RESEARCH TO PUBLICATION

Curriculum Guide for Experienced Researchers

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BMJ

This curriculum guide is designed to help you get the best out of Research to Publication, taking you through the concepts you need to get your great research published. Each module builds on previous learnings.

Simply click on the titles below to get started:

How to succeed in publishing research

How to plan and conduct great research

How to succeed in publishing research

How to develop and report good research questions

The introduction: presenting the research question

Learning outcomes:

- Understand the purpose of the introduction section
- Explain what was known, and not known about the study's topic and about the specific research question
- Report the study's research question clearly
- Understand what makes a good research question
- Use evidence based, effective writing to introduce the study
- Use references/literature review effectively and sparingly.

Related modules and resources on writing:

- Related modules and resources on Research questions
  Developing a research question for your research project
- Video/webinar by Trish Groves: How to develop and communicate good research questions

Developing and writing protocols

How to write and publish a study protocol: overview

Learning outcomes:

- Understand different meanings of the term "protocol"
- Communicate the value of planned research
- Appreciate the characteristics of a good research question
- Match research questions to appropriate study designs
- Identify strengths and weaknesses of published protocols.

Clinical trial protocols: how to write and publish them

Learning outcomes:

- Understand the importance and limitations of trial registration
- Choose the correct guideline for writing a protocol paper
- Understand the key features of ICH GCP E6 and SPIRIT guidelines for reporting clinical trial protocols
- Prepare a real clinical trial protocol for publication in a journal.

How to write a research protocol for a grant application

Learning outcomes:

- Understand when a research grant is needed
- Know how to prepare a grant application
- Understand the principles of grant review
- Appreciate why a research plan for funding must be based on a high quality study protocol
- Use simple language when writing the research plan.

Good medical writing

Learning outcomes:

- How to tell the story of the study using IMRaD format
- How to use structure, style, and language to write well
- Writing in an evidence based style
- "House style" at journals
- Templates to facilitate writing and submission
- When and how to use medical writing and translation services.

Choosing and citing references

Learning outcomes:

- Search published literature for appropriate references
- Pick and read relevant references to support key statements
- Cite accurately and fully, avoiding plagiarism
- Beware of web references
- Ignore or contest journal requests for "self citation"
- Follow journal advice, using Vancouver or Harvard style.

Choosing the best study design

The methods: matching study designs to research questions

Learning outcomes:

- Why the methods section is the most important part
- How to report study methods accurately and fully
- How to report methods to minimise bias and confounding
- How to use reporting guidelines for different study types.

How to do ethical research

Ethics aspects of study methods

Learning outcomes:

- Why and how ethics issues can affect study methods
- How international guidelines on research ethics can affect study methods
- How to report ethics aspects in the methods section of a research paper
- Why medical journals mandate prospective registration of clinical trials, protection of patient confidentiality, and other ethics issues that affect study methods.

How to write a research paper

Reporting statistical methods and analyses

Learning outcomes:

- Report statistical methods and analyses clearly
- Follow the Statistical Analyses and Methods in the Published Literature (SAMPL) guidelines on reporting statistics
- Better understand journal resources and policies on statistical methods
- Learn from examples of good reporting.

The results: reporting all findings succinctly

Learning outcomes:

- Why the results section is less important than you think
- How to report study results accurately and fully
- Pitfalls of reporting results on associations and risks
- How to use reporting guidelines for the results of different study types
- Using tables and figures
- Using supplemental files
- Options for data sharing.

Scientific transparency: the pitfalls of selective reporting

Learning outcomes:

- Why selective reporting of research is wasteful and unethical
- How research waste is bad for health
- Why clinical trial registration is so important
- How to make research reproducible
- What we can all do to make research more transparent:
- Research funders and governments

- Ethics committees
- Drug, devices, and diagnostics industries
- Journals
- Authors.

The discussion: using structure and balance

Learning outcomes:

- Understand the purpose of the discussion section
- Understand the elements of a structured discussion
- Appreciate the need for a balanced, self critical discussion
- Discuss the results of “negative studies” and observational studies
- Explain what was known, and what the study’s results add
- Use evidence based, effective writing to interpret the results and recommend next steps.

Optimising the abstract and title

Learning outcomes:

- Why abstracts of research papers must be accurate and clear
- How to use international, evidence based guidelines on preparing abstracts for different study designs
- How to report the PICO elements of a study in the abstract
- How to write an informative, effective title for a research paper.

The essentials of running a clinical trial

How to write up industry-sponsored trials

Learning outcomes:

- The evidence on misreporting of industry trials
- Potential pitfalls of using composite end points in trials
- Reporting of authorship for industry studies
- How to report industry trials transparently
- Good publication practice (GPP3) for industry studies.

Picking the right journal and getting published

Navigating journal and peer review processes

Learning outcomes:

- Key points to consider when choosing a journal
- Tips on choosing between local, and national, and international journals
- What the term “indexed journal” means
- Measures of impact, particularly journal impact factor
- Publishing with open access
- Typical peer review process
- How journals try to minimise bias in peer review
- Research evidence for different kinds of peer review
- How to avoid predatory journals.

Compliance with journal and ICMJE requirements

Learning outcomes:

- Why journals vary widely and have different editorial policies
- Core requirements for all medical journals
- The Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical
- Journals from the International Committee of Medical Journal Editors (ICMJE)
- Importance of key ICMJE policies (on authorship, conflicts of interest, clinical trial transparency)
- Overview of the authorship rules and the role of the corresponding author
- The rules on clinical trial registration
- Examples of specific journal policies eg The BMJ's patient review of research.

Patients' consent for publication

Learning outcomes:

- Why consent to publication about potentially identifiable living patients matters
- Circumstances in which journals need such consent to publication
- How journals handle consent, and what they do when consent is unavailable or privacy is breached
- Policies, regulations, and laws that protect study participants' privacy.

Surviving peer review

Learning outcomes:

- How to submit an article
- Typical author journey through the peer review process
- Roles and responsibilities of authors, editors, and reviewers during peer review
- Why ORCID (open researcher and contributor ID) is useful
- What peer reviewers do
- How to respond to comments and revise the manuscript
- What happens after manuscript acceptance
- How to approve proofs
- Working with the media
- Using social media to disseminate research
- When to respond to post publication peer review.

What to do with rejections and appeals

Learning outcomes:

- Why journals reject research
- Evidence on what might lead to rejection
- How to interpret rejection letters
- What to do after rejection
- Waste in research and how to avoid it
- When and how to appeal against rejection.

Presubmission inquiries and cover letters

Learning outcomes:

- Why a presubmission inquiry can increase the efficiency and success of peer review for both authors and editors
- When to make a presubmission inquiry

- Key elements of a presubmission inquiry
- How to write the cover letter when submitting research
- When and how to disclose overlapping and prior publication
- When and how to request fast track peer review.

Related modules and resources on writing:

- Journal rules on authorship
- Scientific misconduct, authorship and conflict of interest
- Compliance with journal and ICMJE requirements

Avoiding scientific misconduct

Reporting conflicts of interest

Learning outcomes:

- Why it is necessary to declare conflicts of interest (COI)
- Definitions of COI
- Potential COI in health services research
- Potential COI in industry-sponsored research
- Public reporting of industry payments to health professionals
- Handling COI for other types of journal article
- Potential COI for editors, journals, and publishers.

Journal rules on authorship

Learning outcomes:

- Authorship: how it is defined, and why it matters
- How MEDLINE and journals list authors
- Journal policies and practices to safeguard authorship
- Guest, gift, and ghost authors and other authorship problems
- Attribution for shared datasets.

How and why to avoid plagiarism

Learning outcomes:

- How plagiarism and text recycling are defined
- How common plagiarism is
- Factors associated with plagiarism
- Use of plagiarism detection tools by publishers
- How to avoid plagiarism and how to respond if caught.

How journals uncover scientific fraud

Learning outcomes:

- Scientific fraud as data fabrication and deliberate falsification
- The extent and harms of scientific fraud
- Techniques journals may use to uncover fraud
- Statistical analysis
- Image checking
- Linguistic analysis
- Investigative journalism
- Peer review (pre- and post-publication)
- Data sharing
- Barriers to tackling fraud
- Principles of research integrity.

How journals act on scientific misconduct

Learning outcomes:

- How and why journals respond to suspected misconduct that relates to submitted and published articles
- The role of the Committee on Publication Ethics (COPE)
- The roles of authors' institutions and research integrity organisations in investigating possible misconduct
- Reasons for, and impacts of, retractions in biomedical and health research
- How MEDLINE corrects the literature.

How to plan and conduct great research

How to develop and report good research questions

Developing a research question for your research project

Learning outcomes:

- Identify and describe the characteristics of a good research question
- Explain three key ingredients for developing a research question
- Name and briefly describe the FINER criteria
- Describe several sources from which good research questions arise
- Draft a one-sentence research question and 1/2 page describing the significance of your research question.

Choosing the best study design

Study design

Learning outcomes:

Observational Studies:

- Define cohort studies
- Distinguish between prospective and retrospective cohorts
- Explain the nested case-control design and strategy
- Describe the multiple-cohort design
- Define cross-sectional studies
- Explain why cross-sectional studies yield weaker evidence for causality than cohort studies
- Define case-control studies and their benefits and problems
- Describe case-crossover studies.

Randomized Blinded Trials:

- Define randomized blinded trials
- Explain how to design RBTs
- Describe how to choose the intervention and control conditions
- Describe how to define outcomes and adverse effects
- Describe how to select participants
- Describe how to measure baseline and outcome variables
- Evaluate approaches to randomizing and blinding.

Studies of medical tests

Learning outcomes:

- Understand the definition of studies of medical tests and how these studies differ from therapeutic intervention trials or studies to assess causality
- Explain how to select subjects for a study of a medical test
- Understand how to measure reproducibility of a test including use of kappa and the coefficient of variation
- Define key metrics to use in studies that assess the accuracy of a diagnostic test including sensitivity, specificity, predictive value, ROC curves, and likelihood ratios
- Understand how to design studies of clinical prediction rules and the associated limitations and challenges with this design.

Enhancing causal inference

Learning outcomes:

- Describe cause-effect relationships and enumerate the four rival explanations
- Identify ways to minimize chance
- Discuss bias and identify ways to avoid bias
- Identify ways to make confounding less likely
- Offer several suggestions or strategies for incorporating opportunistic observational designs
- Explain how causal inference can be enhanced by positive evidence.

Subjects and variables

Learning outcomes:

- Define sample and population, and describe how sample and population inform all clinical research
- Identify criteria for a target population
- Compare and contrast approaches to sampling
- Describe several strategies for recruiting a sample of subjects.

Sample size and power

Learning outcomes:

- List the steps for estimating sample size for an analytic study
- Explain other considerations in calculating sample size for analytic studies
- List the steps for estimating sample size for descriptive studies
- Identify strategies to minimize the required sample size
- Explain other strategies for estimating sample size when there is insufficient information.

Statistics

Learning outcomes:

- Define and describe box models
- Define and describe standard error
- Define and describe p-values
- Define null hypothesis
- Select the appropriate statistical tests for your study.

Questionnaires and qualitative research

Learning outcomes:

- Describe steps an investigator can take to ensure that questionnaires and interviews are as valid and reproducible as possible
- Define open-ended questions and closed-ended questions and devise several examples of both types of questions
- Identify desirable question elements as well as pitfalls to avoid
- Design a one-page instrument that is easy to read, easy to understand, and suitable for data entry.

Related modules and resources on writing:

- The methods: matching study designs to research questions
- Reporting statistical methods and analyses
- The results: reporting all findings succinctly
- Scientific transparency: the pitfalls of selective reporting

How to do ethical research

Ethical considerations in research

Learning outcomes:

- Discuss a brief history of research oversight
- Review ethical principles and federal regulations
- Explain institutional review board (IRB) approval
- Define informed consent
- Discuss scientific misconduct, authorship, conflicts of interest, and ethical issues in specific types of research.

History of research ethics

Learning outcomes:

- Identify the ethical code of principles for clinical research that has been adapted worldwide
- Describe 3 key principles of clinical research identified in the Nuremberg Code
- List the 4 ethical principles included in the 1964 Declaration of Helsinki (beyond the Nuremberg Code)
- Describe what the 1966 NIH Ethical Review Policies obligated US research institutions to develop and institute.

Institutional review board (IRB) and informed consent

Learning outcomes:

- Discuss which types of clinical studies need institutional review board approval
- List 5 purposes of informed consent
- Discuss how the Facebook case used or did not use the informed consent process
- Discuss current problems with informed consent process and forms

- Discuss 3 common misconceptions that participants may have even after the completing informed consent process
- Discuss 3 different types of informed consent that might be used for studies with genetic materials.

Data and safety monitoring

Learning outcomes:

- Identify potential safety issues related to your study
- List at least three important duties of a quality control coordinator and/or data and safety monitor
- Describe the function and operation of a Data and Safety Monitoring Board (DSMB).

Principles of research ethics

Learning outcomes:

- Describe 4 ethical principles for clinical trials
- List 3 ethical principles that were violated during the Tuskegee Study
- Describe issues of beneficence in the TGN 1412 Study.

Ethics in "big data" research

Learning outcomes:

- List the four core values that are at stake in Big Data Research
- List 7 fields of study included in Big Data Research
- Discuss the issues of balancing informed consent and governance in Big Data research
- Describe the Ten Simple Rules regarding responsible conduct of research in your country.

Research in resource-poor environments

Learning outcomes:

- Explain why use of placebos in clinical trials may be unethical in developing countries
- Discuss issues related to provision of background and ancillary care, informed consent, access to the study intervention after the trial, and collaboration with host-country stakeholders.

The essentials of running a clinical trial

Course overview and trial designs

Learning outcomes:

- Define randomized controlled trial
- Identify three alternative study designs to randomized controlled trials
- Identify five reasons for not conducting randomized controlled clinical trials
- Identify four reasons for conducting randomized controlled clinical trials
- Describe four randomized trial designs.

Selection of participants

Learning outcomes:

- Explain why it is important to develop detailed and specific eligibility criteria in a clinical trial
- Describe advantages and disadvantages of defining a broader versus narrower population in a trial

- ➔ Describe at least three appropriate reasons for excluding participants from a clinical trial.

Recruitment

Learning outcomes:

- ➔ Describe two goals of recruitment
- ➔ Identify two study design issues
- ➔ Identify three strategies to recruit appropriately
- ➔ Identify four recruitment methods.

Choosing the intervention and controls

Learning outcomes:

- ➔ Describe aspects of the experimental intervention that should be defined in the planning stages of a trial
- ➔ Identify at least three important functions of a control or comparator intervention in a trial
- ➔ Assess the strengths and weaknesses of common controls for pharmacologic, surgical, or behavioral interventions.

Randomization

Learning outcomes:

- ➔ Describe the importance of randomization in clinical trials
- ➔ Describe simple randomization
- ➔ Describe randomized permuted blocks.

Blinding

Learning outcomes:

- ➔ Define blinding and identify ways to blind many interventions
- ➔ Identify three ways that blinding minimizes potential bias for
- ➔ Identify four types of interventions that cannot be blinded
- ➔ Describe strategies to implement if the study cannot be blinded.

Outcome measures

Learning outcomes:

- ➔ Describe at least two reasons for using one primary outcome
- ➔ Identify two types of data that support that a measure is a 'valid' surrogate marker for treatment
- ➔ Identify the main criterion for determining whether a marker is a valid 'surrogate' endpoint
- ➔ Describe two pros and cons for using composite outcomes.

Assessing safety

Learning outcomes:

- ➔ Define a serious adverse event
- ➔ Describe one pro and con of elicited vs volunteered adverse events
- ➔ Describe reasons for using a formal adjudication process for clinical outcomes
- ➔ Identify one disadvantage of adjudication.

Adherence and complete follow-up

Learning outcomes:

- ➔ Describe two important reasons for adherence to the protocol

- Describe five ways that adherence can be measured
- Identify two ways to maximize adherence to the protocol
- Identify four ways to maximize follow up
- Describe three analytic techniques to use for poor compliance during a trial
- Describe two effects of non-adherence.

Ethical issues in clinical trials

Learning outcomes:

- Identify ethical issues in clinical trials
- Describe factors for acceptability of random assignment to a treatment
- Define interim monitoring
- Describe two basic goals of interim monitoring in a blinded trial
- List four reasons to stop a trial early
- List four components of a data monitoring plan
- Describe conflict of interest issues in clinical trials
- Describe three ways of performing scientific misconduct
- Define contributions needed to qualify as an author on manuscript.

Regulatory issues

Learning outcomes:

- Upon completion of this module you should be able to:
- Define regulations that apply to clinical trials
- Describe good clinical practice.

Understanding and avoiding scientific misconduct

Scientific misconduct, authorship and conflict of interest

Learning outcomes:

- Describe the purpose of and criteria for authorship.
- Explain how disputes over authorship might be prevented and/or resolved.
- Define conflicts of interest.
- Discuss the association between conflicts of interest and bias in research projects.
- Discuss how failure of reproducibility may indicate scientific misconduct.
- Discuss how research misconduct may introduce bias into the research findings.

Related modules and resources on research integrity:

- Journal rules on authorship
- Reporting conflicts of interest
- How and why to avoid plagiarism

- How journals act on scientific misconduct.

About Research to Publication:

Research to Publication is a research methodology programme for anyone in healthcare research, brought to you by BMJ in collaboration with University of California, San Francisco (UCSF).

The programme is focused entirely on health research; BMJ's research editors and UCSF's academics guide learners through the entire process from designing a study, to seeing it published in an international journal.

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