

OF THE WEST INDIES



The FMS Research Studies Toolkit Design to Publication: A Practical Guide

Clinical Translational Research Unit Faculty of Medical Sciences The University of the West Indies, Mona



Translating Science from the Bench to the Bedside



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THE UNIVERSITY OF THE WEST INDIES, MONA

FACULTY OF MEDICAL SCIENCES CLINICAL TRANSLATIONAL RESEARCH UNIT

RESEARCH STUDIES TOOLKIT

DESIGN TO PUBLICATION: A PRACTICAL GUIDE

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INTRODUCTION

This Research Studies Toolkit is designed for use by student researchers and research supervisors as a practical guide to support the development of research studies in the Faculty of Medical Sciences (FMS), The University of the West Indies (UWI), Mona Campus. Members of faculty may also find this document helpful in the course of their research programmes. Students of other UWI Mona faculties, as well as other UWI campuses are welcomed to utilize this resource in the course of conducting their research studies.

The toolkit recognizes the Translational Science and Knowledge Translation pathways for the evolution of scientific discoveries and developments. From the 'bench to the bedside', the translational science principle supports applications for clinical research, clinical practice, and population health programming.

The toolkit focuses on quantitative research procedures and takes the researcher on a journey across the various stages of the research process, commencing at the critical Research Conceptualization Phase and culminating in the Research Publication Phase. This document can serve as a resource and support mechanism for students pursuing Research Methods courses offered in the faculty.

The contents of this toolkit cover the phases in a step-wise approach, with illustrations. Readers are directed to appropriate resources to further support selfdirected learning. Frequently asked questions are included as a quick guide.

In this, the first edition of this work, the academic authors and contributors share their own expertise, applying practical experience on a range of subjects spanning the research paradigm and workflow.

This approach is expected to serve as a guidepost to enhance research skills in the FMS, extending to our collaborators across The University of the West Indies and other research partner communities.

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EVIDENCE-BASED DECISION MAKING IN PUBLIC HEALTH, BASIC MEDICAL SCIENCES, CLINICAL STUDIES

As defined by Sackett et al (1996), "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients". Substantially, EBM represents the integration of individual clinical expertise and the highest level of research-driven clinical evidence (from the basic sciences to clinical research) (Figure 1).

Figure 1: Domains of Evidence-Based Medicine



Source: Jacobs et al (2012) Domains that influence evidence-based decision making (adapted from Satterfield JM et al (2009).

Clinical and public health practitioners, as well as policy makers aim to systematically incorporate scientific evidence in management and clinical decisions, programme implementation and policy development. Evidence-based public health (EBPH) engages the target community in the assessment and decision-making process. Coupling this with the use of data and information systems, the best available evidence (i.e., peer-reviewed publications/research) is utilized in making decisions. EBPH engages progamme planning frameworks, inclusive of programme evaluation and dissemination).

Evidence-based science is critical for decision making on a range of health care issues, such as:

- Financing health programmes
- Financing research programmes
- Assigning human resources
- Treatment decisions
- Determining cost-efficiencies in health
- Improving public/ patient knowledge

KNOWLEDGE TRANSLATION AND TRANSLATIONAL SCIENCE

As defined by the World Health Organization, Knowledge Translation is

"the synthesis, exchange, and application of knowledge by relevant stakeholders to accelerate the benefits of global and local innovation in strengthening health systems and improving people's health."

Source: WHO. Knowledge Translation for Health Decision Making. <u>https://www3.paho.org/hq/index.php?option=com_content&view=article&id=14477:knowledge-translation-for-health-decision-making&Itemid=0&lang=en#gsc.tab=0</u>

Research evidence is generated along the Translational Science pathway where new scientific studies and discoveries are evolved to produce applications for clinical and population health (Figure 2). The National Centre for Advancing Translational Sciences (NCATS) posits that

"The translational science spectrum represents each stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public".

Source: NCATS. Transforming Translational Science - <u>https://ncats.nih.gov/translation/spectrum</u>



Figure 2: Spectrum of Translational Science



Source: Transforming Translational Science. National Center for Advancing Translational Sciences – https://ncats.nih.gov/files/NCATS_Factsheet_508.pdf

Popularized by the term 'from the bench to the bedside', each stage builds on basic research, which is the core of the translational science system (Figure 3).



Figure 3: Translational Science Pathway – Levels of Evidence

Basic research – ground floor of the translational science system which provides information on the fundamental mechanisms of biology, disease or behaviour.

Preclinical Research – serves as the connection between the basic science of disease and human medicine.

Clinical Research – involves studies designed to elucidate the disease process in humans which are conducted in relation to cell or animal models. Findings at this level can be used for the purpose of gaining regulatory approval for interventions.

Clinical Implementation – interventions with a demonstrated value are adopted for use in the clinical setting for the general population. This stage is inclusive of implementation research which evaluates the outcomes of clinical trials and also for the purpose of identifying new research questions and care or treatment gaps.

Public Health – at the population level, public health studies provide evidence to assess and determine diseases and their effects, as well as measures for diagnosis, treatment and prevention. This facilitates intervention assessments and guides the development of new therapeutic interventions.

GENERATING SCIENTIFIC EVIDENCE: EPIDEMIOLOGY & BIOSTATISTICS

Last (2001) defines epidemiology as "the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems". While the definition has evolved over the past few decades, with the addition of sub-specialties, in the main the definition has remained the same.

Statistics can be defined as "the branch of the scientific method which deals with the data obtained by counting or measuring the properties of populations of natural phenomena" (Kendall and Stuart 1963). The definition proffered by Kruskal (1968) states that "statistics is concerned with the inferential process, in particular with the planning and analysis of experiments or surveys, with the nature of observational errors and sources of variability that obscure underlying patterns, and with the efficient summarizing of sets of data".

Biostatistics therefore refers to the application of statistical principles to research questions and problems in a range of biomedical sciences, such as basic sciences (e.g. biology), clinical sciences (e.g. medicine, nursing, physical therapy) and public health.

EPIDEMIOLOGY AND BIOSTATISTICS AS COMPLEMENTARY DISCIPLINES

Epidemiology and biostatistics are complementary disciplines in the evidencebased framework. Epidemiological principles guide the scientific process of generating evidence from research design to analysis, while Biostatistics is the application of statistical principles to epidemiological inquiry. This inquiry generates scientific evidence to answer the research question or to test the scientific hypothesis of interest. Principles and practices of epidemiology and biostatistics provide evidence for decision making on health programme development and/or revision as well as health policy formulation.

As illustrated in Figure 4, evidence-based public health requires an assessment and quantification of a particular public health issue. Epidemiology and biostatics serve as complementary disciplines in driving the assessment and quantification processes to inform health programme and policy development.

Figure 4: Framework for Training Public Health Professionals in Evidence-based Decision Making



Source: Jacob R, Duggan K, Allen P. et al. Frontiers in Public Health (2018). https://www.frontiersin.org/articles/10.3389/fpubh.2018.00257/full

RESOURCES: EVIDENCE-BASED PRACTICE

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THE RESEARCH PARADIGM: WORK FLOW PROCESS

The workflow process from research design to publication involves seven key building blocks, orchestrated in a linear, step-wise manner (Figure 5):

- Research conceptualization
- Research proposal development
- Field/Laboratory work, data collection and project management
- Data management
- Data analysis
- Report preparation (dissemination of findings)
- Publication (dissemination of findings)





The key components of each building block are discussed in detail in the ensuing sections of this document, with resources indicated for further reading.

STAGE 1: RESEARCH CONCEPTUALIZATION

At the outset the researcher will need to contemplate the subject matter to be investigated. Significant thought and discussion are required to develop a reasonably sound understanding of the problem or issue to be studied. Key elements to be considered are illustrated in Figure 6.

FIGURE 6: STEPS IN THE CONCEPTUALIZATION STAGE



DECIDING ON A RESEARCH TOPIC; RESEARCH OBJECTIVES & RATIONALE

At the start of your research journey you will need to decide on a topic, subject or problem which you will investigate or study. This topic or subject can be arrived at via multiple means, including:

- An issue of great interest to you arising from personal experience or curiosity
- Observation
- Practical issues
- Previous research
- A topic under study by your academic supervisor or colleagues
- Existing databases from previous studies
- An invitation to join a research team

Your task is to edify or inform yourself on the literature around the subject, as well as the most recent developments in the field. This is most practically done by conducting a thorough literature review and by speaking with experts in the field. This review is informative in identifying the gaps in the literature and new questions in the field of study. This enquiry can serve as a useful guide to assist you in developing a justification or rationale for your study and also in developing and refining your research questions and/or research objectives, as well as your research hypothesis.

RESEARCH DESIGN

IDENTIFYING AN APPROPRIATE RESEARCH DESIGN FOR YOUR RESEARCH OBJECTIVES/RESEARCH QUESTIONS

Research design can be broadly classified as observational and experimental. Observational studies can be further characterized as descriptive or analytic. Descriptive studies can be considered as the first level of analysis, providing a description of the frequency of a disease in a population or sample (e.g. measured by proportion or prevalence). Analytical studies represent a more complex set of analyses, used to examine relationships between risk factors or contributing factors

to a health condition/health status/disease and the resulting health outcome/health status/disease.

Observational:

- Descriptive e.g. cross-sectional; longitudinal
- Analytic e.g. ecological, cross-sectional, cohort, case-control

Experimental

• Analytic (e.g. intervention studies, clinical trials)

Research questions or objectives are important in informing the choice of research design. Typical applications/uses of various research designs, as related to research aims are illustrated in Hart J. (2015) – Characteristics and typical uses of various research design common in orthopaedic research. Research Design and Biostatistics. (Modified from Petrie A, Sabin C: Medical statistics at a glance, Oxford, UK, 2000, Blackwell Science.) and Petrie, A. & Sabin, C. (2000). Medical Statistics at a Glance (4th ed).

For additional reading, see: Applications of different observational study designs in Bonita et al 2006 [Basic Epidemiology -Table 3.3. – page 49]

VARIABLE IDENTIFICATION AND DEFINITION

The researcher will need to identify the respective variables of interest (i.e. explanatory [independent] and outcome [dependent] variables). The researcher should also clarify the variables in terms of operational definitions where appropriate. These definitions will be related to concepts such as type of variable; scale of measurement (i.e., nominal, ordinal, interval or ratio scales unit of measurement; formula and method of calculation or obtaining the measurement.

Additionally, the literature review should indicate where composite measures and their specific components are relevant (e.g., body mass index (BMI) =weight (kg)/ height (metres squared) and how they are classified internationally and expressed in the literature – whether as a continuous variable (e.g. mean BMI) or categorical variable (e.g. BMI categories – i.e. underweight, normal weight, overweight, obese). This exercise should be informed by a thorough literature review, including

specific discipline-based guidelines and will inform the instrument development phase (to identify the specific unit/s of measurement for data collection) (Table 1).

Variable	Type of Variable	Unit of measurement	Classification Unit	Formula
Systolic blood pressure (SBP)	Continuous	mmHg	Mean SBP	
Diastolic blood pressure (DBP)	Continuous/Ratio scale	mmHg	Mean DBP	
Blood pressure category (JNC 7*) Guidelines for Hypertension)	Categorical	mmHg [categories]	Normal; Pre-HTN; Stage 1 HTN, Stage 2 HTN	
Body mass index (BMI)	Continuous/Ratio scale	Kg/m ²	Kg/m ²	Weight (kg)/ Height (m²)
BMI category (WHO)**	Categorical	Kg [categories]	Underweight; Healthy weight (Normal); Overweight; Obese	

Table 1: Variables and Operational Definitions

* Joint National Committee (JNC 7) – <u>https://www.nhlbi.nih.gov/health-topics/seventh-report-of-joint-national-committee-on-prevention-detection-evaluation-and-treatment-high-blood-pressure</u>

**WHO, 2000. Obesity: Preventing and Managing the Global Epidemic-WHO technical report 894, Geneva.

FORMULATING A HYPOTHESIS

You will need to formulate a scientific hypothesis as the basis of your research investigation. Scientific hypotheses theorize relationships or associations between the variables of your study (e.g. explanatory [independent] and outcome [dependent] variables, or between risk factors and outcomes).

The research conceptualization phase can be likened to an iterative process, at the end of which you are able to demonstrate the basis for your proposed study and that you have a reasonably good understanding of the subject matter. Furthermore, this phase enables you to systematically and organically think through the question/s you wish to investigate, develop your concept, establish your hypothesis/es and illustrate the relevant unit/s of measurement.

ASSESSING THE FEASIBILITY OF YOUR STUDY

The researcher should consider the feasibility of the study in terms of being able to successfully undertake the study and complete it within the required time frame. It is recommended that a feasibility assessment be conducted at the early stage of the research process to determine the facilitators, enablers and barriers to the study. This assessment would allow for an interrogation of the practical steps for the study, to include issues and questions such as:

Gaining Entry:

- Do I have ready access to the target population?
 - What institutional engagement and approvals may be required?
 - Have the requisite approvals and permissions been secured?
 - Has the target population been adequately sensitized?
 - Is the target community/population 'on board'?
- Are the members of the target population available?
 - What are the ideal strategies to access them?
 - Where and when?
 - Scheduling conflicts
- How long would it take to enroll participants or to identify cases?
 - Is the case a rare occurrence?
- How long would it take for the outcome of interest to occur?
 - Time to event/outcome (i.e. follow-up time required)

Population and Sampling:

- What is the size of the population?
- Is it appropriate to conduct a census (entire population) vs sampling?
- What is the minimum sample size required?
- Which sampling methodology may be best suited?
 - Is a sampling frame available to pursue probability sampling?

Resources:

- Are the required resources/resource persons available and accessible?
 - Financial, technical resources
 - o Training of team
 - o Approvals for use/adaptation of instruments

Constraints and mitigation plan:

- What are the actual and potential constraints (i.e. cost, scheduling, etc.)?
- What are the options to address these constraints?
 - Formulate a Plan B (to be used as necessary)



FAQS: RESEARCH CONCEPTUALIZATION (STAGE 1)

? How do I generate a research question or hypothesis?

Research ideas can be generated through observation, a review of practical issues (i.e. challenges, expressed needs), and prior research on a subject. Research questions should be assessed on the basis of the potential value and interest of the topic (i.e. an unanswered question, a question which if answered serves to fill a gap in the literature, and an issue for which the practical implications of solving it are of significant value). This value can extend across the academic community, into communities of practice and the general public. Additionally, the feasibility of conducting the scientific investigation (i.e. resource availability in terms of knowledge, time, money, technical equipment and access to target research communities and participants) occupies a central role in the assessment process.

For further reading, see <u>https://opentextbc.ca/researchmethods/ chapter/</u> <u>generating-good-research-questions/</u>

Phow can I locate appropriate articles (literature) for my study?

Literature can be retrieved from a number of sources, including published and gray literature. Use key words from your study topic to search in electronic databases of peer-reviewed literature relevant to your field of study. Article bibliographies, conference proceedings, and grey literature (e.g., technical and government reports) are other valuable data and information sources, Your University library is also a helpful resource in retrieving articles which may be more difficult to access.

How can I access funding to conduct my research study?

You institution may offer funding for student or staff research projects (i.e. intra-mural funding). Contact the office of Graduate Studies & Research (UWI Mona) for further details. For extra-mural funding, the Mona Office of Research and Innovation (UWI) often shares listing of Requests for Proposal (RFPs) from external funding sources. The CTRU also publishes a listing regularly for circulation to the FMS.

Information on past, current and future funding opportunities can be gleaned from a search of local and regional research funding sources (e.g. National Health Fund (Jamaica); Culture, Health, Arts, Sports and Education Fund (CHASE) Fund and other international funders such as the Wellcome Trust and National Institutes of Health, among others.

RESOURCES: RESEARCH CONCEPTUALIZATION

Edith Cowan University. Conceptualising your research – <u>ECU Intranet</u> <u>Conceptualising your research : Designing and undertaking your research :</u> <u>Research journey : For Research Students : Research</u>

Edith Cowan University. Reviewing the literature – <u>https://intranet.ecu.edu.au/research/for-research-students/research-</u> journey/designing-and-undertaking-your-research/reviewing-the-literature

Jain, S., Lindley, S.E. and Rosen, C.S. (2013). How to conceptualize a research project. In: Roberts, L. (eds) The Academic Medicine Handbook. Springer, New York, NY. <u>https://doi.org/10.1007/978-1-4614-5693-3_30</u>

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World Health Organization (2000). Obesity: Preventing and Managing the Global Epidemic-WHO technical report 894, Geneva.

STAGE 2: RESEARCH PROPOSAL DEVELOPMENT & ETHICAL APPROVAL

Researchers are required to develop a research proposal which documents the background, methodology, procedures and ethical considerations for formal review by an Institutional Review Board (IRB) or Ethics Committee. Guidelines are usually provided for the preparation of this document. Figure 9 illustrates the key aspects of the research proposal.

FIGURE 9: RESEARCH PROPOSAL - PREPARATION & SUBMISSION



BASIC ELEMENTS OF A RESEARCH PROPOSAL

In this phase you will commit your understanding of the proposed research topic and procedures to paper by documenting a research proposal. While the format may differ depending on the institution to which the proposal is being submitted, the proposal will typically be expected to cover critical elements such as:

- Literature review
 - o Background and state of knowledge on the subject
- Study rationale
 - Contextual relevance of the study potential research/knowledge translation/public health/clinical/ benefits)
- Study objectives/research questions
- Study methodology (research design and procedures)
- Ethical considerations
- Data analysis plan/ outline
 - Create a matrix of your research questions/objectives, including the relevant explanatory and outcome variables and associated statistical analytical procedures
- Study instruments
 - Questionnaires, data abstraction sheets, observation sheets, etc.
 - Requisite correspondence to target audience and to gain entry to the research site/s
- Limitations
 - Address potential limitations of your study, including methodological issues and implications (e.g. non-random sampling and resulting inability to generalize findings)

For further reading, see Resources: research design in this document.

POPULATION AND SAMPLING

The research process is used to test a hypothesis or to draw inferences or conclusions about a phenomenon in a given population. Sampling is a more practical and cost-

effective means of gathering information about a population. Sampling aims to derive statistics from a subset of the population and then using those statistics to draw inferences or conclusions about the population. The entire population can be used in instances where the researcher has access to the population and it is feasible to include all members of the population. This is referred to as a census.

SAMPLING METHODOLOGY

Sampling methodology and sample size are two crucial issues which arise in the development of the study methodology. In the main, there are two types of sampling methods, probability and non-probability sampling.

Probability sampling involves the selection of units from a population such that each selected unit has a known probability of selection. Probability sampling enables the statistics derived from the sample to be representative of the population parameters. Probability sampling is the gold standard for scientific studies and it reduces or eliminates bias in sampling, allowing for an adequate representation of the target population from which the sample was drawn. Examples of probability sampling are:

- Simple random sampling
- Stratified sampling
- Systematic sampling
- Cluster sampling

Conversely, non-probability sampling involves non-random sampling, which produces data and results which are not representative of the population, thus introducing bias into the study design. Non-probability sampling utilizes the following approaches:

- Convenience sampling
- Purposive sampling
- Quota sampling
- Snowball sampling

POWER AND SAMPLE SIZE ESTIMATION

When applying tests of statistical significance to test a hypothesis or examine relationships between variables, a study requires a pre-determination of the power of the study and the minimum required sample size. Power is the probability that a test of statistical significance will detect an effect that is present. In other words, the aim is to make a correct decision (i.e. to reject or not reject the null hypothesis).

This is possible when the study is adequately 'powered' to reject the null hypothesis if in fact it should be rejected; or to detect a deviation from the null hypothesis (i.e. reject the null hypothesis and accept the alternate hypothesis) if such a deviation truly exists. Accepted levels of power for scientific studies typically range between 80% - 90%.

Sample size is an indication of the required number of units needed to support the power of the study. Inadequate sample size reduces the power of the study, thereby reducing the precision of the estimates derived from statistical computations. Hence the need to determine the required sample size prior to conducting your study. Sample size is determined by a combination of factors:

- Population size
- Confidence level (typically 95%)
- Margin of error (typically 5%)
- Prevalence (of the phenomenon being studied)
- Power of the study

Additional factors may include the hypothesized differences between groups (for comparison of groups) and the population variance.

The choice of the sample size formula which is appropriate for your study is informed by the nature of the research questions you are asking and the hypothesis you propose.

Table 2a below illustrates sample size formulae which can be used. These are based on studies aimed at estimating population parameters and achieving a statistically

significant hypothesis test result. Table 2a references sample size formulae from the text Kirkwood & Sterne (2003). In trying to select online sample size calculators, It would be ideal to identify those which match the Kirkwood & Sterne (2003) formulae.

Table 2a: Examples of Research Questions & Recommendations for Use of Sample Size Formulae (for studies aimed at estimating population parameters and achieving a statistically significant hypothesis test result)

	Research question	Study design	Parameter to be estimated	Sample size formula [Kirkwood & Sterne 2003 ¹]
1	What is the prevalence of smoking among male students at The UWI Mona?	Cross sectional	Population proportion	Kirkwood & Sterne # 3 single proportion
2	Is the prevalence of smoking among males different from the prevalence of smoking among females in the UWI student population?	Cross sectional	Difference in proportions	Kirkwood & Sterne # 6 comparison of two proportions
3	What is the mean age of secondary school children in Jamaica?	Cross sectional	Population mean	Kirkwood & Sterne #1 single mean
4	Is the mean age of secondary school children in Jamaica different from the mean age of secondary school children in Belgium? [Two sample (unpaired) t-test]	Cross sectional	Difference in population means	Kirkwood & Sterne # 4 comparison of two means

¹ Kirkwood Betty R. and Sterne Jonathan A.C. Essential Medical Statistics, Blackwell Science, Oxford, 2003 p. 420-421

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	Research question	Study design	Parameter to be estimated	Sample size formula [Kirkwood & Sterne 2003 ²]
5a	Is the mean blood pressure of men any different from the mean blood pressure of women in Syria?	Cross sectional	Difference in population means	Kirkwood & Sterne # 4 comparison of two means
	[Two sample (unpaired) t-test]			
5b	Is the mean blood pressure of study participants any different after an intervention? [Paired t-test]	Intervention study	Population mean difference (before vs. after intervention)	Kirkwood & Sterne #1 single mean
6	Are the odds of exposure to second- hand smoke the same among persons with lung cancer compared with persons without lung cancer?	Case control	Difference in odds of exposure between cases and controls	Kirkwood & Sterne # 7 case control study
7	Are the odds of lung cancer the same among smokers vs. non-smokers?	Cross-sectional	Difference in occurrence of outcomes between exposed and unexposed (e.g. Odds Ratio)	Kirkwood & Sterne # 7 case control study

² Kirkwood Betty R. and Sterne Jonathan A.C. Essential Medical Statistics, Blackwell Science, Oxford, 2003 p. 420-421
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	Research question	Study design	Parameter to be estimated	Sample size formula [Kirkwood & Sterne 2003 ³]
8	Is the risk of developing lung cancer the same among smokers vs. non- smokers over a 10-year period?	Cohort	Difference in occurrence of outcomes between exposed and unexposed (e.g. Risk ratio,	Kirkwood & Sterne # 6 comparison of two proportions
9	Is the incidence rate of developing lung cancer the same among smokers vs. non-smokers over a 10-year period?	Cohort	Difference in occurrence of outcomes between exposed and unexposed (e.g. Incidence rate ratio)	Kirkwood & Sterne #5 comparison of two rates
10	What is the incidence or risk of developing lung cancer over the next 5 years?	Cohort	Incidence rate	Kirkwood & Sterne # 2 single rate

³ Kirkwood Betty R. and Sterne Jonathan A.C. Essential Medical Statistics, Blackwell Science, Oxford, 2003 p. 420-421 FMS Research Studies Toolkit -Design to Publication: A Practical Guide [March 29, 2023 - 1st Edition] Clinical Translational Research Unit, Faculty of Medical Sciences, The UWI Mona

	Research question	Study design	Parameter to be estimated	Sample size formula [Kirkwood & Sterne 2003 ⁴]
11	Is the survival rate at 10 years different between the lung cancer treatment group (i.e. group receiving new therapy) and control group (i.e. group receiving standard of care)?	Randomized Controlled Clinical Trial	Difference in occurrence of outcome between treatment groups (e.g. Hazard ratio)	Kirkwood & Sterne #5 comparison of two rates
12	Is there a difference in the mean blood pressure of treatment group (new therapy) and control group (standard of care)?	Randomized Controlled Clinical Trial	Difference in population means (i.e. treatment vs. control groups)	Kirkwood & Sterne # 4 comparison of two means

⁴ Kirkwood Betty R. and Sterne Jonathan A.C. Essential Medical Statistics, Blackwell Science, Oxford, 2003 p. 420-421 FMS Research Studies Toolkit -Design to Publication: A Practical Guide [March 29, 2023 - 1st Edition] Clinical Translational Research Unit, Faculty of Medical Sciences, The UWI Mona

USING ONLINE SAMPLE SIZE CALCULATORS

Different online sample size calculators may present formulae utilizing a margin of error approach or a hypothesis testing approach. Hence, the formulae may differ from established textbooks on the subject. Therefore, it is ideal to determine the formula which is more suitable for sample size calculations for your study and then select the software programme/online sample size calculation programme which will match that formula. In trying to select online sample size calculators, it is ideal to identify those which match the Kirkwood & Sterne (2003) formulae as indicated in Table 2a above. In preparing your research proposal, dissertation, technical report or publication, specify the sample size formulae used to produce the sample size and provide a reference.

You are encouraged to access the details and assumptions associated with the various formulae for the online sample size calculators, including the help files. You are advised to seek guidance on the selection of your method as is necessary. Examples of online sample size calculators are listed in Table 2b below:

Sample Size Calculator Software: Paid Versions	Sample Size Calculator Software: Free Versions
nQuery	Sample Size Calculators for designing clinical research (University of California San Francisco). Kohn MA, Senyak J. Sample Size Calculators [website]. UCSF CTSI. 20 December 2021. Available at <u>https://www.sample- size.net/</u>
STATA	Power/Sample Size Calculator – University of British Columbia – <u>https://www.stat.ubc.ca/~rollin/stats/ssize/</u>
SPSS	Sample Size Calculator – https://homepage.univie.ac.at/robin.ristl/samplesize.p hp?test=wilcoxon (Robin Ristl – academic researcher in statistical methodology and applied statistics based in Vienna, Austria)

Table 2b: Examples of Online Sample size Calculation Software: Paid and Free Versions

Sample Size Calculator Software: Paid Versions	Sample Size Calculator Software: Free Versions
SAS	Power and Sample Size Determination – Boston University School of Public Health – <u>Table of Contents</u> (<u>bu.edu)</u>
	Epi Info – <u>https://www.cdc.gov/epiinfo/pc.html</u>
	OpenEpi:Sample Size for X-Sectional,Cohort,and Clinical Trials – <u>http://www.wwww.openepi.com/SampleSize/SSMean.</u> <u>htm</u>
	Select Statistical Service – <u>https://select-</u> <u>statistics.co.uk/calculators/</u>
	Raosoft – <u>http://www.raosoft.com/samplesize.html</u> (for single proportions)
	G Power – <u>https://www.statisticssolutions.com/how-to-</u> <u>determine-sample-size-from-gpower/</u> OR <u>University of</u> <u>Düsseldorf: G*Power (hhu.de)</u>
	R – <u>https://cran.r-project.org/</u> OR <u>https://rstudio.com</u> For further details visit - <u>https://med.und.edu/research/daccota/_files/pdfs/be</u> <u>rdc_resource_pdfs/sample_size_r_module.pdf</u>
	Power and Sample Size .com Calculators – <u>Power and</u> <u>Sample Size Calculators HyLown</u>
	MedCalc – Sample size calculation – https://www.medcalc.org/features/statistics.php

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BIAS & RELATED CONCEPTS - VALIDITY, CONFOUNDING & RELIABILITY

Bias is the presence of any factor, which leads to results, which differ from the truth and is due to systematic errors in the sampling or measurement procedures. The main types of bias are selection bias and measurement (i.e. classification) bias. For further reading on this topic, see Bonita et al (2016).

Validity, reliability and confounding are key concepts in relation to controlling bias in research design, with important implications for instrument development and data analysis.

VALIDITY

Validity relates to the accuracy of the measurement or test being administered (i.e. is it measuring what was intended to be measured? Is it representing the truth?). Measurement validity, internal and external validity are important considerations.

Measurement validity (accurately and appropriately measuring what should be measured):

Content validity: does the test represent what it aims to measure?

Construct validity: does the test measure the relevant concept/s?

Face validity: does the test appear to be suitable for the aims of the study?

Criterion validity: does the test accurately measure the outcome which it is designed to measure?

Internal validity is "the degree to which the results of an observation are correct for the particular group of people being studied" (Bonita et al 2016 p 58). Internal validity asks the question whether or not a causal link/ or association can be reasonably drawn or concluded from the study or experiment conducted.

External validity (also referred to as generalizability) is "the is the extent to which the results of a study apply to people not in it" (Bonita et al 2016 p. 58). External validity asks the question whether or not the findings on conclusions can be generalized to other groups or settings (i.e. applicability of finding to a broader setting or context).
CONFOUNDING

Confounding is a source of bias (and a threat to internal validity) which can occur "when another exposure exists in the study population and is associated both with the disease and the exposure being studied" (Bonita et al 2016 p. 55). Confounding has important implications for the findings and conclusions drawn about hypothesized relationships in a study and can yield misleading results or conclusions, including changing the direction of an association or relationship.

It is Important for the researcher to control for confounders at both the design (e.g., through randomization or matching) and analysis (e.g., through stratification and statistical modelling) phases of the study.

RELIABILITY

Reliability relates to how well the test results or measurement are repeated or reproduced when administration of the test is repeated. This speaks to the internal consistency of the test. Therefore, if the test is repeated (over time) will the same results be obtained?

It is important to determine the reliability of your instrument by pretesting the instrument (to estimate test-re-test reliability). Measures such as percent agreement, kappa statistic for inter-rater reliability and Cronbach's alpha (used to measure the amount of shared variance among items in an instrument) are useful tools for this assessment.

INSTRUMENT DESIGN & DEVELOPMENT

The researcher bears the responsibility of selecting or developing an appropriate instrument for the research question/s and research design. Pretesting the instrument allows the researcher to determine if the questions are understood by the target audience and if there is a logical flow to the instrument. Other factors such as clarity, question structure and flow are important considerations in the instrument design phase.

Considering important issues related to validity, reliability and confounding helps the researcher to determine or assess the utility of the instrument and the 'fitness for purpose'.

INSTRUMENT VALIDITY & RELIABILITY

Some key issues to determine are:

- Pre-existing Instruments/scales
 - Are there pre-existing scales or measurements for the phenomenon of study?
 - Are there studies on its use in previous research and information on limitations?
 - Can the pre-existing instrument/scales be used as is?
 - Do they fit the cultural context of the proposed study?
 - Will they need to be adjusted?
 - If permissible, what is the process to secure approval to adapt the instrument?
 - Contacting authors/developers

- Validity
 - o Is there data on instrument validity?
 - Will the researcher need to independently determine validity?
 - Is there data on the psychometric properties of the instrument?
 - o Is there a theoretical framework embedded in the instrument?
 - o Is this framework appropriate for my study?
- Reliability
 - o Pre-testing instrument
 - Test/re-test measurements (to determine reliability)
- Confounding
 - Have all relevant questions/measures/variables (including known and hypothesized risk factors, outcomes and potential confounders) been included in the instrument?
 - Deciding on how to control for confounders at the analysis stage

For further reading, see Resources: instrument design in this document.

DATA ANALYSIS PLAN

The data analysis plan outlines the research questions, research hypothesis, study design inclusion/exclusion criteria, variables and proposed statistical measures for analysis (Table 3).

In developing the plan, the researcher should delineate the independent (i.e. explanatory variables or risk factors) and dependent variables (i.e. outcome variables), as well as confounder variables and the corresponding type/s of measurements (i.e. Discrete vs. Continuous variables)

Discrete (e.g. nominal; ordinal)

Continuous variables (e.g. interval, ratio)

These distinctions are important to guide the selection of appropriate statistical tools for your descriptive and analytical statistics and to test your hypothesis/es. Notably, attention needs to be paid to the standard definition of each response option to ensure consistency with established classifications and scientific nomenclature (e.g. marital status, body mass index categories).

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Table 3: Elements of the Data Analysis Plan

Research questions	Hypo- thesis	Study design	Inclusion / Exclusion criteria	Variables		Data set (data source)	Statistical methods – descriptive vs. inferential	Statistical software
				Explanatory/ Exposure ¹	Outcome			

¹ Confounding variables should be included

DATA ANALYSIS MATRIX

The data analysis matrix is a useful tool for planning the data analysis phase of your research. The matrix lists the relevant variables for your research questions and indicates the appropriate statistical tests.

For further reading on types of statistical tests, see:

Petrie, A. & Sabin, C. (2020). Medical Statistics at a Glance (^{4t}h ed) [Flow charts indicating appropriate techniques in different circumstances].

Simpson, S.H. (2015). Creating a Data Analysis Plan: What to Consider When Choosing Statistics for a Study. The Canadian Journal of Hospital Pharmacy; 68(4):311-317. DOI: 10.4212/cjhp.v68i4.1471. PMID: 26327705; PMCID: PMC4552232. [Decision tree to identify inferential statistics for measuring a difference].

The Data Analysis Matrix template (Table 4) can be used to identify variables, determine their role and select the appropriate statistical test. You may refer to this table to guide you in selecting the appropriate statistical methods for your data analysis. Tables 5a and 5b are useful additions to aid in applying statistical tests guided by the nature of your research question.

Table 4: Sample Data Analysis Matrix

Variable name	Variable type	Variable role	Summary Statistics Method	Inferential Analysis Method: (Bivariate)	Inferential Analysis Method: (Multivariable) ⁵
	Categorical: Ordinal Nominal	Explanatory/ Confounder/ Outcome	Percentage		
	Quantitative: Continuous/ Ratio/Interval		Mean & SD/ Median		
Blood Pressure (BP)	Quantitative	Outcome (BP)	Mean & SD/ Median	1-sample t-test	
BP	Quantitative	Outcome (BP)		2 sample t-test	-
Sex	Nominal	Explanatory	Percentage	1-way ANOVA	

⁵ Inferential Analysis: Multivariate Analysis Methods (for. e.g. Principal component analysis; factor analysis) examine multiple outcome variables to see the nature of their variation together

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Variable name	Variable type	Variable role	Summary Statistics Method	Inferential Analysis Method: (Bivariate)	Inferential Analysis Method: (Multivariable) ⁵
BP	Ordinal	Outcome (BP)	Percentage	Pearson's Chi-	
Sex	Nominal	Explanatory	Percentage	2-sample Z-test for proportions	
				Ordinal Logistic regression	
BP	Ordinal	Outcome	Mean & SD/ Median	Correlation (Spearman rho)	
Age	Continuous	Explanatory	Mean & SD/ Median	Ordinal Logistic regression	
BP	Quantitative	Outcome	Mean & SD/ Median	Correlation (Pearson's r)	
Age	Continuous	Explanatory	Mean & SD/ Median	Simple linear regression	

⁶ Pearson's chi-squared test assesses differences between categories of the explanatory variable with respect to the distribution of outcome

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Variable name	Variable type	Variable role	Summary Statistics Method	Inferential Analysis Method: (Bivariate)	Inferential Analysis Method: (Multivariable) ⁵
BP	Categorical (binary)	Outcome	Mean & SD/ Median	Pearson chi squared test	Multiple logistic regression ⁸
Sex	Nominal	Explanatory	Percentage	Chi squared test	
Age	Ordinal	Explanatory	Percentage	for trend (using age as explanatory) ⁷	
				Simple Logistic regression	
BP	Quantitative	Outcome (BP)	Mean & SD/ Median	Pearson's correlation co-	Multiple linear regression ¹⁰
Age	Quantitative	Explanatory	Mean & SD/ Median	efficient	

⁷ Chi-squared test for trend assesses whether or not the proportion with the outcome (as measured by prevalence or risk for example) increases or decreases linearly over ordered categories of the explanatory variable

⁸ Multiple logistic regression assesses associations between more than one explanatory variable and one categorical outcome variable ¹⁰ Multiple linear regression assesses associations between more than one quantitative explanatory variable and one quantitative outcome variable

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Variable name	Variable type	Variable role	Summary Statistics Method	Inferential Analysis Method: (Bivariate)	Inferential Analysis Method: (Multivariable) ⁵
ВМІ	Quantitative	Explanatory	Mean & SD/ Median	Simple linear regression ⁹	
BP	Quantitative	Outcome	Mean & SD/ Median	1-way ANOVA	Multi-way ANOVA11
Age cat	Ordinal	Explanatory	Percentage		
Sex	Nominal	Explanatory	Percentage		
BMI cat	Ordinal	Explanatory	Percentage		

⁹ Simple linear regression assesses associations between one quantitative explanatory variable and one quantitative outcome variable ¹¹ Multi-way ANOVA assesses associations between more than one qualitative explanatory variable and one quantitative outcome

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Table 5a: Types of Statistical Tests and their Application

What are we investigating?	Dependent, Response or Outcome Variable Types				
	Continuous variables assuming normal distributions (parametric)	Ordinal variables or continuous variables not assuming normal distribution (non- parametric)	Nominal or Ordinal (Categorical/Qualitative) variables		
Difference between two independent samples	Two-sample t-test	Mann-Whitney U or Rank Sum test	Pearson's Chi-squared test		
Difference between paired data	Paired t-test	Sign test OR Wilcoxon signed rank test	McNemar Chi-squared test		
Differences between two or more samples	Analysis of variance (ANOVA)	Kruskal-Wallis test	Pearson's Chi-square test		
Trend in outcome over ordinal categories	Spearman rank correlation coefficient	Non-parametric test for trend	Chi-squared test for trend		
Linear association between two variables	Pearson correlation coefficient	Spearman rank correlation	Logistic regression		

Source: The Statistics Teaching Team of The Caribbean Institute for Health Research (formerly The Tropical Medicine Research Institute), University of the West Indies

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Table 5b: Types of Statistical Tests and their Application

	Dependent, Response or Outcome Variable Types		
What are we investigating?	Nominal or Ordinal (Categorical/Qualitative) variables	Nominal or Ordinal (Categorical/Qualitative) variables	
	(Large Samples)	(Small samples)	
	Where n x p > 5	Where n x p $\leq 5^{12}$	
Difference between two independent samples	Pearson's Chi-squared test	Fisher's exact test	
Difference between paired data	McNemar Chi-squared test	Exact binomial test	
Differences between two or more samples	Pearson's Chi-squared test	Fisher's exact test	
Trend in outcome over ordinal categories	Chi-squared test for trend		

Source: The Statistics Teaching Team of The Caribbean Institute for Health Research (formerly The Tropical Medicine Research Institute), The University of the West Indies

¹² n = sample size; p = proportion with outcome of interest

UNIVARIATE, MULTIVARIABLE & MULTIVARIATE ANALYSES

Analyses are typically conducted on two levels:

Descriptive or Univariate: a basic overview of the distribution of data (or frequencies) for a single variable using summary measures such as the mean, median, mode and percentages/proportions.

Analytical/Inferential:

- i. Bi-variate: used to examine/test hypotheses about relationships between two variables, usually one independent (or risk factor) and one dependent (or outcome) variable. Different techniques are applied for quantitative (numerical) vs. qualitative (categorical) data.
- ii. Multi-variable: used to examine/test hypotheses about relationships between a multiple (two or more) independent variables and one outcome variable. This allows for an examination of variables which are independently associated with an outcome, or which can independently predict an outcome, in the presence of other variables or risk factors.
- iii. Multivariate analysis is the analysis of data that examines the variation in multiple (outcome) variables simultaneously.

Petrie & Sabin (2020) and Simpson SH (2015) offer readers a quick guide to selecting statistical tools for inferential statistics (bi-variate and multi-variable analyses). You are advised to do further reading on the criteria and assumptions for the application of some of these tests.

ETHICAL REVIEW

The research proposal should be submitted to an Institutional Review Board (IRB) or an Institutional Ethics Committee for a review of methodological and ethical procedures. The review may elicit further questions, clarifications or advice to ensure the ethical and methodological 'soundness' of the proposal.

The aim of this phase is to subject the proposal to a critical review of the scientific merit and ethical requirements, so as to obtain written approval which allows the researcher to proceed with the implementation of the research work.



FAQS: RESEARCH PROPOSAL DEVELOPMENT (STAGE 2)

How do I approach the identification and selection of articles for my literature review?

The search and selection of articles or papers will be informed by your study objective and the key operating terms and measures of interest. Identify key words or key search terms as a guide in searching electronic databases (or hard copy prints/journals) of peer-reviewed literature. You may seek to include research with higher levels of evidence such as scoping reviews, systematic reviews and metaanalyses and studies with higher-order designs (i.e. randomized clinical trials and cohort studies). You may also find valuable information in cross-sectional, casecontrol and case studies. A search of article bibliographies/references, conference proceedings and grey literature (e.g. technical and government reports) may also serve as important resources.

?)How do I assess the quality of an article?

Studies are assessed on their scientific merit, particularly the study design, study population and sampling methodology and ethical considerations, among other issues. The text Basic Epidemiology [Bonita R, Beaglehole R, Kjellström T (2006) pages 178 – 181] offers useful guidance on a step-wise approach to assessing the quality of an article.

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How important is the impact factor of a journal publication1 in selecting articles for the literature review?

The objective of your literature review is to present the established and emerging (current) state of knowledge in a particular field of study. While the impact factor of a journal publication is often used as an indicator of the importance of a journal to its field, it should be noted that useful articles may be located in journals of varying impact factors, as well as other published or unpublished sources.

?) What is a Scoping review?

A Scoping review collates and describes available evidence in a particular field of study and presents a clearly illustrated summary or synthesis of the evidence. Established protocols for scoping reviews enable the improved understanding and utility of published work to support evidence-based decision making among researchers, clinicians, and policymakers.

? How do I decide on a study design?

The study design (observational or experimental) is informed by your research question/s and study objectives. For further information see references – Bonita R, Beaglehole R, Kjellström T (2006). Basic Epidemiology [Chapter 3] and Petrie A and Sabin C. Medical Statistics at a Glance (2020).

How do I determine the required sample size for my study?

Sample size is determined by a combination of factors, including size of the population; confidence level for parameter estimation (typically 95%); margin of error (typically 5%); parameter to be estimated for the study (such as prevalence or hypothesized differences of the phenomenon being studied) and the power of the study. There are various formulae which can be used. Notably, the research question and study design for the study will inform the selection of an appropriate sample size formula. It is important to select the appropriate formula for the purpose of your study.

For further information see Table 2 – Examples of Research Questions & Recommendations for Use of Sample Size Formulae. Additionally, see reference – Lwanga & Lemeshow (1991). Sample Size Determination in Health Studies: A Practical Manual

What are some online resources for sample size calculators?

There are several online sample size calculators available for various purposes. The choice of calculators will be influenced by the nature of the research question or hypothesis as well as they type of variables you intend to use. Be mindful that different sample size calculation formulae underpin the online sample size calculators. See Table 2b for further guidance.

?) What are the appropriate types of statistical tools for data analysis?

This is dependent on the hypothesis to be tested and the specific type of variables involved in the analysis. See Flow charts indicating appropriate techniques in different circumstances [Source: Petrie A & Sabin, C. (2020). Medical Statistics at a Glance (^{4th} ed) and Simpson SH. (2015). Creating a data analysis plan: what to consider when choosing statistics for a study. The Canadian Journal of Hospital Pharmacy. 2015 Jul-Aug;68(4):311-317. DOI: 10.4212/cjhp.v68i4.1471. PMID: 26327705; PMCID: PMC4552232.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4552232/pdf/cjhp-68-311.pdf

?) What does an Ethical review entail?

An ethics review assesses the research proposal on the intrinsic value and 'public good' of the study, as well as its scientific merit and validity. The ethical review process considers the overall risk: benefit ratio of the proposed research and is guided by an assessment or review of four key principles of ethics, namely:

- Beneficence-- benefits of the study to participants and the value to the general public good (i.e. social, economic, technological and clinical value, etc.)
- Nonmaleficence avoidance of harm, unnecessary burden, or unintended negative consequences

- Autonomy right of the participant to make an informed decision about participating in the study
- Justice application of processes which ensure the fair, equitable, and appropriate treatment of study subjects

RESOURCES: RESEARCH PROPOSAL

RESEARCH DESIGN

Bonita, R., Beaglehole, R. and Kjellström, T., (2006). Basic epidemiology (²ⁿd ed). World Health Organization. <u>https://apps.who.int/iris/handle/10665/43541</u>

Gordis, L. (2018). Epidemiology (^{6t}h Ed). Saunders Elsevier [Authors: David D Celentano and Moyses Szklo].

Bland, M. (2000). An introduction to medical statistics (3rd ed.). Oxford University Press.

Petrie, A, & Sabin, C. (2020). Medical statistics at a glance (4th ed.). Wiley-Blackwell.

Abramson, J.H. & Abramson, Z.H. (1999). Survey methods in community medicine (^{5t}h ed.). Churchill Livingstone.

Simpson, S,H. (2015). Creating a data analysis plan: what to consider when choosing statistics for a study. The Canadian Journal of Hospital Pharmacy; 68(4):311-317. DOI: 10.4212/cjhp.v68i4.1471. PMID: 26327705; PMCID: PMC4552232. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4552232/pdf/cjhp-68-311.pdf

Bhuyan, D., Dua, N., and Kothari, T. (2015). Epidemiology and biostatistics: Fundamentals of research methodology. Open Journal of Psychiatry & Allied Sciences. 7. 10.5958/2394-2061.2015.00022.1.

https://www.researchgate.net/publication/283992619 Epidemiology and biostatis tics Fundamentals of research methodology

Mann, C.J. (2003). Observational research methods. Research design II: cohort, cross sectional, and case-control studies. Emerg Med J.; 20(1):54-60. doi: 10.1136/emj.20.1.54. PMID: 12533370; PMCID: PMC1726024. https://pubmed.ncbi.nlm.nih.gov/12533370/

Guidelines for Preparing Research Proposals: A Handbook by the UWI Ethics Committee The University of The West Indies, Mona Campus. The University of The West Indies, Mona

https://www.mona.uwi.edu/mcrec/sites/default/files/mcrec/guidelines_for_prepar ing_research_proposals_toolkit_june_2020_final_1-1.pdf

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STAGE 3: FIELDWORK PREPARATION, & PROJECT MANAGEMENT

Significant planning and preparation is required for the fieldwork and data collection phase. This includes the identification of the field team, training in field methods, administrative procedures and engagement with the target population. Project planning and monitoring are important for the duration of the project to assess and respond to challenges, new developments and opportunities, including the planned and unexpected occurrences (Figure 10).

FIGURE 10: FIELDWORK PLANNING AND PROJECT MANAGEMENT



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FIELD WORK/DATA COLLECTION PREPARATION AND PROJECT MANAGEMENT

As you prepare to enter the fieldwork phase where you will collect data, there are some key preparatory steps. These include the composition of a project team and the provision of training on the instruments and procedures. The aim is to ensure consistency of data collection procedures and protocols across the team with the objective of reducing/eliminating potential sources of bias in the methodological areas of the study. Additionally, this phase requires that the target population be sensitized to the study. Hence the requisite communication and written correspondence should be in place to engage the target community and data collection sites. Project timelines and data collection schedules should be agreed and established and monitored over the life of the project.

In preparation for data collection, finalize all survey instruments and relevant documents, whether in print or electronic mode (review and test). Calibrate all measurement instruments and scales to be used in the field.

This phase ensures the necessary preparation to enter the field for project sensitization and data collection, as well as the required management and oversight over the course of the project.

LABORATORY-BASED RESEARCH

In laboratory-based research these principles are incorporated into the rigour and reproducibility of research. In the realm of basic science the term rigour denotes the strict application of the scientific method to obtain robust results whilst reproducibility denotes the ability to arrive at similar conclusions by one or all of the following techniques e.g. re-analysis of data, reproduction of experimental conditions, reproduction of findings using different experimental conditions and reproduction of findings using different paradigms. Adherence to these principles will allow the re-production and publication of the results of the research.



FAQS: FIELDWORK PLANNING AND PROJECT MANAGEMENT (STAGE 3)

? How are study sites chosen?

A study site may be a physical (geographical boundary) or non-physical space (electronic listing) in which the target population can be located. A study site is selected based on the appropriateness for the defined target population of interest, taking into account the relevant inclusion and exclusion criteria for the study.

What are some important considerations in project planning and management?

The researcher has the responsibility to recruit members of the field team who will execute the study. The selection of a field team is informed by the requisite skills set necessary for the study. Sensitization and training sessions (in various disciplines/expertise) are recommended for members of the field team. A project implementation plan is relevant to identify and manage resources, plan and track the project life cycle to facilitate strategic planning. The plan should indicate the definition and assignment of roles to the team members. A monitoring and management plan to track scheduling, team progress and milestones and monitor constraints and challenges can be supported by tools such as a Gantt chart.

RESOURCES: FIELDWORK PREPARATION & PROJECT MANAGEMENT

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Edith Cowan University. For Research Students--- Research Journey: Project management--- <u>https://intranet.ecu.edu.au/research/for-research-</u>students/research-journey/designing-and-undertaking-your-research/project-management

Abramson, J.H. & Abramson, Z.H. (1999). Survey methods in community medicine (^{5t}h ed.) Churchill Livingstone.

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STAGE 4: DATA MANAGEMENT

Data management covers the creation and maintenance of data throughout the life cycle. Key components of this process include data processing, preservation and access. Figure 11 illustrates steps in the data management process.

FIGURE 11: STEPS IN DATA MANAGEMENT PROCESS



RESEARCH DATA LIFE CYCLE

Data transits through a life cycle, commencing with the creation of data, which requires processing, analysis and preservation, culminating in access (Figure 12). A Data Management Plan provides a framework for the documentation, protection and maintenance of the data life cycle. This ensures the process is logical, organized, and transparent and is beneficial to the research paradigm. A new policy for Data Management and Sharing has been implemented by the National Institutes of Health (NIH) which took effect on January 25, 2023.

Figure 12: Research Data Life Cycle



Source: Surkis A, Read K. (2015) Research Data Management. https://pubmed.ncbi.nlm.nih.gov/26213510/

PRE-CODING & POST-CODING

The process of coding involves assigning a numerical code to each possible response option for each discrete variable.

Data for continuous variables should be collected in that format (e.g. as a continuous or ratio variable (i.e. quantitative variables which measure a phenomenon or concept on a scale with a meaningful zero point – e.g. age, weight, height, systolic and diastolic blood pressure). This ratio variable can be transformed into an ordered categorical variable by grouping or categorizing a range within the scale. – e.g. age groups, blood pressure categories, body mass index categories).

It may be useful to pre-code the data collection instrument (as far as is possible) prior to data collection. Where this is not possible (e.g. open-ended questions) it is recommended that post-coding be done and a data dictionary (Table 6) prepared with the codes for each questions/variable. The process of pre and post-coding facilitates ease of data entry. Notably, with the use of some electronic data management technologies, this process is automatic.

Table 6: Basic Data Dictionary

Variable name/Question #	Response Option	Response Option Code (numerical coding examples)
Sex	Male	1
	Female	2
Area of residence	Urban	1
	Rural	2
Marital status	Single	1
	Visiting	2
	Common-law	3
	Married	4
	Divorced	5
	Separated	6
	Widowed	7
Variable name/Question #	Response Option	Response Option Code (numerical coding examples)
Age (continuous)	Numerical value (entered as absolute numerical values)	8, 9, 12, 25, 36, 42, 56, 61, 72, 84, 97
Age group (ordered categorical)	8 13	1
	14 19	2
	20 25	3
	26 31	4
	32 37	5

'Don't know and 'No response' can be coded as 8, 88, or 888 and 9, 99, or 999 respectively if none of these numbers fall within the legitimate coding range for the variable.

DATA ENTRY

The data entry template (Table 7) consists of subjects or cases and variables. Each data collection record is considered to be a case or subject. Variables are items of data collected on the instrument – e.g. study site number, region, demographics (age, sex, residence) and specific questions. Each variable should be named and each questionnaire/data collection instrument assigned a unique identification (ID) number. Data can be entered in programmes such as Microsoft Excel and exported into data analysis software programmes (e.g. SPSS, STATA, Epi Info).

		Variables				
	ID #	Variable 1	Variable 2	Variable 3	Variable 4	Variable 5
		[Name]	[Name]	[Name]	[Name]	[Name]
Cases/Subjects	101					
	102					
	103					
	104					
	105					

Table 7: Basic Data Entry Template

DATA ENTRY AND VALIDATION

Once all the data have been entered into the spreadsheet, the next step is to check and verify for accuracy. This is done by running the frequency distributions of all the variables. This enables the detection of outliers and the subsequent review to identify the causes (i.e. incorrect coding or data entry) and make the necessary corrections.

This phase should culminate in a final and verified database in preparation for the ensuing data analysis phase.



FAQS: DATA MANAGEMENT (STAGE 4)

Which data entry software should I use?

Data entry spreadsheets can be created in Microsoft Excel and exported to the analysis software packages. Alternatively, data can also be entered directly into data analysis software packages (e.g. Statistical Package for Social Sciences (SPS), STATA, Epi Info, PSPP (a free alternative for IBM SPSS Statistics) and REDCap. The choice of statistical packages will depend on your knowledge of the software and level of training and experience. Online training tools and guides (e.g. video tutorials) can be of assistance in gaining more knowledge and practice.

What are the benefits of pre-coding a data collection instrument?

Pre-coding provides the respondent and interviewer with pre-determined response options on the data collection instrument. Pre-coding is useful in situations where the interviewer/observer is abstracting data from a secondary source, or collecting primary data through interview or observation, or where instruments are being selfadministered. There are many benefits to pre-coding. It simplifies the data collection process, saves time in questionnaire administration or data collection and generally makes for a more efficient data collection process. Adding a category titled 'Other' below the pre-coded response options offers the option of recording data which do not fit into any of the pre-coded options. This can then be postcoded once the data has been collected.

RESOURCES: DATA MANAGEMENT

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STAGE 5: DATA ANALYSIS

In the data analysis phase epidemiological and biostatistical tools and measures are employed to generate findings from the data. Data analysis can be conducted at two levels:

- Descriptive statistics providing summary data
- Inferential statistics providing measures of association from hypothesis testing

Figure 13 denotes key steps in the data analysis process.

FIGURE 13: STEPS IN DATA ANALYSIS

Review Data Analysis Plan & Matrix Descriptive statistics - Summary data/profile of study participants - Univariate analyses: e.g. mean, median, mode, percentages Analytical/Inferential statistics - Test hypothesis/es - Bi-variate analyses: e.g. correlations, chi-squared test, t-test, ANOVA, Odds Ratio, Rate Ratio - Multivariable analyses: e.g. Relative Risk, Odds Ratio (using multiple linear and logistic regression models) Generate tables, charts, etc.

In preparation for data analysis a review of the Data Analysis Plan is relevant and may result in appropriate edits or changes prior to analyzing the data.

DATA DISTRIBUTION

As a first step, the distribution of the data and specific variables should be examined with the use of a frequency distribution such as a histogram to indicate the shape of the distribution (e.g. normal vs non-normal or skewed distribution). This is important information which will determine the type of statistical analyses which are appropriate for the data.

DESCRIPTIVE STATISTICS

Descriptive statistics provide summary data and a general profile of key data elements or concept under investigation. They feature univariate analyses: e.g. mean, median, mode, percentages). A profile for study participants would likely include variables such as mean or median age; sex distribution; are of residence (i.e. urban vs. rural or parish or region); union status, occupational status, educational status.

A clinical profile would also be described by reporting on risk factor/independent variables, as well as dependent/outcome variables (e.g. related to clinical profile, including health or disease status). See Tables 8a and 8b.

INFERENTIAL STATISTICS

Analytical or Inferential statistics are used to identify relationships between variables and to test hypotheses. This enables conclusions to be drawn about a population using statistics from a sample of the population. Analyses can be conducted at the bi-variate (relationships/associations between one independent variable and one outcome variable) and multi-variate levels (relationships/associations between two or more independent variables and one outcome variable). See Tables 9a, 9b and 10.

This process is guided by the research questions/objectives and the process can be further supported by the Data Analysis Plan which identifies the independent and dependent variables.

For further reading see:

- i. Flow charts indicating appropriate techniques in different circumstances [Source: Petrie A & Sabin, C. (2020). Medical Statistics at a Glance (^{4th} ed)].
- Simpson, S.H. (2015). Creating a Data Analysis Plan: What to Consider When Choosing Statistics for a Study. The Canadian Journal of Hospital Pharmacy; 68(4):311-317. DOI: 10.4212/cjhp.v68i4.1471. PMID: 26327705; PMCID: PMC4552232. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4552232/pdf/cjhp-68-</u> 311.pdf

TABLES AND CHARTS

Data can be presented in tabular and graphical formats. Both formats aim to display data in a simple manner, which enables the data to be quickly and easily understood. They should be appropriately titled and contain sufficient information, such that they can 'stand alone' and be readily interpreted without referring to the text.

Sample (dummy) table formats can be set up before-hand for the inputting of data once the analysis has been done. Data includes the frequencies as well as the reported measurement index (i.e. mean, proportion, etc.) for all the relevant variables.

Table 8a: Sample Table-- Profile of the Sample

Independent (Explanatory) Variable or Outcome Variable		
	Frequency (N)	Measure (Mean & Standard Deviation/ Median/ Percentage; etc.)
Explanatory Variable 1		
Explanatory Variable 2		
Explanatory Variable 3		
Outcome Variable 1		
Outcome Variable 2		

The profile of the sample can be represented in a tabular format, presenting a number of variables in a single table. This should include demographic variables as well as the risk factors (independent/explanatory/exposure variables) and outcome variables of interest.

Variable	Response	Frequency (N)	Summary statistics
Mean Age (males)		300	34.65 +/- 4.5
			Mean (SD)
Mean Age		300	32.23 +/- 2.1
(females)			Mean (SD)
Sex	Male	300	50.0%
	Female	300	50.0%
Age group:	18 – 24 yrs	150	25.0%
	25 – 30 yrs	200	33.3%
	31 – 36 yrs	250	41.6%
Area of residence	Urban resident	330	55%
	Rural resident	270	45%
Health Region:	South East	200	33.3%
	North East	100	16.6%
	South	150	25.0%
	West	150	25.0%
Disease 1 (present)		210	35%
Disease 2 (present)		90	15%

Table 8b: Sample Descriptive Summary for Variables --- Uni-variate Analysis

Analytical/Inferential Tables

Tables with analytical or inferential statistics are tables which contain data used in the analysis of relationships between variables and/or testing of hypotheses and their corresponding tests of statistical significance (i.e. bi-variate or multivariable analyses). Bivariate analyses may include data outputs for measures of association (e.g. chi-squared, t-test or odds ratios - with corresponding Confidence intervals and/or p-values) to determine statistical significance of hypothesized relationships or associations.
Tables with results of analytical/inferential analyses present estimates that quantify the relationships between variables as obtained from the testing of hypotheses and their corresponding p-values, indicating the presence or absence of statistical significance.

Inferential data analyses use bi-variate, multivariable and multivariate analyses methods. Bivariate analyses quantify the association between one explanatory and one outcome variable and include methods such as the Pearson's chisquared tests, the two-sample t-test, confidence intervals for the difference between means and cross-tabulation analyses

Importantly, for bi-variate or multivariable analyses, the measure of association to be used is informed by the type of independent and outcome variables in the analysis – i.e. categorical/qualitative (i.e. ordinal or nominal) vs. continuous. For example Relative Risk, Odds Ratio and Adjusted Odds Ratio (aOR) can be used to report on associations between an ordinal outcome and nominal explanatory variables, whereas Beta coefficients are used to report on associations between a quantitative outcome and continuous explanatory variables (See Tables 9, 10a and 10b).

Examples of bi-variate statistical analysis methods include:

- Simple logistic regression analysis:
 - o Odds ratio estimation
- One-way ANOVA
- Pearson's correlation co-efficient
- Spearman's' Rank correlation

Multivariable statistical analysis methods assess the association between multiple explanatory variables and one outcome variable (See Table 10). Examples include:

- Multiple Logistic Regression analysis: Relative Risk & Confidence Intervals; aOR adjusted odds ratio
- Multiple Linear Regression analysis: Beta co-efficient & Confidence Intervals

Multivariate analysis methods (for example Principal component analysis; factor analysis) simultaneously examine the variation in multiple outcome variables and

are usually aimed at reducing the dimensionality of the data while determining the nature of the variation within the set of such variables. Multivariate analyses may include outputs for linear or multiple regression analyses – e.g. odds ratios, relative risk, etc.

Analytical/Inferential Tables for Bi-variate & Multi-Variable Analysis

Table 9 is a sample table for reporting chi-squared measures of association for bivariate analyses. Table 10a can be used as a guide for selecting and reporting the appropriate statistical methods and measures of association for bi-variate and multi-variable analyses for use with either categorical or continuous explanatory or outcome variables. Table 10b is a sample table reporting multi-variable regression analyses using age and blood pressure as categorical vs. continuous outcome variables.

Table 9: Sample Table – Distribution of Prevalence of Outcome over Categories for Explanatory Variables [Used to Report Chi-Squared Cross-Tabulation (2 x 2 Table)]

Independent (Explanatory) Variable	Outcome measure (Percentage) Disease present (%)	N (frequency of counts)	P- value (measure of statistical significance ¹
	Blood pressure categories		
E Variable 1 [Age category]			
E Variable 2 [Sex]			
E Variable 3 [Urban/rural residence]			
E Variable 4 [Income category]			

¹ *p<.05

** p<.01

*** p <.001

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Clinical Translational Research Unit, Faculty of Medical Sciences, March 29, 2023 [1st Edition]

Table 10a: Guide to Selecting Statistical Methods and Measures of Association for Bi-Variate and Multi-Variable Analyses using Categorical or Continuous Explanatory and Outcome Variables

Outcome/ Dependent Variable (Variable Type) Quantitative	Explanatory/ Independent Variable (Variable Type) Categorical	Statistical Method Used to Assess Association One-way ANOVA	Measure of Association Difference between means (Regression
Quantitative	Quantitative	Pearson's Correlation (if data are normal distributed); Spearmen rank correlation (if data are not normally distributed)	Correlation coefficient
Categorical	Categorical	Pearson's chi- squared test	Difference between proportions
Categorical (binary)	Categorical	Binary logistic regression	Odds ratio; Adjusted Odds ratio (aOR)
Categorical (binary)	Quantitative	Binary logistic regression	Odds ratio
Quantitative	Quantitative	Linear regression	Slope of regression line (regression coefficient) ¹³

¹³ Slope is the change in outcome expected for a one-unit change in the explanatory variable

Outcome/ Dependent Variable (Variable Type)	Explanatory/ Independent Variable (Variable Type)	Statistical Method Used to Assess Association	Measure of Association
Quantitative	Categorical	Multi-way ANOVA	Adjusted difference between means (Regression co- efficient)
Categorical	Categorical	Multiple (binary)	Adjusted Odds ratio
(binary)		logistic regression	(aOR)
Quantitative	Quantitative	Multiple linear regression	Adjusted slope of regression line (regression coefficient)
Time to event	Categorical or	Cox regression	Hazard ratio
(quantitative)	Quantitative	model	
Count	Categorical or	Poisson regression	Rate Ratio (Relative
(quantitative)	Quantitative	model	risk)

Report confidence intervals with measures of association (NB: not usually reported for correlation coefficients)

Report p- values

```
<sup>1</sup> *p<.05
** p<.01
*** p <.001
```

Table 10b: Sample Table Reporting Measures of Association Resulting from Multi-Variable Regression Analyses using Age and Blood Pressure as Categorical vs. Continuous Outcome Variables

Independent (Explanatory) Variable	Logistic Regression Measure of Association & 95% Confidence Intervals & P-value	Linear Regression Measure of Association & 95% Confidence Intervals & P-value
E Variable 1 (Age – categorical variable)	Blood pressure (outcome – categorical)	
18–- 24 yrs (reference)	Report:	
25 – 29 yrs	OR, (aOR), RR ¹ [Confidence	
30 – 34 yrs	Intervals] & P values ²	
35 – 39 yrs		
E Variable 2 (Age continuous variable)		Blood pressure (outcome – continuous)
<u>≥</u> 18 - <u><</u> 39 yrs		Report:
		Beta co-efficients ¹ [Confidence Intervals] & P values ²

¹ OR (Odds Ratio) for logistic regression; aOR (adjusted Odds Ratio) for logistic regression; RR (Relative Risk);

Beta Coefficient for linear regression

² *p<.05 ** p<.01 *** p <.001

N.B.: When reporting on measures of association for multivariable analyses, you should indicate that the estimates have been adjusted for other variables. You should also specify which other variables were adjusted for (i.e. included in the analyses).

CHARTS AND GRAPHS

Charts and graphs are intended for the presentation of summary data in a simple, and clear manner, utilizing visual imaging, whereas tables provide more detailed data and information and should be able to 'stand alone' in the absence of text/narrative.

Examples of charts are bar, column and pie charts. Graphs typically represent mathematical relationships and can include histograms, line graphs, scatter plots, etc. For more guidance on the relative advantages of both approaches, see reference-- Epidemiology [Bonita R, Beaglehole R, Kjellström T (2006) - Chapter 4 Basic biostatistics: concepts and tools].



FAQS: Data Analysis (Stage 5)

? Which data analysis software should I use?

Commonly used data analysis software includes Statistical Package for Social Sciences (SPS), STATA, Epi Info, PSPP, Red Cap. The choice of statistical packages will depend on your knowledge of the software and level of training and experience. Online training tools and guides (e.g. video tutorials) can be of assistance in gaining more knowledge on the available. Researchers are encouraged to make enquiries at the Mona Information Technology Services (MITS) department on the various software packages provided by the University of the West Indies, Mona which may be free of charge to the UWI Mona academic community.

? How do I decide which statistical tests to use?

Such decisions are guided by the research questions/objectives, study design, type of independent and dependent variables in the data and the distribution of the data. General guides on the use and application of statistical tests are provided in this resource document— Table 4: Sample Data Analysis Matrix; Table 5a: Types of Statistical Tests and their Application and Table 5b: Types of Statistical Tests and their Application and Table 5b: Types of Statistical Tests and their Application). The text 'Medical Statistics at a Glance' (^{4th} ed)— Petrie A & Sabin C. (2020) provides a flowchart as a quick guide to deciding on statistical tests. The text provides further details on the various types of tests. Additionally, see, Simpson SH (2015). Creating a Data Analysis Plan: What to Consider When Choosing Statistics for a Study. The Canadian Journal of Hospital Pharmacy. 2015 Jul-Aug;68(4):311-317.

How do I decide on using a table or a chart to present my data?

Charts are intended for the presentation of summary data in a simple, and clear manner, utilizing visual imaging. Tables provide more detailed data and information. For more guidance on the relative advantages of both approaches, see reference— Epidemiology [Bonita R, Beaglehole R, Kjellström T (2006)— Chapter 4 Basic biostatistics: concepts and tools].

? What is statistical significance?

Statistical significance is quantified by probability and indicates the strength of evidence that an association (between an explanatory and outcome variable/s) exists or that a parameter is significantly different from the hypothesized value. Hypothesis testing yields a test statistic (such as a T-test, chi-squared test or Z-test statistic) and the associated probability (p value) that indicates evidence of association or significant difference from the hypothesized parameter if p < 0.05. The threshold for statistical significance is usually set at the conventional level of 0.05. A statistically significant finding is one which is unlikely to be the result of a chance occurrence. Hence, it indicates evidence of a real association between the explanatory and outcome variables.

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RESOURCES: DATA ANALYSIS

Petrie, A. & Sabin, C. (2020). Medical statistics at a glance (4th ed.). Wiley-Blackwell.

Simpson, S.H. (2015). Creating a data analysis plan: What to consider when choosing statistics for a study. The Canadian Journal of Hospital Pharmacy; 68(4):311-317. DOI: 10.4212/cjhp.v68i4.1471. PMID: 26327705; PMCID: PMC4552232. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4552232/pdf/cjhp-68-311.pdf

Bonita, R., Beaglehole, R. and Kjellström T. (2006). Basic epidemiology (²ⁿd ed.). World Health Organization. <u>https://apps.who.int/iris/handle/10665/43541</u>

Yamane, T.(1973). Statistics: An introductory analysis (2nd ed.). Harper & Row

Bland, M. (2000). An introduction to medical statistics, (3rd ed.)Oxford University Press.

Rana, R. & Singhal, R. (2015). Chi- squared test and its application in hypothesis testing. J Pract Cardiovasc Sci 1:69-71

Moore, D.S., McCabe, G.P. and Craig, B.A. (2009). In: Introduction to the practice of statistics (^{6t}h ed). W.H. Freeman and Company (pp. 372–81).

Kirkwood, B.R., & Sterne, J.A.C. (2003). In: Essential medical statistics (²ⁿd ed). Blackwell Science Ltd. (pp. 71–79).

Bhuyan, D., Dua, N. and Kothari, T. (2015). Epidemiology and biostatistics: Fundamentals of research methodology. Open Journal of Psychiatry & Allied Sciences. 7. 10.5958/2394-2061.2015.00022.1.

https://www.researchgate.net/publication/283992619_Epidemiology_and_biostat istics_Fundamentals_of_research_methodology

Tenny, S. & Abdelgawad, I. (2021). Statistical significance. In StatPearls. StatPearls Publishing.

Hayat, M,J. (2010). Understanding statistical significance. Nurs Res.; 59(3):219-23. doi: 10.1097/NNR.0b013e3181dbb2cc. PMID: 20445438.

Field, A. (2013). Discovering statistics using IBM SPSS statistics (^{4t}h ed.). Sage Publications.

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STAGE 6: REPORT PREPARATION

A formal report is prepared to document the research process, from background and literature review to study findings and a discussion of the findings. There are established formats for the preparation of this report and depending on whether this is for the purposes of an academic report (e.g. thesis or research paper) or journal publication, researchers should be guided accordingly. Figure 14 illustrates the key components of the report preparation stage.

Introduction - background and context of the study	
Literature review - state of knowledge in the field o	of study
Methods: re-write in the past tense	
Results: Write key results	
- focus on study objectives	
Results: include relevant tables, graphics	
-Descriptive tables/data - demographics & sam	nple profile
-Analytical/inferential tables/data - evidence of	of
associations/relationships/results of hypothes	is testing
Discussion	
- Explain research findings and meaning	
- Compare/contrast findings with literature	
- Discsuss implications of results	
Limitations	
 Methodological/ procedural challenges which have had an effect on study outcomes 	n may
Conclusions	
- Summative statement/s directly related to ac	tual
study results/findings	
Recommendations /Lessons learned	
References (observe required format and style)	
Prepare abstract/summary	
Authentication review of report (utilize plagiar	ism

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WRITING THE REPORT

GUIDELINES & FORMATTING

The desired format of the report should always be observed. The guidelines are usually provided by one's institution of higher learning, journal guidelines or author guidelines from the publishers. It is important to review these requirements beforehand and be guided accordingly. This may include word limits, keywords and reference formatting, as well as formatting for tables, charts and pictures, etc.

IMRAD, an acronym for Introduction, Methods, Results, and Discussion is a common structure for a scientific research report. This format facilitates the documentation of the context of the study and the rationale, the methods employed, the results obtained and the implications of said results.

The diagram below (Figure 15) further illustrates the respective sections of the research report (and their related components) using the IMRAD structure.



Figure 15: IMRAD Format

Source: Wu, Jianguo. (2011). Improving the writing of research papers: IMRAD and beyond. Landscape Ecology. 26. <u>https://link.springer.com/article/10.1007/s10980-011-9674-3</u>

The **Introduction** establishes the background and context of the study. It also addresses the rationale and objectives of the study, as well as the posited hypothesis/es. This section may also include a problem statement.

The **Literature review** (which may be a component of the Introduction) documents the state of knowledge in the field of study and is intended to be extensive and current, highlighting studies of a scientific nature and can include the 'grey' literature such as technical reports and unpublished documents.

Methods should be written in the past tense at the report phase. Technical definitions and scientific methods and procedures are also described in this section. Relevant theoretical application may also be included.

The **Results** presented should relate to the study objectives or research questions posed. Initial results should provide summary statistics on the sample (or population if a census was conducted) and the key explanatory and outcome variables of interest, including demographic data (i.e. age, sex, socio-economic data, etc.). These should be supported by tables and/or graphs. Analytical/inferential data and tables provide evidence of associations or relationships and the relative strength of these. These data are indicative of the outcomes of hypothesis testing.

Discussion follows, with the aim of explaining the findings and their meaning; comparing and contrasting the findings with literature and discussing the implications of the results - i.e. policy, programmatic, clinical, research, etc.

Limitations describe any methodological or procedural challenges which may have an effect on study outcomes. This is included in the Discussion segment.

Conclusions are summative statement/s on the findings of the study and should directly relate to the study objectives or research questions established at the start of the study. Great care should be taken to limit the conclusions to the evidence provided, so as to avoid 'over-reaching' statements (i.e. conclusions which are not supported by the evidence presented in the results section).

Appropriate **Recommendations** should also be documented. In some instances author guidelines may also allow for the documentation of implications of your findings and/or lessons learned.

Referencing is the practice of acknowledging written work and the source. References and in-text citations should be presented in the appropriate format as guided by the institution's thesis guide, journal or publisher guidelines. Referencing styles (e.g. APA; MLA; Oxford; Harvard; Chicago; Vancouver) may differ by discipline. Notably, there are prescribed formats for various sources (i.e. journal article, book, website, text book). Use of a reference manager is recommended.

The **Abstract** represents the summary of the main report and should also be written in the IMRAD structure. There is typically a word limit on the abstract and this should be observed.

Plagiarism Checks

Once completed, the written work should be subjected to an authentication review to ensure appropriate attribution as per recognized guidelines. Plagiarism software can be used to review the document and the relevant guidelines are usually provided by the respective institution, journal or publisher.

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FAQS: REPORT PREPARATION (STAGE 6)

? Do I need to update the literature at the report writing stage?

This may be relevant if there have been new publications on the subject of your study. It is always useful to check for updates in the field before you complete your research paper.

What format should I use for my references?

Guidelines on referencing formats are usually provided a priori and are also discipline-based. Relevant instructions are provided by the academic institution or the journal to which the paper is being submitted. The UWI Mona library and website provide details on organizing, writing and presenting your thesis.

RESOURCES: REPORT PREPARATION

Wu, J. (2011). Improving the writing of research papers: IMRAD and beyond. Landscape Ecol; 26: 1345–1349. <u>https://link.springer.com/article/10.1007/s10980-011-9674-3</u>

UWI Mona Library. Theses Guides. https://www.mona.uwi.edu/library/library/theses-guides

UWI Mona Library. Resources for Graduates. https://www.mona.uwi.edu/library/resources-graduates

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STAGE 7: PUBLISHING YOUR WORK

Having documented your research work in the form of an academic thesis, research report/paper, or technical report, an important consideration is sharing the findings with a wider community. A single report may produce a number of findings of interest or relevance to the scientific community, practitioners and policy makers, as well as the general public. The format and writing approach/style will differ depending on the community you wish to target. Notably, for the general public, the use of simple, non-technical jargon is recommended. For scientific publications, the basic steps (Figure 16) are indicated below.

FIGURE 16: STEPS IN THE SCIENTIFIC PUBLICATION PROCESS

Select topic for publication	
 research report/thesis may hold potential for multiple publications 	
- establish rationale for the paper	
Identify objectives of the paper or research question/s	
Observe established/conventional authorship guidelines (rules for authorship - e.g. ICMJE)	
Discuss and decide on authorship roles for team	
Identify journal/publisher of interest/relevance to the proposed publication material	
Identify data elements/analysis relevant to the objectives/proposed publication	
Produce relevant tables and graphs/charts	
Writing:	
- Observe author guidelines from publisher (i.e. writing format)	
- Review reporting guidelines (to match the research design)	
Make a timely submission via the instructions given and await feedback. Possible responses are:	
- Accepted	
- Revisions required (minor or major)	
 Declined (if this is the case examine/request reviewer comments; revisit the paper as there may be an opportunity to submit elsewhere) 	

GUIDELINES FOR DECIDING ON AUTHORSHIP OF A PAPER

Authorship indicates credit for individual contributions to a research study, and carries a duty of responsibility and accountability, given the significant academic, social and financial implications. As such, ethical guidelines have been established to assure the integrity of the research and publication process. While specific standards may vary across disciplines, in the main, authorship is reserved for persons who have made substantial intellectual contributions in the conception, design, data analysis and interpretation, drafting, and/or critical intellectual review of the work. Persons who have otherwise contributed, but not in those ways should be appropriately acknowledged.

The International Committee of Medical Journal Editors (ICMJE), is an example of an established guideline, with the following criteria for authorship of papers:

- "Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved".

Source: International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors - <u>https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#two</u>

SELECTING A JOURNAL TO PUBLISH YOUR WORK

Examine the journal's aims and scope in details to ensure that the subject focus is a match for your paper. Start by listing peer-reviewed journals which match the subject matter of your research work or publication to arrive at a short list. The rigours of a peer-review system assure the quality of the research paper, as well as the integrity of the publication process.

Additionally, you will need to determine if the journal accepts the kind of paper you plan to write or have written and if the target audience of the journal is an appropriate match for the target audience for your work.

Another question to ask is if the journal is indexed in relevant scientific databases (e.g. SCOPUS, Web of Science, PubMed, PubMed, Central, Directory of Open Access Journals, MEDLINE, Directory of Open Access Books). The impact factor of the journal is also a consideration. You could also speak with academics, tutors, or supervisors on their publication experience with journals.

It is recommended that researchers select journals with a rigorous peer review process and which meet the Committee on Publication Ethics (COPE) guidelines and core practices.

JOURNAL FINDERS

Some publication houses utilize electronic search technology platforms which allow researchers to search for and identify journals which may be best suited for your paper. You will be directed to insert the title of your paper and abstract, and in some instances along with the specified field of research. This search produces results matching your paper to various journals. Some on these online journal finders will also include impact factor scores in the search results. This resource may be especially useful for early career scientists or research students producing their first set of publications.

WRITING YOUR MANUSCRIPT: REPORTING GUIDELINES

Extensive work by leading researchers have produced reporting guidelines for the production of manuscripts. One such example is the EQUATOR (Enhancing the QUAlity and Transparency Of health Research Network which defines a reporting guideline as:

"A checklist, flow diagram, or structured text to guide authors in reporting a specific type of research, developed using explicit methodology."

Source: https://www.equator-network.org/about-us/what-is-a-reporting-guideline/

Additionally, EQUATOR considers a reporting guideline is a "simple, structured tool" with a basic or "minimum list of information", with the goal of the manuscript being: "understood by a reader; replicated by a researcher; used by a doctor to make a clinical decision, and included in a systematic review".

Source: https://www.equator-network.org/about-us/what-is-a-reporting-guideline/

MATCHING STUDY DESIGN WITH REPORTING GUIDELINES

The Equator Network provides reporting guidelines for various types of research and study designs, which cover the key information required.

The flowchart (2015) (Figure 17) below created by EQUATOR serves as a guide to identifying the most appropriate reporting guideline or checklist for your work.



Figure 17: Reporting Guidelines – EQUATOR Network

Source: <u>Selecting the appropriate reporting guideline for your article | EQUATOR Network</u> (equator-network.org)

In a recently edited book, Guidelines for Reporting Health Research: A User's Manual, the EQUATOR team has made sample chapters available online -<u>How to</u> write a great research paper using reporting guidelines | EQUATOR Network (equator-network.org)

Several other resources exist on the Equator network platform which may be useful in the preparation of your manuscript, as well as the design of your study.

KEY ELEMENTS OF THE PUBLICATION REVIEW PROCESS

- 1. Relevance of the work to the core objectives of the journal or publication
 - a. Publishers have established objectives and audiences and the materials submitted should be in sync with the scope of the journal
- 2. Scientific merit of the work/ Quality of the Science
 - a. Is the work scientifically and methodologically sound?
 - b. Does it add to or enhance the state of knowledge on the subject matter?
 - c. Does the work shed new light on an issue?
 - d. Does the work offer a promising outlook for future research in the field?
 - e. Is the work reproducible?
 - f. Appropriateness and quality of analysis and discussions
 - g. Are the conclusions supported by the results presented?
- 3. Academic accountability and integrity of the research
 - a. Can the authorship and respective contributions be verified?
 - b. Is there evidence of plagiarism or inadequate/inappropriate attribution of the work?
- 4. Value of the work
 - a. What is the value of the work and to whom?
 - i. Programmatic value, policy value, clinical value, research development value, etc.
- 5. Editorial quality
 - a. Writing style quality and clarity
 - b. Observance of guidelines for formatting (e.g. format of paper, length/word count, tables and figures, references)

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FAQS: PUBLICATION (STAGE 7)

What are the guidelines for deciding on authorship of a paper?

Authorship should follow established guidelines to assure the quality and integrity of research work and the appropriate credit and accountability for individual contributions to the work. While specific standards may vary across disciplines, in the main, authorship is reserved for persons who have made substantial intellectual contributions in the conception, design, data analysis and interpretation, drafting, and/or critical intellectual review of the work. Persons who have otherwise contributed, but not in those ways should be appropriately acknowledged. The International Committee of Medical Journal Editors (ICMJE), has established four main criteria for authorship of papers.

?) How do I use a Journal Finder?

The process of identifying a suitable journal for your publication is made easier with the use of Journal Finders utilizing electronic search technology. You are required to input information such as the title of your paper and an abstract. Thereafter a list of potential journals will be generated. This is especially useful for early career scientists or research students producing their first set of publications. Some examples of Journal Finders include:

Elsevier JournalFinder-- https://journalfinder.elsevier.com/.

Wiley Journal Finder Beta-- <u>https://journalfinder.wiley.com/search?type=match</u>

Charlesworth Author Services--- https://www.cwauthors.com/Journal-Finder

JournalGuide--- <u>https://www.journalguide.com/</u>

What is the Impact Factor (IF) of a journal?

Journal Impact Factor measures the frequency with which the average article in an academic journal has been cited for a specific year. It is an indicative ranking of the relative importance, influence and authority of a journal in a field of study. The Impact Factor is reported in Journal Citation Reports (JCR). Publishers use the JCR metric to assess the performance of a journal in relation to its competitors, while authors use the same metric to identify appropriate journals for their work.

? What do Journal Reviewers and Editors look for in reviewing a paper?

Reviewers and editors generally assess your paper on the following merits:

- 1. Relevance of the work to the core objectives/aim/scope of the journal or publication
- 2. Scientific merit of the work and the quality of the science
- 3. Accountability and integrity of the research work
- 4. Application and value of the work e.g. academic, social, policy, programme
- 5. Editorial quality i.e. writing style, observance of author guidelines

How do I select the most appropriate reporting guideline for my paper/ article?

The Equator network provides a listing of reporting guidelines which serve as key resources to support authors in deciding on the best match for their study design. Some journals may require that you submit the appropriate checklist/guideline along with your manuscript and this may assist in having your work published. A useful resource is an online tool produced by EQUATOR Network in collaboration with Penelope.ai. <u>https://www.goodreports.org/</u>

Additional resources from the Equator team provide researchers with useful information in preparing their manuscripts as well as supporting the study design

phase. See Guidelines for Reporting Health Research: A User's Manual. Sample chapters from this text are available online -<u>How to write a great research paper</u> <u>using reporting guidelines | EQUATOR Network (equator-network.org)</u>

What is a useful strategy to increase citation of my research/paper?

Papers which address debatable topics, review or meta-analysis papers; multidisciplinary and multi-authored papers may have a higher likelihood of being cited. Sharing your work through presenting at conferences and in other academicfor aa and making your work easily accessible through established research platforms (including posting to repositories) will also help to increase the likelihood of the citation of your work. Another tip is to include key words/terms (related to the field of research or discipline)in the title of the paper as well as the abstract.

RESOURCES: PUBLISHING YOUR WORK

International Committee of Medical Journal Editors. Defining the role of authors and contributors. <u>https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#two</u>

Committee on Publication Ethics. Guidelines. https://publicationethics.org/guidance/Guidelines

Equator Network. What is a reporting guideline? <u>https://www.equator-network.org/about-us/what-is-a-reporting-guideline/</u>

Equator Network. Selecting the appropriate reporting guideline for your article. <u>Selecting the appropriate reporting guideline for your article | EQUATOR Network</u> (equator-network.org)

Equator Network. How to write a great research paper using reporting guidelines. How to write a great research paper using reporting guidelines | EQUATOR Network (equator-network.org)

University of Cambridge. Research Integrity. Guidelines on authorship - <u>https://www.research-integrity.admin.cam.ac.uk/research-</u> integrity/guidance/guidelines-

authorship#:~:text=Guidelines%20on%20Authorship%20Authorship%20provides%2 Ocredit%20for%20an,practices%20differ%20significantly%20from%20one%20discipli ne%20to%20another.

Clarivate. Journal Citation Reports Reference Guide. June 2022. https://clarivate.com/wp-content/uploads/dlm_uploads/2022/06/JCR-2022-Reference-Guide.pdf

Clarivate. The Clarivate Analytics Impact Factor. <u>https://clarivate.com/webofsciencegroup/solutions/the-clarivate-analytics-impact-factor/</u>

Journal Impact Factor 2021 (Updated 2022) – JCR, Web of Science. <u>https://impactfactorforjournal.com/impact-factor-2021/</u>

EQUATOR Reporting Guideline Decision Tree. Which guidelines are relevant to my work?<u>https://www.equator-network.org/wp-content/uploads/2021/11/RG-decision-tree-for-Wizard-CC-BY-26-February-2016.pdf</u>

Equator Network. Guidelines for Reporting Health Research: A User's Manual, Sample chapters from this text are available online - <u>How to write a great research</u> <u>paper using reporting guidelines | EQUATOR Network (equator-network.org)</u>

EQUATOR Network in collaboration with Penelope.ai. Online reporting guideline checklist - <u>https://www.goodreports.org/</u>

THE TOOLKIT: A RESOURCE FOR YOUR RESEARCH JOURNEY

This resource aims to simplify and clarify the research process across the various stages – from research conceptualization to publication. The document recognizes the translational science pathways, especially in relation to the multidisciplinary nature of the training and research programmes of the Mona-based Faculty of Medical Sciences (FMS).

The Research Toolkit supports the inter-disciplinary and transdisciplinary research agenda of The UWI Mona, to foster a more comprehensive and holistic approach to addressing health challenges (via knowledge translation to guide policy, practice, advocacy, training and capacity building for health and development).



Notably, students and faculty members of the FMS who wish to revisit their research work, picking up from where they may have left off along this journey are invited to utilize this resource. This resource may also be informative for students of other UWI Mona faculties, as well as other UWI campuses.

On behalf of the Faculty of Medical Sciences I extend sincere appreciation to all the members of faculty, administration and students who contributed to the development of this work. It is hoped that this will provide a baseline guide for entry-level researchers as well as a refresher for persons who may be at various stages in their research journey.

In closing, I wish to personally acknowledge Professor Rainford Wilks and Professor Affette McCaw-Binns, both of Faculty of Medical Sciences, The University of the West Indies, Mona for their guidance and mentorship during my formative years of academic development and post-graduate research journey.

Jasneth Mullings Ph.D. Epidemiologist & Lecturer, Clinical Translational Research Unit Office of the Dean, Faculty of Medical Sciences The University of the West Indies, Mona March 29, 2023