Perspectives on evidence based practice in ABI rehabilitation. “Relevant Research”: Who decides?

Catherine Wiseman-Hakesa,*, Sheila MacDonaldb and Michelle Keightleyc

aGraduate Department of Rehabilitation Science and Department of Speech Language Pathology, University of Toronto, Canada
bSheila MacDonald & Associates, Toronto, Canada
cGraduate Department of Rehabilitation Science, & Department of Psychology, University of Toronto, Canada

Abstract. Growing evidence suggests that acquired brain injury (ABI) rehabilitation and research should be guided by a philosophy that focuses on: restoration, compensation, function and participation in all aspects of daily life. Such a broad, more pluralistic approach influences ABI rehabilitation research at a number of levels, including both the generation of evidence, and in searching for, critiquing and applying the evidence to practice. The objective of evidence based medicine/practice (EBM/EBP) is to apply and integrate clinical expertise with evidence gained through systematic research and scientific inquiry to medical/clinical practice. While there is abundant literature debating the practical and sociological implications of EBP, there has been limited examination of EBP within the inherently complex nature of ABI rehabilitation and rehabilitation research. This paper provides a framework for clinical decision making regarding evidence based practice in the context of ABI rehab including: 1. A discussion of the purpose of evidence based practice, 2. Levels of evidence relevant to ABI rehabilitation research, and 3. A rationale for incorporating a broader, more pluralistic concept of evidence or “person-centred EBP”. We conclude with a series of key questions for the evaluation and application of systematic reviews of the evidence in the context of ABI rehabilitation.

Keywords: Acquired brain injury rehabilitation, traumatic brain injury rehabilitation, evidence based practice, evidence based medicine, rehabilitation research, treatment evidence, outcome, intervention

1. Background and introduction

Acquired brain injury (ABI), is defined as an injury to the brain occurring after birth that is not related to congenital defect or degenerative disease. Causes of ABI include (but are not limited to) hypoxia, illness, infection, stroke, substance abuse, toxic exposure, trauma, and tumor [3]. Although there is a lack of clarity regarding the definition of ABI internationally, for the purposes of this paper, ABI includes traumatic brain injuries (TBI), strokes, brain illness, and any other kind of brain injury. ABI may cause temporary or permanent impairment in such areas as cognitive, emotional, metabolic, motor, perceptual motor and/or sensory brain function [3]. The most common type of ABI is TBI, which is defined as an acquired injury to the brain due to applied force, and includes closed head injury (e.g. via gravitational force) and open head injury (e.g. with penetration of the skull by a missile [52] TBI); is a leading cause of death and disability world-wide. Injuries to the brain are among the most likely to result in death and permanent disability [27].

An individual with ABI may experience a variety of cognitive, communication, physical, emotional, social and psychological difficulties. These difficulties can create profound disruption and challenges for both the individuals and their families, making return to independent living in the community a primary focus.
Successful community integration, or in effect one’s quality of life, typically involves regaining a sense of ‘self’, relationships with others, independence in one’s living situation and activities to fill one’s time [34,39]. This goal has been reflected in the increasing number of publications focused specifically on quality of life after brain injury [15,34,39,50,59].

Growing evidence suggests that ABI rehabilitation and research should be guided by a philosophy that focuses on: restoration, compensation, function and participation in all aspects of daily life, including consideration of contextual factors, the unique life circumstances of the individual, and the quality of support provided by others [5,61,64]. This philosophy has a direct impact on the way that evidence for intervention is both generated for, and applied in, clinical decision making for ABI rehabilitation. Additionally, this philosophy has led to the call by some researchers and clinicians for a broader and more “pluralistic” approach to evidence based practice (EBP). The term ‘pluralistic approach’ was first identified in the nursing literature on EBP [35]. In the context of ABI rehabilitation, it is an approach that considers the whole person, their daily life contexts, and supports, and thus, should be reflected within evidence generation, evidence search, and knowledge translation [5,31,35,37,63,64]. Taken in its literal sense, a pluralistic approach is one in which there is more than one universally accepted doctrine or methodology. When this pluralistic approach is applied to ABI rehabilitation and rehabilitation research, it is one which advocates for a broader, more inclusive definition of individualized, client centred treatment and thus a broader scope of research methodology.

2. Goals and objectives of paper

A broader, more pluralistic approach to ABI rehabilitation influences ABI rehabilitation research at a number of levels, including both the generation of evidence, as well as in searching for, critiquing and applying the evidence to practice. While there is abundant literature debating the practical and sociological implications of EBP, there has been limited examination of EBP within the inherently complex nature of ABI rehabilitation and rehabilitation research. Thus, we aim to provide a framework for clinical decision making regarding evidence based practice in the context of ABI rehabilitation. Included will be: 1. A discussion of the purpose of evidence based practice and some of the challenges associated with implementing EBP in ABI rehabilitation, 2. Levels of evidence relevant to ABI rehabilitation research, and 3. A rationale for incorporating a broader, more pluralistic concept of evidence or “person-centred evidence based practice”. Finally, we will present a series of key questions for the evaluation and application of systematic reviews of the evidence in the context of ABI rehabilitation, and very briefly, summarize considerations that clinicians can use to determine and critically analyze the evidence. It is our hope that a critical appraisal of evidence summarized in systematic reviews, utilizing specific criteria within a pluralistic approach to EBP [35], will facilitate sound clinical decision making and ultimately ensure the most effective rehabilitation for individuals with ABI. At a minimum, we hope this paper may stimulate further discussion regarding the generation and application of evidence in the context of client-centred care in ABI rehabilitation.

3. Evidence based medicine and evidence based practice; what is it?

Evidence based medicine (EBM) is defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients [46]. The objective of EBM is to apply and integrate clinical expertise and judgment with evidence gained through systematic research, and scientific inquiry to medical/clinical practice, and to improve health outcomes through the implementation of the most effective interventions [4,23]. Over time, the principles of EBM have been extended to a broader rubric of evidence based practice (EBP) which addresses clinical practice in rehabilitation [37]. According to Sackett et al. [45] EBM (with application to EBP) is concerned with a) the scientific processes involved in amassing empirical support for population statements of the form “TX” (some treatment) that is effective or efficacious for “P” (some population), and then b) using these statements to guide the delivery of specific clinical services to specific patients. Those practicing EBM and EBP seek to assess the quality of evidence relevant to the risks and benefits of treatment(s), (including lack of treatment), with the ultimate goal of “best” practice. In the current culture of health care and practice, “best” refers to evidence that is derived from scientific research, based on carefully executed randomized controlled trials, the apex of the ‘evidence hierarchy’ and the gold standard for meeting EBM (and EBP) criteria for validity. However, despite the best intentions of
policy makers and clinicians, and the growing amount of scientific literature specific to ABI rehabilitation [10, 43]. EBP in the context of ABI rehabilitation is fraught with challenges. This may be due in part to the fact that the label of “ABI,” is one of the most challenging with challenges. This may be due in part to the fact that the label of “ABI,” is one of the most challenging to categorize based on diagnosis, as it can result in a myriad of diverse and complex clinical presentations.

4. The challenge of applying evidence to practice in ABI rehabilitation

The application of evidence to clinical practice requires academic and clinical expertise, as well as additional expertise in the retrieval, interpretation and application of scientific studies. This can be a daunting task for busy clinicians for a number of reasons; there may be issues within the hospital/rehabilitation system and culture, such that heavy case loads, the pressure to see more clients/patients, little or no protected time to search the literature, as well as little or no protected time or funding for continuing education opportunities in the area of evaluating evidence and EBP, may (and often does) result in little time being attributed to this important topic. Furthermore where education does take place, it is often based on a rigid definition of evidence.

In fact, as early as 1971, Garvey and Griffith [21] stated that “the individual scientist (and clinician) is . . . overloaded with scientific information, and (can) no longer keep up with and assimilate all the information being produced that (is) related (and relevant to) his primary specialty,” (p. 350). Additionally, as the number of studies evaluating the effects of treatment interventions in ABI continues to grow, difficulties can arise when different studies reach different conclusions as to the merits of a particular intervention. Further, there have been a number of well documented criticisms of EBM, some of which apply directly to EBP for ABI rehabilitation, from the perspectives of science, social science, philosophy and ethics [23,35,37,38,54,55, 64]. The reality of clinical practice is, as described by Schön [47], “messy, complex and enmeshed in ethical conflict. Practice is contextually located and embedded in multiple cultures that are created and re-created by ‘actors’ in that context” (p. 91). While Schön [47] was not writing specifically about rehabilitation, it is directly applicable to and reflective of the complexities of ABI rehabilitation (and thus rehabilitation research) which are influenced by such factors as the heterogeneity of the population, difficulties with prognostication based on the diagnosis, and variations in patterns of presentation and recovery, motivation of the individual, and the support systems available to them. Emotional sequelae including depression, anxiety and loss of sense of self [39,43], among others, can contribute to social problems following ABI and this, coupled with any number of cognitive, communication, behavioural and physical difficulties can result in social isolation. In summary, there are a number of challenges associated with the process of implementing EBP in ABI rehabilitation, which include: defining the problem, conducting an efficient search to locate the best evidence, critically appraising the evidence, and applying it in the context of clinical care [32,54].

5. Meeting the challenges of evidence based practice

Given these challenges, Furlan et al. [20] suggest that a systematic review, (i.e., a synthesis of relevant research in the form of an evidence based literature review), can be an invaluable tool for frontline clinicians, policy makers, and those responsible for the development of practice guidelines, who seek to keep abreast of current findings regarding treatment interventions. According to Furlan et al. [20] a systematic review should resolve any conflicts regarding differing research conclusions by “employing explicit methods to search, select, critically appraise and combine all available primary studies on a pre-specified topic, thereby making objective recommendations about the effects of these interventions” (p. 209).

However, according to Kunz [29], clinicians, policy makers and guideline developers “rightly expect guidance from methodologists in the use and interpretation of those studies (and research synthesis review papers) and their integration into guideline recommendations,” (p. 207). Further, if the definition of a systematic review is contingent upon the term “relevant research”, the question remains, how do we operationalize what qualifies as relevant research and who should be making those decisions? These questions have also been raised by Upsher [53], where he noted the shift to dissemination of digested information such as Cochrane abstracts or publications such as Evidence-Based Medicine. He added that “while this is laudable in many ways, it raises important questions concerning who has the authority to create, interpret and judge evidence,” (p. 95). Thus, clinicians need a consistent method to: 1. Analyze the quality of the review, 2. De-
termine if the evidence presented and the conclusions of the reviewers actually match the clinical profile of their patient/client and the clinical issue in question, and 3. Determine if the research evidence is consistent with the goals of facilitating restoration, compensation, functioning, activity and participation in all aspects of daily life.

6. Interpreting the evidence for EBP

6.1. The systematic review: What is it exactly (and why should we care?)

The reality is that clinicians engaged in patient care, and policy makers involved in the development of guidelines and budgeting, do not have time to be expert reviewers of all available evidence in all areas of intervention. Therefore, the most practical resource is to turn to systematic reviews. A systematic review is a literature review focused on a single question which tries to identify, appraise, select and synthesize research evidence relevant to that question, and most (all though not all) are restricted to including high quality levels of evidence according to pre-determined criteria defining levels of evidence. Thus, systematic reviews are generally regarded as the highest level of medical evidence by EBM professionals. An understanding of systematic reviews and how to interpret and apply them in practice is becoming mandatory for all professionals involved in the delivery of health care.

However, systematic reviews, even those on the same topic, can vary greatly on many levels. There can be differences in the scope and quality of reviews from the perspective of: 1. The types or levels of evidence included, 2. The methodology and framework (which can dictate or influence the meSH terms) used in the gathering and interpretation of evidence, and 3. The translation and application of evidence, given the unique complexities and the contexts of individual client care in ABI rehabilitation [32]. In 1988, Cooper [11, as cited in 12] presented a taxonomy that classifies literature reviews based on 6 characteristics (Table 1).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus</td>
<td>Research outcomes, Research methods, Theories, Practices or applications</td>
</tr>
<tr>
<td>Goal</td>
<td>Integration, a) Generalization, b) Conflict resolution, c) Linguistic bridge building, Criticism, Identification of central issues</td>
</tr>
<tr>
<td>Perspective</td>
<td>Neutral representation, Espousal of position</td>
</tr>
<tr>
<td>Coverage</td>
<td>Exhaustive, Exhaustive with selective citation, Representative, Central or pivotal</td>
</tr>
<tr>
<td>Organization</td>
<td>Historical, Conceptual, Methodological</td>
</tr>
<tr>
<td>Audience</td>
<td>Specialized scholars, General scholars, Practitioners or policy makers, General public</td>
</tr>
</tbody>
</table>

- Is the focus of the review under consideration specific to a sub group of individuals with ABI (example TBI or stroke) or broadly to the heterogenous population of ABI? Does it focus on acute care or community interventions? Do the studies include long term follow up of subjects or immediate results from interventions recently applied? Are there other considerations addressed such as implementation issues (cost, time, level of expertise required for intervention), social validity of the intervention and outcome?

- What is the defined goal of the systematic review and is it consistent with the needs of the clinician? This is important, as even the terminology used in the search strategies may differ depending on the goal. For example, a review of interventions for vegetative state might differentiate terms such as “minimally responsive”, “coma” or “vegetative state”. Conversely, a review designed to identify issues in severe trauma might have a goal of identifying the many interventions available to this population. Thus searching the literature to answer the clinical question, “Does coma intervention work?” would necessitate some interpretation
of the evidence and the goal of article selection applied to related systematic reviews.

- The perspective of the reviewers is also a very important consideration. While objectivity is a desirable goal, analysis of data without a clear understanding of the conceptual framework or terminology for a specific field could lead to errors or omissions in article selection [32]. Reviews conducted by those who are knowledgeable about a given field are more likely to include the breadth and depth of search required. However, a review of interventions after TBI conducted by experts in stroke may apply an incorrect conceptual framework to the process, thus omitting important evidence and reporting incorrect conclusions.

- Finally, issues regarding the coverage or depth of content being reviewed are an important consideration. For example, cognitive rehabilitation may include interventions for communication or conversely a review of communication interventions might benefit from inclusion of studies of cognitive interventions. The coverage and depth of a systematic review must be taken into consideration particularly if interventions have evolved since the review was conducted, if new interventions have been generated, or if terminology has expanded to increase the scope of an area. For example, a term such as “behaviour management” may well have encapsulated all related treatment articles historically; yet new considerations of self regulation or executive control have expanded the scope of these interventions. Thus, consideration of the scope or framework and goals and objectives of the systematic review in question is essential for clinicians as they appraise the conclusions of the authors, and the applicability of the evidence to their own clinical practice.

6.2. Levels of evidence

It is also necessary to consider the levels of evidence included in the review.

Table 1b) Classification of evidence: In North America, the most commonly used and accepted classification system is the one by the U.S. Preventive Services Task Force [56] for ranking evidence about the effectiveness of treatments or screening:

- Level I: Evidence obtained from at least one properly designed randomized controlled trial.

- Level II-1: Evidence obtained from well-designed controlled trials without randomization.

- Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

- Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.

- Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

There is no one specific citation for the inclusion of Single Subject Designs (SSD’s) or Qualitative Designs in the evidence hierarchy. Single subject design is an important and predominant inclusion in the ABI rehabilitation evidence literature [32,63]. Qualitative designs also play an important adjunct role in the ABI rehabilitation evidence literature, as they provide important evidence to answer “how” or “what” questions and to explore, explain or describe a phenomenon or experience from the perspective of the research participants [13,36]. Single subject designs should be considered in any systematic review. Qualitative studies can also be of value for clinicians reviewing the ABI rehabilitation literature as they can elucidate that individual narratives vary greatly and meaning plays an important role in recovery. Both single subject designs and qualitative literature are often included as Level III evidence, which is consistent with that used in many health-related evidence reviews [6,7,42,63,66].

Level I evidence, in the form of randomized controlled trials (RCT’s) is widely considered by methodologists and scientists to be the “gold standard”, in other words, the most reliable, most free of bias and valid method of determining the effects of a particular form of rehabilitation, treatment or intervention for a defined clinical population [29]. Many systematic reviews use inclusion criteria for evidence that is limited to the RCT and a few other high level studies. For example, Chestnut et al. [8] completed a summary report of evidence for the effectiveness of rehabilitation for persons with traumatic brain injury. To complete this report, they reviewed over 3000 abstracts, and the “strongest studies” were critically appraised, and the data placed in evidence tables. They concluded that “a commitment must be made to population based studies, a strong controlled research design, standardization of measures, adequate statistical analysis, and specification of health outcomes important to persons with TBI and their families” (p. 176). Although levels of evidence other than RCT’s are sometimes described within an EBM framework, they are often given little weight.
However, in some domains relevant to the field of ABI rehabilitation such as special education, SSD research is highly regarded as a potential basis for judgments about EBP [26,40,63]. Thus, consideration and analysis of other types of evidence in ABI rehabilitation is important for a number of reasons. In the sections to follow we will discuss whether sole reliance on RCT’s is sufficient and make a case for inclusion of SSD’s as well as other forms of evidence.

7. Limitations of the RCT in the context of ABI rehabilitation

In their paper “Reflections on evidence based-practice and rational clinical decision making”, Ylvisaker et al. [64,65] point out that RCT’s, or indeed, clinical experiments of all types, however desirable they are in the context of responsible clinical practice, do not exhaust the considerations relevant to scientific clinical decision making. Further, there are a number of well documented limitations in relying solely on RCT’s that are highly relevant to ABI rehabilitation, particularly as the results of an RCT are typically applied to a population, rather than an individual, and the two are not necessarily synonymous. Montgomery and Turkstra [37] report that an overemphasis on RCT’s (Level 1 evidence) often results in skepticism when this standard is not attained, yet they conclude that “In the treatment of each individual patient, judgment must be used to some degree, and this requires the use of reason based on information extrinsic to the results of RCT’s”. They report that this is inescapable, and that it is the ability to make those judgments that makes a clinician (p. X). Montgomery and Turkstra [37] present three arguments for caution when interpreting the evidence:

1. “Statistically significant is not synonymous with clinically significant”; the determination of what constitutes both “statistical significance” and a “clinically meaningful result” is a social judgment.
2. Judgment is always required in the case of an individual patient.
3. RCT’s may be either impractical (if not impossible) or inappropriate for answering many important clinical questions.” (p. X).

For research in the field of ABI, particularly in some areas of rehabilitation such as cognition, communication, behaviour, activities of daily living and community reintegration, it is not always practical or appropriate to rely solely on the RCT as the gold standard. There are numerous difficulties and limitations in applying this model to such a heterogeneous and complex population. Mykhalovsky and Weir [38] caution against the standardization of clinical judgment and clinical care.

Kennedy and Turkstra [28] further analyze a number of the limitations of relying on high levels of evidence, particularly the RCT. First, with large sample sizes, group heterogeneity may mask individual treatment benefits. Often, there are differences at baseline, such that each subject’s profile may not be equivalent. Next, blinding of clinician raters and study participants as to group assignment may be impractical. Random assignment does not necessarily mean that all groups will be equal on important variables. Recruitment and drop out rates may be beyond the researcher’s control in a treatment study that extends over several weeks, particularly when participants are trying to return to the community or school. Additionally, as Ylvisaker [63] points out, “The individuals (with ABI) most in need of long term clinical and special education services are often those excluded from, or are outliers in, clinical trials, (e.g., individuals with serious behavioural challenges or psychiatric diagnoses, co-existing or pre-existing impairments such as learning disabilities or attention deficit hyperactivity disorder, unusual life circumstances and the like),” (p. 211).

There are a number of factors unique to ABI which researchers, authors of systematic reviews, and clinicians should consider when generating, synthesizing, and applying the evidence to clinical practice. First, due to the considerable heterogeneity in the ABI population, patient characteristics over and above a diagnosis of ABI and level of severity should be considered. Further, this heterogeneity necessitates that interventions for communication, cognition, behaviour, vocational rehabilitation etc. be individualized depending on a number of equally important criteria including: the person’s stage of recovery, their unique communication/cognitive, physical, psychological and emotional and behaviour profile, the person’s goals, treatment location, the competence and needs of relevant support people, training and competence of the treating clinicians (i.e. expertise in ABI), available time and funding and compliance, in addition to the varying cognitive and communication demands of home, work, or school [9,32,63]. While in earlier studies, severity of injury was used to equate experimental samples, it is now recognized that consideration of the cognitive, communication and behavioural profiles is necessary when comparing subjects [28,32]. To rely solely on
a diagnosis of moderate-severe ABI is erroneous, as there can be many different presentations and needs that accompany this complex designation [66]. The desired outcome of the treatment protocol and the outcome measurement must also be considered from the perspective of the World Health Organization’s International Classification of Functioning, Disability and Health [61]. Does the measure assess outcome from the perspective of disability (including body function and structure) or activity and participation in the context of the individual is also strongly advocated for in ABI rehabilitation [22,63].

8. Other types of evidence in ABI rehabilitation research: Beyond the RCT

A primary limitation of systematic reviews of the literature for ABI rehabilitation which rely on a narrow definition of evidence (i.e. the RCT with a few other lower level studies) is that they typically conclude that the evidence to support rehabilitation in specific areas is limited, and the reader is left to draw their own conclusions. As a result, an ethical dilemma is created when funding sources use these conclusions to deny services. In 2006, Perdices et al. [41] conducted a review of 1298 empirical studies indexed in a web-based resource for brain injury research called PsycBITETM. They found that the largest proportion of rehabilitation studies were single subject design (39%), followed by case series (22%), randomized control trials (21%), non-randomized control trials (11%) and systematic reviews (7%). Most reports were concerned with stroke (41%) traumatic brain injury (29%) and Alzheimer’s and related dementias (22%). The most frequently investigated deficits were communication/language/speech disorders (24%); independent self-care activities (19%) behaviour problems (17%); memory impairments (17%), and anxiety; depression, and stress adjustment (15%). After rating the studies for methodological quality, Perdices and colleagues [36] concluded that the methodological quality of RCT’s across the spectrum of TBI research was modest overall and they presented many reasons for this which concurred with those of Kennedy and Turkstra [28] outlined above.

Single Subject Design (SSD) tends to be the predominant model of intervention research for this population, not because large randomized control studies are a novel concept in rehabilitation but because the complexities and interplay of human communication, cognition, emotion and behaviour, ABI, and individual circumstances combine to make single subject design more applicable to a wider variety of treatment circumstances [28,41,63]. Perdices et al. [41] presented the advantages of single subject design studies and asserted that sophisticated (experimental) SSD’s incorporating, among other things, multiple baselines across subjects, as well as randomization of the order of active treatment phases, can potentially provide a level of evidence comparable to that of RCT’s. In fact, should a clinician be researching interventions for an individual that closely resembles the profile of the subject in a successful SSD, then it may be more clinically rational and responsible to choose the SSD intervention (Class III evidence) than an intervention guided by a population based evidence statement (Class I evidence, RCT) [63]. This is, however, in contrast to a case study design which is less rigorous (i.e. uncontrolled) and thus is less reliable as a source of evidence than an intervention study. For these reasons many researchers of cognitive-communication, behavioural and community based interventions caution that strict adherence to a preordained experimental model such as RCT’s as a filter to accept or reject particular clinical practices in the highly diverse ABI population may result in unsuccessful generalizations from research to treatment outcomes [41,49,64,65]. This is consistent with the opinions of Kunz [29] expressed in her recent editorial, where she states that “while most methodologists continue to maintain that treatment effects coming from RCT’s are-in principle, far better protected against bias than non RCT’s and therefore, deserve a higher credibility than estimates of treatment effects generated from non RCT’s, there are at the same time, a dissenting group of methodologists who dispute the claim of RCT ascendance in similar clinical issues that demonstrate similar treatment effects, at least based on high-quality observational studies” (p. 207). Thus, the heterogeneity of the population and the need to consider the unique etiology of every person with a brain injury renders Class III evidence helpful in guiding the direction of efficacy research even though its generalizability may be limited [22,49]. Given these challenges with RCT’s, it is not uncommon for single subject design to be employed more frequently in rehabilitation research. Further, while the number of well designed controlled studies is increasing in ABI rehabilitation, there is limited high level evidence currently available to support various interventions [14,43].
Consequently, it is beginning to be recognized that for management and practice decisions in which randomized trials are not available, clinicians and guideline developers must still rely on Level II and Level III evidence, including observational studies. Kunz [29] reported that “indeed, for a great many questions of clinical importance, observational studies constitute the best available evidence” (p. 1).

An increased focus on individualized treatment protocols in ABI rehabilitation precludes the use of generalized group treatment programs. For example, a number of specialists in brain injury rehabilitation are advocates of the “Patient Specific Hypothesis Testing” (PHST) approach to treatment, with its goal of “identifying the most effective intervention for a specific patient under specific life circumstances and in relation to specific desired (i.e. individualized and contextually based) outcomes” [64,65,49]. According to Ylvisaker et al. [64], PSHT also relies on the involvement of relevant parties including the individual, their professionals, family members, colleagues, and significant others. In addition to creating the intervention, PSHT also serves to educate the relevant parties about the impairment and intervention, provides strategies and environmental modifications specific to the individual, and most importantly, involves the person with the impairment (disability) in meaningful and systematic problem solving and decision making, which are critical components of executive function [64]. Similarly, the ‘Participate to Learn’ models of intervention focus on roles as goals, learning by experience in real-life contexts, and the use of personal and environmental support to enable participation [5]. These approaches to intervention are incompatible with RCT models in which all subjects receive the same intervention protocol once they have met inclusion criteria. This leaves the research community with a compelling question; Is it possible to develop/utilize an RCT research methodology which allows for some individualization within the standard treatment protocol? Not only would this support a more valid implementation of an RCT research methodology which allows for some individualization within the standard treatment protocol? But, evidence in the narrow view (i.e. RCT’s) is insufficient to capture the broader, yet equally valid aspects of the therapeutic process including: the clinical relationship, context, change in circumstances or therapeutic factors, and extraneous, non-rehabilitation factors.

3. A broader, more pluralistic view is required. Specifically, a pluralistic approach is one that considers the whole person, their daily life contexts, and supports, and is reflected within evidence generation, evidence search, and knowledge translation [4,26,31,35,51,52]. When this pluralistic approach is applied to ABI/TBI rehabilitation and rehabilitation research, it is one which advocates for a broader, more inclusive definition of individualized treatment and thus a broader scope of research methodology.

4. No amount of evidence can override the need for clinical judgment [20].

Mykhaylovsky and Weir [38] identified the concern that (a more narrow view of) EBP does not take sufficient account of patient values, and they stated further that the inherent design of RCT’s makes their outcomes difficult to generalize over a diverse and heterogeneous patient population (such as those with ABI). This is in keeping with the view espoused by Guyatt [24], in the last installment of the Users’ Guide to the Medical Literature whereby clinicians must rely on their own judgment and expertise to define features that affect the generalizability of the results to the individual patient, recognizing the importance of context, and patient values. Qualitative research can also play an important role here in illustrating the individual differences and narratives during the rehabilitation process. Thus, the clinician must judge the extent to which differences in the treatment (including skill and personality of the therapist), the availability of ongoing monitoring to ensure generalizability, or patient characteristics such as age, patterns of neurocognitive impairment, or concomitant treatment may affect estimates of benefit and risk that come from the published literature. Clinicians must further consider if the available studies have measured all important outcomes, if patients were followed up with for a sufficient length of time, and if experimental treatment was compared with the most compelling alternatives [24,37,64,65]. In addition to their clinicians, most survivors themselves would agree that nothing can substitute for the combination of clinical expertise, advocacy, empowerment, involvement in the goal setting and decision making process, and a
sound clinical relationship in determining and meeting the specific considerations relevant to that person.

Thus, according to Guyatt et al. [24], "knowing the tools of EBM/EBP is necessary, but in of itself, not sufficient for delivering the highest-quality patient/client care. In addition to clinical expertise, the clinician requires compassion, sensitive listening skills, and broad perspectives from the humanities and social sciences. These attributes facilitate an understanding of the individuals' illness (disability) within the unique context of their experience, personality, and culture" (p. 1293). This view would seem to be consistent with a broad interpretation of EBP, wherein the term “evidence” is synonymous with reason.

9. Key questions to consider when evaluating the literature (and syntheses of the literature)

Below is a set of Key Questions to consider when generating and applying evidence. These questions encourage a perspective that is broader than “will certain interventions work?” and include considerations of why they work, in what treatment context, for which patients, at what stage of their recovery, etc. [22].

Key Questions:

1. Are specific patient characteristics reported and are those patient characteristics similar to my clinical population?

2. Are subject groups equated by injury severity alone or also by neuro-cognitive, communication and behavioural characteristics?

3. Are treatments individualized or is the same standard protocol used for a group of patients?

4. Are the outcomes measured at the level of impairment/disability, activity limitations or participation?

There was an initial tendency in treatment research to measure improvements solely on standardized tests or clinical tasks [5,61]. However, The World Health Organization’s International Classification of Functioning, Disability and Health [60] provides an expanded framework of analysis of impairment/disability from the perspective of body structure and function, activity limitations, and participation restrictions within the person’s unique environment, as well as consideration of personal factors such as the individual’s motivation, and factors such as family and school supports. This expanded framework has directed clinicians working in ABI rehabilitation towards increased options for outcome measurement [30]. Further, it is now recognized that the effects of communication, cognitive, and behavioural interventions also need to be measured in real world functional situations [9,18,22,28,30,52,58,61]. This generates yet another series of questions specific to treatment outcomes: 1. Are the treatment outcomes measured at the level of impairment, activity limitations or participation? 2. Are the outcome instruments reflective of communication/behavioural/cognitive functioning or are they generic? 3. Are treatment effects maintained over time?

5. What are the types of interventions used in the study?

There are a number of considerations with regards to the type of intervention. Initial comparisons of treatment modalities in ABI efficacy research were restricted to contrasts of restoration and compensation approaches [1,9,69]. Yet treatment modalities have broadened considerably in the past 15 years with the addition of approaches such as participation [5], self coaching [62], apprenticeship models [67], communication partner training [51], and environmental approaches and curriculum based approaches in schools [2]. Optimal use of a treatment modality depends on individual circumstances and needs [9,24]. Carney and colleagues [6] advise that improved efficacy research requires the use of standardized treatment protocols even when individualized dynamic treatment is being employed. One method of achieving standardization within individualized approaches is the use of Goal Attainment Scaling [33], which can allow the clinician to quantify improvements for individual goals, consistent with a philosophy of client-centred practice.

6. Are the treatment methods contextualized for the individual or decontextualized?

Another important consideration in analyzing the type of intervention is to consider whether treatment methods are a) contextualized, that is, for example, based on the cognitive-communication, behavioural and ADL (activities of daily living) demands of the individual’s life, or b) decontextualized, that is, structured, often clinic based, tasks that may have little resemblance to the demands and complexities of daily life. Ylvisaker [54] describes traditional cognitive intervention approaches as “cognitive exercises to restore cognitive processes or skills possibly combined with cognitive exercises to acquire compensatory cognitive behaviours with potentially general application” where-in the generalization sequence involves initial mastery of skills in acquisition tasks followed by generaliza-
Table 2
A Comparison of traditional ABI evidence reviews and broader ‘pluralistic’ ABI evidence reviews

<table>
<thead>
<tr>
<th>Traditional ABI intervention evidence based reviews</th>
<th>Pluralistic, contextual, broader evidence based reviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Treatment variables controlled are those within sessions only</td>
<td>– Contextual factors such as client communication interests, demands of environment and communication partners are considered</td>
</tr>
<tr>
<td>– Same treatment protocol for all</td>
<td>– Individualized treatment protocols</td>
</tr>
<tr>
<td>– Dependent variables or outcome measures tend to be clinic based and then transfer and maintenance are measured</td>
<td>– Outcome measures are functional, activity and participation based – Use of WHO</td>
</tr>
<tr>
<td>– RCT’s = Gold Standard</td>
<td>– Real world performance and communication partner performance are measured</td>
</tr>
<tr>
<td>– Systematic Reviews = Consider RCT’s to be the highest form of evidence</td>
<td>– Systematic Reviews include SSD’s</td>
</tr>
<tr>
<td></td>
<td>– SSD’s include effect sizes</td>
</tr>
<tr>
<td></td>
<td>– Meta analyses analyze treatment effects</td>
</tr>
</tbody>
</table>

RCT, Randomized Control Trial; SSD, Single-Subject Design.

Finally, an interesting and important consideration when evaluating individual studies and systematic reviews is what we call the **evolution factor** [28]. Efficacy studies have evolved over time in terms of the specificity of patient selection criteria, assessment methods, treatment group assignment, treatment methods, measurement of outcomes, and consideration of transfer and maintenance. Clinicians and policy makers reviewing the evidence must place it (the evidence) within its historical context in order to recognize where a study occurred in the evolution of ABI interventions. For example, earlier studies might have borrowed from the stroke literature, and used aphasia tests to determine severity of communication impairments, whereas later studies have focused more appropriately on aspects of participation and social communication. The evolution factor requires that discerning clinicians evaluate the strength and applicability of the evidence, not simply count the number of available studies. Overall, in light of the evolution factor, the complexity of assessment and treatment, following ABI, and the multiple factors to be considered, clinicians will glean the best guidance from systematic reviews that are recent, and that are conducted by experts in the field under review, who know the theoretical framework, appropriate definitions, assessment measures, treatment modalities, and outcome measures.

Finally, there are numerous issues in evidence based practice that are beyond the scope of this paper and
Table 3
Critical appraisal of evidence: A brief guide for clinicians

<table>
<thead>
<tr>
<th>Factors for consideration</th>
<th>Additional questions for clinicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion exclusion criteria provided</td>
<td>Do the participants match the patients/clients in my practice?</td>
</tr>
<tr>
<td>Representative of the population</td>
<td>Are those who dropped out the more vulnerable ‘in need’, harder to treat group?</td>
</tr>
<tr>
<td>Population samples described according to demographics, length of time post injury, severity of injury &amp; impairment,</td>
<td>Are the individual or group interventions relevant to the individual I’m treating?</td>
</tr>
<tr>
<td>Sample size</td>
<td></td>
</tr>
<tr>
<td>Attrition (who dropped out and why?)</td>
<td></td>
</tr>
<tr>
<td>Were efforts made to create contrasting treatment conditions, and to equate samples and decrease bias (i.e. randomization, blind raters, monitoring of treatment provision, analysis of attrition)</td>
<td></td>
</tr>
<tr>
<td>Outcomes; were they standardized, do they measure at the level of impairment, activity or participation</td>
<td>What outcome is my patient/client aiming for</td>
</tr>
<tr>
<td>Were the findings statistically significant?</td>
<td>Does this equate with functionally and or clinically significant for my patient/client?</td>
</tr>
<tr>
<td>Is the description of the intervention sufficient to replicate</td>
<td>Do I have the means to carry out this treatment in my practice</td>
</tr>
<tr>
<td>Was there follow-up to ensure maintenance and generalization of gains</td>
<td>Will the gains be maintained?</td>
</tr>
<tr>
<td>Are there SSD data available for the intervention of choice?</td>
<td>If so, did the study use multiple baselines across subjects and behaviours, as well as randomization of the order of active treatment phases?</td>
</tr>
</tbody>
</table>

clinicians will find the following references helpful [16, 28]. A brief guide to critically appraising the evidence can provide clinicians with important issues and related questions, when applying the evidence to their own clinical practice.

10. Conclusions

This paper advocates for a broader, more pluralistic approach [35] to the generation, synthesis and application of evidence to support individualized, contextually based rehabilitation with participation and quality of life as desired rehabilitation outcomes. There are many issues to consider when evaluating and applying the evidence in ABI rehabilitation. There can be differences in the scope and quality of systematic reviews from the perspective of: 1. The generation of evidence, 2. The synthesis of evidence, and 3. The application of evidence, given the unique complexities and contexts of individual client care. The goal of generation of evidence for application to clinical practice is a noble one. However, there are difficulties in how we marry the often divergent needs, backgrounds and objectives of the authors of systematic reviews, and the divergent needs of strict standardized scientific methodology with needs of client-centred care and best practice. The reality is that evidence based practice may not always be synonymous with best practice (i.e. client centred care), when a rigid or narrow definition of evidence is employed. This also applies when the qualifications, objectives, and theoretical framework of the authors of research synthesis papers, in addition to their search methodology, are analyzed and critiqued.

The ‘key questions’ listed address both ‘intervention research’ itself and act as a framework to evaluate evidence that addresses not so much whether certain interventions work, but why they work, in what treatment context, for which patients, and at what stage of their recovery. By including such key questions in the evaluation of research evidence, clinicians in the field of ABI rehabilitation will be empowered with an additional resource to provide best practice (if not a traditionally defined evidence-based practice) at the point of care, which has the potential to translate into improved quality of life for clients during recovery from ABI.

Acknowledgements

The authors wish to express sincere gratitude to Dr.
Mark Ylvisaker, Dr. Pia Kontos and Dr. Lyn Turkstra for their editorial expertise in reviewing this paper at various stages of its evolution. We dedicate this paper to the memory of Dr. Mark Ylvisaker, colleague, mentor and friend.

Ms. Wiseman-Hakes gratefully acknowledges the support of the Canadian Institutes for Health Research through a Fellowship in Clinical Research, and the Toronto Rehabilitation Institute who receives funding under the Provincial Rehabilitation Research Program from the Ministry of Health and Long-Term Care in Ontario, Canada. The views expressed do not necessarily reflect those of the Ministry.

References

[29] R. Kuntz, Randomized trials and observational studies: still mostly similar results, still crucial differences, Journal of Clin-


