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Georgia Southern Monitors for Adverse Events Post Marketing Approval of Drugs

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Regardless of the efforts of a pharmaceutical company and of the US Food and Drug Administration (FDA) to identify harmful side effects prior to regulatory approval of a new drug, it is not possible to identify all such serious adverse events (SAE’s). There are many reasons for this; chief among them is the fact that the number of patients in clinical development programs of new drugs to prove efficacy are inadequate to detect rare SAE’s. It is therefore in a company’s best interest to develop a post marketing risk based monitoring plan (RBMP) of their drug as it is made available to patients through physician prescriptions after regulatory approval.

This manuscript provides information to those developing monitoring plans for SAE’s following regulatory approval of a new drug. In addition, we (1) illustrate how many patients would need to be treated in order to have high confidence of seeing at least 1 pre-specified SAE, (2) show that absence of proof of a SAE is not proof of absence of that SAE, and (3) identify statistical methodology that could be used for formal statistical monitoring of SAE’s.

“Monitoring for Adverse Events Post Marketing Approval of Drugs,” is published in the International Journal of Allergy Medications.

Dr. Karl E. Peace, professor of biostatistics at JPHCOPH and Georgia Cancer Coalition Distinguished Cancer Scholar was the lead author and Dr. Macaulay Okwuonye, alumni of the Doctor of Public Health in Biostatistics program at the Jiann-Ping Hsu College of Public Health (JPHCOPH) at Georgia Southern University was the co-author.
Georgia Southern Assesses the Needs of Children in a Former Slave Community

December 2, 2015

The overall purpose of this community needs assessment was to explore the perceptions of health and educational needs among youth residing in a rural Georgia community, document existing assets that could be utilized to meet those needs, and to identify socioeconomic barriers and facilitators in health education.

Several health issues were highlighted by the Willow Hill/Portal Georgia community members, including teachers, parents, youth and Willow Hill Heritage and Renaissance Center board members. Some of the health issues identified by youth in the community were low levels of physical activity, obesity, diabetes, lack of healthy food choices, and access to health care services. Including the issues identified by youth, the parents, teachers and board members identified additional health issues in the community such as asthma, hygiene and lack of dental and eye care facilities.

Overall, there is a need for better infrastructure and awareness among community members. Utilizing identified assets, including active community leaders, involved faith-based organizations, commitment of community members, presence of land resources, and commitment to physical activity and sports, could modify the current community landscape.

“The Willow Hill Community Health Assessment: Assessing the Needs of Children in a Former Slave Community,” was published in the Journal of Community Health.

Dr. Moya Alfonso, Associate Professor of community health behavior and education (CHBE) at the Jiann-Ping Hsu College of Public Health Georgia Southern University (JPHCOPH) was lead author. Ms. Gayle Jackson and Mr. Alvin Jackson of the Willow Hill Heritage and Renaissance Center, Inc., Ms. DeShannon Hardy and Ms. Akrati Gupta, DrPH in CHBE students at JPHCOPH were co-authors.
Georgia Southern Examines the Association between Arthritis and Depression

December 2, 2015

Obesity and arthritis are leading chronic conditions, but comorbidity of these conditions and their interaction leading to depression have not been fully investigated. The purpose of this study was to determine the degree to which excess body weight effect-modifies the relationship between arthritis and depressive symptoms.

“Addressing obesity is challenging in itself as it requires substantial behavior change. Adding barriers, like arthritis, to physical activity can compound the problem and cycle of inactivity, weight gain, and depression.”

The association between depression and arthritis was not significant among healthy weight women, but significant among overweight and obese women. The intensifying effect from excessive body weight on the association between arthritis and depression was less salient among men than women. The study concluded that the association between arthritis and depression is intensified significantly by increased body weight, in particular, among women.


Maria Politis, alumni of the Jiann-Ping Hsu College of Public Health at Georgia Southern University (JPHCOPH) was the lead author. Krys Johnson, alumni, Dr. Andrew Hansen, Assistant Professor of Community Health Behavior and Education, Dr. Kelly Sullivan and Dr. Jian Zhang, Assistant Professors of Epidemiology, all at the JPHCOPH were co-authors.
The purpose of this qualitative study was to explore rural/urban differences in service providers’ perceptions of challenges and facilitators to services for children with special health care needs (CSHN) and their families in southeast Georgia.

Service providers discussed a variety of challenges to accessing services related to socioeconomic status and the transition out of the school system. Urban and rural service providers’ perceptions were similar overall, with the exception of lack of transportation and access to a variety of services in rural area. Service providers overcome challenges through identifying parents’ needs and limitations and adapting service provision. Some of the facilitators mentioned by both urban and rural service providers are availability of transportation and resources.

"It All goes Back to the Services": A Rural/Urbann comparison of Service Providers’ Perceptions of Challenges and Facilitators to Disability Services,” was published in the Open Journal of Preventive Medicine.

Dr. Moya Alfonso, Associate Professor of community health behavior and education (CHBE) at the Jiann-Ping Hsu College of Public Health Georgia Southern University (JPHCOPH) was lead author. Dr. Ashley Walker, Associate Professor of CHBE at JPHCOPH, Ms. Akrati Gupta, DrPH in CHBE student at JPHCOPH, Dr. Joseph Telfair, Department Chair of CHBE and Environmental Health Sciences at JPHCOPH, and Dr. Gavin Colquitt, Associate Professor of Health and Physical Education were co-authors.
Georgia Southern Student Inducted into Omicron Delta Kappa National Leadership Honor Society

December 2, 2015

Ms. Gauri Shevatekar, DrPH student at the Jiann-Ping Hsu College of Public Health has been inducted into Omicron Delta Kappa National Leadership Honor Society. Omicron Delta Kappa National Leadership Honor Society was founded on December 3, 1914 at the Washington and Lee University in Lexington, Virginia by 15 students and faculty leaders. It was the first college honor society of national scope to recognize and honor meritorious leadership and service in extracurricular activities and to encourage development of general campus citizenship.

Currently, ODK has 292 active circles across colleges and universities within USA. In last 100 years, ODK has initiated more than 300,000 members. The membership is awarded to undergraduate junior and senior students, graduate students, faculty, staff and alumni and honorary memberships (honoris causa) are offered to qualifying members who achieve professional distinction or render outstanding service through leadership.

The basic unit of ODK is the collegiate Circle. The Georgia Southern Circle of ODK was established in the year 1999. The students who are among top 35% of the class (based on the cumulative GPA) are invited to apply for membership via email, the applications are evaluated on the basis of the 5 phases of campus life which include scholarship, athletics, campus or community service, social and religious activities, campus government, journalism, speech and mass media, and creative and performing arts. Students who qualify for membership are officially invited (via email) to join ODK. The membership in ODK is a mark of highest distinction and honor.

The Georgia Southern Circle initiates new members in Fall only. The induction ceremony for this year took place on October 18, 2015. 29 new members were inducted for the college year 2015-2016. Please see the attached pics of the induction ceremony.

For more information, please see the ODK website: http://odk.org/