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Global dependence on chinese-sourced active pharmaceutical ingredients: Policy analysis and recommendations

R.N. Nang; Office of the Joint Medical Chair for Global Health at National Defense University, Washington, DC, USA

Program/Project Purpose: The Joint Medical Chair for Global Health (JMC) at National Defense University anticipates, prioritizes, and addresses strategic international health and security concerns. A strategic health security issue is unregulated Chinese-sourced active pharmaceutical ingredients (APIs) found in U.S. pharmaceuticals.

Structure/Method/Design: From August 2015 to February 2016, The JMC conducted a literature review and interviews with key players (DoD Overseas Laboratories, Health and Human Services, U.S.–China Economic and Security Review Commission, and Pharmaceutical Companies) to determine whether progress has been made to better protect global pharmaceutical supplies. Our aim is to provide additional DoD-driven policy recommendations to protect the integrity of global pharmaceutical drug sales beyond those made by the U.S.–China Economic and Security Review Commission's 2014 Annual Report to Congress.

Policy Recommendation: The U.S. should partner with alternative API-sourced nations (Brazil, Russia, India, Malaysia, Thailand, Peru, Kenya, and Egypt) based on their emerging pharmaceutical markets, DoD overseas laboratories, and/or access to unique natural resources. Important stakeholders needed to cooperate together to improve the quality and expand global markets for APIs include the Chinese Government, China's Ministry of Health, China's State Food and Drug Administration, U.S.-China Economic and Security Review Commission, Food and Drug Administration, DOD Overseas Laboratories, HHS, U.S. Department of Commerce, UN Office of Crime, Interpol, U.S. Pharmacopeia, WHO, and pharmaceutical companies. USAID and DoD Overseas Laboratories can help support capacity building for APIs to expand global markets.

Outcome & Evaluation: According to the FDA, increasing quality inspectors and use of "Track and Trace" Technology have helped decrease counterfeit and substandard pharmaceuticals, but also encountered were destruction of quality control API reports from Chinese drug manufacturers.

Going Forward: Halting the spread of counterfeit and substandard pharmaceuticals that kill ~1 million people worldwide annually. Next steps include cooperation between the Chinese government and governments that trade with China and other organizations to improve the frequency and sophistication of inspections, the prosecution of counterfeiters, and self-policing within pharmaceutical industries.

Abstract #: *2.034_NEP*

Differential risk factors for colonization of the upper respiratory tract with Gram-positive bacteria between subpopulations with high income inequality

M.A. Marlow[1], F.P. Neves[1,2], M.G. Pinheiro[3], A. Fandino[3], M.F. Freitas[3], R.R. Barros[2], C.A.A. Cardoso[4], F. Aguiar-Alves[3], L.W. Riley[1]; [1]School of Public Health, University of California, Berkeley, CA, USA, [2]Biomedical Institute, [3]Laboratory of Molecular Epidemiology and Biotechnology, [4]School of Medicine, Fluminense Federal University, Niterói, RJ, Brazil

Background: *Staphylococcus aureus* (SA) and beta-hemolytic streptococcal species (BHS), mostly *Streptococcus pyogenes*, commonly colonize the upper respiratory tract. As they are easily transmissible, easy to sample and persistently found in the community, we selected them to investigate differential risk factors for transmission and colonization among subpopulation of a Brazilian city with very high income inequality.

Methods: We conducted a cross-sectional study of outpatients aged 0 to 18 years in one public and two private pediatric clinics in Niterói, RJ, Brazil from May 12 to August 12, 2014. SA nasal colonization and BHS oropharyngeal colonization were evaluated and isolates were characterized. A standardized questionnaire administered by trained interviewers assessed risk factors for colonization. Subpopulations of patients were compared based on clinic attended and self-reported slum residence: private clinic/non-slum residence [high-socioeconomic status (SES)], public clinic/non-slum residence (middle/low-SES), and any clinic/slum residence (slum).

Findings: Among 598 participants, 222 (37.1%) were colonized with SA, 49 (8.2%) with methicillin-resistant *S. aureus* (MRSA), and 24 (4.0%) with BHS. MRSA colonization was twice as high in middle/low-SES subpopulation (14.4%) and was significantly associated with middle income, households not having stable income, receiving government financial assistance and > 5 household members ($p < 0.05$). Slum residence was found to be a protective factor for MRSA colonization among children attending the public clinic (AOR=0.40, 95% CI 0.17 - 0.97). While MRSA SCC*mec* type IV was the most frequent across all three groups (83.7% of the MRSA isolates), type V was only found in patients from high-SES and types I and II were only found in those from middle/low-SES. Middle/low-SES (5.6%) patients were more often colonized with BHS and serogroup B was only found in this SES-group.

Interpretation: Patients from middle/low-SES who live outside the slum were disproportionately colonized by Gram-positive (GP) bacteria and had more diversity in MRSA genotypes. Slum residence appears not to drive GP bacterial colonization and drug resistance in low-income communities.

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Developing a breast fine needle aspiration biopsy service in Peru

Dianna Ng[1], Britt-Marie Ljung[1], Richard Bardales[2], Milagros Abad[3], Manuel Cedano[3], Tara Hayes Constant[4], Jennifer L. Winkler[4], Ronald Balassanian[1]; [1]Department of Pathology, UCSF Medical Center, San Francisco, CA, [2]Outpatient Pathology Associates, Sacramento, CA, [3]Northern Regional Cancer Institute, Trujillo, Peru, [4]PATH, Seattle Washington

Program/Project Purpose: Breast cancer incidence is increasing in low- and middle-income countries and may be related to changes in lifestyle, reproductive practices and life expectancy. In 2010, 57.8% of breast cancers in Peru were stage 3 or higher at diagnosis.