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GLOBAL MEDICINES PROGRAM

RESEARCH • TRAINING • POLICY

Global Medicines Program: Research, Training, Policy

Andy Stergachis, PhD

Lou Garrison, PhD

Presented at the Department of Global
Health, UW, Faculty Meeting

January 5, 2010



DEPARTMENT OF GLOBAL HEALTH
UNIVERSITY *of* WASHINGTON



SCHOOL OF PHARMACY
UNIVERSITY *of* WASHINGTON

Context & Need

- Rapid scale-up of public health programs
- New medicines in pipeline
- Short- and long-term toxicities
- Product quality issues
- Emergence of drug resistance
- Vulnerable, understudied populations
- Need for medication adherence
- Access to essential medicines

Research		Translational			Development		
Lead generation	Lead optimization	Preclinical	Phase I	Phase IIa	Phase IIb/III	Registration	Phase IV
Novartis MP	Novartis series	NITD 609	Tafenoquine	Artemisone	AZCQ	Eurartesim™	Coartem® Dispersible
GSK MP	GSK (2 projects)	MK 4815		OZ 439		Pyramax®	ASAO Winthrop
Broad & Genzyme MP	Genz Aminoindole	P218 DHFR				IV Artesunate	
Pfizer screening	Quinoline Methanols						
sanofi-aventis	Oxaboroles						
AstraZeneca screening	SSJ-183						
Kinases	Aminopyridine						
Natural Products	Pyrazoles						
Antimalarial St. Jude/Rutgers	Quinolones						
8 other Projects	Genz DHODH						
	DHODH						



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Mission:

Improve the use, safety, quality, risk-benefit profile, cost-effectiveness, and affordability of medicines in resource-poor countries

The Global Medicines Program aims to:

1. Generate and disseminate new methods and knowledge on assessing and improving the safe and rational use of medicines by attracting and promoting collaboration among faculty and trainees from various fields, including public health, pharmacy, medicine, law, and nursing.
2. Teach and mentor the next generation of academics and practitioners in global medicines safety and value.

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Peggy Odegard, Don Downing and Andy Stergachis with colleagues in Jimma, Ethiopia, for a Strengthening Pharmaceutical Systems training activity.



NEWS & EVENTS

[Recent Global Medicines Program Events](#)

[Global Medicines Program Participates in First Global Symposium for Health Systems Research](#)

[TIPC concludes study on the risk of Anemia from Zidovudine \(AZT\)-Based HAART in Namibia](#)

[Global Medicines Program participates in American Public Health Association Annual Meeting Nov. 6-10, 2010](#)

[Global Medicines Program participates in key conferences in Accra, Ghana, November 4-5, 2010](#)

Message from the Director



The University of Washington Global Medicines Program was formally launched in mid-2010 as an inter-school, inter-departmental initiative supported, in part, through the Department of Global Health's competitive process for identifying new, signature programs and centers. Administratively based in the Department of

Global Health, the Program is closely affiliated with the faculty and trainees at the School of Pharmacy, University of Washington.

www.globalmedicines.org

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People



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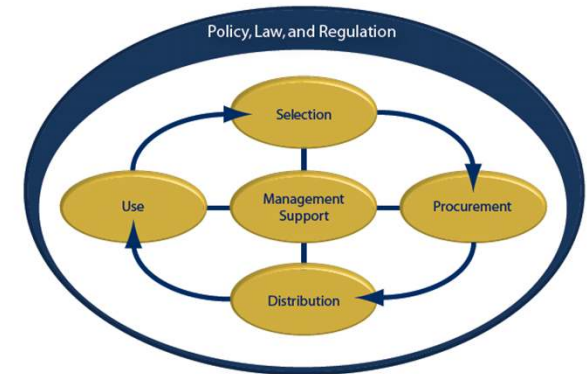
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Major Projects

- Strengthening Pharmaceutical Systems-MSH via USAID
- Pharmacovigilance via BMGF
 - Strategy & Methods Development
 - Malaria in Pregnancy Consortium
- Health Technology Assessment in Developing Countries/Emerging Markets
 - Taiwan, China, Columbia, Argentina, Czech Republic, and Brazil
- Cost-Effectiveness Analysis of Measles Eradication



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Program Organization

- Established press release, metrics, gift account, and web site www.globalmedicines.org
- Recruited and hired research coordinator, postdoctoral senior fellow co-mentored by Kenya Research Program faculty, research assistant Department of Epidemiology MPH Program
- Initiated search for Assistant Professor of Global Health supported, in part, by GMP, eligible for adjunct appointment in Pharmacy
- Planning for 2011: meeting of faculty interested in affiliating with GMP; establish advisory committee; initiate planning for sustainability

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Research

- 22 presentations at regional, national, and international conferences since 6/10.
- 16 articles published in peer-reviewed journals in 2010.
- Award from Malaria in Pregnancy Consortium (funded by BMGF) for “Assessment of the Safety of Antimalarial Drug Use During Early Pregnancy (ASAP)”
 - Research sites in Kenya, Mozambique, Burkina Faso, and Thailand
- Assessment of the risk of anemia associated with AZT-based HAART in Namibia
- Assisted with protocol for pharmacovigilance system in Namibia to Global Fund.
- Pre-proposal for pharmacovigilance study of new antimalarial.
- Health technology assessment in emerging markets report.
- Study of cost-effectiveness of measles eradication.

Recent Publications

TOOLS & INCENTIVES

Assessing A Structured, Quantitative Health Outcomes Approach To Drug Risk-Benefit Analysis

Using a health outcomes approach together could promote co-products and diseases.

by Louis P. Garrison Jr., Ad...

Stergachis et al. *Malaria Journal* 2010, 9:148
<http://www.malariajournal.com/content/9/1/148>



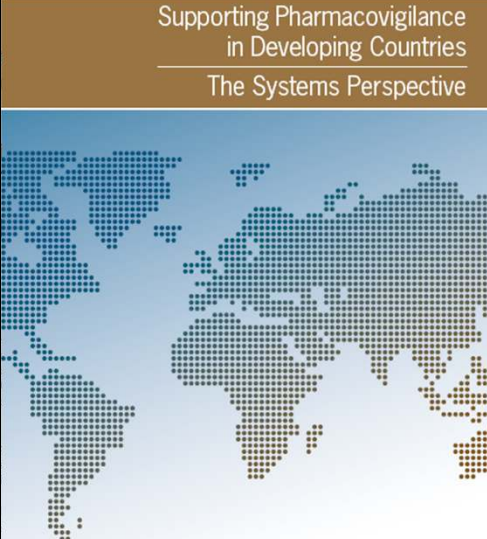
RESEARCH Open Access

A situational analysis of pharmacovigilance plans in the Global Fund Malaria and U.S. President's Malaria Initiative proposals

Andy Stergachis*^{1,2}, Rebecca JK Bartlein¹, Alexander Dodoo³, Jude Nwokike⁴ and S Patrick Kachur⁵

Genital Ulcer Diseases to Acyclovir in Eight African Countries: A Questionnaire-Based Analysis

Catherine Corbell, BPharm, MSc, Patrick Ndase, MBChB, MPH, † L...



Supporting Pharmacovigilance in Developing Countries
The Systems Perspective

USAID SPS Strengthening Pharmaceutical Systems

Background: Herpes simplex virus-2, the most common genital ulcer disease (GUD) globally, is a cofactor in human immunodeficiency virus type-1 (HIV-1) acquisition and transmission. World Health Organization guidelines for sexually transmitted infections recommend acyclovir as first-line syndromic treatment of GUD in high herpes simplex virus-2 prevalence (≥30%).

Objective: To assess the extent of adoption of acyclovir as first-line syndromic treatment for GUD, and describe procurement, distribution, and cost of acyclovir in the public and private sectors of 8 African countries.

Methods: We conducted standardized interviews with Health (MoH) officials, pharmacists, and other pharmacy staff based in the public and private sectors. Interviews were conducted in Botswana, Kenya, Malawi, South Africa, Tanzania, Zambia, and Zimbabwe. Price comparisons were conducted against the 2007 median international reference price (IRP) for acyclovir.

Results: Of the 8 African countries, 4 surveyed had acyclovir as first-line syndromic GUD treatment in both their national lists and sexually transmitted infection guidelines. Country-specific acquisition prices for acyclovir 200 mg were comparable to the median price of 0.04 USD. In 90% of HIV-infected individuals have concomitant HSV-2 infection suggests that HSV-2 contributes significantly to the

ORIGINAL RESEARCH ARTICLE

Drug Saf 2010; 33 (8): 689-703
 0114-5916/10/0008-0689/\$49.95/0
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Pharmacovigilance Activities in 55 Low- and Middle-Income Countries: A Questionnaire-Based Analysis

Sten Olsson,¹ Shanthi N. Pal,² Andy Stergachis³ and Mary Couper²

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- 3 Departments of Epidemiology and Global Health, School of Public Health, University of Washington, Seattle, Washington, USA

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Teaching

- Two courses in conjunction with the School of Pharmacy:
 - PHARM 581/GH 543 Global Health Pharmacy: Medicines, Practice, and Policy
 - PHARM 582/GH 590 Special Topics in Global Health Pharmacy and Medical Products
- In 2010, successful defense of PhD dissertations by two Epidemiology students (Sangare and Lambdin) and two Pharmacy students (Babigumira and Corbell)
- Leadership for Health Economics component of The University of Nairobi Institute of Tropical and Infectious Disease (UNITID) Fellowship Program in Public Health Management.
- Cost and Outcomes in Health and Medicine, PHARM534/HSERV583. Autumn 2010 Class included several Global Health students.
- Health Economics, PHARM568/HSMGMT514. Winter 2011. Will include global health issues.

Service/Policy

- “National Pharmacovigilance Systems: Ensuring the Safe Use of Medicines” Conference Sponsored by USAID (Nairobi)
- Dissemination meeting for results from ARV PV in Namibia
- Support for Global Pharmacovigilance Planning & Toolkits
- Assisting in first-ever Pharmacy Degree Program at the University of Namibia.
- Planning for in-country training workshop for policy-makers and health professionals on global medicines systems for 2011.
- Performance-based risk-sharing in emerging markets

Program Metrics

as of 7/27/10

1. Recruit, in conjunction with co-funding, senior fellow, junior faculty member, and research coordinator during the first year of the Program and establish the Program's infrastructure, e.g., advisory group, affiliated faculty and organizations, space, Web.
2. Prepare and submit at least 4 manuscripts for publication and 3 grant/contract applications for funding support annually on global medicines programmatic research and policy priority topics.
3. Engage with key global stakeholders to offer 2 in-country training workshops/programs for policy-makers and health professionals on global medicines systems strengthening annually.
4. Update, expand, and offer at least 2 interdisciplinary global health medicines courses for UW professional degree and graduate students annually.

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Intra-Departmental Linkages

- **ICRC** – Planning for results of trials
 - Acyclovir guidelines, procurement, access in SSA
 - Pharmacovigilance planning
- **I-TECH** – Medication management
 - Collaborations where there's geographical overlap, UNAM
 - Proposals
- **IHME** – Population-based medication use assessment
 - Participation in “A Novel Integrated Multi-source Surveillance System for Tracking Health Disparities”
- **KRP** – Joint mentorship of postdoctoral fellow

Challenges/Future Directions

- Attract and mobilize interdisciplinary faculty with an interest in collaboration on global medicines issues
- Define and refine topics for focused project development, including funding support
- Planning for growth in Program activities
- Formalize Program affiliations

Discussion



www.globalmedicines.org