CLINICAL SIGNIFICANCE AS IT RELATED TO EVIDENCE BASED PRACTICE: A CONCEPT ANALYSIS

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Abstract
Aim. Analyzes the concept of clinical significance in relation to evidence-based practice.
Background. There has been insufficient inquiry into the evidence base of the definition and use of the term clinical significance in nursing. Delineating a common conceptual meaning and definition for clinical significance will enhance its usefulness in research and practice.

Methods
Rodgers' evolutionary approach to concept analysis provides the framework for interpreting clinical significance in the context of its uses, measurements, and definitions in the nursing literature. After applying inclusion and exclusion criteria and a sampling method, 53 articles were included in the analysis of clinical significance. Using Rodgers' rigorous, evolutionary method of concept analysis, the concept of clinical significance was examined for its significance, use and application as it has unfolded between 1999 and 2010.

Results
Findings indicate that the nursing literature contains various, disparate definitions and applications of clinical significance.

Conclusion
The disparate uses of clinical significance negatively impact standardizing and quantifying research outcomes to discern evidence-based practices. The authors propose a definition of clinical significance inclusive of the multifarious uses that were revealed in the literature and conclude that there is a need for professional nursing consensus to define the term. A standard operational definition of clinical significance would enable consistency as clinicians interpret research findings and facilitate translating research to practice.
Introduction

In 2002, the Mayo Foundation for Medical Education, in collaboration with over 30 collective authors as members of the Clinical Significance Consensus Meeting, published a series of reports describing several problems with the use of the term clinical significance (CS). These problems included inconsistent measurements, changing definitions over time, varying opinions among stakeholders, theoretical inconsistencies, and unclear guidelines for determining CS in group versus individual differences or single item versus multi-item instrument scores. The consensus panel asserted that these problems interfere with the ability of clinicians to clearly interpret research data and detract from the credibility of CS as a concept (Guyatt et. al., 2002; Sloan et. al., 2002; Sloan et. al., 2003).

The importance of CS as concept was illustrated in its comparison to statistical significance: while the P values of a statistically significant finding indicate the likelihood of the change being caused by chance, CS goes beyond statistical significance to identify whether the statistically significant change or difference was large enough to have implications for patient care (Sloan et. al., 2002; Pittman & Rawls, 2008). The potential utility of a concept that consistently indicated significant patient change was perceived to have positive implications for stakeholders including researchers, clinicians, society, and patients. Thus further research by physician scientists ensued to resolve identified disparities and determine valid and reliable measurements of CS. Substantive progress has been made to develop and define methods of quantifying CS. The psychology/psychiatry (Jacobson, Follette & Revenstorf, 1984; Jacobson & Truax, 1991; Jacobson, Roberts, Berns & McGlinchey, 1999) and pain management (Mantha et. al., 1993) specialties have operationalized CS and formal measurement methods. Oncology (Frost et. al., 2002; Guyatt et. al., 2002; Sloan et. al., 2002; Sprangers et. al., 2002 & Symonds,
Berzon, Marquis & Rummans, 2002), pulmonary medicine (Lacass et. al., 2002; Puhan et. al., 2004), rehabilitation (Haley & Fragala-Pinkham, 2006), surgery (Copay et. al., 2008; Carreon, Glassman, Campbell & Anderson, 2010), and other medical disciplines have made great strides in this important undertaking. These combined medical efforts lend credence to the importance of undertaking efforts to determine valid and reliable measures for CS.

As an indicator of patient change, CS has evolved in healthcare to provide measures observable to the clinician/researcher and patient. The patient’s self assessment of change has evolved as the central measure of CS. One current interpretation of CS as a research and clinical term is as follows: a minimal clinically significant/important difference represents the smallest difference in score in the outcome of interest that informed patients or proxies perceive as important, either beneficial or harmful, and which would lead the patient or clinician to consider a change in patient management (Schunemann et. al., 2005). Inclusion of the patient into the calculation of CS has important implications for evidence-based practice (EBP) because patient values are critical to the achievement of best practices (Jones, 2010; Melnyk & Fineout-Overholt, 2011).

While medicine has made substantial progress in defining CS, nursing has not made similar attempts to define the term and substantiate it as a measure of patient response to treatment that fulfills evidence-based standards. Indeed, there has been no formal, integrated theoretical research undertaken by the nursing discipline to define an operational use of the term CS (Jeans, 1992; Burns & Grove, 2009; Dysvik et al, 2009) and there is a general lack of clarity about CS in the nursing literature. It has been variously defined as anything of relevance to nursing (Jeans, 1992), anything that is worth changing practice for (Fawcett, 2009), and a value judgment (LeFort, 1993). In the contemporary nursing literature, CS has been variously defined
as: a measure of patient response to treatment based on pre-determined thresholds (Pittman & Rawls 2008); a change that is at least twice the standard deviation of difference in scores due to measurement errors (Dysvik, Kvaloy, Stokkeland, Natvig, 2009), and meaningful individual change exceeding the Reliable Change Index value that results in the final (post-test) score falling within the 'normal range' (Baird, Worrall, Haslam & Haslam, 2010). Clearly, within the nursing discipline a standard definition of CS has not materialized.

Standardizing definitions, measures, and methodology is essential to disseminating best practices. The lack of clarity when defining CS contributes to uncertainty about the quality of evidence represented by a CS change. According to Rodgers, a concept analysis is necessary when there are inconsistencies in terminology, utilization, or lack of theoretical coherence (Rodgers, 2000). The purpose of this paper is to use Rodgers' evolutionary concept analysis to discern a "state of the art" consensus for CS. A "state of the art" consensus is intended to advance the development of the term to promote consistency in interpreting research findings and facilitate translating research into evidence.

Methods

An extensive review of the literature was conducted. Literature searches were performed to identify articles pertinent to clinical significance. The electronic databases CINAHL, ISI Web of Knowledge, PubMed, Cochrane Database of Systematic Reviews, and Google Scholar were searched using the following keywords: clinical significance, clinical significance measures, clinically significant, clinically meaningful, clinically important, and evidence based practice. The search included papers published between the January 1999 and December 2010. Additional searches were completed on several websites, such as those of the Agency for Healthcare Research and Quality, The Joint Commission, and the Center for Medicare and Medicaid
Services. In addition to computer searches, reference lists of articles on clinical significance provided additional publications that were reviewed.

A search for previous clinical significance concept analyses provided no results. Inclusion criteria for articles used for this concept analysis were that they were printed in English, published in peer-reviewed journals, had a nurse as the first author, and were relevant to the main topic of clinical significance. Approximately 83 articles were located and abstracts read. A total of 56 articles were selected for detailed review and analyzed to obtain understanding of the many facets of clinical significance. Of the 56 articles used for analysis, three did not use clinical significance as a research term. The final number of articles evaluated in this concept analysis was 53.

Clinical significance has been studied and discussed by a wide range of international professionals. Nursing articles were co-authored by physicians, pharmacists, social workers, and mathematician researchers living and working in the United States, Canada, England, Italy, Germany, Denmark, Sweden, Finland, China, and Singapore. International interest is indicative of the relevance of the concept of CS.

**Proposed Definition Based on Findings**

Rodgers asserted that the identification of surrogate terms, (e.g. terms that are frequently interchanged with the concept of interest), promotes elucidating the unique and defining aspects of the concept of interest. In the nursing literature, surrogate terms used most often as synonymous with CS were the terms *clinical importance, clinical relevance, and clinically meaningful*. While these terms were interchanged with CS, it is notable that CS was used more exclusively when quantification, numbers or measures were applied to explain the importance of the finding; this observation is further described in subsequent sections. The common themes, as
they occurred in the nursing literature, are presented as the core attributes of the concept. Synthesizing literature themes to identify core attributes of a concept provides the basis of the “consensus of use” definition. Rodgers asserted that the “consensus of use” definition is equivalent to a “state of the science” overview of a concept, thus it provides a baseline upon which to guide theory development.

In accordance with the Rodgers’ methodology, the first finding to be discussed is a “consensus of use” definition of the term as derived from a thematic analysis of the literature. The definition proposed is broadly inclusive of the various uses of the term: *CS is a patient related difference that the clinician/researcher has judged for nursing knowledge to guide nursing interventions.* This definition is reflective of the literature where in most cases CS was described as resulting from changes in the status of patients which was judged (either subjectively or quantitatively) as relevant to nursing knowledge and interventions. It is important to note that this definition is proposed as an a posteriori observation of the existing literature; further efforts are required to define CS more distinctly and specifically for the nursing discipline.

**Attributes of Clinical Significance**

**Patient related**

CS is associated with three patient related themes: research directly involving patients; patient-related policies and protocols, and medical equipment and procedures. The majority of studies explicitly involved patients in either an inpatient or outpatient setting. Outpatient settings were represented by individuals in rehabilitation (Riegel et. al., 2006; Baird et. al., 2010), or nursing homes (Dowling, Graf, Hubbard & Luxenberg, 2007; Fjelltun et. al., 2008), and those receiving post-surgical care (Wilson & Hagadottir, 2006) or psychotherapeutic treatment...
(England, Tripp-Reimer & Rubenstein, 2005) in their homes or in outpatient clinics. Inpatient settings were represented by individuals receiving treatment for cancer (Cella et al., 2003; Bauer & Romvari, 2009; Swanson & Koch, 2010) and psychiatric conditions (Bowers et al., 2006), as well as obstetrical care (Simpson, Parsons, Greenwood, & Wade, 2001; Callahan & Hynan, 2002; Waltman, Brewer, Rogers & May, 2004), pre and post-surgical care (Kurlowicz, 2001; Gallagher & McKinley, 2009) and intensive care (Happ, Tuite, Dobbin, DiVirgilio-Thomas, & Kitutu, 2004).

A smaller portion of the studies included indirect patient care issues – specifically reviews of healthcare literature (Schaffer, Yoon, & Zadezensky, 2009) and evaluation of patient care-related policies (Doughty et al., 2006) and protocols (Harrington, 2005). The smallest category of studies assessed the accuracy of medical equipment and procedures (Gilbert, Barton & Counsell, 2002; Farnell, Maxwell, Tan, Rhones & Philips, 2005; Zengin & Enc, 2008).

**Difference: Change**

CS was often asserted as having occurred when a difference was detected. The most common differences were those designated as change. The most common changes attributed to CS were patient responses to treatments. The usual indication of this was the improvement or deterioration of a medical or psychiatric condition. Psychiatric treatment responses included reduction of depression, anxiety or distress (Kurlowicz, 2001; Simpson, Parsons, Greenwood & Wade, 2001; Callahan, & Borja, 2008; Gallagher & McKinley, 2009) and inpatient violence (Bowers, Brennan, Flood, Lipang & Oladapo, 2006; Dowling, Graf, Hubbard, & Luxenberg, 2007; Selbaek, Kirkevold, & Engedal, 2008). Responses to treatment often involved pain reduction and changed biopsychosocial functioning (Cella et al, 2002; Frost et al, 2002; Barrett,

**Difference: Comparative**

The second most common differences that were designated as CS in the literature were comparative differences. Comparative differences occurred when a different condition was detected in an individual, group of individuals, or issues related to patient care. In most studies, a CS difference equated with detection of an abnormal psychiatric (Gallagher & McKinley, 2009), medical (Barrett, Brown, & Mundt, 2007), functional (Dysvik et. al., 2010) or pain condition (Kokki et. al., 2003). In other studies the difference was related to an outdated policy (Doughty et. al., 2006), protocol (Harrington, 2005; Ryan-Wenger, Neal, Jones, & Lowe, 2010) or equipment function (Gilbert, Barton, & Counsell, 2002). Adverse outcomes were also cited as CS (Jenkins & Lindsey, 2010).

**Clinician/researcher**

Common themes of judging CS were researcher opinion (Wendler, 2003; Ward-Smith, Korphage & Hutto, 2008; Hogan, 2009; Ryu et. al., 2010), and researcher opinion accompanied by parameters established by expert opinion that involved: a) consensus panels (Farnell et. al., 2005; Doughty et al., 2006): b) government-sponsored guidelines (Skelly, Carlson, Leeman, Soward, & Burns, 2009): c) institution-based guidelines (Gilbert, Barton, & Counsell, 2002; Zengin & Enc, 2008): or d) recommended thresholds or cut-off scores suggested within instruments (Dowling, Graf, Hubbard, & Luxenberg, 2007; Selbaek, Kirkevold & Engedal, 2008). A less common theme involved integrating patient judgments with researchers’ judgments to ascertain CS (Cella et. al., 2003; Baird, Worral, Haslam, & Haslam, 2010; Dysvik et al, 2010).
Judging CS was based upon a diversity of criteria and rationale. Often judgment was based on a measure; the most common measure was mathematical. Mathematical measures included applying instrument-specific numeric cut-off scores (Callahan & Borja, 2003; Dowling, Graf, Hubbard, & Luxenberg, 2007; Selbaek, Kirkevold & Engedal, 2008; Swanson & Koch, 2010) using pre-determined, a-priori judgment by the researchers (Farnell, Maxwell, Tan, Rhodes, & Philips, 2005), using a-posteriori judgments for moderate to large differences (Kurlowicz, 2001; Happ, Tuite, Dobbin, DiVirgilio-Thomas, & Kitutu, 2004; Bowers, Brennan, Flood, Lipang, & Oladapo, 2006; Schaffer, Yoon & Zadezensky, 2009; Skelly, Carlson, Leeman, Soward, & Burns 2009), and using a-posteriori judgment of small to moderate changes or differences (Simpson, Parsons, Greenwood, & Wade, 2001; Wendler, 2003). The second theme involved measuring patient feedback accompanied by clinician-rating functioning (Cella et al, 2002; Frost et al, 2002; Barrett, Brown, & Mundt, 2007; Baird, Worrall, Haslam, & Haslam, 2008; Dysvik, Kvaloy, Stokkeland & Natvig, 2009) CS judgments were not based on measures. Instead, methods of determining CS were attributed to important occurrences including identifying important critical occurrences (Jacobs, Apatov, & Glei 2005; Jenkins & Lindsey, 2010), discovering a deficient protocol (Ruchala, Metheny, Essenpreis, & Borcherding, 2002; Schaffer, Yoon & Zadezensky, 2009) or detecting an important patient condition (Harrington, 2005; Hogan, 2009).

Nursing Knowledge to Guide Interventions

Generally, findings were accompanied by recommendations for application to clinical practice. The recommendations varied in their level of specificity from general admonishments for nurses to become more involved in policy making to prescriptive advice with specific recommendations for practical application. Examples of recommendations to guide nursing
Interventions included recommendations for medication prescribing (Schaffer, Yoon, & Zadezensky, 2009) treating post-surgical pain (Kokki, Kankkunen- Pietila, & Vehvilainen- Julkunen, 2003; Wilson & Helgadottir, 2006), managing medication responses (Bauer, & Romvari, 2009; Marrs & Zubal, 2009), and interpreting or implementing protocols, policies or procedures (Kurlowicz, 2001; Gilbert, Barton, & Counsell, 2002; Ruchala, Metheny, Essenpreis, & Borcherding, 2002; Farnell, Maxwell, Tan, Rhones, & Philips, 2005; Harrington, 2005; Doughty et al, 2006; Zengin & Enc, 2008; Hogan, 2009; Swanson & Koch, 2010).

Antecedents

The main antecedent for CS was that the research involved patient-related variables. The broad objective of the studies was to provide relief of patient distress or deficits. Patient distress or deficits included pain (Kokki, Kankkunen, Pietila, & Vehvilainen-Julkunen, 2003; Wilson & Helgadottir, 2006), cognitive emotional distress (Kurlowicz, 2001; Simpson, Parsons, Greenwood, & Wade, 2001; Callahan & Borja, 2003; Wendler, 2003; Dowling, Graf, Hubbard, & Luxenberg, 2007; Gallagher & McKinley, 2009), medical conditions (Skelly, Carlson, Leeman, Soward, & Burns 2009; Ryu et. al., 2010), and quality of life (Frost et al, 2002; Barrett, Brown, & Mundt, 2007; Baird, Worral, Haslam & Haslam, 2008). Topics that indirectly affected patient distress or deficits involved assessing policies (Hogan, 2009; Schaffer, Yoon, & Zadezensky, 2009), protocols (Harrington, 2005) or equipment (Zengin & Enc, 2008).

Consequences

The consequences of CS, based on the manner in which CS was applied in the literature, include uncertainty about implementation of CS research findings. Because CS was often based on non-standardized measures and definitions, the strength of the evidence is unclear. Strength of evidence is defined as the likelihood that a research finding will produce a measurable patient
outcome (Substance Abuse and Mental Health Services Association, 2006). As CS is currently used in the research literature, it is not always associated with a measurable patient outcome.

Many of the practice recommendations were based on subjective researcher opinion as the basis for determination of CS. Guidelines established for EBP place a low value on effecting nursing practice changes that are based on opinion (Melnyk & Fineout-Overholt, 2011). Additionally, research that does not directly include patient feedback has come under scrutiny (Frost et al., 2002; Lacass et al., 2002; Puhan et al., 2004; Haley & Frugala-Pinkham, 2006; Copay et al., 2008 & Carreon, Glassman, Campbell, & Anderson, 2010); placing further concerns about the application of a CS finding to best practices. In recent years, lawsuits against nurse practitioners have increased and one key recommendation to decrease risk included following evidence-based practice guidelines (Edmunds & Scudder, 2009). In a worst-case-scenario, a practitioner who does not understand or misinterprets CS in the literature could adjust nursing practice by accepting as a priori the importance of a finding reported to be CS.

**Related concepts**

The term CS was often used interchangeably with related concepts to convey clinical importance. These terms include “clinically relevant,” “clinically important,” and “clinically meaningful.” While CS was used interchangeably with these related concepts, it was overwhelmingly used when quantification, numbers or measures were applied to substantiate a research finding.

**Discussion**

The purpose of this concept analysis was to examine the predominant conceptual meaning of CS using Rodgers’ methodology. In an effort to bring a coherent understanding to the concept, a definition of CS was developed based on common themes derived from its use.
over the past ten years in the nursing literature. The end result was a proposed “state of the art”
understanding that is a synthesis of its myriad uses.

There are numerous problems associated with the use of CS in the nursing literature. First, information from the analysis indicated a lack of consensus about the use of the term. Thus, there is a multiplicity of opinions, definition and uses of CS. The absence of a consistent definition creates problems for clinicians trying to interpret validity, reliability, relevance, and the overall safety of findings that are labeled CS. Second, because CS was commonly based on researcher judgment, the term is often used subjectively and findings are prone to bias in favor of positive results. Third, the majority of the studies did not incorporate the perspective of the patient. These problems strongly suggested that a finding labeled as CS should not necessarily inform decisions about nursing practice. In addition, the findings from this concept analysis inferred a need to establish a common definition of CS and general guidelines for its measurement.

In attempting to delineate benchmarks for CS in nursing, it is important to consider some of the problems encountered by researcher/clinicians in non-nursing disciplines. Some authors asserted that while an optimal and highly desirable solution would be to develop a single rule, policy, or guideline for assessing CS, such a goal was unrealistic (Ogles, Lunnen, & Bonesteel, 2001; Cella et al., 2002; Guyatt et al. 2002; Sloan et al., 2002). Other authors assert that a single quantitative method for determining CS was overly simplistic (Jacobson, Roberts, Berns, & McGlinchey, 1999) or suggested that as long as a common definition of CS was agreed upon, a variety of different measures will produce results that are reasonably equivalent (Atkins, Bedics, McGlinchey, & Beauchaine, 2005) Another challenge was that in order to make measures of CS meaningful, the perspectives patients, caregivers, clinician/researchers, and society or health
policy makers needs to be identified because judgment of CS differed among stakeholders (Frost et. al., 2002; Hajiro, & Nishimura, 2002; Greenstein, 2003; Pittman, & Rawl, 2008). Finally, regardless of efforts to objectively quantify CS, subjective value judgments, while (ideally) expertly informed, pervaded clinical management and research decisions (Guyatt et al., 2002; Hajiro, & Nishimura, 2002; Greenstein, 2003; van Roon et al., 2009).

To resolve some of these problems, it is becoming clear that the patient perspective should be the foundation of CS (Kazdin, 1999; Frost et al., 2002; Guyatt et al., 2002; Guyatt et al., 2007; Metz et al., 2007; Copay et al., 2009). While actively soliciting patient perspectives has not traditionally been important for [empiric] research tradition, there has been an increased emphasis on incorporating patient feedback about treatment into research decisions whenever possible (Dysvik et al., 2009; Molnar et al., 2009). Indeed there are current efforts to increase awareness of patient perspectives in clinical and drug trials (Molnar et al., 2009). An emphasis on the patient as the foundation of data about CS is not only appropriate to help inform clinician/researcher decisions, but data derived from patient input is considered appropriate for other stakeholders including society and policy makers. Finally, the inclusion of the patient perspective into the judgment of CS is congruent with the holistic foundation of nursing practice and with EBP standards. Indeed, patient input is receiving increased emphasis within the EBP paradigm (Fawcett, 2010; Melnyk & Fineout-Overholt, 2011). Efforts to quantify patient response and ascribe meaning to treatment have resulted in measures of minimal and maximal change, as well as measures of patient value judgments. These measures will be described next.

In delineating measures of patient response to treatment, there has been a need to identify the minimal response to treatment. While there are a variety of methods to measure minimum difference including minimum clinically important difference (MCID) and minimum clinically
important improvement (MCII), there are indications that the minimally clinically significant/important difference (MID) will become the preferred standard to measure minimal change (Schunemann et al., 2005; Barrett, Brown & Mundt, 2008). MID represents the smallest difference in score in the domain of interest that patients perceive as important, either beneficial or harmful, and which would lead the clinician to consider a change in the patient’s management (Guyatt et al., 2007, p. 377). Variations of MID calculations may be modified to capture intrapatient, interpatient or aggregate group differences (Cella et al., 2002). Additionally, select statistical applications of MID, in conjunction with anchors derived from global and functional scales or distributional methods can provide averaged MID values that are generalizable to other studies (Copay et al., 2008; Molnar et al., 2009).

There are several ways to measure moderate to large or maximal change. Individual differences are commonly measured with the Reliable Change Index, which indicates the likelihood that the large magnitude of individual patient change is real and has not occurred by chance (Jacobson, Follette & Revensdorf, 1984; Jacobson & Truax, 1991; Pittman & Rawl, 2008; Dysvik, Kvaloy, Stokkeland & Natvig, 2010). Measures of moderate to large group treatment response are traditionally measured with effect size, a measure of the difference in treatment effect between the treatment group and the comparator. However, this method has come under scrutiny because it ignores the patient attribution of meaning (Cella et al., 2002; Guyatt et al., 2002). Additionally, results expressed as effect size are not always generalizable to other studies (Molnar et al., 2009). A number of measures are available, however, for understanding the magnitude of effects that include patient perspective. Investigators may relate changes in global score (e.g., quality of life score) to changes in scores in functional assessment, clinical diagnoses, the patients’ global ratings of the magnitude of change they have experienced,
or to the extent that patients rate themselves as feeling better or worse than other patients (Guyatt et al., 2007). Measures of maximum treatment response, while inclusive of pharmaceutical treatment responses, often include responses to non-pharmaceutical treatments including physical, psychological, rehabilitation, surgical, and multidisciplinary therapies (Cella et al., 2003; Dysvik et al., 2009; Metz et al., 2010).

There are other evolving aspects of CS that may be used to help the patient and clinician make informed decisions about treatment plans that reflect patient values. Information about likelihood of benefit to harm, lowest risk reduction, and highest benefit potential may be measured in several ways; the most often cited are minimally clinically important difference (MCID) and number needed to treat (NNT). MCID has been determined in various ways including via anchor-based approaches, “between patients” score change, comparative distributions, and social comparisons (Copay, Subach, Glassman, Polly, & Schuler, 2007). NNT involves calculating the inverse of a percentage to determine the need to treat disorders caused or exacerbated by a treatment effect. This is a percentage calculation that determines how many patients need to receive a treatment in order to obtain one resulting outcome. If one of 100 individuals benefited from a treatment, then 100 individuals would have to be treated to obtain a positive outcome, 200 for two, etc. (Melnyk & Fineout-Overholt, p. 91). These methods indicate the plethora of evolving methods to quantify, predict, and assist patients to make informed decisions about the CS of healthcare treatment options (Guyatt et al., 2007).

**Implications for Further Research**

While nursing has been relatively silent in regards to assigning a specific definition and measurement to CS, the medical community has been actively researching CS. In 2002, the CS Consensus Group met to address problems and solutions related to CS. In 2007, they reconvened
and made suggestions for CS based on the ongoing medical trends and related research (Guyatt et al., 2007). The CS Consensus Group suggested that the definition of CS emphasize patient response to a research or clinical treatment, and the importance and meaning the patient ascribes to treatment effects (Guyatt et al., 2007). Additionally, CS includes the risks and benefits of alternative treatments and the likelihood of benefit or harm from those treatments (Guyatt et al., 2007). The CS Consensus Group suggested that measures to quantify CS are inclusive of the methods described in the above section, and include the various measures of minimum and maximum treatment effects, measures to indicate treatment outcome probabilities, and measures of patient meaning ascribed to treatment (Guyatt et al., 2007).

In addition to emphasizing patient perspective, the CS Consensus Group suggested that CS is most accurately appreciated by measuring multiple domains of patient experiences, including cognitive, emotional, physical, functional, and social spheres of influence. This conceptual model of CS assumes that patient response to treatment is experienced in multiples aspects of their lives; thus, information of biological and physiological variables, symptoms status, functional status, general health perceptions and overall quality of life provide the evidentiary basis upon which informed determinations of CS are made. It is expected that outcome measures specific to relevant medical or nursing research and/or clinical specialty are included in the calculation of CS. Instruments to quantify the holistic measurement of CS from a patient perspective continue to be developed; two examples of these instruments that can be incorporated into the measurement of CS include the Short Form-36 Health-Related Quality of Life Questionnaire and the EuroQual-14. These measures are used widely in the US, Canada, Australia, Japan and eight European countries (Hyak & Engle, 2010). While the patient perspectives can make CS more holistic and meaningful, patient perspectives must also be
considered in relation to the research design. Ideally, patient perspectives to determine CS in research will be conducted using a randomized clinical trial design to reduce the likelihood of the Hawthorne effect.

There are compelling reasons for nursing to adapt the definition and suggested measures recommended by the CS Consensus Group. For one, the measures are based on instruments that have demonstrated validity and reliability. Second, the measures are quantifiable and replicable, and are often the product of random controlled trials; thus the evidence produced is strong and appropriate for application to best practice (Jones, 2010; Melnyk & Fineout-Overholt, 2011). Third, the emphasis on patient perspective exemplifies the philosophical and theoretical foundation upon which nursing is based. Finally, the patient perspective as measured in the biopsychosocial domains reflects the core values of the holistic individual that are espoused by nursing theorists.

The most immediate and tangible advantages to a common conceptual definition and meaning of CS by nursing, regardless of which definition is selected, is less confusion and more clarity. A consensus of meaning, a solid definition and associated valid and reliable measures of both quantitative and qualitative patient information may provide more fruitful and focused research. From a clinician perspective, a solid definition and explicit statistical nomenclature of CS to address clinical applicability may result in improved interpretability of research findings. User-friendly research findings may make research less burdensome for clinicians to read and translate into best practices. Ultimately, the most enduring benefit of a common conceptual definition and measurement for CS is the bridge it provides between research and practice, and the facility with which it promotes the integration of research into evidence based practice.
Conclusion

Given the centrality of CS to interpreting research findings and applying them to practice, there is a need to solidify the definition of and measurements for CS in nursing. National nursing agencies including The National Institute for Nursing Research and Sigma Theta Tau International should make standardizing CS a high priority for targeted funding. One method of doing so would be to support a consensus convergence to review and select the optimal measures of CS for nursing research. Research to increase knowledge about what constitutes measurement and change or CS from the patient perspective is needed. Editors and peer reviewers should encourage authors to include a discussion of CS. Discussions of CS should receive greater emphasis in research journals. It is hoped that the preliminary findings from this concept analysis presented in this article will facilitate the work of such a consensus forum.
References


