



Coagulation Home Testing Improves Outcomes among Atrial Fibrillation Patients on Warfarin Therapy and Enhances Clinical Efficiency, According to New Study

Results Published in Nursing 2014 Show that Self-testing Protocol Reduced Out-of-Range Coagulation Test Results and Need for Clinic Follow-up

WALTHAM, Mass., March 4, 2014 – Alere Inc. (NYSE: ALR), a global leader in empowering individuals to take greater control of their health at home by connecting innovative diagnostics in the hands of patients to their healthcare providers, today announced the results of a study demonstrating that at-home coagulation testing among atrial fibrillation patients receiving warfarin led to improved outcomes versus traditional self-testing management, as well as enhanced clinical efficiencies and reduced costs. Results of the study, which was supported by Alere, were published today in the current issue of the journal *Nursing 2014*.

In the study, an outpatient “management by exception” protocol –was used and patients followed specific clinic-issued, written instructions for managing out-of-range International Normalized Ratio (INR) (coagulation) self-test results within predetermined safety range. With traditional self-testing clinicians typically call all their patients for re-management regardless of how close they were to their target.

Use of the protocol resulted in a 33 percent reduction in dangerously low and high INR test results. Dangerously high or low test results can increase patient risk of major bleeding seven fold and stroke four fold. These results support the findings of the larger Self-Testing Analysis Based on Long-Term Experience (STABLE) study, in which weekly INR self-testing among nearly 30,000 patients improved the quality of warfarin therapy. This study was presented at the 2012 American College of Cardiology meeting, and is pending publication in a peer-reviewed journal.

“Safe and effective warfarin therapy requires consistent maintenance of INR control, but it is a labor intensive effort to call patients for each out of range result,” said Pamela Burgwinkle, ACNP-BC, CACP, Nurse Practitioner, University of Massachusetts Memorial Healthcare and lead study author. “This study demonstrates that a self-testing protocol can keep patients within

normal INR range, while freeing up staff to spend more time caring for patients with more urgent need for intervention.”

Uncontrolled INR increases the risk of adverse events such as bleeding and thrombosis among patients receiving anticoagulation therapy. These and other anticoagulant-related events can be serious and even fatal, and are a major contributor to hospital readmissions, which are now subject to punitive fines as part of the Affordable Care Act.¹

“There is clearly a vital role for self-testing among warfarin patients, but it is currently being utilized by only one to two percent of anticoagulated patients,” said Gary B. Liska, Global Director, Clinical Development & Education, Alere Anticoagulation Solutions. “These results should help increase healthcare providers’ comfort with self-testing by demonstrating that a management by exception protocol can effectively automate patient care, without increasing practice risk, while empowering patients to be a partner in their care. Most importantly, self-testing with management by exception showed an increase in patient safety.”

About the Study

Seventy-two patients with target INR of 2.0 to 3.0 were enrolled in the protocol for six months. As part of the protocol, patients self-tested weekly and were only contacted by their clinic if their INR results were less than 1.8 or greater than 4.0. Significantly out-of-range INRs (less than 1.5 or greater than 5.0) were defined as “critical values.” INR results during the study period were compared with those from each patient’s previous six months, during which traditional self-testing testing was conducted. As part of the study design, all self-testing results were called into their clinic regardless of whether they were in or out of range.

The study achieved its primary endpoint of demonstrating that the investigational protocol was non-inferior to traditional self-testing care. Self-testers achieved similar proportion of time within therapeutic INR range during the six-month protocol use compared to the six months prior to the protocol use (65.6 percent versus 66 percent, respectively). There was, however, a significant 32.5 percent decrease in the number of critical value test results compared to the pre-protocol phase, thus dramatically reducing the risk of bleeding and thrombotic events.

The protocol also eliminated the need for 350 telephone outbound calls to patients, which led to improved satisfaction scores among both patient and participating clinics. The reduction in phone calls translated to a total cost savings of \$2,062.50 among the four participating clinics in the short 6-month window of the study. The Management by Exception study complements the findings of the STABLE study scheduled for publication in The American Journal of Managed

Care this month. The STABLE study determined weekly testing was the optimal testing frequency for patients taking warfarin despite their previous stability.

About Alere

By developing new capabilities in near-patient diagnosis, monitoring and health information technology, Alere enables individuals to take charge of improving their health and quality of life at home. Alere's global leading products and services, as well as its new product development efforts, focus on infectious disease, toxicology, cardiology and diabetes. Alere is headquartered in Waltham, Massachusetts. For more information regarding Alere, please visit www.alere.com.

###

Media Contact:

Jackie Lustig
Director, Corporate Communications
Jackie.Lustig@alere.com
781.314.4009

¹ Institute for Safe Medicine Practices. Leading drug safety issues of 2012. October 17, 2013. Available at <http://www.ismp.org/quarterwatch/pdfs/2012Q4.pdf>.