Challenges in Outcome Measurement

Clinical Research Perspective

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Abstract

Background Comparative effectiveness research evaluates treatments as actually delivered in routine clinical practice, shifting research focus from efficacy and internal validity to effectiveness and external validity (“generalizability”). Such research requires accurate assessments of the numbers of patients treated and the completeness of their followup, their clinical outcomes, and the setting in which their care was delivered. Choosing measures and methods for clinical outcome research to produce meaningful information that may be used to improve patient care presents a number of challenges.

Where Are We Now? Orthopaedic surgery research has many stakeholders, including patients, providers, payers, and policy makers. A major challenge in orthopaedic surgery outcome measurement and clinical research is

providing all of these users with valid information for their respective decision making. At present, no plan exists for capturing data on such a broad scale and scope.

Where Do We Need to Go? Practical challenges include identifying and obtaining resources for widespread data collection and merging multiple data sources. Challenges of study design include sampling to obtain representative data, timing of data collection in the episode of care, and minimizing missing data and study dropout.

How Do We Get There? Resource limitations may be addressed by repurposing existing clinical resources and capitalizing on technologic advances to increase efficiencies. Increasing use of rigorous, well-designed observational research designs can provide information that may be unattainable in clinical trials. Such study designs should incorporate methods to minimize missing data, to sample multiple providers, facilities, and patients, and to include evaluation of potential confounding variables to minimize bias and allow generalization to broad populations.

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Introduction

Current emphasis in clinical research is expanding from the traditional focus on efficacy, which aims to demonstrate a treatment effect in well-defined populations under controlled conditions, to comparative effectiveness research, which seeks to compare and quantify the effects of different treatments in typical clinical populations who are receiving care from community practitioners. According to the Institute of Medicine: “The purpose of comparative effectiveness research is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels” [13]. To address this purpose,

comparative effectiveness research focuses on evaluating current treatments in populations as actually delivered in routine clinical practice and identifying characteristics of patients, providers, and systems that may affect treatment delivery and outcome [30]. We describe some current challenges to orthopaedic surgery outcome measurement in the context of comparative effectiveness research and potential solutions to these challenges.

Where Are We Now?

Effectiveness studies require accurate and responsive measures, large sample sizes, and collection of detailed data describing characteristics of the patients and the context of the episode of care. In addition to efficacy studies and clinical trials, observational studies are anticipated to have a large role in informing comparative effectiveness research [30]. Orthopaedic surgery outcome research also has many stakeholders, including patients, providers, researchers, payers, and other associated industries (pharmacologic, medical device manufacturers, major employers, academic and research institutions, etc), as well as policy makers [13]. Each of these stakeholders approaches outcome data with a different set of questions and purposes (Table 1). A major challenge in orthopaedic surgery outcome measurement across the required breadth of clinical research is providing all consumers with valid information for decision making [20].

This information will need to be collected consistently from orthopaedic surgeons who are practicing in a wide variety of settings (eg, private or group practice, hospital-based, medical school) and environments (eg, Level 1 trauma center, community hospital, outpatient surgery

center) [8]. At present, no comprehensive plan exists that allows for capturing data on such a wide scale and scope.

Where Do We Need to Go?

Practical Barriers: How Are We Going to Collect These Data?

Practical barriers affect our ability to obtain accurate, comprehensive, and meaningful data across the broad spectrum of populations and practice variations required for comparative effectiveness research. Ideally, measures would be standardized to allow for aggregation and comparison of data across providers, settings, and systems. In addition, data collection should capture the structure and multiple aspects of health care, as well as the context of the complex policies, systems, and environments in which the practice of orthopaedic surgery occurs [3]. Barriers impeding these goals include resource constraints and issues related to data collection and management.

Currently, outcome measures are not routinely used by community practitioners in clinical decision making and the delivery of care. This makes it challenging to obtain such data during routine clinical practice without introducing substantial burden and costs. Administration of a clinical practice focuses on delivery of patient care and does not typically have research as a primary focus or objective. Consequently, allocating resources for research-specific activity is a major challenge for data collection during routine clinical practice. Availability of equipment, supplies, floor space, and dedicated staff time and effort for research activity and data collection may be limited and

Table 1. Examples of stakeholder perspectives on clinical outcomes data

Stakeholder	Questions	Uses for clinical outcome data	Examples of meaningful clinical outcome data
Patients	What should be done for me?	Identify best available treatment (and best provider) for their condition Inform expectations	Return to usual activities Quality of life and well-being
Providers	What should I be doing for this patient and for my patients in general?	Identify best available treatment for their patients Improve practice quality and proficiency	Technical treatment success Patient-reported outcomes Case mix information
Payers	What should be done for (and by) everyone in general?	Identify best treatments for many conditions across many patients and providers	Patient-reported outcomes Case mix information Costs
Policy makers	What is worth doing, and how do we get it to people who need it?	Identify best practices and standards for the population Evaluate effectiveness across medical conditions	Costs Preference/utility measures

competing with the demands of providing efficient patient care.

Furthermore, collection of outcome data and other meaningful information for research purposes often involves abstracting multiple clinical and practice administration databases, as well as systems for finance and billing, scheduling, and various other clinic and hospital records. These databases and systems often lack standard content, structure, or format across providers, facilities, and systems, introducing substantial barriers to aggregating data for larger-scale analyses. The data in these systems are often not constructed for research-related data abstraction and may be insufficient or incomplete for research purposes, making retrieval tedious, error-prone, and costly [37, 38]. For example, many of these systems require significant reprogramming to create a single, detailed data matrix of variables in columns indexed by patients in rows, as is typically needed for statistical analyses.

Design Issues: Where and When Are We Going to Collect These Data?

Comparative effectiveness research requires data and study designs that measure and evaluate patients and circumstances encountered in routine clinical practice. This focus on external validity is a key feature of effectiveness research, which differs from the more classic clinical trial focus on internal validity to attribute effects to treatment. To increase external validity, longitudinal data ideally would be collected from samples of patients from many hospitals, practices, and surgeons who are also sampled to represent current practice variations.

An example of such a project is Function and Outcome Research for Comparative Effectiveness in TJR (FORCE-TJR), which began enrolling patients in 2012 [8]. FORCE-TJR is a consortium of orthopaedic surgery practices in the United States, including high-volume academic departments and medical centers, as well as individual and group practices. FORCE-TJR collects patient-centered outcome measures before surgery and annually after surgery but also includes standardized measures of complications and adverse events, patient risk characteristics, surgeons and their practices, and clinical examination data [8]. (Editor's note: For more information on FORCE-TJR, please see the articles by Ayers et al. [2] and Franklin et al. [9], also in this issue of *Clinical Orthopaedics and Related Research*.)

Also, time to recovery varies depending on the diagnosis, treatment, and the defined end point or outcome, so a study design issue arises regarding the number and length of the data collection intervals and the minimum time after treatment required to evaluate each particular outcome. Such complex data collection designs require multisite

collaborations, larger sample sizes, additional data collection, and appropriate statistical methods that incorporate such design elements into the analytical model [6, 22, 24, 25, 36].

Contextual Factors: What (Else) Are We Going to Collect?

Contextual factors, which are characteristics of the providers, facilities, and systems associated with an episode of care, are often ignored in clinical outcome research and efficacy trials [3]. Randomization and experimental control eliminate or balance variability of these contextual factors to minimize their influence on the analyses, since they are considered a source of bias rather than factors of interest.

By contrast, clinical effectiveness research aims to determine how characteristics of the providers, facilities, and systems affect treatment outcome. Consequently, data on those characteristics would also need to be collected, which compounds the data collection task and associated costs considerably. Ignoring these contextual factors in observational studies, including analyses of registry data, confounds interpretation, introduces bias in estimates of the treatment effect, and limits the generalizability and applicability of results.

Incorporating contextual information into outcome research data collection, reports, and databases will improve the ability to identify best practices based on individual patient characteristics, as well as provider, facility, and system-level factors. Ideally, data collection during clinical research would capture variations in population, setting, and system characteristics that may be associated with delivery or outcome of treatment (Table 2).

How Do We Get There?

Practical Barriers: Rethink Current Clinical Processes

Practical challenges to wide-scale outcome measurement exist, but with the continuing trend toward electronic medical records and interconnected administrative systems [27, 37, 38], these issues are ultimately unlikely to be the limiting factor. Some recent systems have been developed and implemented using standard measures and connecting across different data sources (eg, medical records and financial databases) [8, 10]. These systems integrate the collection of research-oriented data into the routine clinical workflow.

In the near term, resource limitations may be addressed by repurposing and redesigning the existing resources to

Table 2. Examples of contextual data at multiple levels of the healthcare environment

Level	Contextual data
Patient	Demographics
	Age
	Sex
	Family status
	Employment status and occupation
	Household income
	Diagnosis
	Stage of disease
	Acuity
	Prognosis
	Health-related risk factors and behaviors
	Smoking
	Drug use
	Obesity status
	Activity
	Diet
	Comorbidities
	Comorbid injury or acute illness
	Chronic disease
	Social and cultural factors
	Personal expectations for health care
	Family/social roles and expectations
	Cultural influences and expectations
Provider (surgeon)	Experience
	Practice size
	Case volume
	Case mix
	Practice setting
Healthcare industry	Academic medical center
	Private practice
	Hospital and surgical systems
	Trauma center
	Community hospital
	Specialty surgery center
	Delivery systems
	Available facilities
	Available services
	Proximity of facilities and services
	Referral relationships
	Industry
	Medical supplies
	Surgical implants and disposables
	Technology and equipment
	Information systems
	Payers and payment systems
	Private
	Public
	Medicare
	Workers Compensation

Table 2. continued

Level	Contextual data
Population and policy	Regional demographics
	Disease prevalence
	Laws, regulations, and policies
	Local
	Regional
	State
	Federal
	Environmental factors
	Urban
	Rural
	Major employers and industry
	Community health programs
	Infrastructure support and funding

increase efficiencies. For example, clinic flow, staff, patient wait time, and clinic space may be reorganized to include outcome measurement as the patient moves through the clinic [8, 10]. In our clinic, patients move in stages from the waiting area to an automated touchscreen data collection system before going to the examination room. The instruments presented to the patient depend on the limb or joint. The data collection takes 15 to 20 minutes, which was the average time that patients previously spent in the waiting area. The touchscreen system requires little monitoring by clinic staff, and the delivery of care is uninterrupted.

There are a number of available and developing information technologies and methods that also may aid in data collection, such as computer-adaptive testing [7, 12, 28]. In computer-adaptive testing, patients are presented only those survey items that most closely match the severity of their condition. Since those items represent a subset of the total survey, reliable data can be collected more efficiently and with less patient burden. Capitalizing on such methods may automate and streamline data collection and provide for instantly available scoring, tabulating, reporting, and storing of data. Inclusion of information services staff or service as a vested partner in the design of the system, including the linking of multiple data systems, can lead to creative solutions and additional efficiencies, such as avoiding duplicate data collection or data entry, incorporating system redesigns into regular system maintenance, and ensuring system functions and outputs match the needs of the end user, the clinician-researcher. Our group practice has been using such a system since the late 1990s, and several recent publications describe similar systems that demonstrate the feasibility of incorporating outcome measurement into clinical practice [8, 10, 27].

Design Issues: Use Complex Data Collection to Capture Complex Effects

In addition to the common “pre-post” clinical research design, recovery may also be modeled as a function of time, which requires three or more data points to create a time course or trajectory for each patient [15]. For example, a study objective may be to determine which of two procedures results in a quicker recovery. Figure 1 shows the results of a fictional study in which the final outcome for both treatments is at the same functional level, but the trajectories for each group show that this level occurs sooner in the “new” treatment (Week 10) compared to the “standard” treatment (Week 16). Patient characteristics and other variables measuring characteristics of the clinicians (eg, experience) and practice or treatment variations (eg, physical therapy duration) may be tested in such a model to determine how they affect the recovery trajectory [15].

Practice registries will likely have a large role in informing comparative effectiveness research but require careful design to maximize their utility. Many existing registries track clinical outcomes such as infection, reoperation rates, and implant failure but have less focus on patient-centered outcomes [8]. Investigation of individual-level variation and determinants of outcomes requires information beyond the set of demographic variables most often captured in registries (Table 2). In combination with cost and utilization data, explaining the individualized time course of functional recovery can provide powerful

Fig. 1 For this fictional study, the recovery trajectory of the “new” treatment differs from the “standard” treatment, although both have the same final effect on outcome scores in terms of preoperative-to-postoperative (Post – Pre) change. Evaluating recovery trajectories requires additional data collection at more time points but may be important when comparing the effectiveness of treatments and the respective societal costs, such as the patient’s time away from work.

information regarding which of several treatments is both effective and efficient, a topic currently of tremendous interest to payers and policy makers.

While randomized clinical trials will remain a mainstay for producing valid medical evidence, rigorous, well-designed observational research designs and methods (case series, case-control studies, cohort studies, etc) are also needed to inform comparative effectiveness research. Guidelines for design and reporting of quality observational trials are available [33, 35]. One approach to obtaining representative data in observational studies is by sampling at multiple levels of the healthcare system. While sampling patients is very common in clinical research, sampling of providers and facilities is less common, although some recent examples do exist [8]. Sampling of payer organizations or large healthcare systems is rare. The process of patient care is affected by the different settings, environments, and policies in which it is delivered, so study designs should consider incorporating measures of these factors when possible. These studies should also include measures of potential confounders, which are variables related to both predictors and outcomes that may increase or decrease the observed relation between the two. Ignoring confounders may result in large bias and spurious findings [4]. When data on these variables are available, an appropriate analytical approach should be used to obtain unbiased results [1, 4].

A challenge for any longitudinal medical research is dealing with missing data and patient dropout [16, 17, 23, 26]. Current recommendations are to incorporate plans for minimizing missing data and dropout at the design stage. A 2010 National Research Council monograph and several recent summaries of that work [16, 17, 23, 26] contain a number of strategies for limiting missing data, including limiting data collection burden for patients and staff (eg, automated and Web-based response systems [19, 31]), closely monitoring data collection during the active study period, increasing incentive amounts for longer followup, identifying patients at high risk for dropout, offering access to other treatments after the study period (if desired), and recording patients’ reasons for withdrawal. These reports also provide recommendations for appropriate statistical strategies and techniques for analyses in the presence of missing data. Some strategies for locating patients who fail to return for followup include using the Internet and other public data sources such as motor vehicle registration records and credit bureau databases [5, 14, 18, 29]. These methods have varying success and often require cross-referencing multiple such resources. Extensive time, effort, and money are required to locate patients long after conclusion of active treatment or dropout, so incorporating methods and resources to minimize dropout during study planning is likely to be a good investment.

Contextual Factors: Capture Variance to Explain Variance

Attaining meaningful and robust contextual data requires collection protocols that focus on gathering information by sampling or targeting multiple units (eg, patients, providers, etc) at each of the multiple levels of the healthcare environment (eg, clinics, hospitals, systems, geopolitical regions). The goal would be to obtain a complex data structure that represents the complex nature of the respective communities and healthcare systems. This complex structure could be used to investigate how factors at all levels interact to produce an outcome in a patient. To the extent that the contextual factors are actionable or alterable, evidence-based recommendations for changes in the delivery and organization of health care may be generated. For example, Martin et al. [21] used data from more than 6000 patients in a state database of nonfederal hospitals that included characteristics of the patients, surgeons, and hospitals to investigate 90-day reoperation and complication rates after lumbar fusion surgery. While complication and reoperation rates varied between hospitals, a substantial amount of the variability was attributable to differences in surgeons' practices even after accounting for patient-level factors (eg, age, comorbidities, diagnosis, severity) [21]. This type of multilevel analysis provides results that may identify potential changes in service delivery to decrease complications and improve outcome.

Discussion

The current shift in focus of orthopaedic surgery outcome research from efficacy toward effectiveness requires a corresponding shift in the type and extent of data needed. The shift in data requirements presents a number of challenges for clinical researchers. To become common in general clinical practice, outcome measures have to add value to the healthcare process and experience for all parties [32]. Development of a set of well-defined purposes and questions to address the values and needs of the outcome data stakeholders would serve to set the clinical research agenda for the upcoming decade [34]. A strong research agenda is needed that outlines priorities to guide decisions for obtaining consistent and comprehensive orthopaedic surgery outcome data.

One good strategy for development of the research agenda would be to involve advocacy groups (eg, Arthritis Foundation), provider institutions (eg, large hospital systems, professional associations), payers, industry, and policy makers directly in the process to consider including them in certain aspects of collection, analysis, and

interpretation of outcomes and associated data. This strategy was used by the Institute of Medicine when assembling its report regarding initial priorities for comparative effectiveness research in the United States [13]. A collaborative approach including stakeholders as partners from all sectors and levels may be the most effective way to develop a plan and strategy.

Practical barriers to more comprehensive outcome data collection appear substantial but are not insurmountable if the data have value for everyone involved. Keys to overcoming practical barriers are to consider redesigning current systems and processes. A series of small changes in elements of time, space, and tasks related to clinic flow and capitalizing on evolving technologic advances to increase efficiency can be sufficient to facilitate data collection. Study planning and data collection protocols need to consider the temporality of the condition and recovery, as well as relevant environmental and systemic influences, and include plans to minimize dropout and other causes of missing data.

Use of rigorous design methods and appropriate analytical methods can mitigate many of the limitations inherent in observational research to inform comparative effectiveness research. Such research designs capture "actual practices" in the community and therefore can have high external validity [11]. As with any type of research, observational studies require careful attention to design, data collection, and analyses to obtain valid conclusions. Care should be taken to ensure that the patients, providers, and systems included in the study are representative of the respective populations to allow generalization to a defined population. Identifying factors affecting individual recovery of function and quality of life, particularly when combined with cost and utilization data, can provide powerful information regarding which treatment is both effective and efficient, a topic currently of tremendous interest to payers and policy makers.

Health care is a complex system, so data collection should capture important aspects of the complex structure. Contextual information about the episode of care aids interpretation and attribution of variability in outcome. Attention should be given to providing meaningful and adequately detailed descriptions of patients, providers, facilities, and systems. The resulting data would provide more complete evidence that may be used to compare treatment options, describe risk-adjusted outcome, explain heterogeneity in treatment response, and inform clinical care and policy-level decisions. Comprehensive outcome data collection on a broad scale can be used to identify optimal treatment choices for specific populations and subpopulations and improve the quality of orthopaedic health care.

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