Editorial

CANDOO and CANOAR, CORRONA and More: Advancing Therapeutics Through Layered-in Clinical Data Collection and Feedback at the Point of Care


RATIONALE

Everyday clinical practice is the final proving-ground for drug therapies to deliver their benefits to patients. It is a complex and data-rich environment in which initial expectations about the efficacy of new drugs, derived from randomized controlled clinical trials, will not always translate into equivalent outcome levels of effectiveness and safety[1,2]. Real-world, albeit unstudied, variations in patient and physician factors modulate the benefits that patients derive from proven efficacious therapies[3,4]. Physicians and patients may try new and unstudied drug combinations as the number of agents grows for chronic conditions such as rheumatoid arthritis (RA)[5]. However, with the exception of individual patient benefit and anecdotal physician experience, there is no "data-driven" increase in our common knowledge, nor even a systematic benefit to physicians or to other patients, that results from all this individual therapeutic activity. It is as though real-world clinical practice is, collectively, an uncountable number of simultaneous prospective experiments that are being undertaken but with no plan in place for systematic recording, analysis, interpretation, or reporting of the aggregate experimental data.

OBJECTIVE

We therefore believe that a great opportunity exists (1) to systematically collect and aggregate a focused set of clinical data from everyday clinical practice, directly and comfortably from the point of care, on an ongoing basis, and on a large scale; and (2) to continually analyze and report the data back to the point of care, in multiple and meaningful formats, and on a timely basis. Such observational data collection programs can achieve at least 2 benefits. Their ongoing processes of data collection (measurement) and linked data reporting (feedback), in a mutually agreed context of program purposes and goals (partnership), can lead to improved processes and outcomes of clinical care in a manner that is analogous to cycles of continuous quality improvement. Further, this documentation can begin to fill some of the clinically important gaps in knowledge that currently exist between information derived from randomized controlled trials and that from analyses of administrative databases and disease registries[6].

METHODS

The defining feature of such prospective longitudinal data collection programs is that they are an integral part of routine clinical care. They can therefore include "nearly all" patients from participating practices (subject only to obtaining informed patient consent for contributing the data anonymously to the program aggregate).

Unlike an academic research clinic or study center, the data collection process cannot afford to be "layered onto" normal clinical care. It needs to be as succinct and practical as possible, i.e., effectively layered into the available time constraints of routine office procedures. But unlike a disease registry or an administrative database, the program must also collect, from a sufficiently comprehensive patient base (ideally, from each entire practice), an appropriately detailed clinical dataset that includes the principal items that (1) support contemporary clinical decision making, (2) record clinically significant therapeutic interventions, or (3) measure clinically important outcomes. The layered-in integration of program participation into normal clinical practice enables the improvement of practice quality and, by extension, of clinical outcomes. This approach also increases the scientific credibility of the aggregate dataset and its analyses. The data collection program can therefore undertake valuable and longitudinal examinations of key factors in the processes and outcomes of disease management (real-world care) including: patient comorbidities, cotherapies, disease activity, disease severity and self-assessment; physician assessment, prescribing practices, and coaching of patients; followup frequency; monitoring intensity; adverse events; and patient acceptance of, adherence to, and persistence with prescribed therapy.

RESULTS

Have comprehensive prospective observational data collection programs been successfully implemented in clinical rheumatology practice on a large scale? Jim Fries, *et al* orga-

nized the ARAMIS database, which successfully collected data from 5 centers in the United States and Canada[7]. Ted Pincus has been a proponent of the value of patient data collection for several decades[8]. Fred Wolfe collects and "mines" data from forms mailed to patients across the United States[9]. The RADIUS network pays rheumatologists significant fees to induce them to collect data from 10 to 20 RA patients in their practices.

The Canadian Database of Osteoporosis and Osteopenia

The Canadian Database of Osteoporosis and Osteopenia (CANDOO) is a successful longterm layered-in data collection collaboration initiated by Rolf Sebaldt and Rick Adachi in 1994[10]. Eight specialists in osteoporosis from across Canada have been using a common set of clinical data forms to document the core of their routine clinical care for their patients with reduced bone mineral density. There is no program-imposed standard for any component of care such as medication use, bone density measurement, or followup interval. There are baseline forms and shorter followup forms. Forms are completed by patients in the waiting room and reviewed and finalized with the physician or nurse in the office.

The dataset is disease-focused and includes fracture history, reproductive history, past and present bone-active and other relevant medications, adverse events, comorbidities, other risk factors, a quality of life scale, bone density measurements, and exit prescriptions. Data are aggregated into standard electronic form at the program's data management center at Clinforma Data Management (Hamilton, ON, Canada), using anonymous identifiers assigned by the participating sites. By the end of 2002, the CANDOO collaboration had aggregated data from 46,481 office visits of 12,237 patients at the 8 centers. The program has produced over 60 published abstracts, 9 published papers, and 6 currently submitted papers.

Examples of early CANDOO analyses include demonstrating the effectiveness of (1) bisphosphonates in corticosteroid-induced osteoporosis and in male osteoporosis, and (2) combined hormonal replacement and bisphosphonate in postmenopausal osteoporosis, all reported before similar results from corresponding randomized controlled trials became available. Other benefits to the collaborators have been the ability to rapidly search the database to retrieve patients meeting inclusion and exclusion criteria for clinical studies, and to have passed a routine Canadian provincial Ministry of Health billings audit in uncommonly brief time because of the program-related completeness and consistency of all clinical chart documentation.

Canadian Acne Epidemiological Survey

The Canadian Acne Epidemiological Survey (CAES), initiated by Jerry Tan in Windsor, is a CANDOO-inspired layered-in clinical data collection program that provides important additional lessons. This survey is a longitudinal observational collaboration, managed at Clinforma, of community and academic dermatologists from 9 centers across Canada. With high speed Internet access available in all offices, Clinforma created a secure Web-based remote data entry system that was enthusiastically requested by the program participants. However, initial discussions on the use of touch screens or laptops for direct paperless data input could not be implemented at inception due to cost considerations.

These and other barriers highlight the potential difficulties that are to be expected when attempting to manage rapid change in well established physician offices, even when such change is willingly embraced. Program participants now use paper forms for primary patient data collection, followed at the end of the day by secretarial data transcription into the Web-based data system. Lightweight, clipboard-like "tablet" computers offer wireless Internet access on portable, full-size, stylus-sensitive screens. We cautiously predict that such devices or their descendants, if affordable and unbreakable, may replace the use of paper-based data forms for some physicians and patients in future programs. However, these systems cannot only be feasible for physicians who are "technophiles": future programs will succeed only if they enable and promote adoption of a layered-in data collection approach on a large and representative scale.

Canadian Osteoarthritis Rx Program

The Canadian Osteoarthritis Rx (CANOAR) program, in contrast to CANDOO, comprises 130 Ontario-based primary care practitioners recruited by Clinforma with an aim to track up to 130 successive office visits of patients with osteoarthritis (OA) at each site and to assess contemporary prescribing practices for OA[11]. CANOAR emphasized the development and use of methods that busy clinicians found valuable in the routine care of their patients with OA. CANOAR also highlighted the value of community physicians' input into decisions about study design and implementation, through the use of focus groups and pilot testing.

This approach ensured that data forms, patient enrollment, and communications processes were as simple and layered into physicians' daily routines as possible. It allowed the clinical chart note to be replaced by the completed program data form, if desired. Data collected on the single-page, checkbox-style data form included location of signs and symptoms of OA, relevant comorbidities and cotherapies, global assessments, past and current therapies for OA, patient drug reimbursement status, and treatments prescribed. Anonymous patient data were faxed toll-free to Clinforma, which served as the program's data management center. Over one year, CANOAR obtained data from 8846 visits from 5947 patients with OA from 119 sites. Among its

numerous results, CANOAR data confirmed that substantial care gaps are present in the management of patients with OA who receive nonsteroidal antiinflammatory drugs. The data suggested that these care gaps may be related, at least in part, to the type of patient insurance coverage for drug reimbursement. CANOAR demonstrated the feasibility of easy, rapid, and prospective data collection from the point of care in the data-rich environment of real-world, community-based care.

Consortium of Rheumatology Researchers of North America

Since 2002, the Consortium of Rheumatology Researchers of North America (CORRONA) has been collecting data from patients and rheumatologists in a network of several hundred participating community and academic rheumatologists from across the United States. CORRONA has a goal of improving patient care by (1) improving the quality of information gathered through the data collection process and (2) providing data-driven feedback to participants via a data-enabled website.

Baseline and followup patient forms track comorbidities, antirheumatic drug treatments, adverse events, the Medical Outcome Study Short Form-36, and the Health Assessment Questionnaire. Serial physician forms track rheumatic diagnosis, disease assessment, hospitalizations, drug toxicities, investigations, and drugs prescribed. There are multiple incentives and benefits for physicians to participate in CORRONA. These include payment for completed forms, a much needed standard documentation for billing purposes, the ability to participate in future CORRONA sponsored research studies funded entirely from its own resources, and the provision of an electronic database of all submitted data through Clinforma's customized interactive data-enabled website.

The data-enabled website provides a rich variety of adjustable views on the accumulated data and allows participating physicians to: (1) track and graph individual patient data longitudinally; (2) easily search the database for lists of patients by inclusion and exclusion criteria; (3) track and graph aggregate longitudinal data of subgroups of patients; and (4) compare practices among doctors within a site or with the entire network.

CORRONA recognized that the process of incorporating the data collection program into the daily practice routine could at first appear daunting, or even onerous. The program therefore works closely with physicians to provide hands-on support during the transition phase of adoption of the forms, demonstrating that the process of gathering routine data systematically on its forms is efficient and actually saves time. CORRONA also works closely with its data management center at Clinforma to exploit the benefits of the center's pragmatic process implementations, proven clinical data systems, and cumulative experience gained from managing many earlier programs and projects. As a result, the acquisition, cleaning/querying, aggregating, feedback, and reporting of CORRONA data have been physician-friendly and reliable as well as efficient, cost effective, adaptable, and scalable. At the time of writing, the CORRONA database contains data of about 4500 patients and is growing at a rate of about 500 patients per month.

SUMMARY

Substantial challenges have been recognized and addressed in developing and implementing the prospective observational data collection programs in clinical rheumatology summarized above. Each program has progressed beyond an initial vision to a working and adaptable implementation that delivers program results efficiently and with longterm sustainability. In meeting the challenge to achieve this result, an essential backbone component has proven to be technically capable, easily adaptable, and cost effective data management processes that support, nurture, provide the benefits of, and sustain the layered-in data collection and feedback approach. Such data collection programs can serve as the source of ongoing relevant and personalized data-driven feedback to both practitioners and their patients about their practices and outcomes, leading to improved patient care and benefits in a continuous cycle of measurement and feedback built on the program partnership. At the same time, analyses of the longterm longitudinal data obtained by such programs can derive a wealth of important and unique new information about treatments, outcomes, and cost effectiveness in real-world care that is not otherwise available.

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