WHITE PAPER

The Combination of Oximetry and Spirometry

The Fifth and Sixth Vital Signs

Cost of Healthcare

The cost of healthcare has taken center stage in the US with constant focus on the price of products and services. Historically, the approach to medicine was the treatment of diseases, rather than prevention. Payment was based on the cost of products and services in a 'fee for service' environment. Recently, there has been an increased awareness of the value of preventative medicine and the ability to control costs by identifying the onset of a problem and preventing the more expensive complications resulting.

Diagnostic procedures were once used only to identify and quantify the severity of a disease. Now, there are many diagnostic options for the identification of a disease and manufactures have developed simple, inexpensive products making testing of patients more routine. Vital signs are taken routinely when a patient visits a health care professional. Heart rate, respiratory rate, blood pressure and temperature are easily obtained and provide a baseline to determine a problem or a trend. Electronic blood pressure monitors and digital thermometers have become common to improve accuracy and ease of data collection. With the improved availability and cost of oximetry and spirometry equipment, many clinicians are calling these two parameters the 'fifth and sixth vital signs'. Research will determine if the routine collection of these two 'new vital signs' will help anticipate and control the progression of a disease and reduce the overall cost of healthcare.

Chronic Obstructive Pulmonary Disease (COPD) is increasing worldwide and is the fourth leading cause of death in the United States, affecting at least 16 million people[1]. Of the top causes of mortality in the US, only the death rate from COPD continues to rise, increasing by 22% in the past decade. In addition, the number of patients with COPD has doubled in the last 25 years, with the prevalence of COPD rising faster in women than in men[2]. COPD causes 50 million days per year of bed disability and 14 million days per year of restricted activity[1]. COPD causes about 100,000 deaths per year, 550,000 hospitalizations per year, 16 million office visits per year, and $13 billion per year in medical cost, including homecare[1].

COPD has an impact on a patient's ability to ventilate and oxygenate. Depending on the stage of the disease, these patients will receive bronchodilators, oxygen therapy or breathing treatments. Monitoring the need for therapy, the level of therapy and the benefits of therapy have always been a good practice, yet not always practical due to the historical cost of diagnostics.

Patient diagnostics are usually done in a medical institution because of the availability of expensive equipment and trained staff. Some clinics and group practices purchase diagnostic equipment to improve their business. As diagnostic equipment evolves, new equipment, called screeners, has entered the market. These devices do not have the depth of information the very expensive products have, yet can give valuable information on trends and changes in a disease. Spirometers have become less expensive and easy to operate, which has lead the major pulmonary associations to suggest that routine spirometry be done to most patients, even if primary lung disease is not suspected[3]. This data can track and trend a patient's pulmonary function, and if lung disease were to develop without symptoms, the information would identify a change.

Spriometry

The benefits of spirometry to identify and trend the changes in lung volumes and flow are well established. The availability of simple, reliable spirometry equipment has created an opportunity to do patient testing routinely. Cost and skill levels are no longer a reason to not perform this testing and the pulmonary associations are encouraging the routine testing of patients seen by general practice physicians. A recent consensus conference on office spirometry published guidelines for routine collection of spirometry data[3]. The National Lung Heath Education Program (NLHEP) has started a public campaign to "Test your lungs, know your numbers" indicating that patients should remind their physician to collect this data if it is not part of a routine visit[4]. With asthma growing at an alarming rate, many patients are aware of lung disease and the value of identifying a problem before it becomes a dangerous situation.

A recent study found routine spirometry to predict overall mortality. Researchers who studied survival rates among a group of people who underwent a forced expiratory volume in on second (FEV_1) test in 1960-1961 have found that FEV_1 can predict overall long-term survival rates in both men and women. This is the first study to report an association between lower levels of pulmonary function and all cause mortality for a follow-up period as long as 29 years.

Oximetry

Pulse oximetry is an example of a major practical advance in technology that allows clinicians to markedly improve assessment of pulmonary function[5], and is an accepted standard for identifying a patient's oxygen saturation level. Patients on long term oxygen therapy (LTOT) qualify for payment of their oxygen therapy from

Medicare if their oxygen saturation is 88% or below. This simple test is easy to administer, and the equipment costs minimal, so spot checking of oxygen saturation is done routinely by most clinicians.

Pulse oximetry has always been a valuable piece of information and is collected routinely when the equipment is available. This is one of the most non-invasive patient tests, which is easy to administer and understand. There has been some debate on the accuracy of pulse oximeters and on signal quality, yet most clinicians accept this information as a good spot check or trending device and do not use this as a final indication of patient oxygenation. Arterial blood gases are still the gold standard of a patient's oxygen status. Clinical research on pulse oximetry has focused on the accuracy of different devices as opposed to the value of the information. It has become accepted that pulse oximetry is used when a patient oxygen status is in question and gives a first data point in that area. Pulse oximeters are routine in anesthesia for monitoring a patient during a surgical procedure. Now with the increase in product availability and cost reductions, oximeters are found in skilled nursing facilities, emergency medicine and home care.

Combined Oximetry and Spirometry

Even though oximeters and spirometers have been available for years, recently, a new product has been introduced that combines the two parameters in one product. The SpirOxCard from QRS Diagnostic is housed in a small PC Card, which can be used in a palmtop ('PDA'), laptop, or desktop computer. The clinical advantages of collecting these data points together has not been documented, yet the value of the individual data points suggests that the combination product should be as valuable.

A combination product for oximetry/spirometry encourages the collection of both parameters. Spirometry is collected when there is a suspicion of airflow problems and oximetry when oxygenation is suspect. It is not known if the two parameters compliment each other and add value to the individual tests, yet in an acute episode of asthma, both parameters have been collected and found to be valuable [6]. If oximetry is done and found to be abnormal, a spirometry test could determine if airflow might be the cause. This would help to differentiate between oxygen therapy and/or bronchodilator therapy. During an acute episode, it is a routine procedure to collect both data points, yet if a patient is borderline, the collection of both parameters could help prevent a patient being sent home and returning to the emergency room hours later.

The convenience of packaging both products encourages the collection of data. As more data is collected, it will be analyzed to determine what value collecting both parameters holds. According to Greg Spratt, National Clinical Director at Rotech Medical Corporation, "Combining the two most common diagnostic tools used in respiratory home care into one device increases both the convenience and availability of this testing. For about the price of a separate oximeter and spirometer, we could equip a therapist with a SpirOx card and a compatible PDA. Although HME employees are prohibited by Medicare from performing qualifying testing, most of Rotech's home clinicians regularly provide both spirometry and oximetry as a part of our home assessments and reports to physicians." Patient data can be collected from a personal computer and stored in a compatible format with other patient documents. The transfer of data can be through electronic means (e-mail or LAN systems) or can be printed and placed with other paper documents. With the trend toward identifying diseases early and preventing complications to control cost, more diagnostic procedures will be incorporated into routine patient care and documented to monitor outcomes.

Conclusion

As healthcare continues to be challenged to improve and show value, diagnostics will become a more valuable tool. Accurate identification of diseases will focus treatments on the specific cure. Continual monitoring of a patient's progress will identify if treatment outcomes were effective at the lowest costs. Diagnostics should be included in an overall care plan for disease management and reimbursed at the same level as the therapy. The combination product of oximetry and spirometry will add to the foundation information that has been accepted as vital signs and open the opportunity to track diseases and prevent costly complications.

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