



Dispensing Strategy:

How to Communicate Effectively through Pharmaceutical Publication Planning

By **Brian G. Bass**

The implementation of a publication plan for a new pharmaceutical may take the medical writer years of sifting through the literature, of research, analysis and strategizing. The president of Bass Advertising and author of *The Accidental Medical Writer* walks us through the processes, step by meticulous step.

When a new pharmaceutical comes on the market, it is typically met with a fanfare rivalling that of the latest pop music sensation. But just as one does not become a rock star overnight, so launching the latest wonder drug takes years of research, testing, and planning – not to mention an investment of nearly a billion dollars, or more. The new rock star will likely have a lifetime of unbridled earning potential to compensate for his or her early struggle, but minimal upfront investment.

Pharmaceutical companies aren't so lucky. The clock starts ticking on exclusive marketing rights the moment a new chemical entity is discovered and patented, although it may take nearly a decade to fully commercialize that new chemical entity and bring it to market. This leaves precious few years for the company to recoup its investment, cover overhead and, dare I suggest, make a profit. If the new drug is not a new chemical entity but similar to a drug already on the market, the company has even less time to make its money back. Add to this the downward financial pressures of capitation and formularies, something your typical rock star wouldn't know anything about, and it becomes easy to understand the *raison d'être* of the publication plan.

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Where It All Begins

Clinical research is the cornerstone of the drug approval process. Soon after discovery, a chemical entity will enter the preclinical research phase, during which it is tested in animals for safety. The few chemical entities that pass this first test then enter phase 1 clinical trials, which are usually conducted in healthy human volunteers to further evaluate safety. The even fewer that pass this second test go on to phase 2 clinical studies, to assess whether they work in patients with a specific disease. The drugs that pass this test and show the most promise advance to phase 3 clinical studies, which are larger controlled studies designed to gather more information about the drug's efficacy and safety.

Collectively, the results of these studies form the basis for the new drug application, which is submitted to the country's governing body for review and (hopefully) approval. Upon approval, data from these studies are used to create the drug labeling, which is also called the "complete prescribing information" or "package insert." If the new drug is fortunate enough to be approved for use, it will then enter phase 4, or "postmarketing trials." These trials are observational, and they collect important

information about the use of the drug in the real-world setting.

Clinical studies are a drug's pedigree. They support the claims made in the prescribing information and provide the backbone for everything the pharmaceutical company can promote about the drug once it is approved for use. Therefore, it is in the pharmaceutical company's best interest to get this information out to the health-care professionals who will ultimately prescribe the drug for their patients. This is the job of the publication plan, and a job for the medical writer.

Ready, Aim, Fire

The publication plan is a written document that lays out the suggested strategy and tactics for increasing awareness of, and hopefully interest in, the new drug, along with a proposed schedule for implementing the plan. But before the plan can be formulated, considerable time and energy must be invested in understanding where the new drug fits in the current therapeutic milieu. This make-ready step is called the "gap analysis," and it is also conducted by the medical writer.

In essence, the gap analysis makes you ready to take aim with the publication plan before you begin firing your messages into the marketplace. It looks back a number of years into the currently available treatments and what has been published about them in the medical literature. A gap analysis can be a relatively small undertaking. For example, last year I developed a gap analysis for a therapeutic device that was already on the market in a rather narrow category of surgery. The device's biggest competitor was surgeons' penchant for doing nothing. Therefore, my research into the competition and what was written about the device in the medical literature over the past three years yielded only a few hundred articles for me to read, digest and assimilate before I could develop the publication plan. However, most gap analyses are not so small and simple. It depends in large part on the therapeutic area.

Another gap analysis I recently developed was for an anti-infective agent. Anti-infectives are generally effectual against a wide range of pathogens that are responsible for causing numerous types of infections, each treated by its own unique regimen, for which there is a broad array of alternative drugs that could be prescribed – some old, some new, and many in between. Further complicating this gap

analysis, the pharmaceutical company wanted me to comb the medical literature for all the diseases (there were five) and all the competing agents (there were eight) going back ten years.

The Search Is On

How does one begin such an overwhelming task? The first step is to develop literature search strings that will identify the articles I need to review. I typically develop a variety of search strings for several reasons: first, because it becomes unwieldy to cram everything into a single search; and second, because it is more efficient to keep certain searches separated. Literature search strings for an anti-infective gap analysis might look like those shown in Exhibit 1. Once developed, the search strings are entered into the U.S. National Institutes of Health – National Library of Medicine – National Center for Biotechnology Information literature database (more commonly known as PubMed, www.pubmed.com).

With all my articles in hand, or more likely in boxes or strewn about my office in organized stacks, the real work begins.

Within the PubMed search, you can set limits based on date of publication, type of article (e.g., clinical trial, meta-analysis, treatment guideline, randomized controlled trial, and review), article language, and subject parameters (including sex and age). Advanced search capabilities enable you to create AND/OR search strings. PubMed search results can be organized by date or relevance. Each listing identifies the article title, authors, journal, publication year, issue volume and number, and page range. If you choose the “Show Abstract” option, a brief summary of each article will also appear, if one is available. The article titles are usually hypertext links, on which you can then click in order to go to the journal or publisher representative for purchase of the article. Fees typically range from US\$25–35, although some can be as low as \$15 and some as high as \$80, or more. But not so fast!

Before I start ordering articles, I review the results of my various searches and manually delete the redundancies. This can save a lot of money. Depending upon the number of articles I need, I may send my electronic shopping list to a service that procures the references for me.

Mind the Gap

With all my articles in hand, or more likely in boxes or strewn around my office in organized stacks, the real work begins. I first develop a template to house the information I

will cull from all the articles I review. A sample template is shown in Exhibit 2. As I fill in the template, I may organize it by year, by competitor, or by target audience, depending upon what is most important to the client. Then it is a matter of reading through each article to capture the necessary information. I prefer to work in Microsoft Word, because it is both word-friendly and reader-friendly, which means client-friendly. Some clients insist on using Microsoft Excel, a choice which makes no sense to me, because it results in a document that is impossible to print out without losing much of the visible text, and because Excel is a data management program (while there is a lot of information in a gap analysis, there is very little data).

Once the template has been completed, the fun of the gap analysis begins. Having read through every article and pulled out the important information, I now have all the details on paper and even more information swirling in my head. The time has come to make sense of it all. This is the analysis portion of the gap analysis, and the goal is to make

sense of all the information that has been compiled, in order to determine where the gaps and opportunities lie for the new pharmaceutical, based upon its known and anticipated properties. Anticipated, because a gap analysis and publication plan are frequently developed while the clinical studies are being conducted, often before some of the phase 3 studies have even begun recruiting patients.

Plan the Plan

With the gap analysis in place, it is now time to consider how the new pharmaceutical will fit, given the past and current states of the marketplace. I develop a publication plan by reviewing all the available information about the drug’s clinical study program. If studies have been completed, I want to read the clinical study reports, or CSRs. If studies are underway, I want to see any and all available interim analyses of the study results. If studies are planned but not yet initiated, I want to read the investigators’ brochures to learn how the studies are being conducted, what the primary and secondary endpoints are, and how the data will be analysed when they become available. Then I brainstorm.

I start by identifying the data from the clinical studies that I believe can and should be brought out in primary manuscripts. That would be data pertaining to primary endpoint results. Then I do the same for secondary manuscripts, including the use of data on secondary

EXHIBIT 1**Sample Literature Search Strings for a Gap Analysis for an Antiinfective**

- sinusitis antibiotic antiinfective treatment adult
- pharyngitis antibiotic antiinfective treatment adult
- otitis antibiotic antiinfective treatment adult
- sinusitis antibiotic antiinfective treatment pediatric
- pharyngitis antibiotic antiinfective treatment pediatric
- otitis antibiotic antiinfective treatment pediatric
- vancomycin azithromycin erythromycin amoxicillin clavulanate augmentin ciprofloxacin levofloxacin gatifloxacin clarithromycin cefprozil cefdinir cefpodoxime

EXHIBIT 2**Sample Gap Analysis**

Year	Month	Citation	Target Audience	Message		Publication Type		
				Positive	Negative	Primary	Health Economic	Pooled/Meta-Analysis
1999	Sept.	Bernstein DI, Berkowitz RB, Chervinsky P, et al. Dose-ranging study of a new steroid for asthma: mometasone furoate dry powder inhaler. <i>Respir Med.</i> 1999;93:603-612.	Pulmonologists	X		X		

EXHIBIT 3**Abstract Submissions**

Meeting	Due Date	Abstract Number	Title
Meeting Annual Conference of the American Academy of Physician Assistants (AAPA)	Early January	1	Randomized, double-blind, placebo-controlled, parallel group, stratified, multicentre, 12-week study of a fixed-dose combination of drug X and drug Y in patients with mild-to-moderate asthma.
Annual Conference of the American Academy of Physician Assistants (AAPA)	Early January	2	Randomized, double-blind, active-controlled, parallel group, stratified, multicentre, 12-week study of a fixed-dose combination of drug X and drug Y in patients with mild-to-moderate asthma.
Annual Conference of the American Academy of Physician Assistants (AAPA)	Early January	3	Long-term, open-label study of a fixed-dose combination of drug X and drug Y in patients with mild-to-moderate asthma.

Manuscript Submissions

Type of Manuscript	Manuscript Number	Title
Primary	1	Pharmacokinetics of a fixed-dose combination of drug X and drug Y following single and multiple doses in healthy volunteers.
Primary	2	Results of a phase 2 clinical study of a fixed-dose combination of drug X and drug Y in adults with mild-to-moderate asthma.

endpoints, as well as the coaxing out of subanalyses (e.g., based on certain baseline characteristics such as disease severity or considering how the drug may have performed in different types of patients enrolled in the study). I then brainstorm backward to what will become the beginning of the publication plan, in order to suggest review articles that will help set the stage for the primary and secondary articles. I do this by addressing key or emerging issues in the therapeutic area or gaps in current knowledge.

But the publication plan isn't finished yet. Next, I work further backward to include abstracts that will be submitted for presentation at medical congresses. Abstracts are very brief summaries of the findings of clinical trials. The reason abstracts go first in the plan, even though they come last in the planning, is that congresses will not accept abstracts that present data which have already been presented elsewhere. For this reason, abstracts must precede articles.

Once all the tactics have been figured out, the big challenge of the publication plan begins, that is, identifying the journals to which each manuscript may be submitted, identifying the medical congresses to which each abstract will be submitted, identifying potential authors for each article and abstract, and scheduling the flow of information as it will roll out across the time frame of the plan. Rollout of a publication plan is typically no less than a year (I have developed plans with rollouts of three years and more).

As you can imagine, a publication plan is a large document. In addition to the grids (Exhibit 3), which comprise all the recommendations as well as the proposed timetable for implementation, there is also a substantial amount of prose to help the pharmaceutical company gain an

overview and a clear understanding of the recommendations (that is, so they don't lose sight of the forest for all the trees).


Work the Plan

The final and most important step in the publication planning process is to implement the plan. Of course, there is an important role for the medical writer here as well, assisting authors in the development of articles and abstracts. For this service, the contribution of the medical writer should be acknowledged in accordance with the American Medical Writers Association's "Position Statement on the Contribution of Medical Writers to Scientific Publications" (*AMWA Journal*, 2003: 18-1,13-16), and the recently updated "Good Publication Practices 2" guidelines published by the International Society for Medical Publication Professionals (*British Medical Journal*, 2009: 339, b4330).

By handling the publication of scientific data clearly, truthfully, accurately, objectively and ethically, medical writers do a great service in helping to improve the health and well-being of society, enhance the knowledge of the medical community, and ensure the financial future of pharmaceutical companies so they can afford to continue advancing the science of medicine.

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