The Pathway Project Mapping Tool-Assisting New Researchers in Writing Research Proposals

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Abstract

The purpose of this article is to describe the Pathway Project Mapping Tool (PPMT). The PPMT was developed to assist all levels of students/trainees in planning for and obtaining consultation on their research proposals. In addition, it intended for use by faculty charged with advising student research projects. The PPMT is divided into 25 sections, which together provides a comprehensive checklist and road map for proposal planning. The PPMT was developed by actively reviewing the content of established nursing research textbooks. In this paper, we describe each section of the PPMT in detail with examples and suggested additional resources, where applicable.

What is already known about the topic?

- New researchers, especially undergraduate and graduate students are often confused and face difficulties with the conceptualization and development of their first/early research proposals. Few tools exist that provide specific guidance to students and their advisors in the development of student research proposals.

What this paper adds

- This article presents the Pathway Project Mapping Tool developed for use by students doing research and faculty who are charged with advising student research projects.
- This article describes each section of the tool, providing examples and suggested additional resources, where applicable.

Keywords: nursing education, project mapping, research proposal, student research

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Introduction

The ability to conduct nursing research or practice-based studies is a core learning objective in nursing education at all levels. Despite the acknowledged importance of research in nursing education, few tools exist that provide structured guidance to students and/or their advisors in the development of student research proposals. To address this gap, we describe the Pathway Project Mapping Tool (PPMT), which can be used to assist all levels of student trainees in planning their research proposals. The PPMT was developed for use by trainees in planning their research proposals and as a guide for faculty charged with advising student research projects. The PPMT (Table 1) is divided into 25 sections that individually and collectively provide a comprehensive road map for planning and obtaining feedback on a new research proposal idea. The tool was developed using methods and content emphasized in established nursing research textbooks[1-3]. In addition, the tool incorporates the National Institutes of Health (NIH) research proposal review criteria, including significance, innovation, methodological rigor, and expertise[4]. Finally, specific examples were provided from the first author's (A.K.M) program of research on smoking cessation research among high risk populations. Each of the 25 sections of the tool are described in detail below. Where appropriate, illustrative examples and links to additional resources are provided.

1. Project Title

The title represents the first introduction of the research project to the reader. It should be concise and informative, reflecting key elements, such as the research design, study population and focus (e.g. key variable(s)). For example, in a series of studies examining a smoking cessation intervention for African Americans, the following titles could be used depending on the study focus or design.

Developmental research: *"Development of a group-based smoking cessation intervention for African American smokers."*

Descriptive study: *"Characteristics of participants enrolled in a smoking cessation intervention for African American smokers."*

Predictions or correlations: *"Substance use predicts smoking status among African American participants of an evidence-based smoking cessation intervention."*

Intervention testing: *"Results of a group-based smoking cessation intervention for African American smokers."*

2. Problem Statement

The initial step in developing a research proposal is to create the problem statement, which is an articulation of the specific problem that a researcher wants to either change (intervene on) or better understand (describe or predict). Students often struggle with identifying a problem area for their research; however, there are multiple strategies for identifying a research problem area. The first is nursing practice. Every day, nurses in clinical practice identity questions about assessment, treatment, prevention and cost-effectiveness of care. For example, poor adherence among clinical providers to practice guidelines stipulating consistent assessment and counseling of smokers is commonly observed in practice settings. As such, research projects aimed at addressing this practice issue are warranted and provide opportunities for new researchers. Another strategy for identifying a research area is to look at national and international health priorities. The World Health Organization, in conjunction with other nations, communicates the most pressing health issues confronting the global community (e.g., *https://www.who.int/news-room/feature-stories/ten-threats-to-global-health-in-2019).* An additional strategy is to build upon an advisor's program of research. All experienced researchers have multiple ideas about important next steps in their area of research and can be invaluable resources in establishing a focused problem area.

The following is an example of a problem statement related to high rates of smoking among African Americans in the United States:

"Smoking is the leading cause of preventable disease worldwide. In the United States, smoking rates among adults are at a 50-year low (14.1%)[5]. Despite the progress in reducing smoking in the general population, smoking rates remain elevated among some underserved populations. For example, in Chicago, smoking rates among low-income African Americans (AA) are significantly higher compared to low-income Whites (27.6% vs. 18.0%, respectively). Smoking contributes to or exacerbates a range of lung conditions including lung cancer, COPD, and emphysema. In Cook County, where Chicago is located, lung cancer rates among AA are significantly higher

compared to Whites (116.9 vs. 81.1 per 100,000 for men and 63.3 vs. 54.7 per 100,00 for women), especially in communities characterized by concentrated disadvantage. Further, the all-cause morbidity and mortality due to smoking is higher among AA smokers due to a higher prevalence of medical comorbidities. Combined, these inequities underscore the need for interventions aimed at reducing tobacco use among African Americans living in Chicago and similar urban areas."

3. Significance of the Problem

An important aspect of describing the research problem is to provide data supporting the significance of the problem to be addressed. As illustrated in the above example, the first sentence of the problem statement should explicitly identify the problem to be studied. The subsequent sentences should provide evidence for the significance of the problem and introduce any specific populations groups that are the focus for the study. Types of evidence that should be used to support the significance of the problem include information about *incidence/prevalence, morbidity/mortality, and health-care costs* to the individual, family or the larger healthcare system. For example, in the above section, the authors start by describing global data provided by the World Health Organization, then cite national data from the United States, and finally present local data from the City of Chicago as that is the location of the proposed study.

4. Theory Guiding the Project

Theory represents the basic underpinning of all nursing research. As such, early in the proposal development phase, the student needs to identify the theory(ies) that will guide or inform their study. In addition to well-established nursing theories, such as Human Caring[6], Transitions Theory[7], Theory of Unpleasant Symptoms[8], students can also use theories from their interprofessional/interdisciplinary colleagues, such as the Health Belief Model[9], the Theory of Planned Behavior[10], the Social Ecological Model[11], and the Integrated Behavioral Model[12].

In the proposal development phase, it is the researcher's responsibility to select and provide a clear rationale for the choice of theory. However, many beginning researchers express a poor understanding of the relevance of theories, the criteria for how to select a theory and limited knowledge about how to apply the theory throughout the research project[13]. In most cases, the selection of a theory will be based on those that have been traditionally used to conduct research in that area of research. For example, a majority of studies that examine the mental and physical health impact of discrimination due to a stigmatized identity status have utilized the Minority Stress Model[14] or the Intersectionality Framework[15]. Regardless of the theory, it is important that the theory clearly informs or aligns with all phases of the research study, including the research question, the literature review, the design, variable selection, and the analysis plan. Resources are available to provide additional guidance on understanding the importance of theory and ensuring the theoretical framework aligns with a project's goals and approach[16-17].

5. Knowledge Gap

A "gap" in the research literature refers to a content area that requires additional study to either better understand or to intervention on a problem[18]. For most subject areas, there will be a lot of unanswered questions given that multiple studies are required to fully understand a given problem area. In general, four types of research questions can be asked about any health problem:

- How often does the problem occur?
- Who is most likely to experience the specific health problem?
- What factors appear to/are known to cause or exacerbate the health problem?
- How can the problem be fixed?

The first type of question relates to the epidemiology of the problem, that is, *"How often does the problem occur?"* Questions related to the prevalence and/or increased incidence of a given health problem are essential to establishing the magnitude of the problem to be studied. The second type of research area relates to which demographic or clinical characteristics are associated with the problem, that is, *"Who is most likely to experience the specific health problem?"* Examining the characteristics of individuals who are experiencing a health problem can help to increase our understanding of individuals and population groups who are experiencing the problem at higher and/or lower rates. The third type of research area relates to understanding the mechanisms and pathways associated with the development of the health

problem. Here questions are focused on understanding, *"What factors cause or exacerbate the health problem?"* The final research focus area is related to intervention development and establishing, *"How can the problem be fixed."*

Gaps in the research literature may relate to one or more of the types of questions described above. In addition, information about important research gaps and next steps are routinely provided in published review articles. Below is an example of a gap statement related to smoking cessation research:

"The need for evidence-based interventions to reduce smoking disparities among African Americans is compelling; yet, little is known about the benefits of culturally targeted interventions for African American smokers or the effectiveness of existing group-based interventions in promoting tobacco use cessation in this population. This study addressed an important gap in the literature by comparing the effectiveness of a culturally targeted versus non-targeted smoking cessation intervention for African American smokers. Study results will have important implications for clinical practice and smoking cessation treatment development"

6. Innovation

The level of innovation associated with a research study has emerged as an important consideration for many funding agencies. For example, grant application guidelines from the National Institutes of Health (NIH) indicate that researchers should clearly describe how their study is innovative. According to the NIH, innovation represents "a challenge or shift to current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions." *(https://grants.nih.gov/grants/peer/critiques/rpg.htm.)* It can be challenging to succinctly and convincingly illustrate study innovations, especially for students/new researchers One suggestion is to begin with an introductory statement when writing one's innovation section, "The proposed study on [culturally targeted smoking cessation interventions] is innovative in the following ways…" Following this sentence, the investigator briefly describes of the nature of the innovation and supporting evidence of that innovation. Below is a sample innovation section:

*The proposed study on culturally targeted smoking cessation interventions is innovative in the following ways. First, **a mixed-methods research design** will be used to identify the relevant "surface" and "deep structure" cultural adaptations for African American smokers. Prior research studies have most often adapted interventions based on surface level cultural factors only. Second, the study will be **guided by the Minority Stress Model,** which for the first time will guide the incorporation of unique stressors experienced by African Americans which may serve as barriers to smoking cessation. Level of acculturation is not routinely considered as a moderator of outcomes associated with culturally targeted interventions. Given that African Americans are not a monolithic group, we will **examine the influence of acculturation** on outcomes associated with the culturally targeted intervention."*

7. Impact

An impact statement is a brief summary of the anticipated outcomes and significance of your research if successfully completed. This statement is used to convince different stakeholders (typically funders) of the value of your research. In most cases, an impact statement clearly describes the contributions of the research to a field of study (e.g., smoking cessation research). As part of the impact statement, it is important to describe who will benefit from your work and in what ways. There are potentially several levels of benefits including individual, organizational, community, and the research community. Below is a sample impact statement:

"If successful, the results of this research will significantly advance knowledge and understanding in the general area of smoking cessation research and more specifically on culturally targeted smoking cessation interventions for African Americans. This understanding has implications for guiding clinical practice and the methods and approaches used in this study have implications for the development and testing of culturally targeted interventions for other high risk populations (e.g., HIV+ smokers)."

8. Research Question

A research question identifies what specific question(s) will be answered by a study. The PICO approach is a specialized framework for forming research questions[19]. In this framework, PICO stands for **P**atient problem or population, **I**ntervention,

Comparison or control condition and **O**utcome. In non-intervention research, **E** is substituted for I and stand for Exposure or Experience. After identifying the main elements of the question using the PICO framework, the research statement can be written. For example, returning to the problem of tobacco use among African Americans, here is an example of using the PICO approach to develop a research question:

P = African Americans living in Chicago who are current smokers;

I = A culturally targeted smoking cessation intervention;

C = A non-targeted smoking cessation intervention and;

O = Quit rates.

The subsequent research question could be written as:

"Among African American smokers, does a culturally targeted smoking cessation intervention result in higher quits rates compared to a non-targeted smoking cessation intervention?"

9. Research Design

As shown in Table 1, there are many potential research designs that can be considered for a study, each with accompanying strengths and weaknesses[20]. The study design should align with the research question. The study research design statement is a blueprint which guides the collection and analysis of data[21]. To be effective, a research design statement should include: a statement of objectives of the study or the research output; a statement of the data inputs required to solve the research problem; and the methods of analysis can be used to analyze the data inputs[21]. Below is a sample description of a research design statement:

"A prospective 2-group randomized experimental design is proposed to test study hypothesizes related to the benefit of the culturally targeted Courage to Quit program versus the standard Courage to Quit program for African American smokers. Participants will be randomly assigned to the targeted or standard interventions. The primary smoking cessation outcome examines point prevalence abstinence. Quit rates will be objectively verified at 1, 3, 6, and 12-months post-treatment. Results will be analyzed to control for the impact of variables like income and education using a generalized linear regression model. Study activities have been approved by the Institutional Review Board of the University of Illinois at Chicago[22]."

10. Phase of Research

When intervention development is the focus of a nurse's program of research, a series of studies are needed to obtain preliminary data to inform intervention development. All intervention research can be thought of as falling into one of five separate phases. The first phase usually includes descriptive survey research or qualitative data collection to increase understanding of the factors contributing to a health problem. The second phase is aimed at obtaining formative research needed to develop or adapt an intervention. The third and fourth phases of intervention development research are to establish the feasibility of the intervention approach and to pilot test the intervention to obtain evidence of benefit. The final phase of intervention testing is to establish the efficacy of the intervention by conducting a rigorous randomized clinical trial.

The following references provide examples of research inclusive of each phase of the research process including descriptive[23], formative[24], feasibility testing[25], pilot testing[26] and efficacy testing[27]. The phase of research a specific project falls into is dependent on how much prior research has been conducted and what information is already known. So, in the case of our earlier example, numerous evidence-based smoking cessation treatments have been developed for smokers[28]. Although ample information exists about the smoking patterns of African Americans, less is known about how to target interventions to the needs of this population. As such, formative research and pilot testing would be required to develop culturally targeted information materials[29] and to conduct the feasibility and pilot testing prior to a full randomized clinical trial.

11. Target Population

Establishing the target population to be included in the research study is fundamental to proposal development. Inclusion criteria help to establish who will be in the study based on demographic (i.e., age, race/ethnicity, gender) or clinical characteristics (i.e., type of disease, severity of disease, treatment status). Alternatively, exclusion criteria describe the characteristics that make an individual ineligible for study participation (i.e., cognitive impairment). Researchers should provide an evidence-based rationale for both inclusion and exclusion criteria.

Many new researchers have questions about

whether a study sample should be homogeneous (all participants are the same on one or several key characteristics) versus a more heterogeneous sample (the sample approximates the diversity of the entire universe of potential study participants). The study sample is dependent on the research question. For example, if we wanted to establish the efficacy of a culturally targeted smoking cessation intervention for African American smokers, the inclusion criteria would be very broad such as: African American, ages 18-70, all genders, and English speaking. On the other hand, if the goal was to determine the efficacy of the intervention in a special population of African Americans, then the inclusion criteria would be more narrowly focused and inclusive of the additional characteristic of interest such as: African American, ages 18-70, male identified, diagnosis of early stage emphysema, and English speaking. It is important to note that there are pros and cons to either heterogeneous or homogenous samples. Jager, Putnick and Bornstein[30] provide additional reading on this topic.

12. Recruitment and Retention Plan

The ability to recruit and retain participants into a study is fundamental to the success of any project. As such, a substantial amount of thought must go into recruitment and retention planning. Failure to recruit and retain adequate numbers of study participants reduces the scientific rigor of the research conducted and the trustworthiness of results obtained. In many types of experimental research, recruitment goals are established by a priori sample size calculations (e.g. power analysis) that provide the optimum number of participants required to be able to arrive at ethically and scientifically valid results[31]. Failure to retain the needed number of study participants contributes to reduced power or trustworthiness as well as contributes to potential bias in the conclusions formed from the research study[32].

Common recruitment approaches include clinic-based recruitment, active/passive community outreach, and social media[33] *(https://www.ccts.uic.edu/content/priority-populations-toolkit)*. Clinic-based recruitment may include flyers and television announcements in the waiting room, letters to patients, and clinical staff referrals. *Active* outreach involves study staff traveling to locations and events where eligible participants are likely to be and distributing study materials. *Passive* outreach includes posting flyers in community locations, advertisements in printed publications, and messages to email lists. Recruitment using social media, such as Facebook and Twitter, have increasingly been found to be successful[34]. Any images in recruitment materials should be reflective of the demographic or clinical characteristics of the population targeted for recruitment[35]. Publicly available recruitment and retention guidelines and templates can be found at the following websites: *https://www.ccts.uic.edu/content/recruitment-templates; https://sc-ctsi.org/uploads/resources/recruitment_retention_toolkit.pdf.*

13. Research Setting

Establishing the research setting is another important decision in the proposal development phase. Although research can take place in an infinite number of settings, the most common types of physical locations include: clinical, community, or university settings. Historically, research has been conducted at universities or other research institutions. There are a number of benefits of such locations, including adequate resources and staff to conduct multiples studies simultaneously. Nevertheless, limitations with conducting research at university settings have also been noted, including the lack of diversity of study participants[36]. Currently, a lot of research is being conducted in clinical settings. Clinical settings include a variety of inpatient and outpatient health care locations. The advantage of conducting research in a clinical location is most evident when the study is focused on a specific medical population which can be easily accessed (e.g., patients with diabetes). Another alternative is to conduct the study in a community location such as churches or schools. Conducting a research study in a community location has a number of important benefits such as facilitating participation by offering the study in a convenient location. Limitations associated with community settings can include problems acquiring space for data collection, participant concerns about privacy, and the need to obtain buy-in from organizational staff about the importance of research. Establishing a community partner can help to overcome some of these limitations and help foster trust between community members and researchers[37-38]. In summary, there are pros and cons

to each type of research setting and the final decision should be contingent on the needs of the research study.

14. Measurement and Measurement Instruments

When a measurement instrument is used in research, it is important to remember that the better the measurement tool, the better the data and conclusions obtained. Where possible, researchers should use a validated measurement instrument for their research projects. The use of a standardized and well recognized measurement instrument is especially necessary if it is being used as the independent and/or dependent variables for the study. Beginning researchers often make the mistake of selecting a few questions from a larger measurement instrument, only using a specific subscale, or altering the instrument in substantial ways. In these cases, the measurement instrument is no longer valid.

Many alterations to standardized measures are made by researchers with the intention of reducing participant burden associated with completing the measurement instrument. To address concerns about participant burden, the National Institutes of Health have developed a series of brief measures for use in adult and pediatric populations. The Patient-Reported Outcomes Measurement Information System (PROMIS) is an initiative to validate patient reported outcomes (PROs) for clinical research and practice. PROMIS measures include brief measures of physical functioning, symptoms including fatigue and pain, and emotional distress, to name just a few. Many of the PROMIS measures have been translated into languages other than English and can be found at *https://www.healthmeasures.net/explore-measurement-systems/promis.*

An additional consideration in the selection of a measurement instrument is whether an objective measurement is required. Most nursing research rely on self-reported outcomes. However, depending on the research area and question, an objective outcome measure may be required. For example, in large survey studies, the scientific community has established that self-reported smoking status is fairly accurate[39]. However, the same is not necessarily true for self-reported outcomes associated with smoking cessation intervention research where significant discrepancies between self-reported and objective smoking status have been documented[40]. The same discrepancies have been found related to weight loss, obtaining early detection screening exams, and physical activity, to name a few. As such, obtaining objectively verified outcomes are considered the gold-standard for intervention and clinical research proposals[41]. Reviewing the literature in your area of research can help determine whether a self-reported or objectively verified measurement is the established best practice.

15. Measurement Time Points

The appropriate time point(s) for data collection is another important research consideration. In a cross-sectional research study, data collection will occur at one time- point only; while longitudinal studies occur over time. In pre-post-test designs, data collection occurs before the intervention, training experience or exposure (pre-test) and again afterwards (post-test); however, the study design and research question will influence when the post-test should occur. In the scenario in which the researcher is trying to establish whether a training resulted in an increase in knowledge or change in attitude, an immediate post-test measurement may be appropriate. However, in those research studies where the purpose is to test whether the training led to a specific behavior change or a lasting change in knowledge or attitude, a longer-term follow-up period may be required.

The best practice for intervention research is to establish both short- and long-term benefits of an intervention. As such, the gold standard for intervention research follow-up is immediate post-intervention and 6 and 12-months after completion of the study[42]. Nevertheless, longer-term assessment is not necessarily a requirement studies in which the objective is to establish the feasibility of the intervention[43]. Understanding the phase of the research study (developmental or efficacy testing), the study design, and the standards of similar research will help to establish when and how many follow-up assessments are required.

16. Sample Size Calculations

A commonly asked question from beginning researchers is, "How many participants do I need?" The answer is, "It depends." Participant sample sizes are dependent on the type of research design, the research question being asked, and the types of analyses to be conducted. In qualitative research

studies, participant sample sizes typically include 20-30 participants[44]. The primary goal in qualitative research is to carefully (e.g. purposefully) select participants in order to reach saturation - the point at which no new insights are generated, as the indicator of an appropriate sample size[44-45].

Determination of sample size in quantitative research differs in that it is calculated before the study. Consultation with a statistician is strongly advised in determining an appropriate sample size. Using published findings from similar types of research findings, will help the statistician understanding the anticipated margin of error, confidence level, and standard deviation[46]. This information will help to make sure that your study is sufficiently powered to detect differences or associations if they exist or to conduct complex multivariate analyses.

17. Plan for Missing Data

Missing data contributes to potential sources of bias, including inaccurate parameter estimates, decreased statistical power, increased standard errors, and weakened generalizability of findings[47]. A clear consensus on how much missing data is acceptable has not been reached; however, a general "rule of thumb" is that missing data of greater than 10% can negatively impact study conclusions[48-49].

Researchers have found that the best management of missing data is to reduce the likelihood of its occurrence[50-51]. Survey methodologists have identified several strategies for reducing missing data, including improving the format of questions, providing clear instructions[52], using computer assisted self-administered questionnaires[53] and pilot testing questionnaires to identity any potential problems with survey completion. However, some amount of missing data is inevitable and will need to be managed as part of the research process.

Dong and Peng[47] identified three aspects of missing item-level data that need to be understood in order to select an appropriate management procedure: how much data are missing, missing data mechanisms (missing at random, missing completely at random, and missing not at random) and the patterns of missing data (i.e., arbitrary missing data pattern). Historically, these data level issues have not been taken into consideration and many researchers have simply used listwise or pairwise deletion or mean substitution to create a complete dataset for analysis[54]. However, the American Psychological Association's Task Force on Statistical Inference warned against use of both of these approaches[55]. Instead, newer methods, such as the multiple-imputation (MI) method, the full information maximum likelihood (FIML) method, and the expectation-maximization (EM) method, take into consideration the conditions under which missing data occurred and provide better estimates for parameters than either listwise or pairwise deletion[56]. Resources are available for assisting new researchers in determining when and how multiple imputations should be used for handling missing data and should be consulted along with a statistician[56].

18. Analysis Plan

In qualitative studies, the specific analytical approach needs to be identified, cited, and outlined. Each approach has its own rules that need to be followed. For example, which type of qualitative content analysis will be used or will the researcher be using narrative analysis or constant comparison. In studies with quantitative data, a statistical consultation prior to study initiation is important to determine the following: an appropriate sample size, the plan for handling of missing data, and to establish a data analysis plan. The analysis plan should be created following consultation with a statistician and should include a plan for cleaning the dataset and addressing missing data. It should also describe the approach for creating scale scores for any standardized measurement instruments used as part of data collection. Measures of reliability (Cronbach's alpha) should always be conducted on all standardized measurement instruments used. A standard statistical analysis plan can consist of three parts, including descriptive analysis, bivariate analysis, and multivariate analysis. The first step in statistical analysis is to describe the data collected in the study. Performing descriptive analysis (e.g., using mean, standard deviation, frequency and percentage) can help a researcher to learn more and describe the characteristics of the study population. For example: *"In the African American smoking cessation study, the mean number of cigarettes smoked per day was 15 (SD = 3.1). The majority of study population were male (70%), married (60%), and had a high school or above (80%)."* After describing the study population, the next step is to identify what factors are associated with study outcomes. Bivariate analysis

(using tests such as chi-square test, independent t test, ANOVA test, Pearson's correlation test and non-parametric tests) can be conducted to examine if there is a significant association and/or difference between two variables (i.e., p-value). For example: *"An independent t-test was conducted to examine the difference in number of cigarettes smoked between African American males and females.* Results showed that the number of cigarettes smoked per day was significantly higher among males compared to females ($p < .05$). Furthermore, bivariate analysis can be used to identify a list of variables that have a significant impact on a study outcome that should be included in multivariate analysis.

Multivariate analysis (e.g., linear regression, logistic regression) is a statistical analysis that allows a researcher to predict the influence of several variables at once on the study outcome while controlling for the influence of each variable on the study outcome. For example: *"Results from a linear regression model showed that African American participants in the culturally-targeted smoking cessation program had a higher quit rate compared to those who participated in a standard smoking cessation program after controlling for demographic characteristics (i.e., age)"*. It is important for a researcher to select an appropriate bivariate test and multivariate test based on the study design, research question, and the measurement of variables.

19. Study Procedures

In order to establish the scientific rigor of a research proposal, a well-detailed methods section is required. The methods section is a step-by-step explanation of all phases of the research study including participant recruitment, eligibility determination and study enrollment, data collection and analysis. The procedures section is part of the methods section and describes, in detail, the "who", "what", "when", "where", "how" and for "how long" aspects of the study. The procedures section should be written in enough detail so that the study could be replicated by someone outside of the current research team. Figure 1 displays a sample flow chart that details the "high level" elements of the study procedures. In addition to the written description in the methods section of the research proposal, a similar type of figure should be included to help reviewers understand the general procedures of the study.

20. Appraisal Tool to Ensure Methodological Rigor

Bias refers to systematic errors in the design, conduct and analysis of research that impacts the validity of conclusions obtained from a research study. Currently, there are a number of tools to instruct researchers on how to evaluate the methodological quality of a study and to determine the extent to which a study has excluded or minimized the possibility of bias in its design, conduct and a nalysis. Examples of helpful tools include the Consolidated Standards of Reporting Trials (Consort) checklist, Joanna Briggs Institute (JBI) (qualitative and quantiative studies), Critical Appraisal Skills Program (CASP) (qualitative and quantitative studies), The Centre for Evidence-based Medicine (CEBM) and the Cochrane Collaborations Tool for Assessing Risk of Bias in Randomized Trials. Although originally designed to help researchers in critically appraising published research, these same tools are highly beneficial in understanding potential sources of bias that can be minimized in the proposal development phase.

21. Study Collaborators and Co-Investigators

It is very rare that one single person has all the relevant expertise to conduct all phases of a research project. As such, the identification and inclusion of research mentors, collaborators and co-investigators is an important aspect of a proposal development. Indeed, most grant reviewers evaluate the strength of the combined research team in making a determination of the likelihood of successful conduct of a proposed research project *(https://grants.nih.gov/grants/peer/guidelines_general/Review_Criteria_at_a_glance.pdf)*. As such, it is important to demonstrate that at least one person on the research team can either guide (serve as a consultant) or perform (serve as a study collaborator or co-investigator) each aspect of the proposed research project.

All projects differ in the types of expertise that are needed. However, the following areas should be considered when putting together a research team. The first is identifying a context expert. That is, someone on the team that has expertise in the primary focus of the study (e.g., smoking cessation) or the key independent (e.g., self-efficacy) or dependent variables (e.g., objective measurement of smoking status) to be examined. Depending on the research topic, the study team may also require a clinical expert, that is, someone with expertise with

a specific clinical population (i.e., nurse who specializes in emphysema). Another important member of the research team is someone who has expertise in the methodological approaches that are being proposed for the study. Methodological expertise can take many forms including expertise with the research design (e.g., randomized clinical trial), measurement approach (e.g., momentary ecological assessment), or intervention approach (e.g., smoking cessation counseling). Given the important role of statistical analyses, a member of the research team should also have expertise in statistics.

22. Study Timeline

Many beginning researchers under-estimate the time that it takes to recruit study participants and to perform data collection. As such, developing a detailed study timeline is very beneficial for mapping out what tasks need to be accomplished and how much time will be allocated to the completion of each task. In a timeline table, each of the major project activities should be listed for each year and approximate months of the study. Consultation with a study collaborator who has expertise in recruiting the target population will be invaluable for establishing realistic recruitment goals and ensuring that the study is completed in a timely manner.

23. Research Proposal Reviewers

Obtaining consistent feedback on your developing ideas for your research project as well as the final proposal is critical to becoming a successful researcher. Ideally, two to three experienced researchers should provide you with feedback on your proposal at multiple points in the development process. There are several types of individuals that should be considered when soliciting feedback on your proposal including your mentor, your study collaborators, and other experts in your field of research. Proposal reviewers should be asked to provide feedback on your problem area, research question, and study methods. Where possible, it is extremely helpful to get written feedback from reviewers and to have the opportunity to ask clarifying questions about critiques raised by reviewers.

24. Budget and Potential Sources of Funding

An important skill for new researchers is the ability to obtain funding to support their research. A range of funding sources exist for all levels of researchers including university or departmental funds, foundations, government, international agencies and pharmaceutical companies. When considering applying for a grant, it is important to understand the mission of the funding agency, who they are willing to fund, what types of projects they will fund, and how many projects they fund each cycle. The most successful applicants will be those whose projects align very closely to the mission of the funding organization.

Once a potential funding source has been identified, it is a good idea to contact the funder to confirm that your project is a good fit for the funding opportunity. In addition, it is beneficial to ask an experienced researcher to share a copy of a successful grant application for you to review. Next, and most importantly, it is imperative to review the grant guidelines for submission. Applicants that do not adhere to all grant instructions run the risk of having their applications rejected. Finally, persistence is needed in revising and resubmitting applications that are not initially funded.

25. Human Subjects

With very few exceptions, studies that involve human subjects require Institutional Review Board approval prior to initiation. The United States Department of Health and Human Services (HHS) provides guidelines for the conduct of research on human subjects *(https://www.hhs.gov/ohrp/)*. The ability of all subjects to provide informed consent is an internationally mandated criterion for research participation. In addition to protecting individuals with cognitive and intellectual disabilities, informed consent protects minors, pregnant women, and incarcerated individuals. The National Institutes of Health also closely monitors populations that have been systematically under-represented in research including women, children, and racial/ethnic minorities. In addition to increasing equity in terms of research participation, study samples that are representative of the larger population increase the generalizability of results obtained. Obtaining a consultation with members of the IRB at your university or hospital setting can help you to identity potential problem areas and the strategies to address them.

Table 1: The Pathway Project Mapping Tool

Project Title	Problem Statement	Significance	Theory Guiding The Project (when applicable)	Knowledge "Gap"
❑	❑	❑ Prevalence:.....	❑ Theory:.....	❑ .....
.....	.....	.....	.....	.....
.....	.....	❑ Mortality:.....	.....	.....
.....	.....	.....	.....	.....
.....	.....	❑ Morbidity:.....	.....	.....
.....	.....	.....	.....	.....
.....	.....	❑ Direct and Indirect Costs:....	.....	.....
		.....		

Innovation	Anticipated Impact	Research Question(s) and/ or Specific Aim(s)	Research Strategy	Phase of Research for Intervention Development
❑ Target Population	❑	❑	Qualitative	❑ Basic/Descriptive
❑ Conceptual Framework	.....	.....	❑ Focus groups	❑ Formative
❑ Methodological	.....	.....	❑ Interviews	❑ Feasibility Study
Approach	.....	❑	❑ Observation	❑ Pilot Test
❑ Statistical Analysis	.....	.....	Quantitative	❑ RCT
❑ Other:.....	.....	❑	❑ Descriptive survey	
	.....	.....	❑ RCT	
	.....	.....	❑ Pre/post test	
	.....	.....	❑ Quasi-experimental	
			Mixed Methods	
			❑ QUAL/QUANT	
			❑ QUAL/quant	
			❑ Qual/QUANT	
			Secondary Analysis	
			❑ National data	
			❑ Existing study data	
			❑ Hospital data	

Target Population	Recruitment Plan	Setting	Measurement/Instruments	Measurement Time Points
❑ Inclusion Criteria:	❑ Passive:.....	❑ Community:	❑ Demographic Variables:	❑ Single time point
.....	.....	❑ Clinical:	.....	❑ Pre/post
.....	❑ Venue Based:.....	❑ University:	.....	❑ Repeated measures
.....	.....	❑ Other:	❑ Control Variables:	
❑ Exclusion Criteria:	❑ Clinical Chart:.....		.....	
.....	.....		.....	
.....	❑ Social Media:		❑ Independent Variables:	
.....	.....		.....	
			.....	
			❑ Dependent Variables:	
			.....	
			.....	

Table 1: (cont.)

Proposed Sample Size & Rationale	RPlan for Missing Data (when applicable)	Proposed Analysis/ Statistical Analysis Plan	Data Collection Procedures	Appraisal Tool to Ensure Methodological Rigor
❑	❑	❑	❑	❑ JBI
.....	.....	.....	.....	❑ CEBM
.....	.....	.....	❑	❑ CASP
.....	.....	.....	.....	❑ Cochran
.....	.....	.....	❑	❑ Other: .....
.....	.....	.....	.....	

Study Collaborators and Co-Investigators	Study Timeline	Reviewers	Budget and Sources of Funding	Human Subjects Concerns
❑ Content:	❑	❑	❑	❑ .....
❑ Methods:	.....	❑	.....	.....
❑ Statistics:	.....	❑	.....	.....
❑ Community partner:	.....		.....	.....
.....	.....		.....	.....

Key questions to be answered during consultation:

1. .....
2. .....
3. .....

Notes:

.....

.....

.....

Conclusions

The proposed development tool described in this paper provides a summary of essential elements to consider in planning for a rigorous research proposal. Although the Pathway Project Mapping Tool provides general guidance in proposal development, indepth details about each type of research design or methodology (i.e., qualitative research methods) is beyond the scope of this paper. The current tool can be adapted to more specifically plan for specific types of methodologies such as qualitative research. Further, efforts should focus on evaluating the benefit of the PPMT as a supplemental educational approach to teaching standard research proposal development.

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