

The Optimality Index – US User Guidelines and Toolkit June 2009

I THE CONCEPT OF OPTIMALITY

The concept of optimality in perinatal health strives for the ‘best’ possible outcome with the minimal number of interventions. Pregnancy and birth are, in general, normal physiologic events that do not need intervention. The concept of optimality capitalizes on this philosophy. It is the woman’s health status that provides the framework for the conduct of care that responds to her dynamic needs. Optimality, specifically defined for perinatal health care, is the maximal perinatal outcome with minimal intervention placed against the dynamic context of the woman’s health status.

II THE MEASUREMENT OF OPTIMALITY

The Optimality Index-US (*OI-US*) is a unique research instrument that shifts the focus of inquiry from (rare) adverse events to evidence-based, “best possible”, or optimal events, in both the processes of care (i.e., the manner in which care is provided) and the outcomes that are achieved.

The Perinatal Background Index (*PBI*) is a 14 item instrument that is used to categorize maternity care clientele according to the usual criteria of preexisting perinatal risk, so that comparisons across groups might be made when evaluating outcomes. Items in this section are not conceptualized as "optimal or non-optimal", but, rather, are scored as such, with reference to the evidence that is used to grade obstetric risk.

The Optimality Index (*OI*) contains 42 items in 4 perinatal domains: diagnostic and therapeutic measures used in the present pregnancy, parturition, neonatal condition before discharge from provider's care, and condition of the mother prior to discharge from provider care. Criteria for optimality were drawn from contemporary obstetric literature; especially work evaluating the evidence-based effectiveness of care in pregnancy and childbirth. An optimal outcome is proposed for each of the items, based on the best available evidence.

An important note about measurement

The concept of optimality as defined for the *OI-US* assumes that the lack of use of interventions during a woman’s perinatal experience represents optimality. Therefore, in the event that an intervention *is* utilized, even under the circumstance when the intervention is used appropriately to address an existing risk factor or complication, the item is still scored as “not optimal” because it reflects a divergence from the “no risk and no intervention” ideal contained in the conceptualization of optimality. This applies to life saving measures that, from an evaluation perspective would seem to be a positive (helpful, important, necessary, indicated) event. However, the fact that the intervention was deemed to be necessary is not optimal. Therefore the item would not be scored as optimal when this instrument is used for measurement.

III PSYCHOMETRIC AND CLINIMETRIC PROPERTIES OF THE INSTRUMENT

A. Validity

The *OI-US* is a clinimetric instrument. This type of measurement index simply documents occurrence or nonoccurrence of a clinical event. (Users may be familiar with the Apgar Score, which is a widely used clinimetric tool.)

The *OI-US* is content valid. Items are included if their relationship to optimal outcomes is documented in the evidence-based literature. Each item included is supported by reference to studies published in the recent literature (randomized clinical trials, cohort studies, synthetic reviews, or consensus opinion). Each of the sources/studies offered as evidence supporting the validity of an index item has been categorized according to rating systems for the evaluation of quality of the evidence. These assigned ratings, in turn, speak to the “strength of a recommendation” for adoption of a clinical practice guideline. Additional ratings were developed in response to a need for different categories of “strength of recommendation” when controlled clinical trials were not available.

B. Sensitivity

The ability of this instrument to discriminate on a sufficiently detailed level is an *a priori* conceptual value of the *OI-US*. Instruments based on rare outcomes cannot distinguish among groups of women who do not experience rare adverse events. Sensitivity has been seen in the pilot studies. A recent validity study (Low and colleagues, 2008) provided further evidence of the ability of the instrument to distinguish between overall optimality of process and outcomes when essentially healthy groups of women were compared.

C. Reliability

In a clinimetric instrument each item is intended to make a discrete, not unified, contribution to the understanding of the concept that is being measured. Therefore the appropriate measure of reliability for this clinimetric instrument is the assessment of reproducibility of scoring, demonstrated via intra- and inter-rater reliability. Several assessments of reliability have been conducted. Inter-rater reliability has reached or exceeded a range of 88% - 98% agreement for all index items that were present in the data set. Inter-rater reliability assessment will need to be conducted prior to utilization of this instrument in every new study due to variance in care practices and documentation procedures at each institution (Seng and colleagues, 2008).

IV INSTRUCTIONS FOR USE OF THE OPTIMALITY INDEX – US

A. Potential users should be aware of these important points.

One: the *OI-US* is used as an aggregate measure to describe the overall outcomes of a particular region, institution, practice group, or profession. For example, demonstration of an overall tendency toward lower optimality scores in one institution, when compared to another with

similar patients, may speak to differences in the process of care. The *OI-US* is not intended for use in judging the “optimality” of an individual woman’s pregnancy outcome.

Two: The *OI-US* is intended to reflect the entire perinatal continuum. It is not appropriate to select study patients according to *OI-US* variables (such as cesarean section vs. vaginal birth). Nor should users plan to select specific items within the index to study, eliminating others. When missing data are an issue, it is critical that each clinical domain be represented by each of the items designated as *essential* within the respective domain; otherwise use of the *OI-US* is invalid.

Three: The Perinatal Background Index component of the *OI-US* includes items that are relevant across all women during the index pregnancy that is being considered regardless of parity. However there are also five items that are specific only to women who have had a past pregnancy. These items address prior (historical) information such as previous IUFD, antepartum complications, cesarean delivery, small for gestational age baby and short interconceptual period.

When completing the PBI for nulliparous women, these items can only be considered optimal; it would not be possible for them to be negative. Therefore when a study population includes only nulliparous women, the investigator could chose to eliminate these items from scoring, because they are not relevant to the study population. The denominator used in calculation of the PBI (and also the *OI-US*) would be reduced to 9, from the maximum possible score of 14 for the PBI.

If the study population contains a mix of nulliparous and multiparous women, the user has two options:

- The items can be included for all women in the sample, because conceptually, a first pregnancy does assume a low risk status until demonstrated otherwise. The denominator (number of items included in scoring) would be the same for all women in the sample (n=14).
- The items can be removed from the denominator when calculating the score for nulliparous (n=9) women, but, of course, included, when calculating the score for multiparous women (n=14). In this instance the percentage scores should be reported separately.

The overall score that is reported for both the PBI and the OI (which together constitute the *OI-US*) is a proportion, and this proportional score can be compared across samples. This discussion of parity is presented only to alert the potential investigator using the *OI-US* that a decision should be made a priori on the manner in which a mixed study population will be assessed.

Four: The *OI-US* is often confused as an instrument that can be used for the purpose of benchmarking outcomes against other practices or settings. However the *OI-US* should not be used as a means of benchmarking the quality of maternity care practice. The *OI-US* captures what is considered to be an optimal outcome according to the current scientific evidence for care practices and health outcomes. However, it does not identify when additional intervention is appropriate or warranted due to changes in risk status. For example, if a woman arrives in the labor and delivery unit with ruptured membranes and meconium stained fluid, fetal monitoring will likely be considered to be an appropriate assessment to determine fetal well-being. During this process, if non-reassuring heart tones are noted, an IV may be considered, and continuous fetal monitoring with an internal fetal scalp electrode may be deemed necessary. In this instance, while the care may be considered appropriate in this setting in the presence of these changing

risk factors, the OI score would be lower because it does not capture the change in risk status described above. Rather, it captures the use of the interventions and change in the process of care. The *OI-US* is scored based on whether the individual care practice (e.g. fetal monitoring) is congruent with the evidence base for the practice. Therefore, use as a benchmark, implying that one practice or setting may have more optimal outcomes than another, is not an entirely accurate reflection of the combination of changing risks and the appropriateness of use of an intervention in a particular circumstance. If an intervention has to be used, regardless of the rationale, it is not optimal that something had to be done and therefore the *OI-US* item is scored as a negative, even if use of the intervention, is thought to be life saving in the particular individual circumstance.

B. Coding guidelines

A codebook has been developed for users of the measurement tool. The codebook provides

- precise definitions of the optimal outcome for each item
- the rules by which each item should be measured, e.g., timeframes of observation; and
- guidelines for decision-making concerning the relevance of an index item within a particular health care delivery setting.

C. Missing data

Two types of missing data have been identified.

- items that will never be found in a particular institution's records (system missing)
- items that should be routinely available in the record but are not in fact present in the particular chart that is being abstracted (random missing).

Coding guidelines allow researchers to declare certain items as “not applicable/not available in this setting.” In these cases, the denominator used in computation of the *OI* and/or for the overall *OI-US* is reduced by the number of “not applicable/not available in this setting” items. When missing data are an issue, it is critical that each clinical domain be represented by each of the items designated as *essential* within the respective domain; otherwise use of the *OI-US* is invalid. (See the Code Book for essential designations.)

Note that there may be other items that are “system missing” (code 8) in a particular setting, but are designated as “essential” in the Code Book. The research team should make a specific determination about such items in the context of their own research. It may be possible to find those items through implementation of additional abstraction efforts. If this is not the case, then the item could be declared code 8 in the particular context. **However**, if there are less than 50% of items remaining in any particular clinical domain, then the *OI-US* should not be used as a measurement tool.

V. DATA ABSTRACTION AND DATA ENTRY

Various tools have been developed by users of the *OI-US* that might be useful in another application, after they have been edited to reflect the most current version of the measurement tool. These tools can be downloaded from this site.

A UCSF Data Abstraction Tool

This WORD document is the paper data abstraction form used to collect data for the *full set of OI-US variables*. The form is based upon the ACNM minimum data set and the February 2002 version of the OI-US.

B UofM Data Abstraction Tool

The U of M OI Case Report Form developed by researchers at the University of Michigan facilitates reliability by stream-lining *intrapartum* abstraction according to delivery scenario (vaginal birth vs. scheduled, first-stage, or second stage cesarean section). This tool already reflects the “not applicable” data coding decisions that would be relevant in these frequently occurring circumstances.

C OI ACNM IP Dataset SPSS Syntax

This is a WORD file in table format explaining the connections between the variables collected in the UCSF data abstraction tool and the recoding of those variables for the OI-US analysis.

D SPSS Variable Names and Labels

This is an EXCEL file containing all of the variable names and labels used in the SPSS spreadsheet.

E SPSS Programming Files

UCSF has also generously provided the SPSS syntax for data entry. **NOTE THAT** this syntax reflects an earlier version of the OI-US, and would need to be revised before use, in order to include all current instrument items and the appropriate coding guideline. However, the syntax file offers the user a very valuable “jumpstart” on programming. The syntax has been reviewed and checked several times. Nevertheless, any researcher wishing to use this syntax should carefully check it for errors. The OWG has no responsibility for programming or output errors that may occur from use of this model syntax in any other application. Dr. Leslie Cragin, a member of the Optimality Working Group, has generously offered to provide individual consultation to those who may wish to use this model syntax.

Directions for downloading the syntax files

- 1) Click on SPSS Programming files
- 2) A pop-up window will appear.
 - a) Enter the UserId **SPSSuser**
 - b) Enter the password **1@#DOR**
- 3) Click on the file **OI_SPSS _syntax_for OIMDS**
- 4) A list of all programming files will appear.
 - a) Click on each of the files, individually
 - b) Save each individual file to your hard drive
- 5) Open each file within your SPSS program to ensure that it has successfully downloaded.
- 6) Proceed to edit the syntax to reflect the most current version of the OI-US.

VI INSTRUCTIONS FOR SCORING THE OPTIMALITY INDEX-US

When using the *Optimality Index-US*, good outcomes are assumed. Scores are not summed to a total, but rather a total optimal score is assumed and points are deducted when optimal criteria are not met. Missing items are subtracted from the denominator. **The resulting percentage score is reported.**

The *PBI* and the *OI* are scored separately from one another, and reported separately as the *PBI* score and the *OI* score. The *PBI* score will enable the user to affirm the equivalence, or difference, between two or more groups in any comparison. Missing items are subtracted from the denominator. **The resulting percentage score is reported.**

The *OI* score provides the opportunity to report clinimetric issues of the process and outcomes of care separately from the impact of the issues addressed in the *PBI*. Missing items are subtracted from the denominator. **The resulting percentage score is reported.**

The Optimality Index **does not contain subscales.** Items in the *OI* are logically arranged within perinatal domains (e.g., antepartum, intrapartum); however, these domains are not individually sub-scored.

The scores of the *PBI* and the *OI* can be combined to create the unified total score of the *OI-US*. “Within group” and “between group” differences can be assessed, but must be reported with reference to the similarity or difference of groups, as determined by the *PBI* score. The issues of missing data and the computation of the percentage score remain relevant.

VII LIMITATIONS IN USE OF THE OPTIMALITY INDEX – US

- The *OI-US* was originally developed for use as a retrospective data collection tool; therefore a number of items may not be available in records received from paper or electronic storage. However, the instrument can be used prospectively, and users can take measures to ensure that all *OI-US* items appear on the prospective data collection tool designed for the purpose.
- The *OI-US* does not assess individual client satisfaction with the process of care. Users may wish to select a second measurement instrument to be used concurrently with the *OI-US* to measure that construct. We do not recommend any particular instrument. However, we can suggest the COMFORTS scale, in light of the psychometric properties that have been reported.
 - Janssen P, Dennis C, Reime B. Development and psychometric testing of the Care in Obstetrics: Measure for Testing Satisfaction (COMFORTS) Scale. *Research in Nursing & Health*. 2006; 29:51-60.
- The *OI-US* is not intended to judge a single woman's care as optimal or non-optimal *in context* (e.g., it may be the case that interventions were appropriate in the individual case; nevertheless, the fact that a procedure was used in the context of care is judged against what is optimal in the best case scenario).
- The *Optimality Index-US* is not a risk assessment tool. While many items in the tool are related to the risk factors and adverse outcomes found in standard risk assessment instruments, the index does not measure risk.
- The *OI-US* is not a benchmarking, peer review or quality assurance tool. Benchmarking is used to *improve* quality by providing a community standard ("benchmark") against which a practice can be measured. Optimality measures what should occur, according to the evidence that supports best practice.