

Clinical Microbiology

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IN THIS ISSUE

43 Documenting Clinical Microbiology Impact: Basic Concepts for Designing Clinical Studies and Outcome Research Using Principles of Biostatistics

49 Clinical Microbiology Q & A

Documenting Clinical Microbiology Impact: Basic Concepts for Designing Clinical Studies and Outcome Research Using Principles of Biostatistics

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Abstract

While most clinical laboratorians do not consider themselves part of a formal clinical research group, many quality improvement projects and method verification studies are, or should be, performed with the rigor of scientific research, even if the project intent is not research. When describing pilot results for business plans and for documenting laboratory impact for interdisciplinary committees, planning for scientific rigor will prove to be very valuable. Clinical, operational, and quality improvement studies in laboratory medicine and clinical microbiology are becoming more data driven, outcome oriented, and evidence based. This trend is expected to continue and to broaden in scope and complexity. As such, laboratory directors, managers, and staff will need to acquire advanced background in experimental study design and in biostatistical methods so they can play an active role in documenting the impact of the clinical microbiology laboratory on the larger health care system. This review translates the design concepts of patient-oriented and clinical research into practical guidelines that can be adapted and relevant to clinical microbiologists. This review focuses on types of experimental designs that may be useful for clinical microbiologists to ensure a successful project and to generate laboratory impact data.

Introduction

While laboratory scientists with patient care responsibilities may take laboratory clinical data for granted, health care researchers do not; the current trend in health care organizations and health funding agencies is to drive improvements with clinical data. Forward thinking researchers and health care leaders need collaboration with medical laboratory scientists who can best interpret laboratory data, upon which 70 to 80% of clinical decisions are based. For this to occur without bypassing the microbiology laboratory, clinical microbiologists need to embed themselves in clinical and operational improvement teams for their laboratory to stay relevant within the organization. Clinical laboratory professionals must come to see their value, not only in generating laboratory data for use in clinical diagnosis, but in data compilation, validation, analysis, and interpretation of their data to

document the pre- and post-analytic impacts of laboratory services at the organization and population levels [1]. Continuous quality improvement activities, implementation of new diagnostic testing processes or assays, patient safety initiatives, and lean laboratory redesign projects can all be used as the keystones to generate data and compile health care outcomes for laboratory impact studies. If designed properly and combined with corresponding clinical information, even data from simple comparison studies of new testing methods can yield valuable insights and pilot data for business plans and downstream impact studies. Thus, clinical laboratories, while continuing to perform their historical analytical studies with exceptional accuracy, must step out of their transactional roles and learn to document and prove laboratory impact in the pre- and post-analytic phases of laboratory medicine [1-6]. While we are medical providers at our core, not full-time

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clinical researchers, we must come to see ourselves as experimental scientists, partnering with analytical teams and clinical researchers to add context and value to initiatives that can improve health care and conserve valuable resources. Now is the time for clinical microbiologists to take a leadership role as stewards of data upon which health care decisions are made. We can do this by obtaining skills in patient-oriented research (POR), evidence-based laboratory medicine practice guidelines (EBLMPG), and patient-centered outcome research. To do so, many new skills and much knowledge must be gained or refreshed.

Patient-Oriented Research

POR is defined as research conducted with human subjects (i.e., research conducted on material of human origin, such as tissues, secretions, blood, fluids, or other specimens) or for which an investigator may directly interact with human subjects who have consented to that study. POR is commonly interventional in design and may occur in collaboration with clinical laboratories. *In vitro* diagnostic research (IVDR) shares many of the basic principles and methodologies used in POR [7], in that diagnostic clinical research utilizes human tissues or fluids. IVDR differs from POR when the specimens used are remnant specimens for which consent has not been obtained and which therefore cannot be linked long-term to a living individual. While clinical laboratory scientists performing IVDR have not historically taken the lead in performing POR, it is certainly time for their role to change. Laboratories are the keepers of 70 to 80% of the data on which clinical, operational,

and financial decisions are made, and yet the clinical laboratory contribution is often overlooked. The clinical microbiology laboratory must advocate for a central role on health care teams and initiatives that include the laboratory as a stakeholder.

New strategic planning and quality initiatives in our local laboratory now focus primarily on pre-and post-analytic impacts and clinical outcomes—our efforts are designed as if they were research studies, but they are not always funded by research funding. The concept of POR is so new to the field of laboratory medicine that our microbiology laboratory coined the term, “diagnostic intervention” to describe this new type of quality improvement project. In this review, we share our microbiology laboratory’s view of POR and describe the literature and textbook information available for all laboratory employees to begin this exciting new journey into the next level of quality improvement and diagnostic interventions. To begin this journey, one must understand several principles of clinical research and POR.

Types of Studies That Are Conceivable in a Clinical Microbiology Setting

Laboratory readers may already be familiar with several types of POR, including:

- Mechanistic (physiological) studies of human disease involving detailed investigation of a biological process
- Therapeutic studies that focus on treatment designed to improve a disease or condition

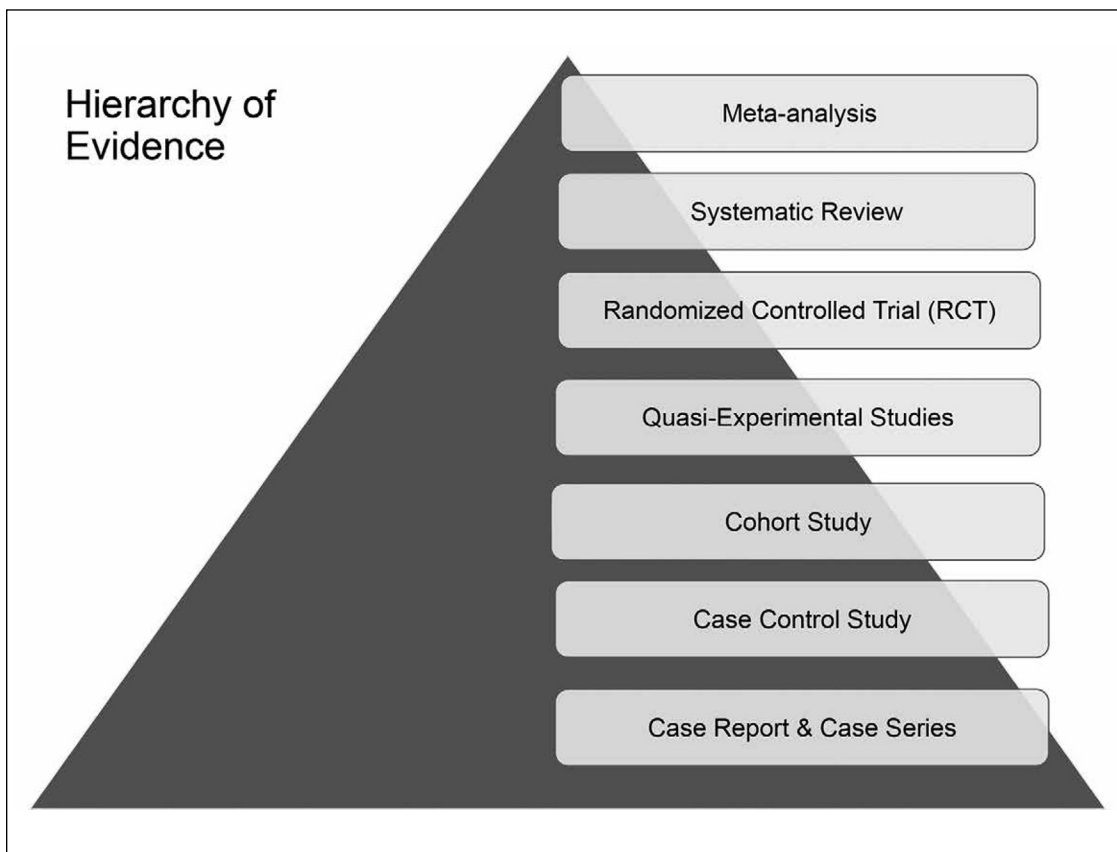


Figure 1. Examples of hierarchy of evidence The higher the position on the pyramid, the more definitive the study conclusions will be. In this example, case reports are the least rigorous and therefore the lowest forms of evidence.

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