What is your research question? An introduction to the PICOT format for clinicians

John J. Riva, BA, DC†
Keshena M.P. Malik, BSc, DC¶
Stephen J. Burnie, BSc, DC, MSc‡
Andrea R. Endicott, LLB, MPPAL£
Jason W. Busse, DC, PhD§*

Introduction

Clinicians often witness impressive treatment results in practice and may wish to pursue research to formally explore their anecdotal experiences. The potential to further new knowledge both within the profession and to the greater healthcare system is compelling. An obvious next step for a practitioner considering research is to connect with experienced researchers to convey their idea for a study, who may in turn ask, "What is your research question?" With limited understanding of how to respond, this interaction may result in the first and last experience these clinicians will have with the research community.

It has been estimated that between 1% and 7% of the chiropractic profession in Canada is engaged in research.[1,2] Arguably, this low engagement could be the result of practitioners' perceived importance of research and levels of research literacy and capacity. However, increasing demands for evidence-based approaches across the health system puts pressure on all clinicians to base their decisions on the best available scientific evidence. Lack of clinician representation in research has the probable effect of limiting growth and new developments for the profession. Furthermore, lack of clinician involvement in research complicates the transfer of study findings into practical settings.

The Canadian Institutes of Health Research describes integrated knowledge translation as a process that involves collaboration between researchers and knowledge users at all stages of a research project.[3] This necessitates involvement of clinicians to help in forming a research question, interpreting the results, and moving research findings into practice. This shared effort between clinicians and researchers increases the likelihood that research initiatives will be relevant to practice.[3] Conversely, it has been reported that there is a growing communication gap between clinicians and academics in chiropractic.[4] Clinicians have important practice-related questions to ask, but many may lack the ability to map out their research strategy, specifically in communicating their question in a manner required to develop a research protocol.

David L. Sackett, Officer of the Order of Canada and the founding Chair of Canada's first Department of Clinical Epidemiology & Biostatistics at McMaster University, highlights the importance of mapping one's research strategy in exploration of the research question: "one-third of a trial's time between the germ of your idea and

† Department of Family Medicine, McMaster University, Hamilton, Ontario.
¶ Graduate Student, Department of Rehabilitation Sciences, McMaster University, Hamilton, Ontario.
‡ Canadian Memorial Chiropractic College, Toronto, Ontario.
£ Senior Policy Analyst, Ontario Chiropractic Association, Toronto, Ontario.
§ Institute for Work & Health, Toronto, Ontario.
* Department of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, Ontario.

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Correspondence: Dr. John J. Riva, Department of Family Medicine, McMaster University, McMaster Innovation Park, 175 Longwood Road South, Hamilton, Ontario; email: rivaj@mcmaster.ca

its publication in the New England Journal of Medicine should be spent fighting about the research question." (personal communication, November 30, 2011) We describe a randomized controlled trial (RCT) example to highlight how clinicians may use existing literature and the PICOT format to formulate a research question on treatment efficacy.

PICOT Defined

The PICOT format is a helpful approach for summarizing research questions that explore the effect of therapy:[5]

(P) – Population refers to the sample of subjects you wish to recruit for your study. There may be a fine balance between defining a sample that is most likely to respond to your intervention (e.g. no co-morbidity) and one that can be generalized to patients that are likely to be seen in actual practice.

(I) – Intervention refers to the treatment that will be provided to subjects enrolled in your study.

(C) – Comparison identifies what you plan on using as a reference group to compare with your treatment intervention. Many study designs refer to this as the control group. If an existing treatment is considered the 'gold standard', then this should be the comparison group.

(O) – Outcome represents what result you plan on measuring to examine the effectiveness of your intervention. Familiar and validated outcome measurement tools relevant to common chiropractic patient populations may include the Neck Disability Index[6] or Roland-Morris Questionnaire.[7] There are, typically, a multitude of outcome tools available for different clinical populations, each having strengths and weaknesses.

(T) – Time describes the duration for your data collection.

RCT Design Example Using PICOT

Dosage effects of spinal manipulative therapy for chronic neck pain

Neck pain is second in frequency only to low back pain among musculoskeletal complaints reported in the general population and among those presenting to manual therapy providers.[8,9] Chronic neck pain (i.e. neck pain lasting longer than 90 days) is a common reason for presenting to a chiropractor's office, and such patients often receive spinal manipulation or mobilization.[10] Recent systematic reviews of RCTs and prior observational studies have shown increases in cervical range of motion,[11,12] and decreases in self-rated neck pain[13,14] following cervical spine manipulation. In 2010, the Cochrane systematic review concluded, "Optimal technique and dose need to be determined."[14]

Despite evidence of benefit, there is a limited understanding of the optimal dose for neck manipulation; as such, frequency and duration of this treatment varies greatly between clinicians. Although patient characteristics and clinicians' beliefs likely account for some of this variation, it seems likely that many cases of mechanical neck pain will require a minimal number of spinal manipulative therapy (SMT) treatments to derive benefit and that no further benefit will result after a certain upper threshold is reached. To properly examine the dose effects of manipulation for neck pain, it is necessary to consider three treatment factors:

1) frequency
2) intensity
3) total number of manipulations

A factorial design RCT allows investigators to consider more than one treatment factor at a time and examine possible interactions between them. This trial design allows for determination of, not only, the effects of frequency and duration, but also whether it is more effective to provide a certain number of manipulations over shorter or longer durations (i.e. an interaction between the two factors). Considering a 3x4 factorial design, patients would attend 1, 2, or 3 sessions per week (i.e. the first 'factor' of frequency) with manipulation provided over a duration of 2 weeks, 4 weeks, 6 weeks, or not at all (i.e. the second 'factor' of duration). To improve generalizability of findings, neck manipulation could be performed using standard rotary or lateral break diversified technique, which is the most common manually applied neck manipulation in chiropractic practice. Pain relief is a common concern among patients presenting with neck pain and detection of a resulting difference of 13 mm on the 100mm Visual Analog Scale (VAS) line is considered a clinically important change in intensity for patients with chronic pain.[15]

Research Question: In adults with chronic neck pain, what is the minimum dose of manipulation necessary to produce a clinically important improvement in neck pain compared to supervised exercise at 6 weeks?

(P) – Population: Adults 18 to 60 years of age, with a clinical diagnosis of chronic mechanical neck pain who have not received cervical SMT in the past year. Patients with non-mechanical neck pain or contraindications to cervical manipulation will be excluded.

(I) – Intervention: Subjects randomized to have manipulation would receive standard rotary or lateral break diversified technique once, twice, or three times per week over a period of 2, 4, or 6 weeks (see Table 1). These subjects would also receive the same exercise regimen given to the control group to eliminate exercise as a second variable affecting outcomes.

(C) – Comparison: A standardized supervised exercise regimen would be used as an active control group. All subjects, regardless of group assignment, would perform a standardized exercise regime at each session over a period of 6 weeks. Using this strategy, we will be able to minimize the non-specific effects due to attending a clinic.

(O) – Outcome: Changes in neck pain, measured using the 100mm VAS for pain.

(T) – Time: The outcome would be measured weekly for 6 weeks.

Table 1 *Frequency and Duration of SMT*

	Frequency of SMT		
	1x/week	**2x/week**	**3x/week**
No SMT	0	0	0
2 weeks SMT	2	4	6
4 weeks SMT	4	8	12
6 weeks SMT	6	12	18

Clinician input, assuming expertise in the 'gold standard' standard rotary or lateral break diversified technique and an ability to teach it, would be helpful during the planning of patient recruitment. Specifically, in leading training initiatives to calibrate each treating chiropractor to deliver his/her manipulation in a similar way (i.e. load, force, angle) and to assist in normalizing communication with study subjects. This standardization, through structured training sessions for those rendering treatment, will help ensure no additional interventions were inadvertently applied (i.e. education, extra advice).

Other Study Designs Amenable to PICOT

The PICOT format example described above represents a factorial RCT methodology that has been informed by the existing literature. While a well-conducted RCT is appropriate for answering many questions on treatment efficacy, they are typically costly, time-consuming and challenging to conduct. Not all research questions that clinicians wish answered are feasible using this research methodology and the use of a PICOT format is also applicable to other study designs.

The clinical research question being asked ideally determines the best research design for a study. A prospective or retrospective cohort design may be an easier methodology to administer in comparison to a RCT; but study results can by affected by confounding due to the comparison of non-randomized groups. Another methodology, used to look for associations between respondent characteristics and outcomes of interest, is a cross-sectional survey. This methodology is faster and less expensive to do in comparison to a RCT since it considers one time-point of individuals in various spectrums of the variables of interest. However, this design can also can be prone to recall problems by respondents who self-report information if investigators ask about events in the past. A case-control study is most appropriate when attempting to identify associations between patient characteristics and outcomes that take a long time to occur or are very rare. For example, the study by Cassidy et al. (2008) looking at risk of vertibrobasilar artery stroke following chiropractic care, whilst more complex in the design approach, used aspects of a case-control methodology.[16]

While these study designs are common in clinical research today, they are not exhaustive of all designs available. Systematic reviews will be familiar to most as a study design aimed at summarizing bodies of studies; but other less familiar individual patient focus designs, such as N-of-1 RCT,[17] also exist which are amenable to the PICOT format depending on the research question that is being posed.

Discussion

Many considerations need to be contemplated in the PICOT formulation: How detailed should the literature search be in breadth and quality level? What study design best fits the research question? Should the patient population include very similar types of patients or will there be

more of a real-world wide variety of participants? Will the intervention be very specific and rendered by a clinical expert or will there be a combination of tailored interventions rendered by a non-clinician with a more general skill set? Will the comparison be against usual care (i.e. 'gold standard') or a sham placebo procedure? Will the outcomes measured be from validated instruments on a form or more from direct patient verbal communication and will these results be presented in a way most important to clinicians, patients or policy-makers? And if so, what amount of difference and how many patients would be required to both statistically and clinically conclude the intervention was effective? Will measurement of outcomes occur at multiple times or once at 5 days, 6 months or 10 years?

While these considerations are clearly complex and not inclusive of the entire process, to develop a strong research question framed in the PICOT format, it is an important basis to understand both the clinical area of investigation and the current literature that exists. As highlighted by the example above, it is necessary to review the type and quality of research that has already been performed in the area of interest to guide development of a question. When initially synthesizing the literature, some key entry questions to examine include:

- what are the important research questions in the field?
- what has been found?
- what areas need further exploration?
- would the proposed study fill a gap and better an understanding?

In our example design, the literature search identified existing knowledge in the respective area. A recent high-quality Cochrane review reported on previously completed RCTs in the area, strengths and weaknesses of these studies and offered direction as to gaps in current understanding that would benefit from further research exploration.[14] As research is a time consuming and often costly endeavour, building on the best available existing knowledge rather than "re-inventing the wheel" is favourable.

Only after a thorough literature synthesis and investigation into these answers should a research question be formulated – in some instances a systematic review methodology may actually align best with the PICOT framework for your research question. Turning an idea into a good research question requires it to be feasible, interesting, novel, ethical and relevant.[18] This feasibility refers to, not only, resources (time and money), but also to whether there is agreement on the meaning of the research question and to whether everything that needs to be measured can be measured by the study design. The question should be of interest to many in the clinical area to drive both team momentum for the project and dissemination of the results. Generating new knowledge in large existing gaps of healthcare provides the opportunity to help large volumes of patients who previously may have had poorer clinical outcomes. Practically, ethical considerations have to be accounted for in related study designs to ensure subjects are not harmed by the study. Finally, reflection is required on how well the study design will apply to the real world.

A strong research question should always pass the 'so what?' test. Who will the research help? What is the benefit? There should be a definitive and strong rationale for the purpose of the research. A well-thought-out focused research question leads directly into hypotheses; the predictions about the nature and direction of the relationship between the variables under study. Hence, the question acts as the foundation of the study.

The importance of moving from studies to empirically supported treatments to evidence-based practices may very well rest on whether or not a clinician views the research as relevant to their daily practice. It is common for clinicians to express frustration that researchers are not asking questions that are of most relevance to practice. Similarly, researchers often find that clinicians have difficulty distilling the important concepts they would like investigated in a way that can be feasibly researched.

To support both clinical and academic interests, an important clinical research question should therefore be one that is developed in conjunction with a diverse team. This expertise should align with the best research methodology available and propose a project feasible to complete through study that will adequately answer the research question asked. In Canada, the Canadian Chiropractic Research Foundation has reported that there are currently 12 university-based research chairs, 15 PhD candidates and 14 Masters students.[19] An opportunity exists to engage these researchers, as well as those from chiropractic schools, in helping to formulate important clinical research questions.

Conclusion

Clinicians interested in research pursuits, related to patient care, should consider the use of a literature search and the PICOT format when engaging clinical researchers. This approach will provide clinicians and researchers an initial basis for mutual understanding, communication and direction to help answer clinical study questions of most relevance.

Key Points

- Clinicians should frame practice-based research questions in the PICOT format
- Look to existing literature for guidance in the formulation of a research question
- Clinicians have an important role in contributing to the integrated knowledge translation of research studies
- Framing of a research question offers a common language between clinician and researcher discourse

References

1. Stuber K, Bussières A, Gotlib A. Chiropractic research capacity in Canada in 2008 – Phase 3. J Can Chiropr Assoc. 2009; 53: 227–30.
2. Canadian Chiropractic Resources Databank (CCRD), 2011. The CCA Report. Winter, 2012; pp 3. Available at: [www.chiropracticcanada.ca]
3. Canadian Institutes of Health Research. Knowledge to action: an end-of-grant knowledge translation casebook, 2010. Cat. No.: MR21–149/2010E–PDF. Available at: [www.cihr-irsc.gc.ca/e/29484.html]
4. Villanueva-Russell Y. Caught in the crosshairs: Identity and cultural authority within chiropractic. Soc Sci Med. 2011; 72: 1826–37.
5. Guyatt G, Drummond R, Meade M, Cook D. The Evidence Based-Medicine Working Group. Users' Guides to the Medical Literature. 2nd edition. McGraw Hill. Chicago. 2008.
6. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. J Manipulative Physiol Ther. 1991; 14: 409–15.
7. Roland M, Morris R. A study of the natural history of back pain: Part 1&2: development of a reliable and sensitive measure of disability in low-back pain. Spine. 1983; 8 141–50.
8. Nachemson A, Waddell G, Norlund AI. Epidemiology of neck and back pain. In: Nachemson A, Jonsson E, editors. Neck and back pain: the scientific evidence of causes, diagnosis and treatment. Philadelphia. Lippincott Williams and Wilkins; 2000: 165–87.
9. Côté P, Cassidy JD, Carroll L. The Saskatchewan Health and Back Pain Survey: the prevalence of neck pain and related disability. Spine. 1998; 23: 1689–98.
10. Cleland JA, Childs Maj. JD, McRae M, et al. Immediate effects of a thoracic manipulation in patients with neck pain: a randomized clinical trial. Man Ther. 2005; 10: 127–35.
11. Cassidy JD, Lopes AA, Yong-Hing K. The immediate effect of manipulation versus mobilization on pain and range of motion in the cervical spine; a randomized controlled trial. J Manipulative Physiol Ther. 1992; 15: 570–5.
12. Whittingham W, Nilsson N. Active range of motion in the cervical spine increases after spinal manipulation (toggle recoil). J Manipulative Physiol Ther. 2001; 24: 552–5.
13. Palmgren PJ, Sandstrom PJ, Lundqvist FJ, Heikkila H. Improvement after chiropractic care in cervicocephalic kinesthetic sensibility and subjective pain intensity in patients with nontraumatic chronic neck pain. J Manipulative Physiol Ther. 2006; 29: 100–6.
14. Gross A, Miller J, D'Sylva J, et al. Manipulation or mobilisation for neck pain. Cochrane Database Syst Rev. 2010; Jan 20: CD004249.
15. Gallagher EJ, Liebman M, Bijur PE. Prospective validation of clinically important changes in pain severity measured on a visual analog sale. Ann Emerg Med. 2001; 38: 633–8.
16. Cassidy JD, Boyle E, Côté P, et al. Risk of vertebrobasilar stroke and chiropractic care: results of a population-based case-control and case-crossover study. Spine (Phila Pa 1976). 2008; 33 (4 Suppl): S176–83.
17. Sackett DL. Clinician-trialist rounds: 4. why not do an N-of-1 RCT? Clin Trials. 2011; 8: 350–2.
18. Cummings SR, Browner WS, Hulley SB, et al. Designing Clinical Research (3rd Ed.). Philadelphia: Lippincott Williams & Wilkins. 2007; pp 20–22.
19. Canadian Chiropractic Research Foundation. Available at: [www.canadianchiropracticresearchfoundation.com]