IN THIS ISSUE:

- Impact of funding on infectious diseases
- Highlight Partner: Cameroon's NTCP
- Undue Inducement and Coercion Revisited

UPCOMING EVENTS:

April 25
World Malaria Day

May 4 - 6
11th International Medical Exhibition and Conference
Cairo, Egypt

May 9 - 11
Leaders in Healthcare Conference Africa
Johannesburg, South Africa

May 16 - 24
64th World Health Assembly
Geneva, Switzerland

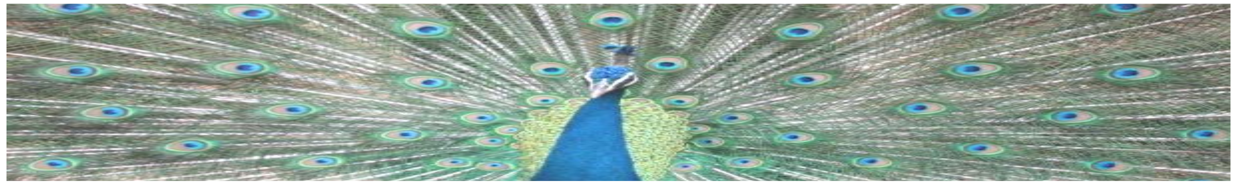
May 31
World No-Tobacco Day

June 1 - 2
2011 Global Business Coalition Conference
New York, NY, USA

June 13 - 17
Global Health Council 2011 Conference
Washington, DC, USA

June 23 - 26
MedHealth-Africa 2011
Dakar, Senegal

CLEAR VIEW



Apr—Jun 2011 Volume 1, Issue 3

THE IMPACT OF FUNDING FOR GLOBAL HEALTH ON THE BURDEN OF INFECTIOUS DISEASES

In 2000, world leaders committed to a collective partnership to reduce extreme poverty by meeting eight Millennium Development Goals (MDGs). Three of those goals are directly related to improving health systems around the world.

In the past couple of decades, a significant amount of funds has been contributed to the global health community for building and strengthening health systems. From 1990 to 2007, development assistance increased from US$ 5.59 billion to US$ 27.79 billion (Global Forum for Health Research, 2009). These funds are originating from a variety of funders such as international development agencies, global health initiatives, development banks, foundations, NGOs and other organizations.

Since 2003, the Global Fund to Fight AIDS, Tuberculosis and Malaria has supported the scale-up of HIV/AIDS, tuberculosis and malaria control in low- and middle-income countries. Global Fund-supported programs reported at the end of 2007 1.4 million HIV-infected persons placed on antiretroviral (ARV) treatment, 3.3 million new smear-positive tuberculosis cases detected in DOTS (directly observed TB treatment, short course) programs, and 46 million insecticide-treated mosquito nets (ITNs) delivered. In addition, an estimated 681,000 lives were saved and an estimated 1,097,000 life-years gained by providing ARVs. DOTS programs are estimated to have saved 1.63 million lives when compared against no treatment, or 408,000 lives when compared against non-DOTS tuberculosis treatment programs. ITN distributions in countries with stable endemic *P. falciparum* malaria were estimated to have achieved protection from malaria for 26 million of child-years at risk cumulatively, resulting in the prevention of approximately 130,000 deaths of children under-5 years old (Komatsu, 2010).

Other international organizations also contribute the fight against infectious diseases. In 2007, $US 2.56 billion were spent on research and development for neglected diseases (Moran, 2009). The leading funders were the U.S. National Health Institute ($US 1.25 billion), the Bill and Melinda Gates Foundation ($US 0.45 billion), the European Commission ($US 0.12 billion). The main recipients were the International AIDS Vaccine Initiative (IAVI), the Medicines for Malaria Ventures (MMV), the European and Developing Countries Clinical Trials Partnership (EDCTP), the International Partnership for Microbicides (IPM) and the Aeras Global TB Vaccine Foundation. In 2008, the World Bank's Development Grant Facility disbursed US$ 178.52 million to health programs and $US 9.4 million (5%) was allocated to research. The World Bank was expected to triple this contribution in 2009. In April 2009, the U.S. President Barack Obama committed to allocate 3% of the country's GDP to science research and development (Global Forum for Health Research, 2009).

Looking at the numbers at face value, one may conclude that there is sufficient funding to address health issues in Sub-Saharan Africa, but unfortunately this is not the case. The global health community has recognized that 10% of the world's health research funds are applied to health problems of 90% of the world's population. This is known as the 10/90 gap in health research. The substantial burden of neglected diseases such as HIV/AIDS, tuberculosis and malaria greatly impact this situation. For the past 10 years, world leaders have been increasingly devoting higher investments of their GDP to combat these diseases as well as other pressing public health issues.

With strained economies and competing priorities, continuing to implement and sustain effective health programs and infrastructure is becoming increasingly difficult.

Continued on Page 3...

STAFF CORNER:

Sylvie Nolna, MPH, MSc
Founder & President

Recently the Deputy Director for Site Development and Epidemiology at Aeras Global TB Vaccine Foundation. She headed capacity building activities for the conduct of TB vaccine research in several African countries and Asia. Mrs. Nolna has also worked with the American Red Cross as a Project Manager for the development of blood derived therapeutics.

Cherise Scott, Ph.D., MPH
Founder & Director

Dr Scott has worked in vaccine development preparing clinical research sites to conduct clinical trials with Sabin Vaccine Institute and the Aeras Global TB Vaccine Foundation. Dr Scott has extensive experience in GXPs and vaccine development, as well as the implementation of quality management systems in organizations in various African countries, South America, Australia and Asia.

GLOBAL HEALTH NEWS UPDATE

De-stigmatizing Mental Health Illness: Can Stigma Research Help?

Science has advanced our knowledge and understanding of most causes of mental illness. Despite the advancement in treating the diseases, the monumental task of reducing the stigma against mental illnesses still persists, which can be just as debilitating to a person's health and wellness as the illness. Mental illnesses represent five of the top 10 leading causes of disability in the world for men and women in their prime years (WHO Report 2001 Mental Health: New Understanding, New Hope). Stigma remains one of the principal barriers to people seeking treatment worldwide. Mental health services and facilities constantly lack funding and are very understaffed. There is a global movement to initiate innovative interventions to address barriers to providing evidence-based treatments for mental illnesses. Groups such as the Movement for Global Mental Health, BasicNeeds, and The Carter Center are spearheading this campaign. http://www.globalhealthmagazine.com/cover_stories/stigma_research

Africa—Pneumococcal vaccine reaching the DRC: Pneumonia is responsible for a quarter of all child deaths under five in the Democratic Republic of Congo (DRC). The (DRC) rolled out its immunization program by including vaccines to combat pneumonia which will initially be expanded in two of the 11 provinces.
http://www.gavialliance.org/media_centre/press_releases/drc_pneumococcal.php

Asia—Booming dementia epidemic in Asia: Dementia is increasing at an alarming rate in Asia placing a huge burden on caregivers. China and India account for the majority of dementia prevalence in the region and both governments are trying to combat the disease. http://www.who.int/bulletin/volumes/89/3/11-020311/en/

Americas—Epidemiological update on dengue fever in the Americas: A total of 206,097cases of dengue have been reported, including 2,744 cases of severe dengue and 223 fatalities in the Americas. This alarmingly high rate of dengue fever activity in several countries has required rapid implementation of management plans by both local and national governments.
http://new.paho.org/hq/index.php?option=com_content&task=view&id=5157&Itemid=2206

Europe—Fighting antibiotic resistance from a food safety viewpoint in Europe: The use of antibiotics in animals used for food is a perfect vector for resistant bacteria and genes to spread from animals to humans through the food-chain. Over 25,000 people die from infections caused by antibiotic-resistant bacteria yearly in the European Union. http://www.euro.who.int/__data/assets/pdf_file/0005/136454/e94889.pdf

Pacific—Healthcare costs burden families in the Pacific region: 1.15 million families in Viet Nam and almost 250,000 families in the Philippines fall into financial hardship due to the rising cost of health care.
http://www.wpro.who.int/media_centre/press_releases/pr_20110323.htm

HIGHLIGHT A PARTNER—NATIONAL TUBERCULOSIS CONTROL PROGRAMME

The National Tuberculosis Control Programme (NTCP) is a branch of the Cameroon Ministry of Public Health (MoPH) and is responsible for administering services and programs to fight against tuberculosis in a comprehensive way. With the help of local and international funding such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, NTCP has had a successful track record in TB control as reported in 2008 to the WHO. This success is marked by the number of Basic Management Units (BMUs) increasing from 133 to 216 in 2008; the number of notified TB patients increasing from 10,548 in 2002 to 25,125 in 2008; and by detecting 86% of the expected cases of sputum smear-positive cases of TB in the community. One of the NTCP's recent achievements is the operationalization of the TB laboratory network in order to ensure continuous quality control.

The NTCP continues to work toward the goal of progressively reducing the morbidity and mortality associated with TB through the proper management of cases. Late in 2010, The NTCP was awarded US$ 7,902,709 for 5 years to continue to meet its target for case finding, treatment, prevention, training, education and epidemiology surveillance. Although the local and international funds allow the program to make great strides in TB control, there are still gaps that require additional resources such as the detection in specific populations such as prisoners, residents of slums, persons living in remote areas.

CLEAR has joined the NTCP in an application for a TB REACH grant offered by the STOP TB Partnership. The main objective of TB REACH is to increase case detection of TB as early as possible and ensure timely and complete treatment while maintaining high TB cure rates. The NTCP proposal aims to integrate informal health providers (IHPs) into the NTCP in order to improve TB case detection in two urban areas (Yaoundé and Douala). Poor quality of IHP services leads to delays in TB diagnosis and irrational use of TB drugs which impedes the TB control efforts of the NTCP. Integrating IHPs into the NTCP will allow the IHPs to become a resource instead of being a liability. A decision on the grant application is expected in May 2011.

Amadu Kamara, MAF
Founder & Director

Mr Kamara has worked for the Tax Accounting and bookkeeping fields. Mr Kamara has extensive experience with not-for-profit businesses and individual tax return preparation.He is a member of the Maryland Association of Certified Public Accountants (MACPAs).

Atlang Mompe, BA
Intern

Ms Mompe recently graduated Magna Cum Laude from Gettysburg College.Ms Mompe has a deep interest in public health issues, especially the HIV/AIDS epidemic. She is currently working for the Social and Scientific System as a Research Associate I.

Rodrigue Ntone
Business Administrator

Mr Ntone is a Business Law Major at the University of Douala, Cameroon. He has skills in business management and has ambition to pursue Project Management Training. He has worked on establishing the official structure of CLEAR in Cameroon by taking care of all the administrative tasks. He aspires to pursue a Master's in Business Law.

IMPACT OF GLOBAL HEALTH FUNDING—CONTINUED

There is a proven record of worthwhile outputs from global health funding and commitments must remain firm from all sectors of society to ensure forward motion and success which will be evidenced by decreased disease burdens and more lives saved.

Citations

- Global Forum for Health Research. (2009). *Global Forum Update on Research for Health Volume 6: Innovating for the Health of All*. Woodbridge, UK: Pro-Book Publishing Limited.
- Komatsu R, Korenromp EL, Low-Beer D, Watt C, Dye C, Steketee RW, Nahlen BL, Lyerla R, Garcia-Calleja JM, Cutler J, Schwartländer B. (2010). Lives saved by Global Fund-supported HIV/AIDS, tuberculosis and malaria programs: estimation approach and results between 2003 and end-2007. *BMC Infect Dis. 10, 109.*
- Moran M, Guzman J, Ropars AL, McDonald A, Jameson N, Omune B, Ryan S, Wu L. (2009). Neglected disease research and development: how much are we really spending? *PLoS Med. 6(2), e30*.

REVISITING THE CONCEPTS OF 'UNDUE INDUCEMENT' AND 'COERCION' IN CLINICAL RESEARCH

Article courtesy of guest author Chi Primus

In clinical research it's not uncommon to find the concepts 'undue inducement' and 'coercion' misused. These concepts need not be misunderstood: undue inducement dangles a positive good, a tempting offer that can cause the bad judgment that leads to harm, while coercion entails a threat that the person considers a worse circumstance if they do not do the desired action (Emanuel, 2005). This article focuses on dispelling the confusion caused by the two words and raises questions about the current norm for research conducted in developing nations.

Undue Inducement

Although the concept of 'undue inducement' is highlighted in a number of ethical guidelines, many of these guidelines however fail to provide a standard definition of the concept:

The Common Rule

"An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." (DHHS, 2005)

OHRP

"…the International Review Board (IRB) should review both the amount of payment and the proposed method of disbursement to assure that neither entails problems of coercion or undue influence. Such problems might occur, for example, if the entire payment were to be contingent upon completion of the study or if the payment were unusually large. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation". (OHRP, 1993)

Undue inducements can be defined as excessively attractive offers that lead people to do something to which they would normally have real objections based on risk or other fundamental values (Dickert, 2006). In other words, it is an offer of a desirable good in excess such that it compromises judgment and leads to serious risks that threaten fundamental interests (Emanuel, 2005). According to Emanuel, an inducement is 'undue' when it fulfills the following conditions (Emanuel, 2004): 1)There is an offered good 2) The good is excessively attractive 3)It leads people to exercise poor judgment 4)Participation involves a risk of serious harm.

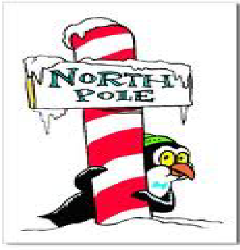
As such, an undue inducement isn't only an excessively good attractive offer but also negatively affects a person's judgment with respect to risk-benefit assessment. An undue inducement is likely to pose some concerns based on the assumptions that (Dickert, 2006): individuals induced by large amounts of money are acting involuntarily and may be exposed to significant risk; they may be blinded to the risks of participation and thus make uninformed decisions; they may lie or conceal information.

Coercion

Just like the concept of 'undue inducement', coercion is equally addressed by a number of ethical guidelines. According to the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, coercion occurs when an overt threat of harm is intentionally presented by one person in order to obtain compliance (*The Belmont Report*, 1979).

Continued on Page 4...

Little Known Facts



Did you know that one cannot catch a cold in the North Pole in winter? The winter temperature is so low that none of the standard disease causing microorganisms can survive in this region of the world. Therefore one cannot become infected with flu or most of the disease transmitting viruses and germs.

The National Electronic Injury Surveillance System (NEISS) estimates that approximately 125,312 people are injured in 1 year while in or around a bed. These injuries resulted from such mishaps as tripping over the bed, hurting oneself on the headboard, or simply falling out of bed. Talk about waking up on the wrong side of the bed!

Source: http://chhamanator.wordpress.com/2008/04/13/STRANGE-MEDICAL-FACTS/

UNDUE INDUCEMENT AND COERCION REVISITED —CONTINUED

In other words, coercion are threats that make a person choose an option that necessarily makes him or her worse off and that he or she does not want to do (Emanuel, 2005). For an action to be described as coercive, it must fulfill the following conditions (Hawkins & Emanuel, 2005): 1)It should have an unfavorably narrowed set of options 2)They should be some human agency to limit a person's options in an attempt to manipulate them 3)They should be a threat.

According to Wertheimer, there are two views of coercion (Wertheimer, 1989):

- A coerces B to do X only if A proposes (threatens) to render B worse off unless B does X. (Threat view).
- A coerces B to do X when A's proposal leaves B with no reasonable alternative but to do X. (No Reasonable Alternative view).

How concerned should we be about these concepts in health research?

Arguably, the concept of coercion is rare in contemporary clinical research while that of undue inducement in clinical research is clearly misplaced. Claiming that a research incentive for a particular project amounts to an "undue inducement" in country A and not in country B and hence the compensation in country A should be reduced raises some concerns on the application of common standards in health research and might even be regarded as some sought of exploitation. The fact that remains is that the risks inherent in any research project remains unchanged irrespective of the size of the compensation package provided for participation. This concept of "undue inducement" is probably coined and propagated by individuals and organizations keen on exploiting the vulnerable status of some research participants especially in developing country settings. It's weird and ironic to consider subjects' participation in clinical research with minimal or no incentives as ethical and the same subjects participating in the same study (with a similar risk-benefit ratio) but with improved incentives as unethical. Stuart Rennie rightly puts it, "what makes inducement 'undue' is whether it motivates people to take dangerous risks." Being worried about inducements that actually benefit people seems a bit strange." (Rennie, 2008) Therefore talks about undue inducements in otherwise thoroughly reviewed protocols that address all the eight principles of ethical research should desist. (Emanuel, 2005)

Citations

- *The Belmont Report*. (1979). Washington, DC: US Government Printing Office: The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- DHHS. (2005). *45 Code of Federal Regulations: Protection of Human Subjects, Part 46*. Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.
- Dickert, N. (2006). Coercion and Undue Inducement in Research: Money and Other Offers. Retrieved 05 March, 2011, from http://ocw.jhsph.edu/courses/EthicsHumanSubjectResearch/PDFs/Coercion.pdf.
- Emanuel, E. (2004). Ending concerns about undue inducement. *J Law Med Ethics, 32*, 100–105.
- Emanuel, E., Currie, K., & Herman, A. (2005). Undue inducement in clinical research in developing countries: Is it a worry? *Lancet, 366*, 336-340.
- OHRP. (1993). *Protecting human research subjects: institutional review board guidebook.* . Washington DC: Office of Human Research Protection, US Government Printing Office.
- Rennie, S. (2008). Resuscitating undue inducement. . Retrieved 28 February, 2011, from http://globalbioethics.blogspot.com/2008_12_01_archive.html.
- Wertheimer, A. (1989). *Coercion*. Princeton, NJ: Princeton University Press.

— Talent Has No Boundaries —

***Mission:** CLEAR seeks to promote global health through the development of independent, sustainable clinical programs and research systems in resource limited settings with stringent compliance to international standards for the conduct of ethical human research and impactful health programs.*

Office—USA
7707 Heritage Farm Drive
Montgomery Village, MD 20886
Office +1 301.591.1609
Fax +1 240.668.9436

Office—Cameroon
Etoudi– Face Pharmacie du Palais
P.O. Box 6986 Yaoundé
Phone: +237 75 35 74 85

How You Can Contribute to CLEAR VIEW

If you are interested in commenting on anything you read on CLEAR VIEW or you want to contribute to the next edition with an article, event or news item please email **info@clear-inc.com**.