

Clinical research and the office-based physician

An untapped data resource may soon be practical and favorable if unified research efforts within the profession succeed.

One of the greatest challenges of current medical research has been to accurately assess the actual practice environment. Most office-based physicians are too busy to participate in research because they lack adequate time for planning, development, and execution. As a result, research that is currently published involves massive efforts by large numbers of individuals to accumulate "retrospective data" from chart histories. Inconsistencies often exist in the language of a chart because of the lack of standardization. This language error may be increased significantly across multiple charts or practitioners' submissions (or both).

Researchers must find interpretation methods for statistical documentation. This process may introduce translation errors into the data pool. Survey participation by physicians can reduce some of the language errors, but interpretation on the part of the submitting physician from personal notes often stretches definitions to "fit the patient data into the proper format."

Research continues to be published and practice guidelines recommended where evidence may not be accurately represented from all sources, resulting in scientifically weakened research and potentially hazardous conclusions. As our medicoeconomic environment continues to change, this error in recording may become progressively more dangerous. Evidence and efficacy studies are already shaping the practice environment in the form of dictates from the insurers on how to practice medicine. Dictates on the practice of medicine are given out as "practice guidelines" from major HMOs. Examples include:

- ☐ Family practice guidelines for the management of non-insulin-dependent diabetes melitus (HIP participating provider newsletter, March 2000). This document describes which drugs are allowable under the plan.
- ☐ Management of hypertension, practice guidelines for the use of blood pressure-regulating drugs (GHI participating provider newsletter, June 2000). This document describes which class of agents should be used as primary, secondary, and tertiary agents in regulation of blood pressure.
- ☐ Policy change memo, November 1999, from Empire Blue Cross Blue Shield requiring an x-ray film as a mandatory procedure before a magnetic resonance imaging study or the procedure will be disallowed.

This "practice guideline structure" is usually based on

insurers' internal actuarial research of billing and submitted claims. As a result, obtaining medically appropriate care is increasingly more difficult as evidenced by multiple studies, surveys, and lawsuits against health maintenance organizations (HMOs) and other insurers.¹⁻²⁸

Efforts by the federal and local granting agencies often rely on data acquired from the insurance providers for large-scale research. This reliance seems reasonable at first glance because insurance providers are in the best position to provide data; however, the data may be source-biased.

The primary care or office-based physician, as well as the office-based specialist, is conspicuously out of the picture. Most of the teaching physicians at osteopathic hospitals and colleges are not participants in research to any large degree and are even less active in uniquely osteopathic research. Even the full-time clinicians at medical education centers are often not participants. In ascertaining why such lack of participation exists, most clinicians personally interviewed at one institutional consortium of more than 12 hospitals answered that they simply do not have time for it. (Personal interviews within the NYCOMEC consortium from 1998 through 1999.) Residents and interns clearly do not have the time, although this group is the largest potential resource the osteopathic medical profession has for gathering current practice data in the hospital setting.

The Osteopathic Research Taskforce, composed of members of the Louisa Burns Osteopathic Research Committee (LBORC) from the American Academy of Osteopathy (AAO), American Association of Colleges of Osteopathic Medicine (AACOM), the American Osteopathic Healthcare Association (AOHA), the American Osteopathic Directors and Medical Educators (AODME), and the American Osteopathic Association (AOA), has made inroads toward resolving some of these problems. A mechanism for easily collecting meaningful data across the entire profession is under development. The methodology proposed and currently under testing may reduce or eliminate duplication of effort. This new use of currently inexpensive and available modern technology can simplify office recording and reporting procedures. It is designed to allow local physicians, as well as university-centered teaching physicians, to participate in large-scale acquisition of data on and for the profession. Using National Institutes of Health (NIH) standards for research, the profession will be able to evaluate and report on general practice activities, cost-effectiveness, educational captured experience tracking, efficacy of modalities of treatment rendered (outcomes studies), utilization of

procedures, complexity of evaluation and management, and far more.

In the early 1980s, the LBORC began developing a national center for the collection of clinical practice data, a National Institute for Osteopathic Research and Education (NIFORE) that will collect secure data over the Internet to a profession-owned data warehouse. Data security is to be designed so that patient identity never enters the system and demographics are limited to geographic regions and economics. An inexpensive electronic medical record is to contain "uniquely osteopathic" data along with standard patient visit information. The system will print out a chartable SOAP note for daily office affairs and records. Submission of a security-encoded modified research record (without direct patient identifiers) to NIFORE is to be completed on a daily or weekly basis. The record calculates the Health Care Financing Administration (HCFA) coding and outputs the Current Procedural Terminology (CPT) and International Classification of Diseases, 9th revision (ICD-9) coding for billing and insurance purposes. This software is to have an open-ended database. Each practitioner is to generate his or her own office-performance evaluations and utilization reviews using widely available, inexpensive data-processing programs. An electronic medical record standardizes language for reporting while allowing for descriptive individual language in a searchable format. Some examples of standardized

languages include Universal Medical Language System (UMLS) and Medical Subject Heading (MeSH) terminology meta-the-sauri.

In the 1990s, several independently run research development projects from professional centers within the AACOM, AAO, AOA, and American College of Osteopathic Family Physicians identified the need for this type of research tool. In December 1999, all these organizations sent members to the Osteopathic Collaborative Clinical Trials Initiative Conference (OCCTIC) in Bethesda, Md, to lay the foundation for the realization of a national center and the further development of research tools. The OCCTIC II is scheduled to meet immediately after this year's AOA conference in Orlando, Florida, on November 2 and 3. All those interested in helping the profession are welcome to attend.

As of July 2000, LBORC is conducting trials on an electronic medical record-associated SOAP note and a Web-based data-transmitting and receiving project. The Osteopathic Research Taskforce has moved forward with plans to secure federal funding for the construction and operation of the NIFORE center. NIH and NCCAM personnel have participated in guiding the development of these projects and are encouraging ongoing collaborative efforts. An introductory research course seminar for clinicians, students, interns, and res-

(continued on page 546)

Editorial

(continued from page 540)

idents has been designed for launch at the AAO convocation in spring 2001. Unity efforts between these organizations have designated the LBORC workforce as agents for the profession to begin the process of "registering" the Osteopathic Language with the Unified Medical Language System (UMLS), Medline, and other key research resources and references. AACOM has begun redesigning its Web site as a research resource. It is developing Web-accessible research guidelines, grant-writing information, procedure manuals, and an updated list of ongoing funded research with key contact information. The Texas Osteopathic College along with Kirksville College of Osteopathic Medicine has moved forward on their grant to provide an osteopathic literature database that will make accessing older osteopathic medical literature far less difficult. NOVA Southeastern has provided crucial information technology expertise and computer time toward these efforts.

Slowly, the profession is coming together on the research front with a potentially powerful instrument, a NIFORE center. The underlying design structure places the local practitioner in a key role as important as that of the university medical center physician. It considers the resident and intern as important members of our professional community. Conservation of data, time, effort, and money are the basis of the project. Security, integrity, and accuracy of the data are the superstructure. Key members across the profession's entire research community are working together for the first time. Their efforts may produce a national and perhaps international milestone—centralized osteopathic and traditional medicine research. ♦

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