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GLOBAL HEALTH GOVERNANCE IS AN OPEN ACCESS, PEER-REVIEWED, ONLINE JOURNAL THAT PROVIDES A PLATFORM FOR ACADEMICS AND PRACTITIONERS TO EXPLORE GLOBAL HEALTH ISSUES AND THEIR IMPLICATIONS FOR GOVERNANCE AND SECURITY AT NATIONAL AND INTERNATIONAL LEVELS.

THE JOURNAL PROVIDES INTERDISCIPLINARY ANALYSES AND A VIGOROUS EXCHANGE OF PERSPECTIVES THAT ARE ESSENTIAL TO THE UNDERSTANDING OF THE NATURE OF GLOBAL HEALTH CHALLENGES AND THE STRATEGIES AIMED AT THEIR SOLUTION. THE JOURNAL IS PARTICULARLY INTERESTED IN ADDRESSING THE POLITICAL, ECONOMIC, SOCIAL, MILITARY AND STRATEGIC ASPECTS OF GLOBAL HEALTH ISSUES.

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Promoting Global Health: Can Law Be the Solution?

Desmond McNeill

In *Global Health Law* Larry Gostin describes and analyses, with great authority and moral commitment, what law may be able to contribute to promoting the health of the world and especially those most disadvantaged. This book will surely serve as a valuable reference source, and inspiration, not only for lawyers but also many others, both academics and practitioners, who are concerned with global health. In this review I will focus on those aspects which relate most closely to the work in which I have recently been involved as a member of the Lancet-University of Oslo Commission on Global Governance for Health[i], namely Chapter 3, Global Governance for Health, but also Chapter 7, The Framework Convention on Tobacco Control, which shows what was in fact possible in one specific and very important case; and Chapter 9, Health, Trade and Intellectual Property, which indicates how great the challenge may be in other cases.

I begin with Gostin's definition of global governance for health (GGH):

> "the organization/collection [the word differs in the two places cited] of norms, institutions, and processes that collectively shape the health of the world's population. It requires remediating the unfair and detrimental health influences of international regimes (e.g., trade, intellectual property, and financial policies), and developing stable, responsive, democratic political institutions that are focused on good governance and capable of implementing an all-of-government approach to health' (17/ 72)

I would make three points arising from this very clear, though quite lengthy, definition. First, that it is normative rather than descriptive. Second, that it picks out certain specific international regimes as examples. Third, that it opens the way for a definition, and further exposition, of the concept of global health law. I will discuss each in turn.

I fully agree with Gostin's wish to define GGH in prescriptive terms. It is the word for (global governance for health) that is crucial here. It is clearly useful to distinguish GGH, as Gostin does, from 'global health governance'; both because the latter is a non-normative, purely descriptive concept, and because it refers primarily to that which lies within the remit of the World Health Organization (WHO). The significance of this wider definition is that it draws attention – crucially – to what we in the Commission sometimes referred to as the political determinants of health. This brings me to my second point: the international regimes that may negatively impact on people's health. And here I quote again, this time from Gostin's 'six grand challenges of global governance for health' of which the sixth is as follows.

> "6. Influencing multiple sectors to promote health.
> Global health actors can achieve only partial success through health sector reform. Multiple sectors – such as trade, intellectual property, migration, and the environment – have a powerful impact on the public's health; sometimes that

> impact is beneficial, but often it is harmful. Currently, the health community is self-contained and somewhat insular, concerned principally with health sector reform". (84)

This coincides very closely with the core of our Commission report, which sought to identify such sectors and to analyze the hindrances that exist to remedial action. It is of course not surprising that the sectors Gostin identifies overlap with ours. (In addition to those I have already quoted, he refers on page 60 to 'trade, food, arms control, labor, and the environment' as examples of international regimes that 'play a major role in promoting – or adversely affecting – health'). But it may be relevant to note that sectors cannot be influenced, actors can. This might seem like nitpicking, but my point is simply to underline that these are political issues; that to achieve change may require confronting the interests of powerful actors – most probably powerful nations or transnational firms.

My third point relates to global health law. Gostin defines this also very clearly in normative terms: "My definition of global health law is prescriptive as well as descriptive". (60) This is consistent with his overall aim:

> "The goal of this book is to show the potential of law, both national and global, to dramatically transform prospects for good health, particularly for the world's most disadvantaged people. … The principles for which I argue in this chapter – those of shared national and global responsibilities, social justice, and the right to health – form the normative perspective that will run throughout this book's evaluation of global health law and governance'.' (18) (emphasis added)

I am no lawyer, so my comments here are those of an amateur; but I wonder whether this is a standard view. Is not law normally seen as following rather than leading the consensus of opinion - reflecting rather than influencing the norms of society? Whether or not this is the case, I would ask, as a political economist, is it a realistic role? Can law make a difference?

Gostin defines global health law as "the study and practice of international law – both hard … and soft … - that shapes norms, processes and institutions to attain the highest attainable standard of physical and mental health for the world's population". (59) And he is quite realistic regarding its potential:

> "Law has inherent limitations in its ability to solve the complex health challenges the world faces. Many – perhaps most – of the grand global health challenges discussed below are not readily susceptible to law's traditional approach of regulatory standards, dispute resolution, and enforcement. (71)

He makes a case for soft law, but again acknowledges its limitations:

> "In one empirical study, for example, 93 per cent of respondents reported that the WHO Global Code of Practice on the International Recruitment of Health Personnel has not had a meaningful impact on policies, practices, or regulations in their countries". (66-7)

And he notes that "there is a risk that soft health norms may be overridden by hard norms in other regimes, such as trade and intellectual property". (67) This is the key challenge with which I am particularly concerned. In Chapter 7, The Framework Convention on Tobacco Control, Gostin shows what was in fact possible in one specific and very important case. How law was successfully used to counter the power of vested interests. The question is: can this experience be repeated, and if so how? Chapter 9, Health, Trade and Intellectual Property, reveals how great the challenge may be. Again the vested interests are very powerful; but here, in contrast to the case of tobacco, the issues are more complex. Trade is, unlike tobacco, not inherently dangerous; indeed despite the many problems that arise trade has on balance made a positive contribution to peace and prosperity in the world. Similarly intellectual property rights, though often abused, cannot simply be abandoned. So what is to be done? Gostin puts much faith in a human rights approach, and in a Framework Convention on Global Health.

With regard to the former he is again realistic:

> "Although weak or vague norms and inadequate implementation are endemic in international law, the problem is particularly acute in the realms of social and welfare rights, including the right to health". (64)

To assess the merits of Gostin's proposals I suggest that it is useful to consider the alternatives. What other means might be used to achieve the very desirable aim of improving global health? What arguments or pressures may be effective to motivate states, and others, to act? The various different approaches may, I suggest, be seen as ranging from cautious/consensus to radical/critical.

1. Enlightened self-interest

Chapter 2, Global Health Hazards, and most notably section 'Globalization and the spread of infectious diseases', provides a basis for this sort of argument - which does seem to be compelling in many arenas, but is surely limited in its scope and may even risk having negative implications for the most disadvantaged in the world.

2. Aid and exhortation

This is how I would describe the standard approach of United Nations conferences and international bodies: 'poor' countries are exhorted to spend more (and more effectively) on health, while 'rich' countries commit themselves to providing development assistance. The model has been modified to some extent in recent years, in part because the 'rich country – poor country' divide is less clear. The Millennium Development Goals are an example of this approach. It is as yet unclear whether the post-2015 Sustainable Development Goals will be similar.

3. Rational economic arguments

This has also been a favored approach, increasingly in recent years, often used in reports commissioned by the UN. Arguments may be based on the idea that expenditure on health is an investment (for example the WHO Report of the Commission on Macroeconomics and Health Chaired by Jeffrey D. Sachs , 2001; and the more recent Lancet Commission on Investing in Health). Or they may employ the concept of 'global public goods' to convince policy-makers.

4. Remedying injustice

Some – and most notably non-governmental organizations – tend to employ this more radical argument, asserting that global health inequities are grossly unjust and demand corrective action. This is a more explicitly ethical/political approach, which may be linked to a human rights argument.

These alternatives are not entirely distinct; sometimes a combination may be used: for example, a mild form of the 'remedying injustice' argument may be used to introduce a report adopting primarily a 'rational economic' argument. And a human-rights based approach may be expressed in formal/legal terms (referring to existing human rights conventions) as well as in more moral/political terms, emphasizing glaring injustice.

Gostin himself refers to 'three global health paradigms that have international recognition' (21). How do these relate to my categorization? The first is 'human security'. According to his account this would appear to lie close to my 'remedying injustice' approach. But there are two very different forms of the 'human security' argument. Gostin refers to the benign version, but there is, I believe, a very different argument which is based on enlightened self-interest and draws on a fear of the foreign, alien, uncontrollable[ii]. It is, in my view at least, problematic that both go under the same name.

Gostin's second paradigm is 'global public goods'. This, as I have noted, is a 'rational economic' argument. What is interesting, though often not discussed, is that when something is classified as a public good this necessarily implies that it is under-supplied by the market and that intervention by a public body is required; a prescription necessarily follows from what appears to be a purely descriptive account. In the case of a nation, the appropriate public body is the state. The problem with global public goods is, of course, that no supranational equivalent body exists. The logic of the argument is just as strong, but the feasibility of following the logic is heavily constrained. Indeed, this is precisely the challenge of global governance.

Gostin's third paradigm is 'the right to health' which he asserts 'continues to evolve and gain international acceptance' (21). Only this, he states, has the force of law. But how forceful is that? This is the crucial question, as I have discussed above. And Gostin himself, as I have shown, is well aware of the limitations of what law can achieve here. He nevertheless does regard this as a valuable approach to pursue, given concrete form in the proposed Framework Convention on Global Health which he fully endorses. Gostin is fully aware of how challenging a task it would be to make this a reality, as I have indicated, and as the following passage states:

> "Undoubtedly, achieving effective GGH is a complex undertaking. The challenge is to pursue a fundamental objective – optimal health, equitably distributed – while navigating various crosscurrents; these include politics (domestic and global) , power dynamics (in the global North and South), vested interests (e.g., the corporate profit motive), economic power (e.g., wealthy states, foundations), security (national and human), and international relations". (72)

To end this brief commentary, I return to the question I posed in the title: can law be the solution? My conclusion after reading this impressive volume is that it can – and should – be part of the solution; but that efforts will have to be made on a number of fronts, employing a number of different instruments and approaches. Global health law can indeed make a major contribution, and with this book Gostin himself has made a major contribution to that end.

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[i] http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62407-1/fulltext
[ii] This has been strikingly exemplified with regard to the recent outbreak of Ebola in West Africa.

Global Health Law: What, When and for What Purpose? A Commentary on Lawrence Gostin's *Global Health Law*

Suerie Moon

INTRODUCTION

The past year has witnessed the largest Ebola outbreak ever recorded. The outbreak spread from rural areas of Guinea, Sierra Leone and Liberia to their capital cities, with panic rapidly spreading to other countries in the region, Europe, the US and all countries linked by modern air connections to the hard-hit West African region. In August 2014, for only the third time in its history, the World Health Organization (WHO) declared a Public Health Emergency of International Concern, triggering greater political attention and an upsurge of desperately needed human and financial resources to the region. With no effective drug or vaccine available, classic public health measures such as contact-tracing, isolation, and palliative care have taken center stage. Meanwhile, the pharmaceutical industry has been criticized for its neglect of diseases of the poor, with Ebola merely the latest example.[1] Médecins Sans Frontières (MSF), which was for months the main international actor providing on-the-ground clinical care to those infected, has criticized the slow and inadequate response from the international community.[2] While pledges of greater international support began to emerge in September (most notably the commitment of US military troops, resources and logistical capacity), as of this writing, the overall response has been frustratingly slow, underfunded, and inadequate to control the epidemic.

The Ebola outbreak puts in clear focus central questions for the global health system: Who is responsible for getting the outbreak under control? What can and should be done by the governments of Guinea, Sierra Leone and Liberia, and by international actors? When health systems are weak or overwhelmed, who can and should step in to provide support? What should be the role of *public* actors such as the WHO, or well-resourced governments, such as the United States or European Union, versus *private* organizations like MSF or the pharmaceutical industry? Who can and should coordinate the international response?

As yet another health crisis reveals the cracks in the global health system, Professor Larry Gostin's new book *Global Health Law* (Cambridge, MA: Harvard University Press, 2014) could not come at a more appropriate time. The book provides essential understanding of the system of international laws that has been constructed to address threats to public health security, such as an international Ebola outbreak, including historically-informed, accessible explanations of legal norms. It will also help readers think critically through some of the difficult questions raised above regarding roles, responsibilities and rights in an era of increasing health interdependence.

While the small body of international health law that we have today has its origins in states' interests in controlling the international spread of infectious disease, today the concept of global health has expanded far beyond such narrowly-defined concerns [3]. Gostin has done a masterful job of covering the breadth of the emerging and evolving field of global health: readers will not only gain an understanding of hard and soft laws intended to better govern international responses to cross-border epidemics,

but also international rules on the right to health, tobacco control, the marketing of breastmilk substitute, and the recruitment of health personnel, among other topics. Importantly, the book also covers bodies of international law that do not have health as their central objective, but can have profound consequences for public health – most notably trade and investment treaties, including those covering intellectual property rights.

Through this introduction to various bodies of law, the reader will also gain an understanding of some of the greatest health challenges of the past several decades – pandemic influenza, HIV/AIDS, non-communicable diseases, equitable access to medicines and strengthening health systems – and an introduction to major players, from the WHO to the World Bank, and the Gates Foundation to MSF. Each of these topics could fill a volume on their own, and we only catch a glimpse of the political story of competing interests and conflicting players that lies behind every convention, regulation, and code of conduct covered in this book. But interested readers can easily find volumes that will tell these stories in greater color and detail. The strength of this book is precisely in the way it succinctly covers a broad field. In other words, Gostin has done us a great service by providing a concise, thorough, historically-informed and straightforward primer on global health law that will be invaluable for general readers and practitioners, as well as students of law, public health, and public policy.

GLOBAL HEALTH LAW: WHAT IS IT?

Gostin offers an expansive definition of global health law as:

> *…the study and practice of international law – both hard law (e.g. treaties that bind states) and soft instruments (e.g. codes of practice negotiated by states) – that shapes norms, processes and institutions to attain the highest attainable standard of physical and mental health for the world's population.*[4]

The definition contains both a descriptive component (e.g. hard and soft law that shapes norms, processes and institutions…) and a normative one ("…to attain the highest attainable standard…"). But combining the two elements runs the risk of conceptual muddiness. What if a law intended to improve public health does not in fact do so? To illustrate, a relatively weak voluntary code of conduct among manufacturers of unhealthy foods could forestall the negotiation of more binding norms. Should it be considered part of the body of "global health law"? Conversely, should a law that impacts global health but does not have the central objective of doing so be considered part of this body of law? For example, many conventions may have beneficial (e.g. environmental treaties such as the 2013 Minamata Convention on Mercury) or harmful (e.g. trade agreements with stringent intellectual property clauses or investment treaties that constrain national health regulation) implications for global health, though health is not their primary focus. Should these fall under the umbrella of "global health law"?

Further conceptual clarity is needed not only on what counts as "global health law," but also on what distinguishes "global health law" from "global health diplomacy," "global health politics," "global health institutions/architecture," "global health governance," and "global governance for health." The latter two appear regularly throughout the book, often interchangeably. (Julio Frenk and I have argued elsewhere

that there is an important distinction between the two concepts, with "global health governance" usually referring to governance of global health actors, and "global governance for health" asking how global governance processes, *within and outside the health sector*, can better be channeled to protect and promote health.[5]) Gostin argues that he considers the concepts of law and governance to be "interrelated, with no clear boundaries: law is a major aspect of governance, and features of governance can take the form of law."[4] Yet part of the potential utility of a more narrowly defined concept of "global health law" is precisely to distinguish it from the broader concept of governance. The burgeoning intellectual field of "global health" remains inchoate, and conceptual clarity is important in a field populated with so many competing terms and concepts.

It may be useful to consider global health law, in both its hard and soft forms, as an important *tool* of global governance. Its utility to address a given challenge can then be compared to others. For example, together with Wolfgang Hein, I have argued elsewhere that widespread shifts in *informal* norms (as opposed to codified hard or soft law) were a critical tool for improving access to medicines in developing counries.[6] Other tools of global governance include the mobilization of expertise, financial resources, multi-stakeholder convening, or accountability mechanisms. Keeping in mind that "if all you have is a hammer, everything looks like a nail," when is the pursuit of global health justice better served by global health law, and when by other tools?

GLOBAL HEALTH LAW: WHEN AND FOR WHAT?

Indeed, a key question that Gostin touches upon but largely leaves open, is when hard or soft law is the most promising, appropriate or powerful tool to be deployed. Binding treaties require enormous political capital, human and financial resources to negotiate, ratify and monitor. Even softer instruments take years to reach agreement, and still lack the bite of binding norms. While international laws can be enormously influential in reinforcing and shaping pro-health norms, policies and behaviors, they are extremely difficult to amend and carry significant normative weight, meaning that they must be crafted with great care. These are not just academic questions but have clear real-world implications. For example, when the public health community seeks to counteract the growing threat of anti-microbial resistance, should it dedicate its limited resources to a binding treaty, a softer instrument, or political declarations like World Health Assembly resolutions? When aid advocates seek to increase the flows of development assistance for health (DAH), what is the instrument most likely to further their goals? And what are the most pressing health issues that will convince states to share a sliver of their jealously-guarded sovereignty by submitting to a set of international rules?

Such policy-oriented questions are particularly relevant in light of the book's strong normative orientation. Rather than a dispassionate legal textbook explaining statutes and citing cases, *Global Health Law* repeatedly returns to the question of how to achieve greater justice in global health. For many, this will be part of its essential appeal. But while it raises the question, and offers some ideas for consideration, the book largely leaves the question unanswered: what approaches to strengthening global governance will be best for global health, and will achieve more equity and justice?

This is not an easy question to answer. Gostin concludes the volume outlining his proposal for a Framework Convention on Global Health, a thought-provoking idea that has generated both supportive and critical attention in recent years.[7] The Lancet

Commission on Global Governance for Health, whose report was published after *Global Health Law* went to press, also wrestled mightily with this question and came to its own distinct conclusions.[8] And in specific issue areas, whether DAH,[9,10] innovation and access to medicines,[11] alcohol,[12], non-communicable diseases,[13] antimicrobial resistance,[14] food security,[15], regulation of multinational firms,[16] climate change or other issue areas, proposals and debate abound on how to make global governance work better for health. Which ideas are most promising for progressing towards greater global health justice?

This area is in dire need of further empirical research, careful analysis and learning. As Gostin has pointed out, much can be learned from past successes, such as the global response to HIV/AIDS, which has broken new ground from civil society strategies [17,18] to the mobilization of unprecedented financing,[19] from re-shaping intellectual property norms on access to medicines [6,20] to driving forward unimagined scientific progress.[18] Tobacco control and immunization are two other areas where global progress has been remarkable, and where rich lessons surely reside. In addition to learning from the past, there is also a need for real-time research and analysis on ongoing events. Hoffman and Röttingen, for example, carried out an insightful analysis of the conditions under which an international treaty would make sense for achieving global health objectives, applied to the case of generating technological innovation to meet the needs of the world's poor.[21] Further such analysis and careful tracking of the impact of new initiatives is needed to inform how we tackle the long list of pressing global health threats.

A clear conclusion from this volume is that global health law forms part of the foundation of the global health system – but a foundation that is flimsy and full of holes. There are numerous areas where the reach of the law needs to be expanded or solidified. But there are also areas where international lawmaking is unlikely to yield much fruit. Having equipped the reader with a sound understanding of the field, *Global Health Law* challenges scholars and practitioners alike to continue grappling with the question of when this uniquely powerful tool for global governance can genuinely advance global health and justice.

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[1] Millman J. Why the drug industry hasn't come up with an Ebola cure. The Washington Post 2014;.
[2] Médecins Sans Frontières /Doctors Without Borders (MSF). New Strategies, More Resources Needed to Curb Ebola Epidemic. Statement by MSF International President. 2014;.
[3] Frenk J, Gómez-Dantés O, Moon S. From sovereignty to solidarity: a renewed concept of global health for an era of complex interdependence. Lancet 2014;383:94-7.
[4] Gostin LO. Global Health Law. Cambridge, MA: Harvard University Press, 2014.

[5] Frenk J, Moon S. Governance Challenges in Global Health. New England Journal of Medicine 2013;368:936-42.
[6] Hein W, Moon S. Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicines. Aldershot, UK: Ashgate, 2013.
[7] Friedman EA, Dasgupta J, Yamin AE, Gostin LO. Realizing the right to health through a Framework Convention on Global Health? A Health and Human Rights special issue. Health and Human Rights: An International Journal 2013;15:1-4.
[8] Ottersen OP, Dasgupta J, Blouin C, et al. The political origins of health inequity: prospects for change. Lancet 2014;383:630-67.
[9] Moon S, Omole O. Development Assistance for Health: Critiques and Proposals for Change. Working Group on Finance, Paper 1. London: Chatham House, 2013. (Global Health Security Working Papers).
[10] Chatham House Centre on Health Security, Working Group on Health Financing. Shared responsibilities for health: A coherent global framework for health financing. London: Chatham House, 2014.
[11] Røttingen J, Chamas C. A New Deal for Global Health R&D? The Recommendations of the Consultative Expert Working Group on Research and Development (CEWG). PLoS Med 2012;9:1001219.
[12] Sridhar D. Regulate Alcohol for Global Health. Nature 2012;482:302.
[13] Magnusson RS. Global Health Governance and the Challenge of Chronic, Non-Communicable Disease. The Journal of Law, Medicine & Ethics 2010;38:490-507.
[14] Anomaly J. Combating Resistance: The case for a global antibiotics treaty. Public Health Ethics 2010;3:13-22.
[15] Prakash A. Safeguarding food security in volatile global markets. 2011;.
[16] Sethi N. UN to draft treaty on human rights violation by multinationals. Business Standard (India) 2014;.
[17] Epstein S. Impure science : AIDS, activism, and the politics of knowledge. Berkeley: University of California Press, 1996.
[18] Smith RA, Siplon PD. Drugs into bodies : global AIDS treatment activism. Westport, Conn.: Praeger, 2006.
[19] Kapstein E, Busby J. Making markets for merit goods: the political economy of antiretrovirals. Working Paper 179. Washington, D.C.: Center for Global Development, 2009.
[20] 't Hoen E, Berger J, Calmy A, Moon S. Driving a decade of change: HIV/AIDS, Patents, and Access to Medicines. Journal of the International AIDS Society 2011;14.
[21] Hoffman SJ, Røttingen J. Assessing implementation mechanisms for an international agreement on research and development for health products. Bulletin of the World Health Organization 2012;90:854-63.

Gender Equity and Global Health Law: A Comment

Rebecca J. Cook

Larry Gostin's book, Global Health Law,[i] *moves us to envision a world in which global health law and governance play a more effective role in reducing gross global health inequities. In so instructing and inspiring us, he gives an insightful overview of the existing international legal landscape, how the law strives to contribute to the elimination of global health inequities, and how it might be improved to do a better job at achieving health equity. Gostin helpfully defines global health law as*

> *the study and practice of international law—both hard law (e.g., treaties that bind states) and soft instruments (e.g., codes of practice negotiated by states)—that shapes norms, processes, and institutions to attain the highest attainable standard of physical and mental health for the world's population. Normatively, the field seeks innovative ways to mobilize resources, set priorities, coordinate activities, monitor progress, create incentives, and ensure accountability among a proliferation of global health actors. The value of social justice infuses the field, striving for health equity for the world's most disadvantaged people. (p. 59-60)*

The aim of my short comment on this book is exploratory: to sketch how global health law might build on accomplishments to date to advance health equity for women. My argument is that global health law and governance have to be far more deliberate in addressing gendered health disparities in order to achieve health equity generally and health equity for women.[ii] *That is, governments have an obligation to set gender health equity as a policy objective and to take the steps necessary to achieve it as a policy outcome.*

HEALTH EQUITY

Health inequities have been defined in various ways, and include "differences in health that are not only unnecessary and avoidable, but also in addition are unfair and unjust."[iii] Health disparities that are avoidable but not avoided contribute to their inequity.[iv] The unfairness and injustice of differences in health derive from their disproportionate effect on disadvantaged sub-groups within nations and among nations.[v]

With a view to reducing health disparities, Gostin raises some over-arching questions (pp. 22-31). Given the space limitations of this comment, I will focus on one of Gostin's questions: What are the essential health services and goods guaranteed to every human being under the right to health (p. 22-25)? He elaborates answers to this question by focusing on public health services, universal health systems and socio-economic determinants of health.

With regard to public health services, he explains that "the first essential condition for good health is population-based services that create an environment in which people and communities can lead healthier, safer lives" and highlights such conditions as proper sanitation, food and nutrition (p. 22). In many societies, women and girl children are the last to be fed, usually with less food, due in part to the societal prejudices against them.

In order for women to lead healthier lives, states have to attend to the social practices of gender, including hostile prejudices and stereotypes that disadvantage them in accessing population-based services.[vi] This is easier said than done because the normality of gender prejudice often blinds societies to its pernicious effects, like the proverbial fish that is blind to the water in which it swims. Eliminating gender prejudice requires dismantling the sexual hierarchies that segregate women into lower paying and lower status positions in different sectors of societies and minimizing the detrimental effects on their physical, mental and social well-being, that is, their health.

Gostin explains that "the second essential condition for good health is a well-functioning health care system to provide clinical prevention, treatment, and palliative care for all people who are ill, injured, or suffering." (p. 23) It is now established that neglecting health care that only women need, such as maternal health services[vii] and services to prevent and treat cervical cancer,[viii] is a form of discrimination against women that societies are obligated to remedy.[ix]

The decision of the Committee on the Elimination of Discrimination against Women (the Committee), established under the Convention on the Elimination of All Forms of Discrimination against Women (the Convention),[x] to hold Brazil accountable for the preventable maternal death of a poor pregnant Afro-Brazilian woman, Alyne da Silva Pimentel Teixeira [hereinafter Alyne][xi] is a significant development.[xii] Health status indicators have shown for years that there have been significant health disparities in maternal health among nations[xiii] and within nations. Significantly, such disparities are now considered a form of legal discrimination that countries are obligated to remedy. Alyne died of postpartum hemorrhage following the stillbirth of a 27-week- old fetus and her lack of access to emergency obstetric care. The Committee determined that the lack of appropriate maternal health services had a "differential impact on her right to life".[xiv] The Committee found the State did not comply with its obligation to "ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period…", because of its failure to accommodate Alyne's "specific, distinctive health needs and interests" during pregnancy.[xv] The Committee also found that Brazil had not taken "all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on the basis of equality of men and women, access to health care services…."[xvi]

Gostin explains that "the third essential condition for good health is elimination of the underlying social and economic causes of injury, disease, and early death, such as inequities based on income and gender, and lack of (or poor quality) education, employment, and housing" (p. 24). When states fail to address these socio-economic determinants of health, they are increasingly held legally accountable for that omission, such as in cases of violence against women,[xvii] or inter-sectional discrimination as seen in Alyne's case as a poor Afro-Brazilian woman trying to access maternity services. The Committee recognized that Alyne's marginal social status placed her in a vulnerable

sector of society regarding access to emergency health services. As a result, the Committee concluded that Alyne "was discriminated against, not only on the basis of her sex, but also on the basis of her status as a woman of African descent and her socio-economic background."[xviii]

The fact that Afro-Brazilian women are seven times more likely than white Brazilian women to die in pregnancy and childbirth[xix] categorizes them by their race. The health disparity between pregnant Afro-Brazilian women and pregnant white women generally provides objective evidence of injustice. In other words, health inequity refers to "health disparities between social groups categorized by some important feature of their underlying social position, *social health disparities* in short."[xx]

HARDENING OF HEALTH EQUITY NORMS

Health equity norms are slowly being elaborated for women and subgroups of women, but have implications for entire health care systems and for the elaboration of Gostin's proposed Framework Convention on Global Health (pp. 430, 435-9). In order to achieve equality in the field of health, states are now required to accommodate the sex-specific and distinctive essential health needs of women and address the socio-economic determinants of their health. Accommodation is therefore required not only for sex-distinctive health needs, but also for distinctive essential health care needs of other population subgroups.

The *Alyne* decision was greatly facilitated by the work of the World Health Organization (WHO) working in partnership with other UN agencies, professional bodies, such as the International Federation of Gynecology and Obstetrics, and international NGOs, such as Family Care International. This partnership, now called the Partnership for Maternal, Newborn and Child Health,[xxi] elaborated what are the "appropriate services in connection with pregnancy, confinement and the post-natal period…" through the publication of *Monitoring Emergency Obstetric Care: a Handbook*.[xxii] By referencing this WHO Handbook, the Committee set the legal standard for emergency obstetric care in order to solidify a set of regulations to which all countries are accountable. In essence, the Committee in the *Alyne* decision legitimized and legalized the WHO standard for emergency obstetric care.[xxiii]

The enunciation of norms might initially be undertaken through soft law instruments, then through their articulation in decisions of domestic courts and international human rights tribunals. Domestic courts often reference international human rights treaties for statement of principles of health equity. For example, the Constitutional Tribunal of Chile referenced the Women's Convention in prohibiting disproportionately higher fees for women's health care services than men's in the private health system because higher fees burden women's access and deny them equal access with men.[xxiv] That is, for health expenditure to be equitable, states are required to treat men and women based on their relative need for medical care, their relative situations or the incidence of ill-health or diseases in their populations.

Global Health Law enables us to understand the outline of global health with the transcending value of justice. How the details of that outline are filled in

will depend on further elaboration of notions of health equity for women and other distinctive health groups. This will be undertaken in different ways through the enunciation of soft and hard law norms, including a Framework Convention on Global Health, and through understanding what in fact health equity should provide to those who do not currently enjoy it.[xxv]

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[i] *Lawrence O. Gostin, Global Health Law* (Harvard University Press), 2014.
[ii] Gita Sen & Piroska Östlin (eds), *Gender Equity in Health: The Shifting Frontiers of Evidence and Action* (Routledge, 2010).
[iii] Margaret Whitehead, "The Concepts and Principles of Equity in Health", 22 *Int'l J. Health Services* 429 (1992) referenced in Joanna N. Erdman, "Human Rights in Health Equity: Cervical Cancer and HPV Vaccines" (2009) 35 *Journal of Law, Medicine and Ethics* 365-387 at 367.
[iv] Paula Braveman, "Health Disparities and Health Equity: Concepts and Measurement," *Annual Review of Public Health* 27(2006): 167-194.
[v] Braveman, *supra* note 4 at 168.
[vi] Rebecca Cook, Simone Cusack and Bernard Dickens, "Unethical Female Stereotyping in Reproductive Health" 109 (2010) *Int'l Journal of Gynecology and Obstetrics*, 255-258. *Available at:* http://www.law.utoronto.ca/programs-centres/programs/irshl-reproductive-and-sexual-health-law/irshl-ijgo-ethical-and-legal (last visited July 21, 2014).
[vii] Alicia Ely Yamin, "Applying Human Rights to Maternal Health: UN Technical Guidance on Rights-based Approaches" 121(2013) *Int'l Journal of Gynecology and Obstetrics*, 190-193. *Available at:* http://www.law.utoronto.ca/programs-centres/programs/irshl-reproductive-and-sexual-health-law/irshl-ijgo-ethical-and-legal (last visited July 21, 2014).
[viii] Erdman, *supra* note 3 *at* 367.
[ix] United Nations. *Report of the Committee on the Elimination of Discrimination against Women. General Recommendation 24 (Twentieth Session)*, A/54/38/Rev.1. (New York: United Nations, 1999). *Available at: http://www.un.org/womenwatch/daw/cedaw/recommendations/recomm.htm - recom24* (last visited July 21, 2014); Rebecca Cook and Veronica Undurraga, "Article 12 [Health]" in M. Freeman, C. Chinkin and B. Rudolf (eds.), *The UN Convention on the Elimination of All Forms of Discrimination against Women: A Commentary* (Oxford University Press, 2012) 311-333.
[x] Convention on the Elimination of All Forms of Discrimination Against Women, adopted December 18, 1979, G.A. Res. 34/180, UN GAOR, 34th Sess., Supp. No. 46, at 193, U.N. Doc. A/34/46, 1249 U.N.T.S. 13 (entered into force September 3, 1981) (ratified by Brazil Feb. 1, 1984) *Available at*: http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm (last visited July 21, 2014) [hereinafter the Convention].
[xi] *Alyne da Silva Pimentel Teixeira (deceased) v. Brazil*, CEDAW/C/49/D/17/ 2008, August 10, 2011. *Available at:* http://www.worldcourts.com/cedaw/eng/decisions/2011.07.25_da_Silva_Pimentel_v_Brazil.pdf (last visited July 21, 2014) [hereinafter cited as *Alyne*].
[xii] Rebecca Cook, "Human Rights and Maternal Health: Exploring the Effectiveness of the *Alyne* Decision," 41(1) (2013) *Journal of Law, Medicine and Ethics* 103-123.
[xiii] World Health Organization, *Trends in Maternal Mortality: 1990 to 2010: Estimates Developed by WHO, UNICEF, UNFPA and the World Bank* (Geneva: WHO, 2012), at 4 (footnotes omitted). *Available at:* http://www.unfpa.org/webdav/site/global/shared/documents/publications/2012/Trends_in_maternal_mortality_A4-1.pdfh (last visited July 21, 2014).
[xiv] *Alyne, supra* note 11, ¶7.6.
[xv] *Alyne, supra* note 11, ¶7.6, citing Article 12(2) of the Convention on the Elimination of All Forms of Discrimination against Women, *supra* note 10.

[xvi] *Alyne, supra* note 11, ¶7.6.
[xvii] United Nations. *Report of the Committee on the Elimination of Discrimination against Women. General Recommendation 19 (Eleventh Session)*, A/47/38 (New York: United Nations, 1992). *Available at: http://www.un.org/womenwatch/daw/cedaw/recommendations/recomm.htm - recom19* (last visited July 21, 2014).
[xviii] *Alyne, supra* note 11, ¶7.7.
[xix] Alaerte L. Martins, "Mortalidade materna de mulheres negras no Brasil [Maternal Mortality among Black Women in Brazil]," *Cadernos de Saúde Pública* 22, no. 11 (Nov. 2006): 2473-2479, at 2476. *Available at:*
http://www.scielo.br/scielo.php?script=sci_abstract&pid=S0102-311X2006001100022&lng=en&nrm=iso&tlng=en
(last visited July 21, 2014).
[xx] Erdman, *supra* note 3, at 367 (footnotes omitted) (emphasis in the original).
[xxi] Partnership for Maternal, Newborn and Child Health. Available at: http://www.who.int/pmnch/about/en/ (last visited July 21, 2014).
[xxii] World Health Organization et al., *Monitoring Emergency Obstetric Care: a Handbook*, Geneva, 2009, at 5-6, 26-39. *Available at:*
http://www.unfpa.org/webdav/site/global/shared/documents/publications/2009/obstetric_monitoring.pdf (last visited July 21, 2014).
[xxiii] Cook, *supra* note 12, at 15.
[xxiv] Tribunal Constitucional de Chile, Constitucionalidad del artículo 38 ter de la Ley Nº 18.933, Rol Nº 1710-10 Inc. (06/08/2010) paras 103, 155-156.
[xxv] João Biehl, "When People Come First: Beyond Technical and Theoretical Quick-Fixes in Global Health," in *When People Come First: Critical Studies in Global Health*, ed. João Biehl and Adriana Petryna (Princeton: Princeton University Press, 2013) 100-130; João Biehl, Joseph J. Amon, Mariana P. Socal, and Adriana Petryna, "Between the Court and the Clinic: Lawsuits for Medicines and the Right to Health in Brazil" 14.1 (2012) *Health and Human Rights: An International Journal* 1-17.

Understanding Brazil, China, and India's Response to Obesity and Diabetes: Proposing an Interdisciplinary Approach to Unifying International Relations Theory, Historical Institutionalism, and Policy-Making

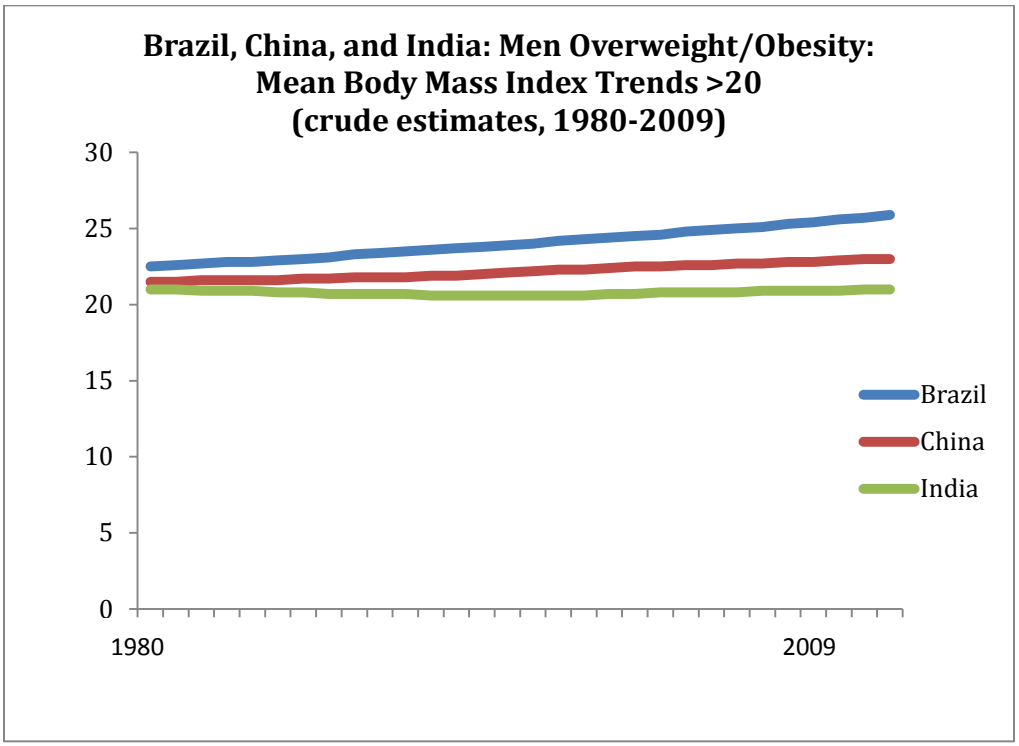
Eduardo J. Gómez

The emerging nations of Brazil, China, and India are currently facing the costly epidemics of obesity and type 2 diabetes. While similar in their pursuit of world prominence, these nations nevertheless varied in the timing and depth of their policy response. Brazil seemingly outpaced China and India in the area of prevention and especially with respect to the universal provision of diabetic medication. Through the introduction of an interdisciplinary theoretical approach combining different strands of international relations theory, it is argued that the Brazilian government's historic interest in simultaneously strengthening its international reputation in health, as well as the institutionalization of access to medicine as a human right, facilitated this more aggressive policy response. While China joined Brazil in having similar geopolitical aspirations, it never institutionalized universal access to medicine as a human right, thus failing to ensure type 2 diabetics with access to medicine. India, on the other hand, has never had these geopolitical aspirations or government commitments to the universal distribution of medication.

INTRODUCTION

Despite sharing similar interests in working together to increase their international political and economic influence, in recent years the emerging BRICS nations (Brazil, India, China, Russia, and South Africa) have differed in their response to health epidemics. Focusing on the cases of Brazil, China, and India, this article examines how these nations responded to obesity and type 2 diabetes, epidemics that have emerged because of these nations' fast-paced economic progress, changes in lifestyles and socioeconomic status. While these governments did not immediately respond, it seems that Brazil eventually outpaced China and India in its national prevention and treatment policies. This was especially the case when it came to providing medication for type 2 diabetes. In contrast to China and India, Brazil's government viewed this policy responsibility as a human right and began to universally distribute diabetic medication.

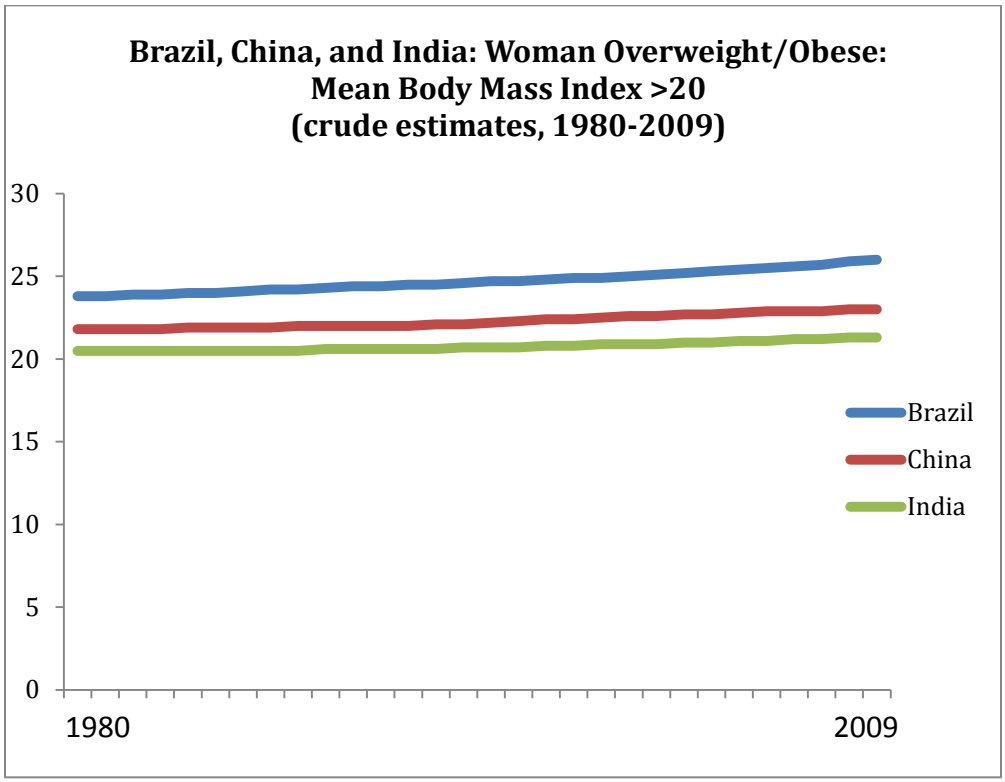
But why did Brazil outpace her emerging counterparts in this manner? When confronted with heightened international criticisms and pressures, by the late-1990s Brazil's political elites pursued a policy tradition that had a long historical precedent: that is, using health policy reform as a *means* to bolster the government's international reputation for having an effective public health system. Furthermore, Brazil established constitutional amendments guaranteeing access to medicine as a human right; this was the product of social health movements advocating these policy ideals while working within government to propose policies harboring these ideals. Yet, these conditions were not present in China and India.



Source: Gómez, 2013b; data obtained from WHO, 2013

Indeed, while China shared with Brazil similar international reputation-building interests and strategies, the government did not explicitly make the universal distribution of medication as a fundamental constitutional human right, thus, in turn, generating few incentives for the government to ensure that all diabetics had access to medication. India, on the other hand, has had no historical and thus contemporary interest in strategically using a heightened response to obesity and diabetes as a way to bolster the government's international reputation, nor has she had these other historical institutional precedents. Consequently, India's response to obesity and type 2 diabetes has been delayed and ineffective, especially with regards to prevention and the distribution of diabetes medicine.

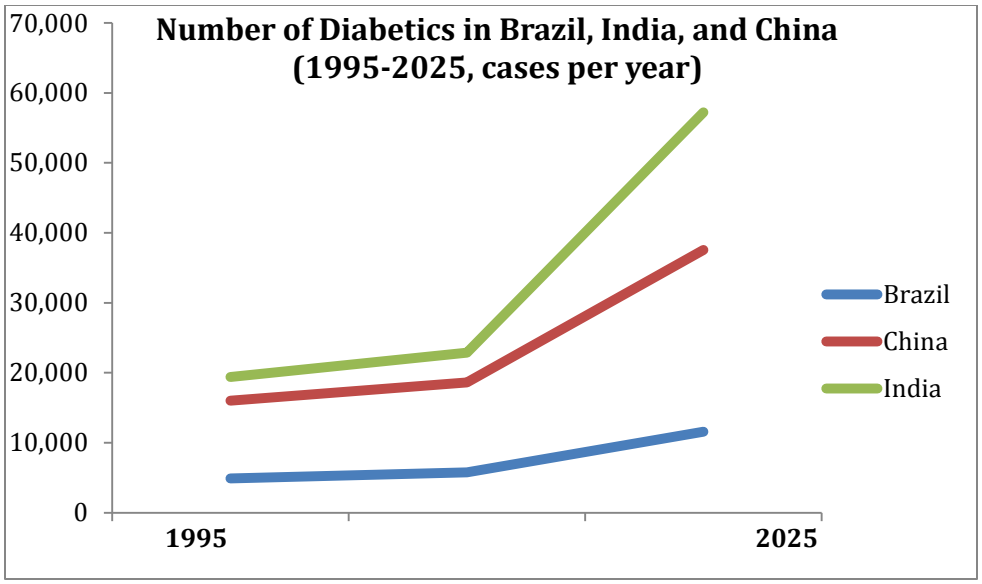
Thus with respect to my causal assertions, what was necessary for a strong policy response to emerge was the combined presence of historical interests in health policy reform as a means to international reputation building *as well as* the presence of a federal constitution explicitly mandating the provision of universal healthcare - especially medication - as a human right, both funded and distributed by the state. Both conditions are necessary because while international reputation building interests may kindle policy reforms, they do not necessarily guarantee that policies will be subsequently implemented; the latter requires that constitutions explicitly state the government's commitment to the universal distribution of medication, so that politicians can be held accountable and, therefore, have incentives to ensure their distribution. In Brazil, both of these causal conditions were present; nevertheless, only one of these conditions was present in China, i.e., health policy reform as a means to international reputation building; finally, both of these causal conditions were absent in India.



Source: Gómez, 2013b; data obtained from WHO, 2013

As seen in Brazil and China, despite the increased prevalence of obesity and type 2 diabetes, as well as the presence of concerned constituencies and civil societal pressures for a policy response, it seems that it was these governments' *international* geopolitical interests and incentives that were the primary catalyst for reform. Better understanding these incentives, as well as the timing and depth of government response, requires a more nuanced understanding of how the international community, its influence and pressures shaped domestic political calculations and policy response.

This article submits a theoretical framework that may help to establish a connection between the international and domestic politics of government response to obesity and type 2 diabetes. In contrast to the prevailing literature, it is argued that better understanding the timing and depth of government response to these epidemics requires that we combine the literature focusing on international health agency pressures and financial aid conditionalities with the literature discussing how nations strategically use health policy reform as a means to bolster their international reputation. By combining these previously isolated schools of thought, we may obtain new insights into why emerging nations exhibit radically different responses to similar types of health threats.



Source: Gómez, 2013b; King et al., 1998

METHODOLOGY

This article took a qualitative methodological approach to its comparative assessment of Brazil, China, and India. The data used to support the authors' causal claims was based on primary and secondary materials, such as peer-reviewed publications, books, research reports, as well as newspaper articles. The primary literature from China was made possible through the usage of on-line news database engines that translated Chinese newspaper articles, such as *Access World News* and *World News Connection*. The authors' fluency in the Portuguese and English language allowed for the citation of primary literature from Brazil and India, respectively. Epidemiological data on obesity and type 2 diabetes trends was also obtained from the World Health Organization's (WHO) on-line database systems.

As cited in the body of this article, qualitative interviews with individuals from non-governmental organizations (NGOs) in Brazil and India were also conducted; however, the author was not able to conduct interviews with NGO members in China. Each interview in Brazil and India was conducted for approximately 30 minutes, during the months of January and February 2013, and was based on identical interview questions. Interviewees were chosen based on their experience and not for their particular policy views. These interviews were conducted via *Skype* on-line telecommunications services.

But why focus on obesity and type 2 diabetes and not any other non-communicable disease, such as cancer, heart disease, and hypertension? Obesity and type 2 diabetes were chosen for the following reasons: First, research finds that there is a very close epidemiological association between obesity and type 2 diabetes, and that approximately 90% of all type 2 diabetic cases in the developing world can be attributed to obesity.[1] Second, while it is certainly true that cancer, hypertension, and heart disease are also associated with obesity, research suggests that the expected growth of obesity and type 2 diabetic cases will be much higher in the near future when compared to these other non-communicable diseases.[2]

The cases of Brazil, China, and India were selected for several reasons. First, the author was interested in examining the BRICS nations and their response to obesity and type 2 diabetes. However, of these nations it was only Brazil, China, and India that exhibited the highest levels of obesity and type 2 diabetic cases.[3] Second, the author choose these cases because of the rich availability of published articles and data on Brazil, India, and China's response to obesity and type 2 diabetes – something which could not be done for Russia and South Africa because these diseases have not yet reached epidemic proportions.

In terms of theory development, these cases of Brazil, China, and India were also selected in order to examine a newly proposed theoretical framework, which, as I explain in the next section, combines two schools of thought in the international relations literature. The goal was not to construct a generalizable claim pertaining to all cases in the world, but rather to evaluate and illustrate my proposed analytical framework's effectiveness with a small range of case studies – thus approximating what Ziblatt[4] refers to as a middle-range theoretical claim. Future research will need to include several more case studies as well as cross-national statistical analysis in order to examine the potential generalizability of my theoretical approach.

THE INTERNATIONAL POLITICS OF GOVERNMENT RESPONSE TO HEALTH EPIDEMICS

The international and domestic politics of responding to health epidemics is a new area of scholarly research. In this literature, the role of the international community in prompting a government response has been of interest. Those writing on this topic have often emphasized the role of international agencies, such as the WHO and the World Bank, and their efforts to directly pressure governments into adopting their health prevention and treatment policies.[5] [6] This is often achieved with the offering of loan packages with attached aid conditionalities as well as through acts of "socialization," where agency officials meet with country health officials, e.g., at conferences and board meetings, in order to persuade them into adopting their policies through the presentation of data.[7] Lieberman (2009),[8] Gómez (2012),[9] and Brown (et al. 2004)[10] claim that these pressure tactics have been instrumental in motivating governments to respond to AIDS, tuberculosis, and obesity.

Another area of research examines governments' interests in creating public health programs in order to increase their international reputation and influence through policy reform. Here, the literature has focused on governments creating bi-lateral health programs, such as financial and technical assistance to other nations for the provision of AIDS medication, funding for the construction of hospitals, labs, and healthcare workers, with the end goal of increasing a nation's image as a benevolent, caring actor. The United States, for example, has engaged in this process in order to rejuvenate its image and reputation in a context of post-war activities in Iraq and Afghanistan.[11] [12] China, others claim, has also engaged in these activities in order to increase its international reputation and geopolitical influence in Asia and other regions, such as Africa. [13] [14] [15]

Nevertheless, what is missing is an effort to *combine* this literature discussing international agency pressures with the literature emphasizing international reputation building in order to account for variation in *domestic* health policy reforms. As the cases of Brazil, China, and India will illustrate in this article, these two theoretical schools of

thought do not need to operate on their own: that is, international criticisms and pressures can prompt international reputation-building interests, which, in turn, motivates political leaders to refrain from focusing on providing international bi-lateral assistance and, instead, to strengthen their domestic bureaucratic and policy response to epidemics. This is especially the case when nations are concerned about their geopolitical position and importance in the world; when political leaders are interested in building their nation's international reputation for having an effective public health system – as a sign of modernity and development; and perhaps when leaders aspire to potentially lead the world in health policy innovation. But not all nations share these geopolitical aspirations. These differences in geopolitical aspirations are often shaped not be contemporary politics but rather by a nation's unique history in working with the international community in response to epidemics.

Indeed, one area of research that has not received sufficient scholarly attention is how a nation's preexisting history in global health diplomacy shapes contemporary political leaders' interest in engaging in international reputation-building pursuits. Several historical factors may account for these interests: 1) a nation's deep history in building an international reputation for having a modern, effective public health system; and 2) having a long history of multilateral cooperation in health; both conditions were present in Brazil and China. Conversely, when these conditions are absent, shaped by a nation's historic interest in being regional and/or global powers as well as isolationist and/or neutral in their geopolitical involvement, these interests will not emerge. As we will see in this article, such was the case in India – other studies suggest that Russia, South Africa, and the United States share similar traits.[16]

What follows is a case study analysis of Brazil, China, and India's response to obesity and type 2 diabetes. I close this study with some key lessons and future areas of research.

BRAZIL

The product of economic growth, trade, and migration, obesity emerged as an epidemic in Brazil during the 1990s.[17] The number of obese individuals increased from 11.4% in 2006 to 15.8% in 2011.[18] Type 2 diabetes also began to emerge as a consequence of overweight and obesity.[19] In 1980, 7.6% of the population aged between 30-69 had type 2 diabetes;[20] 4.9 million individuals would contract this disease by 1989, with a projected increase to 11.6 million by 2025.[21]

Despite being aware of these health threats, the government did not immediately respond. This inaction was mainly due to the government's preexisting commitment to healthcare decentralization as well as a fiscal recession, which limited funding for public health programs.[22] Despite this challenging context, the Congress worked with the Ministry of Health (MOH) to organize a conference addressing nutritional challenges, namely the National Congress of Nutrition (*No Congresso Nacional de Nutrição*). And in 1999, the MOH created the National Policy on Nutrition (*Política Nacional de Alimentação*, PNAN).[23] Through PNAN, the MOH was committed to working with schools to improve the provision of healthy foods, enhanced data reporting, as well as the promotion of healthy eating seminars and research.[24] However, at no point did the MOH and the Congress take concrete efforts to create and implement obesity and diabetes prevention and treatment policies.[25]

The international community responded to this lackluster policy response. By the early-2000s, pressures and criticisms began to emerge from the World Health Organization (WHO), followed by its publication of the *2004 Global Strategy on Diet, Physical Activity, and Health*.[26] In this report, the WHO noted Brazil's (as well as several other nations') unwillingness to respond to obesity and type 2 diabetes while providing several policy suggestions - such as a snack tax and the regulation of fatty foods.[27]

Brazil's president responded positively to these allegations. Seeking to increase the government's international reputation for being able to effectively respond to obesity, in 2010 President Luiz Ignacio "Lula" da Silva worked with congressional lawmakers to implement the National Plan of Strategic Action in Response to Non-Communicable Chronic Diseases (*Plano de Ações Estratégicas para o Enfrentamento das Doenças Crônicas Não Transmissíveis* – DNST). This policy seeks to increase the Congress's funding for obesity awareness campaigns, while establishing policy blueprints for the next 10 years. These policy efforts were followed up with the Health Program for Schools (*Programa Saúde nas Escolas* – PSE), which was created in 2007 by the MOH. Through the PSE, the MOH provides financial and technical support to schools for monitoring children's weight, as well as nutritional and physical fitness classes. The Program of Direct Money to Schools (*Programa Dinheiro Direto na Escola* – PDDE) was also created in 2009; this initiative provides money to schools to purchase healthier foods, primarily from farmers. Nevertheless, this financial assistance was conditional, based on schools' commitment and revelation that they were purchasing foods from local farmers.

But the government also implemented new policy initiatives for diabetes in response to increased international criticisms and pressures. In 2001, for example, the MOH created a National Diabetes Plan, which worked with the medical community and patients to begin discussions, held through national health participatory councils (CONASS, *Conselho Nacional de Secretários de Saúde*) and municipal health participatory councils (CONASEMS, *Conselho Nacional de Secretarias Municipais de Saúde*), about how to respond to type 2 diabetes.[28] The National Plan mainly sought to establish policy responsibilities between levels of government as well as to establish a national registry of type 2 diabetic patients.[29] [30] The MOH also created a federal campaign to monitor and report all new type 2 cases.[31] In 2001, the National Program of Diabetes Education and Control (PECD) was also implemented. Through the PECD, the MOH established local diabetes clinics and medical support – known as "diabetic teams" - through public university hospitals.[32]

But the MOH was also fully committed to providing medication for type 2 diabetes. Building on the government's constitutionally guaranteed tenants of providing universal healthcare as a human right, the MOH committed itself to freely distributing all type 2 diabetic medication, such as oral *metformin* and *glibenclamide* pills, and supplies, such as needle pens, for free at local clinics and pharmacies.[33] Medicines are distributed through the MOH's *Política Nacional de Assistência Farmacêutica*, *Programa Farmácia Popular*, at local clinics and pharmacies throughout the decentralized SUS (*Sistema Único de Saúde*, Unifed Health System) healthcare system. In 2012, approximately 13.8 million individuals received free diabetic medication.[34] Recine and Vasconcellos (2011)[35] claim that the MOH views the universal distribution of diabetic medication as a "human right," deemed an "essential medicine," a view that is

also held for antiretroviral (ARV) medications for HIV/AIDS. Gómez (2013)[36] writes that in 2007, out of a total estimated cost of U$747,000 per 1,000 individuals, 75.4% of these expenses were paid for by the MOH (i.e., approximately US$563,506). The rest were out of pocket expenditures at private hospitals.[37]

But why did the government suddenly respond to the rise of international criticisms and pressures? And why was the government so committed to universally distributing diabetic medication? Answering these questions requires a look at the historical record.

Brazil has a long tradition of engaging the international community in global health. Since the early 1900s, medical scientists traveled throughout the world to discuss Brazil's medical breakthroughs, engaging in collaborative research, while working with Brazilian government officials to invest in public health infrastructure.[38] During this period, health officials established a tradition of strategically using domestic health policy as a means to increase its international reputation, as a nation capable of eradicating disease and developing.[39] Beginning under the Getúlio Vargas administration (1930-45), moreover, the government established a tradition of working in close partnership with other nations in order to create multilateral health agencies, such as the World Health Organization (WHO) and the Pan American Health Organization (PAHO).[40] But the Brazilian government also worked closely with other nations to establish the United Nations (UN)[41] and the UN Security Council, efforts that helped to ensure that there was peaceful multilateral cooperation between nations.[42] [43]

By the late-1980s, when international criticisms and pressures surrounding Brazil's delayed response to AIDS surfaced, the government followed historical precedent by once again strengthening its health policy response; it did so in order to bolster its international reputation as a state capable of eradicating disease.[44] The goal was to show the world that the government had the scientific and infrastructural wherewithal needed to curtail AIDS' spread, thus joining other advanced industrialized nations in achieving the same.[45] Inspired by its principles of providing universal healthcare as a human right, during this period the MOH also worked with other nations to guarantee access to essential medicines, such as ARV medications, through the 2003 Doha declaration, which stated that developing nations had the right to produce generic versions of medication in times of health crisis.[46]

The government's commitment to universally distributing diabetic medication also stemmed from its preexisting constitutional commitment to providing universal healthcare and medications as a human right.[47] Drafted into the 1988 democratic constitution, this principle and policy commitment was the product of social health movements, such as the *sanitarista*[1] movement, and its gradual infiltration of the public health bureaucracy.[48] But it is important to note that the 1988 constitution essentially forced the MOH to distribute diabetic medications, free of charge. Anything otherwise could have led to lawsuits, as seen with citizens' complaints regarding reliable access to ARV medications.[49]

But the federal government was not the only actor responding to obesity and type 2 diabetes. Civil society also responded. As Gómez (2013)[50] maintains, the social health movements in response to type 2 diabetes has a long tradition in Brazil, dating back to

[1] Organized during the 1960s, the *sanitaristas* were a pro-democratic, leftist group of medical doctors, academics, volunteers, and politicians committed to increased equality in access to healthcare as a human right; they also advocated for a decentralized, community based approach to healthcare.

the early-20th century. Gómez (2013)[51] also notes that beginning in the 1940s, mainly in Rio de Janeiro, healthcare workers, activists, doctors, and community members came together to form the Brazilian Diabetes Society (*Sociedade Brasileira de Diabetes* - SBD). This was done in order to increase civil societal awareness of diabetes, as well as increasing the government's interest in a more aggressive policy response.[52] Each year, the SBD organizes bi-annual conferences in several cities. With a membership of approximately 3,000 members, the SBD is also well funded from voluntary contributions.[53] SBD leaders consistently meet with other SBD members in other states, local health officials, visit hospital clinics and community based organizations in order to provide information as well as prevention and treatment services.[54] But the SBD has also worked hard to increase awareness about obesity, working with local health officials and volunteer groups to provide information about nutrition, diet, and exercise.[55] Nevertheless, when compared to the diabetes SBD movement, the obesity movement is new, not very well organized and therefore not as effective in its ability to collectively pressure the government for a policy response.[56]

CHINA

In China, the obesity epidemic emerged as product of fast paced economic growth, the influx of processed, cheap foods, urbanization, and increased sedentary lifestyles.[57] Similar to what was seen in the United States and in Brazil, obesity has also affected children.[58] Approximately 8% of children in urban centers are obese; in Beijing alone, for example, 40% are said to be overweight and obese.[59]

Type 2 diabetes has also increased in recent years and has mainly been attributed to the rise of obesity cases.[60] While in 1980 only 1% of the population had this disease, this number increased to approximately 11.6% in 2010,[61] [62] while the prevalence of the pre-diabetic population was estimated at 50.1% in 2013.[63] Today there are an estimated 92.3 million type 2 diabetics in China, which is approximately four times the amount in the United States.[64] In addition to contributing to escalating deaths due to kidney failure, cardiovascular disease and heart attacks, this disease has also emerged among children and could lead to similar health threats.[65] What's more, the economic costs associated with type 2 diabetes are expected to burgeon: $US 558 billion in national income over the next 10 years, accounting for 14% of total healthcare expenditures.[66] Alcorn and Ouyang (2012)[67] claim that in 2010, 13% of government healthcare expenditures, approximately $US25 billion, was due to type 2 diabetes.

Despite this growing health threat, China's government did not immediately respond to obesity and diabetes. On one hand, in a historical context of poverty and malnourishment, obesity, especially among children, was perceived as a positive health condition, as it connoted a sign of good health and prosperity.[68] On the other hand, the MOH was not convinced that these diseases were riddled throughout the nation, and that they were mainly found among the higher socioeconomic classes, who could afford to take care of themselves.[69]

Similar to Brazil, however, the international community criticized China's lack of response. For example, the aforementioned 2004 WHO *Global Strategy Report* claimed that China joined India in having the highest level of type 2 diabetes cases in the world, and that overweight and obesity was steadily rising.[70] These criticisms in fact piggy-backed off of prior WHO country assessments based on conferences that were held in

China during 2001.[71] Gómez (2013)[72] also maintains that a Beijing AFP newspaper claimed that the WHO criticized and pressured the government to escalate its response to obesity and diabetes,[73] while a myriad of media outlets, such as the *The Guardian* and the *BBC*, also contributed to these criticisms.

Seeking to bolster its international reputation as a nation having the medical and infrastructural capacity needed to curtail the spread of disease, China positively responded to these criticisms and pressures. Beijing wanted to show the world that it was a modern state, capable of safeguarding its citizens and the economy from a health crisis.[74]

Similar to what we saw in Brazil, however, it is important to note that China has a long tradition of building its international reputation in health. Historians have depicted China as a "self-conscious" rising power, incessantly worried about its international reputation.[75] The government was so committed to boosting its global image that in 1980, it created the State Information Office.[76] Moreover, engaging in global health diplomacy, mainly by way of providing bilateral assistance, was viewed as a means to increase China's geopolitical influence and reputation as a benevolent actor.[77]

Similar to what the government did in response to SARS and HIV/AIDS during the 1990s,[78] [79] the Ministry of Health sought to strengthen its policy response to obesity and type 2 diabetes in order to bolster its international reputation. The response to SARS and AIDS set in motion a government interest and incentive to view responding to health epidemics as an opportunity to bolster China's image as a nation that was capable of eradicating disease and developing. Aggressively responding to obesity and diabetes provided yet another opportunity to achieve this.

By the mid-2000s, after years of policy inaction, the government heightened its commitment to responding to obesity and type 2 diabetes. Although there was a *National Plan to Prevent and Control Diabetes and Cardiovascular Diseases,* which was established as early as 1996, in 2010 the State Council authorized the creation of the *National Health Plan for the Promotion of Diabetes Management*.[80] This program was established in order to increase public awareness as well as to establish a multimedia campaign.[81]

Responding to obesity also became a priority. In 2005, new federal laws were enacted emphasizing public awareness about the importance of sound nutrition, food regulations, as well as better quality foods served in public schools.[82] In 2006, the State Council also created the *Sunshine Physical Education Policy*.[83] This initiative required that every student master at least 2 different types of physical education classes.[84] In 2008, the State Council also mandated that every student had to run for one hour in the morning,[85] while in 2010 the MOH enacted the *Regulation to Improve Nutrition*, which sought to monitor nutrition-related diseases as well as periodic reports.[86]

But the government was not committed to ensuring the universal distribution of diabetes medication. In contrast to what we saw in Brazil, type 2 diabetics are increasingly lacking access to insulin and pills.[87] This is especially the case in hard to reach rural areas.[88] According to,[89] approximately 50% of type 2 diabetics also do not have access to clinics where they can periodically take A1C tests (which measures sugar glucose levels in the blood). These areas also lack adequate medical staff to provide healthcare services as well as screening. In response, in 2010, the MOH established a 3-year pilot program to train doctors, nurses, and healthcare workers on how to more effectively screen and treat type 2 diabetic patients.[90]

What's more, the MOH has not provided assistance to the states to fund obesity prevention programs, such as providing grants to schools for the acquisition of more nutritious foods.[91] The municipal governments have borne the brunt of preventative policy expenditures. In Beijing, for example, the municipality raised funds to construct new school gymnasiums.[92]

When compared to Brazil, why was China not as committed to responding to obesity and diabetes, especially with regards to access to medicine? One must look into the past to answer this question.

First, the principle of providing universal access to medication as a human right was never incorporated into the federal constitution. While Article 21 of the Constitution does claim that it is the state's responsibility to protect the general public's health, specifically to "promote modern medicine and traditional Chinese medicine," to "promote health and sanitation," … "all for the protection of the people's health,"[93] it does not explicitly state that the government will, by law, both guarantee the funding and distribution of medicines to all citizens in need – as is the case in Brazil. As a result, politicians never had any reason to ensure that diabetes medication could be universally distributed, while having no fear of lawsuits should the government renege on its commitments. As Huang (2006)[94] asserts, the MOH has behaved in a similar manner when it comes to providing antiretroviral (ARV) medication for HIV/AIDS.

Second, and in further contrast to Brazil, historically there were also no aggressive social health movements or NGOs pressuring the government to create federal public health institutions and policies in response to disease, as well as engaging in partnerships with health officials.[95] Civil society's response to disease was often isolated at the community level; doctors and nurses neither complained nor asked the center for assistance.[96] This was mainly done out of respect to the state, stemming from Confucius principles of duty and obligation.[97]

Not only did this history complicate civil society's response to epidemics such as HIV/AIDS and tuberculosis, but it also posed a challenge for non-communicable diseases, such as obesity and type 2 diabetes. The health movements and civic organizational initiatives that exist act independently of the state. While no civil societal efforts have been made to address obesity, there does exist a *Chinese Diabetes Society* (a constituent body of the Chinese Medical Association).[98] However, while conducting research and helping increase awareness,[99] some maintain that this organization is controlled by the government and is thus politically manipulated.[100] Alternatively, the *Beijing Diabetes Prevention Association* was created in 1996.[101] While this organization seeks to address discrimination in schools and in the work place, it has never pressured the Ministry of Health to strengthen its policy response to type 2 diabetes, nor has it ever worked in partnership with health officials.[102] Thus the historical legacy of civil society neglecting to pressure and/or work with the state continues to ring true.

INDIA

By the 1990s, India also joined Brazil and China in witnessing a heightened level of obesity and type 2 diabetes cases. These diseases have emerged because of the introduction of western diets, increased sedentary life styles, urban migration, as well as the emergence of cheap, fatty foods in urban and rural areas.[103] [104]By 2009,

approximately 58% of the urban population was obese, while 31% of obese cases spread out to rural areas.[105]

As we saw in Brazil and China, overweight and obesity has also triggered a steady rise in type 2 diabetic cases.[106] A total of 37.6 million type 2 diabetics were registered in 2004,[107] rising to 41 million in 2007.[108] The number of type 2 diabetics is projected to increase to approximately 80.9 million by 2030.[109] Siegel (et al., 2008)[110] claims that from 1971 to 2000, the number of people with this disease in urban municipalities heightened from 1.2% to 12.1%, increasing from 2.4% to 6.4% in rural areas over a time span of 14 years.[111] What's more, the medical costs of treating type 2 averaged about $2.2 billion,[112] thus posing a potentially serious burden on the economy.

Despite the government's realization of these growing health problems, the government did not respond. The opinion within government was that these diseases were brought on by new affluent lifestyles, the growing middle- and upper classes.[113] In other words, they were perceived as "diseases of luxury."[114] [115] Politicians and MOH officials reasoned that the biggest nutritional challenge was malnutrition, and that the state needed to address not only this ongoing health problem but also the myriad of diseases found throughout India.

Because of the government's apathy towards rising obesity and type 2 diabetic cases, it joined Brazil and China in being subject to international criticisms and pressures. In 2004, through its aforementioned *Global Strategy* report the WHO singled out India as having the highest level of type 2 diabetes cases in the world, while also highlighting its growing overweight and obesity problem – especially among children.[116] Despite the WHO's release of detailed policy suggestions on how to combat these diseases, such as imposing a sugar tax and regulating the fast food industry, India's Ministry of Health & Social Welfare (MHSW) officials essentially ignored these recommendations.[117] MHSW officials were also critical of the WHO's policies, believing that they could have contributed to a decline in the efficacy of its human labor force as sugary foods were needed in order to supply energy for the working poor. The WHO's remarks were followed up with several criticisms in the media and academic publications, such as in the prestigious *Lancet* and *Nature Medicine* journals, both of which alluded to India's escalating diabetic and obesity problem.[118] [119]

India's defensive response to the WHO unmasked its apathy towards bolstering its international reputation. In contrast to Brazil and China, India's politicians and MHSW officials were far from interested in strengthening their policy response to obesity and type 2 diabetes in order to achieve this geopolitical objective.[120]

But why did the government behave in this manner? As an emerging power, one would assume that India would have joined Brazil and China in striving to enhance its international reputation as a modern state, unwaveringly committed to eradicating disease and developing.

In essence, this response stemmed from India's diplomatic history. Beginning with Prime Minister Jawaharlal Nehru (1947-1964), the government's apathy in building its international reputation derived from its perception of viewing itself as a world power.[121] As such, government officials never believed that they needed to reveal their developmental potential, learn from other nations, or adopt policy proscriptions[122]- especially from western imperial powers.[123] Nehru's foreign policy objective was to strengthen India's sense of autonomy and independence, while taking a neutral stance in international politic.[124] [125] Because of these foreign policy views, the

government never believed in creating aggressive health policy measures in order to bolster its international reputation in health.[126]

Nehru's foreign policy stance was happily adopted by subsequent political leaders. Prime Minister Indira Gandhi (1966-77, 1980-84), Nehru's very own daughter, as well as Indira's son, Prime Minister Rajiv Gandhi (1984-1989), adopted Nehru's views of India's global power status and sovereignty.[127]

By the time the AIDS epidemic emerged, the inculcation of Nehru's foreign policy objectives generated little interest in escalating the government's policy response in order to bolster its international reputation. This was particularly the case for obesity and type 2 diabetes, creating few incentives to escalate the MHSW's policy response.

For instance, when it came to responding to obesity, there were no efforts to create national prevention programs. The closest the MHSW came was the publication of a report revealing the government's commitment to closely monitoring the number of overweight and obese, as well as high at-risk groups.[128] By 2008, the Ministry of Woman & Children's Development (MWCD) introduced a nutritional program that focused on better diet and exercise for women and children.[129] However, no efforts were made to provide grants in aid to the states for the provision of better foods in schools, the construction of parks, classes, and community based activities.[130]

Type 2 diabetes also received scant attention. While the MHSW did conduct surveys monitoring the spread of type 2 diabetes,[131] no formal prevention and treatment policies were implemented.[132] In 2005, however, the MHSW did try to work with the states in providing screening, treatment for diabetes, as well as preventative information through the creation of the *National Rural Health Mission*; yet subsequent research found that this program was ineffective, acting as if it were still in its "draft stages."[133]

In 2005, the *Indian Council for Medical Research* (ICMR) and the WHO did succeed in providing new policy guidelines and recommendations for living with diabetes.[134] And in 2008, the MHSW enacted a pilot program called the *Program for the Prevention and Control of Diabetes, Cardiovascular Disease, and Stroke* (World Health Organization, 2009). Pundits nevertheless claim that once again, the ICMR and the *Program for the Prevention and Control of Diabetes* have not done a good job of collecting data, monitoring diabetes' spread and providing preventative information.[135] In essence, institutions and policies exist, but there is little political will to implement them.

But by far the greatest limitation to the Indian government's response to type 2 diabetes has been its unwillingness to universally distribute medication. In sharp contrast to what was seen in Brazil, the MHSW has not ensured that type 2 diabetics can get access to insulin and oral medications.[136] Essentially, medicine is only available for the middle- and upper-income classes who can purchase insulin, needles, and oral pills from pharmacies and clinics. What is even more perplexing is the MSHW's official claim that diabetic medications are an "essential medicine."[137] There is, therefore, a rather sizable gap between policy rhetoric and action. This is especially surprising in light of the MHSW's efforts to work with Brazil, South Africa, Thailand, and other developing nations to secure access to ARV medication for AIDS, as seen with the 2003 Doha declaration.

Gómez (2013)[138] maintains that because of the MHSW's unwillingness to distribute medications, patients bare most of the costs.[139] It costs approximately RS 7,159 rupees per person each year to obtain type 2 diabetes medications at pharmacies

and clinics.[140] What's more, according to *The Economist* (2007),[141] because of the exorbitant costs, healthcare care insurance providers have become increasingly reluctant to cover diabetes medications and A1C tests.

But what explains the government's reluctance to join Brazil in ensuring that citizens have access to diabetes medication? It seems that the absence of universally distributing medications as a human right shaped the government's response.[142] Indeed, and in contrast to what we saw in Brazil, there never existed a social health movement and/or politicians seeking to create federal laws and/or constitutional amendments requiring that the government provide universal access to medicine. It has only been recently that the government has considered introducing a universal healthcare system.[143] But without a binding legal commitment to distributing medication, the MHSW has no incentive to ensure that type 2 diabetics receive the medicine and treatment that they need.

Civil society has also responded, but to a limited extent. While efforts have been made to collectively organize, NGOs such as the Diabetes Care Foundation and the Heinz Nutrition Foundation of India (which focuses on obesity) have worked in isolation, failing to create a close, cooperative partnership with the MHSW. Most of the NGOs working on diabetes have also been located in major cities, such as Delhi and Mumbai,[144] not in rural areas, where these diseases are beginning to emerge. Despite their efforts to pressure the MHSW to respond to obesity and diabetes, these NGOs are often ignored and/or not taken seriously.[145] At the same time, the MHSW has never provided financial support to NGOs.[146] If anything, NGOs get to use the MHSW's official name and logo, which helps to attract attention and provide credibility.[147] Sans government funding, however, NGOs have had to rely on individual contributions, which is an unreliable source of revenue.[148] This has further complicated efforts to monitor diabetes, provide treatment, and counseling.[149]

But it seems that civil society is also to blame. For there has been no effort to create a unified response between NGOs working on obesity and diabetes. Instead, there is a great deal of competition and tension between these organizations, as they are often vying for attention and voluntary contributions.[150] This has further hampered civil society's role in combating the obesity and type 2 diabetes epidemic.

CONCLUSION

The politics of government response to obesity and type 2 diabetes is a new area of scholarly research. This article has been an exploration into unraveling the international and domestic political and historical factors motivating nations to respond to these epidemics. Our comparative analysis of Brazil, China, and India suggests that the prevalence of these diseases, the growing death toll associated with them as well as civil societal pressures do not motivate governments to immediately respond. Instead, a nation's interest in positively responding to international criticisms and pressures in order to establish their international reputation in health appears to be a more important motivational factor.

This was certainly the case in Brazil and China, though not in India. Furthermore, these differences in geopolitical aspirations and incentives were shaped not by contemporary political interests but by historical institutional legacies of strategically using health policy reform as a *means* to bolster the government's

international reputation, revealing to the world that Brazil and China could overcome the peril of disease and develop. Historically, India had no such aspirations. Consequently, when international criticisms and pressures emerged, no efforts were made to escalate the government's response to obesity and type 2 diabetes.

History, therefore, mattered. Future researchers will need to consider to what extent a nation's history in global health diplomacy shapes their contemporary geopolitical interests in pursuing domestic health policy reforms. This is an unchartered area of research that seems to provide additional insight into why and how politicians suddenly decide to strengthen their response to previously ignored diseases – such as obesity and diabetes.

Analyzing Brazil, China, and India's response to obesity and type 2 diabetes has also revealed the theoretical utility of unifying the literature focusing on the impact of international pressures for health policy reform, on one hand, with the literature emphasizing the creation of health policy as a means to international reputation-building and influence, on the other. A literature that has traditionally been treated as separate and distinct, I have argued that unifying these schools of thought provides new insight into explaining differences in the political incentives, timing, and depth of government response to obesity and diabetes. My combined approach also seems to suggest that geopolitical factors and politicians' interests in pleasing the international community takes precedence over placating domestic interest groups.

This political calculation may nevertheless be unique for the aspiring emerging nations. Brazil, China, and India, as well as South Africa and Russia, have aspired to show the world that they are emerging powers, joining the industrialized world in their economic growth and influence. Whether it is health or economic policy, in contrast to lesser-developed nations, these nations have strived to appease the international community in order to shape other nations' perception and expectations that they will have international influence. Future research will need to examine if these geopolitical calculations are present in other lesser developed and/or the recently emerging economies, such as Colombia, Mexico, Turkey, Singapore, and Indonesia.

Finally, yet another lesson that emerged from our comparison of Brazil, China, and India was not only the importance of a nation's long history of federal intervention to combat epidemics, but also the historical institutionalization of the principle of access to medicine as a human right. As seen in Brazil, this was brought about through the gradual infiltration of social health movements proffering this policy principle into the health bureaucracy. When compared to each other, Brazil was the only nation to exhibit this process, in turn helping to explain why its political leaders were so committed to creating legislation for obesity and diabetes, as well as why they have viewed the universal distribution of diabetic medication as a human right. This approach therefore helps to explain not only the motivation for universally distributing medication and why these nations varied in these efforts, but also why politicians eventually developed an interest in distributing medicines for diseases that were previously ignored and highly contested.

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[1] H. Parvez, B. Kawar, and M. el Nahas, "Obesity and Diabetes in the Developing World – A Growing Challenge", *New England Journal of Medicine,* 356 (2007): 213-215.

[2] R. McKie, "Diabetes Epidemic Affecting 350m – and Western Fast Food is to Blame", *The Guardian*, June 25 (2011); on-line: http://www.guardian.co.uk/society/2011/jun/25/diabetes-epidemic-western-fast-food; accessed on September 27, 2014.

[3] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).

[4] D. Ziblat, "Of Course Generalize, but How? Returning to Middle Range Theory in Comparative Politics" (Forum on Middle Range Theory), *American Political Science Association, Comparative Politics Newsletter*, Vol. 17, No. 2 (2006).

[5] E. Lieberman, *Boundaries of Contagion: How Ethnic Politics have Shaped Government Response to AIDS* (Princeton: Princeton University Press, 2009).

[6] J. Brown, D. Ayvalikli, N. Mohammad, *Turning Bureaucrats into Warriors: Preparing and Implementing Multi-sector HIV-AIDS Programs in Africa* (Washington, DC: The World Bank Group, 2004).

[7] E. Lieberman, *Boundaries of Contagion: How Ethnic Politics have Shaped Government Response to AIDS* (Princeton: Princeton University Press, 2009).

[8] E. Lieberman, *Boundaries of Contagion: How Ethnic Politics have Shaped Government Response to AIDS* (Princeton: Princeton University Press, 2009).

[9] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).

[10] J. Brown, D. Ayvalikli, N. Mohammad, *Turning Bureaucrats into Warriors: Preparing and Implementing Multi-sector HIV-AIDS Programs in Africa* (Washington, DC: The World Bank Group, 2004).

[11] H. Feldbaum, and J. Michaud, "Health Diplomacy and the Enduring Relevance of Foreign Policy Interests", *PLoS Medicine*, 1-6 (2010).

[12] H. Feldbaum, K Lee, and J. Michaud, "Global Health and Foreign Policy", *Epidemiol Rev* 32 (2010): 82-92.

[13] Y. Huang, "Pursuing Health as a Foreign Policy: The Case of China", *Indiana Journal of Global Legal Studies* 17(1) (2010): 105-46.

[14] Y. Huang, *Enter the Dragon and the Elephant: China's and India's Participation in Global Health Governance* (New York: Council on Foreign Relations, 2013).

[15] L. Chan, L. Chen, and J. Xu, "China's Engagement with Global Health Diplomacy: Was SARS a Watershed?" *PLoS Medicine* 7(4) (2010): e1000266.

[16] E. Gómez, *De-Emerging Nations? The BRICS' Struggle to Eradicate Disease*. King's College London (unpublished book manuscript, 2014).

[17] E. Gómez, "Tackling Brazil's Obesity Problem" *America's Quarterly*, June 27 (2012); accessed on September 27, 2014.

[18] E. Gómez, "Tackling Brazil's Obesity Problem" *America's Quarterly*, June 27 (2012); accessed on September 27, 2014.

[19] M. Torquato, R. Montenegro Junior, L. Viana, R. Gonçalves de Souza, C. Lanna, J. Lucas, C. Bidurin, and M. Foss," Prevalência de diabetes mellitus e intolerância a glucose na população urbana de 30 a 69 anos em Ribeirão Preto (SP) – Brasil", *Sao Paulo Medical Journal* 121(2003): 224-230.

[20] L. Bahia, D. Araujo, B. Schaan, S. Dib, C. Negrato, M. Leão, A. Ramos, A. Forti, M. Gomes, M. Foss, R. Monteiro, D. Sartorelli, and L. Franco, "The Costs of Type 2 Diabetes Mellitus Outpatient Care in the Brazilian Public Health System", *Value in Health* 14(2011): S137-S140.

[21] S. Barreto, V. Passos, S. Almeida, and T. Assis, "The Increase of Diabetes Mortality Burden among Brazilian Adults", *Pan American Journal of Public Health* 22(2007): 239-245.

[22] E. Gómez, "A Temporal Analytical Approach to Decentralization Processes: Lessons from Brazil's Health Sector Reforms", *Journal of Health Politics, Policy & Law* 33(2008): 53-91.

[23] C. Reis, I. Vasconcelos, and J. Barros, "Políticas Públicas de Nutrição para o Controle da Obesidade Infantile", *Rev Paul Padiatr* 29(2011): 625-33.

[24] C. Reis, I. Vasconcelos, and J. Barros, "Políticas Públicas de Nutrição para o Controle da Obesidade Infantile", *Rev Paul Padiatr* 29(2011): 625-33.
[25] E. Gómez, "Tackling Brazil's Obesity Problem" *America's Quarterly*, June 27 (2012); accessed on September 27, 2014.
[26] World Health Organization. 2004. *Global Strategy on Diet, Physical Activity, and Health*. Geneva: World Health Organization.
[27] World Health Organization. 2004. *Global Strategy on Diet, Physical Activity, and Health*. Geneva: World Health Organization.
[28] M. Onofrio, *Public Health Policy in Brazil & Mexico: Changing Problems – Common Solutions?* Masters Thesis, Department of History, International and Social Studies, Aalborg University, 2010.
[29] M. Onofrio, *Public Health Policy in Brazil & Mexico: Changing Problems – Common Solutions?* Masters Thesis, Department of History, International and Social Studies, Aalborg University, 2010.
[30] H. Pedrosa, "Diabetes Care in Brazil: Now and in the Future", *Practical Diabetes* 21(2004): 86-87.
[31] L. Nucci, C. Toscano, A. Maia, C. Fonseca, M. Britto, B. Duncan, and M. Schmidt, "A Nationwide Population Screening Program for Diabetes in Brazil," *Pan American Journal of Public Health* 15(2004): 320-327.
[32] H. Pedrosa, "Diabetes Care in Brazil: Now and in the Future", *Practical Diabetes* 21(2004): 86-87.
[33] H. Pedrosa, "Diabetes Care in Brazil: Now and in the Future", *Practical Diabetes* 21(2004): 86-87.
[34] Brazil, Ministry of Health, "Medicamentos gratuitos também podem ser retirados com prescrição de medicos particulares," *Portal Brasil*, January 2 (2013); on-line news available at: http://www.brasil.gov.br/noticias/arquivos/2013/02/01/medicamentos-gratuitos-tambem-podem-ser-retirados-com-prescricao-de-medicos-particulares; accessed September 28, 2014.
[35] E. Recine and A. Vasconcellos, "Políticas nacionais e o campo da Alimentação e Nutrição em Saúde Coletiva: cenário atual," *Ciência & Saúde Coletiva* 16(2011):73-78.
[36] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).
[37] L. Bahia, D. Araujo, B. Schaan, S. Dib, C. Negrato, M. Leão, A. Ramos, A. Forti, M. Gomes, M. Foss, R. Monteiro, D. Sartorelli, and L. Franco, "The Costs of Type 2 Diabetes Mellitus Outpatient Care in the Brazilian Public Health System", *Value in Health* 14(2011): S137-S140.
[38] G. Hochman, *A Era do Saneamento: As Bases da Política de Saúde Pública no Brasil* (São Paulo, Brazil: Editora Hucitec-Anpocs, 1988).
[39] E. Garcia, *O Sexto Membro Permanente o Brasil e a Criação da ONU* (Rio: Contraponto Editora Ltda, 2012).
[40] A. Cervo, *Inserção Internacional: Formação dos Conceitos Braseleiros* (São Paulo, Brazil: Editora Saraiva, 2011).
[41] E. Garcia, *O Sexto Membro Permanente o Brasil e a Criação da ONU* (Rio: Contraponto Editora Ltda, 2012).
[42] A. Cervo, *Inserção Internacional: Formação dos Conceitos Braseleiros* (São Paulo, Brazil: Editora Saraiva, 2011).
[43] E. Garcia, *O Sexto Membro Permanente o Brasil e a Criação da ONU* (Rio: Contraponto Editora Ltda, 2012).
[44] E. Gómez, *De-Emerging Nations? The BRICS' Struggle to Eradicate Disease*. King's College London (unpublished book manuscript, 2014).
[45] E. Gómez, *De-Emerging Nations? The BRICS' Struggle to Eradicate Disease*. King's College London (unpublished book manuscript, 2014).
[46] P. Teixeira. 2003, "Universal Access to AIDS Medicines: The Brazilian Experience", *Divulgacão em Saúde para Debate,* 27(2003): 184-191.
[47] K. Weyland, *Democracy without Equity: Failures of Reform in Brazil* (Pittsburgh: University of Pittsburgh Press, 1996).
[48] K. Weyland, *Democracy without Equity: Failures of Reform in Brazil* (Pittsburgh: University of Pittsburgh Press, 1996).

[49] P. Teixeira. 2003, "Universal Access to AIDS Medicines: The Brazilian Experience", *Divulgacão em Saúde para Debate,* 27(2003): 184-191.
[50] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).
[51] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).
[52] Interview with Laerte Damaceno, President of SBD, February 8, 2013.
[53] Interview with Laerte Damaceno, President of SBD, February 8, 2013.
[54] Interview with Laerte Damaceno, President of SBD, February 8, 2013
[55] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).
[56] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).
[57] P. French and M. Crabbe, *Fat China: How Expanding Waistlines are Changing a Nation,* (New York: Anthem Press, 2010).
[58] P. French and M. Crabbe, *Fat China: How Expanding Waistlines are Changing a Nation,* (New York: Anthem Press, 2010).
[59] F. Balfour, "Why China's Weight-Loss Industry is Gaining", *BloombergBusiness*, June 3, 2010; accessed September 28, 2014.
[60] F. Hu, "Globalization of Diabetes: The Role of Diet, Lifestyle, and Genes," *Diabetes Care* 34(2011): 1249-1257.
[61] Y. Huang, "China's Looming Diabetes Epidemic," The Atlantic, September 13.
[62] Y. Xu, L. Wang, J. He, Y. Bi, M. Li, T. Wang, L. Wang, Y. Jiang, M. Dai, J. Lu, M. Xu, Y. Li, N. Hu, J. Li, S. Mi, C. Chen, G. Li, Y. Mu, J. Zhao, L. Kong, J. Chen, S. Lai, W. Want, W. Zhao, and G. Ning, "Prevalence and Control of Diabetes in Chinese Adults," *JAMA (Journal of the American Medical Association)* 310(2013): 948-959.
[63] Y. Xu, L. Wang, J. He, Y. Bi, M. Li, T. Wang, L. Wang, Y. Jiang, M. Dai, J. Lu, M. Xu, Y. Li, N. Hu, J. Li, S. Mi, C. Chen, G. Li, Y. Mu, J. Zhao, L. Kong, J. Chen, S. Lai, W. Want, W. Zhao, and G. Ning, "Prevalence and Control of Diabetes in Chinese Adults," *JAMA (Journal of the American Medical Association)* 310(2013): 948-959.
[64] International Diabetes Foundation, "China Spends RMB 173.4 Billion (US$25 billion) a year on Diabetes Treatment," 2010.
[65] International Diabetes Foundation, "China Spends RMB 173.4 Billion (US$25 billion) a year on Diabetes Treatment," 2010.
[66] A. Erickson and G. Collins, "Internal Challenge: China's Diabetes Epidemic Highlights how Rising Healthcare Costs could Constrain Economic Growth and Military Spending," *China SingPost*, May 31, 2011; accessed September 28, 2014.
[67] T. Alcorn, and Y. Ouyang, "Diabetes Saps Health and Wealth from China's Rise", *The Lancet* 379(2012): 1; http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60963-5/fulltext
[68] P. French and M. Crabbe, *Fat China: How Expanding Waistlines are Changing a Nation,* (New York: Anthem Press, 2010).
[69] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).
[70] World Health Organization. 2004. *Global Strategy on Diet, Physical Activity, and Health*. Geneva: World Health Organization.
[71] *Xinhua*, "China May Have 200 Million Obese People in 10 Years," September 30, 2001.
[72] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).
[73] AFP, "WHO Urges China to Fight Nation's Top Killer – Chronic Diseases", May 9, 2006.
[74] Y. Huang, Yanzhong, "Pursuing Health as a Foreign Policy: The Case of China", *Indiana Journal of Global Legal Studies* 17(2010): 105-46.

[75] J. Lee, "Soft Power, Hard Choices," *The Sydney Morning Herald*, April 4, 2009.

[76] J. Lee, "Soft Power, Hard Choices," *The Sydney Morning Herald*, April 4, 2009.

[77] Y. Huang, *Enter the Dragon and the Elephant: China's and India's Participation in Global Health Governance*, (New York: Council on Foreign Relations, 2013).

[78] Y. Huang, "The Politics of HIV/AIDS in China", *Asian Perspective* 30(2006): 95-125.

[79] Y. Huang, *Enter the Dragon and the Elephant: China's and India's Participation in Global Health Governance*, (New York: Council on Foreign Relations, 2013).

[80] J. Weng and Y. Bi, "Diabetes in China: The Challenge Now", *Journal of Diabetes Investigation* 1(2010): 170-171.

[81] *Xinhua*, "China's School Running Campaign Hits Public Debate Hurdle," October 10, 2008.

[82] *Xinhua*, "China Plans to Draft Laws on Public Nutrition to Improve Nation's Health", November 24, 2005.

[83] *Xinhua*, "China Vows to Improve Youngsters' Health", December 24, 2006.

[84] *Xinhua*, "China Vows to Improve Youngsters' Health", December 24, 2006.

[85] *Xinhua*, "China's School Running Campaign Hits Public Debate Hurdle," October 10, 2008.

[86] *Renmin Ribao*, "China to Establish National Nutrition-Monitoring System", August 13, 2010.

[87] A. Erickson and G. Collins, "Internal Challenge: China's Diabetes Epidemic Highlights how Rising Healthcare Costs could Constrain Economic Growth and Military Spending," *China SingPost*, May 31, 2011; accessed September 28, 2014.

[88] A. Erickson and G. Collins, "Internal Challenge: China's Diabetes Epidemic Highlights how Rising Healthcare Costs could Constrain Economic Growth and Military Spending," *China SingPost*, May 31, 2011; accessed September 28, 2014.

[89] Z. Wang, *Diabetes Care in China: Impacts of Traditional Chinese Medicine (TCM) and Insurance on Quality and Utilization*. PhD Dissertation, Pardee RAND Graduate School, Santa Monica, California, 2011.

[90] *Xinhua*, "China to train 1,000 community diabetes experts in three years", October 5, 2010.

[91] *Xinhua*, "China: Academy Urges Health Education for Diabetes Control", Translated through *Access World News,* 1998.

[92] *Xinhua*, "Health Experts Call for Action to Curb China's Youth Obesity Crisis", August, 2006.

[93] China Constitution, *Article 21. Government of China*, 2014; available on-line at: http://english.gov.cn/2005-08/05/content_20813.htm

[94] Y. Huang, "The Politics of HIV/AIDS in China", *Asian Perspective* 30(2006): 95-125.

[95] L. Pye, "The State and the Individual: An Overview Interpretation," In Brian Hook (Ed). *The Individual and the State in China*, (New York: Oxford University/Clarendon Paperbacks, 1996).

[96] L. Pye, "The State and the Individual: An Overview Interpretation," In Brian Hook (Ed). *The Individual and the State in China*, (New York: Oxford University/Clarendon Paperbacks, 1996).

[97] L. Pye, "The State and the Individual: An Overview Interpretation," In Brian Hook (Ed). *The Individual and the State in China*, (New York: Oxford University/Clarendon Paperbacks, 1996).

[98] International Diabetes Foundation, "China Spends RMB 173.4 Billion (US$25 billion) a year on Diabetes Treatment," 2010.

[99] L. Ji, "Focus on the Frontline – The Chinese Diabetes Society", *DiabetesVoice* 55(2010): 27-29.

[100] L. Ji, "Focus on the Frontline – The Chinese Diabetes Society", *DiabetesVoice* 55(2010): 27-29.

[101] *ChinaDaily*, "Diabetes Threatens Children", May 31, 2010.

[102] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).

[103] S. Tharkar and V. Viswanathan, "Impact of Socioeconomic Status on Prevalence of Overweight and Obesity among Children and Adolescents in Urban India", *The Open Obesity Journal* I(2009): 9-14; http://www.bentham.org/open/toobesj/articles/V001/9TOOBESJ.pdf

[104] L. Streib, "Waistlines Keep Expanding Around the Globe", *Forbes Magazine* (on-line, 2007), February 19; http://www.msnbc.msn.com/id/17151433/ns/health-forbescom/

[105] R. Gaiha, R. Jha, V. Kulkarni, "Affluence, Obesity, and Non-Communicable Diseases in India", Working Paper, Australian South Asian Research Center (2010), WP 2010/8; http://rspas.anu.edu.au/papers/asarc/WP2010_08.pdf

[106] K. Siegel, K.M. Venkat Narayan, and S. Kinra, "Finding a Policy Solution to India's Diabetes Epidemic", *Health Affairs* 27(2008): 1077-1090.

[107] K. Venkataraman, A.T. Kannan, and V. Mohan, "Challenges in Diabetes Management with Particular Reference to India", *Intl J Diabetes Dev Ctries* 29(2009): 103-109.

[108] *The Economist*, *The Silent Epidemic: An Economic Study of Diabetes in Developed and Developing Countries*, Report of the Economist Intelligence Unit (London: The Economist, 2007).

[109] S. Bjork, A. Kapur, H. King, J. Nair, and A. Ramachandran, "Global Policy: Aspects of Diabetes in India", *Health Policy* 66(2003): 61-72.

[110] K. Siegel, K.M. Venkat Narayan, and S. Kinra, "Finding a Policy Solution to India's Diabetes Epidemic", *Health Affairs* 27(2008): 1077-1090.

[111] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).

[112] K. Siegel, K.M. Venkat Narayan, and S. Kinra, "Finding a Policy Solution to India's Diabetes Epidemic", *Health Affairs* 27(2008): 1077-1090.

[113] R. Irwin, "Chronic Diseases and Marketing to Children in India." Paper presented at the roundtable "Global Health Diplomacy in Asia," London School of Hygiene & Tropical Medicine, November 17, 2010.

[114] R. Irwin, "Chronic Diseases and Marketing to Children in India." Paper presented at the roundtable "Global Health Diplomacy in Asia," London School of Hygiene & Tropical Medicine, November 17, 2010.

[115] R. Gupta, and A. Misra, "Type 2 Diabetes in India; regional Disparities", *British Journal of Diabetes and Vascular Disease* 7(2007): 12-16.

[116] World Health Organization. 2004. *Global Strategy on Diet, Physical Activity, and Health*. Geneva: World Health Organization.

[117] S. Rao, *The Global Strategy on Diet, Physical Activity and Health: Relevance and Implications for India*, Policy Report (Delhi: WHO India Office, 2004). Available at: http://www.whoindia.org/LinkFiles/Health_Promotion_HP_dr_sushila.pdf

[118] D. Yach, D. Stuckler, and K. Brownell, "Epidemiologic and Economic Consequences of the Global Epidemics of Obesity and Diabetes", *Nature Medicine* 12 (2006): 62-66; available at: http://www.nature.com/nm/journal/v12/n1/full/nm0106-62.html

[119] K. Reddy, K. Srinath, B. Shah, C. Varghese, and A. Ramadoss, "Responding to the Threat of Chronic Diseases in India", *Lancet* 366 (2004): 1744-49; available at: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)67343-6/abstract

[120] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).

[121] J. Brown, *Nehru: A Political Life* (New Haven: Yale University Press, 2003).

[122] Interview with Dr. Prabhat Jha, Director, Center for Global Health Research, University of Toronto, January 30, 2013.

[123] J. Brown, *Nehru: A Political Life* (New Haven: Yale University Press, 2003).

[124] A. Tripathi, "Prospects of India Becoming a Global Power", *India Foreign Affairs Journal* 6(2011): 58-69.

[125] S. Cohen, Stephen, *India: Emerging Power*, (Washington, DC: Brookings Institution Press, 2002).

[126] Interview with Dr. Prabhat Jha, Director, Center for Global Health Research, University of Toronto, January 30, 2013.

[127] A. Tripathi, "Prospects of India Becoming a Global Power", *India Foreign Affairs Journal* 6(2011): 58-69.

[128] Government of India, *Recommendations for a National Plan of Action for the Implementation of WHO's Global Strategy on Diet, Physical Activity, and Health in India*, (New Delhi: Government of India, 2006).

[129] S. Parth, "Nutrition Policy for Healthy India on Cards", *iGovernment* News, April 24, 2008. Available at: http://www.igovernment.in/site/nutrition-policy-for-healthy-india-on-cards/

[130] K. Siegel, K.M. Venkat Narayan, and S. Kinra, "Finding a Policy Solution to India's Diabetes Epidemic", *Health Affairs* 27(2008): 1077-1090.
[131] K. Siegel, K.M. Venkat Narayan, and S. Kinra, "Finding a Policy Solution to India's Diabetes Epidemic", *Health Affairs* 27(2008): 1077-1090.
[132] K. Siegel, K.M. Venkat Narayan, and S. Kinra, "Finding a Policy Solution to India's Diabetes Epidemic", *Health Affairs* 27(2008): 1077-1090.
[133] U. Bhojani, BS. Thriveni, R. Devadasan, CM. Munegowda, A. Narayanan Devadasan, B. Criel, and P. Kolsteren, "Challenges in Organizing Quality Diabetes Care for the Urban Poor: A Local Health System Perspective", *BMC Proceedings* (2012).
[134] K. Venkataraman, A.T. Kannan, and V. Mohan, "Challenges in Diabetes Management with Particular Reference to India", *Intl J Diabetes Dev Ctries* 29(2009): 103-109.
[135] K. Venkataraman, A.T. Kannan, and V. Mohan, "Challenges in Diabetes Management with Particular Reference to India", *Intl J Diabetes Dev Ctries* 29(2009): 103-109.
[136] K. Venkataraman, A.T. Kannan, and V. Mohan, "Challenges in Diabetes Management with Particular Reference to India", *Intl J Diabetes Dev Ctries* 29(2009): 103-109.
[137] K. Venkataraman, A.T. Kannan, and V. Mohan, "Challenges in Diabetes Management with Particular Reference to India", *Intl J Diabetes Dev Ctries* 29(2009): 103-109.
[138] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).
[139] S. Bjork, A. Kapur, H. King, J. Nair, and A. Ramachandran, "Global Policy: Aspects of Diabetes in India", *Health Policy* 66(2003): 61-72.
[140] S. Bjork, A. Kapur, H. King, J. Nair, and A. Ramachandran, "Global Policy: Aspects of Diabetes in India", *Health Policy* 66(2003): 61-72.
[141] *The Economist*, *The Silent Epidemic: An Economic Study of Diabetes in Developed and Developing Countries*, Report of the Economist Intelligence Unit (London: The Economist, 2007).
[142] E. Gómez, "Geopolitics, Obesity, and Diabetes: How Brazil, China, and India are Responding", *Harvard International Review,* Summer (2013).
[143] K. Reddy, K. Srinath, B. Shah, C. Varghese, and A. Ramadoss, "Responding to the Threat of Chronic Diseases in India", *Lancet* 366 (2004): 1744-49; available at: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)67343-6/abstract
[144] Interview with Dharini Krishnan, Heinz Nutrition Foundation of India, January 8, 2013
[145] Interview with Dharini Krishnan, Heinz Nutrition Foundation of India, January 8, 2013; interview with Paleru Jagannivas, Heinz Nutrition Foundation of India, January 8, 2013; interview with Sheela Krishnaswamy, Heinz Nutrition Foundation of India, January 24, 2013.
[146] Interview with Vikas Ahluwalia, Director of the Diabetes Care Foundation, New Delhi, India, February 4, 2013
[147] Interview with Vikas Ahluwalia, February 4, 2013.
[148] Interview with Vikas Ahluwalia, February 4, 2013.
[149] Interview with Vikas Ahluwalia, February 4, 2013
[150] Interview with Vikas Ahluwalia, February 4, 2013

Determinants of Global Collective Action in Health: The Case of the UN Summit on Non-communicable Diseases

Chantal Blouin, Laurette Dubé, Ebony Bertorelli and Monique Moreau

This article presents a case study of the policy process leading to the UN High-Level Meeting on non-communicable diseases (NCDs). The case study tests an analytical framework to understand the factors influencing successful global collective to address chronic diseases. Using this framework, we highlighted four factors explaining the weak outcome of this process. We observed a relatively weak mobilization and advocacy of civil society at the national and global level. Second, the financial context of that time, especially in industrial countries, has created the conditions where it is politically and fiscally difficult for donor countries to undertake financial commitments to support global actions. Thirdly, we observe that health actors have done an incorrect assessment as to where the policy process. Finally, we observed a certain lack of clarity on the rationale for global collective action; the key obstacle here is the economic case has not been sufficiently and visibly made to motivate and trigger policy change. After the Summit in the fall of 2011, the global health diplomacy around chronic diseases control and prevention continued. Future research should examine if the proposed analytical framework is a useful tool to analyze these further steps and to prepare for health diplomacy.

INTRODUCTION

In recent years, there has been growing interest in designing concerted actions to address non-communicable diseases (NCDs) at the global level. For instance, in 2008, the World Health Assembly (WHA) endorsed the Action Plan for the Global Strategy for the Prevention and Control of Non-communicable Diseases[1] and in 2010, the WHA adopted a resolution on the marketing of food and non-alcoholic beverages to children.[2] In 2011, these efforts at global collective action moved to the United Nations (UN) General Assembly which held a summit on NCD. This was the only second time in the history of the UN that the Assembly met to discuss a health issue, after the UN Summit on HIV-AIDS in New York in 2001. The global policy discussion on NCDs has continued and moved back to the WHO since 2011, but this case study is applied to the 12 months period of preparations leading to the high-level meeting.

In order to guide policymakers as to how to engage effectively in such an exercise in global health diplomacy, we developed an analytical framework[3,4] focusing on the determinants of global collective action, focusing on NCD prevention and control (see Figure 1). This analytical framework is built on literature from political science and international relations and is structured around 2 main elements: 1) clear rationale for global collective action, 2) and clear purpose adapted to each phase of the policy process. The remaining of this section present this analytical framework which our case study is built.

[Figure 1 here]

CLEAR RATIONALE FOR GLOBAL COLLECTIVE ACTION

When the literature on global collective action examines global health, it tends to focus on infectious diseases, given the perception that it poses the greatest threat. "Globalization creates an increased health interdependency worldwide that stems from enhanced transmission pathways for infectious diseases through greater mobility and transfrontier exchanges. [...] nations will not sacrifice their autonomy with respect to health policy unless the threat is especially dire or they do not have the means to address the challenge alone."[5] Therefore, it has been argued that the incentives for states to engage in global collective action for chronic diseases are less powerful than for issues related to infectious diseases, given the lack of interdependence related to this issue. "Interdependence means that two countries are mutually dependent with respect to specific activities, events, resources or problems."[7]

However, we identified in the literature three main incentives nation-states for collaboration to address NCDs. First, there is evidence that interdependence is not the only incentive for state actors to participate in global health diplomacy. The experience with global health diplomacy around tobacco control highlights that the need to strengthen the position of national regulators and public health agencies faced with well-organized lobbying from the industry represented a different type of incentives for cross-border collaboration.[18].

A second incentive for global collective action for chronic disease prevention and control relates to the nature and definition of interdependence and to transnational economic externalities. The negative impact of ill-health on economic growth can be an incentive for state actors to be involved in global health diplomacy for chronic diseases prevention[7]. Health status at the global level can be considered a global public benefit, given the economic externalities effects associated with it. Beyond the health status and security of their own population, the global burden of chronic diseases can have a very negative impact on the economic growth and the fiscal capacity of a country's main economic partners. Such transnational economic externalities can create incentives to seek collective solutions and participate in global diplomatic efforts to obtain that effect. Given the economic interdependence now linking national economies (through trade in goods and services, foreign investment and financial markets), this economic impact has regional and global consequences.

The third incentive highlighted in the literature to explain is the need for coordinated regulation in a globalized economy. When it comes to the promotion of healthy diets, one could argue that incentives for state actors to engage in cross-border collaboration are strong, given the increasingly globalized nature of the food system. If one wants to transform food systems toward healthier diets, it cannot be done effectively by focusing on local or national actions alone; one has to develop collaborative approaches in which the globalized food industry is fully engaged[8].

The engagement of non-state actors, including commercial as well as not-for-profit organizations, in global collective action is also influenced by a number of incentives. Incentives are related to the costs and benefits of participation *vs.* non-participation and will vary greatly from one actor to another. "Resolving collective action problems requires a clear understanding of the nature, scale and timing of the costs and benefits to different countries and other parties."[9]

In some cases, there may be a clear convergence between the commercial interests of some sectors and public health goals. For instance, producers and processors of fruit and vegetables will have strong incentives to participate to an effort to promote greater availability, affordability and access to fruit and vegetables, given the potential benefits to their operation, as the initiative is likely to increase their revenues. Other factors that can create incentives for the private sector participation are: increases in consumer demand, public pressure from civil society organizations and consumers and the threat of new and potentially more onerous regulation[10].

There have been many non-governmental organizations involved in global health diplomacy. A large and diverse group of actors is included in this category: international federations of professional associations, health advocacy groups, humanitarian and development NGOs, philanthropic organizations. What are the incentives for these organizations to be involved in global health diplomacy? Like commercial actors, if there is a clear convergence between the objectives of a global collective action under consideration and the objectives of the organization, the incentives for collaborating to this exercise in global health diplomacy can be very strong.

Being involved in global health diplomacy also can offer a number of organizational benefits for non-state actors, beyond the achievement of their specific objectives. It can improve their institutional capacity by facilitating networking with like-minded groups and access to decision makers in governments. It can increase their visibility at the national and global level, therefore increasing their capacity to influence decision-makers, to raise funds and to increase membership. Factors which can reduce the incentives for collaboration includes the risks of losing independence from government or private sectors (or being perceived as such), of losing members, funding and credibility if involved in controversial matters where there is no consensus.

CLEAR PURPOSE ADAPTED TO THE PHASE OF THE POLICY PROCESS

Collective action at the global level can be aiming at a number of objectives. The literature focuses on five key objectives: agenda setting; setting of new norms, regulations, standards; information sharing; monitoring functions; and mobilization and channeling of financial resources[3]. Clarity and agreement on what is the purpose of the initiative being discussed is a key ingredient for success.

The policy process includes different phases, and in order to engage in global health diplomacy, policymakers need to have a good understanding of what phase the policy process has already reached. Each phase involves actors in a different manner and therefore, involves a different dynamic, and will mean different objectives for global health diplomacy.[11]

The first step is the agenda setting phase. Policymakers have a limited amount of time and resources to allocate to address policy problems. The policy agenda is composed of the policy problems, which receive the attention of government officials at any given moment[12]. Political scientists have clearly shown how the agenda setting process, like the other phases of the policy process, is not simply a rational unfolding of the bureaucratic assessment of a problem and the design of a solution. Rather, it is a political process where interests, ideas and institutions meet, and where the very definition of what constitutes a problem is open to political contest[13]. If an issue is still

not present or very low on the global health agenda, the objective of global collective action could be to change this state of affairs and bring policy attention to this issue.

If policymakers identify a policy problem still in the agenda-setting phase for which they want to engage in global health diplomacy, what key elements should they consider in order to be effective? One consideration is the impact of the media on the political agenda.. In a review of twenty agenda-setting studies, mostly focusing on domestic policy issues, Walgrave and Aelst suggested that factors such as the type of media under scrutiny can explain variations in the influence of the media in agenda-setting[14]. Indeed, elite media, in contrast to popular media, are considered to play a more active role in the shaping of the policymakers' views on foreign policy[15]. Moreover, the type of issues at stake is a variable to take into account. The role of the media in putting issues on the political agenda is deemed greater in foreign policy than domestic policy, given the unobtrusive nature of these issues. Given that most individuals, including policymakers, do not have direct experience with these issues in their daily lives, they would not be observable without media reporting[16].

The multiple streams model first developed by Kingdon, which has become widely used to study domestic policy processes[17], and more recently foreign policymaking,[11] stresses the importance of events such as crises, disasters, or powerful symbolic actions on agenda setting[13,18]. Dramatic events such as crises, disasters, or powerful symbolic actions have a strong impact on agenda setting[12]. Such events are recurrent in infectious diseases, with outbreak events and epidemics focusing the attention of decision makers; chronic diseases are less likely to trigger such focusing events.

The role of policy champions can compensate for this. Policy champions, also called policy entrepreneurs, can be individuals or groups located inside or outside political or administrative structures. Together, they are active in defining the nature of problems that deserve attention, as well as offering proposals to policymakers regarding the solutions for these problems.[12]

The second phase of the policy process is policy development, where proposals are generated and debated. At that point, the problem is now identified and on the policy radar of authorities, but political actors are developing and putting forward proposals to address the problem. Therefore, policymakers identifying an issue which has reached this phase of the policy process have to adopt a strategy of engagement with communities of experts at home and abroad who are putting forward policy proposals for national and global responses to the rise of chronic diseases. The mechanisms of engagement can include the commissioning of policy papers or review of literature, the convening of *ad hoc* consultative roundtables or permanent expert committees, the participation of officials at academic and policy conferences, *etc.* Whatever the means of engagement, the objective is to collect information in order to develop evidence-based policy proposals.

Moreover, in order to be effective in this phase of global health diplomacy, officials will have to decide what proposals they support, based not only on their assessment of the technical value, but also depending on political feasibility. Therefore, building support among international partners about the purpose and form of those global initiatives under consideration is crucial. These partners can be other national governmental agencies or non-state actors. The development of shared understanding is a key component of pre-negotiations and one important way to achieve a shared

understanding comes in the form of joint fact-finding exercises [19]. "Joint fact-finding encompasses any process by which a group of stakeholders seeks agreement on a set of questions to be investigated, ways to conduct the investigation, experts and others resources, people to be involved and ways to interpret and use the results for decision making" (p. 336)[19].

The third phase of the policy process is the policy selection phase which includes an authoritative choice among those alternatives; in diplomacy, this is the process of negotiation between parties which leads to an agreement. Once officials establish that the policy process has reached that point, they now have to establish their positions in the negotiations and their strategies to achieve their objective. International negotiations are always taking place in the context of power asymmetry. Some countries or some actors have more influence over outcomes than others, given their economic power, their scientific expertise, or other assets. In the context of global health diplomacy, this situation is exacerbated by the fact that health ministries and agencies tend to be less powerful within their own governments. There are two main strategies available to officials to compensate for such power asymmetry: coalition building and preparation for negotiations[19].

The objective of this article is to apply this analytical framework to the policy process which led to the adoption of the UN Political Declaration on the prevention and control of NCDs in 2011. We should note that given the nature of that policy process, our case study does not examine the elements related to the policy selection phase. The proposed analytical framework is meant to be used prospectively and retrospectively to support policy makers and researchers to identify the variables that are most influential in influencing the outcome of such a process.

RESEARCH METHODS FOR THE CASE STUDY

In order to document the policy process leading to the adoption of the political declaration, the case study was built on several documentary sources, interviews and observations. The corpus for the documentary analysis included all relevant WHO and UN official documents produced during the process, the documents preparing for and coming out of the regional consultations and the Ministerial meeting in Moscow, the documents published by NGOs and private sector organizations about the High-level meeting, as well as media reporting on the preparations of the Summit and the event itself.

The research team also conducted twenty interviews with key stakeholders. They were conducted face to face or by phone. The interviewees were selected after a stakeholder mapping exercise to ensure that some of the key actors in the process from different fields and perspectives were represented. The interviews process, as well as the research project in general, has been approved from the Research Ethics committee of McGill University.

Moreover, researchers attended several meetings, or watched webcasts of meetings, that contributed to the preparation of the UN Summit. The team observed the webcasts of the WHO Ministerial Meeting on NCDs which took place in Moscow at the end of April 2011, attended the 64th World Health Assembly and four NCDs-related events in Geneva in May 2001, as well as the informal civil society hearings that took place at the United Nations on June 16th. These hearings were held in preparation of

the High-Level Meeting. We also attended side events organized in New York by civil society, private sector and international organizations around the hearings. We have attended the High-level meeting itself on September 19th-20th 2011, as well twelve side meetings held in New York around the summit.

RATIONALE FOR GLOBAL COLLECTIVE ACTION

The analytical framework identified three factors justifying investment of time and energy negotiate collective responses for NCD prevention and control at the global level, instead of policymakers focusing their energy on local and national initiatives. These three factors were: the need for officials to join force globally to resist pressures or to strengthen their position domestically, the need to reduce the economic risks associated to ill-health, and thirdly, the need for coordinated regulation in a globalized economy

When conducting the content analysis of regional consultations, background and positions papers and when conducting our interviews, we noted that the three rationales were cited by stakeholders, but that the economic incentives were the most often referred to. For instance, the Ministerial Declaration that came out of the High-level consultation of the Americas on NCDS and Obesity highlight the economic consequences of the NCD epidemics. The introduction of the declaration highlights "the increasing impact of the direct costs of NCDS on health systems, the impoverishment of households affected, as well as the loss of productivity that has negative impact on development" and the World Economic Forum Global Risk Reports of 2009 and 2010 which "identified NCDs as global risk in both the developing and developed worlds, with a potential economic impact equal to the impact of the global fiscal crisis over the next ten years."[20]

In the Moscow Declaration's section about the rationale for action, health ministers stated that "NCDs now impact significantly on all levels of health services, health care costs, and the health workforce, as well as national productivity in both emerging and established economies.[21] The first and second paragraph of the political declaration at the UNGA Summit also present NCDs as obstacles to achieve development and economic objectives. [22]

The importance of the economic consequences as an incentive for action was also mentioned in interviews. A representative from a national government stressed that a "constant priority of our government [is] highlighting the increasing impact that it has at the level of the national budget." When asked about incentives for national government to develop global collective responses to NCDs, a representative from a civil society organization answered that "the first incentive is an economic and a foreign policy one. For a lot of governments NCDs are the biggest hole in health budgets. Treating cancer is very expensive, chronic lifelong conditions, so it's a problem that's not just about development; they are diseases that affect every country. The cost to the world economy is huge."

The literature on diplomacy and foreign policy would predict that the priority area for global health diplomacy would be infectious diseases, given the more immediate interdependence and stronger cross-border linkages associated with epidemics. The economic case for the need to negotiate a global response to the rise of NCDs has not been made yet, or at least, not sufficiently, for policymakers to have a strong rationale for investing significant time and political capital.

This view was corroborated by interviewees. For instance, a representative from civil society organizations, when asked about the rationale for global collective actions on NCDs, stressed that the World Economic Forum had well articulated the economic costs associated with the rise of NCDs, but stressed that they are still trying to get global leaders to understand the extent of these economic consequences and trying to "put NCDs on the global agenda as more than a health issue but also as a global economic and security risk."

Our interviewees also identified the need for coordinated action in a global economy as key incentives for global cooperation.

[We need a global response] "because of the nature of the problem to be addressed, because this problem is not exclusively national. It is a problem that affects all countries within the borders, but it also has transnational implications. The risk factors are transnational. To that extent you need to have more than one country being involved in response to the problem of NCDS."(Former representative from international organizations)

However, this rationale for action was much less present in the documents and declarations coming out of the preparatory process. One of the interviewees from the research community argued that the need for officials to collaborate to build their capacity to counteract negative pressures from the industry is a one of the major value-added of undertaking actions at the global level. "There is strength in numbers." The interventions made during the summit regarding the political and legal actions of the tobacco industry to counteract regulatory measures do support this view. For example, the Australian health minister noted in her intervention about the legal and political actions from tobacco industry to fight back the implementation of the Framework convention on tobacco control as it related to packaging the importance of international cooperation to counter-balance such pressures.

"[Tobacco industries] are fighting vigorously because they know plain packaging will hurt them by reducing sales. And they know if Australia succeeds in being the first country to implement these laws, we won't be the last. The Australian Government is very confident that we can withstand these threats and challenges. In fact, the more the tobacco companies fight, the more we know we are on the right track. Fighting back against Big Tobacco does require resources, and political will. But saving lives and improving the health of the global community is an investment that will pay a huge dividend. And so today I urge all of you to consider how your country can take the next steps too, using the Framework Convention on Tobacco Control as the mechanism for reform. The fight against Big Tobacco is one which together, we will win."

Similar views were expressed during the regional consultations in Europe preparing for the UN Summit.[23]

WHAT ARE THE GOVERNMENT FOR NON-STATE ACTORS TO PARTICIPATE IN THIS EXERCISE OF GLOBAL HEALTH DIPLOMACY FOR CHRONIC DISEASES PREVENTION AND CONTROL?

Our interviewees highlighted two types of factors that motivate private business to engage in the current exercise of health diplomacy on NCDs. First, the need to respond to the risks of regulations or other policy measures considered against their interests is a strong incentive for participation for the private sector. For instance, in one interview

with a representative of the food and beverage industry, engagement in the UN process was seen in response to the strong engagement of NGOS at the global level, with a view to prevent measures such a wide ban on advertisement to children, which they deemed unproductive and ineffective. This interviewee added that "what will be decided at the UN High-level meeting will send strong messages to member states, so it is important." Another interviewee, from an international organization, noted the example from the alcohol industry whose producers were lobbying very strongly during the process in order to prevent a regulatory approach that would affect their industry. They were effective to do so, according to this interviewee, because some of the member states were strongly supporting the views of this industry during the negotiations.

Secondly, a number of businesses see a clear convergence between their commercial interests and the objectives of the initiatives being discussed. For instance, when asked what are the factors motivating his\her organization's involvement in the process leading UN summit on NCD, a representative from the private sector stressed that their company is "uniquely focused on technologies which deal with NCDs" and therefore, saw it as an obvious motivation.

In our documentary analysis, we also noted another rationale for the private sector engagement: the direct and indirect economic costs of NCDs for business. The World Economic Forum explains: "Almost half of those who die of chronic diseases are in their productive years. The economic consequences driven by productivity reduction and the increase in costs in workforces caused by these diseases are dramatic." [24]

Many of the NGOs involved in NCDs have tended to work at the national level, not the global level. The UN Summit presented an opportunity to improve their visibility and global networking, while achieving their core mandate of finding solutions to prevention and control NCDs. The importance of global visibility was mentioned by interviewees as an incentive for engagement: "We saw the UN Summit as an opportunity to raise awareness about NCDs at global level; with the media putting the spotlight on the issue, it could put public pressure on governments to commit to actions". (Representative from civil society organization) The importance of global networking as an incentive to engage in a global process was explained by another interviewee from a civil society organization;

"[The High-Level Meeting was] the one thing that could brought all these activists together. A lot of these groups, before this, were competitors. They were not aligned at all. Everybody realized that the interests of cooperating on this goal outweighed the downsides of cooperation. The informal civil society network arose and it was very effective because all participating networks were globally connected networks themselves. With this level of collaboration we championed for government level change, this mobilized a strong campaign."

CLARITY OF PURPOSE, ADAPTED TO THE DIFFERENT PHASES OF THE POLICY PROCESS

When engaging in global health diplomacy, policymakers need to agree on what are the specific objectives and functions of the initiatives under consideration. The analytical framework notes five objectives: agenda setting; setting of new norms, regulations, standards; information sharing; monitoring functions; and mobilization and channeling of financial resources.

However, there was a clear North-South divide as to what were the objectives of this initiative, as many developing countries focused on the opportunity to mobilize financial resources for NCDs from external sources. For several developing countries, this was a key motivation to engage in this process. There has been a great increase in resources for global health in the last fifteen years, mostly for infectious diseases like HIV/AIDS and malaria. Several governments came to the table hoping that the summit would be an opportunity for donors to commit new resources for prevention and treatment of NCDs in low-income countries.

For instance, the Brazzaville Declaration that came out of the WHO regional consultations in Africa did call on "Development partners and civil society organizations to provide new and adequate financial resources to address NCDs without jeopardizing current and future funding of the prevention and control of communicable diseases"[25].

This led to a clear divergence of objectives during the negotiations. The industrial countries did not agree to set the mobilization of resources as an objective, as it has been done previously in global health diplomacy. This divergence is in great part caused by the change in economic context; since 2008, the global economy, and especially the economic and financial situation in most industrial countries, has been precarious and volatile. One of our interviewees from a non-governmental organization emphatically stated the importance of this new context to understand the divergence in objectives:

"I would say the political and the economic environment are extremely challenging. I think there's been constant connections being drawn to the High level meeting in 2001 on HIV/AIDS, to see if there are lessons learned, what can be drawn from what experience, what type of underlying factors need to be happening in order to drive an exponential increase in resources, political commitments from a number of influential donor countries. I think the biggest challenge in the current environment is the extreme difference in the economic environment. In 2001, the US economy was very much on the upswing and there were opportunities for donor governments to expand their reach. The change from that environment to extreme debt issues in Europe and the United States means that, now, there is major fear of resource commitment."

Two interviewees based in national governments echoed this observation. They added that industrial countries considered that they had already done financial contributions, in the context of the MDGs, and expressed that early one, most governments did not intend to invest financially in a global response to NCDs.

The view that one of the key objectives of the Summit was to mobilize resources for NCD prevention and control is also shared by the key non-government organizations present the policy debates around the negotiations of the political declaration. For instance, the propositions from the NCD Alliance as to what should be included in the outcome document included that "bilateral donor agencies and multilateral organizations support NCD programs in low and middle-income countries." Similarly, in the consultations with NGOs led by WHO in late 2010 in Geneva, the WHO reported that "there was a consensus that a key outcome would be to promote a stronger funding base for action globally. This included innovative sources of financing such as taxation on tobacco and possibly a levy on currency transactions. At the international level, it includes the integration of NCDs in ODA." However, NGOs did not expressed a desire

to see a new agency dedicated to NCDS, but rather the inclusion of NCDS in existing global funds and initiatives.

WHAT PHASE THE POLICY PROCESS HAS REACHED?

The policy process includes different phases and in order to engage in global health diplomacy with clear purpose, policymakers need to have a good understanding of what phase the policy process has already reached. Each phase involves actors in a different manner and therefore, involves a different dynamic and will mean different objectives for global health diplomacy.

In the case of global health diplomacy on NCD, at what phase of the policy process are we? Our assessment of the positions and strategies of actors is that many of the public health actors that were active and driving this exercise considered that we were in the policy development phase. However, if one looks at the state of the public debate during the process, it appears that we were rather only still at the agenda-setting phase. This may explain the disconnect between expectations of specific targets and the capacity to get them in the declaration,

This assessment also highlights the central role of timing in global health diplomacy, as it is for policymaking more generally. The convening of the UN High-level meeting took place on a fast track. One NGO explained well this reality during the interview:

"One main lesson to learn is be careful what you wish for. When we started this I used to work for the UN and thought it would take 5 years. Then we found that this whole summit fell into place very quickly and it did that because what we were saying struck a chord with a number of UN member states. 130 UN member states co-sponsored resolution for summit, voted for unanimously to put their names to resolution and everything happened quickly. One lesson is that if you hit the right political moment, things can happen very fast and then you have no choice but to step up to the challenge."

A private sector interviewee stated that he and his colleagues were expecting that it would take almost ten years to get NCDs on the UN agenda, but it only took one year.

AGENDA SETTING

What role could the media play to put the issue on the agenda?

All the interviewees agreed on the importance of the media in order to ensure that NCDs receive greater attention in the global policy agenda. However, they also agree that in the lead-up to the Summit, the level of engagement with the media has not been sufficient in order to trigger the political mobilization necessary for major policy changes. As a former official from a international organization stated, "one thing I think we could do better is have the media pay much more attention to this particular problem and being a major agent for dissemination of information and destroying many of the myths surrounding NCDS."

This was especially true at the beginning of the process. Once the summit was approaching and took place began, media coverage has been substantial, as we noted earlier. Two NGO interviewees presented the situation in these terms:

"The role of the media is absolutely critical we probably have not been able to engage media in the way that we wanted to in the time we had available."
"I think media is absolutely critical. I think it is imperative. We, in the NGOs and civil society community, have not done as good of a job in terms of raising the overall awareness of the public of constituencies who are able to influence decision makers.
There is a strong distinction between how successful things have been with the HIV High level meeting … this being a factor of time period and time table by which the media has been engaged. [NCDs timeline being shorter].
Now, since the announcement of the HLM that the media and communications around the issue has started to pick up."

An official from an international organization also highlighted the importance of presenting the issue as a business opportunity to the media and of also resorting to the social media. "The media helps to set the public agenda. We need the media to see this as an opportunity for their own business. They need to see this as a business opportunity because the private sector is doing this, putting advertisements in the US to point out what are opportunities. As important as traditional media are, the new social media may very well be as important. The social media is a democratic sector and I think it is going to be critical and play a very important role, especially for reaching the youth."

What policy champions contribute to put the issue on the agenda?

The importance of policy champions to bring an issue such as NCDs on the global policy agenda is recognized by our interviewees. A former official from an international organization advised that "you need what some people described as political entrepreneurs, champions to spur the movement forward. You need the agenda to be set appropriately, an agenda crafted in a way that is attractive to all countries." Another interviewee noted that political leaders can be crucial policy champions. "It would be helpful if we could find a major advocate among the G7 countries who would be willing to provide some leadership. Maybe the same way George Bush provided for HIV\AIDS or the way Stephen Harper has done for MDG5 [maternal health]. […] An alternate approach would be to find a child rights champion to address childhood obesity. Maybe Michelle Obama. In the next decade, it could be a starting point for NCDS." (Interview with representative from regional organization.) However, several interviewees regretted the absence of sufficient strong leadership or champions to move the process forward, including champions from the private sector.

POLICY DEVELOPMENT

What mechanisms were used to engage the community of experts on this issue?

The preparatory process leading to the summit did not formally include mechanisms of engagement with the community of experts. However, some of our interviewees identified experts as key actors in the process. For instance, a representative from the private sector stated that the medical journal The Lancet "provided both intellectual leadership and advocacy" and played a role "as a key communications vehicle to set out a clear policy agenda." Moreover, some of the stakeholders have themselves engage with experts when preparing for the negotiations. A representative of an international organization noted that "since this has come onto the agenda, we have held meetings of

our own technicians, i.e. intergovernmental meetings of technicians looking at our own programming." A private sector representative noted that they "held a meeting at the Council on foreign relations on a health investment score card to get that information from them."

Is a global joint fact finding exercise be initiated?

There was two prominent processes of fact finding during the preparations of the Summit. First, the WHO prepared on the "best buys", i.e. the cost-effectiveness of health interventions to prevent and control NCDS.[20] In a parallel process, the World Economic Forum and the World Bank commissioned research on the economic costs of inaction, i.e. documenting what the rising epidemic meant in terms of health care costs, productivity loss and decrease economic growth.[20] These were released at a side-event at the beginning of the summit in New York. The objective of conducting such research was to build the case for global collective action and convince members state to undertake ambitious actions. However, they did not receive a level of attention sufficient to enable such change.

The WHO had documented the level of the epidemics through its research reports submitted to Member States[34]. Those were important exercises in joint fact finding to establish that the scope of the problems ahead. However, the WHO was not mandated before the summit to develop specific targets and indicators. If such exercise in joint fact finding had already be completed before the beginning of the preparations and negotiations of the Political Declaration, it would have provided shared understanding and facilitated the adoption of more concrete objectives in the outcome document.

ARE THERE POLICY CHAMPIONS ADVOCATING AT THE GLOBAL LEVEL FOR THE ISSUE AT STAKE OR A SPECIFIC RESPONSE TO THIS PROBLEM?

The most determinant variable to explain the weak outcome of this exercise in global health diplomacy is the weak presence of grass-root advocacy and activism around non-communicable diseases. One of the key lessons from previous successes in global health diplomacy is the key role of civil society organizations' mobilization in ensuring strong collective response. This explanatory variable has certainly been identified as central in the negotiations of the Framework convention on tobacco control.[18] Grass-roots activism and global mobilization are also key factors behind the changes in financing for and access to treatment for HIV-AIDS patients in the developing world.

The policy process leading to the NCD High-level meeting was not devoid of the civil society actors. On the contrary, we observed that the NCD alliance has been very active throughout the process: conducting consultations internally to develop a proposed outcome document, collaborate to the production and participation to key articles in the main scientific journals such as the Lancet[27] and many articles in the mass media. They also met face to face with a large number of missions in New York and participated in the official meetings such as the Global health forum that took place in Moscow. The civil society hearings in New York attracted the participation of more than 200 CSOs, including the members of the NCD Alliance.

However, what was lacking was extensive grass-roots activism demanding change at the local and national level in terms how governments work to prevent and treat

NCDs. As noted by researchers at the Centre for Strategic and International Studies, "while the NCD Alliance is emerging as a the main force of civil society engagement, in some cases national and international member societies are dominated by medical professionals and do not significantly involve people living with and affected by NCDs"[28]

Such grass-root activism, would have put pressure on political leaders and therefore, on delegations sent to New York, to be more ambitious in terms of what should be achieved at the global level. Moreover, we noted that the lack of non-health NGOs in the public debate. We have not seen unions, development NGOs, faith groups or other types of organizations engaged in making demands and advocating for change at the national or global level.

Other absents from the policy process were the non-health UN agencies. The WHO took the lead in this process, but we have not seen much engagement from agencies such UNDP or the World Bank. Given the economic and development consequences of the epidemic, this is key impediment to effective global health diplomacy. This view was expressed by two representatives from national government, one a regional organization and one from private sector during our interviews:

> *"The WHO has not undertaken the right steps to bring the other sectors and agencies."*
> *"The WHO is dominating the process."*
> *"We should take a whole of society approach which means that we should take a multi-sectoral approach to dealing with NCDs at the global level. The actions should be reflected at the UN level to a whole of UN approach with the relevant UN agencies, not just the WHO."*
> *"The fact of the matter is that virtually the entire UN sector is not doing very much on this at all, which is exactly why this needs to be brought up to the level of the UN general secretariat. I mean that the technical agencies have not been that active. "*

Multi-sectoral collaboration at the global level has not happened in the process leading to the Summit. An interviewee from a national government judged that it was premature to try to do this at the global level.

CONCLUSION

The result of the NCD Summit negotiations process was a relatively weak document, in terms of mandating clear and concrete actions. [29, 30, 31] The declaration is not a legally binding document; this was expected. However, it does not meet the criteria to be considered a strong plan for global collective action. First, specific targets and indicators, which are key in ensuring successful collective action, were missing. The experience from the establishment and monitoring of the Millennium Development Goals (MDGs) highlighted how concrete and measurable targets are powerful to mobilize political attention, financing and actions to achieve these targets. As the Director-General of the WHO stated during the NCD Summit and many times before, "What gets measured gets done."[32]

The document did not create a monitoring and enforcement mechanism, but did mandate the WHO to create voluntary targets and to create a monitoring framework for these in the coming year, which is a step toward effective accountability mechanism.

The prevention and treatment of NCDs requires financial commitments; in the case of low-income countries and to a lesser extent, middle-income countries, domestic resources are not sufficient to provide good prevention and treatment services. External financing from development agencies and philanthropy is essential. The Summit negotiations did not lead to any financial commitments from any parties involved, nor from other actors in the global health architecture.

A criteria for success is the level of ambition of what leaders sets themselves to achieve. If the outcome document is mostly repeating language that is found in existing declarations, agreements and strategies, it is difficult to see the new document as moving forward. A final criteria for success is the capacity of the global process to put the rise of the NCDs on the global policy agenda, in particular raising the profile of this issue in the media. This is one area where the Summit has achieved positive impact. Indeed, in September 2011 alone, more than 7000 stories about NCDS were published in media around the world, a sharp change from the usual lack of coverage[33].

What can explain the relatively weak outcome of the NCD summit? Based on our analytical framework, we point at four main elements to explain the results of the process. First, we observe a relatively weak mobilization and advocacy of civil society at the national and global level; which in turn reduce the pressures on government to take action. Second, the current financial context, especially in industrial countries, has created the conditions where it is politically and fiscally difficult for donor countries to undertake financial commitments to support global actions. Thirdly, we observe that health actors have done an incorrect assessment as to where the policy process. The process was mostly still at the agenda setting phase, not at policy formulation. The issue of timing is indeed key. Finally, we observed a certain lack of clarity on the rationale for global collective action; the key obstacle here is the economic case has not been sufficiently and visibly made to motivate and trigger policy change.

These elements appear to be the most significant factors to explain the outcome of the policy process under scrutiny. Nevertheless, we assessed the significance of all the elements of the analytical framework and observed that they should also be considered when policymakers engage in global health diplomacy for chronic diseases prevention and control.

Our analysis of the preparation and outcome of the UN High-Level Meeting on NCDs did provide a useful case study to test the analytical framework where we identified the factors of success when engaging in global health diplomacy. We believe that the case study validated the usefulness of the analytical framework to explain the weak outcome of this diplomatic process on NCDs. In order to better assess whether these factors are useful to explain outcome of global health diplomacy more generally, we will need to build a larger corpus of well-selected case studies in future research.

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Figure 1: Analytical framework for global collective action for NCDs prevention and control

What are the governments' incentives to participate in this exercise of global health diplomacy for chronic diseases prevention and control?
1) To address jointly a problem that all governments share (ex: pressures against regulation, low profile of health agencies) 2) To reduce the negative economic impacts of the rise of chronic diseases 3) To coordinate regulation in a globalized economy (ex: harmonization of food standards)
What are the incentives for non-state actors to participate in this exercise of global health diplomacy for chronic diseases prevention and control?
1) Clear convergence between commercial interests\mandate of non-state actors and objectives of initiative under consideration 2) Increases in consumer demand for healthier products 3) Public pressures from civil society organizations and consumer groups 4) Threat of a new and potentially more onerous regulation 5) Organizational benefits (networking, visibility, access)

Clarity of purpose

What are the specific objectives and functions of the initiative under consideration?
1) Agenda setting 2) Setting new norms, regulations or standards 3) Information sharing 4) Monitoring functions 5) Mobilization and channeling of financial resources
What phase the policy process has reached?
1) Agenda setting a. What role could the media play to put the issue on the agenda? b. What policy champions could contribute to put the issue on the agenda? 2) Policy development a. What mechanisms should be used to engage the community of experts on this issue? b. Should a global joint fact finding exercise be initiated? 3) Policy selection/negotiations a. What mechanisms should be established for inter-sectoral collaboration and consultations at the national level, in preparation for the negotiations? b. What strategies should be adopted during the negotiations: coalition building, role of broker?

[1] WHO *2008-2013 Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases*. World Health Organization: Geneva, 2008.
[2] WHO, *Resolution on Marketing of food and non-alcoholic beverages to children, WHA 2010*. UN General Assembly (2010, May 13) UN General Assembly: Resolution – Prevention and control of non-communicable diseases – A/RES/64/265.
[3] Blouin, Chantal and Kristina Maud Bergeron with Laurette Dubé and Janet Beauvais, *Analytical framework for global health diplomacy for chronic disease prevention and control*, Report prepared for PHAC, March 11, 2010.
[4] Blouin, Chantal and Laurette Dubé, Global Responses to Chronic Diseases: What Lessons Can Political Science Offer? , *Administrative Sciences*, 2012.
[5] Sandler, T. *Global Collective Action*; Cambridge University Press: Cambridge, UK, 2004. p. 99–100)
[6] Fidler, D. Health in foreign policy: An analytical overview. *Can. Foreign Policy* 2010, *15*, 11–29.
[7] Smith, R.; Beaglehole, R.; Woodward, D.; Drager, N. *Global Public Goods for Health: Health Economic and Public Health Perspectives*; Oxford University Press: Oxford, UK, 2003.
[8] Hawkes, C.; Murphy, S. An overview of global food trade. In *Trade, Food, Diet and Health: Perspectives and Policy Options*; Hawkes, C., Blouin, C., Dubé, L., Henson, S., Drager, N., Eds.; Wiley- Blackwell: Hoboken, NJ, USA, 2010.
[9] Smith, R. Global health governance and global public goods. In *Making Sense of Global Health Governance: A Policy Perspective*; Buse, K., Hein, W., Drager, N., Eds.; Palgrave MacMillan: London, UK, 2009.

[10] Buse, K.; Naylor, C. Commercial health governance. In *Making Sense of Global Health Governance: A Policy Perspective*; Palgrave MacMillan: London, UK, 2009.
[11] Tomlin, B.; Hillmer, N.; Hampson, F. *Canada's International Policies: Agendas, Alternatives, and Public Policies*; Don Mills: Oxford, UK, 2008.
[12] Kingdon J. *Agendas, Alternatives and Public Policies*, 2nd ed.; Pearson Education: Toronto, Canada, 1995.
[13] Cobb, R.; Elder, T. The politics of agenda-building: An alternative perspective for modern democratic theory. *J. Politics* 1971, *33*, 892–915.
[14] Walgrave, S.; van Aelst, P. The contingency of the mass media's political agenda setting power:Towards a preliminary theory. *J. Commun.* **2006**, *56*, 88–109.
[15] Baum, M.A.; Potter, P.B.K. The relationships between mass media, public opinion, and foreign policy: Toward a theoretical synthesis. *Annu. Rev. Polit. Sci.* **2008**, 39–65.
[16] Wood, D.; Peake, J. The dynamics of foreign policy agenda setting. *Am. Polit. Sci. Rev.* **1998**, *92*, 173–184.
[17] John, P. Is there life after policy streams, advocacy coalitions, and punctuations using evolutionary theory to explain policy change? *Policy Stud. J.* **2003**, *32*, 481–495.
[18] Mintrom, M.; Norman, P. Policy entrepreneurship and policy change. *Policy Stud. J.* **2009**, *37*, 649–667.
[19] Chigas, D.; Fairman, D.; McClintock, E.; Najam, A. Negotiating across boundaries: Promoting health in a globalized world. In *Trade and Health: Seeking Common Ground*; Blouin, C., Heymann, J., Drager, N., Eds.; McGill-Queens University Press: Montreal, Canada, 2007.
[20] WHO and WEF, *From burden to "best buys": Reducing the economic impact of NCDs in low- and middle-income countries*, September 2011.
http://www.who.int/nmh/publications/best_buys_summary/en/index.html
[21] First Global Ministerial Conference on Healthy Lifestyles and Noncommunicable Disease Control. *Moscow Declaration*. 28-29 April 2011.
http://www.who.int/nmh/events/moscow_ncds_2011/conference_documents/moscow_declaration_en.pdf
[22] General Assembly of the United Nations, *Political Declaration of the High-Level Meeting on Non-Communicable Diseases Prevention and Control*, September 16, 2011
http://www.un.org/ga/search/view_doc.asp?symbol=A%2F66%2FL.1&Lang=E
[23] WHO Regional Office for Europe (2010, November 25-26) *Regional High-level Consultation in the European Region on the Prevention and Control of Noncommunicable Diseases – Summary Report of the Meeting*. WHO Regional Office *for Europe: Copenhagen*.
[24] World Economic Forum (2011) *Chronic Disease Prevention Initiative: Overview for the WEF Annual Meeting 2011*. World Economic Forum: Geneva
[25] WHO-AFRO, *The Brazzaville Declaration on NCDS prevention and control in the WHO African region,* Brazzaville, Congo, April 4-6.
[26] Blouin, C. and L. Dubé. Global health diplomacy and chronic diseases prevention: Lessons from tobacco control. *Journal of Public Health Policy,* 31, no 2 July 2010.
[27] Beaglehole, R. et al, Priority actions for the non-communicable disease crisis, *The Lancet*, 2011, 377; 1438-47.
[28] Sridhar D., Morrison J.S., Piot P. (2011, February) *Getting the Politics Right for the September 2011 UN High-Level Meeting on Noncommunicable Diseases.* Center for Strategic and International Studies: Washington, D.C.
[29] Chand, Sudeep, *Health at the UN: Risks to Global Economic Growth*, Chatham House, Centre for Global Health Security, September 2011. http://www.chathamhouse.org/media/comment/view/178391
[30] *Two days in New York: reflections on the UN NCD summit*, Editorial, The Lancet Oncology, September 23, 2011.
[31] Amanda Glassman, *WHO and NCD: Another Unfunded Mandate?,* September 20th, 2011 Center for Global Development.
http://blogs.cgdev.org/globalhealth/2011/09/who-and-ncd-another-unfunded-mandate.php
[32] http://www.who.int/dg/speeches/2007/address.to.staff/en/index.html
[33] NCD alliance website www.ncdalliance.org
[34] WHO, *Global status report on noncommunicable diseases 2010, Description of the global burden of NCDs, their risk factors and determinants*, Geneva.

Plants, Patents and Biopiracy: The Globalization of Intellectual Property Rights and Traditional Medicine

Suchita Shah

A controversial international debate has arisen between those who call for stronger intellectual property legislation to protect their scientific innovation, and those who claim 'biopiracy' of their traditional medical knowledge (TMK) under such legislation. This paper firstly presents and contextualises the debate, then argues that the difficulty in its resolution has been fuelled by three main factors: first, the lack of an integrated and comprehensive international rights-based system for TMK, which is mirrored in domestic legislation; second, attempts to redress perceived iniquities present legal, political and logistical problems to developing countries; third, when faced with these constraints, developing countries themselves may not act in the best interests of their TMK holders. The case of India, based on original fieldwork, illustrates these issues.

Due to the complex nature of TMK and diverse positions on its protection, a broad international sui generis system of rights for TMK holders seems a distant prospect in reality. With a view to advancing the debate, this paper highlights local, national, regional and global initiatives to protect TMK holders, examining in particular the potential of four key processes - forum-shifting, linkages to public health, use of transnational networks and normative change in order to achieve incremental gains.

Abbreviations

ACTS	African Center for Technology Studies
CBD	Convention on Biological Diversity
COP	Conference of the Parties
CSIR	Council of Scientific and Industrial Research
CTE	Committee on Trade and Environment
GATT	General Agreement on Trade and Tariffs
IPBN	Indigenous Peoples Biodiversity Network
IPR	Intellectual Property Rights
NBA	National Biodiversity Authority
NGO	Non-Governmental Organization
NIEO	New International Economic Order
PBR	People's Biodiversity Register
PIC	Prior Informed Consent
SRISTI	Society for Research and Initiatives for Sustainable Technologies and Institutions
TK	Traditional Knowledge
TMK	Traditional Medical Knowledge
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
U.S.	United States of America
UNCED	United Nations Conference on Environment and Development
UNCTAD	United Nations Conference on Trade And Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

INTRODUCTION

> Dear Mr. Moore,
> Sub.: **BIOPIRACY AND WTO**
> India is a country which has centuries' old indigenous knowledge systems based on its rich biodiversity… TRIPS[1] has globalised and legalised a perverse and unethical intellectual property rights system which encourages the piracy of our indigenous knowledge … TRIPS is enabling biopiracy… We ask you to immediately amend TRIPS and exclude biodiversity from your global IPR regime…
>
> *Yours truly,*
> Citizens of India and members of Gram Sabhas of villages.[2]

This letter, written to the Head of the World Trade Organization (WTO) in 1999, vividly illustrates a controversial debate that has arisen between the supporters of a harmonized international regime for intellectual property rights and communities who feel that their traditional knowledge is being unfairly appropriated under such a regime.[3] The debate on who has the right to own, access, package, disseminate and benefit from traditional medical knowledge (TMK) has been particularly difficult to resolve. Why? This paper aims to answer this question in three parts. First, by presenting the debate itself, then by analysing key issues hindering progress and, finally, by discussing the implications of these findings for further progress.

METHODOLOGY

This study is literature-based, with fieldwork in India. The sources utilized include primary sources such as legal texts, official and unofficial interviews, and personal e-mail communications, and secondary sources, such as conference reports and proceedings, unpublished articles and essays, as well as textbooks, newspapers and periodicals. The Internet is also a source of primary and secondary material.

PART 1: THE DEBATE

What is intellectual property?

Intellectual property rights (IPRs) are legal rights in *intangible* property. They include patents, copyright, trademarks, unfair competition and confidential information. Each is aimed at "marking out, by means of legal definition, types of conduct which may not be pursued without the consent of the right owner."[4] The term 'IPRs' in this paper will refer mainly to patents, which are the most potent and controversial in relation to traditional medicine. IPRs reward an *individual* (or legal entity) with temporary monopoly rights to use or otherwise exploit the protected subject of the right.[5] However, they also limit the duration and scope of these rights to ensure dissemination of knowledge and innovation for the good of *society*.[4,6,7] Thus, they are believed to be in the public interest. Historically, IPRs were regarded as monopoly *privileges*, rather than private property *rights,* but the latter discourse has somewhat eclipsed the former. It is

of note that IPRs were designed to secure the political and economic interests of colonial powers and, later, industrialized countries.[8] Since 1970s, when these countries began to produce and export intangible knowledge-based goods, such as biotechnology, movies, records and software, a perception emerged that developing countries producing cheap imitations or counterfeits were free riding on their innovations, dubbed 'piracy'. To protect their commercial interests, the industries producing these goods intensely lobbied their home countries to call for stronger intellectual property (IP) protection internationally.[9] The negotiations that ensued were characterized by marked attempts at the global expansion of U.S.-style patent laws, based on dominant neoliberal economic models.[10,11] One landmark result of such activities was the TRIPS Agreement.

The TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was established in 1994 under the auspices of the WTO due to the concerted efforts of a few countries, led by the U.S., with considerable opposition from developing countries. Underpinned by the aim of advancing global free trade 'in a manner conducive to social and economic welfare', the treaty forged an unprecedented link between global minimum standards for IP protection and trade.[12]

In addition to consolidating the basic features of IPRs, TRIPS also broadened their scope. It allows any invention, in any field of technology, to be patented, provided that it is (1) new, (2) involves an inventive step (non-obviousness) and (3) is capable of industrial application.[13] Novelty and non-obviousness are judged against everything publicly known before the invention. This body of public knowledge is called 'prior art.' TRIPS does not define 'new' and 'prior art', which, in the absence of a global minimum standard of novelty, are left for states to decide.[14,15] Patents may be obtained for products and processes, with a 20-year term of exclusive rights for the patent holder starting from the date of filing. TRIPS also introduces the principle of non-discrimination, which ensures that: (1) once a foreign patented product has entered a Member State's national market, the holder of the patent should be treated no differently from nationals (national treatment, Article 3); (2) if granting privileges, nations must treat all foreign nationals equally, with certain exceptions (most favored-nation treatment, Article 4). This is important because TRIPS was brought within the ambit of the WTO dispute settlement system, which confers effective enforcement measures, backed by the threat of trade retaliation, if Members (countries that have ratified the treaty) do not comply with its minimum standards (Articles 63 and 64).

TRIPS obliges Members to treat pharmaceutical inventions like any other technological invention. However, the view that a potentially life-saving drug could be patented in the same way as another 'invention' has not been shared by all:

> My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death. (Mrs. Indira Gandhi, former Prime Minister of India, speaking at the World Health Organization, 1981, quoted by Nachane).[16]

This view exemplifies the idea that medical knowledge is a global public good, to which non-rival and non-excludable access is considered a laudable development goal. The conflicting normative positions on property rights over health-related knowledge,

and inter-state *differences* in the level, scope and mechanisms of protection and strictness of enforcement of IPRs, along with moves towards the *harmonization* of such national laws, have led to a number of problems at the international level.

The Link between IPRs, Traditional Medicine and Health

While there is no universal definition of traditional knowledge, nor a universal definition of traditional medicine (TM) due to differences in its nature and practice, this should not preclude delineation of the scope of the subject matter. One way to define traditional knowledge is in terms of the holders of such knowledge. In this regard, Dr. John Mugabe, formerly of the African Centre for Technology Studies (ACTS), defines traditional peoples as:

> Those who hold an unwritten corpus of long-standing customs, beliefs, rituals and practices that have been handed down from previous generations. They do not necessarily have claim of prior territorial occupancy to the current habitat; that is, they could be recent immigrants.[17]

Thus, the distinction between traditional and indigenous peoples is that traditional peoples are not necessarily indigenous but indigenous peoples are traditional. By this definition, traditional peoples can include both local communities and indigenous peoples. Often these communities are not fully integrated into market economies.[17] Traditional knowledge is embedded in the experiences of indigenous or local people and involves intangible factors, including their beliefs, perspectives and value systems. Thus, "indigenous knowledge is traditional knowledge but traditional knowledge is not necessarily indigenous."[18] The World Health Organization (WHO) defines traditional medicine as:

> the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses.[19]

According to the WHO, over 80 percent of people in developing countries depend on TM for their primary health needs.[20] Some of the best-known codified TM systems include traditional Indian medicine (Ayurveda), traditional Chinese medicine (TCM), and traditional Arabic (Unani) medicine. Many Western pharmaceutical companies also utilize TM to develop drugs, through bioprospecting, which is defined as "the collection and screening of biogenetic resources for industry."[21] Developing countries are particularly rich in plant genetic diversity; in a pioneering study, Farnsworth *et al.* (1985) reported that at least 119 compounds derived from 90 plant species could be considered as important drugs used in one or more countries, with 77 percent derived from plants used in traditional medicine.[22] Examples include digitalis for heart failure, morphine for pain, colchicine for acute attacks of gout and artemisinin for the treatment of drug-resistant malaria. Since it is the traditional knowledge about healing properties of these plants that has guided bioprospecting, there is increasing discontent that the direct benefits from such commercial use are not shared with TMK holders. This is

reinforced by an intellectual property system that confers exclusive rights over biological resources to individuals and corporations, but not to communities.

A counter-argument is that TMK holders have a limited capacity for technological innovation, and insufficient capital to satisfy international standards of safety and reliability. As such, the public benefits of pharmaceutical products need a high revenue stream that can only be guaranteed by strong international IP protection applicable throughout global markets. This view can be traced to the historical development of IPRs as a response by Western society to its own developmental needs and as part of a wider scientific epistemology that separates mind from body, with power accorded to the first half of the duality. [23, 24] In this way, "the expression 'intellectual property rights', with its emphasis on mind, connotes abstraction, de-contextualization, formalization, and the use of written information."[18] In the case of pharmaceuticals, a particular feature (such as an active compound) is isolated from the whole (for example, a plant) and tested out of context (for example, in a laboratory) so that it might be applied in the form of technology.

In contrast, traditional knowledge is often stored in peoples' memories, rather than documented, and is shared orally. Traditional approaches usually examine problems in their entirety, together with their inter-linkages and complexities. Yet, the dichotomy between 'scientific' and 'traditional' knowledge is an over-simplification. First, it is misleading to classify all indigenous knowledge as homogeneous, collective or uniformly innovative.[25] Second, knowledge in traditional communities is only 'traditional' in the sense of its epistemology. The knowledge itself is dynamic, as is the case with formal innovation. Last, knowledge and cultural boundaries are permeable, such that 'global scientific' and 'local indigenous' knowledge are likely to influence each other.[26]

The dichotomy between formal and traditional knowledge becomes critical when the social realities of traditional knowledge are rationalized within the legal and intellectual framework of the patent system, which is based on, and reinforces, conceptual distinctions between the two types of knowledge. What is recognized as an invention, as opposed to a discovery, and how knowledge is established in the public domain, are key distinctions that operate to favor one form of knowledge over another.

Events in the real world illustrate this point. Turmeric (*Curcuma longa*) has been used traditionally in India to heal wounds, and as an antiseptic. In March 1995, two expatriate Indians were granted a U.S. patent for turmeric powder as a wound healing agent.[27] Although the patent was challenged on the grounds of lack of novelty and prior art, and eventually revoked by the U.S., the fact remains that a patent was granted for something already known in the public domain but in a different country. This has been dubbed 'biopiracy', which is defined as, "The unauthorized extraction of biological resources and/or associated traditional knowledge from developing countries, or … the patenting of spurious inventions based on such knowledge or resources without compensation."[28] As a result of such experiences, many have called for a system of IPRs to protect Traditional Medical Knowledge (TMK). I have adopted the term 'TMK', to refer only to traditional medicine (as defined above), as opposed to other cultural knowledge, such as art or agricultural practices. When referring to this wider knowledge and associated set of rights, the term 'Traditional Knowledge' (TK) will be used.

In addition to issues of distributive justice and indigenous rights, the tensions outlined above are significant in the wider context of the health of millions, including

those who benefit from modern medicines derived from TMK, and those who depend on it for their health needs. Accordingly, much is at stake in finding a way to reconcile, or otherwise circumvent these conflicts.

PART II: WHAT IS HINDERING PROGRESS IN THIS AREA

This paper examines three key reasons why this debate has not been resolved. First, current IPR regimes are insufficient to fully protect the rights of TMK holders. Second, trying to introduce national legislation or other measures to protect TMK presents a number of problems to developing countries. Third, when faced with internal and external pressures, developing countries themselves may not act in the best interests of their TMK holders.

1. Current International IPR Regimes and TMK

This section examines the TRIPS Agreement, as the strongest harmonized international regulatory framework for IPRs, with regard to its potential for protecting traditional knowledge. But what is protection? The term is rarely defined explicitly in the literature and at an institutional level appears as a broad and potentially conflicting range of policy objectives. For example, TMK may be protected *by* and *against* IPRs. The World Intellectual Property Organization (WIPO) refers to positive (conferring IPRs on knowledge holders) versus defensive (preventing third parties from procuring IPRs over TMK and associated genetic resources) protection within the IPR system; the latter may be used to prevent misappropriation of TMK and exploitation of its owners, as may restriction of access.[29] Another means of protection is compensation, including equitable benefit-sharing schemes that may allow access to TMK resources under certain conditions, including the prior informed consent of TMK holders. Protection may also mean sustainable development and preservation of TMK.

The above list is not exhaustive. This paper refers to protection as a range of tools and mechanisms to legitimize TMK and to incorporate, rather than restrict, the diverse nature of the scope and beneficiaries of the rights to be conferred. Finally, as Mgbeoji argues, "[w]hile conceptual clarity is desirable, is absence is not necessarily fatal to the status of a concept."[8] Given the diversity of circumstances within this debate, this paper takes a pragmatic, rather than prescriptive, approach.

The core provisions of TRIPS were introduced earlier. Three main potential areas exist within which the rights of TMK holders could be incorporated: (1) prevention of misappropriation, including exclusions from patentability and preventions of misuse contained within the Treaty, (2) the influence of the Doha Declaration amendment to TRIPS and (3) the Treaty's link to the Convention on Biological Diversity. I argue that none are sufficient to protect the rights of TMK holders.

Prevention of Misappropriation

Akin to Mrs. Gandhi's sentiments quoted earlier, an argument could be made that any form of IPRs over life forms such as medicinal plants should be banned, which would prevent exploitation of TMK by third parties.[30] Articles 27(2) and 27(3) of TRIPS define exceptions to the core subject matter of the Treaty. Article 27(2) provides a public

interest exception, allowing Members to exclude from patentability anything that, if commercially exploited, would affect "ordre public or morality[2]"[31]. However, domestic illegality (which might include patenting on all life forms) in itself is insufficient to invoke this exception, which renders the design of legislation, its implementation and related judicial interpretation extremely delicate and vulnerable to attack. Article 27(3)(a) provides a public health exception, excluding diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Article 27(3)(b) allows the exclusion of plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, this exclusion is optional and plant varieties must be protected either by patents or an effective *sui generis* system or by any combination thereof.

Additionally, real world trends that cannot be ignored are towards strengthening IPRs in all areas, including biomedicine and life forms. For example, a landmark 1980 U.S. Supreme Court decision in the *Diamond vs. Chakrabarty* case established that forms of life made in a laboratory are patentable subject matter; indeed, the Supreme Court acknowledged that Congress intended the U.S. Patent Act (found in 35 United States Code § 101) to extend to "anything under the sun that is made by man."[32]

Articles 8 and 40 of TRIPS outline measures that may be taken by Members to prevent abuse of IPRs. Use or manufacture of a patented product, or use of a patented process, without authorization (compulsory license) can be granted by a government if the proposed user has made efforts to obtain permission from the patent holder on reasonable commercial terms and conditions. Interestingly the term 'compulsory licensing' is not mentioned in the TRIPS Agreement. Instead, the phrase 'other use without authorization of the right holder' appears in the title of Article 31. What is considered reasonable is entirely up to national law, and specific limitations are placed on compulsory licensing that merit careful reading. Furthermore, compulsory licensing may not mitigate potential conflicts of interest between TMK holders and a pharmaceutical industry within the same country.

Issues arising out of these provisions have been hotly debated at the WTO ever since an anticipated review of Article 27(3)(b) was due in 1999. While a range of proposals have been put forward, there is still no clear or uniform interpretation of this article, and it appears that an impasse has been reached.[33]

Doha Declaration

The Doha Ministerial Declaration and Declaration on the TRIPS Agreement and Public Health were agreed at the 2001 WTO ministerial conference in Doha, Qatar.[34,335]The latter explicitly recognizes the public health impact of TRIPS on pricing and access to essential medicines, affirming that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. It affirms the right of countries to use compulsory licensing and parallel imports.[36] Furthermore, each provision must be interpreted in accordance with the objectives of TRIPS:

[2] For a discussion on the interpretation of these terms, which TRIPs does not define, see *Xiong, Ping. An International Law Perspective On the Protection of Human Rights In the Trips Agreement : an Interpretation of the Trips Agreement In Relation to the Right to Health. Leiden: Martinus Nijhoff Publishers, 2012.*"

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. [Article 7, objectives, TRIPS].

While this Declaration was unprecedented in terms of mainstreaming a public health agenda into trade and IP sectors, its main impact allowed licensing flexibilities to developing countries under the framework of improving access to essential medicines, which somewhat sidelines the specific issue of TMK. Additionally, its final provisions fell short of original proposals by developing countries and the number of compulsory licenses actually used is small, particularly in countries with little internal pharmaceutical manufacturing capacity.[37] Although the Declaration acknowledges this, encouraging both an expeditious solution and technology transfer from developed countries, it has yet to make any real impact on the ground. Meanwhile, developed countries continue to push for ever more stringent IP regulations, often through other means, such as TRIPS-plus bilateral treaties.[38]

The Ministerial Declaration also mandated TRIPS Council members to examine the relationship between the TRIPS Agreement and another international treaty, the Convention on Biological Diversity (CBD).[39]

Convention on Biological Diversity (CBD)

Like TRIPS, the CBD is a source of international law and also a framework for national, international and regional policy. However, unlike TRIPS, which espouses individual or corporate IPRs, the CBD enshrines the principle of state sovereignty over genetic resources, in the context of conservation of biological diversity and sustainable use of its components. For the first time in a Convention, traditional knowledge and innovations are expressly mentioned. Article 8(j) of the Convention states that each party shall, 'as far as possible and as appropriate':

> Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices [Article 8(j), CBD]

A comprehensive review of the CBD is beyond the scope of this paper, but two of its key provisions affect TMK. First, the use of the word 'holders' in Article 8(j) implies, minimally, the existence of legal entitlements, if not full ownership, to be upheld domestically, either by IPR or other legal/policy measures.[40] In keeping with this interpretation of Article 8(j), the use of the phrase 'indigenous and traditional technologies' in Article 18.4 has led some to argue that such technologies should be no less deserving of protection than other technologies.[41] However, the phrases 'subject to national legislation' and 'as far as possible and as appropriate' are non-committal; they reflect the reluctance of governments during negotiations to prioritize indigenous peoples and their rights. Such rights are not expressly provided for and neither is there any international process to establish these rights, although an Ad Hoc Working Group

on Article 8(j) was established in 1998 to examine ways of protecting and respecting TMK, including the development of *sui generis* systems. The 2010 Nagoya Protocol on Access and Benefit-sharing aimed to provide a transparent legal framework for the implementation of these specific measures within the CBD. It contains several references to the interrelationship between genetic resources and TK, and requires signatories to 'take legislative, administrative or policy measures' (article 5) and 'support' (article 12) indigenous communities with respect to benefit-sharing from TK but, once again, in accordance with domestic legislation.[42]

Second, the CBD does not indicate whether TRIPS is supportive of, or counter to, its objectives. Its wording suggests potential areas of conflict between the two treaties and this is what the Doha mandate aimed to clarify. Unfortunately, little progress has been made. The degree to which the Convention can support developing countries in international trade relations is debatable. Relatively few countries have introduced access and benefit-sharing (ABS) legislation, and the U.S., although a signatory, is still not a party to the agreement.[43] Ironically, the CBD is still struggling to gain observer status on the TRIPS Council and the review of its link to TRIPS, mandated by the Doha Declaration, has yet to occur.

In summary, for the reasons detailed above, *inter alia*, current international IPR regimes are insufficiently flexible to fully protect TMK. Neither TRIPS nor the CBD specifically mandates a framework for the protection of traditional knowledge. Many of the substantive provisions are vague, ineffectively articulated and open to conflicting interpretations. By emphasizing state sovereignty over genetic resources, the CBD fails to address the communal aspects of ownership; similarly, by according IPRs over life forms to individuals, TRIPS overlooks the same point. Greater importance is placed on the economic value of resources, as reflected by the emphasis on access and benefit-sharing, rather than on social value and the fulfilment of basic needs.

These issues reflect more fundamental difficulties with conceptualizing TMK within the framework of IPRs. Underlying any discussions about TK protection are the reasons why it is considered necessary. Not only do these include distributive justice and equity, indigenous rights and health, as mentioned earlier, but also respect for traditional cultures and recognition of their intellectual contributions. IPRs, as a concept, were designed neither with TK in mind, nor with the participation of indigenous peoples, and do not reflect their world-views. In particular, the criteria for novelty and non-obviousness operate to relegate traditional knowledge to a particular interpretation of the public domain by equating it and the resources that give it expression as *res nullius*, the property of nobody – somehow 'wild' or 'naturally occurring'.[39] This prevents recognition of the value of long-term, incremental management by traditional peoples. By contrast, the same criteria of novelty and non-obviousness fail to prevent patents being granted on TMK. If, as Mgbeoji argues, the "intellectual and moral integrity of the current patent system cannot be assumed" then protection of TMK under this system alone is insufficient.[8] However, as highlighted below, any efforts towards TMK protection must work with the realities of IPRs, if not necessarily within their boundaries.

2. State-level Challenges to Protecting TMK

The case of India illustrates some of the challenges to state sovereignty faced by developing countries trying to find ways to protect, and also benefit from TMK. India's biological resources are some of the most extensive in the world; medicinal uses far outweigh any other use of biodiversity by local communities. India also has a growing domestic pharmaceutical industry and faces considerable pressure from industrialized countries to comply with IP legislation. Therefore, how can India reconcile its need to protect TMK from foreign appropriation, to strengthen its domestic pharmaceutical industry, and implement international treaties such as TRIPS, under pressure from countries such as the U.S.?

The turmeric patent described earlier illustrates India's need to protect its TMK from foreign appropriation. Some claim that it may have been a genuine mistake on the part of the United States Patent and Trademark Office (USPTO) and, thus, easy to revoke. However, a senior official at India's Council of Scientific and Industrial Research (CSIR) strongly criticised this assumption.[44] The patent application itself made several claims for the use of turmeric, all of which had to be contested for the patent to be revoked. According to the U.S. patent law at the time, prior use of any invention outside the U.S. had to be documented to preclude patenting of the invention in the U.S. (Section 102 of 35 United States Code). Thus, the challenge was only successful because India was able to produce an ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association, citing prior uses of turmeric.

While U.S. patent law has recently fundamentally changed with regard to what constitutes 'prior art', India holds the view that countries like it do not have the resources to contest every inappropriate patent, and that a legislative framework is required to protect biological resources.[3] An example of such a system is India's Biodiversity Act 2002, which asserts the principle of state sovereignty over natural resources.[45] The objectives of the CBD are quoted in its preamble, yet the Act focuses on stringent restrictions upon access to, rather than the conservation of, genetic resources by foreigners. The creation of a National Biodiversity Authority to govern access, benefit-sharing and intellectual property issues over biological resources further reinforces central control. Section 36 (iv) of the Act provides that the Central Government shall 'endeavour to respect and protect the knowledge of local people relating to biological diversity', emulating the language of the CBD. This may include registration of TK at various levels and other measures to protect TK, including a *sui generis* system.

Any new legislation to protect TMK will be influenced by a key group of stakeholders, India's own pharmaceutical industry, which holds economic potential for the state and is directly linked to public health. It is argued that the relative success of this industry was facilitated by the patent system enshrined in India's 1970 Patent Act which, apart from the universal exceptions of public law, order, morality and injury to human, animal or plant life and health, excludes from patentability (1) methods of agriculture or horticulture; (2) any process for the treatment of human beings, animals

[3] The America Invents Act ("AIA"), which became fully effective on March 16, 2013, has fundamentally changed U.S. patent law. Some of the most important of these changes relate to the scope of 'prior art' available under 35 U.S.C. § 102. If the claimed invention was "patented, described in a printed publication, or in public use, on sale, or *otherwise available to the public* before the effective filing date of the claimed invention" in any country, this now constitutes prior art (italics added). However, although this suggests a move to the recognition of foreign non-documented prior art, in line with many other countries, the words are subject to interpretation, and with exceptions. See, for example, http://www.uspto.gov/aia_implementation/fitf_comprehensive_training_prior_art_under_aia.pdf.

or plants; (3) substances intended for use as food, medicine or drugs; and (4) substances produced by chemical processes.[46,47] Thus, there is an implicit exclusion of microorganisms, plant and animal varieties. For chemicals, pharmaceuticals and food products only processes, and not products, could be patented under Indian law. The rights enshrined in this law were based on considerations of the level of development of the country, as well as philosophical foundations.[48] Industrialized countries such as the U.S. considered these patent laws to be conducive to 'intellectual piracy' and, as described earlier, pushed for stronger international intellectual property protection under the auspices of the GATT. India's ratification of the TRIPS Agreement, and its subsequent defeat at the WTO's Dispute Settlement Panel over a trade dispute with the U.S., have resulted in changes to its 1970 Patent Act. Significantly, the Patent (Third Amendment) Act, 2005, extended patents to products from *all* industry sectors, including pharmaceuticals.[49] Yet, in 2013 India remained on the Office of the United States Trade Representative (USTR) Priority Watch List, as a trading partner judged to have inadequate IPR protection and liable to trade sanctions under Section 301 of the US Trade Act 1974.[50]

India's case highlights not only the difficulties faced by developing countries in reconciling domestic and international obligations, but also the potential political effects of any future domestic *sui generis* system for the protection of TMK vis-à-vis international legal instruments.

It is unclear what the Indian government's exact intentions are – whether to counter biopiracy, to provide local innovators with equitable benefit-sharing without assigning ownership rights over their knowledge, to disseminate knowledge for the benefit of society, to keep it a secret, to maintain national sovereignty over resources and restrict access to foreigners, to protect TK in the same way that other knowledge is protected, or a combination of all the above. What is clear is that, with a growing domestic pharmaceutical industry and increasing economic liberalization, India has much to gain from multilateral trade. Its responses to this complex situation highlight a third tension in the debate on traditional medicine and IPRs: between the Indian state and elements of its society that rely on TMK.

3. Intra-state Tensions between Traditional Communities and Governments

The tribal Kani people, who inhabit the Western Ghat region of the state of Kerala, gave knowledge of the plant *Trichopus zeylanicus* (Jeevani) to the state-owned Tropical Botanic Garden Research Institute (TBGRI) in Trivandrum (also in Kerala). After obtaining a patent to manufacture and sell an anti-fatigue drug based on active compounds in the species, the TBGRI negotiated an agreement to share licence fees and royalties with the Kani, without any legal obligation to do so at the time. However, problems arose because some of the Kani tribe felt that negotiations had not involved all its members and that payments had not been distributed equally. Further problems arose as the plant became a valuable and highly sought-after raw material. While the Kanis were paid to cultivate and provide plant material to the TBGRI, state laws protecting the allegedly rare plant prevented the Kanis from removing it from their settlements to sell to others. Ironically, however, the plant was illegally uprooted by outsiders wishing to sell it at high prices, and a US-based company obtained trademark rights to a similar name but with the same active ingredients.[39] The successes and

failures of this case are described in more detail elsewhere.[51] Though it illustrates that measures to protect TMK may create unintended consequences until a mechanism defining and enforcing the rights of TK holders is established, and until TK holders can participate fully and democratically in state-level decisions that govern their resources and way of life.

PART III: A WAY FORWARD

The first two sections presented a critical view of the problems facing both TMK holders and developing countries, including historical, philosophical and political, as well as substantive and interpretative, challenges to implementing legislation in the field. I have argued that current international IPR regimes are insufficient to fully protect TMK and may even legitimize its misappropriation. It is particularly difficult for TMK to meet the criteria of novelty, non-obviousness and industrial applicability; additional disadvantages include costs and lack of technical know-how to procure IPRs over TMK.

However, a number of local, national, regional and global initiatives to protect TMK – reflecting varying interpretations of this term – cast a more positive light on the story.

Local and National Initiatives

Developing countries mostly articulate concerns about patents granted outside the country that holds the knowledge.[52] In order to assert rights outside the domestic territory, therefore, a *sui generis* international framework for TMK protection might be desirable. However, little progress has been made towards this, and practical benefits for TMK holders are currently most likely to be achieved through national laws.

As discussed earlier, under TRIPS Member States must provide either patents or *sui generis* IP protections for plant varieties. Attempts at such legislation have often been made in the context of plant breeders' rights or biodiversity protection, such as India's Biodiversity Act discussed earlier. Some countries have tried specifically to protect TM, for example China, under a patent framework, and the Philippines and Thailand as *sui generis* legislation.[53]

A different type of national approach is to document TMK, an example being India's Traditional Knowledge Digital Library (TKDL). Hailed as a model innovation, its primary aim is the dissemination of TK, regulating outsiders' access and precluding patenting of these or similar innovations.[54] The documentation and digitization of TK enables the ready identification of wrongful patent applications, so that third party observations (TPOs) can be filed to oppose them. In what seems like an ironic mirroring of the U.S.'s Section 301 Priority Watch List, the database has an integrated global biopiracy watch system for this purpose. Documentation of TMK in this way may preserve it, promote research, assist with clinical practice and teaching, and promote public health.[55] However, it may also facilitate misappropriation, without conferring positive rights on TMK holders.

The above examples suggest that national systems for TMK protection can be developed that are compatible with TRIPS. However, they also highlight potentially competing aims between countries, and reinforce a statist position on TMK and genetic

resources. The last point raises a question about to whom any global *sui generis* system of rights should be accountable – a state or its people.

Regional Cooperation

The Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, adopted by the African Regional Intellectual Property Organization (ARIPO) Member States in August 2010, aims to protect traditional knowledge holders against any infringement of their rights as recognized by this Protocol.[56] The rights conferred pertain mainly to access and benefit-sharing as set out in the CBD. The Protocol also acknowledges that systems for TK protection exist in traditional cultures. The example demonstrates that such systems may, through customary law, be adopted along with international treaties into a legislative framework through regional cooperation.

Global Institutions: New Developments within existing IPR Regimes

Local, national and regional initiatives have shown promise in moving the debate forward. However, as Nair points out, unless these efforts are recognized and accepted more widely, particularly by WTO Member States, they may suffer from the lack of global legitimacy.[57]

Therefore, countries have also tried to influence IPR regimes at an international level. For example, in light of the Doha Declaration and in an attempt to reconcile TRIPS and CBD, an alliance of developing countries led by India and Brazil proposed an amendment to TRIPS. It requires disclosure of genetic source and origin in patent applications, along with evidence of 'Prior Informed Consent' and 'fair and equitable' benefit-sharing.[58]

Several countries have passed national laws requiring disclosure of country of origin.[59] However, while countries such the U.S. and Japan, the heaviest users of the patent system, resist the amendment, it is unlikely to be accepted within the WTO.[60] Furthermore, if disclosure is incompatible with TRIPS then, as one commentator points out, "WTO jurists are likely to reject claims that violating TRIPS is necessary to avoid a conflict with other treaty commitments or regime objectives."[61] This, again, raises questions about the normative legitimacy of the WTO in this debate. The U.S. has argued that discussions on disclosure amendments belong in a different forum. It may be strategically risky, if not pragmatically impossible, for developing countries to leave WTO negotiations altogether. Though the increasing involvement of other global institutions in this debate may represent an opportunity for TMK holders to legitimize their concerns outside the WTO framework (forum-shifting).

Global Institutions: Emerging Players and Forum-shifting

In the same way that IP-reliant countries are promoting their agendas outside the WTO, for example through 'TRIPS-plus' bilateral agreements, there are opportunities for TMK holders also to present their arguments in multiple forums simultaneously. Indeed, in recent years the dialogue on TMK protection has shifted back from the WTO

to other organizations, most notably the World Intellectual Property Organization (WIPO) and World Health Organization (WHO).

The WIPO has been the main intergovernmental institution examining issues relating to TK, biological resources and IPRs. In 2000, at the request of developing countries in response to the CBD, it created an Intergovernmental Committee on Genetic Resources, Traditional Knowledge, and Folklore (IGC) to establish an international legal instrument for the protection of TK.[62] Unfortunately however, successive rounds of negotiations in this forum have been largely unsuccessful. Moving the TMK debate to other forums introduces complexities, requires resources, does not guarantee success, and risks diluting impact through soft law and lack of enforcement measures.[63] However, the next section explores two key ways in which forum-shifting may benefit TMK holders: (1) through linkages with public health and development agendas and (2) through the shaping and diffusion of norms that may influence, or eventually become, law.

TMK and Public Health

The WHO has played a significant role in mainsteaming public health issues into trade and IP sectors, albeit largely through the access to essential medicines agenda.[64,65] In 2008, at the first WHO Congress on Traditional Medicine, representatives of over 70 Member States adopted the 'Beijing Declaration', which stated that "[t]he knowledge of traditional medicines, treatments and practices should be respected, preserved, promoted and communicated widely and appropriately based on the circumstances in each country."[66] In 2004, the WHO established a Commission on IPRs, Innovation and Public Health. Its report, published in 2006, briefly addresses TM but with the acknowledgement that is narrow remit of stimulating innovation and promoting access to new products derived from TMK may not align with broader demands for TMK ownership rights.[67] Is TMK protection at odds with access to essential medicine? The next section examines what commonalities exist between the two agendas and how they may be more closely linked for mutual benefit.

Questions have been raised as to the extent of TMK contribution to modern drug development, and the loss actually suffered by developing countries.[68] Aside from a report suggesting that developing countries lost at least $5bn annually in unpaid royalties to MNCs that appropriate TK, considering TMK protection as purely an economic issue overshadows more legitimate concerns about its safety, efficacy and use in public health.[69]

Highlighting TMK protection within the context of public health first allows allopathic and traditional medical cultures to be brought together for mutual learning and innovation. For example, the WHO has the remit and technical knowhow to evaluate the safety of medicines, and its Traditional Medicine Strategy has scope to incorporate TMK rights as well as to integrate TM into national health programmes.[70] TMK holders may learn from the experiences and relative successes of the WHO and its backing civil society advocates in negotiating a health agenda in trade and law sectors. At the same time, empirical evidence suggests that more bioprospecting is needed to enhance research, which may draw on TMK.[71]

Some argue that strong IPRs correlate positively to pharmaceutical innovation, and even to better health care.[72] However, it may also be argued that the current patent

system incentivises so-called 'lifestyle' drug development for populations with purchasing power, neglecting diseases of the poor. In this way, the system perpetuates health inequalities. At the same time, there are established links between poverty and ill health. TMK holders, being some of the world's most marginalized people, may also experience the poorest health conditions.[73] Financial empowerment through TMK protection, in exchange for knowledge dissemination targeted to treat neglected diseases, may reduce health inequalities.

Third, many forms of TMK protection, such as defensive patents, revocation of inappropriate patents, and ABS measures, do not confer monopoly rights or inherently reduce access. Finally, as WIPO argues, not all access and drug affordability issues are due to the patent system.[74] For example, companies often use bilateral trade agreements to eliminate reference pricing, which can make patented products prohibitively expensive. Even with positive TMK protection rights, we cannot assume that TMK holders will operate in the same way as multinational corporations; in line with their worldviews, as discussed already, many indigenous people have non-economic motivations for disseminating information. However, unless protective measures enforcing the rights of TMK holders are created, a danger exists not only of continued exploitation but also of mistrust and reduced access to potentially life-saving resources.

Rather than TMK protection being regarded as inherently at odds with access to medicines, the two agendas may work together to empower traditional innovators, reduce health inequalities and "neutralize the clout of large pharmaceutical firms in the formation of US and European positions" in political forum.[75] They may both be framed as development issues, with the post-2015 Sustainable Development Goals providing an opportunity to bring these to the front of debate.

Additionally, new inter-sectoral collaborations are setting precedents for the way in which international institutions interact. For example, in February 2013, a joint WTO-WHO-WIPO study, "Promoting Access to Medical Technologies and Innovation," was launched, representing the first such collaboration of its kind.[76]

Whether such collaborations will be successful remains to be seen, but forum-shifting in this manner may create and diffuse normative principles, such as the primacy of health, equity and corporate social responsibility, into global IP interactions such as TRIPS negotiations, and may also harness the support of increasingly influential global actors, namely civil society and transnational networks, to achieve this.

Transnational Networks and Normative Change

Indigenous and local communities themselves are participating in intergovernmental forums and raising public awareness through declarations, domestic lobbying and local initiatives to protect and derive some benefit from their traditional knowledge. For example, it was in civil society organizations that the idea for a disclosure requirement in TRIPS was first suggested.

A defining moment for Indigenous Peoples' groups was the United Nations Conference on Environment and Development, held in Rio de Janeiro in 1992 and more commonly known as the Earth Summit. This laid the foundation for the *sui generis* treatment of all matters relating to TK. It was here that transnational networks active in driving the debate on TM were forged and where the CBD was opened for signature.[77] Unconstrained by a mandate restricted to the conservation of biodiversity, the United

Nations General Assembly in 2007 adopted a Declaration on the Rights of Indigenous Peoples. Article 31 asserts that indigenous peoples have the right to 'maintain, control, protect and develop their intellectual property over' their TK.[78] While not legally binding, such declarations may exert a softer normative influence over, for example, the interpretation of treaty rules.[79] Whether the incremental diffusion of such norms over time may shape international law, which, as we have shown, is neither politically inert nor unchangeable, remains to be seen.

CONCLUSIONS

This paper contends that the debate between those who call for stronger IP legislation to protect their 'scientific' innovation, and those who claim 'biopiracy' of their traditional knowledge under such legislation, has been fuelled by the lack of an integrated and comprehensive rights-based system for TMK. This is underpinned by ideological differences over the value and ownership of knowledge, and the extent to which it should confer economic versus social benefits, with power politics favoring the strongest actors in the current system.

It was suggested that, under current IPR regimes, the treatment of the isolation and modification of plant compounds as 'innovation' offends many communities. As a result, some have argued that any form of IPRs over TMK or its derivatives should be banned, echoing the sentiments of Mrs. Gandhi at the start of this essay. In my view, this is not a way forward. We have seen that developments in the real world make it unrealistic to stem the internationalization of IPRs in areas such as biomedicine and life forms. Second, unless there are measures to protect and derive benefit from TMK, those most closely related to it will remain poor. Finally, genetic resources are physical material and therefore tangible property. But they also have a distinctive quality from industrial inventions, in that they are self-replicating, living resources and carriers of intangible hereditary genetic information, which is the basis for innovations. Traditional knowledge about such resources – an excellent example being medicinal knowledge – has also evolved over time. It is perceived not as the property of an individual, but as the result of the collective efforts of a community and their predecessors. "… in both cases the resource reproduces and transforms itself in a logic that lies beyond, and is independent of, the individualized creativity and innovation from which existing IPRs result."[80] This is a strong reason to discuss the possibility of a *sui generis* system that addresses the unique nature of these resources and associated TK. The diverse nature of TK should not preclude working towards a sufficiently broad system of rights for TK holders, within which individual interests can be accommodated. However, it is a legitimate concern that, if iniquities inherent in the current system are not addressed, expanding IPRs to incorporate TMK risks magnifying the very same factors that are the perceived root of the problem.

The logistics of implementing an international system of rights for TMK holders, as well as ideological differences, may explain why political consensus has been painfully slow in this area. Additionally, the case study of India highlights the mirroring of some of these tensions at a domestic level, with the threat of 'local biopiracy' as domestic pharmaceutical industries gain prominence. However, examples of local, national, regional and global initiatives, along with the increasing role of transnational networks, non-state actors and inter-sectoral collaboration, raise a glimmer of hope.

These real-world examples also highlight the emergence of unclear and potentially differing social objectives: benefit-sharing, prevention of misappropriation of resources, ownership rights over TMK and public health needs, such as access to essential medicines. While this is hardly surprising, given the complexity of agendas on the table, these objectives are not necessarily mutually exclusive and must be delineated within the policy space for the debate to progress. In particular, since the holders of TMK may also suffer the worst health, borne out of poverty and disadvantage, there may be potential for the TMK rights-based agenda to collaborate with global public health agendas and to harness the normative influence of civil society.

Given the number of stakeholders in this debate, if any single justification should underpin a system for the protection of traditional knowledge, it must be a balance between the different interests involved. Thus, what may be developing is an opportunity, rather than a challenge, to countries. Whether they succeed in addressing the issues in a way that commands the acceptance of those affected remains to be seen.

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[1] Agreement on Trade-Related Aspects of Intellectual Property Rights.
[2] "Citizens of India and Members of Gram Sabhas of Villages Respond to Biopiracy and the WTO." *Co-globalizing Gaia's Children*. Accessed 1999. Available at: http://www.ratical.org/co-globalize/BPandWTO.html.
[3] A regime is defined by Krasner as a set of 'implicit or explicit principles, norms, rules and decision-making procedures around which actors' expectations converge in a given area of international relations. Krasner, SD. *International Regimes*. Cornell University Press, 1983.
[4] Cornish, WR. *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights*. 3rd ed. London: Sweet & Maxwell, 1996.
[5] For definitions of legal, juridical and natural persons see Law and Martin, A Dictionary of Law (7 ed.), Oxford University Press 2009. The term 'legal person' includes corporations as well as real individuals, an example of the disjuncture between historical and current beneficiaries of IPRs.
[6] Bainbridge D. *Intellectual property*. 3rd ed. London; Washington, D.C.: Pitman, 1996.
[7] Holyoak JH, Torremans P. *Intellectual Property Law*. London: Butterworths, 1995.
[8] Mgbeoji I. *Global Biopiracy: Patents, Plants, and Indigenous Knowledge (Google eBook)*. UBC Press, 2011
[9] Sell, SK. *Private Power, Public Law: The Globalization of Intellectual Property Rights*. Cambridge University Press, 2003.
[10] Weissman, Robert. "A LONG, STRANGE TRIPS: THE PHARMACEUTICAL INDUSTRY DRIVE TO HARMONIZE GLOBAL INTELLECTUAL PROPERTY RULES, AND THE REMAINING WTO LEGAL

ALTERNATIVES AVAILABLE TO THIRD WORLD COUNTRIES." *University Of Pennsylvania Journal Of International Economic Law* 17, (January 1, 1996): 1069.
[11] Carroll, Amy E. "NOT ALWAYS THE BEST MEDICINE: BIOTECHNOLOGY AND THE GLOBAL IMPACT OF U.S. PATENT LAW." *American University Law Review* 44, (July 1, 1995): 2433.
[12] *Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299*. 1994. Future references to the Agreement will be made in the text.
[13] TRIPS also states that the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with 'non-obvious' and 'useful' respectively [Article 27(1), TRIPS].
[14] Carvalho NP de. *The TRIPS Regime of Patent Rights*. Kluwer Law International, 2010: 807.
[15] For one legal definition of 'prior art' see Regulations(i) Under the Patent Cooperation Treaty, Rule 63. Available at: http://www.wipo.int/pct/en/texts/rules/rtoc1.htm.
[16] Nachane DM. Intellectual Property Rights in the Uruguay Round: An Indian Perspective. *Economic and Political Weekly (India)*. 1995, 30(5):257–67.
[17] Mugabe J. *Intellectual Property Protection and Traditional Knowledge - An Exploration in International Policy Discourse*.; 1998.
[18] Coombe, Rosemary J. "Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity." *Indiana Journal of Global Legal Studies*, 1998.
[19] World Health Organisation. *WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine. Document WHO/EDM/TRM/2000*. Geneva; 2000.
[20] World Health Organization. WHO | Traditional Medicine Factsheet. 2008.
[21] Dutfield G. Between a rock and a hard place: Indigenous Peoples, Nation States and the Multinationals. In: Schmincke KH, ed. *Medicinal Plants for Forest Conservation and Health Care*. Rome: Food and Agriculture Organization of the United Nations; 1995.
[22] Farnsworth N., Akerele O, Bingel AS, Soejarto DD, Gui ZG. Medicinal Plants in Therapy. *Bull. WHO*. 1985;63: 965–981.
[23] For a review of this see Mitchel B. Wallerstein. et al., *Global dimensions of intellectual property rights in science and technology* (Washington, DC: National Academy Press, 1993).; Holyoak and Torremans, *Intellectual property law*.; Bainbridge, *Intellectual property*. and Alison Firth, ed., *The prehistory and development of intellectual property systems*, 3 vols., vol. 1, *Perspectives on intellectual property series* (London: Sweet & Maxwell, 1997).
[24] For a classic dualist position see Renè Descartes, *The Philosophical Writings of Descartes*, trans. Robert Stoothoff and Dugald Murdoch John Cottingham, vol. especially Vol. II pp. 16-23, 51-54, 56-61 and 171-2, and Vol. I pp. 195, 196, 204-5 and 216-19. (Cambridge: Cambridge University Press, 1985).
[25] Gupta AK. Enigma of intellectual property rights: How long shall we miss the opportunities?. Available at:
http://webcache.googleusercontent.com/search?q=cache:npYORvZy63wJ:203.200.225.141/anilg/CONF.PAPERS%25201979-2003/ENIGMA%2520of%2520IPR.RTF+&cd=1&hl=en&ct=clnk&gl=us.
[26] Brush SB. "Whose Knowledge, Whose Genes, Whose Rights?" In: Brush SB, Stabinsky D, eds. *Valuing Local Knowledge: Indigenous People and Intellectual Property Rights*. Washington, D.C.: Island Press, 1996.
[27] Das SK, Cohly HHP. Use of Turmeric in Wound Healing. 1995. Patent no US 5,401,504A.
[28] This term was coined by the North American advocacy group Rural Advancement Foundation International (RAFI). It reciprocates accusations of intellectual piracy made by industrialised countries against such countries as India and Brazil. See G. Dutfield, "TRIPS-Related Aspects of Traditional Knowledge," (London: Personal communication).
[29] World Intellectual Property Organization. *Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions An Overview*.; 2012.
[30] For views on whether cultural knowledge is amenable to ownership see Marilyn Strathern. et al., "Exploitable knowledge belongs to the creators of it: a debate," *Social Anthropology* (1998).
[31] Xiong, Ping. An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement: An Interpretation of the TRIPS Agreement in Relation to the Right to Health. Vol. 108. Martinus Nijhoff Publishers, 2012.
[32] *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

[33] World Trade Organization. TRIPS: ISSUES. Article 27.3b, Traditional Knowledge, Biodiversity. Available at: http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.
[34] *Doha Ministerial Declaration WT/MIN(01)/DEC/1*. Doha; 2001. Subsequent references to this declaration will be made in the text.
[35] *Declaration on the TRIPS Agreement and Public Health WT/MIN(01)/DEC/2*. Doha; 2001. Subsequent references to this declaration will be made in the text.
[36] Parallel importation is importation without the consent of the patent-holder of a patented product marketed in another country either by the patent holder or with the patent-holder's consent.
[37] The South Center. The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation. 2011;(7):1–12.
[38] TRIPS-Plus refers to provisions that either exceed the requirements of TRIPS or eliminate flexibilities in implementing TRIPS. Sell, S.K., 2007. TRIPS-Plus Free Trade Agreements and Access to Medicines. *Liverpool Law Review*, 28(1), pp.41–75.
[39] UN Secretary General. *Convention on Biological Diversity*.; 1992.
[40] Dutfield G, International Union for Conservation of Nature and Natural Resources. *Intellectual property rights, trade and biodiversity : seeds and plant varieties*. London: Earthscan; 2000.
[41] Sahai S. Indigenous Knowledge Confers Rights on Communities. In: Arora RK, Riley KW, eds. *Asia-Pacific Regional Consultation on Plant Genetic Resources*. International Plant Genetic Resources Institute; 1996: 68–72.
[42] *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*. 2010.
[43] Kamau EC, Fedder B, Winter G. The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community? *Law environment and development journal*. 2010;6(3).
[44] Intellectual Property Management Division Senior Official, CSIR, Interview. 2001.
[45] *The Biological Diversity Act*.; 2002. India.
[46] Even though profit margins are comparatively low, as is spending on R&D, Indian pharmaceutical companies have managed to produce a wide variety of drugs at some of the most affordable prices in the world: B. K. Keayla, Interview, April 2001.
[47] *The Patents Act, 1970*.; 1970. India.
[48] Sangal PS, Singh K. *Indian patent system and Paris Convention : legal perspectives*. Allahabad, India: Distributed by Wadhwa and Co. 1987.
[49] Macdonald-Brown C, Ferera L. First WTO Decision on TRIPS," European Intellectual Property Preview, no. 2 (1998). *European Intellectual Property Review*. 1998;2.
[50] Kirk AR. *2012 Special 301 Report*. 2013. Available at: http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf
[51] Chaturvedi S. *Kani Case. A Report for GenBenefit*.; 2007. Available at: http://www.uclan.ac.uk/research/environment/projects/assets/cpe_genbeneift_kani_case.pdf
[52] Brenner-Beck D. Do as I say, not as I did. *Pacific Basin Law Journal*. 1992;11:84–118.
[53] Robinson D, Kuanpoth J. The Traditional Medicines Predicament: A Case Study of Thailand. *The Journal of World Intellectual Property*. 2008;11(5-6):375–403.
[54] Gupta VK. Indian TKDL as a Model to prevent misappropriation. In: *International Conference on "Utilization of the Traditional Knowledge Digital Library (TKDL) as a Model for the Protection of Traditional Knowledge"*.; 2011.
[55] Abbott R. *Documenting Traditional Medical Knowledge*. 2014. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2406649.
[56] *Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore Within the Framework of the African Regional Intellectual Property Organization (ARIPO) Ado*. Swakopmund, Namibia; 2010.
[57] Nair MD. TRIPS, WTO and IPR : Protection of Bioresources and Traditional Knowledge. *Journal of Intellectual Property Rights*. 2011;16(January):35–37.
[58] India, Brazil and Others., 2004. The relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge — elements of the obligation to disclose evidence of prior informed consent under the relevant national regime. IP/C/W/438. Available at: http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm

[59] Queen Mary Intellectual Property Research Institute. *Report on disclosure of origin in patent applications*.; 2004.
[60] WIPO. Annex 1: PCT, Madrid and Hague international applications: top 10 origins. 2013. Available at: http://www.wipo.int/export/sites/www/pressroom/en/documents/pr_2014_755_a.pdf#annex1
[61] Helfer LR. Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking. *Yale Journal of International Law*. 2004;29(1).
[62] WIPO General Assembly. Matters concerning intellectual property and genetic resources, traditional knowledge and folklore. In: *Twenty-Sixth (12th Extraordinary) Session*.; 2000.
[63] For a critique of soft law see e.g. Klabbers J. The Redundancy of Soft Law. *Nordic Journal of International Law*. 1996;65(2):167–182.
[64] Sridhar D. Improving Access to Essential Medicines: How Health Concerns can be Prioritized in the Global Governance System. *Public health ethics*. 2008;1(2):83–88.
[65] Martin G, Sorenson C, Faunce T. Balancing intellectual monopoly privileges and the need for essential medicines. *Globalization and health*. 2007;3:4.
[66] World Health Organization. Beijing Declaration Adopted by the WHO Congress on Traditional Medicine. 2008.
[67] The commission on intellectual property rights innovation and public health. *Public health , innovation and intellectual property rights*. 2006.
[68] Mcclatchey W. Medicinal Bioprospecting and Ethnobotany Research. *Ethnobotany Research & Applications*. 2005;3:189–190.
[69] McLeod 2001, cited in World Bank, Oxford University Press. *Poor People's Knowledge: promoting intellectual property in developing countries*. (Finger JM, Schuler P, eds.). World Bank Publications; 2004:213.
[70] World Bank, Oxford University Press. *Poor People's Knowledge: promoting intellectual property in developing countries*. (Finger JM, Schuler P, eds.). World Bank Publications; 2004:213.
[71] Oldham P, Hall S, Forero O. Biological diversity in the patent system. Pappalardo F, ed. *PloS one*. 2013;8(11):e78737.
[72] Maitland I. Priceless Goods: How Should Life-Saving Drugs Be Priced? *Business Ethics Quarterly*. 2002;12(4):451.
[73] World Health Organization. Health of indigenous peoples Fact sheet no 326. 2007.
[74] WIPO. Striking a balance: the patent system and access to drugs and health care. Available at: http://www.wipo.int/export/sites/www/freepublications/en/patents/491/wipo_pub_491.pdf
[75] Shaffer G. Recognizing Public Goods in Wto Dispute Settlement: Who Participates? Who Decides?: the Case of Trips and Pharmaceutical Patent Protection. *Journal of International Economic Law*. 2004;7(2):459–482.
[76] WHO, WIPO, WTO. *Promoting Access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade*. Geneva: WTO Secretariat; 2012.
[77] Keck ME, Sikkink K. Transnational advocacy networks in international and regional politics. *International Social Science Journal*. 1999;51(159):89–101.
[78] *United Nations Declaration on the Rights of Indigenous Peoples*. 2007.
[79] For an excellent analysis of the varied effects on resolutions of international organizations, see Jochen Frowein, "The Internal and External Effects of International Organizations" *Heidelberg Journal of International Law*. 1987; 49: 778.
[80] Traditional Knowledge and Folklore Intergovernmental Committee on Intellectual Property and Genetic Resources, "Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore An Overview (WIPO/GRTKF/IC/1/3)," (Geneva: World Intellectual Property Organisation, 2001).

Sector Wide Approaches in Health Care: Do They Work?

Eileen S. Natuzzi and Thomas Novotny

International aid policy is evolving. The Rome Declaration on Harmonization, the Paris Declaration on Aid Effectiveness and the Accra Agenda for Action have shifted development assistance efforts toward recipient countries assuming stronger leadership roles in prioritizing, implementing, and coordinating aid programs within their own countries. Central to these donor and recipient partnerships is alignment of aid so that it supports country priorities, harmonizes accountability reporting among donors, and reduces redundancy in programs in order to engender efficiency and cost savings.

Sector Wide Approaches (SWAps) for health care bring donor agencies, civil society, and recipient governments together to work on health systems and health outcomes. The cooperative nature of SWAps and their embrace of the principals endorsed by the Rome and Paris Declarations as well as the Accra Agenda on Aid may enhance aid effectiveness. However, SWAps that have been implemented in over 35 countries have yielded mixed results and have been met with some skepticism. This paper will review what SWAps are, where they have demonstrated success, and where they have failed. Development assistance for improving health system capacity building, achieving Millennium Development Goals (MDGs), and the development of sustainable health programs will be discussed.

THE CHANGING ARCHITECTURE OF HEALTH DEVELOPMENT ASSISTANCE

Global health development assistance has undergone an explosion of activity and partnerships as many new and long-standing actors have become increasingly active over the last two decades. The Millennium Development Goals (MDGs) 2015 deadline has sharpened the focus on aid delivery approaches and measurement of their effectiveness. Achieving most of the health-related goals is unlikely, although there have been modest improvements in child and maternal mortality, expansion of education, and extensive global support for HIV/AIDS treatment[1].

Health aid has traditionally been delivered through independent projects that address specific diseases or on issues such as immunization, health risk behavior, or reproductive health. These types of projects are developed and negotiated between the donor agency and the local national governments.[4] In some countries there can be hundreds of simultaneously conducted health projects that may lead to fragmentation, duplication, and redundancy of spending. Sometimes they pull health ministries in multiple directions in order to comply with donor reporting requirements. For example, in 2002 Vietnam had 25 bilateral donors, 19 multilateral donors, and about 350 international NGOs conducting over 8,000 projects. This type of "donor assault" leads to proliferation-fragmentation of aid and can detract from aid effectiveness through

[4] The term donor agency or donor in this paper will refer to all aid donors including; bilateral and multilateral agencies as well as NGOs and private sector.

such things as transaction costs of monopolizing the time of high-level ministry staff and the indirect costs of pulling workers away from public positions into better paying project positions. Reporting on each project's activities as well as outcomes takes time and human resources[2]. While many projects yield health care results, many are not sustainable and essentially "create islands of excellence in a sea of dysfunction." One possible contributor to proliferation-fragmentation of aid is the fact that large aid agencies work in diverse and a wide number of countries. By reducing the variation of aid environments and the number of countries in which they work, these agencies may become more effective without changing overall aid levels.[3]

For decades, international aid agencies and economists have been concerned that there may be too much direct health aid flowing to developing countries while failing to address the root of the problem for adverse health conditions: poverty.[4] There is some evidence that specific project aid may lead to fungible application of this aid to other priority areas. Others feel there is not enough overall health aid.[5,6] Some form of cooperation among agencies is needed in order to improve health financing and aid effectiveness, but movements toward such cooperative actions have been slow.

A number of high-level meetings on aid delivery have identified areas where aid can be more effectively delivered, especially regarding MDGs 4 and 5 (reduction of child and maternal mortality). The Monterrey Summit of 2002 recommended approaching aid proliferation-fragmentation through new partnerships between developed and developing countries based on mutual responsibility and accountability in support of sound policies, good governance, and the rule of law. Harmonization of aid was addressed at the High-Level Forum on Harmonization in Rome in February 2003 and expanded by the Organization for Economic Cooperation and Development (OECD) Development Assistance Committee's (DAC) Task Force on Donor Practices in their two volume report: Harmonizing Donor Practices for Effective Aid Delivery.[7] The report recommended "good practices" in coordination of aid especially as they pertain to MDGs. These recommendations include:

- Predictable and reliable project aid with time scales for aid delivery (short, medium, long-term)
- Transparent conditionality
- "Ex ante" budget support to prevent the effects of funding volatility.[8]

The Paris Declaration (2005) and the Accra Agenda for Action (2008) reinforced the need for better aid coordination through donor alignment with recipient country needs, local ownership, harmonization, and mutual accountability.[9]

The International Health Partnership (IHP+), a coalition of international health agencies, governments, and donors committed to improving health and development outcomes in developing countries, held a High Level Task Force meeting on Innovative International Financing for Health Systems in New York in September 2008.[10] The meeting summarized the challenges of scale up and financing needed to meet the MDGs. The task force reviewed innovative mechanisms for raising and channeling funds and set targets for domestic health expenditures of 12-15% of GDP as a part of total government expenditure. Some additional but contentious aid funding mechanisms were discussed, including the development of Public-Private Partnerships and pay for performance buy-downs by donors.[11] Working groups also discussed efficiency of aid

delivery in the face of scarce resources, the need for long-term predictability and commitment of aid in order to create stability of programs in developing countries.

Conventional project-oriented aid can be adapted to this approach if "collectives of aid agencies" working in countries are created. Although coordination of donors will likely make aid more sustainable, health system capacity building also requires strong local management, budgeting capabilities, and procurement skills. These require changes in investment from donors, including more technical assistance, pooling of funds, and surrendering of some autonomy. Sector Wide Approaches (SWAps) in health have been used as a mechanism to coordinate aid while developing recipient government capacities. This paper discusses SWAps, how they work, how they fall short, where they are used, and whether SWAps can deliver results in the changing architecture of global health programs.

DEFINITION OF SECTOR WIDE APPROACH (SWAPS) IN HEALTH CARE

A SWAp is an approach used to create a locally owned program for a coherent sector, in this case health, in a comprehensive and coordinated manner. It moves aid control to the recipient country in order to create sustainable long-term health programs. SWAps represent a shift in the focus, relationship, and behavior of donors and governments from traditional donor-designated projects to nationally-defined programs that focus on results. Participation in a SWAp requires donors to pool their finances and/or efforts in order to support the recipient health sector-defined policies. In an ideal SWAp donor-designated projects do not exist, although the health care projects they fund, such as malaria eradication, are financed, evaluated, and managed through the SWAp. All participants must agree to support the priorities defined by the recipient country health sector. As a result, they give up project autonomy and earmarking of funds.[12]

SWAps are not aid instruments; they are top-down development programs that create sector-wide policies, and strategies through robust, legitimate government institutions. In large countries, a SWAp may function at multiple district or state levels, but in small countries they operate at the national level. They can address development as well as service delivery decisions.

Table 1. What distinguishes a sector-wide approach from a conventional project approach? Traditional Project Aid: details items to be funded such as nutrition, vaccination where SWAps reinforce national budgets and policy.

Sector-wide approach	**Conventional project approach**
Country holistic view on entire sector	Focus on projects to support narrowly defined objectives
Partnerships with mutual trust and shared accountability	Recipient accountable to donor
External partners' co-ordination and collective dialogue	Bilateral negotiations and agreements
Increased use of local procedures	Parallel implementation arrangements
Long-term capacity/system development in sector	Short-term disbursement and success of projects

Process-oriented approach through learning by doing	Blueprint approach

Source: Adapted from World Bank (2004), "SWAps in Latin America: A World Bank Perspective", PowerPoint presentation, Tegucigalpa, 8-10 November.

SWAps derived from and are built upon the principals of Sector Investment Programs (SIPs). Alden Winship Clausen, the sixth president of the World Bank Group (1981-86), introduced SIPs as a means to coordinate development aid. Clausen saw the debt crisis of 1982 as a problem of liquidity, which could be overcome by expanding free international trade. This would only be possible through major restructuring of the developing economies through sectorial and structural adjustment operations. SIPs have been used for the development of public goods such as agriculture, transportation, energy and telecommunications. On the other hand, a SWAp is a social development program. In SIPs, the government, the World Bank, and other donors jointly finance an agreed-upon sectorial expenditure program that has a clear public rationale or goal and intends to correct a market failure or to alleviate poverty. The critical objective of a SIP that differentiates it from a SWAp is its goal: to improve the development impact of public expenditures in a sector without crowding out private inputs. In fact, SIPs enable a favorable economic environment for the private sector by influencing regulation and infrastructure, which may in turn prove beneficial to the overall economy.[13] SWAps on the other hand create frameworks within which health programs and policies are implemented. It can include infrastructure upgrades, human resources for health, purchases of medications, as well as public health and MDG-oriented programs. Following the 1997 Danish Government and World Bank meeting with bilateral and multilateral health donor agencies on employing SWAps in health, they have been implemented in over 35 developing countries.

ESTABLISHING SWAPS

Establishing SWAps is a slow process, not easily guided by a formula or an established model. They can be thought of as sector-wide programming development processes as they are incremental and progressive in nature. Implementation involves intensive needs-assessments, strategic planning, and decision-making about resource allocation. The process also requires technical inputs and commitments from both the recipient government and donor partners, and these inputs should be transparent across all participants. SWAps are phased in, incremental, and they have the possibility of adding, removing, and modifying elements as the process evolves (See Table 2).

Given the need for recipient government inputs, fragile states with unstable economic capacities will struggle with implementation, as SWAps require strong and effective government ownership. The first step in establishing a SWAp is to engage the recipient government, including all applicable ministries, such as Health, Finance, and Education in order to reach consensus on priorities along with those of donor partners. Formal government acceptance of responsibilities must be confirmed, and donors must also agree to support the government's health priorities and government arrangements.

Clear objectives for health sector SWAps should follow the establishment of partner commitments. Some SWAps devise a Memorandum of Understanding (MOU) or Code of Conduct that outlines the goals, requirements, and inputs from all

participants. Nevertheless, it is common early in the SWAp development for participants to become bogged down in the structuring of the program (national health plans, financing, budgeting, sector coordination mechanisms etc.). This can result in loosing track of the overall SWAp goals and may necessitate the need for frequent reminders among the SWAp partners to keep development on track.

Development of a sectorial framework also requires a comprehensive baseline inventory of all resources available. This includes local financial institutions and national systems that will be employed by the program. All donors must buy in to the sector-wide approach and be discouraged from supporting disease specific projects outside the SWAp. Donors and governments commit to pooling medium-term development funds in order to create sustainable and reliable financing for the SWAp.[5],[6], However, the SWAp partners set priorities, not pre-requisites, for funding, and members jointly agree upon milestones and targets as well as reporting methods for accountability. An annual SWAp meeting, quarterly review meetings and monthly working group meetings are usually necessary, with oversight from the recipient government and technical inputs from donor partners.

SWAps are most successful when the recipient government is the major overseer of the SWAp and when one ministry handles all administrative responsibilities (planning, budget, and reporting). Inter-sectoral coordination of multiple ministries (finance, health and education) can be challenging, as this requires cooperation across sectors. Parallel projects by donors operating outside the SWAp can weaken it by adding to transaction costs and redundancy in reporting requirements. Every effort should be made to bring as many donors working in the country into the SWAp in order to maximize its performance and administrative efficiency.

SWAPS IN MOTION

About 13% of the World Bank's Health, Nutrition, and Population (HNP) programs in developing countries are supported through SWAps. As of 2013 this included 22 projects in Sub-Saharan Africa, six in Southeast Asia, four in East Asia and the Pacific, two in Latin America and the Caribbean, and one in Eastern Europe and Central Asia. ( ) A review of some of these programs may shed light on the some of the challenges encountered in using SWAps to coordinate aid.

Zambia (running out of gas…)

One of the first Health Sector SWAps was Zambia's SWAp, established in 1993, with the goal of decentralizing the health sector, strengthening partnerships and increasing the efficient use of available health sector funds. Fifteen collaborating partners participate in Zambia's SWAp: the WHO, WFP, UNAIDS, UNFPA, UNICEF, SIDA, DFID, JICA, GTZ, EU, CIDA, DANIDA, Ireland, Netherlands, and USAID. At its inception, there was great enthusiasm for the program within the government and its

[5] Medium-Term Expenditure Frameworks (MTEF): a tool to encourage cooperation across ministries and planning over a longer horizon than the immediate upcoming fiscal year. This holistic approach is preferable to piecemeal, reactive, short-term decisions that ordinarily characterize budgeting. An MTEF creates 3 year spending plans.

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implementation was rapid. To date, the SWAp has demonstrated modest achievements, due partially to an increasing number of disease specific initiatives such as HIV/AIDS programs (PEPFAR, the Presidents Malaria Initiative (PMI), and Global Fund) that continue to function outside the SWAp. Transaction costs have not decreased, and the reporting workload has increased due to outside donors requiring their own reporting and accountability from the recipient government. The SWAp did succeed in increasing budgetary allocations to district level health facilities however; it has not contributed to the achievement of administrative, technical, and allocation efficiencies. Progress on several key process indicators such as drug availability, immunization coverage, and supervised obstetrical deliveries has happened, but this has not translated into better health outcomes. In the case of Zambia, despite its strong government commitment for the SWAp, significant resources are still channeled outside the government system. [15,16,17]

Bangladesh (suffering from fatigue…)

Established in 1998, Bangladesh's SWAp is known as the Bangladesh Health, Nutrition, and Population Sector Programme (HNPSP). There are eight collaborating partners in HNPSP: WB, WHO, DFID, EC, RNE, Sida, UNFPA, CIDA, GTZ. However, the HNPSP story highlights the need to pay close attention to key SWAp principal components, including government leadership and ownership, realistic strategic health plans, and continued external financing. Nowhere have tensions and "donor fatigue" been more apparent than in this largest health SWAp. Its implementation was a political challenge, as there were many conflicts of interest within participating groups. Political corruption, lack of Ministry of Health (MOH) leadership, and high leadership turn over further challenged the SWAp. In 2003, when the Government of Bangladesh decided to reverse the decision to unify the Ministry of Health and Ministry of Family Welfare, the decision led to disagreements with donor partners, reduction in the level of cooperation and caused the suspension of some donor funding. Formerly "pro SWAp" partners shifted back to project-specific aid programs due to the government's poor performance and internal conflicts, while other donor partners maintained the SWAp. The continued stand-alone projects and the new global health initiatives such as PEPFAR, combined with weak leadership and loss of momentum, has delivered a series of blows to Bangladesh's HNPSP. Currently there are several health projects in Bangladesh that are not using common procedures for budgeting, reporting, and evaluation. Recent allegations of irregularities in procurement and other financial management activities have further eroded donor support for the HNPSP.[18,19]

Uganda (decline in coordination…)

Uganda's SWAp, known as the Health Sector Strategic Plan (HSSP) was established in 2000. Members of Uganda's SWAp include: The Africa Development Bank, Belgium, Denmark, the European Union, Ireland, Netherlands, Norway, Sweden, the United Kingdom, and the World Bank. It is a multi-sectoral program involving the Ministries of Finance and Planning, Education, and Health. Early on the program was considered a success story, but its performance has declined in recent years. A number of factors have been responsible to its decline such as decreased government health

spending, changes in aid modalities used by development partners, weakening of government leadership, and poor health sector governance. Having suffered from civil war and conflict for over two decades, the central government of Uganda was weak and faced with a deteriorating health sector as well as numerous public health crises such as HIV/AIDS. Districts were responsible for health care resulting in a lack of central authority. When the SWAp was first established it increased spending for health and established the MOH in the central oversight position. Uganda's initial positive experience working with its health SWAp became a model for others. Over time, government spending on health declined and leadership of the SWAp weakened due to internal power struggles and a lack of inter-sectorial cooperation. The MOH in Uganda now exerts central control over funds and policies at the district level. However, this may add to ongoing power struggles, as the districts are not represented administratively in the SWAp. As has been seen in Zambia and Bangladesh, large funded disease-specific global health initiatives, such as PEPFAR, the Global Fund, and PMI, functioning outside the SWAp, have adversely affected transaction costs and harmonization.[20] Since 2003, the amount of Development Assistance for Health (DAH) earmarked for specific diseases has steadily increased in Uganda despite the presence of its SWAp. Much of this aid goes towards HIV/AIDs, while funding for support to the health system has steadily declined.[21,22,23]

Solomon Islands (fragile states….)

Solomon Islands has suffered from years of intermittent political instability, ethnic tensions and social unrest which has left the country lacking a unified vision for health sector development. Recent instability has spanned nearly a decade, and during this time there has been proliferation of much needed service-focused projects run by donor projects and NGOs. This fragmented DAH has created excessive hosting workloads for health administrators due to the large numbers of visiting missions that must be accommodated. In 2006, Solomon Islands was considered a 'post-conflict fragile state' with a nearly non-existent government.[7] Its main external partners, AusAID and the World Bank, initiated the Solomon Island Health SWAp known as the Health Sector Support Program (HSSP). However, tensions among donor partners and the Solomon Island Government, as well as a lack of government ownership of the SWAp, limited its progress from 2007 to early 2009. Since May 2009, the HSSP has gained additional support from a number of other development partners and committed MOH staff members. The initial perception of SWAps as a funding pool and financial management scheme has been replaced in Solomon Islands with a focus on partnership development and coordination. While great strides have been made in these areas there are still significant challenges in extending DAH program benefits to the outlying provinces where the majority of people live. AusAID is the principal financial donor to the SWAp, but there are many other partners who participate in HSSP who do not pool their funds under it. These include: World Bank, JICA, the EU and the Pacific Secretariat. Recently there has been increased cooperation among a number of donors such as the United Nations, NGOs, and bilateral and multilateral agencies. The US Government and USAID do not participate in the SWAp as they do not currently fund

[7] Fragile states are characterized by a limited capacity or unwillingness of the State to govern or provide services.

DAH in Solomon Islands. In April 2014 deadly flash flooding in the capital city and surrounding areas tested the Solomon Islands SWAp's ability to respond to a large natural disaster. The acute disaster response was well organized. But the presence of the SWAp did not prevent the need for external assistance once infectious disease outbreaks set in and taxed limited supply chains.[24,25,26,27]

Mozambique (Inclusive techniques…)

Established in 2000, Mozambique's SWAp has been a model health sector program demonstrating local ownership and leadership, more effective use of aid, strong policies within the sector, and reduced transaction costs. During its implementation, the government as well as donors signed a "Code of Conduct," known as the Kaya Kwanga agreement, which outlined basic rules of engagement. This code described a common vision for health development, set priorities and goals for improving efficacy and accountability, and sought to coordinate external aid. The SWAps common fund became known as Prosaude. Within the SWAp, public expenditure for health more than doubled between 2001 and 2004 due to increased contributions to the common fund as well as moderate increased government spending on health, but over one-third of DAH funds remain outside the SWAp and earmarked for vertical programs such as PEPFAR, PMI, and the Global Fund. One of the acknowledged weaknesses of the SWAp is its "centralized operation" that fails to employ a district policy framework. This has resulted in increasing numbers of development partners operating outside the SWAp in the districts. To mitigate this situation, the Mozambique government proposed to the Global Fund that it operate from within the SWAp. The robust financial management system for health and the steady success, strategic planning and budgeting procedures have enabled Mozambique to be the first country in the world to integrate resources provided by Global Fund into the health sector's common fund. The Global Fund's Country Coordinating Mechanism (CCM) members work with the SWAp and agree to function as other SWAP signatories and to use nationally agreed indicators, targets, monitoring arrangements, and reporting systems. To date, PEPFAR and PMI continue to operate outside the SWAp, despite the urgings of local health managers to integrate these vertical programs into the primary health care system. As of 2011, however, funding from these sources has dwarfed SWAp funding and has contributed to "internal brain drain" as the vertical program NGOs attract health workers away from the government public health system. At present there are 23 donor partners participating in Mozambique's SWAp with 14 of them contributing to Prosaude. [28,29,30,12]

Ghana (hybrid semi-SWAp approach….)

Ghana, formerly the Gold Coast, was the first African colony to obtain its independence from Britain in 1957. Since its independence, Denmark has been one of Ghana's greatest development partners. In 1994 Ghana, with technical assistance from Denmark (DANIDA) and the UK (DFID), initiated a Health Sector Support Program (HSSP), which was essentially a SWAp, although the Ghanaian government has never referred to it as such. Its development was more gradual than Zambia's, an attribute that is believed to have contributed to its productivity. Each component of a functional

SWAp (donor coordination, government ownership, single reporting) was implemented gradually during the mid-1990s. This created a strong policy and budgetary framework for a National Health Plan. Early on, Ghana's HSSP was described as, "One of the most successful areas of systems development and capacity-building …contributing considerably to the overall efficiency of the health system." ( ) In 2006, 50% of Ghana's DAH was channeled through pooled funds, down from the 60% noted in 2003. This shift in funding mechanisms also reflects the increase in vertical global health initiatives such as Global Fund, PEPFAR, and PMI in Ghana. Ghana's HSSP has made significant attempts to decentralize the health sector and to strengthen district and sub-district delivery of health care. To do this, Ghana engaged donor partners who choose not to pool funds to conduct building block programs focused on delivering a hybrid "semi-SWAp." Currently, 95% of all development partners in Ghana participate in the Ghana Joint Assistance Strategy (G-JAS), an agreement between development partners and the Government of Ghana (GOG) to work in a coordinated fashion. However, after 10 years of Ghana's health SWAp, despite increased use of country systems and better harmonization and coordination of donors, there has been insufficient improvements in health indicators, and the country is not on track to achieve MDGs 4, 5, and 6. Despite these disappointing outcomes in August 2013, Ghana observed the 10-year anniversary of its National Health Insurance System (NHIS) and is moving toward universal health coverage. Members of Ghana's HSSP: the World Bank, DFID, DANIDA, Netherlands, UNICEF, UNAIDS, UNFPA, and the WHO. Earmarked funds outside the HSSP, but part of G-JAS, include those from USAID, JICA, GTZ, and the Saudi Fund.[32,33,34]

MDGs: and Health SWAps

Many of the most important health promoting and sustaining activities that contribute to achieving the MDGs do not fall within a single Ministry's remit and will therefore be outside the classic health SWAp architecture. These issues include nutrition, water and sanitation, and education; all of which impact the health of adults and children. Significant human resources for health (HRH) are needed for every aspect of achieving MDGs 4, 5, and 6, and SWAps must also address these through the SWAp framework. Developing countries using a SWAp to address the MDGs need to create linkages between all the relevant Ministries via an inter-sectorial cooperation framework. Working across ministerial boundaries (Finance, Health, Education, Agriculture, Public services and Infrastructure) requires a strong and cohesive central governance system that does not exist in many low and middle-income countries (LMICs). These inter-sectorial linkages can make SWAps very challenging, and for this reason may not be an ideal mechanism for addressing the MDGs in many LMICs. Most HIV/AIDS, malaria and TB programs are funded outside the SWAp through various global health initiatives. However, the project-oriented donors who participate, and cooperation from inside the SWAp, can cut down on redundancy of reporting and accountability resulting in lower transaction costs. As mentioned above, SWAp time lines are most productive if they are long and gradual. This makes SWAps an undesirable option to facilitate achieving current MDG targets. However, they should be included in discussions surrounding the new Sustainable Development Goals planned for the next round of UN health development planning. Without adaptation and modification, classic SWAps may fail to deliver on development goals. The addition of

"service delivery building blocks" funded by variable tranche funds[8] can supplement SWAps and may push them closer to success using hybrid techniques. [35,9]

PROBLEMS AND PITFALLS OF SWAPS

Leadership and structure

Top-down approaches toward policy, management, and services may affect social and development equity in health projects as a central focus of programs may overlook health end points. Tangible benefits to population health must be demonstrated early in the SWAp process in order to garner support both from donors and from the population impacted by the SWAp. This is a persistent challenge, even in the longest standing SWAps. Some have suggested that a mix of DAH that addresses both sectorial policy and management issues while allowing bottom-up projects based on the community's self-identified health issues will yield better overall results. Bottom-up projects may be funded on their own, but they should be integrated into the SWAp, to assure coherence with overall SWAp goals. Leaders of such projects should participate in quarterly meetings, in monitoring and reporting mechanisms, and in other management activities within the SWAp.[36] The top-down approach may be overly technocratic and centrally driven but its efficacy may be enhanced by the inclusion of local stakeholders perspectives in the development of SWAp policy frameworks.

Because SWAps bring together diverse partners with governments of variable governing capacity, tensions can arise among supporters of different approaches and with differing levels of contribution. Regular dialog is essential to keep programs and collaborators on track, and this can be accomplished through regular SWAp committee meetings, forums and working groups. SWAps may be completely abandoned due to a lack of government ownership as well as leadership, weak frameworks that fail to recognize context specific challenges, corruption, and donor and recipient resistance to transparency. When faced with these challenges, SWAp partners should focus on helping the government and Ministry of Health re-take control of the project but if necessary donor partners can manage the SWAp until government stability improves.[18]

Development and time to "mature"

Some SWAps can take as long as 5 to 10 years before positive impacts on health sector function and results are seen.[37] This long time frame can create frustration among partners due to the lack of immediate gratification. Recipient governments can see the SWAp as a ready pool of money and are disappointed when donors hold back funding until implementation shows measurable success. Changes in governments can cause stops and starts to the SWAp, resulting in significant periods of program disruption. Consistency of SWAp technical and administrative staff can create a sound operational

[8] Twin Funding for hybrid SWAps: an adaptation of tranche. Funding for governing and budgets with conditionality of funding and additional funding resources for the service delivery level (training, equipment, facility maintenance, etc). Fixed tranche-all or none release of funds thru the budget and based upon macroeconomics, Variable tranche-releases funds based upon conditionality. Multiple flows incorporate both and could be a good hybrid approach.

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and long-term foundation. A SWAp does not by design provide effective short-term humanitarian assistance or services, but it can be used to strengthen a health system during recovery from conflict or a disaster, provided adequate governance exists. Government and donor partners must recognize that SWAps are long-term programs that will have ups and downs and that they need time and flexibility to develop and adapt to ongoing challenges.

Donor Partners

Many development partners (both bilateral and multilateral) feel the need to "fly their flag" for their home constituencies in order to justify their presence and to attract program resources. However, the SWAp approach tends to diminish visibility of financial resource origins. This may create a "domino effect" in pursuit of recognition among donors as more development partners become involved in a successful SWAp. (20) SWAp membership size matters, as increased numbers of participants can result in large, unwieldy meetings and coordinating processes. The more donor partners, the more transaction costs may be needed. One way to address this is through "silent" or "delegated" partnerships, created among donor partners; such partners agree to have one representative at the table who addresses policy issues and manages financial contributions for the other silent partners.[38]

Activities and funds outside of the SWAp

Vertical programs operating outside the SWAp can undermine it especially if they are somehow challenged by the SWAp. In the case of the Global Fund, PEPFAR, and PMI requirements for additional reporting, financial supervision, and evaluations can create significant additional work for government officials and defeat the efficiency benefit of the SWAp. A work-around for this has been demonstrated by the Mozambique government's incorporation of the Global Fund's CCM into the SWAp. The Mozambique experience demonstrates that it is possible to adapt management frameworks, monitoring and reporting mechanisms, audit practices, and generally any other vertical program procedures into country systems and priorities as a part of the SWAp framework. Although still not perfect, Mozambique provides a good example of how global programs with unique business models can fit into country-led harmonization efforts.[16, 28]

Concerns about the fungibility of funding within health SWAps have been raised. Reassignment of funds from one sector to another can impact government revenue as a whole rather than just a sector. "Basketed funding" monies can be redirected to other sectors for non-health expenditures, or government financing for health can be decreased in proportion to increased donor contributions. Clear policies on the use of SWAp funds must be established early in order to prevent inappropriate redirection of funds.

"Donor-flight" and "internal brain drain"

The implementation of SWAps has resulted in decreased DAH funding when implemented by some of the poorest LMICs. In some cases, this decrease amounts to a

24% reduction of total health aid. This could be the result of donor caution due to lack of confidence in the recipient government, concerns about corruption in that government or preferential investing in countries that can demonstrate easy wins.[39] Internal Brain Drain is another problem brought on by International NGOs and donor agencies working outside the SWAp. Recruitment of government public health workers by offers of salaries 5-10 times greater than those paid by the MOH has shifted human resources away from the delivery of care and weakened public health development programs.[30]

CONCLUSIONS

Increased funding from global health initiatives, along with unprecedented expansion in health aid in developing countries has intensified consideration of how DAH is delivered. The increasing number of donor-driven projects in developing countries has resulted in what has been described as "open-sourced anarchy."[40] The Rome, Paris, and Accra Agenda meetings, along with The International Health Partnership (IHP+) have pushed for better coordination of DAH through alignment and harmonization of donors with recipient governments. The goals of these declarations is to increase efficiency and to control transaction costs, leaving more funding to support actual health outcomes and to strengthen health systems while keeping specific health program targets in sight. In 1993, the World Bank proposed SWAps as a mechanism to coordinate health sector aid with the presumption that a coordinated effort would decrease redundancy and cost, and increase efficiency of delivery. This review indicates that these expectations have been variably met.

This paper has described what a health SWAp is, what establishment of a SWAp entails, provided some country examples of SWAps and common problems encountered working within SWAps. This analysis has had difficulty reporting on specific health outcomes and health system strengthening outcomes that have resulted from health SWAps. The reason for this limitation has been previously stated by former World Bank official, Richard Skolnik and colleagues, "There is an unacceptable dearth of scientific assessment that demonstrates the impact of SWAps on health outcomes, despite the billions of dollars that have been invested in this approach since the mid-1990s."[41]

From the limited number of gray literature and journal articles on SWAp performance, improved health outcomes and decreased transaction costs have not been reported. What is discussed in the available literature is the operational effectiveness of the SWAp itself, but not its intended outcome: improved delivery of health care and public health successes. More than a decade into the use of health SWAps researchers are still asking: are they effective in reducing illness, disability, and death for the poorest people in the world? The answer is mixed and depends upon who is asked. One of the greatest drawbacks of SWAp approaches is that they become bogged down in the development of management and financial structures such that the health related work is diminished in implementation. As this paper suggests, there are many ways to evaluate the workings of a SWAp, but the end results for health outcomes remain obscure.

The 2009 World Bank Independent Evaluation Group's (IEG) review of SWAps sheds some light on the most "complete-incomplete" data on SWAps. Six countries (Bangladesh, Ghana, Kyrgyz Republic, Malawi, Nepal and Tanzania) programs were evaluated by IEG as to performance, health outcomes, and transaction costs. The report

praised the SWAp process: "Almost all of the tools for improved sector management and coordination were successfully developed and established in all six countries."[15] However, when it came to health outcomes the story was quite different: improvements in maternal and child mortality have been modest, and in most cases reversed the decline in outcomes incurred during the SWAp implementation period. The SWAp's impact on transaction costs was even more questionable:

The performance of SWAps in reducing transaction costs—a major anticipated benefit of the approach—cannot be assessed in any country because they have not been monitored. In fieldwork, IEG was unable to compile any data measuring transaction costs before and after adoption of a SWAp, for the government or for the donors. Nor do there appear to be any studies of staff time allocations across tasks in government or by the development partners before and after adoption of a SWAp.[42]

Nevertheless the news about SWAps is not all bad. While governments and organizations working in LMICs hold relatively little influence over global health initiative designs and goals, some SWAps have demonstrated improvement in quality of care (Zambia) and establishment of cost-effective essential interventions (Malawi).[43] In Bangladesh, where a SWAp has been in place since 1998, coverage and access to basic health services has improved. The World Bank's International Development Association (IDA) staff credits the country's SWAp for a 40 percent reduction in maternal mortality and a 26 percent reduction in under-five child mortality from 2004 to 2010. [44] However, in Nigeria where a health SWAp has been in place since 2006, the country falls short on achieving the health MDGs. Kenya has yet to make progress on improving maternal health, reducing child mortality, and reducing HIV, malaria and TB through its SWAp.[45] Still, other reports hold the World Bank responsible for the lack of health results within SWAps although much of this criticism arises from vertical program supporters.[37]

The lack of data on SWAp outcomes suggests two possibilities: sector wide approaches do not work in health, or the collection of usable outcome data has been overlooked in the technocratic evaluation processes. It is important to note, however, that the World Bank has employed the sectorial approach successfully in agriculture, energy, education, and telecommunications. These sectors may be less complicated within which to work; for example road building to promote agricultural product transportation is intuitive and clearly integrated with sectorial development and requires different sectors to work efficiently together. Health delivery is complex, as it not only crosses many sectors, but it is also impacted by population dynamics, changing diseases, broad geographic areas, development, culture, education, poverty, trade and economics stability. The choice of countries in which a SWAp is initiated can also impact its success. Originally, SWAps were recommended for use in countries with strong financial accountability, a functional government, and the capacity to implement complex programs. Contrary to this set of qualifications, they have often been implemented in post-conflict settings and in countries without basic government structures, thus creating severe challenges to multi-sectorial implementation.

The basic concept behind SWAps, bringing together donors and recipient government in order to create a health sector free of funding volatility, is an admirable one, but the lack of results reported thus far suggest a need for a change in approach. One of the greatest lessons to learn from the paucity of outcome data is the need for less

emphasis on the SWAp process evaluation and more emphasis on health outcome measurements. As mentioned earlier in this analysis, the introduction of a "bookend," or "semi-SWAp approach" might improve end results and yield meaningful outcome data. One example of such a bookend approach is providing education to district health care workers at the local level. The sector assures the educational content is consistent with the overall program goals, addresses the local context and provides the trained education professionals with the financial support needed to retain them in the system. The donor harmonizes its efforts with the sectorial program, delivers the training locally, measures the results and reports back to the SWAp management. Funding for this type of "semi-SWAp approach" does not need to be all or none as donors can deposit funds into two baskets: an operational implementation fund and a bottom-up health service provision fund.

It has been asserted that donors who do not put their funds into the SWAp's common fund basket weaken it. These statements are most commonly directed toward the U.S. Global Health Initiative funds in Sub Saharan Africa, but the health outcomes of PEPFAR, and the Global Fund, cannot be disputed. Perhaps one should consider these earmarked programs as sustaining a portion of the health system while a broader sectoral program is being developed. Engaging donors to develop projects and programs that service provision needs within the health sector can help to make it a stronger system development program.

At the beginning of this paper SWAps were described as being a shift in the focus, relationship, and behavior of donors and recipient governments from traditional donor-designated projects to nationally defined programs that focus on results. The World Bank, responsible for the introduction of health SWAps, has in its current health development portfolio the growth of Universal Health Coverage (UHC) in developing countries.[46] Followers of DAH must ask themselves what this means. Is the Bank now encouraging the development of a health insurance industry in countries devoid of fully functional health systems? If this is true, then is the timing and environment right for this type of DAH? To say that UHC will improve health, the Bank must remember that coverage does not equal access to care unless a functional health system is in place. One wonders if the World Bank's plan is to use health SWAps the same way it employs SIPs; to create more favorable economic environments for private health industry to flourish by influencing LMIC's health regulation and infrastructure through their SWAps. If this is the case, then how will those results be measured?

If SWAps continue to be employed in health system development then there must be greater transparency and regularity of independent outcome evaluations. Perhaps the MDGs' 2015 deadline will provide more information on how SWAps have performed as health system development tools. Nevertheless, governments and their development partners recognize the need for achieving results and modifying SWAp operations based upon robust monitoring and evaluation data. The SWAp technical advisory team must be accountable also, and be open to adapting current SWAp processes to achieve the new Sustainable Development Goals post 2015. They must also be willing to discontinue a country's SWAp when it is determined that it is doing more harm than good. SWAps are a model with a clear label but with unclear results.

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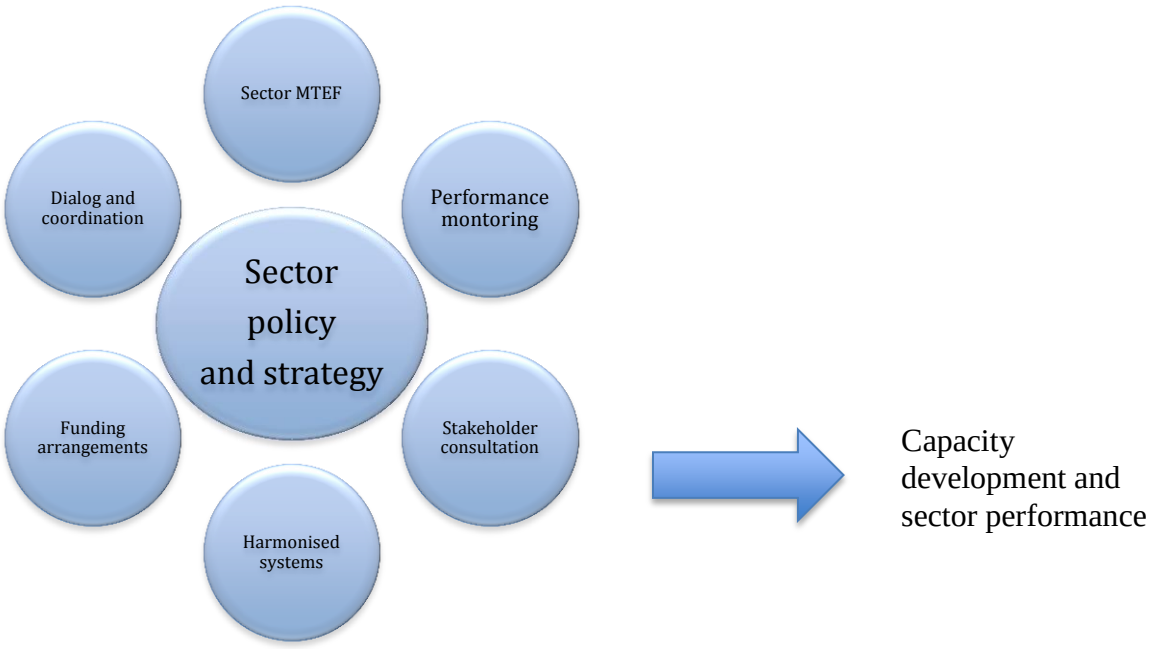
Table 2. Seven core elements that make up a SWAp

1. All significant funding agencies (including the recipient government) support a shared sector policy and strategy as defined by the recipient government.
2. A medium term expenditure framework (MTEP) or budget supports this policy.
3. Recipient government ownership, leadership and transparent decision-making processes.
4. Shared processes and approaches for implementing, managing and monitoring the sector strategy and work program, including reviewing sectorial performance against jointly agreed milestones and targets.
5. Develop formalized processes ensuring coordination and policy dialogue between all members of the SWAp such as joint missions, sector reviews, and periodic meetings that encourage dialogue and discussion.
6. Commitment to move to greater reliance on local government financial management, budget, reporting, procurement and accountability systems.
7. Consultation and technical assistance mechanisms available for all stakeholders.

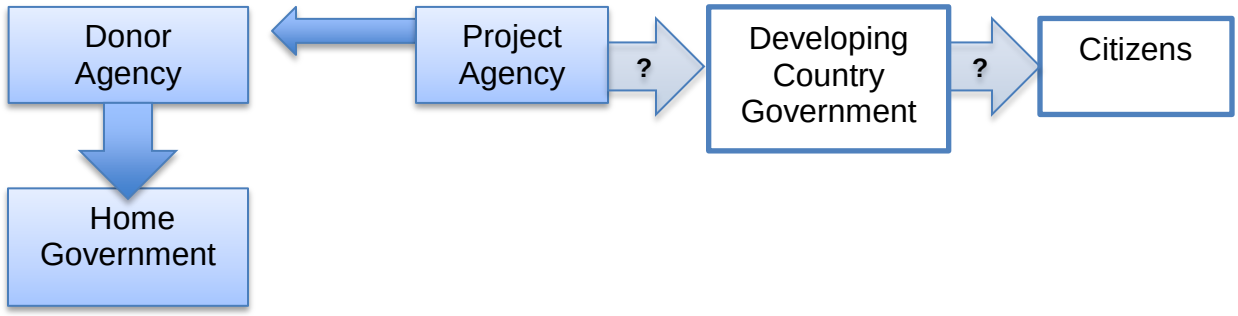
Figure 1: Sector Wide Approach Framework elements[47]



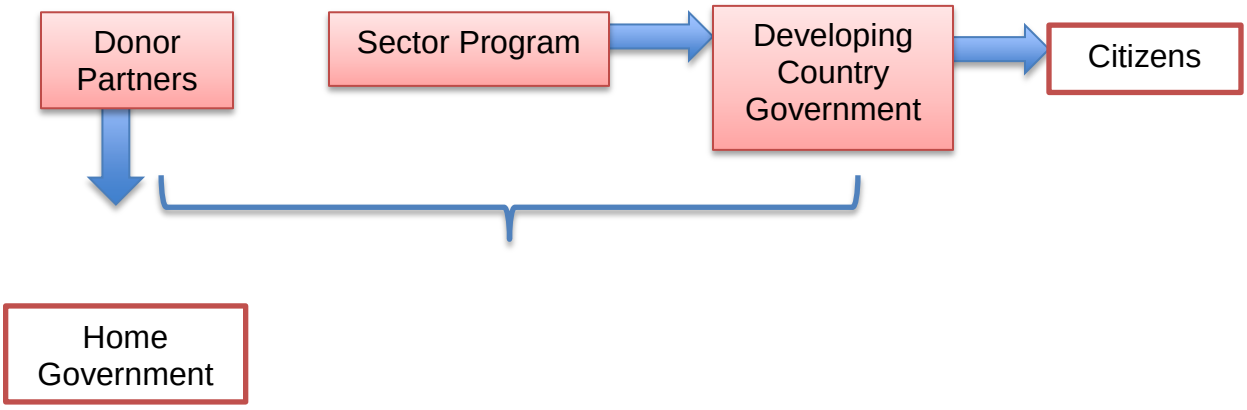
(1)_____
OECD DAC Guidelines: Harmonizing Donor Practices for Effective Aid Delivery, vol 2, 2006.

Figure 2: Accountability of SWAp monitoring versus project monitoring

Project Monitoring



Sector Monitoring



[1]What Will It Take to Achieve the Millennium Development Goals? UNDP Report June 2010. Available at: http://content.undp.org/go/cms-service/stream/asset/?asset_id=2620072
[2] Acharya A, Fuzzo de Lima A, Moore M. Proliferation and fragmentation: Transactions costs and the value of aid, *Journal of Development Studies,* 2006; 42(1) 1-21
[3] Merson M, Black R, Mills A. Global Health:Diseases, Programs, Systems, and Policies. 3rd ed. Burlingame MA. 2012.
[4] Easterly W. The White Man's Burden. New York, The Penguin Press 2006.
[5] Jeffrey Sachs. Health and economic development. Available at: http://www.chathamhouse.org/events/view/178393
[6] Lu C, Schneider M, Gubbins P, Leach-Kemon K, Jamison D, Murray C. Public financing of health in developing countries: A cross sectional systematic analysis. *Lancet* 2010; 375: 1375-87.
[7] Rome declaration on Harmonization of Aid 2003. Available at: http://www.searo.who.int/LinkFiles/Strategic_Alliance_and_Partnerships_1b_Rome_Declaration.pdf
[8] Harmonizing Donor Practices for effective aid delivery. 2006. Accessed 3/15/12. Available at: http://www.oecd.org/dataoecd/53/7/34583142.pdf
[9] OECD, The Paris Declaration on Aid Effectiveness (2005) and the Accra Agenda for Action (2008). Available at: http://www.oecd.org/dataoecd/11/41/34428351.pdf
[10] Alexander D. The International Health Partnership. *Lancet*. 2007; 307. 803-804.
[11]Fryett R, Mills A, Nordstrom A. Financing of health systems to achieve the health Millennium Development Goals in low-income countries. *Lancet*. 2010; 375:419-26.

[12] Cassels A. A guide to sector-wide approaches for health development: concepts, issues and working arrangements. Geneva: WHO, 1997. Accessed 3/20/12. http://whqlibdoc.who.int/hq/1997/who_ara_97.12.pdf
[13] Fostering Sustainable Development: the sector investment program World Bank http://documents.worldbank.org/curated/en/1997/05/438507/fostering-sustainable-development-sector-investment-program
[14] Vaillancourt D. Do Health Sector Approaches achieve results? IEG Working Paper 2009. Accessed 2/20/12. http://tinyurl.com/6pzkvly
[15] Colins C, Sundewall J, McIntyre D, Tomson G, Forsberg B. Exploring SWAp's contribution to the efficient allocation and use of resources in the health sector in Zambia. *Health policy and Planning* 2008; 23: 244-251.
[16] Walford V. A review of health sector wide approaches in Africa. 2007 Accessed 4/13/12. Available at: http://www.hlsp.org/Home/Resources/ReviewofhealthSWApsinAfrica/tabid/1796/Default.aspx
[17] Chansa, C., J. Sundewall, et al. Exploring SWAp's contribution to the efficient allocation and use of resources in the health sector in Zambia. *Health Policy Planning* 2008; 23(4): 244-251.
[18] Martinez J Sector Wide Approaches at Critical Times: the case of Bangladesh. 2008 Accessed 4/14/12. Available at: http://www.hlsp.org/Home/Resources/Sectorwideapproachesatcriticaltimes.aspx
[19] Sundwell J, Forsberg B, Tomson G. Theory and practice-a case of coordination and ownership in the Bangladesh health SWAp. *Health Research Policy and Systems* 2006; **4**(5): 1-8.
[20]Ortendahl C. The Uganda health SWAp: new approaches for a more balanced aid architecture? 2007 Accessed 4/14/12. Available at: http://www.hlsp.org/Home/Resources/UgandahealthSWAp.aspx
[21]Stierman E, Ssengooba F, Bennett S. Aid alignment: a longer term lens on trends in development assistance for health in Uganda. *Globalization and Health* 2013; 9(7). Available at: http://www.globalizationandhealth.com/content/9/1/7
[22] Okwero P, Tandon A, Sparkes S, McLaughlin J, Hoogeveen J. Fiscal Space for Health in Uganda. *World Bank Working Paper No. 186*. 2010. Accessed 4/18/12. Available at: http://tinyurl.com/7c9zat5
[23] Jeppsson A. SWAp dynamics in a decentralized context: experiences in Uganda. *Social Science and Medicine*. 2002; 55(11) 2053-2060.
[24] Negin J, Martiniuk A. Sector wide approaches for health in small island states: lessons learned from the Solomon Islands. *Global Public Health*, 2012; 7:2, 137-148
[25] Negin J. Sector-wide approaches for health: an introduction to SWAps and their implementation in the Pacific region. *Health Policy and Health Finance Knowledge Hub*. 2010; 2(3) 1-16.
[26] Negin J. Sector-wide approaches for health: A comparison study of experiences in Samoa and Solomon Islands. *Health Policy and Health Finance Knowledge Hub*. 2010; 3(3) 1-16.
[27] Negin J. Sector-Wide Approaches for health: lessons from Samoa and the Solomon Islands *Health Policy and Health Finance Knowledge Hub*. 2010; 4(3) 1-16.
[28] Martinez J. Implementing a sector wide approach in health: the case of Mozambique. 2006 Accessed 4/20/12. Available at: http://www.hlsp.org/Home/Resources/MozambiqueSWAp.aspx
[29] Dickenson C, Martinez J, Whitaker D, Pearson M. The Global Fund operating in a SWAp through a common fund: issues and lessons from Mozambique. 2007 Accessed 4/20/12. Available at:http://www.hlsp.org/Home/Resources/GlobalFundMozambiqueSWAp/tabid/1713/Default.aspx
[30] Mussa A, Pfeiffer J, Gloyd S, Sherr K. Vertical funding, non-governmental organizations, and health system strengthening: perspectives of public sector health workers in Mozambique. *Human Resources for Health* 2013; 11(26). Available at: http://www.human-resources-health.com/content/11/1/26
[31] Addai E, Gaere L. Capacity Building and systems development for SWAps: the experience of the Ghana health sector. 2001 Accessed 4/21/12. Available at: http://www.swisstph.ch/fileadmin/user_upload/Pdfs/swap/swap154.pdf
[32] Atun R, Pothapregada S, Kwansah J, Degboste D, Lazarus J. Critical Interactions Between the Global Fund–Supported HIV Programs and the Health System in Ghana. *J Acquir Immune Defic Syndr* 2011;57:S72–S76.

[33] Ghana Health Sector Support Programme. HSPS Phase IV (2008 – 2012) Accessed 4/21/12. Available at: http://ghana.um.dk/en/~/media/Ghana/Documents/HSPS%20IV%202008-2012.ashx
[34] Ghana Joint Assistance Strategy (G-JAS). World Bank Report 2007. Accessed 4/21/12. Available at: http://siteresources.worldbank.org/INTGHANA/Resources/GJAS_Final_270207.pdf
[35] Pearson M. Achieving the MDGs: at what cost? 2007 Accessed 4/20/12. Available at: http://www.hlsp.org/Home/Resources/AchievingtheMDGsatwhatcost/tabid/1694/Default.aspx
[36] McNee, A. Retinking health sector wide approaches through the lens of aid effectiveness. 2012. Accessed 6/10/2014. Available at: http://tinyurl.com/kyktd2n
[37] Hutton G, Tanner M. The Sector-wide approach: A blessing for public health? *Bulletin of WHO*. 2004; 82(12) 893-94.
[38] Ghana Joint Assistance strategy (G-JAS). 2007. Accessed 4/21/12. Available at: http://tinyurl.com/79ahph5
[39] Sweeney R, Mortimer D, Johnston D. Do Sector wide approaches for health aid delivery lead to 'donor-flight'? A comparison of 46 low-income countries. *Social Science & Medicine* 2014; 105: 38-46.
[40] Dodd R, Hill P. The Aid Effectiveness Agenda: Bringing Discipline to Diversity in Global Health? *Global Health Governance*. 2007 I (2): 1-11.
[41]Skolnik R, Jensen P, Johnson R. Aid without Impact: How the World Bank and Developing partners are failing to improve Health Through SWAps. Action Report. 2010. Accessed 4/16/12. Available at: http://www.action.org/site/publications/swaps
[42] Vaillancourt D. Do Health Sector Wide Approaches Achieve Results? Emerging evidence and Lessons from Six Countries. World Bank Independent Evaluation Group. 2009 Accessed 4/22/12. Available at: http://tinyurl.com/kl28x8h
[43] Peters DH, Paina L, Schleimann F. Sector-wide approaches (SWAps) in health: What have we learned? *Health Policy and Planning* 2013;28:884–890
[44] WB Bangladesh: Accelerating Progress Toward the Health MDGs Accessed 2/18/14. Available at: http://tinyurl.com/m54xne8
[45] Kenya Health Policy Report 2012-2030. Accessed 2/19/14. Available at: http://tinyurl.com/labfzr6
[46] The World Bank: Universal Health Coverage Study Series. Accessed 2/19/14. Available at: http://tinyurl.com/ml2g843
[47] A Guide to WHO's role in sector-wide approaches to health development. WHO 2006 Accessed 3/18/12 http://www.who.int/hdp/publications/en/

From the Bench to the Bush: The Children's Vaccine Initiative and Troubled Public-Private Partnerships for Health

Laura L. Janik

Public-private partnerships (PPPs) have the potential to distribute public goods and lessen the development gap between the Global North and Global South. By drawing together public and private entities, PPPs attempt to capitalize on the unique comparative advantages that different actors possess. In the past twenty years, PPPs have proliferated, however such entities are not foolproof and some PPPs do fail. This paper examines the Children's Vaccine Initiative (CVI), a public-private collaboration formed in 1990 and dismantled in 1999. We seek to better understand the obstacles that led to the dismantling of the CVI because the CVI's experience generates lessons that current and future PPPs can learn from. These lessons include, but are not limited to: the need for partnerships to possess realistic end goals and a flexible, but not entirely elastic, structure; the importance of institutional transparency, honesty, and good lines of communication; the timing of the partnerships creation and the need for stable and predictable funding sources; the dangers of underestimating the ability of partners to get along and trust one another; and the need for partners to value one another's contributions.

"From bench to bush" is a common phrase you will repeatedly hear in any investigation into the Children's Vaccine Initiative (CVI). Indeed, it is a phrase that neatly and concisely sums up one of the partnership's many goals: to oversee the vaccine development and distribution process from the bench, where basic research for product development occurs, to the bush, where the vaccine is administered to the recipient (most likely a child). The CVI was a public-private partnership (PPP) for health, spearheaded in 1990 by the Rockefeller Foundation, United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), World Bank Group, and the World Health Organization (WHO). The idea to create a partnership that could potentially discover a magic bullet vaccine for the majority of childhood diseases through the collaboration of public health agencies and industry, while simultaneously contributing to the health needs of children in the global South was, perhaps, an idea too far ahead of its time; the CVI existed for fewer than ten years until the World Health Organization announced its dismantling in 1999.[1]

Many of the CVI's objectives are now encompassed by the GAVI Alliance, most notably the emphasis on producing *new* and *quality* vaccines. Thus, for many of the CVI's founders, the most appropriate way to conceptualize the CVI and the GAVI Alliance is to view the GAVI Alliance as a continuation of the CVI.[2] As Dr. William Muraskin, a CVI social historian notes, "no CVI, no GAVI."[3] With this in mind, the challenges that the CVI faced, the hurdles it was unable to overcome, and its many successes become even more relevant and warrant our

attention, as these experiences can serve as guidelines for future and current PPPs such as the GAVI Alliance and a host of other health-related PPPs, from Roll Back Malaria to the Global Fund. This project intends to reveal these sites of contention, and points of achievement, and put forward policy recommendations that will aid public-private collaborations for health.

There are four questions, therefore, that stand at the heart of this analysis: What challenges did the CVI face that contributed to its dismantling? How did CVI's partners attempt to overcome these obstacles? How did the structure of the CVI impact its effectiveness and functionality? What lessons emerge from the CVI experience? Using interviews as the main mode of data collection in conjunction with archival research, this investigation unearths valuable policy implications. These lessons include, but are not limited to: the need for partnerships to possess realistic end goals and a flexible, but not entirely elastic, structure; the importance of institutional transparency, honesty, and good lines of communication; the timing of the partnership's creation and the need for stable and predictable funding sources; the dangers of underestimating the ability of partners to get along and trust one another; and the need for partners to value one another's contributions.

A PRIMER ON PUBLIC-PRIVATE PARTNERSHIPS

Public-private partnerships (PPPs) are a newer form of governance in the global health arena and possess the ability to provide public goods when markets and the state fail to adequately meet citizens' health needs. In this sense, governance involves "relationships that transcend national frontiers" in the absence of sovereign authority due to the anarchical nature of the international system.[4] For many policymakers, analysts, and scientists, PPPs are positive entities that espouse the ability to reduce health inequalities and suffering throughout the world, address unmet health needs, and fill funding gaps that intergovernmental organizations and states cannot or will not. For example, in his address to the United States Chamber of Commerce, the former Secretary-General of the United Nations, Kofi Annan proclaimed, "the United Nations once dealt only with governments. By now we know that peace and prosperity cannot be achieved without partnerships involving governments, international organizations, the business community, and civil society."[5] Ten years later, when the current WHO Director-General, Dr. Margaret Chan, addressed the World Intellectual Property Organization, her message echoed Annan's testament as to the power of PPPs. Dr. Chan claimed:

> Public-private partnerships have recently emerged as a promising way to develop new products for diseases that disproportionately affect the poor. In the past, the quest for new products for neglected diseases has usually been opportunistic. Existing products, often developed for veterinary purposes, were screened for their potential efficacy in treating human diseases. More recently, this quest has become strategic. An unmet need is identified, an ideal

> product is defined, and a public-private partnership is formed to develop the product.[6]

Whether we like it or not, PPPs are here to stay. The challenge, therefore, is to craft mechanisms that accentuate PPP strengths and minimize their potential weaknesses.

Schafferhof, Campe, and Kaan (2009) claim that global PPPs "constitute a hybrid type of governance, in which non-state actors co-govern along with state actors for the provision of collective goods, and adopt governance functions that have formerly been the sole authority of sovereign nation-states."[7] Reich (2002) takes this definition of PPPs further and notes that such entities must entail at least one for-profit entity and one not-for-profit entity.[8] In reality, most public-private collaborations espouse multiple partners with different comparative advantages.[9]

Aside from these minimalistic requirements, PPPs come in all different shapes and sizes. As Reich (2002) notes, PPPs vary in size, funding levels, objectives, structure, and the types of partners involved.[10] For example, some public-private collaborations such as the Global Polio Eradication Initiative (GPEI) are disease specific, highly centralized, and parochial in vision. The GPEI encompasses four core partners: World Health Organization, United Nations Children's Fund, Centers for Disease Control and Prevention, and Rotary International. While private, for-profit entities play a critical role in the funding and operation of the GPEI, public, not-for-profit entities have the final say when it comes to funding decisions and the partnership's strategic plan.[11] The collaboration is highly centralized too. Because eradication is only possible with the vaccination of every last child, partnership guidance starts at the top and trickles down to ensure that endemic (and non-endemic) countries follow basic GPEI requirements. Finally, the GPEI mission is targeted – polio eradication.

By contrast, some partnerships are much less centralized and hierarchical. The Measles Initiative, for example, was spearheaded by the World Health Organization, United Nations Children's Fund, Red Cross, and UN Foundation and prides itself on its bottom-up approach to measles control activities.[12] The Measles Initiative strives to reduce measles prevalence in endemic countries, with a specific emphasis placed on sub-Saharan Africa and Southeast Asia where prevalence rates are highest. While the Measles Initiative is tilted towards the public side of the equation, the partnership's structure and functioning appear much different than that of the GPEI given the former's bottom-up approach to measles control activities. This bottom-up approach provides the partnership more flexibility when it comes to strategic planning and funding decisions as major decisions do not always emanate from the top.[13]

Finally, public-private collaborations, such as the GAVI Alliance, can be quite large and encompass a multiplicity of goals. Unlike the GPEI and Measles Initiative, the GAVI Alliance provides private entities a much larger say in partnership funding decisions and strategic planning.[14] Indeed, the fact that large for-profit entities hold powerful positions on the GAVI Alliance Executive Board is a major criticism of the partnership. Even so, as this short primer indicates,

there is no "one size fits all" solution when it comes to crafting public-private collaborations for health.

Regardless of size, structure, or mission, there are organizational challenges that confront all public-private alliances. Austin refers to these challenges as "the seven C's of strategic collaboration."[15] The seven C's include: clarity of purpose, congruency of mission, strategy and values, creation of value, connection with purpose and people, communication between partners, continual learning, and commitment to the partnership. According to Austin (2000), when alliances lose sight of, or lack the combined ability to meet these organizational challenges, they are likely to falter or completely fail.[16] The CVI, for example, had difficulties achieving clarity of purpose, congruency of mission, and good communication between partners, and this contributed to its dismantling.

For many in the global health community, the proliferation of public-private partnerships is both welcome and promising.[17] Public-private collaborations, however, are not foolproof and supporters and critics alike warn that PPPs must be closely monitored. For some critics, PPPs suffer from a democratic deficit and subsequently lack legitimacy.[18] In other words, public-private collaborations are powerful entities that can greatly impact a country's public health agenda and primary healthcare system, but the representatives of PPPs are neither elected by the public at large nor do they necessarily reflect consensus on behalf of those that they supposedly represent. How, then, can PPPs be viewed as legitimate governing entities?[19] For others, the concern rests with the inclusion of private, for-profit voices. Private, for-profit entities are profit driven and seek to meet shareholder demands; thus, their presence is suspect because it is assumed that such entities are out for profit and will not necessarily meet the public health needs of the less fortunate. Instead, profit will always trump the public good and public needs if private entities are forced to choose.[20] Another criticism of PPPs is that they may catalyze "brain drain" from the public to private health sector; Buse and Walt (2002) note that PPPs for health may initiate a brain drain whereby scientists and health officials shift employment preferences to higher paying jobs in the private sector and public-private collaborations.[21] This is problematic as the need for public health employees capable and willing to tackle health issues prominent in the Global South is now greater than ever. Lastly, PPPs are criticized for catalyzing unhealthy competition and hostility among UN agencies that are forced to compete with each other for funding and attention.[22] In other words, UN agencies already find themselves resource deprived and short staffed, so initiating more competition for funds generates hostility and forces institutions to divert attention to fundraising activities as opposed to focusing on the mandate of the partnership.

In sum, PPPs may be here to stay but their presence is not entirely welcome, and for some, it is wholly suspect. It is necessary, therefore, to have a firm grasp on what makes PPPs tick and to formulate strategies that PPPs can utilize to avoid these (and other) potential downfalls.

THE CVI IN A NUTSHELL: ORIGINS AND SUCCESSES

The reader should note that this manuscript does not intend to chronicle the history of the CVI. This enormous task has already been capably accomplished.[23] Instead, the goal here is to build on this knowledge and relay to the reader the most important aspects of the CVI – its mission, mandate, structure, and successes, as well as the obstacles that the partnership was unable to overcome, as there are valuable policy implications that result from the CVI experience.

The Children's Vaccine Initiative was officially founded in 1990 and the announcement was made at the World Summit for Children held in New York City.[24] The impetus for the CVI, however, unofficially began in the late 1970s as a result of major breakthroughs in the biotechnological industry that made vaccine production easier and more simplistic, specifically when compared to twenty or thirty years prior.[25] These advances catalyzed some public health officials to consider creating better vaccines (and new vaccines) for children in the Global South who for decades had often not benefited from vaccine breakthroughs and whose health needs were frequently overlooked. Unfortunately, and this still holds true today, even after a vaccine is introduced to the market, consumers in developing countries may wait decades to benefit from the vaccine's creation, as it takes this long to drive down the product price to levels affordable to developing healthcare systems.[26] As the inaugural forum of the CVI states, "[t]he Children's Vaccine Initiative (CVI) is an informal association of public and private groups dedicated to helping the world community focus, accelerate and apply advances in science to the development, manufacture and efficient delivery of new and better vaccines for the world's children."[27] The CVI rested on five pillars: (1) vaccine research, (2) vaccine delivery and operational research, (3) vaccine supply, (4) vaccine production, and (5) individual countries.[28]

The spearheading partners of the CVI included the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank Group, and the Rockefeller Foundation.[29] Each of these partners shared a commitment to aiding children in the global South and possessed an unmatched comparative advantage. The WHO, as "the directing and coordinating authority for health within the United Nations system," was a vital partner given its access to primary health care systems and the health information of developing countries.[30] UNICEF, the UN agency dedicated to ensuring that "the rights of every child are realized," would help fund and guide the CVI.[31] In the early 1980s, UNICEF launched the Children's Revolution that promoted children's health and provided the organization with a more prominent role in global children's health initiatives, making it an even more appropriate CVI partner. Next, the United Nations Development Programme, the "global development network," was concerned with enhancing local capacity and meeting development needs specifically in the developing world; thus, the CVI focus and mandate was very attractive to the UNDP.[32] Additionally, the World Bank Group, "a vital source of financial and technical assistance to developing countries around the world," would help fund the CVI, as the goals of the CVI complemented the World Bank Group's focus on long-term socioeconomic development.[33] And finally, the

Rockefeller Foundation, an organization dedicated to "help[ing] people tap into globalization's benefits and strengthen resilience to risks," would support the CVI through funding and coordination.[34]

The original CVI structure, which remained in place until 1995, consisted of a Standing Committee, Consultative Group, Management Advisory Committee, Task Forces, and Product Development Groups. The Standing Committee was the most powerful CVI entity and made up of the spearheading partners. As Muraskin (2001) notes, the Standing Committee "would function as a board of directors."[35] It was one of the main decision-making bodies of the CVI. The CVI also encompassed a Management Advisory Committee (MAC) "with twenty five members representing a wide-range of organizations and individuals.[36] The MAC met twice a year and represented the needs and interests of the Consultative Group (CG), which was the largest body of the CVI and encompassed all states, NGOs, intergovernmental organizations, and private entities involved with the CVI. Finally, the CVI espoused Product Development Groups (PDGs) and various Task Forces. PDGs were concerned with the latter stages of vaccine development, as opposed to basic research, and CVI Task Forces "examine[d] strategic, logistic, and policy issues relevant to the industrial development and introduction of CVI vaccine products, including such areas as quality control, epidemiologic capability in developing countries, and global vaccine supply."[37] Together, these entities made up the initial CVI structure. Years later, after experiencing a host of insurmountable problems, the CVI was absorbed by the WHO, and took on a very different configuration with the WHO having a much larger say in CVI endeavors. These changes transformed the CVI from a semi-independent entity to one that was absorbed by the WHO.

It's too easy to point to the dismantling of the CVI and focus on the partnership's troubles. Doing so would overlook many of the partnership's achievements as well as the stumbling blocks it was able to navigate through for nearly ten years. Further, as Dr. Richard Mahoney, Vice President and Director of Technology Promotion at the Program for Appropriate Technology in Health notes, calling the CVI "a failure" is misleading.[38] While the CVI was officially dismantled in 1999, terminating the CVI was a rhetorical maneuver intended to garner financial support for the new GAVI Alliance. The spirit, and indeed much of the CVI vision, lives on in the GAVI Alliance even though GAVI's structure and some if its goals are different than those of the late CVI.[39] The CVI's achievements include helping to facilitate communication and a more friendly relationship between industry and the public health sector. This is evidenced by both cohorts working together on common projects, known as Product Development Groups, such as the creation of a more heat stable polio vaccine.[40] Before this, CVI founders noted that the relationship between both entities was akin to a Cold War.[41] Those in the public health sector viewed industry as a profit-driven pariah; those in industry complained that public health employees did not fully grasp the grueling tasks industry had to engage in to get a vaccine to the market for consumption purposes. Clinical trials, for example, are extremely expensive and risky, and industry had to be rational in its calculations; this was not something those in the public sector, according to industry, could understand.[42] Not only did the CVI open up the lines of communication between

the public and private sectors, but it also got each side to view the other groups' contributions as important and worthy.[43]

Next, the CVI pushed scientists, industry, and policymakers to think about vaccines for the developing world.[44] In the 1980s, industry was more reluctant than ever to engage in vaccine development processes due to the rising cost of product development and a nearly nonexistent vaccine market in the Global South.[45] As such, the CVI encouraged new thinking in the global health arena and this new thinking included consideration of the needs of poor children. Additionally, the CVI helped developing country vaccine manufacturers expand their production bases and develop quality vaccines that were safe and effective. In the last *CVI Forum* published, Dr. Roy Widdus, the former CVI Director, claimed, "[t]he CVI has helped change the international health scene in ways that can never be undone."[46] And finally, the CVI paved the way for the creation of the more successful, and currently operative, GAVI Alliance.[47] With this in mind, the CVI may be gone, but clearly its legacy will never be forgotten and continues to be felt, on the ground today, by persons living in some of the most impoverished areas of the world.

Even with all of these successes, there were also many obstacles and stumbling blocks that the CVI could not overcome. The remainder of this project highlights these obstacles so that future collaborations can more fully understand the difficulties that arise when the public and private sectors attempt to collaborate. In essence, the CVI failed for five distinct, but interconnected reasons:

- The CVI was founded amidst financial difficulties, which forced the partnership to change some of its goals, because it did not have the funding to achieve them. This made the CVI appear indistinct and further discouraged donors.
- The partnership found itself at odds with other WHO programmes and never really found its niche. To appease the WHO, the CVI changed some of its objectives. This too made the CVI appear visionless and created rifts within the Standing Committee.
- The CVI was created to deal with deficiencies in the WHO but felt compelled to include the WHO as a core partner because it is *the* UN specialized agency for health. This was a nearly impossible problem to overcome and when things went sour the WHO absorbed the CVI.
- Conflicts within the Standing Committee, largely involving the WHO, not only spoiled the CVI reputation, but also distracted the CVI from accomplishing its larger goals. Furthermore, individual members of the Standing Committee, at times, represented their own views of the CVI instead of representing the perspective of their host institution. This made budgeting and strategic planning increasingly difficult.
- Due to conflicts between CVI members and spearheading institutions, good lines of communication dried up and tainted the

working relationship that developed between industry and the public health agencies.

Lesson 1: Timing Is Everything & Money Helps Too

The debt crisis of the late 1980s and early 1990s, as is evidenced, for example, by the Mexican peso crisis, and frequently associated with the Regan and Thatcher emphasis on financial deregulation and currency devaluation, not only demonstrated how interconnected the global economy had become, but how quickly financial crises can spread to developing and developed states alike.[48] This financial mess led to an increase in unemployment rates, decrease in gross national product, inflationary tendencies, and a general stiffening up of governmental expenditures on new ventures at the national and international levels in many developed states, including the US. Further, with the demise of the Cold War, traditional sources of development assistance had dried up. It was during this timeframe that the CVI was created and this is the first, and perhaps the simplest lesson, that emerges from the CVI experience - timing is everything. The CVI was created in the midst of a financial mess when funding for health activities was at a low point.[49] Given the scope and breadth of the CVI mission, this would prove to be very problematic because without adequate funding the CVI would not be able to carry out its mission. In comparison, the CVI successor was born after the Gates Foundation offered a $750 million donation for the GAVI Alliance startup and operational costs.[50]

There are essentially two separate funding problems that the CVI encountered. First, financial issues pitted the CVI against other international health agencies, namely the WHO. Dr. Philip Russell, former Commander of the U.S. Army Medical Research and Development Command, notes that had there been more health resources available in general, WHO may have "behaved better" and not sought to undermine the CVI.[51] Widdus recalls that towards the end of its lifespan, WHO went so far as to poach Ireland's contributions intended for the CVI.[52]

In turn, these initial funding shortfalls prevented the CVI from achieving its stated goals, which gradually pushed away interested donors. Widdus notes that multilateral and bilateral support for the CVI began to wane just a few years in; UNDP dropped out early due to director/mission changes and UNICEF reduced contributions in the mid-1990s.[53] Even donors who were supportive to the end, as with Japan, gradually reduced their contributions.[54]

Inevitably, financial hardship put the newly formed CVI at a disadvantage. Any new public-private collaboration requires sufficient funding to ensure that: (1) it can hire capable staff who are sufficiently paid; (2) it possesses the necessary tools and equipment to carry out its mission; (3) the partnership can meet the emerging demands from recipients; and (4) it does not have to spend an inordinate amount of time searching for new donors and sources of funding. Given that the CVI did not possess sufficient resources to carry out part of its original vision (creating better and new vaccines), it had to adapt to stay afloat, which also meant downgrading its vision. One might wonder, therefore, what the fate of the CVI would have been if the collaboration was spearheaded

some five or six years later during the global economic recovery and boom of the mid-to-late 1990s. Even though the CVI was still functional at this point, the problems it faced were ultimately too daunting for the CVI to take advantage of these changing economic realities. In this sense, the old adage, "timing is everything," takes on a whole new meaning; had the CVI been able to secure sufficient funding, its untimely dismantling might have been delayed or avoided entirely. Along these lines, the CVI suggests an added C to Austin's seven C's of strategic collaboration and that is continuous sources of reliable funding. Whereas the founders were right to build on the excitement and momentum that came with all the biotech advances in the 1980s, they overestimated private and public sector willingness to ante up.

In line with lesson number one, and many of the other lessons that will soon follow, the Global Fund to Fight AIDS, Tuberculosis, and Malaria (a.k.a The Global Fund) has recently undergone major structural changes that are worthy of mention. The Global Fund, a public-private health collaboration, was created in 2001 and currently accounts for nearly a quarter of all the money spent on international HIV efforts and the majority of funding for international TB and malaria reduction efforts in developing states[55]. Whereas the Global Fund has been praised for "encouraging multisectoral partnerships within each [recipient] country" for the purpose of owning the disease, in recent years, the Global Fund has found itself in hot water for allegedly misusing donor dollars and serious structural and management issues.[56] Further, Global Fund donor contributions seriously declined due to the economic recession of 2007-2008, yet another stressor to the public-private collaboration.[57]

More specifically, as Feachem (2011) notes, a High-Level Independent Review Panel, which was established to critically analyze and review the partnership in light of fraud allegations, suggested that a more functional Global Fund should, "transition from an emergency to a sustainable response; develop new-risk management approaches; strengthen internal governance; institute a new grant-approval process; strengthen decision-making by middle management 'get serious about results.'"[58] Whereas funding gaps for the CVI forced the collaboration to alter its mandate several times, consequentially appearing to be unorganized and schizophrenic, the misuse of donor funding forced the Global Fund to engage with serious alterations, some financial and others of the non-financial variety, in order to please donors and encourage Global Fund contributions. Both entities, however, experienced financial shortfalls and issues that ultimately damaged the partnerships name and reputation. While the Global Fund has enacted methods to avoid fraudulent transactions in the future and more fully meet its founding principal[59] – that funding should be based on performance – there remains serious concern about: 1) the need for more Global Fund investments;[60] 2) overly rigid funding guidelines,[61] and 3) better relationship management.[62]

As the CVI experience demonstrates, in conjunction with our brief discussion of Global Fund reforms, all PPPs, regardless of size and number of donors, must deal with funding and financial issues broadly speaking and must: 1) create sound funding models; 2) establish innovative mechanisms to attract

new donors as well as mechanisms to deal with funding gaps; and 3) appease donor demands while simultaneously staying true to one's mandate and vision.

Lesson 2: Congruency is Compulsory

The timing of the CVI experiment got the partnership off to a rocky start and ultimately limited its scope, but so too did the seemly schizophrenic nature of the CVI mandate. Whereas institutional adaptation is usually seen as a plus when it comes to institutional survival and longevity, the CVI arguably went beyond adapting its goals to real world constraints and transposed its mission in a very unpalatable way. It is possible to locate at least seven goals that the CVI, at some point in time, espoused: (1) create a magic bullet – *the* children's vaccine that could vaccinate kids against all childhood menaces in one shot (2) develop more multi-antigen, single dose vaccines (3) facilitate increased coordination and cooperation between the public and private sectors, (4) produce new vaccines, (5) create better quality vaccines, (6) facilitate an end-to-end mission from basic research to product development and distribution, and (7) expedite communication between the bench and the bush guys.[63] In short, the CVI lacked what Austin (2000) refers to as clarity of purpose and congruency of mission and strategy. To be clear, it is not inherently problematic for PPPs to encompass a multiplicity of goals, but these goals (and goal changes) must be known to all entities involved and contributing to the collaboration. In this instance, they were not, and it was not uncommon for CVI partners to question the CVI mission and mandate at public meetings. Muraskin (2001) notes that at one MAC meeting in Cairo, each member of the Standing Committee presented very different views of what the CVI mission entailed.[64] For example, UNICEF representative, Terrell Hill, offered up a very parochial vision that emphasized quality vaccine production, whereas the Rockefeller Foundation representative, Scott Halstead, continued to stress the magic bullet issue. Because the CVI failed to achieve congruency and consistency, its lifespan was limited.

To make matters worse, not only did the CVI mission change, but throughout its tenure, this mission was gradually downgraded.[65] The CVI started out thinking big and ended up with a much more parochial vision (oversee the entire vaccine development process→product development→quality and supply issues→facilitate communication between those at the bench and those in the bush and incorporation of existing but undersupplied vaccines into routine immunization schedules). Goal fluctuation ultimately made the CVI appear confused and indistinct and this absolutely worked against the partnership.

Revisiting our discussion of the recent Global Fund reforms, worthy of mention is the Fund's attempt to not only restructure its model for funding, but also to establish more coherent and basic standards when it comes to funding decisions, issues of ethics and ethical behavior, and the proper documentation of funding procedures. As the High-Level Independent Review Panel recommended, "[t]he Global Fund needs to create a set of clear, simple and practical basic standards in the rules of fiduciary documentation and ethical behavior."[66] There are already signs that the reformed funding model is problematic. For example, Benjamin's study, which involved interviewing civil society implementers, reveals

that there are still problems with: 1) delays in grant disbursements; and 2) overly rigid financial reporting requirements.[67] In order for the Fund to avoid the mistakes made by the CVI, it will need to review funding decisions and issues on a continual basis.

Lesson 3: Find Your Niche & Know Your Enemies

What is abundantly clear from the CVI experience is that the partnerships problems were interlinked. As previously demonstrated, the downgrading of the CVI mission was partially attributed to CVI funding issues. It was also because the CVI never really fit in or found its niche; in turn, these problems contributed to in-house fist fights, thus further decreasing interest in the CVI.

Almost immediately, the CVI was thrown into turf battles with competing WHO programmes, namely the WHO Expanded Programme on Immunization (EPI) and the WHO Program for Vaccine Development (PVD).[10] The EPI was created in 1974 and sought to increase access to six childhood vaccines: diphtheria, pertussis, tetanus, measles, poliomyelitis, tuberculosis, and now hepatitis B. The EPI was considered the supply and demand branch of the WHO for vaccines.[68] By contrast, the PVD was created in 1984 and was designed to execute basic research for vaccine development. It was the research branch of the WHO. In reality, all three entities sought (mostly) different but complimentary goals; however, the EPI and PVD grew increasingly skeptical of the CVI, whom they saw as a competitor and a threat. Like many other UN specialized agencies in the early 1990s, the WHO was underfunded and the EPI and PVD saw the emerging CVI as yet another threat to scarce WHO resources.[69] Additionally, the EPI and PVD saw the CVI goals of creating new and better vaccines in addition to facilitating the end-to-end process as imposing on the EPI and PVD turf.[70] For the EPI and PVD, the creation of new and better vaccines were already tasks that they were involved in, thus there was no need for the CVI. As a result of this institutional mindset, the CVI was forced to navigate its way through rocky terrain in order to find a niche that was unfilled by any other health institution – a niche that donors would be drawn to. As such, CVI goals gradually shifted to include facilitating the production of quality vaccines, specifically by developing country vaccine manufacturers, and the incorporation of existing but undersupplied vaccines such as the hepatitis B vaccine and the *Haemophilus influenzae* type b (Hib) vaccine into routine vaccination schedules.[71] The CVI that emerged in 1990 looked drastically different than the entity that was eventually dismantled in 1999. It is clear from the CVI experience that for a partnership to succeed, it must not only confront potential "competitors" prior to its creation, but also ensure that it is filling an untapped niche and thus adding value to a specific market.

[10] In 1994, the WHO Global Program for Vaccines and Immunization (GPV) was created and would house the EPI and PVD.

Lesson 4: Address the Elephant in the Room, Don't Conform to It

The rationale observer will likely wonder why the CVI did not try to more fully engage these WHO programmes prior to its creation to ensure that the EPI and PVD did not feel threatened or at the very least intentionally try to undermine CVI success. The answer is simple. The creation of the CVI reflected a growing dissatisfaction with the WHO. What is ironic, therefore, is that the CVI was created to make up for the deficiencies and institutional lethargy within the WHO, only to be absorbed by the WHO years later. Not only did the CVI fail to address the elephant in the room – the WHO's bureaucratic red tape, lassitude, and inflexibility – it was actually eaten up by the elephant. One lesson from which future PPPs can benefit from stems from the CVI's failure to adequately address the institutional deficiencies present, *at the time*, in one of its core partners *before* the partnership's creation.

In the late 1980s and early 1990s there was an increasing dissatisfaction with the WHO within the health community and health-related UN agencies.[72] The WHO, according to its critics, was marred by red tape and bureaucratic politics, and was incapable of adapting to changing realities.[73] Further, critics charged that the WHO was unwilling to deal with the private sector or issues related to intellectual property rights, specifically when it came to combination vaccines owned by multiple companies. The creation of the CVI, at least in part, was a criticism of the WHO and an attempt to make up for its supposed ineptitude. As Muraskin (2001) notes, "while the Initiative was fuelled by the desire of four of the five founding agencies (UNICEF, UNDP, the World Bank Group, the Rockefeller Foundation) to circumvent WHO's power over vaccine development policy, the World Health Organization was nevertheless provided with a strategic position within the five-person Standing Committee that controlled the CVI."[74]

From the outset, the CVI's hands were tied. Whereas it might be possible to create a partnership independent from the WHO, it was impossible to entirely exclude the WHO from the CVI given its mandate as *the* UN agency responsible for global health problems and solutions. Reflecting upon the CVI experience, it is clear that every member of the Standing Committee, sans the WHO, was critical of the WHO in one way or another. As Russell notes, there were serious bilateral tensions between the WHO-UNICEF, WHO-World Bank, and WHO-UNDP.[75] The WHO was the elephant in the room; however, it had to be incorporated despite its supposed flaws and shortcomings.

The CVI founding fathers eventually crafted a plan whereby the WHO would sit on the Standing Committee as one of the CVI founding agencies. As such, the partnership was initially independent of the WHO, despite that the CVI Secretariat was housed at the WHO headquarters in Geneva. In other words, the initial CVI structure provided the WHO a large say in CVI endeavors given its place on the Standing Committee, but the WHO did not run the show or have the final say.

This all began to change during the second phase of the CVI, beginning in 1995, when it experienced major structural shifts and was enveloped by the WHO due to funding issues and dwindling support for the partnership. Namely, a

Director would now guide the day-to-day activities of the CVI; Dr. Roy Widdus was selected for this position and would be the first (and only) CVI Director. Additionally, the CVI and newly formed WHO Global Program for Vaccines and Immunization (GPV), which was home to the EPI and PVD, would share a common head, Dr. Jong-Wook Lee. Dr. Lee, a WHO staff member since the early 1980s, thus wore two hats and many criticized him for favoring the WHO GPV over the CVI. Widdus notes that with this structural shift, which gave the WHO a much more prominent role, Lee actually began discouraging CVI funding and in one case diverted funds intended for the CVI (from Ireland) elsewhere.[76] The final major change that the CVI experienced in 1995 was in relation to the Standing Committee; the Standing Committee was replaced by the Group of 13 (G13) that was a "microcosm" of the Meeting of Interested Parties, the latter being responsible for "CVI management and financial policy."[77] In short, major changes transformed the CVI from a semi-independent entity to one that was absorbed by the WHO. After this absorption process, much of the work (and success) of the CVI was attributed to the GPV leaving CVI officials feeling short-changed and further disheartening central players and donors.

Reflecting upon its nearly ten year existence, it is clear that attempts to create a public-private collaboration that sought to compensate for the supposed ineptitude of the WHO but simultaneously included that very organization as a core partner, was not a good idea. To be fair, it was not possible to exclude the WHO, and with limited funding it was difficult to keep the WHO at arm's length as the GAVI Alliance has done. In order for the CVI to succeed, the relationship between the WHO and other core partners needed to evolve and become friendlier but these relationships simply did not. It is absolutely critical for core partners to value one another's work and move forward to create a more friendly relationship whereby partners work in harmony and do not attempt to undermine one another. The CVI could not seem to accomplish this. One suggestion for how the CVI could have overcome, at least temporarily, some of these issues lies with the CVI decision-making structure, which relied on consensus rather than formal voting to make and enact decisions. Moving away from consensus style decision-making would have prevented the WHO from killing any policy it did not agree with.

Lesson 5: Butting Heads Hurts

There was an excessive amount of head butting and tension between members of the Standing Committee that contributed to the problems the CVI faced.[78] Head butting between CVI agents and the institutions represented proved to be problematic as well. Put differently, Standing Committee agents did not always accurately represent the institutions they stood for, thus creating a divide between the representative and their home agency. Consequentially, rhetoric and reality did not always align and what was said was not always done or supported.

Russell notes, and as we've just discussed, much of the tension present in the Standing Committee was bilateral and involved the WHO.[79] Perhaps the biggest tension existed between the WHO and UNICEF – a relationship that

involved a good deal of "pushing and shoving."[80] UNICEF did not want the WHO to lead the show and WHO was cautious and critical of UNICEF ever since it's "Children's Revolution" in the early 1980s. In many ways, the WHO saw UNICEF as stepping on its turf. As previously stated, for any collaboration to be successful, core partners, and donors, need to view each other as equals and as important entities. Moreover, partnerships need to identify, from the get-go, potential institutional roadblocks and engage prospective competition prior to and during an institutions creation.[81] This was not always the case, particularly in the Standing Committee. As a result, a good deal of time and energy was exerted on scoping out and defending one's turf, which, one must assume, came with a physical and metaphorical price tag – the CVI vision was seen as blurred, donors were turned off by continual in-house fighting, and potentially constructive energy was exerted in unconstructive ways.

Equally as problematic were some of the egos involved in the Standing Committee. Members of it, at times, represented their own vision of what the CVI should be and should do rather than the position of their home agencies. As such, funding promises that were made were not always accurate and assurances were not carried through with. For example, the former Director of UNICEF, Dr. Jim Grant, initially expressed his intent to devote 5% of UNICEF's budget to "applied and operations research."[82] The UNICEF Executive Board ultimately voted against this proposal and UNICEF donations to the CVI were much less than anticipated; thus, from the onset, the partnership was put at a financial disadvantage. In many ways, the Standing Committee, until it was disbanded, encompassed representatives who possessed grand visions but these visions were frequently disconnected from their host institutions that actually possessed the ability to fund and authorize such undertakings.

Based on the CVI experience, it is clear that public-private collaborations that fail to include partners who get along and value one another are bound to encounter a host of organizational, structural, and financial problems that may not be surmountable. Equally imperative is the need for agents to accurately represent the needs and wants of the institutions they stand for. Grand visions will get you nowhere if they are not supported or if they do not have the buck to back them up.

Returning one more time to our discussion of the Global Fund to Fight AIDS, Tuberculosis, and Malaria, internal governance issues were another reason that the partnership engaged with the reform and restructuring process. While the collaboration has undoubtedly made changes deemed necessary and appropriate by critics and supporters alike, the extent of these changes will likely take years to fully play themselves out. The Global Fund will likely have to re-visit many of these problem areas in the future to avoid much of the tension and disagreement that plagued the CVI for so long. More specifically, based on the High-Level Independent Review Panel recommendations, the Global Fund: 1) has appointed a new Executive Director – Dr. Mark R. Dybul; 2) attempted to create a better working relationship between the Executive Director and Inspector General; and 3) has attempted to improve its working relationship with the UNDP.

It was generally accepted that a new Executive Director could potentially breathe new life into the troubled partnership.[83] Whereas critics of the Global Fund will likely point to the fact that Dybul, an American, comes from yet another state in the Global North, his stellar record and experience seem to indicate that Dybul will be eager to take on Global Fund challenges and reforms. Regarding internal governance, the High-Level Independent Review Panel unearthed evidence that there were serious tensions between the Executive Director and Inspector General that warranted immediate attention in order for the Global Fund to function properly and govern soundly. As the High-Level Review Panel noted, "The OIG, the Secretariat and the Global Fund's Board must transform the nature and culture of their relationship into a partnership whose objective is the continued efficient functioning of the organization and the attainment of positive results. Should the unacceptable relationship between the Inspector General and the Executive Director persist, the Global Fund's Board must deal with this problem as a management issue of urgent priority."[84] Finally, the Global Fund was encouraged to "redefine the relationship with the United Nations Development Programme (UNDP) to permit greater accountability to, and access by, the Global Fund."[85] How the Global Fund addresses these issues is critical and as the CVI experience demonstrates, a failure to address internal governance issues and issues with critical partners can be catastrophic. The Global Fund Board almost immediately accepted the recommendations made to it by the High-Level Independent Review Panel, as well as initiating a plan of action to move forward with necessary changes.[86] However, promoting good governance and productive relationships takes years, and thus we will likely not feel the full extent of governance reforms for years to come.

Lesson 6: Good Communication is a Must

Industry and public health agencies, prior to the creation of the CVI, did not play nicely with each other.[11] To create an end-to-end mission whereby both cohorts aided each other in the process of vaccine research and production, the CVI would need to get public and private health agencies to see each other as comrades. As Russell notes, this task was difficult to achieve and only possible through persistent efforts on behalf of the CVI's founding partners.[87] Eventually, the CVI succeeded in getting both entities to warm up to each other as each was operative on the same Product Development Groups and met yearly at the CVI Consultative Group meetings.[88] Unfortunately, about five years in, this goodwill was ruffled, and the CVI experience demonstrates that public-private collaborations must embody good lines of communication and honesty among partner agencies.

For example, one of the areas in which industry and public health agencies were able to work side-by-side was in the creation of a more thermo stable polio vaccine.[89] With the Global Polio Eradication Initiative underway since 1988, polio vaccinators frequently traveled to remote areas where

[11] Industry was apt to complain that the public health sector did not understand what industry did and therefore could not understand why its prices were too high for many consumers to purchase. Public health agencies, by contrast, were motivated by public health needs - a moral, public good - and saw industry as a pariah and an excessively profit-driven enterprise devoid of any concern for public health needs.

temperatures soared and cold-chains to keep the vaccine cool and potent were lacking. Oftentimes polio vaccinators were unable to perform their duties because the vaccine would lose its potency and this ultimately worked against the GPEI goal of vaccinating every last child in an attempt to wipe the disease off the face of the Earth.[90]

Initially industry was very reluctant to engage in this polio effort. The private sector was wary that the polio effort would cost more than it was worth. Eventually, the private sector was won over and public and private health agencies worked together towards creating a more reliable polio vaccine.[91] It was soon discovered that heavy water (deuterium oxide) could help make the polio vaccine more heat stable; however, there was concern among some health practitioners and policy makers that adding heavy water to the polio vaccine would be used by anti-vaccine advocates to promote non-vaccination.[92] This is because heavy water is also used in the nuclear industry and anti-vaccine advocates harp on the radioactive dangers, that is, the potentially negative health consequences that can result from using heavy water to make vaccines more heat stable. As such, in 1995, without consulting industry, Dr. Lee, Executive Director of the CVI and WHO Global Program for Vaccines and Development, unilaterally announced the dismantling of the polio effort. With one abrupt decision, a relationship that had taken years to build was fractured and damaged.

Even though heavy water may not have been the appropriate substance to use to make the polio vaccine less heat sensitive, it is clear that industry, an equal partner in the polio effort, should have been consulted beforehand and that the decision should have been discussed by all partner agencies. In other words, good lines of communication are necessary for success; when PPPs lack communication and honesty this can only work against the partnership.

CONCLUDING THOUGHTS

The CVI may live on in spirit and mission, but the partnership that was formed in 1990 is technically dead. As such, it is imperative to look back and reflect on the CVI experience to better understand the partnership's successes and the obstacles it was unable to overcome. Doing so will allow future (and current) PPPs for health to learn from the mistakes of one of their predecessors. In short, this investigation into the Children's Vaccine Initiative reveals that: 1) the timing of a partnerships formation is critical and so too are reliable and predictable funding sources; 2) partnerships must possess a clearly defined mission and goals to attract funding and delineate boundaries between similar entities. A failure to delineate boundaries may lead to clashes with like institutions and new entities are likely to fail if forced to compete with more established ones; 3) partners must respect each other and value others' contributions to the collaboration. If not, the partnership is bound to fail as a significant amount of head butting and in-house fighting will likely result; 4) public and private representatives must adequately and honestly represent their host institutions in order to effectively guide a partnership; and 5) good lines of communication and honesty are musts. When non-communication and dishonesty abound, partnerships cannot be efficient and partners are likely to turn on one another.

As a new form of governance that musters the potential to provide global health goods that states alone cannot or will not, public-private partnerships for health are becoming more and more significant. Our knowledge of what makes PPPs tick, and die out, therefore, is more pertinent than ever. The CVI, in name, no longer exists, but GAVI has picked up where the CVI left off. It is imperative that this organization, and others, look to the experiences of the CVI to better understand what should and should not be done in the process of partnership formation and in the day-to-day activities that PPPs carry out. A failure to learn from our mistakes comes with an enormous price tag – millions of children's lives are at stake.

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[1] H. Gavaghan, "UN to End Children's Vaccine Initiative," *Science* 283 no. 5410 (1999): 1992-1993.
[2] Author's phone interview with Dr. Richard Mahoney, Vice President and Director of Technology Promotion for Appropriate Technology in Health, July 11, 2011; Author's phone interview with Dr. Roy Widdus, Former CVI Director, July 12, 2011.
[3] Author's phone interview with Dr. William Muraskin, author of *The Politics of International Health* and the CVI social historian, July 25, 2011.
[4] L. S. Finkelstein, "What is Global Governance?" Global Governance 1 no. 3 (1995): 369.
[5] K. Annan, "Markets for a Better World" Address to the World Economic Forum, 1998. Available at: http://www.un.org/News/Press/docs/1998/19980130.SGSM6448.html
[6] M. Chan, "Strengthening Multilateral Cooperation on Intellectual Property and Public Health," July 2009. Available at: http://www.who.int/dg/speeches/2009/intellectual_property_20090714/en/index.html
[7] M. Schafferhof, S. Campe, and C. Kaan, "Transnational Public-Private Partnerships in International Relations – Making Sense of Concepts, Research Frameworks, and Results," International Studies Review 11 no 3 (2009): 451.
[8] M. Reich, "Introduction: Public-Private Partnership for Public Health," In *Public-Private Partnerships for Health*, ed. Michael Reich. (MA: Harvard Center for Population and Development Studies, 2002).
[9] M. Reich, "Introduction: Public-Private Partnership for Public Health," In *Public-Private Partnerships for Health*, ed. Michael Reich. (MA: Harvard Center for Population and Development Studies, 2002).
[10] Ibid.
[11] L. Janik, "Pathogens without Passports: Polio Eradication and the Provision of Global Public Goods for Health," Working paper, Presented at the ISA Conference, March 2011 in Montreal, Canada.
[12] Author's phone interview with Andrea Gay, Director of the UN Foundation, January 2009; Author's interview with Dr. Edward Hoekstra, Senior Health Specialist at UNICEF, December 2008.

[13] L. Janik, "Pathogens without Passports: Polio Eradication and the Provision of Global Public Goods for Health," Working paper, Presented at the ISA Conference, March 2011 in Montreal, Canada.
[14] GAVI Alliance, "Governing GAVI," July 2012: http://www.gavialliance.org/about/governance/
[15] J.E. Austin, *The Collaboration Challenge: How Nonprofits and Businesses Succeed through Strategic Alliances* (Jossey-Bass Publishers, 2000).
[16] Ibid.
[17] N. Crisp, "Global Health Partnerships: The UK Contribution to Health in Developing Countries. Available at: http://www.lj.se/info_files/infosida35432/crisp_article_public_policy_administration_0706.pdf ; M. Reich, *Public-Private Partnerships for Health*, (MA: Harvard Center for Population and Development Studies, 2002); P. V. Rosenau, ed. *Public-Private Policy Partnership*, (MA: MIT Press, 2000); World Health Organization, *The World Health Report: Working Together for Health* (Geneva, 2006).
[18] P. Haas, "Addressing the Global Governance Deficit," *Global Environmental Politics* 4 no. 4 (2004): 1-15; M. C. Lemos and A. Agrawal, "Environmental Governance," *Annual Review of Environmental Resources* 31: 297-325
[19] K. Buse and G. Walt, "Global Public-Private Partnerships: Part I – A New Development in Health?" *Bulletin of the World Health Organization* 78 no. 4 (2000): 549-561; K. Buse and A. Waxman, "Public-Private Health Partnerships: A Strategy for the WHO," *Bulletin of the World Health Organization* 79 no. 8 (2001): 748-754; K. Buse, "Governing Public-Private Infectious Disease Partnerships," *Brown Journal of World Affairs* X no 2 (2004): 225-242; J. Richter, "Public-Private Partnerships for Health: A Trend with No Alternatives," *Development* 47 no. 2 (2004): 43-48.
[20] B. Bull, M. Boas, and D. McNeill, "Private Sector Influence in the Multilateral System: A Changing Structure of World Governance?" *Global Governance* 10 no 4. (2004): 481-498.
[21] K. Buse and G. Walt, "Global Public-Private Health Partnerships: In Search of 'Good' Global Health Governance," In Michael Reich, ed. *Public-Private Partnerships for Public Health*. (MA: Harvard Center for Population and Development Studies, 2002).
[22] W. Muraskin, *The Politics of International Health: The Children's Vaccine Initiative and the Struggle to Develop Vaccines for the Third World*. (New York: SUNY Press, 1998); E. Ollilia, "Health-Related Public-Private Partnerships and the United Nations," In Bob Deacon, Eeva Ollilia, Meri Koivusalo, and Paul Stubbs, *Global Social Governance: Themes and Prospects*. (Helsinki: Ministry of Foreign Affairs if Finland, 2003);V. Haufler, *A Public Role for the Private Sector: Industry Self-Regulation in a Global Economy*. (DC: Carnegie Endowment for International Peace, 2001).
[23] V. S. Mitchell, N. M. Philipose, and J. P. Sanford, eds, *The Children's Vaccine Initiative: Achieving the Mission*. (DC: Institute of Medicine, 1993).; Muraskin, *The Politics of International Health*; W. Muraskin, "The Origin of the Children's Vaccine Initiative: The Intellectual Foundations," *Social Science & Medicine* 42 no. 12 (1996): 1703-1719; W. Muraskin, "The Origin of the Children's Vaccine Initiative: The Political Foundations," *Social Science & Medicine* 42 no. 12 (1996): 1721-1734; W. Muraskin, "The Last Years of the CVI and the Birth of GAVI," In Michael Recih, ed. *Public-Private Partnerships for Public Health*. (MA: Harvard Center for Population and Development Studies, 2002).
[24] V. S. Mitchell, N. M. Philipose, and J. P. Sanford, eds, *The Children's Vaccine Initiative: Achieving the Mission*. (DC: Institute of Medicine, 1993);
[25] Muraskn, *The Politics of International Health*.
[26] L. Janik-Marusov, "Stop Making Excuses: Hepatitis B and the Global Failure to Act," *Global Health Governance* 4 no. 2 (2011).
[27] Children's Vaccine Initiative, *CVI Forum*, v. 1 (April, 1992): 1.
[28] Children's Vaccine Initiative, *CVI Forum*, v. 3 (February 1993).
[29] Children's Vaccine Initiative, *CVI Forum*, v. 1 (April, 1992).
[30] World health Organization, "About Us," Available at: http://www.who.int/about/en/
[31] United Nations Children's Fund, "About Us: Who We Are," Available at: http://www.unicef.org/about/who/index_introduction.html
[32] United Nations Development Programme, "About Us," Available at: http://www.beta.undp.org/content/undp/en/home/operations/about_us.html

[33] World Bank, "About Us," Available at: http://web.worldbank.org/WBSITE/EXTERNAL/EXTABOUTUS/0,,pagePK:50004410~piPK:36602~theSitePK:29708,00.html
[34] The Rockefeller Foundation, "Who We Are," Available at: http://www.rockefellerfoundation.org/who-we-are Accessed 22July 2011
[35] Muraskin, *The Politics of International Health*: 67.
[36] Ibid.
[37] V. S. Mitchell, N. M. Philipose, and J. P. Sanford, eds, *The Children's Vaccine Initiative: Achieving the Mission*. (DC: Institute of Medicine, 1993).
[38] Author's phone interview with Dr. Richard Mahoney, Vice President and Director of Technology Promotion for Appropriate Technology in Health, July 11, 2011.
[39] Ibid.
[40] Children's Vaccine Initiative, *CVI Forum* v. 1 (April, 1992); Children's Vaccine Initiative, *CVI Forum* v. 12 (August, 1996).
[41] Children's Vaccine Initiative, *CVI Forum* v. 11 (June, 1996).
[42] Muraskin, *The Politics of International Health*.
[43] Author's phone interview with Dr. Philip Russell, Former Commander of the US Army Medical Research and Development Command, July 2011.
[44] Ibid.
[45] W. Muraskin, *The War Against Hepatitis B: The History of the International Task Force on Hepatitis B*. (Philadelphia: University of Pennsylvania Press, 1995).
[46] Children's Vaccine Initiative, *CVI Forum* v. 18 (July, 1999): 3.
[47] Author's phone interview with Dr. Richard Mahoney, Vice President and Director of Technology Promotion for Appropriate Technology in Health, July 11, 2011; Author's phone interview with Dr. William Muraskin, author of *The Politics of International Health* and the CVI social historian, July 25, 2011.
[48] D. Balaam and M. Veseth, *Introduction to Political Economy, 4th edition*. (NJ: Pearson, 2008); O. Blanchard, "Consumption and the Recession of 1990-1991," *American Economic Review* 82 no. 2 (1993): 270-274; B. McLean and J. Nocera, *All the Devils are Here: The Hidden Story of the Financial Crisis*. (NY: Penguin Books, 2012).
[49] Author's phone interview with Philip Russell, Former Commander of the US Army Medical Research and Development Command, July 2011.
[50] W. Muraskin, "The Last Years of the CVI and the Birth of GAVI," In Michael Reich, d. *Public-Private Partnerships for Public Health*. (MA: Harvard Cenetr for Population and Development Studies, 2002).
[51] Author's phone interview with Dr. Philip Russell, Former Commander of the US Army Medical Research and Development Command, July 2011.
[52] Author's email correspondence with Dr. Roy Widdus Former CVI Director, August 1, 2011.
[53] Ibid.
[54] Ibid.
[55] R. McEnery, "The Global Fund's Uncertain Future," *IAVIReport* 16 no. 1 (2012): 8-11. Available at: http://www.iavireport.org/Back-Issues/Pages/IAVI-Report-16(1)-TheGlobalFundsUncertainFuture.aspx
[56] Communications Department of the Global Fund, "The Road to Funding: The Global Fund's New Funding Model," *Africa Health* 35 no 1 (2012): 18.
[57] R. McEnery, "The Global Fund's Uncertain Future," *IAVIReport* 16 no. 1 (2012): 8-11. Available at: http://www.iavireport.org/Back-Issues/Pages/IAVI-Report-16(1)-TheGlobalFundsUncertainFuture.aspx
[58] R. G. A. Feachem, "The Global Fund: Getting the Reforms Right," *The Lancet 378* (2011): 1764; High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, Tuberculosis and Malaria, "Turning the Page from Emergency to Sustainability: The Final Report of the High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, Tuberculosis and Malaria," (2011). Available at: http://www.theglobalfund.org/en/highlevelpanel
[59] High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, Tuberculosis and Malaria, "Turning the Page from Emergency to Sustainability: The Final Report of the High-Level Independent Review Panel on Fiduciary

Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, Tuberculosis and Malaria," (2011). Available at: http://www.theglobalfund.org/en/highlevelpanel
[60] A. Glassman, "No Rest for the Weary: Reform 2.0 at the Global Fund," (2012). Available at: http://www.cgdev.org/blog/no-rest-weary-reform-20-global-fund
[61] H. Benjamin, "Examining the Impact on Global Fund Reform on Implementation: The Results From the Global Fund Implementers Fund," (2011). Available at: http://www.opensocietyfoundations.org/sites/default/files/global-fund-implementers-20120305_0.pdf
[62] Ibid.
[63] Children's Vaccine Initiative, *CVI Forum* V. 1 (April 1992); Children's Vaccine Initiative, *CVI Forum* V. 8 (November 1994); Children's Vaccine Initiative, *CVI Forum* V. 14 (June, 1997); W. Muraskin, "The Origins of the Children's Vaccine Initiative: The Intellectual Foundations," *Social Science & Medicine* 42 no.(1996): 1703-1719; W. Muraskin, "The Origins of the Children's Vaccine Initiative: The Political Foundations," *Social Science & Medicine* 42 no. 12 (1996): 1721-1734.
[64] Muraskin, *The Politics of International Health*.
[65] Children's Vaccine Initiative, *CVI Forum* V. 14 (June, 1997).
[66] High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, Tuberculosis and Malaria, "Turning the Page from Emergency to Sustainability: The Final Report of the High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, Tuberculosis and Malaria," (2011). Available at: http://www.theglobalfund.org/en/highlevelpanel/report/
[67] R. McEnery, "The Global Fund's Uncertain Future," *IAVIReport* 16 no. 1 (2012): 8-11. Available at: http://www.iavireport.org/Back-Issues/Pages/IAVI-Report-16(1)-TheGlobalFundsUncertainFuture.aspx
[68] Muraskin, *The Politics of International Health*.
[69] Author's phone interview with Dr. Philip Russell, Former Commander of the US Army Medical Research and Development Command, July 2011.
[70] Muraskin, *The Politics of International Health*.
[71] Children's Vaccine Initiative, *CVI Forum* V. 10 (October, 1995); Children's Vaccine Initiative, CVI Forum V. 14 (June, 1997).
[72] Muraskin, *The Politics of International Health*.
[73] Author's phone interview with Dr. Richard Mahoney, Vice President and Director of Technology Promotion for Appropriate Technology in Health, July 11, 2011;
[74] Muraskin, *The Politics of International Health*: 132-133.
[75] Author's phone interview with Dr. Philip Russell, Former Commander of the US Army Medical Research and Development Command, July 2011
[76] Author's email correspondence with Dr. Roy Widdus Former CVI Director, August 1, 2011.
[77] Muraskin, *The Politics of International Health:* 178.
[78] Author's phone interview with Dr. Richard Mahoney, Vice President and Director of Technology Promotion for Appropriate Technology in Health, July 11, 2011; Author's phone interview with Dr. Roy Widdus, Former CVI Director, July 12, 2011; Author's email correspondence with Dr. Roy Widdus Former CVI Director, August 1, 2011; Author's phone interview with Dr. William Muraskin, author of *The Politics of International Health* and the CVI social historian, July 25, 2011; Muraskin, *The Politics of International Health*; Author's phone interview with Dr. Philip Russell, Former Commander of the US Army Medical Research and Development Command, July 2011;
[79] Author's phone interview with Dr. Philip Russell, Former Commander of the US Army Medical Research and Development Command, July 2011.
[80] Author's phone interview with Dr. Philip Russell, Former Commander of the US Army Medical Research and Development Command, July 2011.
[81] L. Janik and M. Carter, "Institutional Environmental Innovation: When Does It Work" Working Paper, Presented at the ISA-Midwest Conference, November 2011, St. Louis, MO.
[82] W. Muraskin, "The Origin of the Children's Vaccine Initiative: The Intellectual Foundations," *Social Science & Medicine* 42 no. 12 (1996): 1703-1719.
[83] AIDS Action Europe, "Global Fund Appoints Mark Dybul as Executive Director," (2012). Available at: http://www.aidsactioneurope.org/news/archive/global-fund-appoints-mark-dybul-executive-director

[84] High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, Tuberculosis and Malaria, "Turning the Page from Emergency to Sustainability: The Final Report of the High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, Tuberculosis and Malaria," (2011): 62. Available at: http://www.theglobalfund.org/en/highlevelpanel/report/
[85] Ibid.
[86] D. Bryden, "Global Fund Responds to Independent Review Panel Reform Recommendations," (2011). Available at: http://sciencespeaksblog.org/2011/09/28/global-fund-board-responds-to-independent-review-panel-reform-recommendations/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+ScienceSpeaksHivTbNews+%28Science+Speaks%3A+HIV+%26+TB+News%29
[87] Author's phone interview with Dr. Philip Russell, Former Commander of the US Army Medical Research and Development Command, July 2011.
[88] Muraskin, *The Politics of International Health*.
[89] Children's Vaccine Initiative. *CVI Forum* V 8 (November 1994).
[90] L. Janik, "Pathogens without Passports: Polio Eradication and the Provision of Global Public Goods for Health," Working Paper, Presented at the ISA Conference, March 2011 in Montreal, Canada.
[91] Muraskin, *The Politics of International Health*.
[92] Children's Vaccine Initiative. *CVI Forum* V. 10 (October, 1995).

Commentary: Challenges for Implementing Universal Health Coverage in Indonesia

Tiffany Robyn Soetikno , Agus Suwandono and Tikki Pang

The year 2014 has been a landmark and monumental year for Indonesia's health care environment. The year began with the implementation of *Jaminan Kesehatan Nasional* (JKN), a public health care coverage program that aims to cover 121 million Indonesians by the end of the year and plans to gradually cover the entire Indonesian population by 2019. In April 2014, *Seknas Jokowi*, supporters of Joko Widodo, one of two presidential candidates, published *Jalan Kemandirian Bangsa* or the Route to an Independent Nation which emphasized improving education, welfare and health as the salient priorities if Jokowi, short for Joko Widodo, is elected President[1]. When he became governor of Jakarta in 2012, Jokowi created *Kartu Jakarta Sehat* or Jakarta Health Card for citizens of Jakarta of low socioeconomic status. This card allows citizens to acquire medical examination, consultation and treatment for free. Jokowi's recent win in the presidential election of July, 2014 paves the way for significant health improvements in the country. Growing attention towards Indonesia's healthcare sector also includes Bill and Melinda Gates Foundation's collaboration with the Tahir Foundation to establish the Indonesia Health Fund, which secures approximately US$1 million to fund vaccines, such as the upcoming vaccine for dengue fever, and to deal with infectious diseases more generally[2].

Nevertheless, Jokowi's direction on health and the impact of the Indonesia Health Fund remain unclear. Furthermore, JKN is the flagship nationwide, government initiated universal health coverage (UHC) program which follows the global trend to establish UHC schemes, Indonesia instigated its program by creating *Badan Persiapan Jaminan Sosial* (BPJS) as the primary committee to plan, coordinate and execute JKN. By March 28, 2014, BPJS recorded 119.2 million people recipients of the program[1].

In overall terms, implementation of the JKN faces nine major challenges: EQUITY and FAIRNESS in access compounded by physical and logistic difficulties, and a large informal economy; QUALITY of delivered services; poor INFORMATION and data; COORDINATION of existing schemes and local initiatives; EXCLUSION of key stakeholders (e.g. the private pharmaceutical sector, civil society organizations); DISCONNECT between curative (JKN) and public health efforts which focus on preventive measures and health promotion, and between chronic and communicable diseases; FINANCING: capitation fees are decentralized thus giving rise to potential fraud and corruption as most of the budget is spent on medicines; SUSTAINABILITY of the scheme in relation to cost containment; and POLITICAL dimensions and uncertainty associated with the election of a new president in 2014. These challenges for health care reform can also be categorized as internal and external, whereby the former describes unclear budget construction and a lack of coordination among key players, and the latter refers to the recipients' limited knowledge of the program.

Every sustainable UHC scheme requires a strong budget. JKN's funding sources and allocation lack the transparency that is especially required in a nation well known for its problems with corruption. Ambiguity will lead to additional obstacles along the road to complete nationwide coverage. Currently, US$1.7 billion is secured for the program, Hasbullah Thabrany, a health policy expert at the University of Indonesia, estimated that the budget will cover approximately half of the costs of covering more than 100 million Indonesians[3]. Based on the family doctor model, in which a certain number of families in a particular area is assigned to one physician, a doctor will be paid less than $US0.70 per patient, per month. Insufficient financial support may result in underpaid and overburdened health care providers.

Since its establishment on January 2014, the JKN has yet to make a significant impact. On the contrary, the increasing chaos around health care provision indicates poor early performance by the BPJS. Additionally, key stakeholders, such as the pharmaceutical industry, health care providers, health insurers and health care institutions, continue to struggle to follow and adapt to the new system. Various loopholes have been encountered as a result of incomplete planning. According to several personal sources, due to poor coordination and negotiation, DPHO (essential drugs list) tender participants provided low prices, which prevented adequate and sustainable supplies of medication. Moreover, sources have revealed that government owned pharmaceutical companies, sometimes bid beyond their capabilities in supplying a certain percentage of the essential drug list. As a result, these companies were then forced to sub-contract its competitors to complete the order. Infrequent meetings between the BPJS and other key players will exacerbate current difficulties in executing the JKN.

On the other end of the chain, recipients of the health care program, which currently constitute government employees, the army and its veterans, and the elderly poor have found access to be a prominent barrier. Further information dissemination and education regarding the program are required to encourage the people to access JKN's benefits, such as subsidized treatments and medication. For example, due to lack of information a majority of JKN's intended recipients did not register by March 31, 2014[2], a deadline imposed by the government to encourage citizens to sign up on time. Consequently, a fine will be incorporated into these citizens' 2015 taxes.

The role primary health care centers should be strengthened immediately to give priority to preventive and promotive programs. This approach can hopefully reduce the risk factors of NCDs that will increase significantly in the near future. In this way the cost to the JKN for these catastrophic diseases can be reduced. So, in line with JKN, the efforts of public health prevention and promotion should be strongly prioritized

In addition to the general issues above, other concerns include inevitable overlap between local and nationwide policies; uncertainty after the presidential election; and lack of competent human resources in general, as well as in certain parts of the country. The first involves the Jakarta Health Card, for instance, whereby a certain portion of Jakarta's citizens have access to the benefits provided by this city-wide program and the JKN. Ideally, the UHC will be able to

cover the entire Indonesian population, thus making such local policies avoidable. The second stems from possible changes as a result of the election outcome. While the victory for Jokowi is seen as a positive development for health care, details remain to be worked out at the operational level. Some concerns have been expressed for the need for continuity in the implementation of the JKN. The final issue speaks to the inadequate number of health care providers and uneven distribution of such human resources. The JKN operates on a family physician model, which demands an even distribution of physicians and supporting staff members across the archipelago.

Lack of communication is a major, encompassing issue attached to the JKN. Enhancing internal communication and beyond to key players and stakeholders should help resolve problems regarding budget construction and allocation, as well as misunderstandings and poor preparedness of pharmaceutical companies, health care providers, health insurers and health care institutions. External difficulties require continuous education to the public through health care providers and institutions; the media; social media in larger cities; academic institutions, such as schools, universities, and religious academic sites; in addition to coordination with local government to reach rural populations.

Despite all of its problems and challenges, the JKN is a progressive move towards improved health of the nation. As a developing nation and emerging market, Indonesia needs to prepare its people to welcome further growth and advancement. Indonesia's health indicators have gradually improved over the years, yet the JKN will surely drive more improvements. Attention from foreign countries and institutions should not be a source of contentment but an encouragement for the government and the Indonesian people to internally strive for more health improvements and better health equity. In the meantime, as the program continues to be implemented across the nation, research and data collection should be conducted to allow for future evaluation and learning. The current administration has declared that regular assessments in the first months will determine the direction of the scheme and instigate the roadmap to complete its goals by 2019[3]. This gives an important role to health research and development in JKN and will be very crucial to help answer questions and to provide alternative solutions towards many challenges faced by JKN in the coming years. The JKN can become the jewel in the new president's crown and the country awaits its effective and sustainable implementation. Given the complexity and challenges within Indonesia, the implementation of the JKN can also result in valuable lessons for other developing countries wanting to implement universal health coverage.

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Internal and External Public Health Threats of the Syrian Crisis

Jenna Karp

The ongoing political crisis in Syria between the Ba'ath regime and rebel forces has created a humanitarian disaster, with over 150,000 deaths[1] and 2.8 million refugees.[2] Civil war has been raging for over three years, as brutal fighting between forces loyal to President Bashar al-Assad and extremist groups like the Islamic State of Iraq and the Levant (ISIL) persists with no clear signs of accord ahead. The rise of ISIL, which has amassed territory in Syria and Iraq, has further complicated the sociopolitical landscape of the region. Amidst the violent chaos, it has become increasingly difficult to monitor and maintain the health needs of Syrian civilians. Consequently, Syria is facing a growing public health threat that is impossible for the Syrian government and for rebel armies to ignore. While the United States government and humanitarian organizations have already committed funds to address Syria's growing public health challenges, more needs to be done to stop the spread of disease both within the country and in the region.

There are four factors contributing to unsafe public health conditions in Syria and its neighboring region, which require immediate attention and action: First, a lack of medical resources, due to insufficient funds and armed militants, has opened the door to the spread of infectious diseases, including previously eradicated polio. Second, environmental factors are now exacerbated by the conflict, creating food insecurity and unsafe water and sanitation conditions. Third, humanitarian aid workers are unable to deliver treatments due to persistent violence and government resistance. Fourth, an influx of refugees into bordering states is spreading disease, causing economic instability, and threatening Syrians' safety.

LACK OF MEDICAL RESOURCES CONTRIBUTE TO INTERNAL DISEASE BURDEN

Syrians who are exposed to illness do not have access to high quality health care; 60 percent of hospitals have been damaged or destroyed,[3] and in some areas, up to 70 percent of the health workforce has fled.[4] As a result, Syrians who are suffering from illness can often be left untreated, and thus, infections spread and the death toll rises. To make matters worse, population movement due to displacement and worsening sanitation conditions make the outbreak of disease that much more rampant. The World Health Organization (WHO) warned in June 2013 that conditions like dysentery, cholera and typhoid were inevitable if conditions didn't change dramatically, and they have not.[5] As Ramazan Kaya, a member of the Chamber of Medical Doctors in south-eastern Turkey reports, "Syria is known to have had very good healthcare.[6] Since the beginning of this conflict, the system has started to break down, and it is getting worse by the day."

The destruction of health facilities and loss of trained professionals have made it challenging for Syrians to find emergency care, treatment for chronic conditions and vaccines. Women experiencing pregnancy complications are

deprived emergency obstetric care. Patients suffering from diabetes, cardiovascular and kidney diseases struggle to receive professional treatment. Deliveries of priority vaccinations have stopped; national vaccination coverage dropped from 95 percent in 2010 to 45 percent in 2013.[7] Projects to vaccinate children below the age of 5 have failed due to accessibility and security challenges.[8] Some human rights activists assert that President Bashar al-Assad is intentionally withholding inoculations for polio[9] and other infectious diseases from citizens living in rebel-controlled lands as a "weapon of war"[10] to weaken rebel control. Perhaps as a result, polio has reappeared in Syria for the first time since 1999, causing UNICEF to launch the "largest campaign in the history of the Middle East, immunizing more than 22 million children in seven countries," including Syria, Lebanon, Jordan, Turkey, Iraq, Egypt and Palestine. [11]

Armed militants only further deprive Syrians of the medical resources they need. In north-east Syria, Syrian Kurds are under attack by both the Damascus regime and by the Islamist militants of Jabhat al-Nusra, an al-Qaida branch.[12] Jabhat al-Nusra has blocked off the region, stopping deliveries of vital medications and aid supplies. Stocks of medicine have been taken, and medical equipment has not been updated. The pharmaceutical industry has been hit hard by fighting, with 70 percent of local plants experiencing serious damage, making it difficult for local production of medications. Kristalina Georgieva, the EU's European Commissioner for International Cooperation, Humanitarian Aid and Crisis Response, begged the international community to demand that rebels in the blocked region allow health professionals inside.

ENVIRONMENTAL FACTORS THAT ARE EXACERBATED BY THE CRISIS SERVE AS HEALTH RISK FACTORS

During summer months, Syrians are exposed to environmental risk factors that make the onset of disease inevitable. Until June 2014, parts of Syria were suffering from their lowest levels of rainfall in more than half a century,[13] forcing millions into "extreme poverty." [14] As a result of population overcrowding due to displacement, sewage systems have now become overwhelmed and fallen into disrepair.[15] Elizabeth Hoff, WHO's representative in Syria, shared that "at certain shelters, one toilet is being shared by 50 to 70 people. And this is in shelters in Damascus, where people are better off than the rest of the country."[16]

Historically, droughts have had a highly detrimental impact on agriculture in Syria. In 2010, farms suffering from the effects of intermittent rains were unable to match demand for crops like wheat, with a 3.3 million ton yield in 2014 compared to a 3.8 million ton demand.[17] Small-scale farmers suffered a loss of 80 to 85 percent of their livestock due to continuous droughts since 2005.[18] If these food deficits continue during this drought, malnutrition is a likely risk, worsening the public health threat by making Syrians more susceptible to disease.

The UN reports that 9.6 million Syrians,[19] half of whom are children, are facing an increased risk of illness due to water scarcity. UNICEF measured that the availability of safe water is just one third what it was before the crisis began.[20] Before the crisis, the per capita consumption of water was approximately 110 liters per person per day on average while post conflict this number has reduced

to 50 liters per person per day.[21] One can easily see the effects of poor sanitation and lack of clean water on Syrian civilians; last year, cases of acute watery diarrhea and hepatitis A skyrocketed by 172 percent and 219 percent, respectively.[22]

In winter months, internal turmoil continues to worsen the public health implications of unsafe environmental conditions. Factors including indoor air pollution and limited access to medical treatment increase the likelihood of Acute Respiratory Infections. Overcrowding and poor living conditions due to displacement are expected to make children under 5, who are generally most vulnerable, even more susceptible to the infection.

In response to these risk factors, the World Health Organization has committed to providing disinfectants and water purification units in regions where water-borne illnesses have been reported. The organization has also begun relying on the Early Warning Alert and Response System, a surveillance mechanism that can monitor and control sudden disease outbreaks in hard to reach regions.[23] However, other organizations like UNICEF are struggling to deliver sufficient levels of care; its project to alleviate the region's striking water and sanitation crisis is only 20 percent funded for 2014.[24]

VIOLENCE YIELDS UNSTABLE CONDITIONS FOR HUMANITARIAN AID WORKERS

Frequent bombings and targeted attacks have led to the deaths of aid workers throughout Syria. In April, two Syrian Arab Red Crescent (SARC) workers were killed, as reported by the International Federation of Red Cross and Red Crescent Societies.[25] Since the Syrian conflict first began, 13 UN staff members,[26] 36 SARC and seven Palestine Red Crescent Society aid workers have been killed.[27] Aerial attacks have targeted American government supported medical centers, causing numerous deaths and injuries to workers and creating a clear obstacle to treating Syrian patients.

In Yarmouk, Syria, where the Syrian Government and armed militants were reported to have reached an agreement, the UN Relief and Works Agency for Palestine Refugees in the Near East (UNRWA) is still unable to deliver humanitarian aid. The organization has been trying to reach the 18,000 Syrian inhabitants trapped inside for weeks, but was hindered by persistent clashes and shelling.[28] Two weeks after the official declaration of a ceasefire, UNRWA announced on June 30th that they were still unable to reach those inside the Yarmouk camp.[29]

On July 14, the United Nations Security Council voted unanimously (15-0) to launch cross-border emergency aid missions to deliver care to civilians in rebel-held areas without approval from the Syrian government.[30] UN convoys will enter through two crossings in Turkey, one in Iraq and one in Jordan, areas that are beyond Syrian government control. This provision inevitably poses a risk to aid workers; after all, the plan violates President Bashar al-Assad's requirement that all international aid enter only through Damascus, the capital. Assad had originally crafted this rule following reports of weapons smuggling for insurgents through aid convoys. As General Ban Ki-moon noted, monitoring measures must be implemented to ensure that this new aid initiative approved by

the UN does not create any holes for weapon smuggling, which would only further anger Assad and endanger workers on-the-ground.

SYRIAN REFUGEES IMPOSE BURDEN ON NEIGHBORING NATIONS

In February 2014, the United Nations announced that Syrians are on track to surpass Afghans as the world's largest refugee population. Displaced Syrians have sought refuge in Lebanon, increasing the population of the comparably smaller nation by about a quarter (+1 million refugees).[31] Lebanon is now faced with the burden of feeding, housing and treating refugees, a task that has proven highly detrimental to the nation's economy; the Lebanese national debt will reach 148 percent of its GDP in 2014 and unemployment has already risen 20 percent.[32] About 400,000 Syrian refugee children in Lebanon require schooling, a staggering number compared to the 300,000 Lebanese children enrolled in public schools.[33] The UN, aid organizations and the Lebanese government require $1.7 billion in order to support the needs of refugees, but the UN is struggling to secure funding.[34] Lebanon's need for foreign financial assistance is only exacerbated by the violence that has spilled over from Syria, creating a need to bolster their military budget. Begging for help from the Arab world, Gebran Bassil, Lebanon's Foreign Minister, shares, "Lebanon is falling deeper and deeper into terrorism's claws, and it is crucial that the army be propelled to combat it. The Arab world's assistance with this quest is in its own interest."[35] With a dearth of funding, Lebanon is incapable of maintaining proper health conditions for displaced Syrians while also struggling to sustain national and economic security.

Perhaps as a result of insufficient funding to address the needs of over 1.05 million refugees, communicable diseases including measles, typhoid and TB have appeared in cities across Turkey.[36] In fact, only those refugees who are accepted into Turkey's official refugee camps receive medical screenings and vaccinations. Turkey is also at risk of exposure to leishmaniasis, a Neglected Tropical Disease with a fatality rate of 100% within two years if left untreated, which has reached epidemic levels in Syria's northern most region.[37] Because sand-fly vectors are already found in neighboring countries, spread of the disease is a serious concern.

The outbreak of polio in Syria has spread to Iraq, where the disease went unseen for 14 years and where 200,000 refugees reside.[38] Iraqi officials are now scrambling to vaccinate around 5 million children under the age of 5 for polio, a difficult process that requires multiple doses.[39] In Jordan, where 600,000 Syrian refugees are registered, the government recently finished construction on its third refugee camp to accommodate growing numbers.[40] Child marriage among Syrian refugees living in Jordan has doubled since the start of the Syrian conflict, reports Save the Children.[41] Due to persistent poverty and sexual violence threats, parents in refugee camps feel that marriage is the safest option for their daughters. This poses a devastating health threat to these Syrian girls; it is well understood that girls who marry under 18 often experience domestic abuse and have little to no access to sexual and reproductive health resources. Another health risk facing Syrian refugees in Jordan is exposure to coronavirus, which mysteriously reappeared in 2013 after killing 800 people during a 2003

epidemic.[42] Working to monitor and prevent the outbreak of disease among Syrian refugee populations in Lebanon, Turkey, Iraq, and Jordan is an extremely difficult task that is impossible for their administrations to sustain on their own.

FURTHER INVOLVEMENT IS NEEDED TO PROMOTE COMMUNICATION, IMPROVE EMERGENCY RESPONSE AND BUILD INFRASTRUCTURE

Speaking with regard to the need for increased intervention in Syria, Huseyin Oruc, Deputy Chairman of the Humanitarian Relief Foundation, a Turkish NGO, went as far as to say, "Syria has been abandoned by the world."[43] Although Oruc's comment may have undercut the attempts of a few international agencies to provide assistance, his thought is a valid one: Syria's need for large-scale humanitarian aid missions to combat growing public health challenges has been egregiously ignored.

There are five steps that must be taken to alleviate the Syrian disaster. First, international organizations must engage in talks with the Syrian government about increasing access to isolated rebel-controlled areas, citing international human rights law as a driver. A clear gateway into neglected regions would not only save money on covert humanitarian operations but also would save more lives. Second, neighboring nations including Lebanon, Turkey, Iraq, and Jordan must work to create an efficient refugee network system that uses open communication and resource management to share economic burdens. Third, private stakeholders in the area must invest in building operational capacity of organizations that are already on-the-ground and that have access to effected populations. One way is to improve emergency response services that address dire medical, sanitation and dietary needs. Another way is to invest in specialized training that allows workers to deliver humanitarian need under difficult conditions, like in an area controlled by rebels. Fourth, humanitarian organizations must turn their attention towards data collection. Syrian civilians cannot be helped if the international community does not understand the extent of need; more trained workers are needed on-the-ground to assess damage and track the movement of displaced citizens, perhaps through in-person surveys, Twitter, or mobile services. Fifth, existing aid services, including the WHO and UNICEF, should direct more funds to water management and sanitation services. This creates a beneficial ripple effect in two ways: one, an improved water system lessens the need for Syrians to leave their homes and thus lightens the refugee load on bordering nations. Two, better sanitation conditions can limit the outbreak and spread of disease and in turn lessen the demand on health workers.

The implications of ignoring the growing public health challenges in Syria are long-term. From a geo-economic standpoint, withholding aid from Syria's neighbors for refugee programs will only continue to weaken the region; as funds diminish, these countries will become increasingly incapable of meeting their own needs for economic and national stability. Withholding aid from Syria will make it impossible for the country to rebuild once conflict between Sunni and Shia groups dies down. The next generation of Syrians will simply be ill-equipped: Displaced children are under extreme stress and are expected to suffer minor to severe mental health difficulties as they mature. They struggle to receive

an education, as most schools within Syria have been damaged and schools in neighboring regions are inundated with the population influx. These children certainly do not have easy access to basic medical care and health services that are vital in developing years. Lastly, Syrian children are put at risk for recruitment into armed militant groups, and with the prospect of lightening the load on their struggling families, why would they hesitate to join? The risks posed to Syrian children will inevitably create horrifying DALYs (Disability- Adjusted Life Years). If the international community does not step in, Syria will be faced with a lost generation: one lacking in economic productivity, one with a broken health system, one that grew up holding guns, and one that has lost faith in its nation.

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[1] Evans, Dominic. "Death Toll in Syria's Civil War above 150,000: Monitor," Reuters. April 1, 2014. Accessed July 1, 2014. http://www.reuters.com/article/2014/04/01/us-syria-crisis-toll-idUSBREA300YX20140401.

[2] "Syrian Election: Refugees Vote in Lebanon and Jordan." BBC News. May 28, 2014. Accessed July 1, 2014. http://www.bbc.com/news/world-middle-east-27599868.

[3] "Save the Children Describes Healthcare Disaster in Syria." Reuters. March 9, 2014. Accessed July 1, 2014. http://www.reuters.com/article/2014/03/09/syria-crisis-healthcare-idUSL6N0M60M220140309.

[4] "WHO Warns of Syria Disease Threat." BBC News. Accessed July 1, 2014. http://www.bbc.com/news/health-22766084.

[5] "WHO Warns of Syria Disease Threat."

[6] Letsch, Constanze. "Syrian Crisis Fuelling Public Health Emergency, Doctors Warn." The Guardian. November 1, 2013. Accessed July 1, 2014. http://www.theguardian.com/world/2013/nov/01/syrian-crisis-public-health-emergency.

[7] "WHO Warns of Increased Risk of Disease Epidemics in Syria and in Neighbouring Countries as Summer Approaches." ReliefWeb. Accessed July 1, 2014. http://reliefweb.int/report/syrian-arab-republic/who-warns-increased-risk-disease-epidemics-syria-and-neighbouring.

[8] "WHO Warns of Increased Risk of Disease Epidemics in Syria and in Neighbouring Countries as Summer Approaches."

[9] Gladstone, Rick. "Polio Spreads From Syria to Iraq, Causing Worries." The New York Times. April 7, 2014. Accessed July 1, 2014. http://www.nytimes.com/2014/04/08/world/middleeast/polio-spreads-from-syria-to-iraq-causing-worries.html?_r=0.

[10] Gladstone, Rick. "U.N. Council, in Unanimous Vote, Backs Aid Delivery to Syrians in Rebel Areas." The New York Times. July 14, 2014. Accessed July 16, 2014. http://www.nytimes.com/2014/07/15/world/middleeast/un-security-council-authorizes-strengthened-syria-aid.html.

[11] Jones, Sam. "UN Brands Polio Outbreak in Syria and Iraq 'Most Challenging in History'" The Guardian. Accessed July 13, 2014. http://www.theguardian.com/global-development/2014/mar/28/un-polio-syria-iraq-most-challenging-history.

[12] Letsch, Constanze. "Syrian Crisis Fuelling Public Health Emergency, Doctors Warn."

[13] "Lowest Rainfall in 50 Years Latest Threat to Syria's Children." UNICEF Australia. Accessed July 15, 2014. http://www.unicef.org.au/Discover/News/2014-6--June/Lowest-rainfall-in-50-years-latest-threat-to-Syria.aspx.

[14] "SYRIA: Drought Pushing Millions into Poverty." IRINnews. September 9, 2010. Accessed July 15, 2014. http://www.irinnews.org/report/90442/syria-drought-pushing-millions-into-poverty.

[15] Unsanitary Conditions Putting Syrian Children in Peril." UNICEF USA. Accessed July 15, 2014. http://www.unicefusa.org/press/releases/unsanitary-conditions-putting-syrian-children-peril/8263.

[16] Yang, Jennifer. "Syria Facing Disease Outbreaks, The World Health Organization Warns." The Star. Accessed July 15, 2014. http://www.thestar.com/news/world/2013/06/04/syria_facing_disease_outbreaks_the_world_health_organization_warns.html.

[17] "SYRIA: Drought Pushing Millions into Poverty." IRINnews.

[18] Ibid.

[19] Gladstone, Rick. "Syria: Drought Adds to Woes, U.N. Says." The New York Times. June 6, 2014. Accessed July 10, 2014. http://www.nytimes.com/2014/06/07/world/middleeast/syria-unicef-says-drought-adds-to-safe-water-woes.html?_r=1.

[20] Unsanitary Conditions Putting Syrian Children in Peril." UNICEF USA.

[21] "2014 Syrian Arab Republic Humanitarian Assistance Response Plan (SHARP)." ReliefWeb. December 15, 2013. Accessed July 17, 2014. http://reliefweb.int/sites/reliefweb.int/files/resources/2014_Syria_SHARP.pdf

[22] Yang, Jennifer. "Syria Facing Disease Outbreaks, The World Health Organization Warns."

[23] "2014 Syrian Arab Republic Humanitarian Assistance Response Plan (SHARP)."

[24] "Syria's Children: A Lost Generation?- Crisis Report." UNICEF. Accessed July 19, 2014. http://www.unicef.org/infobycountry/files/Syria_2yr_Report.pdf.

[25] "Crisis in Syria." USAID. Accessed July 16, 2014. http://www.usaid.gov/crisis/syria.

[26] "2014 Syrian Arab Republic Humanitarian Assistance Response Plan (SHARP)."

[27] "Crisis in Syria." USAID.

[28] "Syria Crisis: Ceasefire Agreed for Yarmouk Refugee Camp." BBC News. June 22, 2014. Accessed July 12, 2014. http://www.bbc.com/news/world-middle-east-27969293.

[29] "Palestinians in Syria's Yarmouk Camp Now without Aid for One Month – UN." UN News Center. June 30, 2014. Accessed July 12, 2014. http://www.un.org/apps/news/story.asp?NewsID=48166&utm_campaign=KFF: Global Health Report&utm_source=hs_email&utm_medium=email&utm_content=13347723&_hsenc=p2ANqtz_Duus9ZQpSyc2x_j7FqWs_pY_V3cpb_DhwbU65clB3DUY7Mi1Xzx_b5qPCW077udachBKJVOmVkj-Kfgjvd-IoEVt-Uwhttp://www.un.org/apps/news.

[30] Gladstone, Rick. "U.N. Council, in Unanimous Vote, Backs Aid Delivery to Syrians in Rebel Areas."

[31] Ryan, Missy. "Syria Refugee Crisis Poses Major Threat to Lebanese Stability - U.N." Reuters. March 28, 2014. Accessed July 16, 2014. http://uk.reuters.com/article/2014/03/28/uk-lebanon-usa-idUKBREA2R02G20140328.

[32] Solomon, Chris. "Syrian Refugees Pressure Lebanon's Fragile Economy - Global Risk Insights." Global Risk Insights. May 21, 2014. Accessed July 12, 2014. http://globalriskinsights.com/2014/05/lebanon-struggles-to-cope-with-refugee-influx/.

[33] Ryan, Missy. "Syria Refugee Crisis Poses Major Threat to Lebanese Stability - U.N."

[34] Ibid.

[35] Kholaif, Dahlia. "FM Says Syria Crisis Poses Threat to Lebanon." Al Jazeera. March 24, 2014. Accessed July 11, 2014. http://www.aljazeera.com/indepth/features/2014/03/fm-says-syria-crisis-poses-threat-lebanon-201432415125385789.html.

[36] Letsch, Constanze. "Syrian Crisis Fuelling Public Health Emergency, Doctors Warn."

[37] "Leishmaniasis." World Health Organization. Accessed July 15, 2014. http://www.who.int/topics/leishmaniasis/en/.

[38] Gladstone, Rick. "Polio Spreads From Syria to Iraq, Causing Worries."

[39] Forouzandeh, Hossein. "Syrian Polio Outbreak Spreads To Iraq." Mideast Times. Accessed July 19, 2014. http://www.mideasttime.com/syrian-polio-outbreak-spreads-to-iraq/113730/

[40] Winfield, Omar. "Pope to See Syrian Refugee Crisis in Jordan." Yahoo! News. May 24, 2014. Accessed July 17, 2014. http://news.yahoo.com/pope-see-syrian-refugee-crisis-jordan-051420520.html.

[41] "Syrian Child Marriage in Jordan Has Doubled since Start of War, Save the Children Says." Save the Children. July 16, 2014. Accessed July 19, 2014. http://www.savethechildren.org/site/apps/nlnet/content2.aspx?c=8rKLIXMGIpI4E&b=8943305&ct=14076957¬oc=1&msource=wessnmis0714.

[42] Jaslow, Ryan. "Mysterious Coronavirus from Middle East Claims Another Victim." CBSNews. March 13, 2013. Accessed July 20, 2014. http://www.cbsnews.com/news/mysterious-coronavirus-from-middle-east-claims-another-victim/.

[43] Letsch, Constanze. “Syrian Crisis Fuelling Public Health Emergency, Doctors Warn.”