Principles of Clinical Research


Clinical research is the key investigative method to test hypotheses that have a direct influence on our patients. The efficacy of interventions, the prognosis of patients, and the improvement in health-care delivery relies heavily on clinical research, in some cases solely.

This course, a total of 10 hours of learning, provides a foundation to assess and interpret the available orthopaedic literature, and to participate in scientific progress by providing the tools needed to initiate new or contribute to existing clinical research programs.

LearnORS will maximize success by allowing the learners to control the rate at which they move forward through segmented content created by national and international content experts.

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Course Curriculum

Module 1
Principles of Clinical Research:
An Introduction to the Understanding & Design of Clinical Research

Kurt Spindler, MD
Cleveland Clinic Sports Health Center

José F. Vega, MA
Learner College of Medicine
Learning Objectives:

- Understand a basic approach to designing a clinical research study beginning with development of a research question and an appropriate hypothesis
- Be able to differentiate between prospective studies and retrospective studies
- Understand the advantages and disadvantages of the most common clinical research study designs
- Appreciate the role of the institutional review board (IRB) in the research process

Module 2
Measurement in Clinical Research

Joel Gagnier, ND, MSc, PhD
University of Michigan

Learning Objectives:

- To understand the basics of psychometrics
- To understand the various forms of validity, reliability and responsiveness

Module 3
Biostatistics for Orthopaedic Surgeons: A Practical Guide to Understanding Statistical Analysis

Jessica Widdifield, PhD
Sunnybrook Research Institute
University of Toronto, Institute of Health Policy, Management & Evaluation
Institute for Clinical Evaluative Sciences

Learning Objectives:

- To acquire basic biostatistics knowledge in order to effectively interpret and apply the medical literature to patient care
- To understand basic biostatistics → terminology and common statistical methods
- To aid in the understanding of the analysis in a scientific paper
Module 4
Health Services Research

Bheeshma Ravi, MD, PhD, FRCSC
Sunnybrook Health Sciences Centre

Jeremie Larouche, MD, MSc, FRCSC
Sunnybrook Health Sciences Centre

Learning Objectives:
• Gain an understanding of the breadth of health services research
• Understand the advantages and disadvantages of registries
• Understand the advantages and disadvantages of administrative databases
• Gain an understanding of the importance of quality improvement
• Be able to distinguish between quality improvement and standard clinical research

Module 5
Observational Studies:
Cohort Studies, Case Control Studies, Cross Sectional Studies

Stephen Lyman, PhD
Hospital for Special Surgery
Learning Objectives:
- To understand the basic methods for designing an observational study
- To be able critically to appraise observational studies

Module 6
Randomized Controlled Trials: Structure and Management of Bias

Roy K. Aaron, MD
Department of Orthopaedic Surgery, Warren Alpert Medical School of Brown University

Jennifer Racine-Avila, MBA
Department of Orthopaedic Surgery, Warren Alpert Medical School of Brown University

Learning Objectives:
- Learn the structure of a randomized controlled trial (RCT)
- Understand differences between and RCT and others trial designs
- Recognize sources of bias in the structure of an RCT
- Learn strategies for minimizing bias
- Understand intention-to-treat method of data analysis and its weaknesses with crossover data

Module 7
Knowledge Synthesis: Systematic Reviews and Meta-Analyses

Joel Gagnier, ND, MSc, PhD
University of Michigan
Learning Objectives:
- To understand the basic methods for performing a systematic review and meta-analysis
- To be able to critically appraise systematic reviews and meta-analyses

Module 8
Knowledge Translation & Dissemination

David Wasserstein, MD, MSc, MPH(c), FRCSC
Sunnybrook Health Sciences Centre

Learning Objectives:
- Understand the four main components of Knowledge Translation
- List issues of quality in knowledge synthesis tools
- Identify barriers to knowledge translation
- Understand a framework or approach to knowledge translation
- To be able to incorporate a strategy for KT in their own practice

Module 9
Epidemiology: Musculoskeletal Injury and Disease

Jessica Rivera, MD
US Army Institute of Surgical Research, Extremity Trauma and Regen Medicine

Learning Objectives:
- To learn the terminology of epidemiology and how to study epidemiologic questions
- To describe the burden of musculoskeletal injury and disease
- To understand how injury prevention efforts aim to affect injury epidemiology
- To provide examples of how the orthopaedic community contributes to public health