

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

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**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

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**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<sub>mec</sub> 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.

**Funding:** NIH Research Training Grant (Global Health Equity Scholars Program)

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### Developing a breast fine needle aspiration biopsy service in Peru

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**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.

As part of a multi-modal approach, federal and regional Peruvian institutions partnered with several organizations, including UCSF, to improve access to, and quality of breast cancer care in Peru. Phase 1 involved screening with clinical breast exam, creating a community-based referral system for women with masses, and promoting evaluation of lesions using fine needle aspiration biopsy (FNAB) by trained physicians, with treatment at the regional cancer institute. Curricula for each activity were developed and validated. During phase 1, it was recognized in-country FNAB expertise was limited. For phase 2, the critical objective was to solidify local capacity for high-quality FNAB and integrate FNAB into standard of care for breast cancer.

**Structure/Method/Design:** Three main activities were completed during phase 2. Activity 1: Develop a Training of Trainers (ToT) curriculum for FNAB, and identify master trainers and trainees. Activity 2: Facilitate endorsement of a national approach to training FNAB and undertake preliminary rollout in La Libertad region. Activity 3: Strengthen interpretation and reporting of FNA results.

**Outcome & Evaluation:** A 5-day ToT pilot course occurred during October 19–23, 2014. Prior to the course, women with palpable masses were identified during a breast screening campaign and scheduled for FNAB. Local, regional, national and international clinical teams observed, procured and interpreted FNAB. Four new cases of cancer and 8 cases of granulomatous mastitis clinically mimicking tumor were diagnosed. For evaluation, slide quality before and after training intervention will be compared. Following the course, a one-day validation meeting including physicians and national leaders took place at the national cancer center in Lima, Peru. FNAB was endorsed for early diagnosis and triage. Subsequently a senior leader/cancer surgeon and cytopathologist studied at UCSF for 2 days and 2 weeks respectively.

**Going Forward:** To ensure sustainability and expansion of FNAB, cytology fellowships and training centers are needed. Strengthening partnerships will be critical for long-term capacity. An electronic reporting system will be developed to replace paper-based methods.

**Funding:** Norwegian Cancer Society/Norwegian Breast Cancer Society (NCS/NBCS), Susan G. Komen for the Cure®, The PATH Catalyst Fund.

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### Knowledge, attitudes and perceptions about Ebola in Liberia

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**Background:** The Ebola virus epidemic in West Africa has claimed over 11,300 lives with Liberia hardest hit. Community mobilization was considered a key strategy for breaking transmission during the outbreak however little is known as to the best source of messaging or how effective at knowledge delivery and retention this messaging was. The objective of this study was to describe the source of messaging and the acquired knowledge, attitudes and perceptions of Ebola among the community dwellers nationally.

**Methods:** Healthcare access and Ebola knowledge surveys were administered via interview to a cluster randomized sample in the catchment area around Liberia's 21 government hospitals. Data was managed in a mobile data application on smart phones and analyzed using SPSS

**Findings:** A total of 543 heads of household were interviewed equally distributed between male/female and urban/rural. The three most common sources of message across location was radio 76.6%, community health worker 55.5% and community leader 35.9%. Of households surveyed 78% of urban and 54.9% of rural owned a radio. Knowing of someone who had Ebola was 32.3% in urban areas versus 18.9% in rural. Penetration of knowledge about Ebola was high, with an average of 98.9% and 97.4% of respondents having heard of Ebola in urban and rural areas respectively. In urban areas 98% of people believed Ebola to be real as compared to 96.5% in rural. The retained knowledge of ebola symptoms was red eye 100% and 78%, fever 94% and 74.4%, diarrhea 81.9% and 88.7% in urban and rural areas respectively.

**Interpretation:** The most common messaging modalities accessed by community members were radio, community health workers and community leaders. Knowledge of Ebola was consistently high across the country with retention of specific symptoms associated with the disease and the message of transmission prevention. This study provides insight into the best source of information dissemination for future outbreaks.

**Funding:** Paul G. Allen Family Foundation, #TackleEbola.

**Abstract #:** 2.037\_NEP

### Primary CNS lymphoma in immunocompetent chinese patients and the association with chronic Hepatitis B

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**Background:** Primary CNS lymphoma (PCNSL) is an aggressive neoplasm occurring in immunocompromised and competent hosts. The etiopathogenesis in immunocompetent is unknown and conflicting evidence exists on the role of Hepatitis B infection. We performed a retrospective study of our patients with PCNSL in Hong Kong and studied the association with chronic Hepatitis B in this endemic area.

**Methods:** Patients over the age of 18 with a biopsy proven diagnosis of PCNSL between Jan 1st 1997 and May 31st 2015 in the Department of Clinical Oncology, Prince of Wales Hospital in Hong Kong were included. Data regarding demographics, comorbidities, viral co infections, PCNSL disease characteristics, treatment, and outcome were collected by chart review. Data collection was censored as of June 30th, 2015.

**Findings:** 27 patients, all of Han Chinese descent, were identified. Mean age at diagnosis was 57 years. 59% were male and 41% were female. Common symptoms at presentation included focal neurological deficits (74.1%), headache (37%), and higher function defects (33.3%). On imaging, edema or mass effect was seen in 82%, 78% had meningeal disease, and 48% had multifocal disease. 81.5% had at least one deep region involved. 96.3% were tested for HBsAg; 11.5% were positive. 43.5% of the HBsAg negative patients were tested for HBcAb, a marker for prior exposure to the virus. 60% were positive. 77.8% received modified DeAngelis Protocol