Hierarchy of Research Design in Evidence-Based Sports Medicine

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THE SCIENTIFIC METHOD, as outlined in Table 1, provides the best and most unbiased approach to establishing clinical evidence. In evidence-based research, there is a hierarchy of study designs. These designs range from descriptive narratives to experimental clinical trials. The hierarchy of research designs commonly used in clinical studies is shown in Figure 1. It is also important for clinicians to be familiar with some of the terminology frequently used in evidence-based research; Table 2 provides some definitions.

Clinicians should understand the meaning of reported results and how these results should be interpreted based on the design of the study. The purpose of this column is to provide athletic trainers an overview of the hierarchy-of-evidence concept and guidelines for interpreting clinically based research.

TABLE 1. THE FOUR STAGES OF THE SCIENTIFIC METHOD IN CLINICAL RESEARCH

Stage	Description
1.	*Observation and description of a clinical phenomenon* Witness of a diagnosis, treatment, rehabilitation, or complication that is different than what is expected
2.	*Formulation of hypothesis to explain clinical implications of the phenomenon* Comparison between groups with and without the condition
3.	*Use of hypothesis to predict outcomes* Identification of factors that potentially contribute to the incidence of the condition and/or clinical outcomes
4.	*Performance of experimental tests of clinical interventions* Use of studies designed to isolate interventions that affect the clinical outcome

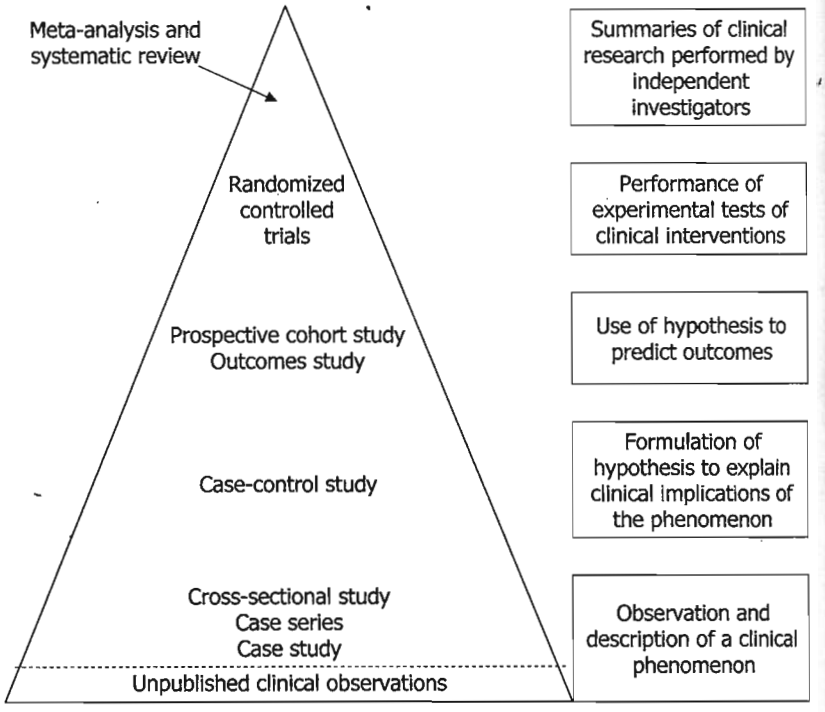

Figure 1 The hierarchy of clinical evidence and study design.

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TABLE 2. IMPORTANT TERMS IN RESEARCH DESIGN	
Term	**Definition**
Blinding	Systematic elimination of background information that would prejudice the outcome or result
Cohort	A defined population group
Experimental treatment	An intervention developed from previous research that is different from the standard treatment and is being tested to establish evidence of efficacy
Incidence	The number of new cases of a condition in a population in a specific time period
Placebo (or sham)	An inactive treatment used to determine the effectiveness of an experimental treatment by comparison
Prevalence	The total number of cases of a condition in a given population at a specific point in time
Prospective	A study that examines an individual's or group's baseline condition and follows that individual or group into the future
Retrospective	A study used to examine an individual's or group's present condition and to look back on events that have already taken place that might have had an effect on the present condition

Unpublished Clinical Observations

The foundation of evidence-based clinical research is unpublished clinical observations. With professional experience, clinicians develop anecdotal evidence to support clinical decisions. Although the results are not published, this is an important first step in evidence-based clinical research.

Case Studies and Case Series

Case studies and case series are published reports of clinical observations. A case study is a retrospective report of a single unique clinical case that presents differently from what would be expected. Case studies are most often expressed as narratives highlighting the differential diagnosis, treatment, rehabilitation, and possible complications of a single observed case.

A case series reports the retrospective outcomes of a group of patients with a given condition that are treated in a similar manner. Because case studies and case series only provide descriptive, not experimental, clinical evidence, they and case studies are considered to be at the lowest level in the hierarchy of evidence-based medicine.

Cross-Sectional Studies

Cross-sectional studies survey specific populations at a given point in time to determine the prevalence of a clinical risk factor, outcome, or phenomenon. For example, a cross-sectional study might report results from an anonymous survey distributed to female high school cross-country runners to identify the prevalence of amenorrhea. Those who currently report the presence of the condition are expressed as a percentage of the surveyed population. Cross-sectional studies are used to retrospectively examine a clinical phenomenon, and no causal relationships can be drawn from reported results.

Case-Control Studies

Case-control studies compare two groups, one with a condition of interest and the other being free of that condition. A condition can represent the presence of a specific disease, the history of a specific injury, or the record of an intervention, such as a surgical procedure or rehabilitation. The design identifies specific differences between these groups. Strict inclusion and exclusion criteria must ensure that the participants with the preestablished condition actually have had the condition and, conversely, ensure that the condition is absent in control participants. For example, there has been considerable research performed to identify factors related to incidence of anterior cruciate ligament injuries in females. A case-control study could be used to retrospectively examine the characteristics of individuals who have sustained a Grade III ACL injury and compare them with those of individuals who have not. Commonly measured characteristics are postural stability and neuromuscular control, gait and landing kinematics, and anatomical features.

Prospective Cohort Studies

In prospective cohort studies, the baseline measurements of identified characteristics of interest in healthy individuals are collected, and these individuals are measured over time. The purpose of the prospective cohort study is to find links between an identified characteristic of interest and the incidence of a particular condition. With regard to the characteristic of interest, the group who developed the condition can then be compared with the group who did not. This design allows for verification of risk factors in individuals who might have a predisposition for the development of the specified injury or illness. Prospective cohort studies are often multicenter studies with large sample sizes that increase the likelihood of the incidence of the condition. The measure of interest is the incidence of a particular injury or illness, rather than the outcome of an intervention that is implemented at each center.

Outcomes Studies

The outcomes study is prospectively used to track individuals with a preexisting condition who receive a specific intervention. These individuals are tracked for a specified time interval, and results are reported in the form of clinical outcomes.

Outcomes can be classified as either disease oriented or patient oriented. A clinician observes or measures disease-oriented outcomes such as range of motion, ligament laxity, or limb girth or physiological measures such as blood pressure or bone-mineral density. Patient-oriented outcomes are self-reported assessments of health status such as pain, perceived disability, and level of function. A drawback to reports of clinician-observed, disease-oriented outcomes is that they might be biased toward improvement because clinicians typically expect their patients to improve. Drawbacks of patient self-reports are that they are often limited by the patient's recall and perception of the results.

An outcomes study can be used to compare the outcomes of two hospitals that evaluate and provide acute care for ankle sprains. One hospital provides its patients with RICE (rest, ice, compression, and elevation), crutches, and towel exercises. The other hospital provides its patients with RICE, crutches, and a balance board. After a specified period of time, all patients are reevaluated by a clinician (disease-oriented outcomes) and complete self-reported outcomes surveys of health status (patient-oriented outcomes). The outcomes of these two groups can be compared. Because the interventions are not randomized, it is impossible to determine which factors might have been responsible for improvement, but the results of outcomes studies can be used to develop studies that tightly control for specific interventions.

Randomized Controlled Trials

The highest level of clinically based experimental research study is the randomized controlled trial (RCT). In RCTs, individuals who are diagnosed with a specific condition are randomized into treatment and control groups. Randomization usually ensures that the two groups are similar at baseline in regard to key outcome measures of interest. The treatment group receives an intervention developed from previous research while the control group receives the standard treatment or a placebo (sham treatment). Outcomes are measured at the end of a specified time period. The RCT allows for testing of an experimental treatment hypothesis, and the outcomes of the two groups can be directly compared with each other. RCTs provide evidence for the efficacy of interventions that can be directly incorporated into clinical practice.

Systematic Reviews and Meta-Analyses

Systematic reviews and meta-analyses are used to critically evaluate the results of multiple similar studies. For both systematic reviews and meta-analyses, an exhaustive search of the literature in regard to the condition and treatment of interest is conducted. A systematic review is a narrative of the critical evaluation of the literature, whereas a meta-analysis provides a quantitative assessment of the pooled statistical results across studies. Both types of summaries allow for a conclusion regarding the consensus, or lack thereof, on the evidence for the treatment of interest. Systematic reviews and meta-analyses can be performed for any of the analytical study designs, but the gold standard is review and analysis of well-designed RCTs.

Conclusions

In clinical research, study designs can range from descriptive to experimental. The distinct features of each study design offer a unique contribution to the

body of knowledge through the scientific method. An understanding of the evidence that can be extracted from each study design leads to a more robust clinical interpretation of the results.

In conclusion, it is important for clinicians to

- Identify the type of study design employed and where it fits into the hierarchy of clinical evidence.
- Recognize the type of research they are consuming and how this evidence might be incorporated into clinical practice.
- Understand the meaning of the results reported in scientific journals and how those results can be interpreted based on the design of the study. ▮

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