

Articulating the “So, What?” in Clinical Research: Insight from the M-CHOIR Group

You J. Kim, BS
Shale J. Mack
Kevin C. Chung, MD, MS

Summary: With the academic culture of “publish or perish,” authors must ensure that they are delivering high-quality data with a meaningful impact on clinical practice. Even for physician–scientists at the top of their fields, establishing the relevance of a study to clinical practice is a challenge. Thus, it is essential that research proposals ask questions that are clinically important, use appropriate methodologies, and examine outcomes that are relevant to both the physicians and the patients. The question of “so, what?” or in other words, “who cares?” is one that can make or break a study’s impact on clinical practice. Researchers should use models such as PICOS (Population, Intervention, Comparison, Outcomes, and Study design) and FINER (Feasible, Interesting, Novel, Ethical, Relevant) and ask why readers will care about their study’s findings before the study is conducted. By doing so, researchers can ensure the successful execution of their study and a meaningful impact of their findings, in both academia and clinical practice. This Special Topic article aims to guide researchers in producing relevant, impactful conclusions of their studies by providing input and resources from the Michigan Center for Hand Outcomes and Innovation (M-CHOIR) group. (*Plast Reconstr Surg Glob Open* 2020;8:e2848; doi: [10.1097/GOX.0000000000002848](https://doi.org/10.1097/GOX.0000000000002848); Published online 21 May 2020.)

INTRODUCTION

A cost-analysis of the various types of implants for proximal interphalangeal (PIP) joint arthroplasty, particularly the costs associated with complications and recurrent surgeries.

—An idea proposed by the M-CHOIR team members.

At first glance, this project is seemingly a good research question with an obvious cohort of patients, a clear objective in mind, and a vision of how it will be executed. However, a thorough breakdown of this research question demonstrates a clear lack in the understanding and consideration of the basic elements of research that separate the realistic, intriguing research questions from the fantasy world (Fig. 1). First, a *cost-analysis* is not a recognized term in economic analysis. The researchers may have wanted to conduct a *cost-effectiveness* or *cost-benefit analysis*, but the identification of this study as a *cost-analysis* discredits the researcher and demonstrates to the journal editors,

reviewers, and other colleagues that the authors are not familiar with economic modeling. Second, there is no database that will show the complications associated with proximal interphalangeal (PIP) joint arthroplasty, which hinders the feasibility of this study. Most large databases are administrative in nature for billing purposes and are devoid of accurate clinical information. Finally (and considerably, the most important critique of this research question), it is well known that complications and recurrent surgeries will cost more, regardless of the condition, treatment, or patient.^{1,2} Thus, researchers are challenged with the most critical questions: “Do I need to conduct this study when the answer is obvious? How will this excite anyone? So, what?”

“SO, WHAT?”

Eighty-five percent of medical research is wasted.³ As research waste remains an issue in the health sciences, there are several initiatives to promote quality over quantity.⁴ In the past few decades, the number of publications in the plastic surgery literature has more than doubled.⁵ Although the quantity of plastic surgery publications has doubled, the quality has not changed.^{6,7} For instance, a citation analysis of the top 50 cited articles in plastic surgery showed no correlation between level of evidence and

From the Section of Plastic Surgery, Department of Surgery, University of Michigan Medical School, Ann Arbor, Mich.

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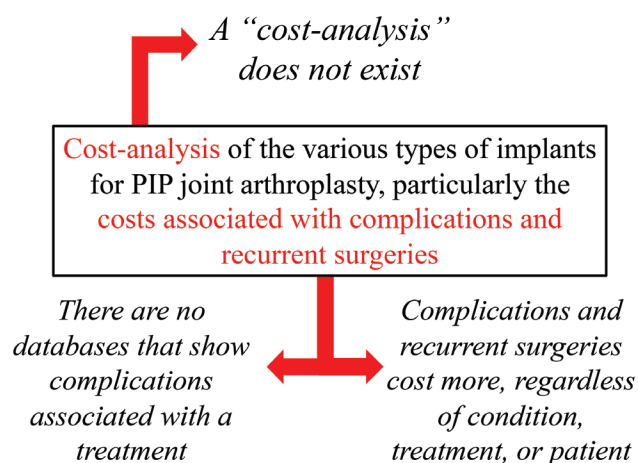


Fig. 1. The breakdown of a failed research proposal.

number of citations.⁶ The authors found that >80% of the articles are considered as level IV or V evidence and that no studies of level I or II evidence are present in the top 50.⁶ With an increase in the number of publications, researchers must understand that the relevancy, influence, and overall *quality* of each article are important factors to consider. Researchers in the health sciences can ensure the delivery of high-quality research by optimizing methodology, generalizability, and relevance, among other factors. Developing a research project with an effective methodology, meaningful results, and an impactful conclusion is not an easy task. In particular, executing a project with meaningful results that can be translated into clinical practice is a challenge among many physicians. Bridging the gap between clinical research and clinical practice is a challenge seen in many specialties, not just in plastic surgery.⁸ In fact, the American Psychological Association launched a special section series in *Psychotherapy* to provide strategies to integrate research into clinical practice.⁸ As physicians, the responsibility lies in searching for evidence and applying it to their practice. As researchers, one must provide evidence that is not only applicable to practice, but feasible and relevant to patients. Thus, researchers must ask themselves constantly, “So, what? Who cares?” and be able to provide the answers to these 2 questions to ensure successful study execution.

A challenge that researchers may face is the ability to identify the “relevance, significance, and wider value of their writing.”⁹ Certainly, this is a challenge for the members of the Michigan Center for Hand Outcomes and Innovation Research (M-CHOIR) group. As the research arm of the University of Michigan Comprehensive Hand Center, M-CHOIR aims to conduct clinical and health services research that will advance the field of hand surgery with a comprehensive application of the full spectrum of research designs, including decision analyses, large database studies, and clinical trials. In the past year alone, M-CHOIR has published over 45 articles in 14 journals, including *JAMA Surgery* and *JAMA Network Open*, and received a National Institutes of Health (NIH)-funded U01 grant for a multicenter randomized clinical trial. With an aspirational value to deliver high-quality research efficiently and promptly, the members of

M-CHOIR implement different strategies to ensure execution of impactful studies. The M-CHOIR team comprised researchers from varying levels and phases in career, including undergraduate students to senior surgeons. Thus, the team members may experience challenges in research design and implementation, especially as junior members learn how to formulate and execute clinical research studies that are impactful and novel. We have strategized and exercised different methods to overcome these challenges. In this Special Topic article, we offer those strategies and provide several examples in (1) drafting a “first page”; (2) critically asking evaluative questions; and (3) devising relevance from the published literature to answer a vital question in clinical research: “So, what?”

CONCEPTUAL MODELS

Conceptual models provide a visual representation of theoretical constructs or variables, which can be translated into action. In clinical research, conceptual frameworks can be used to generate a proposal that ensures the successful execution of the project. For example, Sterbenz et al¹⁰ developed a conceptual model depicting an approach to develop strategies for an effective team. In this model, the authors guide team members in how to strategize and execute a plan to reach a shared goal, leading to desired outcomes.¹⁰ To develop an effective research proposal, researchers must think along the theories of this conceptual framework and ask themselves, “Why?” In the book *Start with Why*, the *New York Times* bestselling author Simon Sinek introduces the idea of the “Golden Circle” to represent the “naturally occurring pattern, grounded in the biology of human decision making.”^{11,12} This concept emphasizes the importance of the “why” before considering the “how” and “what.” Similarly, in clinical research, researchers must know the purpose of their research question before considering how the study will be implemented or what it will do. Following this idea, M-CHOIR uses 2 models to detail a study plan: FINER (Feasible, Interesting, Novel, Ethical, Relevant) and PICOS (Population, Intervention, Comparison, Outcomes, and Study design).^{13–15} Implementing these 2 conceptual models ensures that the 5 Ws (Who? What? When? Where? Why?) and How are answered.

FINER

Following Sinek’s idea of the “Golden Circle,” the framework FINER encourages researchers to consider the “why” of their research proposal.¹² Hulley et al¹³ introduced the concept of *FINER*, which ensures that a study idea is *Feasible, Interesting, Novel, Ethical, and Relevant* (Fig. 2). First, *feasibility* considers the adequacy of participants, technical expertise, affordability in time and money, and manageability.¹⁶ This is an important aspect to consider in larger clinical trials, such as randomized controlled trials. Pilot and feasibility studies can be used to “test-drive” the methodology of a study, identifying any issues or areas of weakness before launching the clinical trial.¹⁷ Second, a study that is *interesting* and *novel* ensures that the study’s results will add new insight to the scientific

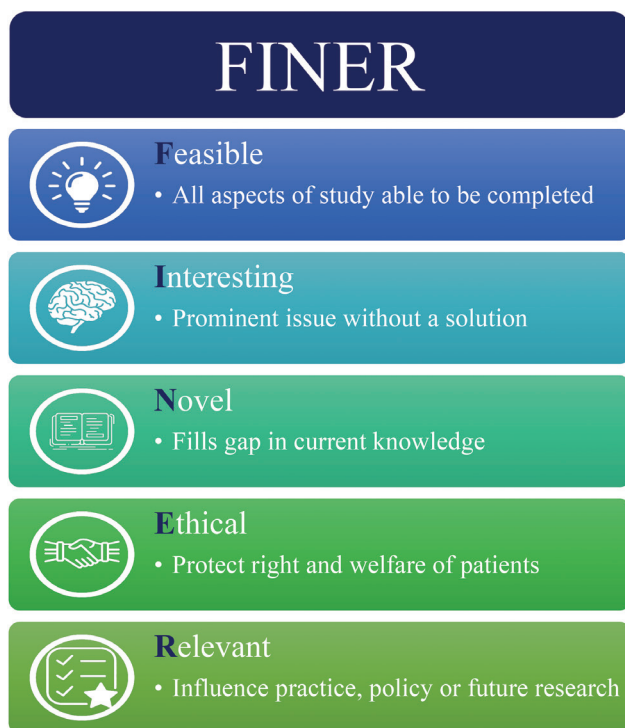


Fig. 2. The FINER model.

literature and be intriguing to the researchers.¹⁶ Third, *ethical* studies guarantee that they will follow institutional review board guidelines and national policies to ensure the optimal safety of study participants.¹⁶ Finally, developing an interesting, novel research question is not a challenge because most researchers pursue topics in which they have a natural interest. However, the challenge for most researchers comes in establishing the last element of FINER: *relevancy*.¹⁶

PICOS

Whereas the FINER framework depicts the development and purpose of a proposal, PICOS provides the answers to the “how” and “what.”^{12,14} *Population*, *Intervention*, *Comparison*, *Outcomes*, and *Study design* are the 5 main categories within *PICOS*.^{14,15} *Population* refers to the patients who are being studied or the condition that is being observed, clearly indicating the eligibility criteria for the study.^{14,15} Whereas the *intervention* is the new treatment, therapy, or surgery that is being tested, the *comparison* is the treatment, therapy, or surgery that serves as the “control” group.^{14,15} Furthermore, the *outcomes* are the endpoints that are used to measure the effectiveness of the different treatment groups.^{14,15} Finally, the *study design* includes the methodology and the statistical design, which will determine the level of evidence of the project.^{14,15} Figure 3 provides additional details about the PICOS model. A viable research question should address all components of PICOS. For instance, Figure 4 displays the impact statement from an article published by M-CHOIR, identifying the 5 elements of PICOS.¹⁸

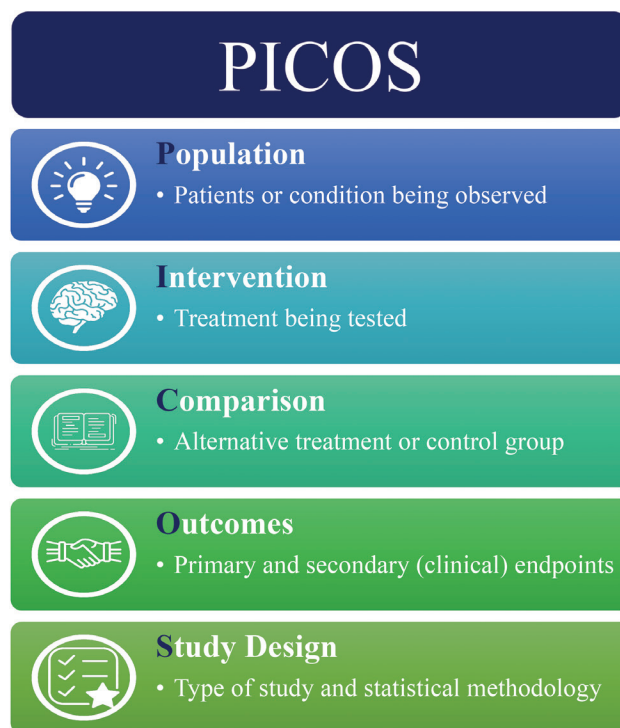


Fig. 3. The PICOS model.

MINIMIZING “RESEARCH WASTE” AND ESTABLISHING CLINICAL RELEVANCE

The goal of clinical research is to improve the delivery of health care to patients.¹⁹ Thus, researchers must address questions that are prioritized by the health care community and examine outcomes that are important to both physicians and patients.³ However, clinical trials may be subject to “research waste” by inadequate planning and incomplete reporting of outcomes.²⁰ “Research waste” can be seen in various ways throughout the proposal and execution of a project. For instance, Chalmers and Glasziou³ identify 4 successive stages of research that are subject to waste: the research question, design and methodology, accessibility of publication, and the quality of research reporting. As professionals who prioritize patient-centered care, researchers should aim to include the input or consideration of patients when developing their research

*The purpose of this systematic review (S) is to demonstrate the effectiveness of each anti-osteoporotic drug (I/C) in preventing secondary fractures (O), and determine which one is the most effective for patients with osteoporotic fractures (P). The outcomes of this meta-analysis (S) can be used to guide clinicians to better understand which types of drugs are most useful for preventing subsequent fractures.**

Fig. 4. Example of research question emphasizing PICOS and clinical relevance. *Saito et al¹⁸.



Fig. 5. Steps to execute a successful research proposal.

protocol. [Figure 5](#) displays the steps that should be taken to ensure a successful study execution.

Relevancy is established by considering the impact of the study's findings to scientific knowledge, clinical and health policy, and future research.¹⁶ The NIH prioritize 3 arms of research: health, society, and scientific knowledge. Their website states "...[The] NIH **improve health** by promoting treatment and prevention, **contribute to society** by driving economic growth and productivity, and **expand the biomedical knowledge base** by funding cutting-edge research and cultivating the biomedical workforce of today and tomorrow."²¹ As the largest funder of biomedical research, this vision should be embodied by researchers in the health sciences to ensure that their study is relevant to health care professionals, patients, and scientists and establishes impactful conclusions.²² Cruz Rivera et al²³ define research impact as "any identifiable benefit to, or positive influence on, the economy, society, public policy or services, health, the environment, quality of life, or academia." Authors should be able to apply their study's empirical findings to a more general idea, providing insight into how their results could make a broader, societal influence. By doing so, authors can minimize research waste to ensure real improvements in health care practice.²⁴ Saito et al¹⁸ establish relevancy in their research question by emphasizing the impact that their study will have on clinical practice: "...to guide clinicians to better understand which types of drugs are most useful for preventing subsequent fractures" ([Fig. 4](#)). Stating this impact directly provides readers with a clear understanding of the societal effects that the study will have.

THE “FIRST PAGE”

Before the start of any research project, the members of M-CHOIR create a “first page” of a NIH grant, whether additional funding is needed or not. In a previous publication from the M-CHOIR group, Sterbenz et al¹⁰ provide insight into the purpose of a “first page,” which is to establish relevancy, define project aims, provide hypotheses,

and state any projected conclusions or impact of the study.¹⁰ Sterbenz et al¹⁰ provide an example to show readers how the “first page” should be formatted: (1) an introductory paragraph discussing what is known, any gaps in knowledge, and the proposed project; (2) a section identifying the aims and hypotheses; and (3) a final section stating any conclusion and impact statements.¹⁰ As seen in the requirements of a “first page,” the members of M-CHOIR are challenged to state the projected conclusion and impact statements of their proposed study before execution. Over the past few years, the expectations of the “first page” have changed to represent several pages of justification, establishing relevance, and considering the impact and implications of the projects. As seen in [Figure 6](#), researchers are entrusted to consider the current state and gap in knowledge, the relevance and impact, the methodology, the potential limitations and biases, and the main take-home points and implications. This exercise informs researchers to practice writing effective and successful grant proposals. However, it also motivates members of the team to think about the clinical relevance of the study before it is executed. By doing so, researchers are keeping in mind the “So, what?” before the study even begins. Some of the questions that should be considered when establishing the “So, what” are outlined in [Figure 7](#).

What Is the Current State of Knowledge? What Is the Gap in Knowledge?

The answer to these questions requires a reflective evaluation of what is known in clinical practice and an extensive search of the literature.²⁵ Without a thorough search, researchers may fail to recognize studies that have already been conducted and published with the same research question. Furthermore, a search of the current evidence may guide researchers in formulating their study question and choosing the appropriate methodology. As a growing field, plastic surgery researchers should find the areas in which there lacks evidence and data. For instance, Waljee et al²⁶ conducted a national, population-based study to examine the utilization of opioid analgesics

Quality Metrics for Hand Surgery: A Systematic Review

What is the current state and gap in knowledge?

- The quality of health care delivery is difficult to define and measure, especially for surgical subspecialties such as hand surgery. Hand surgeons face a unique challenge because the traditional measures, such as mortality and length of hospital stay, are not applicable to the specialty itself.¹
- Quality assessment in hand surgery is usually dependent on patient-reported outcomes, such as satisfaction and health-related quality of life, and functional measures, such as grip strength, key pinch, and range of motion.
- Donabedian classifies the quality of care under three categories: structure (attributes of the settings in which care occurs), process (what is actually done in giving/receiving care), and outcome (effects of care on the health status of patients).²
- Birkmeyer et. al expand further on Donabedian’s ideas by stating that measuring quality depends on two factors: (1) the baseline risks of the procedure and (2) how commonly is performed at individual hospitals. A quadrant model is used as a visual representation, placing procedures on a spectrum of risk vs. volume: (1) high-risk and low volume, (2) high-risk and high-volume, (3) low-risk and low-volume, and (4) low-risk and high-volume.³
- Hand surgery is a field that prioritizes function and aesthetics. Thus, hand surgeons tend to rely on outcome-based metrics to assess the quality of care. However, little is known about the structure- and process-based assessments that are used in hand surgery.
- For hand surgery, there are four domains that seem to encompass the majority of the quality metrics used in assessing care: safety, outcomes, satisfaction, and cost.¹

So, what? Who cares?

- Healthcare is transitioning from a fee-for-service to a value-based reimbursement system and is becoming more transparent to physicians, payers, and most importantly, patients.
- There is a national sense of urgency to start measuring quality using different methods. For example, the Centers for Medicare and Medicaid Services (CMS) is now using excess readmission rates to measure performance for certain conditions and procedures.⁴
- Some believe that quality of care is equivalent to the impact and effectiveness of the health care service. Although this is correct, quality of care should also be measured by the capacity to deliver such care (structure) and how that care is maintained (process).
- The traditional outcomes-based metrics, such as mortality, are no longer sufficient to develop a complete picture of the quality of health care delivery. This is particularly the case for subspecialties that consist of mostly out-patient cases, such as hand surgery.
- Other fields have used structure- and process-based metrics to assess the quality of care, including hospital volume and ratio of providers to patients. Using Birkmeyer’s method of assessing risk and volume of procedures, hand surgeons must understand how these assessments can be measured in their specialty, specific to each procedure.

Research Question: What are the quality metrics that are used in hand surgeries and what is the prevalence of structure, process, and outcome quality metrics in such studies?

Hypothesis: Outcome quality metrics are the most prevalent in studies involving hand surgeries.

How can it be done?

- Study design: Systematic review via DistillerSR
- Study population: Studies from PubMed and Embase databases

Aims:

1. To review the literature and identify the quality metrics used for hand surgery.
2. To determine the prevalence of structure, process, and outcome quality metrics used for elective procedures in hand surgery.
3. To determine in which domain the associated quality metrics are classified: safety, outcomes, satisfaction, and cost.

What are the bias and threats to validity? Can you address the reviewer’s critiques?

- Heterogeneous nature of the included studies is a limitation – we try to minimize heterogeneity by limiting our search to include only RCTs, cohort studies, and case series
- How do you know that you are capturing all hand surgery-related studies that examine quality metrics? With every systematic review, it is not feasible to capture all relevant studies. Furthermore, we only use two databases and we exclude non-English publications. However, a detailed search strategy was created with a librarian to ensure an exhaustive search of the hand surgery literature, resulting in over 5,000 references for our review.
- There is no standardized tool to assess the development of a quality metric – according to the CMS, quality measures are in a constant cycle of conceptualization, specification, testing, implementation, and maintenance, use, and validation. Our review will only include metrics that are at least in the implementation stage of this cycle. Thus, we can be sure that these metrics are in routine use for quality improvement.
- Not all hand surgeries are captured and assessed according to Birkmeyer’s model measuring risk and volume...why? As it is not feasible to conduct a systematic review including all hand surgeries, the procedures that are represented in Birkmeyer’s quadrant represent the data that was extracted from our search. A possible explanation for the lack of certain procedures could be that there are no relevant RCTs, cohort studies, or case series involving X procedure (this is particularly the case for low-volume, traumatic cases).
- The time frame for your search includes 2011 to 2018, why? The Affordable Care Act (ACA) was signed into law in 2010, increasing the rate of health care coverage for Americans. Furthermore, the ACA established the Hospital Readmission Reduction Program in 2012, requiring policymakers to examine non-traditional metrics, such as readmission rates, as a measure of quality. Our review will focus on studies that were published after the implementation of this law in 2010.

Main take-home points:

- Our review identifies the metrics that have been used to measure the quality of care in hand surgery since the implementation of the ACA. The majority of studies measures outcomes, which indicates that there is a need for more quality metrics that assess the structure and process of procedures in the field of hand surgery. As a specialty that consists of mainly out-patient cases, structure and process metrics can be implemented easily with quick results.

Implications:

- Quality is not only measured with the final outcome but includes the characteristics and process leading up to and during the treatment itself.
- Structural, process, and outcomes measures each have unique strengths and weaknesses in their ability to capture the quality of care. Thus, surgeons and policymakers must have an understanding of all three types of metrics to know what is best for certain procedures to provide precise, patient-centered care.

Fig. 6. Example of a “First Page.”

following common upper extremity surgery. The authors report that there is an abundance of research regarding the prevalence of opioid use among patients undergoing orthopedic surgery.²⁶ However, there is little evidence regarding the use of opioids after ambulatory services, such as hand surgery.²⁶ In the introduction alone, Waljee et al²⁶ cite 23 different references to allude to the evidence that exists in the current literature.²⁶ In addition, Fracol et al²⁷ evaluated women after subpectoral implant-based breast reconstruction. The authors present evidence that the use of this particular surgery is growing, but the evidence regarding patient-reported outcomes is scarce. Furthermore, the authors provide 2 studies that have examined patient-reported outcomes, but state that there are no outcomes studies assessing patient satisfaction with validated questionnaires. By explicitly stating the gaps in

knowledge, the authors assured readers of the relevance and need for their study.

How Will We Contribute to the Gap in Knowledge? Why Will Readers Care about Our Findings?

The methodology and outcomes of a study are important elements of the “So, what?” to establish relevancy to the health care community. For instance, the treatment options for PIP joint osteoarthritis have changed in the past few years.²⁸ With multiple treatment options emerging, there are a variety of factors that can be examined, such as patient preference, cost, and postoperative complications, among others. However, researchers should be cautious in designing research questions with outcomes that may not be of major importance to the readers and



Fig. 7. Questions to consider while writing the “First Page.”

ask themselves, “What factors do patients and physicians care about?”

A reflection of what is seen in everyday clinical practice is necessary to inspire the questions that are of high clinical importance.³ For instance, procedures such as breast reconstruction may be costly and require a longer inpatient stay than other plastic surgery procedures. Typically, cost and outcomes can be considered the top 2 priorities of patients. Thus, a cost–utility analysis of inpatient flap monitoring is helpful to understand the point at which the costs start to outweigh the outcomes.²⁹ However, other procedures such as PIP joint surgery may not need this type of analysis because it is not costly enough to be a concern for patients. Thus, researchers should consider other factors and outcomes of the surgery that may be of interest to patients. For example, Harris et al³⁰ conducted a conjoint analysis of patient preferences in PIP joint surgery. Whereas cost may not be a factor in a patient’s decision, other factors such as joint mobilization, reoperations, and strength may strongly influence a patient’s desire for one treatment over another. Although the study’s empirical findings are important, the clinical implications of the study are what contribute to the gap in knowledge. Surgeons can use the findings of this conjoint analysis to gain insight into how osteoarthritis patients make decisions regarding their treatment options. Although physicians may rely on their own opinions and experience with patients, the authors are able to provide real evidence to augment the clinical expertise of the physicians.

USING THE LITERATURE

Establishing the “So, what?” of a research project is certainly a challenge, but there are various sources that may assist researchers in this rigorous process. A source of evidence to not only guide clinical practice but inspire future research is systematic reviews and meta-analyses.³¹ Particularly in clinical research, systematic reviews and

meta-analyses provide the highest quality evidence for decision-making.³² Systematic reviews answer a clear, clinically relevant research question and conduct a systematic, thorough search of the literature to answer that specific question.³² Furthermore, they provide a synthesis of the current evidence in the literature, interpret those findings, and address the strengths or weaknesses of those findings.³² By providing this analysis, researchers could use the results of systematic reviews and meta-analyses to identify knowledge gaps in the literature clearly and precisely. For example, Chan et al³³ conducted a systematic review to compare the outcomes of silicone and pyrocarbon arthroplasties for patients with PIP joint arthritis. The authors were able to synthesize the literature to conclude that pyrocarbon arthroplasty does not demonstrate any clear benefits over silicone implants. However, the authors are also able to demonstrate the lack of evidence in the literature that examined the quality-of-life outcomes of patients who undergo PIP joint arthroplasty, particularly using validated measurement tools.³³ Thus, the authors are able to not only answer their primary research question with a systematic search of the literature but they are able to identify clear gaps in the literature regarding these treatments.³³

In addition to the use of systematic reviews, the M-CHOIR group has conducted root cause analyses to understand the cause of a failed proposal on Dupuytren contracture.³⁴ The authors used the 5-whys method, which forced researchers to ask themselves the question “why” at least 5 times to assess the cause and effect relationship of a failed study proposal.³⁴ The authors identified a few take-away points from this exercise: (1) the possible conclusions derived from the analysis will not differ; (2) previous studies have conclusions that provide more insight; (3) there is insufficient depth of analysis and clinical details; and (4) there is a lack of knowledge about the limitations of the dataset.³⁴ By using a root cause analysis, researchers may prevent the failure of projects before time, money, and resources are wasted to conduct the study.³⁴

CONCLUSIONS

With the push for evidence-based medicine, research proposals should ask important clinical questions using the appropriate methodology and relevant outcomes. However, researchers should take caution in not only considering the clinical questions that may be of interest to them but those that are relevant to their colleagues, patients, and other health care professionals. Using models, such as PICOS and FINER, may seem elementary in practice but they are essential in developing a research proposal. Applying the correct methodology, choosing the relevant outcomes, and establishing the study’s relevance to clinical practice, health policy, and academia are not easy challenges to overcome. Considering the broader sense of *why*, they are asking the question that is being asked and *why* it is relevant will be essential in translating a study’s findings to clinical practice. “So, what? Who cares?”...the constant presence of these questions will drive a proposal through to successful execution.

Kevin C. Chung, MD, MS

Section of Plastic Surgery

Department of Surgery

The University of Michigan Health System

1500 E. Medical Center Drive

2130 Taubman Center, SPC 5340

Ann Arbor, MI 48109

E-mail: kecchung@med.umich.edu

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