Clinical Contributions to the Available Sources of Evidence (CASE) Reports: Executive Summary

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The Case Study and Its Maligned Account

Evidence-based practice (EBP) is the integration of the best available research, clinical expertise, and a patient’s values when making clinical decisions.1 The central principle of EBP is that each patient is unique, and decisions for the patient’s care must be made at the individual, “n-of-1” level.2,3 As more evidence is presented to the clinician each year, whether that evidence actually results in enhanced outcomes for a patient with his or her unique values and preferences is unknown.2

Traditionally, clinical case studies have served as a forum for clinicians to communicate unique findings and experiences when diagnosing or managing a condition. In the realm of EBP, the value of case studies is controversial: they simultaneously sit low on the levels of clinical evidence hierarchy (as anecdotal evidence) but also atop the evidence hierarchy as the hallmark of EBP, the n-of-1 study, in which an investigated medical process (eg, diagnosis, prognosis, therapy, harm) is tested systematically in a “real patient.”3

Despite concerns about the internal and external validity of case studies with regard to the inherent biases introduced by only 1 patient or a few patients, case studies serve as educational narratives for the development of new insights in clinical practice, education, and research. Furthermore, case studies offer an excellent opportunity for clinicians to engage in scholarly activity and contribute to their profession’s body of knowledge.3–5 Although case studies have historically been the primary mode of disseminating clinical information, fewer outlets for case studies are currently available, and many journal editorial boards are questioning the value and influence case studies have in furthering research and clinical practice.5 Additionally, the lack of consistent reporting standards for case studies across journals makes it more difficult to assess their value.6 The intention of the case study is noble (ie, sharing relevant reports of practice-based evidence [PBE]4), but its clinical utility as a source for EBP is unclear.

In the past 20 years, systematic reviews and meta-analyses of the sports health care literature have been conducted to answer clinical questions related to a vast array of injury conditions and management strategies. Well-controlled clinical trials across the 5 major categories of evidence (observational, diagnostic, prognostic, etiological, and therapeutic) offer the most unbiased results from individual studies. The next logical step in clinical research is to test the effectiveness and feasibility of the results from these high-level studies. Case studies offer a unique medium in which the results garnered from these sources of external evidence4 can be implemented. The sports medicine body of knowledge can be substantially enhanced through the reporting of clinical outcomes generated by evidence-based clinical decisions.

We have the opportunity to enhance the value of case studies by not only introducing what might be novel PBE4 but also confirming or refining our EBP.4 Therefore, case studies offer both an entry point into the development of clinical evidence and an endpoint of the implementation of evidence for enhancing clinical decisions and outcomes.3 The vision behind this case study paradigm shift is to provide a robust outlet for practicing clinicians to make meaningful Contributions to the Available Sources of Evidence (CASE) by reporting insights gleaned from using internal and external evidence4 for clinical decision making. It is from this perspective that we introduce the new Clinical CASE Reports paradigm.

A Unique Contribution

Case studies have traditionally been forums for describing the novel, the innovative, or the curiously unexpected clinical experiences, usually focused on diagnosis. Uniqueness is key to the traditional case study model.6 One of the major challenges for case study authors is determining what constitutes a unique contribution to the body of knowledge. In the broader medical literature, case studies provide a medium for describing new conditions, their potential etiologic factors, prognostic timelines, and potentially advantageous therapeutic strategies. To improve the case study, we must focus closely on how we define uniqueness in the context of EBP.7 Within the new paradigm, we propose a standardized method of determining the expectation of uniqueness, which would also assist in establishing the strength and importance of the evidence generated.
Beyond Diagnosis

Case studies are a critical link between the best available research evidence and clinical practice. Diagnosis should not be the only focus. However, along with the uniqueness factor, this is a common oversight in the traditional case study model. Far too much significance is typically placed on the unusual diagnosis, almost to the exclusion of other sources of clinical evidence. Indeed, all sources of external evidence (observational, diagnostic, prognostic, etiologic, therapeutic, etc) can be used in the new Clinical CASE Report paradigm. Each source of external evidence has key features with information that is critical to highlight regarding the clinical decisions we make and the outcomes that ensue. Further, clinical communication is enhanced when we go beyond the unusual diagnosis. Under this new Clinical CASE Report model, clear avenues encourage the reporting of all aspects of clinical practice.

Clinical CASE Reports: A New Paradigm

Within the new paradigm, we propose 2 major classifications of Clinical CASE Reports: validation and exploration.

Validation CASE reports describe clinical decision outcomes that were guided by the best available research evidence. This contribution is based on contrasting the results of meta-analyses, systematic reviews, high-level individual studies, position statements, and clinical practice guidelines with the results of a clinical event in which the external evidence was used to guide clinical decisions. Evidence from validation studies truly embodies the spirit of evidence-based clinical decisions—basing them on EBP, as these reports are the documentation of practicing clinicians guided by the best available external evidence.

In contrast, exploration CASE reports describe clinical decision outcomes that were based predominantly on internal evidence (individual clinical experience within the professional body of knowledge). Because this evidence is generated directly from clinical experiences and professional preparation, these reports exemplify PBE. When valued, both EBP and PBE contribute to greater understanding and a richer evidence-based body of knowledge, and perhaps more importantly, help to close the ever-widening gap between the clinic and the research laboratory.

By reporting the results of implementing the best available external evidence with validation CASE reports, we can determine which evidence should be readily incorporated into professional education and preparation and truly close the circle of EBP. In turn, exploration CASE reports highlight the value of internal evidence derived from direct clinical experience and expertise. Once published, these reports become a source of external evidence for other practicing clinicians and researchers and can guide clinical research by revealing gaps in our knowledge base. Thus, a symbiotic relationship between validation and exploration Clinical CASE Reports is created.

Clinical CASE Reports: Strength of the Evidence

To support the enhanced importance of the case study, a comprehensive and descriptive model for (1) defining the nature of uniqueness and (2) generating a hierarchy of Clinical CASE Reports within the validation and exploration structure was needed. Systematic guidelines, recommendations, or reporting requirements were inconsistent or nonexistent in the scientific health case study literature. The purpose of this paradigm is to provide a logical blueprint to describe the value of these reports in shaping our professional body of knowledge. In the following sections, we present a model for defining 4 levels of evidence for Clinical CASE Reports in the context of validation (EBP) and exploration (PBE). We describe the hallmarks for each level and the value of using external and internal evidence for making clinical decisions, from lowest (level 4) to highest (level 1), to help readers appreciate the logical progression from PBE to EBP (see Table).

Level 4: Rare Event CASE Reports. Reports that are directly relevant to clinical practice must be supported. It would be short sighted not to consider manuscripts that educate clinicians about certain rare conditions that can occur in the physically active population. These rare event CASE reports describe the recognition or treatment of conditions that are both rare in the physically active population and potentially life or limb threatening. Two important discussion points should be considered and provided in rare event CASE reports: (1) the circumstances under which the rare condition presented in an athletic population and (2) the interactions among athletic trainers (ATs) and other health care professionals that occurred in the clinical decision-making processes regarding the rare event. This interprofessional interaction is critically important and should be highlighted within the case. The interprofessional capacity in which other health care professionals were involved and interacted with ATs throughout the case in making clinical decisions should be presented.

Purpose. These rare event CASE reports would afford clinicians information regarding a condition that may be relevant to ATs but may not currently be found specifically within the athletic training body of knowledge. Similar cases, however, will likely have been reported in other health care literature, and ATs’ awareness of the condition needs to increase. The purpose of the rare event CASE report then is to bring attention to conditions that may not be familiar to ATs but are clinically important. The hallmark of these reports is the presentation of typical clinical features derived from other health care literature, including the prevalence, diagnostic and prognostic features, and therapeutic strategies.

Case studies are often not considered for publication because of a negative outcome, such as a misdiagnosis or the patient’s inability to return to participation. However, at times, a great deal can be learned from negative outcomes that are not due to mismanagement. An important
Table. Delineation of the Levels of Evidence for Clinical CASE Reports within the *Journal of Athletic Training* and the *International Journal of Athletic Therapy & Training*

<table>
<thead>
<tr>
<th>Case Manuscript Type</th>
<th>Validation</th>
<th>Exploration</th>
<th>Rare Events</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level of evidence</strong></td>
<td>Clinical CASE Report</td>
<td>Clinical CASE Series</td>
<td>Clinical CASE Report</td>
</tr>
<tr>
<td>Typical</td>
<td>Level 1: Provide confirmation of the application of sound external evidence that can be used in clinical decisions within the population of interest.</td>
<td>Level 2: Provide compelling evidence for the systematic investigation of factors related to the clinical presentation and/or resolution.</td>
<td>Level 3: Provide evidence for advancing the current perspectives for the key features associated with the condition of interest and warrants (at least) investigation at the next level of evidence (case series).</td>
</tr>
<tr>
<td>Typical</td>
<td>Present a series of unique AND similar cases. A strong emphasis on not only unique diagnoses but also unique prognoses, treatments, observations, etc.</td>
<td>Present unique cases: those that have atypical presentation of features. Strong emphasis on not only unique diagnoses but also unique prognoses, therapies, observations, etc.</td>
<td>Present a condition that is relevant to the athletic trainer and that has been documented in other literature. Typical presentations of prognoses, diagnoses, therapeutic strategies, etc, are hallmarks of these manuscripts.</td>
</tr>
<tr>
<td>Typical</td>
<td>Present a case that confirms (or refutes) a previously published result. A strong emphasis on comparing/contrasting methods, results, and interpretations from current case with previous study expected.</td>
<td>Practice-based evidence</td>
<td>Practice-based evidence</td>
</tr>
<tr>
<td>Typical</td>
<td>Practice-based evidence</td>
<td>Practice-based evidence</td>
<td>Practice-based evidence</td>
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Abbreviation: CASE, Contributions to the Available Sources of Evidence.
condition of interest, warranting further investigation. These future investigations could include case series, prospective observational studies, or even clinical trials, if the evidence is available.

Exploration CASE reports strongly emphasize not only unique diagnoses but also unique prognoses, therapies, observations, etc. The conditions themselves may not be unique or even rare, but an element or feature of the case is new. Specific clinical experiences in which there was a unique factor, whether observational, diagnostic, prognostic, therapeutic, harm, or screening, should all be considered. An essential component of the exploration CASE report is the reporting of the critical key feature(s) that led to the clinical decisions and outcomes. Reporting the key features in a case allows us to explore the consistency of these key features in other patients with the same condition. This process can lead to well-reported case series, offering an opportunity to advance the clinical research process.

**Exploration CASE Report Example.** A collegiate track athlete experienced an inversion ankle sprain. Secondary to that injury, the athlete developed subluxing peroneal tendons that made it difficult and painful to compete successfully. In response, the AT developed a novel taping technique to stabilize the tendons, which allowed the athlete to continue to participate successfully for the rest of the season. Key features of the athlete’s specific case, the taping technique that allowed the athlete to fully participate symptom free, and discussion of the outcomes of this case would be expected.

Inversion ankle sprains, even those with subsequently subluxing peroneal tendons, are not rare or unique. The observational or diagnostic features of this case are not what make it unique. However, the taping technique (ie, the therapeutic intervention) in this case defined the uniqueness. Of note, the authors of this type of case study would not simply report the taping technique but would follow the structure of the traditional case study, discussing key features of the athlete, the therapy technique, specific outcomes of the treatment, a discussion of relevant evidence from the literature, and how this case contributes to a potentially important direction of the evidence. In this manner, the exploration case report goes beyond a technical commentary or clinical pearl and examines the case under the lens of the best available evidence associated with the condition.

**Level 2: Exploration CASE Series.** Exploration CASE series present compelling, practice-based unique evidence across multiple patients. These reports offer new insights into the future investigation of factors related to a particular clinical problem and its resolution.

**Purpose.** The purpose of the exploration CASE series is to demonstrate a more definitive and rigorous presentation of the exploration CASE reports. Again, observational, diagnostic, prognostic, therapeutic, and etiologic sources of evidence can all be considered. Specific details of the characteristics that illustrate the similarities of included patients are important; the clinical presentation, treatment strategies, and observation criteria should be described and confirmed in reporting, indicating that a certain level of generalization and external validity exists. Exploration CASE series highlight the clinical decisions made across multiple patients that were based on the clinician’s internal evidence.

**Exploration CASE Series Example.** A clinician developed a novel taping technique that enhanced the clinical outcomes of 3 track athletes with subluxing peroneal tendons. All of the patients were collegiate-level varsity track-and-field sprinters or long jumpers. The technique was successful in that the athletes were able to compete without restriction. As with individual CASE reports, key features of the athletes’ specific cases, the taping technique that allowed them to participate fully and symptom free, and discussion of the outcomes of this case series would be expected.

The clinical strategy within the case series should be described in a way that allows other clinicians to readily reproduce it. Essential elements of a well-designed CASE series are clear descriptions of (1) the patients in the series; (2) the assessments, interventions, or exposures evaluated; and (3) the outcomes used to track the effectiveness of clinical decisions. Further, a discussion comparing each patient’s potentially unique responses to highlight similarities in presentation may be appropriate.

**Level 1: Validation CASE Reports.** Validation CASE reports are the application of the best available external evidence. These reports present clinical decisions and outcomes that confirm (or refute) the results from published external evidence. The expectation for the published external evidence is that it was performed at a high level (eg, rigorous control, low expectations of bias, clearly defined population of interest). Testing the results of a well-conducted systematic review or meta-analysis would be considered stronger external evidence than the results of an individual study. According to the hierarchy of the Centre for Evidence-Based Medicine, level 1 (systematic review or meta-analysis) or level 2 (individual, well-designed randomized clinical trial) evidence would be expected of the previously published study. Position statements and clinical practice guidelines would also be considered high-level sources to be validated.

**Purpose.** The purpose of validation CASE reports is to test the results of published external evidence in an actual clinical environment on an individual patient. Studies that address diagnostic, prognostic, therapeutic, and etiologic factors would all be acceptable. This type of report describes how the techniques and outcomes stated in the best available evidence helped to guide clinical decisions. A strong emphasis on comparing and contrasting the major elements of the validation case report with those of the previously published studies (validation case report patient with previous study participants, similarities in interventions and outcomes, discussion of interpretations) would be expected.

**Validation CASE Example.** A clinician was confronted with a rehabilitation problem. After searching the best available evidence, the clinician decided to use evidence from a published randomized controlled trial. This clinician took care to determine the similarities between the current patient and the study participants. Further, the clinician opted to include outcomes similar to those used in the previous study that were validated and reported. For outcomes that were considerably different, interpretations of these divergences were discussed. Advantages and drawbacks to implementation were also reported.
The role of the validation case report is to complete the circle of clinical research evidence by testing the effectiveness and feasibility of an outcome in real life.

The results of the validation n-of-1 case report help to guide future research and clinical practice by providing a better understanding of what works well and what might be improved, what is well understood and what is still unclear, what is feasible in the typical clinical setting, and what is too expensive or elaborate to incorporate.

The Patient, Intervention, Comparison, Outcome Plays a Critical Role

Many see the patient, intervention, comparison, outcome (PICO\textsuperscript{11}) question as the crux of EBP. The PICO fits nicely into this proposed paradigm with a small revision. The Patient and the Intervention stay relatively the same; the C and O are where the revision makes sense. The case study levels offer no comparison with a control or alternative intervention. The comparison that guides all of these levels is with outcomes within the external evidence that currently exists. Therefore, we propose that the PICO question for case studies becomes the patient, the intervention (ie, therapeutic intervention, diagnostic assessment, or etiologic exposure), and the comparative outcome. For rare event CASE reports, the comparative outcome should reference similar cases in the nonsports medicine literature. For exploration CASE reports or series, the comparative outcome should reference the patient presentation that is atypical to what is currently provided in the literature. Lastly, for validation CASE reports, the comparative outcome is in reference to the previously published study that is the original source being assessed. A more detailed explanation of the case study PICO question and its elements is provided in the “Guidelines for Clinical CASE Reports” (http://journals.humankinetics.com/doi/abs/10.1123/ijatt.2014-01417).

CONCLUSIONS

The Clinical CASE Report paradigm provides a framework for the dissemination of PBE to EBP and highlights their symbiotic relationship.\textsuperscript{2} Further, we aim to provide an outlet for clinicians, educators, and researchers to contribute to this all-important area of clinical communications.\textsuperscript{3} As we validate our external evidence through validation CASE reports, we can determine what is most effective and feasible to incorporate into clinical practice and professional education. As we use internal evidence to generate exploration CASE reports, we supply researchers with the key clinical questions that need to be answered through more rigorous investigations. This paradigm supports the role of the case study and defines the significance of clinical contributions to the available sources of evidence and the body of knowledge at large. The levels also help to characterize the rigor of the evidence that can be derived from each type of Clinical CASE Report. In summary, this new paradigm helps to tie together the best clinical practices, professional education, and research investigations through the common lens of EBP and PBE. For complete, in-depth descriptions of the entire paradigm, please refer to the editorial series published in the International Journal of Athletic Therapy & Training.\textsuperscript{3–5,7,8,11}

REFERENCES