B because chronic kidney disease (CKD) leads to the retention of metabolic waste products and hormonal disturbances, patients often experience skeletal muscle loss and dysfunction. New research published in the *Journal of the American Society of Nephrology* looks into a potential link between CKD patients’ impaired mobility and reduced physical performance and their risk of dying prematurely.

“Physical performance tests are objective measures used in gerontology to assess frailty, risk of disability, and to measure global comorbid burden,” said first author Baback Roshanravan, MD, of the University of Washington. “Little is known about physical performance and its association with all-cause mortality in younger CKD patients not treated with renal replacement therapy who are free of stroke and disability in their activities of daily living.”

**Trial results**

Roshanravan and his colleagues followed 385 patients with CKD without a history of stroke or disability and with an average age of 61 years and an average estimated GFR of 41 mL/min per 1.73 m². Through various tests, the researchers compared handgrip strength, usual walking speed, six-minute walking distance, and timed up and go (the time that a person takes to rise from a chair, walk 4 meters, turn around, walk back to the chair, and sit down). The researchers were hoping to characterize patients’ physical performance and evaluate the utility of physical performance assessment in a referred clinic-based population of patients with CKD.

“First, CKD is associated with poor mobility in this referred CKD population,” Roshanravan said.

Newly enacted legislation has changed requirements for compliance with the Health Insurance Portability and Accountability Act (HIPAA). The new provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act strengthen security measures for Protected Health Information (PHI) and step up auditing and enforcement.

**New HIPAA Compliance Requirements Take Effect**

By Kurtis Pivert

Although the law took effect March 26, physicians and other covered entities have until September 23, 2013, to comply with the new, wide-ranging regulations. The provisions are outlined in the Omnibus Final Rule.

**Changes for providers and patients**

Among the legislation’s significant changes is the broadened definition of a “business associate” (and extension of HIPAA compliance and liability under the law) to include any vendor storing PHI (e.g., electronic health record [EHR] companies) or any subcontractor that uses PHI to generate payments. These entities are now liable even if the practice doesn’t have a business agreement with them. The law also requires that existing contracts with business associates be updated to reflect the new regulations.

The criteria for a PHI breach have been revised from the subjective “risk of harm” standard to a more objective test. A breach is now presumed to have occurred unless the covered entity can demonstrate reasonable diligence in preventing the breach.
Slow Walking Speed

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physical performance compared to the healthy population," Roshanravan said. "Second, objective physical performance testing is an important bedside clinical tool that adds to the value of regular laboratory assessment of kidney function in discriminating those at high risk of mortality even among those without a history of stroke or disability in their activities of daily living."

During an average of three years of follow-up, the investigators found that measures of lower extremity performance were at least 30 percent lower than predicted. Each 0.1-meter-per-second slower walking speed was linked with a 26 percent higher risk for death, and each one-second longer timed up and go was linked with an 8 percent higher risk for death. These associations were also seen even after excluding the subgroup with baseline self-reported mobility disability.

Walking speed and timed up and go more strongly predicted three-year mortality than kidney function or common blood tests. Adding walking speed to common laboratory tests of kidney function significantly improved the prediction of three-year mortality.

"We discovered that even after accounting for renal function, diabetes, and coronary artery disease, worse lower extremity physical performance was associated with all-cause mortality, but unexpectedly, this association after adjusting for renal function and comorbid illness was not seen with handgrip strength," Roshanravan said. "Our findings suggest that lower extremity physical performance testing in chronic kidney disease patients may help identify those individuals who are more burdened by their CKD."

Other experts agree that the findings may have a significant clinical impact. "This novel study demonstrates that physical performance measures can improve the health assessment of persons with advanced chronic kidney disease. The key advantages of these measures are that they are low cost, non-invasive, and highly informative," said Michelle Odden, PhD, who was not involved with the study and is an assistant professor of epidemiology at Oregon State University. "Additionally, these physical performance measures may provide insight into the systemwide health effects of chronic kidney disease."

Odden’s research focuses mostly on kidney disease, cardiovascular outcomes, and loss of physical function in older adults.

Additional studies needed

As with any observational study, caution must be taken in this case against ascribing a causal relationship between lower extremity physical performance. The study provides no insights on whether lower physical activity may be a consequence of or a cause of lower physical performance in individuals with CKD.

Roshanravan also noted that the follow-up time in the study may not have been sufficiently long enough to detect significant differences in survival between those with strong and weak grip strength.

While more research is needed, the study’s findings suggest that measuring lower extremity physical performance may capture a complex set of skeletal muscle and neurologic impairments that develop in CKD patients and substantially affect their survival. The authors encourage additional investigations that look into the biological mechanisms underlying decreased physical performance in patients with CKD and that evaluate whether interventions that improve physical performance in CKD translate to improvements in health and longevity.

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demonstrate, through a risk assessment, that there was a low probability that PHI was disclosed. Provisions in the HITECH Act also strengthen compliance and enforcement of HIPAA regulations by instituting audits for all covered entities—large and small—and by increasing civil and criminal penalties for unauthorized disclosure of PHI.

Other sections of the HITECH Act directly affect patients, who now have to provide additional authorization before their PHI can be disclosed for payment of services. If a medical practice uses EHRs, patients now have the right to obtain an electronic copy of their records.

Preparing for compliance

Before the September 23 deadline, physicians, office staff, and business associates will have to take several steps to meet the new HIPAA compliance requirements.

One of the first actions covered entities will need to take is to appoint a privacy officer and security officer. The practice’s current privacy and security policies and procedures will need to be revised to align with new provisions, and be updated on a regular basis. These should include policies on securing portable electronic devices that may store PHI, as well as protocols to destroy any information on devices that may become compromised. Procedures for encrypting and securely transferring PHI electronically should also be included.

Staff members who use PHI (e.g., those working in the coding or billing departments) must become familiar with new office policies and HIPAA requirements. To ensure that practices are prepared for the new enforcement mechanisms, in-house audits and risk assessments should be conducted to identify and correct any potential compliance issues.

Patient privacy notices

Patient privacy notices must be revised to reflect the requirements for additional authorization before disclosure of PHI for processing payment of services. Entities must also prepare methods to provide copies of a patient’s electronic PHI when requested.

Procedures for how staff should identify, investigate, and report a potential breach of PHI should be drafted and reviewed regularly. Finally, all agreements with business associates need to be updated to reflect the extended HIPAA definition and liability.

Designed to protect and secure sensitive patient data, the new HITECH Act provisions will affect all health care providers this year. For more information on HIPAA and the requirements implemented under the Omnibus Final rule, visit http://www.hhs.gov/ocr/privacy/index.html.

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