AN EVIDENCE-BASED NARRATIVE OF THE EVIDENCE-BASE CONCEPT

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Abstract: This narrative review examines the limited and varied interpretation of what constitutes evidence in evidence based chiropractic practice. The authors report a bias towards only one of the three evidential pillars that Sackett proposed as the basis for evidence-based practice. The literature reveals an increasing number of papers that suggest evidence can be compromised and may therefore at times be of questionable value in the practical clinical setting. The application of evidence to chiropractic practice is shown to be less than inclusive and this paper recommends that bodies with influence over the profession must broaden their understanding and acceptance of the full spectrum of evidence that sits within Sackett et al's established model. To continue with a view that the only acceptable evidence are published studies in medical journals will continue to diminish the value of evidence drawn from the experience of chiropractors and the expectation of their patients. Regulators are urged to accord the same evidential value to the literature of chiropractic as to the broad literature of medicine; to do otherwise is to create an elitist perspective to the detriment of the conventional chiropractic practitioner.

Indexing terms: evidence, EBP, EBM, chiropractic

Introduction

The frequent citation of Sackett et al's principles of Evidence Based Medicine (EBM) demonstrates that EBM is a hot topic for clinicians of all professions not the least being chiropractic. In this paper the term EBM is synonymous with Evidence Based Practice (EBP). Sackett's editorial advanced three pillars of EBM which seem to have been reduced to one by primarily placing emphasis upon the pillar of best available published evidence. This has the effect of overshadowing the other two pillars of practitioner experience and patient input. This paper strongly advocates that all three pillars need to be equally considered in chiropractic and other clinical settings. (1, 2)

'... the application of evidence based principles is far from even let alone equal resulting in papers published by chiropractors being seen as having less evidential value.'

Quick Tap or Scan:

For the Sackett Principles to be properly adopted the clinician must consider the following key elements of Integrating individual clinical expertise with:

- The best currently available external clinical evidence from systematic research especially from patient centred clinical research;
- Individual clinical expertise including the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice;

- The thoughtful identification and compassionate use of individual patient's predicaments, rights, and preferences and;
- The efficacy and safety of therapeutic, prognostic, rehabilitative, and preventive regimens. [Adapted from Sackett et al 1996 (1)]

When these elements are considered in toto, the practice of limiting the EBM concept to best available evidence is somewhat muted. Also in 1996, rather than a solitary hard and fast rule, Sackett also recommended the need for the judicious use of evidence in clinical practice. Some thirty seven categories of evidence are listed in Table 1.

In suggesting that EBM could have multiple aspects implies that it should not be limited, Sackett and Haynes also note that '*As in other forms of clinical research, there are several different ways studying the potential or real diagnostic value of a physical sign or laboratory test, and each is appropriate to one kind of question and inappropriate for others*.' (3)

Cohen et al note a number of issues which question the EBM concept. These include a '*narrow definition of evidence*', a '*lack of evidence of efficacy*', and significantly, '*a threat to the autonomy of the doctor/patient relationship*'. This latter point suggests an undermining of the practitioner's experience and judgement. Gupta also noted the need for broader definitions of evidence in EBP. Slowther et al are quite strident when they state there are '*...concerns among primary care clinicians that evidence based medicine is not always relevant to primary care and that undue emphasis placed on it can lead to conflict with a clinician's duty of care and respect for patient autonomy*.' In urging collaboration in EBM, Zuiderent-Jerak notes that '*Guidelines should reflect all knowledge, not just trials*'. (4, 5, 6, 7)

Review

Reports on the appropriateness of blinded randomised controlled studies, case series and meta analyses as the gold standards for clinical practice are being raised more frequently. (8, 9) While superficially their status sounds a lofty ideal, it seems more appropriate as a laboratory status rather than in the clinical setting where there are many variables. (10) In noting the difference and suitability of a medical model of the evidence base for non-medical models of care, Borgerson states that '*The validity of evidence-based medicine (EBM) is the subject of ongoing controversy' and recommends that alternative care should 'work to develop new research designs and new standards of evidence that reflect their approach.*' (11)

The authors also argue that academic assertion has seized attention at the expense of clinical reality to the extent that the emphasis on the more formal forms of evidence over-shadows other critical elements at the clinical-patient coal face. Tonelli states firmly that EBM is '*... insufficient to provide for optimal clinical care. A gap exists between empirical evidence and clinical practice*.' (12)

Misak outlines the case clearly when she argues '*... that evidence-based medicine (EBM) imposes methodological limits that constrain the practice and study of medicine in unfortunate ways. EBM attempts to rid the study of medicine of the subjectivity of individual judgements, while in fact, any use of any kind of evidence requires judgement. On this basis, I argue that there are compelling reasons to broaden the range of evidence employed in EBM, and in particular, to include both straightforward and evaluative narratives. This would mark a shift from the current focus of EBM on purely quantitative data to the inclusion of qualitative data as well. I conclude by emphasizing that objectivity in medicine must come not from the exclusion of wide swaths of potentially valuable evidence, but from the careful application of our critical practices.*' (13)

Kovarsky also recognised the patients' subjective contributions in case reports as complementing the evidence base when he notes that. '*Personal experience narrative is suggested as one means for understanding experienced outcomes.'* (14)

Variables

By definition, clinical health care practices are not part of the pure sciences. Manual therapies are not necessarily subject to or suitable for laboratory-type experiments or mathematical modelling in the pure science sense. The many variables presenting in each case and the range of possible responses may not then result in predictable outcomes under the confines of EBP. Percentage outcomes report both positive and negative results, so that EBP-based guidelines cannot foresee an individual's response. Outcomes may or may not lead to total resolution, with care management depending on case presentation and patient response. This is despite attempts to try and relegate treatment to defined parameters when a degree of flexibility under the practitioner's management is essential for the optimal level of recovery for the individual patient. Fava states '*It is time to substitute the fashionable popularity of a strategy developed outside of clinical medicine with models and research based on the insights of clinical judgment and patient-doctor interaction*'. (15, 16)

It is submitted that a reliance on EBP as a gold standard is not always appropriate; reservations as to EBP reliability in the clinical setting have been raised elsewhere. (17)

EBP or best available evidence is open to individual assessment due to the many variables in its interpretation, evidence, condition presentation and individual characteristics of patients, and the reliability of published material. Miles et al highlight the rather tenuous and ambiguous debate by stating '*… no author has been able convincingly to show the superiority of the EBM "approach", "paradigm", "methodology", "philosophy", "system" or "process" and neither has it been demonstrated that EBM is unquestionably the right approach to follow in Medicine.*' As recently as 2015 recognition of the reliability of medical evidence was published in The Lancet. There, Horton stated that '*… much of the scientific literature, perhaps half, may simply be untrue.*' (17, 18, 19)

Cummings raises the issues of replicability and unidentified false positives and states that '*No one knows what proportion of published papers contain such incorrect or overstated results, but there are signs that the proportion is not small.*' (20)

Others raise issues about EBM such as bias, (21) clinical applicability, (22) quality, (23) and reliability. (24, 25, 26, 27)

In addition, there is mounting evidence to suggest that the evidence in EBP may not be reliable in some 37% of papers, especially if derived from early stages of their trials. The Australian Doctor medical newsletter cited a Mayo Clinic paper which reported (27) '*Grossly exaggerated results have been found in more than one in three early clinical trials, according to an analysis of almost 1000 randomised controlled trials (RCTs) from reputable journals.*'

The findings, published in Mayo Clinic Proceedings, suggest decision makers should treat early evidence with caution.

'The researchers found exaggerated results in 37% of early clinical trials and that these trials reported an effect that was 2.67 times larger than what was eventually shown when subsequent trials were published.

'This comes after reviewing 70 meta-analysis articles during an eight-and-a-half-year period that included the results of 930 clinical trials. (27)

In 2015 the Australian Health Minster Sussan Ley stated, '*Unfortunately the current system is lagging in the last century, with only 3% of all 5700 Medicare items assessed or tested to see whether they actually work, are out-of-date or even harmful.*' (28)

Some may regard certain types of papers that present subtle or abstruse symptoms as not being of sufficient evidential quality. Subject to prudence, others may regard them as a genuine

attempt to share and bring that clinical information to the attention of colleagues. El-Gilany recognises a role for reporting unusual or challenging presentations by stating that they may *'capture and describe important scientific and clinical observations that may be missed or undetected in "higher hierarchy" designs such as clinical trials.*' Riley also recognises that individual case reports '*have meaning not only to that patient and his or her healthcare provider but to the broader medical community as well.*' (29, 30, 31, 32)

It could be considered remiss of a practitioner not to report and record observations that they considered relevant even if they were of exceptionally rare, obscure, or atypical in nature, and more so if they felt they were critical to a case. Such a clinical finding may not appear under the higher levels of the hierarchical evidence pyramid and therefore not in the evidence base archive. Manchikanti and colleagues opine that '*The concept of hierarchy of evidence is not absolute.*' They go further to state that '*Placebo controlled RCTs have multiple shortcomings.*' It is suggested here that EBM may be more relevant to the more advanced medical conditions and perhaps not so much to the everyday clinical presentations. (10, 33, 34, 35)

Charles Limb clarified the practical element of clinical practice and reservations of the perils of being bound by certain rules of evidence when he stated:

> '*However, the delivery of health care is not a pure scientific process.*
>
> '*There are many cases in which a patient's satisfaction with his or her treatment will take precedence over the provider's view of how well the treatment adhered to the best available evidence. And in the end, all of the evidence in the world may provide little comfort to a patient who has a poor outcome. There is a wide range of variables beyond a provider's control that ultimately may have as huge an impact on a patient's outcome as any randomized controlled trial.*
>
> *'Even when randomized controlled trials exist, it is often unclear how the results should be applied to patients whose profiles do not quite match those of the patients who were enrolled in the trials.'* (36)

Discussion

While the term EBP is in common use, there does not seem to be any clear or useful determination as to what actually constitutes acceptable clinical evidence. Some regard case reports, narratives or anecdotes as evidence, other do not. There is a wide variety of versions of EBM and also debate over the relevance of the pyramidal hierarchical levels of evidence. There also appears to be different emphasis on each of Sackett's three pillars of EBP with patient preference and the clinician's experience seemingly relegated to a lesser level of importance resulting in a dominance of best external research evidence. The once relegated category of case reports are again being suggested as a notable contribution to the overall evidence in being pragmatic and necessary. (37, 38, 39, 40, 41, 42)

To incorporate the term acceptable evidence implies a judgemental element. As such, its interpretation must be broader than is currently adopted. There is a need however to differentiate the clinical trials and laboratory testing from the clinical setting.

Medicine has fostered the impression that it is an exact science. It may be based on aspects of science but it has been deemed an inexact science because it is based as much on the art or probability, subjective judgement and variabilities. (43) '*In medicine, exact explanation of causes of diseases, concise diagnosis and absolute predictability of outcome of treatment are difficult, if not impossible!*' (44)

All health care professions incorporate anecdotal evidence - be it subtle or overt, as it comprises a significant part of the clinical experience as one of Sackett's pillars. No health profession would evolve if clinical observations were not exposed, noted, explored and shared. Anecdotal findings are an essential part of everyday practice both for positive and negative

findings and therefore should play an important role in case reports. Enkin stated that; '*If evidence-based health care is to meet its potential, the important role of anecdotes must be acknowledged, studied and utilized.*' A further paper by Marchikanti and colleagues acknowledge the potential contribution of observational studies but also note that at times '*... there can be a critical discrepancy between the experts and the evidence.*' (45, 46, 47)

In deference to the patients' contribution Ioannidis opines that '*perhaps the most influential experts nowadays are patients themselves*.' (48)

The evidence base

The term chiropractic has been largely avoided in medical and physiotherapy papers on spinal manipulation yet no reason is given for this oversight. (49) Indeed such papers seem to go out of their way to eschew citing papers from chiropractic journals despite adopting chiropractic concepts which they had earlier rejected. At the same time, there are many European medical journals which contribute to discussions on the manipulative management of certain conditions that are overlooked by many English language journals. One dilemma here is whether to recognise this European medical literature base, or the UK, USA, Australian published medical literature which tend to contradict the Continental evidence. A second is the expectation that commentators are expected to take a global not national perspective. (50, 51, 52)

Even the *Chiropractic Board of Australia* (CBA) and the *Australian Health Practitioner Regulation Agency* (AHPRA) seem equivocal as to what is supporting evidence with the term acceptable evidence being ambiguous and open to interpretation:

> *'The Code of conduct requires practitioners to practice in an evidence-based and patient-centred manner to ensure they provide the best healthcare for their patients. Evidence-based practice involves a practitioner considering available acceptable evidence, including research and other sources of information, in addition to their clinical experience and the patient's values during their clinical decision-making process.'* (53)
> [Emphasis added. The authors note that the last sentence incorporates Sackett's three-pillars of EBP.]

Surely acceptable evidence must be clarified to include the evidence from refereed chiropractic journals. By being pro-active on this issue the CBA could be seen as determining the criteria that is used. This is a practical, clinical and academic exercise, not just an academic or bureaucratic determination alone. (54)

The 2019 Safer Care Victoria (SCV) review saw Cochrane Australia set its own criteria on efficacy and came up with different findings to that of the recent British Columbia report on the same topic. In spite of these different interpretations of evidence, both reviews confirmed the safety of chiropractic manipulative management of children. This example effectively demonstrates the variables in interpreting what is evidence, and what is demanded of that evidence to meet perceived or selected criteria. It is up to the profession to offer and submit to the Chiropractic Boards and other professions what is acceptable by way of recognised, published evidence. We strongly argue that refereed chiropractic papers should be included. (55, 56)

Furthermore, we see no regulation requiring '*chiropractic evidence*' to be published in medical journals, nor for chiropractic papers to cite only medical studies for them to be regarded as quality evidence.

We would argue that chiropractic leaders must take a firm stand in support of legitimate chiropractic evidence to allay the notion that evidence does not exist. Claims of this nature have been a baseless ploy used against the profession for too long in our view. Far too often critics have claimed there is an absence of chiropractic evidence. We consider this a weak, unsubstantiated excuse to avoid recognition of the chiropractic model and its concepts. Essentially such a claim constitutes a persistent denial of the chiropractic evidence that does exist. In turn, such a claim

ignores the evidence from papers with chiropractic concepts adopted by medical manipulators, as well as '*Sato-type*' somatosensory neurophysiological studies. (57, 58, 59)

Chiropractic's Research Agenda

We are critical of chiropractic continually investigating lower back pain (LBP) and view this as a wasteful exercise of reinventing the wheel. LBP is recognised as the most extensively researched topic and the chiropractic model is highly recognised particularly in the United States. To persist with this field of research means other critical areas are being neglected. It would be in the interest of patients and for the chiropractic profession if research was to be focussed on a range of topics including topics fundamental to chiropractic. It is difficult to reconcile putting so many limited research dollars into LBP when the profession has already established convincing and well recognised evidence – even though its general acceptance by medicine and physiotherapy is still essentially absent. (60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72)

Clinical Guidelines May Not Be Evidence Based

Clinical guidelines are purported to be based on the best available evidence or acceptable evidence. In the case of AHPRA, the recommendation for that is solely based on external evidence without emphasis on the other two critical elements from Sackett's three pillars. This appears to be an overemphasis on the source, relevance, inclusiveness, study design, quality, and strength of the evidence. (73)

In a consideration that has concerned us Saarni and Gylling raise an aspect regarding the ulterior misuse of the EBM model. They state that '*Using EBM as a powerfully attractive tool for disguising political programmes as science will only frustrate both doctors and patients.*' (74)

Leeder also emphasised the importance of broader criteria for guidelines when he stated, '*No CPG can take full account of patient preferences or the clinical or social realities that might be critically important in the management of that individual, however strong the evidence on which it is based.*' (75)

In 2010 Buchan and colleagues found that less than 20% of studies have the highest level of available evidence in clinical guidelines in relation to ten leading causes of mortality in Australia. Venus and Jamrozik found similar percentage of clinical practice guidelines a decade later, as also reported by Calafiore. (76, 77, 78)

Calafiore also '*stressed not all recommendations required justification through high-level evidence, and that some consensus-based recommendations could be regarded as common sense.*' (78)

There are further reservations as to the relevance of evidence-based guidelines. A 2014 Australian study concluded that '*The level of RCT support for common orthopaedic procedures compares unfavourably with other fields of medicine.' and further that 'the majority of orthopaedic surgical interventions are not based on RCT evidence.'* (78) A recent Australian study of physiotherapy practices found that 25% of physiotherapists provide treatments with little or no evidence, and that 27% used treatments that were expressly not recommended by guidelines. (79, 80, 81)

Horwitz averred that '*there are large areas in which the evidence to guide clinical decisions is incomplete, contradictory, or inconsistently interpreted.*' Maynard notes that the Cochrane Collaboration has enhanced the EBM model, but feels to be effective it requires '*major change' for 'better services to patients.*' He also feels that the EBM model is retrogressive rather than a '*population-health ethic of efficiency.*' (82, 83)

The current state of EBM could be regarded as somewhat fluid with the Academy of Medical Royal Colleges (AMRC) issuing a list of forty unnecessary medical interventions in the UK, and

450 in the USA. For this revelation to even be raised after 20 years of EBM seriously challenges the system if not the model, and raises further questions about the persistence of entrenched habits. (84)

Sackett also recognises that '*In practising evidence-based medicine, we also apply evidence-based guidelines*' which may incorporate '*the critical appraisal of economic evidence*' as a further consideration in EBP. This factor dilutes focus on the sole pillar of external evidence even further. (85)

As guidelines are based primarily on published evidence, that value of the evidence is further questioned when 90% of published evidence is never cited and 50% of papers are only read by '*their authors, referees and journal editors.*' (86)

Conclusion

The chiropractic profession must be fully supportive of the premise and application of an evidence based model of practice applying across all health professions, but not to the exclusion of different forms of evidence that are considered valid and acceptable, and are in common use.

It would be a great service to patients, the chiropractic profession and the evidence base as a whole for the professional chiropractic associations to take a stand, by stating a policy recognising chiropractic papers and case studies as being legitimate evidence. Such action would call to order the current ostracising of chiropractic material as having no basis for being considered as evidence.

In the interest of patients, it is critical that the acceptable evidence be brought into perspective with practitioner experience and expertise as well as patients preferences. This may well mean that the emphasis on external evidence be relaxed as being the sole criteria for the EPB model.

The concept of evidence based practice is supported, however the experience of precedence and the pragmatic aspects of practitioners' and patients' own considerations must be considered in a greater role as being of equal value to evidence from published studies if Sackett's precepts are to be followed.

In effect, the ultimate outcome criteria of efficacy are the patients' well-being and their own sense of that state.

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Cite: Rome P. Waterhouse JD. An evidence-based narrative of the evidence-base concept. Asia-Pacific Chiropr J. 2020;1:004 DOI https://doi.org/10.46323/2021004

Table 1: List of categories extracted from a variety of evidence pyramids, it highlights the ambiguities involved for the practitioner trying to extract so-called acceptable evidence.

Anecdotal.
Animal research, laboratory studies
Background information
Case controlled studies
Case reports
Case series
Clinical practice guidelines
Clinical reference texts
Clinical research critiques
Cohort studies
Conceptual studies
Controlled longitudinal studies
Critically appraised individual articles (article synopses)
Critically-appraised topics (evidence synthesis)
Cross sectional surveys
Cross-sectional studies
Descriptive studies
Editorials
Evidence summaries
Expert opinion
Generalised studies
Ideas
In vitro research.
Meta-analyses
Narrative reviews
Opinion
Other reviews of the literature
Placebo controlled studies
Prospective
Reviews
Quasi-experimental studies
Randomised controlled double blinded studies
Randomised controlled trials
Retrospective studies
Single case study
Systematic reviews
Uncontrolled longitudinal studies

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