Sophisticated research design in chiropractic and manipulative therapy; what you learn depends on how you ask. Part C: Mixed Methods: *"why can't science and chiropractic just be friends?"*

Lyndon G. Amorin-Woods, BAppSci (Chiropractic), MPH[1]

[1] *Senior Clinical Supervisor; Murdoch University Chiropractic Clinic*
School of Health Professions, Discipline of Chiropractic
Murdoch University South Street campus, 90 South Street, Murdoch, Western Australia 6150

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Abstract

Many commentators have recognised the limitations and inapplicability of the traditional quantitative pyramid hierarchy especially with respect to complementary and alternative (CAM) health care, observing the way Evidence-based Practice [EBP] is sometimes implemented is controversial, not only within the chiropractic profession, but in all other healthcare disciplines, including medicine itself. A phased approach to the development and evaluation of complex interventions can help researchers define the research process and complex interventions may require use of both qualitative and quantitative methods. The chiropractic profession has little to fear from evidence-based practice; in fact it should be used productively to improve patient care, clinical outcomes and the standing of the profession in the eyes of the public, other health professions and legislators.

Keywords; Chiropractic; Evidence-Based Practice; Mixed Methods; Research Design
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INTRODUCTION

Many scientists have recognised the limitations and inapplicability of the traditional quantitative pyramid hierarchy especially with respect to complementary and alternative (CAM) health care, including chiropractic. Over the last decade some authors have suggested refinements of the model, for instance; in the place of an evidence hierarchy, Jonas (1) suggested the construction of an "evidence house" with "rooms" for different types of information and purposes and later presented a refined circular model (1).

Jonas observed (1):

> *"... the best evidence may be observational data from clinical practice that can estimate the likelihood of a patient's recovery in a realistic context (2). Patient's illnesses are complex physical, psychological, and social experiences that cannot be reduced to single, objective measures (3). Personal experience of illness might sometimes be captured only through qualitative research (4). The "best" evidence thus may be the meaning that patients give to their illness and recovery. At other times, the "best" evidence may come from laboratory studies (5). Arranging types of evidence in a "hierarchy" obscures the fact that sometimes the best evidence is not objective, not additive, and sometimes not even clinical (6)".*

This 'house' model evolved to be depicted by Walach et al as being circular instead of hierarchica l(7). This model was derived from the experience and history of evaluation methodology in the social sciences (8, 9). Again, rather than postulating a single "best method" this view acknowledges that there are optimal methods for answering specific questions, and that a composite of all methods constitutes best scientific evidence. Sometimes there may exist nothing but expert opinion on a

clinical question; thus, it becomes 'best evidence.' However when making decisions with respect to patient care, it is imperative to use the highest-level evidence available. When evidence is lacking, clinical decisions may still be made on biological plausibility, cost-effectiveness, feasibility and avoidance of harm (10-12).

In chiropractic science, a frequent objection to RCT's is that the chiropractic clinical encounter is so complex that it is impossible to identify controls as valid comparisons, especially that of designing a valid placebo for chiropractic spinal manipulative therapy (CSMT) (13-16). Complexity certainly presents challenges for those designing and conducting clinical trials however, this is by no means a challenge unique to chiropractic and should not be viewed as overly daunting. Clinical interventions in the fields of nursing, mental health and psychology are also inherently complex, but this has not prevented this sector from being extensively investigated via RCT's (17,18).

Scientists in all the health care disciplines recognise that clinical encounters are composed of a kaleidoscope of constituent parts, which are able to act both independently and interdependently. These include client/patient behaviours, goals and expectations, and practitioner characteristics as well as locale, demographics, and personality; of both patients and clinicians (19,20). All these criteria are certainly characteristic of chiropractic practice.

Certainly controlled trials and other sophisticated research designs have been applied to chiropractic (and SMT) for many decades. There is now an impressive body of literature exploring the management of spinal pain which after all constitutes the vast majority of chiropractic practice (21-23). There are more than 2500 controlled trials of treatments for back and neck pain listed in the Cochrane database, 32 Cochrane systematic reviews of randomised trials, 13 national clinical guidelines and 2 international guidelines (24-27).

Other researchers went to some lengths to illustrate what may be to some, surprising limitations of RCT's; 1) RCT's usually lack external validity since they tend to employ such strict inclusion and exclusion criteria that the participants are not representative of the general population; 2) RCT's may actually increase health risks in the general population since people with complex health problems are not usually participants in RCT's; 3) The premise that RCT's are the only form of evidence capable of providing an unbiased estimate of treatment effects is false (28); 4) The averaged results derived from RCT's often offer insufficient or even incorrect guidance on how to approach a specific case (29); and 5) The excessive expense of RCT's leads to vulnerabilities in the quality of evidence (30). The payment of participants creates incentive to 'bury' negative reports and bias toward areas where commercial funding is possible (i.e. pharmaceuticals) and a brief intervention time to evaluate efficacy (31).

In the later part of the last decade, as inadequacies in traditional RCT's have become increasingly debated, a literal plethora of innovative designs have been proposed, summarised articulately by Rosner in a treatise on challenges faced by EBM (32). These include; *Pragmatic trials*, in which the intervention is intended to represent "real-world" care; *Factorial designs*, comparing single modalities to a combination of modalities; *Preference trials*, in which participants with no treatment preferences are randomised as usual, but those with distinct preferences in their

care receive their favoured treatment; and *n-of-1*, a single patient trial with multiple crossovers between a treatment period and a placebo or standard treatment period (33). Rosner goes on to summarise important RCT design evolution; '*Randomised Encouragement'* design: to encourage adherence to the trial protocol, participants are either given strong incentives that are outside usual practice or are allowed to choose or decline a specific treatment to which they have been assigned (34); *Pragmatic clinical trials* (PCT's), which ask practical questions about the risks, benefits, and costs of intervention as they would occur in routine clinical practice (35); *Whole systems research* (WSR), which uses observational studies and includes qualitative as well as quantitative research (36). Finally, *Patient-oriented evidence that matters* (POEM) which focuses only on what is important useful information at the point of care (37). There is a growing movement to employ these methodologies (38), aiming to examine all the influential variables (including physiological, psychological, spiritual, social, and personal preference/utility) and to recognise that each patient is unique with respect to these dimensions (39,40)

Then there is the known limitations phenomenon of A+B vs. B studies; where A+B is likely to show superior outcomes even if A is a placebo. There is however, emerging thought that intentionally choosing usual-care controls, even when a satisfactory placebo exists, may allow capture of non-specific therapeutic benefits that are common to all interventions. This is especially true if the primary intent is to explore the value of an intervention for improving the lives of patients; that is, a 'pragmatic trial' (41,42).

Campbell et al recognised and outlined a phased approach to the development and evaluation of complex interventions to help researchers define clearly where they are in the research process and significantly, noted evaluation of complex interventions requires use of both qualitative and quantitative evidence (43). Foster described the key features of high-quality randomised controlled trials;1) sample representative of the patient group; 2) randomisation of individuals; 3) appropriate control or comparison treatment (sometimes a placebo); 4) concealment of the intervention from both patients and practitioners; and 5) an intention-to-treat analysis. The methodological challenges posed by studying 'complex' interventions thus include the need to define the various components of the intervention including their anticipated specific and non-specific effects, determine the characteristics of patients that may respond to a multi-modal intervention and ensure consistent and high-quality delivery of the treatment programme (19,44).

Mixed Methods Research (MMR)

What is Mixed Methods Research?

Creswell (45) defines mixed methods research (MMR) as;

> *"… a method, that focuses on collecting, analysing and mixing both quantitative and qualitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone (45, p5)".*

Mixed methods research (MMR) thus provides many strengths that offset the weaknesses of either quantitative or qualitative designs, the key strengths being: (a) the voices of participants are directly 'heard' and recorded in qualitative research, (b) all of the potential tools of data collection are all available to the researcher when both methods are used, and (c) the researcher is enabled to utilise all the various types of data available to answer the research question (46,47). A prominent example is 'Pragmatism', with its focus on 'what works' which allows the researcher to move beyond philosophical questions about mixing or combining methods and allows for an integrated methodology for the health and social sciences (48,49).

Aim

The aim of this paper was to identify various mixed methods models of research design and discuss their applicability to complex and sophisticated research in the complementary and alternative space, particularly chiropractic and manipulative therapy.

METHOD

Five databases were searched in addition to 'Google Scholar' in December 2012. These databases included Medline, Web of Science, EMBASE, SportDiscus, and The Cochrane Library. The search criteria used were "*complex research*" OR "*mixed methods*" AND "*chiropractic research*" OR "*complementary*" AND "*alternative*" AND ''*model.''*

RESULTS

Various designs of mixed-methods design were identified broadly fitting four major types according to a typology described by Creswell and Plano-Clarke (45). Note: examples are presented as representing study design and no evaluation is made of study quality. Abstracts are sometime quoted verbatim where indicated.

The Four Major Types of Mixed Methods Designs

1. *Triangulation Design*

The triangulation design is the most common and well-known MMR design, which was previously known as the 'concurrent triangulation design' (50). Researchers implement both methods during the same timeframe and with equal weight. The purpose is to obtain different but complimentary data on the same topic. The intent is to bring together the differing strengths of quantitative methods (large sample size, trends, generalisation) with those of qualitative methods (small n, details, in-depth perspectives). This design is used when a researcher wants to directly compare and contrast quantitative statistical results with qualitative findings or to validate or expand quantitative results with qualitative data. The traditional model of triangulation mixed methods design is the convergence model where integration occurs during the interpretation phase (Figures 1 a-d) (51).

Figure 1(a). Triangulation Design

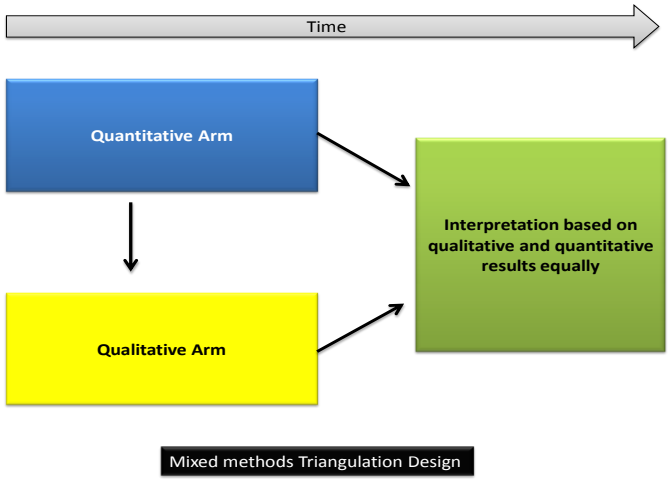


Figure 1(b). Data Transformation Model

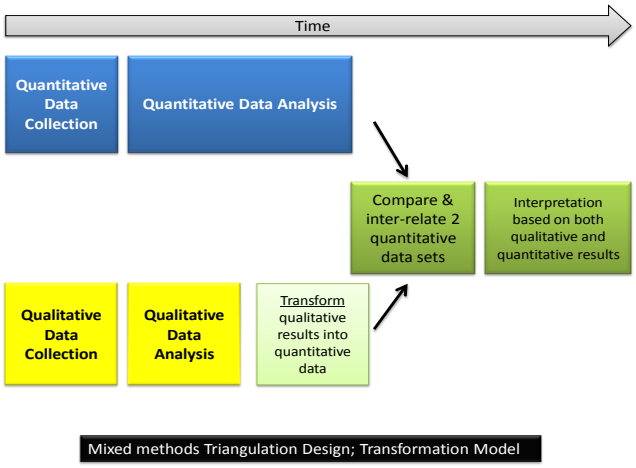


Figure 1(c). Validating Quantitative Data Model

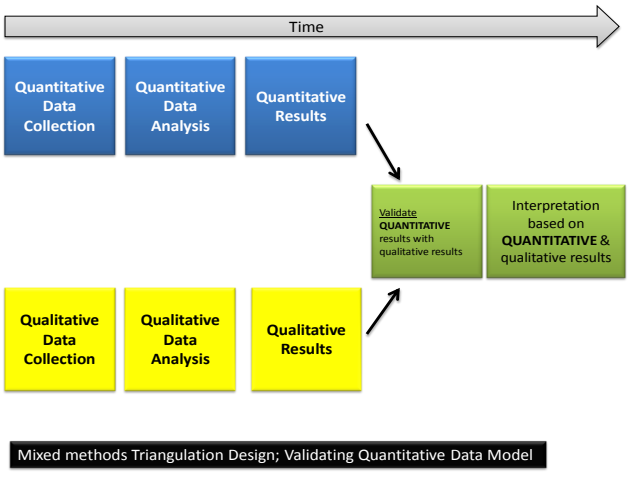
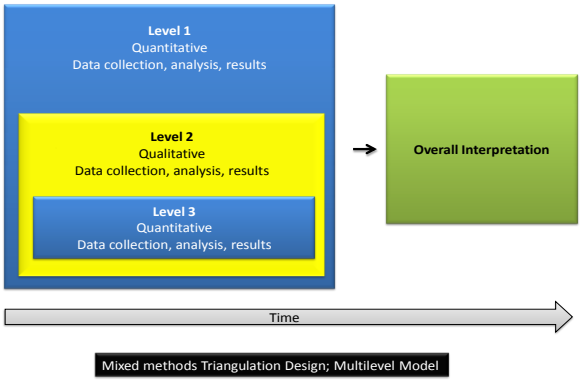


Figure 1(d). Multilevel Model



CAM Example;

> Kopansky-Giles (52), Teaching an inter-professional approach to the management of musculoskeletal problems in primary care – a pilot study. "Pre-and-post program semi-structured focus groups with students were conducted to explore satisfaction with the program, and perceptions of program impact on the acquisition of collaborative competencies in MSK care. Key informant interviews with teachers were conducted to determine program content and the different educational approaches to be used. Inductive thematic analysis and triangulation of data sets was utilized to evaluate qualitative data(52).

2. Embedded Design

The embedded design, is characterised by having one dominant method, whereas the other data set provides a secondary or supportive role where priority is given to the quantitative methodology, and the qualitative data set is subservient (51). Experimental Embedded Design is the most commonly used variant of the embedded design and has qualitative data embedded within an experimental design (such as a true experiment or a quasi-experimental design) and the qualitative data set is subservient within that methodology. A variant is the 'Correlational Embedded Design' where researchers collect qualitative data as part of their study (Figures 2 a-c).

Figure 2(a). Embedded Design

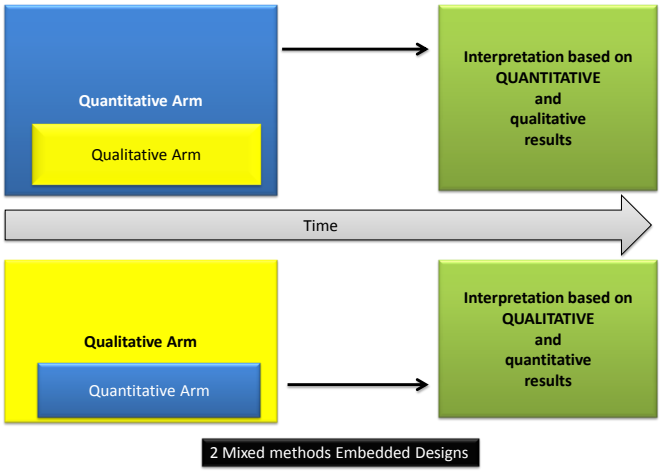


Figure 2(b). Embedded Experimental Design

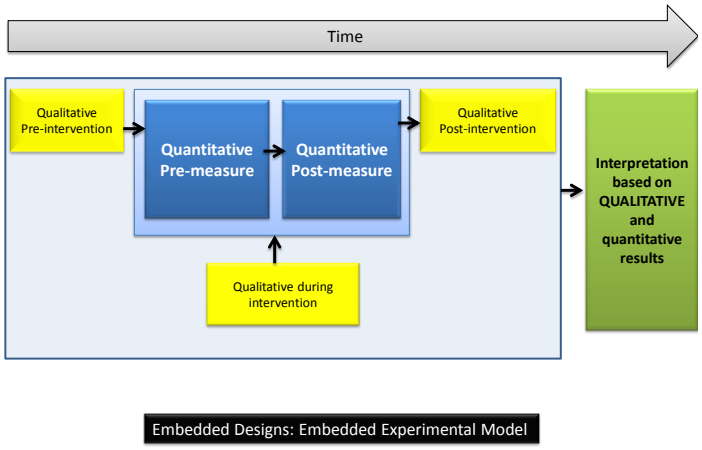
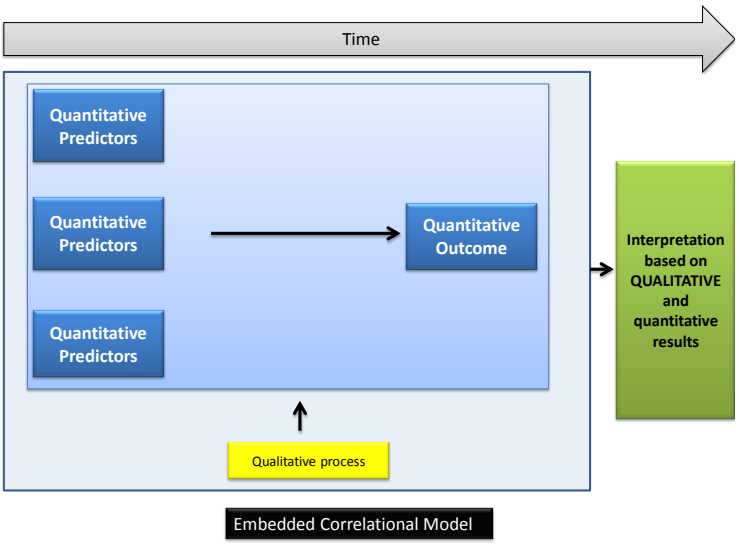


Figure 2(c). Embedded Correlational Model



CAM Example;

> GP attitudes and self-reported behaviour in primary care consultations for low back pain. A national UK-based survey of GPs and physiotherapists with an embedded qualitative study. "This study qualitatively examined the attitudes and self-reported behaviour of GPs in relation to guideline adherence for patients with LBP(53)".

3. Explanatory Design

These are two phase mixed-method designs; the purpose of which is to use qualitative data to help explain or build upon initial quantitative results (Figures 3 a-c). Sequential explanatory design consists of two phases, beginning with the quantitative phase and then the qualitative phase, which aims to explain or enhance the quantitative results. There are two main variants—the follow-up explanatory model and the participant selection model. Within the follow-up explanatory model, the researcher identifies specific quantitative findings, such as unexpected results, outliers or differences between groups that need further exploration using qualitative methodology, whereas the qualitative phase has priority in the participant selection model, and the purpose of the quantitative phase is to identify and purposefully select participants (51).

Figure 3(a). Explanatory Design

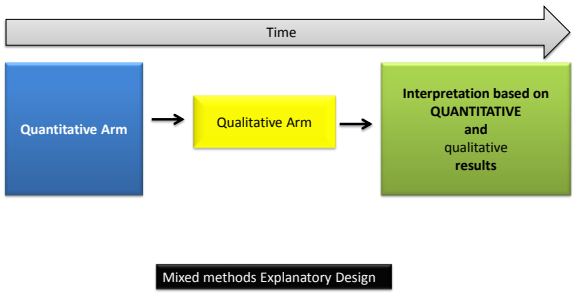


Figure 3(b). Follow-up Explanations Model

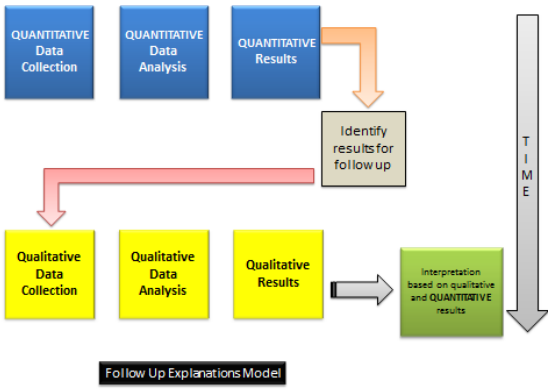
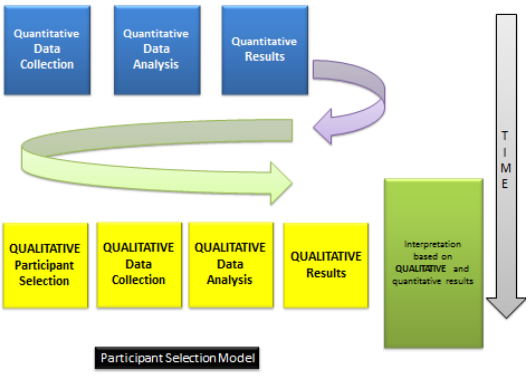


Figure 3(c). Participant Selection Model



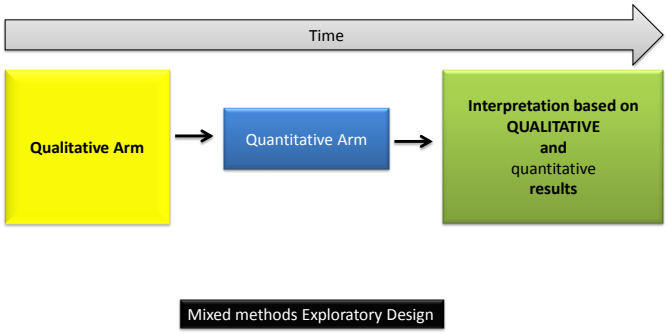
CAM Example;

> Ritenbaugh (54), Developing a patient-centered outcome measure for complementary and alternative medicine therapies. “Patients receiving complementary and alternative medicine (CAM) therapies often report shifts in well-being that go beyond resolution of the original presenting symptoms. The authors undertook a research program to develop and evaluate a patient-centered outcome measure to assess the multidimensional impacts of CAM therapies, utilizing a novel mixed methods approach that relied upon techniques from the fields of anthropology and psychometrics (54)”.

4. Exploratory Design

The exploratory design is a sequential design where the first phase, qualitative, helps in the development of the quantitative phase(51). These are two phase studies with the intent of using results of the first method (qualitative) to help develop or inform the second method (quantitative), based on premise that an exploration is needed – for, for example: measures or instruments are not available, the variables are unknown or there is no guiding framework or theory. Applications include; Instrument Development Model, Taxonomy Development Model (Figures 4 a-c).

Figure 4(a). Exploratory Design



Chiropractic example;

> Jones-Harris (55), Are chiropractors in the UK primary healthcare or primary contact practitioners? a mixed methods study. “A sequential study of exploratory design was used; this model is characterised by an initial phase of qualitative data collection and analysis that precedes and informs the quantitative phase of data collection and analysis. In this study, interviews with members of chiropractic teaching faculty were used to inform the development of a questionnaire used to survey the opinions of chiropractors in the UK(55)”.

Figure 4(b). Instrument Development Model

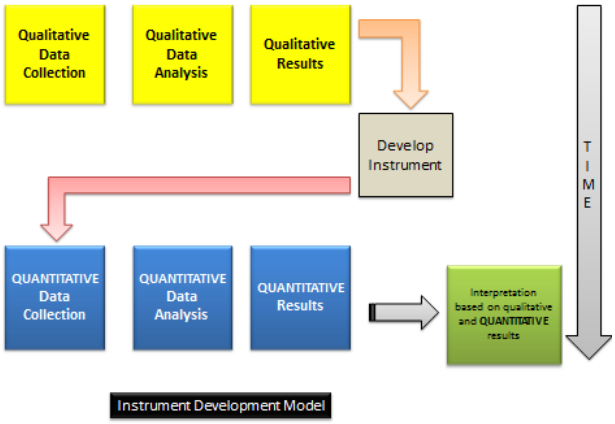
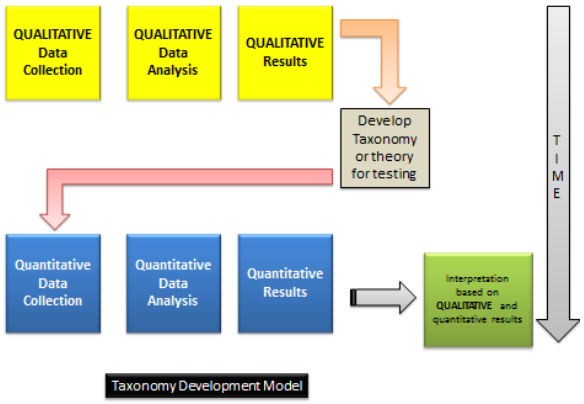


Figure 4(c). Taxonomy Development Model



Discussion

The way EBP is sometimes implemented is controversial, not only within the chiropractic profession, but in all other healthcare disciplines, including medicine itself(56). Criticisms are well-documented in the healthcare literature, eloquently summarised for example by Mykhalovskiy and Weir (57). RCT's have long had strident critics, notably within mental health, nursing and the social sciences; fields not entirely dissimilar to chiropractic with respect to complex clinical encounters. Vocal among these are for example;

> McManus (58), *"contrary to the wilder claims of their advocates, randomised controlled trials should not be construed as gold standards, the highest forms of knowledge on which evidence based medicine can be based. They are*

> *perhaps the smallest units of knowledge, consisting only of crude empiricism devoid of theory* (58)"...
>
> and Rolfe (59); *"Therapeutic relationships are not merely more or less complex examples of a general and measurable intervention; they are unique instances that need to be understood in very different ways. That is not to say... that the RCT has no place (in nursing), but that the RCT should know its place (59)".*

As the debate regarding the application of EBP in chiropractic continues, it is perhaps timely to reflect that if health care were to ubiquitously hold all treatments and interventions for any condition, in any profession, to 'Level 1' or high level evidence [or recommendation level 'A'], that is in effect a proposal to revert most of healthcare back to the dark ages. Those who criticise the (lack of) scientific (RCT) basis of chiropractic would do well to reflect on the absence of (RCT) clinical trials of, for example; dental root canals and spinal surgery.

Alcantara (60) points out;

> *"the RCT design minimizes or excludes the impact of the doctor-patient relationship (i.e., the non-specific effects) on outcomes, while in chiropractic (as with other alternative therapies), the non-specific therapeutic effects of the clinical encounter is embraced and considered an important aspect to wellness care* (60)".

It is an unavoidable observation that research evidence and EBP is often ostensibly crafted to support political or policy agendas rather than to ensure equitable access for patients to care or to drive evidence-based healthcare services. For example, the scientific evidence for the treatment of low back pain is published in national and international clinical guidelines, yet adoption of these guidelines in clinical practice by relevant disciplines including physiotherapy and medicine is nonetheless very poor (61-64). Consequently, there is a major drive to educate patients and practitioners about evidence-based management of spinal pain, with a view to translate research into practice (24,65). One can rest assured however; there will be an even greater focus on evidence-based treatment and practice in the emerging healthcare milieu of the future, with cost containment and streamlining of care practices being at the centre of attention (66). The bottom line is this – EBP has gained favour across the majority of healthcare disciplines and organisations, and is here to stay for the foreseeable future (67).

Some chiropractors may continue to rail against, and even fear of EBP, but this will do little to promote and advance the profession. This attitude is also misplaced since as this series points out, a substantial amount of research evidence already exists that supports many of the measures chiropractors use in day-to-day practice (68, 69). Correspondingly, there is also an marked absence of evidence *contrary* to the chiropractic paradigm, even in areas for which there is not yet compelling *supportive* data, such as for non-musculoskeletal conditions, wellness/well-being and paediatric care. There is a marked difference between a question having been asked and so results are known, and the (right) question not been asked in the right way thus results not being available. For example; for some time it has been thought neck manipulation is no more effective than mobilisation (and was less risky) (70),

however this belief is rapidly being superseded by emerging high level evidence (71, 72). Thus, extant evidence should rather be used to promote and improve the professions' profile using an EBP approach. It is, therefore worth reminding readers at this stage that EBP is not purely a research exercise; that is only one part of the EBP cycle, but rather a continuous process of; a) accessing and synthesising relevant healthcare, b) acting on the evidence by incorporating the evidence into practice, and c) evaluating if actions taken have had the desired effect in practice (73-76).

I am thus of the view that the chiropractic profession should further embrace EBP; using the positive aspects of this approach to the advantage of the profession and setting aside unnecessary defiance of an approach that is already the most significant influencing factor in healthcare decision-making of our time. In other words, generate research evidence that can influence healthcare policy by demonstrating that a) chiropractic has a definite role to play within the boarder healthcare system, b) that chiropractors are amenable and able to work within multidisciplinary settings, and c) that chiropractors have effective and cost-effective care to offer patients. Translational research and the gathering of practice based evidence is understandably assuming an increasing importance (65).

There are certainly those critical of the slower than ideal trend in increasing rigour of (CSMT) RCT's, however an exciting part of contemporary research and EBP is that research designs can now measure the effectiveness of complex interventions – interventions where the outcome is a result of the interplay and effect of the various management components (43,77-79). This confirms that there are indeed research designs, in the form of pragmatic practice-based clinical trials that can test complex treatments. This type of research does not seek to explain the effect of an individual treatment, but rather the effect of a "package" of care and the patients' "care journey" (80). This is the type of research that can be embraced by the chiropractic profession to influence healthcare policy and clinical practice, using the EBP approach. Investigators should not be daunted by the challenge, rather embrace new and creative approaches to evaluating for example; 'in situ' clinical encounters such as in PBRN's (81,82).

Chiropractic scientists are indeed rising to the challenge. Those who doubt the disproportionate influence of chiropractic researchers may have been somewhat surprised when *The Spine Journal* announced its *"Top 25 Hottest Articles";* the most downloaded articles for 2011. Thirteen of the 25 articles have at least 1 author who was a chiropractor. In addition, 10 of the 25 include content relating to spinal manipulation or chiropractic,; 6 of which included the terms in their title (83). A positive spin-off of evidence-based practice is that it can influence the evolution of the chiropractic profession by challenging many traditional practices, it questions use of interventions that are merely the preference of the practitioner and it helps evaluate the role of chiropractic within a contemporary healthcare landscape. As with all healthcare disciplines, the goal is to improve by, if necessary, adopting new ways of doing things and to set aside those practices that clearly are not effective or in the best interest of patient subgroups.

> "*If we are serious about coming to know something, then our research methods will have to be adapted to the nature of the phenomenon that we are trying to understand"*(84).

Landmark recent publications have built on evolving knowledge over the last decade to provide all health practitioners with guidance on how they can design and evaluate complex studies (19,85,86). Chiropractic scientists have embraced this trend and this paper argues that the chiropractic profession should adopt such thinking more widely.

CONCLUSION

The examples presented in this series illustrate, what can be achieved by relatively few dedicated chiropractic research scientists with meagre resources. Complex challenges and limited funding are not, therefore, a reason to avoid sophisticated research. In fact, the complexity of chiropractic care and the ubiquitous lack of financial resources, make it even more important to use rigorous methods to conduct research. This series of papers has attempted to illustrate that a major objection to sophisticated research in chiropractic – that chiropractic is too complex to be studied, can be overcome by careful attention to methodology and detail; and utilisation of appropriate design. It is emphasised that the strength of inventive chiropractic research in the authors' opinion lies in the combination of both qualitative and quantitative research, and in the gathering, replication and application of research findings in the 'real world' of clinical practice.

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