33rd Annual International Conference of the IEEE EMBS
Boston, Massachusetts USA, August 30 - September 3, 2011

# Assessing disease and wellness in the occupational setting: Electrodiagnostic Functional Assessment from wired to wireless

Adam Seidner, M.D. M.P.H.

*Abstract*— **Technology Assessment is the study and evaluation of new technologies. It is based on the premise that developments and discoveries within the scientific and medical communities are relevant to the population at large. Proper technology assessment is an approach that is vital to address the current limitations of the worker's compensation system. The aim of this presentation is to discuss the need for objective diagnostic tools, such as Electrodiagnostic Functional Assessment (EFA), in the workers' compensation system with a focus on musculoskeletal disorders (MSD). Workers' compensation musculoskeletal claims may benefit from a wireless assessment to diagnose and monitor soft tissue injuries and this technology may be applicable to wellness and healthcare programs.**

## I. INTRODUCTION

MANAGED Care allows for the ongoing measurement, evaluation, and improvement in the distribution and access of medical services. It is designed to ensure that optimal interventions are applied at the appropriate time to the right individual. In medicine, the premise is to offer the best care possible while doing the least harm. A beneficial methodology in healthcare as well as workers' compensation is to adhere to the practice of evidenced based medicine (EBM). EBM allows the provider to apply the best available evidence gained from the scientific method to clinical decision making. [1][2][3] EBM seeks to assess the strength of evidence of the risks and benefits of treatments and diagnostic tests to assist informed decision making. [4] [5]

The following is an overview of evaluating technology, the need for such evaluations in the workers compensation system, outcomes reached using EFA assessments for work-related soft tissue injuries compared with standard diagnostics, and the rationale and need for a more portable system.

### *A. Evaluating Technology*

An important consideration when evaluating technology is the Collingridge *dilemma* that states the impact of new technologies cannot be easily predicted until the technology is extensively developed and widely used. However, management of a technology is difficult once it is widely disseminated. In addition, one must take into account the effectiveness, access and cost of said technology.

There are a number of private technology assessment companies and government groups such as the Agency for Healthcare Research and Quality (AHRQ) that are involved in developing information resources for applied scientific research in healthcare. One of their goals is to help establish best practices and improve patient care.

The regulatory body that approves new devices in the United States is the Food and Drug Administration (FDA). The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. Many companies planning to introduce a medical device to the US market need to submit an application to the FDA called a 510(k). An FDA 510(k) application is based on a comparison of the submitted device to another medical device that has already been cleared by the FDA (called the Predicate Device) and must be "substantially equivalent". It is the most common regulatory pathway for medical devices to bring safe and innovative products to the market.

The 510(k) is needed for some Class I devices, nearly all Class II devices and a very small number of Class III devices. Intended Use refers to the general functional use of the device. Indication for Use refers to the specific surgical, therapeutic, or diagnostic use of the device, i.e., the disease, condition, or pathology for which the principal effect of the device is used to prevent, treat, cure, mitigate, or diagnose. A medical device may be marketed and sold in the United States after it is cleared by the FDA. [6]

The FDA process is rigorous and has come under fire by some as unpredictable, inefficient, and expensive. According to a Stanford University report, more than three-quarters of the cost to bring a medical device from concept to the U.S. market is spent clearing FDA regulatory hurdles. The average cost to bring a 510(k) product from concept to market is $31 million and takes two years longer to reach patients in the U.S. than in other countries. [7] The 510(k) approval process promises to become even more complex with the advent of wireless technology.

### B. Technology Concerns

When evaluating technology, one must be cognizant of questionable ideas as well as questionable products and services, regardless of the sincerity of their promoters. Unproven methods consistent with established scientific concepts may be considered experimental or investigative. Legitimate researchers and practitioners engage in responsible, properly-designed studies. Public policy makers should monitor and evaluate evolving technologies that have the potential for acceptance and use. The first step in evaluating technology is a medical literature review of all evidence-based, scientifically valid information. New technology that has cleared the FDA 510(k) registration has demonstrated safety; however application in a medical setting should reveal additional metrics as to its clinical value.

## II. Experience with EFA

One proprietary industry study evaluated the Electrodiagnostic Functional Assessment (EFA) and its ability to assist in the management of chronic musculoskeletal disorders (MSD). The EFA is an FDA Registered 510(k) Class II physical medicine and rehabilitation device. The EFA utilizes surface electromyography (sEMG) to monitor and evaluate skeletal muscle groups at rest and during full range of motion.

It was found that the implementation of EFA as a case management tool can assist in the case management process. One objective of study was to enhance the level of discussion between treating providers, injured workers, and claim professionals.

22 injured workers presenting with soft tissue injuries in California and Nevada were evaluated using the EFA. We compared our results with a control group of 151 injured workers. The control group was obtained by matching claims from the Managed Care Database using ICD-9 code (3 digit), standard industrial classification (SIC), Age, Gender, Avg. Weekly Salary, Pre-existing Conditions and Attorney Involvement. However, the EFA group consisted of slightly older individuals and more males to females. The injured workers occupational mix was comprised of several of the leading occupations at higher risk for MSD to include nurses, drivers, and material handlers.

Results: The EFA group average return to work (RTW) was 213 days versus 275 for the Control group or an average of 62 days sooner. Direct costs include medical and lost wage payments to injured workers and their healthcare providers, were 25% lower in the EFA group for an average saving of $10,000 per claim versus Control.

## III. Evaluating Technology Challenges

In worker's compensation, one of the challenges with technology assessments is the ability to apply it to a wide variety of claims and diagnosis. A critical step is defining which type of claims would benefit from the technology. Since we are applying the technology to achieve best practices and outcomes, our evaluation should also measure cost-effectiveness or cost containment. A problem with some research studies is that they are often limited in scope or fail to provide enough information on the value of healthcare technology.

There are a number of economic evaluations to include cost-minimization, cost-effectiveness, cost-benefit and cost-utility. While it may be demonstrated that technology can assist in reducing healthcare cost, one must also balance the potential for improving quality-of-life.

A cost minimization evaluation compares treatment A with treatment B i.e. technology A to technology B and evaluate the outcomes. Then after evaluating the outcomes, if similar, simply chooses the least expensive program.

Cost-effectiveness analysis compares technology A versus technology B. It is used to evaluate the outcomes and compare the outcome to the cost per unit of effect. In this case, the costs are related to a single common effect. Evaluate the difference in magnitude between alternative programs and look at cost per unit of effect or the effect per unit of cost.

Cost-benefit analysis: attaches a measure of value to the effects resulting from a particular technology or program. Express the value in terms of dollars. In the case of EFA analysis, the technology resulted in a quicker return to work and direct dollar savings per claim. This method, in theory, provides information on the absolute benefits of a program or technology as well as information on its overall and relevant performances. This method estimates the value of resources used by each program or technology compared with the value of the resources the program or technology might save or create.

Cost utility analysis: When defined utility is the value of a specific level of, or improvement in, health status and can be measured by the preferences of individuals or institutions for a particular set of health outcomes. The utility of an outcome is different than the effect or level of an outcome. This method allows quality-of-life adjustments to a given set of outcomes while providing a common denominator for a comparison of costs and outcomes of different programs. The common denominator is usually expressed as "healthy days" or "quality-adjusted life-years." The outcomes are expressed in terms of the cost per "healthy day" gained by using one technology instead of another.

When a technology is deemed to show benefits another major consideration is the availability of the technology. The technology should be readily available. If the technology is difficult to access, then safety and effectiveness is of limited consideration.

## IV. WHY WIRELESS

Wireless technology can directly impact medicine in terms of increasing access and level of patient care as well as potentially reducing healthcare costs. Wireless technology will redefine the way medicine is practiced over time. It may promote a more proactive and cost effective approach to healthcare, thereby satisfying many of the analysis criteria used to bring new technology to the marketplace. [8]

## REFERENCES


[1] Timmermans S, Mauck A (2005). "The promises and pitfalls of evidence-based medicine". *Health Aff (Millwood)* **24** (1): 18–28. doi:10.1377/hlthaff.24.1.18. PMID 15647212.

[2] Sackett, David L., et al. 1997. "*Evidence-Based Medicine: How to Practice and Teach EBM"*. New York: Churchill Livingstone.

[3] Hadorn DC, Baker D, Hodges JS, Hicks N. "Rating the quality of evidence for clinical practice guidelines." J Clin Epidemiol. 1996;49: 749-754

[4] Elstein AS (2004). "On the origins and development of evidence-based medicine and medical decision making". *Inflamm. Res.* **53** (Suppl 2): S184–9. doi: 10.1007/s00011-004-0357-2. PMID 15338074

[5] Sackett DL, Rosenberg WM, Muir Gray JA, et al. "Evidence-based medicine: what it is and what it isn't." BMJ. 1996;312:71.

[6] FDA 510(k) Clearance overview for devices http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/default.htm

[7] FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies • November 2010

[8] Niewolny D, "Freescale Semiconductor: Welcome to The Wireless Age: Connectivity to Drive Medical Device Innovation.", - Design News February 9, 2011.