

## Investigational immuno-autonomics treatment strategy projected to improve care and reduce cost in rheumatoid arthritis

Immuno-autonomics treatment may affect the way patients, rheumatologists, the pharmaceutical industry and especially payers view treatment strategies in rheumatoid arthritis (*RA*).

November 6, 2017 – Researchers today unveiled a pilot health economics study(1) exploring the potential impact on payer costs and patient outcomes using immuno-autonomics, a new approach to RA treatment.

Marita Zimmermann, MPH, PhD, a research scientist in Health Economics and Outcomes Research in the Pharmaceutical Outcomes Research & Policy Program at the University of Washington, and her colleagues at Consultants in Global Health, LLC presented their findings at the 2017 American College of Rheumatology Annual Meeting in San Diego.

Immuno-autonomics is the intersection of immune function and stress, controlled within the brain by the autonomic nervous system (ANS). The importance of addressing how ANS stress, i.e. fight-or-flight activity, impacts RA activity and treatment has been proposed. (2-4)

ANS stress has been hypothesized to play a significant role in RA activity and treatment response. The study was funded by Inmedix, Inc., a Seattle-based life science company. Its exploratory diagnostic and therapeutic research was incorporated into health economic models to initiate a conversation about the degree to which this novel approach to RA treatment might affect payers.

Immuno-autonomics applies biomarkers of ANS state, measured by ECG-based heart rate variability (HRV), as potential predictors of treatment response. A number of companies, including SetPoint Medical, Glaxo Smith Kline, Galvani and Inmedix have in turn pursued ANS optimization research strategies to reduce the adverse impact of ANS stress on RA activity.

Zimmermann incorporated data presented from two exploratory Inmedix studies into proprietary Consultants in Global Health economic models. A 2008 prospective study identified elite heart rate variability (HRV) measures of ANS state as predictors of 52-week treatment response using tumor necrosis factor inhibition (TNFi) treatment in RA. (5) A 2015 exploratory, retrospective study reported significant improvement in TNFi treatment of RA through incorporation of a putative ANS optimizing strategy utilizing medications not FDA-approved for RA, but approved for treatment of restless legs syndrome (RLS). (6)

Zimmermann reported that use of HRV testing to eliminate TNFi use in patients predicted to fail to achieve remission in RA could reduce TNFi expenditure by payers by \$21.9 billion in the United Sates over ten years without loss of benefit to patients.

An incremental cost-effectiveness ratio (ICER) was calculated by dividing cost of care (\$) by quality of life years (QALY). Cost effectiveness was defined as less than \$150,000/QALY. Applying HRV testing with ANS optimization in patients with RA eligible for treatment with FDA-approved biologics was projected to increase QALYs by more than 200,000 over ten years at an ICER of \$10,000 -\$80,000/QALY depending on biologic utilization.



In a purely exploratory third scenario, Zimmermann addressed the potential impact of HRV combined with ANS optimization applied to less expensive non-biologic RA treatment. To date, investigators have not yet established whether immuno-autonomic strategies are effective for non-biologic treatment with disease-modifying antirheumatic drugs (DMARDs), but its potential impact - if possible - was of interest. If accomplished, HRV coupled with ANS optimization of DMARD treatment could save \$50-100 billion and increase QALYs by more than 1.5 million over ten years depending on the positive predictive value of HRV testing in a non-biologic setting.

"Although this analysis is exploratory and based on early and limited data," notes Dr. Zimmermann, "I believe it demonstrates an important message about costs for rheumatology patients. We have shown that heart rate variability testing technology has the potential to save billions of dollars in the U.S., while maintaining or increasing patient well-being. It was important for us to explore economic impacts now, so that costs can be thoroughly considered as research and implementation of this technology continues."

Andrew J. Holman, MD, CEO and co-founder of Inmedix adds, "It's a remarkable study to begin exploring the potential health economic impact of immuno-autonomics in rheumatology. While far too early to draw definitive conclusions without additional validation and studies, it begins to reveal the scope of what may be at stake for patients and for those providing healthcare."

About Consultants in Global Health, LLC.

Consultants in Global Health (CGH) is a health economics consultancy based in Seattle, WA. CGH works with clients to identify and execute projects to increase value in healthcare. Common projects include cost-effectiveness modeling, budget impact modeling, and program evaluation. CGH staff has been trained at the University of Washington and has worked with academic, industry, and non-profit clients worldwide.

About Inmedix, Inc.

Seattle-based Inmedix is committed to engaging in world class research to discover innovative solutions for pressing healthcare needs related to the autonomic nervous system (ANS). Inmedix's ANS Neuroscan<sup>TM</sup> is the leading heart rate variability (HRV) application as an informative diagnostic tool in autoimmune disease, beginning with patients with rheumatoid arthritis (RA). The company's science and technology hope to raise therapeutic outcomes so that patients will no longer need to cycle through failure of one therapeutic intervention after another. For more information, visit <u>http://www.inmedix.com</u>.

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