VCU / VERNOVA FUNCTIONAL EVALUATION PROTOCOL VALIDATION DOCUMENT BA Ruiz PhD 2005

I. Introduction

There is much confusion about the terms validity and reliability. Many individuals and even organizations do not understand the difference or the related application of each in the area of Functional Evaluation. Validity is a description of whether a test or protocol truly tests what is purported to be tested and yields an answer to what is in question. Reliability is a description of the consistency of the results obtained from a test or protocol and if the variance is within acceptable ranges. Together validity and reliability are the "cornerstones" of Classical Test Theory and are required for a "strong" true test score. It is obvious that a significant percentage of testing that is currently being conducted in North America is non-predictive, discriminatory, and may even be unsafe. Referral sources are paying for information that is useless, and evaluators are relying on unscientific protocols, which lack a validation methodology and yield unreliable results. The VCU/VERNOVA protocol, and the sub-tests that compose the protocol, utilize each of the three major classes of validation methodology- Construct, Content and Criterion. The VCU/VERNOVA protocol also adheres to the other required foundational evaluation principles of Safety, Standardization, Reliability, Practicality and Utility. It should be noted that there has never been an injury or a successful challenge of the data generated by the VCU/VERNOVA protocol to the date of this printing.

II. Legal Issues

A. Expertise of the Evaluator

• The VERNOVA System is a tool that makes competent health care professionals more efficient and effective. It is not a substitute for

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competent health care professionals. Instead, it streamlines the cumbersome and time-consuming tasks like data entry and report generation and lets the user focus on the assessment of the patient's condition.

• The VERNOVA System generates a draft report based on objective data collected from the testing session. The health care professional has the responsibility to review the report. Often, they will augment the report with additional findings and medical conclusions. The quality of the report is partially determined by the competence and thoroughness of the Health Care Professional.

B. Data Entry Errors Reduced

• The system substantially reduces data acquisition, transcription, and calculation errors. Each instrument, such as the hand dynamometer, generates an analog signal. Each signal is converted into digital form then transmitted to the computer. Human error involved in reading and interpreting manual instruments then re-keying the information or performing manual calculations is eliminated.

C. Calibration

- Calibration is a significant issue that is often overlooked in the manual reading setting. The VERNOVA software allows for quick and easy calibration of instruments. This facilitates frequent calibration to ensure accuracy of the data collection.
- Manual systems are much more difficult to calibrate. Proper calibration requires returning the instrument to the factory. Often it takes 2 weeks or more to have the instrument returned. As a result, manual instruments are calibrated much less frequently.

D. Protocol Validation

- The VERNOVA system focuses on three main bases of physiological evaluation: strength, range of motion, and cardiovascular conditioning. Standardized sub-tests that are part the system can assist the health care professional to follow an established testing pattern. This can enhance inter and intra tester reliability. These sub-tests are common in the industry. They were developed by professionals in accordance with the Equal Employment Opportunity Commission (EEOC) Uniform Testing Guidelines.
- The foundational suggested protocol was developed by a multidisciplinary panel of professionals at Virginia Commonwealth

University/The Medical College of Virginia. After over a year of research and collaboration on findings, the current standardized methodology of physiological measurement was released. The VCU/VERNOVA protocol is currently the only university developed system available. As an effort to follow the peer review process for the protocol, VCU/VERNOVA developed a relational post-graduate <u>Scientific Foundations</u> course based specifically on the aforementioned protocol. As of this printing, since 2000, over 350 professionals have reviewed and been educated on the VCU / VERNOVA protocol.

- In an illustration of **Applied Validly** can be seen in the study conducted in Canada, for the province of Ontario. The claims and adjustments expenses for Accident Benefits during the five years prior to study exceeded five billion dollars. The number of claims in the year 2000 alone was 75,300 with an average cost per claim of \$16,395.00*. These facts precipitated a pilot program with Liberty Mutual Canada and VerNova Inc. The directive was to evaluate these claims with the goal of reducing the average cost per claim and returning the individual to pre-accident status sooner. The program consisted of a structured objective evaluation program using VERNOVA's Functional Testing System and incorporating it into Liberty Mutual's existing Return to Work Rehab Program. The total time, during which the claimant's file was open, was reduced by 80 days. Overall, the result was that the claimant's ability to return to preaccident status was expedited and subsequently the average cost per claim was reduced by \$6,697.29. See, "Loss Reduction Through **Utilization of Enhanced Claims Management Processes**" *Liberty* Mutual, D. McTavish, Regional Claims Mgr. Can., V.P. Claims Liberty Insurance Co. of Canada, J. Mclean, Claims Manager, N. Neumann, Team Manager, E. Pleasance, Rehab Coordinator.
- However, the system is still flexible enough to allow users to develop their own testing protocols. These custom protocols can use components of the standard protocols, or be completely unique. This allows the practitioner to tailor the test to emulate specific job tasks.

E. Reliability Checks

 The Workers' Compensation Board of British Columbia commissioned an independent third party, PricewaterhouseCoopers, to research the VERNOVA testing system and provide findings. See <u>"External Preferred Provider Project Report"</u>, Workers' Compensation Board of British Columbia, (March 1998). The study had a focus on the consistency of the evaluation system, objectivity of the process and even included client satisfaction and application success in the field. *"Overall we conclude that the VERNOVA/EPP impairment evaluation process is objective, consistently applied and produces valid ratings."* (PriceWaterhouseCoopers). In a blind test study of inter-tester and intra-tester reliability also conducted by PriceWaterhouseCoopers, less than 2% variance was found between clinic and less than 1.3% variance with the same clinic. The PriceWaterhouseCoopers survey of clients yielded an excellent 4.6 satisfaction rating on a scale of 1 to 5 with 1 being poor and 5 being excellent.

- The computer automatically and instantaneously calculates reliability and consistency measures like standard deviation and the coefficient of variation. These calculations are based on objective analysis of discrete data points. These sincerity checks are used to identify inappropriate patient behaviors that can suggest submaximal effort.
- Another sign that may suggest submaximal effort is Heart Rate Monitoring. Studies have shown that acute pain and significant exertion are usually accompanied by an increase in heart rate. A health care professional can review the results of the heart rate monitor while a patient is performing the test. See "Assessing Reliability of Performance in the Functional Capacity Assessment", L. A. Owens, Journal of Disability, Vol. 3, Num. 14, pp. 152, (Jul 1993).
- One of the benefits of using computerized strength testing equipment is the ability to see data displayed real-time. This is especially beneficial to the practitioner in the analysis of static force curve shapes. Certain static force curve patterns can suggest submaximal effort.
- Distraction techniques can also be used with the VERNOVA system to ensure validity of the results. One common distraction technique that is used is horizontal displacement. Patients are tested at various horizontal distances from the subject weight. Studies have shown that the ability to lift is partially dependent on the horizontal displacement with relation to the subject weight. The system will automatically calculate anticipated differences as the patient moves closer or further from the subject weight. See "Horizontal Strength Changes: An Ergometric Measure for Determining Validity of Effort in Impairment Evaluations-A Preliminary Report", Berryhill et al, Journal of Disability, Vol. 3, Num. 14, pp. 147, (Jul 1993).

F. Safety

- Injured persons are tested on the VERNOVA system during return to work and baseline testing. With an injured patient, it is important to ensure that the testing methodology will not cause an exacerbation of the injury. The VERNOVA system helps the health care professional to test patients safely.
- The VERNOVA system allows health care professionals to use both static and dynamic testing. Studies have shown that static testing is a safe and accurate method to determine maximum voluntary effort. See "Static Ergonomic Strength Testing in Evaluating Occupational Back Pain", Harber & SooHoo, Journal of Occupational Medicine, Vol. 26 No. 12 (Dec 1984). Patients are given instructions to provide force until discomfort (FUD). This allows the patient to immediately respond to dangerous amounts of pain that could lead to injury. The results of the static lift are used by the clinician to design proper testing parameters during a dynamic lift, if the dynamic lift is used.
- During the dynamic portion of the test, clinicians are trained to identify signs that indicate if a patient is experiencing discomfort that may cause injury. If the clinician witnesses these signs, then they terminate the test. Static tests are used as a screening device to ensure that the dynamic portion of the test is structured in such a way to minimize the risk of injury.
- The VERNOVA system has other safety mechanisms to reduce the risk of injury. Heart rate monitoring is used to help prevent injury from occurring during the dynamic tests. When a patient's heart rate exceeds acceptable norms, the test automatically terminates. The acceptable norms are defined by aged determined targets based on a percentage of a patient's maximal hart rate normally 85% or in excess of 75% continuously for one minute.

III. Threat to Validity

A. Protocols

• The VERNOVA system allows a user to develop and use a custom protocol. This protocol is not peer reviewed and may not be valid. However in certain tests, the documentation of the VERNOVA report will describe the protocol that was used. This allows a finder of fact to understand the process that was used in a particular case to conduct a test. If the health care professional added additional job specific criteria, then it will be reported. If the clinician failed to properly test for job specific criteria, then the failure will also be shown.

B. Calibration

- The VERNOVA system uses sensors in each instrument to generate signals that are converted to digital form and then transmitted to the computer. The table in Appendix A describes the reliable tolerances of each device along with its minimum and maximum operating range. As with all sensitive force measuring equipment, it is important to periodically calibrate the device for accurate operation.
- The VERNOVA software contains a calibration utility and maintains a log of when the instruments are calibrated. The utility is quick and easy to use. However, currently the software does not require the user to calibrate the instruments. Instead, the task of calibration is left to the discretion of the user. VERNOVA recommends during the operator training certification that the instruments be calibrated at least once a month under normal use.
- The calibration utility uses a single point calibration for most instruments. The single point of calibration can be on any range of values. We recommend using a value of between 20% and 50% of the maximum expected measurement value. We have found that the sensors we use are extremely linear. Therefore, we are confident that single point calibration is sufficient to get an accurate reading throughout the useful range of the sensor. When we have questions about the linearity of the measuring instrument, we require a multipoint calibration. Currently, we have instituted a multi-point calibration on only the electronic goniometers.

C. Job Analysis

- Under the <u>Uniform Testing Guidelines</u>, validation of a test can be accomplished by either performing a statistical study or a job analysis. Performing a statistical study in most companies can be very difficult because the population may be too small to establish statistically significant results. Armed with a properly prepared job analysis, an employer can demonstrate a test's job-relatedness and, by extension, its validity.
- An inaccurate determination of essential demand level of a job will make it difficult for an employer to determine how well a test relates to actual job requirements. An inaccurate determination can be defined as one that omits significant job duties, misstates job requirements, or is otherwise deficient. Inadequate information makes it much more difficult for the health care professional to develop an accurate testing protocol.

IV. Case Precedence

A. Witness v. Report

- Health care professionals who practice in the occupational medicine field are regularly called to participate in legal disputes arising from facts and circumstances regarding their diagnosis and treatment. The VERNOVA testing system is designed to provide those health care professionals with as much objective and accurate information as possible. We believe that placing accurate and objective data in the hands of a knowledgeable and competent health care professional is the best strategy for improving diagnosis and treatment. The VERNOVA system is not a substitute for competent health care providers. Instead, it makes competent providers more efficient and effective at gathering, analyzing, and reporting their results.
- We are not aware of any cases that successfully attempted to impinge the credibility of the system as a testing device. Although, we have not developed an accurate method to track cases that involve health care professionals testify using the VERNOVA testing system. However, a number of physicians who use our system have voluntarily reported their experience using the VERNOVA testing system in court. They tell us that it is almost never questioned. When it is questioned, it always enhances the credibility of the examining physician. Often when the opposing counsel learns about the results of an objective fact specific reporting tool, they prefer to settle. After all, it is difficult to argue that more accurate and objective data in the hands of a competent health care professional has a negative impact on the accuracy of the diagnosis and treatment.
- A list of cases is located in Exhibit B. This list represents a small sample of cases where the court relied on testimony of a physician using the VERNOVA testing system.

V. Medical Research by Product

A. VERNOVA ST/LC - Static

- Isometric Strength Testing in Selecting Workers for Strenuous Jobs, William M. Keyserling, University of Michigan, (1979).
- Pre-employment Strength Testing: An Updated Position, Don B. Chaffin, PhD., Journal of Occupational Medicine, Vol. 20 No. 6 (June 1978).
- Work Practices Guide to Manual Lifting, Donald Badges PhD., NIOSH

- Ergonomics Guides: Ergonomics Guide for the Assessment of Human Static Strength, Don Chaffin, PhD., American Industrial Hygiene Association Journal, (July 1975).
- Static Ergonomic Strength Testing in Evaluating Occupational Back Pain, Harber & SooHoo, Journal of Occupational Medicine, Vol. 26 No. 12 (Dec 1984).
- Trunk Strength Testing with Iso-Machines: Part 1: Review of a Decade of Scientific Evidence, Newton & Waddell, Spine, Vol. 18, No. 7, pp. 801-811 (1993).

B. VERNOVA ST/LC - Dynamic

- Progressive Iso-inertial Lifting Evaluation: A Standardized Protocol and Normative Database, Mayer et al., Spine Volume 13 Num. 9, pp. 993 (1988).
- Simulated Physiological Occupational Tolerance, B. Ruiz, International Ergonomics Corp., (1990).
- Rationale for Using the SPOT Protocol, B. Ruiz, Ph.D., VERNOVA (1997).

C. Hand Dynamometer and Pinch Grip

- Grip and Pinch Strength: Normative Data for Adults, V. Mathiowetz et al., Arch Pys Med Rehab, Vol. 66, pp. 69 (Feb 1985).
- The Seriously Uninjured Hand-Weakness of Grip, H. Stokes, Journal of Occupational Medicine, pp. 683-684 (Sep 1983).
- Grip Strength in a Disabled Sample: Reliability and Normative Standards, L. Matheson, et al., Industrial Rehabilitation Quarterly, Vol. 1, no. 3, (Fall 1988).
- Detection of Submaximal effort by use of the rapid exchange grip, Hildreth et al., Journal of Hand Surgery, pp. 742 (Jul 1989).

D. Range of Motion

- Guides to the Evaluation of Permanent Impairment American Medical Association, 4th ed., pp. 112-135 (1993).
- Guides to the Evaluation of Permanent Impairment American Medical Association, 3rd ed., pp. 81-102 (1990).

E. Goniometers

- Guides to the Evaluation of Permanent Impairment American Medical Association, 4th ed., pp. 90-92 (1993).
- Guides to the Evaluation of Permanent Impairment American Medical Association, 3rd ed., pp. 20-38, 101 (1990).

F. Manual Muscle Tester

• Hand-held Dynamometry for Measuring Muscle Strength, A.W. Andrews, Journal of Human Muscle Performance pp. 35 (Jun 1991).

G. Non-Organic Signs of Submaximal Effort

- Horizontal Strength Changes: An Ergometric Measure for Determining Validity of Effort in Impairment Evaluations-A Preliminary Report, Berryhill et al, Journal of Disability, Vol. 3, Num. 14, pp. 143, (Jul 1993).
- Assessing Reliability of Performance in the Functional Capacity Assessment, L. A. Owens, Journal of Disability, Vol. 3, Num. 14, pp. 149, (Jul 1993).

H. Method Time Measurement, MTMs.

The VCU/VERNOVA protocol uses a criterion-referenced system based on the Methods-Time-Measurement of the Industrial Standard. The Industrial Standard is the time it takes an average worker with average skill to perform a task through out an average 8-hour day with appropriate allowances without undue stress or fatigue. The average worker is defined as two standard deviations below the mean of all workers between 18-65. This system of determining functional abilities over an 8-hour day is based in extensive research that was first published in the 1940's. Other functional evaluation models incorporate clinical observation of a functional task over an arbitrary standard of repetitions or time. The client's demonstrated functional performance is then rated based on the evaluator's clinical judgment. While these factors are also incorporated into Method-Time- Measurement testing, each of the functional activities also has a specific criterion that can be used to directly compare this client's performance to those currently performing these tasks in the workplace today.

- Acker, M. and Thompson, D. A. (1960) "Development of the prevocational unit: Stanford Rehabilitation Service". Archives of Physical Medicine and Rehabilitation, 41, 195-198.
- Anderson, D.S. and Edstrom D.P. "MTM Personnel Selection Tests; Validation at a Northwestern National Life Insurance Company". Journal of Methods-Time Measurement, 15, (3).
- Barnes, D.W. (1997). Practical Performance Rating Application, Ft. Lauderdale, FL: Barnes Management Training Service.
- Birdsong, J.H. "MTM and rehabilitation: A combination for potential profits". Journal of Methods-Time Measurement 17, (4), 3-8.
- Birdsong, J.H. and Chyatte, S.B. (1970) "Further medical applications of methods-time measurement". Journal of Methods-Time Measurement, 15, 19-27.
- Brickey, "MTM in a Sheltered Workshop". Journal of Methods-Time Measurement, 8, (3) 2-7.
- Carton and Rhodes, "A Critical Review of the Literature on Rating Skills for Perceived Exertion", Sports Medicine 1985; (2) pp. 198-222.
- Chyatte, S.B. and Birdsong, J.H. (1972) "Methods time measurement in assessment of motor performance". Archives of Physical Medicine and Rehabilitation, 53, 38-44.
- Drewes, D.W. (1961) "Development and validation of synthetic dexterity tests based on elemental motion analysis". Journal of Applied Psychology, 45, 179-185.
- Foulke, J.A. "Estimating Individual Operator Performance". Journal of Methods-Time Measurement, 15, (1) 18-23.
- Frievalds, A., and Goldberg, J.H. (1969) "Specification of Bases for Variable Relaxation Allowances: Standing, Abnormal Positions and Use of Muscular Energy". Journal of Methods-Time Measurement, 14, 2-7.

- Grant, G.W.B., Moores, B. and Whelan, E. (1975) "Applications of Methods-time measurement in training centers for the mentally handicapped". Journal of Methods-Time Measurement, 11, 23-30.
- Karger, D.W. and Hancock, W.M. (1982) Advanced work measurement. New York: Industrial Press.
- Karger, D.W., and Bayha, F.H. (1987) Engineered work measurement (4th Edition). New York: Industrial Press.
- Lowry, H.B., Maynard, H. B., Stegemerton, G.J., Time and Motion Study, 3rd ed. New York: McGraw-Hill Book Company, 1940.
- Maynard, H. B., Stegemerton, G.J., and Schwab, J.L. (1948) Methodstime Measurement, New York: McGraw-Hill.
- McQuaid and Winkler, "Using PMTS in handicapped workshops". Journal of Methods-Times Measurement, 8, 50-58.
- Mink, J.A. (1975) "MTM and the disabled". Journal of Methods-Time Measurement, 11, 23-30.
- MTM Association for Standards and Research. (1972, 1990). MTM-1 User Manual, Des Plaines, IL.
- Poocke, G. K. "Prediction of Elemental Motion Performance Using Personnel Selection Tests". Research Report No. 115, Methods-Time Measurement Association, Fair Lawn, N.J., 1968.
- Rucker, K.S., Wehman, P., and Kregel, J., Analysis of Functional Assessment Instruments for Disability/Rehabilitation Programs. Virginia Commonwealth University Medical College, Richmond, VA.
- Safrit, M.J., and Wood, T. M. (ed.) (1989). Measurement Concepts in Physical Education and Exercise Science. Champaign, IL: Human Kinetics Books.
- Todd, H.C., Chyatte, S.B. and Decker, R.S. (1979) "Predetermined time standards: Their application in workshop settings". Archives of Physical Medicine and Rehabilitation, 60, 222-226.
- Wilcock, R. (1980) "Some new dimensions on manual skills assessment and training in industry". Journal of Methods-Time Measurement, 7, 20-27.

- Wilcock, R. and Mink, J.A. (1982) "The International MTM Directorate Rehabilitation Project". Journal of Methods-Time Measurement, 9, 2, 2-11.
- Woeber, W.A. "Application of Learning Curves to MTM Values". Journal of Methods-Time Measurement, 7, (2) 22-28.
- Yokomizo, Y. (1985) "Measurement of abilities of older workers", Ergonomics, 28, 843-854.

Sensor	Accuracy ¹	Minimum	Maximum
ST Load Cell	1 lb or 1%	5 lbs	500 lbs
LC Scale	1 lb or 1%	5 lbs	150 lbs
Hand Dynamometer	1 lb or 1%	3 lbs	200 lbs
Pinch Grip	.5 lbs or 1%	2 lbs	75 lbs
Range of Motion	1 degree	0 degrees	360 degrees
Goniometers	1 degree	0 degrees	240 degrees
Manual Muscle Tester	1 lb or 1%	3 lbs	100 lbs

VI. Appendix A

VII. Appendix B

Allstate Ins. Co. v. Orthopedic Evaluations, Inc., 300 N.J. Super. 510, 693 A2d 500 (N.J. SuperA.D. 1997). Richard v. Dollar General Store, 606 So.2d 831 (La.App. 2 Cir. 1992). Allen v. City of Shreveport, 595 So. 2d 340 (La.App. 2 Cir. 1992). Bernard v. O'Leary Bros. Signs, Inc., 606 So.2d 1331 (La.App. 3 Cir. 1992). Britton v. Morton Thiokol Inc., 604 So.2d 130 (La.App. 2 Cir. 1992). Prudhomme v. DeSoto Pro Home Health, 579 So.2d 1167 (La.App. 2 Cir. 1991). Burr v. Huthnance Drilling Co., No. 87-1757 (W.D. La. 1988). Chevalier v. L.H. Bossier Inc., No. 92-888. (La.). Manson v. City of Shreveport, No. 22221CA (La.). Willis v. Solida Construction, No. 20341CA (La.). Jones v. Kentucky Fried Chicken, No. 17482CA (La.). Morgan v. General Motors Corp., No. 16521CA (La.). Hudges v. Webster Parish Police Jury, No. 14878 (La.). Molman v. Reliance Ins. Co., No. 14808 (La.). Scott v. Sears, Roebuck, & Co., No. 14700 (La.). Reliford v. Fitzerald Contractors, Inc., No 14554 (La.). Thomas v. McInnis Bros. Construction, No. 14572 (La.).

¹ When properly calibrated and correctly used, measurements are accurate to the larger of the value listed.

<u>Henderson v. Union Pacific RR</u>, No. 890301816 (Multnomah County, OR 1989). <u>Allen v. Tri-County Multnomah Transportation</u>, No. C890137CV (Anacelto Montes, OR 1989).

Kohrman v. Transport Asset Mgt Corp, No. 84462016 (Id. Work Comp). Blackwood v. S.A.I.F Corp of Oregon, No. 89-21907 (Or. Work Comp). Kay v., Freightliner Corp, (Or. Work Comp).

Ray v. IML Freight, No. 87-07878 and 86-12747 (Or. Work Comp).

Flores v. Coastal Hydro Service, Inc., No. 14-96464, (Dept of Labor)