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ISI's Medical Documentation Service (MDS)— Monitoring the Literature for the Pharmaceutical and Biomedical Industries

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Soon after arriving in Philadelphia in 1954, I encountered the venerable College of Physicians Library, founded in 1788 by the College of Physicians of Philadelphia. This library was considered to be the local counterpart of the National Library of Medicine, due in part to its extensive journal collection.

My coming to Philadelphia was prompted by a six-month consulting assignment with Smith Kline & French Laboratories. Working out of the literature department, I soon realized that SK&F and other pharmaceutical companies relied heavily on the resources of this library. As June Fulton describes in the article that follows, this is not unusual considering the document delivery needs of such organizations.

The Food and Drug Administration has long imposed informational requirements that go beyond a drug company's interest in finding uses or mentions of its products in the literature—in particular, reports of adverse or unexpected reactions.

Scanning and searching the literature is a complex information-gathering operation that combines human intelligence with computer-aided expert systems, and even artificial intelligence. The need for industry intelligence is especially acute in the pharmaceutical and biotechnology industries.

A significant part of this activity is not only multilingual but also interpretive, as one could easily swamp a client with irrelevant information that simply mentions a product in passing. Yet, on occasion, even a mere mention is quite relevant or significant.

Many a drug introduced for one purpose eventually proves to be even more consequential for another. Chlorpromazine (Thorazine) was originally prescribed for nausea and vomiting, but later proved to be a potent psychotherapeutic agent.

Fulton, director of the Medical Documentation Service™ (MDS™) for the last nine years, is a distinguished member of the Academy of Health Information Professionals. As president-elect of the Medical Library Association (MLA), she is recognized by her peers as a leader in her profession. She and many of her highly trained staff came to ISI® when it acquired MDS from the College of Physicians in 1989. Her 22-person staff regularly reads, cover-to-cover, more than 1,000 key international journals in the biomedical literature. It is this human element that makes this service truly unique; staff members make data collecting judgments that would not be possible by present electronic scanning techniques. However, some 5,000 additional periodicals are electronically monitored.

Service Dates Back to 1953

To monitor the literature for adverse drug reactions, as well as for other product-related information (e.g., regulatory compliance and market intelligence) requires a well-designed system for both data capture and retrieval. MDS is designed to do just that. It was started at the College of Physicians of Philadelphia back in 1953.

ISI, of course, has long provided data of interest to the biomedical and pharmaceutical industries. In fact, *Current Contents*® was founded as a result of consulting work I performed for Miles Laboratories.[1,2]

Over the years, ISI and the College of Physicians had many common goals regarding the dissemination of information; but, because the college was a nonprofit organization, mutual effort was precluded.

Basically, the service fulfills the need of pharmaceutical companies to know what is being reported in the literature about their products. MDS identifies, indexes, and abstracts articles on specific materials, compounds, and drugs. The service offers translations of foreign language publications in recognition of the fact that many companies today operate globally. Of course, some already have sophisticated information systems for tracking both their own and competitors' products. But these systems are costly, requiring a large investment in journal subscriptions and trained personnel. Indeed, a key factor in the college's decision to finally divest MDS was the sharply rising cost of journal subscriptions. ISI monitors more than 7,000 journals around the world. Thus, its vast resources have enhanced MDS's capabilities to the point where it now serves as a viable, realistic alternative for cost-conscious companies seeking this type of information—one that provides a large measure of confidentiality and customization.

The Welch Library Indexing Project

June's election to head MLA is certainly an honor. ISI, of course, has had a long association with MLA. We began sponsorship of the MLA Doctoral Fellowship back in 1986. This fellowship was designed to "foster and encourage superior students to conduct doctoral work in medical librarianship or information science."[3] This year's winners were Gary D. Byrd, Health Sciences Library, University of North Carolina, Chapel Hill, and Zoe Stavri, School of Library and Information Studies, University of Wisconsin, Madison. My own first contact with MLA dates back to 1951 when I was associated with the Welch Medical Library. Space does not permit more than a brief mention of the pioneering Welch Library Indexing Project at Johns Hopkins University and its seminal role in solving indexing problems related to biomedical literature. But, I have written on this at length before: indeed, *Index Medicus (IM)* was one of the major beneficiaries of this research.[4] And, my long friendship with the former director of the National Library of Medicine led to the establishment of the Frank Bradway Rogers Information Advancement Award, which ISI also sponsors.[5] The 1992 award winners were Jocelyn Rankin, professor and director of the medical library of the Mercer University School of Medicine, Macon, Georgia, and Jean Williams Sayre, director and chief medical librarian of the Northeastern Ohio University College of Medicine, Rootstown, Ohio.

Since then, another service similar to *IM* has evolved—*Excerpta Medica (EM)*.[6] While both are information retrieval services concentrating on the biomedical (especially clinical) literature, *EM* features its abstracting capabilities, while *IM* is primarily an indexing service, although MEDLINE now includes abstracts. But, neither of these services offers the tailor-made reports that MDS provides to its clients.

Fulton earned a master's degree in 1967 from the University of North Carolina, Chapel Hill, and worked at the University of North Carolina, Greensboro, and the University of Alabama, Huntsville, before joining the College of Physicians in 1971. There, she became director of MDS in 1983 after heading up its Mid-Eastern Regional Medical Library Service from 1976 to 1982.

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REFERENCES

1. **Garfield E.** *Current Contents*—ninth anniversary. *Current Contents* (9):5-8, 21 February 1967. (Reprinted in: *Essays of an information scientist.* Philadelphia: ISI Press, 1977. Vol. 1. p. 12-5.)
2. ----------. An international perspective on drug bulletins and their place in the review literature. *Current Contents* (7):3-9, 18 February 1991.
3. ----------. To recognize and encourage excellence: ISI-sponsored awards. Part 2. Fellowships and lecture programs. *Current Contents* (35):3-7, 31 August 1987. (Reprinted in: *Op. cit.*, 1989. Vol. 10. p. 242-6.)
4. ----------. Some reflections on *Index Medicus. Current Contents* (51):5-11, 17 December 1979. (Reprinted in: *Ibid.*, 1981. Vol. 4. p. 341-7.)
5. ----------. Bringing the National Library of Medicine into the computer age: A tribute to Frank Bradway Rogers. *Current Contents* (2):3-9, 9 January 1984. (Reprinted in: *Ibid.*, 1985. Vol. 7. p. 5-11.)
6. ----------. *Excerpta Medica*—abstracting the biomedical literature for the medical specialist. *Current Contents* (28):5-10, 14 July 1980. (Reprinted in: *Ibid.*, 1981. Vol. 4. p. 522-7.)

ISI's Medical Documentation Service: Support for Biomedical and Pharmaceutical Research

By June H. Fulton

ABSTRACT

This article discusses the Medical Documentation Service™ (MDS™) of the Institute for Scientific Information® and the information services it provides to assist biomedical and pharmaceutical companies in managing and controlling published product literature. MDS works individually with each client to establish criteria for regularly updating in-house databases and other product literature files in support of postmarketing surveillance, market intelligence, and related activities. The services offered include scanning, indexing, abstracting, document delivery, and translating.

The Medical Documentation Service™ (MDS™) provides information services to assist biomedical and pharmaceutical companies in managing and controlling published product literature. MDS was established at the College of Physicians of Philadelphia in 1953. It was acquired by the Institute for Scientific Information® (ISI®) in late 1989 to complement and to enhance ISI's long-standing services in support of pharmaceutical research.[1] The composition of MDS's services has not changed since the relocation to ISI; however, the resources to provide these services have expanded through access to ISI's vast journal collection and advanced computer technology.

June H. Fulton

The services provided by MDS have been shaped by the critical need of pharmaceutical companies to track information on their marketed products in the scientific literature. Many pharmaceutical companies have developed sophisticated information systems for monitoring, analyzing, storing, and retrieving product literature. Traditionally,

these functions have been performed internally, with each company maintaining its own database.

MDS has emerged as a viable alternative for updating internal product literature databases because of its ability to customize this information according to each client's requirements. While MDS is often called upon to duplicate the features of an existing system, at other times the request is for the design of a new system. MDS is adept at responding to either request. To gain a better perspective on specific attributes of the MDS service, it is first necessary to review why product literature is so crucial to pharmaceutical companies.

Postmarketing Drug Surveillance

Pharmaceutical companies routinely conduct postmarketing drug surveillance to respond to governmental regulatory requirements, as well as to provide information for clinical, research, legal, marketing, and other strategic corporate activities. Because clinical trials carried out in the preapproval of a drug are insufficient in numbers and types of populations to uncover all potential problems, the monitoring of marketed products for adverse drug reactions (ADRs) often provides the first signal that a potential hazard exists. While the consequences of undetected ADRs warrant self-imposed vigilance by the pharmaceutical industry, stronger measures are in place requiring the submission of ADR reports to the Food and Drug Administration (FDA).

Requirements for postmarketing reporting of ADRs by manufacturers to the FDA are detailed in Title 21 of the Code of Federal Regulations, section 314.80. Serious and unexpected ADRs must be reported as soon as possible, but not later than 15 working days after receiving the information. Periodic submission of reports is required at quarterly intervals for three years from the date of approval of a drug application and annually thereafter. The 15-day reporting requirement extends to reports found in scientific and medical journals, either as case reports, as the result of a formal clinical trial, or from epidemiologic studies or analyses of experience in a monitored series of patients. Reports must be accompanied by a copy of the published article. Currently, the number of ADR reports exceeds 70,000 per year.[2]

The value of the published literature as a source of ADR information has been termed "tremendously important" by Susan M. Wood, head of the Adverse Drug Reactions Unit at the Department of Health in England. There are many examples, according to Wood, where the literature has provided primary and confirming evidence of drug hazards.[3]

Industry Drug Information Systems

To monitor the voluminous scientific literature for ADRs and other product-related information requires a well-designed system both for data capture and data retrieval. An overview of industry drug information services concludes that "the industry-based drug information provider has such a large volume of information available concerning company products that customized automated data retrieval systems are virtually mandatory."[4] This conclusion is supported by a 1990 survey, conducted by Sattler, of product literature monitoring groups at 10 large pharmaceutical companies.[5] The survey confirmed that all 10 companies are updating automated databases that have been created to access product literature information.

The most common approach used to retrieve relevant citations from the scientific literature is manual scanning, supplemented by recurring searches of major online databases. Once citations are identified, the value and accessibility of the information are enhanced through tailored, customized indexing, abstracting, and quality filtering of the literature for inclusion in in-house databases. These procedures are not only labor intensive, but they require a high level

of expertise. The trend in the pharmaceutical industry is, when possible, to contract work out rather than to increase permanent, full-time personnel. Therefore, many companies choose to utilize the services of MDS as part of their ongoing product literature surveillance because they find that MDS offers the same (sometimes enhanced) quality, timeliness, and reliability as their in-house operations.

MDS Services and Staff

Pharmaceutical companies may select from a menu of services depending on whether they wish MDS to be fully or partially responsible for their product literature database. For example, some companies choose to have MDS scan the literature, while they themselves furnish the indexing. In addition to scanning and indexing, MDS provides abstracting, translating, and document delivery. Whatever the service configuration, detailed specifications are developed in close consultation with the client before services are initiated. Options also are available for format, record layout, and delivery method of the data, including hard copy, magnetic tape, diskette, or electronic transmission. All work performed by MDS is done in observance of the concern of clients for confidentiality.

The staff of MDS consists of information professionals, scanners, indexers/abstractors, translators, editors, computer systems specialists, and support personnel. All work is performed in-house, with the exception of full translation services. The scanners and indexers/abstractors have degrees in the biomedical sciences and facility in one or more foreign languages.

All staff members are linked through a network of personal computers (PCs) to the ISI mainframe computer. This dual-platform system enables the staff to switch transparently between PC-based and mainframe-based functions, utilizing in one procedural operation the best features of both. The introduction of this new computer system in MDS has enabled the staff to convert from paper to online scanning and indexing. It has been one of the primary advantages of the move to ISI.

Scanning

The MDS scanning operation consists of both manual and electronic techniques. Unlike many pharmaceutical companies' in-house manual scanning operations that normally cover 300 to 600 core journals,[5] MDS staff scan a core collection of 1,000 journals, with a better representation of foreign journals than is found in most pharmaceutical libraries. In addition to this manual scanning, MDS electronically scans another 5,000 journals to identify articles of possible interest to clients. These articles are then subjected to manual scanning to determine definite relevance based on profiles and scope notes that codify guidelines established in consultation with clients.

Although some profiles are designed to cast a very broad net to capture any mention of a product in the literature, others are very specific and are designed to narrow and focus retrieval. Scanning criteria always include ADRs, but may also include drug interactions, new therapeutic uses, and efficacious results. The length of time a product has been on the market is also a factor in determining the scope that governs retrieval. For example, a pharmaceutical company may request any mention of a newly marketed product, but only significant information for one that has been on the market for several years. Near the end of a product's patent life, only reports of ADRs and new indications may be requested. MDS filters the literature according to whatever guidelines are established.

Articles are retrieved through manual scanning that would be missed by searching online databases because the product name was not in the title, abstract, or index. The advantages of human scanning are most apparent when the request is for any mention of a product, however minor,

or when the scope is highly specific. At times, scope notes will specify criteria that can only be determined through manual scanning.

Consider a client who wants information on a specific drug and not on the various other marketed salts of that drug. In addition, this client wants only articles where the drug is used in a clinical setting and is administered by a particular route. The ability of MDS to precisely match retrieval to a client's profile results in an extremely high degree of relevance of reported references.

In addition to routine journal literature, MDS scans meeting abstracts and conference proceedings, literature that is not well covered in publicly available databases. Without the manual scanning MDS performs, this information, which is of great importance to the pharmaceutical industry, would be missed.

In Sattler's survey, a primary rationale given for manual scanning was the need for currency of product information. Two of the 10 companies surveyed had actually implemented same-day alerts of important information. MDS also has found that currency is a prime concern of clients. Incoming journals at ISI are routed to MDS first, usually within a day of receipt. According to a recent in-house study, MDS is significantly more current in its reporting than the most current of the three major online biomedical databases. To further reduce the time lag for getting information into the hands of those who need it, MDS provides a copy or tear sheet of almost all reported articles at the same time the bibliographic information is delivered on tape or diskette.

Indexing

Although some clients receive only scanning and document delivery services, the majority use MDS for indexing as well. MDS staff work closely with each client to design an indexing form that represents all specific areas of interest to the client. Indexing forms are segmented into fields that correspond to the areas of interest (e.g., study population, treated disease, dosages, and adverse effects). It is the client's decision as to which fields are included on the indexing form and to what depth articles are indexed.

The number of fields on the form is usually an indicator of the specificity desired. Some clients select partial indexing for some products and full indexing for others. MDS staff write specifications for the selection of indexing terms and how they will be represented in each field. Oftentimes there is a marked similarity between the indexing fields and the areas on Form FDA-1639, which is the form that is used to submit reports of ADRs to the FDA.

All indexing focuses on the client's product, whether the product is the major subject of the article or only a short paragraph in a lengthy paper. The indexing vocabulary is selected by the client and may consist of an internal thesaurus or a standard dictionary such as Medical Subject Headings (MeSH). The indexing specifications prepared by MDS duplicate as much as possible the decision criteria the client would use if doing their own indexing. This indexing is different from that of general biomedical indexing services. They do not ordinarily treat an article from the pharmaceutical point of view (e.g., by highlighting particular compounds or dosages reported in the article). Each MDS indexer is assigned a specific group of clients and becomes thoroughly familiar with an individual company's products and specifications.

Abstracting

Like indexing, abstracts written by MDS staff focus on the client's product. Abstracts provide a concise summary of the article, but with all relevant information included from the pharmaceutical point of view. Not all articles need to be abstracted. Some clients request that only foreign language ar-

ticles be abstracted. Others may want abstracts only for articles that lack an author's abstract. Still others may only want abstracts for papers on specific products. And, other clients request that MDS supply the author's abstract for selected types of articles and write the abstracts for other articles.

Translating

To round out its services, MDS provides a translation service with facility in more than 20 languages. Titles of foreign language articles are routinely translated as part of the scanning or indexing service. Full article translations are performed only on request.

Translation services were part of the original core group of services provided by MDS when it began, as were Selective Dissemination of Information (SDI) reports and abstracting. Personalized service was the hallmark of MDS then as it is now. Further information follows on the origin of MDS.

Background

The growth of MDS, culminating in its sale to a leader in the information industry, is a tribute to the vision of those who established the service. Elliott H. Morse, who served as Librarian of the College of Physicians of Philadelphia from 1953 to 1981, was tireless in his efforts to find creative ways to promote the outreach services of the library, while at the same time garnering much-needed financial support for programs. Through his efforts, MDS became an entrepreneurial adjunct to the library when Virginia Beatty, who privately operated the service for the first three years, left Philadelphia. Whitfield Bell's bicentennial history of the college describes the success of the MDS operation over the years and notes that "substantial" income was produced for the college.[6] Annual reports of MDS reflect obvious pride in the contribution made by MDS to the library's overhead, while at the same time performing a much-needed service for subscribers.

A number of factors conspired in the late 1980s to cause the college to reassess its mission. As a result, the library was restructured and the journal collection was significantly reduced. MDS, dependent on the library and its journals, faced an uncertain future. Fortunately, ISI offered a new home. MDS is now embarked on a course that is already producing new growth and vitality.

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REFERENCES

1. **Garfield E.** An international perspective on drug bulletins and their place in the review literature. *Current Contents* (7):3-9, 18 February 1991.
2. **Faich G A.** Postmarketing surveillance: lessons learned. *Drug Inf. J.* 25:531-5, 1991.
3. **Wood S M.** Postmarketing surveillance: viewpoint from a regulatory authority. *Drug Inf. J.* 25:191-5, 1991.
4. **Colvin C L, Collins G E, et al.** Drug information services provided by the pharmaceutical industry. *Amer. J. Hosp. Pharm.* 47:1989-2001, 1990.
5. **Sattler P.** Handling published literature: survey results. PMA Information Management Subsection, 20th Annual Meeting, Orlando, Florida, April 22-25, 1990. 6 p.
6. **Bell W J.** *The College of Physicians of Philadelphia: a bicentennial history.* Canton, MA: Science History Publications, 1987.