In this issue of *Medical Writing*

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To coincide with the 1-day symposium at the recent EMWA conference in Manchester, this issue of *Medical Writing* focuses on health economics. For those of you not already familiar with the subject, health economics is the study of efficient and effective allocation of health resources. As Stuart Mealing puts it in his guest editorial in this issue of *Medical Writing*, health economists assumes 'that there is a fixed pot of money available for healthcare expenditure, which needs to be used as efficiently as possible in order to maximise the overall health of the nation or of insurance plan members'. Effectively communicating the results of economic evaluation is of enormous clinical importance.

Ruth Whittington, who gave an excellent talk during the health economics symposium, provides an excellent article to help us understand this field better. She explains in her article that medical writers can make a big difference in this increasingly important area because health economics research is often poorly communicated, but she emphasises that a good understanding of the terms and concepts is necessary for medical writers to become 'useful members of the publications team'. To assist us, in addition to her article, she provides a useful glossary of health economics terms.

In addition, we are pleased to have contributions in this issue from the European network for health technology assessment (EUnetHTA), from the National Institute for Health and Care Excellence (NICE) in the UK, and from the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) in Germany. Julia Chamova and Julie Lange describe how EUnetHTA is striving to maximise the use of existing health technology assessment evidence and avoid overlap in activities in Europe. Helen Barnett discusses NICE guidance on health technologies and explains the important role of its editors. The situation in Germany is discussed by Natalie McGauran and Michael Köhler, where early health benefit assessment must be made for new drugs. They describe the resources available to help pharmaceutical companies (and particularly medical writers) to prepare the dossiers required for this assessment.

2012 EMWA salary survey

The results of the 2012 EMWA survey are presented in this issue by Andrea Rossi and Karin Eichele. These results should help medical writers benchmark where they stand, although Andrea and Karin caution that salary satisfaction generally does not correlate with job satisfaction.

Document collaboration in a virtual team

An article by Kris Saether of Xait describes the difficulties of document collaboration in a virtual team. He explains how technology can help simplify producing documents from collaborative teams that may be working at several different sites.

New profile series

Laura Collada Ali provides the first in a series of profiles in which she will be interviewing medical writers and translators on behalf of *Medical Writing*. The first installment of this interesting series is an interview with Blanca Mayor Serrano on health literacy in Spain.

Further improvements to your journal

We continue to make improvements to *Medical Writing*. As you will notice in the table of contents, we have begun listing individual articles in each regular section. If you have any ideas for further improvements, issue themes, or articles, please write to me at editor@emwa.org.

Happy reading!

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Medical Writing

Health Economics

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Contents

Themes of upcoming issues of *Medical Writing*

December 2013: The theme will be '**Good Pharma**'. This issue will be on efforts to improve transparency and ethics in the pharmaceutical and device industries and is being assembled in collaboration with the International Society of Medical Publication Professionals (ISMPP). The deadline for feature articles is August 20, 2013.

March 2014: The theme will be '**Software for Medical Writers**'. This issue will be designed to help medical writers more efficiently use Microsoft Office, Adobe Acrobat and Reader, and EndNote and to introduce other useful software packages. The deadline for this issue will be October 29, 2013.

We are currently considering further themes for 2014 themes, possibly including special populations, related areas in which medical writers may work (e.g. veterinary medicine, cosmetics, nutrition), and medical topics (e.g. neuroscience).

If you have ideas for themes or would like to discuss any other issues, please write to editor@emwa.org.

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Message from the President

Andrea Rossi

EMWA President

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president@emwa.org

Dear Medical Writers

This is my first message as president of EMWA. I'd like to update all members about the plans and activities of the new EMWA Executive Committee (EC).

The spring conference in Manchester was a great success and was the most attended ever. Answers to the post-conference survey confirmed that the conference had fulfilled attendees' objectives and that both registration and workshop fees were good value for money. The full-day symposium on Writing for Health Economics and Market Access included a plenary session led by international experts and brilliant interactive discussions. The symposium was highly appreciated and attracted about half of the conference attendees. Almost all of the attendees who answered the feedback questionnaire were willing to attend future symposia if the theme will be of interest.

The EMWA student scholarship dedicated to the memory of Geoff Hall, a former EMWA president and one of the founder members of the organization, was officially launched in Manchester. The details on how to apply for 2014 will be published on the website and are published on page 172 of this issue. Briefly, each year, two students will be awarded 2 years of free membership and free conference registration, along with one free foundation course at their first conference.

The freelance survey and the salary survey were also presented and inspired thoughtful feedback and interactive discussions. Also, member's feedback from the E-learning survey was the basis to begin developing online training. Although distance learning obviously cannot (and will not) replace the EMWA conferences, the EC is aware that many members are unable to regularly attend. Therefore, the possibility of online training could add to the repertoire of the organisation and enable more members to profit from their EMWA membership. The EC is also working on a major overhaul of the website to eliminate the double-login, simplify navigation, and improve its usefulness. Media, Twitter, and Facebook activities have been fuelled with new enthusiasm and content, including Twitterviews of EC representatives. Finally, some new exciting workshops will be included in the educational programme.

The programme of the future autumn conference in Barcelona has already been established. The format has been changed so that it will be possible to attend up to four workshops at these events, and a new schedule of events has been adopted, including two evening sessions where EMA and Spanish medical writing and translation associations will be able to participate.

I hope to see all of you in Barcelona very soon and look forward to a lively and well-attended conference.

Ciao

Andrea Rossi

EMWA President

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Thirty-seventh EMWA Conference, 7–9 November 2013, Barcelona, Spain

EMWA's 37th Conference will be held at the Fira Palace Hotel in Barcelona from Thursday, 7 November to Saturday, 9 November 2013. The Fira Palace Hotel is ideally situated in the trade-fair and exhibition area and is a short walk from Barcelona's Plaça d'Espanya. The hotel has excellent and spacious facilities for the conference and exhibition and is only a short bus ride from Barcelona airport, making it very easy and inexpensive to reach.

Extended workshop schedule

EMWA's autumn events traditionally focus on a full programme of workshops and networking events. From this year onwards, the autumn conference will be starting on Thursday lunchtime and finishing on Saturday lunchtime, so that we will now be offering workshops in four sessions instead of three. Also, workshops will be starting and finishing earlier in the day to provide more time for early evening events and networking. The exhibition will also be bigger than at previous events. These changes have been made to comply with wishes expressed by members to use the time at conferences more effectively, increasing value for money.

Presentation on medical writing at the EMA

As part of an effort to increase collaboration between the EMA and EMWA, the EMA will be giving an overview of the Agency's activities, including its role in the assessment of marketing authorisation applications, referral procedures, pharmacovigilance activities, evaluation of applications for orphan designation in the EU, and provision of information to patients, healthcare professionals, and the general public. In addition, the presentation will cover how the EMA works with other bodies in the EU, including the European Commission and national regulatory agencies, for the protection of public health.

Collaboration with other Spanish medical writing and translating associations

EMWA has invited representatives of AERTeM, Tremedica, and METM to the opening event to take advantage of the Barcelona location and provide a platform for networking between these organisations and EMWA. This is complemented by the usual programme of informal social events on the Friday evening.

For further information

For further information, visit http://www.emwa.org/conferences/Barcelona-November-2013.html or contact EMWA head office at info@emwa.org.

We look forward to welcoming you to Barcelona!

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Announcing the Geoff Hall Memorial Scholarships

At the conference dinner in Manchester this year, the creation of two very special scholarships was announced. The scholarships are in memory of one of the founding fathers of EMWA, Geoff Hall, who sadly passed away in 2010.

Geoff Hall

Geoff was not only a founding member of EMWA, but was also a past president, wrote the original EMWA constitution, was an extremely experienced workshop leader, and a stalwart of the social scene. However, aside from his vast knowledge and talent as a medical writer, he will also be remembered for his incredible ability to inspire and include people. Many EMWA members (myself included) have lots of blurred memories of social gatherings in EMWA conference hotel bars, and Geoff would make sure that everyone knew everybody else by the end of the conference, if not the evening!

Geoff felt very strongly that the future of EMWA (and any organisation) lies with younger members joining and moving through the organisation to become workshop leaders and members of the EMWA committees – and he was right. So with that in mind, the Executive Committee has decided to honour Geoff and his huge contribution to EMWA by focusing on younger members with the creation of the Geoff Hall Memorial Scholarships.

Two scholarships will be awarded each year to new medical writers, on the basis of an essay that will be judged by the Nick Thompson Fellows, plus John Carpenter and myself. The title of the essay will change each year, and the winning entries will be published in *Medical Writing*. In line with Geoff's personality, the scholarships are very generous – each one will entitle the winner to 2 years' membership of EMWA, free conference registration throughout the 2 years, and a free Foundation level workshop at their first conference.

The title of this year's essay is: *Where does medical writing fit in research?* The essay should be no more than two pages long, and the judges will be looking for inspiration and logical thought rather than a 'right' or 'wrong' answer. Anyone who has been a medical writer for less than 1 year may apply, and essays (plus a CV) should be submitted to EMWA Head Office (info@EMWA.org).

Although Geoff will never be forgotten by those who met him, I believe that the scholarships are a truly fitting way for Geoff's memory to live on in EMWA. I know that wherever he is now, he will love the fact that he will still be 'meeting' new EMWA members for a very long time to come.

Lisa Chamberlain James
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Exclusive discount on EndNote for EMWA members

EMWA has partnered with Adept Scientific to offer members an exclusive discount on EndNote. Members can now buy and download a single-user EndNote X7 licence for just £85 + VAT. This is a savings of nearly 50% (normally £159 + VAT).

This is a fantastic opportunity to get your hands on EndNote. To take advantage of this special price, send your contact details and inquiry about the EMWA discount to **biblio@adeptscience.co.uk**.

About EndNote

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- Share references with colleagues.
- Access and manage your research from anywhere.
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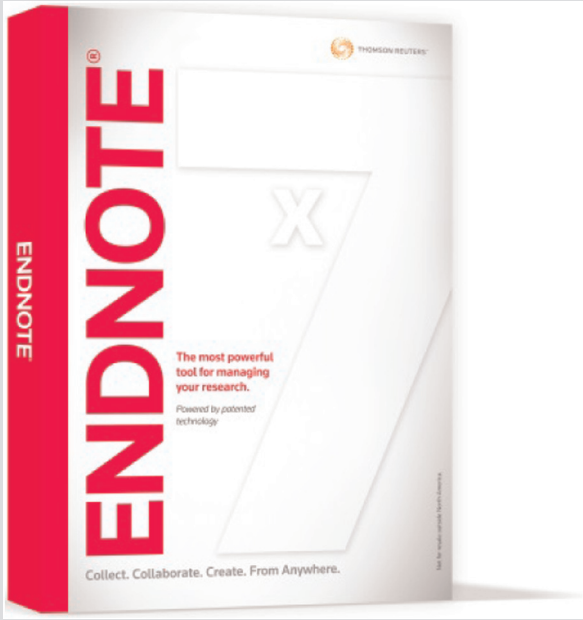

Health economists and medical writers: Collaboration or collision?

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Abstract

Medical writers are perceived by many health economists to be incompetent in health economics writing. Medical writers need to abolish this common perception, and so must develop an understanding of cost-effectiveness, cost-utility, and other health economic concepts. To be accepted as useful members of the publications team, medical writers must also adapt to and understand health economists and their needs. Health economics research is often poorly communicated and medical writers can make a great deal of difference in this increasingly important area.

Keywords: Health economic, Medical writer, HTA, Health economist

Health economics and outcomes research is becoming increasingly important for healthcare decisions and policies. Health economic data are now permeating into healthcare delivery at primary levels, with budget impact analyses used by most fund holders, and many therapeutic guidelines influenced by health economic study results. Therefore, medical writers need to understand health economic concepts and study methods in order to support effective communication of this research. Understanding the history of health economics can also make working with health economists more effective. This article provides a background to health economics as a discipline, explains how health economists are trained and therefore might perceive writers, and discusses some of the issues (with solutions) that may occur when health economists and medical writers work together. Much of this advice is based on personal experience over 20 years and so may not reflect your own perceptions! A glossary of common health economic terms and concepts is also provided after the end of this article.

Background to health economics

The history of health economics is an interesting one: long periods of nothing much happening at all, interspersed with spurts of activity. And, considering the recent sudden world attention to it, health economics has a longer history than one might suspect. For example, the American Medical Association set up the Bureau of Medical Economics in 1931 to study all economic matters affecting the medical profession. However, the first real start of health economics as a discipline is attributed to Kenneth Arrow,[1] who, in 1963, compared the economics of healthcare to that of other goods and services. (Note: medical economics and health economics are synonymous, with health economics the standard nomenclature today.)

Another very important concept was Michael Grossman's model of health production, which views each individual as both a producer and a consumer of health. Health is viewed as a sort of capital, which degrades over time in the absence of 'investments' in health. Therefore, health is both a 'consumption good' that yields direct satisfaction and utility (e.g. improved quality of life), and an 'investment good' that yields satisfaction to consumers indirectly through increased productivity, fewer sick days, and higher wages. Investment in health is costly as consumers must dedicate time and resources to health, such as exercising at a local gym, which conflicts with other goals.[2] Grossman's theoretical approach has influenced many of the practical aspects of health economic analyses.

Before proceeding any further, it may be helpful to distinguish between health economics, pharmacoeconomics, and health technology assessment (HTA) (Fig. 1; see also the Glossary provided after the end of this article). Much of the current focus in pharmacoeconomics is in preparing submission dossiers for HTA organisations; alongside the clinical value dossier, many countries demand

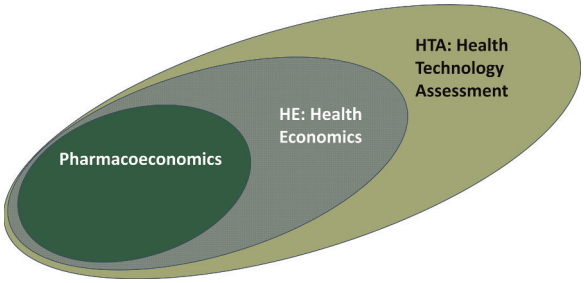

Figure 1: The interrelationship between health economic-related disciplines.

complementary health economics data. A medical writer is likely to be needed for these dossiers as well as for health economic publications and presentations.

In the health economics field, we tend to think of the USA as behind the times compared with Europe – for example, the USA does not really have a formalised system of HTA. In fact, America was a very early player in the HTA process: the US Office of Technology Assessment was founded in 1965. Ironically, it was disbanded in 1995 for political reasons, just as other countries were getting interested in HTA – but many HTA organisations are loosely based on the Office of Technology Assessment, for example, Sweden's Council on Health Technology Assessment which came into being in 1987.

Up until about the 1970s, studies purporting to be cost analyses were few and far between (what *was* the Bureau of Medical Economics doing?). However, as can be seen in Fig. 2, the number of health economics articles increased rapidly from 2003 onwards. As usual, pharmaceutical companies' interest in health economics (and therefore big injections of funding into such studies) took an upswing around the time the first government regulatory bodies started asking for cost data alongside clinical data. Oddly enough, it was Australia's Pharmaceutical Benefits Advisory Committee (PBAC) and Canada's Agency for Drugs and Technologies in Health, which were the first to request such information in the 1980s. But because those agencies were not based in key markets, global change was very slow until the 1990s. In fact, although PBAC was requesting health economics information, it was not until 1992 that formal guidelines for reimbursement were established in Australia. The National Institute for Health and Care Excellence (NICE) in the UK did not come into existence until 1999 – but as its decision processes are transparent, and the UK is a key European market, it had and continues to have a strong influence on other countries and their set-up of HTA organisations. However, just as in the PBAC, it took some years before NICE was clear about the information it wanted: at health economics congresses an underlying complaint was that research was performed after advice from the agency, but subsequently disallowed.

Starting in the late 1990s, HTA organisations have been and are continuing to be set up worldwide. Most have different evidence requirements for the assessment of healthcare and reimbursement (and are often unclear). However, since 2005, EUnetHTA (the European network for Health Technology Assessment) organisation (www.eunethta.eu) has been working to set up high-quality standard information sets that all European HTA bodies can use. Although this organisation is making good progress, at present, each HTA organisation wants different information or formats, and writers and health economists should consider them as unique entities, and approach each dossier afresh.

Understanding health economists

In the early days of health economics, the subject was taught as an adjunct to other studies; for

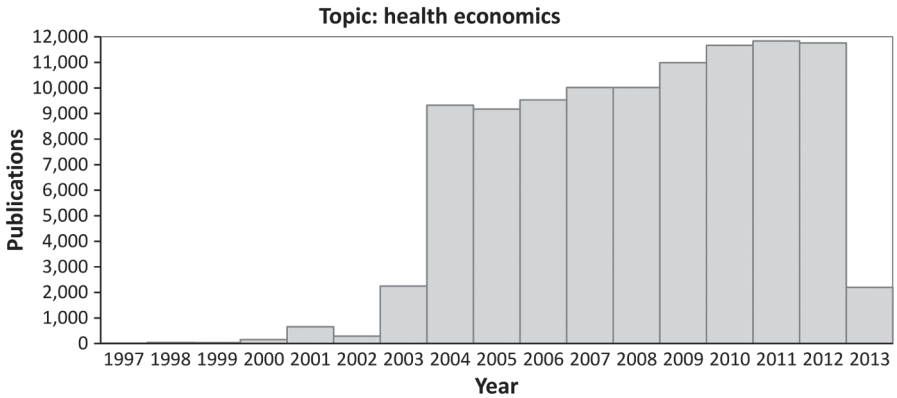

Figure 2: Growth in the volume of health economics publications. From: http://www.Gopubmed.org, search term 'health economics' accessed 12/06/2013. Reproduced with permission from Transinsight GmbH.

example, as a part of health policy, statistics, or epidemiology courses. Typically, the first health economists in pharmaceutical or medical device companies were statisticians or people from other disciplines who had an interest in health economics. In pharmaceutical and medical devices affiliate companies, you may still find that the health economics work is undertaken by medical directors or even marketing directors. Even now, there are more health economics jobs available than there are experienced people to fill them – it is a familiar lament among heads of health economics departments in the commercial sector. Although academic departments of health economics began being set up in universities in the early 1980s, these were not widely available for would-be students until the 1990s when the subject became suddenly more fashionable (at least among health economists).

A common problem with well-trained health economists is that they have rarely entered their profession to be skilled communicators. Typically, if their passion is health economic modelling, and/or they have a background in statistics or epidemiology, they will tend to believe that nobody can understand their research as well as they can, so they are likely to look on medical writers with doubt and even derision. However, with the complex statistics behind mixed treatment or indirect comparisons, for example, and more complicated analyses being developed every year, they may have justification for scepticism. This negative perception is also widespread in health economics agency researchers, who instead often use their most junior health economists as writers, with predictably dismal effect. Similarly, the number of assumptions that may have to be made to derive health economics data may cause the clinically trained medical writer to assign health economics to fantasy land. The issue, unsurprisingly, is that health economics data are often hard to obtain.

Potential communication issues and solutions

Writers: Lack of health economic understanding

Writers who wish to be successful in this field must put a great deal of their own time into mastering the basics of health economics. The attached Glossary is a good starting point; Wikipedia is useful, and there are introductory texts[3–5] on the market, although many of these books are designed for would-be health economists. The International Society of Pharmacoeconomics and Outcomes Research (www.ispor.org) has a great deal of free resource material on its website and also offers books, courses, and workshops. This is, however, a mere starting point, and to understand a health economist's explanation of his or her study, the following tactics may be useful for the inexperienced writer:

- Ensure that you get a chance to review the data and study protocol (if there is one) before discussing the study with the health economist. You will need it.
- Look up similar studies in the field on PubMed and familiarise yourself with the types of information included and the key points that the manuscript or document should cover.
- Use a checklist to ensure that you know the key components of a health economic study (e.g. perspective, design, data sources, analyses done) and therefore any gaps in the information supplied. Look at the CHEERS guidelines for health economic research (http://www.ispor.org/taskforces/EconomicPubGuidelines.asp) to help identify sensible questions to ask the health economist researcher regarding study limitations or missing information. (This is very important as not all health economic data packages are complete at the project initiation.)

Health economists: Continual data adjustments

One point about health economic studies that may not be obvious from the data package you receive is that the model may still be undergoing change as more information is added or parameters and functionality are altered. This is a common trait among health economics modellers – they like to tweak their models continuously to determine the effect on the results and thereby improve their understanding of the drivers that determine the outcomes. Therefore, the printed report from the model in the data package may not be the one from the last version of the model, and you will need to check frequently during the production of publications whether you have the final dataset. Check also the following:

- If working with a health economist who has built a modelling study in Excel, ask for the working model and check you have the latest version.
- If working with a report from other software (e.g. TreeAge or Arena), check the date on it to ensure that it is the most recent.
- Check that the sensitivity analyses are part of the report; you will need these for the publication. Few models or analyses will be accepted for publication if sensitivity analyses are not included.

Writers: Improving your reputation with health economists

In my experience, many health economists have had bad experiences with medical writers on global publications teams, who may have been very experienced in the therapeutic field but less so in health economics. While a good knowledge of the disease area and available therapies is very important, it is not enough. Admitting that you are not an expert in health economic analyses is much better than trying to bluff your way through. Showing that you have done some background health economics reading and have made an effort to understand will help, especially if your questions regarding the data package are relevant. Unlike clinical trials data, you cannot assume that one health economics study design is the same as another.

Health economists: Ignorance of publications policies and ethics

Publications policies and ethics are not important to a health economist, until you spend some time educating him/her accordingly. Health economists often come from academic backgrounds and will have published a few articles beforehand, usually with their research supervisor as the lead author. They therefore think that publication processes are an open book and there is not much you can teach them about it. If you have worked as a publications manager in a pharmaceutical company, you may be aware how problematic Health Economics Departments can be regarding timelines, review stages, authors, and other aspects of the publication process. Here are some ways of alleviating this problem:

- Ensure that you are familiar with your health economist's company publications policy and processes, and do your best to make them as easy for your client as possible. This will endear you to them and will potentially overcome their reaction to any silly questions you might ask about their work.
- Scare tactics about ghost authorship and bad publicity may help.

Conclusion

In conclusion, medical writers who make an effort to understand the field of health economics can reap a number of rewards. Apart from being constantly in demand as one of the elite, you will also be privy to some of the most interesting, provoking, frustrating, complex, and challenging projects a medical writer has to face. Once you have won the respect of health economists and their publishers, you can truly consider yourself a master of your craft.

Acknowledgements

The author wishes to thank all the wonderful health economist clients in the past 20 years who have truly been a joy to work with. Apologies to any of those erudite beings who take exception to the generalisations mentioned above.

Conflicts of interest and Disclaimers

The author declares no conflicts of interest. The above article contains personal opinions and unsubstantiated assertions. To be read with tongue firmly in cheek.

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Author information

Ruth Whittington's career paths have included nursing, academia, teaching, medical writing, sales, and company ownership. As a medical writer, Ruth wrote some of the inaugural drug evaluations in the journal PharmacoEconomics. In her company Rx Communications, approximately 60% of the projects involve health economics communications. Ruth is also a charter member for ISPOR (International Society of Pharmacoeconomics and Outcomes Research). Her health economics experience spans over 20 years.

Health economics glossary

Group of terms/term	Definition
Health economics	A sub-discipline of economics that is concerned with the efficient allocation of healthcare resources. It analyses the economic aspects of health and health care, and usually focuses on the costs (inputs) and consequences (outcomes) of health care interventions.
HTA	Includes the assessment of drugs, devices, medical and surgical procedures, diagnostics and the systems, processes and programmes that deliver health care. HTA is a broader concept than health economics, and is designed to assist in healthcare provision and policy decisions.
Pharmacoeconomics	A sub-discipline of health economics which focuses solely on pharmaceutical products.
Difference between cost, price, and value	
Cost	The amount of money that has been used up to produce something (e.g. the cost of manufacturing and marketing a medicine or the cost of a specific medical device). For pharmaceutical products, the cost incorporates a number of components including: • R&D expenses (for this product and others that may not have made it to market) • Manufacturing costs of the product • Distribution costs for getting the product from the manufacturer to the patient via the necessary intermediaries (e.g. wholesalers) • Marketing costs to advertise the availability of the product to increase demand (and, therefore, sales) These costs are to some degree fixed for a given product and will play a part in influencing the price.
Price	The amount of money that is paid for the item. The price of an item is often different from its cost and is often a reflection of its value to the purchaser. It is possible that there are a number of prices associated with any given product. For example, in the UK, the relevant prices to consider are: • Ex manufacturer price – the price paid if purchasing from manufacturer • Ex wholesale price – the price paid by pharmacies purchasing from wholesalers • Public/list prices – the cost to the public purse In healthcare, considerations that set the price are complex, taking into account the novelty of the product, the cost to bring it to market, the competitive arena, and the global market competition, i.e. how many other alternative products and services exist worldwide.
Value	The decision as to whether something is 'worth' the price depends on a wide range of factors and is highly influenced by perspective. The value of any given product will be different for a payer, a prescriber, and a patient and very often, the more valued an item, the higher the price that can be charged despite the costs remaining the same. In many cases, the party who pays for the healthcare is not directly involved with either the delivery of it or the party who receives it. Therefore, with decisions about value of healthcare being made on another's behalf, it is important to consider how value is perceived by the different stakeholders in health care.
Cost types in health economic analyses	
Direct medical costs	Costs directly associated with the treatment or intervention (e.g. drug price, cost of physician office visits, costs of staying in hospital)
Direct non-medical costs	Costs associated with the use of the intervention but not as part of the medical treatment, (e.g. transport to clinic, childcare)
Indirect costs	Costs that result from loss of time due to illness (e.g. loss of productivity)
Intangible costs	Costs related to health *per se* and quality of life that can be difficult to measure (e.g. impact of poor health or time away from social activities)
Opportunity costs	The cost of an alternative that must be forgone in order to pursue the chosen intervention
Incremental costs	Additional total costs of a healthcare product or service compared with an alternative
Marginal costs	Additional or reduced costs that result from slight changes to the treatment or intervention
Benefits	Economic evaluations consider both the costs and benefits of alternative courses of action. A 'benefit' in health economic terms has the same meaning as elsewhere – it simply refers to a positive or favourable outcome of the treatment. There are two ways we judge benefit and assess treatment progress and they are termed intermediate endpoints and final outcomes.
Intermediate endpoints	Markers used to determine therapy benefit (e.g. mmHg dropped in patients undergoing anti-hypertensive therapy)
Final outcomes	The end result of treatment. Outcomes research may simultaneously measure economic, clinical, and humanistic outcomes: • Clinical: treatment outcome, lives saved • Economic: costs spent and/or saved • Humanistic: patient reported outcomes or preference-based outcomes or utilities, e.g. QALYs

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Group of terms/term	Definition
Quality-adjusted life-years (QALYs)	A utility score (0 = worst, 1 = best) based on the quality of life experienced by a patient during the life-years gained from treatment.
Types of health economic analysis	
Cost-effectiveness analyses (CEA)	The most common analyses used in health economics to decide between different treatments for the same condition. In a CEA, costs are measured in monetary units, while the benefits are measured as final outcome measures or in natural units such as life-years gained or symptom-free days. The costs are then correlated with the treatment's effectiveness to calculate a cost-effectiveness ratio (CER). The lower the ratio (i.e. the lower the costs per unit of effectiveness), the more this treatment is preferred, if resources are in short supply. When a new treatment is introduced, it is often necessary to examine the additional costs that one service or programme will incur, as well as the additional effects, benefits, or utilities that it will offer compared with the existing treatment. This is assessed using the incremental CER (ICER), which reveals the cost per unit of benefit of switching from one treatment to another treatment. The ICER is calculated as (cost of A–cost of B)/(benefits of A–benefits of B). If the ICER is within what is considered to be an acceptable range by the payer/provider of healthcare, then there is little reason for the treatment to be rejected on the grounds of cost-effectiveness.
Cost–benefit analysis	A form of economic evaluation in which both costs and benefits are given in monetary units (e.g. €, £, $). In this way, very definite criteria can be set and compared. Any treatment or service for which the benefits are greater than the costs is considered 'worthwhile'.
Cost-minimisation analysis	Compares the costs of alternative forms of treatment or management that produce equivalent health outcomes. The goal is to find the least expensive way of achieving those outcomes.
Cost-utility analysis	A form of CEA in which costs are assigned to health outcomes defined as 'utilities'. Utility values are numerical values assigned to measure the extent of improvements in health brought about by different treatment methods. The most commonly used utility unit is the QALY, which combines the benefits of survival and quality of life during the survival period. Healthy-years equivalents and disability-adjusted life-years are other frequently used utility values.
Cost-consequence analysis (CCA)	A variant of a traditional CEA, in which total costs and consequences are not combined to a single ratio, but instead are computed and tabulated. By not placing units of value on each component, a CCA provides a detailed breakdown of the costs and cost savings in a transparent fashion, allowing decision-makers to select the costs and outcomes that are relevant to them.

Early benefit assessment of new drugs in Germany: Framework for submission of dossiers by pharmaceutical companies

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Abstract

For the early benefit assessment of new drugs in Germany, medical writers are involved in the preparation of dossiers submitted by pharmaceutical companies to the main decision-making body of the German statutory healthcare system, the Federal Joint Committee (*Gemeinsamer Bundesausschuss*, G-BA). These dossiers are generally assessed by the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*, IQWiG). The present article summarises the documents that are publicly available to guide dossier preparation and to ensure transparency. These documents detail the requirements for the structure and content of the dossier, procedures for dossier submission, assessment by IQWiG, and decision-making by the G-BA. Medical writers should adhere closely to the available guidance to help ensure that the submitted dossiers fulfil the formal and content requirements.

Keywords: Medical writing, New drugs, Early benefit assessment, Dossier assessment, (German) Act on the Reform of the Market for Medicinal Products

Most industrialised countries make comparative assessments of the efficacy and/or effectiveness of drugs to inform national reimbursement decisions.[1] Until recently the price of a new drug in Germany (i.e. a drug with a new active ingredient) was not regulated or negotiated by a healthcare or governmental body but was set solely by the pharmaceutical company. This led to high prices of patented drugs and increasing costs in the pharmaceutical sector of the healthcare system.[2] In an attempt to counter this development, the Act on the Reform of the Market for Medicinal Products (*Gesetz zur Neuordnung des Arzneimittelmarktes*, AMNOG) was introduced on 1 January 2011.[3]

Social Code Book V (*Sozialgesetzbuch*) provides a legal framework for health services regulated by statutory health insurance (SHI). In accordance with Paragraph 35a of Social Code Book V, when a new drug (or an established drug with a newly approved therapeutic indication) enters the market, the pharmaceutical company must submit a dossier containing evidence of the drug's added benefit for patients compared with an appropriate comparator therapy (ACT).[4,5] The ACT is specified by the Federal Joint Committee (*Gemeinsamer Bundesausschuss*, G-BA), the main decision-making body of the SHI system.[6] The G-BA is responsible for the procedure of early benefit assessment.

Procedure of early benefit assessment

Medical writers (employed by pharmaceutical companies or contracting agencies, or commissioned as freelancers) are heavily involved in dossier preparation, which follows a standardised procedure. German-language writers are mainly involved, as the actual dossier text is in German. However, English-language writers may also prepare texts that are subsequently translated.

To assist pharmaceutical companies with dossier preparation and to ensure transparency, various documents (including those in English) relating to the early benefit assessment are published on the websites of the G-BA and the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*, IQWiG[7]) (Table 1).

In addition, the G-BA offers consultation on the documents and studies to be submitted and on the ACT. This consultation, which must be paid for by the companies, can take place at an early stage, i.e. before the start of Phase III studies submitted in the drug approval process.[9]

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Table 1: Publicly available information sources to assist dossier preparation and to ensure transparency for the early benefit assessment of new drugs in Germany[a]

Type of information	G-BA website	German	English	IQWIG website	German	English
Overall procedure						
General information	Summary information	X	X	Summary information	X	X
	Questions and answers	X	X			
Methods and other requirements	Rules of Procedure	X	–	General methods, Version 4.0	X	X
	Dossier template	X	–	Methods for classifying extent of added benefit[b]	X	X
For each new drug						
Dossier	Modules 1–4	X	–			
Assessment results of IQWiG	Full dossier assessment	X	–	Full dossier assessment	X	(X)[c]
				Executive summary	X	X[d]
				Health information	X	X
Commenting procedure	Submitted comments	X	–			
	Responses by G-BA	X	–			
	Minutes of hearing	X	–			
Resolution by the G-BA	Text of resolution	X	X			
	Reasons for decision	X	–			

G-BA, *Gemeinsamer Bundesausschuss*; IQWiG, *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*.
[a]Adapted translation.[8]
[b]Appendix to dossier assessment A11-02.
[c]An English extract of the dossier assessment is available (generally sections 2.1–2.6: executive summary, methods, results and conclusions).
[d]Included in the English extract.

The flowchart of the early benefit assessment is shown in Fig. 1: the G-BA generally commissions IQWiG to assess the dossier and evaluate the probability and extent of added benefit of the drug. These 'dossier assessments' are published on the websites of the G-BA and IQWiG within 3 months after market entry, and the pharmaceutical companies responsible, as well as other specified scientific and commercial parties, are given the opportunity to submit comments in a written hearing, followed

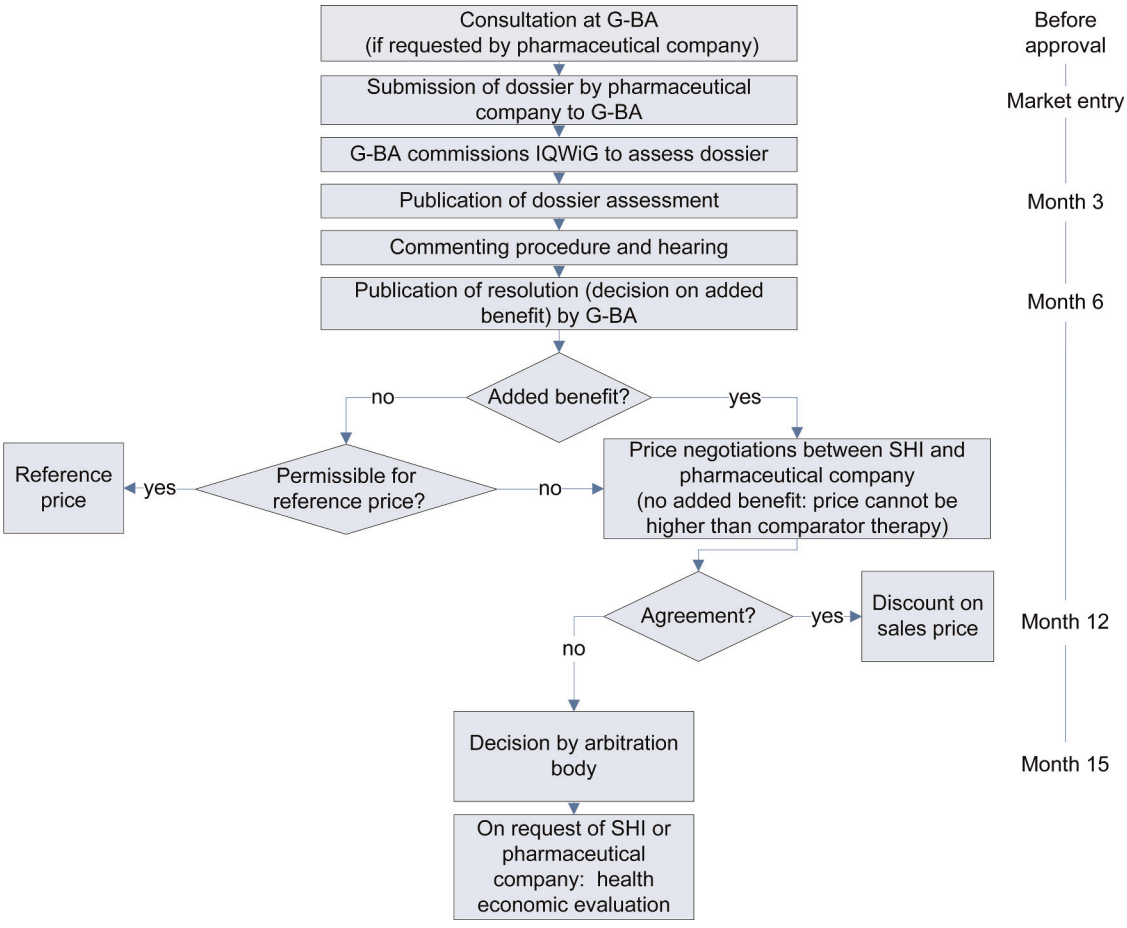

Figure 1: Flow chart of early benefit assessment (adapted translation from IQWiG presentation materials).

by an oral hearing. Three months after publication of the dossier assessment the G-BA passes a resolution based on the assessment and the results of the hearing; the main issues specified are the extent of added benefit of the new drug, eligible patient groups, requirements for quality-assured administration, and cost of treatment with the drug.[9] This resolution forms the basis for price negotiations between the SHI umbrella organisation and the pharmaceutical companies.

Exemptions to the above procedure apply for orphan drugs, where the main responsibility for the dossier assessment lies with the G-BA, and specific regulations apply.[10]

Legal requirements and methods

The G-BA's Rules of Procedure

Paragraph 35a of the Social Code Book V provides the overall legal framework for the early benefit assessment. Chapter 5 of the G-BA's Rules of Procedure[11] specifies detailed aspects of the assessment procedure, for example:

- Scope
- Specification of processes, e.g.:
  - consultation at the G-BA
  - submission, assessment, and publication of the dossier (and the dossier assessment)
  - conduct of the commenting procedure
  - publication of the resolution by the G-BA
- Specification of definitions, e.g.:
  - drugs with new active ingredients
  - ACT
  - benefit and added benefit
  - extent of added benefit (see categories below)
- Requirements for pharmaceutical companies for deriving proof of added benefit, e.g.:
  - *design of submitted studies*: preferably randomised controlled trials directly comparing the new drug with the ACT
  - *type of outcomes investigated*: preferably patient-relevant outcomes such as mortality, morbidity, and quality of life
  - assessment and consideration of study quality
- Requirements for dossier content (see below)
- Requirements for special situations (e.g. assessment of orphan drugs)

IQWiG's methods

The general methods applied in the early benefit assessment are published in IQWiG's methods paper.[12] The specific methods applied to determine the extent of added benefit are published in the appendix to the first dossier assessment for a newly marketed drug, ticagrelor.[13] In brief, on the basis of the scientific data analysed, IQWiG draws conclusions on the (added) benefit or harm of a new drug compared with the ACT for each patient-relevant outcome (i.e. an outcome describing 'how a patient feels, functions, or survives'[14]). Depending on the number of studies analysed, the risk of bias, and the direction and statistical significance of treatment effects, conclusions on the probability of (added) benefit or harm are graded into four categories: (1) 'proof', (2) 'indication', (3) 'hint', or (4) no conclusions can be drawn from the available data or no data are available at all.[12] Should an added benefit be shown, the extent of added benefit or harm is graded into three categories: (1) major, (2) considerable, and (3) minor. (In addition, three further categories may apply: non-quantifiable extent of added benefit, no added benefit, or less benefit.)[13] In a final step, the results for the various outcomes investigated are aggregated qualitatively into a single conclusion.

Structure and content of the dossier

The dossier has a modular structure and contains five modules (Fig. 2). Modules 1–4, among other things, contain a systematic review of the evidence, including the classification, by the pharmaceutical company, of the extent of added benefit. In this context, 'evidence' generally comprises results of all available (i.e. both published and unpublished) relevant clinical trials of the new drug directly compared with the ACT. In the absence of such direct comparisons, the evidence may also comprise trials that can be used for indirect comparisons. Regardless of the method chosen, it is required that study medications were administered in accordance with the approval status of the new drug and of the ACT. Furthermore, information on the cost of treatment is provided (drug cost only). Module 5, among other things, contains the full evidence base, including full clinical study reports of all manufacturer-sponsored trials of the drug under assessment.

The dossier must be submitted in specific templates, available on the G-BA website.[16] These templates not only provide the format of the dossier but also specify requirements for content (including methods). All template requirements should be followed because non-adherence increases the probability of submitting an inadequate dossier, leading to the conclusion that no added benefit of the new drug is proven. In addition, a completed checklist must be submitted for assessment of the formal completeness of the dossier.[17]

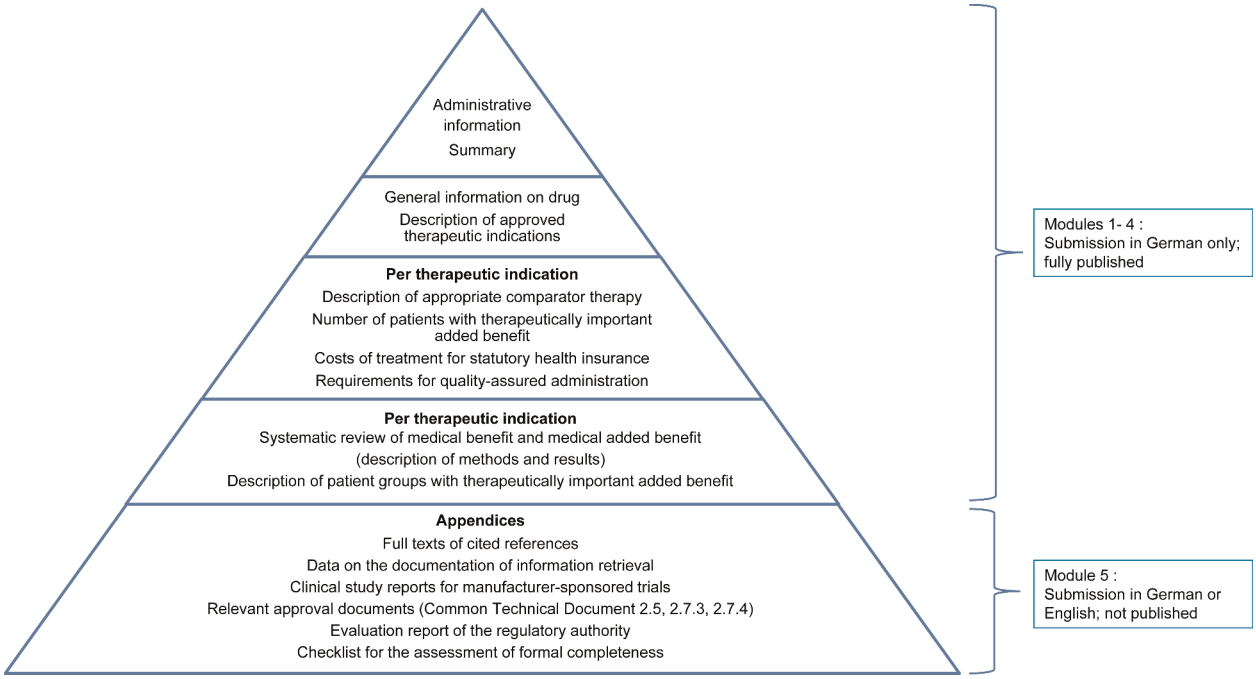

Figure 2: Structure of dossier: Modules 1–5 (adapted translation[15]).

Mandatory publication

To ensure transparency, there is a legal obligation for the G-BA to publish Modules 1–4 of the submitted dossiers, as well as the corresponding full dossier assessments and resolutions.[5] Various additional documents are also published, for example, health information for patients and consumers relating to the results of the dossier assessment (Table 1).

Results so far

Some 30 dossier assessments have so far been completed. A recently published analysis of the first 21 dossier assessments (excluding orphan drugs) showed that 13 of them provided adequate data for evaluation.[18] Some of the eight inadequate dossiers revealed gaps in the evidence or did not adhere to the ACT specified by the G-BA. However, all in all the findings indicate that the early benefit assessment of new drugs is feasible.

Assessment of older drugs

Assessment of the existing market, that is, of drugs already approved before the implementation of AMNOG, has been introduced as a further component of drug assessment in Germany. The first group of drugs assessed are gliptins for the treatment of type 2 diabetes,[19,20] meaning that for the first time an assessment covers a whole group of drugs (i.e. both older and newly approved), a further milestone in comparative effectiveness research. Further groups of drugs have been called up for assessment.[21]

Conclusions

Numerous documents to assist the preparation of dossiers for the early benefit assessment of new drugs in Germany are publicly available. Medical writers should closely adhere to the guidance on dossier preparation to help ensure that the submitted dossiers fulfil both the formal and content requirements.

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Conflicts of interest

Both authors are employed by IQWiG.

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A Great Books guide to when a medical writer should be involved in a project

'In the beginning was the Word'. So begins the most influential text in western history. It is from this Word that the Bible claims the Judeo-Christian God created the universe, including the ancestors of today's research scientists. Unfortunately, the Bible doesn't specify which word. It is nice to see the Word given such importance; certainly more flattering than 'the beginning of what we can theorise with probability was the Big Bang. Before that, well…'; however, this universe-from-a-Word business doesn't really make sense in any logical way. Let's move on.

Homer's *Iliad* and Virgil's *Aeneid*, pillars of the western classical tradition, would be more accurate for medical writers. Not because we are great warriors (although I'm sure some of us are, in our own gentler ways) or because we write in dactylic hexameter but rather because they start *in medias res*, that is to say, the writer gets involved somewhere in the middle of the project.

More realistic is Emily Bronte's *Wuthering Heights*. Not because it is a work with a high degree of human degradation but because it is a framed narrative. The narrator, who did not participate in the action or participated on the fringes, relates the story that he heard from someone who had. The action is over, the writer just describes what was done, why, and why it matters. The story's action is finished and we're getting it second hand. Legally, it's hearsay. It can make for great fiction but it's not the ideal pattern for medical writers and authors to follow.

The best model is Chaucer's *Canterbury Tales*, the first important piece of creative literature in English since the Norman Yoke. Chaucer died before he finished it, true, but it has some great lessons for the medical community. Really (you ask), a long and occasionally bawdy fourteenth century poem with an unreliable narrator? Yes (I answer), and here's why: the narrator/writer is involved from the beginning of the project. There is a strong project leader who keeps the project on course and doesn't tolerate any non-sensical digressions, all participants gave their consent, and whoever tells the best story wins a prize. (Do medical writers win prizes? No. Should we? Yes.) Lastly, the project design was hatched in an inn (or tavern), i.e. they had a kick-off meeting. And a tavern is a wonderful place for thinking and a good place to meet a writer before setting out on a (metaphorical) journey together.

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NICE guidance on health technologies and the role of editors

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Abstract

The National Institute for Health and Care Excellence (NICE) is the independent organisation in England responsible for developing national guidance, standards, and information on providing high-quality health and social care, and preventing and treating ill health. Editing plays a major role in this process, by helping to ensure that published guidance from NICE lacks mistakes, omissions, and ambiguities and that it is easy to understand for both healthcare professionals and the public.

Keywords: Economic evaluation, Health technologies, Medical editor, NICE, Guidance, Recommendations

The National Institute for Health and Care Excellence (NICE) is the independent organisation in England responsible for developing national guidance, standards, and information on providing high-quality health and social care, and preventing and treating ill health.[1] NICE produces evidence-based guidance and advice for health, public health, and social care practitioners; develops quality standards and performance metrics for people providing and commissioning health, public health, and social care services; and provides a range of information services for commissioners, practitioners, and managers across the spectrum of health and social care.[2]

NICE is internationally recognised for the way in which it develops its guidance recommendations, which are developed by independent and unbiased advisory committees using a rigorous process centred on using the best available evidence and including the views of experts, patients, carers, and industry.

NICE and economic evaluation

The technical ability of the National Health Service (NHS) in England to provide care far exceeds its ability to afford all of this care. This means choice cannot be avoided and that decisions on what the NHS provides have to be made. One of NICE's roles is to provide guidance to the NHS on the clinical and cost effectiveness of selected new and established health technologies, as formally requested by the Department of Health.

Health technologies referred to NICE include medicinal products, medical devices, diagnostic techniques, surgical procedures, therapeutic technologies other than medicinal products, systems of care, and screening tools. NICE's Centre for Health Technology Evaluation (CHTE) develops the guidance on these health technologies. Its technology appraisals programme carries out many of the evaluations, but many technologies are considered by other programmes within NICE:

- *Technology appraisals*[3] assess the clinical and cost effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, as well as some procedures, devices, and diagnostic agents. The NHS in England and Wales has a legal obligation to put technology appraisal recommendations into practice,[2] usually within 3 months of guidance publication.[4]
- *Diagnostics technologies guidance*[5] evaluates diagnostic technologies that have the potential to improve health outcomes but the introduction of which is likely to be associated with an overall increase in cost to the NHS. The diagnostic assessment programme concentrates on pathological tests, imaging, endoscopy, and physiological measurement. Diagnostic technologies may be used for various purposes, including diagnosis, clinical monitoring, screening, treatment triage, assessing stages of disease progression, and risk stratification.
- *Medical technologies guidance*[6] assesses technologies that may offer similar health outcomes

at less cost or improved health outcomes at the same cost as current NHS practice. Products that might be included are medical devices that deliver treatment (such as those implanted during surgical procedures), technologies that give greater independence to patients, and diagnostic devices or tests used to detect or monitor medical conditions.

- *Interventional procedures guidance*[7] assesses the safety and efficacy of (mainly) new procedures that are used for diagnosis or treatments that involve incision, puncture, entry into a body cavity, or the use of ionising, electromagnetic, or acoustic energy. It does not consider the cost effectiveness of these procedures.

The rapid increase in healthcare expenditure has led to a more serious consideration of value for money by general practitioners prescribing drugs and referring patients; hospital doctors deciding whether, how, and when to investigate and treat; hospital managers on the basis of meeting a budget or a target; and policy makers and commissioners of care. This need to provide value for money also affects patients and their care because it can influence what treatments are available. Accordingly, guidance from the CHTE includes economic evaluation, which has been defined as '…the comparative analysis of alternative courses of action in terms of both their costs and consequences.'[8] Technology appraisals and diagnostics guidance include cost-effectiveness analysis, in which effectiveness is usually measured in quality-adjusted life years with standardised instruments such as EQ-5D, and cost is usually measured in expenditures by the NHS and social services. NICE often also uses economic models to model costs and cost effectiveness, and carry out sensitivity analyses. A simpler form of economic modelling is also included in the medical technologies assessments. Cost-consequence modelling is used instead of cost-effectiveness modelling because this guidance is only concerned with whether a greater benefit can be attained for the same or lower cost or if the same benefit can be attained at a lower cost.

NICE guidance contains the recommendations made by a committee and sets out the evidence and views considered by the committee. In general, it starts with the recommendations and then has sections describing the technologies and what they are used for, a summary of the clinical and cost-effectiveness evidence, and an outline of the committee's discussion and interpretation of the evidence that underpins the recommendations.

The role of editors in economic evaluation and NICE guidance

Editing plays a major part in helping to make sure no mistakes, omissions, or ambiguities occur in published NICE guidance. Editors at NICE also ensure that guidance documents are clear and easy to understand for the people who use them even though they often contain complex and technical information. To this end, all NICE guidance is written according to its principles of effective writing, such as:

- Writing in plain English
- Avoiding repetition
- Varying sentence length but keeping sentences as short as possible
- Avoiding jargon
- Using short rather than long words
- Not using two words when one will do
- Avoiding nominalisations (turning verbs into nouns, for example 'for treating' rather than 'for the treatment of').

There is an editorial subteam responsible for editing all NICE guidance developed by the CHTE on the use of new and existing medical technologies. The team includes five senior medical editors (hereafter, referred to as 'editors'), each of whom 'leads' the editing of appraisals from one of the technology appraisal's committees and one other programme (i.e. diagnostics, medical technologies, or interventional procedures).

Each of the editors in the CHTE editing team receives basic training in health economics to ensure that they are familiar with the terminology and they understand the fundamentals of how economic evaluations are carried out. This helps them make sure that jargon is avoided and that complex economic information is clearly explained. It also helps the editors communicate with their colleagues in the CHTE.

The editors in the CHTE editing team work in collaboration with technical analysts and other colleagues in the CHTE. The analysts draft the guidance documents, and the editors take editorial responsibility for the published documents, including the consultation and final guidance documents, for their committee and their programme. To help in this process, the editors usually attend the committee meetings as observers.

The editors edit and proofread guidance documents and, for certain programmes, carry out a fact check using supporting documents such as the manufacturer's submission and the independent technology assessment. In addition to copyediting

for sense, clarity, consistency, accuracy, grammar, and house style, the editors also check that the recommendations are clear and unambiguous, reflect the scope of the guidance, and are supported by the evidence and the committee's considerations section (see Text Box 1 for more about writing NICE recommendations). They may make suggestions about the wording of specific recommendations to improve their clarity, and may raise wider issues relating to the recommendations. The editors also check for consistency with other NICE guidance and guidelines, and they verify that any changes in later drafts are carried through to all relevant sections of the document. An important editorial check is that accepted terminology is used for groups protected under equalities legislation. The editors are also responsible for preparing the final guidance for upload onto the NICE website in digital format, and for checking it once it is up on the live site.

Text Box 1: Writing NICE recommendations

The style of recommendations and the standard forms of wording used are different for different NICE guidance programmes, but the general principles of effective writing used are the same:

- For every recommendation, make sure it is clear what the patient group or target population is and exactly what the professionals need to do.
- Start with the action if possible and include only one action per recommendation or bullet point.
- Be specific. For example, if other treatments should be tried first, state how many and for how long.
- Use 'and' and 'or' in lists of criteria to make it clear whether all or only some of the recommendations have to be met.
- Alternatively, add a phrase such as 'if all of the following criteria are met' to the introduction (useful if the list of criteria is long, or certain criteria have to be met).
- Leave out background information and commentary.
- Make every word count and make the recommendation a direct instruction if possible, particularly if the recommendation is aimed directly at healthcare professionals.

The editors are in charge of all editorial processes associated with the guidance documents (e.g. developing and maintaining editing notes and check lists) and ensure that these processes are embedded into guidance production as part of the quality control, and they work collaboratively to develop templates for the documents. Editors often juggle several guidance documents at different stages of the editorial process and are required to work to very tight deadlines.

Other editorial responsibilities

NICE has an obligation to ensure that its guidance is clear and accessible to the people who use NHS services. To this end, NICE produces a 'lay translation' of each piece of clinical guidance and quality standard that it publishes – referred to as 'information for the public' or 'IFP'. It is the editors' job to write and edit this information. For technology appraisals, for example, these leaflets include information about what NICE has said about the technology, who can have the technology, and why NICE has made the recommendations it has. The leaflets also include a brief explanation of how the technology works and an explanation of the condition it is used to treat. Finally, the leaflets explain what the recommendations mean for patients, and list up to five organisations that can provide more information and support for people with the condition and their carers.

Editors in the CHTE editing team are also responsible for working on NICE Pathways, an interactive web-based tool that offers an easy-to-use, intuitive way of accessing a range of information from NICE about health, public health, and social care. Nice Pathways provides up-to-date NICE guidance, quality standards, and related information. The editors amend the pathways to include technology appraisals, interventional procedures, medical technologies, and diagnostics guidance.

NICE editors are also responsible for editing patient access schemes, which are special ways in which manufacturers and sponsors can submit proposals to the Department of Health for innovative pricing agreements that are designed to improve cost effectiveness and to facilitate patient access to specific drugs or other technologies. They also edit advice and tools to support the local implementation of NICE guidance, such as costing tools or statements, and audit support tools. All NICE programmes must have one or more published guides to their process and methods, all of which are also edited by members of the CHTE editing team.

To help everyone at NICE write more effectively, the senior medical editors run 'Writing for NICE' workshops, 'Word at NICE' workshops, and other editing and writing courses as needed, and they all help to maintain the NICE style guide. They are also involved, along with their CHTE colleagues,

in induction training for new members of the appraisals teams.

A personal view of working as an editor at NICE

I have found working for NICE as a senior medical editor to be really fulfilling, with lots of variation and challenges. It allows me to use my experience as a medical editor and writer, as well as my medical knowledge as a pharmacist. For me, the independence, rigour, and high quality of the work at NICE, coupled with its international reputation, were important factors in why I wanted to work for the organisation. It feels good to know that what I do at NICE is part of something that makes a meaningful difference to people.

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European network for health technology assessment – EUnetHTA

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Abstract

In 2004, health technology assessment (HTA) was recognised as a 'political priority' by the EC and Council of Ministers, which led to a call to establish an effective and sustainable European network for HTA (EUnetHTA). The result was the establishment of the EUnetHTA Project in 2006. Since then, the work of this network for cross-border HTA cooperation within Europe has continued through various phases. The most innovative deliverable is the HTA Core Model® - a methodological framework that facilitates the production and sharing of HTA information. The current, Joint Action 2, phase of EUnetHTA aims to strengthen both the practical application of its tools and approaches to cross-border HTA collaboration, and to deliver recommendations on the implementation of a sustainable EUnetHTA.

Keywords: HTA, Health technology assessment, Network, EUnetHTA, Methodology

Most European countries have public agencies to evaluate health technologies. These agencies undertake health technology assessments (HTAs), to bring together and summarise scientific evidence to inform policy makers, clinicians, and the public on the safety, effectiveness and costs of new or established health technologies. Although HTAs are specific to particular countries with their diverse national priorities and systems, there is inevitably considerable overlap between the assessments undertaken in the different European countries.

In 2004, the European Commission and Council of Ministers targeted HTA as 'a political priority' recognising *an urgent need for establishing a sustainable European network on HTA*.[1]

This call for a European network on HTA to inform policy decisions was answered in 2005 by a group of 35 government-appointed organisations throughout Europe, which led to the establishment of the European network for HTA (EUnetHTA) Project in 2006. The ensuing activities of the network were organised through establishment of the EUnetHTA Collaboration in 2009, the EUnetHTA Joint Action in 2010–2012, and the current EUnetHTA Joint Action 2 in 2012–2015.

The strategic objectives of EUnetHTA are:

- To increase collaborative production of timely and fit for purpose HTA information that is applicable in national or regional HTA production and decision making.
- To increase reliability, quality, and relevance of HTA thus expanding its applicability for policy making.
- To build capacities in HTA.

The EUnetHTA network aims to maximise the use of existing evidence and reduce overlap of effort in HTA activities in Europe. EUnetHTA supports collaboration between European HTA organisations that facilitates the efficient use of the resources available for HTA, creates a sustainable system of HTA knowledge sharing, and promotes good practice in HTA methods and processes.

The most innovative scientific and practical product of EUnetHTA, so far, is the HTA Core Model® – a methodological framework for developing and sharing HTA information. This model provides a common structured format to facilitate effective national and transnational production and sharing of HTA results, and represents a wide range of perspectives.

Among other current results of EUnetHTA activities are methodological guidelines for assessing the relative effectiveness of pharmaceuticals focusing on clinical endpoints, composite endpoints, surrogate endpoints, health-related quality of life, internal validity, applicability, choice of comparator, direct and indirect comparisons, and safety.[2]

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The EUnetHTA Planned and Ongoing Projects (POP) Database and The Evidence Database on New Technologies (EVIDENT) are additional key deliverables of EUnetHTA. EVIDENT allows sharing and storage of information on the reimbursement or coverage status of technologies, and on requested additional studies (under development or implemented),[3] and POP allows EUnetHTA partners and associates to share information on planned, ongoing, or recently published projects of participating agencies. The aim of POP is to facilitate collaboration among European HTA agencies and reduce duplication of work.[4]

In October 2012, EUnetHTA embarked on the latest stage of its work through a second Joint Action, which will last until 2015, focusing on strengthening the practical application of the tools developed for cross-border HTA cooperation in Europe with the objective of developing a general strategy, principles, and an implementation proposal for a sustainable European HTA collaboration according to the requirements of Article 15 of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.[5]

The collaboration among European countries through EUnetHTA can support and improve national HTA processes. Further information and updates on work in progress and the achievements of EUnetHTA can be found at www.eunethta.eu.

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Julia Chamova has more than 15 years of experience in coordinating cross-border HTA collaboration projects and activities for both private and public healthcare organisations. As Director of Operations for EUnetHTA, Julia has been in charge of operational management, development of the governance and organisation structure of the European HTA network, its stakeholder involvement policy, and long-term strategy development.

Julie Lange has a master's degree in International Business Communication and European Studies. As the communication officer of EUnetHTA, she manages both internal and external communication activities in cooperation with EUnetHTA's Work Package 2 on Dissemination.

Guest Editorial

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Medical writing and health economics/market access: A health economist's view

Having had the pleasure of attending the one-day symposium on health economics and market access at this year's Spring EMWA conference, and of teaching a workshop on health economics at the conference, two points struck me.

First, perhaps unsurprisingly, I could not accept the caricature of health economists that was portrayed by the opening speaker, only partially in jest I fear, in her otherwise excellent introduction to health economics. Her view of health economists was not dissimilar to the view of scientists portrayed in bad 1960s B movies: nerdy men with poor social skills locked away in darkened rooms to focus solely on technical matters. Well, I protest, though I admit that this view may have some foundation, perhaps particularly in academia. The health economists who work in and for the pharmaceutical and devices industries are, however, very much in touch with the real world. Health economics is a rewarding field to work in, demanding a combination of scientific rigour and commercial acumen.

The world that health economists live in is usually predicated on the assumption that there is a fixed pot of money available for healthcare expenditure, which needs to be used as efficiently as possible in order to maximise the overall health of the nation or of insurance plan members. In this world, the 'opportunity cost' (the cost incurred by making one choice over another) is not money but health. If you choose to pay for something expensive that offers questionable clinical benefit, less money is available for others to be treated, and sooner or later people will suffer or even die as a consequence. We cannot escape the fact that expenditure on healthcare in all developed countries is increasing exponentially, and tough choices about what to pay for can no longer be avoided.

For pharmaceutical and medical device companies, demonstrating that a product represents good value for money has become a fundamental aspect of successfully bringing it to market. Further, health technology assessment (HTA) has emerged as a coherent framework used by reimbursement agencies all over the world to assess value-for-money. Such assessments constitute the so-called 'fourth hurdle' over which companies must now leap in order to gain access to a given market (the first three hurdles being the conventional ones required for regulatory approval). HTA attempts, explicitly and coherently, to trade off the costs and benefits of a given health technology (i.e. a drug, device, diagnostic test, or public health initiative) in a particular disease area to answer the simple questions 'Is it better than what we already have?' and 'Does it represent good use of money compared with what we already have?'.

Global acceptance of HTA as the gold standard reimbursement framework has also led to the emergence of market access as a distinct standalone discipline. A good market access professional understands the need to present complex concepts simply and concisely, within an overall communication strategy, to present a convincing case for the clinical and economic value of the product. The skills needed are similar to those needed by a good medical writer. Even nerdy health economists, such as myself, have rapidly come to understand the value of good communication.

This is why I see health economics and market access as an area where medical writers can add real value. The majority of health economics, like medical writing, takes place in the commercial setting and not in academia. We (the economists) need help in getting our work into top tier clinical journals rather than backwater technical journals. Our clients need a high quality, well written, single information resource covering the epidemiological, clinical, and economic literature as well as the global corporate strategy for a product in a given indication (the 'global value dossier').

Further, too often, companies have their products rejected by agencies such as the National Institute for Health and Care Excellence (NICE), not because the product is poor but because the materials they submit to the agencies are substandard. At the Manchester symposium, a current member of a

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NICE committee gave examples whereby at the end of reading the economics section of a submission he did not know what sort of model had been built, and by the end of the clinical section he was unclear about what the target indication for the drug was. I have also seen submissions that say one thing in the clinical section and a contradictory thing in another (i.e. show poor editorial control).

This brings me to my second, more positive, observation, namely that the medical writing community, as represented at the EMWA meeting, seems to be well aware that their input in the health economics field is much needed. Both the symposium and my workshop were very well attended and there was a high level of engagement in both. My hope is that the coming together of the disciplines of health economics and medical writing continues, and that we can together ensure that the technologies that are likely to be of greatest benefit to patients are adopted and/or reimbursed. We should together also try to ensure that both the public and the medical community understand the need to use only those technologies whose costs can be justified by their clinical benefits.

Results of the 2012 EMWA salary survey

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Abstract

EMWA members were surveyed in late 2012 and early 2013 about their current salary levels. A total of 320 individuals responded. Most were women, between 31 and 50 years of age, and native speakers of English or German. About half had 2–10 years of experience. Mean annual income was €61 505 (median €54 000), more than 10% higher than reported in 2006. Men earned more than women and income rose with work experience and responsibility. Highest academic degree and native language did not appear to influence income, but members with an EMWA Professional Development Programme certificate earned more than those who did not. The results suggest that salary depends more on professional skills and knowledge than on formal requirements and might be increased by gaining experience and expanding professional skills; however, formal conclusions about influencing factors cannot be made because statistical comparisons were not performed due to potential sample bias.

Keywords: Medical writer, Salary, Income, Survey, Language, Experience

Introduction

The first EMWA salary survey was conducted in 2006.[1] In that survey, 145 members answered the structured questionnaire. The survey was repeated in late 2012 and early 2013 to obtain a more current picture of the salary levels of medical writers and medical communicators within EMWA and to see how they have changed in recent years. Factors that typically influence salary levels, such as education and work experience, were analysed.

Methods

Salary survey

The present survey was based on the 2006 questionnaire with a few alterations (see Supplemental material 1 http://dx.doi.org/10.1179/2047480613Z.000000000135.S1). Questions on age, native language, and document language were introduced; some of the answers to multiple choice questions were slightly modified for subject of academic degree (to include 'other life science'), EMWA Professional Development Programme (EPDP) certificates (multidisciplinary and specialised foundation certificates now recorded separately), classification, and size of employer (pharmaceutical and biotech companies grouped together; company offering medical writing services and government body introduced; employer size adapted for smaller companies and institutions), job title (translator and regulatory affairs specialist introduced), and job activity (training included as an option). Finally, a 10-point scale was introduced for job and salary satisfaction questions.

The survey was set up as an online questionnaire using Survey Monkey (http://www.surveymonkey.com). EMWA members were invited to participate via email, social media, and an announcement on the EMWA website. A reminder was sent to all invitees. The survey was open for participation from 5 November 2012 to 8 January 2013. All answers were collected and kept strictly confidential. Missing data were not queried.

Statistical analysis and calculations

Data on demographics, background, and job characteristics were calculated for the full analysis set, which was defined as all individuals responding to the survey. Means, standard deviations, and medians were calculated for the salary analysis set, defined as all individuals providing income data. Missing values were not replaced. Non-Euro currencies were converted to Euros using exchange rates for 28 January 2013 (€1 = £0.8580; €1 = 1.3463 US dollars; €1 = 131.6129 Pakistani rupees; €1 = 1.2936 Australian dollars; €1 = 1.2477 Swiss francs; €1 = 8.6368 Swedish Kronor; €1 = 7.4605 Danish kroner; €1 = 72.7431 Indian rupees; and €1 = 1.6669

Singapore dollars). Pearson's correlation coefficient (r) was calculated for income vs. job satisfaction, income vs. income satisfaction, and income satisfaction vs. job satisfaction.

Results

Respondent characteristics

A total of 320 EMWA members responded to the survey. The majority of respondents (70%) were women, and most (74%) were between 31 and 50 years of age, most (70%) spoke English or German as their native language (Table 1), and most (68%) had an advanced academic degree. The most common fields of study were biological and other life sciences and healthcare (81%). About half of the participants had 2–10 years of experience in the field of biomedical communication and 83% described their role as 'Medical Writer'. Most worked for pharmaceutical or biotech companies (31%), contract research organisations (30%), or a company offering medical writing services (18%). Of women, 24% reported working part-time, whereas only 5% of men reported working part-time. Over 50% spent more than half of their working time on writing activities. Common additional activities were editing, proofreading, quality control, supervision or administration, and training. The workload covered all types of documents to a rather similar extent. Most of the respondents were fairly satisfied with their work and salary.

Of the 320 respondents (full analysis set), full-time equivalent income levels were provided by 223. Characteristics of the respondents in the full analysis set and for those providing income data were similar.

Gross annual income

Two respondents were excluded from further analysis because their reported salaries were considered to be too low to be plausible: a medical writer from Pakistan who reported a salary of €270/year and a medical writer from Denmark who reported a salary of €6916/year.

Mean annual full-time gross income was €61 505 (median, €54 000). Mean annual income was €68 026 (median, €59 750) for men and €59 218 (median, €53 057) for women. The mean full-time equivalent income of part-time employees was slightly lower than for full-time employees (€58 855 vs. €62 040).

Table 1: Native languages of participants in the EMWA salary survey ($N = 320$)

Native language	*n* (%)
English	160 (51.0)
German	61 (19.4)
French	23 (7.3)
Dutch	10 (3.2)
Spanish	9 (2.9)
Danish	6 (1.9)
Indian	6 (1.9)
Swedish	6 (1.9)
Flemish	5 (1.6)
Italian	4 (1.3)
Greek	3 (1.0)
Polish	3 (1.0)
Portuguese	2 (0.6)
Russian	2 (0.6)

Table 2: Income according to job satisfaction ($N = 220$)

Level of job satisfaction	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
0–3	25 (11)	46 545	16 549	43 706
4–7	110 (50)	57 134	24 514	50 058
8–10	85 (39)	71 839	43 101	67 560
Salary vs. job satisfaction Pearson's *r*				0.29

Job satisfaction was assessed using a 10-point linear scale, where 0 indicated absolute dissatisfaction and 10 indicated absolute satisfaction.

Relationship between annual income and job and income satisfaction

Fewer than one in five respondents were dissatisfied with their job or with their annual income (job or income satisfaction score 0–3), while approximately 40% reported being very satisfied with their job and with their salary (job or income satisfaction score 8–10) (Tables 2 and 3). There was no clear correlation between actual salary and either job satisfaction ($r = 0.29$) or salary satisfaction ($r = 0.32$). However, salary satisfaction correlated with job satisfaction ($r = 0.78$).

Relationship between experience and annual income

Mean annual income rose between €5000 and €10 000 for every additional 5 years of work experience (Table 4). Senior medical writers with supervisory tasks earned more than twice as much as medical writers at the entry level. Salaries increased

Table 3: Income according to income satisfaction ($N = 220$)

Level of income satisfaction	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
0–3	39 (18)	46 993	21 845	42 000
4–7	88 (40)	57 539	22 958	52 250
8–10	93 (42)	71 596	41 942	65 000
Salary vs. salary satisfaction Pearson's *r*				0.32

Income satisfaction was assessed using a 10-point linear scale, where 0 indicated absolute dissatisfaction and 10 indicated absolute satisfaction.

Table 4: Income according to work experience ($N = 221$)

Experience (years)	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
<2	26 (12)	41 267	21 577	35 483
2–5	52 (24)	51 381	23 555	44 000
6–10	68 (31)	63 236	25 126	55 038
11–15	36 (16)	68 131	22 481	71 282
>15	39 (18)	79 363	55 090	70 000

Table 5: Income according to seniority and responsibilities of job ($N = 220$)

Seniority/level and supervisory responsibilities	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
Entry level	27 (12)	37 962	11 712	37 762
Middle – no supervision	67 (30)	50 563	19 270	46 620
Middle – supervision	30 (14)	62 560	27 570	55 600
Senior – no supervision	60 (27)	68 329	27 031	65 995
Senior – supervision	36 (16)	87 751	53 802	78 419

in steps of approximately €6000 to 12 000 with advances in career, with a larger increase (nearly €20 000) at the highest level (Table 5). Variability (i.e. standard deviations) increased in parallel.

Relationship between income and type of employer and country

Mean annual income for medical writers working for pharmaceutical or biotech companies was about €20 000 more than for medical writers working for other types of employer and was lowest for writers working in academia, although only four writers were included in this category (Table 6). Mean annual income, converted to Euros, was highest and over €90 000 in Switzerland, Denmark, and Australia and lowest and below €39 000 in 'other' countries (India, Ireland, Poland, Portugal, and Singapore) and Italy (Table 7).

Table 6: Income according to type of employer ($N = 214$)

Employer	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
Academic	4 (2)	50 348	13 965	46 183
Communications agency	21 (10)	59 208	23 457	57 000
Medical writing services company	41 (19)	59 930	55 333	43 000
Contract research organisation	66 (31)	52 626	17 564	48 000
Pharmaceutical or biotech company	69 (32)	70 753	25 622	67 560
Other[a]	13 (6)	73 372	41 238	72 000

[a]Self-employed (9), pricing and reimbursement, and market access (1), medtech (1), publishing (1), and a non-profit organisation (1)

Table 7: Income according to country ($N = 216$)

Country	*n*	Gross annual income (€)		
		Mean	SD	Median
Austria	3	46 800	14 058	39 600
Australia	3	90 188	15 621	92 764
Belgium	13	51 927	14 679	43 200
Denmark	7	90 870	18 572	93 291
France	15	71 385	79 684	54 000
Germany	57	66 979	26 021	65 000
Italy	4	38 111	21 829	30 822
Netherlands	6	50 450	15 492	47 600
Spain	8	60 250	39 329	48 500
Sweden	4	62 924	11 719	65 997
Switzerland	11	111 578	17 971	112 206
UK	76	49 086	19 066	44 289
USA	3	84 429	23 375	71 307
Other (India, Ireland, Poland, Portugal, and Singapore)	6	37 521	23 366	30 967

Relationship between income and language

Mean annual incomes for English and non-native English speakers did not differ greatly (Table 8). Similarly, annual incomes were similar among writers who predominantly write documents in their native language and those who predominantly write in a foreign language (Table 9). Also, annual income was similar for native-English and non-native-English speakers writing in English (Table 10).

Relationship between income and education

Mean annual income was roughly the same for those with a bachelor's, master's, or advanced degree, although medians increased with the level of education (Table 11). On average, medical writers with a background in humanities were earning less (mean, €53 383) than medical writers who studied in the fields of biological sciences (mean, €60 318) or healthcare (e.g. in medicine or

Table 8: Income of native English speakers vs. non-native English speakers (regardless of document language) ($N = 220$)

Native language	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
English	113 (51)	60 286	29 277	49 534
Non-English	107 (49)	62 684	37 492	55 200

Table 9: Income according to whether documents are written in native language ($N = 220$)

Document language	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
Documents not written in native language	100 (45)	62 586	38 183	55 600
Documents written in native language	120 (55)	60 800	29 044	50 816

Table 10: Income of native English speakers vs. non-native English speakers where most documents (76–100%) are written in English ($N = 175$)

Native/non-native	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
Native English speakers	91 (52)	60 119	28 438	52 448
Non-native English speakers	84 (48)	64 811	40 428	58 550

Table 11: Income according to academic degree ($N = 221$)

Degree	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
Advanced (MD, PhD, or equivalent)	156 (71)	62 394	34 728	55 000
Master's degree or equivalent	30 (14)	59 104	32 054	53 000
Bachelor's degree or equivalent	35 (16)	59 601	28 849	49 500

Table 12: Income according to EPDP certification ($N = 220$)

Certification	*n* (%)	Gross annual income (€)		
		Mean	SD	Median
No EPDP certificate	153 (70)	59 632	35 849	49 534
EPDP certificate	67 (30)	65 443	26 973	60 606
Total	220 (100)			

pharmacy; mean, €67 004). Finally, mean annual income was higher for respondents with an EPDP certificate than for those who did not have a certificate (Table 12).

Discussion

This salary survey, conducted between 5 November 2012 and 8 January 2013, was completed by 320 EMWA members. This was a good response given that EWMA included approximately 1000 members at that time. In addition, this was more than in the 2006 survey, which included 145 EMWA members.[1]

Salaries also rose from an average of €54 924 (median, €50 000) in 2006 to €61 505 (median, €54 000), suggesting that employers are increasingly aware of the importance of and are willing to invest in professional medical writers. There was substantial variability in salaries, suggesting that the medical writing professional market is still developing.

This survey found that annual income increased with experience and position. Compared with the 2006 survey,[1] mean annual incomes increased for middle level writers and senior writers with no supervision but changed little for entry level medical writers and senior medical writers with management responsibilities. Medical writers with a scientific or medical background appeared to have higher incomes than those with a humanities background, although only nine respondents were included in the latter group, precluding firm conclusions. The level of formal education appeared to have little influence on income, but the results were not broken down by years of experience as in the 2006 survey, which found that respondents with <2 or >15 years of experience had higher mean incomes when they had an advanced degree.[1] Interestingly, respondents with an EPDP certificate had higher average incomes than those that did not. Thus, for medical writers, income appears to depend more on technical expertise than on formal requirements and appears to be linked with gaining experience and expanding professional skills, for example, through EPDP training. However, the influence of EDPD training does not take into account the fact that employees with only a few years of work experience probably do not have the chance to complete an EPDP certificate, so this result may have been confounded by years of experience or level of responsibility.

The survey also found that job and salary satisfaction did not correlate with annual income. However, salary satisfaction correlated with job satisfaction. This suggests that it is not salary but rather work conditions that are the main factors determining satisfaction.

These survey results should allow medical writers and communicators to compare their salaries with other relevant benchmarks. However, as with the 2006 survey,[1] formal conclusions about the influence of most of the factors cannot be made because, except for analysing the association between income and work and job satisfaction, no statistical comparisons were made. Also, the number of respondents in some categories was very low. For example, several of the countries had only three or four respondents. The analysis also did not take into account cost of living or purchasing power in the respondent's country or that the respondents were volunteers and not randomly selected. Furthermore, in several cases, only indirect comparisons can be made with the 2006 results because of changes in the survey. Finally, this survey was limited to EMWA members, so the results may not be representative of all medical writers in the responding countries.

Conclusion

Overall, the mean annual income of EMWA members in this 2012 survey was higher than in 2006. The results suggested that income is influenced more by professional skills and experience than formal requirements or language. Medical writers are generally

content with their jobs and salaries, although satisfaction with salary did not correlate with the salary level, and regardless of salary, satisfaction with income was closely connected to job satisfaction.

Acknowledgements

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Disclaimers and conflicts of interest

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Medical Writing Jumble # 8

1. Re-arrange 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.

by Anuradha Alahari

Illustration: Anders Holmqvist

SGORS

DUWON

COKBL

TRAKEM

Answer:

See page 224 for the answers.

Successful document collaboration in a virtual team

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Abstract

When several contributors are working on the same document, challenges are often created for both managers and contributors. This article discusses how technology can be used to help produce documents in collaboration.

Keywords: Document collaboration, Simultaneous co-editing solutions, Virtual teams

Today's working environment is rapidly changing. Many international organisations have a large part of their workforce working in alternative workplaces, and the workforce often expects flexibility. Yahoo CEO Marissa Mayer recently created an outburst with her 'no-work-from-home' memo for remote workers[1] in which she stated her belief that working from home has an adverse impact on her employees' work performance.

Major factors behind people working from non-co-located sites include mobile technological developments and online collaboration solutions, in addition to the globalisation of organisations. The need for sustainable operation costs and access to knowledge workers is further increasing the demand for working in a virtual team environment. A virtual team consists of participants that primarily interact through mobile devices. Virtual team members may be in the same office or across continents.[2]

Producing documents in a virtual team environment carries many challenges, including communicating effectively, keeping track of people, building a team rapport, working towards common goals, and dealing with language and cultural differences as well as technology barriers. Working virtually can also allow some to avoid completing jobs and can lead to feelings of disconnectedness. With an increasingly flexible workforce that often works in different cities, countries, and regions, maintaining control of document production often becomes a challenge for the principal company. The pressure to deliver high-quality business-critical documents on time is vital for winning new and retaining existing clients. This article focuses on having the right document collaboration and production tools for a flexible workforce.

Traditional word processors are essentially advanced typewriters

The word processor descended from the typewriter and early text formatting tools. Probably as a result of its heritage, the word processor was created from the perspective of a single writer and the need to make frequent edits to a document as it is developed without the need for correction fluid. Although a major efficiency improvement, the word processor was never intended as solution to collaborative challenges.

Document management systems are essentially sharing and collation software

Document management system (DMS) providers often claim that their software is a collaborative application. In reality, DMSs are *sharing and collation software* that cannot change the fact that information is stored in files. They simply add an extra layer of information (metadata) and provide a control mechanism for accessing these files.

With a DMS, as with Microsoft Word, organisations need to break the document into sub-documents, assigning responsibility for each part. This leads to a fragmented and serial production process. This is exactly the point where the project managers lose control. Then, towards the end of the process, the person responsible for compiling the document needs to collate a variety of files, generate the document, and ensure that the formatting and layout are consistent.

The solution: Document collaboration solutions

Document collaboration solutions allow documents to be edited simultaneously by multiple contributors.

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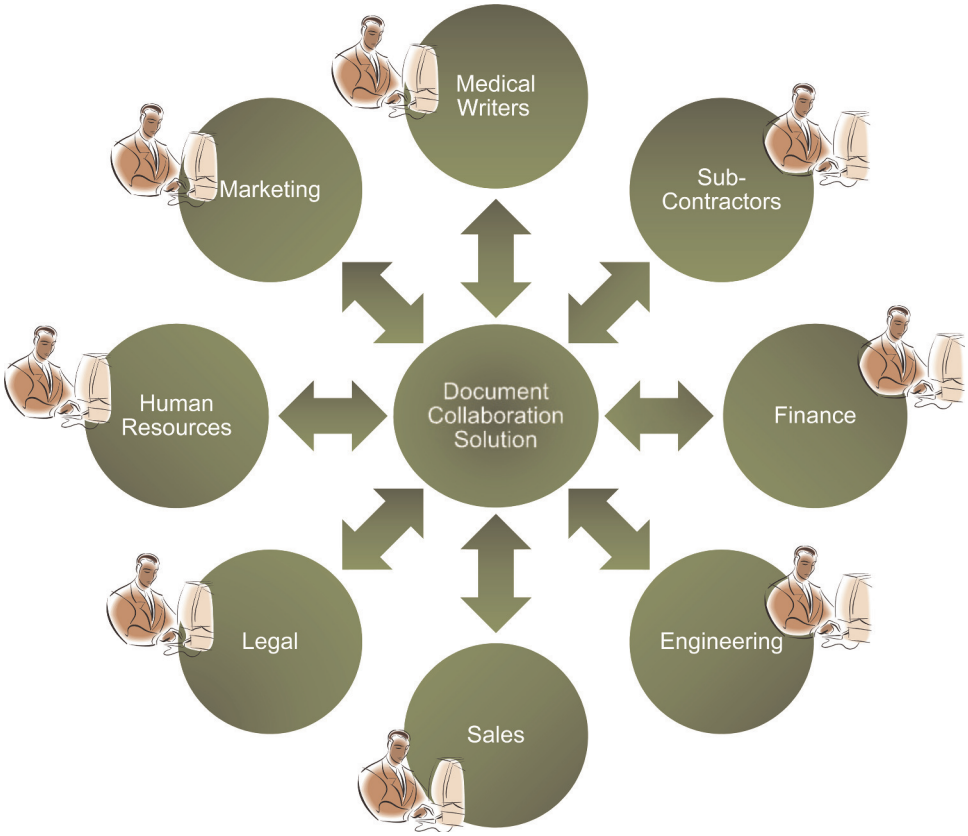

Figure 1: True document collaboration solutions enable teams to work simultaneously on the same document at the same time.

True collaborative solutions are built on databases, and allow for different sub-sections of a document to be edited in parallel. Basically, everyone can work on the same document at the same time, while management has complete control of the process (Figure 1). Automatic formatting, layout, and numbering ensure that writers focus solely on content. Web-native solutions (solutions that are accessed via the web and are not locally installed) enable contributions from multiple locations and organisations, and managers have complete control of the production process from day one. This helps organisations to increase the quality of their content.

Document collaboration solutions also often come with the added benefit of features such as master data management (MDM, authoritative management of single-source content) and composite content management (ability to use the same content automatically in many variations and documents). This means that end users can easily keep their data in a single-source repository, maintain consistency, and update all live documents at the same time, while using the content dynamically for various types of documents.

Single-source authoring allows the same content to be used in different documents or in various formats. It is a broad approach to content aimed at enabling creation of information products targeted to specific audiences, automatically – and without manual intervention or reworking. Use of this content can be increased mechanistically, by automated tools.[3]

According to Menon, the interest in composite content applications has increased over recent years due to the rising need for business process improvements and ways to address challenges around requirements for rapid and flexible changes.[4] Such applications can deliver substantial value by leveraging both content and process services for the better orchestration of people and processes, and can empower organisations to automate routine tasks and aggregate information from multiple sources in a collaborative work environment that enables rapid decision making.

MDM is a comprehensive method of enabling an enterprise to link all of its critical data to one file, a master file, which provides a common point of reference. When properly done, MDM streamlines data sharing among personnel and departments.[5]

Master content management is the 'workflow process in which business and IT work together to ensure the uniformity, accuracy, stewardship and

accountability of the enterprise's official, shared information assets; in this case, content assets, such as employee, supplier and customer contracts, new customer intake forms and other content types that must be managed as enterprise information.'[6]

Combining single-source authoring with composite content management and master content management can provide a very powerful solution for organisations. Organisations that master this can ensure that global virtual teams work with consistent content across all documents when their output is used in a wide variety of documents. The result is increased control of content provided by virtual teams, and reduced costs to make it happen.

When organisations deliver the 'same' service, effective communication is key

Knowledge organisations are often not willing to embrace new technology that seems to replace something they already manage in some way or other. Senior management often believes that Word solves all document challenges, as that is what they use and have used in the past. They may not fully understand that they need to embrace change to compete effectively. However, with an increasingly mobile workforce and virtual document production becoming almost the norm, traditional tools are just not adequate.

Author information

Kris Sæther is a sales director and member of the Executive Management team at Xait. For more than 15 years, he has helped corporations deal with their document collaboration and team productivity challenges. Xait is behind XaitPorter, an online document collaboration solution used globally. Xait was named a Cool Vendor in Content Management by Gartner in 2013.

Conclusion

With knowledge workers working globally in virtual teams, one would not rely on typewriters, so why rely on a word processor that is descended from the typewriter? There are many solutions that can assist your organisation in overcoming the challenges inherent to working in virtual teams. Start your research today.

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Profile

An interview with Blanca Mayor Serrano on the state-of-the-art of health literacy in Spain

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There seems to be a move towards 'patient-centred' health care as part of an overall effort to improve the quality of health care and to reduce costs. Individual patients and providers have to work together to ensure effective communication. Patients need to take an active role in health-related decisions and develop strong health information skills; healthcare providers have to utilise effective health communication skills; health educators have to write printed and web-based information using plain language.

Not many professionals have a better understanding of the Spanish healthcare scenario than Blanca Mayor Serrano (BMS). She has a PhD in Translation and Interpreting Studies and a Master's in Terminology. She is the brains behind the blog *Comunicación y educación en salud/Health Communication and Education*[1] as well as the LinkedIn Group *Alfabetización en salud/Health literacy*. She has published more than 40 papers on teaching medical translation, contrastive analysis, medical communication, and revision of medical texts for patients, among which the book *How to write patient information leaflets*[2] received an excellent welcome from field professionals. *Medical Writing* (MEW) turned to her to address some of the most interesting issues within this field.

MEW: Health literacy is defined as 'the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make basic health decisions'.[3] *In your opinion, are patients unable to understand basic health information or are we unable to write it?*

BMS: Let me ask you a question, quoting Stockton's paper on health literacy[4]:

Can you read this?

.htlaeh ruoy tuoba egassem tnatropmi nA

Probably, but would you have even tried if
Your reading skills were limited?
Your native language were other than English?
You were overloaded with work?
You were scared, stressed, or sick?

Probably not, in which case you would have missed
'An important message about your health'.

In Spain, a good deal of health information for patients is usually too complicated, explained in terms that are meaningless to them and loses sight of their communicative needs and background knowledge. This fact deters people from reading it, mostly those with low literacy skills. That is why designing clear, visually appealing, and easy-to-read patient education materials is of immense importance.

I must say, nonetheless, that various Spanish 'health actors' – non-profit and educational organisations, patient organisations, health centres, and hospitals, for example – are getting more concerned about the importance of health literacy. This is both for patient safety and for healthcare system sustainability. But although its importance is increasingly recognised and the interest in health literacy has become more internationalised over the past decade, there is still plenty of room for improvement with regard to accessing, understanding, appraising, and applying health-related information within the health care, disease prevention, and health promotion settings.

MEW: We find many scientific publications concluding that poor understanding is associated with poor prognosis. This may have huge ethical consequences for the general population. What are our responsibilities when writing texts for patients?

BMS: Research has shown that people with low health literacy make more errors with medications, are less likely to complete treatments, and are more likely to use healthcare services[4] like hospitalisation. The latter may even imply longer length of stay. That is why all health actors ought to ensure support of disadvantaged groups. And whatever the text is and its target audience, it ought to observe the three essential features that should characterise every scientific language: truthfulness, precision, and clarity.

MEW: Then, how can we approach a population with low health literacy?

BMS: In Spain the concept of health literacy is only marginally integrated in research, policy making, and in practice. Moreover, we had no data on the Spanish population health literacy level until recently. Now, thanks to the European Health Literacy Survey[5] conducted across eight European countries (Austria, Bulgaria, Germany,

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Greece, Ireland, Netherlands, Poland, and Spain) during the summer of 2011, we know that only about 37% of the Spanish respondents have an adequate functional health literacy. Therefore, researchers, policy makers, and healthcare professionals still have a long way to go.

As medical writers we cannot formulate health literacy policies, pursue public policy changes, or implement initiatives and programmes enhancing patient empowerment and health literacy. But we can indeed improve patient health literacy by fostering effective communication – which is a cornerstone of patient safety. We can do this by creating information appropriate to the health literacy needs of a specific population and by providing audiences with information in ways they can understand.

MEW: What key advice would you have for someone having to prepare written materials for patients?

BMS: A person engaged in writing patient materials should have a very good command of language in the field of medicine and health care. This might sound obvious, I know, but in practice we can find lots of examples of misleading texts due to such lack of knowledge.

Having a good command of medical language does not only mean being able to use terms appropriately but also knowing how language varies in different genres for different audiences. For example, drug slang is quite common in leaflets on HIV/AIDS directed to drug addicts – something unthinkable if the target audience is the general population.

Also, how 'determinologisation' functions to make concepts relevant to and understandable by non-experts is a must for medical writers preparing written materials for patients. But, what is determinologisation all about? – you'll probably wonder. Determinologisation is a cognitive and communicative phenomenon covering a set of strategies for the treatment of specialised lexical units. These strategies, aimed at making texts understandable to lay readers, are, for instance, explanation, definition, exemplification, analogy, and comparison and substitution by a more popular term.

And last but not least, knowing the complex and broad spectrum of medical and healthcare communication and settings in this field is essential. For example, the following should be considered: What will be the channel of communication? What genre are we going to use – handouts, leaflets, guides, comics, booklets, informed consent forms? Is the material intended to be disseminated in digital campaigns or for pick-up in waiting rooms? Are we designing the material to fulfil the wishes and needs of a specific group of patients, e.g. the elderly, kids, or teens, or is it intended for educators, patients' relatives, or the general public? Are we elaborating audiovisual materials to promote healthy behaviour? Being able to deal with all these and with many other questions is critical before preparing written materials for patients.

In short, I would say that the tricks of the trade are: a very good command of the language, knowledge of procedures required to make specialised information accessible to non-experts, an understanding of the target group and its specific cognitive, social and communicative needs, an appraisal of the communicative situation, and aiming for readability of the material.

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What can twitter do for me?

Like everything, the usefulness of twitter depends on what the user does with it.

Here is an assortment of information that can be obtained if you selectively follow organisations with twitter accounts relevant to your interests or requirements.

@GAPPTeam 28 Jun We've published an article about ethical authorship http://www.theannals.com/content/early/2013/06/25/aph.1S178.abstract #medcomms

@cochranecollab 6 Jun Find out if you're eligible for free access to The #Cochrane Library: http://cot.ag/dVuJ9P

@BMJ_Qual_Saf 21 May How to write a paper about patient safety or quality improvement http://qualitysafety.bmj.com/content/early/2013/05/13/bmjqs-2012-001603

@theNCI 19 May Need information about cancer drugs? It's all right here, from A to Z: http://1.usa.gov/15Z3yby

@TheSfEP 14 May Style sheets for users of PerfectIt - http://www.intelligentediting.com/stylesheets_multiplestylesheets.aspx

@CScienceEditors 13 May Free webinars from @AllenPress to cover social media, APCs, author guildelines, marketing, copyright agreements: http://bit.ly/2LYfLp

@AIDSinfo 9 May Looking for fact sheets on #HIV/AIDS-related topics? We have a variety of plain language fact sheets for you! http://go.usa.gov/Ts3m

@wellcometrust 3 May Apostrophes seem to be topic of the week here so we thought we'd share this piece on neurodegenerative disease names https://peerj.com/articles/67/

Of course you can also use it to follow your favourite band:

@RichardHawley 14 Jun For Your Lover Give Some Time http://fb.me/FGfmqGx6

Or even listen to birds tweeting while writing:

@AAGmedical 22 May Are you up early enough to hear tweet of the day on BBC radio 4? I was yesterday…lovely way to start the day http://www.bbc.co.uk/podcasts/series/totd

If this has stirred your interest, sign on, get yourself an account and join the twitterati*.

For more information on setting up an account go to https://twitter.com/about

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Follow me on twitter @AAGmedical

**Definition of Twitterati (from oxforddictionaries.com): keen or frequent users of the social media website Twitter*

In the Bookstores

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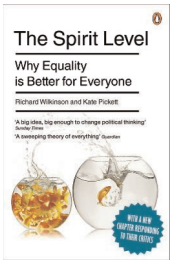

The Spirit Level: Why Equality is Better for Everyone
by Richard Wilkinson and Kate Pickett;
Penguin Books, 2010.
ISBN: 978-0-241-95429-4.
10.99 GBP. 375 pages.

The Spirit Level

Ever had a 'ping' moment? This book might have been mine. I'm not a natural pessimist, but Western society today seems less cohesive and people more materialistic, stressed, unhealthy, and unhappy than in times gone by. Wealth and status seem to be valued above everything else. Consumerism is seemingly unstoppable as the world hurtles towards an Armageddon of its own making. My personal views are not that uncommon, as discussions with friends and family show. Why we are in this situation and what can be done about it is less obvious. What I really need is someone to join up the dots …

Wilkinson and Pickett, both UK-based academics with economics and epidemiology backgrounds, present a compelling ideological argument, apparently underpinned with copious economic and political evidence. They hypothesise how material success has led to social failure and back this up with statistical meta-analyses of international (23 of the world's 50 richest countries) and US-based (50 American states) socioeconomic data. Graphs – with advice on how to interpret them – are used to convey key outcomes messages. The graphs mostly show income inequality (x-axis) in relation to various health and social outcomes (y-axis) with a regression line to show the 'best fit' relationship.

The outcomes are broadly defined as community life and social relations (including trust, women's status, and spending on foreign aid); mental health and drug use (including mental illness, mental distress, and use of illegal drugs); physical health and life expectancy (including infant deaths); obesity (both adults and children); educational performance (including literacy scores, high school drop out, and 15-year olds aspiring to low-skilled work); teenage pregnancy (both births and abortions); violence (including homicide and children's experience of conflict); imprisonment and punishment (including prisoner numbers); and social mobility.

Most of the negative health and social outcomes, it seems, are more prevalent in more unequal societies, and the positive measures (levels of trust between members of the public and women's status [as a combined index of women's political participation, employment, earnings, and social and economic autonomy]) show higher values in more equal societies. This is apparently true both internationally and in the US. The authors claim that the relationships are too strong to be dismissed as chance findings; the differences between more and less equal societies are large, and these differences are applicable to whole populations rather than subgroups. The conclusion is '… that greater equality usually makes most difference to the least well-off, but still produces some benefits for the well-off'.

The individual outcomes are combined into a single index of health and social problems, shown in relation to income equality, in Figure 1.

The findings are balanced to an extent by limited discussion of whether or not inequality plays a causal role, and other possible explanations. In this 2010 edition of *The Spirit Level*, the authors address the critics of the original 2009 edition in a new chapter and add evidence that came to light after the spring of 2008 – when they finished writing the original book – and overwhelmingly supports their findings.

So, what can be done to iron out inequalities when political will is seemingly lacking? The authors assert that 'greater equality can be gained either from using taxes and benefits to redistribute very unequal incomes or by greater equality in gross incomes before taxes and benefits, which leaves less need for redistribution', indicating multiple routes to greater equality. Research apparently also suggests that many of us want to narrow income differences – just think of the banking and corporate bosses with more than 500 times the earnings of their average employees.

The alternatives include developing the already huge non-profit sector, including community schemes and co-operatives, and limiting business

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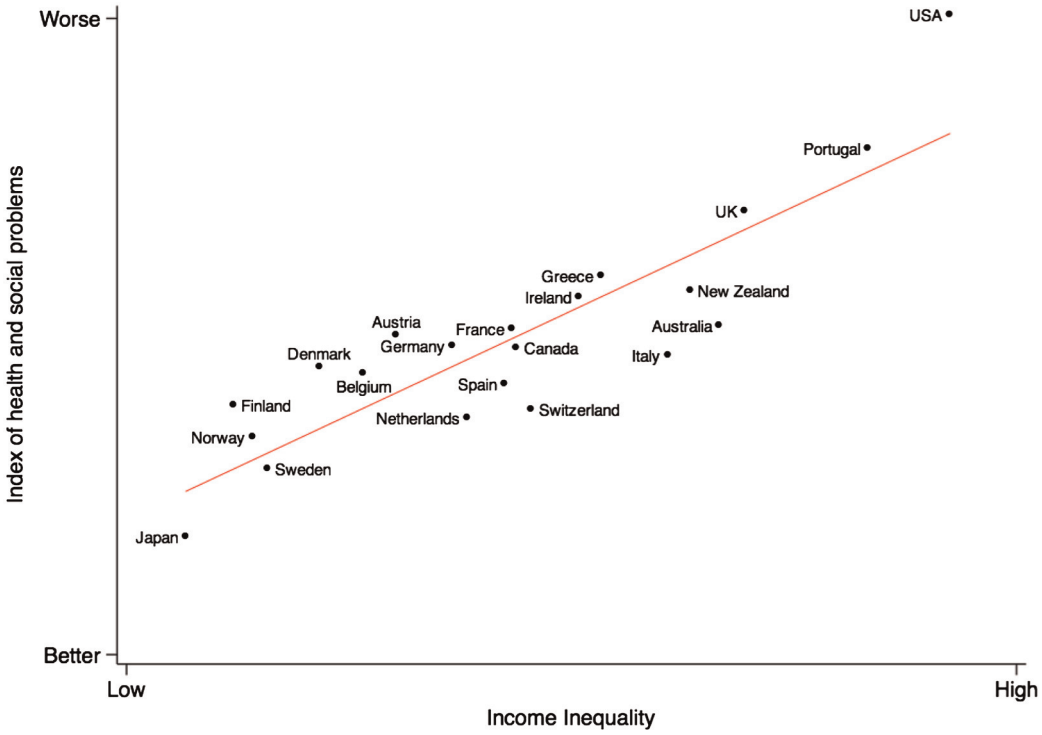

Figure 1: Index of health and social problems in relation to income inequality.

expenses and bosses' pay. A key proposed solution is democratic employee ownership (where share ownership is combined with participative management). This leads to bottom-up rather than top-down management; the authors feel this could transform our societies. They assert that such a business model can co-exist with conventional models in operation now, so the transformation can be gradual, controlled, and gain in strength if supported by government incentives.

On a hopeful note, we should consider that the human urge for equality and fairness has continued throughout time, and that our 'moment' could conceivably be a blip. Let us hope so. In the meantime, visit the Equality Trust's website (http://www.equalitytrust.org.uk), founded by the authors, for further insights into their ideas.

Now what did I say earlier about a possible 'ping' moment? As I read on, and as you may have detected, doubts began to creep in. Why did the authors narrow their 50 richest countries to only 23? Why was there little or no discussion around other possible causative factors besides inequality? Why, when this theory was publicised in 2009, have governments the world over not made drastic policy changes at grass-roots level? And why did the new chapter addressing their critics barely admit to any criticism, let alone address it? I'm no expert in socioeconomics or epidemiology. Time to find someone who is …

Acknowledgements

The Equality Trust, on behalf of Richard Wilkinson and Kate Pickett, kindly granted permission for the use of Figure 1. Figure 1 is a reproduction of Figure 2.2 originally published in *The Spirit Level*.

Reviewed by Stephen Gilliver
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The Spirit Level Delusion: Fact Checking the Left's New Theory of Everything
by Christopher John Snowdon;
Democracy Institute/Little Dice, 2010.
ISBN: 978-0-9562265-1-8.
8.99 GBP. 172 pages.

The Spirit Level Delusion

Snowdon, an author and freelance journalist based in the UK, systematically critiques the claims made in *The Spirit Level*. He reminds us that at the time of its release, *The Spirit Level* was 'rapturously received by much of the media …' and became '…one of the publishing sensations of the year'. By early 2010, *the*

Spirit Level's analysis, oft-cited in the British House of Lords, was threatening to shape government policy.

Snowdon points out that Wilkinson and Pickett wrote their book as though they were informing the public about issues that were established and agreed upon by the academic community, although this was not so. He asserts that they often misrepresented other authors' work and based claims on their own published reviews of the work of others. Wilkinson and Pickett also misled by presenting only supportive data, leaving the (non-expert) reader with the impression that little or no debate existed among experts on the information they present as fact. When added to the fact that only 23 of the world's 50 richest countries were included in the analysis, and that more recent data was sometimes omitted, the suggestion is that data were selected and manipulated to fit an argument.

In *The Spirit Level*, countries with populations of under 3 million (to incorporate tax havens) together with countries without reliable data on inequality were excluded. Snowdon agrees that tax havens should have been excluded, but he suggests – rather sensibly – that known tax havens should simply have been ignored, rather than being excluded through an arbitrary population cut-off of 3 million. He also re-examines the exclusion of countries with 'unreliable data' and reinstates those inexplicably excluded where reliable data clearly are available. Reinstated countries include notable absentees from the Wilkinson/Pickett list of 23 of the 50 richest countries, such as Slovenia, Singapore, Republic of Korea, Hong Kong, Czech Republic, and Hungary. In his analyses, he retains the same measure of inequality and use of linear regression analysis as in *The Spirit Level*, adds the square of the correlation coefficient (allowing easier comparisons between datasets), and encourages readers to use their own judgement for scatter graph interpretation. The same sources of data are used as in *The Spirit Level*. Further methodological detail and discussion are available at www.spiritleveldelusion.com.

Graphs based on the expanded country cohort for the outcomes in *The Spirit Level* show the disappearance of the relationship between the outcomes and inequality, with the odd country outlier here and there. Snowdon re-examines all outcomes investigated in *The Spirit Level* and rightly discusses other possible causative factors including culture, religion, diet, race, and genetics, as well as considering the differences between individual countries in methods of recording data and in their welfare, prison, and other national systems. The myth of inequality as the root cause of just about all social ills is dismantled.

Wilkinson emerges as a somewhat isolated figure in his own academic community, with a known history of questionable selection of data in order to make a point. Snowdon's thorough appraisal of available data and literature, and examination of alternative causes – all underpinned by acerbic wit – sees to that. Snowdon reminds us to remain sceptical at all times – as indeed we must, both here and in aspects of our work as medical writers too. This paired book review is a noteworthy reminder of our profession's responsibility to remain objective; exacting in research; and mindful of the implications and ramifications of drawing conclusions from 'selected' data.

Reviewed by Sam Hamilton
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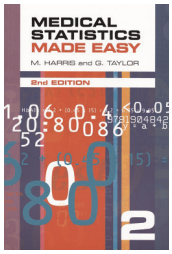

Medical Statistics Made Easy 2
by M Harris and G Taylor;
Scion Publishing Ltd., 2008 (2nd edition).
ISBN: 978-1-904-84255-2 (trade paperback).
15.99 GBP. 116 pages.

Any book title that promises *Made Easy* or the more widely imitated, jocular *For Dummies* stokes our hopes in big ways. We expect its topic to be unquestionably demystified. We expect it to transmit its contents to us instantly, as if through a metempsychotic education. Not infrequently, however, what we get is less than what we want, and we surrender in our quest of effortless learning. A book *For Dummies* on building websites, to give one example, is organised for effortless navigation between its sections, but it is 760 pages and weighs just short of 1.2 kg. To its credit, it is presented as a 'desk reference'. *Medical Statistic Made Easy 2* (*MSME2*), on the other hand, is free of most of the common deterrents to the satisfying use of books specifically targeted to neophytes to a topic. It endears itself even as it emerges out of its shipping bindings. It is sized to be handled comfortably and with a tactile pleasure enhanced by its satiny cover. The smile-inducing colourful graphics of its cover bring to mind a

luscious ice cream cone – and the intense urge to lick it.

An uncustomary amplitude of white space in this book strikes the reader on first glimpse of its innards. On reflection, this aspect is entirely logical and compatible with, in fact necessary to, the fulfilment of the promise of the book's title. First, it increases readability. Second, definitions and descriptions are given discrete individualities by being separated from each other by extra spaces (a sort of highlighting by excision of neighbouring chaff). Crucial ideas stand out without being run into each other in long, dense paragraphs. Finally, to render any text 'easy', it must be edited and pared extensively down to the fundamentals of its topic. It takes hard work to make things look easy to learn. The blank spaces in this book are the results of a Herculean effort to simplify concepts to their bare bones. I imagine the authors sitting down with a much longer text and highlighting (in yellow, let's say) essential ideas, and then debriding and excising a lot of repetitious/prolix passages, and leaving in their places white spaces. The authors clearly know medical statistics; otherwise we would have had a longer book with pretensions of having made its topic 'easy'.

The book is for '… health care students and professionals who need a basic knowledge of when common statistical terms are used and what they mean'. For each concept of statistics, the authors first note, on a scale of 1–5 (using stars for example), a measure of importance (frequency of use [read incidence and prevalence] in medical literature). They follow that with a rating of how easy the concept is to understand (the frequency of use of a concept in medical literature does not coincide with increased comprehensibility of the concept). The situation in which a statistical concept would be used is described next, and following that its meaning, i.e. what information it communicates to the reader of a clinical report, for example. Clear graphs and tables (where appropriate) and applied examples (in boxes) complement the textual treatment of each concept. Under the subheading 'Watch out for …' the authors post alerts to potential misconceptions and common pitfalls and how to avoid them.

The motivated reader is going to find the authors intelligent, reflective, and reassuringly dedicated to their readers. Deep and honest reflection will convince many of us that many statistical concepts are contrived constructs. To demystify a subject that is in part comprised of conventions, one must be ready to adopt slightly irreverent attitudes. Who would not be alerted, cheered, and edified by free-standing declarations the authors make, such as 'Even easier than mean!' (about the comprehensibility of median)? Or de-stressed by the statement 'It is not an intuitive concept' (about standard deviation)? Or by 'It is not important to know how the *P* value is derived—just to be able to interpret the result'. 'Aha' one says, and stops feeling like a dense, maladroit dummy. In another chapter, titled *Statistics At Work*, the authors present extracts from some papers actually published in journals such as BMJ, *The Lancet*, and NEJM, and discuss the statistical treatments used in them.

Infrequent inconsistencies in formatting (copyediting and productional oversights) and the occasional distraction provided by telegraphic sentence fragments aside, I did not discover any errors or omissions in my reading of this book. The contents of this book are a distillate of the corpus of medical/scientific statistics. Nothing important or relevant seems to have been left out. A reliable opinion on the volume's accuracy and completeness should, however, come from a qualified statistician. A glossary at the end is quite useful: its entries recapitulate the principal concepts and, like a supplemental index, refer the reader to the sections where they were elucidated. Surprisingly improvident, and inexcusable, is the absence of a short list of suggested readings from this non-fiction, instructional book. A 5-, 6-item bibliography (there are a couple of seminal titles that come to mind immediately) would have staved off this criticism; and it would have served well those who may wish to delve beyond the excellent introductory distillate the authors have provided.

Although many of us medical writers and editors do not need to have an operational command of medical statistics and do statistical analysis *per se*, we do need to have familiarity with its concepts and applications. For that purpose, I would recommend taking an introductory workshop (such as those offered at EMWA conferences or by AMWA) *and* at the same time buying *MSME2* – to browse for review, for additional details, or for reference. Its utility aside, the pleasure and reassurance provided by the knowledge that such user-friendly books can be, and are, written and published is well worth the price of what rightly can be considered the eminently provident ultimate chapbook of medical statistics.

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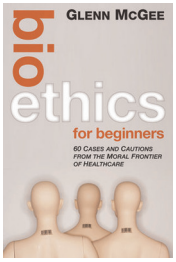

Bioethics for Beginners 60 Cases and Cautions from the Moral Frontier of Healthcare
by Glenn McGee;
Wiley-Blackwell, 2012.
ISBN-13: 978-0470659113.
14.99 GBP. 169 pages.

Deeply flawed (non-)introduction to bioethics

Bioethics for Beginners comprises 60 "Cases" – short articles (mostly opinion pieces) written by bioethicist Glenn McGhee for blogs and magazines – that are intended to introduce the reader to some of the ethical issues around science and medicine. Some of its better passages provide interesting introductions to subjects such as ethical training for researchers, the unacceptable exploitation of poor and uneducated people in clinical trials in India, and conflicts of interest. Other highlights are Cases 20, 37, 40, 41, and 50, which respectively deal with human cloning, quarantine, sanitation, codes of conduct for Internet health, and the misrepresentation of case reports.

The problem is, for a book purporting to be about bioethics, there is very little discourse on ethics. Rather there is much discussion of pragmatic issues relating to biotechnological advances. For example, the essence of Case 1 is that synthetic organisms are okay if there are safeguards. This is not bioethics! Instead of debate, we get opinion, hearsay, and politics. Case 2 can be summarised as McGee dislikes the teaching of intelligent design. So do I, but this is just opinion. The book's title led me to believe that it would illustrate key bioethical issues with pertinent examples. It doesn't. Most cases are simply not instructive.

According to the information on the inner front cover, the book boasts 'the very latest from the frontiers of science and medicine'. That is plain misleading. Some of the material dates back as far as 1998, and certain statements are dreadfully dated ('Most physicians know about and have used the Internet in some way' – find me one who hasn't). Updating the book to include mentions of Facebook, Twitter, and apps does nothing to hide the fact that much of the content is old.

And just who is McGee's audience? While he makes multiple references to films such as Blade Runner and TV shows such as Star Trek, indulges in cheap plays-on-words, and describes joining DNA sequences as 'stacking the bits together like toy blocks', he uses words such as mesenchymal, pluripotent, and parthenotes without defining them. The truth is there is no one audience. These articles were written for different blogs/websites/magazines with different readerships/users.

The inner front cover describes *Bioethics for Beginners* as 'eminently readable' and demonstrating 'clear thinking'. Nothing could be further from the truth. This passage from Case 8 (*Stem Cells: The Goo of Life and the Debate of the Century*) is not unrepresentative:

> *Everyone is up in arms about stem cell research: adult versus embryonic, iPSCs, and parthenotes. And maybe not up in arms exactly. But certainly everyone has a champion, a favorite kind of stem cell, the cell on the verge of curing cancer, macular degeneration, or male pattern baldness.*

You what?!

Many of the articles that make up the book are poorly written. Some sentences I read several times without making sense of them. There are problems with logic, typos, ('*sue* of the raw materials'), and repeated explanations of the same thing. The president of an institute is quoted as saying 'What will not stop this from happening misgovernment oversight.' I'll bet he didn't say that! And then there is the logic-defying reference to 'more than both senses of the word'. These and the many other issues suggest a complete lack of editorial involvement, while the following note, appended to one case, gives a clue as to how much care McGee invests in his writing:

> *A previous version of this story incorrectly said that 45 to 100 million Americans die each year of medical mistakes.*

Perhaps trying to connect with non-scientist readers, McGee revels in his own ignorance: 'If you are like me you won't be able to read the articles about the human genome in the prestigious journals *Nature* and *Science*. … the articles are no more comprehensible than the actual DNA code itself – TAC, CTA, GAS and so on'. He confesses to being 'clueless about what it is that nanotechnology means', while his statement that 'We don't really know how to turn genomics on and off, and we can't quite figure out whether it is working for us or against us' shows that he has not even bothered trying to understand genomics.

Bioethics for Beginners has a clear US perspective, rooted in 'American family values', money, fear of

bioterrorism, and controversy surrounding stem cell research, and assumes a fair amount of knowledge of US institutions. More than this, it has a partisan tone that borders on the offensive. McGee writes that 'the real concern isn't that the other guys are winning, it is what happens when they bend the rules to do so'; that 'ethics can get forgotten as other nations … race to fill the void'; that 'Only a properly funded US stem cell research program will guarantee oversight and the protection of all involved.' A lot of this seems to stem from the Hwang Woo-suk cloning scandal in Korea, which McGee returns to over and over again and which appears to have coloured his view of non-US research. He refers, insultingly in my view, to a 'grossly irresponsible lack of American leadership in the regulatory and funding arena' in the context of the Woo-suk case.

The book's standout passage is Case 59, an extended and highly enjoyable introduction to and repudiation of William Hurlbut's pseudoscientific stem cell research, which has been challenged in several forums, including the *New England Journal of Medicine*.[1,2] But how many readers will make it that far? Viewed individually, many of the articles that make up *Bioethics for Beginners* are deeply flawed. Viewed as a collection, they are a total mess. This book was poorly conceived and poorly executed. The idea of assimilating an author's multiple works on a range of subjects under a misleading heading ('bioethics') is a shabby contrivance. Those seeking a more coherent introduction to the subject could do worse that get hold of a copy of *White Coat, Black Hat* by Carl Elliot,[3] on whom McGhee repeatedly (and inexplicably) pours scorn in his writings.

Wrapping things up after the last case, McGee argues that the race to make scientific advances must not lead to ethical issues being ignored, but embarrasses himself by explaining (again) who Woo-suk is, having previously referred to his fraud at least half a dozen times. The disjointed nature of this conclusion, which comprises unrelated articles originally published in 2005 and 2007, encapsulates one of the book's main problems: a lazy approach, and one that should not be rewarded with your money.

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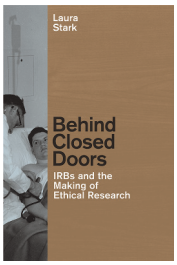

Behind Closed Doors: IRBs and the Making of Ethical Research
by Laura Stark;
University of Chicago Press, 2012.
ISBN-13: 9780226770871.
£18.00 GBP. 229 pages.

A fascinating insight into how IRBs operate and why they exist

Researchers and investigators the world over must look upon ethical review as a pesky hurdle to overcome before getting started with a study, but just how do institutional review boards (IRBs, ethics committees) operate and how did our system of ethical review come into being? In *Behind Closed Doors: IRBs and the Making of Ethical Research*, assistant professor Laura Stark seeks to answer both these questions.

In part one (of two), Stark describes her experiences of the decision making process from sitting in on meetings of three IRBs. Her source material includes recordings of 19 IRB meetings, complemented by interviews with 33 IRB members and a random sample of 20 IRB chairs. The far reach of ethical review is highlighted by the fact that the author's proposed research for this book was itself subject to IRB scrutiny.

The three chapters that make up this half of the book collectively describe the ways IRB members argue for their views to be accepted, and how the handling of previous applications guides the way IRBs deal with new ones. Other interesting topics that are highlighted include situations where consent can be waived and times when ethics and laws come into conflict. The author also considers the way requests for minor language changes in study documents can affect the conduct of a study.

Her account is revealing. The operations of the IRBs she observed were greatly affected by the

biases/prejudices/backgrounds of their members, and researchers were judged based on the writing of their applications, including typos and inconsistencies.

What becomes clear is that IRBs operate by a process of case-based learning (using previous decisions as the basis for future ones), rather than the application of a general set of rules or principles. This leads to different IRBs making different judgements, which can be a big problem for multi-site studies, where IRBs covering different sites may request different amendments. As a way of increasing consistency in decision making, the author proposes training IRB members with a common set of real cases.

Stark argues cogently that the fact that IRB meetings are closed allows subjective experience (e.g. the experiences of family members and acquaintances) to have a greater influence on decision making than it might if the meetings were open. Interestingly, she further asserts that IRB meeting minutes provide a selective picture, obscuring disagreements, giving the impression of consensus, and shielding individual board members from being linked to particular requests for changes, thereby enabling them to make such requests without fear of reprisal.

The book's second half paints a less than noble picture of ethical review as a form of insurance, a way of preventing lawsuits, a system instituted to protect the interests of researchers, the National Institutes of Health (NIH), and the NIH Clinical Center, rather than those of patients.

Stark explains how the system of medical research ethics we have today was developed at the NIH Clinical Center in the 1950s and 60s, including the move away from trusting in the judgement of the individual researcher, in matters relating to patients/research subjects, to reliance on committees of experts. She argues that the obvious alternative, a code of ethics, was not adopted because it would have curbed the freedom of researchers to a greater extent, and also claims that the policy at the Clinical Center in the early 1950s was that research came first, patients second.

To place the development of research ethics at the Clinical Center in context, Stark provides details of its operations during its formative years, which included efforts to increase the number of healthy research subjects ('Normals') by recruiting prisoners and conscientious objectors (to whom becoming a test subject was sold as an heroic service). Some of these research practices, by today's standards, defy belief. Take this telling description of one Normal's time at the Clinical Center:

> *After a year on several other wards for studies of the thyroid and of new steroids, Sarah moved to the 3-West nursing ward as the only person in the control arm of Dr. Savage's studies that examined whether LSD helped schizophrenics in psychotherapy.*

A year? The only person in a control arm? This is not the kind of research the *New England Journal of Medicine* is interested in.

One especially absorbing chapter is devoted to consent. Here Stark describes the initial resistance to the use of signed informed consent forms; the battle over signed consent/liability release forms between lawyers who wanted to protect the NIH from litigation, and researchers who wanted to do as they pleased; and the astonishing argument that there must be something inherently wrong with young people who volunteer for medical testing, and that they are thus incapable of providing meaningful consent.

In the final chapter Stark outlines how and why ethics committees spread to other sites, arguing that it was a way of transferring liability from the NIH to the institutes where it funded research, and of placating Congress (responsible for approving NIH funding) and a concerned public. While somewhat less fascinating than the rest of the book, this discourse nevertheless reinforces the author's apparent view that ethical review was established in the interests of anyone but patients and research subjects.

In summary, Stark's exploration of the history and workings of IRBs should appeal to anyone with an interest in research ethics. Those keen to find out more about topics of particular relevance to medical writers – the importance of ethics applications being well written and targeted to the right audience, and the potential role of medical writers in preparing such applications – could perhaps also read the reflections of a current EMWA member who sits on an ethics committee.[1,2]

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Journal Watch

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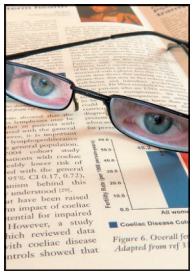
Journal impact factor, errors in references in medical literature, medical writers and ethical publishing practices, and the 'dark side of publishing'



Journal impact factor

The journal impact factor, approximately the average number of times that primary research papers published in 2 consecutive years are cited in the following year, is the most widely used method of assessing the quality of a journal. However, this metric also includes citations to other non-primary content such as reviews and news articles. Other shortcomings are that citations accumulate slowly in many fields, and the average number of citations per paper can be skewed by a few highly cited manuscripts. A recent editorial in *Nature Materials*[1] discusses the appropriate use of the impact factor. First they show that the impact factor of a journal is a good predictor of citations to primary research articles. For a sample of 100 journals across the spectrum of science and engineering (physical and chemical sciences, biological and medical sciences, earth and environmental sciences, engineering), the 2011 impact factor was found to correlate well with the 5-year median of citations to primary research papers published in 2008–2012. The values for the median correspond to the minimum number of citations received by half of the papers and are therefore robust to outliers and variations in the shape of the distribution. Citations to reviews, news, editorial material, and other non-primary research articles were excluded from the calculations of the median. The editorial then goes on to argue that the impact factor does not generally correlate with the performance of individual researchers. If the papers published 5 years ago by a scientist are ranked in decreasing order of citations alongside the impact factor of the corresponding journal in that year, there is generally a weak correlation at best with numerous outliers. Therefore, scientists should not be rated on the basis of their total number of publications weighted according to the impact factor of the journals where they have been published, as this is a poor indicator of the future performance of individual researchers. Rather, article-level metrics should be used when assessing a small subgroup of papers or authors, and impact factors should not be used in grant-giving, tenure, or appointment committees.

Errors in references in medical literature found to be higher than expected

The bibliography of references section is an important component of a manuscript, directing the reader to relevant background literature, allowing the work of other researchers to be acknowledged, and supporting the authors' statements. If an article contains many errors in the references, the accuracy of other information in the article may be doubted by the reader. The reference list is also used to help calculate the impact factor of a journal. It is therefore very important that all references are cited correctly, i.e. the reference citations should match the source exactly. Samad *et al.*[2] have compared two premier Pakistani medical journals (the *Journal of Pakistan Medical Association* [JPMA] and the *Journal of College of Physicians and Surgeons Pakistan* [JCPSP]) for errors in references of original articles published in the year 2008. All original articles published in these two journals were included in the study. Only journal citations were included in the study; references to other sources (books, internet articles, websites, newspapers) were excluded. All types of error were evaluated and categorised into author errors, article title errors, journal title errors, year of publication errors, volume errors, and page number errors. The data were analysed through SPSS 16.0. The Chi-square test was used to determine statistical significance; a difference with P-value ≤ 0.05 was considered statistically significant.

Two hundred articles (100 from each journal) fulfilled the selection criteria and were evaluated. Only 9.5% of articles (19/200) were completely free of any error in the references; there was no significant difference between the two journals ($P < 0.469$). In total, 3783 references were assessed; 1715 (45.3%) for JPMA and 2068 (54.7%) for JCPSP. The overall reference error was 1.015 (26.8%). There were 531 (31%) and 484 (23.4%) incorrect references in the JPMA and PCPSP, respectively, and the difference

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was not statistically significant ($P < 0.744$). The error most commonly observed was related to the author component ($n = 490$; 13%) followed by errors related to page numbers ($n = 297$; 7.9%), article title ($n = 222$; 5.9%), journal title ($n = 189$; 5%), volume ($n = 28$; 0.7%), and year ($n = 22$; 0.6%). JCPSP had more errors in the article title component ($P < 0.001$) and JPMA has more errors in journal title ($P < 0.001$) and page number ($P < 0.001$) components. No statistically significant differences were observed between the two journals regarding the other error components. The authors discuss their findings and compare their data with published reports of both local and international studies. They propose that the higher than expected magnitude of reference error may be rectified by more careful formatting of the initial manuscript and providing the final manuscript to the author for proofreading.

The role of medical writers in supporting ethical publishing practices

In a recently published review, Karen Shashok discusses the role that medical writers have in ensuring ethical publishing practices.[3] During the development of a manuscript for publication, the medical writer consults with the investigators about the purpose of the study and the main results, and prepares a first draft of the manuscript. The medical writer also co-ordinates the review process, preparing revised drafts of the manuscript in response to comments from the investigators until all the authors agree that the research has been reported accurately and effectively. During this process the medical writer should raise any concerns over possible spin and underreporting of results, although the investigators may choose to disregard such advice. The medical writer is responsible for ensuring the content of the manuscript is accurate and clear, whereas decisions about what information should be included are made by the investigators. Consequently, the medical writer does not generally qualify as an author as defined by the International Committee of Medical Journal Editors (ICMJE) criteria. Rather, the role of the medical writer should be disclosed in the acknowledgements section of the manuscript, as recommended by current professional guidelines. A list of guidelines that have been developed by medical writers and other stakeholders to ensure transparency and best professional practice, including the checklist to discourage ghostwriting, is included in the review. By following the steps outlined in these documents, medical writers can ensure that their work is professional and that their contributions are reported accurately. The review concludes with some suggestions for actions that could be undertaken by stakeholders to support ethical publishing practices. These include a switch to contributorship rather than authorship to make the roles of communication professionals, guest authors, and industry employees more transparent. Such a change is strongly supported by The Good Publication Practices Guidelines but has not yet been adopted by the ICMJE.

The 'dark side of publishing' in the era of open-access

In a recent article in the *New York Times*,[4] Gina Kolata puts the spotlight on 'a parallel world of pseudo-academia'. The article begins by describing how scientists who thought they had been selected to present to the leading professional association of scientists who study insects (Entomology 2013) discovered too late that they had in fact been signed up for Entomology-2013; the speakers for this conference had been recruited by email and were not vetted by leading academics. Those who agreed to appear were later charged a fee. Meanwhile, a doctor from Mexico who sent two articles to *The Journal of Clinical Case Reports* after receiving an email invitation was shocked to receive a bill for publishing after the articles were accepted. The journal eventually waived the publication fee.

The number of journals and conferences with names nearly identical to those of established, well-known publications and events has increased rapidly in recent years as scientific publishing has moved toward open-access, where authors or their funders pay for articles to be published online so that anyone can read them for free. Well-regarded, peer-reviewed journals such as those published by the Public Library of Medicine are listed in databases like PubMed. However, some researchers feel that there has been a rapid increase in the number of online journals that appear to print anything for a fee. Some academics report that they have found it very difficult, sometimes impossible, to get themselves removed from the editorial board of such journals once they have mistakenly agreed to become members. Another researcher, a plant pathologist who accepted an invitation to serve on the editorial board of Plant Pathology and Microbiology, reports that he found that he was listed as an organiser and speaker on a website advertising Entomology-2013; the publisher of the plant journal was also organising the entomology conference. It took many weeks for the publisher to comply with a request from the researcher to be removed from the website and journal editorial board.

A recent news report in *Nature*[5] highlights the 'rise of questionable operators' and discussed if

these journals should be blacklisted or if it would be better to create a 'white-list' of open-access journals that meet certain standards. The article also includes a checklist on 'how to perform due diligence before submitting to a journal or a publisher'.

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The Webscout

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Pricing and reimbursement

Public health funding constitutes a big part of European social systems' expenditures. Governments and health insurance companies are thus interested in reducing spending. Applying pricing initiatives to innovative products confronts pharmaceutical companies with problems in the context of new product launches. The financial crisis in Europe has increased the pressure, as noted by the European Federation of Pharmaceutical Industries and Associations:

http://www.efpia.eu/topics/industry-economy/pricing-of-medicines

When initiating price control measures, EU Member States must follow the EU transparency directive, which can be found at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0105:en:HTML

This directive, however, leaves governments substantial freedom in how to regulate the market.

One way of saving money within the healthcare system is to reduce medication costs by regulating pricing and reimbursement. In general, this can be regarded as a common goal of European countries.

Approaches to regulate the pharmaceutical market differ greatly between countries. A number of practices have been established – price control, cost-sharing, reference pricing, and generics policies.

Price regulation is used by many countries, including Sweden and the UK. Usually, a ceiling price is determined, initially limited to a certain product, and, later, the ceiling price is applied to the whole product class. Details of price regulation methods differ between countries, leading to different prices for the same medication in different countries. Ways to determine the price may include evidence-based evaluation of clinical data and price negotiations. A report by the Andalusian School of Public Health that summarises six established practices of pricing and reimbursement, including price regulation and reference pricing, can be found at:

http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/study_pricing_2007/andalusian_school_public_health_report_pricing_2007_en.pdf

Often health economic and health technology assessment tools are used in these processes. Pharmacoeconomic methods and tools were introduced in a previous issue of the Webscout.[1]

Besides methods for regulating prices, reimbursement is regulated to reduce healthcare costs. Reimbursable products most often are subject to price control, whereas non-reimbursable products usually allow for free pricing. The same applies to generics. Many countries regulate generics by linking the price to that of the originator including a predefined deduction of 20–50%. A recent survey analysed the effect of pricing and reimbursement initiatives with respect to generics. The report can be found here:

http://gabi-journal.net/the-impact-of-pharmaceutical-pricing-and-reimbursement-policies-on-generics-uptake-implementation-of-policy-options-on-generics-in-29-european-countries%e2%94%80an-overview.html

European countries continue to optimise their pricing and reimbursement processes. This results in a wide variety of procedures across Europe. Networking activities should help spread knowledge in this field between countries. The Health Economics Department of the Austrian Health Institute has been designated a WHO collaborating centre for pharmaceutical pricing and reimbursement policies to help these networking initiatives. Their website is an excellent source of information about pricing for those of you who want to continue reading about this topic:

http://whocc.goeg.at/

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Regulatory Writing

Developments in paediatric regulation

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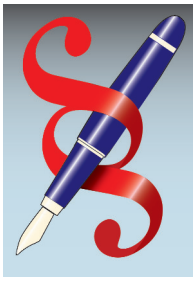

Abstract

Recently, both sides of the Atlantic have seen developments in paediatric regulation. In Europe, the EMA has published a new template for the paediatric investigation plan (PIP), which should help dispel some (but by no means all) doubts and inconsistencies regarding the PIP document. In the USA, the Food and Drug Administration Safety and Innovations Act (FDASIA) has effectively made it mandatory to submit a paediatric study plan (PSP, the US equivalent of a PIP) soon after completion of phase II of development. Drug companies will need to work out how best to manage having two approved plans in parallel and avoid discrepancies.

Keywords: Paediatric investigation plan, PIP, Paediatric study plan, PSP

Those of you who have taken a recent EMWA workshop on paediatric investigation plans (PIPs) will be aware that it is not always easy to second guess what the Paediatric Development Committee (PDCO) – the EMA body responsible for reviewing the PIPs – is looking for. Briefly, for readers who are not familiar with paediatric regulation, a PIP is a document that a company prepares during clinical development of a new investigational medicinal product. It outlines the plan for development in children and the broad aim of this requirement is to ensure that appropriate paediatric studies are performed so that treating children with innovative products is no longer largely a matter of guesswork. An approved PIP (or a PIP waiver if the company does not believe that paediatric development is necessary or feasible) is mandatory for approval of a product in adults. After approval in adults, the PIP is checked for compliance, that is, whether the company has done what it said it would. Approval can be revoked in the event that the company has not complied with its obligations. In general, the company will try to limit the scope of the commitments as far as possible, particularly as it is hard to predict the exact direction of future clinical development and the company wants to avoid studies that add no value to their product.

The PIP guidance was sometimes contradictory as to the exact content and structure of the scientific part (i.e. Sections B–E), perhaps because the legislation was new and everyone was on a learning curve. The seemingly erratic header numbering, with a mixture of letters and Arabic and Roman numerals, did not help matters. Companies for the most part would be keen to produce compliant PIPs, but the way forward was not always clear.

European developments: New PIP template

Recently, some of the uncertainties would seem to have been cleared up with the publishing of a new PIP template on the EMA website in February.[1] The headings are largely equivalent to headings indicated under previous guidance. However, the new template provides the exact structure that the PDCO is expecting to see in the PIP document (it states on the EMA website that 'applicants are invited to use the preformatted template', which I think we can take as 'use this template'), as well as slightly more detailed guidance as to the sort of content that is expected under each heading.

One of the main novelties is the new 'key binding elements' forms. These outline what the applicant is actually committing to, and will be used to check compliance with the PIP during and after approval. Compared with the previous synopsis forms, these new forms contain less information, which is good from the companies' point of view. This will probably make PIP writing easier because the actual commitments will often be what generate most discussion within a team working on a PIP. That is not to say that the clinical strategy does not have to be carefully thought out and presented in the PIP document.

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Paediatric regulation in the USA

There have also been developments in paediatric regulations in the USA, with the Food and Drug Administration Safety and Innovations Act (FDASIA) being signed into law last year.[2] Part of the FDASIA included provisions for strengthening existing legislation on paediatric development (Pediatric Research Equity Act (PREA) and Best Pharmaceuticals for Children Act (BPCA)). Before, a paediatric study plan (PSP), the US equivalent of the PIP, could be submitted after the product had been approved in adults. Now, it must be submitted at the end of phase II development (within 60 days of the end-of-phase-II meeting), although it can be submitted earlier. This is more in line with the PIP, which should be submitted as early as possible (and preferably when adult pharmacokinetic data are available, that is, before phase II). The requirement for an early submission gives the agencies a much greater say in the paediatric development and can ensure that the paediatric programme is sufficiently detailed and, importantly, expedite paediatric approval and so reduce the window of off-label use in children (with the greater uncertainties about dosing, efficacy, or safety).

In addition to the different timing in the submission, there are other differences that are worth highlighting. First, the structure of the two documents is different (see Table 1). Although the PIP structure appears much more complex, if both documents adhere strictly to guidance, they should be of similar length (in the case of a PIP, the Q&A section on the EMA website suggests a maximum of 50 pages per condition, while a PSP should not exceed approximately 60 pages if the lengths for each section indicated in the template are observed[3]). Often, some of the material from one type of plan can be slotted into another; for example, material from Section B.1.1 of the PIP could be used in Section 1 of the PSP. Adaptation will often be necessary, however. The epidemiological data in particular will require a European focus for the PIP and a US focus for the PSP. In addition, the approach to waivers is somewhat different. In the case of a PIP, the grounds can be expected lack of efficacy and safety, disease not occurring in the target population (and this means almost literally zero cases, not just extremely low incidence or prevalence), and lack of significant therapeutic benefit. Like a PIP, a PSP waiver can also be granted for expected (i) lack of efficacy and/or

Table 1: Comparison of structure of paediatric investigation plan (PIP – EU) and paediatric study plan (PSP – USA)

PIP	PSP
Part B – Overall development of the medicinal product	***Part E – Applications for deferrals***
B.1. Discussion on similarities and differences and pharmacological rationale	1. Overview of the disease in the paediatric population
B.1.1. Similarities and differences of the disease/condition between populations	2. Overview of the drug or biological product
B.1.2. Pharmacological rationale and explanation	3. Overview of extrapolation to specific paediatric populations
B.2. Current methods of diagnosis, prevention, or treatment in paediatric populations	4. Request for product-specific waivers
B.3. Significant therapeutic benefit/fulfilment of therapeutic needs	5. Summary table of planned non-clinical and clinical studies
Part C – Applications for product-specific waivers	6. Paediatric formulation development
C.1. Overview of the waiver request(s)	7. Non-clinical studies
C.2. Grounds for a product-specific waiver	8. Addition data to support studies in children
C.2.1. Grounds based on lack of efficacy or safety	9. Clinical studies
C.2.2. Grounds based on the disease or condition not occurring in the specified paediatric subset(s)	9.1 Paediatric clinical studies
C.2.3. *Grounds based on lack of significant therapeutic benefit*	9.2 Clinical effectiveness and safety studies
Part D – PIP	10. Timeline of the paediatric development plan
D.1. Existing data and overall strategy proposed for the paediatric development	11. Plan to request deferral of paediatric studies
D.1.1. Paediatric investigation plan indication	12. Agreements for paediatric studies with other regulatory authorities
D.1.2. Selected paediatric subset(s)	
D.1.3. Information on the existing quality, non-clinical, and clinical data	
D.2. Quality aspects	
D.2.1. Strategy in relation to quality aspects	
D.2.2. Outline of each of the planned and/or ongoing studies and steps in the pharmaceutical development	
D.3. Non-clinical aspects	
D.3.1. Strategy in relation to non-clinical aspects	
D.3.2. Overall summary table of all planned and/or ongoing non-clinical studies	
D.3.3. Synopsis/outline of protocol of each of the planned and/or ongoing non-clinical studies	
D.4. Clinical aspects	
D.4.1. Strategy in relation to clinical aspects	
D.4.2. Overall summary table of all planned and/or ongoing clinical studies	
D.4.3. Synopsis/outline of protocol of each of the planned and/or ongoing clinical studies	
D.5. Timelines of measures in the PIP	

safety or (ii) lack of significant therapeutic benefit. In the case of a PSP however, the third category is 'necessary studies are impossible or highly impracticable (because for example, the number of patients is small…)'.[4] My reading of this is that epidemiological arguments of low patient numbers are more likely to be successful in a PSP. For particular age groups, the PSP can also include partial waivers based on difficulties developing an appropriate paediatric formulation. In the USA, if a waiver is granted on the grounds of expected lack of efficacy or safety, this must then be reflected explicitly in the product label.

New challenges

As a result of these new developments in the USA, regulatory affairs departments will now face the challenge of managing two paediatric plans with different timelines and somewhat different formats, while attempting to maintain an overall coherence in global paediatric development. This may be particularly problematic when the PIP and PSP review procedures overlap. The supposed greater dialogue between the EMA and the US FDA may in principle help limit diverging opinions, but differences will surely arise from time to time, given the different structures of the document and differences in the underlying legislation. The companies themselves will be keen to ensure that the commitments of the PIP and PSP are fully compatible to avoid further unnecessary burdens on the company. For the moment, both companies and agencies are still feeling their way.

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English Grammar and Style

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We have three articles in this edition. Pamela Haendler's contribution deals with the medical writer as a reviewer and quality checker. Because of their close involvement with all of the documentation on a project, the medical writers involved are often the only members of the team who have an overview across documents. This inevitably results in the medical writer – in the regulatory area at least – taking on the function of a reviewer and quality control person, ensuring consistency across documentation and compliance with guidelines. Pamela has some recommendations on how to handle this. Our first GWP article continues Debbie Jordan's deliberations on 'Writing for the Audience', this time covering regulatory documents, journal articles, and writing for the public and official websites of government agencies. This is complemented by Alistair Kidd's reflections on 'appropriate tone' in scientific and medical writing under Points of view, where he highlights the importance of pitching the level of language correctly for the expected audience.

Good Writing Practice

GWP is not a formal set of rules about how to write.[1] The aim is to highlight that the focus of all writers should always be on their readers, providing advice on practical aspects of writing to make texts easier to write and read. The aim is to keep contributions short so that a variety of topics can be covered in each issue. If you have any ideas or wish to agree or disagree with any of the advice or add new aspects, please do send in a contribution to Wendy Kingdom (info@wendykingdom.com) or Alistair Reeves (a.reeves@ascribe.de), however long or short. Ultimately, we hope to bring everything together in an EMWA Publication.

Reference

1. Reeves A, Kingdom W. Good Writing Practice. TWS 2010;19(4):281.

Writing for the Audience (2)

Following on from part 1 of Writing for the Audience,[1] which outlined some basic principles, I would now like to develop this topic by considering the various audiences we write for and the key features of each style of writing.

Regulatory documents

Regulatory documents are structured and there are many guidance documents that specify the format. So we are often constrained by these guidelines when writing regulatory documents. However, in most cases the guidance templates are just that and are for *guidance*. They are not enshrined in law. It is better to adapt the structure so that it helps the reader rather than sticking to the letter of the template and making it hard for the reviewer to navigate through the document. When writing these documents, you need to consider that the audience is a highly educated and qualified person at the regulatory agency who is capable of reading and understanding scientific information. So be wary of 'dumbing down' the information too much, i.e. there is no need to spell out in full abbreviations such as UK and USA. Regulatory documents should be scientific and factual with no room for ambiguity or interpretation. However, they should also be easy to read so do not overcomplicate the language or use technical jargon because you think it sounds more intelligent. You should avoid large blocks of text; use bullet points and section headings to guide the reader, particularly in a study protocol. You can also help the reader by putting all of the information relating to one topic in the same place so that it can be found easily, and by putting similar topics close together.

Journal articles

A journal article should provide new information to the scientific community. Journals vary in their target audience, the degree of technical information

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required, and their instructions for authors, but most are specialist journals targeted at a specific audience that is interested in a particular therapeutic area. As such, most of the readers are familiar with the medical issues in the therapeutic area, so it is not appropriate to include lengthy background information on the disease or current treatments. The focus should be on what is new, or the unmet need that is being filled by the research. People rarely read a journal from cover to cover; they skim through it, and most readers will read only the title, and if interested, the abstract. Therefore, the title and abstract should capture the reader's attention so that they want to read more. Remember that the key messages for a publication may be different from that of the clinical study report (CSR) – the CSR systematically reports the results of the study endpoints, but the purposes of a publication are to provide new information to the medical community and to add to current medical knowledge, which includes negative as well as positive information.

Writing for the public

Examples of writing for the public are the patient information leaflet for a clinical trial and the package insert for a marketed product. When writing for the public, it is important to bear in mind that the patient is usually not interested in the fact that a study is being conducted or the research in general; the patient is interested in taking something that will cure their illness, alleviate their symptoms, or reduce their risk of a serious event, such as a stroke. Therefore, you need to address the person and focus on what is important to them. Your language should address the individual who is reading the leaflet, e.g. 'you will be asked to come to the hospital three times', rather than the impersonal language used in other documents such as 'the patient will need to attend the hospital for three visits'. The patients are unlikely to be medical experts, so the language needs to be straightforward. In particular, avoid medical and technical jargon. However, you should not treat the patient like an idiot and oversimplify the information so that it becomes inaccurate or unclear. For example, stating that 'the tablets may affect your bowels' could mean that the tablets may cause diarrhoea, constipation, wind, or something else. The text also needs to present a professional image in terms of language and appearance since this is the company's only direct communication with the patient. The information should also be ordered logically, which might mean that it differs from the order of the trial conduct. For example, it might be appropriate to inform the patient that they will have blood samples taken five times during the study, rather than listing the tests to be done at each visit. It is important to remember the message that you need to convey to the patient – the patient does not need to understand how to do the study and they do not need extensive details on the disease. However, they do need to understand what will be done to them, and the risks and benefits of taking part. It is always useful to ask a lay person, who is not familiar with the study, to read a draft of the document and ask them to point out any parts that they do not understand.

Writing regulatory information to be published on official websites

Details of protocols of all clinical trials now have to be published on a public website, and there are moves to make it mandatory in Europe to publish all results of clinical trials (it is already mandatory in the USA). Most companies post the synopses from the CSRs on their own websites, but it might become a requirement to provide both a technical summary and a summary suitable for a lay person. The published information is available to patients, patient lobby groups, physicians, and opinion leaders, as well as to competitors developing similar products and the generic companies. The varied audience of these documents presents a challenge to the medical writer, since there is a delicate balance between providing enough information to be transparent, without providing company sensitive information to competitors or journalists. The requirement to provide a lay version as well as the technical CSR synopsis might help to define the audience for each document more accurately, and to avoid the current situation of trying to write a synopsis that is an accurate summary of the CSR for the regulatory authorities, but understandable to the lay person.

In summary, it is important to think about the audience for each document you write and to target the language, layout, and style appropriately. Medical writers are increasingly relied upon to have the skills and the expertise to mould their work and writing style as required, and the best way to do this is to think about the reader (the audience) and their requirements.

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Are medical writers and editors also reviewers and quality checkers?

Despite their name, medical writers often spend as much of their time reviewing documents as writing them. However, the scope of review is seldom as well defined as the task of writing. If you are assigned to write a clinical study report, the understanding is usually that you will produce a final report, complete with in-text tables, a hyperlinked table of contents, and a list of abbreviations. A number check and technical quality check (QC) might be negotiated too, but these should be done by someone else, either in your organisation or outside of it, even if you are responsible for getting them done.

The review of documents by medical writers often leaves room for much interpretation, so a priority should be to clarify the scope of the review and the time available. I can roughly divide the texts I review into the following categories:

- Outsourced regulatory document owned by Medical Writing (e.g. CSR)
- Regulatory document owned by Medical Writing and written by colleague
- Regulatory document not owned by Medical Writing (e.g. Statistical Analysis Plan)
- Non-regulatory company document requiring official input from Medical Writing (e.g. Standard Operating Procedure [SOP])
- Presentation slides
- Publication
- Website or other text

Whatever category the text falls into, I also need to define the capacity in which I am reviewing, i.e. as a medical writer, a native English speaker, a mentor, or maybe just as a second pair of eyes. In these different capacities my role will vary, and with it the style and extent of my review. How much of the text I then permit myself to correct will depend on my role and what I feel is the extent of my responsibility.

The aspects of the review can be divided into what I consider to be formal requirements, content, consistency, and language.

Formal requirements

Any regulatory document coming out of a Medical Writing department must adhere to the formal requirements of authority guidelines and company SOPs and templates. On this level, medical writers should have the full authority to change the text and bring it in line, indeed it is their job to do so. The correct numbering of paragraphs, tables, and figures could be seen as formal requirements too, but these are often reviewed as part of a technical QC done separately.

Content

The extent to which medical writers can review the content of the text will vary enormously and it is difficult to come up with hard and fast rules about what the extent of our involvement should be. My recommendation would be only to go as far as you are able and confident to go, and to remember that most documents are the result of team work, and teams have their specialists. Medical writers can make an important contribution by asking questions of the other specialists, but any interpretation must be made with great care. We may notice points that in some way trouble us, even if we do not have the necessary scientific, statistical, or medical background to fully grasp the complexities, and this can be very helpful to authors. Note: it is quite possible to perform a detailed review of all other aspects of a text while actually understanding little of the content.

Consistency

The ability to write consistently and coherently is a pre-requisite for medical writers. Equally, as reviewers we are often the ones to point out inconsistencies, and this aspect of reviewing has to be one of the most important, regardless of the type of text we are dealing with. Inconsistencies look sloppy and can lead to confusion, but ironing them out can be painstaking work that invariably takes much longer than anticipated. If you have already worked on other documents from the same project, you will have insight that the author might not have, and as well as making the text consistent in itself, you will want to compare it with other texts. Such a full review needs to be agreed up front if you are to have the time to do it thoroughly. It should be noted, however, that it really is a job worth doing, whether or not you stand to benefit personally from such harmonisation, e.g. when writing the clinical summaries. The project, whatever it is, will definitely benefit.

Language

As a native English speaker living in Germany, I am often asked to 'take a look at the English'. This in itself can be interpreted in many ways, and depending on whom the request comes from and the type of text it is, can mean anything from 'could you read this and make sure I haven't made any howling mistakes' to 'could you read this, translate the bits I couldn't, re-phrase as necessary, and while you're about it use your amazing Word skills to make this rough draft suitable for publication?'.

The language review might be the most difficult one to gauge beforehand, unless you know the quality of the work the author is likely to produce. All writers are familiar with the length of time it can sometimes take to formulate a single sentence satisfactorily, and having someone else's imperfect draft in front of you does not necessarily make the job easier.

Making language corrections is also a very sensitive issue. Authors do not usually take offence at having the SOP quoted at them – many will take pleasure in explaining the intricacies of their subject to the uninitiated, and are grateful to a nit-picker for pointing out their inconsistencies – but hardly anyone enjoys having their prose pulled apart by someone else. Reviewers need to tread carefully! Knowing when it is not appropriate to correct a text, due to the author's individual style or personal preferences, or when it is simply out of the scope of the mandate, is essential. If you start micro-editing you need to see it through to the end, and after 5 pages of an 80-page document you might realise that you have wildly underestimated the amount of work involved. If you only have half a day to review a long document, try to establish what the absolute minimum is. While you are reading through and checking consistency, get a feeling for the style. You might notice recurring mistakes in vocabulary or grammatical errors, and you could decide to correct these, even if you have no time for a full-text review. But it is wise to make the extent of your corrections clear to the author. We have all heard the complaint of '… but I had it checked by a native speaker!'.

So, if you want to avoid the pitfalls and be appreciated for your honest reviewing, stick to your own rules, which might look something like this:

- Clarify the level of review the author expects.
- Establish whether anyone else is doing an official QC or number check.
- Ensure that you can fit the expected feedback into the time you have.
- Once agreed, do not exceed the mandate.
- Do not attempt to make the text sound like your own.
- If in doubt, leave well alone.

You might then become a favourite reviewer and get more work than you actually want, but you will be accused neither of skimming nor of nit-picking.

Anyone who needs more advice on reviewing and where to draw the line on correcting other people's texts might like to read the following articles that appeared in MEW last year:

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2. Reeves A. Lost causes (2) MEW 2012;21(4):319.
3. Kingdom W. Consistency MEW 2012;21(1):74.

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Points of view

Appropriate tone: a sprinkling of subjectivity over painstaking, objective research

Tone in writing is difficult to define, but it is generally agreed that tone reflects the author's attitude to the subject. Note that I write 'reflects'. It need not necessarily *be* the author's attitude (after all, as an author you can appear to the reader to be fully engaged – or even enthusiastic – but actually be bored by the subject and need a holiday). If we use this reflection of attitude as a working definition, then it begs the question 'what attitude is best reflected in medical writing?'.

A scientific attitude? What exactly is that? The words 'objective' and 'impartial' spring to mind. If you use a neutral, balanced tone, it may make the reader feel confident that you are not being overly biased in your conclusions. And that is surely a good thing. (Of course, this is entirely separate from any bias there may be in the choice of data presented, which is another issue altogether.) It is also important that the reader

feels that he/she is being treated as an equal and not being patronised, so words like 'obviously' have no place in scientific writing.

Let's take this idea of reflecting a neutral, balanced attitude one step further. How do we achieve it? Avoidance of strong language, humour, and contractions will obviously bring the reader closer to accepting my credentials as a serious scientist, but is it all about choice of words? Can I command respect in other ways? The grammar must of course be up to scratch for the author(s) to be taken seriously. How much abstraction you use and how you handle strings of nouns may also play a part. And then there is the issue of voice. Nowadays, the lack of single-author papers has led to a changeover to the active voice. It is much more comfortable to write 'we' than to write 'I'. I believe that using a good balance between active and passive voice is smart because in a subtle way it reflects the same all-pervading balanced attitude to the subject that should be apparent throughout the document.

You can also affect the tone of a document if your work with tenses isn't quite right. In my experience, one crucial consideration in this context is figure legends (captions). These often require far more work in this respect than the authors are prepared to give to them.

Let us now consider choice of words. How important is it? If you are faced with two or more synonyms for exactly the same thing, how do you make the choice? This is surely the most difficult part of handling tone in a scientific document, as it is so subjective. Those who read my contribution in the December issue about the use of 'seems' and 'appears' got a taste of what I mean here. Some feedback from other medical writers was entirely in line with my own ideas, and some of the feedback – often from people with a linguistic background – indicated that there was a clear difference of opinion.

Consider the phrases 'we think that…' and 'we believe that…' in the Discussion section of a scientific paper. Most native English speakers would say that 'think' is too informal here and that in the right context 'believe' would be quite acceptable. But the difference in meaning is difficult to explain, as both words have a range of meanings and they certainly overlap. So why would we prefer 'believe'? I can continue with other synonym pairs: *nearly* and *almost*, *maybe* and *perhaps, too* and *also*, *big* and *large*. Is it because we use the first of the pair more in everyday conversation?

What about words that help us with arguments, such as 'therefore', 'thus', and 'hence'? I hear some of you cringe – '*hence*'? This word belongs more and more to the past, but fields that rely wholly on logic (such as mathematics) actively use it and they will probably retain it. Where do you stand on use of the words 'thus' and 'hence'? Are they too stuffy? Perhaps you still use 'thus' but have shifted your way of using it so that it no longer starts a sentence? Or perhaps you *only* use it at the start of a sentence?

Have you thought about when you use 'approximately' and when you use 'about'? Some people would say that 'around' is too informal for scientific writing. Where do you stand on this issue?

We all have our own opinions and biases. It would be difficult to find two individuals working in medical writing who have exactly the same range of preferences and behaviour patterns concerning choice of words. Fortunately there are trends in these preferences, though, and we should perhaps value these trends more than we do. They are all that we have. There are no definitive guidelines on scientific tone, and perhaps that is a good thing. Some authors of recent books on writing in biomedical research don't even mention the concept of tone (perhaps because they assume that it is intuitive). They do say, though, that you should use the simplest word that expresses your meaning, which will certainly help eradicate the use of pompous tone, and quite rightly ('showed' rather than 'exhibited', for example). This is often used by insecure newcomers to medical writing, either consciously or subconsciously, for the sake of impressing.

A related issue: apart from choice of words, we must consider choice of phrases. Some books refer to *empty phrases* or even *dead wood*: material that stands in the way of the direct message. Do you like the phrase 'in order to', for example, when you can simply use 'to'? But does this really affect the tone? I am not sure, unless the whole document is dogged by empty, time-wasting phrases such as 'displays the presence of', 'is often subject to', 'in close proximity to', 'it has recently been found that' and so on. In such cases, the reader will quickly develop a negative attitude to the tone of the author(s)!

We must also be prepared to adapt to developments in tone in scientific writing: for example, the extinction of some terms and the ever-increasing use of others (such as 'impact', which I have personally avoided until now because I feel that, whether it is used as a noun or a verb, it always looks like an exaggeration).

If the choice of words and phrases to give appropriate scientific tone is so subjective and perhaps even controversial, isn't this a very serious consideration when trying to publish what might amount to years of scientific work, which has cost many thousands – if not millions – of euros? When so many people entrust us with work which has serious consequences for them and perhaps even for society as a whole, it feels good to have EMWA and *Medical Writing*, a line of communication and bouncing board that actually works.

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Answers to Medical Writing Jumble #8:
GROSS, WOUND, BLOCK, MARKET
'The entomologist spent more time in the library than in field work because he was a BOOKWORM'.

Medical Journalism

How I evolved from a veterinarian to a medical journalist and PR consultant

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medical journalism

Rather a pen than a scalpel

Before I write about my way from vet to journalist, I would like to make clear that neither my love for animals nor my admiration for James Herriot was the reason why I became a vet. When I was a kid, I dreamt, like many little girls, of being a vet because I loved animals and wanted to save them all. But I realised early on that loving animals only seems to be a strong motivation to study veterinary medicine at first glance, and it is not really a good reason to do so.

Unrequited love is not an option

Loving animals as the only motivation for being a vet would make this career choice frustrating, as most animals hate vets. Lifelong dedication to an unrequited love may be a romantic idea for teenagers, but it is not an option for adults. In addition, as a vet you have to do a lot of unpleasant things, such as monitoring the slaughtering of cattle or doing research on laboratory animals, which are difficult to reconcile with a naïve love for animals. Do not misunderstand me: all the vets I know do love animals, but they are also professionally committed to the well-being of humans, be it in research or in food manufacturing.

I always loved to watch the BBC series 'All Creatures Great and Small', which was produced based on the stories of the veterinarian James Alfred Wight, better known under his pen name of James Herriot. The main character of the series worked as a veterinarian in the 1940s and 1950s in rural Yorkshire. The series was very popular in Germany and created an idealistic image of the veterinary profession. James Herriot was surely the hero of most veterinary students of my age, but we all knew that the vet's life Wight was describing in his stories would have nothing to do with the work of a vet nowadays.

What really convinced me to study veterinary medicine was the broad variety of subjects that vet students have to learn. Veterinary medicine is nowadays so much more than vaccinating cows or neutering cats. I had to learn, for instance, how to distinguish good grazing land from bad, as well as receptor theory, which colour of egg yolk consumers prefer, how the complement system functions, how cheese is produced, and tumour cell pathology.

The gap between medicine for humans and medicine for pets is shrinking more and more. Research, diagnostics, and therapy in small animal medicine do not differ much from the methods in human medicine. New treatment options such as immunotherapy and gene therapy are not only tested in laboratory animals, but also they are used in them. In modern veterinary clinics, pets benefit from the results of the latest medical research.

Journalism training

As much as I liked the variety of subjects of veterinary medicine, I disliked the practical work once I was a vet. I found out that I was much better at explaining complex biological and medical issues to the owners of the animals than doing surgery. On top of this, I always loved writing. My teachers at school regarded me as a gifted writer of German and always encouraged me to study German literature instead of veterinary medicine. After a year of veterinary practice, I realised that my teachers were probably right and that working with words would be a better choice for the rest of my life.

Of course I knew that enthusiasm is not enough to be a professional writer, so I decided to study journalism by taking a year-long postgraduate course. I learned writing techniques for different target groups and media and acquired knowledge of journalistic research, media law, ethics, and standards of good journalism. The course also included training in communication skills and PR.

After finishing the course I got a job as an editor for the pet owner magazines of Gong Verlag, a publishing company in Munich. This period was crucial for getting practical experience in journalism and for learning a lot about the needs and expectations of readers without a medical background.

KISS the reader: Keep it short and simple

Writing about medical or biological issues for lay readers first of all means thinking about what is really interesting for the audience. What is important for them to know? What is exciting for a scientist may be boring for a lay reader. Students and

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professionals often have to read texts which they find exhausting or difficult. Unfortunately, you cannot force buyers of a pet magazine to read a certain article. If the reader is bored, he or she just quits, switches on the TV, or goes for a walk with the dog.

Just as important as finding an interesting subject is making yourself understood. People reading articles during their leisure time do not want to Google technical terms. They do not want to think too hard. If they do not understand a sentence immediately, they will give up. However, even if the reader is interested in the subject and thrilled by the story, he or she will not be willing to spend half a day reading it. Most readers prefer brief texts, so I learned to keep it short and simple.

I really enjoyed my work as a magazine editor, but after two and a half years I quit this job because I had an offer to become the press officer of the Bavarian State Chamber of Veterinarians (Bayerische Landestierärztekammer). As a press officer I could apply the PR knowledge I acquired in the journalism course. I got to write texts for a great variety of readers, including press releases for lay or professional publications, as well as speeches and official protocols. While working as a press officer, I started to write as a part-time freelancer. As I got more and more writing assignments from publishing companies, as well as from clients in industry and commerce, I decided to freelance full-time and left my employment.

Freelancing in the press and in PR

I have been working as a freelance journalist and PR consultant for nearly 10 years now. Ethically, the combination of journalism and PR is a delicate mixture: as soon as you start working for a company you are inevitably biased, but as a journalist you have to be impartial. So it is crucial to strictly separate PR jobs from journalism. Therefore, as a journalist, I never write articles about products or services I had to deal with in a PR job.

In the past I sometimes had customers who did not understand how important this ethical rule is. It was not always easy for me to decline their projects because it could mean missing out on a profitable contract. But I never regretted these ethical decisions. A lot of my customers appreciate my ethical standards because they know they can trust me.

Confidence, however, is the basis of many jobs I get. For example, I am often involved in preparations for the launch of a new product. Customers have to rely on my utmost discretion when I am writing press releases, product brochures, or other information months in advance of the actual launch. As many of my clients have been loyal to me for years, they seem to be content with my work and trustworthiness.

Medical writing?

In the summer of 2012, a client asked me whether I was a medical writer. At that point I had never heard that expression. So I did a little research on the Internet and found EMWA. The broad range of workshops appealed to me and I became a member. I went to my first EMWA conference in Berlin last year and attended my first workshop. I was delighted with the atmosphere at the conference and enthusiastic about the quality of the workshops I attended. While Berlin was superb, Manchester was even better.

I am mainly interested in medical communications workshops, but to open up my horizons I also attend basic workshops on regulatory affairs. I do not know whether I will ever get involved in regulatory writing, but having an idea of what it is and what kind of documents exist has already helped me to communicate better with my clients in the pharmaceutical industry.

I am very happy with my professional life as a medical communicator. The opportunity to continue studying new topics and the great variety of tasks are inspiring. I really love to translate exciting science into understandable and hopefully thrilling stories, be it for lay readers or for doctors (who also appreciate short and simple articles after a long day of hard work).

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Medical Communications

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Dear all,

Having left the office for 5 days to go to the EMWA Spring Conference, I returned to the obligatory email avalanche. While it was mostly junk (and unfortunately still no 'congratulations on winning the lottery' message…), there were some messages from friends I had just seen at the conference, and this reminded me again what a special organisation EMWA really is. I have spent a long time doing 'the conference circuit' both as an academic and as a medical writer covering meetings and helping to create them, but I have never before come across an organisation that can offer excellent training, great networking, and the chance to meet people so open and willing to help others in their field. That all of this is done voluntarily by the workshop leaders and members of the EMWA committees is just astounding, but is testament to how much EMWA means to everyone involved. This year's Spring Conference was another record breaker – over 400 delegates attended and the theme was 'Health Economics and Market Access'. There were some fantastic symposia throughout the week, and the opening session was a MedComms Networking event, run jointly by EMWA and Network Pharma Ltd: 'Better communication means better patient outcomes: vision or illusion?'. This session also let us all play with some gadgetry – IML hand-held keypads that allowed delegates to interact directly with the session chair, asking questions, making comments, or answering questions set by the panel. Great fun, and obviously with a valuable application for meetings (when not in the hands of a bunch of medical writers!).

For anyone unable to get to the Spring Conference this year, this section has a brief summary of this really interesting session. I hope you find it useful, and I hope to see you in Barcelona in November!

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EMWA Spring Conference 2013 – Networking Event and Welcome Lecture

Better communication means better patient outcomes: Vision or illusion?

This session was led by Mark Duman, Director of MD Healthcare Consultants and Chair of the Patient Information Forum (PiF). The audience was introduced to the IML kepypads and in a few clicks of the buttons it was established that the audience was composed of 89% EMWA members, and in terms of main work areas, 27% of the audience were 'regulatory/CRO writers'.

Mark then introduced the panel: Eveline Wesby-van Swaay (a Global Safety Physician from AstraZeneca), Ben Bridgewater (a Consultant Cardiac Surgeon from University Hospital of South Manchester), Paul Woods (a Compliance and Ethics consultant, ex-AstraZeneca and previous Chair of the European Federation of Pharmaceutical Industries and Associations [EFPIA] Information to Patients Task Force), and Jane Lamprill (who runs a paediatric research consultancy).

Mark started by asking the audience if they were 'patients'. In all, 53% said 'no' (10% 'didn't know'!), and he explained that we are *all* potential patients (the panel included) – a very important point considering the topic of the session. He explained that consumer health information (CHI) concerns helping patients and the public make informed decisions about their lifestyle and well-being, their medical conditions and treatments, and their choice of provider (a new concept in the UK). In all, 41% of the audience had never worked on CHI, but Mark explained that the quality of the information provided to patients is vital in effecting positive outcomes; preventing diseases, and allowing patients to control their health.

The PiF has produced a report showing the power of high-quality information, but there are still many challenges: CHI is not integrated into patient care provision, there is a lack of quality standards, a low level of investment, too much duplication, a

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focus on measuring provision rather than outcomes, and a lack of recognition of the expertise required. In addition, clinicians have very little ongoing education about communication skills, and there is not enough acknowledgement that 'one size' does not fit all patients. This was confirmed by the audience, who returned a wide range of answers to the question 'how well informed were you the last time you had to make a medical decision?'.

Paul Woods explained that EFPIA aims to promote factual, non-promotional information, and suggested that in the future, medical writers could use their skills in social media, as well as in traditional formats, to provide non-promotional information to patients. He suggested that in pharmaceutical companies, medical departments should assume responsibility for patient information rather than marketing departments.

Eveline Wesby-van Swaay outlined the difficulties of explaining medical information to patients, which are caused by the variety in patients' ability to understand and interpret medical data. She stressed that information should be tailored to individuals as much as possible, and that the drop in MMR vaccination rates is a good example of how important it is to explain scientific data to patients clearly and in a non-promotional way. Eveline proposed that if Andrew Wakefield's study had been properly explained to the general public, the MMR vaccine may not have received such a negative response.

Ben Bridgewater concurred, and has found that the public have a huge appetite for scientific and medical data. His own experience is in the publication of cardiac surgery outcomes and the transparency in this area has led to decreased mortality rates and improved cardiac outcomes. Such transparency is being embraced in the UK. However, Ben emphasised that information must be contextualised for patients; they should not just be given 'raw data'.

Jane Lamprill discussed information about clinical trials for children, their parents and grandparents, and stressed the importance of targeting information appropriately. This is particularly difficult in paediatric studies because there may be a wide variety of reading and cognitive ages in the children involved; in fact, the Organisation for Economic Co-operation and Development has shown that 20% of all 15 year olds have reading difficulties. Words and phrases with more than one meaning for children are particularly difficult e.g. study, trial, and genetic makeup. However, Jane also agreed that better information equated with improved patient outcomes.

The panel was asked if they thought that the pharmaceutical industry could be trusted to give correct information. All the panel members believed that good medical writers were needed, but thought that the problem may lie with 'overzealous' marketing departments. Thinking specifically about package inserts, the panel stressed that it was important to consider patients' needs, as well as those of the regulators, and they felt that the pharmaceutical industry (and clinicians) must earn public trust by increasing their transparency.

Although risk–benefit information can be very difficult to explain, the panel recommended giving different 'levels' of information, so that patients can decide for themselves on the level of detail required. For example, when the MMR vaccine was publicly questioned by Andrew Wakefield, none of the caveats or assumptions made in his study were explained to the general public, and so they did not have the 'full story' to enable them to make an informed decision. Furthermore, the panel believed that it is important to think carefully about how information is presented to patients, e.g. number needed to treat figures should be communicated very carefully and explained so that they are put in context. It should also be noted that an informed patient is not always an obedient patient!

Finally, the panel was asked if they believed that times are changing with respect to transparency and firewalls, and they all agreed that they are. They believed that the pharmaceutical industry is trying to 'do the right thing' and to be a responsible partner in healthcare, and that regulators are thinking of safety first.

The session ended with a final 'key pad' question – how the audience had rated the value of the session. The answer? Most rated it over 8 out of 10 – a commendable score from a very thought-provoking opening session.

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Manuscript Writing

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How to start writing a scientific manuscript

Getting started writing a manuscript – or any other document for that matter – can be difficult. Manuscripts are large projects, sometimes taking hundreds of hours and many months to complete. Faced with a blank page or screen, one might be tempted to simply start typing, attacking the project by the path of least resistance, but working in this way can lead to a poorly defined text that may even stray into tangential or irrelevant areas. Having a clear, organised plan of attack can save a manuscript writer a lot of time and avoid many headaches.

In this article, I explain how to start writing and organise the early stages of a manuscript in the best manner.

Step 1: Write a problem statement

In my experience working on manuscript projects and teaching medical writing, I have seen that the biggest problem for most writers is clearly defining what the manuscript is about. In a September 2012 article in MEW, Marina Hurley calls this process defining the 'problem statement'.[1] Briefly, the problem statement is one or two sentences describing the purpose of the manuscript. The problem statement is directly related to the objective, aim, hypothesis, or central question. Distilling these ideas into a single statement can be difficult, especially for less experienced writers, but going through the process is an excellent way to start writing a coherent, effective, and interesting text. Two typical examples of problem statements are shown below. In both examples, the first sentence describes the overall problem and the second describes the specific problem for the manuscript:

> Many candidate HIV vaccines have been developed but results in animals have not been predictive of efficacy in humans. *A reliable animal model for predicting the efficacy of HIV vaccines is needed*.

> Despite several initiatives to improve the treatment of epilepsy in low- and middle-income countries, in many countries, as many as 95% of people with epilepsy remain untreated. *Clear, simple goals that can be immediately put into action are needed to reduce the epilepsy treatment gap*.

Both examples directly and succinctly describe the problem and will enable the writer to define a clear and simple process for the article.

Step 2: Prepare a concept outline

With a well-defined problem statement, outlining is the essential next step in building a manuscript. As asserted by Robert Taylor, also in the September 2012 issue of MEW, 'Using outlining to organise your writing project can help keep you on a straight path and avoid wandering into the wastelands of irrelevance'.[2] I would add that outlining saves a lot of time and is therefore critical for meeting time and financial budgets. Like Dr Taylor, I have found that outlines reduce problems in collaborative projects because they can be used to get the contributors to comment and agree at an early stage.

I like to use two kinds of outline, which I call 'concept' and 'detailed'. The concept outline is a first step and is a skeleton on which to build a detailed outline. A concept outline contains the main sections of a manuscript followed by one bullet point for each major subsection or point that you want to make. This is a good way to get past a blank screen. As you can see in the example in Figure 1, the bullet points in the concept outline are mostly place-fillers to help organise thoughts.

Step 3: Build a detailed outline

The detailed outline goes into extensive detail and contains essentially all the information to be included in the final manuscript. Providing the detailed outline to collaborators saves substantial time because it is easier to make major changes in content or organisation than at the first draft stage because little time has been put into crafting and perfecting the prose.

Building a detailed outline is simple with a good concept outline. For each bullet point in the concept outline, simply fill in all the details from whatever source materials are available, which can

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- **Introduction**
  - Background of SLE
  - Current treatment of SLE and the need for improvements
  - Compound X in SLE and what information is needed/missing
  - This study
    - Objective
    - This study: dose-escalation study of safety, immunogenicty, and efficacy of compound x in adults 18 to 50 years of age with SLE
- **Methods**
  - Study design
  - Subject population
  - Treatments
  - Assessments
    - Safety
    - Immunogenicity
    - Efficacy
  - Statistical analysis
- **Results**
  - Disposition & demographics
  - Safety
  - Immunogenicity
  - Efficacy
- **Discussion**
  - Major points
  - Discuss safety findings in comparison to literature
  - Discuss immunogenicity findings
  - Limitations and strengths
  - Conclusions/recommendations

Figure 1: Example of a concept outline.

include clinical documents (clinical study report, protocol, statistical analysis plan, statistical output, or investigator's brochure), presentations, posters, and abstracts. Writing the detailed outline can be done in any order, although a logical method is to start with the results and then continue with the methods, followed by the introduction and, finally, the discussion.

The results section of a detailed outline should include the detailed findings that directly address the problem statement and the principal objective, question, aim, or hypothesis. This section can be populated by extracting the data (i.e. cutting and pasting) from the clinical study report, statistical output, poster, or presentation (Figure 2). Figures and tables are included directly in the sections or at the end of the detailed outline.

Once the results section is complete, what to include in the methods section should be obvious; each result must have a method. In addition, the methods should conform to the CONSORT or other relevant guidelines.[3] Keep in mind that problems with the methods or methods section are the main reason that manuscripts are rejected.[4] By populating this section now, it will become clear what information is missing, allowing it to be requested from collaborators early in the writing process. For this section, wherever possible, cut and paste from the protocol, clinical study report, or other texts containing methodological details.

The introduction section is the next logical part of the detailed outline to complete. Include detailed information for each point in the concept outline, for example specific definitions, descriptions, epidemiological data, and clinical data. Refer to your problem statement and, if you have them, the study objectives to make sure that you are addressing them. This section can be populated by copying and pasting text from the introduction of a study protocol or clinical study report or with background information from a slide presentation, monograph, or other printed information, but be aware that data or references in these documents are often out of date or inaccurate, so consider any such information preliminary and do your own literature search to find valid, up-to-date information and ideas. Including references in the introduction section of the detailed outline will avoid having to later track down sources and will allow the co-authors to determine whether you are using the references they prefer. Listing the references by author rather than as numbered citations will simplify this for you and the co-authors.

The discussion section is the most difficult part of a detailed outline to complete because it is difficult to know what the co-authors want to say and because

Introduction

- Background:
  - SLE general background (Johnson et al., 2002; Smith et al. 2011):
    - Chronic autoimmune disease
    - Affects virtually all organs, but more frequently the skin and mucosa, muscles and joints, the kidneys, the hematopoietic system and the central nervous system.
    - Autoantibodies
    - Clinical course
    - Prognosis
  - Epidemiology (Weber et al. 2012):
    - Primarily affects young women
    - Global prevalence (Thompson et al. 2013)
- Treatment:
  - Current treatment (Smith et al. 2011):
    - Current therapies

...

Methods

- Study design:
  - Design: double-blind, randomized, placebo-controlled, staggered dose, multicenter, phase I/II
  - Dates: May 6, 2010 to August 3, 2011
  - Sites: Belgium, Israel, Switzerland, Austria
  - Ethical considerations:
    - Performed in accordance with the available EMEA guidelines on clinical evaluation of new vaccines, EMEA guidelines on evaluation of medicinal products of subjects suffering from SLE.
    - Performed in accordance with ICH efficacy and safety guidelines (e-guidelines, particularly E6 concerning good clinical practice (GCP).
    - Conducted according to cGCPs, cGMPs, and cGLPs.
    - Subjects gave written informed consent before being included in the trial.
- Subject population for phase I/II study:
  - Inclusion criteria:
    - 18- 50 years

...

Results

- Disposition:
  - 28 subjects were included in the study
  - 3 discontinuations, none for AEs
- Demographic Characteristics

	30 MCG	60 MCG	120 MCG	240 MCG	PLACEBO
N	3	6	6	6	7
Female (%)	100	100	100	100	100
Age (Mean,Years)	36	39.3	34.2	34.8	40.1
Race					
White-Caucasian (%)	100	100	100	100	85.7
Asian (%)	0	0	0	0	14.3
Duration SLE disease (Mean Years)	10	8.9	7.3	11.9	6.5
Concomitant Medications					
Corticosteroids (%)	100	66.7	83.3	66.7	100
Anti-Malarial (%)	0	66.7	50	66.7	71.4
Methotrexate (%)	0	16.7	16.7	16.7	14.3
Azathioprine (%)	0	16.7	16.7	16.7	0

- Immunogenicity:
  - Time course:
    - Peak after 15 weeks at lowest 3 doses, after 25 weeks at highest dose.

...

Discussion

- Major points:
  - This was a first-in-human study of compound X.
  - Compound X is well tolerated with no major safety issues in this phase I/II study.
  - Compound X is immunogenic in 100% of patients.
  - Immunization with Compound X down-regulates IFN-related genes.
- Discuss safety findings in comparison to

...

Figure 2: Example of a detailed outline.

the messages may change up until the last draft of the manuscript. Therefore, this part of the detailed outline is often much less detailed than the other parts, but include at least the main points that you think should be part of the discussion so that the co-authors have a framework to begin considering what should be in this part of the manuscript.

As a final step in preparing a detailed outline, include a cover page containing a proposed title, the names and affiliations of the co-authors, the target journal (or proposed target journals), and key information about the target journal, such as limits for the number of words and figures or tables.

Step 4: Convert the detailed outline into a first draft

To generate the first draft of the manuscript, simply connect the individual points in the detailed outline to a text. Be sure to avoid plagiarising any information that you copied from another document or reference and, of course, make sure that the manuscript is formatted according to the instructions to authors for the target journal.

Conclusion

Writing a manuscript is simplified by starting with a clear problem statement and then developing it first into a concept outline and then a detailed outline. With a detailed outline – and hopefully comments on it from the co-authors – writing the text is easy.

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Out On Our Own

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Editorial

We hope that you enjoyed the summer months and found time to step away from your desks and relax. This time last year, Kath organised her first 'Medical Writers' Retreat', the aim of which was to provide an opportunity for fellow freelancers to spend a day away from the office to 'work on their business', network, and attend a group coaching session with international life and business coach Elaine Bailey. In this issue of Out On Our Own, Kath describes her motives for organising the event and her experiences as organiser, while fellow freelancer Alysia Battersby gives an attendee's account.

How did we all keep in touch before Facebook and Twitter? Social media is taking up space in our personal lives, and is becoming an increasingly important tool in business for networking, marketing, and keeping in touch with clients. In the first of a new series on different aspects of social media for freelancers, Jane Tricker explores how social media can be used for networking.

Our Freelance Foraging feature will help keep those holiday spirits alive and make you smile, with a couple of amusing snapshots courtesy of Sam. You'll never look at an aircraft safety card in quite the same way again! Please send us your humorous photos for publishing in future editions of Out On Our Own.

The minutes for the Freelance Business Forum (FBF) at the May 2013 EMWA Spring Conference in Manchester are now on the EMWA website and we look forward to catching up with you in person once more at the EMWA conference in Barcelona on Friday, 8 November 2013 at 17.15. With so many new freelancers joining us at each FBF, we see a repeat of questions largely relating to acquiring clients and setting up and running a business. If you require such information, please go to the Freelance Resource Centre (FRC) on the EMWA website (www.emwa.org). Log in to the 'members-only' section, click 'Resources', then 'Freelance Resource Centre', and browse. The FRC contains a plethora of information about different aspects of business management as well as many other useful documents and guidelines relating to medical writing.

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A medical writers' retreat

From concept to reality

It was while riding my horse, Wilbur, through the autumnal woods close to home that the idea came to me. Why not organise a medical writers' retreat to provide a support network for freelancers based in the UK?

I am a member of a similar and regional network of freelance clinical researchers who meet once a year to discuss topics relevant to their role. I have found these meetings invaluable and a fantastic opportunity to meet like-minded people. I am also actively involved in the EMWA Freelance Business Forum and have been involved in the Institute of Clinical Research Freelance Forum, so I have experienced, first-hand, how useful these meetings can be.

The task seemed daunting at first but I enlisted the help of business coach Elaine Bailey, who acted as a sounding board for my ideas, adding suggestions from her own experience of setting up workshops and training retreats. I knew the idea was good, but I was still uncertain of how to move forward. Why would anyone want to come along to something I had organised and was there a

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Photo 1: Our group of solopreneurs.

need for such a forum in the UK? Elaine laid down the gauntlet – if I organised one for 2012 she would come along to provide group coaching to the attendees. It was a deal. This would provide the perfect launch and provide participants with an opportunity to receive sound business advice, while networking with their peers. My objective was to offer my fellow freelancers a day away from the office in comfortable, informal surroundings where everyone could concentrate, without the distractions of work or home life, on developing themselves and their businesses alongside others in a similar situation. I wanted to bring everyone together to swap ideas, thoughts, and concerns.

I am fortunate to have a fantastic network of freelancers and colleagues, many of whom have been mentors to me since beginning my freelance career, while others are considering a move into freelancing, and I have been happy to answer any queries they have about that. The first step was to contact everyone I knew within that network and ask them whether they would attend such a retreat. The response was overwhelmingly positive. It seemed my intuition was correct – freelancers do value support from their peers and an opportunity to network with like-minded people.

I kept the venue for the meeting local to my home to aid the organisational logistics. The Greyhound is a pub in the village where I live and the proprietors very kindly agreed to let me have the use of a room to conduct the retreat. A questionnaire was sent out to the participants beforehand to establish their needs so that, with Elaine's help, we could tailor the training to meet their requests. The day of the retreat dawned and all my concerns melted away. People travelled from all over the UK to be there. The energy and enthusiasm in the room was palpable. We mixed group discussion with smaller break-out sessions and covered a wide range of topics in relation to managing a business, dealing with client demands, and understanding our own value as medical writers. Everyone went away feeling positive and enthused and this was evident from their feedback. On that note, I will hand over to Alysia who attended the medical writers' retreat to give you her perspective.

I have value, do you want some?

Throughout the day, the atmosphere in the room was buzzing. As soon as I sat down I was drawn into conversation with the other freelancers around me. The range of freelance experience in our group was varied and so were our client portfolios. The honest revelations and often humorous contributions from the floor, combined with Elaine's clever guidance using descriptive keywords and quotes, helped us to collate a fantastic bundle of ideas and tools with which to improve our careers as freelancers.

When asked what issues we wanted to tackle in our freelancing lives, most of our concerns fell into two categories: how to become better freelancers and how to optimise client relationships. Some of us wanted to improve our time management and be more effective at our jobs, others wanted to learn how to best deal with criticism without feeling devalued. Some of us felt that we had taken on too much work, while others wanted to attract more clients through better marketing. All of us felt uncomfortable in talking about money with our clients.

After putting our heads together, a number of valuable strategies emerged on how a freelancer can grow and improve, including how to master

Photo 2: Hard at work, brain storming.

self-leadership and how to believe in our own self-worth. Our discussions also covered the practical sides of running a freelance business, including the value of online visibility in the form of freelance registries, a business website, and social media sites.

With all that brain storming we were ready for a late lunch at the pub! After good food and drink we all returned home. Had it been worth the long drive over? Definitely and I am looking forward to the next one.

Acknowledgement

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SoMe and me: Networking

I was a reluctant convert to social media (SoMe). The Web, of course, is an invaluable resource for medical writing (in fact it's hard to remember how we used to cope without it), but what about the interactive aspects? Not for me, I thought. I didn't want to share my photographs and video clips with the world. I didn't want everyone to know who my friends are, and I preferred email or telephone for contacting them. More than that, I was absolutely convinced that joining the social web would end up in my being buried in spam or, worse still, hacked.

Well, I haven't changed my mind about sharing my personal life with the world, but I have changed my mind (or perhaps I should say that I have had my mind changed) about the value of social media in business. In this and forthcoming issues of Out On Our Own, I will be sharing my experiences of using social media in my freelance business. I'm not an expert, although I have been lucky to receive some good advice and support along the way. This is a distillation of things that seem to work for me.

I could classify my use of social media under three main headings: networking; training and education; and marketing and business development. The nature of social media, however, means that these are false divisions. For example, if I contribute to a discussion in EMWA's LinkedIn group, then ostensibly I am networking, but the fact that I have commented will be shared with my contacts and everyone that has opted to receive updates from that group. This reminds my contacts that I am around and also means that my name and the fact that I'm a freelance writer is reaching some people who aren't connected with me – including some potential clients. More than that, by participating in the discussion I can garner opinions about an issue,

adding to my knowledge and understanding of the subject.

I do have a couple of rules that I try and stick to when using social media. I try not to talk about my home life and my family, and I don't say anything that could identify my clients or my clients' clients.

Networking

In the remainder of this article I will focus more closely on networking and building a network.

When I first started freelancing, I had a card index for collecting the names of contacts within publishing companies and medical communications agencies. These were mostly former colleagues that I would mail or email periodically with my latest curriculum vitae (CV) and/or to ask if they needed any freelance assistance. This index was gradually transferred to Outlook and was expanded over time with clients and the names of other freelancers that I could recommend if I was unable to take on a project myself.

Those lists of contacts are now almost entirely superseded by LinkedIn, which maintains my contact with those people in a much more dynamic way. LinkedIn tells me when my contacts have moved on to new jobs – something that I would only have discovered if the person had contacted me in the days of my old card index. It also tells my contacts when I have added skills, experience, qualifications, etc. to my profile without having to send an updated CV.

I have actually met and/or have worked with more than 90% of my contacts on LinkedIn. Once I've worked with someone a couple of times I ask them to connect with me, along with recruiters, agency staff, and other freelancers that I've met at conferences and networking meetings. I've also grown my network by noticing who my contacts are connecting with. I've found a number of former publishing colleagues and colleagues from my lab days, and others have found me. For me, LinkedIn is all about people.

By contrast, Twitter is about information. I joined Twitter to provide a strong back link to my website and, simultaneously, to make sure that my home page was updated every day by my Twitter feed, both of which help with the site's Google ranking. But membership came with an unexpected bonus – I discovered that I could use Twitter to follow announcements from the major science and medical journals; organisations such as the Association of the British Pharmaceutical Industry (ABPI), EMWA, and the International Society for Medical Publications Professionals (ISMPP); pharmaceutical companies; and medical charities and news feeds.

Twitter presents me with access to papers, articles, advice, and opinions that inform my work as a medical writer and editor. By following hashtags – like #EMWA, used at the May 2013 Spring Conference in Manchester – I can read about what people are saying at conferences (and even respond) in real time or in my own time after the event, and read collections of opinions on particular issues or events. You don't have to be part of Twitter to read those – try Googling #badpharma, #sunshineact, #arseniclife, or #OAintheUK to get a feel for what Twitter can do.

So what about the spam and the hacking worries? Well, of course I receive spam and malicious emails, some of which I can almost certainly attribute to having a social media presence – but there are software tools and site options for limiting my exposure to them. There are also best practice guidelines for protecting myself.

On balance, having a Web-based social network means that I am better informed. It has brought me more work and more ways of finding work. It has put me in touch with people outside my own areas of expertise and this, in turn, has opened doors that I didn't know existed. These are topics that I'll expand on in forthcoming articles.

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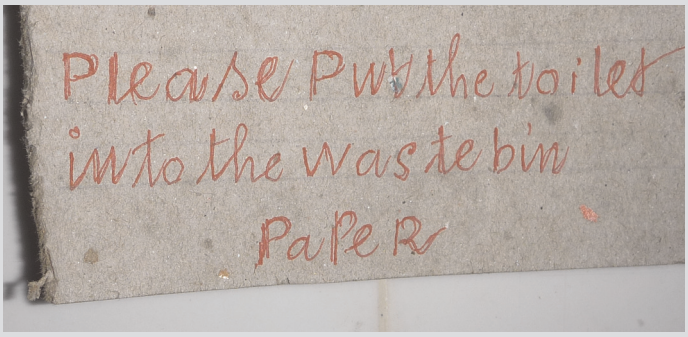
Freelance Foraging

It is all about the word order. This sign in a Vietnamese restaurant rest room says it all!



This aircraft instruction conjures images of balloon people!

Please keep us smiling and send us your photos. Thanks, Sam and Kathryn.

The Light Stuff

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Decoding the Japanese

Code 1: Yes means yes, and no does not exist

At a recent dinner, my husband and I were chatting with a university professor, a Japanese fellow who has lived and worked in Europe and the US. We talked about cross-cultural differences in communication styles, and in particular the legendary habit of the Japanese of taking excessive care to avoid saying 'No'.

He explained, 'In general, Yes is the only affirmative answer, anything else should be taken as a No!'.

He then told us an anecdote. A friend of his in Tokyo was organising a farewell party, and sent out an email in which the invitees were asked to answer the simple question, 'Would you like to come to the party'. Two choices were given to answer this question:

Illustration by Anders Holmqvist

(a) Yes.
(b) Yes, but I may be busy!!!

He was not in Tokyo at this time and replied to the email, respecting the code, 'Yes, but I am in the US'.

Please note, even the question is framed in a way that the responder can avoid saying the N-word.

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Code 2: Do not let cultural differences stop us from relating as people

And while we are visiting the 'Land of the Rising Sun' for discussions on communication, I would like to relate a short story from several years ago when I was working with a Japanese client. As those of you who have done this know, the requisite end of the day evening dinner can be quiet difficult when trying to socialise.

Sure enough, I was at one of these dinners and somehow ended up in a corner of the table next to a particularly taciturn Japanese gentleman. Well, I may be known for being able to talk to anyone, but this was a real challenge as this particular case had fairly limited English skills and was in any case never very talkative. So we sat there studying the menu intensely and occasionally making pointless small talk.

However, I could not help but notice that the necktie he was wearing had small silhouettes of battleships on it. As a fan of neckties with small pictures on them (a great tradition from years ago that has unfortunately become much less common today), I was rather intrigued, as usually one sees ties with school crests or little animal figures or sports logos – but battleships? Still, I was not sure how to ask him, but my curiosity eventually overwhelmed me and I asked him what was on his tie. He told me it was the battleship his father had served on in WWII. Now I was even more curious, because this is not really your usual necktie decoration – especially in Japan, which has had a strong non-military policy for many years – so without really thinking, I blurted out, 'That is interesting, would you mind if I asked you a question about your personal opinion?'. Much to my surprise and delight, he looked at me very seriously, straight in my eyes, and replied,

> *I would be most honored if you would ask me a question about my personal opinion.*

For the rest of the evening, we had a lively discussion about militarism in modern Japan, much to the amazement of the rest of the table.

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