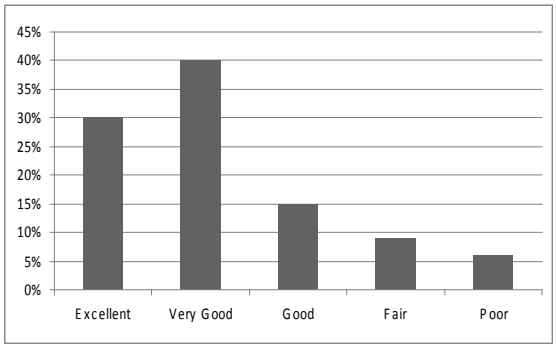
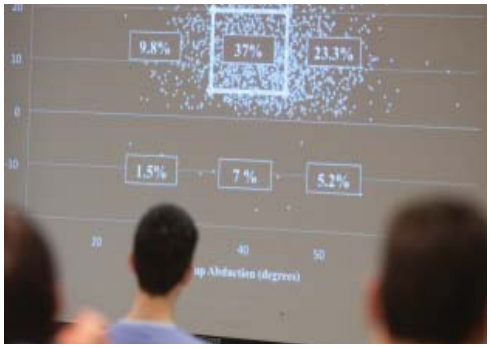
The Research Guide

A primer for residents, other health care trainees, and practitioners

Editors

Bart J. Harvey | Eddy S. Lang | Jason R. Frank





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The Research Guide: A primer for residents, other health care trainees, and practitioners

Editors

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Preamble

The motivation to create this guide

arose from our efforts as clinician-educators to support and supervise trainees—predominantly, residents from a variety of medical specialty training programs—who wished or were required to complete a formal research project. Our experiences repeatedly highlighted the fact that many health trainees lack formal education in the design and conduct of research. As a result, a large portion of the initial stages of each trainee's research project was spent addressing a variety of knowledge gaps, often through a series of one-to-one tutorials. Moreover, as we endeavoured to provide effective guidance on a diverse range of research efforts we often became aware of the limitations of our own knowledge. Over the course of our careers, it has become clear that this individualized teaching of the fundamentals of research is neither efficient nor sustainable. Even more important, we became only too aware that, for a variety of reasons, many promising research initiatives are never completed. This is regrettable on at least two levels. First, progress in research is a keystone of contemporary health care: patients and health care providers alike demand continual, evidence-based improvement in the quality and effectiveness of care. Second, the ability to critically appraise research, along with at least a basic familiarity with the conduct of research, is an important dimension of the competencies of all health care professionals. Within the domain of medical practice, these research competencies have been articulated in terms of the CanMEDS Scholar Role.

Assembling a guide such as this one is not a challenge to be undertaken idly, and so our first step was to determine whether the kind of resource we envisioned already existed. Was there a text that could guide health care trainees through all the steps of successfully designing and completing a research project? Although several excellent textbooks on research methods are available—and many are referenced in this guide—none offered the kind of "self-study" resource we had in mind. To test our impression of the scope of existing resources we also contacted several Canadian and American health training programs and specialty associations. Although our discussions did not result in the discovery of a suitable resource, many of the clinician-educators we spoke with highlighted the potential value of such a resource. At the same time, we were encouraged by the example of some successes in research training, such as the well-received two-day "introduction to research" course that has been offered for several years to residents in Obstetrics and Gynaecology by the Association of Professors of Obstetrics & Gynaecology of Canada. The organization and content of this course informed our thoughts about the possibility of creating a one-stop, comprehensive guide to research for trainees in all health care professions and specialties. We are grateful to that course's key faculty members, Robert Reid and Phil Hahn, for their helpful discussions, their generous input throughout the development of this guide, and their contribution as co-authors, collectively, of three of its chapters.

Once we were persuaded of the merits—and feasibility—of creating a research guide for health professions trainees, we drafted an outline, a working table of contents and a prospective "abstract" for each of the proposed chapters. We then set out to identify and invite potential authors or co-authors of what would eventually become a complement of 32 chapters. Clearly, the final product—The Research Guide: A primer for residents, other health care trainees, and practitioners—would not have been possible without the generous contributions of this capable and diverse group of authors! We are also very grateful to the dozens of reviewers who kindly provided feedback on early drafts and helped to strengthen the organization, content and relevance of each chapter. The names and affiliations of these chapter authors and reviewers are listed on pages vi–vii and 294–295, respectively . We are particularly appreciative of the contributions of Tom Lang, David Streiner and Ross Upshur, who not only served as chapter authors but also provided rapid and informative peer review of several chapters.

The Research Guide is organized into seven sections, each comprising up to eight chapters. Core components recur through the book to facilitate reading: thus, where appropriate, each chapter begins with an illustrative case, a set of learning objectives and a list of "key terms" to set the context and relevance of the topic being addressed, and concludes with a "postscript" to the illustrative case, one or more exercises, and a summary checklist. For readers who would like to explore some aspects of a topic further, an annotated list of additional resources is included at the end of each chapter.

If you are new to research, The Research Guide will ease you into the journey. Each chapter is intended to walk you through what you need to know and what you need to do to ensure success in your project. The sections of the Guide are meant to present a logical progression in step with the development of your project, but each stands alone. You can use the Guide as a personal modular curriculum for the development of research skills, or as an introductory reference to be consulted as needed. The universe of research could not possibly be compressed into a brief text, and so we have designed this book to be accessible, practical and succinct. We wish you an eye-opening, informative and rewarding experience. This is your opportunity to better understand and even contribute to progress in the vast world of modern health care.

If you are a supervisor of new researchers, this guide is also for you, and has been written by your peers, who know what it takes to support and mentor those less experienced in the process of a scholarly inquiry. If you need an accessible curriculum to help your trainees understand what needs to be done, this text can form the basis of a research handbook. If you need short readings to make your supervision more efficient, you can direct your trainee to the relevant chapters in the Guide.

This project would not have been possible without the support and "home" provided by the CanMEDS Office at the Royal College of Physicians and Surgeons of Canada. We are particularly indebted to Wendy Jemmett from the CanMEDS Office, who very capably managed this project throughout. We would also like to express our gratitude to Anne Marie Todkill for her editorial support and expertise in helping to transform each draft chapter into a more efficient, readable and satisfying form.

The Research Guide is meant to make the lives of novice researchers and their supervisors easier. We would like to hear from you, the reader, about how well we have achieved this goal. Please tell us how future editions of this guide could be improved. Are there gaps to address? Ways to make the Guide more relevant and easy to use? We welcome all comments and suggestions at canmeds@royalcollege.ca

In the meantime, we hope you will enjoy the guide and your research journey!

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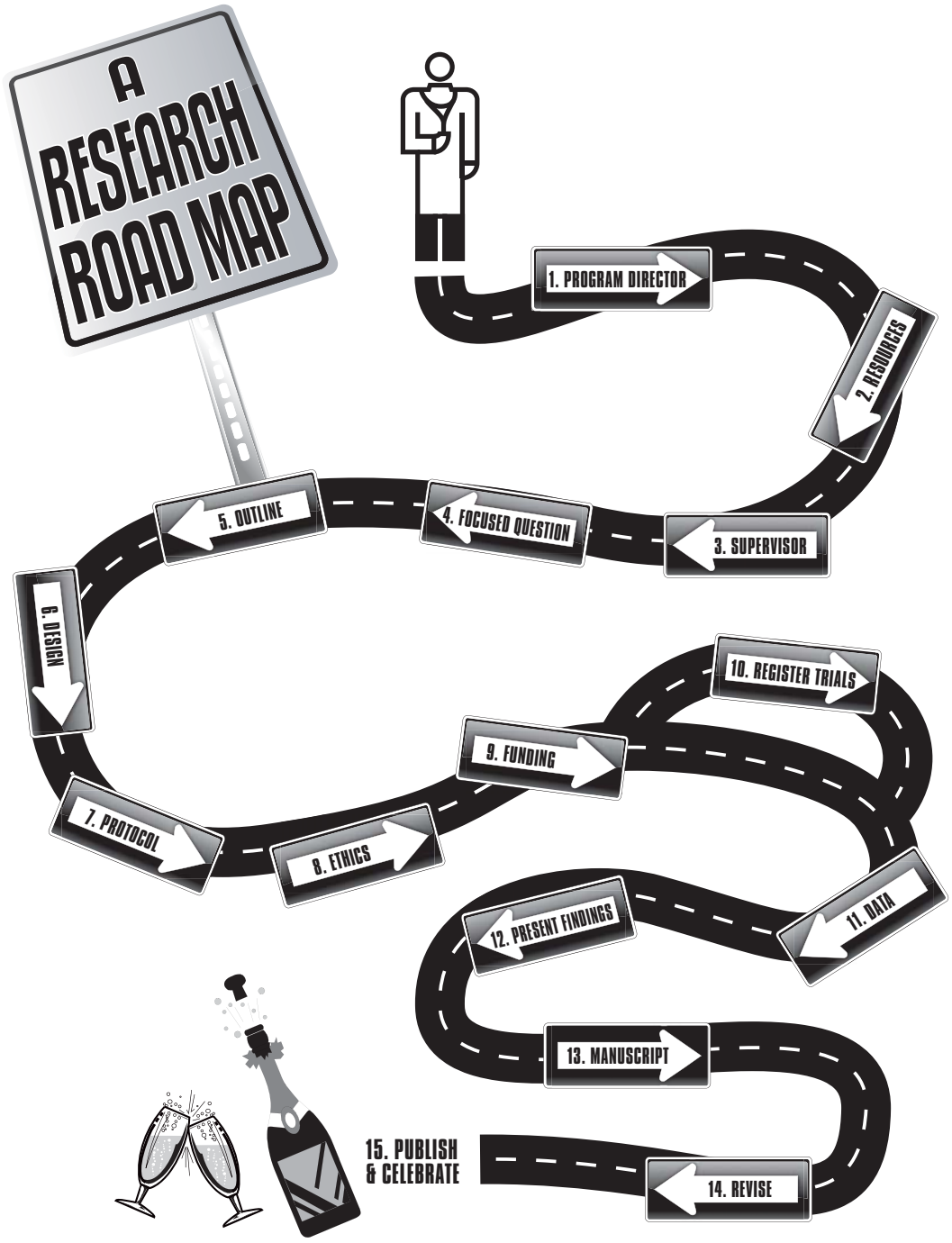

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A research road map: Fifteen steps to a successful research project (and ten pitfalls to avoid)

Philip M. Hahn, MSc

Are you thinking about starting a research project, either because of a particular interest or to satisfy a requirement of your training program? If so, reading this chapter is a good way to begin. It offers a road map to research, outlining what is involved in conducting a research project, how to get started, what to anticipate at each phase and how to stay on track to finish your project within a reasonable time. Remember that successful research begins with careful planning: you won't be able to fix at the analysis stage any shortcomings in your study design.

1. Meet with your program director or departmental research coordinator as soon as possible.

- Find out what is expected by your program or department.
- Talk about potential research areas and suitable faculty members who might be available to support you in the completion of a research project.

2. Look for resources that provide an introduction to the basic concepts of research methodology and critical appraisal.

- Read through this guide.
- Attend local or national resource courses or training programs.
- Consult the references and additional resources listed at the end of this chapter.

3. Find a research supervisor (ch. 3).

- Look for someone whose expertise is relevant to your field of interest and who is able to devote sufficient time and effort to supporting and supervising your work. Most health trainees and junior practitioners have limited research experience and will need someone to guide and advise them along the way. Finding a suitable supervisor is one of the most important steps to success in planning and completing a research project.
- Consider the following in your selection of a research supervisor:
  - publication record
  - access to research funding
  - availability to provide timely advice
  - reports from current and former research trainees
- Agree on expectations, including those with regard to authorship of any publications that result from your project

4. Pose a focused and specific research question (ch. 6).

- Make sure your research question is novel, answerable and feasible
- Consider the PICOT approach to framing a research question.[1] This involves describing the **P**opulation involved in the study and, as applicable, the **I**ntervention, **C**omparator, **O**utcome and **T**ime frame. For example, in women expected to deliver before term (**P**) do corticosteroids (**I**) compared to placebo (**C**) decrease the incidence of neonatal death (**O**) at delivery (**T**)?
- Also consider the FINER criteria.[1] Is your research question **F**easible, **I**nteresting, **N**ovel, **E**thical and **R**elevant?

5. Develop a research outline.[2]

- Conduct a thorough literature search (ch. 7).
- If your project is designed to examine a therapeutic intervention, check for applicable systematic reviews in The Cochrane Library.[a]
- Collaborate with content and methodological experts. Your supervisor should be able to suggest suitable individuals and to facilitate an introduction to them.
- Determine which study design is the best fit and the most practical approach to framing your research project (ch. 9).
- Write an outline.
  - — Focus on the primary objective or question of the proposed research.
  - — Include a brief background statement highlighting the importance of your research question.
  - — Estimate how much time you will need to complete each of the anticipated stages of the research.
  - — List available and required resources and, if applicable, provide a budget estimate.
  - — If you already have a variety of interesting ideas to talk about, be sure to keep track of them, but for the purposes of your study outline you will need to boil them down to a single, focused, primary study objective.
  - — Make sure your outline is concise—a maximum of two pages is best at this point.
  - — With the outline of your proposed research project in hand, arrange to meet with methodological specialists (Step 6) in preparation for writing a more detailed protocol (Step 7).

6. Meet with methodological (especially biostatistical) specialists with particular expertise in your area of study.

- Refine the study's primary objective.
- Discuss pertinent design issues, focusing on the primary study objective.
- Be realistic.
  - — Bear in mind that planning and completing a retrospective study (such as a systematic review, case-control study, chart review or practice audit, for which the data already exist) generally takes less time and fewer resources than a prospective study (such as a cohort study or randomized trial, for which primary data collection will be required).
  - — Consider conducting a clinical audit, systematic review or survey as a manageable project for your first venture into research.
- As necessary, estimate an appropriate sample size.[3,4]
  - — Focus your energy on addressing the primary research objective/question with just the right number of subjects. A study with too many subjects can expose participants needlessly to potential risks. A study with too few subjects might not have sufficient statistical power to detect a clinically important difference.
  - — Design an appropriately sized, simple study rather than a small, complicated one.[5]
- Discuss the anticipated data collection and analysis methods (chs 22, 24 & 25).
- Select the tools (calculators, databases, and statistical and data-entry software) that will be appropriate for your analysis of the study data.
- Investigate which file formats for data recording will allow your study data to be imported into an appropriate application for statistical analysis (e.g., Excel spreadsheet for import into SPSS).

7. Develop the research protocol[6] (ch. 17).

- Create an expanded version of the outline created at Step 5.
- Include details on:
  - — research team members and their roles (chs 3 & 4)
  - — recruitment of study participants (ch. 20)
  - — inclusion and exclusion criteria
  - — design features such a criterion standard for a clinical practice audit,[7] the sampling technique for a survey,[8] or the random allocation technique and creation of placebos for a randomized controlled trial.[9]
  - — any secondary objectives, questions and outcomes
  - — statistical issues such as estimating sample size and methods to analyze the data (chs. 24 & 25)

a See www.thecochranelibrary.com

- your timetable for starting and finishing the project, as well as the anticipated time frame for each phase of the research project.
- ethical considerations such as safety, confidentiality and informed consent[10] (ch. 18).

- The proposal should contain as much detail as possible and provide the framework for ethics submission (ch. 18) and ultimately drafting a manuscript (ch. 29).

8. As applicable, obtain institutional and research ethics approval (ch. 18).

- Obtain approvals specific to your institution or research centre.
- Seek help from your research supervisor and other university and hospital personnel who are knowledgeable about and experienced with approval processes and requirements.
- Find out whether your project is eligible for an expedited review, which will take less time than a full Research Ethics Board (REB) review. A clinical practice audit, for example, might be eligible for an expedited review.
- If your research involves humans or human tissues, review the Tri-Council policy statement[11] and complete the Tri-Council tutorial on the ethical conduct for research involving humans.[12]

9. Seek necessary funding (ch. 19)

- Consult with your research supervisor and collaborators to identify potential funding sources for your project.
- Seek departmental and university resources first.
- If appropriate, submit a grant to an external funding agency such as the Physicians' Services Incorporated Foundation,[b] or the Canadian Institutes of Health Research.[c]

10. If you are conducting a clinical trial, ensure that it is registered with ClinicalTrials.gov[d] (ch. 18).

- Member journals of the International Committee of Medical Journal Editors (ICMJE), also called the Vancouver Group, require, as a condition of consideration for publication, registration of all clinical trials in a public trials registry.[13] Complete the trial registration before any study participants are recruited and enrolled.

11. Collect and analyze the data (chs 22, 24 & 25).

- Follow the data collection and analysis plan described in the research protocol.
- Report confidence intervals, if appropriate, in addition to *P* values for the results of the primary and any secondary research questions. As Martin Gardner and Douglas Altman note, "Overemphasis on hypothesis testing—and the use of P values to dichotomise significant or non-significant results—has detracted from more useful approaches to interpreting study results … . In medical studies investigators are usually interested in determining the size of difference of a measured outcome between groups, rather than a simple indication of whether or not it is statistically significant."[14]

12. Present your findings (chs 27 & 28).

- Remember that one of your responsibilities as a researcher is to communicate your results.
- Find appropriate venues in which to present your work as soon as possible, such as your department's annual research day and relevant local, national and international meetings.

13. Prepare and submit a manuscript describing the study and its results to a suitable journal (ch. 29).

- Be prepared for some hard work on preparing your research report for publication. In an excellent review on preparing manuscripts for submission to medical journals, Gill Welch outlines a systematic approach

b See the PSI Foundation website at www.psifoundation.org/ResidentResearchPrizes.html

c See the CIHR website at www.cihr.ca/

d The registry can be accessed at www.clinicaltrials.gov/

for making it easier to prepare a readable paper.[15] His take-home points are:

- — Start writing before your project is completed.
- — Focus your attention on what readers are most likely to look at: the title, abstract, tables and figures.
- — Develop a systematic approach to the introduction, methods, results and discussion.
- — Improve the paper by learning how to obtain and incorporate useful feedback.

- Familiarize yourself with the guidelines and checklists that you will need to follow in reporting your methods and results and in disclosing competing interests. An awareness of these standards before you begin will guard you against any deficiencies that could make your report ineligible for publication.
  - — For examples of guidelines for the reporting of findings, see the CONSORT Statement on the reporting of randomized controlled trials as well as its extensions for other study types; the PRISMA Statement for the reporting of systematic reviews and meta-analyses; and the STARD Statement on the reporting of diagnostic accuracy studies.[e]
  - — For an example of a checklist for reporting competing interests, see the Financial Conflicts of Interest Checklist 2010 for Clinical Research Studies developed by Rochon and colleagues.[16]
  - — A fuller list of reporting guidelines is available on the website of the EQUATOR Network, an international initiative to improve the reporting of health sciences research.[f]
- Familiarize yourself with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals outlined by the ICMJE;[g] these requirements are applied by most peer-reviewed medical journals.
- Establish authorship, and the order of authorship.
  - — As early as possible, establish authorship credits, including the order in which authors will be listed. The first author is generally the individual who has, overall, contributed the most, while the last (or second) author is generally the project supervisor.
  - — The ICMJE criteria for authorship credit state that authorship requires: (1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published.[17]
  - — Be prepared to describe the contribution of each author. Many journals require on submission a description of each author's contribution and publish a contributors' statement at the end of each article.
  - — Also consider those whose contribution should be acknowledged in the published article. Many journals require written permission from anyone identified in an acknowledgement.

14. If your manuscript is accepted, revise it according to the editors' and reviewers' comments.

- If your manuscript is rejected, take into account the editors' and reviewers' comments and consider submitting the revised paper to another appropriate journal (ch. 29).

15. Celebrate with your coauthors.

- You have just completed a research project and have contributed to the creation and dissemination of new health science knowledge. Don't let this accomplishment pass without taking time to celebrate with your co-investigators and others who have supported you and the project.

e The most recent guidelines for CONSORT, PRISMA and STARD can be viewed at www.consort-statement.org/consort-statement/, www.prisma-statement.org/ and www.stard-statement.org/

f See the EQUATOR website at www.equator-network.org/resource-centre

g Available at www.icmje.org/urm_main.html

TEN COMMON RESEARCH PITFALLS

1. Not establishing a focused, answerable question.
2. Enlisting a research supervisor who doesn't make sufficient time to advise and help you throughout the stages of the project.
3. Picking a topic about which you have little interest.
4. Planning a small, complicated study that attempts to answer many questions, rather than an appropriately sized, simple study focused on one primary objective/question.
5. Not taking the time to draft a research outline to keep your research team coordinated and on schedule.
6. Not being realistic about how much time and effort your project will take (see "Tips for Staying on Track").
7. Basing a prospective study on outcomes that are rare or take a long time to occur.
8. Entering your data into an Excel spreadsheet using formats that are not compatible for importing into a statistical application such as SPSS. The only thing worse than entering data is having to enter it twice.
9. Not meeting with a statistician to talk about the analysis before you begin collecting the data.
10. Waiting too long to begin (see "Tips for Staying on Track").

TIPS FOR STAYING ON TRACK

As you've no doubt already recognized, your biggest obstacle to successfully completing a research project will likely be finding the time.[18–20] Here are some tips for staying on track to finish a research project.

1. Carving out one or more blocks of protected time is key.[18] Use this time to develop your research proposal and start off on the right foot; additional blocks of time can be used for data collection, analysis or write-up.
2. If you are in a two- or three-year program, consider a study design that will allow you to finish on time, such as a medical record review or practice audit, for which the data should be comparatively easy to access and for which an expedited ethics review might be feasible.
3. If you are in a longer program, such as a five-year medical or surgical specialty, consider the following timelines and milestones.
   - In your first year, introduce yourself to the basic concepts of research methodology by taking a dedicated course or intensive workshop. Identify a research supervisor.
   - Identify a methodological specialist to help you develop your research question, study design and research protocol in your second year. Submit your study for ethics approval and funding opportunities. If you are conducting a clinical trial, remember to register your study before you begin to enrol participants.
   - Collect and analyze your data, and then present your findings locally, nationally or beyond by the end of your third or fourth year.
   - Begin drafting your manuscript, aiming for completion in year four.
   - Submit your manuscript to a suitable journal early in year five, leaving your final term free to prepare for your certification exam and life after graduation.

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ADDITIONAL RESOURCES

I recommend the following books to busy professionals who want to improve their understanding of key concepts in biostatistics and epidemiology.

Biostatistics

Altman DG. *Practical statistics for medical research*. London (UK): Chapman & Hall; 1991.

- Douglas Altman is Director of the Centre for Statistics in Medicine in Oxford, England. By discussing both the use and misuse of statistics this book equips the reader to judge the appropriateness of the methods and interpretations presented in papers published in medical journals.

Altman DG, Machin D, Bryant TN, Gardner JM, editors. *Statistics with confidence: confidence intervals and statistical guidelines.* 2nd ed. London (UK): BMJ Books; 2000.

- As Gardner and Altman say elsewhere,[14] "Overemphasis on hypothesis testing—and the use of P values to dichotomise significant or non-significant results—has detracted from more useful approaches to interpreting study results, such as estimation and confidence intervals." This book gives guidelines for calculating and using confidence intervals around just about any point estimate.

Norman GR, Streiner DL. *PDQ statistics*. 3rd ed. Hamilton (ON): B.C. Decker; 2003.

- That's PDQ for "pretty darn quick": with this book, you can rapidly find concise descriptions of statistical tests that you might come across while reading journal articles.

Epidemiology

Sackett DL, Haynes RB, Guyatt GH, Tugwell P. *Clinical epidemiology: a basic science for clinical medicine*. 2nd ed. Toronto (ON): Little Brown and Company; 1991.

- This text applies the principles learned in epidemiology to the complex clinical decisions that must be made every day.

Streiner DL, Norman GR. *PDQ epidemiology*. 2nd ed. Hamilton (ON): B.C. Decker; 1998.

- This efficient study guide in the "pretty darn quick" series introduces the reader to the world of epidemiology; it covers data-gathering, sampling procedures, study designs, biases, measuring reliability and validity, and much more.

Evidence-based medicine

Godwin M, Hodgetts G. *The Bedford murder: an evidence-based clinical mystery.* Philadelphia (PA): Hanley & Befus; 2003.

- This murder mystery novel reveals clinical pearls and the concepts of evidence-based medicine.

Greenhalgh T. *How to read a paper: the basics of evidence-based medicine*. 3rd ed. Oxford (UK): Blackwell Publishing; 2006.

- One of the best-selling texts on evidence-based medicine, this book is used by health care professionals and medical students worldwide. With chapters on topics such as "statistics for the non-statistician," it serves as a good critical appraisal primer for journal clubs.

McKibbon A, Wilczynski N. *PDQ evidence-based principles and practice*. 2nd ed. Shelton (CT): People's Medical Publishing House; 2009.

- "Provides a plain-language approach to basic principles of evidence generation and application" (Brian Haynes, Chief, Health Information Research Unit at McMaster University). This text has a good section on systematic reviews.

Riegelman RK. *Studying a study & testing a test: how to read the medical literature*. Boston (MA): Little, Brown and Company; 1981.

- This self-study, active-participation book was written to show clinicians how to read the medical literature thoughtfully and efficiently. It includes a good chapter on diagnostic test statistics, covering sensitivity, specificity and predictive values.

Straus SE, Richardson WS, Glasziou P, Haynes RB. *Evidence-based medicine: how to practice and teach EBM*. 3rd ed. Edinburgh (UK): Elsevier Churchill Livingstone; 1997.

- In the preface to this short and practical text, David Sackett is acknowledged as the senior author of the first edition and mentor to Sharon Straus.

Heath measurement scales

Streiner DL, Norman GR. *Health measurement scales: a practical guide to their development and use*. 2nd ed. Oxford (UK): Oxford University Press; 1995.

- This text enables experienced and novice researchers to develop accurate, sensitive and easy-to-use measurement scales.

Knowledge translation

Straus SE, Tetroe J, Graham ID. *Knowledge translation in health care: moving from evidence to practice*. Oxford (UK): Blackwell Publishing; 2009.

- Insights from Canadian leaders in knowledge translation, especially on approaches for researchers to use to foster the application of their results.

The media

Cohn V, Cope L. *News & numbers: a guide to reporting statistical claims and controversies in health and other fields*. 2nd ed. Ames (IA): Blackwell Publishing Professional; 2001.

- "Victor Cohn of the Washington Post has prepared this manual to help reporters cut through statistical tangles. By such efforts, scientists and writers may gradually upgrade the whole communication system, scientific and journalistic" (Frederick Mosteller, Professor Emeritus of Mathematical Statistics, Harvard University).

Woloshin S, Schwartz LM, Welch HG. *Know your chances: understanding health statistics*. Berkeley (CA): University of California Press; 2008.

- Written by leaders in knowledge translation, particularly in the area of risk management, this book explains how to see through the hype in medical news, ads and public service announcements.

Publishing

Lang TA. *How to write, publish, & present in the health sciences: a guide for clinicians & laboratory researchers*. Philadelphia (PA): American College of Physicians; 2010.

- "Lang's earlier book on how to report medical statistics proved so useful that I bought a second copy to keep in my home office. His new book features the same type of pragmatic advice on the nuts and bolts of scientific writing" (David Grimes, University of North Carolina School of Medicine).

Lang TA, Secic M. *How to report statistics in medicine: annotated guidelines for authors, editors and reviewers*. 2nd ed. Philadelphia (PA): American College of Physicians; 2006.

- This text is an excellent guide to reporting and interpreting statistical presentations.

Research design

Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. *Designing clinical research: an epidemiologic approach*. 3rd ed. Philadelphia (PA): Lippincott Williams & Wilkins; 2001.

- This book offers thorough coverage of all elements of designing retrospective, prospective and experimental studies. It addresses sample size estimation with examples for different study designs.

Jadad A. *Randomised controlled trials*. London (UK): BMJ Books; 1998.

- This is a good little text for readers who wish to understand the basic principles of randomized controlled trials and their role in health care decisions.

Pocock SJ. *Clinical trials: a practical approach*. Toronto (ON): John Wiley & Sons; 1983.

- This excellent text contains good chapters on methods of randomization, crossover trials and sample size estimation.

Schultz KF, Grimes DA. *The Lancet handbook of essential concepts in clinical research*. Edinburgh (UK): Elsevier; 2006.

- "Few doctors would quibble with the view that their skills in evaluating clinical research are modest. This book provides a superb and indispensible guide to the interpretation of research for the busy doctor" (Richard Horton, Editor, *The Lancet*). Each chapter represents a peer-reviewed article published in *The Lancet* from 2002 to 2005.

Survey research

Alreck PL, Settle RB. *The survey research handbook*. Boston (MA): Irwin/McGraw-Hill; 1995.

- This handbook covers topics from planning and designing a survey to analyzing the data and has a good chapter on sampling.

Dillman DA, Smyth JD, Christian LM. *Internet, mail and mixed mode surveys: the tailored design method*. 3rd ed. Hoboken (NJ): John Wiley & Sons; 2007.

- This edition emphasizes the use of the Internet in conducting surveys.

Salant P, Dillman DA. 1994. *How to conduct your own survey.* New York (NY): John Wiley & Sons; 1994.

- Start with this book, a step-by-step guide to survey research.

SUMMARY CHECKLIST

- ❑ Meet with your program director or departmental research coordinator as soon as possible.
- ❑ Look for resources that provide an introduction to the basic concepts of research methodology and critical appraisal.
- ❑ Find a research supervisor.
- ❑ Pose a focused and specific research question.
- ❑ Develop a research outline.
- ❑ Meet with methodological (especially biostatistical) specialists with particular expertise in your area of study.
- ❑ Develop the research protocol.
- ❑ As applicable, obtain institutional and research ethics approval.
- ❑ Seek necessary funding.
- ❑ If you are conducting a clinical trial, ensure that it is registered with ClinicalTrials.gov
- ❑ Collect and analyze the data.
- ❑ Present your findings.
- ❑ Prepare and submit a manuscript describing the study and its results to a suitable journal.
- ❑ If your manuscript is accepted, revise it according to the editors' and reviewers' comments.
- ❑ Celebrate with your coauthors.

2
Research in residency, other health care training, and practice: Why, when and how?

Robert L. Reid, MD, FRCSC

ILLUSTRATIVE CASE

A second-year Obstetrics and Gynecology resident is told by her program director that she must present a research project at the annual resident research day next year. She is swamped with clinical work and is using every spare moment to study for an upcoming departmental exam. The last thing she needs to add to her workload is a research project, and so she asks her director if she can duck the "researcher role" and spend the extra time and energy becoming a better clinician.

The CanMEDS 2005 Physician

Competency Framework[1] identifies seven overlapping core competencies as essential in the preparation of physicians to meet the needs of patients in the 21st century. Among these, the Scholar Role serves to anchor contemporary medical practice in continuing professional development, research literacy, critical appraisal skills and the ability to educate others. The best practice is informed by scholarship. A failure to adequately equip graduates with skills in critical appraisal and an understanding of research methodology has been identified as a common deficiency of training programs,[2] and examples of the devastating effects of this scientific illiteracy abound.[3]

To fulfill the Scholar Role, physicians must demonstrate that they:

- maintain and enhance professional activities through ongoing learning;
- critically evaluate information and its sources, and apply this appropriately to practice decisions;
- facilitate the learning of patients, families, students, residents, other health professionals, the public and others, as appropriate; and,
- contribute to the creation, dissemination, application and translation of new medical knowledge and practices.[1]

This guide has been designed to provide a framework to help learners acquire basic skills as researchers, in keeping with the fourth component of the Scholar Role. However, research experience enhances the other competencies of the Scholar by fostering lifelong learning along with skills in critical evaluation and the translation of new knowledge to others. Experience in the conduct of research helps clinicians and other health care practitioners to more capably challenge claims based on faulty research or improper interpretation, and to confidently incorporate into their practice those innovations that have been demonstrated to improve the quality of care.

CHAPTER OBJECTIVES

After reading this chapter, you should be able to:

- describe why scholarly activity, including research, is an essential prerequisite for residents, other health care trainees, and practitioners;
- list the key components of the CanMEDS Scholar Role; and
- highlight the two most critical choices in planning a research project—especially one's first.

The chapters of this guide provide a road map for the novice health care researcher. They examine what constitutes a scholarly project; emphasize the importance of finding a qualified supervisor or mentor and a working environment that supports research; and explore the fundamentals of conceiving and formulating a research question, conducting literature searches, choosing an appropriate study design, obtaining institutional approval, collecting and analysing the data, and reporting the results. Annotated lists of references and resources are provided to assist in the planning and implementation of a research project. Throughout the guide, the authors—all of whom are experienced investigators—offer practical advice on building a solid foundation for successful health research.

Why me?

No doubt, many resident physicians, other health care trainees and practitioners reading this introduction will think, "That's all fine, but I didn't decide to become a health professional so that I could do scientific research. I'm not looking for a Nobel Prize. I just want to be a competent and caring health care practitioner."

The answer to "Why me?" lies in the many career paths open to graduates of residency and other health care training programs. Graduating practitioners are charged with two responsibilities: (1) to provide the highest possible quality of health care to patients and populations; and (2) to educate the next generations of health care practitioners. Research is essential to evaluating and improving performance in both of these roles.

You may think at the start of your training that a research role would be better left to your colleagues who received Masters or PhD degrees before they entered health practice training. Although it is true that such individuals bring specialized knowledge and research skills to their training, many excellent researchers were not "turned on" to a research career until they encountered a challenging practice-based problem during their residency, other health training, or practice. Moreover, often because of lifestyle factors or the influence of mentors, many health science students and trainees change career course during clinical training, and so it is wise to keep one's options open as long as possible for advanced supplementary training—where research involvement is often expected.

Those who choose to enter practice as soon as they complete their training will need to acquire at least the basics of critical appraisal skills if they hope to elevate discussions with patients above the level of what they hear from popular media. New health care practice subscription services are emerging on the Internet that identify and summarize important discipline- and specialty-specific research findings while providing a short critical appraisal of the quality of the research. Although these services can be extremely helpful to busy health care practitioners, they generally require a basic understanding of key research concepts and sufficient skill in critical appraisal to judge the quality of evidence and facilitate meaningful interpretation and discussion. In addition, practitioners who acquire basic knowledge and skills with regard to health research will be better equipped to contribute to relevant research themselves, such as by identifying patients who meet the enrolment criteria for a clinical trial or even by serving as a study co-investigator.

When can I find time?

The trainee in our case example is no doubt experiencing the same worry about participating in research as many of her peers have before her: she wonders where in the world she will find the time—and the energy—to fit a research project around all of her clinical responsibilities.

Within the time frame of a health care practitioner training program, it is generally unrealistic to expect to have a significant period of protected time in which to conduct research. Exceptions are the Royal College Clinical Investigator Program and a few residency programs that are able to offer a one- or two-year deferral for the completion of a Masters or PhD degree. For most trainees, however, any research project will need to be undertaken simultaneously with training activities. A short elective devoted to the development of a research project can be ideal, although this is not available in all programs. Given the demands of any training program, it is important to plan a research project realistically and at an early stage. Time will be needed to identify and meet with a qualified supervisor or mentor, to develop the research idea, establish necessary collaborations, and prepare the proposal and other documentation for ethics review. Care in the planning stage will pay big dividends later on.

For a first foray into research, it often makes sense to design, in consultation with a supervisor or mentor, a project that examines data retrospectively; examples are a systematic review, survey-based study or chart audit. More

ambitious projects that collect data prospectively, as in a clinical study of a new test or treatment or a multi-centre trial, require considerably more preparation and, of course, the requisite funding. It is better, at first, to think small and see a project through than to start an enormous project that falls apart for want of time, funding or subject recruitment, or because of investigator burnout.

Where do study ideas come from?

Dramatic innovations in health and science over the past 60 years have propelled us into the 21st century with a momentum that is already revolutionizing the delivery of health care and the way we live our lives. Did these discoveries happen by accident? Although there are many serendipitous findings in science, discovery and "happy accident" often occur to those who are the most alert and prepared. Many of the most exciting revelations result when discoveries in the basic sciences are brought to bear on pressing clinical problems by those with an open mind and a willingness to critically challenge existing dogma. Witness the discovery by Australian clinician-scientists Robin Warren and Barry Marshall that peptic ulcers are not, in fact, caused by stress or the consumption of alcohol or spicy food, but by infection with the bacterium *Helicobacter pylori*. Marshall and Warren challenged conventional thinking on the subject, "rewrote the book" on peptic ulcer disease, and were awarded the 2005 Nobel Prize for Medicine or Physiology for their insight and efforts.

Those who work in the trenches of health practice face common problems for which there appears to be little progress toward a solution. An unwillingness to explore new strategies is often explained by a shortage of time, which seems to lead to complacency. Unfortunately, many accept what appears to be a suboptimal approach simply because "that's the way it's always been."

Novel ideas arise when old problems are considered from a new perspective. However, new ideas are often dismissed with a quick rebuke: "If the solution were that obvious, someone else would have done it already." Good hunches can be discarded for any number of reasons. Albert Szent-Györgyi, the first scientist to isolate vitamin C, made important discoveries by paying attention to results that another researcher had literally poured down the drain. Not all ideas work out. But, to use a phrase attributed to Nobel Prize winner Linus Pauling, "The best way to have a good idea is to have a lot of ideas." Health care leaders emerge from those who are willing to take the time to pursue a new idea, accept failure if it occurs and move on with other attempts to solve the problem.

"A discovery is said to be an accident meeting a prepared mind."[4]

Albert Szent-Györgyi (1893–1986)
Nobel Prize laureate in 1937

How do I get started?

When you have an idea for a solution or a new approach to a problem, write it down before it vanishes among all the other issues arising from the countless health care concerns you encounter in the course of a day. Then, when you have more time, do a thorough literature search to see whether someone has tested your idea before. Make sure, before you embark on a research project, that you won't end up simply reinventing the wheel.

If, like many health trainees and practitioners, you feel stuck for a clever or feasible research idea, turn to your supervisor or mentor for help. Qualified supervisors and mentors have a track record of productive research. Typically, they have a host of ideas relating to their own research but not enough time to pursue each one. A keen trainee who is willing to tackle one of these projects can forge a long-term collegial relationship that can potentially benefit both parties for years to come.

Conclusion

An understanding of the basics of research methodology and practice are essential for all health trainees and practitioners to allow them to critically evaluate new health science developments. During your health practice training, you will have valuable opportunities to enhance these skills by entering research training programs, studying texts such as this one, participating in activities such as journal clubs and research projects, and interacting with experienced researchers at your university. Taking advantage of these opportunities at an early stage of your career will help you to become a well-rounded practitioner and to develop further the important competencies of the Scholar Role. ■

CASE POSTSCRIPT

Searching her department's website, the resident informed herself about the range of research projects that were in progress within the department and about the research interests and activities of individual staff. She asked senior residents about the quality of supervision, support and mentorship offered by different staff. She then approached a qualified and supportive faculty member to see if he would be willing to serve as her research supervisor. The resident spent a one-month elective later in the year developing a research idea and writing her proposal. This involved several meetings with her faculty supervisor. Her supervisor facilitated a meeting with a statistician during the planning stages to ensure that the study's sample size would be adequate to demonstrate a difference between two labour-induction protocols. Knowing that the project was well planned and adequately powered, the resident and her supervisor submitted the protocol to the university and hospital Research Ethics Boards and received approval. The resident then involved several other residents from the labour and delivery floor in data collection over the next year, and all contributed as co-authors to a prize-winning paper presented at the departmental research day one year later. The resident was also gratified to have her findings published in a leading journal of Obstetrics and Gynecology several months later.

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SUMMARY CHECKLIST

- ❑ Describe at least three reasons to get involved in the world of research.
- ❑ Consider, personally and professionally, what you want to get out of being involved in research.
- ❑ List three people you can talk to about research.
- ❑ Get started. Let this book be your guide!

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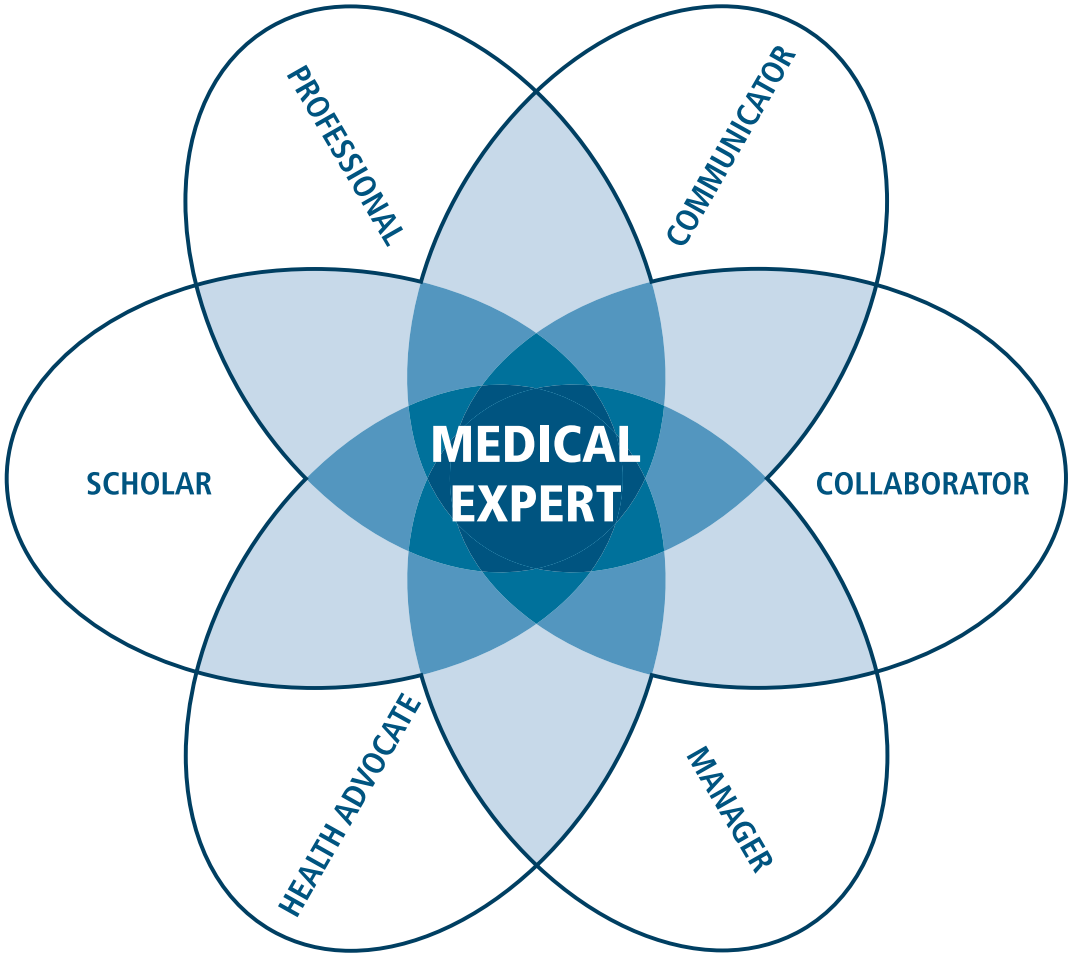

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