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Background: Under the current paradigm, cost-effectiveness studies provide limited value to policy makers in low-resource settings. Studies appear with substantial delays in the academic literature and are often based on large-scale multi-intervention assessments in settings with drastically different infrastructure, resources and cultures. Timely and contextual evidence is rarely available. Given recent developments in standardizing the analysis of the global burden of disease (GBD), we believe a similar approach can be applied to the generation of cost-effectiveness estimates. To achieve this, we are developing a systematic protocol and guidelines for conducting cost-effectiveness analyses based on the integration of information. We are applying this approach to two low-income countries — Kenya and Zambia — as a proof of concept.
Methods: We define cost-effectiveness as a combination of five inputs: incremental costing, the current coverage of interventions, the remaining burden of disease that needs to be addressed, efficacy of interventions, and the gap between efficacy and effectiveness, which we label as quality. The first step is to identify a set of interventions based on highest potential impact and strategic priorities of the two countries involved. The list of interventions for Kenya is currently being finalized. To develop cost functions, we will use data collected through the Access, Bottlenecks, Costs and Equity (ABCE) project that incorporate facility-level efficiency. GBD estimates will be used to determine the burden. We will initially develop first order approximations of coverage based on available survey data, or encounter data for interventions that are not normally included in demographic health surveys. We will map from efficacy in the units reported in the literature to changes in disability-adjusted life years (DALYs) checking for consistency with GBD assumptions regarding prevalence, case-fatality rates, severity distributions and disability weights. To account for the impact of provider quality and consumer behavior on the real-world effectiveness of interventions, we are collaborating with Emory University in developing a framework to estimate effectiveness and its determinants.
Findings: Bringing together data on the five inputs will allow us to produce estimates of the cost-effectiveness of the interventions of interest to policy makers in Kenya and Zambia. We aim to produce our first round of estimates in 2015 for a subset of those interventions.
Interpretation: Developing a system that is able to generate timely, evidence-based, setting-specific and up-to-date estimates of cost-effectiveness for each country will take multiple iterations. Ultimately, the aim is to be able to determine the fraction of each disease that can be averted over a defined period with policies that meet certain threshold definitions of cost per DALY averted, while incorporating uncertainty.
Funding: Disease Control Priorities Network through the Bill & Melinda Gates Foundation.
Abstract #: *01GMHE003*

Determining demographic risk factors for receiving counterfeit cancer drugs

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Background: Context: In 2012, the U.S. FDA reported it had detected counterfeit versions of the anti-cancer drug Avastin in the legitimate drug supply chain. These counterfeit medications had traversed a complex global network of drug distributors, including those in Turkey, Switzerland, Denmark, the United Kingdom, and Canada. Drug safety warnings were sent to U.S. medical clinics where FDA suspected patients may have been exposed to counterfeit Avastin. Why the study was done: This study was done in order to identify demographic risk factors associated with clinics receiving a counterfeit Avastin notice. Aim: The aim of this study was to determine which demographic characteristics are associated with geographic areas that received counterfeit Avastin warning notices.
Methods: Study Design: Geospatial analysis was conducted across 30,431 zip codes in the United States. We also identified zip codes for clinics where legal prosecutions were pursued by the U.S. Department of Justice. Participants: FDA safety notices were received by 781 zip codes. Interventions: N/A Analysis: This research utilizes a multidisciplinary approach to analyze FDA drug safety notifications and legal prosecutions for counterfeit Avastin incidents using geospatial, regulatory, and legal analysis. After geocoding clinics that received an FDA safety warning, we used a basemap from the U.S. Census Bureau linked to 44 demographic characteristics (at the zip code-level) and used multivariate analysis to determine which characteristics were most associated with zip codes where notices were sent. (IRB N/A)
Findings: Participants: Researchers identified 781 zip codes as receiving counterfeit Avastin notices and 29,650 zip codes that had not received these notices. Outcomes: Geospatial analysis provided a visual depiction of where counterfeit Avastin receipt is most likely to occur. Zip codes receiving FDA safety notices were positively associated with demographic characteristics of elderly populations (over the age of 65) and ethnic white populations. These were the demographic variables where Pearson's correlation coefficients were highest. We observed a greater number of counterfeit Avastin incidents in major U.S. states including California (17.7% of all zip codes), Texas (9.2%), Florida (8.5%), and New York (8.2%).
Interpretation General Interpretation: These results identify demographic risk factors that can aid future efforts to proactively respond to detection of counterfeit medicines and efforts to improve patient safety. Limitations and Strengths: The main limitation of this research is that the notices sent to medical clinics correspond to locations where the FDA believed, but had not verified, that counterfeit Avastin was used. The main strength of this research is that it is the first study to analyze how demographic variations correspond geographically and statistically to detection of counterfeit cancer medications.
Funding: This study was funded by the American Cancer Society.
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Measuring the impact of U.S. global health engagements, an econometric approach

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Program/Project Purpose: The National Defense Authorization Act of FY13 states that the Department of Defense (DoD) "shall develop a process to ensure that health engagements conducted by the Department of Defense are effective and efficient in meeting the national security goals of the United States," including ensuring security, stability, and enduring partnerships in areas of interest throughout the world. Directly addressing this topic, the Measures of Effectiveness in Defense Engagement and Learning (MODEL) study, executed through the Uniformed Services University of the Health Sciences (USUHS) and conducted at the Center for Disaster and Humanitarian Assistance Medicine, was funded in 2013 to determine the effectiveness of Global Health Engagements (GHEs) as a Theater Security Cooperation (TSC) tool.
Structure/Method/Design: The MODEL study employs a hypothesis-based, econometric methodology, retrieving DoD health engagements from the Overseas Humanitarian Assistance Shared Information

System (OHASIS) to gauge the intensity of GHEs through budget allocations. OHASIS engagements are tested against controls and variables from open-sourced databases to determine the effectiveness of GHEs on U.S. Partner Nations (PNs). The analysis is conducted in STATA and consists of two-staged least squares regression models controlling for selection effects. Regression models are computed for health (e.g., infant mortality, tuberculosis disability adjusted life-years [TB DALYs], maternal mortality) and policy (e.g., ideal point differences, fragility index) measures of effectiveness (MOEs).

Outcomes & Evaluation: The results indicate that OHASIS-funded health engagements have a statistically significant relationship with the selected health and policy MOEs. A 1% increase in OHASIS GHE funding is associated with a 0.6%, 0.3%, and 0.2% decrease in PNs' infant mortality, maternal mortality, and TB DALYs, respectively. Likewise, the results indicate that a 1% increase in OHASIS health funding results in a 0.005 unit decrease in PNs' disagreement with U.S. policy preferences and a 0.05 unit decrease in PNs' fragility index.

Going Forward: Overall, DoD GHEs have a strong statistical impact on policy MOEs, with an even greater impact on health MOEs. The findings indicate positive national-level policy effects, thereby encouraging further research on GHE's impact at the local level. Researche

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Lives saved accountability scorecard

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Background: With an eye toward encouraging further progress on reducing child mortality, the Office of the United Nations Secretary-General Special Envoy for Financing the Health Millennium Development Goals (MDGs) sought to construct a "lives saved" accountability scorecard. Such a scorecard would relate health expenditure for child health and the number of child lives saved. With this scorecard, partner organizations could gain information about how to optimize impact from their investments in child mortality reduction. While there is consensus around the need for this scorecard, it remains a complex measurement task.

Methods: Given the time lags in the measurement of child mortality in developing countries, we focus on estimates that can provide direction in the near future. To best influence advocacy and decision making, we look at the marginal cost per child life saved. We base our estimates off two principles: first, the reporting of disbursements and the estimation of lives at the country level provides the most intuitive and pragmatic numbers to aide decision making; second, within a country, every dollar contributes equally to years of life saved. With these principles as a foundation, we estimate the time series of government expenditure and development assistance on child health by country and by year. We use these estimates to calculate cumulative change in expenditure over two MDG time periods. Next we estimate child deaths both with and without controls for changes in GDP, maternal education, and HIV. We also look at the cumulative change in child deaths over the two time intervals. Finally, we look at the ratio of change in expenditure to change in child deaths, and from this we make an approximation of the marginal cost of saving an extra child life.

Findings: We have undertaken empirical analysis to assess the likely marginal cost per year of life saved at the regional level over two MDG time periods: 2000-2006 and 2006-2011. We selected two separate time periods because higher expenditure and faster rates of child mortality occurred in the second half of the decade. Our preliminary analysis shows a marginal cost per child life saved of $65,497 in all developing countries, with strong regional variation.

Interpretation: While the relationship between expenditure and health is vastly more complex than can be adequately conveyed through a scorecard, the simplicity of this metric and our approach is beneficial. We have created a common accountability mechanism that is easy to communicate and conceptualize for those facing resource allocation decisions. Our results provide a preliminary analysis which can serve as a framework for discussion and policy intervention among donors and governments.

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Ethical approval process considerations for research in resource limited settings globally

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Program/Project Purpose: In the context of global health, human subjects research in low- and middle-income countries (LMICs) has significantly increased over the past few decades among academic institutions based in higher income countries. While research holds tremendous potential to alleviate the burden of disease, conducting research in vulnerable participants must be carefully considered. Investigators from higher income countries are mandated to undergo review and approval by an Institutional Review Board (IRB) prior to initiating research, receiving federal funds or obtaining scientific journal acceptance. This regulation is often non-existent or partially enforced in many LMICs.

Structure/Method/Design: Resources from the World Health Organization and Council of International Organizations of Medical Sciences provide guidelines for ethics but leave regulations to each autonomous nation, many without the resources to establish a formal system. There is high variability regarding ethical reviews between countries, which leaves room for interpretation and can lead to negative consequences. We describe a process while seeking approval in an international setting from our experience through an epidemiologic-genetic, case-control study in Democratic Republic of Congo (DRC), Honduras, Mexico, Morocco, Philippines and Vietnam. Various potential stakeholders of the ethical process are explored through five levels: (1) national, (2) institutional, (3) regional, (4) local and (5) individual.

Outcomes & Evaluation: A layout was constructed to facilitate identifying stakeholders in the broad and specific community in which research was being conducted: 1. National considerations: National laws on clinical trials, genetics, biotechnology, etc. Banned or highly regulated research procedures Import/export of research data or specimens Formal application or procedures for foreign investigators 2. Institutional considerations: Requirements at home institution IRB filing and approvals Enlisting in-country co-investigators University or hospital ethics committees 3. Regional considerations: Ministries of Health Provincial or regional government Differing regional regulations Additional health structures 4. Local