University of Nebraska Medical Center

BREAKTHROUGHS FOR LIFE.®

Research Project

Planning Workbook

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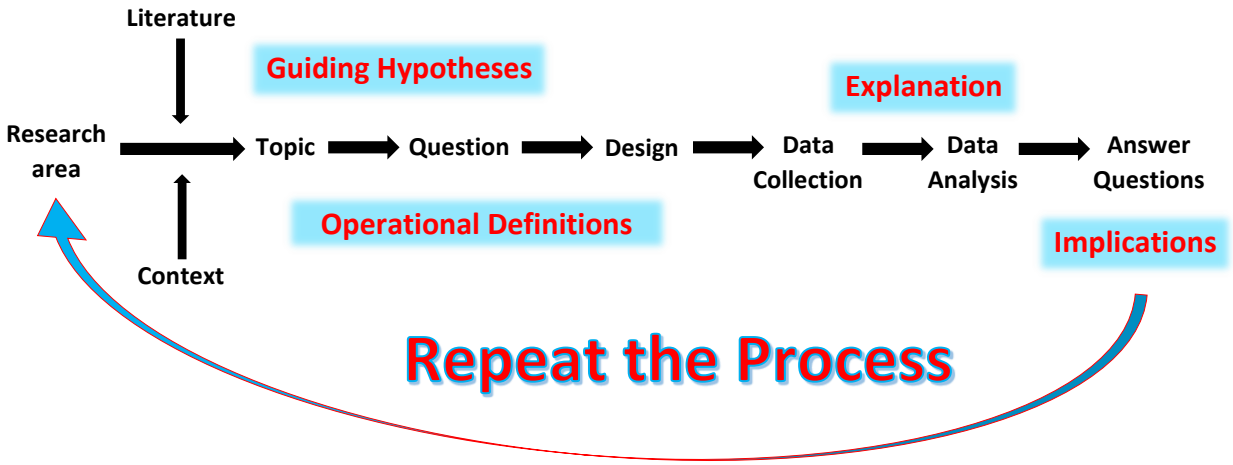
THE PROCESS OF RESEARCH

Science is an iterative process. Truly "paradigm-shifting studies" are rare, and even those studies stand on the shoulders of prior research. On the surface, this iterative process may be misconstrued as duplicative. However, repeated studies are necessary to confirm — or refute — hypotheses and to refine our understanding of the truth. In publishing the results of research, investigators have an obligation to not only articulate their methods and their findings, but to highlight the limitations of their research — thus enabling future studies to improve upon past work and move the field forward.[1]

[1]Phipps, AJ. (2017) Science is an iterative process. *HemOnc Today*.



If we knew what it was we were doing, it would not be called research, would it?

~Albert Einstein

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STEP 1: SELECT THE TOPIC – RECOGNIZE AND DEFINE THE PROBLEM

Supporting Documents

- ✓ Getting Started: The Anatomy and Physiology of Clinical Research (Hulley, Newman, Cummings, 2013)
- ✓ Why Most Clinical Research Is Not Useful (Ioannidis, 2016)

A successful research project typically involves an interest in a practical problem. You may begin with a "big" question (i.e., the best insulin regimen to treat diabetes mellitus) and can narrow your scope during the study design. Brainstorm with your mentor, discuss your interests with colleagues, and read recent publications in your discipline. Answer the following three questions based on your observations and experience.

1. What is your general "research question(s)?" What would you like to investigate?
   It is important to choose a topic that is of great interest to you. Why did you choose this topic?

2. How will this study contribute to the field? Define the target audience who may benefit.
   Why is it necessary to conduct this research? Can your idea be considered "new" information?

3. What is unique about your perspective, principles, methods, or techniques?
   Are you replicating an existing study or applying an old method? Are you challenging an established idea in the body of literature?

STEP 2: CONDUCT A PRELIMINARY LITERATURE REVIEW

Supporting Documents

- ✓ Searching the Literature and Selecting the Right References (Rau, 2004)
- ✓ Undertaking a Literature Review (Cronin, Ryan, Coughlan, 2008)

A literature review is to present a comprehensive understanding of the current state of knowledge on a topic.

1. List key words or phrases and Boolean operators (i.e., AND, OR, NOT) specific to your topic that you can use to search. Refer to Rau (2004) for searching in PUBMED tips. Watch this UMNC McGoogan Library *Formulating Your Question* video https://www.youtube.com/watch?v=Il2jUo3RiuQ&feature=youtu.be for helpful hints.

   a.

   b.

   c.

   d.

   e.

   f.

2. Locate six articles published within the **last five years** related to your topic (refer to Cronin, 2008 to guide your search). Search for studies that you could replicate, studies (very) specific to your topic, and studies using similar methodology on a related topic. If the list is long, choose the most recently published articles. *If you plan to target a journal, search it first for relevant publications.*

3. Complete the table in Appendix A with the following information. An electronic copy is available in the supporting documents folder.
   a. Year the article was published
   b. Lead author
   c. Title of the article/Journal name
   d. Purpose/Subjects
   e. Total sample size
   f. Relevant results
4. Use citation software to help you track your references. Guides may be found here:
   EndNote http://unmc.libguides.com/endnote
   RefWorks http://unmc.libguides.com/RefWorks

5. Locate resources to assist in the definition of the problem (i.e., morbidity/mortality, hospital/clinic statistics). Reputable disease-specific websites (American Cancer Society) often have good information. UNMC McGoogan Library Health Statistics Guide: http://unmc.libguides.com/c.php?g=713720.

STEP 3: DEVELOP AND REFINE YOUR RESEARCH QUESTION

Supporting Documents

- ✓ Conceiving The Research Question and Developing the Study Plan (Cummings, Browner, Hulley, 2013)
- ✓ Developing Great Research Questions (Lipowski, 2008)
- ✓ Exploring the Nature of a Research Question in Mixed Methods Research (Creswell, Tashakkori, 2007)

The research question(s) will guide the study design, data collection, and analysis methods. In some types of studies (i.e., patient experience, education, psychosocial), you may modify your research question/purpose prior to the formal write-up due to unexpected results.

1. Based on your literature review and study idea, refine the research question(s) by completing the table in Appendix B with the following information. An electronic copy is available in the supporting documents folder.

PICO Framework for Development of a Research Question	
Components of the research question	Population - type of person
	Intervention (exposure) - type of exposure
	Comparisons - type of control
	Outcomes - type of outcome
Refining the research question: Are antibiotics effective for otitis media?	Population • Otitis media according to physician diagnosis? • Otitis media based on tympanometry readings? • Fever and ear pain? • Do you consider infants and adults?
	Intervention • Which antibiotic? • At what dose? • For what duration?
	Comparisons • Vs. no treatment or decongestants only? • Vs. placebo? • Vs. another antibiotic? • Vs. myringotomy?
	Outcome • Reduction in pain? • Earlier resolution of symptoms? • Prevention of long-term hearing loss or other complications? • Cost?
Refinement Example	Are anticoagulant agents useful in patients who have had a stroke?
	Do anticoagulant agents improve outcomes in patients with acute ischemic stroke compared with no treatment?
	Does enoxaparin administered for the first three days at 1 mg/kg bid compared with no anticoagulation after acute ischemic stroke increase the proportion of patients discharged without residual neurologic deficit?

2. For each research question, draw a concept map using the data elements (groups) necessary for analysis to visually represent the relationship between the variables. Examples are located in Appendix B. If a CONSORT diagram is applicable use this template: http://www.consort-statement.org/consort-statement/flow-diagram

STEP 4: BRIEFLY OUTLINE THE PROBLEM, EVIDENCE, AND PURPOSE

Supporting Documents

- ✓ Reviewing the Literature: Essential First Step in Research, Quality Improvement, and Implementation of Evidence-Based Practice (Bernhofer, 2015)
- ✓ The Principles of Biomedical Scientific Writing – Introduction (Bahadoran, Jeddi, Mirmiram, Ghasemi, 2018)

The IRB requires a background section that allows the analyst reviewing the application to understand the justification and purpose of the research. This information is also required in a research or grant proposal.

1. Using the journal articles and other information you have compiled, write three paragraphs outlined below to demonstrate how your study will add value to the current body of evidence. Complete the table in Appendix C with the following information. An electronic copy is available in the supporting documents folder.

Paragraph	Purpose	Example
Paragraph 1	The problem statement. Why is this topic important? It may be due to the number of patients impacted, the severity of the condition, the size of the potential opportunity for improvement, the costs, etc.	Over 7 million surgeries are performed in United States hospitals each year. Among these surgeries, approximately 85% are noncardiac, nonvascular (NCNV) procedures.1,2 Although the preoperative use of an angiotensin-converting enzyme inhibitor (ACEI) can be expected in as many as 13% of these surgeries,3 the optimal preoperative ACEI management strategy for patients undergoing NCNV surgeries is poorly understood.
Paragraph 2	The evidence. Often the first sentence of this paragraph is something like "The evidence shows this, but not that." The remainder of the paragraph gives a very general outline of the evidence for "this" and "that." A more detailed review of the evidence will take place in the discussion section. The goal of this paragraph is to show a gap in the current evidence.	First sentence Despite diagnostic errors being morbid and sometimes deadly in the hospital, little is known about how residents and learners approach diagnostic decision making. Or In contrast to the ambulatory setting, the influence of physician continuity of care on inpatient outcomes has not been studied frequently.
Paragraph 3	The aim. How does this study aim to fill the gap(s) in evidence that were described above? This short (typically just 1-2 sentences) paragraph may also include some information about the setting or size or design of the study depending on the gap in evidence.	The purposes of this exploratory study were to (1) assess patient attitudes surrounding readmission, (2) ascertain whether these attitudes are associated with actual readmission, and (3) determine whether patients can estimate their own risk of readmission.

STEP 5: COMPLETE A COMPREHENSIVE LITERATURE REVIEW

Supporting Documents

- ✓ Ten Simple Rules for Writing a Literature Review (Pautasso, 2013)
- ✓ Literature Reviews and the Hermeneutic Circle (Boell & Cecez-Kecmanovic, 2010)

A literature review is a systematic, explicit, comprehensive, and reproducible method for identifying, evaluating, and interpreting the existing body of original work produced by researchers and scholars.

1. Conduct a comprehensive literature search and complete the table in Appendix D with the following information.
    a. Publication Year: In addition to the year, add your references to a list or citation manager for future use.
    b. Lead Author: You may wish to add more authors if there are several articles with the same lead author/year.
    c. Purpose/Topic: What was the specific topic for this study (i.e., drug, procedure)?
    d. Inclusion Criteria/Design: Define the population and design (i.e., adult men, randomized)
    e. *n*: The total number of subjects included in the analysis.
    f. Definitions: Did the methods define specific variables (i.e., BG result required for hyperglycemia, "minimally invasive" surgery)
    g. Significance: Yes/No
    h. Results: Which results are relevant to your study?

2. You may wish to add columns to the document that are necessary to track your literature review. A blank copy of Appendix D can be found in the supporting documents folder.

STEP 6: DESCRIBE YOUR SUBJECTS/DATA

Supporting Documents

- ✓ Methods and dimensions of electronic health record data quality assessment - Enabling reuse for clinical research (Weiskopf, 2012)
- ✓ Seeing Beyond the Margins - Challenges to Informed Inclusion of Vulnerable Populations in Research (Gehlert & Mozersky, 2018)

It is important to define the study population in as much detail as possible during the planning process. This information will populate a study flow diagram.

1. What is the inclusion criteria for this study? If this is a retrospective study, provide the date range for record extraction.

2. Who will be excluded from this study?

3. In Appendix E, list the variables you will need for the analysis in this study. An electronic copy is available in the supporting documents folder.

4. List the specific steps/protocol to obtaining your data.
   Is this a prospective or retrospective study? Where will you obtain the data? Who will be responsible for recruitment and data collection?

STEP 7: CREATE A PROJECT PLAN/TIMELINE

Supporting Documents

- ✓ Doing Interdisciplinary Mixed Methods Health Care Research - Working the Boundaries, Tensions, and Synergistic Potential of Team-Based Research (Hesse-Biber, 2016)

Clearly defining team roles during the planning process is critical to a successful project.

1. List your target dates for presenting your research to the Hospital Medicine core research team.

   Study Idea/Outline/Team _____

   Literature Review/Study Design_____

   Results/Final Product _____

2. List the tasks required, who will be responsible, and the deadline in the table below.

Task	Responsible Member (s)	Due Date

STEP 8: COMPILE INFORMATION FOR THE IRB APPLICATION

Supporting Documents

- ✓ Human Subject Regulations Decision Charts (2016)

Most of these questions will be required when completing an IRB application. Learn more about Institutional Review Boards by watching the video at the link below.
https://www.youtube.com/watch?v=U8fme1boEbE

1. What type of study is this?
   _____ Medical Records Retrospective
   _____ Human Subjects Prospective
   _____ Medical Records & Human Subjects

2. What is the number of subjects (or medical records) that will be participating in this research?

   i. What is the statistical justification for this number?

3. List the approximate date range for this study.

4. What is the age range of the subjects?

   i. What is the rationale for selecting this age range?

5. Does this study involve review of identifiable private health information (PHI)?
   If yes, check all applicable categories of PHI.
   ___Dates
   ___Postal address
   ___Telephone numbers
   ___Fax numbers
   ___Electronic mail addresses
   ___Social security numbers
   ___Medical Record Numbers (MRN)
   ___Health plan beneficiary numbers
   ___Account numbers
   ___Certificate/license numbers
   ___Vehicle identifiers and serial numbers, including license plates
   ___Device identifiers and serial numbers
   ___Web Universal Resource Locators (URL) Internet Protocol (IP) address numbers
   ___Biometric identifiers, including finger and voice print
   ___Full face photographic images [and any comparable images]

6. Will unique subject identifying number (i.e., S1, S1), characteristic or code be used to link data to any of the identifiers listed above?

7. How will prospective subjects be identified?

8. How do investigators have ethical access to the names of potential subjects?

9. How will potential subjects be contacted for recruitment into the study?

10. What are the potential risks associated with this research?

11. What is the overall risk classification of this research?
    ___ Minimal risk
    ___ More than minimal risk

12. Describe how the risks of the research will be minimized.

13. What are the anticipated benefits (if any) to the subjects that may reasonable be expected from participation in the research?

14. What are the anticipated benefits to society which may be reasonable expected to result from the research?

15. Will any of the information be purposefully withheld from the subject during the research or after the completion of the research?

16. What specific information will be withheld?

17. What is the justification for this non-disclosure?

18. Will information that has been withheld eventually be shared with the subject?

ALL members of the project team will need to complete CITI Training before the application will be approved.

Faculty, employees, students and other institutional representatives at UNMC/Nebraska Medicine/CH&MC and UNO are required to complete the Human Subjects Research (HSR) Course via the Collaborative Institutional Training Initiative (CITI) website if they will be working on a research project that involves human subjects. The course is presented as several modules with a brief quiz at the end of each module to assess understanding of the material. A cumulative passing score of 75% is required for successful completion and is valid for a period of 3 years at which time a refresher course must be taken. It takes approximately 2-3 hours to complete the Basic course. However, the training does not have to be completed in one sitting but can be spread out over time if needed.

UNMC/Nebraska Medicine/CH&MC - Instructions
All individuals at UNMC/Nebraska Medicine and/or CH&MC involved in the conduct (i.e., listed on the IRB application) must complete either Group 1 or Group 2. The group assignment is explained below:

Group 1: If none of the IRB application(s) that you are or may be listed on (in the foreseeable future) are considered a clinical trial involving drugs or devices, you must complete Group 1.

Group 2 GCP: If any of the IRB application(s) that you are or may be listed on (in the foreseeable future) are considered a clinical trial involving a drug or device, you must complete Group 2 and Group 1.

STEP 9: DOCUMENT STUDY DESIGN PROTOCOL

Supporting Documents

- ✓ "You Don't Know Me, But . . . ": Access to Patient Data and Subject Recruitment in Human Subjects Research (Schonfeld, Brown, Amoura, Gordon, 2011)

A study protocol document is important for reporting methods in enough detail to allow replication by others.

Study Procedures

1. Outline the experimental design of the study (e.g., observational, randomized)

2. Sampling plan including inclusion/exclusion criteria (subject and disease characteristics)

3. Recruitment
    a. Where will recruitment occur?

    b. Where and when will consent be obtained?

    c. Who will obtain consent?

    d. What is the advertising plan, if applicable?

    e. What recruitment materials will be provided to the potential participant (brochures/information sheets/video presentation)?

4. Screening
    a. What procedures are required for screening?

b. What is the screening schedule (number of visits, length of visits)?

c. Which screening tests/procedures are part of the standard of care and which are for research purposes only?

d. What happens with screen failures (including any data gathered during screening)?

5. Randomization procedures (if applicable)

6. Intervention
    a. Active intervention description

    b. Control group, if applicable

7. Study Assessments and Activities
    a. Describe the study procedures, assessments, and subject activities

    b. Provide a schedule of assessments and subject activities

STEP 10: CREATE AN ANALYSIS PLAN

Supporting Documents

- ✓ Creating a Data Analysis Plan: What to Consider When Choosing Statistics for a Study (Simpson, 2015)
- ✓ Bridging Clinical Investigators and Statisticians: Writing Statistical Methodology for a Research Proposal (Adams-Huet & Ahn, 2009)

A biostatistician will assist with your analysis methods once you have identified your research question(s) and the variables necessary in the analysis.

1. Based on your research question(s), define the variables and type of analysis by completing the table in Appendix F with the following information.

Research Question	Variables	Data Type	Analysis Method
Is there a difference between diabetes patients with diabetes and non-diabetes patients who experience perioperative hyperglycemia?	Demographic Data Diabetes (Y/N) Diabetes Type I/Type II Glucose Time/Date	Nominal/Categorical Scale	Frequencies Pearson's *r* Regression Analysis
Do patients with diabetes react to the use of IV-administered steroids differently than those without a diagnoses of diabetes?	Demographic Data Diabetes (Y/N) Diabetes Type I/Type II Glucose Time/Date Steroid Time/Date/Dose	Nominal/Categorical Scale	Frequencies/Means ANOVA Regression Analysis
Do non-diabetes patients have significantly longer average hospital stays than DM patients?	Demographic Data Procedure Duration Steroid Administration ASA Class Length-of-Stay	Nominal/Categorical Scale	Frequency Analysis Pearson's *r* Regression Analysis

Data Types: Nominal/Categorical (Gender), Ordinal (Survey Scale), Interval/Scale (weight/age)

STEP 11: CREATE A DATA DICTIONARY

Supporting Documents

- ✓ Development and Validation of a Data Dictionary for a Feasibility Analysis of Emergency Department Key Performance Indicators (McCabe, Fhailí, O'Sullivan, Brenner, Gannon, Ryan, Butt, Schull, Wakai, 2019)

Creating a code book is required during the data analysis process. Biostatisticians need this information to perform an accurate analysis.

Study Procedures

1. The data dictionary should contain the definition of the variable or survey question, the name/label included in the database, and the assigned values for each response. Complete the table in Appendix G with the following information.

Variable/Question	Database Name	Response Values
What is your gender?	gender	Male = 1 Female = 2
What is your job role?	job_role	Physician = 1 APRN = 2
I spend the majority of my time on the following service:	service	Co-Management = 1 Grissom = 2 Loomis = 3 Meyer = 4
I have a strong awareness of the importance of effective clinician-patient communication.	pre_aware_comm	1 = Stongly Disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Agree
Number of years in practice:	years_practice	Raw #
ED_DISPOSITION	1	Admit
	2	AMA
	3	Discharge
	4	Eloped
	5	Hold Discharge
	6	Transfer to Another Facility
	7	Other
	99	Missing
PRIMARY_ADMIT_DX	0	No
	1	Yes
	99	Missing
ICD10_ETOH	#	ICD-10 Code
DX_NAME	text	ICD-10 Code Name
SMOKING_STATUS	1	Never
	2	Quit more than 12 months ago
	3	Current
	4	Tobacco Screening not performed for Medical Reasons
	99	Missing

STEP 12: ANALYZE RESULTS

Supporting Documents

- ✓ Research Fundamentals: Statistical Considerations in Research Design: A Simple Person's Approach (Jones, 2008)
- ✓ Overcoming "Analysis Paralysis" (Zuckerburg, 2008)
- ✓ Guidelines for Responsible Data Management in Scientific Research (*Electronic copy available in the supporting documents folder*)

Statistics describes a set of tools and techniques that is used for describing, organizing, and interpreting information or data.

1. Clean and organize your data. Review the output to ensure the format is correct. Replace any labels (text entries) with numeric values listed in the data dictionary.
2. Run descriptive statistics (mean, median, mode, frequencies, range) to describe the characteristics of your data set. Identify any variables with a large amount of missing data.
3. Document decisions regarding excluding cases, combining/converting categories, and with the final data set.
4. Create Table 1 with relevant descriptive data (see example below).
5. Run histograms (a visual representation of frequency) or review the mean/range for each variable to determine if your data is normally distributed.
6. Analyze your data (or send it to a biostatistician) based on the analysis plan.

Table 1 Example

	Blood Glucose < 180 mg/dL (n = 470)			**Blood Glucose ≥ 180 mg/dL (n = 264)**		
	NDM	**DM**	*p*-value	**NDM**	**DM**	*p*-value
Number	444 (94.47)	26 (5.53)		162 (61.36)	102 (38.64)	
Age, mean (SD)	53.08 (17.36)	63.85 (14.62)	0.002	56.38 (17.19)	65.05 (12.21)	<0.0001
Sex			0.55			0.8005
Male, no. (%)	212 (47.75)	14 (53.85)		84 (51.85)	55 (53.92)	
Female, no. (%)	232 (52.25)	12 (46.15)		78 (48.14)	47 (46.08)	
Insurance						0.003
Institutional, no. (%)	214 (48.20)	9 (34.62)		72 (44.44)	26 (25.49)	
Medicare/Medicaid, no. (%)	183 (41.22)	16 (61.54)		70 (43.21)	66 (64.71)	
Self-pay, no. (%)	3 (0.68)	1 (3.85)		19 (11.73)	9 (8.82)	
All other, no. (%)	44 (9.91)	0 (0.00)		1 (0.62)	1 (0.98)	
BMI, mean (SD)	28.78 (8.55)	33.26 (6.72)	0.012	28.32 (6.49)	31.30 (8.21)	0.0017
Race			0.398			0.2293
White, no. (%)	383 (86.85)	24 (92.31)		140 (86.96)	86 (84.31)	
Black or African American, no. (%)	28 (6.35)	1 (3.85)		8 (4.97)	8 (7.84)	
Asian, no. (%)	2 (0.45)	0 (0.00)		3 (1.86)	0 (0.00)	
American Indian/Alaska Native, no. (%)	2 (0.45)	1 (3.85)		0 (0.00)	1 (0.98)	
Native Hawaiian/Pacific Islander, no. (%)	1 (0.23)	0 (0.00)		0 (0.00)	0 (0.00)	
Multiple Race, no. (%)	7 (1.59)	0 (0.00)		1 (0.62)	3 (2.94)	
Unknown or Other, no. (%)	18 (4.08)	0 (0.00)		9 (5.59)	4 (3.92)	
Hispanic, no. (%)	25 (5.67)	0 (0.00)	0.385	12 (7.45)	6 (5.88)	0.8031
Diabetes			<0.0001			<0.0001
Type 1, no. (%)	0 (0.00)	0 (0.00)		0 (0.00)	6 (5.88)	
Other, no. (%)	0 (0.00)	26 (100.00)		0 (0.00)	96 (94.12)	
Length of Stay, mean (SD)	12.46 (12.39)	11.01 (18.26)	0.69	14.40 (24.96)	13.20 (19.09)	0.66
GCS on Presentation			0.059			0.0033
9-15, no. (%)	380 (85.78)	24 (100.00)		121 (75.63)	92 (90.20)	
3-8, no. (%)	63 (14.22)	0 (0.00)		39 (24.38)	10 (9.8)	
Steroid Administration						
DOS, no. (%)	42 (9.46)	4 (15.38)	0.307	21 (12.96)	16 (15.69)	0.5865
POD1, no. (%)	48 (10.81)	3 (11.54)	0.754	26 (16.05)	21 (20.59)	0.4091
POD2, no. (%)	51 (11.49)	2 (7.69)	0.755	37 (22.84)	21 (20.59)	0.7606

STEP 13: CREATE TABLES WITH ANALYSIS RESULTS

Supporting Documents

- ✓ Effective Writing and Publishing Scientific Papers Part VII: Tables and Figures (Kotz & Cals, 2013)
- ✓ Graphs, Tables, and Figures in Scientific Publications: The Good, the Bad, and How Not to Be the Latter (Franzblau & Chung, 2012)
- ✓ Acceptability, Feasibility, and Cost of Telemedicine for Nonacute Headaches: A Randomized Study Comparing Video and Traditional Consultations (Müller, Alstadhaug, Bekkelund, 2016)

Tables should contain information to answer your research question(s) or support the aim of the study.

1. Refer to the article by Muller, Alstadhaug, and Bekkelund (2016) for examples of a study flow diagram, tables, and graphs. Using the guide in Appendix H, choose the best type of chart or graph to visually represent your data. Video tutorials to create charts and graphs in Excel can be found at the following links:

    a. Line chart - *How to create a Line Chart in Excel*
    https://www.youtube.com/watch?v=gpyqoVv3jgw

    b. Column chart - *How to create a Column Chart in Excel*
    https://www.youtube.com/watch?v=pIlEcUzy7p0

    c. Pie chart - *How to create a Pie Chart in Excel*
    https://www.youtube.com/watch?v=wIt5K3Uu8kA

    d. *How To... Plot Multiple Data Sets on the Same Chart in Excel 2010*
    https://www.youtube.com/watch?v=MHNpG__dNnc

    e. *Creating a Boxplot in Excel 2016*
    https://www.youtube.com/watch?v=TxuretcM5Uk

    f. *How to Edit and Format an Excel 2010 Chart For Dummies*
    https://www.youtube.com/watch?v=sWLR5MBpWa

STEP 14: PLANNING FOR PUBLISHING

Supporting Documents

- ✓ Twelve Tips for Getting Your Manuscript Published (Cook, 2016)
- ✓ An Approach to the Writing of a Scientific Manuscript (Cetin & Jackam, 2005)

7. List the authors (in order) as they will be listed on the manuscript.
    a. First author

    b. Last author (Consultant/Subject Matter Expert)

8. List 3 journals you will target for publication and the details for each.

Journal Name	Type of Article	Abstract Type (Structured/ Unstructured)	Abstract Word Limit	Article Word Limit

STEP 15: TELL YOUR STORY – WHAT'S THE "SPIN?"

How do you wish to frame your results? What is the story you would like to tell your reader?

Using your results, write 3-4 summary statements describing your conclusion(s).

Example: *A statistically significant difference was found for each of the six National Resident Matching Program competency scores when comparing UNMC medical school graduates (n=27) and non-UNMC graduates (n=35).*

Summary Statement
1
2
3
4

STEP 16: ALIGN RESULTS WITH SUMMARY STATEMENTS

For each summary statement, list the corresponding results.

Example: *The mean average PC score across the 6 time points for non-UNMC grads was 2.99 compared to 3.25 for UNMC grads.*

Med School Type	*n Obs*	*Variable*	*n*	*Mean*	*Std Dev*	*Median*	*Min*	*Max*	*Variable*	*p-value*
Not UNMC	35	pc_avg_Mean	35	2.99	0.32	2.97	2.30	3.68	pc_avg_Mean	0.0056
		mk_avg_Mean	35	3.11	0.69	3.00	2.20	6.63		
		sbp_avg_Mean	35	3.10	0.30	3.08	2.50	3.69	mk_avg_Mean	0.41
		pbl_avg_Mean	35	3.00	0.25	2.97	2.48	3.52		
		prof_avg_Mean	35	3.18	0.35	3.17	2.53	3.85	sbp_avg_Mean	0.0072
		ics_avg_Mean	35	3.28	0.30	3.22	2.75	3.88		
UNMC	27	pc_avg_Mean	27	3.25	0.41	3.38	2.60	4.23	pbl_avg_Mean	0.0021
		mk_avg_Mean	27	3.23	0.46	3.17	2.58	4.38		
		sbp_avg_Mean	27	3.34	0.36	3.38	2.65	3.94	prof_avg_Mean	0.0023
		pbl_avg_Mean	27	3.23	0.32	3.25	2.73	3.72		
		prof_avg_Mean	27	3.52	0.47	3.53	2.56	4.35	ics_avg_Mean	0.0006
		ics_avg_Mean	27	3.59	0.39	3.71	2.86	4.17		

Statement 1

Statement 2

Statement 3

Statement 4

STEP 17: OUTLINE STUDY METHODS

For each summary statement, describe the method used in collecting/analyzing related data.

***Example: ACGME** milestones core competency scores were averaged across six time points over a three-year period. Spearman's Rho was used to determine relationships between the two groups.*

Statement 1

Statement 2

Statement 3

Statement 4

STEP 18: ALIGN RESULTS WITH THE STUDY PURPOSE

For **each** summary statement, list the objective/purpose related to statement.

Example: The purpose of this study was to analyze the relationship between individual rank order developed for NRMP and core competency scores.

Statement 1

Statement 2

Statement 3

Statement 4

STEP 19: ADD SUPPORT TO THE BACKGROUND/LITERATURE

A literature review is a summary of research, not a list outlining individual studies. The topic sentence makes a general point. The sentences that follow make a specific point(s) that is supported by several studies. The last sentence is a summary and a bridge to the next paragraph. Your background/literature review should guide your reader through general context, provide specific support regarding your topic, and ultimately lead to the purpose of your study.

For **each** summary statement, write 4-6 sentences using published literature to support the reason you chose this research question.

Sentence 1: Topic/main idea
Sentences 2-3: Supporting information
Sentence 4: Significance/value/importance

Statement 1

Statement 2

Statement 3

Statement 4

STEP 20: WRITE IT UP!

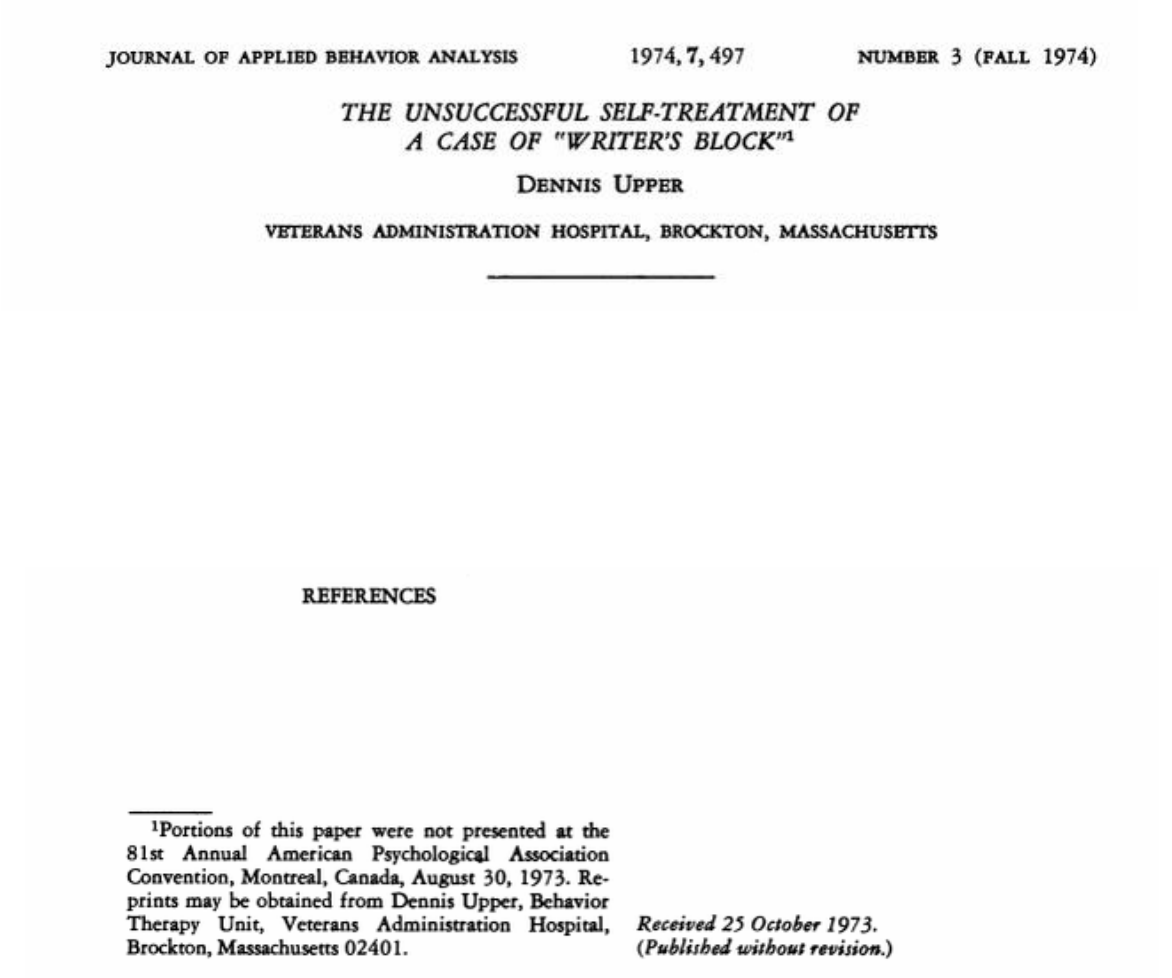
Supporting Documents

- ✓ A Curious Researcher's Guide on Successfully Publishing Scientific Manuscripts (Zhang, Tran, Papanagnou, 2018)
- ✓ Avoiding Manuscript Mistakes (Grindstaff & Saliba, 2012)
- ✓ Organising a Manuscript Reporting Quality Improvement or Patient Safety Research (Holzmueller & Pronovost, 2013)
- ✓ English for Writing Research Papers (Wallwork, 2016)

1. **Locate an example to use as a guide for your write-up**. Ideally, it would have been recently published in the target journal with a similar design, topic, setting, and subjects. The best examples often come from different disciplines. For example, if you are studying urinary catheters and infection for inpatients, also search for articles published on central venous catheter and infection.

2. **Update your literature review with current publications**. There is typically a gap between the initial literature search and manuscript draft. Cite articles from recent issues of the target journal and other relevant and recent publications.

3. Using the information in Steps 13-17, create a draft of your manuscript following the guidelines from the target journal. Tip: If you experience "writer's block" refer to your recently published



JOURNAL OF APPLIED BEHAVIOR ANALYSIS 1974, 7, 497 NUMBER 3 (FALL 1974)

THE UNSUCCESSFUL SELF-TREATMENT OF A CASE OF "WRITER'S BLOCK"[1]

DENNIS UPPER

VETERANS ADMINISTRATION HOSPITAL, BROCKTON, MASSACHUSETTS

REFERENCES

[1]Portions of this paper were not presented at the 81st Annual American Psychological Association Convention, Montreal, Canada, August 30, 1973. Reprints may be obtained from Dennis Upper, Behavior Therapy Unit, Veterans Administration Hospital, Brockton, Massachusetts 02401.

Received 25 October 1973.
(Published without revision.)

APPENDIX A – PRELIMINARY LITERATURE REVIEW

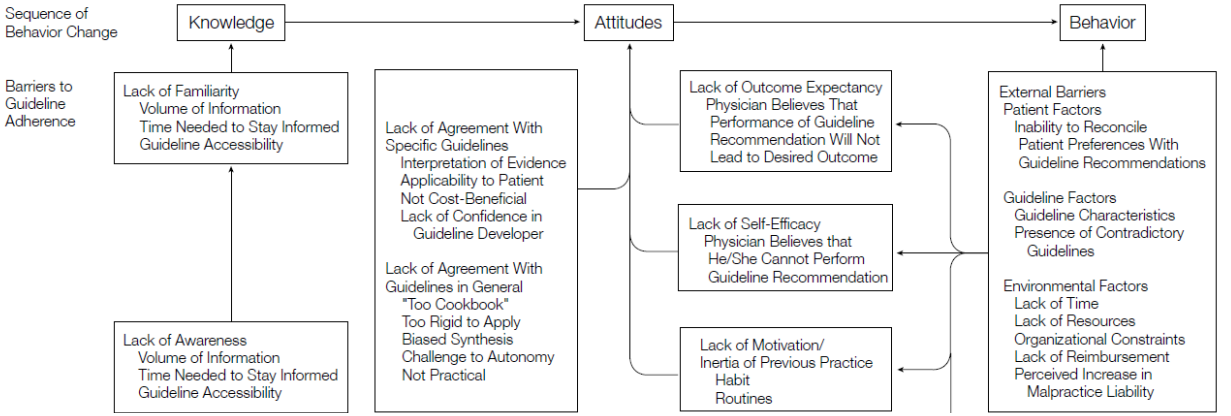
	Year	Lead Author	Title/Journal Name	Purpose/ Population	*n*	Results
1						
2						
3						
4						
5						

APPENDIX B – RESEARCH QUESTION DEVELOPMENT

PICO Framework for Development of a Research Question	
COMPONENTS OF A RESEARCH QUESTION	
Population - type of person	
Intervention (exposure) - type of exposure	
Comparisons - type of control	
Outcomes - type of outcome	
REFINING THE RESEARCH QUESTION	
Population • Otitis media according to physician diagnosis? • Otitis media based on tympanometry readings? • Fever and ear pain? • Do you consider infants and adults?	
Intervention • Which antibiotic? • At what dose? • For what duration?	
Comparisons • Vs. no treatment or decongenstants only? • Vs. placebo? • Vs. another antibiotic? • Vs. myringotomy?	
Outcome • Reduction in pain? • Earlier resolution of symptoms? • Prevention of long-term hearing loss or other complications? • Cost?	
FINAL RESEARCH QUESTION(s)	

APPENDIX B – CONCEPT MAP EXAMPLES

Figure. Barriers to Physician Adherence to Practice Guidelines in Relation to Behavior Change



Source: https://jamanetwork.com/journals/jama/fullarticle/192017

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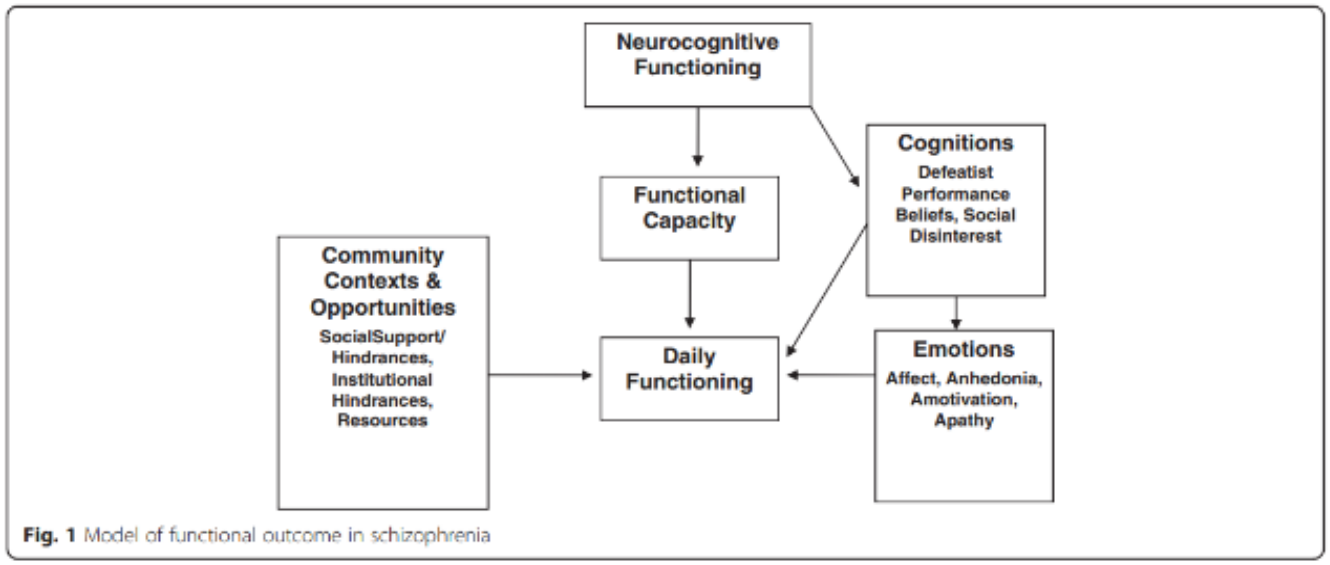
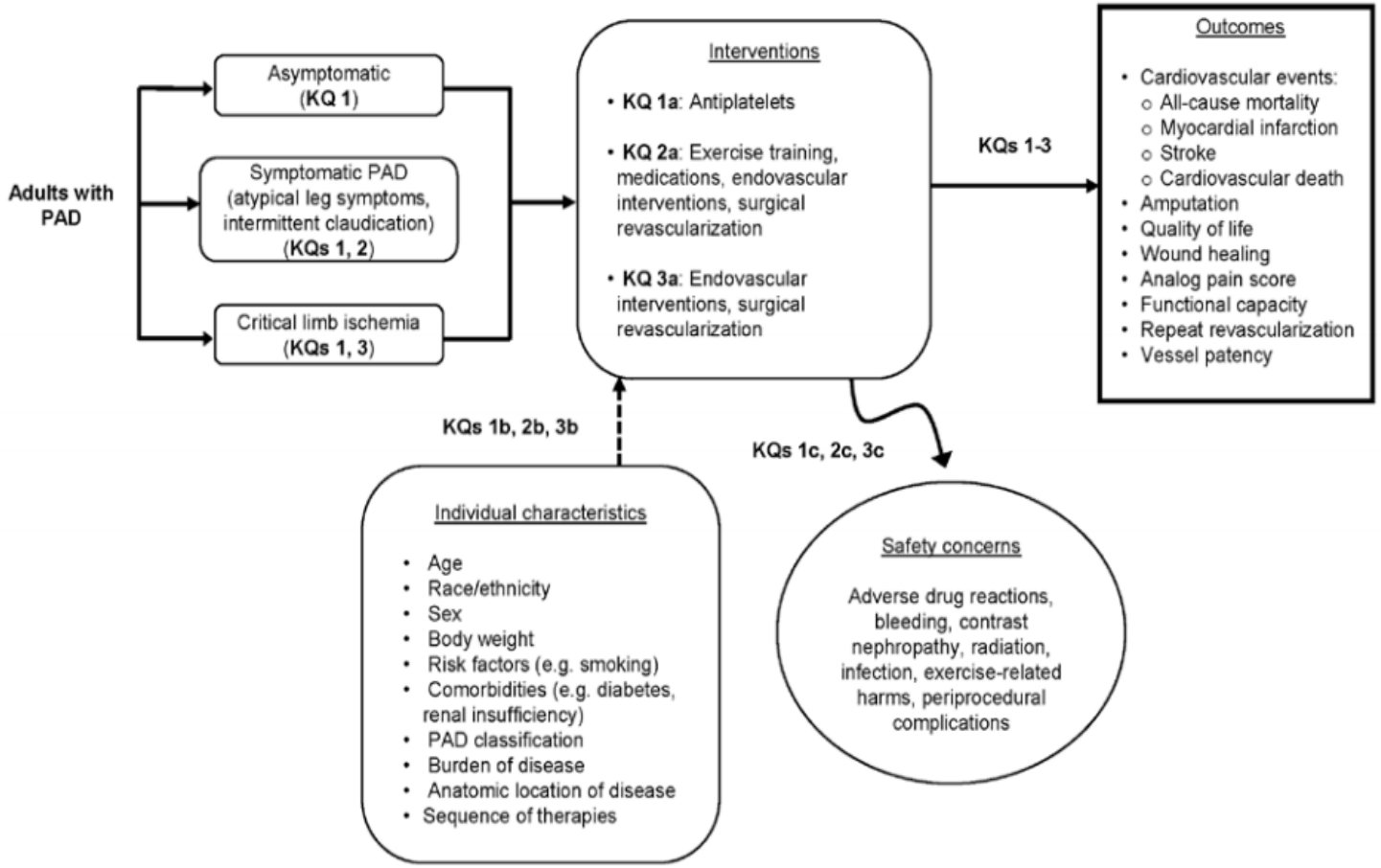


Fig. 1 Model of functional outcome in schizophrenia

Source: https://trialsjournal.biomedcentral.com/track/pdf/10.1186/s13063-015-0967-8

APPENDIX B – CONCEPT MAP EXAMPLES

Figure 1. Analytic framework



Abbreviations: KQ=Key Question; PAD=peripheral artery disease.

Source: https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/downloads/id70g.pdf

APPENDIX C – OUTLINE THE PROBLEM, EVIDENCE, AND PURPOSE

PARAGRAPH 1: THE HOOK Why is this topic important?
PARAGRAPH 2: THE EVIDENCE How does this study aim to fill the gaps in evidence?
PARAGRAPH 3: THE AIM What is the purpose of this research?

APPENDIX D – COMPREHENSIVE LITERATURE REVIEW

Year	Lead Author	Purpose/Topic	Inclusion Criteria/Design	*n*	Definitions	Significance	Results

APPENDIX D – COMPREHENSIVE LITERATURE REVIEW

Year	Lead Author	Purpose/Topic	Inclusion Criteria/Design	*n*	Definitions	Significance	Results

APPENDIX E – DATA VARIABLES LIST

DEMOGRAPHICS	HEALTH STATUS	PROCEDURE	INPATIENT	BILLING	OTHER

APPENDIX F – ANALYSIS PLAN

Research Question	Variables	Data Type	Analysis Method

Data Types: Nominal/Categorical (Gender), Ordinal (Survey Scale), Interval/Scale (weight/age)

APPENDIX G – DATA DICTIONARY (CODE BOOK)

Variable/Question	Variable Name (EHR label)	Response Options/Values

APPENDIX H – CHARTS AND GRAPHS TO REPRESENT YOUR RESULTS