When there is little or no research evidence: a clinical decision tool

Bernadette Murphy, DC, PhD¹
Peter C Emary, DC, PhD²
Marco De Ciantis, BSc (Hons) DC, MHSc³
Jessica M. Parish, BA (Hons), MA, PhD⁴
John Srbely, DC, PhD⁵
Anita Chopra, BA, DC⁶
Brian Gleberzon, BA, DC, MHSc, PhD⁷

Despite advancements in research and guidelines of healthcare, there are still situations where clinicians may lack experience or face limited evidence to inform decision-making. In these situations, healthcare providers should provide care within their scope of practice considering all available evidence-based options, the patient's preferences, and the clinical context through a clinical expertise lens.

This decision-making tool serves as a guide for patient-centred clinical decision-making in chiropractic care. It integrates clinical expertise with the pillars of evidence-based practice, taking into account the best

Lorsqu'il y a peu ou pas de données de recherche: un outil de prise de décision clinique

Malgré les avancées dans la recherche et les lignes directrices en matière de soins de santé, il existe encore des situations où les cliniciens peuvent manquer d'expérience ou faire face à un manque de données probantes pour orienter la prise de décision. Dans ces situations, les professionnels de la santé devraient fournir des soins dans le cadre de leur champ d'exercice en tenant compte de toutes les options fondées sur des données probantes disponibles, des préférences du patient et du contexte clinique au moyen du prisme de l'expertise clinique.

Cet outil d'aide à la prise de décision sert de guide pour la prise de décision clinique axée sur le patient en soins chiropratiques. Il intègre l'expertise clinique avec les piliers de la pratique fondée sur des données

- Faculty of Health Sciences, Ontario Tech University, Oshawa, Ontario, Canada
- Michael G. DeGroote National Pain Centre, McMaster University, Hamilton, ON. Chiropractic Department, D'Youville University, Buffalo, NY. Chiropractic Clinician, Langs Community Health Centre, Cambridge, ON
- ³ Private Practice, Castlegar, BC
- School of Public Policy and Administration, Carleton University, Ottawa, ON
- ⁵ Human Health and Nutritional Sciences, University of Guelph, ON
- ⁶ Private Practice Brampton, ON
- Private Practice, Toronto, ON

Corresponding author: Bernadette Murphy, Ontario Tech University, 2000 Simcoe St North, Oshawa, Ontario. L1G 0C5.

Tel: (905) 721-8668 ext 2778

Email: Bernadette.Murphy@ontariotechu.ca

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available research evidence, patient preferences, and the clinical context. Examples are provided on using the tool within chiropractic care for conditions with large bodies of supporting evidence (e.g., low back pain), and conditions with little to no evidence (e.g., Parkinson's disease), to illustrate the broad applicability of how to use (and how not to use) this tool in the field of chiropractic care.

Author's Note: This paper is one of seven in a series exploring contemporary perspectives on the application of the evidence-based framework in chiropractic care. The Evidence-Based Chiropractic Care (EBCC) initiative aims to support chiropractors in their delivery of optimal patient-centred care. We encourage readers to review all papers in the series.

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probantes, en tenant compte des meilleures données probantes disponibles, des préférences des patients et du contexte clinique. Des exemples sont fournis sur l'usage de l'outil dans les soins chiropratiques pour des problèmes de santé ayant un grand nombre de données probantes (par exemple, la douleur lombaire) et des problèmes de santé avec peu ou pas de données probantes (par exemple, la maladie de Parkinson), afin d'illustrer la vaste applicabilité de la façon d'utiliser (et de ne pas utiliser) cet outil dans le domaine des soins chiropratiques.

Note de l'auteur: Ce document fait partie d'une série de sept documents examinant les perspectives contemporaines sur la mise en œuvre du cadre fondé sur des données probantes pour les soins chiropratiques. L'initiative de soins chiropratiques fondés sur des données probantes (SCFDP) vise à soutenir les chiropraticiens dans la prestation de soins optimaux axés sur le patient. Nous encourageons les lecteurs à consulter tous les articles de la série.

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MOTS CLÉS: chiropratique, outil de prise de décision clinique, pratique fondée sur des données probantes, prise de décision clinique

Introduction

"Evidence does not make decisions, people do" - R. Brian Haynes, PJ Devereaux and Gordan H Guyatt, 2002. (doi: https://doi.org/10.1136/bmj.324.7350.1350)¹

Chiropractic care, including manual therapies, such as spinal manipulative therapy (SMT), has been found to be both safe and effective for treating back or neck pain and other musculoskeletal (MSK) or neuro-MSK (nMSK) conditions (e.g., cervicogenic headache).^{2–5} As a conservative approach, chiropractic care has also been shown to be cost-effective in the treatment of these conditions,^{6–8} though further research is needed^{9,10}. Indeed, the evidence-base for chiropractic continues to evolve at an impressive pace, with recent years witnessing innovative and systematic research in previously under

investigated areas (e.g., maintenance care), 11-13 as well as expansion of available tools such as evidence-based clinical practice guidelines (CPGs) through the work of organizations like the Canadian Chiropractic Guideline Initiative (CCGI). Nevertheless, there may still be instances in practice when clinicians are faced with scenarios in which they lack experience with managing particular aspects of a patient's presenting clinical complaint (e.g., diagnosis, etiology, therapy, prognosis). Further, in certain cases there may be contradictory evidence, or little or no high-quality clinical research evidence available that is relevant to the patient's clinical state and circumstances to inform the shared management decision between the patient and clinician. 14,15 Importantly, little or no research evidence does not just include a lack of evidence in general, it also applies to situations where existing evidence

may not be obviously applicable to a specific patient. For example, previous research on a clinical topic may have been exclusively conducted on adults aged 18 to 65 years of age, but the specific patient is a youth or older adult, and guidance is needed on how to proceed.

When there is no clear research evidence that directly addresses a patient's particular situation, it may be possible to move forward with providing care, ¹⁶ as long as the proposed treatment is in line with the best available research evidence, is in the patient's best interest, falls within the chiropractic scope of practice, and adheres to the standards of practice, guidelines and policies set out by the regulatory body of the jurisdiction in which the chiropractor is practicing. To guide the systematic exercise of patient-centred clinical decision-making in cases where clarity is lacking, this paper introduces a clinical decision tool, which is a three-step decision algorithm.

Following the evidence-based medicine (EBM) model first proposed by Sackett et al. in 1996, 17 and later refined by Haynes, Devereaux and Guyatt in 2002,18 we view clinical expertise as the lens through which the three pillars of evidence-based practice (EBP) are integrated: (1) best available research evidence, (2) the patient's preference and actions, and (3) the clinical state and circumstances¹⁴. When there is little or no high-quality evidence (e.g., from systematic reviews or randomized controlled trials [RCTs]¹⁴) to inform decision-making for a particular patient circumstance such as a therapeutic intervention, the clinician must incorporate the remaining pillars of the evidence-based model, and perform a critical assessment of the evidence that does exist (e.g., cohort or case-control studies). The clinician must also incorporate the highest-quality evidence for related conditions (e.g., systematic review of RCTs supporting the treatment of a condition such as Tennis elbow to inform the management of a patient with Golfer's elbow), basic science studies, and generally accepted mechanisms to help inform biological plausibility. Biological plausibility is one of the nine criteria in epidemiology proposed by Bradford-Hill to help determine whether measured or observed associations are causal.19 In the context of chiropractic treatment, biological plausibility would include consideration of whether there are known anatomical or physiological mechanisms which indicate that a given condition (e.g., cervicogenic headache) or set of symptoms (e.g., whiplash-associated disorder) might arise from MSK-related

issues, and thus benefit from chiropractic treatment. We discuss biological plausibility in more depth below (see 'Biological Plausibility').

Decision tools are commonly used across healthcare disciplines to help people and organizations make effective and reliable evidence-based decisions, in contexts often characterized by a significant degree of complexity and uncertainty. Such tools may be designed to support clinicians to make evidence-based diagnostic or treatment decisions, 22-24 or they may be targeted to organization level decision-making in areas such as service delivery, guideline development or health policy initiatives. There are also numerous tools that have been developed to support patients' healthcare decisions by providing patients with information about treatment or screening options that are available, as well as the benefits and harms associated with these options.

We searched three databases (Scopus, Web of Science and PubMed) for chiropractic or MSK-related clinical decision aids that were published in the past 10 years (since January 2012) and which were aimed specifically at supporting evidence-based clinical decision-making in instances where there is a paucity of research evidence. This search affirmed Leboeuf-Yde et al.'s16 previous finding that most clinical tools are directed towards chiropractic care in specific domains^{28–30}. To our knowledge no general guidance applicable to instances in which the research evidence base remains underdeveloped have since been published. Indeed, our search turned up only two tools which met our criteria for broad applicability^{16,31} and only one which addressed the challenge of proceeding in an evidence-based manner when little research evidence is available¹⁶.

In 2016 Amorin-Woods and Losco³¹ published a tool called "'PICO-D' Management" which provides a useful general framework for evidence-based clinical decision-making, in instances where there is an established evidence base. Originally developed as a pedagogical tool, it was published in the expectation that practitioners "may also find it useful for applying defensible evidence-based practice." (p. 1).³¹ The model is based on making a decision to treat based on a comparison between chiropractic, "usual medical care" and/or "natural history" (e.g., do nothing). It includes within its broader framework a ranking of available evidence (syntheses such as systematic reviews and CPGs appearing at the top, followed by

strong, moderate, weak, or absent evidence) for both chiropractic and "usual medical care".³¹ The tool may therefore be useful for supporting decision-making situations where one or more of these evidence bases is well developed. However, other than a reference to the "traffic light model" (p. 8) (discussed below) the tool is largely silent on what to do in situations where this is not the case.³¹

By contrast, the model developed by Leboeuf-Yde et al. in 2013 is expressly aimed at guiding clinical decision-making in the absence of high-quality research evidence.16 The latter decision framework is called the "Traffic Light System", and is based on three questions that are designed to be applicable to most clinical situations, including and especially those for which research evidence is limited, absent or conflicting. The present decision-making tool therefore updates and expands upon this earlier model to include additional clinically oriented scientific considerations for the practitioner, as part of the evidence-based decision-making process. These additions are offered in the spirit of further enhancing the work of Leboeuf-Yde et al. to help guide clinicians in the delivery of evidence-based chiropractic care, particularly in instances where research evidence is absent or conflicting.16

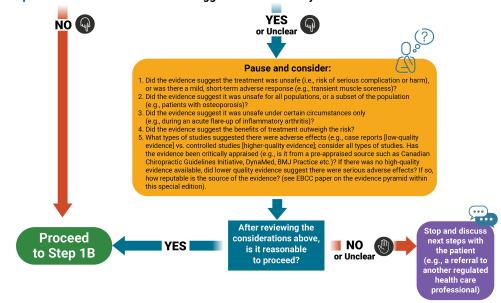
The present tool is structured around a series of questions, organized into three steps. Figure 1 outlines this principle-based

The Three-Step Decision Algorithm

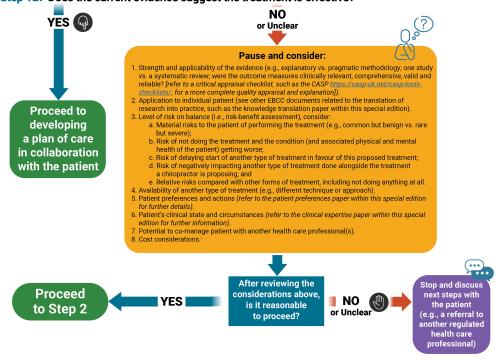
If a patient has a condition for which a standard of care exists, the patient should always be referred for this care prior to proceeding further with the decision tool.

STEP 1: Critical Appraisal of the Quality and Applicability of the Evidence

Step 1A: Does the current evidence suggest there are safety issues?



Step 1B: Does the current evidence suggest the treatment is effective?



Step 2: Are there other scientific considerations (e.g., biological plausibility, experimental evidence, evidence of effectiveness with related conditions or in different populations, temporality, etc.) that suggest that the proposed treatment will have a positive impact on the patient?" or Unclear Proceed Stop and discuss next steps with patient (e.g., a referral to another to Step 3 regulated health care professional) **STEP 3:** Assessment of Clinical Training and Experience Step 3: Is the procedure or treatment based on generally accepted clinical training and/or experience?iii Pause and consider: procedure or treatment widely accepted by the profession? In assessing whether a treatment is widely used, one should consider if it falls within the chiropractic scope of practice and is taught within an accredited, degree granting chiropractic program. If it was not previously taught, is the diagnostic or therapeutic procedure now in the core curriculum, post-graduate curriculum, or continuing education division of an accredited chiropractic educational institution? For example, there may not be an RCT of thoracic spine manipulation for mid-back or rib pain currently available, but this procedure is nevertheless taught within accredited chiropractic programs. Therefore, it would be considered as widely accepted within the profession. Is the justification of this treatment or procedure based on preliminary evidence from other sources (e.g., successful clinical observation, published case studies, cohort studies, qualitative studies, consensus expert opinion, etc.)? Your own individual clinical expertise and experience in treating a particular condition. For example, have you had previous experience with a successful trial of therapy in treating the condition? Do you have recognized specialty training in an area (e.g., sports chiropractic) that gives you an additional level of expertise relative to the clinical condition? After reviewing the considerations above, is it reasonable to proceed? NO YES 😱 Discuss potential Stop and discuss next steps with patient (e.g., a referral to another trial of therapy regulated health care professional with patient

In looking at costs, there are several elements to consider. Are the outcomes of the chiropractic treatment better than alternatives? If the outcomes are similar (i.e., chiropractic care vs. alternative), is the cost of the chiropractic treatment lower (e.g., manual therapy vs. surgeny)? What are the social costs associated chiropractic treatment resus the alternatives (e.g., manual therapy vs. pharmaceutical approach to pair management)? For instance, is there a risk of addiction with certain pharmaceuticals, such as opioids, in pair management? Does chiropractic treatment result in faster return to work or recovery time for patients? Are there additional psychosocial and emotional costs to consider? With any cost analysis or economic evaluation, the perspective (i.e., patient, institution, healthcare system societal) and time horizon (e.g., 3 months, 1 year, 10 years, or lifetime) matters. In many cases, chiropractic care has the potential to represent lower cost and fewer risks than surgical or other invasive interventions (e.g., injections), while also having the benefit of keeping people active and productive.

STEP 2: Assessment of Scientific Considerations

Figure 1.

Proposed three step decision tool for use within chiropractic practice.

approach to designing a trial of therapy. Assessment of the research evidence relative to these steps will assist the chiropractor in deciding whether and when to stop and discuss other options, such as referral to a different healthcare professional, or proceed with an N of 1 clinical trial of therapy, tailored to the individual patient. In the latter case, as always, clinicians should initiate treatment and management with discretion. In addition to the tool, it is important to note that although it is challenging to master the skills of critical appraisal, learning and practicing critical appraisal of the literature is extremely valuable for practitioners. For example, a study may not have had an adequate control group, lacked an appropriate randomization strategy, or was unclear on inclusion criteria. These limitations could impact the outcome of the research, and hence the practitioner's trust in the study's conclusions. We refer readers to the Critical Appraisal Skills Program (CASP) for specific checklists and guidance on critically appraising different types of study designs (https://casp-uk.net/casptools-checklists/).

It should also be pointed out that dependent on the practitioner's expertise and/or patient preference, it is possible to reach different conclusions using the tool. For example, a chiropractor with advanced fellowship training may have knowledge and expertise that a colleague does not, enabling them to apply that expertise in a trial of care. Therefore, different clinical decisions are an acceptable outcome, as long as the full tool has been utilized

and carefully evaluated at each step, and the individual patient's safety, best interests, their clinical state and cir-

[&]quot; Hill, AB. The environment and disease: association or causation? Proc R Soc Med. 1965;58:295–300

[&]quot;It is important to keep in mind that the decision to move forward in Step 3 is based on the critical decision in Step 2 of whether there are other scientific considerations (e.g., biological plausibility, experimental evidence, evidence of effectiveness with related conditions and/or different populations, temporally, etc., that suggest the proposed treatment may result in positive outcomes for the patient. We are aware that suggesting the proposed treatment should be widely accepted runs the risk of argumentum ad populm, the, a fallacious argument that concludes a proposition to be true because many or all people believe it, it alleges that "if many believe so, it is so"). However, on balance, we believe it is a reasonable consideration to make. At the same time, relying only on long-term and/or widely accepted treatments can limit the potential for clinicians to deliver care that may be beneficial to certain patients. For instance, a treatment that is not widely used may be uninvestigated because only a few people have undertaken the education and training to administer it. Similarly, conditions that are less prevalent may not be extensively researched, simply because there has not been a sufficient number of patients to conduct a formal, randomized controlled trial. In addition, there is oftentimes only limited funding available to conduct investigations on the clinical effectiveness of chiropractic care, and what funding that does exist tends to be prioritized towards studies on major morbidities such as low back and neck pain, rather than mid-back pain or other neuromusculoskeletal conditions. Furthermore, certain populations (e.g., seniors) may not be included in the research.

cumstances, and the best available evidence, have been accounted for.

Biological plausibility

In line with Leboeuf-Yde et al.,16 we define biological plausibility as the degree to which a concept, procedure, or treatment aligns with the chiropractic and scientific communities' understanding of biological or scientific principles. When the underlying rationale of a procedure or concept is biologically plausible, it means that it makes sense in the context of established scientific knowledge and principles. In such cases, if accredited educational institutions and the majority of clinicians also accept the concept, it is likely to be considered relatively acceptable.16 However, if a concept or procedure is deemed biologically implausible, it means it contradicts or lacks support from scientific understanding. In such cases, clinical expertise alone is insufficient to justify its use and alternative options such as referral must be considered. This is because a biologically implausible concept is unlikely to be clinically valid, as it does not align with established scientific principles.

Biological plausibility may include conditions or symptoms in which plausibility is connected to the patient presentation and circumstance. For example, research suggests there is a link between the pathophysiology of myofascial trigger points (MTrPs) and central sensitization,³² central sensitization and migraines,³³ and MTrPs and migraines^{34–36}. An understanding of these mechanisms and relationships makes it biologically plausible that treating central sensitization (CS) through spinal manipulation may assist in treating MTrPs and migraines. Importantly, the incorporation of biological plausibility as a component of our decision tool is intended to eliminate clinicians proceeding with care in biologically implausible circumstances (see Supplemental File 3, chiropractic treatment of Parkinson's disease).

Considerations of risk

Risks must always be considered when making a clinical decision. Furthermore, the probability of risk should also be considered. For instance, a clinician should consider whether each of the risks outlined below are rare, low, or high. The risks to the patient to consider would be five-fold:³⁷

- 1. Material risks to the patient of performing the treatment (e.g., common but benign vs. rare but severe),
- 2. Risk of not doing the treatment and the condition (and associated physical/mental health of the patient) getting worse,
- 3. Risk of delaying start of another type of treatment in favour of this proposed treatment,
- 4. Risk of negatively impacting another type of treatment done alongside the treatment a chiropractor is proposing, and
- 5. Relative risks compared with other forms of treatment, including not doing anything at all.

If a chiropractor is planning on proceeding with a treatment that has limited research evidence, the chiropractor must discuss with the patient, as part of the process of obtaining informed consent:

- The benefits of the proposed course of care,
- The potential risks of the proposed course of care, including the potential risk of delaying another type of treatment,
- The possibility that there may be risks that are not yet known, given that there is little or no clinical research evidence (e.g., if the patient is receiving concurrent treatment for a condition and possible interactions are not known) and,
- Whether the proposed treatment may interfere with any concomitant care the patient may be receiving.

This is the case even where new, and limited, evidence has been published, such as thrust manipulation for shoulder impingement, which is recommended in a recent systematic review and clinical practice guideline.^{38,39}

In Canada, provincial legislation and standards of practice, guidelines and policies set out the minimum requirements for consent to treatment. For Ontario chiropractors, please see https://cco.on.ca/wp-content/up-loads/2018/12/S-013.pdf.

If a decision is made to treat or co-manage the patient with another regulated healthcare professional/s, there are three types of care the chiropractor can provide: (i) acute care, (ii) care for chronic or recurrent conditions, including supportive care, ⁴⁰ and (iii) preventive/maintenance care ^{41,42,ii}. If a referral to another regulated healthcare professional (e.g., orthopedic surgeon, neurologist, physio-

therapist, etc.) is required, the patient should be referred appropriately.

N of 1 trial of therapy

"In an era that promotes patient centred research, comparative effectiveness, and personalised medicine, N-of-1 trials allow clinicians and patients to evaluate health interventions in a rigorous fashion and to re-evaluate chronic therapies to ensure therapeutic effectiveness is still achieved. N-of-1 trials are a unique tool to elicit patient preferences and to facilitate shared decision-making, hence evidence-based medicine, in real clinical practice" 43

CONSORT extension for reporting
 N of 1 trial 2015 statement

An "N of 1" trial is a clinical research method that draws on key methodological elements of group RCTs, to assess the efficacy of a given treatment for a particular patient. The methodological principles of an N of 1 trial can also be used outside of the research context to design a high quality, time limited trial of therapy that integrates available research evidence with the specific clinical circumstances, preferences and values of the patient. The N of 1 trial design, first published by Guyatt, Sackett and colleagues in 1986, is a more rigorous method than the informal trials that were common in medicine prior to this, and provides a more reliable basis for inferring the effects of a treatment.

N of 1 trials can be used to evaluate a range of conditions and interventions, including MSK and nMSK disorders and manual therapies commonly used by chiropractors. ⁴³ Patients with rare MSK or nMSK conditions, as well as those with co-morbidities or who are undergoing concurrent treatments, may be especially likely to benefit from a trial of therapy. ^{43,47} In the case of rare MSK or nMSK conditions (e.g., complex regional pain syndrome) there may be little or no clinical research on which to base treatment decisions. Likewise, since patients with co-morbidities or who are receiving concurrent treatments are often excluded from fastidiously designed RCTs, further clinical investigation will be necessary, even where the high-quality evidence otherwise suggests that the treatment is safe and effective. ⁴³

Blinding and randomization are typical features of N

of 1 trials conducted for research. Although these features reduce bias and confounding they are not necessary if the intention is solely to provide optimal patient care, and not to publish or disseminate the results of the trial.^{44,iii}

Nevertheless, N of 1 trials are not appropriate to all conditions. As a form of controlled trial, confounding factors should still be minimized. N of 1 trials are therefore best suited to stable chronic conditions for which progress can be observed/tracked over time, and where the interventions are designed to address these conditions.⁴⁷ Where a concurrent treatment is present, this should also be stable throughout the trial.⁴³

Due to the highly individualized nature of an N of 1 trial, the frequency and duration of treatment should not be determined *a priori* (e.g., an 'x amount of treatment' plan). Rather, these parameters should be determined on a case-by-case basis, and based on a patient's response to treatment as well as with regard to relevant legislation in the jurisdiction in which the clinician practices. A principles-based approach is outlined in the seven steps below, and emphasizes safety, patient preferences and input, and clinical judgement. As always, where information is relevant and available, clinicians should consult systematic reviews, CPGs and other forms of high-quality research to inform their clinical judgements.

When co-designing a trial of therapy with a patient, the following seven principles should be observed as part of the informed consent process, in compliance with the regulations set out by the regulatory body in the jurisdiction in which the clinician is practicing. Expanding on the general informed consent process described above, a well-designed N of 1 trial should be developed in partner-ship with the patient and include:

- 1. Discussion of risk, benefit, any potential side effects, and alternative treatments prior to commencing the trial:
- Clearly defined, patient-centred outcome(s) (e.g., pain relief, physical and emotional functioning, patient satisfaction) defined at the outset. Outcomes should be relevant to the patient, and be targeted to the patient's chief complaints and goals with respect to those complaints;
- 3. Clearly defined time horizon, including frequency and duration of treatments agreed prior to commencement

of trial (e.g., see CPG for chiropractic care of low back pain by Whalen *et al.*⁴⁸);

- 4. Regular, frequent re-evaluation to assess progress using objective and/or subjective tests and patient-reported outcome measures (e.g., numeric pain rating scale [NPRS], visual analogue scale, or functional capacity questionnaires such as the Bournemouth Questionnaire, Oswestry, or Neck Disability Index)⁴⁹, including if/when there is material change to the plan of management or a change in patient status that would materially change the risk-benefit profile;
- 5. Ongoing self-observation by the patient between clinical encounters to monitor symptoms (e.g., pain diary, MYMOP2 [Measure Yourself Medical Outcome Profile v.2]), and at regular intervals (e.g., daily or weekly) to minimize patient recall bias;
- 6. Investigation and documentation of the presence or absence of adverse events; and
- 7. Investigation and documentation of secondary benefits not directly related to the MSK or nMSK condition/goals (e.g., improved sleep quality).

If the patient is showing serious or persistent side effects, or not showing progress, the nature of the trial of therapy should be reconsidered and discussed with the patient. A trial of therapy should be ceased if/when any of the following occur:

- The agreed upon time limit is reached and there is no sign of improvement,
- The patient is getting worse,
- The patients' goals are achieved,
- The patient has a significant change in health status, whether related or unrelated to the condition for which they are receiving treatment, or
- There is a change to informed consent.

Guide to the supplemental files: using the decisionmaking framework with a patient's clinical state and circumstances

There are conditions which chiropractors see every day in practice for which there is no high-quality research evidence of direct treatment effectiveness; however, patients report improvements when chiropractors treat the MSK- or nMSK symptoms associated with these conditions rather than the underlying disease or condition itself.

For example, a patient with post-traumatic stress disorder (PTSD), or someone who has cardiovascular disease and is on cholesterol lowering medication, might also suffer with chronic back or neck pain symptoms. A patient's therapeutic goal may not be to cure the PTSD condition, but rather to manage the MSK symptoms associated with the condition through supportive care or improving their activities of daily living. It may be that a chiropractor is co-managing the condition with other health professionals for whom the underlying disease or condition squarely falls within their respective scope of practice yet there exists an MSK or nMSK component related to the symptoms.

As such, we have developed a series of three supplementary files, which demonstrate how the tool might be used to answer three different clinical questions. The first is related to therapy for a specific nMSK condition (migraine headaches), the second is related to the concept of maintenance care, and the third is related to the treatment of a non-MSK condition. For this last example, we chose Parkinson's disease to illustrate how the tool prevents chiropractic treatment of non-MSK conditions but supports the co-management of MSK or nMSK symptoms associated with these conditions. Our goal in these files is to demonstrate how the tool can be used by clinicians to answer different types of clinical questions. Although we present three examples related to questions about therapy, the tool may also be useful for addressing other types of clinical questions (e.g., diagnosis, etiology, prevention, prognosis).

The authors of this paper have operationally defined research evidence as scientific findings vetted through the scientific community (e.g., during either conferences attended by subject matter experts or by the peer-review journal process).

ii The three types of chiropractic care are: chiropractic care for acute conditions, chiropractic care for chronic/recurrent conditions, including supportive care and chiropractic care for prevention/ maintenance.⁴⁰⁻⁴²

iii N of 1 trials are more reliable due to their prospective crossover design, which allows the clinician to compare the effects of two or more interventions. ^{45,47} This is commonly referred to as "ABAB" testing where "A" represents the tested intervention and "B" represents a comparator. ⁴⁷

Supplemental file 1. Treatment question: treatment of patients with migraine headache

Migraines are a condition commonly treated by chiropractors with varying levels of evidence and conclusions supporting the use of spinal manipulative therapy (SMT) for migraine treatment. 50-54 One of the challenges related to migraines is the large number of different types of headaches that may overlap with, or be confused with, migraines. Version 10 of the International Classification of Diseases (ICD) classifies migraine as a category of headache. However, even within the migraine classification there are 13 different codes that describe the variation and diagnosis of migraine headaches in greater detail. 55 Use of the decision tool for migraine via chiropractic care is discussed below, however, as an example of utilizing the decision tool in clinical practice, please refer to Figure 2 at the end of this section.

Patient profiles

Patient A:

- 37-year-old, Caucasian female suffering from migraine headaches and less intense headaches for over 20 years.
- The migraine headaches occur 2-3 times per month, and are associated with neck and jaw pain, photophobia, and cause nausea. They are triggered by stress, weather changes and commencement of her menstrual cycle.
- Her less intense headaches occur 1-2 times per week.
- She has been prescribed gabapentin, toradol (as needed) and naproxen (2X per week).
- She suffers from anxiety and has a stressful lifestyle.
- She has no other significant co-morbidities.

Patient B:

- 45-year-old, Caucasian female with a 30-year history of severe headaches and syncope.
- The headaches are debilitating and can cause nausea and vomiting. They are triggered by stress, certain chemical odours, red wine, and dark chocolate, and occur 2-3 times per month.
- Manual, chiropractic care provided significant relief 10 years ago, but was discontinued after moving to a different city.
- Syncope is triggered by very high stress or excitement and can last for 2-10 minutes. These attacks occur rarely.

- MRI within the last year demonstrated an aneurysm where the basilar artery bifurcates in the circle of Willis. The aneurysm is being monitored every 6 months.
- She is a single, yoga instructor with a low stress lifestyle.

The decision tool was used in the consideration of using high-velocity, low-amplitude, manual chiropractic manipulation as a treatment for Patient A and Patient B.

Step 1A. Does the scientific evidence suggest the treatment is unsafe?

Patient A: There is no evidence to suggest that chiropractic treatment of migraine headaches is unsafe. Therefore, move to Step 1B.

Patient B: While there is no evidence to suggest that chiropractic treatment of migraine headaches is unsafe, the presence of an aneurysm adds an additional risk factor. Therefore, proceeding with a high-velocity, low-amplitude, manual chiropractic manipulation as a treatment would be considered unsafe.

Options: refer to another healthcare professional *or* return to Step 1A to determine whether treatment with a low-force technique may be reasonable.

Step 1B. Does the scientific evidence suggest the treatment is effective?

Recent systematic reviews and randomized controlled trials have examined the evidence for chiropractic and manual therapy as a treatment for migraine. 5,51-53

Key takeaways:

• There is evidence to support the effectiveness of chiropractic care for relief of migraine headache, but it is limited or of a low quality.^{5,51} For example, one systematic review concluded that "SMT may be an effective therapeutic technique to reduce migraine days and pain intensity"; however, the authors acknowledged that there were methodological limitations in the studies that were included and that these results should be interpreted as preliminary.⁵ Another systematic review found no evidence of an effect of SMT on migraine⁵³; however, the number of included studies was limited. A response to this review indicated that none of the reviewed literature demonstrated a negative impact of

SMT on migraine patients, and that the evidence suggests more research in this area is warranted before any definitive conclusions can be drawn.⁵⁴ Due to the small number of studies, and the low grade of quality for some studies, any recommendations for treatment should be cautious. However, a trial of chiropractic care for migraine is justifiable, provided no contraindications for manual therapy are present.

Patient A: High-velocity, low-amplitude, manual chiropractic manipulation

- The research evidence about chiropractic treatment and migraine is inconclusive but evolving.
- Move to Step 2

Patient B: Low-force chiropractic technique

- The research evidence about chiropractic treatment and migraine is inconclusive but evolving.
- Move to Step 2

Step 2. Are there other scientific considerations (e.g., biological plausibility, experimental evidence, evidence of effectiveness with related conditions or in different populations, temporality, etc.) which suggest that the proposed treatment will have a positive impact on the patient?

Yes. Several laboratory-based studies (i.e., experimental evidence) suggest there is a link between central sensitization (CS) and migraine headaches. 33,36,56,57 The emerging research on CS and SMT, reviewed elsewhere in this collection,⁵⁸ is elucidating a possible physiologic mechanism responsible for the clinical presentation of migraines, among other conditions. Furthermore, research on CS is also advancing our understanding of the mechanism through which conservative techniques such as SMT, dry needling, and therapeutic ultrasound, may decrease the pain and disability experienced by migraine sufferers.^{5,34,59,60} For example, deactivation of myofascial trigger points (MTrPs) has been shown to reduce both migraine pain and associated allodynia³⁴, while peripheral magnetic stimulation of MTrPs in the trapezius and deltoid muscles has also been shown to reduce migraine frequency⁶⁰. Moreover, SMT has demonstrated potential in reducing migraine days and pain intensity, providing a plausible biological mechanism for chiropractic care in treating migraines, despite noting the dearth of research in this area rendering these conclusions preliminary.⁵ Regardless, when considered safe, treatments targeting CS should therefore be considered for their clinical application in managing migraines.

Biological plausibility is one of the key considerations for establishing causality of disease or treatment effectiveness in epidemiology (i.e., the Bradford-Hill criteria). These considerations include the strength, consistency, specificity, temporality, dose response, coherence, experimental evidence, and analogy of association. This research linking CS and migraine headaches, 33,36,56,57 as well as SMT and other conservative techniques with CS and migraines, 5,34,58-60 provides biological plausibility of chiropractic care in the safe, effective, and evidence-based management of migraine symptoms.

Patient A: High-velocity, low-amplitude, manual chiropractic manipulation

- There is growing evidence for biological plausibility between chiropractic care and migraine headache.
- Move to Step 3

Patient B: Low-force chiropractic technique

- There is growing evidence for biological plausibility between chiropractic care and migraine headache.
- Move to Step 3

Step 3. Is the procedure or treatment based on generally accepted clinical training and/or experience?

As noted above, migraines are a condition commonly treated by chiropractors. Knowledge about the treatment of migraines is gained through education and training in internationally recognized accredited chiropractic programs. This knowledge is also tested as part of official licensing examinations.⁶¹

In its 2020 national survey, the National Board of Chiropractic Examiners (NBCE) noted that chiropractors reported providing care nearly once a day to patients with headaches, making it the most common nMSK condition treated by U.S. chiropractors.⁵⁰ Over 75% of chiropractors also reported making the initial diagnosis of headaches for patients at least half the time.⁵⁰ Close to 25% reported co-managing headaches with other health professionals, while 70% reported treating the condition themselves.⁵⁰

As identified in Note 3 within Figures 1 and 2, a treat-

The Three-Step Decision Algorithm



Chiropractic Care for Migraine

STEP 1: Critical Appraisal of the Quality and Applicability of the Evidence

Patient Profile

- 37-year-old, Caucasian female suffering from migraine headaches and less intense headaches for over 20 years.
- The migraine headaches occur 2-3 times per month, and are associated with neck and jaw pain, photophobia, and cause nausea.
- They are triggered by stress, weather changes and commencement of her menstrual cycle
- Her less intense headaches occur 1-2 times per week.
- She has been prescribed gabapentin, toradol (as needed) and naproxen (2X per week).
 She suffers from anxiety and has a stressful lifestyle.

Step 1A: Does the current evidence suggest there are safety issues?



There is no evidence to suggest that chiropractic treatment of migraine headaches is unsafe. Therefore, move to Step 1B.

Step 1B: Does the current evidence suggest the treatment is effective?





Pause and consider:

1. Recent systematic reviews and randomized controlled trials have examined the evidence for chiropractic and manual therapy as a

Key Takeaways:

- There is evidence to support the effectiveness of chiropractic care for relief of migraine headache, but it is limited or of a low quality. 5, 51 For example, one systematic review concluded that "SMT may be an effective therapeutic technique to reduce migraine days and pain intensity"; however, the authors acknowledged that there were methodological limitations in the studies that were included and that these results should be interpreted as preliminary.⁵ Another systematic review found no evidence of an effect of SMT on migraine⁵⁵; however, the number of included studies was limited. A response to this review indicated that none of the reviewed literature demonstrated a negative impact of SMT on migraine patients, and that the evidence suggests more research in this area is warranted before any definitive conclusions can be drawn.
- Due to the small number of studies, and the low grade of quality for some studies, any recommendations for treatment should be cautious.
 However, a trial of chiropractic care for migraine is justifiable, provided no contraindications for manual therapy are present.
- 2. Application to individual patient (see other EBCC documents related to the translation of research into practice, such as the knowledge
- translation paper within this special edition).

 3. Level of risk on balance (i.e., risk-benefit assessment), consider:

 - a. Material risks to the patient of performing the treatment (e.g., common but benign vs. rare but severe); b. Risk of not doing the treatment and the condition (and associated physical and mental health of the patient) getting worse;
 - c. Risk of delaying start of another type of treatment in favour of this proposed treatment;
 d. Risk of negatively impacting another type of treatment done alongside the treatment a chiropractor is proposing; and

- Risk of Regardery impacting another type of recament done anongoice the retainent a chimoprocon is proposing, and
 Relative risks compared with other forms of treatment, including not doing anything at all.
 A. Availability of another type of treatment (e.g., different technique or approach).
 Patient preferences and actions (refer to the patient preferences paper within this special edition for further details).
 Retainer's clinical state and circumstances (refer to the clinical expertise paper within this special edition for further information).
- Potential to co-manage patient with another health care professional(s) Cost considerations.



After reviewing the considerations above, is it reasonable to proceed?



High-velocity, low-amplitude, manual chiropractic manipulation The research evidence about chiropractic treatment and migraine is inconclusive but evolving. Move to Step 2

STEP 2: Assessment of Scientific Considerations

Step 2: Are there other scientific considerations (e.g., biological plausibility, experimental evidence, evidence of effectiveness with related conditions or in different populations, temporality, etc.) that suggest that the proposed treatment will have a positive impact on the patient?"



Several laboratory-based studies (i.e., experimental evidence) suggest there is a link between central sensitization (CS) and migraine headaches. 33, 36, 36 The emerging research on CS and SMT, reviewed elsewhere in this collection, 30 is elucidating a possible physiologic mechanism responsible for the clinical presentation of migraines, among other conditions. Furthermore, research on CS is also advancing our mederstanding of the mechanism through which conservative techniques such as SMT, dry needling, and therapeutic ultrasound, may decrease the pain and disability experienced by migraine sufferers. This research therefore provides for the biological plausibility of chiropractic care in the safe, effective, and evidence-based management of migraine symptoms.

Biological plausibility is one of the key considerations for establishing causality of lesses or treatment effectiveness in epidemiology (i.e., the Bradford-Hill criteria). These considerations include the strength, consistency, specificity, temporality, dose response, coherence, experimental evidence, and analogy of association.

Move to Step 3

STEP 3: Assessment of Clinical Training and Experience

Step 3: Is the procedure or treatment based on generally accepted clinical training and/or experience?



Pause and consider:

- Is the procedure or treatment widely accepted by the profession? Migraines are a condition commonly treated by chiropractors. Knowledge about the treatment of migraines is gained through education and training in internationally recognized accredited chiropractic programs. This knowledge is also tested as part of official licensing examinations. In its 2020 national survey, the National Board of Chiropractic Examiners (NBCE) noted that chiropractors reported providing care nearly once a day to patients with headaches, making it the most common nMSK condition treated by U.S. chiropractors. On the interference of the condition treated by U.S. chiropractors.
- common nMSK condition treated by U.S. chiropractors.⁵⁰
 2. Is the justification of this treatment or procedure based on preliminary evidence from other sources (e.g., successful clinical observation, published case studies, cohort studies, qualitative studies, consensus expert opinion, etc.)?
 3. Your own individual clinical expertise and experience in treating a particular condition. For example, have you had previous experience with a successful trial of therapy in treating the condition? Do you have recognized specialty training in an area (e.g., sports chiropractic) that gives you an additional level of expertise relative to the clinical condition?

After reviewing the considerations above, is it reasonable to proceed?

Is it reasonable to proceed to a trial of therapy?



Multimodal chiropractic care, including high-velocity, low-amplitude, manual chiropractic manipulation

- In looking at costs, there are several elements to consider. Are the outcomes of the chiropractic treatment better than alternatives? If the outcomes are similar (i.e., chiropractic care vs. alternative), is the cost of the chiropractic treatment lower (e.g., manual therapy vs. surgery)? What are the social costs associated chiropractic treatment versus the alternatives (e.g., manual therapy vs. pharmaceutics). approach to pain management)? For instance, is there a risk of addiction with certain pharmaceuticals, such as opioids, in pain management? Does chiropractic treatment result in faster return to work or recovery time for patients? Are there additional psychosocial and emotional costs to consider? With any cost analysis or economic evaluation, the perspective (i.e., patient, institution, healthcare system, societal) and time horizon (e.g., 3 months, 1 year, 10 years, or lifetime) matters. In many cases, chiropractic care has the potential to represent lower cost and fewer risks than surgical or other
- invasive interventions (e.g., injections), while also having the benefit of keeping people active and productive.

 ii. Hill, AB. The environment and disease: association or causation? Proc R Soc Med. 1965;58:295–300.

 iii. It is important to keep in mind that the decision to move forward in Step 3 is based on the critical decision in Step 2 of whether there are other scientific considerations (e.g., biological plausibility, experimental evidence, evidence of effectiveness with related conditions and/or different populations, temporality, etc.) that suggest the proposed treatment may result in positive outcomes for the patient. We are aware that suggesting the proposed treatment should be widely accepted runs the risk of argumentum ad populum (i.e., a fallacious argument that concludes a proposition to be true because many or all people believe it; it alleges that "if many believe so, it is so"). However, on balance, we believe it is a reasonable consideration to make. At the same time, relying only on long-term and/or widely accepted treatments can limit the potential for clinicians to deliver care that may be beneficial to certain patients. For instance, a treatment that is not widely used may be uninvestigated because only a few people have undertaken the education and training to administer it. Similarly, conditions that are less prevalent may not yet be extensively researched, simply because there has not been a sufficient number of patients to conduct a formal, randomized controlled trial. In addition, there is oftentimes only limited funding available to conduct investigations on the clinical effectiveness of chiropractic care, and what funding that does exist tends to be prioritized towards studies on major morbidities such as low back and neck pain, rather than mid-back pain or other neuromusculoskeletal conditions. Furthermore, certain populations (e.g., seniors,) may not be included in the research.

Figure 2:

Proposed three step decision tool for use within chiropractic practice

ment that is not widely used may be uninvestigated because the condition may be rare and there have been insufficient numbers of patients to conduct a formal, randomized controlled trial. The same concept applies to the current question of whether the proposed treatment is widely used. It may be that the treatment is so unique that only a few chiropractors have undertaken the education and training to perform it. This does not mean the patient cannot benefit from the treatment, but rather the clinician should consider whether this is the case when determining if a treatment is widely accepted. At all times, a chiropractor should consider the best available evidence and their own individual clinical expertise, related to treating the condition and the treatment plan being proposed, along with their patient's clinical state and circumstances.

If an informed decision is made by the patient to move forward with a trial of therapy the chiropractor and patient should agree on the desired outcomes being sought from the treatment as well as the length of the trial of therapy, prior to commencing treatment. This information should be thoroughly documented in the patient record. Ongoing reassessments of the patient's condition should also be conducted at regular, pre-determined intervals to assess whether a change in treatment approach or referral to another healthcare provider is necessary. See 'N of 1 trial of therapy' section above for further details on conducting a trial of therapy.

Patient A: Multi-modal chiropractic care, including high-velocity, low-amplitude, manual chiropractic manipulation

• It is reasonable to proceed to a trial of therapy.

Patient B: Multi-modal chiropractic care, emphasizing low-force chiropractic techniques

• It is reasonable to proceed to a trial of therapy.

Supplemental file 2. Treatment question: maintenance care for patients with low back pain

Maintenance care is a secondary or tertiary preventative healthcare strategy that is used by chiropractors to prevent future episodes and/or to manage persistent bothersome (activity-limiting) pain. 11,12,42 In this treatment approach patients are seen at regular, planned intervals rather than by timing treatments to respond to the (re)emergence of symptoms.

Low back pain is increasingly understood to be a per-

sistent, recurring and often life-long condition. For this reason, effective management strategies are highly desirable for patients, employers, and healthcare payers alike.

A summary of the research regarding chiropractic maintenance care for low back pain is highlighted below in Step 1.

For further information about the different types of research designs that best answer different clinical questions (i.e., diagnosis, therapy, prognosis, etiology, prevention, or harm), please refer to our paper in this JCCA series on the evidence hierarchy.¹⁵

Patient profiles

Patient A:

- 42-year-old female, works full-time shift work as a personal support worker
- Recurring job-related low back pain
- Has experienced success with SMT for low back pain in the past; otherwise has good self-reported physical and mental health
- Has limited extended health coverage through workplace benefits, and limited discretionary funds for outof-pocket healthcare services

Patient B:

- 82-year-old female with osteoporosis
- Lives independently and wishes to continue to do so, but has begun to experience episodes of low back pain which temporarily interfere with independence in daily living
- Has experienced positive outcomes from chiropractic care in the past
- Struggles periodically with depression and isolation
- Has excellent private health insurance coverage and financial means to pay out-of-pocket if necessary
- Is seeking a preventative strategy to avoid low back pain episodes and maintain independence in daily living

Step 1A. Does the scientific evidence suggest the treatment is unsafe?

Patient A:

- No, there is no evidence to suggest that chiropractic maintenance care is unsafe for this patient
- Move to Step 1B

Patient B:

- Yes, there is evidence and expert consensus that highforce, high-velocity treatments are unsafe for patients with osteoporosis
- No for lower force/velocity techniques
- Consider moving to Step 1B to assess the merits of a preventative maintenance care strategy of exercise, gentle manipulation/mobilization, and soft-tissue therapy

Step 1B. Does the scientific evidence suggest the treatment is effective?

The research on maintenance care is evolving. Pursuant to systematic reviews completed in 1996 and 2008 which concluded that evidence for this practice was lacking, a group of researchers in Northern Europe established a systematic research program, known as the "Nordic Maintenance Care Program".⁴²

Considering the new research evidence generated through the Nordic Maintenance Care Program^{11–13} as well as studies of maintenance care in the U.S., Canada and Egypt, a new systematic review was undertaken and published in 2019.⁴² The review looked at a total of 14 qualitative and quantitative research articles published between 2007 and 2019, four of which were RCTs. Authors of the 2019 review include members of the Nordic research group, as well as those involved in previous reviews of maintenance care.

Key takeaways:

- Maintenance care can be considered an evidence-based method of secondary or tertiary prevention for patients with previous episodes of low back pain (LBP) who have responded well to treatment
- There is insufficient evidence to support the use of maintenance care on all patients who receive chiropractic care
- Further research is required to understand which patients respond best to maintenance care and which components of maintenance care are most valuable and for which patients
- The cost-effectiveness of maintenance care is unknown

Patient A:

• Yes, a recent systematic review (high-quality evidence) by the Nordic Maintenance Care group⁴² suggests that maintenance care can be an effective therapeutic ap-

- proach for patients with previous episodes of LBP who have responded favourably to treatment
- Consider that the patient has limited resources to offset the cost of this care, and the cost effectiveness of maintenance care is unknown

Patient B:

- Yes, a recent systematic review (high-quality evidence) by the Nordic Maintenance Care group⁴² suggests that maintenance care can be an effective therapeutic approach for patients with previous episodes of LBP who have responded favourably to treatment
- Consider that the above-mentioned systematic review of the maintenance care literature suggests that maintenance care is typically understood to incorporate a range of treatment modalities (e.g., manual therapy, exercise prescriptions, advice on ergonomics, diet, weight loss, and stress management) and that sessions tend to "resemble ordinary consultations".⁴²

Step 2. Are there other scientific considerations (e.g., biological plausibility, experimental evidence, evidence of effectiveness with related conditions or in different populations, temporality, etc.) which suggest that the proposed treatment will have a positive impact on the patient?

Other scientific considerations could include patient population, temporality, and biological plausibility, as they pertain to the patient's clinical state and circumstances. For example, clinicians might consider whether the patient has any risk factors associated with chronic or recurrent LBP, such as depression, obesity, or workplace risk factors. 12,13,42,62

A recent secondary analysis¹² of previously published RCT data¹¹ looked at the differences in outcomes for patients across three different psychological subgroups, as classified by the West Haven-Yale Multidimensional Pain Inventory: adaptive copers, interpersonally distressed and dysfunctional. They found that patients who received maintenance care had "flat pain trajectories around each new treatment period and reported fewer days with pain compared to patients receiving the control intervention". However, this entire effect was attributable to the patients in the group labeled with the "dysfunctional" psychological profile, defined as patients with high pain severity, marked interference with everyday life, high

affective distress, low perception of life control and low activity levels. The study concluded that "Understanding how subgroups of patients are likely to be affected by maintenance care may help align patients' and clinicians' expectations based on realistic outcomes".¹²

There is also emerging evidence that cortical reorganization and altered brain functional connectivity may predict the transition from acute/episodic to chronic pain. 62 This provides preliminary experimental evidence and biological plausibility on which a clinician could potentially identify individuals who are vulnerable to developing chronic pain. The clinician could then discuss a trial period of maintenance care with their patient, with the aim of slowing or arresting the transition to chronic pain.

There is also accumulating research suggesting CS is a key driver in the pathophysiology and clinical manifestation of broad profile chronic pain conditions, including LBP.^{63–65} Further research suggests that SMT may achieve its therapeutic benefits by directly modulating CS.⁶⁶ Biological plausibility exists, therefore, to consider the role of SMT in a maintenance care plan for ongoing or persistent chronic pain conditions.^{11,12,42} Please refer to Vazic *et al.* (2023)⁵⁸ in this JCCA collection for a detailed discussion on the mechanisms of SMT that suggest its role in an effective maintenance care program for persistent chronic pain.

Patient A:

- Consider that the patient does have workplace risk factors which may support the biological plausibility of maintenance care as an effective strategy in this instance
- Consider emerging research evidence to support the biological plausibility that SMT used as maintenance care may slow/prevent disability related to osteoarthritis⁵⁸
- Consider that this patient does not match the psychological profile of the patient population which had the greatest impact on the outcome of the above discussed RCT
- Proceed to Step 3

Patient B:

- Consider the risk of the LBP becoming chronic
- Consider whether a patient who experiences depression and isolation may benefit from periodic check-ins to see if they are keeping up with exercises, etc.

Consider whether it is biologically plausible that maintenance care could still be an effective secondary or tertiary prevention strategy in the absence of SMT

Step 3. Is the procedure or treatment based on generally accepted clinical training and/or experience?

Maintenance care is used by many chiropractors in the United States, Canada, Europe and the South Pacific. ^{12,42,67} For example, it has been reported that "About 98% of all chiropractors who are members of the Swedish Chiropractic Association consider a treatment strategy known as maintenance care (MC) to be clinically useful and beneficial for patients with recurrent and persistent MSK pain." ¹² The United States National Board of Chiropractic Examiners 2019 survey also found that 65% of American chiropractors report providing care for "wellness and the maintenance of health". ⁵⁰ Maintenance care is also taught in accredited chiropractic training programs.

If an informed decision is made by the patient to move forward with a trial of therapy the chiropractor and patient should agree on the desired outcomes being sought from the treatment as well as the length of the trial of therapy, prior to commencing treatment. This information should be thoroughly documented in the patient record. Ongoing reassessments of the patient's condition should also be conducted at regular, pre-determined intervals to assess whether a change in treatment approach or referral to another healthcare provider is necessary. See 'N of 1 trial of therapy' section above for further details on conducting a trial of therapy.

Patient A:

 A time-limited trial of therapy which includes consideration of the patients' financial circumstances in the balance of risks and benefits may be appropriate

Patient B:

A time-limited trial of therapy appropriate to the clinician's level of skill and experience with this patient population may be appropriate

Supplemental file 3. Treatment question: treatment of a patient with a non-musculoskeletal (non-MSK) condition – Parkinson's disease

Parkinson's disease is a complex brain disorder characterized by slow neurodegeneration (i.e., the progressive loss

of structure and function of neurons in the basal ganglia). In the early stages of the disease, degeneration of the central nervous system presents chiefly as a loss of motor function, with symptoms including tremors, rigidity, and difficulty with walking, balance and co-ordination. Other symptoms may include depression, anxiety, and difficulty with sleep and sensory systems (e.g., a loss of smell). In more advanced stages of the disease, Parkinson's dementia also becomes common.^{68–73}

The underlying cause of Parkinson's is dopamine deficit caused by the death of cells in the portion of the midbrain responsible for motor function. Dopamine is an organic chemical that plays a number of important roles, including as an inhibitory neurotransmitter which facilitates communication between the brain and the nervous system. Dopamine deficiency causes overexcitation of the motor cortex and is responsible for typical Parkinson's symptoms such as tremors and rigidity.^{71,73} The ultimate cause of Parkinson's disease is unknown, but it is believed that heredity and environmental factors may both play a role.⁷¹ It is also hypothesized that head and neck trauma may be a risk factor.⁷³

There is no cure for Parkinson's. However, there are several pharmacological and non-pharmacological therapeutic interventions which may assist patients in managing symptoms and/or slowing the progression of the disease.^{69,72} Pharmacological interventions are mainly focused on mitigating symptoms by temporarily replenishing or imitating dopamine (e.g., dopamine replacement therapy).^{70,71,73} Dopamine replacement is helpful in reducing tremors and rigidity and is therefore associated with improved ability to carry out activities of daily living, quality of life, and mortality rates.^{71,72}

Parkinson's disease medications are also associated with several side effects, including motor fluctuations and dyskinesia (e.g., involuntary, erratic, writhing movements of the face, arms, legs, or trunk), fatigue, osteoarthritis, and hallucinations. Moreover, the efficacy of dopamine replacement therapy tends to wane over time and to be less efficacious in treating gait and balance issues, pain, and sleep disorders among other symptoms.

Other symptom management interventions include physical/manual therapy to assist with mobility and balance, exercise prescription to support functional abilities and recommendations for how to move safely, speech language pathology for the management of speech dif-

ficulties, and psychiatric or psychological care for the management of cognitive and emotional effects of the disease.^{69,71,72}

Patient profiles

Patient A:

- 42-year-old Caucasian, male, physiotherapist who has been a patient for many years
- Has played intramural rugby since high school
- Over the past 10 years, the patient attended for acute episodes of neck and low back pain related to work and rugby
- Patient responds well to soft-tissue therapy, mobilizations, and spinal manipulative therapy
- Typically requires 10 treatments for his spinal pain to resolve
- Does not attend for treatments between acute episodes of back pain, despite your recommendations he do so
- Excellent overall health: non-smoker, social drinker, not on any medications and takes a multi-vitamin daily
- No history of significant falls, injuries, surgeries, or hospitalizations, but some fractured fingers and ankle strains related to rugby
- One year ago, patient was diagnosed with Parkinson's disease, after reporting to his medical doctor the onset of hand tremors at rest, occasional dizziness, and some gait disturbances unrelated to rugby
- Patient is under the care of a neurologist and has recently started taking Levodopa
- Patient has reduced how often he plays rugby in favour of swimming, weight training and walking and is considering career change to a less physical job
- Patient presents today with neck and low back pain related to his physical activity, in addition to the stress of having to cope with Parkinson's disease

Patient B:

- 71-year-old Caucasian male
- Retired teacher, self-reported excellent overall health
- Recently diagnosed with Parkinson's disease, is visibly upset and fearful of the future progression of the disease
- New patient, has never received chiropractic care previously
- Is seeking chiropractic care in the hope that it can slow

the progression of disease and therefore help to maintain independence by minimizing symptoms such as loss of balance

Step 1A. Does the scientific evidence suggest the treatment is unsafe?

Patient A:

- No. There is no evidence that the use of soft-tissue therapy, mobilizations, or spinal manipulation for treating spinal pain in a person with Parkinson's disease is contraindicated
- Move to step 1B

Patient B:

- Not applicable. There is no high-quality research on treating Parkinson's disease with chiropractic care.
 - There are some case studies (lower quality evidence) which suggest that chiropractic interventions, including SMT, have no added safety concerns for patients with Parkinson's disease.^{70,71,73}
 - Regardless, these and other case reports constitute low-quality evidence. As such, when using this form of evidence to provide direction on proceeding with care, clinicians must proceed with caution. In this case, it is acceptable to proceed to Step 1B as there is no evidence of chiropractic treatment being unsafe for individuals with Parkinson's.
- Move to Step 1B

Step 1B. Does the scientific evidence suggest the treatment is effective?

Patient A:

- Yes, for spinal pain, no for treating signs and symptoms directly related to Parkinson's disease.
- Move to Step 2

Patient B:

- There is no high-quality research on treating Parkinson's disease with chiropractic care.
- There are some case studies (lower quality evidence)
 which suggest that chiropractic interventions, including SMT, may be successful in assisting in the
 management of MSK-related Parkinson's disease
 symptoms.^{70,71,73} Consideration of this evidence would

- necessitate a reframing of the clinical/treatment question to ask whether chiropractic care may be useful in assisting a particular patient to manage the MSK symptoms associated with their Parkinson's diagnosis, such as in the scenario for 'Patient A'.
- For example, Anderson, Oakley, and Harrison reported improved mobility and quality of life through a chiropractic postural rehabilitation program⁷⁰; and Elster provided upper cervical chiropractic care to a Parkinson's disease patient who had experienced substantial previous head and neck trauma, and recorded subjective and objective improvement in the patient's MSK-related Parkinson's disease symptoms.⁷³
- Regardless, the limited evidence available should not be used on its own to justify the use of chiropractic treatment for slowing the progression of Parkinson's disease (i.e., the clinical question for this particular patient), which at this time is an incurable neurodegenerative disease. However, these and other reports can be used to inform chiropractic care to manage symptoms associated with Parkinson's, including MSK functional capacity (e.g., posture, balance and LBP). 62,63,65
- Move to Step 2.

Step 2. Are there other scientific considerations (e.g., biological plausibility, experimental evidence, evidence of effectiveness with related conditions or in different populations, temporality, etc.), which suggest that the proposed treatment will have a positive impact on the patient?

Patient A:

- Yes. Patient has responded favourably to chiropractic care in the past for spinal pain (patient preference) and you have successfully treated many patients with spinal pain (clinical experience)
- There is no biological plausibility, experimental evidence, or evidence of effectiveness that chiropractic care can resolve his signs or symptoms of Parkinson's disease.
- Move to Step 3

Patient B:

• No. The underlying cause of Parkinson's disease is dopamine deficit caused by the death of cells in the portion of the midbrain responsible for movement.

- There is no current biologically plausible rationale to predict chiropractic intervention, broadly defined, would heal, or interrupt the progressive degeneration of a complex brain structure.
- Stop here and discuss next steps with the patient, including referral to another healthcare provider.

Step 3. Is the procedure or treatment based on generally accepted clinical training and/or experience?

Patient A:

- Yes. Proceeding to a trial of therapy is reasonable.
- Ensure that the patient understands that you are treating a person with spinal pain who also has Parkinson's disease but are not treating the disease itself.

Patient B:

- There is no cure for Parkinson's disease, and treatment of the neurodegenerative cause of the disease falls outside of the purview of generally accepted chiropractic training and experience.
- Stop here and discuss next steps with the patient, including referral to another healthcare provider.

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