

THE JOURNAL OF BONE & JOINT SURGERY

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J Bone Joint Surg Am. 2009;91:80-86. doi:10.2106/JBJS.H.01623

This information is current as of May 1, 2009

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Publisher Information

The Journal of Bone and Joint Surgery
20 Pickering Street, Needham, MA 02492-3157
[www.jbjs.org](#)

Multicenter Collaboration in Observational Research: Improving Generalizability and Efficiency

By Sheila Sprague, MSc, Joel M. Matta, MD, and Mohit Bhandari, MD, MSc, FRCSC, on Behalf of the Anterior Total Hip Arthroplasty Collaborative (ATHAC) Investigators*

Utilizing a multicenter approach in observational clinical research allows for improved generalizability of the results, a larger sample size, and, consequently, improved efficiency. This paper highlights important issues with regard to the organization of multicenter observational studies in orthopaedic research. Specifically, we emphasize the development of trial committees, stress the importance of having a methods center for the purpose of coordinating day-to-day study activities, and describe the roles of the participating clinical sites. The successful conduct of multicenter studies requires careful study organization, a dedicated and experienced methods center, and motivated participating surgeons and study staff at the clinical sites. To illustrate the organization of a multicenter initiative, we use the example of a total hip arthroplasty collaborative.

Introduction

A large clinical study conducted cooperatively at multiple centers has a number of important advantages over a small study performed at a single center or small number of centers. Multicenter studies have the advantage of increased generalizability of the results¹. Typically, the more surgeons and the more clinical sites participating, the more generalizable to other patient populations the results of the study become. Multicenter collaborations also offer the potential of recruiting more patients within a much shorter time frame¹. In other words, multicenter clinical research is more efficient than single-center research because it allows the accrual of sufficient numbers of diverse participants in a substantially shorter period of time than could be effected at a single center.

Reports on large multicenter trials, international trials, and large cohort outcome studies are generally sparse in the orthopaedic trauma literature², whereas single-center observational studies are frequently reported. One major limiting factor of single-center initiatives is the difficulty of enrolling a sufficient number of participants from one clinical site within

a reasonable time frame to answer the research question³. To provide a valid answer to a clinical question, a sufficient number of patients must enter the study and then be available for follow-up at the end of the trial. Despite the volume of observational studies in the orthopaedic literature, there are few adequately powered observational studies. Although some conditions of interest to orthopaedic surgeons are common, such as back pain and lower-extremity osteoarthritis, many are relatively rare. For this reason, the participation of multiple investigators at multiple sites is necessary to obtain sufficient numbers of subjects for much of the research that is needed in our field⁴. Unfortunately, most studies still include one or only a few centers, which results in limited external validity². In other words, if a study is not adequately powered, the results may not be believable, as the outcomes may be due to chance alone. Consequently, single-center and especially single-surgeon studies may not produce results that are generalizable across different jurisdictions.

Observational studies can be useful in assessing patient profile, objective outcomes, and appropriate clinical end points before beginning a larger clinical trial². These observational

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Disclosure: In support of their research for or preparation of this work, one or more of the authors received, in any one year, outside funding or grants in excess of \$10,000 from DePuy. In addition, one or more of the authors or a member of his or her immediate family received, in any one year, payments or other benefits in excess of \$10,000 or a commitment or agreement to provide such benefits from commercial entities (Stryker, DePuy, Mizuho OSI).

studies can establish a baseline for interventional trials in which an implant or procedure is tested². In addition, in many situations, a multicenter observational study is the only ethical study design that can address a research question.

One of the barriers to conducting large multicenter observational studies is their relatively complex organization. However, these studies can be designed to reduce complexity by giving careful forethought to the development, implementation, and execution of the study from its inception to completion at each participating institution³. One common method is for a single investigator to establish the necessary local or national collaborations⁵. One of the limitations to this approach is the need to recruit collaborators and develop infrastructure for every trial⁵. A second method has been for groups of surgeons to form collaborative networks supporting one or more trials⁵. A very successful example of this approach is the Canadian Orthopaedic Trauma Society, a collaborative of Canadian orthopaedic surgeons who have completed and published multiple research studies together. A potential disadvantage of this approach is that a permanent infrastructure may not exist; consequently, the network runs the risk of dissolution with gaps in funding or investigator interest⁵. Wright and Gebhardt also suggested national leadership from organizations (e.g., the American Academy of Orthopaedic Surgeons); however, they concluded that such organizations have broad mandates and that their members were not likely to have sufficient shared interests to make such organizations successful in facilitating randomized clinical trials⁵. They concluded that the musculoskeletal specialty societies (e.g., the Orthopaedic Trauma Society) would be the more logical groups to have the potential to facilitate clinical trials, as specialty societies have the necessary shared interest to promote the trials⁵.

Models for Multicenter Observational Collaborations

Several large orthopaedic collaborative groups have been established with the goal of conducting large multicenter observational studies. The Lower Extremity Assessment Project (LEAP) investigators successfully completed a multicenter, prospective, observational study to determine the functional outcomes of 569 patients with severe leg injuries resulting in reconstruction or amputation⁶. Eight level-I trauma centers participated in the LEAP study, and they enrolled patients from March 1994 to June 1997⁶. The LEAP study provides an excellent example for the justification of multicenter collaboration, as, prior to the LEAP study, the observational studies that evaluated limb reconstruction were small and retrospective, making the results less than definitive. In addition, many of the results of those studies were contradictory⁶.

Another recently developed collaborative is the Anterior Total Hip Arthroplasty Collaborative (ATHAC). This is a multicenter research group with an interest in cooperative research aimed at improving knowledge about this surgical technique. They have recently completed a retrospective multicenter observational study that was conducted at nine clinical centers in the United States and that evaluated function and complications associated with the anterior approach to total hip arthroplasty

in 1152 patients. The ATHAC study was coordinated by an independent and experienced methods center in Canada.

The purpose of this manuscript is to provide an overview of key elements of a multicenter collaborative and to discuss some considerations for organizing a successful collaboration and completing an observational study.

Overview of Key Elements of a Multicenter Collaborative

Multicenter trials will only be successful with appropriate infrastructure⁴. A high-quality multicenter observational study requires as much time in its planning, preparation, and organization as it does in its execution⁷. Every successful clinical study requires a motivated, cooperative, and competent research team⁷, and multicenter observational research studies require a much larger and more organized team of professionals than single-center observational studies do. Typically, this research team should have clinical experts (orthopaedic surgeons), biostatisticians, health-research methodologists or epidemiologists, and research staff, including a project manager and research coordinators. Ideally, individuals with previous experience or expertise in observational research should be included as part of the study team.

Figure 1 shows how a multicenter observational study can be organized. The steering committee is responsible for the trial oversight. Other important committees include the central adjudication committee, the data safety and monitoring board, and the writing committee. At the center of the activities is the methods center of the study. The methods center is responsible for the overall coordination of the trial and the day-to-day activities. The clinical sites are responsible for enrolling patients into the study and collecting the data. Dedicated, organized, and efficient clinical sites are essential for the successful completion of any observational study.

The ATHAC study used a model similar to the one shown in Figure 1. Since their study was retrospective, they did not include a data safety and monitoring board or a central adjudication committee. In addition to the steering committee, they had a subcommittee that was responsible for the design and finalization of the study protocol. A methods center coordinated the trial committees and the daily activities, including the communication with the clinical sites. Nine dedicated clinical sites participated in this study, submitting data on more than 1000 patients. The data were then validated and analyzed at the methods center. A writing committee was established to prepare the manuscript for publication.

Study Committees

Steering Committee

The complexity of a study with multiple participating centers requires key organizing committees to oversee the conduct of the observational study¹. A steering committee can be comprised of individuals who are directly involved in the trial or individuals who are not active participants of the trial¹. Members often include the principal investigator(s), a biostatistician, a research methodologist, multiple clinical experts, and other key individuals who are deemed important to the

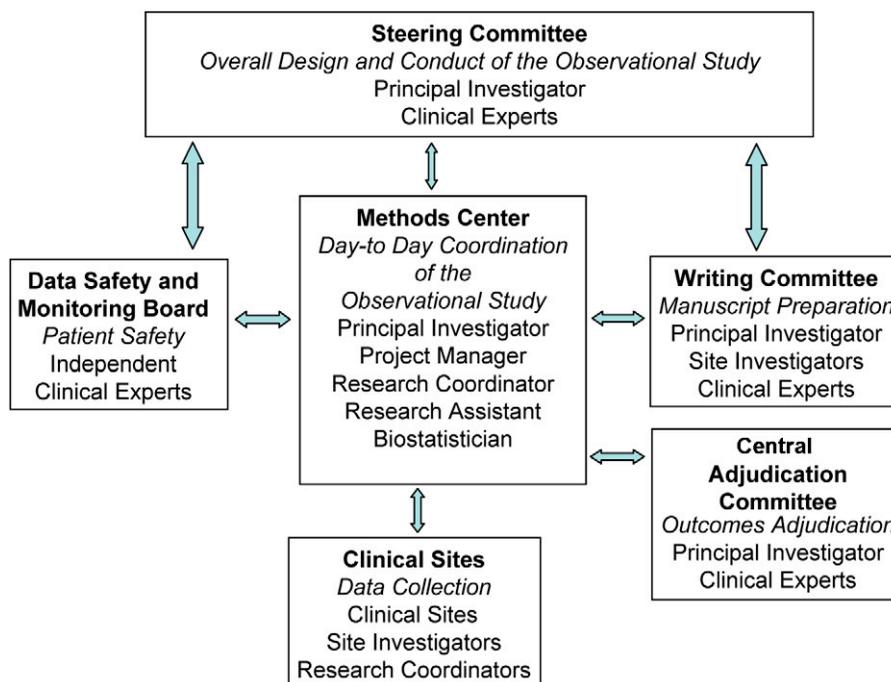


Fig. 1
Organization of multicenter trials. This figure provides a model of how to efficiently organize a multicenter observational study.

design and conduct of the study¹. The size of the steering committee often depends on the size of the initiative and the complexity of the research question and study design. The steering committee should have a sufficient number of experts to adequately oversee the design and conduct of the trial, but not so many that it becomes inefficient and dysfunctional. The steering committee is usually responsible for developing and finalizing the study protocol and procedures. During the planning and conduct phases of the observational trial, the steering committee communicates frequently with the methods center and the participating clinical sites regarding any issues that arise, such as protocol deviations, recruitment issues, and data-quality issues. At the completion of the trial, the steering committee maintains responsibility for the data analysis and is responsible for the organization of the writing committee.

The ATHAC steering committee was comprised of the principal investigator and two clinical experts, and these individuals were responsible for the overall design and conduct of the observational trial. Two additional clinical experts provided a substantial amount of input into the study protocol.

Data Safety and Monitoring Board

Data safety and monitoring involves reviewing accumulated outcome data from an ongoing clinical trial to ensure the continuing safety of current participants and those yet to be enrolled. The data safety and monitoring board also ensures the continuing validity and scientific merit of the trial. Most clinical trials, especially randomized controlled trials that are evaluating a new or existing treatment, require a safety monitoring plan. A data safety and monitoring plan should be tailored to the na-

ture, size, and complexity of the research protocol, the expected risks of the research, and the type of patient population being studied. Items to consider are the type of data or events that are to be captured under the monitoring plan (such as adverse events), who will be responsible for reviewing the safety data, time frames for reporting adverse events or unanticipated problems to the methods center, and definitions of study stopping rules for patient safety. After reviewing an analysis of the study's safety data, it is a fundamental responsibility of every data safety and monitoring board to make recommendations to the steering committee concerning the continuation of a study. The data safety and monitoring board may recommend that the study continue as designed, that the study be terminated because it is causing harm to the participants, that the study continue with major or minor modifications, or that the enrollment and/or study intervention be temporarily suspended until some uncertainty is resolved¹.

The individuals responsible for monitoring patient safety must be completely independent from the study and the study investigators. Many sponsors and funding agencies have set guidelines for establishing data safety and monitoring boards. Data safety and monitoring boards are typically made up of experts in the clinical field being studied and they often include a biostatistician or an epidemiologist. The ATHAC study did not have a data safety and monitoring board; however, the safety was analyzed and included in the final report.

Central Adjudication Committee

The central adjudication committee may review patient eligibility, study end points, and protocol deviations to determine if

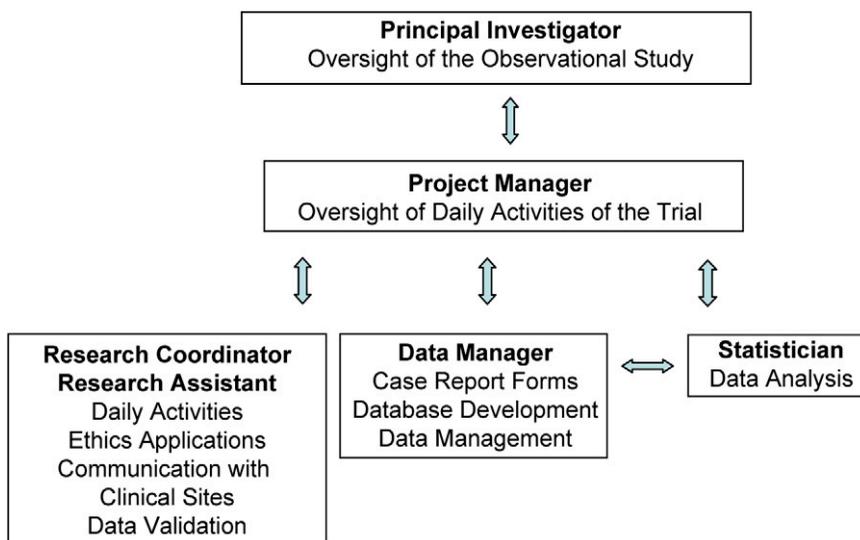


Fig. 2

Organization of the methods center. This figure shows the roles and responsibilities of the key personnel at the methods center.

they meet protocol-specific criteria. The central adjudication committee should be blinded to treatment allocation¹. This adjudication process is an important method of reducing bias and is necessary when the items of interest are subjective in nature. The central adjudication committee will review radiographs, operative notes, and clinical notes to ensure that the patient was eligible for the study, to determine if any protocol deviations occurred, and to determine if the patient had any of the study outcomes. The ATHAC study did not have a central adjudication committee, which is one of the limitations of this study.

Writing Committee

At the onset of a multicenter observational study, the steering committee should develop the writing committee. Often the writing committee includes the steering committee members and several additional clinical or methodological experts. The authorship policies should be established by the steering committee relatively early in the course of the observational study, so everyone is aware of how credit for their work will be presented. Options for authorship include group authorship (for example, the ATHAC Investigators), representatives of the collaborative who are publishing on behalf of the other investigators (for example, Author A, Author B, and Author C on behalf of the ATHAC Investigators), or individual authorship (for example, Author A, Author B, and Author C). Responsibilities of the writing committee include the planning, oversight, and interpretation of the data analysis and the drafting of the manuscript. Depending on the study policies, the steering committee and/or all site investigators may be required to review and provide input into the study manuscript. If several manuscripts are anticipated to result from a large observational study, several writing committees may be formed. This provides many individuals with the opportunity to prepare a manuscript and be

involved with one of the trial committees. The ATHAC writing committee was comprised of the steering committee and four clinical experts.

Methods Center—Overall Organization

In multicenter observational trials, the methods center is responsible for the day-to-day management and coordination of the trial¹. Typically, a number of different staff members are required for the successful coordination and completion of a high-quality observational study (Fig. 2). The tasks and individuals required at the methods center depend on the scope of the study and the phase the study is in. The number of personnel required for an efficient methods center depends on the size and the complexity of the observational study. In the ATHAC study, the study staff at the methods center included a project manager, a research coordinator, a research assistant, and a statistician.

During the start-up phase of an observational study, individuals at the methods center are responsible for finalizing the study protocol, designing the case report forms, writing the manual of operations, programming the data-management system, obtaining approval from the ethics board, and selecting clinical sites. The methods center is also responsible for preparing grant applications to secure funding for the observational study. The methods center may also conduct pilot testing or pretesting prior to the initiation of an observational study. In the ATHAC study, prior to the distribution of the case report forms to all participating centers, the methods center project manager conducted a pilot data-abstraction site visit to one of the clinical centers. The project manager reviewed and abstracted a random sample of 100 patient records, and, as a result, the piloted case report forms were revised to include patients who underwent bilateral total hip arthroplasty, questions on the case report forms were rearranged to make data abstraction

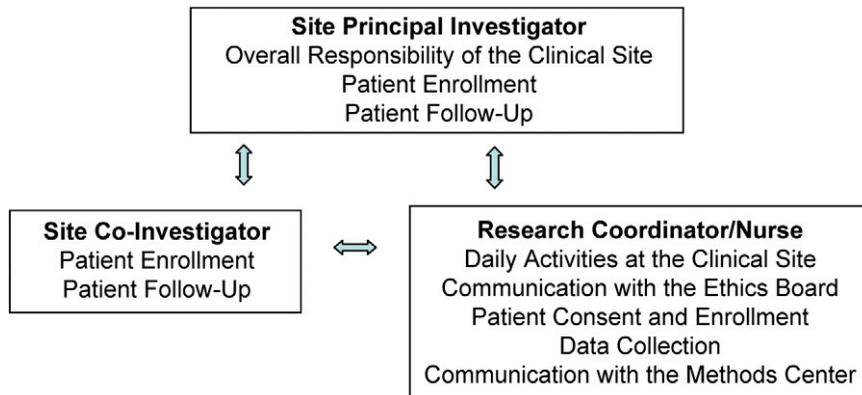


Fig. 3
Organization of the clinical site. This figure shows the roles and responsibilities of the key personnel at the clinical sites.

as efficient as possible, and other minor changes were also implemented.

The methods center is also responsible for sending the study supplies (i.e., protocol, manual of operations, and case report forms) to the clinical sites and ensuring that the personnel at the clinical sites are trained in the study methods to ensure high-quality data collection. Study training may be completed by hosting an investigators meeting, holding a teleconference or Internet meeting, or visiting the individual clinical sites. In the ATHAC study, personnel at the sites received training through participation in investigators meetings and by means of teleconferences. It is important to review the protocol, study procedures, and expectations at the investigators meetings. Proper training is invaluable in conducting high-quality research.

During the data-collection phase, the methods center is responsible for overseeing the collection of the data at the clinical sites and validating the data as it is submitted to the methods center. Data can be submitted via an electronic data capture system, by facsimile with use of a system such as DataFax (Clinical DataFax Systems, Hamilton, Ontario, Canada), or by courier, depending on the resources available and the organization of the methods center. It is important that data be submitted and reviewed in a timely fashion to facilitate quality assurance. Documents summarizing the queries and outstanding data should be sent to the clinical sites frequently to ensure that clean data are available for the analysis. This approach often helps to avoid missing and inconsistent data. In addition, the research coordinators at the methods center should be available to answer any questions raised at the clinical sites.

In the ATHAC study, data abstraction was conducted with use of one of two methods. The majority of the clinical sites retained all patient information in personal and medical records. There were a few clinical sites that recorded all information into an electronic database. The demographic, surgical, and outcome data for each patient were recorded on study-specific case report forms that were submitted to the methods center by fax or courier for validation. The methods center staff was available to answer any questions from the clinical sites re-

garding data collection. In addition, the staff at the methods center contacted the clinical sites with questions about any inconsistent or missing data that were noted during the validation process. Three centers required site visits by the research coordinator from the methods center to assist with completion of the case report forms.

Once data collection is complete, the tasks required to complete an observational study include data analysis and manuscript preparation. The statistician, under the guidance of the writing committee, is responsible for the data analysis. The project manager typically assists with the organization of the writing committee and the manuscript preparation.

Clinical Sites

The primary responsibilities of the clinical sites in an observational study are the identification of eligible patients and the collection of high-quality data (Fig. 3). The clinical sites are led by a site principal investigator, usually an orthopaedic surgeon, who assumes the overall responsibility of the study at the site. This individual should be committed to the completion of the study and have sufficient time to oversee all aspects of the trial and ensure that patients are enrolled and data are collected. Most surgeons interested in clinical research would like to be intellectual partners, and these surgeons do not want to be presented with someone else's approved project and be invited only for their ability to enroll patients⁴. Instead, the success of the project requires that a core research team be developed early enough to critically assess the potential of the research question and that the members of the team then work as a group to define, design, and drive the project⁴. It is imperative to include key site principal investigators on trial committees.

Additional orthopaedic surgeons may participate in the study at the clinical site as co-investigators. Their role is typically patient enrollment and follow-up. Site investigators should not be so overburdened that they cannot devote the requisite time to manage the clinical trial⁵. If the protocol is complex, it is best to collaborate with a few surgeons who are dedicated to the study and are willing to learn and follow a complex protocol³.

As surgeons do not have sufficient time to monitor the daily activities at each site, dedicated personnel are required to conduct day-to-day study operations⁴. The success of the study is ultimately dependent on the expertise and commitment of these individuals⁴. A research coordinator or research nurse, under the supervision of the site principal investigator, is responsible for the day-to-day activities at the clinical site. These responsibilities include obtaining ethics approval to conduct the study at the clinical site; this approval may be obtained either through the local institutional review board or through a central institutional review board, if this option is permitted by the institution. Opting to obtain approval from a central institutional review board can reduce the burden of obtaining local ethics approval, as the protocol, informed consent template, and other study documents are submitted to the central institutional review board by the methods center and are approved for the study as a whole. Individual sites can then submit their own site-specific information and informed consent and receive approval quickly and easily rather than having to obtain independent approval from their local ethics board. Other responsibilities include obtaining patient consent, data collection and submission, and communication with the methods center. The research coordinator and the site principal investigator work together to ensure compliance, data quality, and effective communication with the methods center¹. The research coordinator should be well organized and detail oriented and able to independently troubleshoot, problem-solve, and maintain communication with all parties involved in the study³.

The ATHAC observational study included nine clinical sites across the United States. Each site had a site principal investigator, some sites had co-investigators, and most sites had a research coordinator. If a clinical site did not have a research coordinator, a research coordinator traveled to the clinical site to complete the data collection. This was appropriate due to the retrospective nature of this observational study; however, this approach will not work very well in large prospective studies because of the costs involved.

International Collaboration

International collaboration in multicenter observational research is relatively uncommon in orthopaedics. Advantages to international collaboration include an increased generalizability of the study results and the opportunity to enroll more patients in a shorter time frame. Countries such as India⁸ provide an excellent opportunity for multicenter collaboration outside of North America. Accelerated urbanization and industrialization in India, with its population of 1.2 billion people, has resulted in an alarming increase in traumatic injuries and, consequently, orthopaedic procedures. In addition to high patient volume, research output from India is currently insufficient and unfocused, which provides an excellent opportunity for developing research initiatives⁸. During the last decade, the number of clinical trials that are being conducted in India has increased rapidly⁸. It is estimated that nearly 20% of all global research studies will include clinical sites in India by 2010⁸. India is well on its way to attracting high-quality researchers

TABLE I Considerations for Organizing a Successful Collaboration and Completing an Observational Study

Collaborative-Specific Considerations	Study-Specific Considerations
Have committed leadership at the steering committee level and site level	Develop a feasible protocol
Develop a cohesive study team	Conduct pilot tests to ensure feasibility and efficiency
Establish a communication and decision-making process	Ensure protocol adherence
Obtain adequate funding	Ensure data quality
Foster a cohesive spirit	Monitor site performance
Establish a dedicated methods center	Adhere to the analysis plan
Set realistic goals and timelines (and stick to them)	Adhere to good clinical practice

and establishing itself as having a global capacity for research studies⁸. Potential challenges of international collaborations include an increased complexity of the study, challenges in the standardization of the study protocol and procedures due to variations in practice patterns, a potential for increased costs, and difficulties communicating if language barriers exist.

Considerations for Organizing a Successful Collaboration and Completing an Observational Study

A number of components are essential for successful collaboration and the completion of a high-quality observational study (Table I). The success of any multicenter clinical trial depends on the collaborative efforts of a highly functional and cohesive team, and this team requires strong leadership to provide motivation, to keep tasks progressing, and to ensure that a high-quality project is completed in a timely fashion³. Other items to consider are the establishment of a detailed communication and decision-making process, methods of obtaining adequate funding to support the initiative, the establishment of a dedicated and qualified methods center, and the setting of realistic study goals and timelines.

Developing a feasible and realistic protocol is essential to the successful completion of an observational study. If a study is not feasible, the study will not be completed, regardless of any other factors. It is important to conduct pilot tests to ensure the feasibility and efficiency of the study protocol and procedures. Although this may seem like an additional step and may delay the start of a larger study, proving feasibility is vital. Another factor to consider is adherence to the study protocol. During the pilot phase, all protocol deviations should be recorded. The methods center should monitor data quality and site performance throughout the study. If a clinical site is not enrolling a sufficient number of patients or if data quality is poor, the problems need to be addressed at the site immediately. Finally,

when the study is complete and all data are validated, data analysis should begin. It is extremely important to adhere to the data analysis plan and ensure that the data are not dredged for additional findings. A final point is to ensure that all clinical sites adhere to good clinical practice to ensure that the rights and the safety of all study participants are protected.

Summary

Multicenter observational studies require vigilance to detail, comprehensive planning, and collaboration with colleagues. While challenging, such studies offer great potential for building a scientific base for the practice of orthopaedic surgery. Several large observational studies have been conducted in the field of orthopaedic surgery. Future collaboratives should in-

clude international sites in addition to North American sites for the purpose of improving external validity and efficiency. ■

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