clinical writing

Social learning theory suggests that learning best occurs through observation and exposure to content and context. This certainly applies to clinical

Date/ Time	Focus	Pain Scale 1 - 10	DATA / ACTION / RESPONSE NOTES
14 Feb. 2013 @ 2130 hrs	*post-op pain management*	*7*	*Pt. continues to complain of deep pain in the epigastric region, 3 cm above incision line. Dressing dry and intact. No fever. T 36.8. IV in situ. Using PCA on schedule. Offered and given acetaminophen 500 mg po prn now for pain relief. Remains on bedrest.---------- -- MJugaru, RN*

Figure 2: Example of cryptic writing in nurses' focus notes.

writing. Exposure to authentic clinical writing enriches learning. It provides opportunities for learners to follow role models, develop writing skills, and build new word repertoires, and it provides insights into how medical language is used in specific contexts with specific target audiences.[1] Teachers of clinical writing and clinical writers both benefit when they can experience how medical terminology and jargon are used in context.

Exposure to writing in a clinical setting helps develop best practices in clinical writing education. The learner can observe and read samples of authentic material and interact with other health professionals to ask about the writing and its content and its style. Legal issues such as patient confidentiality can complicate access to this learning environment, gaining access to charts can be difficult, and clinical placements can be hard to find. Despite these complexities, authentic clinical writing can be accessed at the workplace for a number of hours if the learner seeks permission and is clear about the goals of the activity. This is best done through the appropriate administrative channels at care facilities or clinics. The learner will have to sign a confidentiality agreement and the learner and teacher may be asked to not take any notes or pictures while viewing patient documents.

When workplace experiences are unavailable, health or medical professionals can teach, demonstrate, and even coach clinical writing as guest speakers, especially if they provide examples of their own writing. In this way, patient confidentiality is not breached.

Working collaboratively with a health professional will enrich learning about clinical writing. If the teacher of clinical writing is not a health professional, access to someone who is can be very useful. A learning activity can be designed in which students do some clinical writing and the guest critiques it. The teacher and the guest can critique the work produced as a large group in class or individually at a later time.

Key topics in clinical writing

Specificity, accuracy, conciseness, and professionalism are essential to good clinical writing. Each of these has safety ramifications for patient care. If the writing is too wordy, its message is lost. Busy health professionals rarely have the time to wade through long chart entries or consultation reports. The content of the writing needs to be specific and accurate. Clinical readers need to know the subject of the writing, priority of care, and if treatment, intervention or assistance has or will occur. Verb choices are significantly important. Specific attention needs to be paid to tenses when talking about patient care. Errors in this regard can lead a reader to believe a treatment already occurred when indeed it was still pending. The result could be that the treatment is never administered. Again, the importance of clear, accurate, and concise written communication and the safety of patients and their care cannot be overstated.[6]

Teaching clinical writing

Adult learners may bring a wealth of career-specific knowledge with them to their writing. Their learning goals are highly relevant to their career goals, maybe more than for other English language learners. However, subject matter in medicine may be beyond the expertise of many language teachers. This may catch some teachers off guard, especially if they are unprepared to work through questions and problems related to clinical language style. Wu and Badger[7] describe how this negatively impacts both the teacher's self-perception and students' perception of the teacher. Many teachers choose to either avoid these situations or take wild risks by providing incorrect answers.[7] Table 1, which provides examples of charting errors,

Table 1: Examples of charting errors and their corrections

Chart entry	Rationale: why this is an error	Correction
Patient calmed down after getting shot	This sounds like the patient was shot with a gun and that this act led to him being calmer now	Patient settled with an injection of anti-anxiety medication, XYZ 5 mg IM, right VG
Pt presented in ER with complaint of stabbing pain in chest. No evidence of wound. Non-urgent. Waiting his turn in ER Waiting Room	The writer has taken what the patient said literally not knowing that the expression *stabbing pain* is used as a diagnostic cue to heart attack (myocardial infarction). As a result, the patient could possibly die in the Waiting Room	Pt presented in ER with complaint of stabbing pain in chest. Urgent status. Admitted stat. Being seen now by physician

Abbreviations: ER, emergency room; IM, intramuscular; Pt, patient; VG, ventrogluteal muscle.

illustrates these points. Without medical knowledge and an awareness of career-specific language, a clinical writing teacher might consider all of the chart entries in the left column correct. They are not. The table provides the rationale and the correction for each entry.

Professional development of clinical writers

Teachers of clinical writing need to be competent not only in intermediate-to-advanced English but also in the authentic language of medicine and the health professions. If teachers do not have sufficient experience with the authentic language of clinical writing, they can seek out help from experts in the professional healthcare community. Developing a partnership with them is far more effective than a simple consultation. The internet too provides access to real-life source material.

Professional development activities that use the language of medicine and healthcare can also ease the burden of teaching medical writing for non-medically trained teachers. Courses in clinical writing can help but so can simple exposure to the context. Opportunities to observe and read clinical writing in a true clinical setting are also useful, as are short courses, for example, in first aid or cardiopulmonary resuscitation. At the end of these classes, it may be possible to approach the health professional to discuss clinical writing. These and other opportunities can help build a support network of clinical writing mentors.

Teachers also greatly benefit from transdisciplinary collaboration where faculty members from different disciplines work together to deliver a cohesive, learner-focused curriculum.[8] In such a situation, the different disciplines work collaboratively and are aware of course content and curriculum goals for each related programme.[9] For example, the clinical writing teacher would meet with teachers from nursing, anatomy, physiology, or medicine once per month to share their teaching plans and subjects. The teacher of clinical writing would benefit from knowing which subjects are being taught and when and could develop writing exercises to coincide with the other courses. An interdisciplinary collaborator could also be recruited to offer samples of clinical writing or to review the teacher's examples.

Finally, clinical writing teachers can easily access textbooks on the foundations of nursing and medicine. Each of these includes chapters on documentation (clinical writing). They also provide numerous examples of blank and completed medical records and charts. The examples can be extremely useful templates for clinical writing learning activities.

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Are you sic [*sic*] of poorly worded tweets?

You may or may not love Twitter and tweeting, but there's no arguing that it has been good news for the word *sic*. Derived from the Latin phrase '*sic erat scriptum*' (thus it had been written), it has been widely used by journalists when quoting tweets. Take this example, a charming tweet from an English footballer, as (needlessly) reported on the *Daily Mail* website:[1]

'You're married correct !! But ur married to a raging s**t bag [sic]'.

The word *sic* is a very useful device for indicating the origin of mistakes in quoted information. In the above example, the journalist reporting the tweet used *sic* to indicate that the person who wrote the tweet is responsible for the errors it contains. The journalist thereby avoided being accused of writing error-strewn copy (readers of online articles often respond quite angrily to errors, even minor ones).

Perceived inappropriate use or overuse of *sic* can, however, meet with criticism. Writing *sic* at the end of a longish piece of text without indicating where the errors are may be interpreted as some form of criticism of the content itself. And what about this example from *The Telegraph*:[2]

'Simple google [sic] search does it'.

Does the failure to use a capital letter really warrant a *sic*? Google is so ubiquitous (as both a proper noun and a verb) that it may at some point cease to be regularly capitalised anyway (think biro).

As for using *sic* to highlight an error that isn't in fact an error, as in the following example from *The Huffington Post*, well, that just makes you look stupid:

'Savile refers in the letter to the excitement of his "girl patients" and "paralyzed (sic) lads"'.[3]

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Your professional association: A great way to expand your skills and advance your career

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Abstract

Many medical writers and translators are not members of professional associations. While online networking is clearly accepted as a key element for success in business, the benefits of joining associations are still not obvious to all, even though effective networking and having a public profile are viewed as key tools in today's business world. This article highlights the reasons for joining professional associations and the career advantages of membership.

Keywords: Professional associations, Collegiality, Recognition, Awareness, Continuous education

Surprisingly, many professionals still don't fully appreciate how professional associations can help them. They view associations as training grounds in a given field, and once they obtain their longed-for certification, they believe the association has no more to offer. Why professional associations give this impression is not discussed here, although this is a potential topic for further discussion.

Professional associations exist to benefit their members in various ways: by promoting recognition of the value of the profession, both in society and in business; by facilitating communication and networking among members; by establishing standards of competence and ethics; and by educating and informing members.

Professional associations raise the profiles of the professionals they represent

Many professions, such as doctors, teachers, and politicians, are highly visible. Everyone is aware of them and has at least some understanding of their work and their role within society. With this visibility comes respect for the skills involved. The public interacts directly with these professionals and therefore appreciates their value and the likelihood that they will be needed well into the future. Members of such professions enjoy widespread promotion of their roles. Their interests are protected by high-profile associations, who also monitor standards and seek to protect their members and the public.[1]

Likewise, a low profile may result in a lack of respect for work done and skills required. If people (especially colleagues from different professions) are unaware of what certain professionals do, or how they do it, they may have unrealistic expectations. For example, fellow professionals may not appreciate how long it takes for a medical writer to write a full protocol and may expect it to be done in a couple of days. A lack of visibility also leads to under-appreciation and therefore poor remuneration, which, combined with lack of respect, can lead to poor morale among the members of a profession. A lack of status in society may also discourage future generations from entering the profession. Without the support of high-profile associations, individual practitioners will find it hard to promote their profession and to avoid poor standards due to a lack of professional education. Lack of a high-profile association also reduces the reputation of individual practitioners, their ability to find work, and the recognition they receive for their skills.

One of the major aims of professional medical writing associations is to defend and promote medical communications professions and thus improve working conditions. Associations may join forces, and pool resources and energy, to ensure that their professions are recognised, respected and valued, and to make sure that they gain the public dimension and visibility they deserve.

Professional associations provide a forum for networking and communication

Socialising with colleagues within the profession and getting known as a professional by them is also important. Such visibility equates to having a

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good reputation and a defined role within a given field, whereas a lack of visibility within a profession means isolation, under-appreciation, and lack of recognition.

Professional associations make networking easier. Reaching out to strangers and introducing oneself can be intimidating and strange. Professional associations catalyse this process by hosting events where networking is actively encouraged. Such networking events are an excellent opportunity to establish long-lasting friendships and collaborations.[2] Many associations also offer formal mentoring programs, LinkedIn groups, Facebook® pages, Twitter® accounts, and job boards to facilitate member networking.

Collegiality refers to the cooperative relationship between fellow members of a profession united in a common purpose and respecting each other's abilities to work towards that purpose. Professional associations can help foster collegiality, as fellow association members are usually happy to help colleagues, whether they are well-established professionals dealing with a highly technical problem or new or young members who need advice on basic issues such as pay scales. Also, professional associations have directories of professional members, LinkedIn groups where members can post new discussions and even Twitter® accounts, where members can find fellow members ready to help.

The Brazilian educator and philosopher Freire, known for developing popular education, advocated dialogue – an exchange of ideas and opinions – as a type of pedagogy. He believed that dialogue allowed individuals to learn from one another in an environment of respect and equality. For him, dialogue was not just about deepening understanding but also about making positive changes in the world.[3] Professional associations are an excellent place for discussions and debates on matters of common interest. Such discussions help eliminate the isolation often experienced by freelance writers and translators. Taking an active role in a professional organisation allows members to meet new people, put forward ideas, learn to respect the opinions of others, feel useful, and participate in a group project.[4]

Professional associations raise professional standards

Associations raise standards in medical writing or translation by developing and publishing professional and ethical standards, as well as sound and fair business practices. These standards may deal with topics such as confidentiality, independence and objectivity, misconduct, legal issues, handling clients, and conflict of interest. Association members are encouraged to act in accordance with these standards to maintain the reputation of the profession. Professional organisations also promote standardisation initiatives, for example, by developing technical guidelines or holding targeted workshops. Maintaining standards can, for example, help safeguard wages and working conditions.

Professional associations provide professional education and information

Learning is essential for professional development. Many would agree that lifelong learning is, in itself, a good aim. Although some professionals do a reasonable job without developing substantially, others seek actively to challenge and stretch themselves, often in their own time. Many want to develop professionally, and while mindful of the need for a healthy work-life balance, are prepared to find the time to learn, develop, and improve their working practices.[4]

Continuing education may include certificate and non-certificate accredited courses, online and in-person training, self-paced and one-on-one training (perhaps using Skype, email, or another mutually agreed platform), and webinars (online presentations in real time in a virtual platform).

Professional associations can be a great help in all this. They often schedule training but may also ensure that the training is of a high standard. EMWA is an excellent example of this with its numerous high-quality workshops held at annual conferences in spring and autumn. These workshops cover all areas of medical writing and related topics such as marketing, statistics, and English.[5] Organisations may also offer online courses and webinars, which are an excellent opportunity to learn without leaving the office. EMWA is currently exploring this as an adjunct to in-person workshops.

Professionals are frequently recommended to learn as much as possible about the industries and companies that need their services. Whether working in-house or freelance, knowledge of the market is extremely important because it provides a competitive advantage and assists in professional growth. Keeping abreast of current trends and the latest industry news is also vital. Industry education and research therefore should be a daily activity and should not be postponed in lieu of more pressing matters. Professional associations can help with

this by providing access to exclusive industry publications, databases of company information, news about legislative issues affecting the field, and salary studies that help establish standards of pay and benefits. Subscribing to all of an association's news alerts and online and offline publications is important for remaining fully informed about the profession. Following fellow association members' business accounts on LinkedIn and Twitter® may also be a useful source of information.

Joining a professional association increases prestige

Adding a professional association to a c.v. professionalises it as it shows an understanding of the importance of professional networking, of being up to date with what's happening within the field, of continuing education, and of other important professional issues. It also suggests an investment in the chosen career area. In other words, listing membership of an association on your c.v., particularly an association that is a leader in the field, creates a good impression.

Conclusions

Professional associations are open and representative organisations of in-house and freelance professionals. They are active in all career areas and work for the benefit of individual professionals and of the profession as a whole. Membership in an association is a 'must' for professional advancement.

In a professional environment like medical writing – which is constantly challenging and is not immune to the current economic downturn – professional associations are often overlooked as a resource. They provide support and training within a particular field. Because they vary in size, level of activity, and breadth of membership, identifying the most suitable association is not always easy. Regardless, joining the association(s) that best meet(s) your needs and becoming active is professionally and personally rewarding.

Whatever your field, there is an association for you. Get involved, learn, meet new friends, and reap the benefits.

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Pleasing the reader by pleasing the eye—Part 2 Page layout and readability

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Abstract

The purpose of page layout is to consciously arrange text and graphics on a page in a way that supports the reading process and allows the reader to effortlessly follow the flow of information. It should blend words and images into an effective whole. Many of the basic principles of page layout in use today date back to the times when book printing was born in the Renaissance. The Industrial Revolution and Gestalt theory likewise have left their distinctive imprints on page design. The page designer's job, then, is to read and digest the text before making specific style choices and creating a layout that supports the writer's message.

Keywords: Readability, Layout, Page design, Gestalt theory, White space, Classical page layout, Modern page layout

> A layout is really a piece of abstract art. You're fiddling with basic shapes in different tones and trying to get them to sit comfortably, logically and interestingly together in order to tell a story and impart information clearly.
>
> – David Whitbread[1]

In the first part of this series on the role of format and design in readability we left off characterising page layout as the part of graphics design that deals with arranging content on a page, and this is what we will be looking at in this sequel.

The whole is other than the sum of its parts

Page layout is the first thing we perceive when we look at a piece of printed matter. It either draws us into the text or repels us – well before we have even started reading. The purpose of page layout is to consciously arrange text and graphics on a page in a way that supports the reading process and allows the reader to effortlessly follow the flow of information. It should blend words and images into an effective whole. Page layout is visual information management.[2]

Book printing and the birth of the Renaissance

Our eyes and brains long for order. This principle was at the very heart of the efforts of Renaissance book printers to devise the perfectly harmonious page, first among them Johannes Gutenberg in the 15th century, whose invention of movable type played a crucial role in the development of the Renaissance, and, ultimately, the Scientific Revolution. So successful were the Renaissance printers in their attempts that their principles are still in use today. Books at the time were not only a luxurious commodity, they were also stunningly beautiful. Their design was based on a set of rules whereby the pages and the blocks of text they carried would work together to form a harmonious unit (Fig. 1).

The golden ratio

One of these rules is that of the 'golden rectangle' (Fig. 2A), whose side lengths use the 'golden ratio,' or 'divine proportion'. Mathematically, the golden ratio is approximately 1:1.618.

Removing a square from the golden rectangle leaves us with another golden rectangle. If this process is repeated again and again, the corresponding corners of the squares combine into an infinite sequence of points on the 'golden spiral' (Fig. 2B). Amazingly, this aesthetically pleasing ratio lies at the heart of many shapes in nature, such as the

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Figure 1: Gutenberg Bible, 1 Epistle of John (paper copy), Volume 2 Folios 306v and 307r (courtesy of the British Library Board).[3]

human face, sea shells, and sun- and broccoli flowers, and it has also been used in architecture and art, such as the Parthenon temple, the Cheops pyramid – and the Apple logo (Fig. 3).

Canons of page harmony

Another set of page design principles, known as the canons, was used in many Renaissance books and later rediscovered by modern-day designers. One of several modern interpretations of this page layout is that by Van de Graaf from the Netherlands, based on analyses of books such as Gutenberg's Bible of 1455. In his *Divina proporción tipográfica* published in 1947, the Argentinian designer Raúl Rosarivo also analysed Renaissance books and found that their pages were divided into ninths both horizontally and vertically. The diagonals establish the width and height of the text block (Fig. 4, right panel).

In 1953, German typographer Jan Tschichold published his golden canon, which largely reflected what others had found before him. Yet, Tschichold also defined a new rule, namely that the height of the text block is the same as the width of the page, as illustrated by the circle (Fig. 4, left panel).

The industrial revolution and the decline in book printing

The fundamental changes brought about by the Industrial Revolution of the 18th century affected every aspect of life. Mechanisation brought not only unprecedented economic growth, but also a dwindling importance of the arts and crafts, including book printing. In response to these developments, the British *Arts and Crafts Movement* led by William Morris was founded in 1860. Morris held that art should satisfy the needs of society and that the form of an object, rather than mimicking the heavily decorated style of preindustrial times, should reflect its function and the qualities of the new materials being used.

Bauhaus and Gestalt theory

In Germany, another movement, the *Bauhaus*, formed in the wake of World War I. In part influenced by Morris, it shared many principles with the left-wing political and cultural developments following the Russian Revolution, i.e. *Constructivism*, or the Dutch *De Stijl* movement of artists such as Piet Mondrian, who sought to promote functionalism and a machine aesthetic that captured the spirit of the time. Advocating

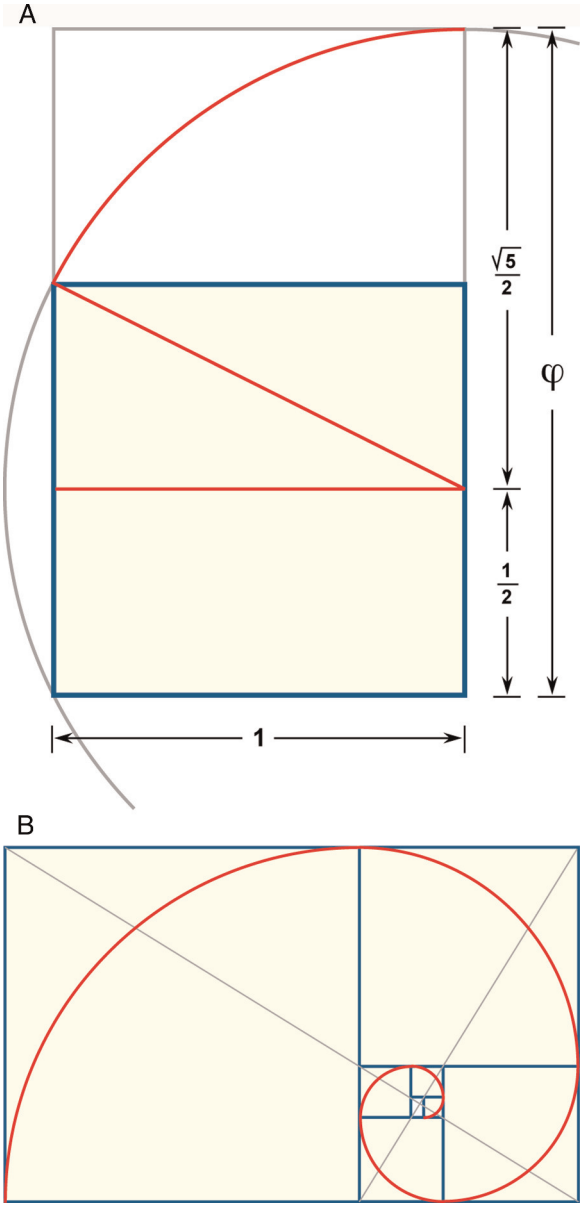


Figure 2: Constructing the golden rectangle (A) and drawing the golden spiral (B).

abstraction and a reduction to the essentials of form and colour, they were fascinated with exploring geometric alignments and asymmetric composition, had a predilection for sans-serif typefaces, made ample use of white space, and rejected ornaments.

The designers of the German *Bauhaus* began to discover that Gestalt theory offered a conceptual framework for explaining the aesthetics of their time. According to Gestalt theory, we perceive objects in their entirety before seeing their individual components. '*Das Ganze ist etwas anderes als die Summe seiner Teile*' (The whole is other than the sum of its parts), gestaltist Kurt Koffka said. Fig. 5 illustrates what he meant. It depicts three blue circles, each with one wedge cut out. Another way of looking at the three circles is to see white corners placed on top of each of them that imply the shape of a triangle. The whole, therefore, is not greater than, but different from, the individual parts it consists of.

Similarly, readers first perceive a page as a whole, taking in the colours and shapes, before they begin to zero in on, first, the graphics and images if available and, then, on the most intellectually challenging part, i.e. the text (Fig. 6).

Fundamentals of page layout

Many of today's designers draw on the principles of Gestalt theory to explain why some layouts work while others do not.[6,7] A fundamental Gestalt principle is the *law of prägnanz*, which states that we strive to eliminate confusion and complexity and to introduce orderliness into what we see.

Figure–ground principle

Page design should create a clear visual logic.[2] According to the *figure–ground principle* of Gestalt theory, we perceive elements as either figures (i.e. the focus of attention) or ground (the background carrying these figures). Determining the figure–ground relationship is the first thing we do when we scan a page (Fig. 6). We cannot perceive figures unless they clearly stand out from their background. Therefore, rather than seeing a page as empty space needing to be filled, we should think of it as a shape that helps us organise the elements we place on it.

Similarity

Because our minds love patterns, a major hurdle to readability is inconsistency. Good design uses consistent typefaces, colours, graphics, and typography to help the reader effortlessly navigate the layout. Consistency makes a text more predictable and decreases the learning curve. The Gestalt *law of similarity* posits that when we perceive a collection of elements that resemble each other, we see them as belonging together. Also, similar appearance is perceived to represent similar function. Therefore, applying a consistent style for text and graphics guarantees unity across pages. Repetition here is not synonymous with boredom. Rather, it determines the personality of our document.

For example, because readers use headings as signposts to find the information they need, we should guide them through a document using consistently formatted headings that reflect the hierarchy in the text. Likewise, elements aligned along a shared axis appear more related to each other, whereas a lack of alignment makes a document look unorganised. The spacing between paragraphs should also be consistent, and there should be a

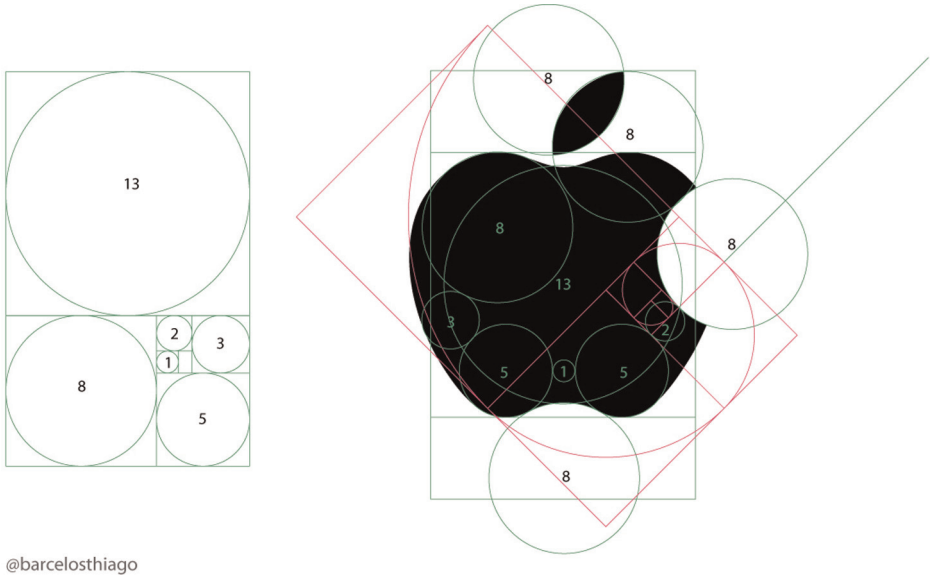


Figure 3: Apple logo based on the golden rectangle (courtesy of Thiago Barcelos).[4]

logic to why spaces are the width they are. The text in the left column of Fig. 7, consisting of running text and interspersed text samples, illustrates how illogical spacing can separate elements that actually belong together and group those that do not – an example of poor 'closure.' According to the Gestalt *law of closure*, we perceive objects as being whole even when they are not complete. A figure or page area with disrupted closure confuses us, because we will try to establish relationships that may not be intended. The reformatted text in the right column of Fig. 7 corrects this by using consistent and logical spacing between paragraphs.

Contrast

The flip side of similarity is contrast. Whereas consistency reinforces similarities, contrast highlights differences. The text in the left column of Fig. 7 has an additional problem – the reader has a hard time differentiating between running text and text samples. Changing the typeface and indentation takes care of this problem by better emphasising content relationships (Fig. 7, right column).

The greater the difference, the greater the contrast should be. For example, headings should provide enough contrast to jump out of the grey body copy. To achieve contrast, we can enlarge the type, format headings in bold, or use a different typeface or colour. Varying tone is another effective means of producing contrast. A readable layout is generally one with a balanced interplay of dark and light areas.

Proximity

The Gestalt law of proximity states that we perceive objects that are close to each other as forming a group. It is a principle that is frequently violated, even with simple layouts. The table in Fig. 8A

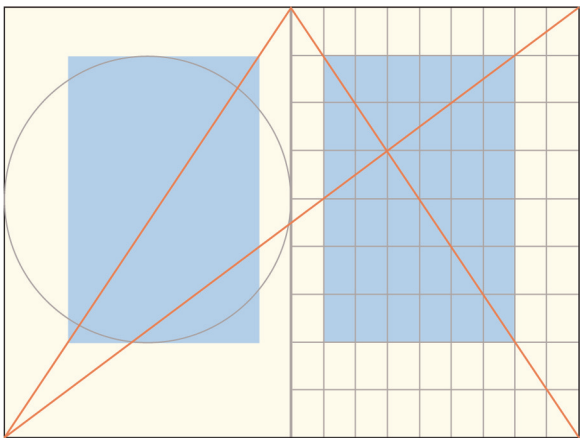


Figure 4: Tschichold (left panel) and Rosarivo (right panel) canons of page design.

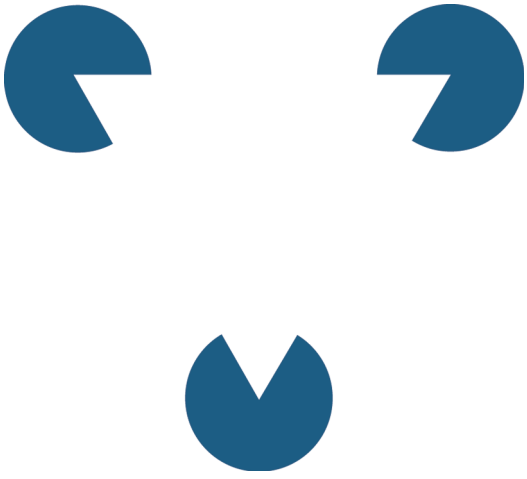


Figure 5: Kanizsa triangle.[5]

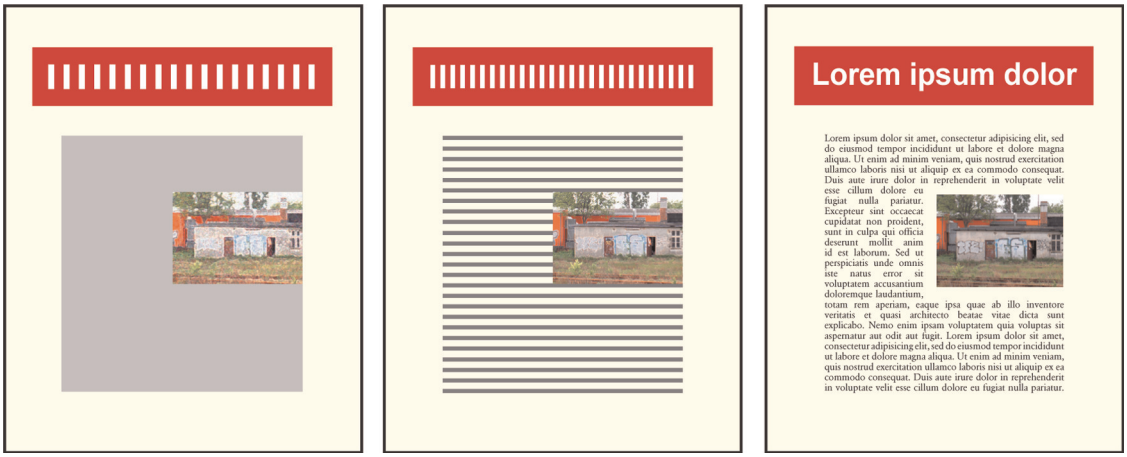


Figure 6: Reader's scanning process: from contour and contrast to content (adapted from Lynch and Horton).[2]

groups columns that should not be grouped. In Fig. 8B, the error has been resolved.

Also, headings are frequently misplaced to the effect that they are equidistant to both the previous and the following paragraphs. With headings functioning as signposts, we should not leave the reader puzzled as to where a heading belongs. Do not just have the headings jump out of the grey through contrast – stick them to the paragraph they introduce.

Balance

According to the Gestalt *law of balance,* or *symmetry,* we perceive objects as forming around a centre point. Balance refers to elements being distributed on a page so that the page does not topple over to one

Figure 7: Paragraph spacing gone wrong (left) – and corrected (right).

A **Law of proximity violated…**

Day	Mean	Day	Mean	Day	Mean
0	640	6	530	12	526
1	600	7	529	13	510
2	580	8	527	14	530
3	585	9	520	15	520
4	550	10	523	16	525
5	540	11	525	17	510

B **…and corrected**

Day	Mean	Day	Mean	Day	Mean
0	640	6	530	12	526
1	600	7	529	13	510
2	580	8	527	14	530
3	585	9	520	15	520
4	550	10	523	16	525
5	540	11	525	17	510

Figure 8: Law of proximity violated (A) and corrected (B) (adapted from Moore and Fitz).[7]

side or slip towards the bottom. Balanced layouts will look good when viewed right side up and when viewed upside down.

We have two basic options to achieve balance. One is based on the style developed in the Renaissance – the symmetric layout. The feeling it conveys is one of stability. While balance in symmetric designs is fairly easy to achieve, it is important to lift the elements on the page to its optical centre, which is always above the physical centre. Therefore, the margin at the bottom of a page should generally be larger than the top margin.

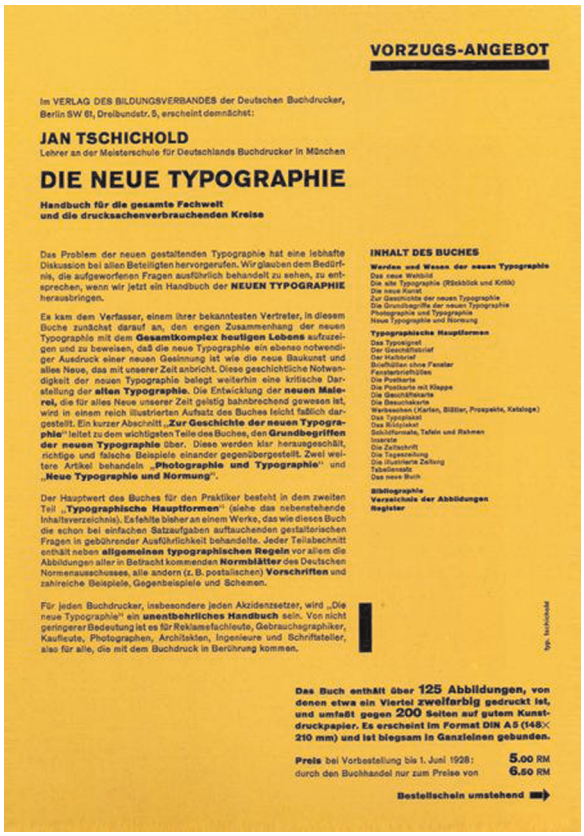
The second option is asymmetric balance, which is achieved when the left and right sides of a page are unequal. Asymmetric designs are less predictable and therefore more exciting. With asymmetry, it is more of a challenge to achieve balance than with symmetric designs. Whitbread compares asymmetric balance with an adult and a child on a seesaw: to achieve it, the adult and the child must be placed in different positions.[1] Asymmetric modernist layouts often rely on a grid, whose modularity is perfectly in line with the needs of the information age. Grids help assign functional page areas and allow information to be organised into logical units.[1]

A leading proponent of the asymmetric design was the printer and calligrapher Jan Tschichold. He used to work in the classical style until he came in touch, in the 1920s, with the paintings of El Lissitzky, who was later going to influence the Russian *Constructivits*, the Dutch *de Stijl* movement, and the German *Bauhaus.* Tschichold's most important work, *Die neue Typographie* (The New Typography), was a manifesto of modern design, and his philosophy is reflected in an announcement for his book (Fig. 9). After World War II, the modernist graphic design became a cohesive movement referred to as the International Typographic Style.[8]

Although Tschichold originally thought of asymmetric design as more effectively representing modern life, he abandoned his firm views in the early 1930s and returned to classical print design, analysing incunabula for the secret canon of page design described earlier (Fig. 4). Between 1947 and 1949, he lived in England, where he was responsible for the redesign of the Penguin paperback books.[9] Overall, Tschichold initiated many of the typographic practices that are largely taken for granted today.

White space

Consistency, contrast, proximity, and balance are merely some of the principles that make page layout work and, as we have seen, they do not function in isolation but in concert with each other. Ultimately, they all do one thing: they manage white space. White space is 'determined by placement of design elements within space'.[1] The less crowded a page, the less likely it is to overwhelm its readers. White space provides breathing room for the eye. For example, Google makes optimal


VORZUGS-ANGEBOT

Im VERLAG DES BILDUNGSVERBANDES der Deutschen Buchdrucker, Berlin SW 61, Dreibundstr. 5, erscheint demnächst:

JAN TSCHICHOLD
Lehrer an der Meisterschule für Deutschlands Buchdrucker in München

DIE NEUE TYPOGRAPHIE

Handbuch für die gesamte Fachwelt und die drucksachenverbrauchenden Kreise

Das Problem der neuen gestaltenden Typographie hat eine lebhafte Diskussion bei allen Beteiligten hervorgerufen. Wir glauben dem Bedürfnis, die aufgeworfenen Fragen ausführlich behandelt zu sehen, zu entsprechen, wenn wir jetzt ein Handbuch der NEUEN TYPOGRAPHIE herausbringen.

Es kam dem Verfasser, einem ihrer bekanntesten Vertreter, in diesem Buche zunächst darauf an, den engen Zusammenhang der neuen Typographie mit dem Gesamtkomplex heutigen Lebens aufzuzeigen und zu beweisen, daß die neue Typographie ein ebenso notwendiger Ausdruck einer neuen Gesinnung ist wie die neue Baukunst und alles Neue, das mit unserer Zeit anbricht. Diese geschichtliche Notwendigkeit der neuen Typographie belegt weiterhin eine kritische Darstellung der alten Typographie. Die Entwicklung der neuen Malerei, die für alles Neue unserer Zeit geistig bahnbrechend gewesen ist, wird in einem reich illustrierten Aufsatz des Buches leicht faßlich dargestellt. Ein kurzer Abschnitt „Zur Geschichte der neuen Typographie" leitet zu dem wichtigsten Teile des Buches, den Grundbegriffen der neuen Typographie über. Diese werden hier herausgeschält, richtige und falsche Beispiele einander gegenübergestellt. Zwei weitere Artikel behandeln „Photographie und Typographie" und „Neue Typographie und Normung".

Der Hauptwert des Buches für den Praktiker besteht in dem zweiten Teil „Typographische Hauptformen" (siehe das nebenstehende Inhaltsverzeichnis). Es fehlte bisher an einem Werke, das wie dieses Buch die schon bei einfachen Satzaufgaben auftauchenden gestalterischen Fragen in gebührender Ausführlichkeit behandelte. Jeder Teilabschnitt enthält neben allgemeinen typographischen Regeln vor allem die Abbildungen aller in Betracht kommenden Normblätter des Deutschen Normenausschusses, alle andern (z. B. postalischen) Vorschriften und zahlreiche Beispiele, Gegenbeispiele und Schemen.

Für jeden Buchdrucker, insbesondere jeden Akzidenzsetzer, wird „Die neue Typographie" ein unentbehrliches Handbuch sein. Von nicht geringerer Bedeutung ist es für Reklamefachleute, Gebrauchsgraphiker, Kaufleute, Photographen, Architekten, Ingenieure und Schriftsteller, also für alle, die mit dem Buchdruck in Berührung kommen.

INHALT DES BUCHES

Werden und Wesen der neuen Typographie
Das neue Weltbild
Die alte Typographie (Rückblick und Kritik)
Die neue Kunst
Zur Geschichte der neuen Typographie
Die Grundbegriffe der neuen Typographie
Photographie und Typographie
Neue Typographie und Normung

Typographische Hauptformen
Das Typosignet
Der Geschäftsbrief
Der Hektograf
Briefhüllen ohne Fenster
Fensterbriefhüllen
Die Postkarte
Die Postkarte mit Klappe
Die Geschäftskarte
Die Besuchskarte
Werbeschriften (Karten, Blätter, Prospekte, Kataloge)
Das Typoplakat
Das Bildplakat
Schriftformate, Tafeln und Rahmen
Inserate
Die Zeitschrift
Die Tageszeitung
Die illustrierte Zeitung
Tabellensatz
Das neue Buch

Bibliographie
Verzeichnis der Abbildungen
Register

Das Buch enthält über 125 Abbildungen, von denen etwa ein Viertel zweifarbig gedruckt ist, und umfaßt gegen 200 Seiten auf gutem Kunstdruckpapier. Es erscheint im Format DIN A 5 (148 × 210 mm) und ist biegsam in Ganzleinen gebunden.

Preis bei Vorbestellung bis 1. Juni 1928: 5.00 RM
durch den Buchhandel nur zum Preise von 6.50 RM

Bestellschein umstehend

Figure 9: Book announcement flyer: Jan Tschichold's *The New Typography* (1928).

use of white space, ending up with one of today's most powerful and easy-to-use designs on the web.

> If economy and conservation were your chief concern, then white space would be at a minimum; obviously you would use it all up. So white space is used for purely semiotic values; for values of presentation which transcend economic values by insisting that the image of what you present is more important than the paper you could be saving. . . . White space is a negative cost right down the production line—except for giving style.
>
> – Keith Robertson[10]

Classical versus modern page layouts

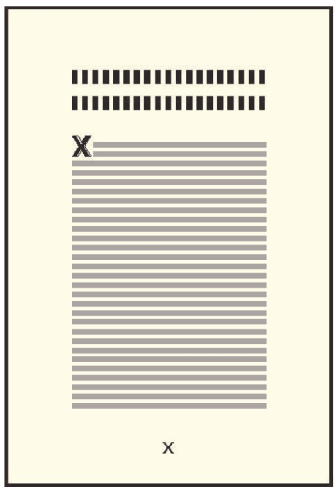
As one might guess from all of the above, page designs are generally of one of two basic types: classical or modern. The classical design is based on the Italian book design of the Renaissance and has been the dominant style used in books (Fig. 10).

The modern style was influenced by the *De Stijl* movement, *Constructivism*, and the German *Bauhaus*, and refined by the Swiss (Fig. 11).

The choice of styles carries semantic content, providing the reader with visual hints as to how an organisation wants to be viewed. Thus, whereas the modern style presents an organisation as being at the cutting edge of modernity, the classical style implies that an organisation relies on tried and trusted values.

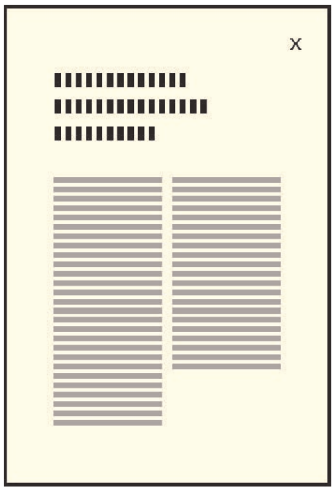
Conclusion

The designer's job is to 'provide a layout that respects the motives of the writer and the reader'.[11] This requires the designer to read and digest the text and understand its message and audience before making specific style choices. Is there, then, something like a layout error? Waller defines six typographic genre levels differing in their degree of being rule-bound.[11] For example, legislative acts or medicines labels are highly rule-bound,



- Generous margins that relate to each other
- One-column set-up
- Centred page number
- Strong serif typeface (e.g., Bembo, Garamond, Times, Baskerville, or Palatino)
- Paragraphs indented by about 5 mm, with no extra space between them
- Justified type with generous leading
- Centred heading
- Initial drop capitals at the beginning of a chapter and centred dingbats at the end
- Constant page depth, with the bottom line of the text block defined by the bottom margin

Figure 10: Classical page layout (adapted from Whitbread).[1]



- Light margins, with top and side margins about the same; the bottom margin should be slightly larger
- Text block divided into 2 or 3 columns separated by a narrow gutter
- Right-aligned page number
- Sans-serif typeface with extensive font family (e.g., Helvetica, Univers, Frutiger, Gill Sans, or Futura)
- Flush left, unjustified, and with a generous leading to separate the sans-serif lines for easy reading
- Block paragraphs, not indented and separated with a half to one line space
- Headings formatted in different point sizes and weights; use of capitals to be avoided
- Varying page depth, with each column filled to a logical paragraph break, but not down to the bottom

Figure 11: Modern page layout (adapted from Whitbread).[1]

so much so that their layout may be legally enforceable. Biomedical publications are institutionally enforced and have to conform to internationally agreed or journal-specific guidelines. Newspapers are rule-bound by convention, and advertisements are hardly rule-bound at all, yet form a unique genre through purpose and imitation. The more rule-bound a genre, Waller says,[11] the more specific the concept of error. In the case of medicines labels, a layout error may arise merely from not complying with the legal provisions. For the least rule-bound genres, the designer commits an error only if he fails to achieve his goal. For example, the layout of a medicine advertisement has failed if the physician never even gets to read the name of the product. Thus, while layout is the first thing we perceive when looking at a piece of print, there's more to it than first meets the eye.

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Implications of clinical trial data sharing for medical writers

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Abstract

Major clinical research funders are increasingly adopting policies supporting or mandating data sharing. These moves should improve the transparency and availability of clinical trial data and are likely to impact the work and responsibilities of medical writers. Medical writers are likely to play a prominent role in standardising policies and procedures and have the opportunity to lead the development of an efficient and feasible system for promoting clinical trial data sharing. These efforts will ensure that the research community can derive the full benefit from the enormous resources devoted to human clinical trial research and will help build patient trust in the research process.

Keywords: Clinical trials as topic, Information dissemination, Access to information, Peer review, Research

Over the past few years, a number of major clinical research funders have adopted policies supporting or mandating data sharing. These include the US National Institutes of Health,[1] the UK Medical Research Council,[2] and the Bill and Melinda Gates Foundation.[3] Similarly, major regulators, most notably the European Medicines Agency (EMA),[4] are contemplating the adoption of open data access policies, as are several companies in the pharmaceutical and medical device industries.[5–7]

These moves toward greater transparency and availability of clinical trial data are likely to impact the work and responsibilities of medical writers, who play a major role in preparing regulatory documentation and peer-reviewed manuscripts on behalf of the clinical research team. This commentary introduces the concept of data sharing and discusses implications of clinical trial data sharing for medical writers.

Why share clinical trial data?

Most of the data generated and information elicited from clinical trials are currently not available to the scientific and clinical communities.[8–10] Today, physicians and other clinicians often recommend treatment options to patients on the basis of information that is incomplete: not all clinical trials are published and made available and not all outcomes collected during a clinical trial are reported and made available, even when the trial is published.[9,11,12]

In clinical research, data sharing is the practice of a research team making trial data available to individuals with whom they are not collaborating. Before discussing the specifics of data sharing, it is worth pausing to consider the rationale for engaging in such an exchange. Briefly, sharing clinical trial data increases the value of all clinical trial research by encouraging the use of data already collected. Sharing clinical trial data also reduces the potential for inaccurate or incomplete reporting of study outcomes that distort the medical evidence, and it ultimately ensures the reliability of the evidence base upon which clinical decisions are made by patients and physicians.[13–15] As the number of data sharing initiatives grow, the scientific community will be able to adopt a more open approach to research.

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When clinical trial data are made more widely available, science can function as a community, continually vetting, critiquing, and building upon each other's ideas.

Clinical trial data sharing

There are two principal methods by which clinical trial data are shared. First, investigators may share trial data on their own terms in response to individual requests. Second, investigators may share trial data by depositing it in a repository, which is an archive of data with terms of access defined by the organisation that maintains it.

Sharing data in response to individual requests is less predictable because it is never clear if or when individual requests for data sharing will be made. Individuals seek out research teams who have generated clinical trial data on a subject in which they are interested, making requests to use the data for analysis, perhaps as part of a larger meta-analysis, to validate the original findings, or even to pursue a secondary question not addressed by the original research team. The decision to share data is made one request at a time and, if approved, the data are transferred directly between the research teams.

In contrast, sharing data through repositories requires a standardised approach and is predictable in practice, as investigators must prepare the data for sharing, regardless of whether the data will ever be accessed. For the repository process to be effective, the data need to be deposited in a publicly accessible repository, such as DRYAD,[16] allowing it to be used according to the rules that govern data access. The repository includes the data files, along with accompanying metadata and documentation. The decision to share is made *a priori* and data are transferred after study completion, once all data management and preparation issues have been resolved.

Data sharing – the role of medical writers

Both data-sharing methods are likely to increasingly involve medical writers, particularly for industry-funded trials and as the method of data sharing becomes standardised. Medical writers can play a critical role in several steps of the data-sharing process, but their chief responsibility is likely to be preparing the metadata and documentation needed by secondary users of shared clinical trial data. Structural metadata include the design and specification of data structures, whereas descriptive metadata include information about the data content. Both are required by any secondary user to orient them to the data structures and content, thereby improving the usability of the clinical trial data.

The research team needs to prepare a clean, well-annotated data set for deposit that includes supporting documentation to allow for secondary analysis. The data set needs to be clearly organised and follow standard logic and coding formats. Variables need to be clearly defined with no ambiguity. Without strict adherence to best practice for data preparation and documentation, the practice of data sharing will be largely limited. Moreover, standards for data definition will need to be adopted to ensure comparability of the information generated across trials and to ensure that data can be pooled for summary analysis. For example, if several different trials studying acute myocardial infarction events all use different definitions for the endpoint, the ability to summarise and interpret data across multiple studies will be limited.

Medical writers can also play a critical role in identifying the most appropriate and effective policies and advocating for funders to move towards standardised procedures. Currently, policies and procedures for preparing data for deposit in a repository vary among clinical trial research funders, and few funders are making a concerted effort to adopt uniform policies and procedures. If all clinical trial research funders adopt different policies and procedures for data sharing, such as different data definitions and documentation requirements, data sharing may devolve into an inefficient use of resources, time, and energy. As the field evolves, medical writers can lead the way towards standardised policies and procedures.

Managing data sharing

Beyond these two chief responsibilities, medical writers may be forced to consider several other technical issues when preparing data for sharing individually or through deposit in a repository.[17] These issues are likely best managed by medical writers in conjunction with other investigators from the research team as well as from the data analysts. Several of these issues are covered in brief below to introduce the potential challenges facing the field.

Defining the data

Far more data are generally collected within the context of a clinical trial than are reported in any single biomedical journal article. So how is the data set defined? Limited guidance suggests that the data set is the aggregated collection of patient observations (including socio-demographic and

clinical information) used to produce the summary statistical findings presented in the main report of the research project, whether previously published or not.[17] Thus, the data set should include all pre-specified and intentionally collected primary and secondary outcomes as well as safety endpoints, in agreement with the clinical trial registration and results reporting requirements of ClinicalTrials.gov.[18,19]

De-identification

To protect patient confidentiality, all direct and indirect patient identifiers must be removed from the data set. Experts disagree on the complexity of the task; recent presentations at a workshop at the Institute of Medicine suggested that de-identification could require an hour to an afternoon to weeks.[20] However, it is clear that patient confidentiality issues are of greater concern for small trials of rare diseases than for large, multi-centre trials of common conditions where identifying patients is extremely difficult.

Copyright/licensing agreements

Data ownership must be resolved prior to deposit. Clinical research funders may decide to prospectively address this issue by requiring that data be deposited in a repository, transferring any ownership by the funder or research team to the public. Moreover, as most clinical research data are generated through collaborations between multiple researchers (nearly all of whom are paid for their effort), it may not be possible to determine who actually owns the data.[21] Others contend that patients are the rightful owners.[22] The best guidance on this issue is from recommendations on the publication of raw data in journals, which recommend that copyright should be transferred to the publisher for publishing data sets as supplementary material, that the supporting data should be separated from the article itself, and that transfer of copyright for the data is not required as a condition of publication.[17] However, individual repositories are likely to enact their own policies.

Patient consent

Data-sharing plans are rarely discussed with patients as part of the informed consent process. While de-identification of the data may preclude the need for patient consent prior to sharing, going forward, institutional review boards and ethics committees should encourage clinical trial researchers to discuss data-sharing plans when obtaining informed consent, along with any safeguards that will be instituted to protect patient privacy. Everyone's interests would be best served if patients explicitly consented to the sharing of their de-identified clinical research data.

Conclusion

For data sharing to be successful, policies and procedures need to be standardised. Medical writers are likely to play a prominent role in these initiatives, not only by preparing data and documentation for sharing but also by establishing the standards for data definition and documentation and advocating the adoption of procedures that best support effective data sharing. Many outstanding issues remain. Medical writers have the opportunity to lead the development of an efficient and feasible system for promoting clinical trial data sharing. These efforts will ensure that the research community can derive the full benefit from the enormous resources devoted to human clinical trial research and will help build patient trust in the research process. The data generated and information elicited from clinical trials needs to be available to the scientific and clinical communities so that treatment decisions are based on all known information.

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Conflicts of interest

Drs Ross and Krumholz receive research support from Medtronic, Inc. to develop methods to promote data sharing. Dr Ross reports that he is a member of a scientific advisory board for FAIR Health, Inc. Dr Krumholz reports that he chairs a scientific advisory board for UnitedHealthcare.

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EMWA Social Media – 3 modern ways to stay informed about EMWA

Looking for simple ways to keep up with EMWA happenings outside of the website and journal? Then check out the range of EMWA social media options available. Thanks to the hard work of the newly constituted social media team, up-to-date information is only a click away.

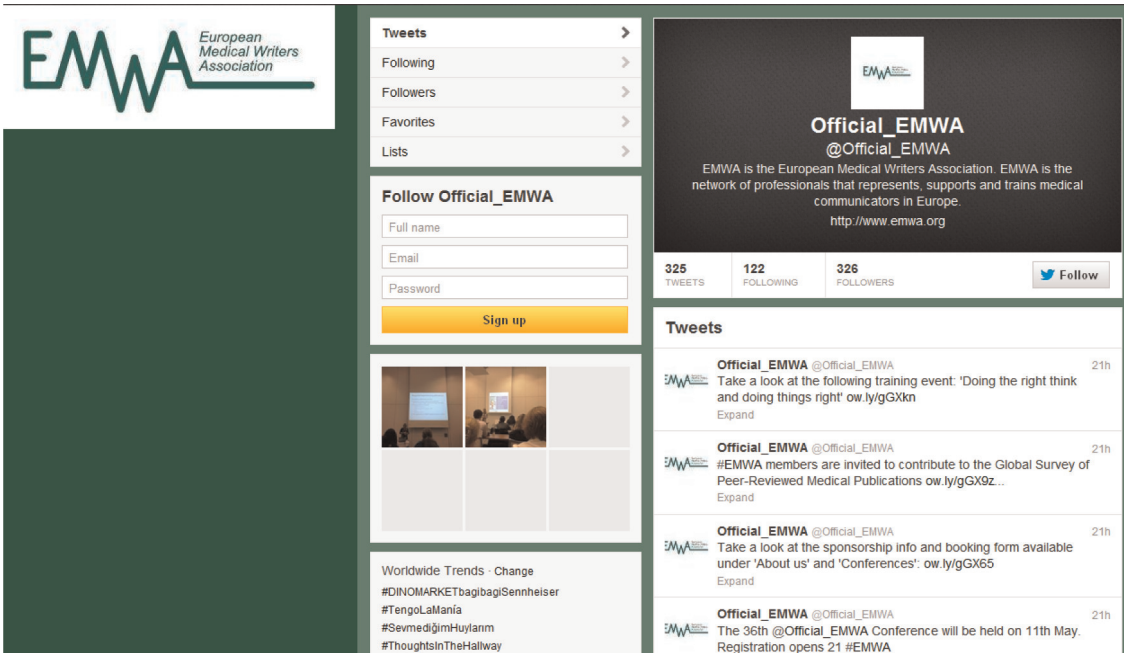
The EMWA LinkedIn group now has over 2,000 members, and new discussion topics – relating to medical writing and medical communications in general – are posted on almost a daily basis by group members from a wide range of career backgrounds, based in Europe and the rest of the world.

The EMWA Facebook site has over 300 'likes'. Join and share your experience with medical writers around the world. Stay up to date with EMWA's activities on Facebook.

EMWA is also now very active on Twitter and has over 320 followers. Short tweets on EMWA and medical writing in general are sent out at very regular intervals.

Please take some time to check out our social media offerings and choose the channel (or channels) that suit you best! Links can be found on the EMWA website.

If you would like to help support the social media team or have feedback to offer, please feel free to contact Diarmuid De Faoite, the EMWA website manager: webmanager@emwa.org.



Caption: Screenshot of the EMWA Twitter page (January 2013).

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In the Bookstores

Bad Pharma: How drug companies mislead doctors and harm patients
by Ben Goldacre
Fourth Estate, 2012.
ISBN: 978-0-00-735074-2 (paperback).
13.99 GBP. 448 Pages.

Bad Pharma

Bad Pharma is the latest book by the well-known anti-quackery campaigner Ben Goldacre, and attempts to explain to us that medicine is broken. Despite the title, he criticises not only the pharmaceutical industry, but also regulators, doctors, academic clinical researchers, ethics committees, and various other players in the world of clinical research. His take home message (I don't think a spoiler alert is really needed here!) is that we simply can't trust the evidence that we see about the efficacy and safety of drugs in common use.

The book is divided into six chapters, which cover different aspects of the pharmaceutical industry. Chapter 1 is entitled 'Missing data', and describes at considerable length the important problem of publication bias. The take home message from this chapter is that we cannot assess the evidence for a particular drug if not all the trials on it are published, and, worse still, those that are not published tend to be different from the ones that are. Chapter 2 is a brief and well put-together description of the drug development process. Chapter 3, 'Bad regulators', does what it says on the tin, and explains the many ways in which Goldacre believes that drug regulation isn't working. Chapter 4 talks about the design of individual clinical studies and how they can be flawed. Chapter 5 describes how pragmatic randomised trials could be (but very rarely are) incorporated into routine clinical practice. This seems a little out of place, as it is not really about 'bad pharma' at all, but is interesting nonetheless. Chapter 6, the longest chapter of all at over 100 pages, talks about marketing in the pharmaceutical industry.

Goldacre has a well-earned reputation as a fearless debunker of dodgy scientific claims. His previous book, Bad Science, mercilessly took to pieces the dubious tricks played by various pedlars of pseudoscience. He regularly writes articles both on his own blog and for the popular media in which he rigorously dissects questionable claims, pointing to the flaws in the scientific and statistical methods used by those who make them.

So if you are familiar with Goldacre's reputation, then you would expect that this book would be backed up with similarly rigorous scientific arguments. However, you would be disappointed.

Goldacre tells us at several places in the book (quite correctly) about the importance of using systematic reviews and being careful not to cherry-pick examples that back up a specific point, and promises to cite systematic reviews to make his points. Sadly, the reality of the way he presents his evidence does not live up to those fine promises. He certainly presents the results of some systematic reviews, but he is far from consistent in doing this. At one place he presents a single study, which is not a systematic review, but describes it as a systematic review anyway. In many places he does exactly what he warns against and cherry-picks unrepresentative cases to make a point. He sometimes ignores evidence that contradicts his message. The overall impression is that he decided from the start that he was going to tell as powerful a story as possible that the whole system of drug research is flawed, rather than attempting to follow the evidence in a scholarly manner.

It would, however, be a mistake to dismiss this book as being based on poor scholarship and therefore unworthy of our attention. Despite the shortcomings in his use of evidence, Goldacre does make some important points whose validity is not in doubt.

One such point is that much of the evidence on how well drugs work is not available to patients and prescribers: the problem of publication bias that he describes in the first chapter. Many attempts have been made to fix this problem, and most big pharma companies now commit to publishing all their trials, although Goldacre describes these efforts (without presenting evidence) as 'fake fixes'. Nonetheless, it would be overly optimistic to assume that every study that takes place is published, and until we can be sure that it is, then we all need to try harder to ensure more complete publication. Goldacre also makes the very good point that even if incomplete publication has now been fixed, there is still a mountain of studies that were

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done in the past and are still not published, even though their results are still relevant to today's medical practice. So we should not consider the problem solved until it has been solved retrospectively as well.

Goldacre's criticisms of the secrecy that surrounds the regulatory process are also very well made. He points out that it is unjustifiable that regulators have access to huge amounts of data on the drugs they approve, but do not publish them. It is hard to argue with this. I personally cannot think of any valid reason why regulators do not routinely make submission dossiers available via their websites, and we could all have far more confidence in the regulatory process, as well as know far more about the drugs that we use, if they did.

Medical writers will find some parts of the book frankly offensive. Goldacre seems to use the terms 'medical writing' and 'ghostwriting' interchangeably, completely ignoring the considerable efforts that EMWA and other medical writing organisations have made to combat ghostwriting in the medical literature. He describes professional medical writing thus: 'They [pharmaceutical companies] pay professional writers to produce academic papers, following their own commercial specifications, and then get academics to put their names to them.' This is a caricature of the work of the medical writer based on a few examples of bad practice mostly dating from the 1990s, and EMWA members will be acutely aware that this bears little resemblance to the way medical writing is practised in real life today, even though Goldacre describes ghostwriting papers for academics who have no input into them as 'bread-and-butter activities' of medical writing. If you are offended by this mischaracterisation of the medical writing profession, then I am not surprised. It is telling that Goldacre does not provide any evidence to back up this claim, other than to quote some old individual cases where some companies did not play by the rules in the past. This is cherry-picking of the worst kind: there is no evidence whatever that those kinds of abuses were common even back in the 1990s when most of them occurred, let alone today. It would be like making the claim that most doctors are serial killers, and backing it up with reference to Harold Shipman.

Of course, if you did claim that most doctors were serial killers, no-one would believe you, because most people are very familiar with who doctors are and what they do, and know that most of them are conscientious and caring individuals. Sadly, however, medical writing is not such a well-known profession, and it is probably true that many people who read the book will not be familiar with what medical writers do, and so will simply believe Goldacre's flagrant mischaracterisation of our profession.

At 448 pages, Bad Pharma is a long book. It is probably longer than it needs to be: Goldacre's fondness for using anecdotes about specific cases to make his point adds more to the emotive qualities of the book than it does to the scientific data presented.

EMWA members will probably not learn much from this book that is new to them. There are some good explanations of how drug development works, but this will already be familiar territory. The book does, however, provide much food for thought. Although Goldacre goes beyond the evidence and overstates his case in places, he does, as I mentioned earlier, still make some valid points. If any EMWA members who read this book are prompted to give some more thought to how they can help to ensure that the trials they work on are always published, then it will have fulfilled a useful function.

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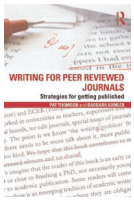
Note from Editor: EMWA has published guidelines on the role of medical writers in developing peer-reviewed publications and has reiterated these in the position statement on ghostwriting found on Page 3 of this issue.

Greg Morley also discusses Bad Pharma in the Regulatory Writing column on page 61.



Writing for Peer Reviewed Journals
Strategies for getting published
by Pat Thomson and Barbara Kamler:
Routledge, 2012.
ISBN-13: 978-0-415-80931-3.
22.99 GBP. 190 pages.

A guide aimed at junior social science researchers which contains some information applicable to other disciplines and of use to other types of writers

The blurb on the back cover of *Writing for Peer Reviewed Journals* asserts that it 'assists anyone concerned about getting published' and 'uses a wide range of multi-disciplinary examples'. This information could at best be described as somewhat misleading: it is clearly aimed at junior researchers, for whom there is a lot of (quite useful) information on converting the PhD thesis into journal articles, and even structuring the thesis with such articles in mind. Moreover, it is squarely focussed on the social sciences. The book's authors, Pat Thomson and Barbara Kamler, both work in education and while they refer to conventions in other disciplines, most of their examples are taken from their own field. Nonetheless, they do provide some information that will be useful to medical writers.

In the book's introduction, Thomson and Kamler clearly set out their goal: to focus on scholarship rather than writing development; to offer a pedagogical and 'theorised approach rather than a set of tips and tricks.' In its first chapter proper (*The Writer*), they argue cogently that the moulding of a scholarly identity is acutely influenced by what one writes and how one writes it. While of little practical benefit, this philosophical discourse is rather interesting.

The book's remaining eight chapters variously deal with fundamental and practical facets of writing. The authors provide a brief summary for each chapter in the introduction to allow readers to skip straight to a particular chapter if they so wish. By referring back to previous chapters in which key concepts are introduced and defined, they almost (but don't quite) make it possible to read individual chapters in isolation.

Chapter 2 (*The Reader*) emphasises the importance of writing with a specific reader in mind; *What's the Contribution?* and *So what? Who cares?* largely focus on writing abstracts in a way that makes clear the nature and importance of one's work; *Beginning work* and *Refining the argument* deal with writing and revising/editing articles; and *Engaging with reviewers and editors* does exactly what you would imagine it does.

The eighth chapter, *Writing with others*, is excellent (albeit it is targeted to junior researchers). It introduces three different types of collaborative writing and, with the aid of comments from successful writing partnerships, explains how to make writing collaborations work. Importantly, it notes that it is not possible to write with everyone, but fails to acknowledge that you don't always get to choose whom you write with!

The book's last chapter (*Living hand to mouse*) concludes with some smashing advice about peer reviewing, including sets of questions the reviewer should ask him/herself when reading a manuscript and rules to follow when writing the review. As the authors note, how to be a good peer reviewer is a neglected topic. *Have a look at this manuscript* was the only instruction I and no doubt many others got when starting out.

This advice on peer reviewing is complemented by tips on responding to reviews: don't ruin your article by accepting wholesale all the reviewers' comments; be authoritative; and don't fawn. I once edited a set of point-by-point responses to reviewers' comments in which the author thanked each reviewer for each and every comment. Twice!

Thomson and Kamler claim an 'international approach' and an 'accessible style'. While they describe the increasing requirement to publish in English as 'contentious and sometimes extraordinarily difficult,' they do not employ the simplest English imaginable. I am grateful to them for adding several new words to my vocabulary; less patient readers may be less appreciative. The book's 'international approach' is in fact limited to (i) a couple of lines on the writing difficulties of individuals whose mother tongue has different cultural conventions than those of English and (ii) problems non-native English speakers have interpreting nuanced comments from peer reviewers (e.g. 'I would suggest…' = 'You should…'). These are interesting topics that warrant more detailed analysis.

For experienced writers and researchers the points of real interest may be limited to a few pages here and there. Key passages deal with avoiding signing off with an empty, lazily written conclusion and ways of improving abstracts (illustrated with real examples). Other topics such as choosing which journal to submit to and reasons for rejection are covered in more detail in recent articles in *TWS/Medical Writing*.[1,2] Whether to write the abstract first

or last is another important subject Thomson and Kamler cover. They advocate an abstract-first approach to writing. That is, decide what you want your article to say before you start writing it (don't just write all your results down and try to weave them into a story). Others, however, disagree.[3]

The value of writing retreats and writing groups, where writers can receive constructive criticism on their efforts, is emphasised. This seems smart. I don't know what has happened in the three years since I abandoned research, but I lacked and could have used a forum for getting feedback on my early writing efforts.

The authors should be credited for drawing the reader's attention to a number of helpful online resources. These include Manchester University's Academic Phrasebank (www.phrasebank.manchester.ac.uk), a set of phrases that can be useful in academic writing, and Authorder (www.authorder.com), a tool for determining author sequence.

Writers of scientific papers will have to disregard some of the advice, e.g. to avoid the IMRAD (*I*ntroduction, *M*ethods, *R*esults, *A*nd *D*iscussion) structure. Nor should they worry unduly about another problem the authors identify: the 'incapacity … to *literally* insert [oneself] on the page'! Easier to accept is their advice to anticipate potential objections from readers when formulating your argument. The assertion that writers should reference previous papers published in the journal to which they are submitting may be astute, but it must clearly not be done in a contrived way.

A big minus for me is Thomson and Kamler's obsession with attaching fancy names to concepts without clearly explaining what they mean. Despite reference after reference to 'text work/identity work' (one of the authors' central concepts), I couldn't tell you what it is. Still, the authors do, in spite of their idiosyncratic lexicon, manage to imbue their writing with wit and empathy, although their default perspective of writing as scary and horrible will presumably not strike a chord with most EMWA members.

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Journal Watch

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Retracted publications, the issue of poor results reporting, and the increasing value of online teaching methods

Causes of retracted scientific publications

Fang *et al.*[1] think that it is important to evaluate scientific publications that have been retracted because they feel studying projects that have failed can give a vital indication of the current state of errors in the scientific process. In May 2012, Fang *et al.* undertook a search and detailed review of all English-language biomedical and life science research articles indexed by PubMed as retracted. They identified 2047 retracted articles, with the earliest article published in 1973 and retracted in 1977. They then classified the articles according to the cause of the retraction: fraud (i.e. data falsification or fabrication), suspected fraud, error, plagiarism, duplicate publication, other reasons, or unknown reasons. Additional information was also found as needed in reports from the Office of Research Integrity and a variety of other public records.

The majority of articles (67.4%) were retracted owing to misconduct, which included fraud or suspected fraud (43.4%), duplicate publication (14.2%), and plagiarism (9.8%). Only 21.3% of retractions were owing to error, which is in contrast to previous research in the area cited by the authors that has suggested that error is a more common cause of retraction than fraud. Other or unknown reasons accounted for the remaining percentage. The authors argued that 'incomplete, uninformative, or misleading retraction announcements have led to a previous underestimation of the role of fraud in the ongoing retraction epidemic'. They calculated that the percentage of published articles retracted because of fraud or suspected fraud has increased nearly 10-fold since 1975. They also found that the cause of retraction varied according to the country of origin. For example, studies from the US, Germany, Japan, and China accounted for three-quarters of retractions owing to fraud or suspected fraud. In addition, journal impact factor showed a highly significant correlation with the number of retractions for fraud or suspected fraud and error ($n = 889$ articles in 324 journals, $R^2 = 0.08664$, $P < 0.0001$), an association that has also been found in previous research. Fang *et al.* put forward that their findings highlight the importance of the individuals involved in the publication process (editors, reviewers, readers, etc.) in identifying and tackling misconduct, and suggest that there is a need for increased and ongoing ethical training for scientists and researchers involved in publishing their results.[1]

Using medical writers to improve compliance with reporting research results

In an editorial published in Current Medical Research and Opinion, the Global Alliance of Publication Professionals (GAPP) highlighted the problem of low reporting rates and low publication rates of results from clinical research.[2] The authors touched upon a number of studies which have shown that the majority of results from clinical trials have not been shared as quickly or completely as they should have been, and this includes poor results posting on websites such as ClinicalTrials.gov and worryingly low and slow publication rates in peer-reviewed journals. The evidence also suggests that the problem is worse in academia and government-funded research than pharmaceutical industry-funded research.

GAPP offered a potential solution to the problem. They proposed that trained professional medical writers (making a clear distinction between the fully acknowledged professional medical writer and the hidden ghostwriter) could help researchers meet their reporting responsibilities and play an important role in making sure trial results are conveyed in a complete, timely, accurate, and ethical manner. At this point the authors emphasised the time it takes to complete all the tasks associated with preparing a manuscript for publication and how medical writers can carry some of this workload. They go on to provide evidence from a number of studies that suggest that when authors use professional medical writers 'manuscripts are less likely to be retracted for misconduct, are more compliant with best-practice reporting guidelines,

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and are accepted more quickly for publication'. The authors conclude by suggesting that the accurate and timely communication of research results is ultimately beneficial to patients. They also suggest that more thought should be put into funding the use of professional medical writers in reporting research results, even proposing that an item for medical writing services should be included in research grant applications. GAPP argue that 'Requesting medical writing services should not be seen as shirking a responsibility. Instead, requesting medical writing services should be seen as a sign that researchers are well aware of the deficiencies in results reporting and that they are committed to gaining and allocating the services required to report results appropriately'.[2]

Classroom versus online methods for teaching scientific writing

Writing and the communication of ideas is obviously crucial in the scientific community, and is the core aspect of our jobs as medical writers. A number of studies have compared different teaching methodologies, including traditional methods such as classroom seminars and workshops, and newer methods such as online e-learning and virtual simulation. However, Phadtare *et al.*[3] were unaware of any studies into different methods specifically for teaching scientific writing. Therefore, in 2009 they carried out a randomised controlled trial to compare traditional and online methods for training novice researchers in scientific writing. Forty-eight participants, recruited from medical, nursing, and physiotherapy programmes in the US and Brazil and with minimal previous writing experience, were randomised to one of two training methodologies ($n = 24$ in each group). The standard writing guidance group received standard instruction in a classroom setting, while the online writing workshop group used virtual communication (PowerPoint presentations, audio conferences) supplemented by email, Google Docs, and writing templates as other instruction tools. Mentors were assigned to participants in both groups. The outcomes were manuscript quality, assessed using the Six-Subgroup Quality Scale (SSQS), and self-reported participant satisfaction, measured using a Likert scale. There was also a post hoc analysis of the number of communication events (e.g. emails, phone calls) between participants and their mentors. Manuscripts were analysed by three expert reviewers, and excellent inter-observer reliability was found among them. Nonparametric tests were used to assess efficacy.

Overall manuscript writing quality was higher for the online group compared with the standard group (average ± standard deviation SSQS scores of 75.5 ± 14.2 and 47.3 ± 14.6, respectively; $P = 0.0017$). In addition, online group participants were more satisfied with their learning experience (4.3 ± 0.7 versus 3.1 ± 1.1, respectively; $P = 0.001$) and had more communication events with their mentors (0.9 ± 0.8 versus 2.1 ± 1.2, respectively; $P = 0.0219$) than standard group participants. Phadtare *et al.* concluded that online scientific writing instruction was more effective than standard face-to-face instruction and therefore argued that more thought should be put into using Web-based teaching and instruction and that larger studies in the future should expand on their results.[3]

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The Webscout

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Adult learning

Teaching adults is somewhat different from teaching children. The science of adult learning is called andragogy. There is one name you will always come across when reading about andragogy: Malcolm Knowles. He developed principles that can be applied to most adult learning situations. Knowles' assumptions describe characteristics of an adult learner, like the readiness and motivation to learn and the experience of an adult, which influence the way an adult learns in contrast to child learners. These assumptions are supplemented by multiple theories about adult education and learning, such as action learning, project-based learning, experiential learning, and self-directed learning. Elements of these different theories are used in effective modern classes and workshops. You can find out more on these concepts on the following webpages.

http://www.infed.org/thinkers/et-knowl.htm

This page summarises Knowles' assumptions and principles. Knowles describes five key assumptions about the characteristics of adult learners that are different from child learners and thereby claims a difference between pedagogy and andragogy. He describes an adult learner as a self-directed human being with a reservoir of experience and internal motivation to learn. Learning itself is more problem centred and oriented to the tasks of an individuals' social role.

http://www.youtube.com/watch?v=skQJo3Vpqvc

This video runs through the different stages of an action learning process in a real-life example. Action learning means learning by working in a group on a real project or problem. It involves experience, reflection, and interaction. A coach guides the group through the process.

http://www.youtube.com/watch?v=LMCZvGesRz8

This video gives a short explanation of what is meant by project-based learning. It is not restricted to adult learning and has become increasingly popular in pedagogy. Students are required to work on a complex question or challenge in groups. A teacher applying project-based learning needs to carefully plan, manage, and assess projects. This method is most suitable for promoting skills like collaboration, communication, and critical thinking.

http://www2.le.ac.uk/departments/gradschool/training/resources/teaching/theories/kolb

This website explains experimental learning. Experiential learning theory was developed by D. Kolb and published in 1984. It is best described as 'learning by doing'. In contrast to a pure didactic method, which is in its narrow sense a learning method using lectures, experiential learning is characterised by reflection. The theory divides experiential learning into four stages: concrete experience, reflective observation, abstract conceptualisation, and active experimentation. Many teaching activities (e.g. simple text reading or homework) can be allocated to the different stages of the experimental learning concept.

http://ccnmtl.columbia.edu/projects/pl3p/Self-Directed%20Learning.pdf

This link directs you to a pdf summarising self-directed learning, its history, challenges, and controversy. Self-directed learning requires the individual's initiative and responsibility to select and assess learning activities. The term self-study or autodidacticism, which both mean 'learning on your own', is often referred to when speaking about self-directed learning.

http://adulted.about.com/od/teachers/a/coursedesign.htm

This link gives you a short overview on how to build a lesson for adults. After having gone through the information provided by the previous links, you might recognise elements of the different learning theories within.

If you have any further questions or you have any other comments or suggestions, please email me at: karin.eichele@novartis.com.

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Scandinavian Languages: Danish, Faroese, Icelandic, Norwegian, Swedish, and … er … English?

Scandinavia has given the world many fine things (dynamite, *The Scream*, Spotify, Tetra Pak, Lego, A-Ha), but did you know that it invented English?

That's the conclusion of Jan Terje Faarlund, a professor of linguistics at the University of Oslo, as reported in *Appolon* (a research magazine published by his own university),[1] which not unreasonably describes his assertion as a 'sensational claim'.

Faarlund's argument is based on the fact that: (1) the indigenous population in England adopted from its Scandinavian colonisers words for things that already had names (rather than just for new things); and (2) the English syntax is similar to that of (other) Scandinavian languages. As an example, he cites word order:

I have *read* the book (English)

Jag har *läst* boken (Swedish)

Ich habe das Buch *gelesen* (German)

The verb precedes the object in English and Swedish, but not in German or Old English (Anglo-Saxon), from which English is widely believed to have descended.

Faarlund notes that 'wherever English differs syntactically from the other Western Germanic languages – German, Dutch, Frisian – it has the same structure as the Scandinavian languages.' Okay, but couldn't one equally argue that wherever it differs syntactically from Scandinavian languages it has the same structure as other Western Germanic languages?

While taking words from other languages is commonplace (ironically, the import of English words is an ongoing concern for many in the Scandinavian countries), borrowing syntax and structure is, according to Faarlund, 'highly irregular'. So why did it happen in the case of English? That is a question Faarlund is yet to answer.

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Manuscript Writing

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As a medical writer, can or should I be listed as an author of an article?

For manuscripts, medical writers often go far beyond providing basic services and therefore may feel entitled to authorship. Medical writers are often the main force behind an article and may provide much more intellectual input than simply putting the client's ideas into words, including interpretation and sometimes analysis of data, production of graphs and tables, and intellectual input into the presentation of the data and ideas. The medical writer often has much more input than some of the listed co-authors. Accordingly, many medical writers feel that they should qualify for authorship, perhaps even first authorship. Should they? And is it a good idea?

This touches on the sensitive issues of ghostwriting and ghost authorship, which are not discussed here but are discussed in EMWA's guidelines on the role of medical writers in developing peer-reviewed publications,[1] as well as in EMWA's position statement on ghostwriting, which is published on EMWA's website and on page 3 of this issue.

What ethical guidelines have to say on authorship

The main guidelines for determining who should receive authorship are those published by the International Committee of Medical Journal Editors (ICMJE).[2] Good Publication Practice 2 (GPP2) guidelines also refer to the ICMJE guidelines on the subject of authorship.[3] The ICMJE guidelines on authorship and contributorship include the following statements:

> An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors' ability and integrity.

And further down in the text:

> Authorship credit should be based on 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. Authors should meet conditions 1, 2, and 3.

Although a medical writer may make 'substantive intellectual contributions' to an article, including 'analysis and interpretation of data' and is obviously responsible for 'drafting the article', a medical writer probably cannot 'identify who is responsible for each other component' or their 'co-authors ability and integrity', or have any role in 'final approval of the version to be published'. To paraphrase these guidelines, authorship implies accepting liability for what is published. This is very likely something a medical writer does not want and could imply purchasing expensive liability insurance.

EMWA's guidelines on the role of medical writers in developing peer-reviewed publications provide further guidance:[1]

> Medical writers should not agree to be listed as authors on publications if they do not fulfil the authorship criteria of the target journal. To qualify as an author, according to the Vancouver criteria [ICMJE guidelines], the writer would need to have made a substantial contribution to the analysis or interpretation of the data and feel able to take public responsibility for the research. In practice this means that professional writers are unlikely to be named as authors on primary research publications. However, they may qualify for authorship of review articles, for example if they have conducted an extensive literature search. It is important to note that by agreeing to be listed as an author, the medical writer takes public responsibility for the research.

> Although the Vancouver criteria [ICMJE guidelines] have been widely adopted, some journals

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> supplement the traditional author by-line with a contributor list indicating each individual's contribution to the research and the publication. In such cases, it might be appropriate to list a medical writer who had prepared a first draft or made some other significant contribution to the publication. Any specific requirements of the journal in this respect should be followed.

To summarise, medical writers should not be listed as authors unless they are willing to take public responsibility – and therefore accept liability – for the article and its contents.

So, how should a medical writer's efforts be acknowledged?

Here's what the ICMJE recommends:[2]

> All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chairperson who provided only general support.

Furthermore, EMWA's guidelines on the role of medical writers in developing peer-reviewed publications recommend that:[1]

> The involvement of medical writers and their source of funding should be acknowledged…. If writers are not listed among the authors or contributors, it is important that their role be acknowledged explicitly. Vague acknowledgements of the medical writer's role, such as 'providing editorial assistance' should be avoided as they are open to a wide variety of interpretations. We suggest wording such as 'We thank Dr Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd.'

Conclusion

Although medical writers might feel that they deserve authorship, they should not be listed as authors unless they are willing to take public responsibility – and therefore accept liability – for the article and its contents. Instead, a meaningful acknowledgment of the medical writer's work and the source of funding for that work should be made in the Acknowledgment section of the article.

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A guideline for manuscript flow Part 1 – The introduction

New medical writers and students of medical writing are often unfamiliar or unsure of the sort of information that should go into each section of a manuscript. But even when writers are familiar with the appropriate contents for each section, they are frequently unsure of how to link it all together so that it flows smoothly from one idea to the next.

A scientific or medical manuscript essentially tells a story about what happened. That story includes why the study was done (introduction), how it was done (methods), what was learned (results), and what the findings mean (discussion). Unlike clinical documents or technical reports, which may contain every detail of a study and hundreds of tables or figures, a manuscript only needs to describe the highlights. Also, unlike a clinical study report, a manuscript must put the outcome in the context of the current literature.

When you are writing an article, keep in mind that you are essentially telling a story. Imagine that you are guiding the reader through a presentation

about what was done and what was found. Thinking in this way will help you create a logical flow of information within each section as the manuscript moves from one section to the next.

This article is the first in a series and focuses on structuring the flow of the introduction. Subsequent articles in this series will focus on the flow of the methods, results, and discussion sections and how to tie them all together.

The flow in the introduction

The introduction is the beginning of your story and introduces why the study was done. In the first sentence, put the main topic up front. The reader should know right away where you are headed. For example:

> *Herpes zoster, also known as shingles, is a common and often debilitating disease that occurs primarily in older or immunocompromised individuals.*

In this case, the reader knows immediately that the subject is herpes zoster.

This approach is relevant not only for clinical studies but also for basic research. For example:

> *Activation of the epidermal growth factor receptor stimulates the growth of many cell types and is implicated in some forms of breast and other cancers.*

In this case, the reader knows immediately that you are going to talk about the epidermal growth factor receptor.

Continue developing the first paragraph with a general background of the area. This is the place to describe, for example, the incidence and prevalence of a disease, its specific effects on the patient, and the economic impact; or for basic research, the essential characteristics of the system. What information you include depends on the journal's audience. For an expert audience, you do not need to provide basic information, but for a more general audience, you might need to present fundamental information about the research area or the disease. For example, if publishing in a journal about infectious diseases, you might not need to explain what streptococcal bacteria are, but you might need to furnish some of this information for an article destined for a molecular biology journal. Generally, this type of background information should be limited to a single paragraph.

Once you have established the general background, describe where things stand now for your topic. For example, how is the disease currently treated, or what is the current level of understanding? If discussing a disease, what treatment options or solutions are there? Have improvements been made? Are there new developments in the field? Where are things headed? If you used a special technique or method in your study, this is a good place to establish its validity.

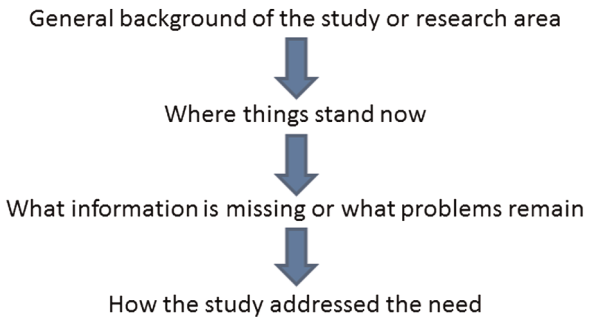

Figure 1: Summary of flow of the introduction.

Now you have brought your audience up to the current state of affairs, but what information is missing or what problems remain to be solved? Explain what the study or group of experiments tried to solve. And make sure that you explain why this question is important.

At the end of the introduction, talk briefly about what was done in this study. For a clinical study, what kind of study was it and what were the principal objectives? For basic research, what did you set out to determine? If you had a specific hypothesis, state it here.

In the old days, the introduction in some articles would end with a summary of what was found in the study. If you are working for a crusty old professor, he might insist that this is appropriate. However, I recommend that you don't do this; the abstract includes a summary of the results, and the goal of the introduction is to explain why the study was done, not what was found.

Conclusion

The introduction is the place to explain why a study or set of experiments was done. As summarised in Fig. 1, it should flow smoothly from a general background through to what was done. Finally, the introduction should be approximately 500 to 600 words. Any more than that and you will bore your readers and lead them astray.

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Regulatory Writing

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Bad Pharma and the regulators

The recent publication of the book *Bad Pharma* by Ben Goldacre[1] has caused quite a stir in the medical writing community (and indeed throughout the pharmaceutical industry). Before I read the book, I had thought that it would mainly target the marketing side of the pharmaceutical industry and that the criticism of the regulatory side would be relatively light. Well, I was wrong. Ben Goldacre dedicates a whole chapter to the regulatory agencies and they receive regular mentions throughout the book. He essentially suggests that the regulators give the drug companies a relatively easy ride, indeed that they are toothless and easily influenced by the all-powerful drug companies who do pretty much as they please. This point of view does not, however, fit well with my impressions from working with regulatory affairs departments. In my experience, companies are very conscious of what the regulators think and, in general, if a regulator says 'jump' the company jumps.

Toothless regulators or compliant companies?

As evidence of the toothless nature of the regulators, Ben Goldacre explains that drugs have very rarely been taken off the market by the regulators, whether for safety reasons or due to lack of efficacy in long-term studies following marketing authorisation. And this is no doubt true. However, one problem with using this fact as evidence of soft regulators is that many drugs are voluntarily withdrawn by the company. If you turn Ben's logic on its head, this could even be taken as an indicator that companies *are* afraid of the regulators. An illustrative example is natalizumab, a treatment for multiple sclerosis and by all accounts a very effective one. The company decided to withdraw the drug because three patients on natalizumab developed progressive multifocal leucoencephalopathy (PML), a rare but serious and often fatal condition caused by an opportunistic infection of the nervous system. Before the drug was reintroduced, the company negotiated a comprehensive risk management plan with the authorities. Neurologists and patients are now made aware of the importance of being vigilant for early signs of PML. As a result of starting treatment for PML earlier and a better understanding of which treatments are most effective, the death rate associated with the condition is declining. The labelling was also changed so that it was only indicated in patients with more aggressive disease (and those who would most stand to benefit from the treatment). The strenuous efforts to stratify risk as more data became available mean that patients can now make informed decisions about the benefits (a very effective treatment compared with other available options) and the very real but now much more quantifiable risks.

Ben Goldacre also criticises the fact that many of the studies required by the health agencies as a condition for granting marketing authorisation (especially when the approval is based on surrogate endpoints) are not actually performed, or that the data are not handed over to the health authorities. Although the lack of compliance might, at first glance, seem high (one in three according to figures quoted in the book), once again it does not tell the whole story. Often these additional studies, or follow-up measures or post-authorisation commitments as they are also known, are fairly long (for example, studies of overall survival in a fairly indolent cancer) and so difficult to perform. For example, other effective treatments may become available over time and investigators are no longer willing to enrol patients into the study and give them what they consider an inferior treatment.

Off-label use

Often, follow-up measures will refer to a specific indication. When the study associated with the follow-up measure is negative, the indication will often be withdrawn. Ben Goldacre argues that because many of these withdrawals refer to specific indications only, the drug is still available (as it is approved for another indication) and susceptible to off-label use (thanks in part to the powers of marketing). The European Medicines Agency (EMA) is not entirely blind to the possibility of off-label use, as illustrated by a 'questions as answers document' which discusses off-label use of celecoxib in patients with familial adenomatous polyposis.[2] My impression of talking to doctors in Spain is that they are often aware of the labelling and are uneasy about off-label use.

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The increasing regulatory burden

So I would not call the regulators entirely toothless. In fact, there seems to be the generalised impression among drug companies that there is an ever-greater regulatory burden. I do not have any metrics to back this impression up, but there are some examples of recent legislation that seemingly increase the regulatory burden. For example, in Europe, it is now a requirement for an approved Paediatric Investigation Plan (PIP) to be in place before marketing authorisation can be granted. Such a plan commits the applicant to perform the agreed studies in children, although it could be debated as to whether the effort might not be better employed in other developmental activities. However, regardless of the usefulness of the PIP legislation, the fact is that it is rigorously enforced, as reflected when the decision by the EMA to oblige a company to consider paediatric indications other than those included in the adult programme was challenged in the European Court of Justice as a 'misuse of power'.[3] The court upheld the EMA's original decision.

Are things improving?

Although a reading of the above text might lead to the conclusion that I am an apologist for the pharmaceutical industry, I can assure you that this is not the case. I think that the pharmaceutical industry is and has been involved in some rather dubious practices (for example, I have attended medical congresses and seen first-hand the lavish outlay on promotional material and slick satellite symposia). And Ben Goldacre does have some very interesting points to make. On the regulatory side, yes, there have been some failures. His suggestion that, to avoid a natural reluctance to admit mistakes, there should be a proper separation between the body responsible for approving a drug and the one responsible for monitoring a drug once approved (with powers to withdraw a drug) is an interesting one.

In his concluding remarks, Ben contends that the measures that have been taken are largely cosmetic and that the abuses by the pharmaceutical industry continue. He mentions the lack of compliance with the Food and Drug Administration requirement that companies are now required to publish the results of a completed study within a year on the clinicaltrials.gov database, citing a 'recent' study.[4] However, the study considered trials that were completed in 2009. As the results part of the database was only launched in late 2008, it might be reasonable to think that things have changed since then as companies implement their result-disclosure mechanisms. Incidentally, the same study suggests that industry-sponsored trials are more likely to report results within the 1-year timeframe compared with non-industry trials.

In the case of transparency or lack of it (a central theme throughout the book), the EMA does now have its central clinical trials database up and running. It is not perfect, for sure, but it is better than nothing at all. On its website, the EMA does publish European public assessment reports and withdrawal assessment reports, which give some insight into the thinking of the regulators when they authorise or refuse to authorise a drug. This is not perfect transparency, obviously, and it does not address issues such as the release of old clinical study reports and other documentation by the regulators, but it is a start. I remember reading about the case for evolution put forward in *The Blind Watchmaker*, by Richard Dawkins. The creationists ridiculed the idea that something as complex and apparently perfect as an eye might result from chance mutations driven by natural selection. The point that Dawkins makes is that even an imperfectly functioning eye is better than no eye at all and so can serve as a stepping stone to a perfect one. In the case of the drive for transparency, surely a small step in the right direction is better than no step at all? It is important, though, that there is a constant push towards improvement. In this sense, *Bad Pharma*, for all its hubris, may serve its purpose by bringing some of the very real issues facing the pharmaceutical industry into the public eye. And Ben Goldacre is right that public scrutiny is extremely important.

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Note from Editor: A review of *Bad Pharma* also appears on page 50 of this issue.

Medical Journalism

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From science writing to journalism: How 'The Ghost Writer' changed my life

How can a medical writer become a science journalist? That is the question I was asked to answer in an article inaugurating the Medical Journalism column of *Medical Writing*. If you expect me to write about the classical way to achieve this shift, you may be a little disappointed to learn that I don't really know how I became a journalist. Actually, the course of my career has been more driven by my taste for words than by anything else. I love using words to reveal the pictures emerging from the fog of my sensations, and I don't feel satisfied until I find the exact words which give shape to those pictures. And the more I am able to create a whole picture reflecting the complexity of reality, the happier I feel.

When I read the exercises that participants send me after my workshop 'Health communication: how to achieve your objectives?', which is part of the EMWA education programme, I notice that a significant proportion of medical writers truly care about using the right words to shape their writing exercises with accuracy, while taking into consideration the reader's point of view. I cannot but encourage these people to let themselves be driven by their love of words, and to trust themselves enough to find a way to write stories. Although there are several ways to achieve such career evolution, mine may be instructive. Thus, I will try to highlight the lessons I learnt.

As I mentioned above, the evolution of my career has been driven by my love of writing. But there is also another factor that influenced it: the issue of authorship. Like the central character in Polanski's movie 'The Ghost Writer', I used to write texts without putting my name to them. Being an author and writing as a journalist or as a writer means more than writing well. It also means assuming a point of view that may be challenged by others. I did not feel strong enough to do this, and it was thus 'easier' for me to give up my author's rights than to put my name to what I wrote.

Although I never practiced ghostwriting as it is defined in the medical literature (bringing a hidden intellectual contribution to a published article), I used to give up my copyright to my clients, and my writing was published for communication or medico-marketing purposes. However, it was genuine writing that should have been credited to an author and corresponded more to review articles dealing with science markets and policy than to writing formatted for communication, marketing, or medical writing. Later, as I sharpened my writing, I felt increasingly frustrated. There was a growing gap between my fear and my will to be identified as an author. This conflict was still unconscious until the day I watched Polanski's movie. I fully identified with the main character in this movie, and I suddenly understood that I needed to write on my own.

Thus, I began to look for ways to return to journalism, an activity that I had experienced just after my Ph.D. I could rely on my writing skills. Besides my work, I had attended a writing course dealing with short stories and two of the stories I wrote, 'Le Gros' and 'Le bow-window', were appreciated by several French editors. 'Le Gros' was published in 2011 and was well-liked by people who came to me to talk about my story. Meanwhile, I also wrote several opinion columns that were accepted for publication in *Liberation* and *Le Monde*. Collectively, this experience gave me the impulse to assume authorship and this is how I began to write as a science journalist.

Some medical writers, like me, may be attracted to writing. For them, communication and journalism may be an interesting option for career evolution. If so, they could look for more straightforward ways than mine to achieve this. They could, for example, seek education programmes for journalism and communication. Another option would be attending workshops dedicated to communication and writing skills within the EMWA education programme. Based on my experience as a workshop leader, such workshops are particularly useful for medical writers who have never written for communication purposes. They make them aware of

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the need to target an audience and how to do so, notably by mastering writing techniques.

The World Federation of Science Journalists (http://www.wfsj.org/) offers an online course in journalism that provides an overview of the different aspects of science journalism and training in writing techniques. Medical writers could also seek opportunities within their professional environment that could gradually help them to improve their communication skills. Writing for patients, for example, is a good exercise, as it requires the writer to take into account the reader's point of view.

Ultimately, people who are attracted to writing should wonder whether they feel the need to be an author or not. If not, communication and corporate journalism could provide good opportunities for narrative writing. But those who want to write as named authors should be aware that such career evolution involves a cultural shift. Writing as a journalist requires being neutral, and not having conflicts of interest.

In my case, I achieved this by writing about topics far removed from medical writing. In the beginning, it felt a little frustrating. But now I really appreciate writing about topics that are entirely new to me. I have to trust the journalistic approach of seeking the truth, a different approach from the one I learnt during my studies in science. This fits well with my open mind and with my desire to always move forwards.

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Medical Writing Jumble # 6

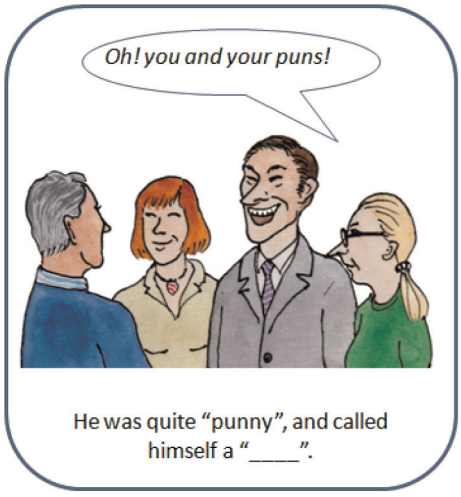
1. Rearrange the jumbled letters to get a meaningful word related to medical writing.
2. Next, take the circled letters from each word and make two new words that will answer the riddle in the cartoon. Hint: The answer is probably a pun.
3. Use British English.

GATES ☐◯☐☐☐

SUNMI ☐☐◯◯☐

DIBNL ☐☐◯☐◯

SHAPE ◯☐☐☐☐



Answer: ☐☐☐☐☐☐

by Anuradha Alahari | Illustration: Anders Holmqvist See page 78 for the answers.

Medical Communication

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Introducing the Medical Communication section: The wild side of medical writing!

Hello and welcome to a brand spanking new section of *Medical Writing*. When the Editor of *Medical Writing*, Phil Leventhal, approached me to create a new section, he asked me to cover 'medical communications'. But medical communications is a whole grey area (unfortunately more '5 shades' than 50 …) that's often the cause of much consternation. For instance, medical communications agencies argue strongly that manuscript writing falls under their remit, but many medical writing companies focused entirely on the regulatory side count manuscript writing as one of their core competencies.

So how do we sort it out? Well … I don't think we do. I don't think it matters who writes a document as long as it's written well and is fit for purpose. So, I'd like this section to be as inclusive as possible, and I'm happy to discuss any and all types of writing and documents that perhaps don't 'fit' in the other sections. Areas that we will definitely cover in this section include:

- Medical education
- Medical marketing
- Patient information

But if you have other topics that you would like to discuss, I'm more than happy to include them (within reason!). Please let me know if you have something you'd like to share. It doesn't have to be a long article, a couple of paragraphs is fine, or you could pose a question to the section Agony Aunt – maybe about a difficult situation or client or document – we often learn more from things going badly than we do from those that go well. You can even just let me know if there is an area you know nothing about but would like to know more, and I'll do my best to grab an expert for their 'top tips'. Any and all ideas will be very gratefully received.

This edition's article, by Sarah Richardson, offers an insight into how to write a symposium review … without even being there!

I hope that you enjoy the section, and I'd love to hear your thoughts and comments.

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How to write a meeting report … when you weren't there

Writing a meeting report from an audio recording and presentation slides is possible but can be challenging. A medical writer could be asked to write a meeting report by a number of different clients, ranging from patient organisations, through to pharmaceutical companies or academic institutions. The reasons for requesting it will depend on the client; it could be purely a straight forward academic account of the meeting, or a promotional piece for a company's drug. In all cases, the aim of the finished document is to provide an accurate, well-written report of each speaker's presentation which is precise, scientifically correct, and conforms to the relevant code(s) of conduct. The content of the presentations are often complex and specialised, and the presenters are usually experts or 'key opinion leaders' in the subject area being discussed. Therefore, they generally have considerable knowledge of the topic, and with that, an expectation that the acronyms, euphemisms, and scientific or technical principles used are understood by everyone.

Hazards of writing a meeting report when you weren't there

There are several possible hazards in writing a meeting report when you weren't there. The quality of the audio recording is a key component

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in writing a factually correct account of a meeting presentation. If the quality of the recording is poor, the writer will have difficulties making sense of what is being said. In addition, quite frequently the speaker's first language is not English, and they have a strong accent, which can make both what is being said, and the nuances of the meaning of what is being said, difficult to understand. This can make understanding the intricate detail of the presentation inaccurate, particularly if the content is complex and presents the risk of a discrepancy between the speaker's objective and the writer's interpretation.

The slides provided should contain the facts and the figures that the speaker presented at the meeting. Hopefully, the slides provide the key information that was being presented and back up what has been recorded on the audio. This sounds straight forward, but it is not always as straight forward as it sounds! Speakers do not conveniently mention which slide they are talking about, they miss out slides, and they often speak very quickly. This presents a challenge for the medical writer. Also, the scientific and technical information can be unclearly presented, and if it is not your specialist area, may take time to decipher, creating a reasonable risk of making embarrassing scientific and technical errors.

Meetings are frequently sponsored by a company who want to promote a product in the area being discussed. From the writer's perspective, this can create issues of fair representation. Not all speakers will necessarily be promoting the product and may simply be trying to disseminate their research findings. However, there is potential for controversy between the marketer who organised the meeting (who naturally wants the product to be fully discussed and the highlight of the report), and the speakers (who are not necessarily supporting the product but are presenting relevant clinical findings or research in the subject area). The difficult part is keeping everyone happy while still producing a fair and balanced report. A general principle is to give each speaker the same amount of page space and the same number of graphics, but expect discussion in the review cycle.

How to write a meeting report when you weren't there

So, how can you write a meeting report when you weren't there? One method is to familiarise yourself with the slides and then write a transcript of each speaker, fitting the slides into the text as the transcript is written. This is time consuming. If a speaker speaks for an hour, it could take between 3 and 4 hours to transcribe, particularly if the recording is poor or the speaker's accent makes what is being said difficult to understand. Nonetheless, the end result is a written, word-for-word account that indicates where the slides fit into the dialogue. This method produces a lot of information, some of which is potentially irrelevant to the focus of the report. This makes editing an onerous, time-consuming task. The information in the transcript then needs to be honed and the key points presented in an acceptable format for the desired audience. This is not easy. There is also the science to consider and the opinions of the expert and the sponsor.

Another method is to look at the slides thoroughly, identify the key points of each slide, and get a general feel about the speaker's message. Then listen to the audio recording in conjunction with looking at the slides, make detailed notes about each slide, including references to the points made, and indicate whether the graphics presented would be suitable for inclusion in the publication. The end result of this method is a first draft of the meeting report. The draft 'just' requires editing down to the required size, but all references are in place and graphics are indicated. This is much faster, and potentially more accurate, as the focus is on understanding the speakers' points rather than simply writing down what is said.

So … can you write a meeting report when you weren't there? The answer is YES. It is not as easy as if you were there, but your skills as a medical writer make it possible.

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Editorial

Welcome to the first issue of Out On Our Own (OOOO) for 2013. First, a big thank you to Raquel Billiones for her tremendous work as sub-editor, and in coordinating the content of OOOO over the past 2 years. Raquel will still be contributing and in particular, to the regular Toolbox feature, which, in this issue, describes the application of QR codes – those little black and white maze-like squares – in medical and scientific fields.

We are also pleased to report the much-anticipated results from the Freelance Business Survey 2012. This is the fourth survey of its kind, initiated in July and closed in September 2012, with 123 responses. This regularly conducted survey helps maintain awareness of typical freelance charges and our main business activities. Thank you to Anne McDonough for authoring the report and to Alistair Reeves for his ongoing support with this initiative.

Amy Whereat's and Ann Bless' articles echo the medical education theme of this issue of MEW. Amy describes the opportunities available to medical writers in the field of teaching spoken medical English. With our command of scientific English and ability to communicate clearly, our skills-base allows us to offer this niche service. Ann shares a day in her teaching life with us as she works with a small group of biomedical researchers.

We invite you to submit any humorous photos you may have lurking on your hard-drive for publication in OOOO. The photos must feature comical or witty text in English (or otherwise captioned with a translation). Maybe you have strange road or street signs in your area or have seen something amusing while on holiday. Thank you to Raquel for submitting the first one to get you in the mood!

And finally, we look forward to catching up with you in person. Make a date in your diary to join us at the Freelance Business Forum in Manchester on Friday, 10 May 2013 at 17.45.

The fourth EMWA freelance business survey

Introduction

This fourth survey follows those conducted in 2003, 2007, and 2010.[1–3] The first survey was conducted with a paper questionnaire distributed to both freelancers and small businesses with up to seven employees at the Freelance Forum during the EMWA conference in Lisbon in 2003. In 2007, the survey was conducted in electronic form and addressed to only freelancers, or those engaging in freelance activities in Europe. These practices continued for the 2010 and 2012 surveys. Response had grown steadily over the administrations from 63 respondents in 2003 to 101 in 2007 and 130 in 2010.

Methods

The EMWA Freelance Team developed the 2012 web-based survey by starting with the 2010 instrument and revising the questions to correct anomalies in data collection and to account for changes in the medical writing field. The 10-question survey was produced on SurveyMonkey, and user testing was conducted before release. The instrument allowed only one response per computer and did not allow respondents to change answers once the survey had been submitted. EMWA sent an e-mail with the survey web link to all members, and an announcement was also posted on EMWA's LinkedIn page.

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The survey was open to anyone conducting freelance medical writing activities of any kind in Europe (respondents did not have to be EMWA members) and was available from 12 July to 21 September 2012.

Results were analysed using SurveyMonkey's analysis component and Microsoft Excel. The results of this survey were compared with the results of previous surveys as appropriate; comparison was not always appropriate because the content of some questions had changed or the responses were newly grouped.

For the results provided in Tables 1 to 4, respondents were asked to complete a fixed series of categories giving percent values that totalled 100 and to enter zeros for any categories that did not apply. Many respondents left categories that did not apply blank, and others entered zeros as requested. Blank cells were therefore regarded as equal to zero, and the mean per category was calculated by dividing the sum of the responses for that category by the total number of responses to the question and not the number of positive (i.e. not equal to zero) responses to that category. This method ensured that the sum of the means over all categories equalled 100. The 2007 and 2010 results were recalculated in the same way to preserve comparability. This recalculation explains differences from the previously published figures for 2007 and 2010; differences did not result in shifts in the proportional relationships between categories within each year.

Results

Number of responses and countries

The number of respondents in 2012 decreased slightly to 123. The specific country of residence of respondents was not collected this year; instead a question was asked about residence and work in Europe. Most respondents (84, 68%) reported that they were based in a European country and worked for clients in different countries, 32 (26%) reported that they were based in a European country and worked solely for clients in their country of residence, and 7 (6%) live outside Europe but worked for clients based in Europe.

Types of freelancers and hours worked

Fig. 1 displays types of freelancers who responded and their membership in EMWA.

Six respondents did not answer the question. Most respondents (78, 67%) work full-time freelance, 30 (26%) work part-time freelance, and 9 (8%) respondents are employed by a company (full- or part-time) and also do freelance work. Among the three categories, 99 (85%) are EMWA members. These results are similar to those from past surveys.

The number of hours worked has remained steady over the last three surveys. Of 118 respondents to this question, 56 (47%) work 30 or fewer hours per week on average, 55 (47%) work 31 to 50 hours per week, and 7 (6%) work more than 50 hours per week.

Sources of work

Respondents were asked to indicate their sources of work (totalling 100%) from a list of categories, and the results are shown in Table 1.

Results from 2012 followed a pattern similar to those in the previous surveys. Repeat business accounted for half (50%) the respondents' work,

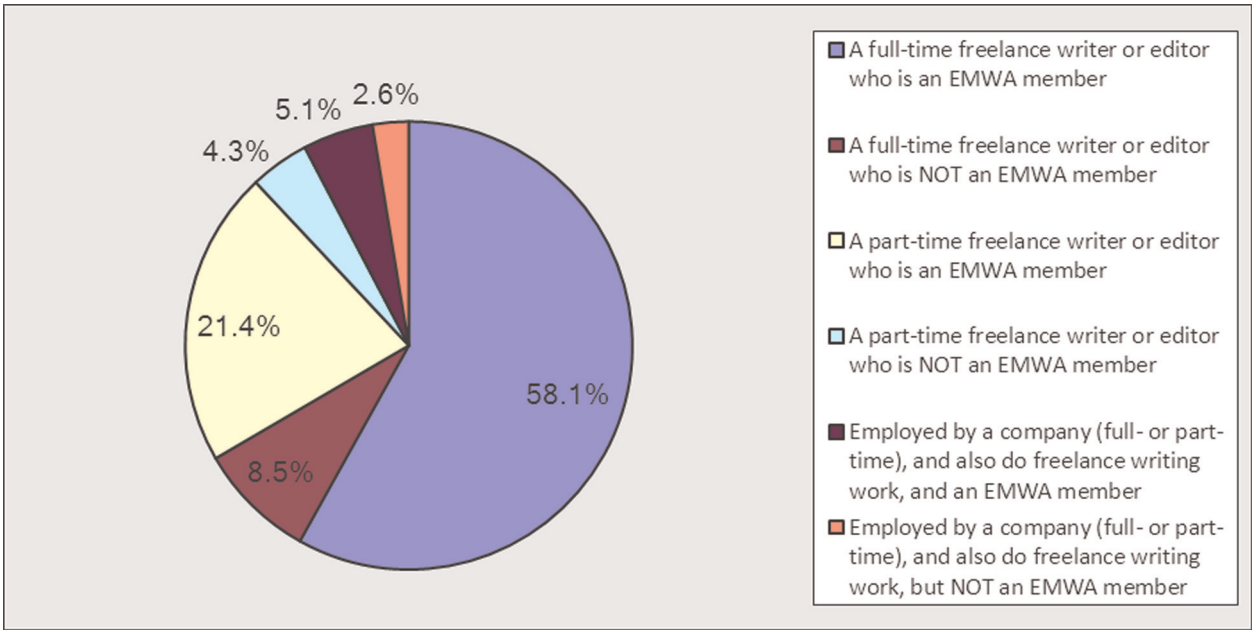

Figure 1: Types of freelancers and EMWA membership in 2012 ($N = 117$).

Table 1: Sources of freelance work from the past three surveys

Source	Mean % of work		
	2012 $N = 110$	2010 $N = 123$	2007 $N = 77$
Longstanding customers	50	46	41
Referrals from colleagues	17	16	16
Referrals from customers	13	13	9
Own advertising, including website, if you have one	7	7	6
EMWA freelance directory	4	6	7
Clients who searched the internet 'looking for a medical writer'	4	–	1
Other freelance directories	1	3	1
Contract research organisations/ agencies	–	5	15
Networking with EMWA colleagues	–	2	–
Others	4	2	3

–, category not present in that year's survey.

and referrals from both colleagues (17%) and customers (13%) remained important sources of work. Freelance directories, including EMWA's, played a smaller role than in past years.

Types of work providers

In a new question this year, respondents were asked to indicate their types of work providers (totalling 100%) from a list of categories, and the results are shown in Table 2.

Pharmaceutical companies (28%) and medical communication agencies (24%) were the most common providers of work to the respondents,

Table 2: Types of work providers in 2012 ($N = 107$)

Type of work provider	Mean % of work
Pharmaceutical companies	28
Medical communications agencies	24
Academic institutions or academia-based individuals	16
Contract research organisations	10
Publishing companies	5
Medical devices companies	4
Non-profit organizations	3
Biotechnology companies	3
Work placement agencies	1
Others	6

Table 3: Types of activity from the past three surveys

Type of activity	Mean % of work		
	2012 $N = 105$	2010 $N = 122$	2007 $N = 75$
Writing	61	55	62
Editing	15	14	14
Translation	6	11	6
Consultancy work	6	8	3
Training events	4	4	4
Quality control	3	4	4
Proofreading	3	3	3
Electronic publishing	0*	1	1
Others	2	2	2

*The value for this year was 0.4 (five respondents reported this activity from 5 to 15% of workload).

while academia (16%) and contract research organisations (10%) were also large providers.

Types of activity

Respondents were asked to indicate their types of work activity (totalling 100%) from a list of categories, and the results are shown in Table 3.

Writing (61%) and editing (15%) continue to be the major activities for respondents.

Types of documents

Respondents were asked to indicate the types of documents on which they work (totalling 100%) from a list of categories, and the results are shown in Table 4.

New response categories were used in 2012, so the responses cannot be compared directly with those from earlier years, but scientific articles (36%) and clinical trial and regulatory documents (34%) continue to dominate the workload of respondents.

Hourly charges for medical writing and related activities

The respondents were asked to provide average hourly charges for medical writing and related activities in euros for the categories listed in Table 5. Just over three-quarters of the respondents (93, 76%) provided this information. Two respondents entered implausible hourly rates. These values are listed below and were excluded from the analysis:

- Writing: €507, €250
- Editing: €507, €300
- Consultancy work: €507, €400
- Quality control: €250
- Proofreading: €507, €220
- Translation: €200

Table 4: Types of document in 2012 ($N = 101$)

Type of document	Mean % of work
Articles for scientific journals and the scientific press	36
Documentation used for non-clinical and clinical testing, including all documents contributing to or submitted for drug/medical device approval	34
Marketing materials, including congress materials and proceedings	7
Presentations	6
Educational materials for patients and health professionals, including audiovisual media	4
Medical and scientific text books	2
Training documentation	2
Websites	2
Post-marketing documentation (e.g. periodic safety update reports, pharmacovigilance)	2
Standard operating procedures	1
Product information	1
Consultancy documentation	1
User manuals for devices	0*
Others	2

*The value for this year was 0.1 (two respondents reported working on this type of document for 1 and 5% of workload).

One other respondent provided a project rate rather than an hourly rate, and this information was excluded.

Table 5 summarises the average hourly rates for 2003, 2007, 2010, and 2012.

Hourly rates in 2012 for all activities were approximately the same as or lower than those in the previous surveys going back to 2003. The highest rates in categories other than consultancy work and other were €125/hour for translation and €135/hour for writing, editing, quality control, and proofreading. For writing, 12% of respondents and for editing, 6% of respondents achieved rates of at least €100/hour. Some respondents, however, charged low hourly rates for all activities surveyed. For editing, 12% of respondents reported rates of less than €50/hour; for writing, editing, translation, quality control, and proofreading, the proportion was between 3 and 7%.

Since respondents had been asked for average hourly rates, they were also asked to indicate whether they charge different fees for different client groups. Response counts in Table 6 show whether the fee charged to each client group is lower than, the same as, or higher than hourly rate reported as the average rate, or whether the respondent does not work for that client group.

For all client groups except academia and non-profit organisations, the majority of respondents who worked for that client group said that the average rate reported was the same as charged for that client group. Of respondents who work for academic institutions or academia-based individuals, 56% reported charging lower fees to this client group; the figure for non-profit organisations was 62%. 'Pharmaceutical companies' was the client group for which the largest proportion of respondents (38%) reported charging higher than average rates, followed by other (25%), medical device companies (21%), and biotechnology companies (20%).

Charges for training

Thirty-three (27%) respondents provided information on charges for training. All charges were to be given in euros as average rates for the time periods in question. Again, some respondents entered implausible values. One respondent

Table 5: Hourly rates for medical writing and related activities from all four surveys

	Hourly rate (€)[a]										
	2012			2010			2007			2003[b]	
Activity	*N*	Mean (SD)	Median (range)	*N*	Mean (SD)	Median (range)	*N*	Mean (SD)	Median (range)	*N*	Median (range)
Writing	85	77 (23)	75 (20–135)	96	79 (27)	80 (11–200)	76	76 (23)	75 (29–140)	55	80 (20–160)
Editing	59	69 (25)	70 (10–135)	72	68 (22)	65 (25–130)	52	71 (26)	75 (29–140)	48	70 (20–150)
Consultancy work	33	93 (33)	82 (25–175)	33	106 (52)	87 (50–300)	26	105 (50)	91 (29–250)	26	105 (20–>160)
Quality control	26	70 (27)	68 (20–135)	35	73 (28)	74 (10–150)	26	73 (31)	65 (30–150)	21	75 (20–>160)
Proofreading	25	64 (28)	60 (5–135)	38	63 (26)	59 (20–140)	34	69 (29)	62 (125–140)	24	55 (20–150)
Translation	24	63 (23)	60 (10–125)			—			—		—
Electronic publishing	2	80 (1) and 135 (1)		10	93 (21)	93 (63–125)	3	65 (2) and 200 (1)		5	60 (20–150)
Others	8	90 (48)	85 (25–175)			—			—		—

SD, standard deviation; —, category not present in that year's survey.
[a]Inclusion of the implausible values from two respondents hardly affects the median values. The mean (SD) values are as follows: writing 84 (54), editing 80 (68), consultancy work 102 (62), quality control 77 (43), proofreading 86 (93), translation 68 (35).
[b]Mean and standard deviation were not calculated for the 2003 results.

Table 6: Fees compared with average hourly rate for different client groups in 2012 ($N = 92$)

Client group	N	Fees compared with average hourly rate (%)			Do not work for this client group (%)
		Lower	Same	Higher	
Pharmaceutical companies	88	0	45	27	27
Academic institutions or academia-based individuals	84	33	25	1	40
Medical communications agencies	84	11	42	7	40
Medical devices companies	83	1	25	7	66
Contract research organisations	83	10	34	4	53
Non-profit organisations	81	22	14	0	64
Publishing companies	81	6	22	2	69
Work placement agencies	80	2	13	1	84
Biotechnology companies	79	0	25	6	68
Others	69	4	9	4	83

Table 7: Charges for training from all four surveys

Source	Hourly rate (€)[a]											
	2012			2010			2007			2003[b]		
	N	Mean (SD)	Median (range)	N	Mean (SD)	Median (range)	N	Mean (SD)	Median (range)	N	Median (range)	
Whole day	23	932 (457)	900 (400–2040)	21	766 (502)	950 (500–2500)	19	815 (406)	1000 (400–2300)	16	955 (850–>1150)	
Half a day	16	437 (233)	338 (200–820)	27	390 (271)	500 (120–1200)	15	510 (238)	475 (200–1000)	14	517 (475–775)	
Hourly	13	85 (29)	80 (45–128)	27	83 (33)	85 (50–200)	7	107 (62)	100 (46–200)	8	NC (40–190)	
Hourly rate for preparation	5	84 (22)	70 (70–120)	18	73 (27)	80 (50–143)	8	84 (34)	84 (48–150)	3	NC	

NC, not calculated; SD, standard deviation.
[a]Inclusion of the implausible values from three respondents results in the following values for median, mean (SD): whole day 400, 557 (430), half day 850, 1009 (760).
[b]Mean and standard deviation were not calculated for the 2003 results.

entered very high rates of €4000 for a whole day of training and €2000 for a half day of training, and two respondents gave lower rates for a whole day than for half a day (€500 and €1000, €300, and €600); these values were also excluded from the analysis. One respondent gave a range for the half-day rate, and the average in the range was used. Table 7 summarises the average training rates for 2003, 2007, 2010, and 2012.

Mean whole-day and half-day rates were slightly higher in 2012 than in previous years, but median values were slightly lower.

Discussion

This paper presents nearly a decade's worth of data on work patterns and rates charged by medical writers in Europe. Responses from the 123 respondents to the 2012 survey were similar to those for past surveys as measured by hours worked, sources of work, and types of work providers, activities, and documents. A new question in this survey revealed that nearly three-quarters of respondents are working for clients outside the country in which are based whether they were in a European country or outside Europe.

For all categories of activities, the remuneration rates reported have generally remained the same or decreased slightly since the first survey in 2003. An analysis of changes in individual writers' rates cannot be discerned from these data since different individuals may have participated in every year's survey. Additionally, fluctuating conversion rates between the euro (the currency used for the surveys) and currencies in which the respondents charge may also confound the interpretation of the data. Nonetheless, the overall trend observed – or more correctly the lack of a trend – as well as the very low rates charged by some respondents present a concern for freelance medical writers working in Europe.

Acknowledgements

Thanks to Alistair Reeves and Dr Anja Loos, Statistician, for advice on data handling. Thanks to all the respondents for taking the time to complete the survey.

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Teaching medical English: An opportunity for medical writers

English is the lingua franca of medical research and international business. Yet many highly experienced health professionals are unable to communicate effectively in Shakespeare's tongue! Clinical experts are often required to share their knowledge at international conferences, at multinational work groups, or with potential investors. Also, opinion leaders and rising stars who effectively express themselves in English are preferred by the pharmaceutical industry to collaborate in research and medical affairs. In other words, good spoken and written English is necessary to be recognised and respected as an opinion leader in global medical research and business.

Although many clinicians and researchers can read articles in English, many struggle to write clearly, and others are completely tongue-tied when presenting to or discussing with an international audience. In many professional situations, a solid command of spoken English is needed to be able to present work, respond to criticism, and influence others. Being unable to do this is a lost opportunity: sloppy communication in English makes the opinion leaders appear incompetent to an international audience.

This is where medical writers can help. As professional communication experts in English, we are well placed to provide this specialised training.

What skills do you need to teach medical English?

Knowing how to teach language is one of the most important skills required. A language teaching qualification is very useful. Strong communications skills are also essential. Having a good knowledge of English grammar and medical vocabulary is useless if you are unable to communicate it effectively to your learners! Listening skills are equally valuable. Learning is more effective when learners practise speaking for themselves. Additionally, an understanding of 'pharma speak' and culture may be useful when advising a learner on appropriate content or language tone. So, language learners can actually benefit from a broad mix of technical and professional skills.

Knowledge of English grammar and vocabulary

To teach medical English, you obviously need excellent English language skills. Knowledge of English language structure and being able to explain the use of different sentence constructions is essential. Many learners will have a good knowledge of the vocabulary in their field, but they will have difficulty producing the grammatical scaffolding that holds the vocabulary together. Word order differs between languages, such that when transposed directly in English, the sentence may sound strange, and being able to explain why can help. Learning to use tenses correctly in verbal situations is essential for good communication. You will also need to convince the learner that spoken English is stronger when the sentences are shorter and more direct, and that flowery adjectives and long clauses distract the listener from the key message being communicated.

Familiarity with your learner's own language and culture

Being bilingual is useful for identifying problems and tailoring your training to work on common mistakes. For example, the French often say 'the characteristics of the patients' where 'patient characteristics' are better. Also be aware of false cognates, which are words that look the same but have different meanings, such as, *evolution* in French, which means *development,* whereas *evolution* in English is more often used to refer to Darwin's theory of evolution. Understanding differences between the learner's culture and Anglophone culture can be useful too. Again using the example of the French, they have a Cartesian way of thinking and like a logical construction to their argument, but in an international setting, getting straight to the point may be more effective.

Understanding of pronunciation patterns

In spoken language, part of the speaker's power comes from the way their voice is used. Vocal techniques such as stress and pause add *emphasis* and retain the attention of the audience. In English, the stress is more on the key words and less on the

grammatical words. Inflection (the music of our voice) changes: for example if we are asking a question, the inflection goes up at the end of the phrase and if we are making a statement it goes down. Use of pause gives the speaker time to think, and the listener time to absorb. Many presenters are unaware of this 'music' and transpose the music of their native language to the English words. To the listener, this may sound at best monotonous or at worst staccato, which may distract the listener from the key message.

Strong presentation skills

Being a teacher means using good presentation skills, all of the time. Be a model for your learners. Use clear language and give clear instructions. Use appropriate body language and good voice control. By being a confident speaker yourself, learners gain confidence in you. Leading by example helps learners to try and *look* confident themselves. Teaching learners to *look* confident when they speak, even if they do not feel so confident makes them look more knowledgeable.

Medical knowledge

As with medical writing, general medical knowledge and a good knowledge of different specialities will allow you to come up to speed quickly with the learner's specific subject matter. But do not waste too much preparation time learning about the subject.

Industry knowledge or experience

Being able to provide professional assistance beyond language teaching is a plus. Industry knowledge and experience may be valuable because you can use it to help your client improve the content of their presentation, giving them that extra edge. For example a clinician may need help pitching presentations to different audiences within a company, such as marketing, research, and business development. Knowledge of good clinical research practices may also be an advantage when working with hospital research teams. Marketing experience may be useful in preparing convincing presentations or selling research ideas to investors. Graphic experience may be invaluable in designing a slide set. Medical writing experience may be important when advising on written materials or slide presentations. Medical writers often have extensive professional experience and therefore can provide more than just language skills.

A passion for teaching

Like many professional roles, having a passion for what we do makes all the difference. To be a successful teacher, you need to enjoy working with people and help them achieve their goals. You also need to be a good listener to quickly understand the learners' needs. Being enthusiastic and encouraging will also make you a more effective teacher and will help the learner overcome a lack of confidence, shyness, fear, or stress associated with public speaking.

Training

Teaching, like other skills, can be learned and improves with practice and regular auto review. A language teaching qualification, such as TEFL (Teaching English as a Foreign Language) or CELTA (Cambridge Certificate in Teaching English to Speakers of Other Languages) is helpful to learn specific pedagogical techniques. These courses also cover most major grammar rules and specific issues for non-native English speakers. Alternatively, there are many books written on effective teaching methods (see the bibliography for a selection of my favourites).

Is it worth teaching medical English?

Teaching medical English is complimentary to medical writing, especially for freelancers. Such a service could be useful to gain new or maintain existing clients and often, medical English teaching develops into medical writing, or vice versa. Clients realise that they are too busy to produce all of the work they need. Once they know that you are an expert in medical English, they will probably turn to you for help with other projects. Most organisations have separate training budgets, particularly, in industry, which has to be spent each year before either June or December. If already working as a medical writer, you may be able to obtain an extra contract for medical English lessons from such a budget. Medical schools and universities usually offer a variety of medical English courses. Some are tailored to patient consultation vocabulary and others more to research communications. Also, some small research teams and clinicians are keen to increase their international profile and may be able to dedicate a part of their English translation budget for language training. However, these groups are hard to contact directly, so finding them requires well-developed networking skills! Nevertheless, it does pay to be inquisitive and look out for supplementary budgets and for training needs.

Although general English teaching is often poorly paid, medical English is considered a highly specialised service, so you can demand the upper end of the scale. For example, in France, teaching at a

university starts at €40 per hour. However, rates vary from about €65 per hour for a research team, to €150 per hour for an industry training workshop. As for any professional service, rates may be negotiated on an hourly basis or as part of a total package that includes other medical writing or editing jobs.

Teaching requires time for preparation, which is usually factored into the hourly rate. It is not the *done thing* to pay for preparation time. Having said that, *some* organisations may accept a slightly higher hourly rate if the course is new. The good news is that once the training materials are developed, they can be used again for other clients. So, as preparation time is an investment, keep your course materials and lesson plan clearly filed and labelled for further use.

Training periods are erratic. The advantage of this is that a workshop might fill up some down time between projects or when deadlines change. In Europe, the peaks are similar to those for medical writing, i.e. September (back-to-school fever) and around January (New Year's resolutions). If possible, plan ahead of time to avoid clashes with other deadlines. Industry clients tend to lock in dates early and researchers tend to work on an *ad hoc* basis. The quiet summer break is a good time to work on training materials.

Speaking the speech

Spoken English is needed today for researchers and clinicians to be successful in global medical research. Non-native English speakers may have valuable ideas, yet are disadvantaged when trying to communicate them. Medical writers are well placed to help these health professionals to achieve their goals. It can be an extremely rewarding experience and for freelance writers, in particular, teaching medical English is a great way to bring in new clients.

Acknowledgement

Thanks to Phil Leventhal for his interest in what I do and for encouraging me to put it down on paper and then promptly editing the resulting text! Thanks also to Anu Alahari for her very kind and constructive comments.

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The QR code

They are everywhere. These little black and white maze-like squares are almost ubiquitous, in airline boarding cards, in many retail products, even in mugs and T-shirts used as marketing tools. But I never really got to find out what they are for and what they can do until I became a part of a digital contract research organisation and got one on my business card. And I am proud to say – I am now QR-coded (see Fig. 1)!

QR code stands for 'Quick Response' code and it has its roots in the Japanese automobile industry but has caught on like wildfire in other business sectors. It is sometimes referred to as 'the 2D barcode', even though there are many other codes of its kind.

A single QR code can store thousands of alphanumeric characters such as urls, contact details, and text messages. The PCMag encyclopedia gives a short explanation of the 'anatomy' of a QR code.[1]

Why care about QR codes?

As medical writers, we should take a closer look at QR codes as they have made their way into the scientific and medical fields. Below are a few nifty uses of the QR code.

Popular and scientific media

The QR code in Fig. 2 links to a BBC radio 4 programme called REPORT on clinical trials,[2] which

Figure 1: A QR code containing contact details.

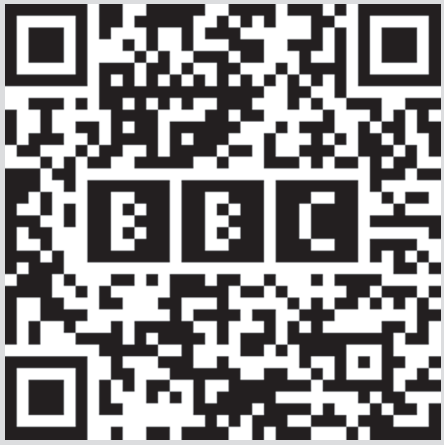

Figure 2: A QR code containing a logo and a link.

enabled me to listen to it on my phone. This one even incorporates a logo which personalises the code.

Medical and scientific journals are using QR codes to embed links and additional information in publications. Take the example of the article by Shirani *et al*.[3] in the July 18 issue of the Journal of the American Medical Association. At the upper right corner is a QR code with the caption 'scan for author video interview'.

Healthcare

Some tech-savvy doctors use QR codes to market their services and 'engage' their patients. QR codes can contain links to online appointment systems or YouTube patient testimonials.[4] In Taiwan, the feasibility of digital prescription using QR codes is being evaluated.[5]

Medical information

QR codes are used in France to contain medical information that is vital in case of emergencies. For an annual subscription, a French company will convert your most important medical and personal data into a QR 'code d'urgence'. The code is then printed on stickers that can be placed on helmets, cars, wallets, medical IDs, and phones etc. The information is stored on a Ministry of Health-approved server. The code on the stickers can only be read by medical professionals using a restricted app on their smartphones.[6]

Figure 3: A QR code containing a DNA sequence.

Genetic information

DNA sequences may be stored in a QR code as shown in Fig. 3.[7] The code can be easily stored, exchanged, or printed and used to label biological samples for efficient identification and tracking.

How to read QR codes

Reading QR codes is easier than you think. All you need is a smartphone with a camera and a QR code scanning app. Free scanning apps are available for most smartphones. With your phone, you can scan codes printed on paper, or shown on a computer screen, or a screen of another phone. Depending on the app and the complexity of the code, scanning takes only a few seconds. Once a code is scanned, the alphanumeric information it contains can be transferred to and saved in your mobile phone. For a review of different QR code readers, check out http://www.cellphone-barcode.com/qr-code-readers/ or http://www.qrstuff.com/qr_phone_software.html.

How to create your own QR code

So now you might want to try your hand in creating a QR code. Well, there are many QR code generators available, some for free, some with price tags. For a

Figure 4: A QR code containing a message.

review of different QR generators, check out http://qrmedia.us/generators/.

Finally, I am sending you a secret message in the QR code I generated as shown in Fig. 4. Okay, the end product will never be shortlisted in the Most Beautiful QR Code Competition,[8] but I still hope the message gets across. So come on, let's get QR coding.

Acknowledgements

Fig. 2 is used with permission from the BBC. Fig. 3 is used under the terms of the Creative Commons Attribution License. Figs. 1 and 4 were generated using goqr.me.

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A day in the life of a teacher of scientific writing

Today, the first day of a 4-day writing course, I face a new group of 12 biomedical researchers from various disciplines. I start by asking, 'While reading a scientific journal, how many of you need to read a sentence at least twice to understand it?' Most of the participants nod and one of them adds 'And this makes me feel so stupid!' I reassure them that the fault is rarely with the reader but with the writer. The ice is partially broken; some of the group smile.

For the first exercise, I ask the group to read four different versions of part of a scientific article adapted from John Kirkman's book *Good Style: Writing for Science and Technology*[1] and to say which of the styles they think is best. A heated discussion follows. One participant, who had chosen the wordiest and most complicated as the best style, announces 'But you *must* understand that *we* scientists write like that!' Silence in the group. This person is obviously a senior scientist.

Taking advantage of the silence, I address the whole group: 'Tell me, does a scientist write for his or her own ego or to communicate?' This sets them thinking. 'To communicate, obviously', say a few. The senior scientist looks a little uncomfortable but manages a smile. We continue discussing the four texts and then I hand out comments made by the members of the Biochemical Society on each of the four styles. The Biochemical Society members voted for the most direct version, with verbs in the active voice, sentences of various lengths, and statements that are not too complex.

I now introduce the first aim of my course: improving readability. We work with examples of clumsy, roundabout, and woolly sentences; empty words; noun clusters; and sentences packed with too much information.

Now it is time for a break. Over a cup of coffee and a croissant, I get to learn about the participants' problems (writer's block, lack of time to write, coping with rejection). I will use this information to help them with these problems by discussing them in class.

After a break, I introduce the second aim of my course: understanding the structure of a scientific manuscript. I know no better way to introduce the subject of the abstract than to go over the article written by Munise Ohri and Keith Dawes in *The Write Stuff*.[2] I subsequently hand out a published abstract and ask the participants to write its title. They then choose the title they think is best from among those they have come up with themselves and the original title (without knowing who wrote which title). The original title does not even get one mention. When I tell them which it is they are most surprised. It is three lines long with many unnecessary details.

We next turn to the introduction. Using an example from a paediatrics journal, I ask them to think about whether it tells a story and whether there are too many references, interrupting the flow of the text. The group launches into another lively discussion. As a teacher it is important to realise that participants may learn as much from each other as they learn from you.

On the second, third, and fourth days, we will continue working on the abstract and introduction and will move on to the other sections of the manuscript. But today, the five hours are almost up and I can see that the group is beginning to wilt. Half-an-hour later, I am relaxing in my little garden overlooking vineyards, mountains, and Lake Geneva, and looking back on a good day's work with an enthusiastic group.

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The Light Stuff

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Welcome to The Light Stuff

One of the unwritten laws of EMWA is 'Never talk to the editor of the journal if you don't want to end up working on it in your spare time'. I can joke about this because as I was the editor of the EMWA journal from 1998 to 2004 back in the days when it was called *The Write Stuff*, and during my tenure, people avoided me at meetings like I was infected with the plague. It sometimes seemed that the only thing that was needed to empty the bar of people at an EMWA conference was for me to enter. So I definitely should have known better than to talk with Phil Leventhal, the current Editor of *Medical Writing*, at the recent EMWA conference in Berlin. We were naturally discussing the EMWA journal past and present when I foolishly mentioned that I missed the humour section of the journal that we had in *The Write Stuff* entitled 'The Lighter Side'. I instantly regretted it as I saw Phil's eyes twinkle and he pounced on me like a spider on the unsuspecting fly who has just stumbled onto the web and said, 'Well then why don't you bring it back for *Medical Writing*?' As one who firmly believes that nothing in life is worth doing if we cannot keep our sense of humour, I agreed. So here we are with the revival of what I hope is a great tradition. I thought that a name combining the old title of the humour page (The Lighter Side) combined with the old title of the EMWA journal (*The Write Stuff*) would be perfect and thus the name was born . . . 'The Light Stuff'.

In the coming months we will be continuing the tradition of (hopefully) humorous quotes and anecdotes about medical writing from 'The Lighter Side' which some of you may still remember, as well as cartoons with a medical writing theme. Of course, I will be overjoyed to consider ideas or material submitted by the readers, so if there is anything you might like to share with the EMWA members, PLEASE let me know. Indeed, if we can make you laugh or even smile occasionally, then it will all have been worth doing, for as Andrew Carnegie (Scottish-American Industrialist and Philanthropist) said, 'There is little success where there is little laughter'.

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Answers to Medical Writing Jumble #6:
STAGE, MINUS, BLIND, PHASE
He was quite "punny" and called himself a "PUNDIT".

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